A Novel Framework for Upper Limb Rehabilitation Using Automated and Robotic Systems

by

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A mi amada familia que siempre me ha motivado y apoyado:
mi padre Daniel, mi madre Martha, y mi hermana Cyntia.
To my beloved angel...

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Abstract

This thesis proposes a conceptual framework of rehabilitation under an innovative paradigm of integration of robotic and automated systems into a holistic health strategy. This framework considers the traditional rehabilitation cycle as a reference of design, analysing its components and current issues in order to develop automated alternative systems that keep the clinical meaningful.

The research work primarily focused on developing one of the core components of the framework, that is, the automated assessment systems (AAS). The assessment stage is strongly influenced by “one-on-one” patient-therapist interactions, difficult management of patient’s results, and time-consuming and labour-intensive procedures due to the nature of manual administration. Therefore, the AAS aims to face these limitations and to augment the clinicians’ capabilities by providing them with automated tools. In this regard, this thesis presents the process of automation of a traditional and well-known clinical test for the assessment of upper extremity (UE) motor function. The Box and Blocks Test (BBT) of manual dexterity was the primary outcome measure taken as a case of study. The automation process considered different approaches (computer vision, proximity sensors, VR) in order to provide the clinicians with an objective, reliable, and automatic tool denoted as the automated box and blocks test (ABBT). Additionally, this thesis reviewed the limitations of current robot-based interventions focusing on devices for UE treatment. Thus, this analysis resulted in the identification of a need for systems for complementing the task-oriented training performed for rehabilitation robotics. In this line, this work also explored the use of virtual reality for the rehabilitation of UE motor function. As a result, a set of video games were implemented. These video game served as an intervention tool for a treatment protocol in hospital in order to improve UE functioning and, concurrently, evaluate the feasibility of the ABBT.

Finally, the nature of hospital-oriented perspective requires testing the developed systems in clinical environments. Hence, part of the research consisted of piloting of the ABBT in a hospital facility and correlating the metrics obtained from the manual and automatic procedures. Besides, a treatment focused on improving the UE functioning using the serious games developed in this thesis was conducted in clinical settings. This way, this research work also provides a methodology for the validation of systems with the ultimate purpose of hospital applicability.

Resumen

La presente tesis propone un marco conceptual de rehabilitación bajo un paradigma innovador de integrar sistemas robóticos y automáticos en una estrategia de salud holística. Este marco considera el tradicional ciclo de rehabilitación como referencia de su diseño, analizando sus componentes y actuales limitaciones para desarrollar alternativos sistemas automatizados pero que mantengan la significancia clínica.

El trabajo de investigación se enfocó principalmente en el desarrollo de uno de los componentes centrales del marco propuesto, es decir, los sistemas automatizados de evaluación. El proceso de evaluación está fuertemente marcado por la interacción uno-a-uno entre paciente y terapeuta, el difícil manejo de los resultados, y la demorosa y laboriosa administración de este proceso manual. Por ello, los sistemas automatizados de evaluación buscan reducir estas limitaciones y aumentar las capacidades del terapeuta dotándole de herramientas automatizadas. Así, esta tesis presenta el proceso de automatización de una conocida prueba clínica para medir la funcionalidad de la extremidad superior (ES). Dicha prueba de referencia es el Box and Blocks Test (BBT) que mide la destreza manual. En su automatización se estudiaron diversas tecnologías (visión por computador, sensores de proximidad, realidad virtual) para provisionar al terapeuta con una herramienta objetiva, fiable y automática, que se ha denominado el automatizado box and blocks test (ABBT). Por otro lado, la presente tesis también revisa los principales inconvenientes de las actuales terapias basadas en robot para el tratamiento de la ES. Así, este análisis condujo a identificación de la necesidad de complementar los tratamientos orientados a la tarea que implementa la terapia basada en robots. En esa línea, la tesis exploró el uso de la realidad virtual como medio para mejor la funcionalidad motora de la ES. Como resultado, se implementó un conjunto de *serious games* que fueron probados como herramienta de intervención en hospital y, en paralelo, evaluar la fiabilidad del ABBT.

Finalmente, la naturaleza del considerado enfoque clínico requirió la validación de los sistemas en un entorno hospitalario. Por ello, parte de la investigación consistió en realizar estudios piloto del ABBT en un hospital y estudiar la correlación entre las métricas obtenidas con el método manual y automático. Estos ensayos se sumaron a la validación clínica de los *serious games* en una clínica. En consecuencia, esta tesis también proporciona una metodología para la validación clínica de sistemas enfocados a un uso en hospital.

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Part I

Research Work

CHAPTER 1

Introduction

1.1 Preamble

The purpose of this section is to explain the motivation and objectives of the present doctoral dissertation. Firstly, the significance of this research work is exposed, according to healthcare needs and social impact. Secondly, the clinical and technological needs of current health strategies are stated based on reviewing the clinical procedures and state-of-the-art in rehabilitation robotics. The rationale of the above aspects led to the definition of a novel framework of rehabilitation, where neuroscience and robotics form two sides of the same coin. Finally, the particular objectives of this thesis are summarised.

1.2 Overview and research significance

Globally, neurological disorders are the leading cause of disability and the second cause of death worldwide [1, 2]. Common neurological disorders include stroke, Parkinson's Disease (PD), spinal cord injuries, multiple sclerosis, among others. The global statistics show that the risk of neurological diseases is high. As an example, approximately 500,000 people experience a stroke in the U.S. and about 1.1 million in Europe, yearly [1]. Over 6.1 million individuals have PD around the globe [3]. Persons with restricted mobility, cognitive impairments and chronic diseases composes roughly 10% of the present population of the European Union (EU). These data shows the relevance of such diseases and their consequences. Besides, it is also essential to consider that the population aged 65 years, and over, is increasing dramatically worldwide [4]. One of the primary demands of elders is the need for care or support from third-parties. Furthermore, the risk factors for major disabling neurological disorders increases with ageing, although the predisposition for a neurological deficit does not depend on gender, race, or age.

As a result of the above, it produces a significant impact on society and healthcare systems. The number of persons who need care from clinicians specialised in neurological conditions is very elevated. The same happens in the case of assistance to the elderly population, having a very high degree of dependence on family or third-party carers. Therefore, healthcare providers are facing a sustained growth demand for treatment, rehabilitation, and support services for people with neurological disorders, elders, or both [5]. This fact represents a tremendous public health problem. In this regard, the application of robotic technologies can help persons with a disability to obtain a higher quality of life by giving them more independence or optimising the process of recovery by technical aids focused on rehabilitation.

For the latter, a variety of robot-based solutions has been investigated to support clinicians in their daily activities [6, 7]. Thus, there are available robotic systems to directly (surgery, limb mobilisation, bed transfer, etc.) or indirectly (logistic, data management, etc.) assist medical professionals. In the case of neurological rehabilitation, the focus of attention has been the development of systems for using in rehabilitation as intervention, namely, the execution of rehabilitative treatments. However, it must be noted that the process of neurological rehabilitation is made up of several stages other than the intervention one.

Overall, the final goal of robotic systems for rehabilitation is to improve treatment quality (maximising health gains), optimise the therapist's productivity (reducing time spent, subjectivity, etc.), and reduce the inpatient costs (burden for hospitals). However, the number of rehabilitation robotic systems in clinical use is small, despite its large development and research effort. Even more, the design of systems to assist clinicians in neurorehabilitation stages other than intervention is poor.

This thesis presents a novel framework for the physical rehabilitation of patients with a neurological deficit based on the automation of the rehabilitation cycle and its stages. By automation, a more objective and reliable rehabilitation process of the patient's motor function can be achieved. The proposed framework aims to merge, in the same paradigm, the clinical knowledge of traditional medical procedures with the enhanced capabilities of robotic systems. Previously to review the fundamentals of current systems for rehabilitation, the following section presents the scope of this work.

1.3 Scope of thesis

This thesis has been developed under the umbrella of the RoboHealth (DPI2013-47944-C4-1-R) project funded by the Spanish Ministry of Economy and Competitiveness. This project is in accordance with the challenge of Health of the State R&D Plan (Spain), which establishes Robotics as a field of interest. Furthermore, the euRobotics, an organisation created to set out the preferences of the new European research funding plan Horizon2020, include into their lines of work topics as 1) assistive robots in health-related settings and 2) rehabilitation robotics. Similarly, the plans presented in 2013, 2014 or 2015 by the Information and Communication Technologies (ICT) Work Programme defines in section Robotics the theme of Health.

The central aim of the RoboHealth project is the development of assistive and rehabilitation systems in smart hospital places, aiming to contribute to the advancement of the Spanish National Health System. The complexity of the tasks addressed in the project and the close relationship with the medical application required composing an interdisciplinary consortium to ensure a successful result. Thus, in addition to the technical research team, one of the partners is the team of the Motion Analysis Laboratory, Biomechanics, Ergonomics and Motor Control (LAMBECOM). This clinical group also belongs to the Fuenlabrada University Hospital, which provides a pragmatic and realistic hospital-oriented point of view to the conducted research.

Hence, hospital-oriented usage is the principal requirement of design for the systems developed in this thesis. Currently, one of the major limitations of robot-aided systems for rehabilitation is their reduced adoption in hospital settings. The complexity in operation, maintenance, or adaptability are some of the reasons that explain the concerns of clinicians to use this technology in their daily practice. For that reason, it is necessary the research on novel strategies of rehabilitation towards increasing the adoption of robot-based and automated systems in hospital environments. The following section presents an overview of the issues of rehabilitation robotics and automated systems for its deployment in clinical environments.

1.4 Background

Neurological rehabilitation or neurorehabilitation can be defined as a process focused on reducing the functional limitations of people with a neurological deficit. This is a quite challenging and long-term process since the limitations caused by a neurological disorder are usually multidimensional (e.g., physical, cognitive, psychological) and very complicated (the same pathology may affect in a different level to each person). Thus, the final goal of neurorehabilitation is to optimise the person's participation in society and sense of well-being [1, 8] and, ultimately, increase their autonomy in performing activities of daily living (ADL).

Motor functionality is essential to perform the ADL autonomously. Therefore, one of the most disabling deficits is the related to problems of motor control, which can produce motor impairments of upper, lower or both extremities. This fact supports that a relevant objective of neurological rehabilitation is to regain motor function. Traditionally, this process of recovery is based on extremities mobilisation and efforts for the patients, where the clinician manage the intensity and repetition of movements during one-on-one sessions. Hence, considering the nature of manual procedures and long-term treatments, in recent decades, it has been highlighted the sizeable need and opportunity to deploy technologies such as robotics for healthcare applications in general, and particularly, for rehabilitation.

Overall, the use of robotic technology in healthcare can be grouped into three large domains: medical, assitive and rehabilitation robotics [9]. Medical robotics domain includes devices that provide support in medical processes of healing (surgery) and care (diagnosis). Assistive robotics domain covers devices for assisting in task related with the healthcare process (delivery of medical supplies, surveillance, bed transfers, etc.), either to carers or patients, in clinical facilities. Rehabilitation robotics domain, being the application area of this thesis, covers a range of different forms of post-operative or post-injury care where direct physical interaction with a robot system will either enhance recovery or act as a replacement for lost function.

Rehabilitation robotics covers a varied range of devices, such as prostheses, orthoses, or therapeutic aids (devices not covered in prostheses nor orthoses). Prostheses are devices to replace a physical body structure. The development of prostheses has been strongly linked with the evolution of assistive robotics and being currently one of the flagship products in biomedical engineering. Bebionic robotic hand is an example [10], which in addition to the body structure replacement, it restores the user's hand functionality via electromechanical technology. Contrary to the macro-level of limb prostheses, there is also research efforts towards developing micro prostheses, denoted as neuroprosthesis [11]. Opposite to brain-computer interfaces which connect the brain to a computer, they are similar to cochlear implants. Neural prostheses aim to substitute a motor, sensory or cognitive modality, being a promising alternative in neurological rehabilitation.

Ortheses are external (wearable) devices used to replace/augment a loss or deteriorated functionality, being robotic orthoses also denoted as exoskeletons. Robotic exoskeletons can provide active or passive operation modes. In the case of active orthoses, the device applies forces to the user's limb via the actuators. In a passive orthosis, the user must apply force to the device for starting the movement. According to the body structure to support, orthoses can assist to the upper or lower extremities or both (full-body). Cutting-edge products in this category are the HAL series [12] having devices for upper, lower and full-body assistance. Lokomat is a relevant example of lower limb therapy support, currently used in Spanish hospitals. Armeo-Power is another device nowadays used in hospitals but focused on assisting during upper limb rehabilitation.

Therapeutic aids category include devices not covered within prostheses' and orthoses' definitions. That is, devices whose assistance strategy require moderate physical contact (neither fixed to the body structure nor wearables). Examples of therapeutic aids are end-point systems such as the InMotion robot [13] that is partially in contact (usually hand-held) with the patient when training, or non-wearable electromechanical devices that the user must grab when employing, such as Pressmatic [14]. Figure 1.1 illustrates the organisation of rehabilitation robotics domain.

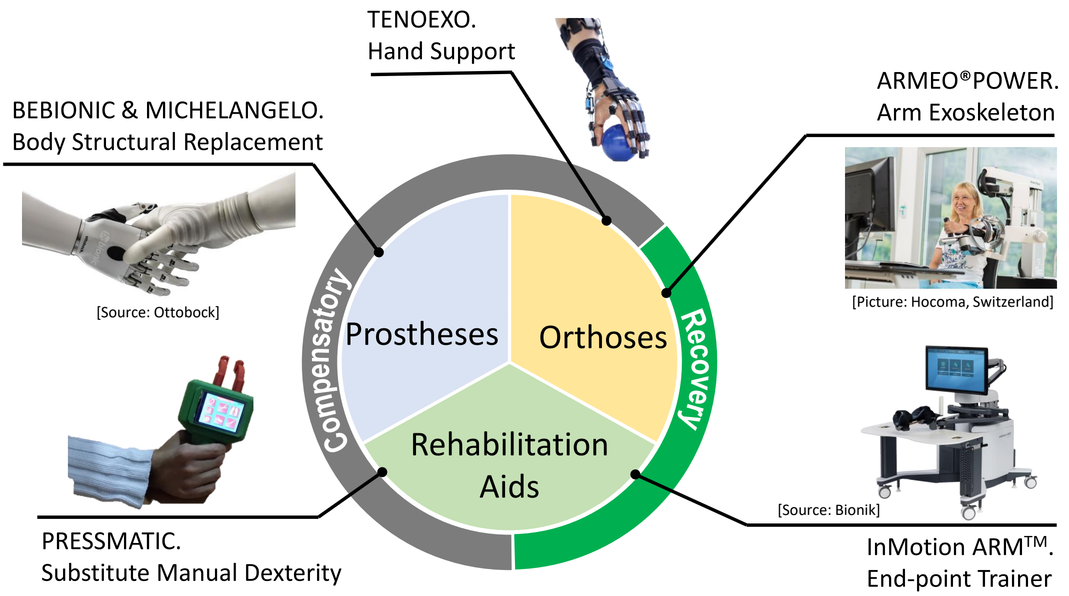


Figure 1.1: Description of systems included in rehabilitation robotics domain.

However, regardless of the device morphology, it must be noted that the same device can serve for different purposes. A clear example is the case of an orthosis (exoskeleton), which could serve as a replacement of a loss of function, a means to recovery motor capability, or even to augment functionality. In this way, a descriptive organisation is according to the role to play of the robotic system, namely, for recovery or compensatory purposes. In the case of recovery purposes, the role of the robotic device focuses on giving back the capability of the individual to perform a task using natural movement mechanisms previously used. Contrary, in the case of compensatory purposes, the role of the robotic device can be described as atypical approaches to meet the requirements of the task using alternative mechanisms not typically used.

Hence, focusing on robotic systems (end-point or exoskeletons) for recovery, the most extended approach taken in consideration by robotic aids is to reproduce the traditional procedures of physical rehabilitation, such as single (passive, active) or mixed (passive-active) techniques of limb mobilisation. Thus, robot-based interventions aim to ameliorate the capacity to move of patients through repetitive limb mobilisations based on traditional techniques but powered by the robotic device. However, robots can perform several modalities of physical human-robot interaction, such as assistive, path guidance, active, active-assisted, resistive, among others [15].

In this regard, robot-mediated therapy not only offers the possibility of a more efficient therapeutic routine but also provide additional performance-based information about the user's progress. This extended data could help to enhance the diagnosis of impairments, the personalisation of treatments according to the own user's profile of recovery, and the automatic management of electronic health records (EHR). Furthermore, comparing the outcomes from conventional and robot-based therapy, the gains obtained from the only utilisation of robotic aids does not exceed the improvements obtained by using traditional therapy. However, robot-mediated therapy allows for conducting additional training sessions with minimal supervision of the therapist and, in this case, the results are better than those obtained with conventional therapy. Besides, robots provide an ideal platform for objective, reproducible, continuous measurement and control of therapy.

Despite the above advantages and the extensive development of rehabilitation robotics in recent decades, the adoption of these systems in clinical practise remains limited. The scientific literature demonstrates the effectiveness of robot-mediated treatments [16, 17, 18, 19]. Additionally, human-robot interaction provides a safe, predictable and trusty environment where the complexity level of interplay can be controlled or progressively modified [20]. Consequently, it seems the most significant hurdle faced in new therapeutic robotics is not the technology *per se* but its clinical validation and best usage towards optimal and sustained over time outcomes.

In this sense, there is evidence about the motor gains obtained from robot-based training are often not transferred to the performance of the ADL [21], which is a relevant concern. Thus, it is essential to identify if the current robot-based health strategies promote the achievement of functional gains transferable to the ADL properly, according to the health procedures with proven efficacy. Due to functional recovery is a continuously evolving process depending on the patient's response, the customisation of robot-based therapy utilising self-adaptive strategies seems to be practical and might be a crucial element for achieving optimal assistance.

Additionally, it is also important to analyse if other clinical demands of the rehabilitation process are not covered by current assistance. It is clear that modern robot-aided systems primarily focuses on the therapeutic intervention. However, since the complexity and long-term condition of rehabilitation processes, there are stages other than intervention that requires support to the clinician. One of them is the assessment stage, which is essential to determine the effectiveness of treatments. The inclusion of robotic systems in this stage of the recovery cycle has been poorly addressed in the scientific literature, even for commercial available systems [22]. This fact motivates the main research line of this thesis.

At present, considering robots as advanced therapy tools under a therapist's guidance is a well-received approach in clinical settings. However, the proper integration in robot-based assistance of advances in technology and clinically significant approaches could lead to more autonomous and smart processes in neurorehabilitation.

1.5 Research purpose

From the above, it can be appreciated some issues in the robot-based assistance for rehabilitation, which can be studied from the perspectives of the process or the device (tool).

On one side, the traditional process of neurological rehabilitation present opportunities for automation by nature. Firstly, a typical characteristic of the practice of clinical neurology is one-on-one interplay during therapy. This evidence implies manual and labour-intensive procedures. Secondly, neurological rehabilitation is not a process limited in time. Recovery of functionality, in general, depends on the level of affectation and the response of each individual to treatment. Consequently, the following of improvements is a fundamental phase, and it must be performed throughout the treatment. Nevertheless, performing several tests to assess longitudinal changes in functional gains can be difficult in terms of patient burden and cost, even for healthcare providers. This fact also highlights the importance of assisting in most of the phases of the rehabilitation process towards improving its quality and efficiency. Considering adequate therapy relies on outcome measurement, the assessment stage might be a particular focus of attention for research. Finally, providing objective metrics and more descriptive than traditional ones is another challenge for systems focused on monitoring the evolution of patient health status.

On the other side, robot-based aids for rehabilitation usually works under the principle of high-intensity (movement repetitions) during treatment, a purpose for what robots are especially suitable. However, considering the complexity of the internal processes of the central nervous system (CNS), a single intensity-based principle must not be the golden standard. On this basis, one concern about robot-based interventions is that improvements are often not transferred to the performance of activities of daily living. A possible reason for this issue could be that the exercising paradigm of robot-aids, mainly focused on mobilisations, is overlooking factors other than task-related, which also intervene in proper movement generation. These other factors are those related to the patient (cognition, perception, action) and the context of performing the task (environment), which should be integrated into the same paradigm. Another concern of robot-aided strategies is the complexity of the devices and their configuration. This condition reduces the usability of these strategies, making difficult its adoption in clinical settings. In this sense, provide the clinicians with a tool different from the one they are used to employ daily seems does not a proper approach.

1.5.1 Objectives of thesis

The primary motivation of this research is to develop a framework for a more autonomous process of neurological rehabilitation, aiming to be feasible in clinical environments. In this manner, this framework aims to support clinicians in their regular practice through automated and robotic systems.

Mainly, the research of this thesis focuses on treatments related to the upper extremity. Therefore, the general objectives of this thesis are:

- to analyse the traditional process of rehabilitation searching for the best approach that robotic systems can interact as a holistic health strategy. The clear dual-perspective (clinically-significant and technically-viable) of the topic of the thesis requires analysing the needs of healthcare providers and studying the limitations of current robot-based applications, in order to design an optimal solution.
- to define a conceptual framework of rehabilitation based on automated and robotic systems for enhancing the traditional rehabilitative process.

After defining the conceptual framework and its components, the thesis focuses on identifying the technical requirements for the development of the proposed framework. As a result, it has been identified a gap in the state-of-the-art for the case of automated systems for assessment. Thereby, the focus of research primarily points to the following goals:

- to develop an objective, more descriptive, and automatic assessment system based on a traditional clinical test for measuring upper extremity functionality.
- to investigate robot-based strategies and related-technology for the development of rehabilitation (intervention) systems for recovery of upper extremity motor function.
- to evaluate the feasibility of proposed systems in real hospital scenarios with patients with a neurological disorder.

Note that the intervention strategies addressed in this thesis has two purposes: (1) serve as a deployable tool in a hospital environment, and (2) produce changes in upper extremity functionality in order to evaluate the feasibility of the automated assessment system.

1.6 Organisation of document

The research conducted in this thesis produced a total of seven journal articles. Hence, this thesis uses the format of a compendium of publications for its submission. Figure 1.2 associates the publications with the topics of research, according to the framework proposed in this thesis. A yellow star marks the topics resulting in a journal publication.

The structure of the document establishes ten chapters grouped into three parts: (1) introduction, (2) results, and (3) conclusions. The organisation of the chapters is the following:

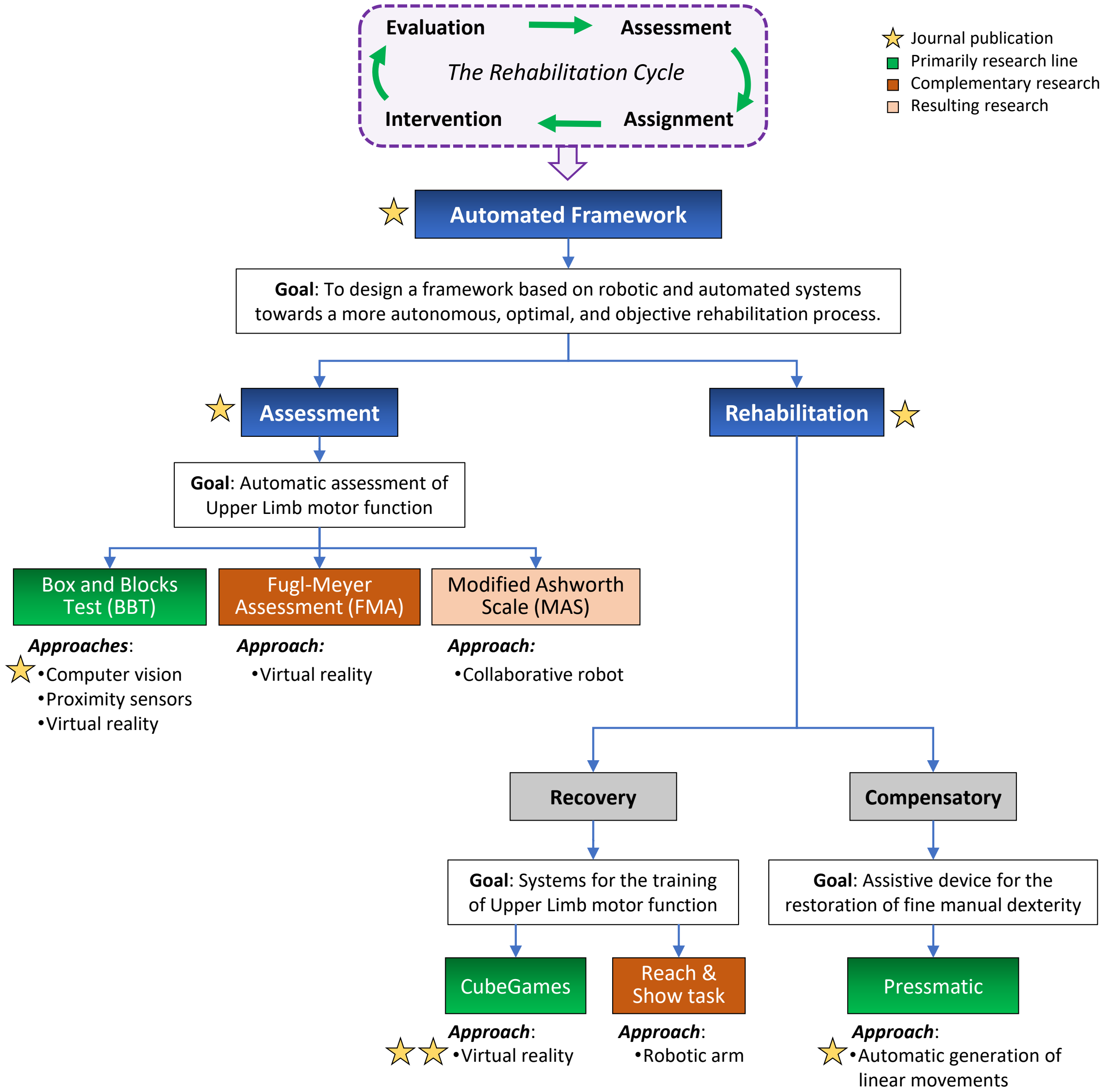


Figure 1.2: Outline of publication milestones according to research topics.

- The current **Chapter 1** presented the research significance from the technical and clinical perspectives, the scope of the thesis, a brief overview of the relevant issues of state-of-the-art rehabilitation robotics and, ultimately, the goals of this doctoral dissertation.

- **Chapter 2** presents an overview of the conceptual framework for autonomous rehabilitation using automated and robotic systems that are proposed in this thesis. Three components compose the novel framework: (1) automated assessment systems (AAS), (2) rehabilitation robotic systems (RRS), and (3) decision support systems (DSS). These elements are strongly linked with the rehabilitation cycle followed in clinical practice. This chapter also describes the systems developed according to the proposed framework of rehabilitation.

- **Chapter 3** presents the journal publication that describes in detail the components and functionality of the conceptual framework for autonomous rehabilitation.
- **Chapter 4** presents the journal publication that describes in detail the fundamentals, technical requirements and taxonomy of automated assessment systems, that is the main focus of research of this thesis.
- **Chapter 5** includes the journal publication that details the fundamentals, technical requirements and perspectives of robotic rehabilitation systems for its extended use in clinical practice.
- **Chapter 6** includes the journal publication that detail the fundamentals, design considerations, functionality and clinical validation of a system for automatic assessment of manual dexterity, denoted as the Automated Box and Blocks Test (ABBT).
- **Chapter 7** presents the journal publication that summarises the fundamentals, design considerations, functionality description and feasibility study of the gaming-based system for improving the functionality of upper extremity.
- **Chapter 8** presents the journal publication that supports the clinical validity of the video game-based system. The chapter presents the results from a pilot trial in a hospital with a moderate sample of patients with Parkinson's Disease (PD).
- **Chapter 9** presents the journal publication that describes the design and development of an assistive device that helps the user in task required of manual dexterity.
- **Chapter 10** includes the research conclusions and outcomes, future research opportunities and challenges, and potential directions for the project.

CHAPTER 2

Novel framework for neurorehabilitation

2.1 Introduction

The purpose of this chapter is to describe the fundamentals and components of the proposed conceptual framework of rehabilitation, which aims to cover any rehabilitative process; for instance, functional rehabilitation of upper extremities. The remainder of this chapter is as follows: Section 2.2 summarises the description of the rehabilitation cycle as a general process and the fundamentals of motion generation. The components of the rehab cycle serve as a design reference for the framework presented in this thesis. Section 2.3 presents the definition of the conceptual framework and its components. This framework aims to implement a more autonomous, reliable, and objective rehabilitation process but keeping the clinical meaning of the traditional rehabilitation cycle. Section 2.4 describes the systems developed for automatic assessment of hand motor function. Section 2.5 presents the strategies implemented as intervention tools with hospital application. Finally, Section 2.6 describes the general model for clinical validation of the developed systems.

2.2 Overview and fundamentals

The previous Chapter 1 exposed the needs and limitations that are facing the healthcare systems to provide assistance and rehabilitation support to patients with a neurological deficit. Also, the high prevalence of neurological diseases brings increased problems to healthcare providers worldwide. In order to enhance the current methods of rehabilitation, this thesis proposes a novel framework to become as autonomous as possible the stages of the rehabilitation process. In this way, problems such as limited available equipment, long-time treatments, or the period of inpatient attention can be reduced. Additionally, the health strategy of this framework may serve as a link between medical professionals and researches towards jointing efforts to optimise the process of neurological rehabilitation. Thus, the systems implemented under the umbrella of this framework could be more feasible to be adopted in clinical settings, since the ambiguity between clinical usefulness and technical viability will be reduced. Since the fundamentals and components of the traditional rehabilitation cycle are the design reference, before presenting the proposed framework, the following section describes the components and principles of the rehabilitation cycle.

2.2.1 The Rehabilitation Cycle

Rehabilitation is a term difficult to define but, very briefly, it denotes a package of measures or health strategies designed to lessen the impact of disabling conditions [1, 8]. Despite the strategies could be different, they can share a series of stages throughout the rehabilitation process. These stages involves the identification of a person's problems and needs, relating the problems to relevant factors of the person and the environment, defining rehabilitation goals, planning and implementing the measures, and assessing the effects [23]. This problem-solving approach is named the Rehabilitation Cycle [1, 23, 24]. Figure 2.1 depicts the Rehabilitation Cycle and all its stages. However, in a simplified manner, the process includes four essential stages: assessment, assignment, intervention, and evaluation [25].

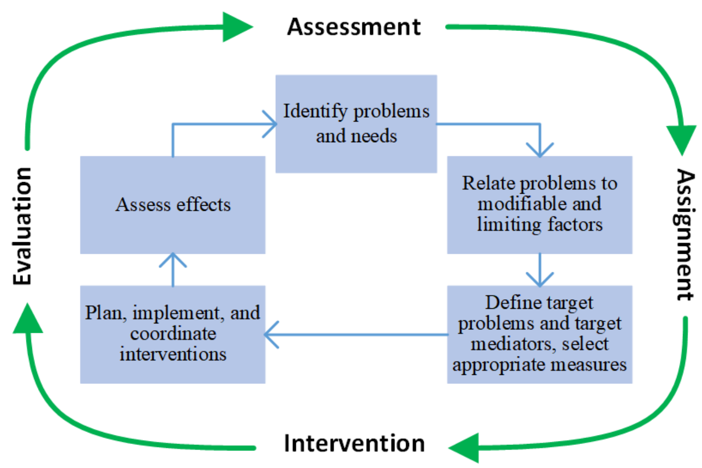


Figure 2.1: The Rehabilitation Cycle [1].

The assessment stage includes the identification of the problems, the review and potential modification of the service or goals of the intervention program, the definition of the first goals of the rehabilitation cycle, and the objectives of the intervention. The assignment stage refers to the allocation of professionals and health interventions necessary to achieve the intervention objectives. The intervention stage consists in the specification of the techniques, measures, and the definition of target values that must be achieved within a predetermined period of time. Finally, the evaluation step determines the achievements of the objectives with respect to the specific indicators, the goals of the rehabilitation cycle, and, ultimately, the goals of the intervention program. It also includes the decision regarding the need for another intervention cycle based on a new assessment.

It must be noted that the starting and ending steps of this cycle are assessment and evaluation, respectively. In both stages, a series of standard tools (tests) are employed for measuring the physical condition of patients. These measurements help to make a diagnosis and determine the effectiveness of treatments (goal achievement), at the beginning and the end of the cycle, respectively.

The rehabilitation cycle can be considered as a general model for any rehabilitative process. However, in the case of neurological rehabilitation, particular aspects must be considered. The following section provides an overview of the main aspects and fundamentals of neurological rehabilitation.

2.2.2 Factors involved in motion generation

Neurologic rehabilitation is "an active and dynamic process through which a disabled person is helped to acquire knowledge and skills in order to maximise their physical, psychological, and social functioning" [8]. In this context, the concepts of neural plasticity, motor control, and motor learning are gaining relevance as essential principles underlying such a process. There are several theories of motor control (aiming to explain the manner that the brain governs movement) and motor learning (aiming to describe the nature and control of the acquisition/modification of movement). An in-depth study of such theories is out of the scope of this thesis. However, due to the high relevance of movement recovery in the design of robot-mediated therapies, this section describes the essential concepts and factors that participate in motion generation.

Neuroplasticity is the brain's ability to create new connections and pathways or change how its circuits are wired. Thus, proper interactions may produce neuroplastic changes which reflect into functional consequences. This approach is the basis of motor recovery and, consequently, the keystone of therapeutic interventions under the assumption of neural connections rewires in response to training.

Motor control can be defined as the ability of brain to regulate the mechanisms essential to movement [26]. Namely, this science try to describe how the brain controls the movement and which factors are involved in the process. There are many theories related to motor control; for instance, the hierarchical, reflex, systems, motor programming, among others. The assumptions about how movement is controlled from these theories are the basis of specific practices used to examine and treat the patient with functional impairments.

Motor learning is a change in motor behaviour associated with practice or experience, being such a change 'relatively permanent' [26]. This interpretation highlights the contrast between learning and performance. An improvement of performance can result from practice being a temporary change in motor capability, while learning implies a permanent change in behaviour. This fact explains that certain practice effects in robot-mediated therapy can improve performance initially but are not necessarily retained, which is a condition of learning.

Due to the association with experience, learning results from an interaction of the individual with the task and environment. Figure 2.2 depicts the factors concurring in movement organisation. Furthermore, focusing on the individual's characteristics, motor learning involves more than 'motor' factors, but rather it emerges from a complex set of processes that includes perception (integration of sensory information), cognition (organisation to achieve intentions), and action (the context of motion performing) [26].

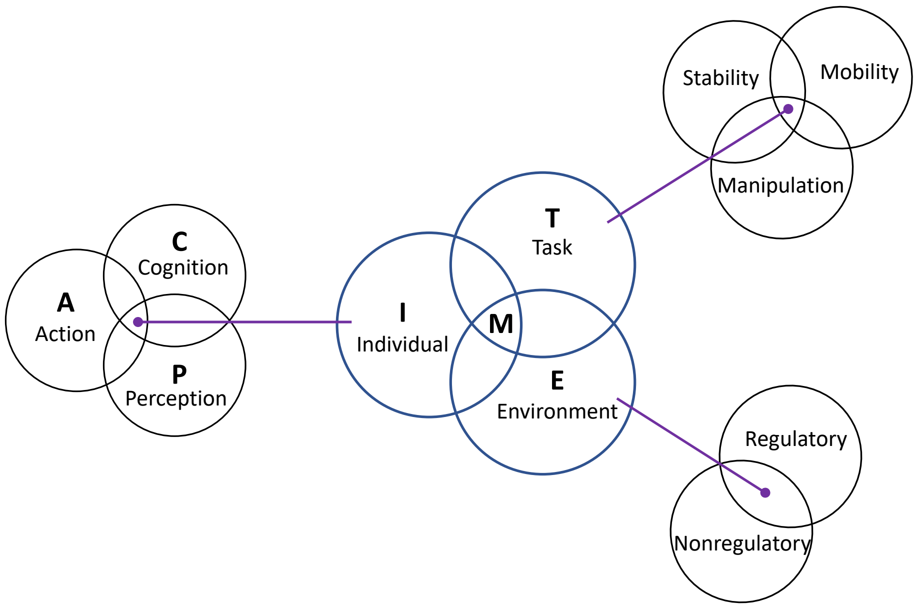


Figure 2.2: Factors involved in organisation of movement. Adapted from [26].

Currently, it is not clear whether modern robot-mediated treatments can stimulate all the factors (individual, task, and environment) that compose the nature of the movement correctly. Understanding the influence of these factors in clinical practice towards the consolidation and retention of skills has potential implications in robot-based rehabilitation, as this knowledge may translate into improved training-based neurorehabilitative interventions. Hence, a complete rehabilitation strategy must address (1) the processes within the individual to generate proper stimuli, (2) the attributes of the exercise (task), and (3) the context (environment) in which motion is performed. This approach implies the correct stimulation of the individual's capacity to meet interacting tasks and environmental demands. As a result, the final goal of robot-based treatments must not be only practice but promoting learning of skilled actions. This way, the functional achievements are translated into long-term gains, which are likely more transferable to the ADL.

2.3 Conceptual framework of automated rehabilitation

This thesis proposes a conceptual framework of rehabilitation that combines in the same paradigm the principles of the rehabilitation cycle and the advances of robotics and automation. On one side, the traditional process of rehabilitation lack of any degree of automation (as a holistic process). However, there is a huge potential for automation in several stages of the process. On the other side, robotics and automation are mature sciences with a large development for healthcare purposes in recent years. However, the adoption of this technology in hospital settings is still limited. The conceptual framework proposed in this thesis aim to make as autonomous as possible the process of rehabilitation, while analysing the main limitations and barriers for its adoption in clinical environments.

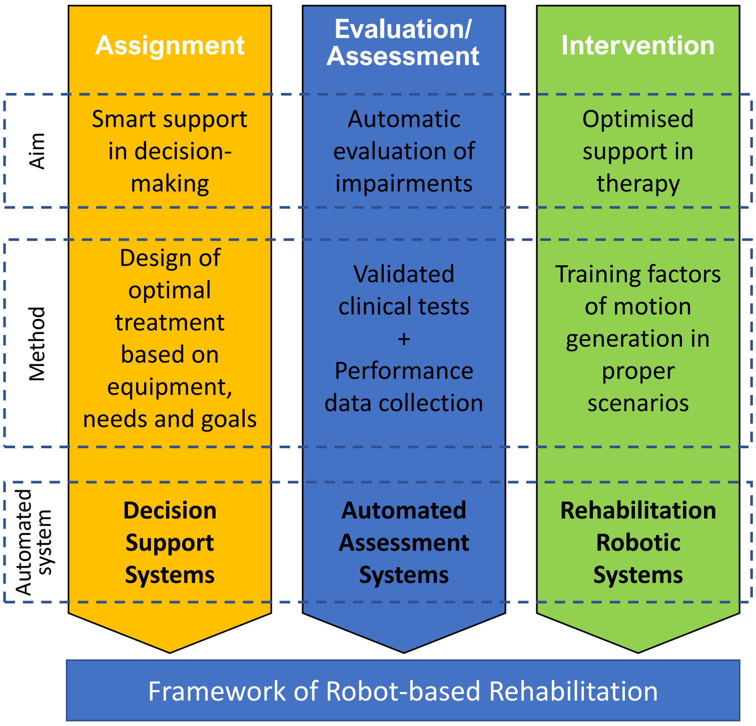


Figure 2.3: Conceptual framework of automated rehabilitation.

In order to automate as much as possible the rehabilitation process, it is first necessary to identify how the process is developed and identify which are the most susceptible elements to be automated, as well as the requirements and limitations to achieve this purpose. For that purpose, a systematic literature review on robotic systems for rehabilitation was conducted [27]. Thus, three phases of the rehabilitation process were labelled as susceptible for automation. These phases are (1) the evaluation of treatment's effectiveness, (2) the implementation of interventions, and (3) the planning of treatment protocols.

It can be appreciated that these phases are strongly linked with the components of the simplified cycle of rehabilitation. Thereby, by using the simplified version of the rehab cycle as a design reference, the traditional rehabilitation process is transformed into a more autonomous process that represents the novel framework. This transformation is depicted in Figure 2.3. Consequently, the proposed framework of rehabilitation is composed of three automated components that are directly correlated with the blocks of the original rehab cycle. These automated components are denoted as: (1) automated assessment systems, (2) rehabilitation robotic systems, and (3) decision support systems. This transformation does not alter the rehabilitation cycle, but adds to the process the benefits of automation. It also maintains the philosophy centred on the user and the clinical meaningfulness of procedures.

According to this novel strategy, three main actors interact during the rehabilitation process: patient, clinician, and automated systems. In this conceptual framework, the main actors (patient and clinician) are supported by several automated systems. The interaction between these three participants during the course of an automated neurological rehabilitation process is described in Figure 2.4.

Firstly, an initial evaluation (interview and exploration-based) is carried out by the clinician to identify the patient's problems and needs, resulting in the selection of most appropriate treatment measures. Also, the suitable scales for functional assessment are chosen to quantify the level of impairments to treat.

Secondly, the functional assessment is conducted using the scales chosen by the clinician. In this stage is where the first automatic system acts, the automated assessment system (AAS), to perform the functional evaluation using strategies based on clinically accepted scales and, consequently, providing similar metrics. The results of evaluation using the AAS are automatically updated in the patient's clinical history or electronic health record (EHR). In addition, these results serve as input parameters to the second automatic system, the decision support system (DSS).

The DSS aims to design optimal treatment protocols for the patient, generating the specific intervention plans that fits the particular patient's needs. Since neurological rehabilitation actively considers the patient's goals, the therapist discusses with the patient to review and adjust the objectives, deciding which treatment plans proposed by the DSS will be adopted. This treatment plan includes the selection of the intervention resources that best fit the treatment goals. Research has demonstrated a link between shared decision-making and positive patient outcomes, and indicates that patient-therapist collaboration on intervention goals results in both shorter hospital stays and better goal attainment [28].

Then, the selected rehabilitation robotic systems (RRS) perform the intervention. After the intervention with the RRS, an assessment of functionality similar to the initial one is carried out

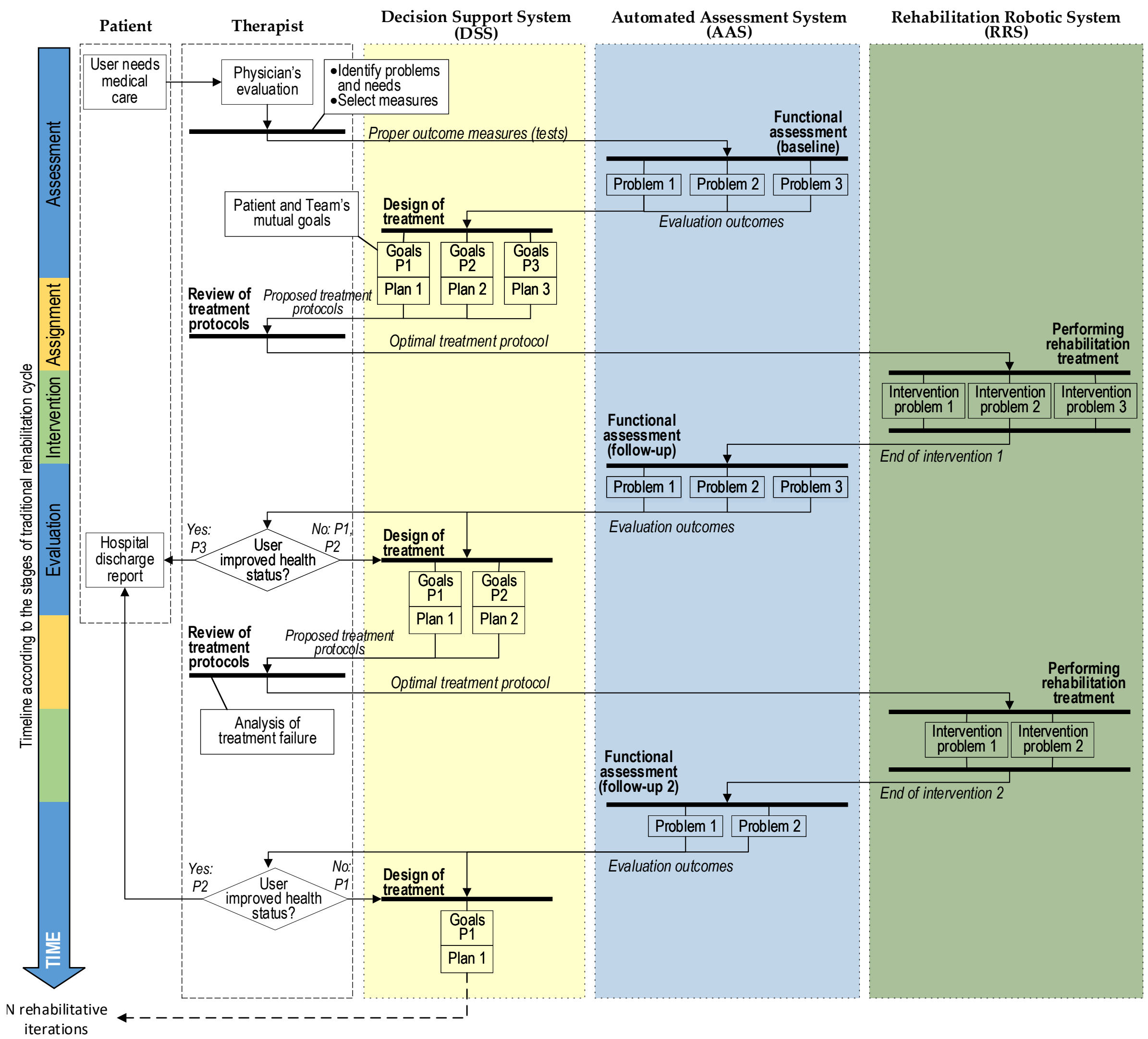


Figure 2.4: Framework for the automation of the rehabilitation cycle: activity diagram.

again, in order to quantify the effectiveness of the therapeutic measures. For that purpose, the AAS is used again. Finally, if all the problems identified are considered resolved or accepted by both the clinician and the patient, the rehab cycle is concluded. Otherwise, the necessary iterations will be made to try to solve the remaining problems.

It can be deduced that the proposed automated systems operate separately and independently but that they are intrinsically connected and depend on each other for efficient operation, in coordination with the clinician and the patient. Thus, the proposed framework can be considered as a distributed strategy. A complete description of the conceptual framework of rehabilitation is available in Chapter 3. Nevertheless, the following section briefly describes the functionality of each component of this distributed and automated framework.

2.3.1 Automated assessment systems

The conceptual framework defines as automated assessment systems (AAS) those that can automatically measure outcomes and determine the treatment effectiveness, under the paradigm of taking as a design reference the traditional and golden-standard clinical scales used in clinical practice. The main motivation for this approach is described as follows; however, a complete description of the fundamentals and technical requirements for developing the AAS is available in Chapter 4.

The final aim of clinical tests is to estimate the functioning level of a patient objectively. However, clinicians perform the assessment procedures manually and usually based on observation. This condition suggests drawbacks as labour-intensive administration, variable reliability (intra-operator) or reduced objective (inter-operator) in measurements. Besides, the nature of visual inspection implies errors that may come from a variety of sources (e.g., movement variability, observer appreciation). Furthermore, the neurologic rehabilitation process usually implies long-term treatments since the effectiveness depends on the response of the patient and the disease' characteristics.

The above drawbacks could be reduced via automation of traditional assessment tools and procedures. Most of the evaluation tests are composed of well-defined exercises or tasks (e.g., point-to-point movements, reaching tasks, object displacement) that are rated by numerical scales, which may be susceptible to automation. By automation, an objective evaluation of the patient's motor functionality could be achieved. Furthermore, the clinician could be provided with more time to assess the results and, based on this, to correct the therapy protocol, modifying the level of difficulty or adding other tasks. Thereby, three main aspects were identified as essential to implement the AAS, namely, the administration of the test, a reliable data acquisition, and automatic rating of performance. Figure 2.5 depicts the main requirements for implementing the AAS.

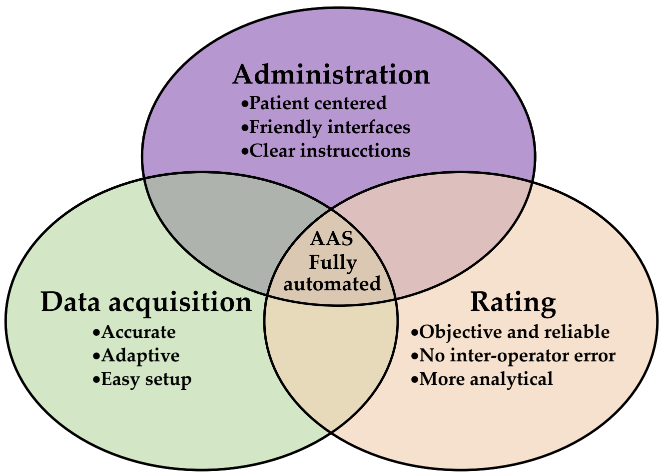


Figure 2.5: Main requirements for fully-automated assessment systems [22].

Contrary to the traditional manual procedure, the use of AAS could provide some advantages when measuring impairments. It is undeniable that automatic data acquisition systems can gather a more considerable amount of biomechanical data (measurements) related to the patient's performance. Additionally, an automatic assessment method must be able to transform the raw data (performance-based variables) into clinical metrics that can be taken as an objective clinical evaluation (impairment indicators). Consequently, objectivity in measurement would be improved by the AAS, even providing results in high-resolution metrics.

According to the rehabilitation cycle [1], the assessment and evaluation stages are the initial and final steps of the rehabilitation process, respectively. Firstly, the assessment stage serves for the identification of impairments and helps to establish a baseline in treatment planning. Secondly, the evaluation stage (or re-assessment) serves for measuring the effectiveness of rehabilitative treatment and helps to define the next steps in the recovery process. Therefore, functional assessment is a doubly important stage in the process of neurological rehabilitation. This fact is the major motivation to develop the AAS in this thesis.

2.3.2 Rehabilitation robotic systems

This component of the conceptual framework of rehabilitation includes systems based on robotics and automation technology for its usage as an intervention tool. The intervention step of rehabilitation cycle is inherently a labour-intensive process and has historically been heavily reliant on one-on-one manual interactions during several sessions. Thereby, the use of the rehabilitation robotic systems (RRS) is a promising paradigm to face the demands and budget restrictions of neurorehabilitation. The complete description, purpose, and technical requirements for the development of the RRS is available in Chapter 5. Nevertheless, the principal design considerations are presented as follows.

At present, most of robot-aided systems are based on intensive movement repetitions. This approach is referred to as task-specific training, and it is likely the most popular approach when developing robot-based systems for neurological rehabilitation. However, the reduced adoption of these systems in clinical settings generates some concerns about the suitability of this single paradigm. Evidence suggests that effective rehabilitation treatments require the practice of activities in the most relevant possible environments, rather than undertaking analytical exercises aimed at changing motor capability. Hence, according to the fundamentals of movement generation are described in section 2.2.2, suitable addressing of such factors could help to increase the effectiveness of robot-based treatments.

The understanding of the above led to the design of a novel model for robot-assisted therapy, which is presented in Figure 2.6. This model highlight the importance of aspects as human-robot interactions (patient-robot and therapist-robot) and proper exercise elaboration (task and environment) in order to optimise motor learning and promote the transference of gains to the ADL performing [29].

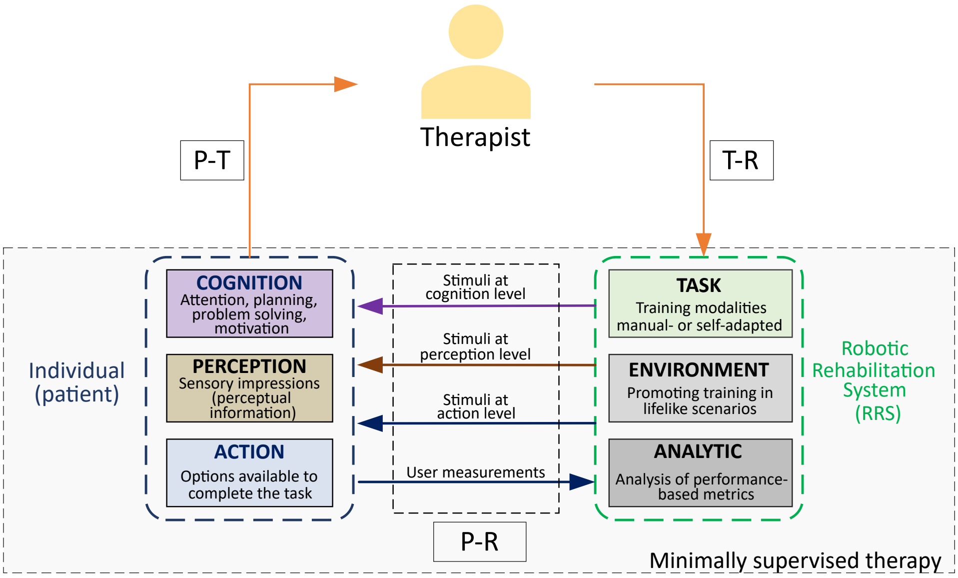


Figure 2.6: Model for optimal robot-aided therapy in clinical practice.

Thus, the development of RRS advocates the integration of novel strategies that promote learning instead of performance improvement. For that purpose, learning principles must underlay in the training strategies towards a suitable integration of perceptual (sensory information) and cognitive (e.g., attention, motivation, problem-solving) agents into the task-oriented approach.

2.3.3 Decision support systems

This component of the conceptual framework is linked with the assignment stage of the rehabilitation cycle and includes smart systems focused on supporting medical professionals in decision-making. Clinical decisions are an essential component of the rehabilitation cycle since they involve the goals definition and treatment protocol design. Thereby, the decision support systems (DDS) can be useful in tasks like the management of a large amount of data and the design of optimal (goals and equipment) treatment protocols. Currently, the support provided by modern robotic systems in decision-making is via making available for the clinician further reliable and objective information about the motor performance of the user or allowing the execution of several types of intervention procedures that can be configured by the clinician. Consequently, two manual steps of the assignment stage could be automated or empowered, for instance, by using artificial intelligence (AI) techniques: the planning of intervention treatments and the assignment of the appropriate RRS for intervention.

The generation of proper protocols must consider different factors as the type of lesion or how it affects the development of the patient's daily living activities. Many of the intervention strategies are systematised in order to deal with a particular effect (concrete measures for specific problems), but there is no reason to believe that a "one-size-fits-all" optimal treatment exists. Instead, therapy should be tailored (intensity, number of repetitions and duration of the intervention) to each patient's needs and abilities [30]. Besides, the protocol planning should consider the available tools (RRS) to execute such a protocol in order to the optimal assignment of resources.

Therefore, the development of suitable DSS must address some requirements as (1) coherence between technological and traditional outcome measures towards therapeutic interventions based on technology and the problem-solving approach; (2) differentiate these measures according to the level of the effect (mild, moderate, severe); (3) holistic models to identify the parameters that define an adequate physical condition according to the demographics of the patient and healthy profiles; (4) capability of estimating the physical condition of the user to compare it with the welfare reference model; (5) generation of feasible protocols that can be executed by the available intervention systems.

These requirements imply that the integration of an AI-powered DSS in the automated cycle requires as input parameters the results of the evaluation systems (AAS) and, based on them, generates an optimised treatment protocol that can be executed by the systems of automatic intervention (RRS). The development of strategies for allowing the integration and collaborative execution of the above automated systems require special attention.

2.4 Development of automated assessment systems

The first challenge to develop systems for automatic assessment is the proper selection of the clinical test for reference. The use of a well-known clinical test would make easy the integration of technology in the daily activities of clinicians. However, there is available a broad set of clinical tests; each one focused on assessing specific impairments of functional limitations caused by a neurological deficit. Following the International Classification of Functioning, Disability and Health (ICF), clinical tests can be sorted in body structure, activity or participation levels. Examples of tests classically encompassed at the level of body functions are the Fugl-Meyer Assessment (FMA) of Motor Recovery after Stroke, or the Modified Ashworth Scale (MAS). For evaluating activity limitations, the therapist can choose among tools as the Box and Blocks Test (BBT), the Nine-hole Peg Test (NHPG), the Action Research Arm Test (ARAT), or the Wolf Motor Function Test (WMFT). More tools are available. Finally,common scales used for evaluating participation level are the Canadian Occupational Performance Measure (COMP), the EuroQol Quality of Life Scale (EQ), the Reintegration to Normal Living Index (RNLI), the Stroke Impact Scale (SIS) and the Stroke Specific Quality of Life Scale (SQL). Detailed descriptions of the features of the above tests and more are available in [31, 32].

2.4.1 Rationale of clinical tests

Considering the variety of outcome measures, the first step to automate an assessment procedure was to identify which are the most suitable ones for that purpose. In this regard, three main features of clinical tests were studied: (1) the method used, (2) the metric provided, and (3) the frequency of use. Regarding the method, those tests that are administered without direct contact of the professional are more susceptible to be automated. But it requires a proper patient performance, so a previous explanation of the procedure or a wizard to assist them is needed. Concerning metrics, it is essential to assess which ones give relevant information and are less invasive for the subject to be evaluated. In regard of frequency of use of outcome measures, a recent systematic literature review conducted by Santisteban *et al.* established which upper limb outcome measures are most commonly used in stroke studies [33]. The frequency of use of outcome measures obtained from that study is presented in Figure 2.7.

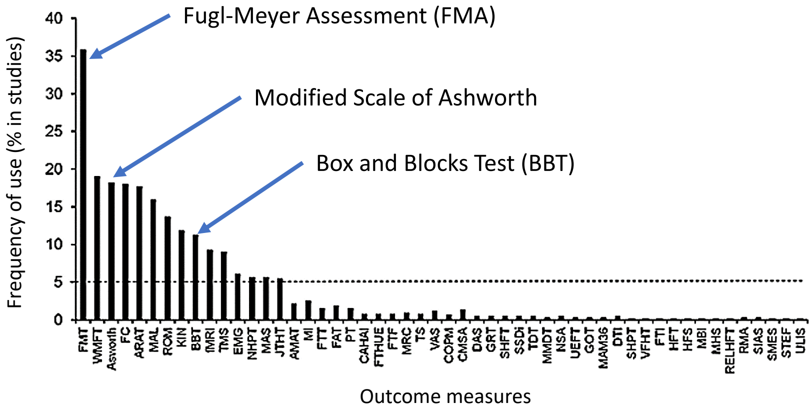


Figure 2.7: Frequency of use of different upper limb outcome measures. Adapted from [33].

On account of the above, the Box and Blocks test (BBT) of manual dexterity was chosen as a suitable clinical test for automating. The outcome of the BBT is simple (total cubes transferred), the test administration (rules and instructions) is systematic and clear, and the mechanics and stages of test are well defined. Besides, it is frequently used in clinical settings as an evaluation system in rehabilitation processes of people who have suffered a stroke. Additionally, the Fugl-Meyer Assessment (FMA) was considered for automation considering it is the most frequently test used in intervention studies. Besides, the FMA is one of the most laborious intensive test to administer due to the large set of items (or tasks) of which is composed. Other limitation of the FMA is the rating of user's performance based on visual inspection. This fact could lead to an inaccurate evaluation.

The following section describes the main characteristics of the BBT and FMA, including the equipment used for evaluating, the administration procedure, and the way of rating the performance of patients. Finally, the identified drawbacks of each test are summarised.

2.4.1.1 The Box and Blocks Test (ABBT)

The Box and Blocks Test (BBT) is a clinically validated tool for measuring the gross manual dexterity and coordination [34]. This outcome measure is widely used in clinical practice with patients with a neurological deficit, primarily stroke. The physical components of the BBT are shown in Figure 2.8-(a). The set includes a wooden box with two 290mm wide square compartments, 150 wooden 25mm cubes in colour (red, green, yellow, and blue), and a 100mm high partition. The partition is positioned between the two compartments as a central barrier.

(a) Components (b) Mechanics

Figure 2.8: The Box and Block Test (BBT).

The mechanics of the test (see Figure 2.8-(b)) is to transfer as many cubes as possible, one at a time, from one compartment to the opposite in one minute. The higher displaced cubes, the better motor performance. The rules of the BBT include that the patient's hand must overcome the central barrier to an attempt being valid; if the subject transports two or more blocks at the same time, this has to be noted and the number subtracted from the total; the blocks that are thrown from one compartment to the other must be penalised.

For the administration, the therapist face the patient to read the test's instructions before the test begins. The BBT box with all the blocks must be placed lengthwise along the edge of a table and the patient must be seated facing the box. While the test is performing, the clinician must observe the user's movements to check if each attempt of displace a cube accomplish the rules of the test. Finally, to estimate the level of manual dexterity, the clinician must manually count the total amount of transferred cubes at the end of each test's stage. The non valid attempts must be discounted from the total for obtaining the final score.

On account of the above, some drawbacks about the traditional BBT-based assessment procedure can be identified. Firstly, the test administration is time-consuming and labour intensive. Secondly, the outcome is obtained by manual counting of the transferred cubes and observation-based rating of valid attempts, which could lead to an error in the measurement. Finally, the obtained information is limited, since it does not provide additional information about the user performance. There is evidence supporting that motion analysis (quality) is feasible based on the BBT mechanics [35].

2.4.1.2 The Fugl-Meyer Assessment (FMA)

The FMA is a stroke-specific, performance-based index to assess the sensorimotor impairments in individuals with a neurological deficit, and primarily, who have had a stroke [36]. The FMA is made up of five domains, each one composed of a set of single movements or tasks, denoted as items, being 155 items in total. The FMA's domains covers: Motor functioning (in the upper and lower extremities), Sensory functioning, Balance, Joint range of motion, and Joint pain. Considering the broad scope of the FMA, there is a simplified version that focuses on the upper extremity functioning, denoted as the Fugl-Meyer Upper Extremity (FMA-UE) [37]. This subset is made up of 33 items distributed among sensation, passive joint motion, joint pain, and motor functionality. The latter domain includes items for assessing movement, coordination, and reflex action of the shoulder, elbow, forearm, wrist, hand.

(a) Demonstration stage (therapist)

(b) Imitation stage (patient)

Figure 2.9: Mechanics when administering the FMA.

Overall, the mechanics of the test consists of the therapist showing an item (movement) and verbally asking the patient to perform it. Then, the subject must imitate such an item. Figure 2.9 depicts the mechanics of FMA's administration.

The therapist must directly observe the patient's performance for scoring each item. The outcome is given on the basis of ability to complete the item using a 3-point ordinal scale (0 = unable to perform, 1 = partially performed, 2 = fully performed). The total possible scale score is 226 points for the FMA and 66 points for the upper extremities subsection (FMA-UE).

On this basis, it can identified some limitations of the traditional FMA procedure. Firstly, the FMA is a very lengthy and labour intensive test to administer, because of the large number of items [38]. Secondly, the assessment process is based on the visual inspection of user's movements or performance, being susceptible to the effect of motion variability and inter-operator appreciation. Finally, other criticism of the FMA is the reduced resolution in movement's rating due to the three levels of performance. Hence, increasing the resolution of the scale could be beneficial for measuring the quality of items.

2.4.2 The Automated Box and Blocks Test (ABBT)

The automated version of the BBT implemented in this thesis is referred to as the Automated Box and Blocks Test (ABBT). This system has three main goals: (1) automatic scoring of displaced cubes, (2) autonomous as possible administration of the test, and (3) gathering of additional metrics about the user's performance.

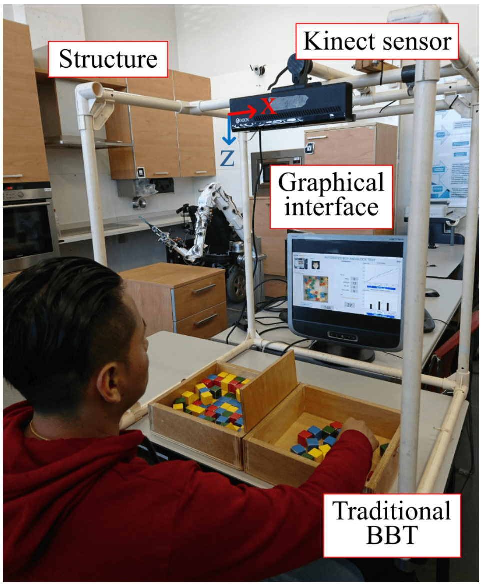
For that purpose, three different approaches were considered: (1) not including changes in the traditional physical setup [39], (2) including the minimal changes in the traditional physical setup [40], (3) exploring the feasibility of gaming technology for developing a new tool [41]. Following section describe each automating approach.

2.4.2.1 System based on computer vision

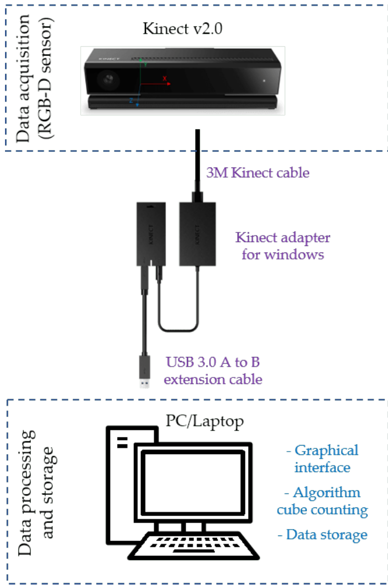
The design principle of the first strategy used for the automation of the BBT considered not altering its physical composition. This fact implies that not including sensors in the BBT box and the cubes was a design requirement. Since the classical process of evaluation is based on directly observing the patient's movements, the ABBT was implemented using an approach based on computer vision for monitoring the cubes' displacement and hand motion. For this application, the chosen sensor was an out-of-the-shelf camera, such as the Kinect sensor. Hence, the data acquisition method of the ABBT is similar to the visual inspection performed by the therapist.

The physical setup of the ABBT is depicted in Figure 2.10. It is made up of a portable and lightweight cube-shaped structure placed on a standard desk. At the top of the structure, a Kinect for Windows V2 sensor is fixed. Thus, the structure serves as a portable physical support for the sensor. The classical BBT box is located on the desk and in the centre of the structure. This setup is perfectly transportable, allowing an outpatient evaluation.

According to the previously mentioned requirements for proper automation of the test, the data acquisition of the ABBT is based on an accurate and reliable sensor as Kinect. Initially, this sensor was developed as a gaming accessory for the Xbox 360 console. However, it has been widely used in



(a) Setup for assessment



(b) Hardware connection

Figure 2.10: The Automated Box and Blocks Test (ABBT) [39].

applications related to healthcare, body tracking, image processing, video games, etc. In particular, one of the main advantages of this sensor is the reliability for tracking of human body joints without the need to attach markers to the user. Besides, the high portability and low cost of Kinect makes this device adequate for our application.

Concerning the administration, a graphical user interface (GUI) was implemented for helping the patient throughout the development of the test. The main functionalities of the GUI are to provide the instructions to the patient via text and audio messages, show to the therapist information of cubes' detection, and store all the treated raw data automatically. The latter feature helps in the management of an electronic health record (EHR) of the patient by centralising the data obtained into the patient's profile.

About automatic scoring, the outcome (number of cubes) is automatically rated through an in-home-developed algorithm. This algorithm was implemented in Matlab software that provides hardware support packages, includes a set of toolboxes and libraries for image processing, and offers the development environment GUIDE to create graphical interfaces. The algorithm for automatic cube counting is made up of three phases: detection of compartments, colour segmentation, and score validation.

Firstly, both the left and right compartments of the BBT box are identified by seeking the edge of the box. For that purpose, the depth information from the Kinect sensor is useful. Once the compartments are identified, the empty compartment is chosen as a region of interest (ROI) for the cubes counting. This ROI is cropped frame-by-frame from the whole scene captured by the camera. Subsequently, the ROI is segmented in the CIELab colour space for detecting the cubes according to colour. For that purpose, it is necessary to quantify the features of the cubes. Thus, several experiments were performed to define some colour markers to identify the colour of the cubes inside the compartment. The average size of a single cube was also measured during experiments. Finally, it is necessary to check if the rules were accomplished for scoring a cube as a valid attempt. To this end, a time vector to compare very close events is used during the performance of the test. On the basis that a healthy individual takes about a second to move a cube, it is detected whether two or more cubes have appeared in very close time instants and within a period of less than a second. In that case, the additional cubes are discarded, and the global counter is only incremented by one unit.

It is necessary to highlight the capability of extracting additional objective and performance-based metrics using the ABBT. Firstly, not only the total amount of displaced cubes is given, but also the time instants in which they were detected. By analysing such information, different trends in the displacement of cubes can be appreciated, which are linked with the hand speed and grasping ability. Hence, the richer information generated by the ABBT can extent the traditional clinical indicators of patient's health status. On one side, for example, the slopes represents the average speed of cubes displacement and they can be obtained for each hand. Comparing the performance of both hands can estimate the effectiveness of treatment, and thereby, an improvement in motor functionality. This fact is important because the goals of therapy must be personalised for each patient. The comparison of the performance of their own arms could be a good strategy to reduce the effect of heterogeneous procedures. On the other side, the instantaneous speeds, that depends on the time periods elapsed to transfer a block and the next one, are also useful to compare the level of functionality. This partial times could be used as an indicator of coordination in the arm movements, related to the dispersion of the samples.

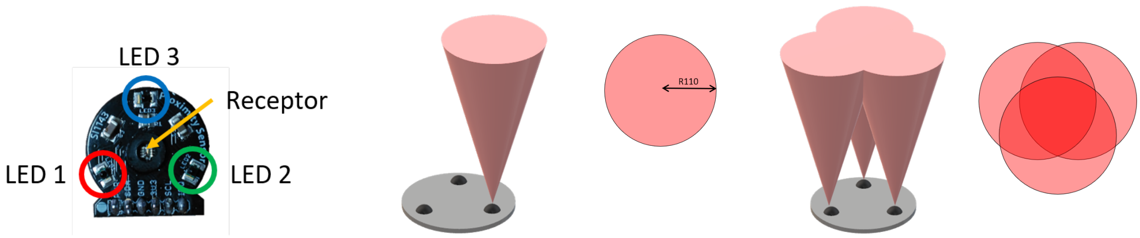
The complete description of the ABBT and the study of the hypothesis previously stated regarding the novel metrics of motor functionality can be found in the papers that supports this thesis. For facilitating the review, the publications related with this part of the thesis are summarised in Appendix A.2.

2.4.2.2 System based on proximity sensing

The second approach was to develop a sensor-based strategy with the minimal modifications of the physical setup. As previously described, at the beginning of the test, all the cubes are placed in one compartment while the opposite one is empty. In the evaluation process, the user must transfer as many cubes as possible to the empty compartment, overcoming the central barrier in all the attempts. By analysing the development of the BBT, it can be observed that the mechanics of test keeps similar in all the stages (training, affected hand, or non-affected hand). Hence, considering that the main goal is to automate the test's outcome, it is necessary to detect the instant time when the cubes are falling in the empty compartment.

For this purpose, it is necessary to define the best approach to place sensors in the BBT box and chose the best technology. The final idea is to obtain an affordable, reliable, and optimal (minimal number of sensors) solution for not increasing the cost of the BBT. Therefore, the first step was to compare the current solutions for small object detection having in mind the above requirements.

On account of the above, a system based on proximity sensing was chosen for this application. The chosen proximity sensors are based on the SI1143 chip, which includes photo-diodes and driver circuitry for three LEDs [42]. Figure 2.11 depicts the proximity sensor board.



(a) SI1143 sensor (b) Detection area for one LED (c) Detection area for three LEDs

Figure 2.11: Proximity sensors employed for detecting cubes.

The technical specifications for the SI1143 proximity sensor are available in [42]. However, several empirical trials were conducted for more complete characterisation of detection area. As a result, the following features and limitations were identified:

- *Maximum detection distance*: The sensing range is reduced with moving objects, also depending on the size, material and shape. Hence, the effective detection distance was empirically identified as **20 cm** for small cubes.

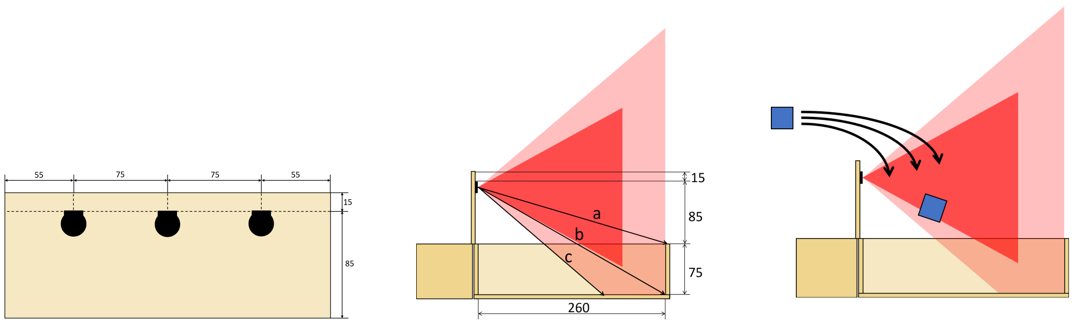
- *Sensing area*: it can be approximated by a solid of revolution given by a cone, having one photo-diode at the vertex (see Figure 2.11-b). The radius of the base of such a detection cone is 110 cm. Since three photo-diodes are available on the board, the area of detection is three times wider (see Figure 2.11-c).

- *Dead angle*: there is a blind spot on the sides of the photo-diode due to the sensing area is estimated by a solid of the revolution.

- *Positioning restrictions*: A sensor located nearby the walls of compartments or corners receive interference of surrounding. Lifting the sensor's position from the bottom reduces the effects of the surrounding.

- *Susceptibility to crosstalk-like effect*: When having two sensors, if they are located facing each other, the possibility of signal interference is high. It is recommended that the sensors are located in a shared plane.

According to the above specifications, the central barrier was determined as the best location for a sensing bar. The central barrier is at a high position, it provides a common plane for sensors, and it is far from the compartments' walls. A total of three proximity sensors were employed to compose the sensing bar. The position of sensors is depicted in Figure 2.12-a.



(a) Proximity sensors distribution (b) Detection area (c) Usual cube trajectories

Figure 2.12: Bar of proximity sensors employed for detecting cubes.

Figure 2.12-b depicts the effective sensing area of the proximity sensors in the proposed setup. It can be noted that the useful sensing area covered by the sensor bar is a bit lesser than the size of a compartment. However, the typical trajectories of cubes are nearby the central barrier since the release point is when the user has overcome it (see Figure 2.12-c). On this basis, it is expected that most of the cubes pass through the useful sensing area when they fall inside the compartment.

For this system, the principle of cube detection is simple, and it is based on detecting the flags in the sensing bar. The triangular arrangement of photo-diodes is helpful to recognise both the rinsing and falling edges of the signal produced when a cube cross the sensing bar. Thus, the typical downward trajectory of cubes can be identified. This fact is useful to reject undesirable events. For example, if a cube rebounded off the bottom, this event will be recognised and discarded as a new cube.

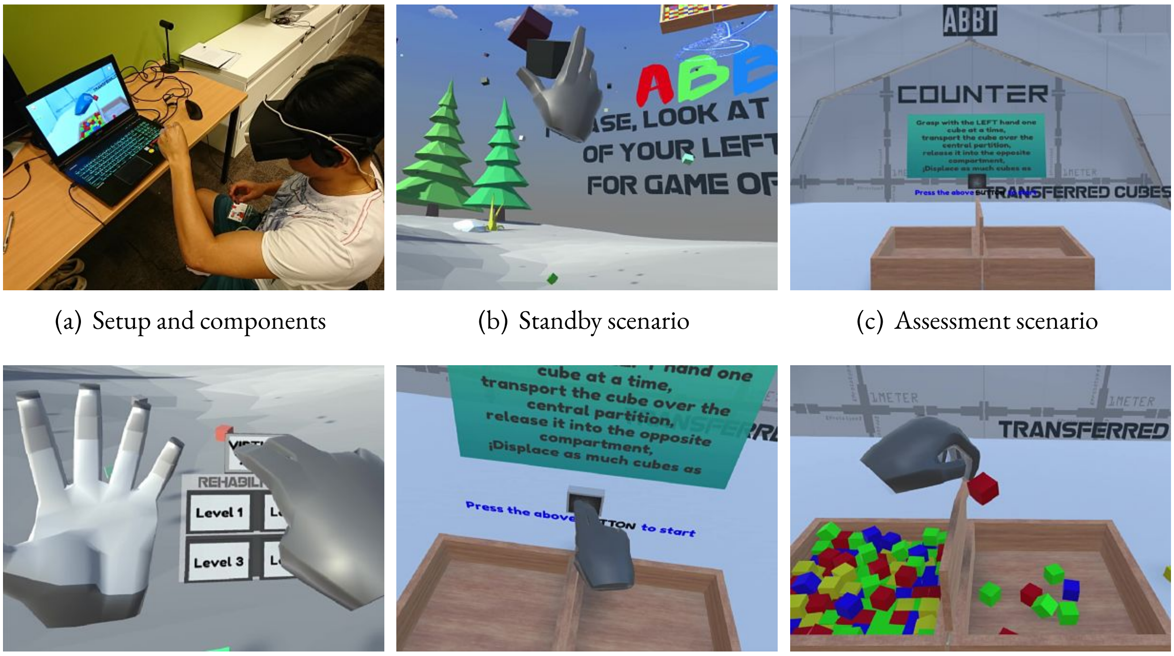
To evaluate the feasibility of this approach, a 3D printed replica of the central barrier was built and three proximity sensors were placed on the sides. An Arduino Mega board was used to control and process the signal received from proximity sensors. The effectiveness of cube counting was tested in the laboratory with healthy users. As a result, the success rate in cube detection was stated as 98.22% in average up to 150 cubes. A detailed description of experiments and results is available in [40].

2.4.2.3 System based on virtual reality

With the evolution of video game industry in the last years, game controllers have evolved into reliable human body tracking sensors, such as Kinect, Leap motion controller (LMC), Nintendo Wii or Sony Play Station Move. The typical applications of video games for healthcare has been to promote the physical exercise in a virtual environment. These type of video games are referred to exergames, and it feasibility to enhance the motor function has been proved. However, the advantages of gaming technology for the assessment of motor function have been not yet fully explored. Hence, considering the potential of gaming technology in health care, in this thesis it was studied a new paradigm for the assessment of motor function using virtual reality (VR).

On this basis, a game-like system focused on the automatic assessment of manual dexterity based on the BBT was built. The implemented system was denoted as the virtual-reality-based box and blocks test (VR-BBT), since the fully immersive experience. This VR-based system includes a reliable data acquisition of hand movements by using the LMC sensor. The therapist-patient interaction during the performance of the test is embedded in the gameplay for an automatic administration. Finally, an automatic outcome generation according to the traditional test mechanics is implemented by sensing the interplay into virtual environment. Additionally, a higher level of immersion with a 3D workspace in VR is obtained via using a VR headset. The integration of such aspects makes this system potentially useful in a clinical setting as it combines clinical knowledge with more refined capabilities of biomechanical capture systems.

Figure 2.13 shows the setup of the VR-BBT and the process for automatic test administration. Two scenarios were implemented: standby and assessment. The standby scenario (Figure 2.13-b) is an outdoor space represented by a forest where 2-inch size cubes are moving around the user for interacting. The goal of this scenario is to help the user to become familiar with grasping virtual cubes and offer the user the possibility of exploring the actions that they can perform. This stage is similar to the training stage of the traditional BBT. The assessment scenario (Figure 2.13-c) is oriented to measure the manual dexterity as the BBT mechanics demands. This environment is made up of the BBT box, a black button to control when the test starts, various panels to display information (time, score, instructions, etc.), and a clear-grey table as a reference plane to support the previous components.



(a) Setup and components (b) Standby scenario (c) Assessment scenario

(d) Interactive menu (e) Navigation clues (f) Evaluation mode

Figure 2.13: The virtual-reality-based box and blocks test (VR-BBT).

Assessment-oriented gameplay One of the relevant features of virtual reality is the capability to model easily the user-game interaction. This characteristic is specially useful in the VR-based BBT in order to administer the evaluation step-by-step in a friendly and automatic manner. This automatic administration of the test is obtained via pre-programmed gameplay and reinforced for an interactive navigation menu and informative panels.

The process of evaluation is described as follows. From the standby scenario, the user might launch the assessment stage when she/he feels comfortable with the nature of VR and virtual grasping action. There is no a time limit to stay in the standby environment. To launch the assessment scenario, a gesture similar to looking at the palm of the left hand will deploy the navigation panel and the user must use the right hand to activate the assessment button. The gameplay of the system is designed to automatically lead the user to the proper assessment phases, that is, dominant and non-dominant hand, respectively. This automatic sequence of execution takes as reference the user's profile where the therapist must define which is the affected side. If not stated, the system will evaluate firstly the left hand by default.

In each assessment phase (dominant and non-dominant hand), the system provides the user the corresponding instructions through text and audio messages prior the execution of test. The user must confirm he/she is ready to start by pressing a virtual black button. After pushing the button, a regressive counting (Ready, Steady, Go) is activated and displayed on a frontal panel. According to the dominant hand, the virtual cubes will appear at the corresponding left or right compartment. The previous procedure is repeated by the non-dominant hand. When both stages were completed, a farewell message is displayed, and the video game closes the assessment level and goes back to the standby scenario.

It must be highlighted that the grasping action of virtual cubes can be performed naturally. That is, the user can use a pinching grasp (thumb and index fingers), three fingers (thumb, index and middle fingers), or a fist action. Besides, the hand movements are automatically stored, the same as with the number of transported cubes. Tracking of hand movements make possible a post-session analysis of the paths performed by the patient, allowing to assess the quality of motion. This feature is quite relevant since it offers a cost-effective alternative to expensive and complex motion capture (MoCap) systems like Vicon or OptiTrack. Finally, the flexible modelling of VR-based systems allows for implementing new or adapted assessment strategies. The presented VR-BBT system offer four assessment levels which are slight variants of the native assessment mode where all the cubes appears.

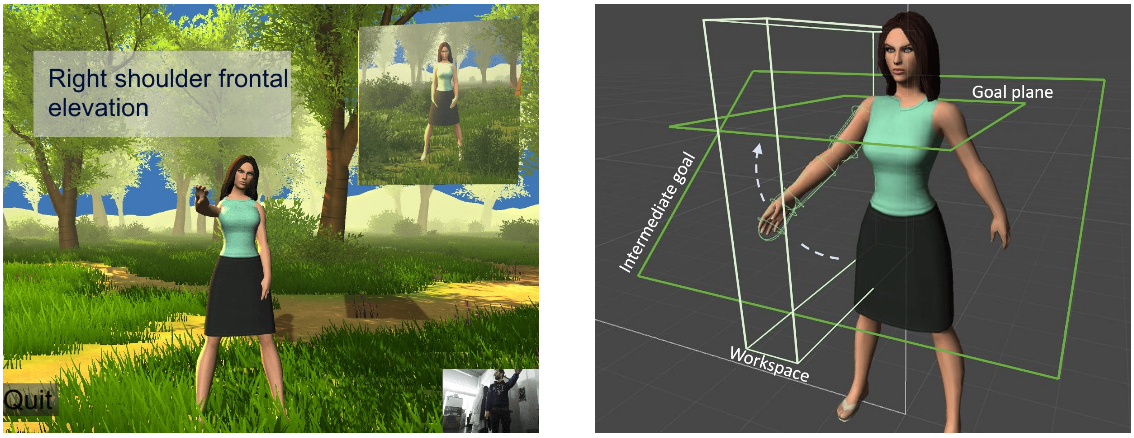
A complete description of the VR-BBT system and a feasibility study can be found in part of the papers that supports this thesis. For facilitating the review, the publications related with this part of the thesis are summarised in Appendix A.3.

2.4.3 The Automated Fugl-Meyer Assessment (AFMA)

As previously mentioned, the FMA process presents some inconveniences, such as labour intensive administration, low-resolution information of motor impairment, and observation-based rating. In order to reduce such limitations, in this thesis it was explored the feasibility of using virtual reality for the automation of the FMA, focusing on the upper extremity subsection.

The implemented system was denoted as the Automated Fugl-Meyer Assessment (AFMA). The principle of working of the AFMA is to replicate the therapist-patient interaction (administration) and to measure the patient-environment interaction (rating) by utilising a virtual environment. A Kinect sensor capture the user's movements (data acquisition), which are replicated in the virtual scenario by an avatar. In this way, the user can see a virtual representation of his/her movements. The virtual environment is designed to detect the user's motion and, ultimately, to categorised the performance of movements according to a criterion based on the FMA scale. The assessment mechanics of the AFMA is detailed as follows, separately describing the administration and rating processes.

On one side, the virtual scenario gives the chance of guiding the patient to perform specific movements through visual and audio messages (see Figure 2.14-a). This interplay is similar to the one delivered by the therapist when demonstrating the movements the patient must try to imitate.



(a) Assessment scenario (b) Measurement strategy

Figure 2.14: The Automated Fugl-Meyer Assessment (AFMA) setup.

Since the FMA is divided into several items (or movements), a video recording for each item is played. The video recording represents the clinician demonstrating the required movement. Additionally, a description of the item is given to the patient via text and audio messages, concurrently with the video playing. After the demonstration, the system asks the patient to imitate the movement displayed in the video recording. Then, the user must repeat the movement as similar as possible to the demo. Here, the administration is completed and the next stage is focused on measuring the user's performance.

On the other side, the virtual environment can be modelled to detect the trajectories of the arms. For that purpose, virtual objects denoted as colliders are employed in the AFMA. Colliders are invisible objects available in several geometric shapes which can detect physical collisions. In this way, it is possible to register the trajectories of the arm by placing colliders into motion pathway. Detection of motion based on colliders is a simple approach but useful to measure the motor impairments in terms of the 3-points ordinal scale of the FMA.

Considering the FMA scale, a motor deficit can be classified in three levels of performance by identifying if an item is not completed (0 points), partially completed (1 point), or fully completed (2 points). Thus, in the case of the AFMA is only needed to place colliders along the path of the required item to rate the degree of completion, similarly as the FMA scale. The implemented system use three plane-shape colliders: one at the beginning to detect the motion starts, one at the middle to detect partially completed movements, and one at the end to detect fully completed actions. Thus, the correspondent points are given when the arm reaches these planes. Note that the partially completed motion is understood as reaching the middle of the required path. Additionally, it was established a workspace to detect trajectories different from the optimal (minimum distance) paths. This workspace is a cube-shape collider that envelops the starting point and endpoint of the demanded movement.

Thus, trajectories fully completed but different from the optimal omes can be penalised in the final score, giving an extra degree-of-freedom to classify impairments. Figure 2.14-b illustrates the location of colliders and workspace volume to measure the elevation movement of the right shoulder.

For better explanation of scoring process, the AFMA rating for the elevation movement of right shoulder (Figure 2.14-b) is described as follows. If the user's arm is not able to reach the intermediate plane, zero points are given. In the case of the user's arm reaches the intermediate plane, the movement is established as partially completed and 1-point is given. In the case of the user's arm reaches the goal plane, the movement is identified as fully completed and 2-points are given. However, if the goal plane is reached but the user's arm got out of the workspace volume, the attempt is penalised and the movement is classified as not properly completed.

The proposed strategy is to divide the expected arm trajectory into areas of performance and delimit an optimal volume of motion given by the path of minimum distance. The AFMA consider two areas of item performance in order to score likewise to the FMA scale. However, the strategy implemented by the AFMA not only allows to obtain a numerical impairment indicator but also to analyse the quality of motion or increase the resolution of the measurement.

Firstly, the actions required in the FMA test can be considered as discrete point-to-point movements. The scientific literature suggests that point-to-point reaching movements are good candidates to assess movement smoothness of upper limbs. Besides, the reliable tracking of arm motion with the Kinect sensor makes it possible to store the joint trajectories for post-processing data with moderate accuracy (depending on the body plane of tracking). An analysis of movement smoothness of kinematic data gathered with Kinect can provide the therapist with richer information about the user's performance.

Secondly, a big drawback of the 3-point scale of the FMA is the low-resolution of the measurement [43]. For that reason, it is difficult to quantify a minor improvement in the patient's motor function. To address this issue, in the AFMA, the expected road of movements can be divided into several areas of performance. This approach, in addition to the smoothness analysis, seems to be a feasible strategy towards a more objective, higher resolution, and automatic process of assessing the upper limb motor function.

A complete description of the AFMA system and a feasibility study can be found in part of the papers that supports this thesis. For facilitating the review, the publications related with this part of the thesis are summarised in Appendix A.4.

2.5 Development of rehabilitation robotic systems

The RRS presented in this thesis have been designed in accordance with the requirements summarised in Section 2.3.2 and wholly described in Chapter 5. The following section presents the resulting RRS and the technology employed to implement them.

2.5.1 System based on an assistive robotic arm

The first system describes a novel robot-based strategy for the training of the upper limbs that includes additional factors to promote the assimilation of motor gains. This strategy encourages the active mobilisation (without assistance) of the arm using a general-purpose robotic arm, but also adding some cognitive load to the physical tasks. For that purpose, the systems must address the human-robot interactions (patient- and therapist-robot), the better elaboration of exercises (task and environment), and the improvement of analytic capability.

A strategy denoted as reach-and-show was implemented to accomplish with the above requirements. The methodology of this strategy is to require the user to grab and object and show it to the robot. Figure 2.15 illustrates the setup for the proposed strategy. The main components of this approach are a general-purpose robotic arm, a set of coloured small-size objects, a webcam placed at the robot gripper, a graphical user interface, and a Kinect sensor.

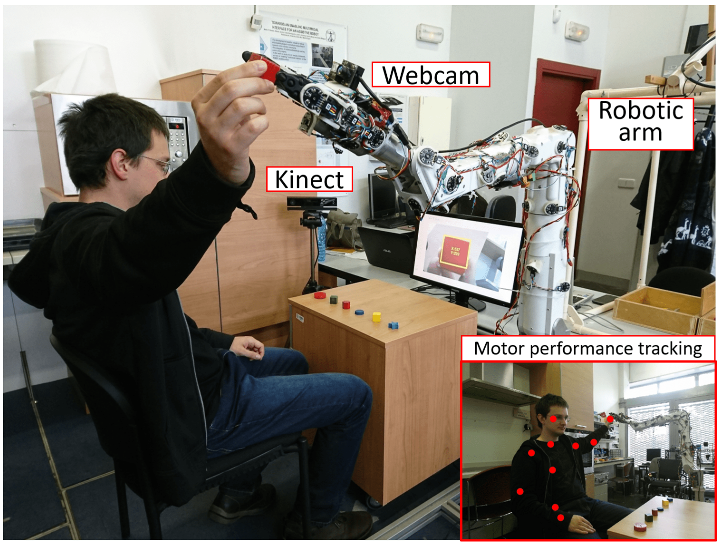


Figure 2.15: Setup for the reach-and-show task.

The sequence during the task performing is described as follows. Firstly, the user is asked to show to the robot an object displayed in the graphical user interface. The user must choose the required object from a set of different articles that are available in front of him. Then, the user must present the object to the robot to check if correct. For each item, the robot will place its gripper in a different spacial location inside the user's space of reaching. The robot recognises the object through a webcam located at the robot gripper (eye-in-hand configuration). Object recognition by the user adds a cognitive load to the physical tasks of grasping and reaching. Note that during all the patient-robot interaction the Kinect sensor is tracking and storing the user's movements.

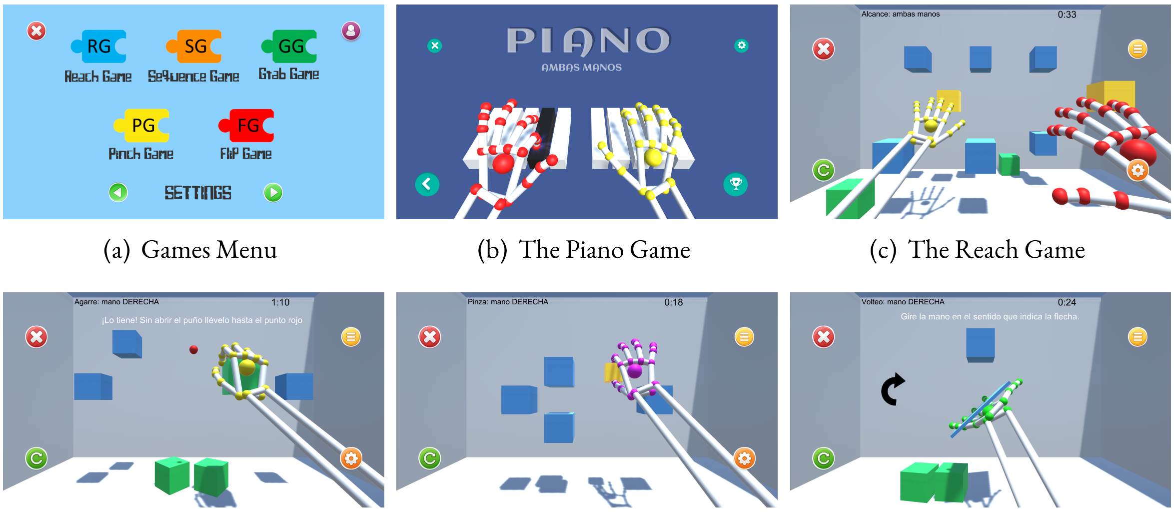
In this way, this system includes a module for marker-less tracking of motion towards strengthening analytical capacity. The tracking module gathers kinematic data of user's actions, which serves to estimate the ranges of motion (ROM), trajectories, and it also provides information about the time spent to complete the task (reaction times). All the above data allows the system to adapt the task difficulty to the user's needs and, more importantly, these adjustments can be made autonomously. A detailed description of the strategy and modules (object recognition, robot control, motion tracking) is available in [44].

2.5.2 System based on Serious Games

Since a few decades ago, there is a general enhanced interest in serious games as a complement to rehabilitation treatments. This burgeoning interest in gaming technology for fitness and healthcare have promoted the development of several applications to improve the health status of elders, people with neurological deficits, among others. Gaming technology offers several advantages for a viable application in clinical settings. From the design perspective, video games are a friendly, intuitive, and safe approach to model the interplay between patient and system. Besides, the interaction into virtual reality is measurable. Thus, kinematic data and events of interest could be gathered automatically and transparently for the user. From the required setup perspective, the components (off-the-shelf game controllers, laptop, VR displays) for this type of systems are portable, compact, and affordable. This fact provides a great opportunity to its use in healthcare facilities.

On this basis, a set of video games aimed at motor rehabilitation of upper extremities was developed on this thesis. These video games combine the relevant factors of motion generation into a play-centric approach to promote motor gains. The Leap Motion Controller (LMC) device was employed to detect the hand movements of users. The virtual scenarios were created using the Unity3D Game Engine software.

Figure 2.16 illustrates the set of video games developed for improving the UE motor function. Each video game can be launched easily by the therapist from a main chosen menu (see Figure 2.16-a). A total of six training environments are available, each one focused on exercising a specific arm functionality. Recovery of fingers dissociation is promoted by means of a piano-like scenario (see Figure 2.16-b). Reaching capability, that comprises movements of shoulder, elbow and hand in synergy, is addressed through placing reaching targets at several locations within the user's workspace



(a) Games Menu (b) The Piano Game (c) The Reach Game

(d) The Grab Game (e) The Pinch Game (f) The Flip Game

Figure 2.16: Serious games developed for the recovery of UE functionality.

(see Figure 2.16-c). Note that this environment does not require the user to grab the target but only touching. In this sense, another scenario focuses on improving the combined motion of reaching and grabbing capability (see Figure 2.16-d). For that purpose, the user must reach the required target, grab it, and finally drag and drop the target in a specific location. The mechanics of the Grab Game increases the difficulty of task performance in a similar scenario to the Reach Game. Even more, in order to training fine motor capability, the Pinch Game presents a mechanics that, in addition to reach the target, where the user must perform pinching movements (touching index and thumb fingers) to explode the targets (see Figure 2.16-e). Finally, other essential arm capability is prono-supination, which is promoted by the Flip Game (see Figure 2.16-f). The mechanics of this game invite the user to hold a tray and flip-flop objects to get points. A complete description of the video games is available in [45].

Two significant features of these video games are the adaptability and flexibility of operation. On the one hand, the video games offer several customisation options to adapt the level of difficulty to the patient needs or the purpose of rehabilitation. These settings can be tuned by the therapist at any moment of the training session. On the other hand, they can be executed in unilateral (each hand separately) or bilateral (using both hands) modes. Thus, each game has a double-purpose functioning mode that expands the benefits of this method as a complementary tool in neurological rehabilitation.

The video games have been piloted with participants with Parkinson's Disease. The effectiveness of video games-based treatment was measured using various well-known clinical tests such as Jamar Handgrip, BBT, or Purdue Pegboard. All the outcome measures showed an improvement in the health condition of participants. This fact, in addition to the favourable user's experience, supports the strategy proposed in this thesis and demonstrate the feasibility of using serious games as a deployable tool in clinical settings. A complete description of the pilot trials and results can be found in the papers that supports this thesis. For facilitating the review, the publications related with this part of the thesis are summarised in Appendix A.5.

2.5.3 System based on end-point electromechanical device

The previously presented systems cover the need for functional rehabilitation of people with impairments caused by a neurological deficit. This approach is based on the assumption that the target population has no permanent disabilities, existing a margin for recovery. However, some neurological deficits can cause permanent damage that leads to a disability. This one is the case of people after suffering a spinal cord injury.

In this population, the remaining motor capabilities may vary according to the level of damage. A particular case is of those who retain the mobility of the upper limbs, but they have difficulties to accomplish tasks that require fine dexterity of hands. Therefore, using little utensils (such as scissors, tweezers, nail clippers, etc.) to perform autonomously daily activities is challenging for people with this type of impairment.

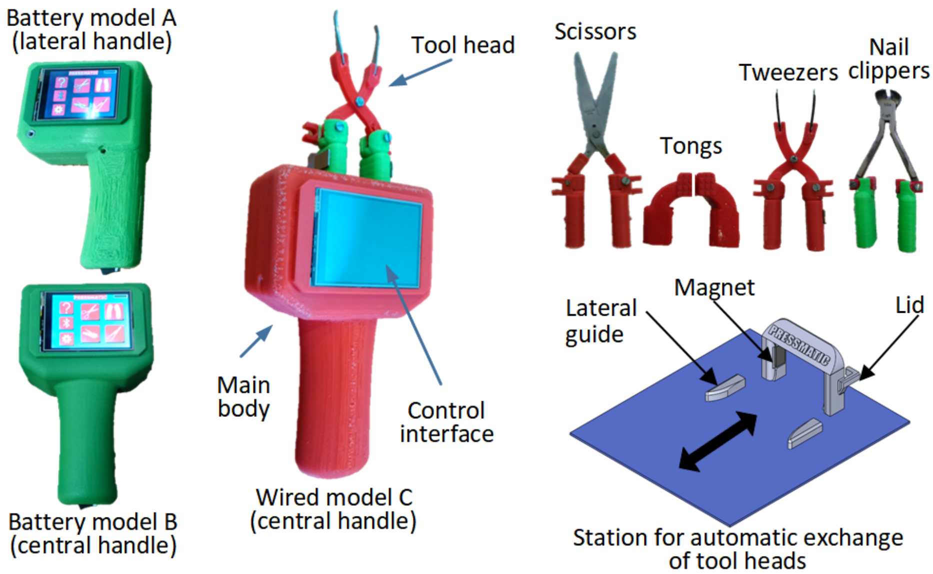


Figure 2.17: Pressmatic and the components of the system.

On account of the above, a novel device was implemented to face the need for assistance in tasks requiring manual dexterity, oriented to people with reduced hand mobility. The operation principle of this device consists of the automatic generation of opening and closing movements through electromechanical elements. The artificial motion is transferred to the actuator located at the device's tip to perform a task. Using a multi-tool approach, the actuator is exchangeable with other ones depending on the job to accomplish.

Figure 2.17 presents the assistive device and all the components of the system. Three models with different ergonomics were implemented to enhance the usability of the system. It also can be appreciated the set of tools designed to help the user when cutting, fine/gross grasping or nail cutting. This device is denoted as Pressmatic.

The main body of Pressmatic houses the electromechanical components for motion generation and a touchscreen to command the device. The touchscreen is the principal commanding channel. However, an APP for smartphone is available to control the device remotely, elevating the device's accessibility. Regardless of the communication channel, the automatic motion generation takes into account a tool-oriented methodology. Namely, the user must choose the actuator to employ, and then the device produces automatically pre-programmed movements suitable for the task corresponding to such an actuator.

Finally, the autonomy level of target users when performing tasks with and without the device was piloted. Thus, the contribution of the system to improve the user's independence was estimated. The complete description of the assistive device and the (usability and acceptance) results of clinical trials can be found in the papers that support this thesis. For facilitating the review, the publications related to this part of the thesis are summarised in Appendix A.6.

2.6 Clinical validation

According to the strongly hospital-oriented context of this thesis, it was necessary to conduct the clinical validation of the developed systems. Thus, in order to determine the effectiveness of implemented systems, many pilot trials with patients with a neurological disease were carried out. All the trials were conducted in public hospitals or private clinics.

For that reason, the process of clinical validation was designed as a generic model to test the performance of systems in an objective and reproducible manner. Figure 2.18 illustrates the general model of system testing. This model consist of a protocol of intervention combined with three functional assessment stages focuses on measuring the therapeutic effectiveness of the intervention strategy. Thus, the outcomes provided are in terms of functional gains following the traditional metrics. Regarding the functional assessment stages, they are conducted at three specific phases of treatment: (1) at the beginning in order to determine the baseline level of impairments, (2) at the end of treatment to measure the final functional gains (if any) and, (3) at a proper time period after the

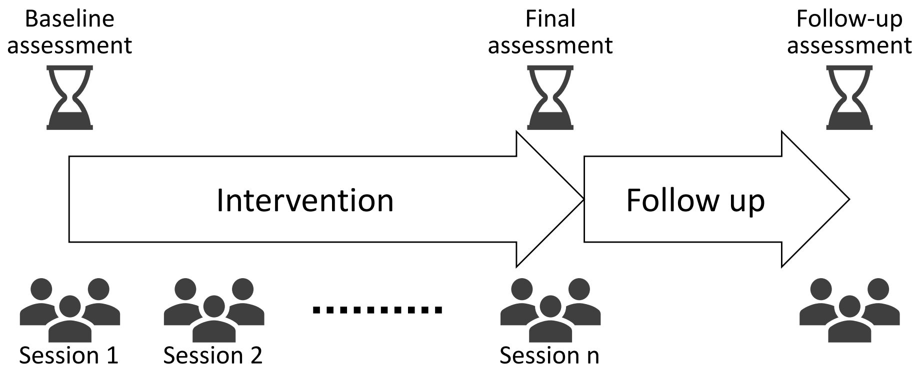


Figure 2.18: General model for clinical validation of systems.

finish of treatment to estimate the sustainment of functional gains.

On each functional assessment stage, several clinical scales directly related to the purpose of treatment are employed; for instance, treatment for improving the UE functionality requires of clinical test to measure the UE functioning. This model aims to standardise the process of system testing to allow future comparison of results from clinical trials.

The following sections present the particular adaptions of the general model in order to test the performance of the developed automated systems for functional assessment and intervention.

2.6.1 Evaluating the automated assessment system

The first system evaluated was the Automated Box and Blocks Test (ABBT). For that purpose, this automated tool was included as part of the set of clinical scales used for the functional assessment. Note that the same tools were employed in the three assessment phases. The primary goal of system testing was to measure the correlation level between the manual and automated systems when measuring the same variable (manual dexterity) with the same users. Therefore, the functional assessment tools chosen for this procedure were: the box and blocks test (BBT), the ABBT (the automated version of the BBT), the Jamar handgrip dynamometer and the Purdue Pegboard test.

A secondary objective of this procedure was to measure the correlation agreement between the automated system and the rest of the clinical scales used in the functional assessment. In this way, the reliability of the outcome provided by the ABBT can be studied with respect from other similar indicators of the user's performance. This approach could be useful to explore the viability of providing, in addition to the classical metric, predicted metrics based on the correlation of scales. This approach is currently only addressed by a commercial device as InMotion [13].

Results from the application of the general model of system testing for the particular case of the ABBT are available in Chapter 6, including the characteristics of the sample of patients and

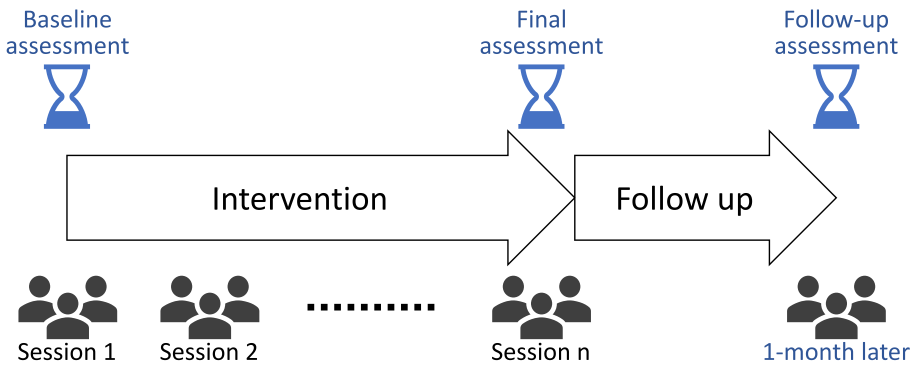


Figure 2.19: Model for clinical validation of the Automated Box and Blocks (ABBT).

statistic analysis for outcome correlation. Additionally, a preliminary study with patients with motor problems caused by a stroke is available in [46].

2.6.2 Evaluating the effects of serious games in health status

The second automated system for testing was the serious games-based system in a real intervention protocol. The main objective to evaluate the effectiveness of the intervention method in the improvement of upper limb functioning. This particular protocol of feasibility testing, depicted in green colour in Figure 2.20, was made up of twelve rehabilitative sessions. This protocol of treatment was conducted in a sample of participants with Parkinson Disease, according to the clinical team suggestion. The intensity and difficulty of treatment were progressively increased according to the treatment's progress.

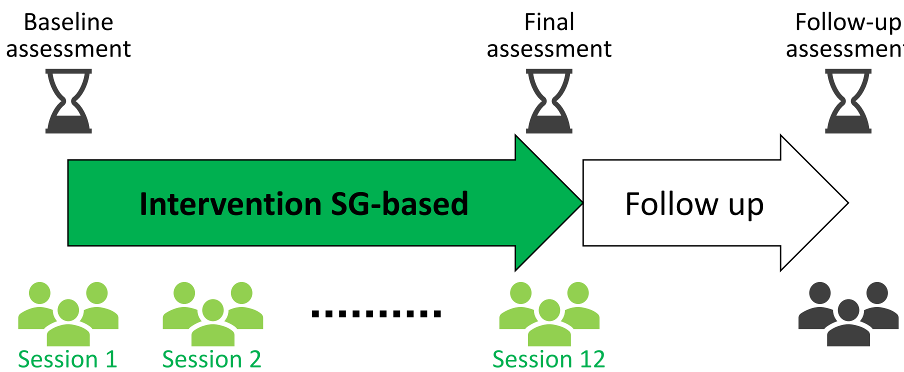


Figure 2.20: Model for clinical validation of serious games-based treatment.

Note that a secondary goal was to estimate the viability of the serious games-based system as an intervention tool aiming to intuitive use mode, personalisable functions, and deployable capability in clinical settings. Results from the application of the general model of system testing for the particular case of the intervention strategy are available in Chapter 7, including the description of the participants and statistic analysis for outcome correlation. Chapter 8 details the statistical analysis of outcomes from the clinical point of view and the therapist's acceptation.

Part II

Results

CHAPTER 3

Conceptual Framework of Rehabilitation

3.1 Overview

This chapter presents in detail the conceptual framework of autonomous rehabilitation proposed in this thesis. A systematic review of scientific literature helped to understand the relationship between modern robotic systems for rehabilitation and the process of rehabilitation. The comprehension of the above led to the conceptual framework definition, including the technical requirements, components and intrinsic interplay.

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Review Article

A Review of Robotics in Neurorehabilitation: Towards an Automated Process for Upper Limb

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Robot-mediated neurorehabilitation is a growing field that seeks to incorporate advances in robotics combined with neuroscience and rehabilitation to define new methods for treating problems related with neurological diseases. In this paper, a systematic literature review is conducted to identify the contribution of robotics for upper limb neurorehabilitation, highlighting its relation with the rehabilitation cycle, and to clarify the prospective research directions in the development of more autonomous rehabilitation processes. With this aim, first, a study and definition of a general rehabilitation process are made, and then, it is particularized for the case of neurorehabilitation, identifying the components involved in the cycle and their degree of interaction between them. Next, this generic process is compared with the current literature in robotics focused on upper limb treatment, analyzing which components of this rehabilitation cycle are being investigated. Finally, the challenges and opportunities to obtain more autonomous rehabilitation processes are discussed. In addition, based on this study, a series of technical requirements that should be taken into account when designing and implementing autonomous robotic systems for rehabilitation is presented and discussed.

1. Introduction

According to the findings obtained in the context of a Global Initiative on Neurology and Public Health carried out by the World Health Organization (WHO), many of the neurological disorders are chronic and progressive, constitute a global public health problem [1], and affect especially the elderly people. In addition, a higher life expectancy makes the population of people over 60 increasingly higher [2]. The main patient groups served by the rehabilitation service in the United Kingdom are for neurological pathologies, as a survey reported [3]. 70% of respondents provided neurological rehabilitation services for people with stroke, multiple sclerosis, traumatic brain injury, degenerative neurological diseases, and other neuromuscular conditions. Other services that were represented were those that provided rehabilitation to people with severe single-incident brain injury (10%), spinal injury (9%), amputees (5%), musculoskeletal disability (4%), learning disabilities (1%), and pain (1%). In Spain, a similar situation is detected where musculoskeletal and articular disability (50%), neurological diseases (15%), traumatic injuries (29%), and others (6%) were treated in the rehabilitation services [4].

This situation, together with the need for rehabilitation and assistance for people with disabilities, means that robotic care and rehabilitation may play an important role in the years ahead.

Nowadays, research on the use of robotic systems in different fields related to healthcare is widespread [5–7]. In the field of rehabilitation, scientific literature shows various classifications of such systems according to their level of interaction [8], the extremities that are treated [9–12], the modularity of the rehabilitation robots [13, 14], control strategies [15, 16], and the effectiveness of treatment

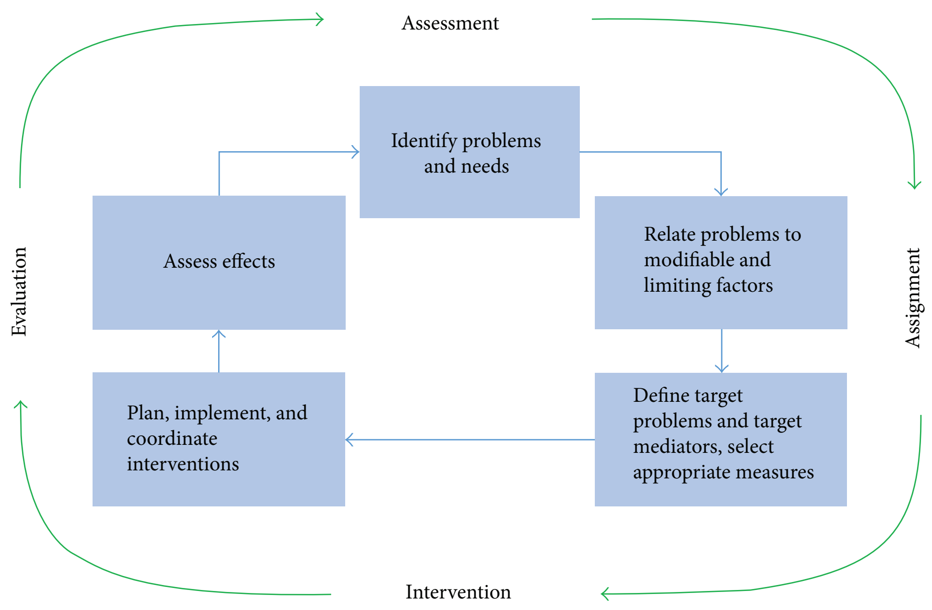

Figure 1: The rehabilitation cycle [21].

[17–20]. However, no analysis has been done of the rehabilitation process as such, and the contribution of robotics in the different stages of the rehabilitation cycle or process has not been studied.

In this paper, a systematic literature review is conducted to identify the contribution of robotics for upper limb neurorehabilitation highlighting its relation with the rehabilitation cycle and to clarify the prospective research directions in the development of an autonomous rehabilitation process.

2. The Rehabilitation Process

The World Report on Disability by the WHO and World Bank [21] provides a definition of rehabilitation: "a set of measures that assist individuals who experience, or are likely to experience, disability to achieve and maintain optimal functioning in interaction with their environments."

Despite this, the term rehabilitation covers a wide field of applications, being a subject to different connotations in a world characterized by a profound cultural diversity. Meyer et al. [22] provided a conceptual description of rehabilitation: "it is the health strategy which is based on the WHO's integrative model of functioning, disability, and health, with the goal to enable persons with health conditions experiencing or likely to experience disability to achieve and to maintain optimal functioning in interaction with the environment."

The health strategies can be different, but they can share a series of steps to improve the patient's health status throughout the rehabilitation process. This process involves the identification of a person's problems and needs, relating the problems to relevant factors of the person and the environment, defining rehabilitation goals, planning and implementing the measures, and assessing the effects [21]. This approach is named the rehabilitation cycle (see Figure 1), which is taken from the World Report on Disability [21], and it was previously stated by Stucki and Sangha [23] and modified by Steiner et al. [24].

In a simplified way, the rehabilitation cycle includes four steps: assessment, assignment, intervention, and evaluation. The process takes place on two levels: the first corresponds to the guidance provided along the continuum of care and the second refers to the provision of a specific service [25].

From the point of view of the care guide, the assessment consists of the identification of the problems and needs of the person, the analysis of rehabilitation potential and prognosis, the definition of the long-term service, and the goals of the intervention program. Assignment refers to the inclusion of the person in a program of intervention in the most appropriate service for the treatment of their needs. For the guidance perspective, no specifications appear in the intervention. Evaluation refers to the service and the achievement of the intervention goal.

From the perspective of providing a specific service, the assessment includes the identification of the problems, the review and potential modification of the service or goals of the intervention program, the definition of the first goals of the rehabilitation cycle, and the objectives of the intervention. The assignment step refers to the allocation of professionals and health interventions necessary to achieve the intervention objectives. The intervention consists in the specification of the techniques, measures, and the definition of target values that must be achieved within a predetermined period of time. Finally, the evaluation determines the achievements of the objectives with respect to the specific indicators, the goals of the rehabilitation cycle, and, ultimately, the goals of the intervention program. It also includes the decision regarding the need for another intervention cycle based on a new assessment.

2.1. The Rehabilitation Team. Rehabilitation requires the services of multiple healthcare providers who possess unique skills, training, and expertise that are employed for the full restoration of the patients' function and their optimal reintegration into all aspects of life [26]. Rehabilitation professionals have recently favoured the concept of "patient-centred therapy." This is not meant to trivialize the patient's needs but rather to emphasize the patient as the director and arbiter of the interventions according to the patient's own desires [27].

The integration of the different medical means can be done through three working models [26, 28]: *(a) multidisciplinary team model*—in which team members interact and communicate among themselves, knowing the work of all the components and offering an evaluation and parallel but independent work; *(b) interdisciplinary team model*—where the team members share a formal space in which information is exposed (designed to facilitate the flow of lateral communication) and decisions are made around one or several common objectives (in this way, the treatments performed by the different professionals are not independent); and *(c) transdisciplinary team model*—which not only promotes communication among group members but also acquires knowledge from other related disciplines and incorporates them into the practice [29].

Because the interdisciplinary model is designed to facilitate lateral communication, it is theoretically better suited for rehabilitation teams [28].

2.2. Rehabilitation Measures and Outcomes. Rehabilitation measures are a set of recovery actions that target body functions and structures, activities and participation, environmental factors, and personal factors.

Rehabilitation outcomes are the benefits and changes in the functioning of an individual over time that are attributable to a single measure or set of measures [30]. These outcomes can be evaluated by the three main dimensions of the International Classification of Functioning, Disability and Health (ICF) [31]: body functions and structures, activities, and participation.

3. Neurological Rehabilitation

A particular case of rehabilitation is aimed at treating the problems caused by disorders affecting the nervous and neuromuscular system, known as neurorehabilitation. These types of disorders can produce mental or physical disabilities or both and are chronic and/or progressive.

Neurological rehabilitation can be defined as a process that aims to optimize a person's participation in society and sense of well-being. This definition highlights several important features: rehabilitation is not a particular type of intervention; the focus is on the patient as a person; the goals relate to social functioning, as well as health or well-being; and it is not a process restricted to patients who may recover, partially or completely, but applies to all patients left with long-term problems [32]. This will act on the deficiency, the limitation of activity, and the restriction of participation, constituting a holistic therapeutic approach [33].

The complexity of the problems caused by a neurological damage highlights even more the need for a team to work on its treatment, the interdisciplinary model being the most used [34]. The composition of the interdisciplinary team in neurorehabilitation is not completely defined, but there is a consensus on the basic members who should constitute the team. According to the Union of European Medical Specialists (UEMS), the interdisciplinary team must include the following medical professionals: physical therapist, rehabilitation nurses, rehabilitation physicians, occupational therapists, speech-language pathologist, psychologists, social workers, orthopaedics, and nutritionists [35].

The rehabilitation cycle shown in Figure 1 applies to the case of neurological rehabilitation with some nuances that are discussed below.

3.1. Assessment. The rehabilitation process starts with collecting data from the patient and others to establish: the problems; the causes of, and factors influencing, each problem; and the wishes and expectations of all interested parties. It is also important to consider the prognosis based on the diagnosis, natural history, distribution, and severity and type of the impairment, as well as other personal, social, and environmental factors [36].

To this end, a series of objective scales have been developed to assess the level of independence of patients. The three main domains of the ICF can be used with this aim as a clinical tool [37, 38]:

(i) Impairments: the typical body functions that need to be assessed in the neurological patient are those related to the functions of the joints, muscles, movements, and sensation and cognitive functions. Thus, some constructs of relevance are muscle, ranges of movement, attention, memory, and balance. There are scales classically encompassed at this level such as Beck Depression Inventory, Behavioral Inattention Test, Canadian Neurological Scale, Clock Drawing Test, Frenchay Aphasia Screening Test, Fugl-Meyer Assessment of Motor Recovery after Stroke, General Health Questionnaire-28, Geriatric Depression Scale, Hospital Anxiety and Depression Scale, Mini-Mental State Examination, Modified Ashworth Scale, Montreal Cognitive Assessment, Motor-Free Visual Perception Test, National Institutes of Health Stroke Scale, and Orpington Prognostic Scale.

(ii) Activity: when examining a patient's activities, the therapist will examine whether they can do not only the tasks but also the quality with which the task is performed. According to Lennon's study [39], one of the most used scales for measuring the independence in stroke rehabilitation was the Barthel Index, followed by the Rivermead Motor Assessment and Functional Independence Measuring. More than a quarter of therapists (28%) were using outcome tools that they had devised themselves, which had not been tested for reliability or validity. Other examples of scales at this level are the following: Action Research Arm Test, Berg Balance Scale, Box and Blocks Test, Chedoke-McMaster Stroke Assessment

Scale, Clinical Outcome Variables, Functional Ambulation Categories, National Rehabilitation Reporting System, Frenchay Activities Index, Modified Rankin Handicap Scale, Motor Assessment Scale, Nine-Hole Peg Test, Rivermead Mobility Index, Timed "Up and Go" Test, and Wolf Motor Function Test.

(iii) Participation: this a more complex concept than impairments and activities, but it is fundamental to understand the patients and their life and help with planning treatment. Physiotherapy assessment of participation therefore focuses on those activities or roles in which patients take part in, patients are hindered in, and patients wish to work on and which could be improved and will inevitably deteriorate. Common scales used are the following: Canadian Occupational Performance Measure, EuroQol Quality of Life Scale, London Handicap Scale, Medical Outcomes Study Short Form 36, Nottingham Health Profile, Reintegration to Normal Living Index, Stroke-Adapted Sickness Impact Profile, Stroke Impact Scale, and Stroke Specific Quality of Life Scale.

3.2. Planning of Treatment. According to the pathology, the rehabilitation team designs a specific plan based on the diagnosis (problems identification) and disability of the patient. It is necessary to identify clear objectives related to the functional problems. Rehabilitation objectives normally follow the SMART rule because they must be specific, measurable, achievable, relevant, and time-limited [32].

There are three key areas that the rehabilitation process is broken down: (1) approaches that reduce disability; (2) approaches designed to acquire new skills and strategies, which will maximize activity; and (3) approaches that help to alter the environment, both physical and social, so that a given disability carries with it minimal consequent handicap. The planning of a neurological rehabilitation program should consider the previous three approaches, in addition to the SMART rule.

3.3. Intervention: Specific Methods. Specific rehabilitation interventions include those related to physical medicine, occupational therapy, speech and language therapy, dysphagia management, neurophysiological interventions, psychological assessment and interventions, nutritional therapy, and other interventions [25]. A wide range of specific techniques is used in the practice of rehabilitation [40]. These techniques used to treat different patients vary considerably across different geographical locations.

At present, the evidence suggests that to be effective, rehabilitation requires the practice of activities in the most relevant possible environments, rather than undertaking analytical exercises aimed at changing impairments [41]. This is sometimes referred to as task-specific training. However, other approaches are known such as facilitation techniques (such as Bobath concept, Brunnstrom technique, Kabat method, or Rood method), modern techniques (such as treadmill training with body weight support, constraint-induced movement therapy, or functional electrical stimulation), or compensation techniques.

3.4. Evaluation. In this phase, the physical condition of the patient is reevaluated in order to determine the effectiveness of the treatment, based on the SMART objectives [32] initially raised. The considerations for discharge in the case of the neurological patient are very varied, since the clinician must determine whether the improvement achieved is sufficient from the medical point of view of the patient (patient-centred practice).

Previous quantitative investigations and case studies have shown that the use of patient-centred goal planning with adults undergoing neurological rehabilitation can improve self-perceived and observed goal performance and satisfaction [42]. A patient-centred approach involves goals that are set by the patient on the basis of his or her own definition of the problems. This approach enables greater self-determination and control and enhances the person's potential for active participation.

In addition, one must take into account the underlying pathological process, the chronic nature of certain pathologies, the need for supervision and/or the continuity in the absence of an expressive face-to-face rehabilitation treatment, or the degenerative and progressive character of some neurological pathologies, such as Parkinson's disease, multiple sclerosis, or Alzheimer's disease.

4. Robotics in Healthcare: Neurorehabilitation of Upper Limb

In this section, this review will highlight the particular aspects of the rehabilitation cycle applied to upper limb neurorehabilitation performed with the assistance of any kind of robotic system.

4.1. Material and Method

4.1.1. Search Methods. The authors undertook a literature search in October 2017 about robot-assisted upper limb rehabilitation in neurological diseases, using keywords such as robot, neurological, rehabilitation, upper, limb, extremity, arm, hand, neurorehabilitation, intervention, assisted therapy, treatment design, and various combinations. The databases were Brain, Science Direct, PubMed/Medline, and IEEE. Only papers written in English were considered, and the search was extended to the whole database. Studies were included when (1) systems for upper limb training (uni- and bilateral) were used; (2) systems are based on end-effector and exoskeleton devices (commercially available or not); (3) the clinical intervention was conducted; and (4) the effects of the robot-assisted therapy were investigated.

4.2. Robotics in Neurorehabilitation of Upper Limb. According to the Strategic Research Agenda for Robotics in Europe (SPARC) [43], healthcare is seen as a combination of three subdomains: (1) clinical robotics—systems that support care (diagnosis) and cure (surgery) processes; (2) rehabilitation—covering postoperative or postinjury care where direct physical interaction with a robot system will either enhance recovery or act as a replacement for lost function; and (3) assistive robotics—covering other aspects of robotics within the healthcare process where the primary function of the robotic system is to provide assistive help either to carers or directly to patients either in hospital or in a specialist care facility.

Thus, devices to train (robot-aided therapies), support (exoskeletons), or replace (prosthesis) impaired activities or impaired body functions and structures are covered in rehabilitation robotics. In this way, robots are presented as a useful tool in the recovery process in neurological treatment. Such systems participate actively and help the therapist to perform a better rehabilitation process. However, it is not clear in what way and to what extent robotic systems provide this help during the rehabilitation cycle. To improve the quality of help provided, it must be identified how and when the aid is administered.

The summary presented in Table 1 collects the information obtained from the study of several robot-aided neurorehabilitation systems for the upper extremities. The systems selected have been used in clinical trials with patients suffering motor function problems derived from different neurological disorders. A comprehensive reading has been made to identify how robotic assistance has been used, how it has contributed and in which phases of the rehabilitation process. Thus, the present review identifies what the robotic system contributes to the rehabilitation cycle in a quantitative way (measurements), the way it does it (automatic or not), and the phase in which it participates (assessment, assignment, or intervention). Notice that the same robotic systems could cover several phases of the rehabilitation cycle. The more phases are covered, the more automated will be the rehabilitation process.

Rehabilitation, like many aspects of human behaviour, can be thought of as a purposive problem-solving activity [44]. The following review draws upon the problem-solving process from a patient-centred perspective in neurorehabilitation.

4.2.1. Assessment Approaches. As previously indicated, the starting and ending component of the rehabilitation cycle is the functional assessment. It is important to take into account that most of the assessments performed by robotic systems are not functional assessments (carried out in baseline and follow-up stages of treatment), and its provided outcomes are indicators of a patient's performance. Currently, functional assessment is still carried out by traditional tests and scales provided by therapists. The main features of the robot-aided systems reviewed related to the assessment phase of the rehabilitation cycle are described as follows:

(1) Assessment Mode. Assessment of the patient's performance can be carried out in two modes: automatic or nonautomatic. The automatic mode corresponds with the online data analysis, that is, during the development or at the end of the session. On the contrary, the nonautomatic mode corresponds with the offline data analysis (after of the end of the session).

(2) Assessment Method. Robotic rehabilitation systems present evaluation methods that are based on the biomechanical data they are able to acquire. Based on such data, a rapid report that could be performed in an online or offline mode is provided to the therapist. 74% of the reviewed systems have not specified assessment methods, but propose an evaluation method based on the offline analysis of the biomechanical data acquired during therapy. In these studies, a later analysis of the stored information is done, applying algorithms to obtain information on the patient's performance. However, besides having an automatic record of information, only 26% of the systems perform online processing of these parameters by using specific software (e.g., INMOTION, IPAM, AMADEO, ARMEO, and T-WREX).

(3) Provided Outcome. Robot-assisted systems have the advantage of providing a reliable and objective quantitative rapid assessment, based on the comparison of the metrics acquired during therapy. However, this assessment is at the level of impairment but does not provide information on how such impairment influences the activities of the patient's daily life. The most automated are commercially available systems like INMOTION ROBOTS, ARMEO-SPRING, AMADEO, REOGO, and DIEGO. They have an online processing that generates a report at the end of the therapy session. However, the reliability of these automatic assessments, although they are based on objective measures, has not been validated with respect to determining, on their own, whether the rehabilitation has been adequate or not. Also, robot-mediated measurements have even smaller dissemination. For this reason, most of the systems reviewed carry out additional clinical evaluation, using functionality scales that are of standardized use at the clinical level, such as those mentioned in Section 3.1, which are still the "gold standard" for measuring outcomes. The interpretation of these scales allows the therapist to determine in an objective way the health condition of the patient and the effectiveness of the treatment.

(4) Functional Assessment. Given the importance of making a correct evaluation, it is necessary to highlight the need to use standardized tools and procedures. The classification of the ICF is very useful for this functional assessment. The use of these standard functional scales as the main output of the rehabilitation systems would provide a better and more collaborative way to determine the effectiveness of the therapy based on the metrics obtained by the rehabilitation systems themselves. Currently, this issue is addressed by INMOTION software (INMOTION EVAL) that, based on multiple regression models, calculates Fugl-Meyer Assessment (FMA), Motor Status Score (MSS), Motor Power (MP), and Modified Ashworth Scale (MAS) from the robot-based metrics. These measurements of motor control are highly correlated with the traditional scales [45].

4.2.2. Clinical Decision Support. As previously mentioned, it is important to emphasize that the complexity of a neurorehabilitation treatment usually requires the participation of a work team. Therefore, it is important that the patient's

Table 1: Review of robot-aided system for upper limb neurorehabilitation.

	Assessment				Assignment		Intervention				
System	Automatic assessment	Assessment method	Provided outcome	Functional assessment	Therapy planning support	Method	Rehabilitation target	Task-specific training	Method	Interaction	Measurements
End-effector-type system											
ACT-3D [61]	No	Offline data analysis	Difference between sessions	FMA	No	N/A	Shoulder; elbow	Yes	Reach (payload simulation)	VR; haptic; auditory	Kinematic data; force
ARM GUIDE [62, 63]	No	Offline data analysis	Difference between sessions	CM; RLAFT	No	N/A	Shoulder; elbow	Yes	Passive; active assisted; active resistance	VR; haptic	Kinematic data; force; straightness; smoothness
BRACCIO DI FERRO [64, 65]	No	Offline data analysis	Difference between sessions	FMA; MAS	No	N/A	Shoulder; elbow	Yes	Active assisted; active resistance; gravity compensation	VR; haptic	Kinematic data; force; smoothness; accuracy
GENTLE/S [66, 67]	No	Offline data analysis	Visual comparison of data trends (slopes)	FMA; MoAS; MAS; NSA; SCT	Yes	Haptic Master software allows the therapist to define the exercise path	Shoulder; elbow	Yes	Passive; assisted; active; trajectory correction	VR; haptic	Kinematic data; force
INMOTION ARM [59, 68]	Yes	INMOTION EVAL software; 5 evaluation tests, robot generates 4 evaluation reports	Robot calculates 13 evidence-based measures of motor control that are highly correlated with traditional scales	FIM; FMA; MP; NIHSS	Yes	Selection of the therapeutic exercise games; progress measurement of determined medical necessity; assesses treatment based upon measurable gains	Shoulder; elbow	Yes	Passive; active assisted; active resistance; gravity compensation	VR; haptic	Kinematic and kinetic data (position, direction, distance, area, time, force, smoothness, accuracy); performance measures
IPAM [69, 70]	Yes	IPAM software	Virtual environment feedback	FMA	Yes	Automatically generated exercises based on a clinical assessment of the patient (automated tasks)	Shoulder; elbow	Yes	Passive; active resistance; active; reach	VR; haptic	Kinematic data; force

Table 1: Continued.

System	Assessment				Assignment		Intervention				
	Automatic assessment	Assessment method	Provided outcome	Functional assessment	Therapy planning support	Method	Rehabilitation target	Task-specific training	Method	Interaction	Measurements
MEMOS [71, 72]	Yes	Online data analysis	Score proportional to the voluntary motor activity developed during the task	FMA; MSS; MRC; MP	No	N/A	ARM: not a specific joint	Yes	Passive; active resistance; active	VR; haptic	Kinematic data; force
MINE [73]	No	Offline data analysis	Difference between sessions	FMA; MSS; BI; FIM; MP; MAS	No	N/A	Shoulder; elbow	Yes	Passive; active assisted; active resistance; bilateral	VR; haptic	Kinematic data; force [bimanual]
NEREBOT [74, 75]	Yes	Online data analysis	Feedback based on patient's effort	FMA; MRC; FIM; MAS; FAT; BBT	No	Therapist defines the exercise by choosing via points and adjusts robot parameters according to the type of exercise	Shoulder; elbow; forearm	No	Passive; active assisted; active	VR; auditory	Kinematic data; patient effort (cable tension based)
REHAROB [76, 77]	Yes	Online data analysis	Feedback based on patient's effort	FMA; FIM; MAS; RMA; BI; BMR	Yes	Therapist can choose exercises from any therapeutic school (Bobath, Kabat, etc.)	Shoulder; elbow; forearm	No	Passive	N/A	Kinematic data
AMADEO TYROMOTION [78–80]	Yes	TyroS software	Difference between sessions	FMA; MRC; MI; MAS; FIM; COPM	Yes	TyroS software creates a therapy report and therapy progress	Hand: prehension	Yes	Passive; active assisted; active	VR	Kinematic data; force; tonus; spasticity
BIMANUTRACK [81, 82]	No	Offline data analysis	Difference between sessions	FMA; WMFT; RMA; MAS	Yes	Programming of individually adjusted natural gait trajectories; real-time simulation of the programmed foot trajectory	Forearm; wrist	No	Active; passive [bilateral]	N/A	Kinematic data; force [bimanual]
HWARD [83, 84]	No	Offline data analysis	Difference between sessions	ARAT; BBT; FMA; NIHSS; GDS; NSA; 9-HPT; SIS; MAS	No	N/A	Wrist; hand	Yes	Passive; active assisted; active resistance	VR	Kinematic data; force

Table 1: Continued.

System	Assessment				Assignment		Intervention				
	Automatic assessment	Assessment method	Provided outcome	Functional assessment	Therapy planning support	Method	Rehabilitation target	Task-specific training	Method	Interaction	Measurements
REOGO [85, 86]	Yes	Advanced management software	Evolution of measurements	FMA; MFT	Yes	Library with a wide range of engaging exercises and games for various rehabilitation objectives	Shoulder; elbow; wrist; hand	Yes	Passive; active; guided; free	VR; haptic	Kinematic data; accuracy; smoothness; force; muscle tone
DIEGO [78, 87]	Yes	TyroS software	Evolution of measurement	N/A	Yes	Selection of therapy games	ARM: not a specific joint; shoulder	Yes	Passive; assistive; active; gravity compensation [uni- and bilateral]	VR; haptic	Kinematic data; motoric function; force proprioception
Exoskeleton/Orthosis system											
L-EXOSPERCRO [88]	No	Offline data analysis	Difference between sessions	FMA; MAS; BAS	Yes	Selection of different trajectories in the same virtual environment	Shoulder; elbow	Yes	Active; active assisted; gravity compensation	VR	Kinematic data; force; accuracy
MYOPRO [89–91]	No	EMG signals	Difference between sessions	MAS; BBT; FMA; MAL-AOU; MAL-HW	No	N/A	Elbow	Yes	Active assisted	Haptic	Kinematic data; force
WREX [92]	No	Offline data analysis	Difference between sessions	N/A	No	N/A	Shoulder; elbow	Yes	Active assisted; gravity compensation	N/A	Kinematic data; force
ARMEOSPRING (T-WREX) [93–95]	Yes	Java Therapy 2.0 software	Difference between sessions	FMA; RFT: BBT: BBTD	Yes	Selection of therapy games	Shoulder; elbow; forearm	Yes	Passive; gravity compensation	VR; haptic	Kinematic data; force
MENTOR PRO (hand) [96–98]	No	Offline data analysis	Monitoring of patient's progress in DLA	N/A	No	N/A	Wrist; hand; fingers	No	Active (only extension)	VR	Kinematic data
HEXORR [99]	No	Offline data analysis	Difference between sessions	ARAT; FMA; MAS	No	N/A	Metacarpus [interfalangica]	Yes	Passive; active assisted; active; gravity compensation	Haptic	Kinematic data; force grasping patterns

Table 1: Continued.

	Assessment				Assignment		Intervention				
System	Automatic assessment	Assessment method	Provided outcome	Functional assessment	Therapy planning support	Method	Rehabilitation target	Task-specific training	Method	Interaction	Measurements
RUTGERS MARTER II [100, 101]	Yes	Online data analysis	Performance meter	JTHF; FMA	No	N/A	Hand	Yes	N/A	VR; haptic; auditory	Kinematic data; force
SUPINATOR-EXTENDER [102]	No	Offline data analysis	Difference between sessions	N/A	No	N/A	Forearm; wrist	Yes	Active assisted	VR; haptic	Kinematic data; force; grasping patterns
T-WREX [95, 103]	Yes	Java Therapy software	Monitoring of a patient's progress by skilled rehabilitation therapist	FMA; RFT; BBT	No	N/A	Shoulder; elbow; forearm; wrist; hand	Yes	Passive; gravity compensation	VR	Kinematic data; force
WOTAS [104]	No	Offline data analysis	Difference between sessions	FTMTRS	No	N/A	Elbow; forearm; wrist	Yes	Tremor control	Haptic	Kinematic data (voltage coming from gyroscopes)
ARMEOPOWER (ARM-IN III) [93, 105, 106]	Yes	GIANTS game engine	Difference between sessions	FMA	Yes	Choose from several VR therapy tasks	Shoulder; elbow; forearm; wrist; hand	Yes	Active; passive; active assisted; active resistance; gravity compensation	VR	Kinematic data; force
ARM-IN [107, 108]	Yes	Online data analysis	Difference between sessions	N/A	Yes	Allows different therapy modes, robot interface for patient (PRI) and therapist (TRI)	Shoulder; elbow; forearm; wrist	Yes	Passive; active assisted; active	VR; haptic	Kinematic data; force
GENTLE/G [109]	Yes	Online data analysis	Performance meter	N/A	Yes	HMI module for interaction between the user and the Gentle robot; database for storing patient information	Shoulder; elbow; hand	Yes	Passive; assisted; active; trajectory correction	VR; haptic	Kinematic data (position, direction, distance); force

Table 1: Continued.

System	Assessment				Assignment		Intervention				
	Automatic assessment	Assessment method	Provided outcome	Functional assessment	Therapy planning support	Method	Rehabilitation target	Task-specific training	Method	Interaction	Measurements
Rupert [110, 111]	No	Offline data analysis	Difference between sessions	WMFT; FMA	No	N/A	Shoulder; elbow; forearm; wrist	Yes	Passive; active assisted; active	VR; haptic	Kinematic data; force; [motor activity; stroke impact scale; stroke recovery scale]

9-HPT: 9-Hole Peg Test; ARAT: Action Research Arm Test; BAS: Bimanual Activity Scale; BBT: Box and Blocks Test; BBTD: BBT (without picking up blocks); BI: Barthel Index; BMR: British Medical Research; CM: Chedoke-McMaster; COPM: Canadian Occupational Performance Measure; FAT: Frenchay Arm Test; FIM: Functional Independence Measure; FMA: Fugl-Meyer Assessment; FTMTRS: Fahn-Tolosa-Marin Tremor Rating Scale; GDS: Geriatric Depression Scale; JTHF: Jebsen Test of Hand Function; MAL-AOU: Activity Log-Amount of Use; MAL-HW: Motor Activity Log-How Well; MAS: Modified Ashworth Scale; MFT: Manual Functional Test; MI: Motricity Index; MoAS: Motor Assessment Scale; MP: Motor Power; MRC: Medical Research Council; MSS: Motor Status Score.

progress information is available to the entire work team, according to the interdisciplinary model. The management of information is one of the more time-consuming tasks that facilitate the decision-making of the therapist. Currently, there are several electronic medical record (EMR) software for the management of the patient's data [46], including based on artificial intelligence [47]. Thus, one of the important aids incorporated in robot-assisted systems is the administration and storage of data automatically, which allows the generation of updated monitoring reports.

The results of the review show that 45% of the systems (the commercial ones) also provide some kind of help in the elaboration of the therapy. The most common assistance is through offering a set of exercises, games (REOGO, DIEGO, and ARMEO), or therapy protocols (INMOTION system) that can be configured or combined by the therapist. One of the systems (REHAROB) also allows the option of selecting exercises that are based on the intervention methods most used in physical rehabilitation, such as the Bobath or Kabat method. On the other hand, in-depth analysis of the data recorded robot-aided therapy, as well as allowing rapid functional assessment, serves as a tool for decision support to determine the patient's discharge. The INMOTION system allows discharge plots to be generated based on the performance of 5 tests that register kinematics and kinetics data. To the authors' knowledge, there are no commercial systems able to automatically generate a complete rehabilitation strategy from the initial functional assessment data and thus the therapist still has to properly identify the patient's problems by means of a reliable diagnosis and the right choice of clinical measures to evaluate the effectiveness of the treatment.

4.2.3. Rehabilitation Approaches and Outcomes. Typically, rehabilitation occurs for a specific period of time but can involve single or multiple interventions delivered by an individual or a team of rehabilitation workers and can be needed from the acute or initial phase immediately following recognition of a health condition through postacute and maintenance phases. Rehabilitation reduces the impact of a broad range of health conditions. Further, neurorehabilitation is often still based on therapists' expertise, with competition among different schools of thought, generating substantial uncertainty about what exactly a neurorehabilitation robot should do [48].

Robot-aided systems allow the training of an impaired limb in multiple sessions and in a systematic way, without loss of efficiency. With respect to the target region of treatment, the number of joints that the same system is capable of treating has been identified. No devices covering the movement of all joints of the upper limb have been found, that is, the shoulder, elbow, wrist, and hand (including fingers joints). The ARMEOSPRING, INMOTION, and ARMEOPOWER systems manage to cover the shoulder and elbow joints and also to train the flexoextension of the wrist and the manual grip, excepting finger joints.

The effectiveness of treatments based on task-specific training in robot-assisted interventions is demonstrated. So it is understandable that 86% of the review systems consider this approach. It is observed that the systems have more than one operating mode (passive, active, active-assisted, or active resistance). This represents a great advantage when considering treatment measures in a flexible way and better adapted to the type of injury. Some systems describe the mechanisms of action of the robots, which can offer assistance to the movement or gravity compensation through cable-based transmissions or pneumatic actuator systems. The pneumatic actuator systems offer the advantage of producing large forces with low weight added to the device, while cable transmission systems have greater shock absorption, smoothness in movement, and greater versatility in their passage through the joints.

Finally, all the robotics rehabilitation systems reviewed are able to acquire and automatically store biomechanical metrics during the therapy. Depending on each robotic system, it can measure the workspace, joint movement ranges, and force exerted, as well as the quality in terms of the precision and smoothness of the trajectories. Other measures derived from the previous ones for a certain interval of time are the speed of execution and completion of the tasks, as well as the reaction times. The acquisition and storage of these parameters are immediate due to the inherent sensorization of the robotic systems (encoders, force sensors, current sensors, etc.). These are objective records due to the robotic intrinsic sensory systems.

5. Towards Autonomous Rehabilitation Processes?

The development of autonomous systems is an active line in robotics in general, and with increasing presence in healthcare applications, it is already generating beneficial results as it has done in industry [49]. That is the case of surgical robots in minimally invasive procedures for executing autonomously simple surgical tasks, based on the accuracy of robot movements, image processing algorithms, and cognitive systems. There are many other examples than surgical robotics of translational research applied to healthcare.

The common understanding in the robotic community is that the goal of robotic rehabilitation devices should be to assist therapists in performing the types of activities and exercises they believe give their patients the best chance of a functional recovery. But several barriers have been identified, for the particular case of rehabilitation robotics. The first identified barrier is the lack of effective communication in the planning stage of designing robotics aids, between engineers and therapists. Second, many of the devices are incredibly complicated, from both an engineering and a usability point of view. In fact, "simple-to-use" devices are more likely to be adopted by the clinical community than those that have long set-up times or require multiple therapists and/or aids to use [50]. Another well-known barrier relates to the cost and availability, its relation to the effectiveness of the treatment, and how long the robotic treatment must be applied. Many works discuss these issues. Recent examples are those by Acosta et al., who show that while video games can provide a motivational interface, they are the most effective if designed to target specific impairments [51]. Burgar et al. highlight the importance of providing higher therapy

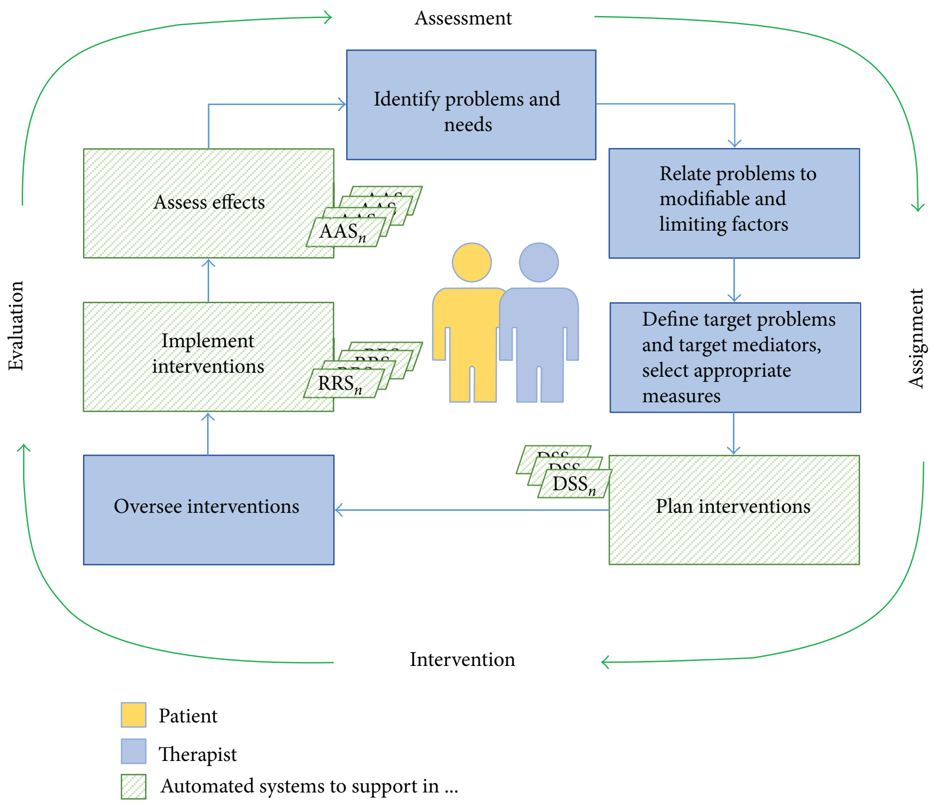

Figure 2: The automated rehabilitation cycle.

intensities (hours of therapy per day) in an acute stroke study using the MIME robot [52]. Telemedicine and telerehabilitation are promising topics for building remote monitoring and easy to use rehabilitation systems that could allow the work of therapist with patients at home. Serious games and low-cost sensory devices are arising as very promising tools for breaking this barrier. The last barrier, but not the least from the authors' point of view, is the lack of automation, which greatly increases the total cost of the treatments. There is a huge potential to automate the treatment process.

To apply this automation approach to the rehabilitation process, it is first necessary to identify how the process is developed and identify which are the most susceptible elements to be automated, as well as the requirements and limitations to achieve this purpose.

Based on the review presented in this article, we have identified three main areas within the rehabilitation cycle where robotics is contributing to automation: planning treatment protocols, implementing interventions, and evaluating the treatment's effectiveness. This rehabilitation cycle, shown in the previous Figure 1, is being transformed into a more automated cycle as shown in Figure 2. This transformation adds more detail but does not alter the rehabilitation cycle, thus maintaining the philosophy centred on the user. In this figure, the main actors (patient and therapist) are supported by several automated tools, as it will be explained below.

5.1. The Automated Rehabilitation Cycle. This paper proposes a framework for the development of the rehabilitation cycle that clearly identifies which parts of the process are more likely to be automated, as well as the actors and elements involved. The autonomous rehabilitation cycle would be composed in this way by five elements that are directly correlated with the blocks of the original cycle. According to this approach, three main actors have been identified: user, clinician (understood as the team), and automated systems. Although several automated systems could be available, as denoted in Figure 2, to simplify, we assume that the one used is the best fitted to each case. The appropriate collaboration between the therapy work team and the automated systems is essential to obtain an effective patient-centred rehabilitation process.

The interaction between these three participants during the course of an automated neurological rehabilitation process will be described in Figure 3. First, an initial evaluation (interview and exploration-based) is carried out by the clinician to identify the patient's problems and needs and select the most appropriate treatment measures. Also, the appropriate scales for functional assessment are chosen to quantify the level of functionality impairment caused by the neurological injury. Here, where the first automated system is, the automatic assessment system (AAS) performs the functionality assessment using the same clinically accepted scales. The results obtained with the AAS are automatically updated in the patient's clinical history. In addition, these results serve as input parameters to the second automatic system, the decision support system (DSS). The DSS aims at designing the most optimal treatment protocol for the patient, generating

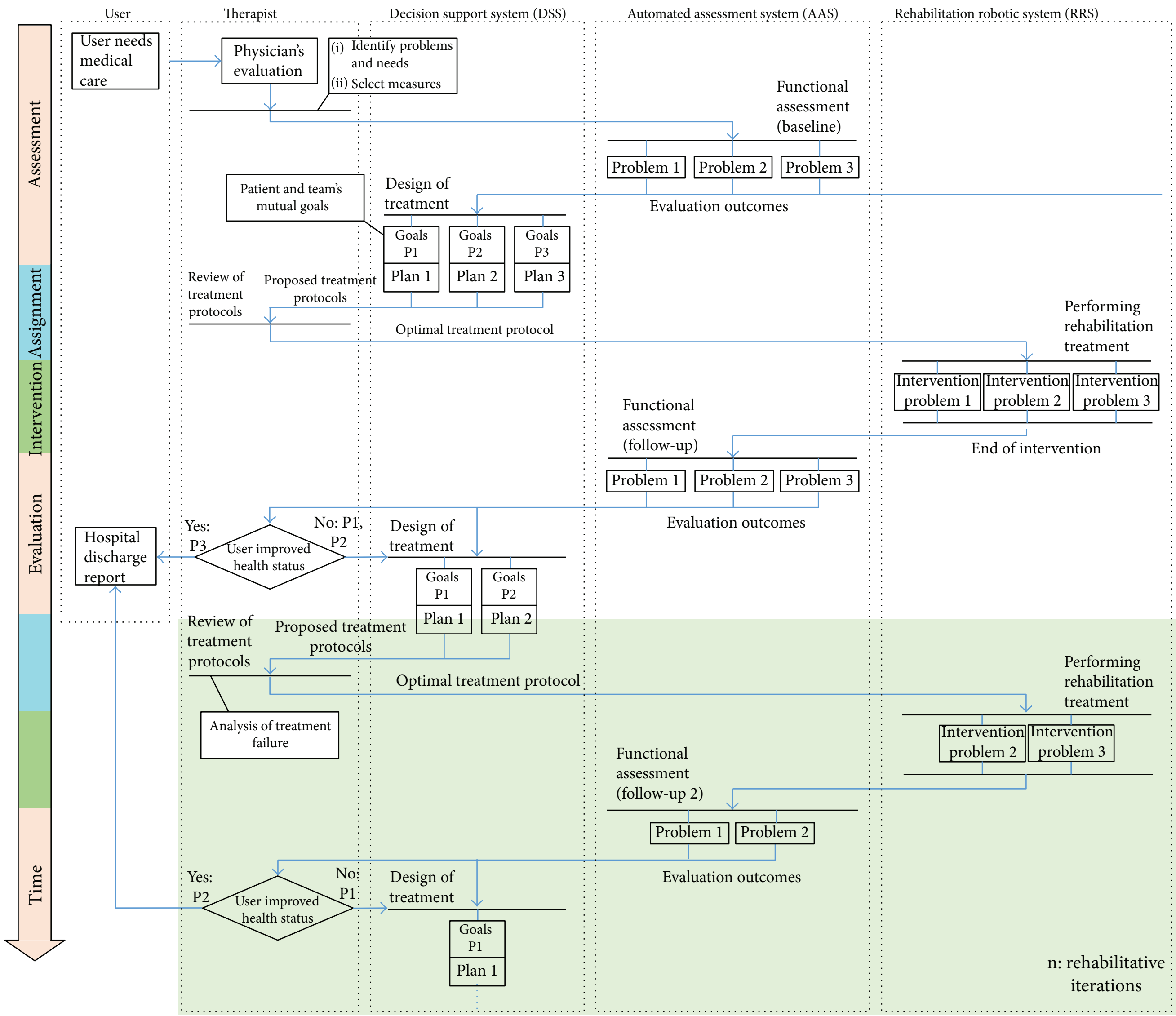

Figure 3: Activity diagram for the automation of the rehabilitation process. In the example shown, three functionality problems were identified in the assessment phase: problem 3 is solved after the first intervention, but problems 1 and 2 remain. Then, the rehab cycle is repeated for *n* iterations.

the specific intervention plans. This figure is based on the lacks identified in the literature review previously presented.

The therapist discusses with the patient to review and adjust the objectives, deciding which treatment plans proposed by the DSS will be adopted. Then, the selected robotic rehabilitation systems (RRS) perform the intervention. After the intervention with the RRS, an assessment of functionality similar to the initial one is carried out again, in order to quantify the effectiveness of the therapeutic measures. For this, the AAS is used again. Finally, if all the problems identified are considered resolved or accepted by both the clinician and the patient, the rehab cycle is concluded. Otherwise, the necessary iterations will be made to try to solve the remaining problems.

It can be deduced that the proposed automated systems operate separately and independently but that they are intrinsically connected and depend on each other for efficient operation, in coordination with the clinician and the patient. The methods to extract metrics and share them and their degree of acceptance by both users and health professionals should be rationalized and assessed, as a prerogative to achieve the automation. To design assistance rehabilitation systems, although the focus is on the subject to be treated, it is important to systematize the understanding of the requirements demanded by therapists in order to enable an easier integration of technology in their daily activities [53].

By providing low-cost and easy to access tools for implementing this automated rehabilitation cycle, the viability of extending the rehabilitation cycle can be increased, not only as a temporary activity but also as a lifelong rehabilitation, as needed, for example, for affordable robotic therapy in maintaining function in degenerative disorders.

Thus, in the opinion of the authors, the requirements that the components of a rehabilitation cycle must meet to be more autonomous are described below.

5.1.1. Automated Assessment Systems (AAS). As revealed by the analysis of assessment methods in neurorehabilitation, the use of traditional motor and functional scales is the main approach to determine the effectiveness of the rehabilitation process. For this reason, the development of methods based on traditional assessment scales that are widely used and known by specialists in rehabilitation is one of the lines of research that have been highlighted to achieve a more autonomous rehabilitation cycle.

There are already oriented studies in this line of work, taking into account two premises: the method and metrics. Regarding the method, tests that are administered without direct contact of the professional are more suitable to be automated. Concerning metrics, it is essential to assess which ones give relevant information and are less invasive for the subject to be evaluated [54].

It can be seen that the FMA is one of the most used scales employed for the motor assessment in the clinical trials that this review included. So it appears reasonable that the potential for the automation of these kinds of assessment methods is being studied. The application of RGB-D sensors, inertial measurement sensors, and other sensors has allowed the scoring of a part of the FMA to be automated [55]. However, one of the biggest problems with the evaluation using traditional tests is the time they take the therapist to administer. Other works address automatic administration of assessment procedures, such as the case of BBT [56]. Even so, a large number of scales and the variety of methods (sensor-based, tracking systems, computer-based, etc.) make the topic of automating the assessment a very promising line of research.

In this respect, the literature also presents several projects that are focused on the automation of the traditional and still "gold standard" scales. As traditional scales are widely used in clinical trials in rehabilitation, as seen in this article, and because the administration of the evaluation is time-consuming, it appears reasonable that the automation of these kinds of assessment methods is being studied. There is an important difference in emphasis between clinical assessment and measurement. Traditional scales comprise several items. However, measurement concerns the quantification of an attribute and some studies [57] demonstrate that multi-item measures need only a few carefully chosen items to generate reliable and valid estimates.

Following the model of the rehabilitation process, most of the systems reviewed (based on end-effector or exoskeletons) are clearly located within the intervention stages of the rehabilitation cycle. However, a percentage of them (46% end-effector and 43% exoskeletons) addresses the assessment stage, based on the metrics that are obtained from the use of systems in therapy. This assessment serves as a method of "rapid assessment" to support the therapist and inform the patient of the effectiveness of the rehabilitation process, but there are few works that report comparative studies or clinical trials to validate nonclinical metrics.

5.1.2. Decision Support System (DSS). Decision support systems based on artificial intelligence (AI-powered DSS) are one of the most active fields in recent years, and it is expected that they will soon contribute to the decision-making process. In healthcare, a variety of software for EMR management is already available (see Section 4.2.2) to help the therapist in decision-making. However, the diagnosis of diseases still presents serious limitations. We can find numerous smartphone apps that allow an online diagnosis, yet the reliability of the diagnosis is not yet consistent with that of a doctor [58]. Besides, researchers in the artificial intelligence community have started to design robot-assisted rehabilitation devices that implement artificial intelligence methods to improve upon the active assistance techniques found in Section 4.2.3.

Clinical decisions are an important component of the rehabilitation cycle, since they involve the determination of the objectives and design of the rehabilitation treatment. As can be seen in this review, the support provided by automated systems for this kind of task is by providing more reliable and objective information about the motor performance of the user during the intervention, as well as allowing the execution of different types of intervention procedures that can be configured by the clinician.

Regarding the assignment stage of the rehabilitation cycle, there are two steps that could be automated by using artificial intelligence techniques: the planning of intervention treatments and the assignment of the appropriate RRS for intervention.

Related to the planning of intervention treatments, the generation of these protocols is based on different factors that depend on the type of lesion and on how it affects the development of the patient's daily living activities. Many of the intervention measures are systematized in order to deal with a particular effect (concrete measures for specific problems), but there is no reason to believe that a "one-size-fits-all" optimal treatment exists. Instead, therapy should be tailored (intensity, number of repetitions, and duration of the intervention) to each patient's needs and abilities [59]. In addition, the protocol planning should consider the available tools (RRS) to execute such protocol in order to assign the appropriate RRS to the type of lesion (e.g., a hand injury cannot be trained by a device designed for elbow training).

Thus, we have identified some requirements that must be met to develop intelligent systems for treatment planning: (1) coherence between technological and traditional outcome measures, for the purpose of a therapeutic intervention based on technology and the problem-solving approach; (2) differentiating these measures according to the level of the effect (mild, moderate, and severe); (3), based on models, to identify the parameters that define an adequate physical condition according to the demographics of the patient and healthy profiles; (4) to be able to estimate the physical condition of the user to compare it with the welfare reference model; and (5) to generate a protocol that can be executed by the available intervention systems.

These requirements imply that the integration of an AI-powered DSS in the automated cycle requires as input parameters the results of the evaluation systems (AAS) and, based on them, generates an optimized treatment protocol that can be executed by the systems of automatic intervention (RRS). This is why special attention is needed to the development of strategies that allow the integration and collaborative execution of these automated systems.

5.1.3. Robotic Rehabilitation Systems (RRS). The developments in medical robotics systems and RRS are fields that have awakened most interest for research in robotics. Due to the direct participation in the intervention phase, the different methods used in rehabilitation (task-oriented, constraint-induced, etc.), and the understanding of what constitutes the most, appropriate therapy has the potential to become an intensively active topic of research [59].

Two main issues have been highlighted: the ability of the RRS to acquire multiple information on patient performance during the development and the fact that from these data an assessment of patient functionality is obtained, even in the same type of score as the traditional scales.

However, the type and amount of information that is obtained depend a lot on the type of robotic system (end-effector or exoskeleton) and the intrinsic sensory system. Also, the parameters derived from the measurements, as indicators of quality (accuracy, smoothness, etc.), can be very heterogeneous. Therefore, a critical issue is to unify the metrics acquired by the RRS, so that they provide as much information as possible for a rapid assessment by the therapist and not just raw data. Thus, among this type of metrics we have the following: range of movement, speed, precision, efficiency, percentage of work of the patient and percentage of work of the robot, and degree of attention in the task. All the works reviewed coincide in capturing the kinematic data; however, they do not address high-level indicators such as the percentages of robot and patient work (excepting NeReBot that gives it as a percentage) nor the degree of attention.

Another important issue is to promote the adherence of the user to therapy. It is necessary to provide an adequate feedback that motivates the patient. Using virtual reality systems is the most widely used solution for this purpose. However, it is important not only the way in which the feedback is given but also the information provided to the user. In this sense, therapists agree that a visual feedback that tells the user if he has improved his score during the execution of the therapy would be beneficial. Other high-level indicators such as the percentages of robot and patient work, control signal, or kinematic data could be helpful to the user only if they help to show the relevance of the patient's progress.

RRS-type systems are already integrated into the rehabilitation cycle, due to their imminent nature in the intervention; however, addressing the aforementioned questions would allow the rest of the automated components indicated in this paper (AAS and DSS) to take advantage of the objective information that is acquired with the RRS.

6. Conclusions

A new automated rehabilitation framework has been proposed based on a literature review of robotic rehabilitation systems (RRS) for the upper limb treatment, highlighting its relation with the rehabilitation cycle. This framework has been presented regarding the implementation of more autonomous rehabilitation procedures. Three automated elements were described to make up the proposed framework: automated assessment systems (AAS), decision support systems (DSS), and robotic rehabilitation systems (RRS).

The development of AAS should be based on the traditional assessment methods, since the traditional scales are still the "gold standard" for measuring outcomes and determine the effectiveness of treatment. In addition, the outcome provided by the AAS is obtained in an objective way, generating additional information about the user's performance.

Those systems must be complemented with a novel DSS to help in clinical decision-making and treatment planning. The management of the patient's data (EMR) is currently addressed by using specific software based on high-level algorithms and also on artificial intelligence (AI). Optimized treatment protocols customized to the patient's condition are expected to be automatically generated by these DSS. For this purpose, AI is a promising tool. Dealing with multiple objectives in decision-theoretic planning and reinforcement learning algorithms [60] could contribute to allow the optimal protocols to be generated. Thus, the treatment protocols could require only approval or adjustment by the clinician.

To conclude, the implementation of the proposed framework should consider some issues that are summarized as follows:

(i) The development of strategies for allowing the integration and collaborative execution of these automated systems is needed. It must be considered a proper data management in order to allow the AAS and DSS to use the objective information that is acquired with the RRS. In this way, a communication channel similar to the interdisciplinary team model will be enabled for the automated elements.

(ii) In the case of the AAS development, the automatic administration of the assessment must be considered and not only the automation of the outcome. Knowledge of the user is as important as system functionality, since without the user's cooperation and acceptance, the system's functionality may be ineffective.

(iii) The complexity of neurological disorders and its effect normally presents additional diseases concurrent with the primary disorder (comorbidity) that could limit the patient recovery.

(iv) The feasibility of using AI to generate optimal treatment protocols is still unclear, but considering that AI is a mature science at present, the potential to contribute to the implementation of the proposed DSS is encouraging.

(v) Clinical protocols are validated through randomized control trials (RCT) where a large number of patients undergo the same treatment. In this regard, the most homogeneous samples must be recruited for RCTs that is challenging because of the inherent nature of neurological disorders.

Robots are currently viewed as advanced therapy tools under a therapist's guidance. However, the implementation of the above-mentioned systems could lead to more autonomous and intelligent processes in neurorehabilitation.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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CHAPTER 4

Automated Assessment Systems

4.1 Overview

This chapter presents the main technical requirements, guidelines and challenges that face the development of automated assessment systems (AAS), focusing on the functional evaluation of upper extremity. It also provides analysis and classification of current systems in this field, according to the level of automation, the employed systems to gather performance-based data and the type of output metric.

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Review of Automated Systems for Upper Limbs Functional Assessment in Neurorehabilitation

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ABSTRACT Traditionally, the assessment of upper limb (UL) motor function in neurorehabilitation is carried out by clinicians using standard clinical tests for objective evaluation, but which could be influenced by the clinician's subjectivity or expertise. The automation of such traditional outcome measures (tests) is an interesting and emerging field in neurorehabilitation. In this paper, a systematic review of systems focused on automation of traditional tests for assessment of UL motor function used in neurological rehabilitation is presented. A systematic search and review of related articles in the literature were conducted. The chosen works were analyzed according to the automation level, the data acquisition systems, the outcome generation method, and the focus of assessment. Finally, a series of technical requirements, guidelines, and challenges that must be considered when designing and implementing fully-automated systems for upper extremity functional assessment are summarized. This paper advocates the use of automated assessment systems (AAS) to build a rehabilitation framework that is more autonomous and objective.

INDEX TERMS Automatic assessment, biomedical engineering, motor function, neurorehabilitation, rehabilitation robotics, robotics and automation, upper extremity.

TERMINOLOGY

To reduce the ambiguity in the clinical terminology, the definition of the terms that will be used along the text are given as follows.

- **Test or clinical tool:** this is understood as the procedure that the patients must perform in order to assess the functionality of the upper extremities. It encompasses a series of steps and rules for its proper administration. It can be single or multi-item.
- **Item:** the movement or single task that the patient must perform.
- **Outcome measure:** the result of a test that is used to objectively determine the UE function.

I. INTRODUCTION

A particular case of rehabilitation is aimed at treating the problems caused by disorders affecting the nervous and neuromuscular systems, known as neurorehabilitation. In this case, patient needs are usually multi-dimensional, including physical, cognitive, psychological, and medical, and may be very complex. Neurological rehabilitation can be defined as a process or cycle that aims to optimize a person's participation in society and sense of well-being [1]. The starting and ending steps of this rehabilitation cycle are assessment and evaluation, respectively [2]. At the beginning of the rehabilitation process, the assessment step is focused on collecting data about the patient to identify the problems, the causes of functional limitations, and the wishes and goals of the rehabilitation. At the end, the evaluation step refers to assessing the achievement of the goals of the intervention programme [3], [4]. These goals are measured as changes in the functioning or autonomy.

Additionally, a proper evaluation of the therapeutic effectiveness of rehabilitation is also important due to it being a laborious process of expensive interventions [5]. Because of the complexity of neurological diseases, rehabilitation

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processes mostly are long-term treatments. This fact highlights the importance of the assessment step to provide proper economic management in healthcare facilities, and even more importantly, in public institutions. Assessment requires specialized workers and adequate space and material [1]. Thus, factors such as the optimal administration of clinical procedures (optimizing clinicians' time), the appropriate management of resources (workspace and equipment), and proper management of results (patient record) are quite important.

Regarding the procedure's administration, the assessment process is commonly performed by health professionals themselves using standardized clinical tests in order to have objectivity in the evaluation. For the assessment of upper extremity (UE) motor function, such clinical tests are made up of a set of items or procedures that aims to objectively determine the patient's functioning level. However, the evaluation of motor functionality is a manually performed procedure, and it has some drawbacks.

First, current diagnosis of UE motor impairment is based on the observation of select movements (or tasks) by a trained clinical specialist. This estimation aims to be reliable (intra-operator) and objective (inter-operator). However, the nature of visual inspection includes some degree of uncertainty (subjectivity) that may come from a variety of sources (movement variability [6], [7], observer appreciation [8], etc.). Second, neurological rehabilitation is not a process bounded in time. Recovery of motor function in general, and for UE in particular, depends on the characteristics of each individual and the kind of disease (stroke, Parkinson's disease, etc.). Thus, performing several tests to assess longitudinal changes in motor performance can be difficult in terms of patient burden and cost [9], even for healthcare providers.

On this basis, previously mentioned drawbacks could be reduced via automation of traditional assessment tools. Most of the evaluation tests are composed of well-defined exercises or tasks (e.g., point-to-point movements, reaching tasks, object displacement) that are rated by numerical scales, which may be susceptible to automation. By automation, an objective evaluation of the patient's motor functionality could be achieved. Furthermore, the clinician could be provided with more time to assess the results and, based on this, to correct the therapy protocol, modifying the level of difficulty or adding other tasks.

This automation approach in the assessment of motor function has been considered by the research community in recent years. Different methodologies have been used to automatically measure motor function, but the clinical knowledge provided by traditional examination tests has been retained.

In this paper, a systematic review of systems that address the automation of traditional tests for the assessment of UE motor function, used in neurological rehabilitation, is presented. To the best knowledge of the authors, this is the first review to classify the automated methods for upper limbs functional assessment in general, and in terms of motor function in particular. This review presents an analysis of the literature in this field according to the automation level, the employed technology, the focus of assessment, and the method for automatic outcome generation. The remainder of this paper is organized as follows: Section II provides an overview of UE functional assessment and its fundamentals. A description of the traditional tests and procedures is included. In Section III, the results of the literature review are summarized. These results are presented under different scopes. In Section IV, a series of requirements, guidelines, and challenges that must be considered when designing and implementing automated systems for upper limbs functional assessment are presented. Also, the findings and perspectives are discussed. To conclude, some final remarks are presented in Section V.

II. UPPER LIMBS FUNCTIONAL ASSESSMENT: TRADITIONAL METHOD

Overall, the rehabilitation cycle (shown in Figure 1) involves the identification of a person's problems and needs, relating the problems to relevant factors of the person and the environment, defining rehabilitation goals, planning and implementing the measures, and assessing the effects [1]. In a simplified way, it is made up of four steps: assessment, assignment, intervention, and evaluation.

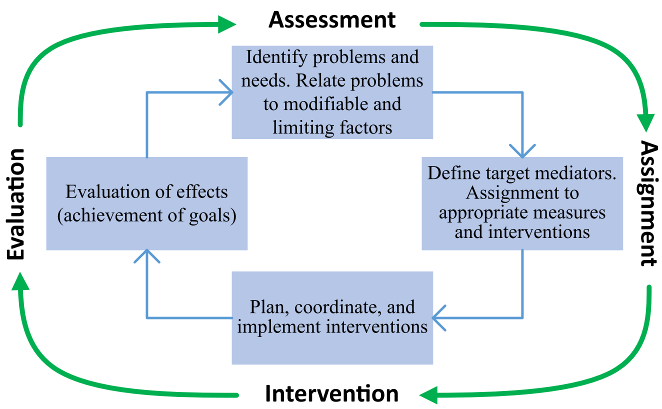

FIGURE 1. The Rehabilitation Cycle [1].

Regarding the assessment stage, functional assessment refers to the determination of a person's ability to perform everyday tasks and requirements of living. Functional assessment is used to establish a baseline, to predict rehabilitation results, and to evaluate therapeutic interventions [10]. Fundamentally, the evaluation process will utilize a number of variables to act as indicators (outcome measures), and these can be compiled to form a clinical assessment to provide a clinically meaningful deduction from the measurement [11].

An outcome measure is the result of a test that is used to objectively determine the functioning level of a patient throughout rehabilitation treatment. Traditionally, outcome measures have focused on the individual's impairment level. However, this provided a limited description of disability. In 2001, the World Health Organization (WHO) adopted the International Classification of Functioning, Disability and Health, commonly known as ICF [12], which provides a common framework for describing the consequences of health conditions and an international standard to describe and measure health and disability. In clinical settings, ICF is used for the evaluation of functional status, goal setting, treatment planning and monitoring, as well as outcome measurements. The ICF model of disability involves three levels: body functions and structure (impairment), activity limitations, and participation.

In the scope of this paper, evaluation of the upper extremities (UE) covers two key factors related to the ICF model: 1) identification of the impairments limiting normal movement, and 2) the initial level of activity limitations and participation restrictions arising from these impairments [13]. For that purpose, standard clinical tests are used to determine the baseline function limitations of a patient at the beginning of treatment. Once treatment has been initiated, the same test(s) can be used to determine progress and treatment efficacy [1], [4]. Nevertheless, the tests for outcome measure gathering are greatly varied with respect to the number, type, and scoring of the tasks used to determine performance levels, their degree of standardization, and their predictive validity [14], [15]. The following section aims to show an overview of the variety of the traditional tests commonly used in neurorehabilitation, including their method of administration and fundamentals for outcome generation.

A. A VARIETY OF AVAILABLE ASSESSMENT TOOLS

Numerous assessment tools are readily available to clinicians to measure disability and function limitations in the neurorehabilitation process. The use of appropriate, valid, and reliable tests can improve the understanding of how disease progresses, the level of structural impairment, and how this impacts on the individual in terms of function and participation [11]. These assessment tools can be categorized according to the functioning levels (ICF model) that we aim to evaluate.

On the one hand, the typical body functions that need to be assessed in the neurological patient are those related to the functions of the joints, muscles, movements, cognitive functions, and sensations. Thus, some constructs of relevance are muscle strength, ranges of movement, attention, memory, and balance. Examples of tests classically encompassed at this level are the Fugl-Meyer Assessment (FMA) of Motor Recovery after Stroke, or the Modified Ashworth Scale (MAS). FMA [16] is a stroke-specific, multi-item, and performance-based impairment index. Test items are scored on the basis of the patient‘s ability to complete the item using a 3-point ordinal scale (0: unable to perform, 1: performs partially, and 2: performs fully). The total possible scale score is 226 for the FMA and 66 for the upper extremities subsection (FMA-UE). Similarly, MAS for measuring spasticity comprises six ordered categories of increasing spasticity that are assigned sequentially in a 5-point scale.

On the other hand, when examining a patient's activities, the therapist will examine not only whether they can do the tasks but also the quality with which the tasks are performed. Example of tools at this level are the Box and Blocks Test (BBT), the Nine-hole Peg Test (NHPG), the Action Research Arm Test (ARAT), or the Wolf Motor Function Test (WMFT). BBT and NHPG are tools for the individual measure of manual dexterity and coordination. For the score, the therapist must manual count the total amount of objects (cubes and pegs for the BBT and NHPG, respectively) transported. WMFT and ARAT quantify upper extremity motor ability through timed and functional tasks (lift objects, reaching, etc). The items are rated on a 6-point scale in the case of WMFT, and a 4-point scale for the ARAT.

Furthermore, participation is a more complex concept than impairments and activities, but it is fundamental to understand the patients and their life and to help with planning treatment. Common scales used are the Canadian Occupational Performance Measure (COMP), the EuroQol Quality of Life Scale (EQ), the Reintegration to Normal Living Index (RNLI), the Stroke Impact Scale (SIS) and the Stroke Specific Quality of Life Scale (SQL). These scales are written questionnaires in which the person has to answer a series of questions that are asked. Detailed descriptions of the features of the tests that are available for functional assessment in neurological rehabilitation are summarized in [15] and [17], according to the ICF model.

Despite the variety of available tests, all of them should accomplish some requirement for clinical acceptance. The outcome measures should evaluate the particular aspect of function that they are reported to assess (validity), and the results should be the same (or similar) regardless of who administers the test or when it is administered (reliability). Additionally, they should actually be able to assess change whatever is being evaluated over time (responsiveness).

B. A PRAGMATIC POINT-OF-VIEW

Classifying the tests within the ICF framework can be difficult and is often controversial [18]. Many of them include items considered an activity within the ICF (e.g., a task performed by an individual), as well as items related to participation (e.g., the societal level of functioning).

In this sense, assessment tools can be also divided into two categories: (1) performance measures, where the clinician rates or times a series of UE actions that are performed by the patient, or (2) self-report measures, where the clinician asks a series of questions about UE actions that are answered verbally by the patient [13]. The traditional tests most commonly used in neurological rehabilitation, according to performance or self-report measures, are listed in Table 1. The tests that fully or partially cover the assessment of UE functionality are marked with * or ** symbols, respectively.

1) PERFORMANCE MEASURES

Performance measures do not measure individual performance but rather analyze the person's process and evolution in activities. These tests shares some characteristics considering two distinctions: some tests analyze the body functions and the others evaluate the activity.

On one side, within the body function domain, we can divide it into three types of tests: the ones that evaluate

TABLE 1. Abbreviations of traditional tests commonly used in neurological rehabilitation, sorted according to Performance and Self-report measures. ICF domains are also indicated (MT: Motor components; CO: Cognitive components; VS: Vital signs; FN: Functional components).

	Abbr.	Test name	ICF
Performance Measures	ARAT	Action Research Arm Test*	MT
	BBT	Box and Block Test*	MT
	BI	Barthel Index	FN
	BIT	Behavioural Inattention Test	CO
	CDT	Clock Drawing Test	CO
	CMSA	Chedoke McMaster Stroke Assessment*	VS
	CNS	Canadian Neurological Scale**	VS
	FAST	Frenchay Aphasia Screening Test	CO
	FIM	Functional Independence Measure	FN
	FMA	Fugl-Meyer Assessment**	MT
	GHQ-28	General Health Questionnaire-28	VS
	MAS	Modified Ashworth Scale**	MT
	MoAS	Motor Assessment Scale**	MT
	MJHFT	Modified Jebsen Hand Function Test*	MT
	MMSE	Mini-Mental State Examination	CO
	MOCA	Montreal Cognitive Assessment	CO
	NHPG	Nine-Hole Peg Test*	MT
	PPT	Purdue Pegboard Test*	MT
	RMA	Rivermead Motor Assessment**	FN
	RPS	Reaching Performance Scale*	FN
	UPDRS	Unified Parkinson's Disease Rating Scale**	MT
	WMFT	Wolf Motor Function Test*	MT
Self-Report Measures	BDI	Beck Depression Inventory	CO
	COPM	Canadian Occupational Performance Measures	FN
	EQ-5D	EuroQol Quality of Life Scale	VS
	GDS	Geriatric Depression Scale	CO
	HADS	Hospital Anxiety and Depression Scale	CO
	LHS	London Handicap Scale	FN
	NHP	Nottingham Health Profile	VS
	RNLI	Reintegration to Normal Living Index	FN
	SA-SIP30	Stroke-Adapted Sickness Impact Profile	VS
	SIS	Stroke Impact Scale*	VS

*Focused on upper extremity (UE); **Includes UE section.

cognitive components, the ones that assess motor components, and the ones that assess clinical states or vital signs.

In the tests that evaluate the cognitive components, a final score and a cut-off point are obtained with which we can compare normality. Most of them are a battery of questions in which the examiner asks the person to perform a series of tasks. In some tests, there may be a time limit, that is to say that the person has to do the activity within a specific time standardized by the test itself; in others, it is not necessary. The type of instruction used in these tests is verbal, that is, the therapist explains what he/she has to do in each activity.

The tests that evaluate the motor components are standardized procedures in which a final score and a cut-off point are obtained with which to compare normality. They are based on a set of items in which the examiner explores different movements of the person. That is, the therapist asks the patient to perform different movements, motor tasks, or adopt different positions with his body to explore whether the person is able or not to perform them. These tests can be controlled by time, as is the case for the BBT in which the patient is asked to move all the necessary cubes for a minute, or they can be simply observational by the therapist in which the action is analyzed and the score is written down. The type of instruction that is used in these tests is verbal in most cases (the therapist explains to the person what he/she has to do).

The scales that assess vital signs are those in which a series of examinations are performed by the examiner to make a clinical judgment, usually derived from the patient's symptoms. They do not have a time limit, and it is the examiner who, based on the evaluations and questions asked in the tests, rates the different scores.

On the other side, the tests in the activity domain are of the so-called functional type, where the individuals are asked to perform different activities or answer questions about how they carry out the activities. Most of them have a set of questions with several response options that range from normality to functional impossibility. It is the examiner who asks the person and records the score based on the scale instructions. The most remarkable thing about these scales is that they evaluate the function, and many of them are linked to the performance of the activities of daily life, so they give the perspective of whether the person can become independent in their day-to-day life.

2) SELF-REPORT MEASURES

These self-report measures are usually a series of questionnaires in which the respondents read the question and select a response for themselves without the researcher's interference. Those questionnaires serve to inquire about the feelings or attitudes of the person, being more often used in observational studies. Because of these measures or self-reports are subjective, problems related to validity could occur, since the patient can be confused by reporting less of the severity of the pathology or, on the contrary, increasing it. In these measures, the intervention of the examiner is not mandatory. Thus, the person can take the questionnaire to his/her home and complete it in a quiet way. Usually the instructions come at the beginning, which explain how to complete the questionnaire. Some of these have a final score, but most are based on the subjective perceptions of the patient. Normally, it is estimated mental states and participation in the environment that give the examiner an idea of the patient's emotional status and the degree of autonomy in different daily activities.

In summary, a wide variety of assessment tools are available for the estimation of functional status by clinicians. Despite the variety, not all of them are (fully or partially) focused on the UE functional assessment. However, it can be appreciated that the dynamics of the assessment of UE functioning, in most of the tests, are susceptible to automation (performance of single movements or tasks, instructions given verbally, observation-based ratings). This fact has been considered by the research community in recent years regarding the development of automated assessment systems. Thus, the following section presents the results of a systematic review focused on analyzing automated systems for assessment of UE functional status where the traditional clinical tests are taken as a design reference.

III. LITERATURE REVIEW SUMMARY

In this section, we highlight the particular aspects of the automated systems for functional assessment of upper limbs in neurorehabilitation. This paper does not intend to be a comprehensive analysis of the utility of the automated assessment systems; rather, it aims to compile the information published in peer-reviewed articles. On this basis, different aspects of automated systems, such as focus of measurements, reliability of data provided, approaches for rating, or clinical feasibility can be discussed.

A. SEARCH METHODS

The authors undertook a literature search in August 2018 about the use of automated systems for the assessment of upper limb motor function in neurological rehabilitation, using keywords such as automated, robot, neurological, rehabilitation, upper, limb, extremity, neurorehabilitation, motor, function, and various combinations of these. The databases were Science Direct, PubMed/Medline, and IEEE. Only papers written in English were considered, and the search was extended to the whole database. Studies were included when: 1) systems for assessment of upper limbs motor function (uni- and bilateral) were addressed; 2) systems were based on traditional tests used in neurorehabilitation, including those that only address the outcome automation; 3) the measure to be automated was a performance measure; 4) the automation of at least one test item was included; 5) clinical trials with real patients were conducted.

B. AUTOMATED APPROACHES FOR FUNCTIONAL ASSESSMENT OF UPPER LIMBS

The results of the systematic review of systems that address the automation of traditional assessment tests used in neurological rehabilitation are summarized in Table 2. The chosen studies were allocated different identification numbers (ID) to better explain them throughout the text. Studies were sorted according to the method used for obtaining the test outcome. To the best knowledge of the authors, this is the first review to classify the automated methods for upper limbs functional assessment.

Next, this paper presents an analysis of the literature review results according to the frequency of use in the automation of the traditional tests, the automation level of the chosen systems, the employed technology, the method for automatic outcome generation, and the focus of the assessment.

1) MOST COMMON AUTOMATED TESTS

A total of 24 automated systems were found in this review. It should be noted that all studies were focused on the automation of a performance-based test for assessment of upper limb functionality.

The frequency of use of each test was calculated based on how many times a specific clinical tool appeared in the third column of Table 2 across the total studies ($n = 24$). The FMA test is clearly the most frequent (46% of studies) test that is considered to be automated. The ARAT, BBT, and WMFT tests are in second place with a frequency of use of 12.5% for each one. Finally, the MJHFT, NHPG, RPS, and UPDRS tests were the third most frequently chosen tests (4% for each one) for automation.

Most of the systems were focused on the automation (partially or completely) of a single test. However, some studies have chosen different items from two tests (ID: 12), or they were able to provide the score of more than one test (ID: 22).

The results of this review are consistent with the Santisteban [55] findings, which showed that the FMA is the most commonly used upper limb outcome measure in intervention studies in stroke rehabilitation. The Santisteban [55] study also concluded that the frequency of use of the tests varies widely, between 36% and 1%. Only 15 measures were used in more than 5% of studies. The WMFT, ARAT, and BBT are included in this range.

The above mentioned tests are able to measure several aspects of motor function, and also can provide a clear perspective about the patient's health status. In this sense, it could be reasonable to develop automated systems based on the most frequently used tests, and therefore, the ones most appropriate to measure functionality.

2) LEVEL OF AUTOMATION

As was previously described in Section II, the assessment process involves test administration and the rating of the test's tasks. That is, a system must address both approaches for full automation. In Table 2, studies that have considered automatic administration of the test are marked via the ✓ symbol. Additionally, the percentage of automated items is indicated.

On the one hand, only six of the reviewed studies dealt with the administration of the assessment in an automatic manner. For this purpose, the most common approach is to give the test's instructions to the patients via a Graphical User Interface (GUI). Different channels can be used for giving the instructions, and it depends on the technology used for automation. In all the systems the instructions are given by audio messages that explain and describe the task. However, most of these also include a visual channel, which displays a video recording in the GUI for demonstration of how the movement (or task) must be performed. The video can show a clinician or an avatar performing the movement.

On the other hand, most of the functional assessment tests are not focused on evaluating specific cognitive or motor functions. That way, the tests can be composed of subsections or domains focused on the assessment of a specific extremity (upper and/or lower) and can evaluate different sensorimotor functions. An example is the FMA test [16], which is made up of five domains, and there are 155 items in total: motor functioning (in the upper and lower extremities); sensory functioning (evaluates light touch on two surfaces of the arm and leg, and position sense for eight joints); balance (contains seven items, three seated and four standing); joint range of motion (eight joints); and joint pain. Hence, 33% of the studies in this review were able to automatically evaluate

TABLE 2. Automated assessment systems based on traditional tests for functional evaluation of upper limbs.

ID	Source	Based on	Automation level		User interface	Technology used for automation			Test outcome obtained by	Outcome provided	Focused on
			Adm*	Items		Sensors	Method	Characteristics††			
(1)	Simonsen, D. (2017) [19], [20]	MJHFT	✗	3 items (100%)	None	IMS (Kinect)	Computer vision for detecting the interaction	Accuracy: ✦✦ Portability: ✦✦✦ Adaptability: ✦✦✦	**DS**: Image segmentation and point cloud analysis to limit the time measurement	Time spent performing tasks†	Manual dexterity
(2)	Cho, S. (2016) [21]	BBT	✗	All items (100%)	Yes: Virtual interface to develop the test	IMS (Kinect V1)	Virtual reality for modelling the environment and detecting interactions	Accuracy: ✦✦ Portability: ✦✦✦ Adaptability: ✦✦✦	**DS**: Detecting objects in a virtual environment for cube counting. A classifier based on linear discriminant analysis (LDA) for hand poses (grasping and non-grasping) detection	Number of cubes†	Manual dexterity (gross)
(3)	Oña, E.D. (2018) [22], [23]	FMA	✓	6 items FMA-UE (19%)	Yes: Virtual interface to develop the test and to guide the user by means of auditive messages and video demonstration	IMS (Kinect V2)	Virtual reality for modelling the environment and detecting interactions	Accuracy: ✦✦ Portability: ✦✦✦ Adaptability: ✦✦✦	**DS**: Detecting collisions between the avatar's joints and virtual detectors (colliders) placed along the required movement path	3-points scale†; *Additional*: Movement smoothness	Motor function (Shoulder, Elbow)
(4)	Hsiao, C.P. (2013) [24]	BBT	✗	All items (100%)	None	IMS (Kinect V1)	Computer vision for detecting interactions	Accuracy: ✦✦✦ Portability: ✦✦✦ Adaptability: ✦✦✦	**DS**: Image segmentation and point cloud analysis for cube counting	Number of cubes†; *Additional*: Hand movements, speeds and locations	Manual dexterity (gross)
(5)	Oña, E.D. (2018) [25], [26]	BBT	✓	All items (100%)	Yes: GUI to guide the user, provide the test instructions, show results and store data	IMS (Kinect V2)	Computer vision for detecting interactions	Accuracy: ✦✦✦ Portability: ✦✦✦ Adaptability: ✦✦✦	**DS**: Image segmentation and point cloud analysis for cube counting	Number of cubes†; *Additional*: Partial times; Cube colours	Manual dexterity (gross)
(6)	Gagnon, C. (2014) [27], [28]	NHPG	✗	All items (100%)	Yes: GUI to display in a virtual environment the test apparatus	MMS (Phantom Omni haptic sensor and Force sensors)	Virtual reality for modelling the environment + Haptic sensor to measure interactions and give feedback	Accuracy: ✦✦✦ Portability: ✦✦✦ Adaptability: ✦✦✦	**DS**: Counting of displaced virtual pegs and time measurement	Time taken to perform tasks†; *Additional*: Grasping force, Acceleration zero-crossings, Number of times a peg is dropped, Trajectory error, Mean collision force	Manual dexterity (fine)
(7)	Cruz, V.T. (2014) [29], [30]	WMFT	✗	2 items (12%)	None	IMU (Magnetic, Angular Rate, Gravity [MARG] sensors)	Analysis of biomechanical data	Accuracy: ✦✦✦ Portability: ✦✦ Adaptability: ✦✦	**DS**: Time measurement by the identification of velocity changes. **CS**: Analysis of kinematics movement by means of a Decision Tree classifier for FAS scoring	Time spent performing tasks and the Functional Ability Scale (FAS): 6-points scale†	Motor function (Forearm, Elbow, Hand)
(8)	Scano, A. (2018) [31], [32]	RPS	✗	6 items (100%)	None	IMS (Kinect V2)	Analysis of movements (optical motion tracking)	Accuracy: ✦✦ Portability: ✦✦✦ Adaptability: ✦✦✦	**CS**: Movement classification using a normative database of healthy subjects' performance (reference ranges of biomechanical performance based on kinematical, dynamical, and motor control parameters)	4-points scale†	Motor function (Shoulder, Elbow, Grasping); Trunk displacement
(9)	Lee, S.H. (2018) [33], [34]	FMA	✓	26 items FMA-UE (79%)	Yes: GUI to provide linguistic guidelines and instruction video to the patient	IMS (Kinect V2) and MMS (Force Sensing Resistor [FSR] sensor)	Analysis of movements (optical motion tracking) and force sensing	Accuracy: ✦✦✦ Portability: ✦✦✦ Adaptability: ✦✦✦	**CS**: Binary logic-based classification of each item to rate the 3-point scale, without learning procedures	3-points scale†; *Additional*: Range of motion, Grip strength, Time of movement execution	Motor function (Shoulder, Elbow, Forearm, Hand); Co-ordination; Grasping force

*Considering the automatic administration of the test (✓ = Yes; ✗= No); †Same metric as the traditional one; ††Given in levels (Low:✦ , Medium:✦✦ , High:✦✦✦)

TABLE 2. ***(Continued.)*** **Automated assessment systems based on traditional tests for functional evaluation of upper limbs.**

ID	Source	Based on	Automation level		User interface	Technology used for automation			Test outcome obtained by	Outcome provided	Focused on
			Adm*	Items		Sensors	Method	Characteristics††			
(10)	Otten, P. (2015) [35]	FMA	✓	25 items FMA-UE (73%)	Yes: GUI to allow the user to choose the test movement, display instructions. Voice command to start data recording and automatic finish movement detection	IMS (Kinect) and IMU (Inertial sensors) and MMS (glove sensor and Force Sensing Resistor [FSR] sensor)	Analysis of movements (optical + wearable motion tracking) and force sensing	Accuracy: ✦✦✦ Portability: ✦✦ Adaptability: ✦	**CS**: Using Support Vector Machine SVM or Backpropagation Neural Network BNN algorithm (machine learning) for movement classification	3-points scale†; *Additional*: Limb orientation, Joint angle, Movement smoothness, Amount of movement, Grip strength, Finger flexion and extension	Motor function (Shoulder, Elbow, Forearm, Wrist, Fingers); Coordination; Grasping force
(11)	Panardi, A. (2010) [36], [37]	WMFT	✗	15 items (88%)	None	IMS (Overhead camera) and IMU (Inertial sensor and computer)	Computer vision for detecting interaction + wearable inertial sensor	Accuracy: ✦✦ Portability: ✦✦✦ Adaptability: ✦✦	**DS**: Real time image processing and sensor's flag for measuring task time. **CS**: Signal processing and Naive Bayes classifier to estimate (algorithm is trained with 5 tasks) the FAS score	Time taken to perform tasks† and the Functional Ability Scale (FAS): 6-points scale†	Motor function (Shoulder, Elbow, Forearm); Grasping ability
(12)	Olesh, E. (2014) [38]	FMA and ARAT	✗	10 movements taken from FMA and ARAT	None	IMS (Kinect)	Analysis of movements (optical motion tracking)	Accuracy: ✦✦ Portability: ✦✦✦ Adaptability: ✦✦✦	**CS**: Algorithm to reconstruct movements and Principal Component Analysis (PCA) for score estimation	3-points scale†; *Additional*: Joint angles	Motor function (Shoulder, Elbow, Wrist)
(13)	Lee, T.K.M. (2016) [39], [40]	ARAT	✗	1 item (5%)	None	IMU (Accelerometers) and MMS (Force Sensing Resistor [FSR] sensors)	Instrumenting the objects used in the test	Accuracy: ✦✦✦ Portability: ✦✦ Adaptability: ✦✦✦	**CS**: Feature combination (6 features) of data signals and a Decision Tree classifier for movement classification	4-points scale† incorporating the time limits	Grasping task
(14)	Piro, N. (2016) [41]	UPDRS	✗	1 item of PART III (6%)	Yes: GUI to allow offline teleassessment by showing an avatar imitating the user movements	IMU (Magnetic, Angular Rate, Gravity [MARG] sensors)	Analysis of movements (wearable motion capture)	Accuracy: ✦✦✦ Portability: ✦✦ Adaptability: ✦	**CS**: Feature selection and movement classification using a J48 algorithm trained on 86 data sets	5-points scale†; *Additional*: Speed of movement (hand turnings) and the angle of the rotation reached	Forearm (pronation-supination, rhythm, speed, and amplitude decrement)
(15)	Kim, W.S. (2016) [42]	FMA	✓	13 items FMA-UE (40%)	Yes: GUI to provided instructions by means of video playback and audio guidelines	IMS (Kinect V1)	Analysis of movements (optical motion tracking)	Accuracy: ✦✦ Portability: ✦✦✦ Adaptability: ✦✦✦	**CS**: Principal component analysis (PCA) and artificial neural network (AAN) learning from the saved motion data	3-points scale†; *Additional*: Smoothness	Motor function (Shoulder, Elbow, Forearm supination)
(16)	Carpinella, I. (2014) [43]	ARAT	✗	All items (100%)	None	IMU (Single inertial sensor at wrist level)	Analysis of movements (wearable motion capture)	Accuracy: ✦✦✦ Portability: ✦✦✦ Adaptability: ✦✦	**CS**: Task segmentation and detecting (semi-automated procedure) the instants of onset and termination of each phase. Extraction of quantitative parameters (duration, jerk index) for movement classification	Z-scores related to the mean item duration and jerk index	Grasp, Grip, Pinch, Gross movements
(17)	Patel, S. (2010) [44], [45]	WMFT	✗	Total FAS score (88%)	None	IMU (accelerometers)	Analysis of movements (wearable motion capture)	Accuracy: ✦✦✦ Portability: ✦✦✦ Adaptability: ✦✦	**CS**: Feature selection and Random Forest based algorithm to classify eight reference tasks. **IS**: Linear regression model using 6 tasks to predict the total FAS score	FAS: 6-points scale†	Motor function (Shoulder, Elbow, Hand); Reaching and Manipulation

*Considering the automatic administration of the test (✓ = Yes; ✗= No); †Same metric as the traditional one; ††Given in levels (Low:✦ , Medium:✦✦ , High:✦✦✦)

TABLE 2. ***(Continued.)*** **Automated assessment systems based on traditional tests for functional evaluation of upper limbs.**

ID	Source	Based on	Automation level		User interface	Technology used for automation			Test outcome obtained by	Outcome provided	Focused on
			Adm*	Items		Sensors	Method	Characteristics††			
(18)	Villán, M.A. (2018) [46], [47]	FMA	✗	5 items FMA-UE (16%)	None	OMS (Infrared BTS-SMART-D system)	Analysis of movements (marker motion tracking)	Accuracy: ✦✦✦ Portability: ✦ Adaptability: ✦	**CS**: Generation of reference healthy kinematic models (HKM) for a later comparison with the users' motions	3-points scale†; *Additional*: Range of motion	Motor function (Shoulder, Elbow)
(19)	Wang, J. (2014) [48]	FMA	✗	4 items FMA-UE (12%)	None	IMU (wireless inertial sensors)	Analysis of movements (wearable Wireless Body Sensor Network [WBSN] for motion capture)	Accuracy: ✦✦✦ Portability: ✦✦ Adaptability: ✦✦	**IS**: Support Vector Regression (SVR) model using 14 selected features based on RelieffF-SVR. The total score is estimated by sensor data of a single task	3-points scale†; *Additional*: Velocity, Energy, Angle of movement	Motor function (Shoulder; Elbow)
(20)	Yu, L. (2016) [49]	Short FMA	✗	7 items SFMA (100%)	None: Remote video conferencing software to administer the test at home	IMU (Accelerometers) and MMS (Flex sensors)	Analysis of movements (wearable motion capture)	Accuracy: ✦✦✦ Portability: ✦✦ Adaptability: ✦✦	**IS**: A extreme learning machine (ELM) algorithm to map the sensor data to clinical scores (RRelief algorithm was applied to find the optimal features subset)	3-points scale†	Motor function (Shoulder, Elbow, Wrist, Fingers)
(21)	Del Din, S. (2011) [50]	FMA	✗	Total score FMA-UE (motor)	None	IMU (Inertial sensors)	Analysis of movements (wearable motion capture)	Accuracy: ✦✦✦ Portability: ✦✦ Adaptability: ✦✦	**IS**: Random Forest algorithm fed with features derived from wearable sensor data recorded during the performance of a single item of WMFT (lifting a can)	3-points scale†; *Additional*: Energy, velocity, Jerk metric	Motor function (Shoulder, Elbow, Wrist, Hand)
(22)	Bosecker, C. (2010) [51]	FMA, MSS, MP, MAS	✗	Total score FMA	None	MMS (MIT-Manus robot)	End-effector robot for detecting and measuring interactions	Accuracy: ✦✦✦ Portability: ✦ Adaptability: ✦✦✦	**IS**: Linear regression models to estimate clinical scores from the robot-derived metrics from the unconstrained reaching movements (point-to-point) and the circle drawing task	Same as traditional scale for each test†; *Additional*: Shoulder strength	Motor function (Shoulder, Forearm)
(23)	Julianjatsono, R. (2017) [52]	FMA	✗	6 items FMA-UE (18%)	None	IMS (Kinect V2) and IMU + MMS (Glove with Inertial sensor, Force Sensing Resistor, and Flex sensor)	Analysis of movements (wearable motion capture) + sensorized wearable glove	Accuracy: ✦✦✦ Portability: ✦✦ Adaptability: ✦✦	**IS**: Several regression algorithms were implemented to generate high-resolution scores and to classify the movements	High-resolution score (14 fractional digits)	Motor function (shoulder, Elbow, Wrist)
(24)	Prochazka, A. (2015) [53], [54]	N/A	✓	RAHFT tasks	Yes: GUI and software that introduces each component of the test with a three-dimensional animation accompanied by an audio recording	MMS (ReJoyce station)	End-effector robot for detecting and measuring interaction	Accuracy: ✦✦✦ Portability: ✦ Adaptability: ✦✦	**DS**: Subjects perform a variety of movement tasks while playing computer games	Percentage of maximal displacement and Time to completion	Motor function (shoulder, Elbow, Wrist), Grasping ability and force

*Considering the automatic administration of the test (✓ = Yes; ✗= No); †Same metric as the traditional one; ††Given in levels (Low:✦ , Medium:✦✦ , High:✦✦✦)

all of the items (IDs: 7, 8, 16) or the tasks (IDs: 1, 2, 4, 5, 6) of the reference test. Seventeen percent of studies had greater than 70% automated items (IDs: 9, 10, 11, 17).

Regarding the automation level of automated systems, all the test items and their automatic administration must be considered for fully automation. Therefore, only three studies (IDs: 5, 9, 10) can be treated as fully-automatic (or almost) systems.

3) TECHNOLOGIES UTILIZED FOR AUTOMATION

It can be seen that all of the reviewed studies can be considered as performance-based measures (see previous Section II-B.1). Therefore, the test score is based on how the movements are performed by the patient or how long they take.

Consequently, capturing the patient's movements is essential for rating test items. This process of recording human movement is referred as human motion capture, and the systems designed for that purpose as known as MoCap (motion capture) systems.

Several MoCap technologies can be integrated for the automation of traditional tests. In general, five working principles can be distinguished in human motion capture [56]: optoelectronic measurement systems (OMSs), electromagnetic measurement systems (EMSs), image processing systems (IMSs), ultrasonic localization systems (UMSs) and inertial sensory systems (IMUs). Additionally, a different family of techniques can be included: mechanical measurement systems (MMSs) [57]. By means of direct physical interaction, they are able to detect motion (end-effector robot or flex sensors) or can even measure ranges of motion (exoskeletons with angular encoders) of the user.

Four such techniques (OMS, IMS, IMU, MMS) have been identified as commonly used in automatic assessment approaches. The frequency of use (number of studies/total studies) of each technique and different combinations are presented in Figure 2. Details of the employed sensors in each study are included in Table 2.

A total of 33.3% of studies only used vision-based sensors (IMS) for movement tracking, 25% of studies only used inertial sensors (IMU), 12% of studies only used mechanical systems (MMS), and 4.16% only used optoelectronics systems (OMS). The most common combinations were IMS + MMS, IMU + MMS, IMS + IMU, and IMS + IMU + MMS, with frequencies of use in studies of 8.3%, 8.3%, 4.16%, and 4.16%, respectively.

Nevertheless, some clinical tests not only consider the capability of properly performing a task, but also another related feature, such as strength, which is directly related to the ability to interact with the environment. This is the case for the FMA test, which includes an item to specifically gather a resistance measurement when tugging at an object that the user holds. Automatic systems can objectively measure the exerted force during task performance using force sensors (IDs: 9, 10). Other studies (IDs: 6, 22) provide the force measurement as an additional outcome, even though it is not considered in the traditional test.

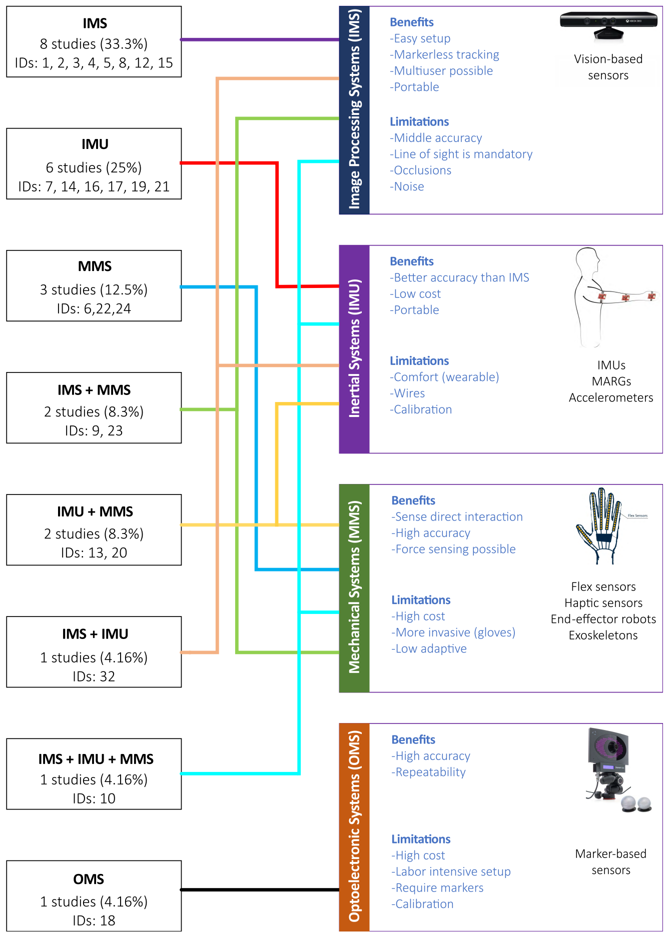

FIGURE 2. **Frequency of use and main features of motion capture technologies in automatic assessment approaches.**

Moreover, the methodologies for using sensors in test automation are varied. Systems that monitor the user-environment interactions by means of computer vision techniques (IDs:1, 4, 5, 11) were identified. Another approach is to adapt the environment (IDs: 2, 3, 6) or the tools (IDs: 13) to sense the user interaction. In addition, a novel approach is to use an end-effector robot that, via its embedded sensors, is able to measure the interaction (IDs: 22, 24). A more extended approach is the analysis of movements based on the registered performance-based data that is considered by the remaining systems.

These methodologies offer some relevant features in regard to automation, such as accuracy, portability, and adaptability to the user's body complexion. First, the accuracy in the data acquisition is high in most of the approaches. Optical sensors allow non-intrusive motion capture. However their accuracy depends on the lighting conditions and a line of sight is required. Wearable sensors give better accuracy at the expense of patient comfort. However, nonetheless, they are not incompatible given an intermediate solution. Furthermore, systems based on these kinds of sensors are portable, being adequate for use outside of clinical settings. This is a drawback for the more accurate motion capture systems like OMS-based or robot-based systems. Finally, due to the nature of neurological disorders, the degree of motor limitations is wide. The target population can vary from elders and children to wheelchair-bound persons. This condition requires that systems can easily adapt to the patient's characteristics. Thus, adaptability is a clear requirement of automated systems to increase their usability. Systems based on non-intrusive sensors seem adequate for fitting to the physical condition of the patients with an easy setup. Proper combination of the sensors and the automation method is a big challenge to obtain the best solution in terms of accuracy, portability, and adaptability.

4) OUTCOME GENERATION

The most relevant advantage of automated systems is the possibility of generating objective outcomes. The general process for automatic generation of outcome measurement is depicted in Figure 3. Different procedures can be applied to obtain a measurement of function based on kinematic data of patients. As a starting point, the goal is to automatically achieve the traditional score. However, novel scores or extended versions of traditional ones can be achieved, considering the richer information that it is obtained by automatic data acquisition systems.

There are two common steps prior to the scoring process, that is, the data acquisition process and signal processing. Different indicators of user performance can be gathered according to the data acquisition method (e.g., IMS: trajectories, range of motion; IMU: kinematic data; MMS: exerted force, etc.). However, these native measurements can be affected by noise. Therefore, a signal processing step is almost mandatory for proper data analysis. Then, different features can be extracted from the enhanced dataset. Such features can feed algorithms for outcome generation.

Regarding the scoring process, three approaches have been identified for automatic generation of clinical outcomes: Direct Scoring (DS), Classification-based Scoring (CS), and Indirect Scoring (IS).

Direct Scoring (DS) systems are those whose outcome is obtained by sensing and analyzing the interactions between the user and the environment. The output is directly calculated from the measurements, and it does not require a trained dataset. A clear example of this approach is when the outcome is given by a measurable variable, such as a time period (IDs: 1, 6). Additionally, countable variables, such as the number of blocks (IDs: 2, 4, 5) can be obtained by direct scoring. Virtual reality can be also useful for the detection and measurement of user-system interactions, providing scores, such as the number of displaced objects (IDs: 2, 6) or a performance-based impairment index (ID: 3).

Classification-based Scoring (CS) is denoted for those systems based on algorithms (with or without learning procedures) that best map input features to an output variable. In this case, a specific dataset is used as a reference for rating

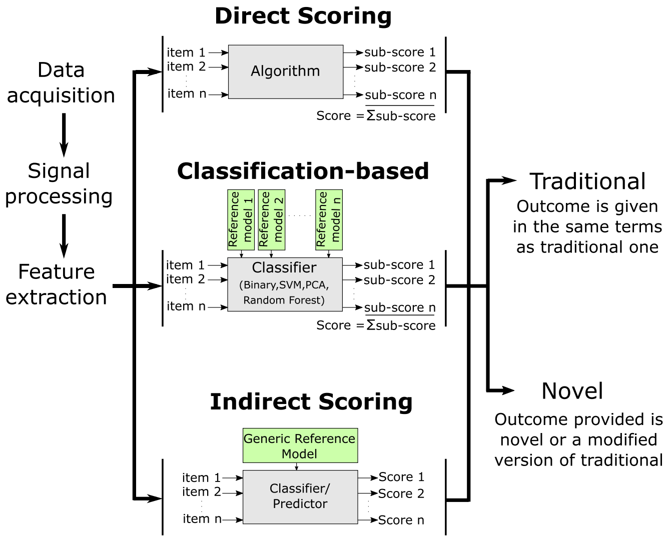

FIGURE 3. **Methodologies for automatic outcome generation.**

the movements of the test. That is, during the evaluation procedure, each movement is compared with its reference model (features) and it is mapped to determine the best fit. A reference model for each movement (or task) of the test is used. Classic classification algorithms, such as Decision Tree (IDs: 7, 13), Support Vector Machine (ID: 10), Random Forest (ID: 17), and Neural Network (IDs: 10, 15) can be employed. However, in-house-developed algorithms (IDs: 8, 16, 18) were also identified.

Indirect Scoring (IS) is denoted for those systems that use a single reference model for the item rating procedure. Note that a generic/comprehensive reference model is used instead of a model for each movement or task. In ID:19 study, this approach was applied for the prediction of the total score of the FMA test, using sensor data of a single task. However, in this study it also was demonstrated that the prediction performance of single task models was enhanced by building a comprehensive model. In ID:20 study, seven weak regression models for each exercise were established first and then combined to build a comprehensive quantitative FMA (short version) assessment model.

One step beyond, indirect scoring systems are able to estimate another related outcome score. That means, the generic reference model can be used for the prediction of the score of other related outcome measures, without the need to administer the specific tests to measure them. Outcome prediction is based on comparative studies of metrics that are different among them, but keep some correlation. An example is ID:21 study, where the FMA score was estimated using a reference model built based on the data recorded during the performance of a single item (lifting a can) of WMFT. In ID:22 study, different clinical scores (FMA, MSS, MP, and MAS) were estimated from unconstrained reaching movements (point-to-point) and a circle drawing task, using an end-effector robot.

5) EXTENDED OUTCOMES

On the one hand, the main outcome provided by all of the automated systems is the traditional score. In Table 2, the traditional outcomes are labelled by the † symbol. It must be highlighted that, the generated results are more objective than the ones obtained by the clinician observation due to reduced inter-operator variability.

On the other hand, due to the nature of the sensorized systems, additional information about the user performance is directly gathered. In some cases, such extra data can be used for the generation of a modified outcome that gives a better description of impairment than the basic outcome (IDs: 16, 23). Besides, even novel measurements that do not depend on human judgment can be achieved, such as in the method proposed in [53] (ID: 24), and could be an automated alternative to the ARAT or FMA. However, the main drawback of novel outcome measures is the need for clinical validation, as opposed to traditional outcome measures that are already well accepted and widely used by clinicians.

6) FOCUS OF REHABILITATION METHODS

Neurological assessment includes the exploration of cognitive function, language and speech, motor function, reflexes, and sensitive exploration. It can be seen that the automatic systems summarized in this review are based on outcome measures mainly focused on motor function assessment.

The reaching and grasping ability are the motor functions most commonly evaluated by automated systems. The assessment procedure, in more detail, involves the tracking of various joints in order to assess representative motor capabilities such as range of motion, coordination, grasping force, or fine manual dexterity.

IV. TOWARDS AUTOMATED ASSESSMENT SYSTEMS

According to the WHO, the rehabilitation cycle, in a simplified way, is made up of four steps: assessment, assignment, intervention, and evaluation [1]. This rehabilitation cycle, shown in the previous Figure 1, is being transformed into a more automated cycle [58], as shown in Figure 4. This transformation adds more detail but does not alter the rehabilitation cycle, thus maintaining the philosophy centered on the user.

In the past few decades, robotics research has been mainly focused on developing systems in the field of rehabilitation as interventions (systems for recovery/support/training of motor function) [58]. A low percentage of such systems address the assessment stage using the metrics that are obtained during therapy development. Nevertheless, it is important to distinguish that most of the assessments performed by robotic rehabilitation systems (RRS) are not functional assessments, conventionally carried out at baseline and follow-up stages of treatment using standard outcome measures. On the contrary, this type of assessment serves as a method of ‘‘rapid evaluation’’ to inform the therapist about the treatment evolution, by comparing biomechanical data among rehabilitative sessions. However, these outcomes (in terms of trajectories, kinematic data, etc.), despite being indicators of the patient’s performance, are nonclinical metrics requiring comparative studies or clinical trials to be validated.

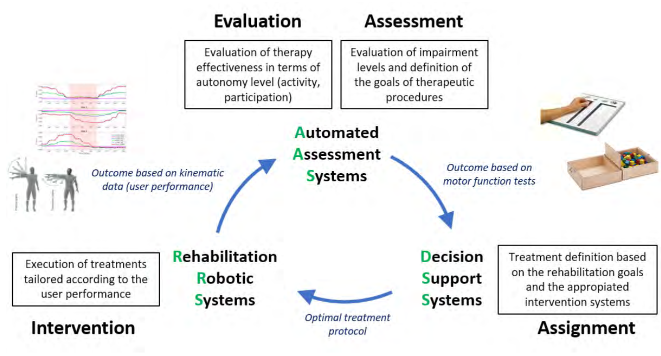

FIGURE 4. **The Automated Rehabilitation Cycle [58].**

On the one hand, one of the biggest problems with evaluation using traditional tests is the time taken by the therapist to administer them (e.g., FMA [59]). In this way, the report provided by RRS as a rapid evaluation method may be useful. However, the need for clinical validation of results is a drawback. For that reason, the development of automated methods based on traditional assessment scales, that already are clinically validated, widely used, and well-known by specialists in rehabilitation, is certainly desirable. As a result of using automated assessment methods based on traditional tests, the time it takes clinicians to get results will decrease and additional validation will not be required.

On the other hand, the major concern during the evaluation procedure is reducing the subjectivity in assessment. Procedures based on clinician observation could be affected by inter-operator errors. That is, the rating of the same impairment can vary among different clinical professionals. Automation could contribute to reducing inter-operator errors, and could even generate extended performance-based metrics.

In this way, as revealed by the review presented in this paper, the use of traditional clinical tests as a reference for the design of automatic assessment systems (AAS) is a feasible approach. However, there is still room for improvements. Most of the systems are mainly focused on automatic outcome generation. Nevertheless, the assessment process also involves human factors in the test administration that have not yet been completely solved. In the following section, the main challenges, technical requirements, and guidelines that must be considered when designing and implementing the AAS for upper limbs are discussed in order to obtain fully-automated assessment systems.

A. CHALLENGES FOR FULL AUTOMATION

Figure 5 depicts the three main aspects that were identified as mandatory for considering assessment systems to be fully-automated: administration, data acquisition, and rating.

The three components are strongly linked, and they depend

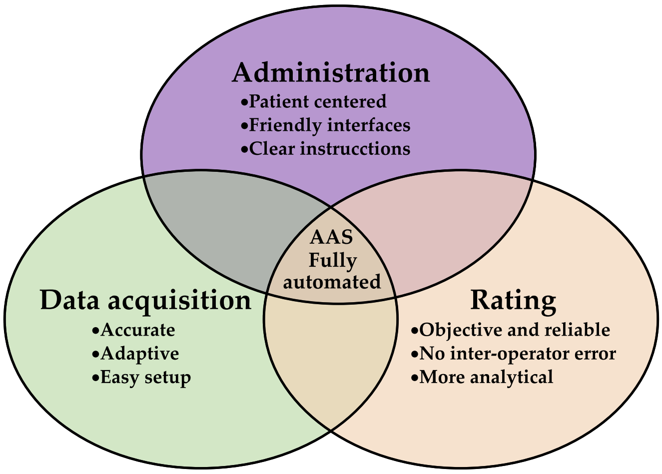

FIGURE 5. **Basis for fully-automated assessment systems (AAS).**

upon each other for adequate performance. Namely, good data acquisition not only depends on the reliability of the sensors, but also the method of administering the test. An incorrect way of giving the instructions to the patient could lead to incorrect movement execution, caused by trouble understanding the instructions instead of a real impairment. This incorrect data registration will produce an incorrect item rating and thereby an incorrect assessment.

Therefore, proper integration of these aspects could lead to fully-automated assessment systems, based on the combination of clinical knowledge provided by traditional examination tests with the more refined capabilities of biomechanical capture systems. Next, the issues related to the automatic processes of administration, data acquisition, and rating are addressed separately.

1) AUTOMATIC DATA ACQUISITION

The body is characterized by a high number of muscles and joints, all of which must be controlled during the execution of coordinated functional movement [60]. Despite the fact that not all variables involved in movement execution can be measured, some variables related with muscles (activation, strength) or joints (angles, trajectories, velocity, etc.) can be measured by state-of-the-art sensors.

On the one hand, one of the major concerns in the assessment process is obtaining accurate outcome measurements [61]. Additionally, the person being monitored would not even notice the existence of the sensing device or procedure. Unobtrusive sensing technologies, which can be implemented in the form of optical motion tracking or small wearables and Internet of Things (IoT) devices may be a good solution. However, there is a difficulty in deriving useful information from low quality signals. Thus, improving the quality of signals must be the focus of research for future development. So, one of the key requirements for AAS is to detect as many movement indicators as possible, accurately and sustainably in various scenarios.

On the other hand, the assessment scenario can vary according to the patients' characteristics (adults, children, stature, or even clothes) and their mobility restrictions (standing or wheelchair). This fact highlight the acquisition systems must be able to easily adapt to changes in the physical characteristics of the patients, allowing a quick setup. A variety of technologies are currently used to track a person's health and wellness status. They include electrodes, optical sensors, strain gauges, and ultrasound devices, each of which has some drawbacks in terms of user experience such as comfort and convenience. In this way, although the challenges with accuracy and robustness must be still improved, markerless motion capture systems are likely to have a stronger impact on AAS development regarding comfort, adaptability, and easy setup.

Data acquisition systems should be selected according to their accuracy, portability, adaptability, and comfort. Thus, the best solution may be obtained by combination of different types of sensors to increase the accuracy. Proper sensor selection will provide clinicians with useful metrics, and increase the speed and repeatability of the analysis by removing subjective components.

2) AUTOMATED ADMINISTRATION

The main concern about the feasibility of automatic test administration is considering the best way to address the human factors. It should be taken into consideration that the assessment is focused on the patient (patient-centered evaluation). In certain stages of the recovery process, especially in the early stages, the role of the therapist is irreplaceable. Consequently, the usability of AAS will have a niche bounded by the level of affectation of the patients. It seems barely feasible to use for individuals with severe impairments.

Furthermore, the level of interaction between a patient and an automatic system would be not comparable with the clinician-patient interaction level in either case. The therapist's role is not limited to evaluation but also to offer some social skills to encourage the patient throughout the test development, or simply to have a dialog. In this regard, advances in interactive systems (virtual or augmented reality based) or social assistive robots (SAR) are promising in order to implement more reliable dialog systems. Currently, the SARs offer enhanced interaction features, intelligence capabilities, and good acceptance by the users. Thus, including a SAR to monitor the assessment process seems a feasible approach to provide a friendly interaction method, even for telerehabilitation.

In any case, independently of the used interaction method, the test instructions must be provided in a clear manner. This issue is highly important for accuracy in data acquisition, and thereby, in the impairment rating. The more communication channels (audio, text, visual) used, the better.

3) AUTO-RATING

There is an important difference in emphasis between clinical assessment and measurement. It can be seen that automatic data acquisition systems make a greater amount of biomechanical data (measurements) available for the therapist. Some variables (e.g., time and strength) can be measured directly. Other variables (e.g., disability, motor function, or quality of life) are measured indirectly by how they manifest. Interpretation of impairment manifestations is carried out by clinicians using the appropriated outcome measures. Therefore, an automatic assessment method must be able to transform the raw data (performance-based variables) into clinical metrics that can be taken as an objective clinical evaluation (impairment indicators). This is the auto-rating process. As identified in this review, current automated systems use three auto-rating methods (Direct, Classification-based, and Indirect) for the automatic generation of objective clinical outcomes. In addition, the use of auto-rating methods could reduce the inter-operator variability towards reliable measurements by nature.

One step beyond, a more analytic rating procedure is possible by using the AAS. On the one hand, data obtained by traditional outcome measures, both item scores and total scores, are ordinal level, which means that the values are rank ordered [61]. Consequently, these measurements are not precise measurements of an individual. For example, the FMA scale has three categories that are ordered in terms of increasing mobility. Since the main goal of AAS is providing the traditional score, the obtained outcome could have the same drawbacks, despite such methods using richer information gathered by accurate data acquisition systems.

In this way, the sensor data gathered by automated systems could enable the generation of metrics with increased resolution. An example is the ID:23 study, which was able to provide a high resolution outcome for the FMA test while maintaining the classical dynamic in the assessment procedure. This could be a research line to be considered by future works in order to better use sensor data.

On the other hand, automatic rating can be tackled by applying several algorithms (Extreme Learning Machines, Principal Components Analysis, Support Vector Machines, etc). Most of them use a reference model (single or comprehensive) for the classification/prediction of clinical outcomes. Using a comprehensive model appears to be adequate since some studies have demonstrated that multi-item measures need only a few carefully chosen items to generate reliable and valid estimations. Besides, AAS not only must be able to detect the evolution of individuals but must also try to identify whether such changes are clinically significant.

However, most of the studies have considered small samples and they are only suitable for group-level comparisons. Therefore, one of the major challenges in obtaining automatic outcome measures that detect clinically significant changes at the level of the individual is building appropriate reference models including large samples and different populations.

In this regard, based on the capability of AAS for the automatic acquisition and storage of biomechanical data, it is possible to build healthy kinematic models that better fit healthy ranges or patterns. To this purpose, it is necessary to produce a joint effort by researchers and practitioners. Currently, Artificial Intelligence (AI) is a mature science, and digital health (eHealth) transformation using the information and communication technologies (ICT) is a stronger trend in healthcare. Benefits of including such technology in auto-rating in particular, and in AAS development in general, is a research line which is yet to be fully discovered.

B. LIMITATIONS

This review is not without its limitations. Our study was limited to the functional assessment of upper extremities in general, and motor function evaluation in particular. Besides, only automatic systems based on traditional tests were considered. However, there are several developments of automatic assessment systems that propose different methodologies than the traditional ones, even for the lower limbs. Thereby, novel clinical outcomes are obtained that need to be validated. Future works could extend the literature analysis to cover novel automatic systems, including their validity, reliability, and responsiveness.

V. CONCLUSIONS

The objective and automatic measurement of rehabilitation outcomes is a new and developing field. In this paper, a total of 24 works focused on the automatic assessment of UE function in neurorehabilitation were reviewed. On this basis, some remarkable findings in understanding the benefits and challenges when developing automated assessment systems (AAS) were identified.

The development of the AAS should be based on the traditional assessment methods, since the traditional scales are still the ‘‘golden standard’’ for measuring outcomes and determine the effectiveness of treatment. The combination of clinical knowledge provided by traditional examination tests with the more refined capabilities of biomechanical sensors can enhance the outcome measures. Consequently, the outcomes provided by the AAS will be objective, reliable, and will generate additional information about the user's performance.

In addition, we found that the automatic outcome generation of the AAS is based on three methods: Direct Scoring (DS), Classification-based Scoring (CS), and Indirect Scoring (IS). With the exception of the DS case, all of the methods need a (single or comprehensive) healthy reference model to compare the tested movements with the normal ones. Thus, an important issue to solve is the creation of a framework by clinicians and researchers to build appropriate healthy reference models.

Automatic administration of the tests must be also considered, not only the automation of the outcome, to develop fully-automated assessment systems. Knowledge of the user is as important as system functionality, since without the user's cooperation and acceptance, the system's functionality may be ineffective.

In conclusion, it is our opinion that the benefits offered by the AAS can enhance the rehabilitation process, and that these kind of systems will become a complementary tool for common clinical practice.

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CHAPTER 5

Rehabilitation Robotic Systems

5.1 Overview

This chapter describes technical requirements and proposed training paradigm for the implementation of rehabilitation robotic systems (RRS). The fundamentals of this approach come from reviewing the scientific literature in the field of robot-aided systems for upper limb rehabilitation. Several aspects of current robot-based strategies, such as analytic capability, human-robot interactions, safety or adaptation capability, were analysed in this study.

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applied sciences

MDPI

Review

Robotics in Health Care: Perspectives of Robot-Aided Interventions in Clinical Practice for Rehabilitation of Upper Limbs

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Abstract: Robot-aided systems to support the physical rehabilitation of individuals with neurological impairment is one of the fields that has been widely developed in the last few decades. However, the adoption of these systems in clinical practice remains limited. In order to better understanding the causes of this limitation, a systematic review of robot-based systems focused on upper extremity rehabilitation is presented in this paper. A systematic search and review of related articles in the literature were conducted. The chosen works were analyzed according to the type of device, the data analysis capability, the therapy method, the human–robot interaction, the safety strategies, and the focus of treatment. As a conclusion, self-adaptation for personalizing the treatments, safeguarding and enhancing of patient–robot interaction towards training essential factors of movement generation into the same paradigm, or the use of lifelike environments in fully-immersive virtual reality for increasing the assimilation of motor gains could be relevant factors to develop more accepted robot-aided systems in clinical practice.

Keywords: robotics; neurological; rehabilitation; motor function; upper extremity

1. Introduction

Neurological disorders are the leading cause of disability and the second cause of death worldwide, representing a huge public health problem [1,2]. Common neurological disorders include multiple sclerosis, Parkinson's disease (PD), stroke, and brain injuries, among others. Each year, approximately 500,000 people experience a stroke in the U.S. and about 1.1 million in Europe [1]. In 2016, roughly 6.1 million individuals had PD around the globe, and statistics pointed out the growth in disease prevalence [3]. Hence, the number of patients who need care from clinicians with expertise in neurological conditions is very elevated. Since populations are growing and aging [4] and the prevalence of major disabling neurological disorders steeply increases with age, healthcare providers will face increasing demand for treatment, rehabilitation, and support services for neurological disorders [5].

The needs of patients with a neurological disorder are usually multi-dimensional, including physical, cognitive, psychological, and medical, and they may be very complex. The typical consequences are related to the impairment of upper, lower, or both limb motions. Traditionally, recovery procedures include extremities mobilization and efforts for the patients. Hence, one of the goals of neurorehabilitation is to regain motor function, which is essential to perform activities of daily living (ADL) autonomously.

In this regard, a variety of robot-based devices has been investigated to support clinicians in neurorehabilitation [6,7]. Consequently, there are several studies available that aim to categorize the contribution of this type of system from global or specific perspectives. The global perspective studies the effect of robot-based treatments [8–11] or the relationship with the rehabilitation cycle as a holistic approach [12]. The specific perspectives analyze different intervention-related aspects of the systems. Thus, scientific literature shows various classifications according to the type of feedback [13], the focus of treatment [14–17], the mechanical modularity of devices [18], the control strategies [19,20], the intervention techniques [21], or the user interfaces (EEG/EMG based) [22–24].

On that basis, robotic rehabilitation systems (RRS) have been proven to reduce costs, improve treatment quality, and increase therapist productivity. However, the number of robotic rehabilitation systems in clinical use is small. Besides, it is not clear which ones are the more useful strategies for transferring the motor gains to the performance of ADL.

In this paper, a systematic review of robot-based systems focused on the rehabilitation of upper extremity (UE) motor function was conducted. This review presents, from the specific perspective of intervention, an analysis of the literature of the RRS in order to identify the treatment strategies, the analytic capability of performance-based metrics, and the gaps in human–robot (patient– and therapist–robot) interaction channels. The way that the RRS address the patient's safety and the stimulation factors (individual, task, and environment) involved in motion generation are also analyzed. A better understanding of all the above aspects could help to develop new strategies or promote the most effective ones in order to overcome limitations for the use of robot-aided systems in clinical practice. The reminder of this paper is organized as follows: Section 2 provides an overview of neurological rehabilitation and its fundamentals. Essential factors in movement generation are highlighted. Section 3 describes the advances of robotics in the rehabilitation domain. In Section 4, the different strategies in robot-based training are described. In Section 5, the results of the literature review are summarized. These results are presented under different scopes. In Section 6, perspectives and challenges that must be considered when implementing autonomous systems for the rehabilitation of UE motor function are discussed. To conclude, some final remarks are presented in Section 7.

2. Neurological Rehabilitation

Neurological rehabilitation or neurorehabilitation can be defined as a process that aims to reduce the functional limitations of a patient. These limitations come from motor control problems, and the final idea is to optimize the person's participation in society and sense of well-being [1,25]. Therapeutic interventions in neurological rehabilitation are often oriented toward changing movement or increasing the capacity to move of patients who have functional movement disorders due to motor control problems.

Understanding the nature of movement and motor control is critical in clinical practice. Therefore, it is also important to consider the development of robotic rehabilitation systems (RRS) that have the goal of being adopted in clinical settings. Due to the complex nature of the movement, there are several theories of motor control. These theories try to interpret how the brain controls the movement and which factors are involved in the process. According to Shumway-Cook et al. [26], movement is a result of combining three factors: the individual, the task, and the environment.

Despite the variety of motor control theories, motor learning is the principle behind therapeutic intervention techniques. Motor learning is based on the ability to adapt to the central nervous system (CNS) due to changes in the environment or lesions (neural plasticity). Motor learning is defined as a set of internal processes associated with practice or experience. The idea is to produce changes in motor activity that were relatively permanent. Regarding motor function, therapeutic treatments aim to keep the remaining skills, relearn the lost skills, and learn new skills.

Overall, there is not enough convincing evidence to support that any therapeutic approach is more effective in recovery than any other approach. At present, the evidence suggests that effective rehabilitation treatments require the practice of activities in the most relevant possible environments, rather than undertaking analytical exercises aimed at changing impairments [27]. Essential aspects of training include functional exercises, with high intensity and with the active contribution of the patient in a motivating environment [21]. Sometimes, this is referred to as task-specific training [28], and it is the most considered approach in developing a robot-based system for neurorehabilitation.

Additionally, focusing on the internal processes of individuals, movement emerges via the cooperative effort of many brain structures and processes [26]. The term "motor" control in itself is somewhat misleading since movement arises from the interaction of multiple processes, including those that are related to perception (integration of sensory information), cognition (organization to achieve intentions), and action (the context of motion performing).

On account of the above, it is not clear whether the current robot-mediated treatments are able to stimulate all the factors (individual, task, and environment) that compose the nature of the movement properly. Hence, a complete rehabilitation framework might consider the processes within the individual to generate proper stimuli, the attributes of the exercise (task), and the context (environment) in which motion is performed. Proper addressing of such factors (correct stimulation of an individual's capacity to meet the interacting task and environmental demands) could help to increase the effectiveness of robot-based treatments, making the adoption of this technology in clinical settings closer. The following section presents an overview of the robotic application in healthcare in general, and for rehabilitation purposes in particular.

3. Robotics in Healthcare: Rehabilitation Domain

Development of robotic technology for healthcare purposes can be sorted into three domains: medical, assistive, and rehabilitation robotics. [29]. The medical robotics domain includes robotic systems that provide support in medical processes of healing (surgery) and care (diagnosis). Likely, medical robots for surgery are the most adopted systems in clinical settings. The domain associated with assistive robotics covers systems that provide assistance in task-related healthcare processes, either to carers or to patients, in care facilities. This assistance involves logistic tasks, surveillance, bed transfers, etc. Finally, the rehabilitation robotics domain covers a range of different forms of post-operative or post-injury care where direct physical interaction with a robot system will either enhance recovery or act as a replacement for lost function.

Figure 1 depicts systems related to the rehabilitation robotics domain, which are numerous and different. They can be organized from into two perspectives: the level of physical contact (morphology) or the role of the device (recovery or compensatory). On one side, the rehabilitation robotics domain according to physical contact can be divided into distinct sub-sectors: prostheses, orthoses, and rehabilitation aids.

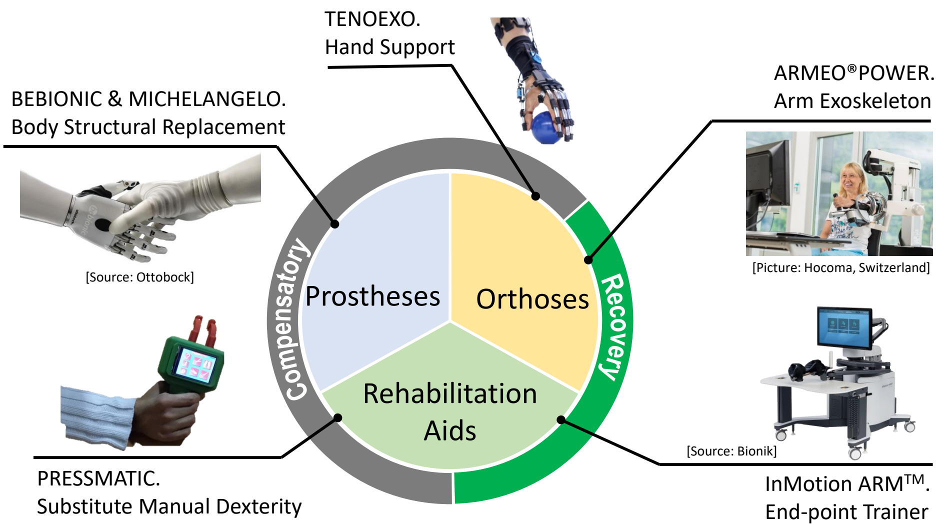

Figure 1. Rehabilitation robotics domain according to device morphology and expected role it plays.

Prostheses are defined as external devices that partially or totally replace a limb. This definition includes any device placed within the body for structural or functional purposes [30]. In general, this definition includes classical external devices that are intended to substitute amputations. In the case of upper limbs, modern alternatives are robotic hands such as the Bebionic robotic hand or the Michelangelo prostheses hand manufactured by Ottobock [31]. In addition to the amputation replacement, robotic hand technology allows the patient to control with great dexterity some hand functions like grasping. Additionally, the development of internal body devices (artificial organs) clearly applies to this subsection. This type of device that has been inspired by biological systems is referred to as a bio-robotics system [32]. Another example is a neuronal prosthesis that aims to restore the damage from neurological injuries. Neuronal prostheses are brain–machine interfaces that register the neuronal activity of the brain and decode the cellular activity in control signals. Then, these control signals can be used to operate a device [33–35]. The development of implantable neural prosthesis is a proposal to treat conditions such as stroke, traumatic brain injury, or neurodegenerative diseases [36].

Orthoses are the external devices that are used to modify the structural and functional characteristics of the neuromuscular and skeletal system [30]. They do not replace a body part or an organ, but replace or reinforce its functionality. The presence of robotics in the development of orthoses is through the so-called active orthoses or exoskeletons. An active orthosis applies forces to the limb of a person through the actuators of the device. Contrarily, a passive orthosis is defined as a device for which the patient is required to apply force to move. There are some potential applications for active orthoses in healthcare. One of these is a therapeutic and diagnostic device for physiotherapy or an assistive device for physical human capacity augmentation (therapist or patient). An example is the Tenoexo hand exoskeleton [37] to assist patients in grasping tasks during physiotherapy and in ADL such as eating or grooming. Another example is the rehabilitation suite for upper limb developed by Hocoma [38]. Overall, there is a variety of actuation mechanisms for upper limb exoskeletons, such as electric engines [39,40], springs [41], electro-pneumatic actuators [42], hydraulic actuators (4-DOF) [43], or shape memory alloy (SMA) fibers [44,45].

Rehabilitation aids include systems or devices that not are covered within prostheses' and orthoses' definitions; namely, systems with a moderate level of physical contact (neither fixed to the body structure nor wearables). An example of rehabilitation aids is end-point robots that are partially in contact (usually hand-held) with the patient when training, such as the InMotion system [46]. Another example is a non-wearable electromechanical device that the user must grab to employ, such as Pressmatic [47].

On the other side, devices included in the rehabilitation robotics domain could also be categorized from the perspective of the expected role they play. That is, the same robotic device could be used for different purposes in healthcare, depending on the patient's prognosis. An example is a device for giving support to a person with reduced hand functionality, specifically problems when grasping. In the case that such a limitation of grasping functionality is due to the effects of a stroke, the purpose of the device is helping to functional recovery. Contrarily, if the limitation is an effect of a spinal cord injury, the purpose of the device is to compensate for the permanent lack of hand function. Hence, from the perspective of the role they play, the rehabilitation robotics domain could be divided into devices for recovery or compensatory purposes.

In the case of recovery purposes, the role of the robotic device is defined as giving back the capability of the individual to perform a task using mechanisms previously used. This is the case for some exoskeletons (orthoses) and end-point robots (rehabilitation aids). Examples are the ARMEO®POWER and InMotion ARM™ systems, respectively. They are used to support extremity mobilization for motor training.

In the case of compensatory purposes, the role of the robotic device can be described as atypical approaches to meet the requirements of the task using alternative mechanisms not typically used. For example, the restoration of fine grasping function can be addressed via a wearable device (orthosis) or an electromechanical device (rehabilitation aid) that the user must hold. In both cases, the robotic system is compensating the lack of grasping ability by assisting the fingers' movement [48,49] or automatically generating the movement [47], respectively. Compensatory strategies can also reflect modifications to the environment that simplify the demands of the task itself.

On account of the above, this paper focuses on reviewing robotic systems developed for upper limbs with the target role of motor function recovery. This field includes end-point robots and exoskeletons for supporting the clinicians in therapeutic interventions. For recovery, different modalities of physical human–robot interaction can be used in motor training [21]. The following section presents an overview of the interaction methods between the patient and the robotic system in robot-mediated training of upper extremities.

4. Robot-Aided Modalities for Upper Limb Training

Most of the robotic devices oriented toward clinical practice for UE recovery offer the possibility of choosing among different training modalities. Three main blocks for physical human–robot interaction (pHRI) in robot-aided interventions have been defined: assistive, active, and passive. These terms relate to conventional therapy modes used in clinical practice and refer to the subject's status during the interaction. In the assistive block, the voluntary activity of the patient is required throughout the movement in therapy at all times, while the robot can provide help to complete the task, either through weight or forces. In this case, both subject and robot work together in the movement performance. In the active block, the robot is used as a device to measure movement. The performance arises only from the patient's contribution. Finally, in the passive block, the robot executes all the work independently of the patient's response.

In the assistive block, two modalities can be defined: the basic "assistive" and the "gravity compensation" methods. In the basic assistive method, the robot can be helping constantly or not. This help will depend on the strategy of the therapy. The tremor suppression system is an example. The gravity compensation method only cancels the gravity force, so that the patient is focused on the purpose of the movement. In this case, the forces are oriented towards weight support when the movement is against gravity.

In the active block, three modalities can be defined: the basic "active", the "active-assisted", and the "resistive" method. The basic active method only measures the evolution of the movement. The system never provides power to the patient's limb. In the active-assisted method, assistance to complete the task is provided only when the patient is not capable of performing actively. It is like triggered assistance. The robot observes continuous performance. If the task is not completed, the robot intervenes, taking full control. In this stage, the subject experiences a passive movement of the limb. In the resistance method, the robot provides opposing force to the movement. The device opposes movements through an elastic or damped force that attempts to return to the initial position.

In the passive block, also three modalities can be defined: the basic "passive", the "bilateral", and the "guided" method. In the basic passive method, the system takes care of all movements independently of the patient's activity. The bilateral method (also called passive-mirrored) is applied to bimanual robots when the unimpaired limb is used as an input to control the passive movement of the affected side. Finally, in the guided method, the robot aims to lead the subject when he/she deviates from the predefined path. In this method, tunnels are usually used. These devices produce haptic feedback only if the error exceeds a threshold. This error indicator device is related to corrective strategies.

In summary, eight modalities for physical human–robot interaction in rehabilitation of upper limb motor function have been defined. These modalities are: assistive (AS), gravity compensation (GC), active (A), active-assisted (AA), resistive (R), passive (P), bilateral (B), and guided (G). This classification is sufficient to describe the type of pHRI of all the systems that are evaluated in this article. However, a more specific categorization of methods of robot-mediated therapy was presented in a recent literature review [21]. These abbreviations will help to simplify and understand better the table shown in the next section. Besides, it is important to consider that the different robotics systems can be focused on one or more modalities and even have a combination of these modalities. This feature depends on the purpose of the system, the kind of therapy, its morphology, etc.

5. Literature Review Summary

Robots have emerged as a useful tool to enhance the recovery process of motor function in neurological treatments. Robot-based systems participate actively in training and help the therapist to perform a better rehabilitation process. However, it is not clear to what extent robotic systems provide this help according to the rehabilitation principles. The most important is to improve the quality of help provided and to make the adoption of this technology in clinical settings easier. Therefore, the technical barriers and clinical limitations to be overcome must be identified.

In the following section, this review will highlight the particular aspects of the robot-aided approaches focused on recovering the upper extremity motor function with the assistance of a robotic system.

5.1. Materials and Methods

Search methods: The authors undertook a literature search in February 2019 for robot-assisted systems for dealing with motor function problems of upper limbs caused by neurological deficits, using as keywords: robot, neurological, rehabilitation, motor, function, upper, limb, extremity, arm, hand, neurorehabilitation, intervention, assisted therapy, treatment design, and various combinations. The databases were Brain, Science Direct, PubMed/Medline, and IEEE. Only papers written in English were considered, and the search was extended to the whole database.

Studies were included when: (1) systems for upper limb training (uni- and bilateral) were used; (2) systems were based on end-point or exoskeleton devices (commercially available or not); (3) the clinical intervention with real patients was conducted; and (4) the effects of robot-aided therapy on health outcomes were formally analyzed. Additionally, in the case of systems for which two versions of the same device were available, the newest version only was included in this study.

Limitations: This review is not without its limitations. Our study was limited to robotic rehabilitation systems for upper extremities in general, and motor function treatment in particular. Formal appraisal of the literature using quality-scoring tools was not carried out; instead, more practical aspects of the robot-based systems in neurological rehabilitation have been considered. This was intended to enhance the usability of the report for clinicians.

5.2. Robot-Aided Rehabilitation of Upper Limb Motor Function

Table 1 summarizes the collected information from several studies of 28 robot-aided systems for the motor training of upper extremities. The selected studies were organized according to the system used for the intervention. All of the systems selected have been used in clinical trials with various patients with motor deficits derived from different neurological disorders. The effect of robot-mediated treatment on UE motor function was explored through traditional outcome measures, such as the Action Research Arm Test (ARAT), Fugl–Meyer Assessment (FMA), etc. A comprehensive reading was done to identify how the robotic systems support the clinician during therapy in terms of data analysis capability, level of patient– and therapist–robot interaction, safety strategies, and options for treatment personalization.

According to the classification of the rehabilitation robotics domain presented in the previous Section 3, all of the systems included in Table 1 aimed to recover motor functionality. Systems are listed by end-point and exoskeletons. Furthermore, some information about the actuators and degrees of freedom (DoF) of the devices are included.

Table 1. Robot-aided systems for upper limb neurorehabilitation.

System	*Market Available* †	*Type of Device*	*Data Analysis Capability*	*Methods for Therapy Adaptability*	*Focus of Rehabilitation*	*Type of pHRI* ‡	*Safety Strategy*	*Channel For Presenting Tasks (Environment)*	*User Feedback*
ACT-3D (2007) [50–52]	✗	End-point; 2 DoF; electrical engines	Low	Variation (progressive) of abduction loading therapy	Shoulder; elbow	A	Software limits in force	2D-VR (flat screen) showing an arm avatar	Haptic; audio
ARM-GUIDE (1999) [53–55]	✗	End-point; 3 DoF; electrical engines	High (tone, spasticity, incoordination)	Modification of targets for reaching task	Shoulder; elbow	P; AA; R	Back stops; software limits in force	2D-VR (flat screen) showing the target point	Haptic (off-axis force generation)
BRACCIO DI FERRO (2006) [56,57]	✗	End-point; 2 DoF; electrical engines	High (performance evaluator	Adaptive controller to set the force loading automatically based on user's performance	Shoulder; elbow	AA; R; GC	Back stops; emergency push button	2D-VR (flat screen) displaying a path to follow	Visual; haptic (attractive force field)
GENTLE/A (2012) [58,59]	✗	End-point; 3 DoF; magnetic mechanism	High (lead-lag performance)	Self-adaptation of duration to execute movements according to the user's performance; definition of exercise path	Shoulder; elbow	P; AA; A; G	Software limits in force	3D-VR (flat screen) showing several ping-pong balls in a 3D configuration	Visual; haptic; audio
INMOTION-ARM™ (2010) [60,61]	✓	End-point; 6 DoF; electrical engines	High (software specific)	Adaptive therapy protocols; selection of exercise (games); progress measurement to determine medical necessity;	Shoulder; elbow	P; AA; R; GC	Backdrivable hardware; software limits in force	2D-VR (flat screen) with a variety of games/task	Visual; haptic; audio
IPAM MkII (2011) [62,63]	✗	End-point; 6 DoF; pneumatic engines	High (specific software)	Automatic generation of exercises (automated tasks)	Shoulder; elbow	P; R; A	Compliance control; emergency push button; software limits in force	2D-VR (flat screen) 4 scenarios: beach, gym, city, or countryside	Visual; audio; haptic
MEMOS (2006) [64–66]	✗	End-point; 2 DoF; electrical engines	Moderate	Variable gain of force loading	Shoulder; elbow	P; R; A	Emergency push button	2D-VR (flat screen) displaying the target points	Visual; audio; haptic
MIME (2006) [67,68]	✗	End-point; 6 DoF; electrical engines	Low	Variety of therapeutic modalities	Shoulder; elbow	P; AA; R; B	Back stops; emergency push button	Physical (real physical objects) promoting 3D reaching tasks	Visual (direct visualization of targets); haptic

Table 1. Cont.

System	*Market Available* †	*Type of Device*	*Data Analysis Capability*	*Methods for Therapy Adaptability*	*Focus of Rehabilitation*	*Type of pHRI* ‡	*Safety Strategy*	*Channel For Presenting Tasks (Environment)*	*User Feedback*
NEREBOT (2007) [69–72]	✗	End-point; 3 DoF; cable driven	Moderate	Exercise customization (via-points and setting of robot parameters)	Shoulder; elbow; forearm	P	Backdrivable hardware; back stops (magnetic attachment)	No user interface (hands-on movements)	Visual (direct visualization of movements)
REHAROB v2 (2017) [73]	✗	End-point; 7 DoF; electrical engines	Moderate	Exercise programming available via a graphical user interface (includes a program simulation interface)	Shoulder; elbow; forearm	P	Emergency push button; software limits in ROM	No user interface (hands-on movements)	Visual; haptic
AMADEO® (2012) [74–76]	✓	End-point; 5 DoF; electrical engines	High	Adjustable therapy and assessment modes	Hand (fingers)	P; AA; A	Software limits in force, speed and ROM; back stops (magnetic attachment)	2D-VR (flat screen) with serious gaming in one- and two-dimensional movements	Visual (video games); haptic
BI-MANU-TRACK (2003) [77–79]	✗	End-point; 2 DoF; electrical engines	Low	Selection of (two) operation modes	Forearm; wrist	A; B	Emergency push button; software limits in force (mechanical breaks)	Digital display showing the number of cycles	Visual (direct visualization of movements)
HWARD (2005) [80,81]	✗	End-point; 3 DoF; pneumatic engines	Moderate	Selection of standardized training protocols	Wrist; hand	P; AA; R	Backdrivable hardware; emergency push button; software limits of force; software shutdown	2D-VR (flat screen)	Visual; audio; haptic
ReoGo™-J (2008) [82]	✓	End-point; 3 DoF; electrical engines	High	Library with several exercises and games	Shoulder; elbow; wrist; hand	P; A; G	N/A	2D-VR (flat screen) presenting several real scenarios	Visual; audio; haptic
DIEGO® (2017) [83–85]	✓	End-point; 4 DoF; cable driven	High	Selection of therapy games. Intelligent gravity compensation (IGC); cooperative sequences of movement	Shoulder; elbow	P; B; AS; A; GC	Backdrivable hardware	3D-VR (fully immersive) with interactive games	Visual; audio; haptic (training with objects)
ADLER (2006) [86–88]	✗	End-point; 6 DoF; electrical engines	High (specific software)	Selection of training modes.; movement programming available via pre-defined trajectories	Forearm; Wrist	A; AA; R	Backdrivable hardware; emergency push button; software limits in force	2D-VR (Flat screen) displaying the target points	Visual; haptic

Table 1. Cont.

System	*Market Available* †	*Type of Device*	*Data Analysis Capability*	*Methods for Therapy Adaptability*	*Focus of Rehabilitation*	*Type of pHRI* ‡	*Safety Strategy*	*Channel For Presenting Tasks (Environment)*	*User Feedback*
L-EXOS (2007) [89–91]	✗	Exoskeleton; 5 DoF; cable driven	Low	Selection of different trajectories in the same virtual environment	Shoulder; elbow	A; AA; GC	Compliance control;back stops	3D-VR (flat screen)	Visual (physical objects)
MYOPRO (2006) [92–94]	✓	Exoskeleton; 2 DoF; electrical engines	Low	Distributed control mode for training different muscles	Elbow	AA	Software limits in forces	Physical (quotidian environments due to its portability)	Visual; haptic (physical objects); EMG
WREX (2004) [95,96]	✓	Exoskeleton; 4 DoF; elastic bands	Low	Variation (manual) of force loadings	Shoulder; elbow	AA; GC	Compliance control	Physical (quotidian environments due to its portability)	Visual; haptic (physical objects); EMG
ARMEO®SPRING (2006) [97–99]	✓	Exoskeleton; 5 DoF; electrical engines	High	Selection of therapy games; self-directed therapy option	Shoulder; elbow; forearm; wrist; hand	P; GC	Software limits in forces	3D-VR (flat screen)	Visual; audio; haptic
Mentor Pro™ (2004) [100–102]	✓	Exoskeleton; 1 DoF; pneumatic engines	Low	Selection of difficult/comfort levels; selection of (three) control modes	Wrist; hand; fingers	A	Compliance control; back stops	Physical (for increasing ROM in a real scenario)	Haptic, EMG
HEXORR (2010) [103–105]	✗	Exoskeleton; 2 DoF; electrical engines	Low	Selection of multiple exercises	Hand	P; AA; A; GC	Software limits in velocities; back stops	2D-VR (flat screen) with basic graphics	Haptic
RUTGERS-MASTER-II (2002) [106–108]	✗	Exoskeleton; 20DoF; pneumatic engines	Moderate	Selection of exercises and setting of parameters	Hand (fingers)	P; AA; R	Compliance control; software limits in forces; back stops	3D-VR (flat screen) training with games	Audio; visual; haptic
SUPINATOR-EXTENDER (2011) [109]	✗	Exoskeleton; 2 DoF; pneumatic engines	Low	N/A	Forearm; wrist	AA	Compliance control; emergency push button	N/A	Haptic
WOTAS (2005) [110]	✗	Exoskeleton; 3 DoF; Electrical engines	Low	Selection of assistance modes	Elbow; forearm; wrist	AS	Software limits in forces; back stops	Physical (keeping a target in a real scenario)	Haptic

Table 1. Cont.

System	*Market Available* †	*Type of Device*	*Data Analysis Capability*	*Methods for Therapy Adaptability*	*Focus of Rehabilitation*	*Type of pHRI* ‡	*Safety Strategy*	*Channel For Presenting Tasks (Environment)*	*User Feedback*
ARMEO®POWER (2008) [111–113]	✓	Exoskeleton; 6 DoF; electrical engines	High	Selection of several VR therapy tasks	Shoulder; elbow; forearm; wrist; hand	A; P; AA; R; GC	Backdrivable hardware; software limits in forces and loads	3D-VR (flat screen) training with games	Audio; visual; haptic
GENTLE/G (2007) [114,115]	✗	Exoskeleton; 9 DoF; cable driven	Moderate	Distributed control for training arm and/or hand; grasp therapy option	Shoulder; elbow; hand	P; AA; A; G	Compliance control; software limits in forces	3D-VR (flat screen) showing tasks in real environments	Audio; visual; haptic; scoreboard; rewards
RUPERT (2008) [116,117]	✗	Exoskeleton; 5 DoF; pneumatic engines	Low	Progressively challenging tasks	Shoulder; elbow, forearm; wrist	P; AA; A	Backdrivable hardware; compliance control	3D-VR (flat screen) showing the target point	Visual

† Commercially available (✓ = Yes; ✗ = No); ‡ abbreviations for pHRI: assistive (AS), gravity compensation (GC), active (A), active-assisted (AA), resistive (R), passive (P), bilateral (B), and guided (G).

Note that the newest version of some systems is listed in the table. That is the case for systems, such as GENTLE/A (GENTLE/S (2003) [118,119]), InMotion ARM™ (MIT-MANUS (1998) [120,121]), IPAM MkII (IPAM (2007) [122]), REHAROB V2 (REHAROB (2005) [123,124]), ARMEO®SPRING (T-WREX (2004) [125,126]), ARMEO®POWER (ARMin (2006) [127–129]), and ReoGo™-J (ReoGo™ (2008) [130]).

5.2.1. Data Analysis Capability

One of the most significant advantages of using robot-based devices is the data acquisition capability, which is objective, reliable, and automatically stored. In agreement with that, the reviewed systems offered the possibility of analyzing the user's performance based on the metrics gathered by the robotic devices themselves. This data analysis can be performed during the therapy session or when it is finished (post analysis). In other words, it can be in an online or offline mode, respectively. In this way, we identify the data analysis capability of the robotic systems themselves rather than the post analysis using stored data. In this regard, three levels of data analysis capability of robotic systems have been defined: low, moderate, and high. Systems with a low level of analysis capability are those that only stored the patient scores and sensors measurements. In this category, we have included end-point systems such as ACT-3D, MIME, and BI-MANU-TRACK and exoskeleton systems such as L-EXOS, MYOPRO, WREX, Mentor Pro™, HEXORR, SUPINATOR-EXTENDER, WOTAS, and RUPERT. A moderate level of analysis capability is denoted for those systems that provided the therapist with a rapid report about the user's performance. Thus, it we obtain an overview of the patient's evolution. This report is generated in online mode, and it is based on the outcome comparison between the current therapy session and the previous one. End-point systems such as MEMOS, NEREBOT, REHAROB, or HWARD and exoskeleton systems such as RUTGERS MASTER or GENTLE/G are included in this category. Finally, a high level of analysis capability is defined for those systems that can provide extended metrics. Besides, they can provide additional information by online analysis of the raw data of the sensors. A total of ten systems (eight end-point: ARM-GUIDE, BRACCIO DI FERRO, GENTLE/A, InMotion ARM™, AMADEO®, ReoGo™, DIEGO®, and ADLER; and two exoskeletons: ARMEO®SPRING and ARMEO®POWER) were classified as high level.

The storage and sharing of big data from patients, and in an efficient way, comprise two of the most important issues for the ongoing digital healthcare era. In this way, the properties of robotic rehabilitation systems could contribute to enhancing the management of a large amount of information. This fact could make the integration of robotic technology into a digital healthcare framework easier.

5.2.2. Adaptability of Treatments

The systems included in this review make available to the therapist different methods for adapting the treatment to the patient necessities. A wide variety of options for therapy customization are available for therapists. According to this adaptability, two categories of systems were identified. These systems are manually adapted and self-adaptive. The first category denotes for those systems that offer the clinician options to customize the therapy. For personalizing, the options are the selection among operation modes, exercises, or games (InMotion ARM™, MIME, AMADEO®, BI-MANU TRACK, HWARD, ReoGo™, ADLER, L-EXOS, HEXORR, RUTGERS MASTER, WOTAS, ARMEO®POWER, GENTLE/G, MYOPRO, Mentor Pro™), tuning of robot parameters to modify the workspace (ARM-GUIDE), or the training intensity (ACT-3D, MEMOS, NEREBOT, RUPERT, WREX), and even creating new exercises (REHAROB). The second category denotes for those systems that automatically set the therapy parameters or the tasks, based on the user's performance. This one requires more advanced control and data analysis capabilities. This approach is covered by systems such as BRACCIO DI FERRO to fit the loading force, GENTLE/A to modify the task duration, DIEGO® and ARMEO®SPRING to adapt the support level, and iPAM to vary the movement range.

A well-known feature of robotic systems, in general, is the capability to perform repetitive and controlled movements, keeping a high level of accuracy. Such a feature is also beneficial in the particular case of robot-aided systems for rehabilitation. Nevertheless, control strategies regarding the automatic modeling of the patient–robot interaction or the autonomy of therapy have not been fully explored. Note that in the manually-adapted systems, the customization depends on the clinician criteria, and thereby, an autonomous and unsupervised therapy would be not possible. In this regard, cutting-edge systems are considering new strategies for allowing cooperative treatments (DIEGO®) or even self-directed therapies (ARMEO®SPRING). Noteworthy as well is the RECUPERA system [131], a lightweight dual-arm exoskeleton with a high level of modularity (the system can be used as a wheel chair-mounted system or as a full-body system) and multi-therapy options. This system is promising for enabling mobile support, as well as for self-training during a hospital stay or at home. Overall, it can be seen that a trend towards more autonomous robot-based recovery procedures is arising.

5.2.3. Intervention and Safety Strategies

Therapists use a variety of techniques to help the upper extremity to gain better motor functionality. Some of these techniques involve physical contact between the therapist's hands and the patient's body, and they are referred to as hands-on treatments [132]. These types of treatments primarily use manual techniques for limb mobilization. The idea is to increase the range of motion (ROM), facilitating movement, and improving function. Therefore, this type of therapy is such that robot-aided systems aim to support or complement it. Besides, the close physical interplay between the patient and the robotic device require that safety must be granted.

On one side, the interaction in robot-aided interventions involves partial or full contact between the patient's extremity and the links of the robotic device. Usually, this kind of interaction is denoted as physical human–robot interaction (pHRI). As described in the previous Section 4, we considered eight types of pHRI strategies in robot-aided interventions. In Table 1, the abbreviations of the pHRI strategy that the selected robotic systems can implement are summarized. Note that the same robotic system could be able to perform various pHRI strategies.

It can be seen that seven systems (ACT-3D, NEREBOT, REHAROB, MYOPRO, Mentor Pro™, SUPINATOR-EXTENDER, and WOTAS) used a single pHRI strategy. On the opposite side, only two systems were able to perform up to five pHRI strategies. This is the case of both the DIEGO® (passive, bilateral, assisted, active, gravity compensation) and ARMEO®POWER systems (active, passive, active-assisted, resistive, and gravity compensation). The remaining systems implemented a number of pHRI strategies between two and four, both inclusive.

On the other side, the inherent physical contact in the mobilization of the patient's extremities implies that the robotic rehabilitation systems must implement safety strategies to ensure patient well-being. In this regard, unlike with human beings, the interaction with a robot could provide a safest, predictive, and reliable environment. This is possible because such an interaction can be controlled and progressively modified.

Hence, the patient's safety may be ensured via different strategies, primarily hardware or software related. In the mechanical part, there are three different strategies. The easiest strategy to implement is the emergency stop button (emergency push button). This type of system helps to block the robotic system. Usually, the therapist is in charge of the activation of this button in case the robot fails or the rehabilitation task is out of control. There are some cases like the robotic systems MIME or HWARD, which adjust the intensity of the control or the task when the button is pushed. This kind of strategy is typical of end-point robots (BRACCIO DI FERRO, IPAM MKII, MEMOS, MIME, REHAROB, BI-MANU-TRACK, HWARD, or ADLER). The second system is back-stops. These systems are based on the mechanical limitation of the range of motion of the robotic system to avoid damage to the patient. A curious example is the AMADEO® or NEREBOT system, which have a magnetic attachment system. This strategy allows the patient to be released quickly from the end-effector robot if critical forces are reached. A mechanical limitation is one of the most common strategies, and we have included end-point systems such as ARM GUIDE, MIME, BRACCIO DI FERRO, NEREBOT, or AMADEO® and exoskeleton systems such as L-EXOS, Mentor Pro™, HEXORR, RUTGERS MASTER, or WOTAS.

The third system is called mechanical compliance. This system is related to the form of mechanical design. In this case, the implementation of the robot is associated with soft and light characteristics, providing impedance movements. Patient safety is assured because the robot will absorb excessive movements of the patient and return to the task. Systems that use backdrivable actuators are included in this group. Because it is more difficult to implement, only the systems InMotion ARM™, NEREBOT, HWARD, DIEGO®, ADLER, ARMEO®POWER, and RUPERT had this strategy.

In the software part, there are also three different strategies. The easiest strategy to implement is the shutdown button. This type of system deactivates the robotic system. These systems are used in extreme cases because the therapist has not pressed the emergency button in time for the therapist's slip or malfunction of the robot. We only have included the HWARD system in this category. The second system is the software limits. These systems are based on limiting system properties to avoid damage to the patient. The most typical parameters that are handled are the forces, speeds, or loads. An unusual example is the BI-MANU-TRACK system, which controls the maximum force by activating mechanical brakes. This is the most used strategy via software for both types of robotics systems. We have included end-point systems such as ACT-3D, ARM GUIDE, GENTLE/A, InMotion ARM™, IPAM MKII, REHAROB, AMADEO®, HWARD, or ADLER and exoskeleton systems such as MYOPRO, ARMEO®SPRING, HEXORR, RUTGERS MASTER, WOTAS, ARMEO®POWER, or GENTLE/G. The third system is the control compliance. This system is related to the way of controlling the robotic system. In this case, the implementation of the controller is associated with the dynamics of the movements, allowing smoother movements for the patient (without sudden movements). This kind of controller is easier to implement in a system with pneumatic engines or a cable drive, and also, this kind of strategy is typical of exoskeleton robots (L-EXOS, WREX, Mentor Pro™, RUTGERS MASTER, SUPINATOR-EXTENDER, GENTLE/G, RUPERT).

5.2.4. Focus of Treatment

The human arm is a complex chain of bones and muscles. It can be divided into the upper arm, which extends from the shoulder to the elbow, the forearm, which extends from the elbow to the hand, and the hand. The arm model can be simplified into a model of two links (upper arm and forearm) or seven DoF. In this definition, the fingers' joints are not considered.

It can be seen that regardless of the type of robot, a common approach is focused on the rehabilitation of the shoulder and elbow joints. Forty percent of the reviewed systems (primarily end-point systems) covered the training of such joints. However, 27% of systems extended its primary use for shoulder and elbow training to cover other arm parts such as forearm, wrist, or hand. Besides, another portion is focused on specific movements of forearm and wrist (BI-MANU-TRACK, SUPINATOR-EXTENDER, WOTAS, ADLER), only elbow (MYOPRO), or hand and fingers. It must be noted that regarding hand training, it can be with (AMADEO®, RUTGERS MASTER) or without (HWARD, Mentor Pro™, HEXORR) fingers' dissociation.

Different advantages and drawbacks could arise depending on the morphology of the robotic device. For example, due to the condition of exoskeletons as a wearable device, it allows for aligning the joints of the patient with the exoskeletons'. In this case, the therapist has better control of the patient's movements. However, one of the main drawbacks of exoskeleton-type systems is the risk of joint misalignment in arm mobilization. Modern developments are promising to obtain exoskeletons with a natural and wide range of motions [133].

In the case of end-point robots, the mobilization is performed with the user's arm partially attached to the device. This feature implies a good trajectory control for the joints attached to the robotic device. However, there is a loss of control on the non-attached joints. Hence, compensatory movements can be performed, reducing the effectiveness of the treatment. The use of external systems for monitoring the user's movements could help to detect these abnormal actions.

5.2.5. Interaction Channel and Feedback for the User

Regarding the interaction channel, virtual reality (VR) is used for a vast portion (67%) of the systems included in this paper. Within systems that use VR, 55% of systems (ACT-3D, ARM-GUIDE, BRACCIO DI FERRO, InMotion ARM™, IPAM, MEMOS, AMADEO®, HWARD, ReoGo™, ADLER, HEXORR) implement a two-dimensional environment, and 45% of systems (GENTLE/A, DIEGO®, L-EXOS, ARMEO®SPRING, RUTGERS MASTERS, ARMEO®POWER, GENTLE/G, RUPERT) implement a three-dimensional environment. All these systems (except for DIEGO®) display their environments on a flat screen. It must be highlighted that the DIEGO® system uses a VR headset for running the game-like interface. This VR headset allows a fully-immersive experience for the user.

Opposite, the remaining systems (23%) have not implemented a graphical interface. This is the case of the NEREBOT and REHAROB systems, for which it is the therapist who must interact with the patient in the traditional way, but having support in limb mobilization. Besides, other systems were identified (MIME, MYOPRO, WREX, Mentor Pro™, WOTAS) with a lack of graphical interface to interact, but they promoted training with real (physical) objects. This approach is focused on optimizing the assimilation of motor gains. In the exercise, the patient is in a scenario closer to a daily living one. Note that portability seems essential for such an approach considering the predominance of exoskeleton-type devices.

It can be seen that VR technology serves as a means of encouraging the patient and promoting task development in a friendly environment. Besides, gaming technology is useful for modeling more attractive (environment other than a hospital room) or challenging scenarios (with digital games) to perform the tasks.

Regarding the feedback given to the patient, it can be appreciated that the most used ways for stimulating the patient's senses are by visual and audio feedback. This contactless stimulation could be empowered with the use of virtual reality. However, tactile feedback is also vital in motor function recovery. Therefore, another common source of stimuli is haptic feedback. The reviewed systems provide direct haptic stimuli via control techniques (software) or in an indirect manner via strategies that imply the manipulation of physical objects.

6. Framework for Robot-Aided Systems in Clinical Practice

The research review carried out in this article shows that in spite of the great progress achieved, robotic rehabilitation systems (RRS) will confront important challenges in order to be successfully integrated into routine practice. Cost reduction is one of the most known concerns about the use of robot-aided systems. Nevertheless, at present, health providers are realizing that robotic technology could provide benefits in terms of shorter in-patient treatments, enhanced data administration, improved decision-making, and easier management of electronic health record (EHR). Thus, a clear example is the increasing use of surgical robots in hospitals to perform minimally-invasive procedures. These systems based on the accuracy of robot movements, image processing algorithms, and cognitive systems are able to execute autonomously simple surgical tasks. Thereby, automation of procedures seems to be a key point towards reducing expenses and enhancing traditional rehabilitation treatments.

This review has shown that the development of more autonomous systems is a rising trend in the field of rehabilitation robotics for the upper extremity. The increasing of automation and better exploiting of data analysis capabilities are aligned with the current digital health concepts. Therefore, it is expected to be progressively accepted in healthcare processes within the ongoing e-health framework. However, it is necessary to highlight the main technical requirements that should be addressed in the near future, in order to facilitate the adoption of robot-aided systems in healthcare.

In that sense, Figure 2 presents a framework for robot-aided rehabilitation, taking into account aspects such as the human–robot interactions (patient-robot and therapist-robot), proper exercise elaboration (task and environment) in order to optimize motor gains, and data analysis capabilities to increase the treatment autonomy. The following section aims to describe what, in the opinion of authors, are the needs that robotic rehabilitation systems must address towards increasing their usability and autonomy in clinical practice. Strategies for improving the human–robot interaction, boosting and assimilation of motor gains, and obtaining more autonomous devices are presented.

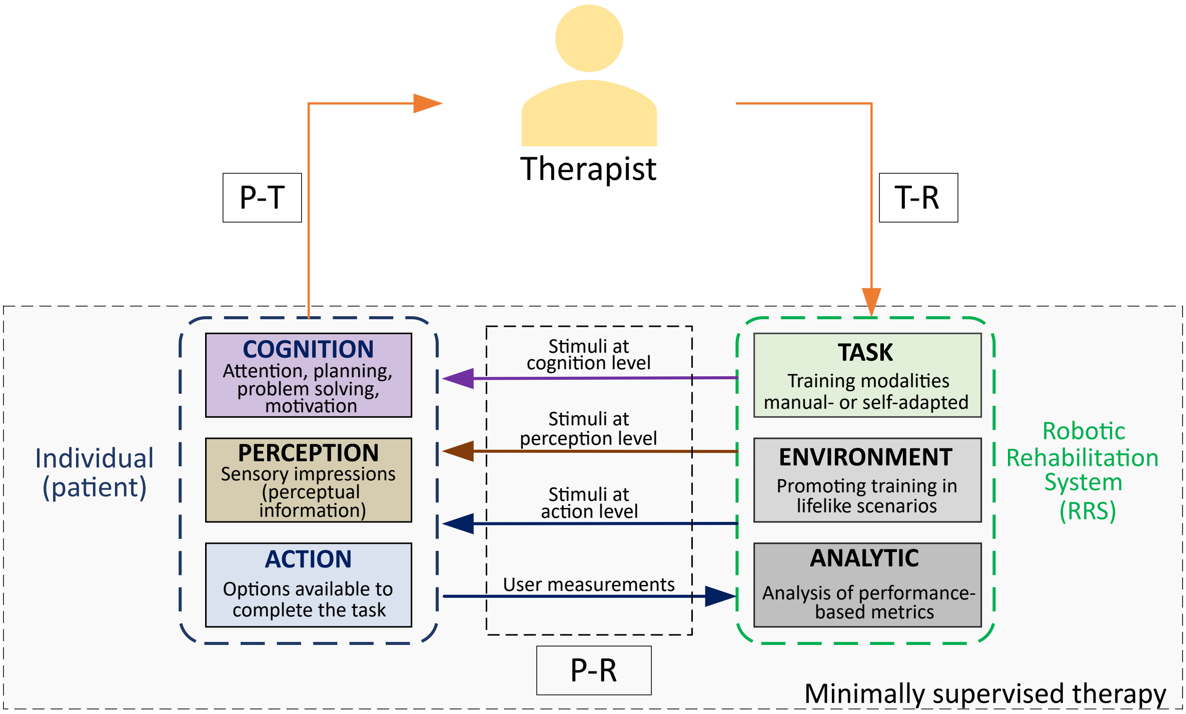

Figure 2. Framework for robot-aided therapy in clinical practice. T, therapist; R, robot; P, patient.

6.1. *Efficient Human–Robot Interactions*

In the above-presented robot-aided framework, the three participants of the process can be appreciated: therapist, patient, and robotic device. Thereby, human–robot interaction can be considered from two perspectives: between therapist and robot (T-R) and between patient and robot (P-R). Enabling proper channels for such interactions is essential for increasing the effectiveness of therapy.

From the point of view of the patient, proper stimulation of factors such as cognition, perception, and action is quite important to promote movement recovery. These factors comprise the patient's capacity to meet interacting tasks and environmental demands [26]. Therefore, it is strongly related to the patient's autonomy in ADL performance.

Firstly, at the cognitive level, current robot-aided treatments include methods (usually video games) for capturing the user's attention and promoting his/her motivation during therapy. The game-based methods offer also the possibility of training the planning and problem-solving capabilities of individuals by means of reaching goals in challenging scenarios. Indirectly, stimulus at this level is likely the most developed strategy of the RRS.

Secondly, at the perception level, the most commonly-used methods focus on stimulating the senses of vision, audio, and touch. Regarding visual and audio stimulus, digital games are also useful tools. However, the lack of tangible feedback is a clear limitation for gaming technology. Here, the use of haptic feedback covers such a limitation. In this way, the optimal solution in order to generate more effective stimulation at the perception level could combine the digital games with haptic feedback.

Finally, the action level is related to the context within the movement performed. Considering the degrees of freedom of the human arm, there are multiple ways a movement can be carried out. This is similar to finding the inverse kinematic solution for a robotic arm. This problem of choosing among equivalent solutions and then coordinating the many muscles and joints involved in a movement has been referred to as the "degrees of freedom problem" [26,134]. Most of the robot-based systems focus on repetition of tasks, but it is also relevant to provide the patient with several options of accomplishing a particular action. In the case of approaches based on end-point devices, the freedom to chose a "solution" to perform a particular action is greater than in the case of exoskeleton-based approaches. Consequently, the control of patients' movements is reduced in systems based on end-point devices, and compensatory movements can be used by the patient. Balancing of the benefits and drawbacks of systems based on end-point and exoskeleton devices is a big challenge. In the case of end-point systems, one solution could be the use of external systems to monitor the patient during the execution of tasks and detecting compensatory movements. Thus, compensatory movements are not prevented, but detected, leaving the interpretation of this being clinically meaningful to the therapist. Regarding exoskeleton-based systems, the high number of DoF that are necessary to get closer to the human arm motion is a big issue to solve. Hence, more redundant devices are required for allowing the user as many as possible joint configurations corresponding with reaching the same target position, which is fundamental in a rehabilitation context.

From the point of view of the interaction with the clinician, the common understanding in the robotics community is that the goal of robotic rehabilitation devices should be to assist therapists in performing the types of activities and exercises they believe give their patients the best chance of functional recovery. This fact implies that the robotic devices must implement proper methods for enabling the therapist to customize the intervention to the patient's needs. As presented in Table 1, robot-based systems offer options such as the selection of exercises (game-based or not), the selection of operation modes (to perform different physical interactions with the patient), and also hands-on collaborative treatment (using physical objects). Additionally, tuning of robot parameters (to regulate the number of repetitions, the intensity, the workspace, the assistive or resistive loading, among others) and selection of training options are commonly available for the therapist via graphical user interfaces.

However, beyond the customization of interventions via a GUI, future developments may stress implementing friendly strategies for allowing the therapist to create new robot-based exercises or tasks. This issue was addressed by the REHAROB system, where the therapist can program new exercises and simulate them before execution. Note that this approach is also used by industrial robots. However, it must be considered that simple-to-use devices are more likely to be adopted by clinicians than those that have long setup times [135]. One way of enabling flexible and intuitive strategies to create new exercises could be robot programming by demonstration [136]. This way, therapist-robot interaction is moving from purely preprogrammed robots to very flexible user-based interfaces for training robots to perform a task.

On account of the above, it can be seen that it is not only important to empower the patient–robot interaction, but also the therapist–robot interaction. On one side, integration of movement and proprioception training in the same experimental paradigm is beneficial for motor learning. On the other side, the development of intuitive methods for adapting the therapy elements and, more importantly, for creating new robot-based exercises is required to increase the usability of the RRS.

6.2. Safety in Physical Human–Robot Interaction

Safety is one of the biggest concerns about the extended use of the RRS in clinical practice. The fear of an accident or injuries produced by a robotic device is understandable, considering that robots can be dangerous to humans if used without care. This concern is not only applied to rehabilitation robots, but also the ones used in the industry (likely its origins). However, the growth of robots in the industry has led to the development of effective methods to increase the protection of workers, even allowing them to work sharing the same workspace for the case of collaborative robots. The same result is expected for the rehabilitation robots, save the differences.

One of the unique aspects of the RRS is that they must enforce the safety of the patient as an object within the workspace, while also being able to treat the patient. This dichotomy creates the need for specific safety strategies that can allow the robot to interact with the patient, while also enforcing all necessary safety precautions [137]. The common hazards in robot-aided treatments include collisions (when a robot link hits the user), pinch injury (when a robot traps a body part), and interior factors (such as sudden spasms or twitches). It must be noted that the probability of a specific risk depends on the type of robotic device. For example, it is more likely that a collision will happen when interacting with an end-point-type robot. Conversely, spasms or twitches may be more dangerous in the case of an exoskeleton, since the patients are basically encapsulated in the device.

As presented in the previous Section 5.2.3, safety strategies of the RRS may consider the hardware and software points of view. The security strategies mainly involve compliance control, backdrivable mechanisms, pneumatic actuators, stroke limits (hard stops or software-based), emergency stop button/handle, or force/speed limits. It is relevant to realize that safety is not an absolute concept. A system can only be built to reduce the risk of an accident to an acceptable level [137].

Notwithstanding all of the strategies aimed to reduce the risks of patient's damage in human–robot interactions, the broad variety of safety strategies requires measures to control reliability and safeguarding. Such a standardization could facilitate the use of the RRS in clinical settings. As an example, in the case of industrial robots, safety has been regulated by several standards to overcome technical barriers in international commerce and foster market growth. Unfortunately, there is no available industry-standard approach to design safety-critical robot systems for rehabilitation.

In this sense, considering the great amount of research in robots for healthcare-related applications, there are many standardization bodies currently dealing with the safety of human interaction with rehabilitation robots. The most influential ones are the International Organisation for Standardisation (ISO) and the American National Standards Institute (ANSI). As a result, dedicated standards for rehabilitation robotics devices are under development, such as the standard IEC/DIS 80601-2-78. It can be appreciated from the different standards that the most relevant functional requirements for safe robotic applications are related to limiting the forces, speed, and power of the robot [138]. This ongoing effort of standardization in rehabilitation robotics is promising in order to contribute to the acceptance of robot-aided procedures in clinical settings.

6.3. Scenarios for Boosting Motor Gain Assimilation

As presented in the previous Section 2, movement generation depends on the individual, the task, and the environment within which the motion is performed. It can be appreciated that the research community has been focused on developing intervention strategies [12]. This is primarily associated with task-related factors in movement generation. Complementary to this, VR technology has been used for modeling the patient–robot interaction in a friendly scenario (environment), in addition to motivational purposes.

The effects of robot-assisted therapy on the motor and functional recovery have been evaluated by different studies [9]. This demonstrates that robot-aided treatment improves motor function. Besides, the benefits of gaming technology for enhancing the mood of patients have also been proven. In spite of this, there is evidence that motor function improvements are often not transferred from robot-based therapy to the performance of ADL [8,139]. A possible reason for the limited transferring of motor gains to ADL could be that factors other than task-related ones that intervene in movement generation have not been addressed enough.

In this sense, it is clear that gaming technology could contribute more to transfer motor gains from therapy to ADL. On one side, tasks are performed in a variety of environments in daily life. Functionality depends on consideration of environment attributes when planning task-specific movements [26]. On the other side, the literature shows that motor preparation is affected by the meaning of the action, even when the action is only virtual [140]. This fact suggests that performing of movements into a virtual scenario similar to a real one could be beneficial.

On this basis, VR technology could be a useful tool for creating environments as similar as possible to daily life ones and modeling the attributes of such environments towards increasing motor gains of patients. Current robot-aided systems are not tapping the full potential of VR. It can be seen that a high percentage of the systems included in this review used a VR-based environment running on a flat screen, even when a three-dimensional scenario was built. Despite the more realistic environment, the perception of the tasks was reduced due to lack of depth information. This limitation is currently addressed by cutting-edge systems such as DIEGO®. This system used a three-dimensional therapeutic area with a fully-immersive VR-based environment. This aimed to enable the ideal transfer of what it has learned during therapy into everyday life.

Currently, serious games and VR technology are increasingly used for rehabilitation purposes and have been shown to be an effective alternative to traditional rehabilitation therapies [141,142]. However, methods purely based on gaming technology lack the feedback possibilities that robots can provide. Hence, the proper integration of both technologies could lead to more effective treatments. More immersive exercises that include biofeedback and gaming technology might be considered as deployable solutions for clinical settings. As previously argued, gaming technology is widely used as a channel for motivating the user and asking to perform specific tasks. However, flexibility for modeling life-like scenarios and the capability of measuring interaction have not been fully exploited.

6.4. Towards More Autonomous Interventions: Self-Adaptive Versus Sizeable Systems

Therapeutic strategies that help the patient to relearn how to perform functional tasks, taking into consideration underlying impairments, are essential to optimize the recovery of functional independence. However, the selection of the more suitable tasks, the order, or even the moment for the intervention is an aspect that depends on the patient needs. When treating neurological disorders, patient needs are usually multi-dimensional and may be very complex. This fact highlights the importance of making adaptive systems available for neurological rehabilitation.

A good example of the necessity to adapt the intervention systems could be as follows. A patient who has just started the rehabilitation of a limb should start with passive exercises. In these exercises, the robot would perform all the movement to recover the mobility of the patient. Afterwards, a guided intervention system could be applied. At this point, the therapist wants exercises in which several joints collaborate with more complex tasks at the same time. The idea is to remember how the muscles should move. Then, the robotic system could assist with simple tasks, in such a way that the patient begins to be more active. Then, through more active methods, the patient would recover part of or all of his/her motor function. Finally, a method of resistive intervention could be applied to increase and consolidate everything learned. Obviously, if the robotic system is more adaptable to the needs of the patient and the therapist's suggestions, rehabilitation will be better.

A recent review o physical rehabilitation approaches for the recovery of function and mobility after stroke [143] suggested that the selection of treatment components is a key implication in practice. This customization-based approach has been considered by most of the robot-based systems included in this review. In this case, it is the clinician who manually adapts the parameters of the robot towards training a specific motor problem. Therefore, this type of system is denoted as manually adapted.

Beyond, the present review has shown that various robot-aided systems include high data analysis capabilities for interpreting the performance-based information. This information about the user's performance is automatically gathered by the robotic device itself. In the case of manually-adapted systems, the treatment selection is based on the assessment of the individual and the clinician's interpretation. Contrarily, more autonomous robot-based systems can tune the parameters of treatment based on the measurements from sensors about the user progress. Therefore, this type of robotic device is denoted as self-adaptive.

Personalizing robot therapy by means of self-adaptive interaction strategies seems to be practical and might be a crucial element for achieving optimal assistance [56]. Artificial intelligence (AI) could be a key component in order to obtain a better interpretation of performance-based data. AI also may play an important role in building appropriate healthy reference models. The benefits of self-adaptive robot-aided treatments is a research line line that is yet to be fully discovered.

In summary, this study highlights that key factors for adoption of robot-aided systems in clinical practice are the capability of customization to the patient needs and the flexibility to administer different treatment techniques. Additionally, it was identified that robot-aided systems could include high data analysis capability in order to self-adapt the treatment to the patient needs. Self-adaptation of robot assistance could be a relevant factor for overcoming the barrier between improvements in the control parameters and functional achievements in ADL.

7. Conclusions

Robotic rehabilitation systems comprises one of the fields that has been widely developed in recent decades. However, the adoption of these systems in clinical practice is less than expected. Aside from the well-known affordability issues, this review focused on identifying the technical requirements of robot-aided systems for facilitating their adoption in clinical practice.

One concern about robot-based interventions is that improvements are often not transferred to the performance of activities of daily living. A possible reason for this limited transference of motor gains to ADL is that the robot-aided systems have been mainly focused on developing mobilization techniques (task-related), but factors other than task-related and that also intervene in movement generation have not been sufficiently addressed. These other factors are those related to the patient (cognition, perception, action) and the context of the task (environment).

In regard to patient stimulation, gaming technology has been widely used in robot-aided systems. The primary purpose is to encourage the patient and modeling the interaction with the robotic device in a friendly way. In order to extend the cognitive and perceptual stimulation, challenging tasks using more sensorial channels are required. Combined exercises that include biofeedback and gaming technology might be considered for deployable solutions for clinical settings.

Regarding the context of tasks, better use of VR technology is required in order to promote a long-term recovery of motor function in terms of ADL performance. The principle is that aspects of motor preparation are affected by the meaning of the action, even when the action is only virtual. Based on that assumption, building fully-immersive VR-based environments as similar as possible to lifelike scenarios could promote the transference of motor achievements in robot-aided interventions to ADL.

Additionally, high adaptability of robotic systems to the patient needs would be beneficial in terms of the effectiveness of treatments. Adaptability can come from the mechanical level (hardware) or the software level (control).

At the hardware level, systems with a high level of compliance are necessary in order to provide the patient with several options of accomplishing a specific task. This is related to the "degrees-of-freedom" problem in neurological rehabilitation. However, it is also important to make available strategies (embedded or external) for detecting the compensatory movements and security. Since robot-aided therapy implies a high degree of physical human–robot interaction, it is very important to implement security systems that ensure patient well-being. For that purpose, the use of collaborative robots that are considered intrinsically safe systems could be a feasible alternative.

At the software level, an investment in better use of performance-based data for enhancing the therapy adaptability is necessary. Thus, more efficient treatments could be obtained via self-adaptation of robot parameters according to the rehabilitation needs. In this regard, integration of artificial intelligent agents into the software of robotic devices could lead to more intelligent interventions.

Finally, another significant issue to address is the development of reliable and effective strategies for guaranteeing the patient's safety during robot-aided therapy. Thereby, international safety standards form part of the primary basis to facilitate the adoption of rehabilitation robots in clinical practice, paving the way toward the market for reliable and secure robotic products.

The framework presented in this paper suggest an ecosystem in which therapist can organize the rehabilitation session with a more effective support of robotic devices. This approach could be obtained via increasing the adaptability of robots, enhancing the human–robot interactions, and empowering the decision-making capability. Proper addressing of such aspects could lead to the sustainable transference of motor gains and better acceptance of robot-aided systems in clinical practice.

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CHAPTER 6

Automated Box and Blocks Test

6.1 Overview

This chapter presents the development and validation of the automated version of the Box and blocks test (BBT). The implemented system uses image segmentation in CIELab colour space and the Nearest Neighbour (NN) rule to detect and count the number of transferred cubes automatically. This automatic system was piloted in order to determine the reliability in measuring the level of manual dexterity in participants with Parkinson's disease (PD).

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Automatic Outcome in Manual Dexterity Assessment Using Colour Segmentation and Nearest Neighbour Classifier

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Abstract: Objective assessment of motor function is an important component to evaluating the effectiveness of a rehabilitation process. Such assessments are carried out by clinicians using traditional tests and scales. The Box and Blocks Test (BBT) is one such scale, focusing on manual dexterity evaluation. The score is the maximum number of cubes that a person is able to displace during a time window. In a previous paper, an automated version of the Box and Blocks Test using a Microsoft Kinect sensor was presented, and referred to as the Automated Box and Blocks Test (ABBT). In this paper, the feasibility of ABBT as an automated tool for manual dexterity assessment is discussed. An algorithm, based on image segmentation in CIELab colour space and the Nearest Neighbour (NN) rule, was developed to improve the reliability of automatic cube counting. A pilot study was conducted to assess the hand motor function in people with Parkinson's disease (PD). Three functional assessments were carried out. The success rate in automatic cube counting was studied by comparing the manual (BBT) and the automatic (ABBT) methods. The additional information provided by the ABBT was analysed to discuss its clinical significance. The results show a high correlation between manual (BBT) and automatic (ABBT) scoring. The lowest average success rate in cube counting for ABBT was 92%. Additionally, the ABBT acquires extra information from the cubes' displacement, such as the average velocity and the time instants in which the cube was detected. The analysis of this information can be related to indicators of health status (coordination and dexterity). The results showed that the ABBT is a useful tool for automating the assessment of unilateral gross manual dexterity, and provides additional information about the user's performance.

Keywords: colour segmentation; CIELab; automatic counting; NN-based classifier; manual dexterity; assessment; neurological rehabilitation

1. Introduction

Neurological disorders are diseases of the central and peripheral nervous system [1]. It involves damage of the brain, spinal cord, cranial nerves, peripheral nerves, nerve roots, autonomic nervous system, neuromuscular junction, and muscles. These disorders include epilepsy, Alzheimer disease, cerebrovascular diseases including stroke, multiple sclerosis, Parkinson's disease, among others. The measurement of motor function is critical to the assessment and management of neurological diseases. This assessment has the potential to provide a glimpse of the patient's clinical state beyond the consultation [2]. Clinical measures that quantify upper limb (UL) function are needed for the accurate evaluation of patients and to plan intervention strategies [3].

The functional assessment is commonly performed by health professionals themselves, using standardized scales for the sake of an objective evaluation. One of the most commonly used scales in clinical trials is the Fugl Meyer Assessment (FMA) test [4]. FMA is designed to assess motor functioning, balance, sensation and joint functioning of both upper and lower extremities [5]. Focusing on the upper limbs assessment, the Wolf Motor Function Test (WMFT) or the Action Research Arm Test (ARAT) can be found as the most common performance-based outcomes measures in stroke rehabilitation [4]. The Box and Blocks Test (BBT) [6] or the Nine Hole Peg Test (NHPT) are categorized as appropriate outcome measures in manual dexterity assessment.

Despite the previously mentioned scales intending to be objective, they could be influenced by the subjectivity of the observer [7]. In this regard, advances in technology could allow for the objective assessment of motor performance and may be used to explore motor impairments in neurological rehabilitation [8,9]. The development of objective and quantitative rehabilitation treatment assessment methods to address that issue is a non-trivial problem [10].

On this basis, several works can be found focusing on automation of the previously presented scales for upper limb functional assessment. For example, a framework for automating upper-limb motor assessments that uses low-cost sensors to collect movement data is presented in [11]. This framework is used to automate the 73% of the upper limb portion of the FMA. A recent study for FMA automation is presented in [12] that uses Kinect v2 (Microsoft Corp., Redmond, WA, USA) and force sensing resistor sensors owing to their convenient installation as compared with body-worn sensors. An automated system based on the WMFT is proposed in [13], using wearable sensors to measure the time spent in completion on 7 of the 17 test items. The sub-set 4 of ARAT is considered for automation in [14], using a sensorized cube of 7.5-cm size. Additionally, a study to automate the Timed Up and Go (TUG) test in order to discriminate low vs. high risk of fall individuals as objectively as possible using several quantitative parameters is presented in [15].

Regarding manual dexterity assessment, a digital version of the Box and Blocks Test (DBBT) is presented in [16]. Such work proposes an algorithm for automatic cube counting by using a Kinect V1 sensor. The success rate in cube counting is of 100% until 20 cubes. In addition, the hand movements are tracked. In one of the most recent works [17], using the Kinect V2 and computer vision is presented. In this case, the success rate in cube counting is 100% until 30 cubes. In addition, the automatic test administration was addressed by means of a graphical interface. These kinect-based systems offer a non-invasive method to hand motion tracking and data acquisition, in contrast with the use of systems based on wearable sensors such as a glove [18] or inertial measurement units [10,19]. It can be noted that a common goal is to obtain automatic evaluation platforms that are objective, that have repeatability, and can provide additional information than the one obtained with the traditional scales.

In this paper, a feasibility study of a Kinect-based system to automatically obtain the score of the BBT for gross manual dexterity assessment is presented. The remainder of this paper is organized as follows: Section 2 presents the material used and the design considerations for system implementation. Section 3 explains the process to automatically obtain the number of cubes, based on image segmentation in the CIELab colour space and the pixels classification using the Nearest Neighbour (NN) rule. Section 4 describes the pilot trial conducted to evaluate the proposed system with real users. Three sessions for assessing the motor function of the hand, with nine participants with Parkinson's disease, were carried out. The methods used for usability and statistical analysis are also shown. Section 5 summarizes the results of the pilot trial. The objective data obtained with the proposed system are presented, including the effectiveness in cube counting. The reliability of the ABBT is studied, by analysing the correlation between the manual counting (BBT) versus the automatic one (ABBT). Section 6 discusses the performance and feasibility of the proposed system as a clinical tool. Finally, concluding remarks are presented in Section 7.

2. Material and Methods

2.1. The Box and Blocks Test (BBT)

The BBT is a clinically validated system for the individual measure of gross manual dexterity and coordination. The BBT can be used with a wide range of patients, including those with hand function deficits from neurological diseases. The test consists of a wooden box with two 290 mm side length square compartments, and 150 wooden cube-shaped blocks of 25 mm. A 100-mm high partition located between the two compartments must be overcome with the user's hand to count the block as valid. In Figure 1a, the structure of the box used for the test is shown.

(**a**) (**b**)

Figure 1. Box and Blocks Test. (**a**) Components: wooden box, coloured cubes and stopwatch; (**b**) user during test development.

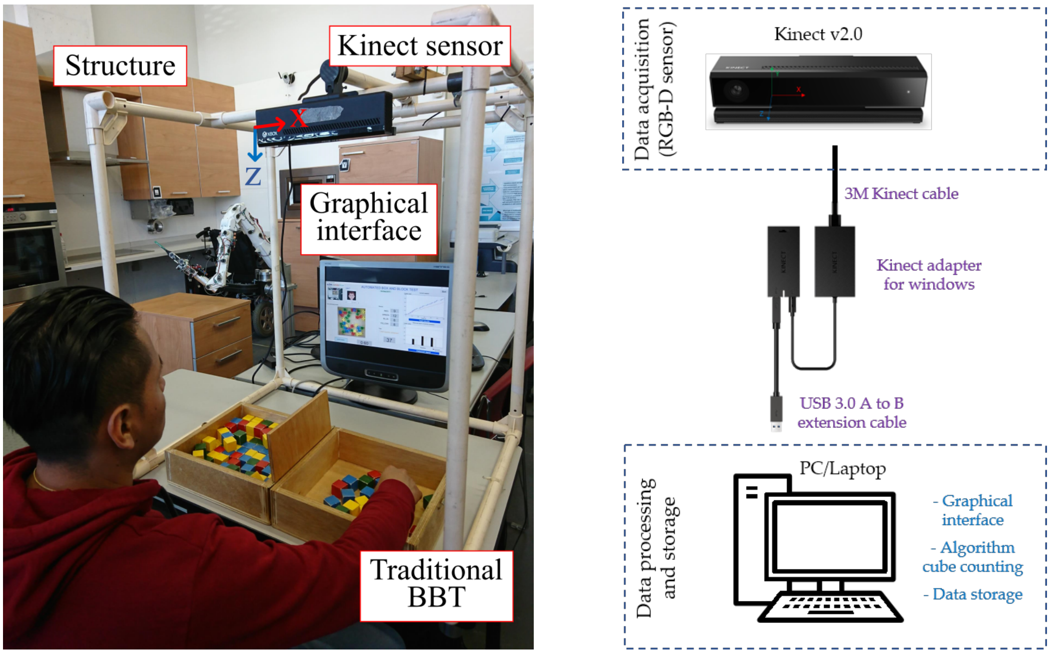
The goal of the test is to transport the maximum number of cubes from one compartment to the other in one minute, as it is shown in Figure 1b. For the score, the therapist must manually count the number of cubes transported. The development of the test includes three stages: a 15-s trial prior to testing, the procedure done with the dominant hand in one minute, and the procedure executed with the non-dominant hand in one minute. When testing begins, the subject should grasp one block at a time, transport the block over the partition, and release it into the opposite compartment to score. The blocks that are thrown from one compartment to the other must be penalized. If the subject transports two or more blocks at the same time, this has to be noted and the number subtracted from the total.

For the test administration, the wooden box with 150 blocks should be placed lengthwise along the edge of a table of standard height and the subject should be seated on a standard height chair facing the box, with the patient's hands on the sides of the box. The examiner faces the subject and reads the instructions before the test begins. The rules and the instructions for the examiner and the subject are available in [6,20].

2.2. The Automated Box and Blocks Test (ABBT)

In a previous work [17], an automated system for evaluating gross manual dexterity, based on the BBT, was presented. It was referred to as the Automated Box and Blocks Test (ABBT). The automation of the test scoring was implemented by means of a counting algorithm based on colour segmentation in the RGB colour space. Additionally, the automatic administration of the test was addressed by using a graphical interface to guide the user during the performance of the test. The instructions for the test were given to the user by voice messages, in the same way as they would be provided by a clinician.

The components of the ABBT are shown in Figure 2a. The system is made up by: (a) a portable and lightweight cube-shaped structure; (b) a Kinect for Windows V2 sensor; (c) a graphical interface (display) running on a laptop where the system also executes the counting algorithm; and (d) a traditional BBT box. The hardware architecture is depicted in Figure 2b.



(a) (b)

Figure 2. The Automated Box and Blocks Test. (**a**) Components: Kinect sensor (at the top of the portable structure), the BBT box, and the graphical Interface to allow the automatic test administration; (**b**) hardware connection.

To perform the test, the support structure is placed on a standard desk. At the top of the structure, the Kinect sensor is fixed with the *z*-axis of the sensor pointing to the desk. This is used for detecting the number of cubes displaced, as well as the hand movements while the subject performs the test. The BBT box is located on the desk and in the centre of the structure. In addition, a display is placed on the desk to guide the user and to show the results. The user must be seated in front of the BBT box, in the same manner as when conducting the test in the traditional way.

Problem Statement

The BBT is a clinically validated tool for assessing the unilateral gross manual dexterity and coordination, commonly used in neurological rehabilitation. However, the test administration is time-consuming and labour intensive. In addition, the outcome is obtained by manual counting of the transferred cubes, which could lead to an error in the measurement and it does not provide additional information about the user performance.

The ABBT, an automated version of the BBT, was previously used in a pilot study to measure the gross manual dexterity in people after a stroke [17]. This study showed that the effectiveness of the cube counting by using colour segmentation in RGB colour space was decreased by the influence of the ambient light conditions and the higher displacement speed of the cubes when they are transferred with the dominant hand.

For that reason, in the present paper, the need to improve the effectiveness of the algorithm for cube counting is addressed. Taking into account the high contrast between the colours of the cubes (red, green, blue and yellow) and also with the background of the box (beech colour), the CIE L*a*b* colour space [21], also referred to as CIELab, is employed so as to improve the success rate in automatic cube counting.

Furthermore, one of the design principles for the proposed system was to not alter the physical structure of the BBT box and the cubes. That is, using a white background or changing illumination conditions are not allowed. Thus, the effects of the reflective surfaces must be reduced, taking into account that the finish of the BBT box and the cubes is lacquered and glossy, respectively. The properties of the CIELab colour space are also appropriated to solve that issue, since the lightness channel is independent of the colour channels. This property also helps by nature to reduce the sensitivity to changes in ambient light.

3. Automatic Process for Cube Counting

The automatic procedure for cube counting is developed in three steps. The first step is a procedure to identify the empty compartment of the BBT box. It should be noted that it must always be an empty compartment at the beginning of the test. The cubes will be transferred to this compartment. This compartment could be the right or the left one, according to the hand to be evaluated (dominant or non-dominant hand). In order to start the test, the algorithm looks for the edges of the box, using the depth data of the Kinect sensor. Consequently, both the left and the right compartments of the box are identified. Based on this, a region of interest (ROI) in the colour image is extracted to be processed.

The second step is to run the algorithm for cube counting. This algorithm is based on colour segmentation in the CIELab colour space and the Nearest Neighbour (NN) rule. Until the period of time for the test is over, the counting process is executed.

For the third step, the validity in cubes displacement is checked since it is only allowed to displace one cube at a time. When the period of time of the test is over, the results are displayed through the graphical interface.

This three-step sequence is used for each test stage. This method, combined with voice and text messages to give the instructions to the patient, allows the ABBT to be administered automatically. The following sections detail the steps for the automatic cube counting.

3.1. Compartments Identification

The procedure to detect the edge of the box and to identify the empty compartment is described in the following. The Kinect sensor is placed on the top of a structure at a vertical distance of 80-cm from the desk surface. This position remains unchanged. First, the user is asked to remove their hands from the box compartments, through a message in the graphical interface. A colour image of the scene is shown in Figure 3a. Then, depth data of the scene is captured (see Figure 3b) and a height threshold is applied. This height threshold was empirically obtained by several trials in laboratory. The distance from the Kinect sensor to the compartment edges remains unchanged, since the sensor is fixed to the structure.

It can be noted that the size of the colour image and the depth image are not the same. Thus, prior to the thresholding process, the depth and the colour images must be aligned (see Figure 3c). Since the Kinect depth camera has limited range, some pixels in the depth image do not have corresponding 3D coordinates in the colour image. However, this fact is not relevant due to the whole user workspace being covered by the camera placement.

The depth data under the threshold level are discarded, including the values corresponding to the desk and the bottom of the BBT box. Thus, the remaining image offers a clear view of both the empty and the full compartments (see Figure 3d). Morphological operations to reduce noise and to label the detected areas are applied to the thresholdized image.

Extracting features from the processed image makes it possible to detect the location of the empty compartment. A matrix with the size ($M \times N$ pixels) and the position of centroid and vertices (3D coordinates) of the rectangles containing the detected areas is obtained. Based on such features, it is possible to identify the empty compartment, and if it is the right (see Figure 3e) or the left (see Figure 3f) compartment.

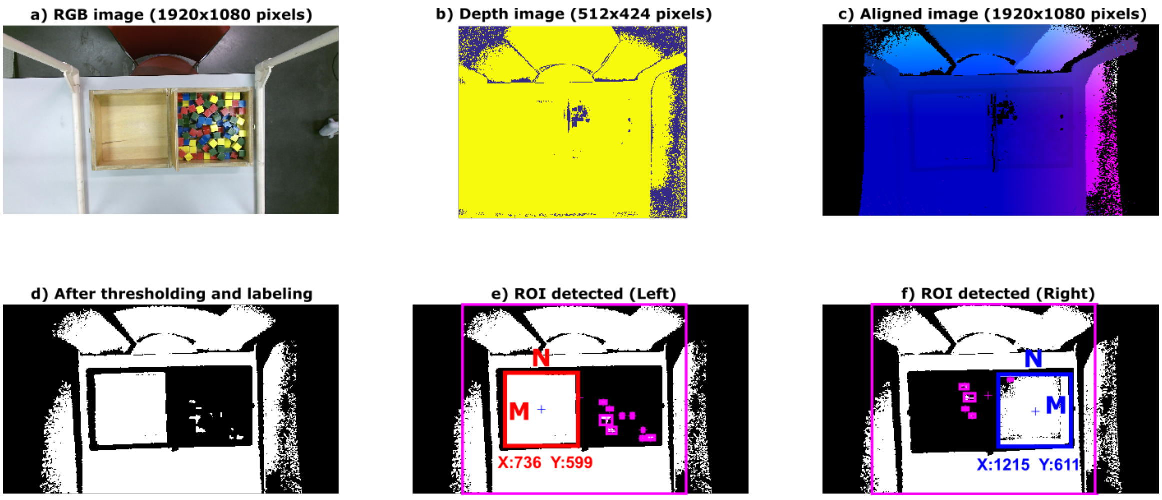


Figure 3. Procedure for automatic compartment identification. (**a**) Colour image (1920 × 1080 pixels); (**b**) depth image (512 × 424 pixels); (**c**) colour and depth images aligned (1920 × 1080 pixels); (**d**) image after the threshold of height is applied; (**e**) left compartment detected with the position of centroid (red line); and (**f**) right compartment detected with the position of centroid (blue line).

The compartments' identification is quite important because it is the basis to find the ROI in the colour image to be processed by the counting algorithm. Note that, due to the depth image's alignment to the colour image, their pixels have corresponding 3D coordinates. That is, the coordinates of the vertices and centroid of the empty compartment in the colour and depth image are the same.

Furthermore, before the counting process starts, the system checks if the compartment is empty by means of the depth sensor. If it is not empty, the graphical interface prompts for the remaining cubes to be removed and does not start the counting process.

3.2. Colour Segmentation and Nearest Neighbour Classifier

The colour of an object can be described by several colour coordinate systems, and some of the most popular systems is the CIELab colour space [22]. Unlike other colour models (RGB, HSV, CMYK), the CIELab colour space correctly approximates human vision [21,23]. Similar to the RGB model, the CIELab colour space has three channels: L*, a*, and b*.

The CIELab colour axes are designed based on the fact that a colour can not be both red and green, or both blue and yellow, because these colours oppose each other. On each axis, the values run from positive to negative. On the a–a′ axis, positive values indicate the amounts of red while negative values indicate the amount of green. On the b–b′ axis, yellow is positive and blue is negative. For both axes, zero is neutral grey. The L* component represents the luminosity of the colour.

Thus, the use of the CIELab colour space is suitable for the identification of the cubes, since their colours are the same ones on which this colour space is based. Therefore, the identification of a cube's colour only needs two colour axes (a*, b*) and the separate lightness axis (L*) is not mandatory (unlike in RGB, CMYK or HSV, where lightness depends on the relative amounts of three colour channels). This is advantageous, in that it significantly reduces the effect of changes in the environmental lighting conditions and reflective surfaces.

3.2.1. Colour Markers

In automated object counting, the count is generated by capturing an image and then applying step by step image processing operations. The object counting can be done either by using a single feature or multiple features and then, by using cut-off values for those features, the final count is calculated [24]. To that end, the main features used in the present application to count the cubes are their colour, size, and shape.

First of all, it is necessary to quantify the features of the cubes in the scene. For that purpose, several experiments were performed to define some colour markers to identify the colour of the cubes inside the compartment. The average size of a single cube was also measured during experiments.

In Figure 4, the process to define the colour markers is described. The left side column shows the reference colour images taken for the calibration process. It can be noted that the colour tone is not homogeneous and it depends on the compartment zone where the cube is located, as well as environmental lighting.

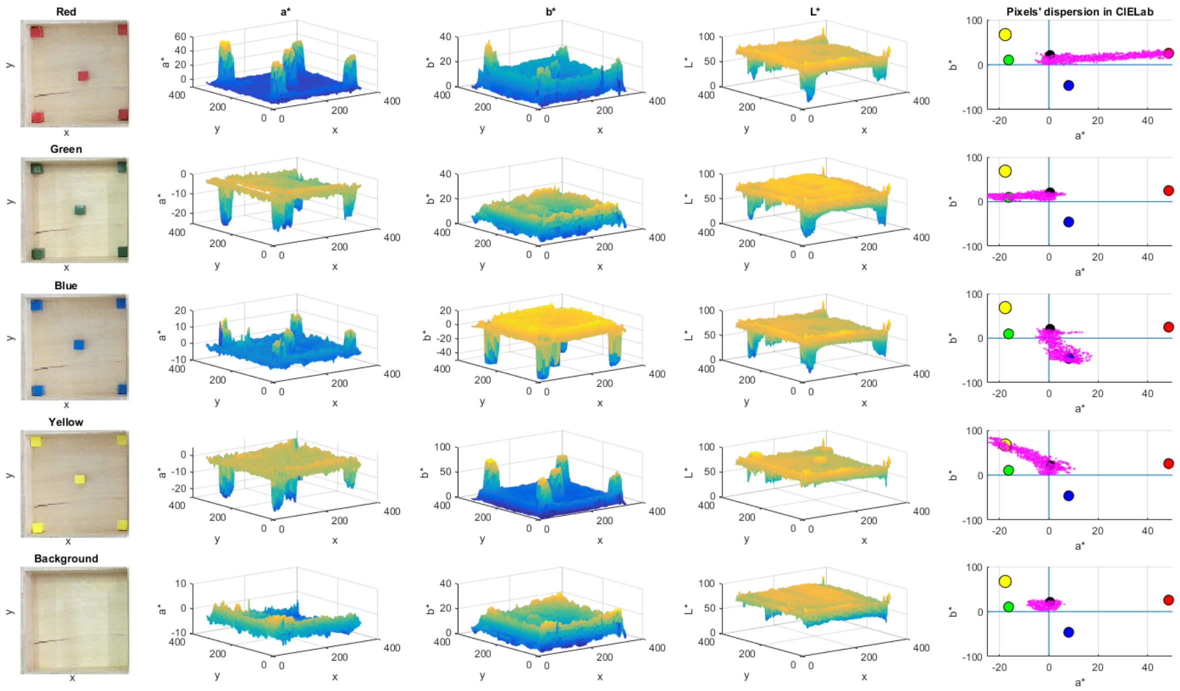


Figure 4. Description of the procedure to define the colour markers. The first column shows the image used for colour calibration (cubes are placed on the corners and the centre of the compartment). Columns 2 to 4 depict the a*, b*, and L* values of the scene, according to the pixel's location (x,y). The last column describes the colour markers location and the dispersion of the CIELab colour space for each scene.

For that reason, five cubes were placed in different compartment zones to define the values of colour markers. The chosen zones were the corners and the centre of the empty compartment. The three central columns in Figure 4 shows that the values of a* and b* channels of each colour are clearly different with respect to the background and other colours. In addition, the intensity levels of brightness in the L* channel is displayed.

A Canny-based edge detection is used to define the cubes' boundaries, and to extract the colour regions. The region inside the cube frontiers is converted to CIELab colour space and its values are averaged. This procedure is repeated for each cube colour. In the case of the background, the sample positions were manually chosen from the image.

A total of 5 colour markers were defined, since the colour background of the box was included. Each colour marker has an average L*, a* and b* values. The right side column in Figure 4 depicts the location of each colour marker in the CIELab colour space, including the scatter plot of the colour pixels (denoted in magenta) for each sample image. It can be noted that the pixels are dispersed between the colour markers of the background and the corresponding colour. Thus, each pixel in the scene tends to be close to their corresponding colour marker.

3.2.2. Nearest Neighbour Classifier

In Figure 5, the procedure for automatic cube counting is presented. The size of the colour image captured by the Kinect sensor is 1080 × 1920 pixels in the RGB colour space.

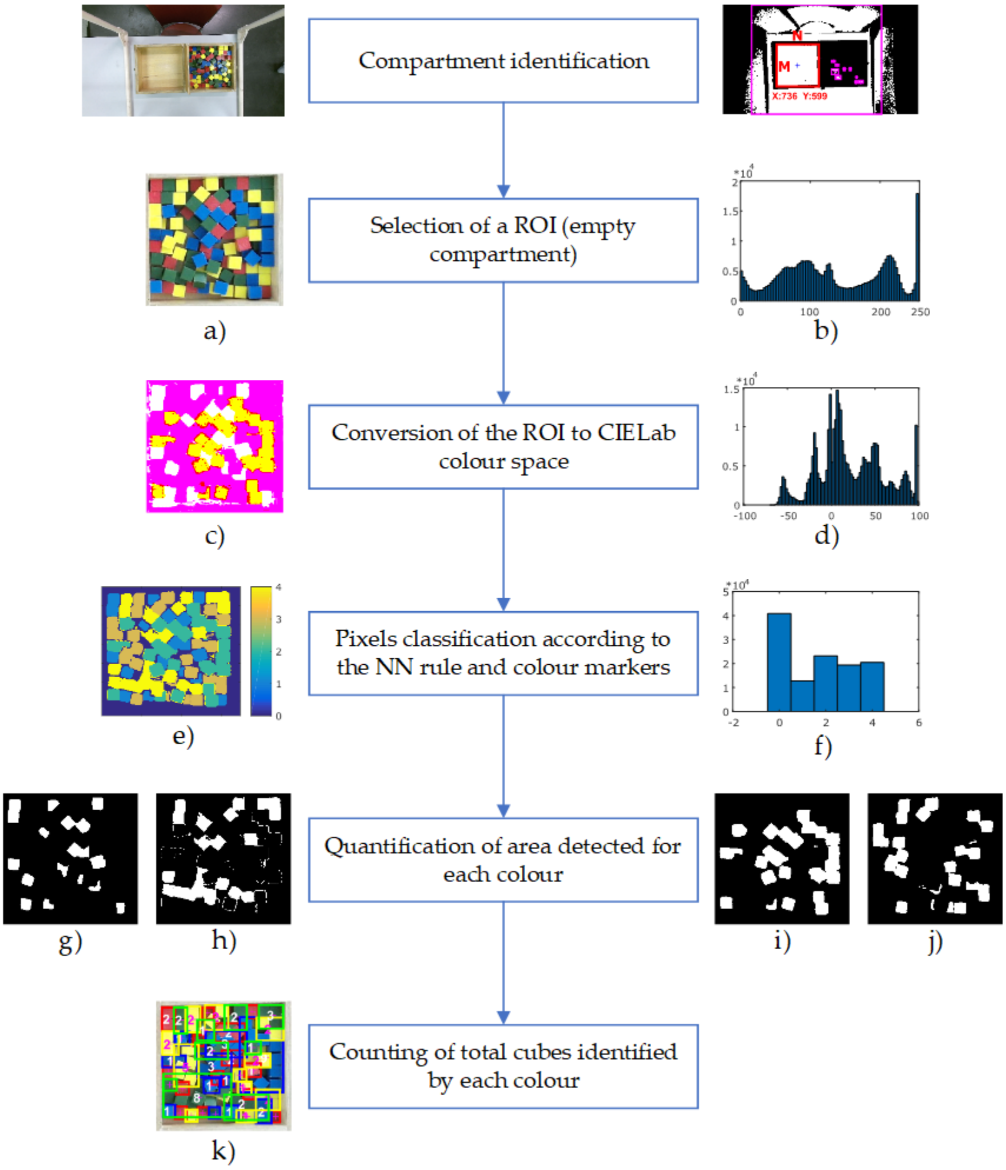


Figure 5. Procedure for automatic cube counting: (**a**) ROI extracted; (**b**) histogram of ROI in RGB colour space; (**c**) ROI in CIELab colour space; (**d**) histogram of ROI in CIELab colour space; (**e**) ROI labelled based on colour markers; (**f**) histogram of ROI labelled; (**g**) detected region for red colour; (**h**) detected region for blue colour; (**i**) detected region for yellow colour; (**j**) detected region for green colour; (**k**) total cube scoring for the ROI (Red: 17; Green: 22; Blue: 24; Yellow: 21).

Based on the compartment identification procedure, an ROI is extracted from the whole colour image (Figure 5a). This region corresponds to the empty side of the box (where the cubes will be transferred), and it depends on whether the test is performed for the non-dominant or dominant hand of the subject. The colour ROI is considered as an $M \times N$ matrix (see Figure 3e), where $M \times N$ is the image size in pixels. Since the compartments' identification procedure is automated, the ROI size could be slightly different. However, the common size of this ROI is 330 × 330 pixels. The ROI is converted to the CIELab colour space so as to be processed (see Figure 5c). Then, all the pixels are classified by using the pre-calibrated values of the a* and b* channels.

The Nearest Neighbour (NN) rule is used to classify the colour pixels according to the colour markers. This algorithm assigns to a test sample the class label of its closest neighbour, based on the Euclidean distance between the sample and the class reference [25]. This technique is simple, efficient, and does not require a learning or training phase [26]. Thus, considering the colour pixels as the test sample and the colour markers as the class reference, the appropriate class label (red, green, blue, yellow or background) is assigned to each pixel in the colour image.

Euclidean distance d between the pixels and each colour marker is calculated by Equation (1):

$$d = \sqrt{(a^*{}_{pixel} - a^*{}_{marker})^2 + (b^*{}_{pixel} - b^*{}_{marker})^2}. \tag{1}$$

Each colour pixel is labelled according to the minimum distance to the colour markers. For example, if the distance between a pixel and the red colour marker is the smallest, then the pixel would be labelled as a red pixel. Figure 5e depicts the colour map after the classification process, where background, red, blue, yellow and green colours are labelled as 0, 1, 2, 3 and 4, respectively.

Thus, after the previous procedure, the regions of each colour (red, green, blue, yellow, and background) can be distinguished. Such regions are well defined and can be differentiated by colour labels, as is shown in Figure 5g–j. Using their colour labels, the segregated cubes are easy to detect, while in the case of cubes that are grouped, the area of each group is divided by the average area of a single cube. This average area was empirically calculated per each colour. In this way, the total amount of transferred cubes can be counted (see Figure 5k), by processing the Kinect data frame-by-frame and incrementing a global counter during the execution of the test. The classification procedure can be observed by means of the histogram of the scene. The histogram of the original scene in RGB colour space, the scene in CIELab colour space, and finally the scene after NN classification are shown in Figure 5b,d,f, respectively.

3.3. Score Validation

Neurological disorders cause pathophysiology of grasping due to the inability to efficiently regulate the coordination of grip and load force during object manipulation [27]. The most common deficits are paresis, ataxia, spasticity or tremor, including lack of sensitivity.

Considering such motor problems, it is possible that some individuals have trouble grabbing only a single cube, and take two at a time. In such cases, and according to the test rules [6], the additional cubes must be discarded and must be counted as one. Bearing this regulation in mind, a time vector to compare very close events is used during the performance of the test. On the basis that a healthy individual takes about a second to move a cube, it is detected whether two or more cubes have appeared in very close time instants and within a period of less than a second. In that case, the additional cubes are discarded and the global counter is only incremented by one unit.

3.4. Method for Automatic Test Administration

The flowchart for the administration of the automated test is shown in Figure 6. The three stages of the test are administered automatically and sequentially by means of a graphical interface. First, the patient or the therapist must select the user profile, where the results of the test will be stored. In the case of a new patient, a new user profile can be created that includes the demographic data of the patient (e.g., name, age, gender, pathology, most affected side).

Once the user profile has been chosen, the test sequence is executed automatically: training, dominant hand, and non-dominant hand. At the beginning of each stage, the instructions for the test are given to the patient. Such instructions are provided by both text and voice messages through the graphical interface. Before the test starts, a dialogue box is displayed to check whether the user has understood the instructions. If not, the instructions will be given again.

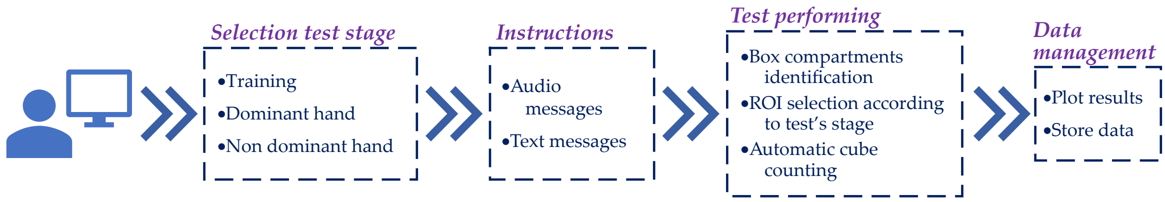


Figure 6. Flowchart for the test administration. The ABBT executes the appropriate sequence according to the traditional test's rules: training, dominant hand and non-dominant hand.

At each stage of the test, the automatic procedure for counting the transferred cubes is executed. Data acquired is automatically stored in the local PC at the end of each stage.

Graphical Interface

The implemented graphical interface is shown in Figure 7. This is the visible part of the algorithm of cube counting and it has been designed to assist the patient during the test.

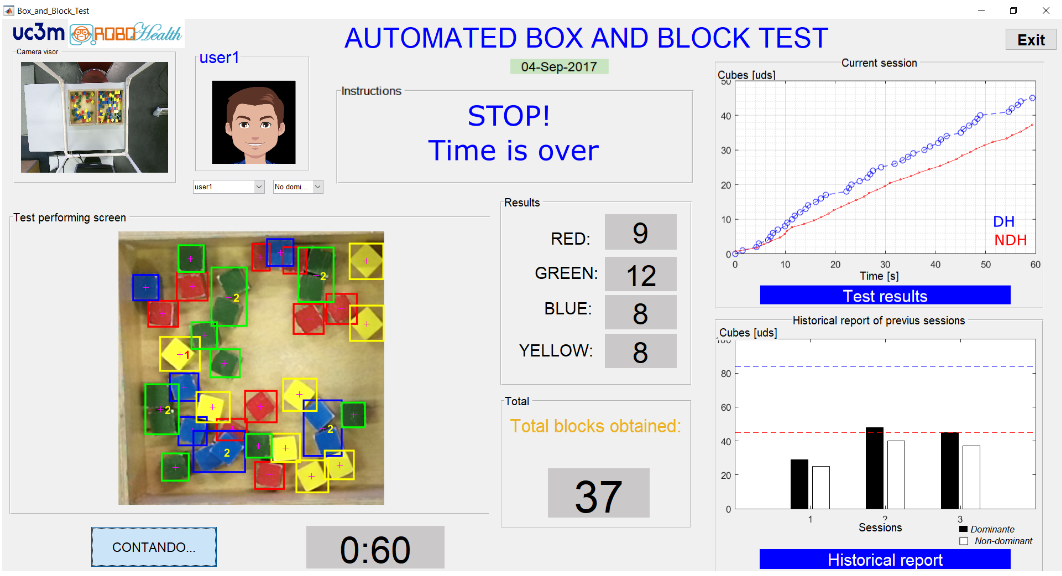


Figure 7. ABBT graphical interface.

The graphical interface allows for observation of the results of the test during its execution. A full view of the Kinect colour sensor is presented in a small window (see the upper left-hand corner of Figure 7). The scoring of the cubes obtained, by colour, is also shown in the middle of the image. Furthermore, in addition to the count of the cubes by colour, there are two windows to display the results. In the first one, the cubes obtained and their times of detection for each stage are plotted (see Figure 7, upper right corner). In the second window, after the third test stage has been completed, a comparative graph of the current session along with the previous sessions is presented (see Figure 7, lower right corner), giving a historical report. Furthermore, a line that indicates the average number of cubes transferred in one minute from normative data [6] is displayed, according to the user's demographic data.

3.5. ABBT Outcome

The total count of the cubes and the time instants in which they were detected are both stored for each stage of the test. This data is grouped by dominant and non-dominant hand for each subject.

On the one hand, the main outcome of the ABBT is the total amount of displaced cubes that is online calculated by the previously described algorithm. Such outcome is similar to the one provided by the traditional test.

On the other hand, therapist could be provided with additional outcome (more objective and based on user's performance) by analysing the stored data. First, a fairly linear trend can be appreciated in the displacement of the cubes (see the top right-hand corner of Figure 7 or the figure included in Table 2) and it is related with the hand speed in transferring cubes. The linear trend can be estimated by using a simple linear regression (SLR) [17]. SLR considers only one independent variable, employing the relation $y = \beta_0 + \beta_1 x + \epsilon$, where β_0 is the y-intercept, β_1 is the slope (or regression coefficient), and ϵ is the error term.

Suppose that the set of n observed values of x and y is given by (x_1, y_1), (x_2, y_2), ..., (x_n, y_n). In our case, x_n represents a detected cube and y_n is the time instant when it was detected. Using the SLR relation, these values yield a system of linear equations. If the line is forced to start at zero, then the system could be simplified as $Y = B \cdot X$, where B is the slope or regression coefficient.

Then, if the variable Y is the register of cubes detected (NC) and the variable X is the time instants (t) when they were detected, by applying the SLR to the results obtained with ABBT, the relation that defines the ABBT outcome is:

$$NC = V_{avg} \cdot t, \tag{2}$$

where V_{avg} is the slope (B) from the linear fit, and it represents the average velocity in the cubes' displacement. It is calculated for the case of dominant and non-dominant hand. The variation among the slopes can be related to the subjects' health condition.

In addition, the partial times (PT), these being understood as the time elapsed between the displacement of one cube and the next one, are obtained from the test. Both the mean (m) and the dispersion (σ) of the partial times are also calculated.

4. Pilot Study Description

A pilot study to assess the feasibility of the automatic counting system in a real situation was conducted in a healthcare facility. A total of nine participants with Parkinson's Disease (PD) were chosen to assess their manual dexterity. However, the participants' symptomatology is not quite relevant to the goal of this study because the study is focused on comparing the accuracy between the manual and the automatic cube counting. Three assessment stages were carried out in different months. The first assessment was conducted in May; the second assessment in July; and the third assessment in September, all in 2017.

The ABBT settings were the same as those shown in previous Figure 2a. For each of the three assessment stages, the measurements were carried out on different days of the week. Thus, the environmental conditions were different too. As the BBT rules show, after the training period, the individuals proceed to perform the test by starting with their dominant hand (the one least affected). Then, the test was carried out with their non-dominant hand (the most affected). At the end of each test stage, one of the therapists proceeded to double count the total number of cubes displaced. This manual scoring will be compared with the automatic one.

It must be noted that the participants were attending to their regular therapy between the assessment sessions. However, the analysis of the effect of the treatment on the improvement of the health status of the participants is outside the scope of this paper.

4.1. Participants

Demographic data and health status of the participants in the study are summarized in Table 1. Nine individuals with PD were selected according to the following inclusion criteria: patients with PD who fulfilled the modified diagnostic criteria of the Brain Bank of the United Kingdom; patients in stages II, III and IV of the Hoehn and Yahr scale; >60% Schwab & England functionality scale; patients whose motor response to pharmacological treatment was stable or slightly fluctuating; and who were not receiving specific UL rehabilitation treatment at the time of the study.

The exclusion criteria were: the diagnosis of other diseases or serious injuries that limited occupational performance; patients presenting Parkinsonism symptoms other than PD; cognitive impairment affecting language or comprehension and the ability to follow the instructions of the study; refusal to participate in the study; stages I or V of the Hoehn and Yahr scale; and visual impairment not correctable by glasses.

Table 1. Demographics and health status of participants.

Participant	Age	Gender	Dominant Hand	Diagnosis Year
P1	72	Male	Left	2002
P2	57	Female	Left	2006
P3	54	Female	Left	2012
P4	55	Male	Left	2013
P5	45	Male	Left	2017
P6	70	Male	Left	2011
P7	65	Female	Right	2016
P8	73	Male	Left	2009
P9	71	Female	Right	2004

4.2. Satisfaction Assessment

We evaluated clinicians' perceived usability and acceptability of the ABBT by a satisfaction questionnaire. Four items are rated on a Likert-type scale from 1 to 5 (strongly disagree—strongly agree): (1) "Are you satisfied with the ABBT?"; (2) "Have the ABBT been useful in order to assess unilateral gross manual dexterity?"; (3) "Would you recommend the ABBT to other clinicians?"; (4) "Do you think that the ABBT has advantages compared to the BBT?" The arithmetic mean across all items provides the total satisfaction score. The patient's degree of satisfaction with the ABBT was evaluated with a satisfaction questionnaire. This questionnaire consisted of a single item in which it was evaluated if the patients were very satisfied, satisfied or not at all satisfied.

4.3. Statistical Analysis

Since both the automated and the manual scoring are quantitative variables, Spearman's correlation coefficient (r_s) is employed to analyse the results. The strength or magnitude of the correlation between the variables is defined based on the following criteria: negligible (correlation coefficient between 0.0 and 0.3), weak (a value between 0.3 and 0.5), moderate (a value between 0.5 and 0.7), strong (a value between 0.7 and 0.9), and very strong (a value between 0.9 and 1.0) [28]. The Shapiro–Wilk and Kolmogorov–Smirnov test were used to verify the normal distribution of the samples. The statistical analysis was performed using SPSS 24 (SPSS Inc., Chicago, IL, USA) for Windows (Windows 10, Microsoft Corp., Redmond, WA, USA).

On the one hand, to assess the reliability of the outcome obtained by using the ABBT, we performed a correlation analysis between the BBT and the ABBT scoring (manual vs. automated). In addition, the correlation between the BBT and the slopes (SLR) calculated from the single linear regression timeline dispersion obtained during the transferring of the cubes was also analysed using the same statistical method.

5. Results

Figure 8 shows the number of the blocks estimated by the algorithm above described. Since the algorithm employs the segmentation by colour in CIELab colour space for cube counting estimation, it is less sensitive to changes in light conditions. After several tests, it is found that the system has 100% of accuracy when 35 blocks are transferred.

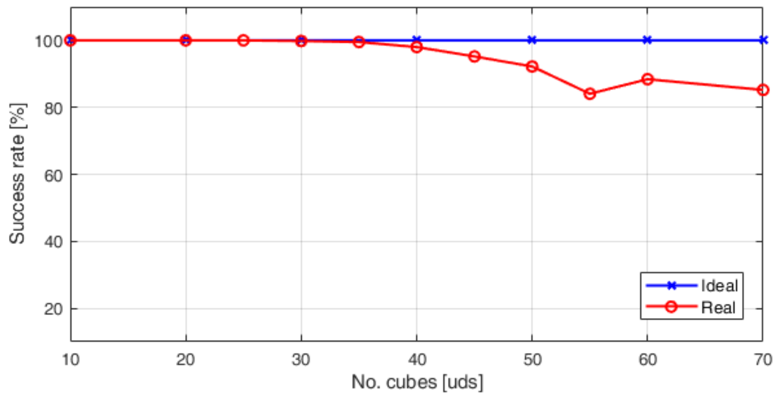


Figure 8. Success rate in cube counting in laboratory settings.

In these conditions, a pilot trial was conducted to assess the proposed system in a real situation. Several users of rehabilitation were encouraged to perform the complete test, in the same way as they perform it in a traditional assessment session, but with minimal intervention of health professionals. The system is built based on an Intel Core i7 computer (Intel, Santa Clara, CA, USA), with a Kinect for Windows V2 sensor. The implemented algorithm is able to process 3.98 images per second on average, which corresponds to a time complexity of 251 ms. The code and the graphical interface were developed in a Matlab (MATLAB R2017b, The MathWorks Inc., Natick, MA, USA) environment.

5.1. Data Gathered with ABBT

The data obtained by using the ABBT are summarized in Table 2, according to the assessment stages and the participants.

Table 2. ABBT outcome for each participant (DH: dominant hand, NDH: non-dominant hand; NC: number of cubes; V_{avg}: average velocity in cubes/second; PT: Average of partial times in seconds.)

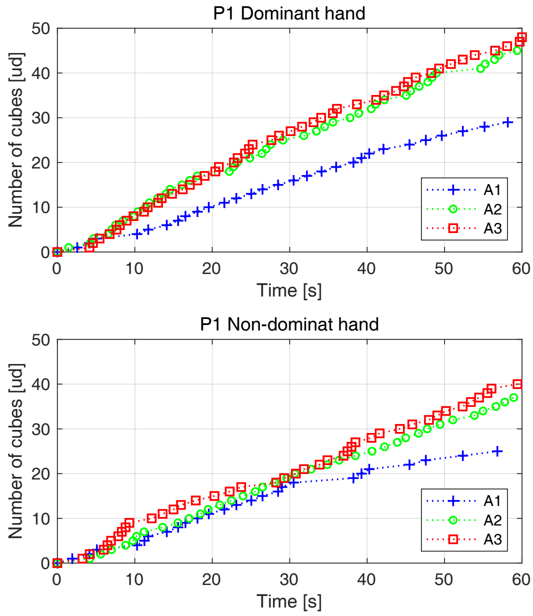
(a) First Assessment				
Participant	**Evaluated hand**	**NC**	V_{avg}	**PT** ($m \pm \sigma$)
P1	DH	29	0.520	2.21 ± 0.06
	NDH	25	0.503	2.27 ± 1.19
P2	DH	46	0.751	1.10 ± 0.05
	NDH	41	0.729	1.14 ± 0.02
P3	DH	45	0.845	1.19 ± 1.17
	NDH	39	0.718	1.11 ± 1.11
P4	DH	38	0.691	1.15 ± 1.19
	NDH	32	0.540	1.17 ± 0.03
P5	DH	55	1.076	1.18 ± 1.15
	NDH	47	0.852	1.18 ± 1.15
P6	DH	47	0.825	1.12 ± 0.09
	NDH	41	0.759	1.14 ± 0.04
P7	DH	41	0.808	1.13 ± 0.08
	NDH	37	0.664	1.15 ± 1.13
P8	DH	38	0.658	1.15 ± 0.08
	NDH	34	0.550	1.16 ± 1.19
P9	DH	45	0.787	1.10 ± 0.02
	NDH	45	0.789	1.10 ± 0.08

Table 2. *Cont.*

(b) Second Assessment				
Participant	**Evaluated hand**	**NC**	V_{avg}	**PT ($m \pm \sigma$)**
P1	DH	48	0.835	1.15 ± 0.03
	NDH	40	0.681	1.19 ± 0.03
P2	DH	42	0.782	1.11 ± 0.04
	NDH	43	0.776	1.10 ± 0.09
P3	DH	48	0.828	1.15 ± 0.05
	NDH	41	0.712	1.16 ± 0.02
P4	DH	48	0.878	1.13 ± 0.05
	NDH	47	0.855	1.16 ± 0.09
P5	DH	54	0.900	1.10 ± 0.09
	NDH	46	0.818	1.10 ± 0.06
P6	DH	52	0.862	1.15 ± 0.01
	NDH	52	1.035	1.15 ± 0.07
P7	DH	43	0.720	1.18 ± 0.03
	NDH	38	0.687	1.16 ± 1.17
P8	DH	41	0.692	1.14 ± 0.09
	NDH	36	0.637	1.16 ± 0.08
P9	DH	44	0.751	1.16 ± 0.06
	NDH	38	0.636	1.14 ± 0.06
(c) Third Assessment				
Participant	**Evaluated hand**	**NC**	V_{avg}	**PT ($m \pm \sigma$)**
P1	DH	45	0.797	1.12 ± 1.13
	NDH	37	0.622	1.19 ± 0.03
P2	DH	50	0.846	1.10 ± 0.05
	NDH	47	0.824	1.15 ± 0.07
P3	DH	42	0.737	1.11 ± 0.09
	NDH	37	0.613	1.11 ± 0.01
P4	DH	52	0.887	1.13 ± 0.06
	NDH	42	0.693	1.12 ± 1.12
P5	DH	58	1.055	1.13 ± 0.08
	NDH	55	0.967	1.19 ± 0.06
P6	DH	43	0.758	1.17 ± 0.08
	NDH	44	0.757	1.13 ± 0.07
P7	DH	36	0.601	1.16 ± 1.12
	NDH	36	0.657	1.18 ± 0.01
P8	DH	41	0.728	1.15 ± 0.05
	NDH	38	0.658	1.17 ± 0.06
P9	DH	49	0.813	1.11 ± 0.07
	NDH	46	0.808	1.10 ± 0.07

Table 2. *Cont.*

(d) Detail of Data for Participant 1



It can be seen that more information is obtained by using the ABBT than the one obtained with the BBT (only the number of cubes manually counted). The outcome of the ABBT is based on the analysis of the cube displacement and is made up of: the number of cubes transferred (NC), the average velocity (V_{avg}) in cubes displacement, and the partial times (PT). The V_{avg} and PT were calculated from of previous Equation (2) and by simply subtracting the time periods that cubes were detected, respectively.

This richer set of outcomes could be useful for the clinician for improving the evaluation of the patient. A detailed comparative of the acquired data among assessment sessions for participant 1 is shown in the figure included in Table 2. It can be clearly noted that the smoothness in cubes displacement is different by comparing the plots for the dominant and non-dominant hand.

5.2. Analysis of the Performance of the ABBT

However, as was shown in a previous work [17], the scoring obtained by the automated method was influenced by changes in the environmental light conditions. Similarly, the hand speed in cubes displacement (different in the case of dominant and non-dominant hand) can affect to the total count. The average success ratio in such study was of 90.75% for the non-dominant hand, and of 74% for the dominant hand.

On this basis, the analysis of the performance of the ABBT with the improved algorithm was carried out. The number of cubes automatically counted by the ABBT and the manual counting of cubes (in bold) are summarized in Table 3, according to each participant and in the case of both the dominant (DH) and the non-dominant hand (NDH). The error (ϵ) in the measurement, which is understood as the fraction of $Ncubes\_loss/Ncubes\_total$ on each trial, is also presented.

The total average success ratio for automatic cube counting based on the CIELab colour space is 93.45% for the dominant hand, and 94.42% for the non-dominant hand. The error (ϵ) in the counting was calculated for each trial. The maximum errors in the measurement were 13.8% and 10.8%. However, there are no more measurements above the 10% of error in addition to those two measurements. That is, the success rate of the cube counting is above 90% in 96.3% of the performed trials (52/54).

Table 3. Success rate in automatic cube counting during assessment sessions. Scoring for the ABBT and the BBT (in bold) grouped by dominant hand (DH) and non-dominant hand (NDH) for each participant and for the three assessment sessions. The error in the measurement is (ϵ). Histogram of cubes loss is included.

(a) First Assessment

Participant	DH	ϵ	NDH	ϵ
P1	29/**32**	0.094	25/**29**	0.038
P2	46/**50**	0.080	41/**45**	0.089
P3	45/**46**	0.022	39/**42**	0.071
P4	38/**42**	0.095	32/**35**	0.086
P5	55/**59**	0.068	47/**51**	0.078
P6	47/**52**	0.096	41/**45**	0.089
P7	41/**45**	0.089	37/**37**	0.000
P8	38/**40**	0.050	34/**36**	0.056
P9	45/**49**	0.082	45/**46**	0.022
Success rate:	92.2%		93.32%	

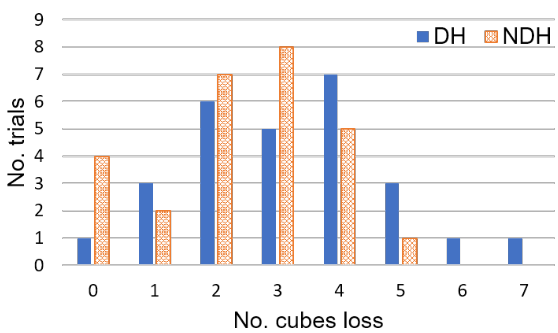
(b) Second Assessment

Participant	DH	ϵ	NDH	ϵ
P1	48/**49**	0.020	40/**40**	0.000
P2	42/**46**	0.087	43/**47**	0.085
P3	48/**53**	0.094	41/**42**	0.024
P4	48/**53**	0.094	47/**49**	0.041
P5	54/**55**	0.018	46/**48**	0.042
P6	52/**58**	0.003	52/**54**	0.037
P7	43/**45**	0.044	38/**40**	0.050
P8	41/**43**	0.047	36/**39**	0.077
P9	44/**47**	0.064	38/**40**	0.050
Success rate:	93.34%		95.5%	

(c) Third Assessment

Participant	DH	ϵ	NDH	ϵ
P1	45/**47**	0.043	37/**37**	0.000
P2	50/**50**	0.000	47/**50**	0.060
P3	42/**44**	0.045	37/**40**	0.075
P4	52/**55**	0.055	42/**42**	0.000
P5	58/**65**	0.008	55/**60**	0.083
P6	43/**46**	0.065	44/**47**	0.064
P7	36/**39**	0.077	36/**39**	0.077
P8	41/**45**	0.089	38/**41**	0.073
P9	49/**51**	0.039	46/**48**	0.042
Success rate:	94.42%		94.43%	

(d) Histogram of Lost Cubes



These results prove that the algorithm for cube counting based on the CIELab colour space has a better performance than the one based on the RGB colour space, considering also that both the sample size ($n = 54$) and the average number of cubes transferred (45.8 cubes) are larger than those studied in [17].

However, it is important to identify the causes of this error in order to still further improve the success rate of the cube counting. Figure included in Table 3 shows the histogram of lost cubes during the trials. The median number of cubes lost is 3. Between two to four cubes are lost in 70.36% of trials. The percentage of lost cubes is 48.15% and 42.59% for the dominant and non-dominant hand, respectively. Thus, the loss of cubes is equal for each hand with which the test is performed. In this sense, future developments must consider as a main source of error the occlusions caused by the layer-by-layer stacking of cubes.

5.3. Reliability Analysis

There were three functional assessment sessions and nine participants. Both arms were evaluated in each session. Thus, a total of 54 samples were obtained for statistical analysis.

On the one hand, the reliability of the automatic (ABBT) versus the manual (BBT) counting have been statistically analysed. The global coefficient of correlation, considering the total sample ($n = 54$), between ABBT and BBT is $r_s = 0.98$ (Spearman's correlation coefficient, $p < 0.001$). On this basis, the relationship between the manual and automated scoring is found to be very strong. Figure 9 shows the previously mentioned correlation levels. Additionally, the relation between the BBT and the average velocity (V_{avg}) of cubes transferred has also been calculated. The coefficient of correlation is $r_s = 0.94$, giving also a very strong level of significance.

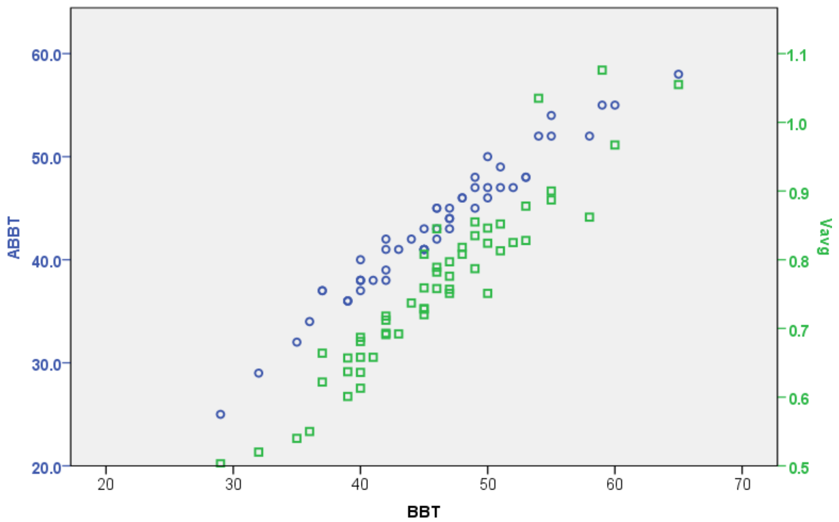


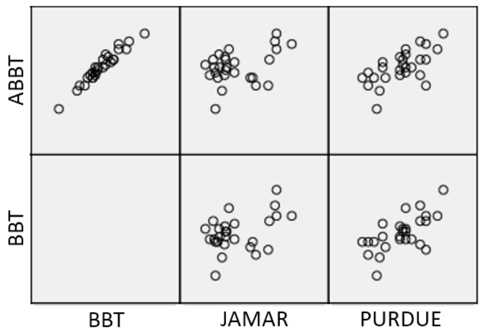
Figure 9. Correlation plot among test outcomes: automatic scoring (ABBT), manual counting (BBT) and average velocities (V_{avg}). BBT score is considered as ground-truth.

In principle, such a global relationship could be misleading for a comparison of the performances of the dominant and the non-dominant hands. However, the coefficients of correlation between the ABBT and BBT are $r_s = 0.967$ for the dominant hand and $r_s = 0.978$ for the non-dominant hand. It can be appreciated that these levels of correlation are slightly lower than the global coefficient, but they are still very strong in both cases. This fact is consistent with the difference between the success ratios of cube counting for the dominant and non-dominant hand.

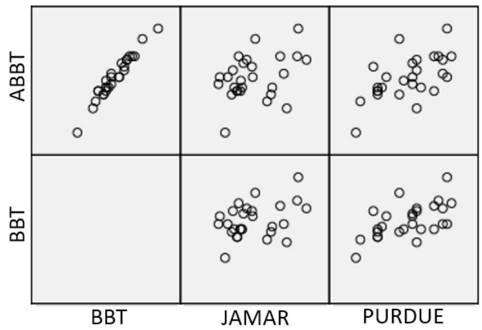
On the other hand, an additional analysis of the correlations between the ABBT score and another tools used for functional assessment was carried out. As it is generally done in functional assessment sessions, several tools are used for evaluation of motor function. In our case study, the clinicians measured the handgrip strength and the fine manual dexterity of participants using the Jamar dynamometer and the Purdue Pegboad Test (PPT), respectively. Such outcomes were obtained at the same time that the BBT. It was part of the regular therapy treatment of participants in the healthcare facility.

For the analysis, the hypothesis was that the relationship between the BBT and the other tools could be similar to the ABBT with the same ones. The data considered was the total sample ($n = 54$). First, the coefficient of correlation between the gross manual dexterity (BBT) and the handgrip strength (Jamar) is $r_s = 0.363$ (Spearman's correlation coefficient, $p < 0.004$). The relationship between the BBT and the PPT is $r_s = 0.623$ (Spearman's correlation coefficient, $p < 0.001$). Second, the coefficient of correlation between the gross manual dexterity measured by the ABBT and the handgrip strength (Jamar) is $r_s = 0.361$ (Spearman's correlation coefficient, $p < 0.004$). The relationship between the ABBT and PPT is $r_s = 0.636$ (Spearman's correlation coefficient, $p < 0.001$).

It can be noted that the coefficient of correlation between the BBT and Jamar is low, and that between the BBT and PPT is moderate. Nevertheless, the same levels of correlation were obtained when using ABBT. The coefficients of correlation between outcomes are summarized in Figure 10a,b, for the dominant and non-dominant hand, respectively.



(**a**)



(**b**)

Figure 10. Correlation plot among three outcomes commonly used for upper limb functional assessment: (**a**) for the dominant hand, and (**b**) non-dominant hand.

Considering the previous levels of correlation, it can be observed that the error between manual and automatic measurement is not significant. In addition, the correlations obtained between the different tools suggest that the information provided by the automatic method is as reliable as the manual one, despite of the error in the measurement.

5.4. Usability Assessment

The perceived usability and acceptability of the ABBT proposed here varied across clinicians. The clinicians' answers are summarized in Table 4. The four clinicians evaluated "agreed or strongly agreed" with the satisfaction with the ABBT. Three clinicians reported that the ABBT was useful in order to assess unilateral gross manual dexterity ("strong agreement"), but the other one reported "neither agreement nor disagreement" in this regard. Regarding the degree of recommendation of the ABBT, three clinicians reported to be in "agreement or strong agreement"; however, the other participant indicated to be in "neither agreement nor disagreement". Finally, all participants declared to "agree or strongly agree" with the advantages compared to the BBT; all the patients showed a high degree of satisfaction with the ABBT.

Table 4. Results of satisfaction questionnaires.

Clinicians	Items	Strongly Disagree	Disagree	Neither Agreement Nor Disagreement	Agree	Strongly Agree
1	(1)					x
	(2)					x
	(3)			x		
	(4)					x
2	(1)					x
	(2)					x
	(3)				x	
	(4)					x
3	(1)					x
	(2)			x		
	(3)					x
	(4)					x
4	(1)					x
	(2)					x
	(3)				x	
	(4)					x

6. Discussion

In this study, the improvements to a Kinect-based system, using colour segmentation and a NN-based classifier, for automatically obtaining the score during assessment of gross manual dexterity were presented. A pilot study to evaluate the performance and feasibility of the proposed method was conducted. The viability of the proposed system was studied by including this automated method among the tools for manual dexterity assessment of patients with PD. The results obtained for each measurement were compared in order to quantify the reliability of the ABBT.

6.1. Comparison of the Manual and Automated Method

Correct assessment of motor function is essential for optimal rehabilitation management. There is a great need for continuous and objective monitoring of motor symptoms in neurological patients. Most of the motor scales are sufficiently validated and widely used in clinical practice. However, regarding inter-rater reliability, the motor scales have limitations [29]. The need to quickly and safely obtain accurate and reliable data is essential for clinicians to evaluate patient's mobility status of upper extremities and determine the appropriate rehabilitation treatment. In addition, the analysis of the data gathered during the rehabilitation process is useful to detect the improvements that have occurred. The BBT is a rating scale used to measure unilateral gross manual dexterity. The test–retest reliability of the BBT is high (intraclass correlation coefficients [ICC] of 0.89 to 0.97), and the validity of the BBT has been shown by the significant correlations between the BBT and functional independence measurement [30].

On this basis, the BBT study was considered since the outcome is simple (total cubes transferred), the test instructions are systematic and clear, and the test development is well defined (three stages: training, dominant hand, and non-dominant hand) [6,31]. In addition, outside of the test design itself, it was selected for its wide use in clinical settings as an evaluation system in neurological rehabilitation [4]. The ABBT is the automated version of the BBT and provides more information than the traditional BBT. This information is stored directly in the patient's register, easing the update of the medical history. Additionally, the cubes' colours and the time period when they were detected are obtained and registered by the ABBT.

Regarding the performance of the automatic system of cube counting, the statistical analysis showed a very strong correlation ($r_s = 0.98$) between the BBT and the ABBT scores. The success rate of the cube counting was improved by means of applying the CIELab colour space to detect the cubes. The results show an average success rate in the counting of cubes of 92.5% in the worst case and a maximum error of 13.8%.

In this way, the effectiveness in automatic cube counting of the proposed method, based on colour segmentation in the CIELab colour space and the Nearest Neighbour (NN) rule, has been better than previous works [16,17]. The measurement error was small and consistent during the different assessment sessions. It must be noted that the colour markers used for the NN classifier were the same during all the sessions, which were conducted in different days and months. This fact shows that the selection of the CIELab colour space is well suited for the BBT automation, since it is not significantly affected by environmental lighting conditions.

However, future developments must consider the main source of error that remains due to the nature of the application. Cubes can be stacked in different layers. This issue produces occlusions and loss of visual data. The use of depth sensors could detect this problem and the visual processing algorithm could be modified to deal with it. In addition, the use of a fuzzy logic approach is also considered for increasing the algorithm performance [32].

Regarding the clinical value of the additional data provided by ABBT, a linear relationship between the ABBT and BBT outcomes can be observed in Figure 9. In this figure, a stronger relationship between the BBT score and the displacement slopes (V_{avg}), given by the simple linear regression (SLR), is also depicted. However, as it was shown in the statistical analysis, the correlation level between BBT vs. SLR is lower than the BBT vs. ABBT. This can be attributed to the fact that automatic outcome is larger and more detailed than the one obtained with the BBT, since the automatic outcome not only considers the number of cubes transferred but also the movement quality. That is, given the same number of cubes transferred, the SLR can be different depending on the smoothness in the movement (level of dispersion in PT). The analysis of this information can be related to indicators of coordination or dexterity. This approach requires further trials to be refined.

6.2. Feasibility of the Automated Method

This study demonstrated the suitability of the ABBT to assess unilateral gross manual dexterity in an automated way. The use of the ABBT was simple, and its outcome reliable, during the functional assessment of real patients. Therefore, it would be possible to carry out this type of evaluation in clinical environments.

The clinicians were satisfied when using the tool as it would solve a primary complaint of having to be exceedingly cautious and attentive when counting the cubes to avoid possible counting errors. Thus, having mistakes when counting and consequently repeating the test could be avoided by the tool automation. Patients additionally showed high satisfaction with the ABBT. They commented that they did not find any difficulty in performing the test automatically as compared to manually, that they understood the instructions perfectly and that it was quick and easy.

Regarding the advantages of the automated method, it was highlighted by the clinicians that the possibility of having a tool like the ABBT would allow for improving the assessment by focusing attention on the patient and not on the test. For example, the physician may detect if the individual performs some type of compensation to assist in the movement, such as leaning the torso forward or forcing the shoulder. In addition, if the patient would have a problem such as fatigue or pain in the arm when performing the test, the clinician could detect it immediately due to not being aware of the cube count. In the same way, the clinician could observe the way in which the patient performs the scopes and grips of the cubes, to have a slight idea of the deficits in the upper limb. In this way, the ABBT could be a useful tool to assist the evaluator during the assessment process in clinical settings.

Additionally, it is clear that the use of ABBT in particular, and of automated systems in general, for tele-rehabilitation is promising. However, some concerns must be carefully considered. A lot of the work by the clinicians is not simply instructing or counting but keeping a check on the patient (i.e., if they are tired, bored, or need assistance). These human factors (patient encouragement, friendly interfaces, etc.) must be addressed to allow the integration and to increase the utility of such systems in tele-rehabilitation.

In conclusion, the obtained performance and the objective information provided by the proposed system, as well as the acceptance by the clinicians and patients, further support the development of automated methods for functional assessment in rehabilitation processes.

7. Conclusions

In this paper, an automated system using a Kinect V2 sensor for the assessment of unilateral gross manual dexterity was described. The reliability of this approach was studied as the main goal of the present article. For this purpose, the ABBT was included among the tools for assessing the upper limbs motor function of a group of patients with PD. The test was administered to nine participants in three assessment sessions. A total of 57 samples were obtained.

In this way, we proposed a hybrid method of colour segmentation and nearest neighbour classification, which deals naturally with the traditional test setting, does not need a training dataset, has reasonable computational complexity at run time, and yields excellent results in practice. In addition, since automatic counting is objective, reliable and reproducible, it improves the outcome obtained by manual counting.

In addition, taking into account the high level of correlation between the manual and the automated counting ($r_s = 0.98$) and the additional information obtained using the ABBT, the results suggest that the proposed system can be used as a tool for the automatic assessment of manual dexterity.

The ABBT may be a promising and feasible evaluation tool for tele-rehabilitation processes, even for assessing of a group in clinical settings. This system presents important advantages like its portability, ease of use, commercial availability, inexpensiveness and non-invasive nature.

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Abbreviations

The following abbreviations are used in this manuscript:

ABBT	Automated Box and Blocks Test
BBT	Box and Blocks Test
CMYK	Cyan, Magenta, Yellow, Key
HSV	Hue, Saturation, Value
RGB	Red, Green, Blue
ROI	Region of Interest
SLR	Simple Linear Regression

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CHAPTER 7

Serious Games as an Intervention Tool

7.1 Overview

This chapter describes the design, development and feasibility study of a system based on serious games designed to improve the functionality of upper extremity. The proposed system was mindfully designed to cover the particular needs of patients with neurological deficits, promoting the motor gains from treatment.

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Research Article

Effectiveness of Serious Games for Leap Motion on the Functionality of the Upper Limb in Parkinson's Disease: A Feasibility Study

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The design and application of Serious Games (SG) based on the Leap Motion sensor are presented as a tool to support the rehabilitation therapies for upper limbs. Initially, the design principles and their implementation are described, focusing on improving both unilateral and bilateral manual dexterity and coordination. The design of the games has been supervised by specialized therapists. To assess the therapeutic effectiveness of the proposed system, a protocol of trials with Parkinson's patients has been defined. Evaluations of the physical condition of the participants in the study, at the beginning and at the end of the treatment, are carried out using standard tests. The specific measurements of each game give the therapist more detailed information about the patients' evolution after finishing the planned protocol. The obtained results support the fact that the set of developed video games can be combined to define different therapy protocols and that the information obtained is richer than the one obtained through current clinical metrics, serving as method of motor function assessment.

1. Introduction

Parkinson's disease (PD) is defined as a chronic neurodegenerative disorder caused by the destruction of dopaminergic neurons located at the basal ganglia. These central nervous system (CNS) neurons are used as primary neurotransmitter dopamine, which is responsible for transmitting the necessary information for the correct control of movements [1, 2]. It is considered the most frequent neurodegenerative disease after Alzheimer's disease and the most common movement disorders [3, 4].

PD prevalence and incidence present a marked geographic variation. In the world population, it can be found that 1-2/1000 people suffer the disease [5]. In Europe, a prevalence rate of 1.6% of the total European population is estimated [6, 7]. PD is characterized by a symptomatic tetrad that consists of resting tremor, stiffness, bradykinesia, and alteration of the straightening reflexes [2, 8]. It also presents other symptoms such as decreased facial expression, sialorrhea, arterial hypotension, depression, and cognitive impairment, among others, with the nonmotor symptoms of the disease being important [9]. These symptoms impair the performance of their daily activities, reducing their level of independence [10].

Currently, there is no curative treatment for PD. The treatment focuses on the symptomatology and to prevent the progression of the disease. The drugs currently used are indicated to compensate the dopamine deficit [11]. The most commonly drug used is levodopa, although dopaminergic agonists, catechol-O-methyltransferase (COMT) inhibitors, anticholinergics, and amantadine are also used [2, 12].

However, not only can therapies with specific drugs be improved, as SG have been shown to play an important role. There is scientific evidence about the benefit of rehabilitation treatment in PD [13–15]. In the field of neurorehabilitation, virtual reality (VR) and interactive video games, such as immersive VR devices, are beginning to be accepted as adjunctive therapeutic tools in the treatment of neurological patients, through real-time simulation and multiple sensorial channels, providing the opportunity to perform functional, repetitive, and rewarding activities [16–19]. Commercial video game consoles such as the Nintendo Wii, the Play Station Eye Toy, or Microsoft XBOX with their Kinect device have been quickly adapted in the clinical setting as low cost options in rehabilitation treatment in patients with PD with various studies which support its clinical use.

New devices have appeared on the market as the Leap Motion Controller (LMC), framed within semi-immersive RV equipment that records movement of the patient's upper extremities without the need to place sensors or devices on the body. Thus, a virtual image of the upper limbs can be generated on a computer screen in which the patient will have to perform movements according to the exercises purposed (touching and picking up objects, ordering figures, playing a piano, flipping hands, among others). However, scientific studies are needed to support its therapeutic use in the treatment of motor disorders of the upper limbs in PD, since it is frequent that a wide repertoire of limitations in the development of functional activities appears, as well as restrictions on participation due to alterations of the upper limbs, throughout the progression of the disease.

In this paper, the feasibility of the LMC-based video games as a rehabilitation tool in the PD treatment is studied. For that purpose, a pilot study was conducted at Parkinson's center with patients using a series of LMC-based video games, during a training protocol defined by therapists. In Section 2, related works are exposed. The proposed methodology and the design principles of the games are described in Section 3. The development of the LMC-based video games and the functionality of each one are shown in Section 4. The definition of the treatment protocol and the obtained results are presented in Section 5. The effectiveness of treatment focused on the video games contribution is discussed in Section 6. Finally, the conclusions are summarized in Section 7.

2. Related Works

The use of the Leap Motion Controller (LMC) has been extended from its initial purpose in the entertainment industry, towards different applications based on gesture-recognition such as remote control, sign language translation, and augmented reality and also in health care. In healthcare applications, due to the ability to detect with high precision the finger joints and their movements, the LMC has been used in systems oriented to the rehabilitation of fine and gross manual dexterity, enhanced by a virtual environment that stimulates to the patient.

On the one hand, several works focused on hand motor recovery using only the LMC and a virtual environment are found. In [20], the prefrontal cortex haemodynamic responses during the executions of demanding manual tasks performed in a semi-immersive VR environment are studied. The LMC is used to track the hand movements and to enable subjects to transpose their hand movements within a virtual 3D task. In [21], the user-centered methodology for the design of SG based on LMC is presented. The implemented exergame accomplished with both the users and the therapists considerations for the hand rehabilitation. In [22], the Fruit Ninja game was modified to use LMC for the finger individuation training. The results suggest that Fruit Ninja's score is a good indicator of the hand function according to the high correlation with the standard clinical assessment scores such as Fugl-Meyer (FMA) and Box and Blocks Test (BBT). In [23], the LMC as a gesture controlled input device for computer games was studied. The experience with the LMC into two different game setups was evaluated, investigating differences between gamers and nongamers with 15 participants. Results indicated the potential in terms of user engagement and training efforts for short-time experiences. However, the study results also indicated that gesture-based controls are rated as exhausting after about 20 minutes. While the suitability for traditional video games was thus described as limited, users saw potential in gesture-based controls as training and rehabilitation tools.

Thanks to the portability and low cost of the sensor, the LMC is appropriated to perform exercises at home and remotely supervised by clinicians. Thus, for example, a tool for doctor on which they can prescribe patient to imitate standard exercise hand motion and get automatic feedback, such as score, is proposed in [24]. According to similarity in the scoring, the rehabilitation effect is enhanced. Another similar study, but focused on the cerebral palsy treatment, is shown in [25]. Because the purpose of these systems is to measure the similarity between the standard gestures and those performed by the patient, an immersive virtual environment is not necessary. A study for the treatment of motor and cognitive impairments in children with cerebral palsy is addressed in [26]. Integration between patient and virtual environment occurs through the LMC plus the electroencephalographic sensor MindWave, responsible for measuring attention levels during task execution. Based on results, the level of attention can be correlated with the evolution of the clinical condition.

Besides, others studies integrate support devices in addition to the LMC to assist the patient. In [27], the fusion of the LMC and the Omega.7 haptic sensor with force feedback capabilities has enabled a bilateral rehabilitation training therapy. The LMC tracks the healthy hand and the Omega.7 device haptically interacts with the impaired hand. It allows bilateral complementary tasks for the training of the coordinated cooperation of the paretic arm and intact arm. Other assisted rehabilitation systems are addressed in [28], using the LMC to visualize in a virtual environment the feedback forces sent by a 3D-printed hand orthosis. The hand orthosis is also commanded by four servomotors that eases the full development of the proposed tasks.

On the other hand, the LMC not only has been used as a rehabilitation tool, but also has been used to automate the assessment of the functionality of the hand. This issue is addressed in [29], where an automated system based on the Simple Test for Evaluating Hand Function (STEF) was implemented. In the case of the Parkinson treatment,

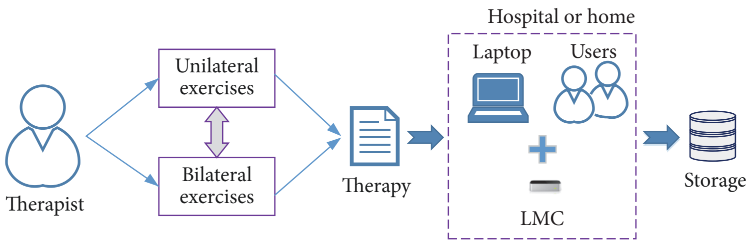


Figure 1: Framework for the upper limb rehabilitation.

a novel index of finger-tapping severity, called "PDFTsi," was introduced in [30]. This index quantifies the severity of symptoms related to the finger tapping of PD patients. Several works are focused on the use of LMC to measure the hand tremor. In [31], the authors propose the implementation of an unobtrusively system to detect tremor, using the LCM and the Vuzix M100 smart glasses. Similar work but using only the LMC is studied in [32]. A novel approach of tremor quantification based on an open-source mobile app is presented in [33].

Due to the fact that the integration of LMC technology into healthcare applications has begun to occur rapidly, the validation of the sensor data output [34] and the feasibility in neurorehabilitation [35] are important research goals. The results of these studies provided a proof of concept that LMC can be a suitable tool for videogame-based therapy in hand rehabilitation.

3. Material and Methods

The Serious Games (SG) developed for this study try to imitate exercises included on traditional physical therapy, such as palmar prehension, fingers' flexion, and extension or hand pronation-supination, with the added value that the immersive virtual environment tries to hook the patient to the point of not focusing on the fact of being in a rehabilitation session. This rehabilitation method using SG is proposed for patients with limited mobility in order to restore their ability to independently perform the basic activities of daily living (ADL) or to recover a lost or diminished function by performing exercises on a regular basis. To cover these specific objectives, several video games have been created to exercise different purposes proposed by healthcare professionals. These SG not only are beneficial to recover physical mobility, but also favor the perception of visual acuity, whether the subject has it atrophied or not. This means that although the idea of these games is mainly to work at motor level, they also exercise the cognitive and perceptive capacities of the users. Although the study was carried out with patients with PD, the games try to be as less selective as possible with the target public, being able to be particularized considering the injuries and physical conditions of each user. In this way, it has been determined that the games are favorable for subjects with motor limitations due to suffering any of the following pathologies: PD, people who have suffered a stroke, arthritis, osteoarthritis, manual stiffness, wrist and/or fingers fracture, tennis or golfer elbow, and shoulder injuries.

3.1. Design Principles. In this section, we expose the methods used for the creation of the video games, together with a detailed description of them. The idea was to develop a flexible game platform that allows the clinics to perform the rehabilitation sessions. The video games should include a record of the patients' progress and a minimum set of "how to play" instructions and must be able to give feedback of goals achievement to both patients and therapists. After deep review of LMC sensing capabilities and discussions with occupational therapists, a set of design requirements were chosen to achieve the rehabilitation goals. In Figure 1, the main components of the proposed framework for the development of SG for rehabilitation are described. Then, it was agreed that the implementation of these video games should fulfill the next specifications.

3.1.1. User Interface. It is essential for the interface to allow patients run the video games easily and in an intuitive way, along with simple and clear instructions. For easiness and portability, a simple laptop should be enough to run the games. In the design, it has been noticed that voice instructions complement those shown on screen, so the games count with guide through messages, images, and audios to assist favorably to any type of user. Furthermore, attractive graphics awake interest and help patients to get involved in the exercises. These games try to influence the users' mood while doing rehabilitation by motivating them in a comfortable and innovative virtual environment.

3.1.2. Game Dynamics. The games' sessions ought to be intuitive and straightforward. They are oriented to execute different tasks in which users will be able to perform free articular movements, but a few conditions will be imposed in the way the exercises must be done with the intention that patients are forced to make specific actions and movements which will be part of the therapeutic evaluation. To assure the usability, the games include adjustable features in order to allow physiotherapists make the games suitable for each patient's pathology and conditions. Therapists design the right set of exercises and the sequence of them to be performed by the user, generating the specific treatment protocol scheme as a "recipe" for the specific disease and patient. This is represented in Figure 1 as therapy component.

3.1.3. User's Incentive. As the user performs the unilateral exercises (moving only one arm each time) and bilateral exercises (using both arms) the games save how much time the patient has spent on completing each mission. These results are shown on screen through a bar chart proportional to the time, this way the users can compare how long it has taken to make the exercises with each finger or hand, depending on the game. This system motivates players to improve their times, stimulating their progress during the rehabilitation process.

3.1.4. Clinical Outcomes. An essential outcome to obtain from this rehabilitation through video games is the clinical data to be analyzed by healthcare professionals. Based on therapists' directives, the developed games extract and store information about the human joints' trajectories together with movement ranges during the exercises and the time it takes to perform each game. This recorded data informs about the quality of the exercise performance, the progress of the patient along the sessions, so after its analysis we could conclude about the utility of the virtual therapy.

3.1.5. Automatic Data Store. The information obtained in each session will be automatically stored in the patient's record in a format that medical staff can easily handle to make their evaluations. In this case, CSV files easily match the specifications required and its content can be simply managed. This way, it is possible to access to an updated report of each patient, allowing the physician check remotely the therapy's progress. Each patient record is identified by a code, so their privacy is guaranteed.

3.1.6. Reliable Data Acquisition. Tracking patients' movements is one of the most important issues in order to do a diagnosis or evaluation. Including this data in the generated report allows the therapist to obtain more detailed data to analyze and follow the patient's recovery. The video games technology provides useful way of tracking the patient movements and automatically registers such information, giving support to follow closely the patients' evolution. The idea is to validate if a low cost and portable device, such as LMC, is good enough to develop autonomous tool for "at home" rehabilitation therapies.

3.2. Development Tools. The previous Figure 1 includes the main components needed to use the developed SG, mainly a laptop or a PC plus the LMC plugged to its port. Due to this minimum infrastructure, the system could be used everywhere.

3.2.1. Hardware Tools. Leap Motion has been chosen as the most suitable capture instrument for the video games developed due to its portability and low cost; its good precision in the tracking of the different parts of the hand, even its SDK includes functions that facilitate the measurement of the movements and positions of the joints of the fingers and the palm of the hand; its clear results; its ease of use, because thanks to not needing markers for the tracing, it is not intrusive with the patients and it is quick to install. Using the Leap Motion device, interaction with the computer without any physical contact is allowed.

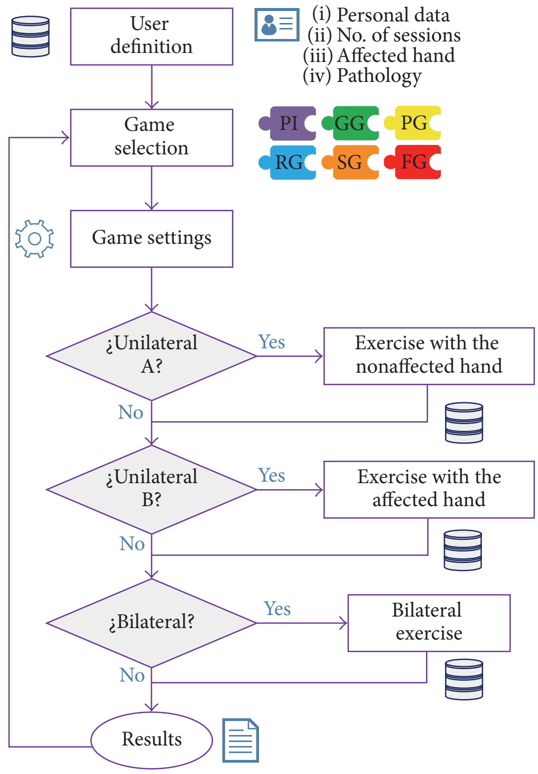


FIGURE 2: Flowchart of the videogames execution.

3.2.2. Software Tools. The games were developed using the game engine Unity and C# scripting for the game scripts. This open-source engine allows the video games created to be accessible and free. The source code of the project is hosted by Github in the link, where also several screen-shots are available.

4. Games Development

A series of video games focusing on the physical rehabilitation of the upper limbs of patients suffering from some type of motor limitation were designed. According to the requirements and indications from healthcare professionals, six games were developed: Piano (PI), Reach Game (RG), Sequence Game (SG), Grab Game (GG), Pinch Game (PG), and Flip Game (FG); each one of them focused on diverse rehabilitation workout.

Users must follow a set of screens in order to accomplish all the exercises. As showed schematically in Figure 2, the execution of the games is as follows. The first menu screen requests for personal information about the subject, the number of the sessions, which hand is more affected, and what pathology takes the patient to carry out the rehabilitation therapy. If the user is already in the DDBB, after login, a new session identifier is automatically assigned. Once this data is collected, a set of games is available. Then the game follows the defined rehabilitation protocol, understood as the selection of which games, and the proper sequence of games for each session previously defined by the therapist.

By default, if no protocol has been defined, the user must select in a menu the game to play from the ones described in next section. After the game activation, when the hands are introduced over the Leap Motion device, they will be virtually represented on screen and patients will be required to move them within the device's area of detection and to perform different gestures to execute the different exercises.

This type of rehabilitation with video games, in contrast to the traditional one, contributes on a motivating context, presenting rich and functional stimuli for the patient. Therefore, these games have been created with the purpose of engaging, thus increasing the active participation of the subject in the rehabilitation program.

4.1. Implemented Games

4.1.1. Piano Game (PI). This game simulates a piano with ten keys, each one corresponding to one finger of each hand. During the game, the highlighted key that is indicated must be pressed by the appropriate finger, keeping the hand open and lowering the finger that will take down the key until it sounds. The keys are highlighted first in order, from the pinkie to the thumb, and then in random sequence. Series will be played in order of each hand and then for both hands simultaneously. It seeks to exercise the dissociation of the fingers by situating each finger over a piano key, stretching them individually downwards, and then recovering the initial position with the hand completely open. These finger movements involve a fine motor unilateral and bilateral coordination and a fine manual dexterity. Note that, along the performance of the game, arm posture control is required, keeping the hand over the Leap Motion device that virtually places the hands on the piano. Furthermore, the game includes a section where the patient must remember a sequence of a certain number of keys that are illuminated and must repeat (after the series shown). This feature adds to the video game the attention and retention training component.

4.1.2. Reach Game (RG). During this game, the patient's virtual finger must touch the indicated cube among several cubes that appear on screen. As the cubes are reached, they fall to the floor and the next target cube is indicated until the last of them has been dropped. The cubes on the screen are located at different heights and depths. Thus, the sensation of the patients' spatial perception is created, making them move the arms in the space above the LMC device until the correct position of the target cube is found. The highlighted one is the goal to be touched and the rest of them become obstacles to be avoided. The purpose of this exercise is to motivate the users to move the upper limbs of the body to reach the virtual cube, so they have to make specific movements of extension of the fingers, contraction, and stretching of the elbows and abduction and adduction of the shoulders. Also, the subject trains gross motor unilateral and bilateral coordination.

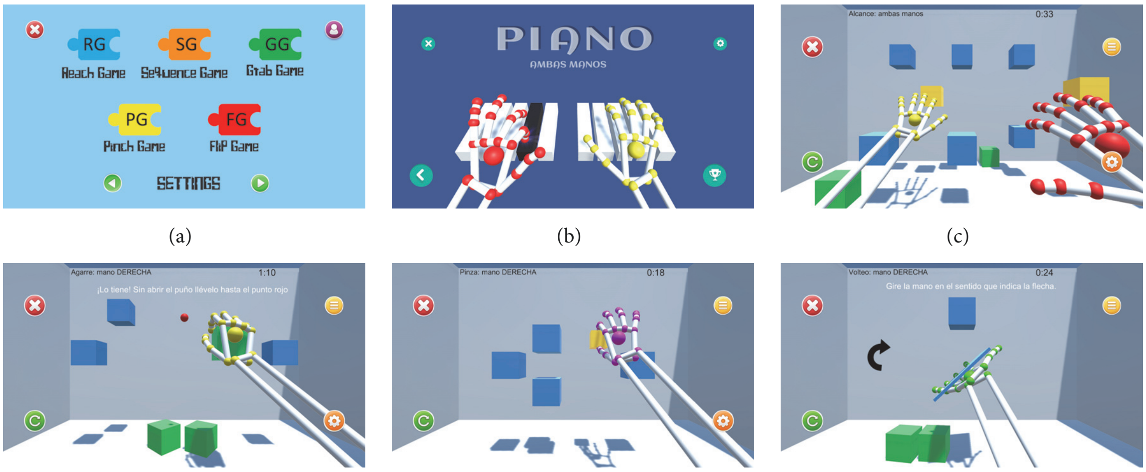
4.1.3. Sequence Game (SG). In this game, the patient's objective is to memorize the sequence that is reproduced through a color change of the cubes that appear on the screen. At the end of the sequence, the user must repeat it by reaching the cubes in the same order in which they were shown. As in the Reach Game, the physical movements and skills mentioned before are trained, but this game adds the exercising of visual sequential memory.

4.1.4. Grab Game (GG). The target of this game motivates the patient to perform the movements of closing and opening the hand without resistance. A set of cubes is arranged in a specific layout and a red sphere is shown in the central part of the screen. The user must reach the indicated cube, make the gesture of grip with all the fingers flexed, and then with the fist closed move the grabbed cube to the red sphere and, once they come into contact, open the hand with all the fingers stretched to release the cube. In the Grab Game, the objective is to work both the muscle tension and distension on the hands and fingers (i.e., flexion and extension), unilateral and bilateral gross motor coordination, and gross manual dexterity due to the grabbing gesture. As in the Reach Game, the cubes are positioned at different heights and depths. Thus, the patient will be able to exercise, in addition to hands, the elbows, and shoulders and spatiality.

4.1.5. Pinch Game (PG). The opposition of the fingers is an exercise used in occupational therapy to recover fine motor skills. In this game, the bidigital grip is trained by performing the pincer movement through the terminal or subterminal opposition, both of which are valid. The patient must touch the index finger with the thumb from an initial position with extended fingers. When making this gesture close enough to the objective cube, this will acquire smaller size as the fingers approach until it disappears completely. As the cubes are reached, unilateral and bilateral gross motor coordination is trained, and additionally, in order to perform the specific task of this game, fine manual dexterity is required.

4.1.6. Flip Game (FG). The user must situate his hand palm up over the Leap Motion device as a waiter holds a tray. A small tray filled with a cube appears in the center of the screen. The patient has to spin the palm downwards. Doing this tray rotation, the cube detaches from tray and it falls to the bottom. This game is created due to the need to exercise pronation and supination of the forearm, but also a posture control is required because it is necessary to keep the hand on the tray during the spin. In Figure 3(f), the user hand holding the small tray and an arrow to indicate the direction of rotation are shown. Once again unilateral and bilateral gross motor coordination is needed in order to reach the objects placed on the virtual space of the game. This exercise, as the previous ones, is performed individually with each hand and later the bilateral integration is carried out, taking part on the game both hands. In this case the user must coordinate the spin movement of each hand tray to drop both cubes at the same time.

4.2. Games Settings for Therapist. The developed games try to be as less exclusionary as possible with the target audience and the most adaptable to particularize the exercises according to each patient. In order to achieve this, a settings



(a) (b) (c) (d) (e) (f)

Figure 3: Serious Games used on protocol: (a) Games Menu, (b) Piano Game, (c) Reach Game, (d) Grab Game, (e) Pinch Game, and (f) Flip Game.

menu will appear in each game to adjust a set of parameters to fit the best to the capabilities and needs of the subject.

In the Piano Game, some parameters regarding the execution of the game can be changed:

(i) Number of repetitions: this will determine how many times the user will have to play the piano keys in order randomly and the number of sets of sequences to remember.

(ii) Maximum time: this value will define maximum time period that is allowed without pressing a highlighted key, before a fail is registered and the game moves on to the next step. If this field is not filled, the game will wait as long as it takes until the current active key is pressed.

(iii) Number of keys to remember during each sequence.

Also, the visual appearance of the Piano Game can be modified making use of a series of sliders to accommodate it to each patient:

(i) Hands' height: this is the height at which the user feels comfortable (within the Leap Motion's detection area) to complete the exercises with the hands in the air over the device. Once the patient meets the right position, the virtual hands must be placed, making use of the corresponding slider, at a height from which the keys can be pressed by only bringing down each finger.

(ii) Distance between keys: this distance not only must be adjusted so the patient executes comfortably the exercises, but also it will define the dissociation degree between fingers.

(iii) Key thickness: this variable establishes how much surface each key will have, thus the area that the user can touch to press them.

(iv) Pressing height: while using the settings menu, a thin colored layer appears under the keys. When the keys are pressed and lowered until they make contact with this layer, a musical note is played, as it happens when playing a real piano. The pertinent slider can be regulated to set how much distance the key must move down to give the pressing action as valid and move on to the next one.

On the other hand, the rest of the games (RG, SG, GG, PG, and FG) can also be adjusted at performance and appearance levels:

(i) Number of cubes: the number of cubes shown on the screen is equivalent to the number of repetitions of each task, because the game will be completed when the exercise has been performed on each cube and all of them have fallen down to the virtual floor. In the case of bimanual exercises, the number of cubes will be double in order to match the same number of repetitions as in unilateral exercises, because each task will be executed on two cubes at a time (one target object with each hand).

(ii) Size of the cubes: it can be chosen between small, medium, and big. The therapist can choose among them with a view to the level of difficulty.

(iii) Depth scenario: it can be selected, depending on the protocol exercising of the patient, if the cubes appear at the same plane or at different depth distances. If it is decided to use deepness in the game, the patient will have to visually make depth discrimination and then flex and stretch the elbow to find the correct distance at which the cube is situated.

(iv) Static or motion cubes: cubes can be arranged at a fixed position in the screen or in motion, increasing the level of difficulty. In this last case, the speed of the movement can also be chosen.

(v) Number of cubes to remember during the Sequence Game.

(vi) With which finger or fingers it is valid to touch the cubes during the Reach Game: it can be selected between any combination of fingers, according to what is most appropriate for the patient's exercising. The target will be considered as reached just when it is touched with the virtual fingers which have been indicated in the settings.

(vii) Fist closing and opening degree in the Grab Game: since not all the users have the same physical condition, a patient can find it more or less difficult to perform the grabbing gesture depending on his pathology. For this reason, the therapist is able to set up the Grab Game to be played by both a healthy user and someone who cannot close the fist completely, validating a closure degree appropriate to the user's condition (representing "0" the hand completely open and "1" totally closed). It can also be modified according to the patient's progress or to the level of difficulty of each session.

(viii) Hand's spin in the Flip Game: when it comes to carry out the pronosupination task, the turning angle that the hand must turn during the game can be set. The values for the pronation and the supination exercises can be different between them.

These settings must be fixed before the game begins, but they can also be accessed during the exercises by pressing the settings button. This data will be registered in the user's CSV file in order to be contemplated in the patient's evaluation, but also it is useful to have them noted down in case if the exercises should be repeated under the same conditions. Although these options are available for the games, for the protocol established for the study of the Serious Games on patients with PD, it has been decided to maintain the same conditions for all the subjects and during all the sessions, so the data analysis according to patients and sessions was comparable.

4.3. Clinical Aspects Covered. These video games are focused on training different movements associated with daily activities. But in addition to the physical rehabilitation that is executed during each exercise and that were detailed before by each game, it has been noticed that all of them act at the same time at a cognitive and perceptive level. Table 1 summarizes the clinical aspects.

Relative to the cognitive aspect the following features are present during the games:

(i) Sustained and divided attention: users must be concentrated and follow the instructions that the game will give through text, images, and voice, all of them intending to facilitate the comprehension of the exercises.

(ii) Hand avatar: it is important that users, while playing, are able to identify and locate their virtual hands with respect to the other objects represented on screen.

(iii) Sequencing and short-term memory: during the games that include sequence memorization, users must remember the order in which the game has shown the sequence and replicate it just after it finishes.

(iv) Laterality: all the games take advantage of all the space that appears on the screen. The patient must be able to distinguish between the images that appear on the left, center, and right side of the screen. In unilateral exercises, the subject must reach the indicated object with the hand that corresponds on that turn, and in bilateral exercises the user must use each hand for the objects that appear on each side, respectively (i.e., objects on the left side of the screen must be reached by the left hand and vice versa).

(v) Executive function: it involves some cognitive processes, such as planning, organizing, or problem-solving that are required to properly perform the exercises, according to instructions the patients are given.

Regarding the perceptive factor, these video games contribute to the visuoperceptive coordination that integrate the movements of the hands and eyes and turn out to be vital in the activities performed day by day. A figure-background discrimination to hit the correct object, color discrimination which indicates targets, hits, and fails, and depth discrimination in order to find the correct position of the object to be reached is also required.

In order to compare the dexterity of each hand and its respective evolution, the exercises will be done unilaterally first with the hand less or none affected and then with the most affected. Following, in all games except in the Sequence Game, the same exercise will be performed bilaterally requiring the involvement of both hands and thus training the bimanual coordination.

4.4. Outcomes Storage. Rehabilitation with video games is currently intended to serve as a strong complementary tool to the traditional rehabilitation therapies. The inclusion of motion capture systems in the clinical activity provides the capability of automating some activities such as data gathering [36] and offers accurate information about the human skeleton, its joints, and their respective movements to be analyzed later by the therapist. In each one of the games created, the main variable that is recorded is the time. The partial and total times that the patient spends in each exercise are stored in a CSV file that can be easily imported into Excel, simplifying the evaluation of the results and the progress of the patients by the therapist. The user will have to fill in his details: name and surname, session number, most affected hand, and reason for the rehabilitation. This information will be stored in a CSV file named after the user's name so the results are always collected in the same file to make each patient's analysis easier. On the one hand, in the Piano Game the time that the user dedicates to press each of the keys is registered and, based on them, the average of the time spend with each finger of each hand is recorded at the end of the

TABLE 1: Clinical aspects covered by the SG according to cognitive, motor, and perceptive functionality.

		Piano Game PI	Reach Game RG	Sequence Game SG	Grab Game GG	Pinch Game PG	Flip Game FG
Cognitive	Sustained attention	X	X	X	X	X	X
	Divided attention	X	X	X	X	X	X
	Body image	X	X	X	X	X	X
	Sequencing	X		X			
	Short-term memory	X	X	X	X	X	X
	Problem resolution	X	X	X	X	X	X
	Executive function	X	X	X	X	X	X
	Laterality	X	X	X	X	X	X
Motor	Reaching		X	X	X	X	
	Fine motor unilateral and bilateral coordination	X					
	Gross motor unilateral and bilateral coordination		X	X	X	X	X
	Fine manual dexterity	X				X	
	Gross manual dexterity				X		
	Movement dissociation	X					
	Pronation and supination						X
	Flexion and extension				X		
Perceptive	Visuoperceptive coordination	X	X	X	X	X	X
	Figure-background discrimination	X	X	X	X	X	X
	Color discrimination	X	X	X	X	X	X
	Depth discrimination	X	X	X	X	X	X

Table 2: Demographics and health status of participants.

	Age	Gender	Affectation	Side	Taking medication
User 1	72	Male	Unilateral	Left	Yes
User 2	57	Female	Unilateral	Left	Yes
User 3	54	Female	Unilateral	Left	Yes
User 4	55	Male	Unilateral	Left	Yes
User 5	45	Male	Unilateral	Left	Yes

game, facilitating an immediate comparison between each fingers and both hands performances. On the other hand, in the rest of the games (i.e., RG, SG, GG, PG, and FG) the data recorded in the file is the time that the user takes to perform the corresponding task on each cube and the global time destined to play with each hand or both. In addition, in the Grab Game, the average degree of closure of the user's hand is computed (with "0" being the hand completely open and "1" being totally closed) and the game saves this data for its evaluation.

5. Feasibility Study

To evaluate the feasibility of the use of the LMC as the main capture device in a rehabilitation process, a pilot study was carried out at Asociación de Pacientes con Parkinson (APARKAN) in Alcorcón (Madrid). The main goal of the study was to validate the effectiveness of the proposed games in people in a mildmoderated stage of the PD. The pilot therapy was designed to improve the muscular strength, coordination, fine motor skills, and functionality of the upper limb in people with PD. Besides, one part of the study was focused on gathering the opinion of the participants, related to the satisfaction and the degree of adherence of them, in order to evaluate the usability of the system.

The present study obtained the favorable report from the Ethical Committee of Clinical Research of the King Juan Carlos University.

5.1. Pilot Trial Design

5.1.1. Participants. Five individuals with PD were chosen by medical professionals to participate in this study. Participants were selected according to the following inclusion criteria: subjects with PD who met the modified diagnostic criteria of the Brain Bank of the United Kingdom; subjects in stages II, III, and IV of Hoehn & Yahr scale; sex: men and women; stable or slightly fluctuating motor response to pharmacological treatment; not having received at the time of the study a specific treatment of rehabilitation of the upper limbs; signature of informed consent form.

The exclusion criteria were diagnosis of other diseases or serious injuries that limited occupational performance; patients with other types of parkinsonism than PD; cognitive impairment affecting the language comprehension ability to follow the instructions of the study evaluation tools; refusal to participate in the study; subjects in the evolutionary stage I or V of the Hoehn & Yahr scale; visual alterations not correctable with ocular devices.

Demographic data and health status of participants in the study are summarized in Table 2.

5.1.2. Treatment Protocol. Patients with PD improve their physical performance and activities of daily living through exercise, but there is no standardized exercise program for specific problems associated with PD [37]. Due to the flexibility and easy use mode of the SG presented in this paper, it is possible to make a treatment program to train different problems of motor function. The configuration of a specific treatment protocol can be seen as the pieces of a puzzle to be fitted together, according to the therapist criteria and the patient needs. Each piece of the puzzle corresponds to each video game (PI: Piano Game; GG: Grab Game; PG: Pinch Game; RG: Reach Game; SG: Sequence Game; and FG: Flip Game).

Considering the rehabilitation features (see previous Table 1) and the unilateral and bilateral training capability of each game, an appropriate game combination can be generated by therapist to deal with different cognitive, perceptual and motor problems.

The treatment protocol followed in this study is shown in Figure 4. Training with the LMC-based video games consisted of 2 sessions a week of 30 minutes each for 6 weeks (total of 12 sessions), with the presence of a healthcare professional throughout the process. All the participants received the treatment in sedestation, with a table at the height of the middle third of the trunk and with an initial elbows flexion of 90°. In those patients who required it, manual help was provided by the therapists on the most affected side. The difficulty of the exercises was increased as well as their number as the protocol progressed, always considering the particular needs of each patient and respecting rest periods to avoid fatigue.

5.1.3. Functional Assessment Method. Some standard clinical tests are used to evaluate the health condition of participants at the beginning (T0) and at the end (T1) of treatment. All participants were evaluated in the Laboratorio de Análisis del Movimiento, Biomecánica, Ergonomía y Control Motor (LAMBECOM) of the King Juan Carlos University (Madrid).

The primary outcome measure of this study was the variation between the initial (T0) and the final (T1) functional assessment, in order to quantify the effectiveness of the LMC-based training in people with PD. For that purpose, the evaluation used the following tools:

(i) Jamar handgrip dynamometer: it is an instrument to measure the maximum isometric strength of the hand

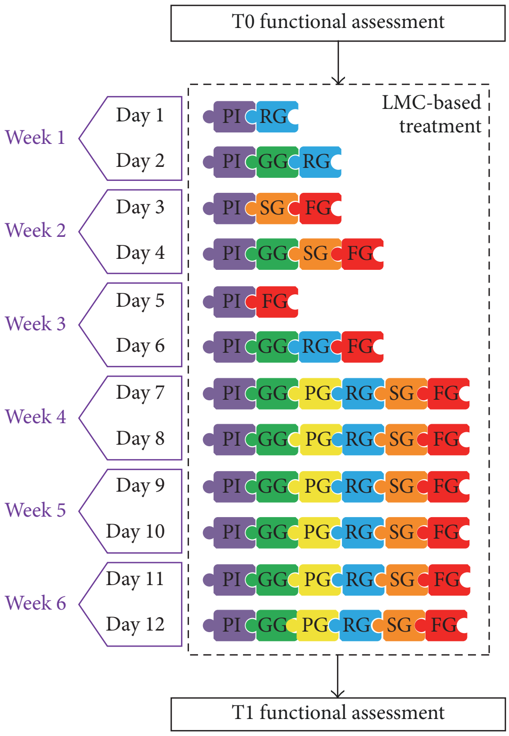


Figure 4: Treatment protocol scheme.

and forearm muscles. It consists of a sealed hydraulic system with adjustable hand spacing that measures hand grip force. The strength reading can be viewed as pounds or kilograms. The dynamometer is used for testing the hand grip force and for tracking the grip strength improvements during rehabilitation.

(ii) Box and Blocks Test (BBT): this test is used to measure unilateral gross manual dexterity in children and adults. It consists of moving the largest possible number of cubes from one compartment to another in a wooden box one by one for one minute. The results obtained in each extremity are compared. This manual procedure is automated in [36].

(iii) Purdue pegboard test: the purpose of this test is to measure unimanual and bimanual finger and hand dexterity. Initially it was used to evaluate finger skill and manual precision in the selection of personnel who had to carry out jobs that required fine dexterity and coordination for handling small parts. At present, it is used in the clinical environment to evaluate manual dexterity. It consists of four tests: the first one consists of inserting pegs on a board with the dominant hand; the second one is to insert pegs into the board with the nondominant hand; the third one is to insert pegs with both hands; and the fourth one is to perform an assembly test using both hands alternately.

Besides, the comparative between the functional assessment results and the video games outcome will give an idea of whether the video games outcome, by itself, can be a reliable indicator of the improvement of the physical condition.

5.1.4. Usability Testing. Secondary outcome measure was related to the user experience. Participants were invited to fill in a questionnaire for assessing the usability of the videogames. Questions were classified on three categories: utility, playability, and use mode. These games features were individually evaluated by each user, who expressed their opinions via a range of satisfaction scores, from −2 (strongly disagree) to +2 (strongly agree). Regarding the number of users for a proper usability assessment, five is a proper sample size for usability testing [38, 39].

5.2. Pilot Trial Results

5.2.1. Games' Outcome. The results obtained by the video games usage are shown in this section. On the one hand, the main outcome was the time spent to complete the exercises of each game. The average of the total time results of all users in each session is shown in Figure 5. Data are plotted according to the unilateral exercises (right or left arm) and the bilateral exercises (bimanual), including a trend line to observe the results tendency. The gaps in the curves are related to the treatment protocol, since not all the video games were used in all sessions, with the exception of the Piano Game.

In the case of Piano Game, it may be seen in Figure 5(a) that the curve corresponding to the left hand (orange line) is above the curve corresponding to the right hand (blue line). This implies that participants spent more time performing the exercises with the left hand, which is the affected hand. However, a decreasing trend is appreciated throughout the sessions.

The outcomes obtained with the Reach Game (Figure 5(b)) presents similar results for both the left and the right hand. The bimanual tasks required more time to be completed, as the curve in grey color illustrates.

In the case of Grab Game (Figure 5(c)), it can be seen that the unilateral exercises for the left hand (orange line) are very similar to the bilateral exercises (grey line). These curves are above the curve obtained with the right hand (blue line).

Data showed in Figure 5(d) are obtained by the Pinch Game. Very little variations among the values of the different sessions are observed in the case of the right and the left hand. Also, there is a remarkable variation with respect to the bimanual task that implies that the bimanual pinching task was more difficult than the unilateral one. This suggests that manual coordination was more impaired than the pinching function.

The results for the Sequence Game are shown in Figure 5(e). The measurements are very similar for both hands and it presents a clear decreasing trend. Since this video game is focused on the cognitive aspect, the results are related to a memory improvement.

Finally, in the case of the Flip Game (Figure 5(f)) the results obtained for both the right and the left hand are closely similar. Bilateral task spent more time as the line above the unilateral task shows.

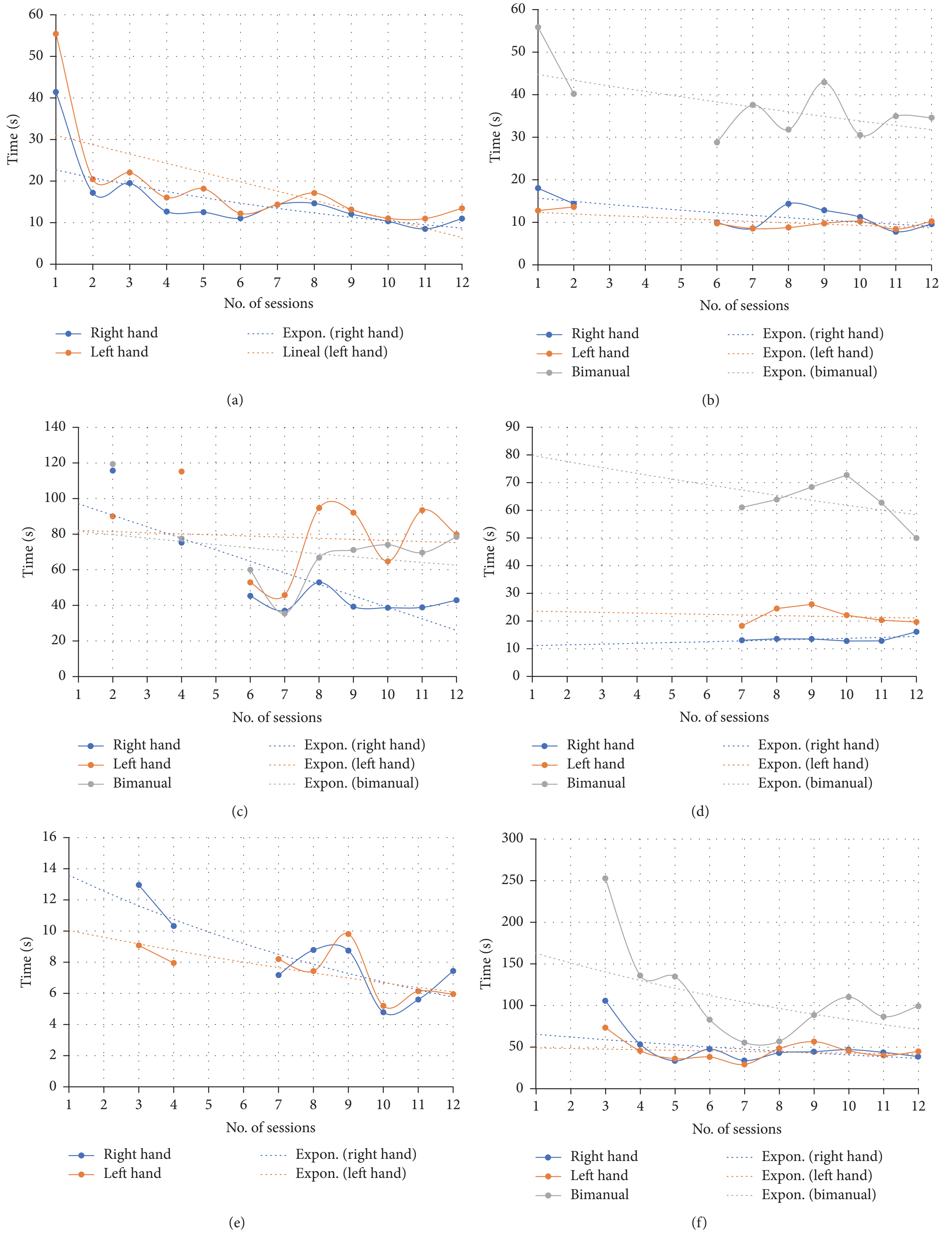


FIGURE 5: Mean of total time spent to complete the videogames tasks by sessions: (a) Piano Game, (b) Reach Game, (c) Grab Game, (d) Pinch Game, (e) Sequence Game, and (f) Flip Game.

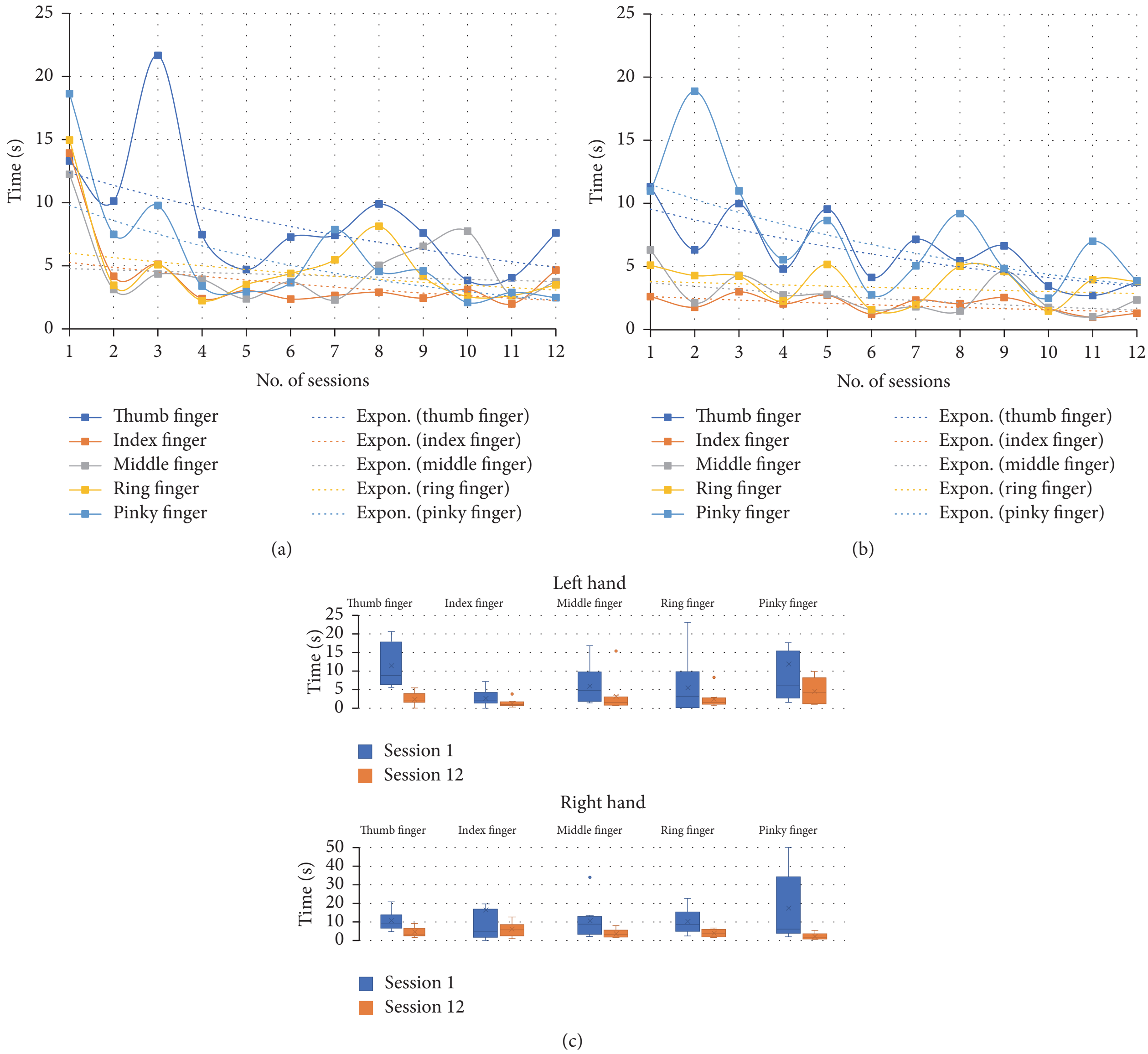


FIGURE 6: Results obtained in the Piano Game for the user 1: (a) time spent by fingers of the right hand, (b) time spent by fingers of the left hand, and (c) box plot of the partial times obtained in sessions 1 and 12, according to the left and right hand fingers.

On the other hand, other outcomes are the partial times that the patient spends to respond to a stimulus; for example, the time spent on reaching a cube in the Reach Game or pressing a key in the Piano Game. The partial time is counted from the moment the target is activated until the user "touches" it. The results obtained for user 1 in the Piano Game are shown in Figure 6. The averages of the total time spent by each finger, including unilateral and bilateral exercises, are shown in Figure 6(a) for the right hand and in Figure 6(b) for the left hand. It can be noted that the keys corresponding to both the thumb and the little finger requires more time than the rest when playing. Moreover, a box plot of the partial times obtained for the left and right hand fingers in sessions 1 and 12 is shown in Figure 6(c), to compare the user performance between the initial and final session. It can be appreciated that the data dispersion and the average in session 12 were reduced with respect to session 1. This suggests that the time of response of the fingers to a stimulus was improved in the participants.

5.2.2. Functional Assessment Results. With respect to measure the efficacy of LMC-based training in PD treatment, the improvements in terms of hand grip strength, and both gross, and fine manual dexterity are shown in Tables 3, 4, and 5, respectively.

In terms of hand strength, given by the Jamar dynamometer measurement, a significant increase was obtained in four patients for the unaffected hand, while one patient (User 3) obtained a slight negative value. In the case of the affected hand, four of the participants also presented a significant improvement in grip strength, while one of the participants (User 4) obtained a remarkable negative value (see the left

TABLE 3: Jamar handgrip dynamometer scoring in pounds (lb).

	Initial assessment		Final assessment		Variation	
	Right hand	Left hand	Right hand	Left hand	ΔRH	ΔLH
User 1	41,7	28,3	56,7	48,3	15,0	20,0
User 2	26,7	21,7	33,3	38,3	6,7	16,7
User 3	40,0	20,0	38,3	31,7	−1,7	11,7
User 4	120,0	106,7	121,7	98,3	1,7	−8,3
User 5	130,0	120,0	155,0	131,7	25,0	11,7

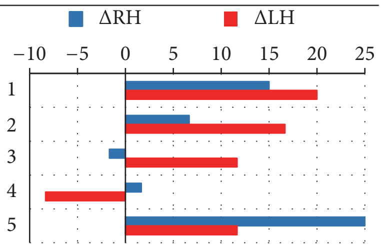


TABLE 4: Box and Blocks Test scoring.

	Initial assessment		Final assessment		Variation	
	Right hand	Left hand	Right hand	Left hand	ΔRH	ΔLH
User 1	32	27	49	40	17	13
User 2	39	40	46	47	7	7
User 3	46	42	55	44	9	2
User 4	42	35	49	45	7	10
User 5	43	35	55	48	12	13

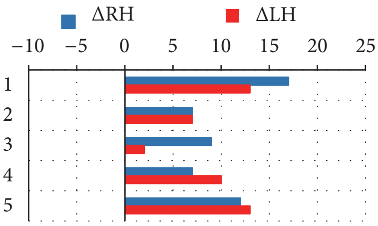
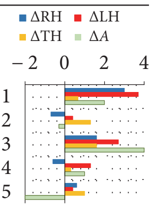


TABLE 5: Purdue Pegboard Test scoring.

	Initial assessment				Final assessment				Variation			
	Right hand	Left hand	Two hands	Assembly	Right hand	Left hand	Two hands	Assembly	ΔRH	ΔLH	ΔTH	Δ*A*
User 1	9	6,3	5	12,3	12	10	5,66	14,3	3	3,7	0,66	2
User 2	12	10,6	7,3	19,6	11,3	11	8,6	19,3	−0,7	0,4	1,3	−0,3
User 3	13	10,6	8	23,6	14,6	13,3	9,6	27,6	1,6	2,7	1,6	4
User 4	14,6	11	10,3	26,6	14	12,3	10,6	27,6	−0,6	1,3	0,3	1
User 5	14	12,6	9,3	31,3	14,6	13	10,3	29,3	0,6	0,4	1	−2



side figure in Table 3). The worsening in the results of user 4 can be attributed to a blow that he received in the left arm (affected side) days before the final evaluation and that caused him pain on the day of the evaluation.

Gross manual dexterity improved in all participants, according to the variation between T0 and T1 assessment in the number of the blocks that users were able to transfer by performing the BBT. As may be seen in the right side figure in Table 4, these variations in the number of blocks are very similar for both the left and the right arm of each patient, except for user 3 that is more remarkable.

The analysis of the Purdue scoring shows a general improvement by the fine manual dexterity and the eye-hand coordination (see right side figure in Table 5). It is noted that the fine manual dexterity is increased for the left hand (affected side) in all participants, while for the right hand (unaffected side) it was slightly reduced in the case of users 2 and 4. The bimanual tasks of the Purdue test require both hands coordination to be completed. Thus, the results of both the "two hands" and the "assembly" tasks revealed an improvement in the hand coordination for all participants, except for user 2 with a slight decrease and for user 5 with a more negative value in the "assembly" task.

5.2.3. Usability Results. User experience by using the proposed LMC-based video games was satisfactory. Questions were classified into three categories and the results are summarized in Table 6. On the one hand, the best results were obtained in both categories "utility" and "playability," with an average scoring of 1.68 and 1.64, respectively. Thus, the proposed video games were regarded as a useful tool to improve the independence of users in their daily living activities. The intuitive graphical design and the ease of playing were also highlighted. On the other hand, the "use mode" category obtained the worst results, with an average scoring of 0.96. Most of the participants agreed that bilateral tasks were more difficult than the unilateral ones. Bilateral exercises required more effort to be performed, and most especially in the Flip Game where some rest periods were necessary.

Table 6: Results of the usability questionnaires.

Number	Question	User 1	User 2	User 3	User 4	User 5	Mean	Mode
	Utility							
Q1	Are sessions with video games more entertaining?	2	2	2	0	2	1,6	2
Q2	Have the games been interesting to you?	2	2	2	1	2	1,8	2
Q3	Do the games meet a real need?	2	2	2	1	2	1,8	2
Q4	Would you continue use the games if you could?	2	2	2	0	2	1,6	2
Q5	Would you use the games at home?	2	2	2	0	2	1,6	2
	Playability							
Q6	Have the games been intuitive to play and easy to understand?	2	2	2	2	2	2	2
Q7	Have you been able to play without therapist's support?	−1	2	2	2	1	1,2	2
Q8	In case you have been helped, has the therapist's support been important?	2	2	2	0	2	1,6	2
Q9	Has the graphic design of the games been adequate (piano, cubes, etc.)?	1	2	2	2	2	1,8	2
Q10	Are the elements used in therapy sessions adequate (sensor leap motion, laptop)?	1	2	1	2	2	1,6	2
	Use mode							
Q11	Have you been able to perform all the games successfully?	1	2	1	2	2	1,6	2
Q12	Have single-handed exercises been simple to perform?	2	2	2	2	2	2	2
Q13	Have the exercises with both hands been simple to perform?	−1	2	1	−1	1	0,4	−1
Q14	Have the games taken a lot of effort from you?	−1	−2	−1	−1	1	−0,8	−1
Q15	In general, the difficulty level of the games is adequate?	2	2	1	1	2	1,6	2

6. Discussion

The most significant feature is the flexibility of the proposed games to define a specific therapy protocol that is easy to customize to the patients particularities. Another relevant characteristic, in addition to the capability to exercise, is the potential of the proposed system as an assessment tool, taking into account the results shown in the previous section. Data for completion times (see Figure 5) has been compared with the traditional tests of manual dexterity: Purdue Pegboard Test and Box and Blocks Test. The decreasing times gathered in each session by the SG are coherent with the improvement of the physical condition of the patients, measured by the traditional tests. Although the measured times are influenced by the sensitivity of the sensor and the conditions of fatigue and mood of the users, the obtained results show a clear downward trend. This fact is consistent with the appreciation obtained by the classical metrics.

On the one hand, the improvement in the fine manual dexterity evaluated by the first part of the Purdue test presents a clear correspondence with the decrease of the average times in completing the game of Piano Game and Pinch Game. The gross manual dexterity trained mainly by the Grab Game and Piano Game has been also improved, according to the BBT results. The results obtained in bilateral execution of all the games that require bimanual coordination are consistent with the ones obtained in the second part of the Purdue test that cover this issue by means of the assembling task.

On the other hand, the fact of moving and holding the arms entails activation of the set of intrinsic and extrinsic muscles of the forearm. The training of these muscles is related to the recovery of hand strength and ability to grasp. This training of the forearm is especially enhanced by the Flip Game, thanks to pronation and supination movements. A continued and more or less intense use of the games could be related to the recovery of force measured in all the users by means of the Jamar handgrip dynamometer.

Finally, PD is extremely challenging so future technological developments could include machine learning methods to automate the rehabilitation process using LMC, by adapting the levels of difficulty and exigency of the exercises based on the subject's performance and other factors (such as fatigue, errors and success rate); serving as a complementary tool to the therapist's supervision. Additionally, there is a real challenge related to the acceptance of new technologies by the elderly population. Knowledge of the user is as important as system functionality, since without the user's cooperation, functionality may be ineffective. In this regard, a satisfaction survey was designed for gathering the impressions of participants to assess the acceptance of the proposed games, taking into account different aspects such as usability, playability, and use mode. Although, in general, the proposed video games were positively valued by participants and clinicians, the survey scores revealed the need to enhance the use mode. So, future studies should consider the effort, the difficulty, and the kind of tasks in order to facilitate the acceptance of these LMC-based video games and the integration of these technologies in a holistic rehabilitation context.

7. Conclusions

Despite the outcomes of the LMC-based video games were different among the training sessions, a clear decreasing trend is found throughout the treatment protocol. The improvement of health condition of participants was validated by the clinical assessment tools. The correlation between the decreasing trend and the increase in the health condition validates the video game outcomes as an indicator of improvement. This approach requires more trials to be consolidated, but it is encouraging. The influence of the mood of participants and the reliability of data acquisition must be considered also.

The Serious Games implemented in this work are a versatile tool in rehabilitation processes, since different functional problems can be treated according to the configuration defined by the therapist. Different treatment protocols can be created in an easy way.

Based on the user experience, the use of the LMC-based video games in the treatment of Parkinson's has been favorably accepted. The utility and playability of the games have been highlighted by the users; however there are certain exercises that have been difficult to perform and required the help of the therapist or breaks. This situation should be taken into account by the therapist to define a home treatment program.

Although the number of patients is not sufficiently representative to give a clinical validity to the obtained results, it is nevertheless convincing about the effectiveness of the use of these games for a double function, as an evaluation method as well as a complementary rehabilitation instrument; and it is also supported by the user experience.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Acknowledgments

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CHAPTER 8

Clinical Validation of Serious Games

8.1 Overview

This chapter presents the in-depth clinical validation of the effects of the therapy based on serious games for the improvement of upper limb functioning. This study focuses on analysing the significance, from the clinical perspective, of the functional improvements derived from the use of the implemented intervention tool.

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Q1 (4/65) in Rehabilitation; **Q1** (16/80) in Engineering, Biomedical; Q2 (97/267) in Neurosciences.

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RESEARCH

Leap motion controlled video game-based therapy for upper limb rehabilitation in patients with Parkinson's disease: a feasibility study

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Abstract

Background: Non-immersive video games are currently being used as technological rehabilitation tools for individuals with Parkinson's disease (PD). The aim of this feasibility study was to evaluate the effectiveness of the Leap Motion Controller® (LMC) system used with serious games designed for the upper limb (UL), as well as the levels of satisfaction and compliance among patients in mild-to-moderate stages of the disease.

Methods: A non-probabilistic sampling of non-consecutive cases was performed. 23 PD patients, in stages II-IV of the Hoehn & Yahr scale, were randomized into two groups: an experimental group (n=12) who received treatment based on serious games designed by the research team using the LMC system for the UL, and a control group (n=11) who received a specific intervention for the UL. Grip muscle strength, coordination, speed of movements, fine and gross UL dexterity, as well as satisfaction and compliance, were assessed in both groups pre-treatment and post-treatment.

Results: Within the experimental group, significant improvements were observed in all post-treatment assessments, except for Box and Blocks test for the less affected side. Clinical improvements were observed for all assessments in the control group. Statistical intergroup analysis showed significant improvements in coordination, speed of movements and fine motor dexterity scores on the more affected side of patients in the experimental group.

Conclusions: The LMC system and the serious games designed may be a feasible rehabilitation tool for the improvement of coordination, speed of movements and fine UL dexterity in PD patients. Further studies are needed to confirm these preliminary findings.

Keywords: Virtual reality; Non-immersive video games; Leap Motion Controller; Parkinson's disease; Upper limb; Dexterity

Introduction

The second most common neurodegenerative disorder, after Alzheimer's disease, is Parkinson's disease (PD), which is prevalent in approximately 1% of people aged 60 years or older [1,2]. This disorder, which predominately impairs motor function, affects 1-5% of individuals aged 65-69 years of age and 1-3% of those above 80 years of age. The cardinal symptoms are: *bradykinesia*, defined in part by James Parkinson as being "lessened muscular power", and which manifests as slowness of movement; *rigidity*, defined as an increased muscular tone when the limb is passively moved and which is usually experienced as a sense of feeling stiff and uncomfortable; *resting tremor*, defined as a repetitive back-and-forth movement of any limb, which occurs when that part of the body is not actively moving; and *postural instability*: which refers to an impaired reaction when balance is perturbed. Additionally, patients with PD typically suffer from a wide range of motor and non-motor problems [3]. These signs and symptoms impair the performance of their daily activities, reducing their level of independence. At present, there is no curative treatment for PD, rather, treat-

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ments are focused on the symptoms and prevention of the progression of the disease [4,5].

Throughout the various stages of PD, impaired dexterity is among the most frequently reported disturbing symptom and a major contributor to the burden of the disease [6]. Dexterity deficits impair typical activities of daily living and may be present even in mild to moderate stages of PD. Patients with PD become dependent on caregivers because their motor and cognitive disabilities interfere with their ability to perform daily activities [6].

Scientific evidence to date supports the benefits of rehabilitation treatment in PD [7,8]. In the field of neurorehabilitation, technology-based rehabilitation systems, such as virtual reality (VR), are promising and may be able to deliver a client-centered task-oriented rehabilitation. Several studies have addressed the positive effects of VR systems as being a complementary therapy to neurological rehabilitation [9]. These systems are based on computer-based technology that allows users to interact with simulated environments and receive feedback on performance within real-time scenarios, therefore providing the opportunity to perform functional and repetitive activities, facilitating motor learning and neuroplasticity through increased intensity during task-oriented training [9].

Video games based on VR technology are emerging as valid tools used in neurorehabilitation for patients with neurological disorders, and as a low cost and easily accepted adjunct to traditional therapy. Standard games such as the Nintendo Wii, Playstation Move and Kinect plus XBOX 360 have been used in PD rehabilitation. However, often these are either too difficult for patients or the games progress too quickly, failing to provide impairment-focused training or specifically address patients' needs [10]. Therefore, it is necessary to develop specific serious games for PD patients. Serious games are defined as games designed for a primary purpose other than that of pure entertainment, and which promote learning and behavior changes for PD patients.

In this context, new low-cost markerless devices have emerged, such as the Leap Motion Controller (LMC) System®, which uses a sensor that captures the movement of the patient's forearms and hands without the need to place sensors or devices on the body. This generates a virtual image of the upper limbs on a computer screen and the patient is prompted to perform movements according to the functional task proposed. This system presents important advantages over other motion capture systems, namely thanks to its portability, ease of use, commercial availability, low cost and non-invasive nature. However, evidence is lacking that supports the therapeutic use of LMC in the treatment of upper limb (UL) motor disorders in PD. Furthermore, to our knowledge, no specific serious games have been designed for PD patients using the LMC system.

Therefore, the primary aim of the present study was to evaluate the effectiveness of the LMC system using serious games designed for improving UL grip muscle strength, coordination, speed of movements and fine and gross dexterity. Furthermore, we sought to assess satisfaction and compliance levels among those in mild-to-moderate stages of the disease.

Materials and methods

Participants

All patients were recruited from the Association of Patients with PD Aparkam in Alcorcón (Madrid, Spain). Non-probabilistic sampling of non-consecutive cases was performed. The inclusion criteria were: patients with PD who fulfilled the modified diagnostic criteria of the Brain Bank of the United Kingdom; patients in stages II, III and IV of the Hoehn & Yahr scale; $> 60\%$ Schwab & England functionality scale; patients whose motor response to pharmacological treatment was stable or slightly fluctuating, and who were not receiving specific UL rehabilitation treatment at the time of the study. The study exclusion criteria were: the diagnosis of diseases other than PD or serious injuries affecting the UL; the inability to understand instructions and actively cooperate in the tasks indicated based on a score ≥ 24 in the Mini-mental Test; refusal to participate in the study; stages I or V of the Hoehn & Yahr scale; and visual impairment not correctable by glasses.

Procedure

The sample was randomized into two groups: an experimental group, who received UL treatment based on serious games designed by the research team, using the LMC system; and a control group, who received a specific UL intervention based on conventional physical therapy (based on shoulder, elbow, wrist and finger mobilization, strengthening of UL extensor muscles, stretching exercises for UL flexor muscles) [7,8] and with functional task practice trying to imitate the movements of the serious games designed for the experimental group (– i.e. reaching movements, dexterity, grasping and pincer grasp movements using objects of daily living, such as coins, keys, balls, cups, plates-).

This protocol was approved by the local ethics committee of the Rey Juan Carlos University. Informed consent was obtained from all participants included in this study.

All groups received the intervention at the Aparkam Association, between May and July of 2017. Both the experimental group and the control group received two

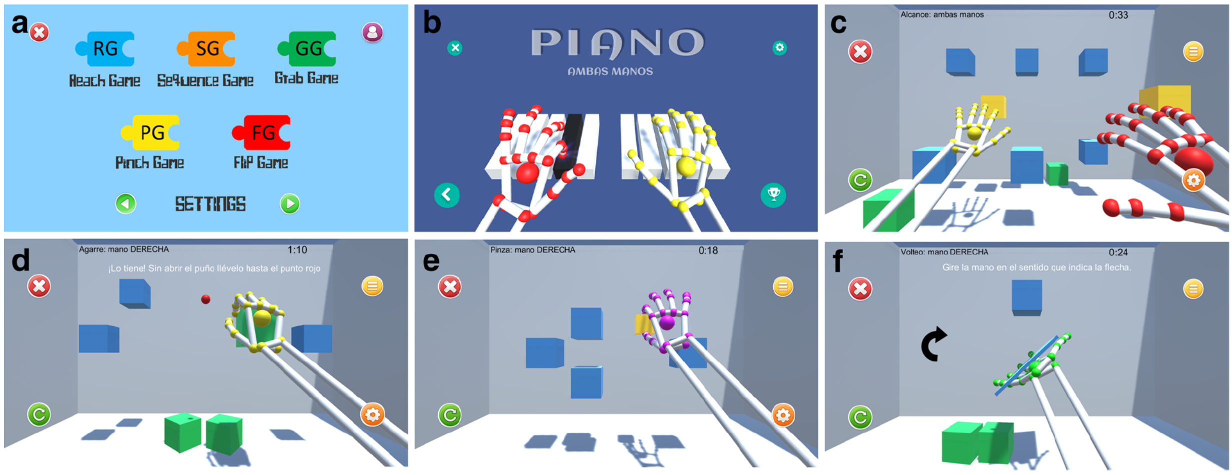

Figure 1 Serious games designed for the Leap Motion® System. *Serious games used on protocol: a) Games Menu, b) The Piano Game, c) The Reach Game, d) The Grasp Game, e) The Pinch Game, and f) The Flip Game

30 minute sessions per week over a six-week period (a total of 12 sessions for each group). A physical therapist was present throughout the process. The experimental group used the LMC system while seated at a table placed at mid-trunk height and with the elbow placed at an initial 90° elbow flexion. When necessary, manual assistance by the physical therapist was provided on the patient's most affected side.

The serious games performed in this study aimed to imitate exercises and movements commonly included in conventional rehabilitation, such as palmar prehension, finger flexion and extension or hand pronation-supination (Figure 1). Patients performed six games: the Piano Game (PI), the Reach Game (RG), the Sequence Game (SG), the Grasp Game (GG), the Pinch Game (PG) and the Flip Game (FG). Each of these games was based on a different rehabilitation goal.

Description of the video games

A set of video games was developed, aimed at UL motor rehabilitation. The Leap Motion sensor was used to capture the users' hand movements and different virtual environments were created using Unity3D Game Engine software. In total, six video games were developed: the PI, the RG, the SG, the GG, the PG and the FG. Each game focused on different rehabilitation purposes, based on requirements and guidelines suggested by clinical experts on PD neurorehabilitation. The games were performed firstly unilaterally (each hand separately) and then bilaterally (both hands at the same time). The user interface allows therapists and patients to easily navigate through the games. For this purpose, the instructions are given clearly and precisely via texts and audio cues. It has been described that individuals with PD may move more quickly or easily when their actions are in response to environmental stimuli (i.e., exogenously evoked) than when their actions are spontaneous and self-initiated (i.e., endogenously evoked) [10], so using this task switching paradigm, visual and acoustic cues were given to the patients to incite the specific movements on each game. A full description of these games is provided in a previous study [11]. However, the main features and procedures of the video games are described below:

PI: This video game features a virtual piano keyboard with ten keys, each corresponding to a single finger on each hand (see Figure 1-(b)). The user is encouraged to play each piano key with the corresponding finger. During the game, the required key to be pressed lights up. The keys are lit up first in an ordered sequence, from the little finger to the thumb, and then in a random sequence. Each key that is correctly pressed is recorded and a point is added to the score. Higher scores equal better performance of the game.

RG: In this game, several cubes are shown in different spatial positions, placed within the reaching range of the user's upper extremity (see Figure 1-(c)). A highlighted cube indicates the target to be touched. When the user reaches the cube, it falls to the floor of the virtual scene. To complete the game, the user must reach all cubes.

SG: This game uses the same set-up as the Reach Game. A sequence of cubes is presented to the user, who must memorize the sequence and repeat it by reaching the cubes in the same order shown.

GG: This game encourages the user to perform finger flexion and extension movements, similar to grasping movements. A series of cubes are shown, including a red circle in the center of the screen (see Figure 1-(d)). When a cube is highlighted, the user must grasp the cube and move it to the red circle while keeping their fist closed. The cube may only be released when it touches the red circle.

PG: The purpose of this game is to train bidigital grip via the performance of a pinching movement between the thumb and the index fingers. As in the previously explained games, a set of spatially distributed cubes are presented to the user, (see Figure 1-(e)). When a cube is highlighted, the user must place their hand near the target cube and make the cube smaller, using a pinching movement, until the cube disappears.

FG: This game trains pronation and supination movements of the forearm. The user must place the palm of the hand over the Leap Motion device imitating a waiter holding out a tray (Figure 1-(f)). A small tray with a cube in the middle appears in the center of the screen. The patient should then turn the palm downwards. Upon doing so, the cube detaches from the tray and falls to the ground (Figure 2).

Figure 2 A Parkinson's disease patient practicing a video game based on cubes (Flip Game).

The games are easy to customize according to the patients' needs and skill level. The settings can be defined by therapists at the beginning of the training session, or during the performance of the video game. The physical appearance of the piano keyboard can be adjusted by using slider controls in order to better accommodate the game to each patient. These sliders are used to modify the keyboard properties, such as the distance between keys (defining the degree of dissociation between fingers), the width of each key (allowing a large or small contact area), the height required for pressing each button (depth that the user must push the key), or the keyboard height. The latter is a particularly relevant feature as it allows therapists to first identify the optimal hand position (the hands are placed in the air over the device) that the user is comfortable with, and then the keyboard can be moved up or down until it is in contact with the virtual hands.

Overall, the remaining games (Reach Game, Sequence Game, Grab Game, Pinch Game, and Flip Game) can also be adjusted for performance and appearance. The settings options include: (1) the number of cubes, which is related to the number of repetitions of each task; (2) the size of the cubes, by choosing among small, medium, or large sizes; and (3) the number of cubes for users to remember during the Sequence Game.

The information obtained in each session can be automatically stored in the patient's record in a format that medical staff can easily handle in order to perform their evaluations. In this way, CSV files easily match the specifications required and its content can be effortlessly managed. Conversely, it is possible to access an updated report of each patient, allowing the physician to remotely supervise the patient's progress. The record of each patient is identified by a code, to guarantee privacy.

Therefore, different interventions can be designed by combining two or more games that focus on a specific pathology and patient population. The protocol used in this study is shown in Figure 3. As the patient progresses, the difficulty and number of the exercises increases. Rest periods are built in depending on the individual patients' needs.

All measurements were performed at the Movement Analysis Laboratory located at the Health Sciences Faculty of the Rey Juan Carlos University. Two evaluations were conducted: pre-treatment and post-treatment. The intervention and all tests were performed within two hours of administration of anti-Parkinsonian medication, during the "on" phase of the medication cycle, as this is the period during which patients perform most of their daily activities.

Outcome measures

A Jamar® hydraulic hand dynamometer was used to measure grip strength. This dynamometer offers accurate and repeatable grip strength readings scaled in pounds and kilograms. All the patients performed three grip movements, and the mean values were recorded. The data for the less and more affected sides were recorded in kilograms. The Jamar® hydraulic hand dynamometer is one of the most used objective tools to assess grip strength, being considered a device of excellent reliability, sensitive, and ease of use. It is recommended by the American Society of Hand Therapists and by the Brazilian Society of Hand Therapists [12]. The Box and Blocks Test (BBT) was performed

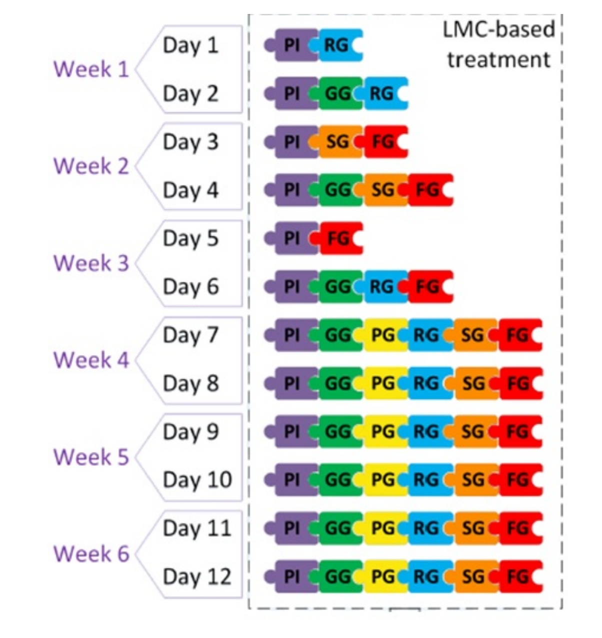

Figure 3 Experimental protocol.*PI: Piano Game; GG: Grasp Game; PG: Pinch Game; RG: Reach Game; SG: Sequence Game; and FG: Flip Game

to measure unilateral gross manual dexterity in both the less and more affected side. The BBT consists of moving the maximum number of blocks from one compartment of a box to another, one by one, within one minute. The BBT is a quick, simple, and reliable measurement of manual dexterity. Its administration procedure is standardized and its validity has been shown in elderly subjects with upper limb disability [13,14].

The Purdue Pegboard Test (PPT) was used to assess coordination, speed of movement and fine motor dexterity. The PPT features a board with two columns with 25 holes each and a specific number of pins, washers and collars placed in four containers across the top of the board. The test consists of inserting as many pins as possible in three distinct phases, with a time limit of 30 seconds for each. First, the test is performed with the less affected side, then with the more affected side, then with both hands at the same time and, finally, an assembly test is performed (60 seconds). The number of pins inserted is subsequently recorded. The PPT is a reliable assessment to evaluate manual dexterity in PD patients [15,16].

The Client Satisfaction Questionnaire (CSQ-8) evaluates the satisfaction of health service users. This is a self-administered post-treatment questionnaire, comprising eight items which evaluate the level of satisfaction regarding the care and quality of the service received and the level of fulfillment of the patient's expectations regarding the treatment administered. The total score of the questionnaire is 32 points, with higher values meaning higher satisfaction with the treatment received [17,18].

Additionally, we recorded the attendance rate (%) for therapy sessions (compliance).

Statistical analysis

The statistical analysis was performed using the SPSS statistical software system (SPSS Inc., Chicago, IL; version 22.0). The Shapiro Wilk's test and the Kolmogorov-Smirnov test were used to screen all data for normality of distribution. Additionally, the Wilcoxon test for related samples and the Mann-Whitney test for non-related samples were used for to compare variables. The statistical analysis was performed with a 95% confidence level, and significant values were considered as $p < 0.05$. We used the mean and the standard deviation of parameters to calculate de effect size for the comparisons using the Cohen's d statistic. Mean differences of 0.2, 0.5, and 0.8 standard deviations are considered 'small', 'medium', and 'large' effect sizes respectively.

Results

The sample consisted of a total of 23 patients, 11 male and 12 female, of the 26 selected at the study onset. Three subjects were excluded due to an inability to attend the assessment and/or treatment sessions. The age of the patients ranged from 45-79 years (mean age 66.65 $\pm$ 10.14 years). In 15 patients, the more affected side was on the left, whereas the right side was the most affected for the remaining eight patients. The Schwab and England scores of patients ranged from 100 to 60% of independence (73.50 $\pm$ 12.25%). The patients were randomly assigned into two groups, 12 of whom were assigned to the experimental group while 11 were assigned to the control group (Table 1). Within-group and intergroup statistical analysis are summarized in tables 2 and 3.

The within-group statistical analysis for the experimental group showed significant improvements in all post-treatment assessments, except for the BBT on the less affected side. Significant improvements were observed on the Jamar for the more affected side (p=.003) and the less affected side (p=.005); the BBT for the more affected side (p=.014); the PPT for the more affected side (p=.003), the PPT for the less affected side (p=.009), the PPT both hands (p=.005) and the PPT assembly (p=.003) (Table 2). The effect size was large (> .80) for Jamar (more affected side) and PPT assembly; and medium (> .50) for PPT (both sides) (Table 4). Clinical improvements were observed for all assessments in the control group, but statistical significance was only reached for the PPT on the more affected side (p=.024) (Table 3). According to the statistical intergroup analysis, no significant difference was observed between either of the two groups in terms of baseline clinical characteristics. In the experimental group, significant improvements were found for the PPT on the more affected side (p=.036) and the PPT assembly (p=.006) post-treatment, when compared to the control group (Table 4). The effect size was large (> .80) for the PPT assembly (Table 4).

The CSQ-8 showed a high degree of satisfaction for both groups. The experimental group obtained a mean of 29.6 (1.51) points and the control group obtained a mean of 28.75 (.5) points out of the maximum of 32. Of the eight items considered by this questionnaire, the entire sample gave the maximum score in response to questions N° 4 (If a friend were in need of similar help, would you recommend our program to him or her?) and N° 7 (In general, are you satisfied with the services you have received?). The experimental group also gave the maximum score for N° 1 (How do you evaluate the quality of the service you received?) and the control group also gave the maximum score for N° 5 (Are you satisfied with the help you have received?) and N°8 (If you were to seek help again, would you come back to our program?). None of the participants expressed disagreement or dissatisfaction in response to the remaining questions (Table 5). Furthermore, compliance to the interventions was excellent (100%) and no adverse side-effects were observed for both groups.

Discussion

Parkinson's disease affects millions of people worldwide. Since the disease strongly influences the quality of life of patients, raising the burden of care and the costs for society, optimal solutions for the treatment of PD are needed [9,19]. Serious games based on the LMC system present promising tools for UL neurorehabilitation in people with PD. The purpose of this study was to evaluate the effectiveness of the LMC system using serious games specifically designed for the UL in people with PD in mild-to-moderate stages of the disease. In the experimental group, significant improvements were observed in all post-treatment assessments, except for the BBT on the less affected side. For the control group, statistical significance was observed for the PPT on the more affected side. However, according to the statistical intergroup analysis, significant improvements were found for the PPT on the more affected side and the PPT assembly post-treatment in the experimental group, with an excellent satisfaction and compliance.

Our results suggest an improvement in UL coordination, speed of movements and fine dexterity using the LMC system. These findings are in line with previous studies. Allen et al. [20] showed that PD patients improved UL speed of movements compared to the control group after using the Unity game development software and measured with the Nine Hole Peg Test (NHPT), considered as a gold standard measure of manual dexterity. The sessions were performed at home, three times a week, for twelve weeks. Two of the games developed in this study (the 'marshmallow' game and the 'chicken' game) focused on UL movements. These two games were played in the same session and thus the patients played each game twelve times. Participants were provided with auditory and visual feedback during both games to assist them and improve their performance. Upon completion of each game participants received feedback on their overall performance, including information about the number of successes, the number of errors and an overall score. Scores were adjusted according to the level of difficulty, so that higher scores were achieved when playing at a more difficult level. Each game had four levels of difficulty to choose from: easy, medium, hard and extreme.

No differences were observed for the other measures used in this study. This may indicate that 12 sessions of semi-immersive VR using the LMC system and the serious games designed for this study may be insufficient for improving UL grip strength and gross dexterity. However, improvements were found for the experimental group in all post-treatment assessments. These positive results may indicate that LMC could be an interesting tool for the UL rehabilitation of PD patients in the mild to moderate stages of the disease, however further studies are needed with longer training periods and a larger sample size.

To our knowledge, there is a lack of published studies that have used the LMC system or any other markerless motion capture system for training functional UL skills in PD. However, several authors have used these devices in other neurological diseases. Iosa et al. [21] developed a pilot training protocol based on the LMC for stroke rehabilitation. A crossover pilot trial was conducted in which six sessions of 30 minutes of the LMC system were added to conventional therapy. This trial showed improvements in hand abilities measured using the Abilhand Scale and grasp strength measured using a dynamometer. Our results differ with the aforementioned study by suggesting that the design of the proposed protocol and the intrinsic conditions of the serious games designed do not improve grip muscle strength. Wang et al. [22] measured the improvements in functional abilities using the Wolf Motor Function Test in a sample of stroke patients after a Leap Motion-based VR training compared with conventional therapy. In the experimental group, patients were given

Leap Motion-based VR training for 45 minutes, once a day, five times a week for four weeks, as well as conventional occupational therapy for 45 minutes, once a day, five times a week for four weeks. In the control group, the patients only received conventional occupational therapy training twice a day, each for 45 minutes, five times a week for four weeks. Their results showed that both groups obtained significant improvements in the motor function of the affected ULs and in the action performance time, however the improvements were greater in the experimental group. Our results also showed post-treatment improvements on the more affected side. Vanbellingen et al. [23] observed that improvements in dexterity in stroke patients could be due to an intensive, highly repetitive and task-specific training with LMC assessed with NHPT. The intervention consisted of nine 30 minutes training sessions spread out over a three week period, i.e. three training sessions per week. Our results are line with this study.

The LMC system has also been used as an assessment tool for other motor symptoms of PD, such as tremor. Hironobu and Masashi [24], attempted to measure tremors using the Leap Motion sensor. The purpose was to detect hand motion, which made it possible to measure tremors in the hands without touching them. Chen et al. [25] developed a rapid, objective, and quantitative system for measuring severity of finger tremor to quantify frequency and amplitudes using the LMC system. Butt et al. [26] evaluated motor dysfunction in PD patients, such as slowness of movements, frequency variations, amplitude variations, and speed. In our study, we have not used LMC as an assessment tool for the UL in PD patients. Further studies should include this technology as a quantitative method, in order to provide more accurate parameters for the evaluation of UL motor impairments.

This motion capture rehabilitation method using serious games may be used to treat the UL disorders of PD patients by performing functional exercises in a virtual environment. Moreover, immersive virtual environment attempts to engage the patient to the point of not focusing on the fact of being in a rehabilitation session. Our findings show that the experimental protocol designed for UL rehabilitation in PD is feasible with an excellent satisfaction. Furthermore, all patients completed the protocol with excellent compliance. This is in accordance with other virtual reality studies in which the performance of functional tasks with increasing difficulty and interactive video game environments are shown to enhance motivation and adherence to treatment [9]. These findings, added to the low cost of this semi-immersive VR system, could contribute to the acceptance of this kind of technological treatment as a complementary tool for UL rehabilitation in PD patients.

These results, in terms of the CSQ-8, showed a high level of satisfaction among participants. These data are comparable to Iosa et al. [21] who employed the Pittsburgh Rehabilitation Participation Scale to assess participants' satisfaction. This study provided a proof of concept that, with a high level of active participation, the LMC system may be a suitable tool, even for elderly patients with subacute stroke. Our results showed an excellent satisfaction with both interventions, with higher values for the LMC treatment.

Limitations

Although our findings are encouraging, some limitations of our study should be noted. First, the results cannot be generalized for all patients with PD, therefore it is necessary to interpret these findings with caution. Our sample was limited to people with PD in mild-to-moderate stages of the disease. Moreover, the sampling methods could have resulted in a selection bias. Additionally, the use of different outcome measures may have resulted in more significant results (such as NHPT and Action Research Arm Test). Further randomized controlled trials with larger samples, follow up assessment, in order to evaluate side effects, and more intensive dosage are required to verify these results.

Conclusion

The LMC system and the serious games designed and used in this study represent a rehabilitation tool that may benefit certain PD patients for the improvement of coordination, speed of movements and fine dexterity in UL interventions. This system presents important advantages over other motion capture systems, namely thanks to its portability, ease of use, commercial availability, low cost and non-invasive nature. Future studies are necessary to further research and verify the outcome of this tool and to determine whether there is an ideal patient type who may benefit more from these interventions.

Abbreviations

Box and Blocks Test (BBT); Client Satisfaction Questionnaire (CSQ-8); Flip Game (FG); Grasp Game (GG); Leap Motion Controller (LMC); Nine Hole Peg Test (NHPT); Parkinson's disease (PD); Piano Game (PI); Pinch Game (PG); Purdue Pegboard Test (PPT); Reach Game (RG); Sequence Game (SG); Upper limb (UL); Virtual reality (VR)

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Authors' contributions
AJ, EDO, CB designed the experimental protocol. JMP, SCV recruited the patients. PFG, MCT, EMP, PSHB, ACG, RCC, FMR performed the treatments. JMP, SCV performed the assessments, PFG, ACG, SCV analyzed the data. PFG, MCT, EMP, PSHB, ACG, RCC, SCV, FMR, AJ, EDO wrote the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials
All the data and materials could be found at Faculty of Health Sciences of Rey Juan Carlos University.

Ethics approval and consent to participate
The study was approved by the Human Ethics Committee of the Rey Juan Carlos University.

Consent for Publication
Consent to publish was obtained from all the participants

Competing interests
The authors declare that they have no competing interests.

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Table 1 Patient features

Groups (n)	Age (years) Mean (± Standard deviation)	Gender	Hoenhn & Yahr	More affected side	Schwab and England score (%) Mean (± Standard deviation)
Experimental group (12)	65.77 (±7.67)	6 Male 6 Female	II (5) III (6) IV (1)	3 Right 9 Left	73.33 (±12.24)
Control group (11)	67.36 (±12.12)	5 Male 6 Female	II (6) III (4) IV (1)	5 Right 6 Left	73.63 (±12.86)

Table 2 Outcome scores (experimental and control groups)

Variable			Experimental group		Control group	
			Median (IR)	p-value	Median (IR)	p-value
Jamar	More affected	Pre	14.66 (9.00)	.003*	18.66 (14.66)	.123
		Post	27.33 (17.33)		19.66 (12.83)	
	Less affected	Pre	19.33 (15.67)	.005*	20.00 (11.50)	.944
		Post	26.33 (28.00)		24.00 (9.67)	
BBT	More affected	Pre	42.00 (23.00)	.014*	39.00 (17.50)	.293
		Post	46.00 (12.00)		45.00 (8.50)	
	Less affected	Pre	46.00 (26.00)	.090	48.00 (16.00)	.141
		Post	49.00 (13.00)		49.00 (11.00)	
PPT	More affected	Pre	8.00 (4.33)	.003*	8.66 (3.67)	.024*
		Post	12.33 (8.33)		9.66 (3.00)	
	Less affected	Pre	9.00 (5.00)	.009*	10.00 (3.50)	.248
		Post	11.66 (5.00)		10.50 (2.50)	
PPT both hands		Pre	8.66 (3.33)	.005*	10.66 (7.67)	.722
		Post	10.33 (8.00)		12.00 (6.33)	
PPT assembly		Pre	12.66 (13.66)	.003*	14.66 (7.67)	.237
		Post	23.66 (13.67)		16.00 (4.17)	

BBT: box and block test; PPT: Purdue Pegboard Test. Data are expressed as median and interquartile range (IR). *p value < 0.05 using the Wilcoxon test for related samples

Table 3 Comparison of outcome scores between the experimental group and the control group

Variable			Median (Interquartile range)		p-value
			Experimental group	Control group	
Pre	Jamar	More affected	14.66 (9.00)	18.66 (14.66)	.648
		Less affected	19.33 (15.67)	20.00 (11.50)	1.000
	BBT	More affected	42.00 (23.00)	39.00 (17.50)	.424
		Less affected	46.00 (26.00)	48.00 (16.00)	.909
	PPT	More affected	8.00 (4.33)	8.66 (3.67)	.819
		Less affected	9.00 (5.00)	10.00 (3.50)	.879
	PPT both hands		8.66 (3.33)	10.66 (7.67)	.447
	PPT assembly		12.66 (13.66)	14.66 (7.67)	.790
Post	Jamar	More affected	27.33 (17.33)	19.66 (12.83)	.087
		Less affected	26.33 (28.00)	24.00 (9.67)	.210
	BBT	More affected	46.00 (12.00)	45.00 (8.50)	.381
		Less affected	49.00 (13.00)	49.00 (11.00)	.518
	PPT	More affected	12.33 (8.33)	9.66 (3.00)	.036*
		Less affected	11.66 (5.00)	10.50 (2.50)	.447
	PPT both hands		10.33 (8.00)	12.00 (6.33)	.879
	PPT assembly		23.66 (13.67)	16.00 (4.17)	.006*

BBT: box and block test; PPT: Purdue Pegboard Test. Data are expressed as median and interquartile range; *p value < 0.05 using Mann-Whitney test for not related samples

Table 4 The effect size estimators for the comparisons

Variable		Experimental group (pre vs. post)	Control group (pre vs. post)	Experimental vs. control (pre)	Experimental vs. control (post)
Jamar	More affected	.91	.07	.26	.50
	Less affected	.31	.37	.048	.11
BBT	More affected	.21	.43	.14	.09
	Less affected	.14	.07	.09	.00
PPT	More affected	.62	.29	.16	.42
	Less affected	.53	.16	.23	.29
PPT both hands		.27	.19	.33	.23
PPT assembly		.80	.21	.18	.75

Cells in gray are differences with statistical significance

Table 5 The Client Satisfaction Questionnaire (CSQ-8)

Variable	Experimental group	Control group
1. Quality of service	4 (0)	3 (0)
2. Kind of service	3.4 (.54)	3 (0)
3. Met need	3.2 (.44)	3.5 (.57)
4. Recommend to a friend	4 (0)	4 (0)
5. Amount of help	3.8 (.44)	4 (0)
6. Deal with problems	3.4 (.54)	3.25 (.5)
7. Overall satisfaction	4 (0)	4 (0)
8. Come back	3.8 (.44)	4 (0)
Total Score	29.6 (1.51)	28.75 (.5)

Data are expressed as mean and standard deviation

CHAPTER 9

Compensation for Lack of Manual Dexterity

9.1 Overview

This chapter presents the development and validation of an assistive device mindfully designed for people with reduced manual dexterity. This device generates movements of opening and closing automatically in order to compensate for the reduced motor functioning of the hand. The device was piloted with people with a spinal cord injury, providing insights about the device's usability and acceptance.

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Towards an Affordable Assistive Device for Personal Autonomy Recovery in Tasks Required of Manual Dexterity

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ABSTRACT This paper reviews the results of a challenging engineering project that arose with the goal of implementing an electromechanical, automatic, portable, and inexpensive device. The device should be able to assist people who lack of dexterity in their hands to use small tools and everyday utensils, such as scissors or tweezers. In this paper, the hardware development and software functionality are described. The original specifications were developed to implement an affordable functional prototype able to serve as a low-cost assistive technology. Several commonly used electronic devices were integrated to create an innovative application. A simple mechanical system based on gears and a worm screw is used to convert the stepper motor rotation to a linear movement on the device tip. A tool-oriented control to increase the device usability was designed through two simultaneous communication channels: touch-screen and smartphone app. Pilot trials were conducted at healthcare facilities to evaluate the technical feasibility, the obtained functionality, as well as the device acceptance by target users. Based on user experience design, the app functionality was enhanced and subsequently tested. Finally, a review and reformulation of the specifications of the original design were accomplished. These changes helped to achieve a system with a lower manufacturing cost and better acceptance, while considering the user in the development cycle.

INDEX TERMS Assistive technology, electromechanical devices, grasping, manual dexterity, rehabilitation robotics, research and development, user interfaces.

I. INTRODUCTION

Assistive robotics aims to improve the quality of life of individuals with severe or degenerative disabilities, motor or cognitive limitations (such as the severely disabled and elderly), or to substitute a lost function [1]–[3]. Currently, in Spain and the rest of the world there are millions of people who have some kind of functional disability [4]. Among the causes of this situation are spinal cord injuries, osteoarthritis, paralysis by stroke, etc.

This population requires help from third parties to perform the basic activities of daily living (DLA). According to their level of mobility, many of them are in a situation in which, while retaining much of the functionality of their upper limbs, they have difficulty to perform tasks that require some manual dexterity. Thereby, employing little tools used in DLA such as scissors, tweezers, nail clippers, etc. is difficult or even impossible for people with this kind of injury.

Related to this fact, a low cost assistive device has been designed with the aim to autonomously operate different tools that in a natural way require the grasping movement of the thumb and index fingers (i.e. a scissors). The operating mode consists of the substitution of natural grasping movement of fingers by an artificial movement generated by the electromechanical elements of the device. This artificial movement is transferred to a tool attached to the tip of the device, that is automatically actuated.

The device is made up of two basic parts: a main section and exchangeable tool heads. The main section houses, inside a case, the subsystems of the device: driving force, mechanical transmission, electronics, battery (in some models), and a touch-screen. The different exchangeable tool heads can be attached to this main section.

In this paper, both the hardware development and the software functionality of the assistive device are described. The remainder of this paper is organized as follows: Section II provides a brief overview of the initial design and a description of the device components. Section III describes the principle to generate a controlled linear movement on the device tip. The design process of the mechanical solution is also presented. Besides, the tool-oriented control designed to increase the device usability is detailed. Section IV summarizes the results of a pilot study of usability and manufacturing costs. The device features grouped by utility, ergonomy, use mode and control options, were assessed considering the participants' opinions. Based on the users' experience, a later improvement in the most control option was performed and subsequently tested in a second stage of trials. Then, the device performance in second trial and the contribution of the assistive device to improve the user autonomy in the DLA performing are studied. In addition, a review of original design specifications considering the influence of the individual device components on the global device functionality in order to reduce the manufacturing cost is included. Section V discusses the obtained results and the device performance in pilot trials. Finally, concluding remarks are presented in section VI.

A. RELATED WORK

The grasping and control of everyday tools is one of the main problems faced by the users to whom this device is addressed. Although there are solutions that will facilitate the grasping of daily utensils [5]–[8], which are only adaptations, the lack of control in the movements is a problem that still remains. This issue represents an important barrier to personal autonomy.

In a different way, several solutions based on wearable systems to assist the fingers movements are proposed [9]. In a study by Goutam and Aw [10] a cable drive and spring mechanism is used to provide an assistive downward force for the middle phalanx of the finger while the user grips an object. The cable tension simulates the functionality of a tendon. For the return action, the spring is used to transfer the linear actuator force. The prototype is implemented on a glove. Another system based on cable drive and linear actuators is presented in [11]. This device supports the movement of the thumb and forefinger. A complete hand exoskeleton is addressed in the Baker *et al.* study [12]. In this case, several aluminum bands are incorporated into a tight-fitting glove. The mechanical exoskeleton will be actuated using braided polymer cables attached to three linear actuators.

The previous systems addressed the lack of movement control, however they are research projects rather than operational devices. As an advantage over the use of a hand exoskeleton, our device presents a less intrusive solution, since the user is only required to grasp it in the same way as holding a smartphone.

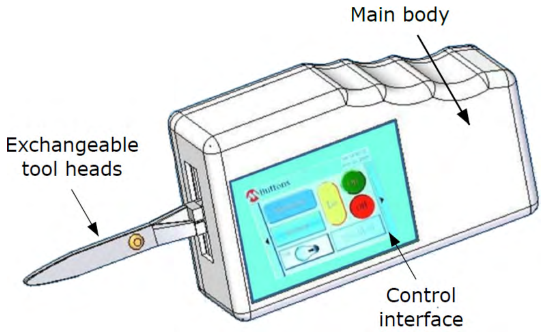

FIGURE 1. The assistive device's main subsystems according to the initial specifications.

II. METHODOLOGY

The portable assistive device has been designed to automatically generate opening and closing movements at the tip. It is aimed to assist people, who lack the manual dexterity required to use everyday tools such as scissors, nail clippers, or tweezers. This device can restore the lost ability by the user. The original idea consists of three basic elements: a main body, exchangeable tool heads and control interfaces. These elements are described as follows (see Fig. 1):

a) *Main Body:* This hosts the actuator, transmission, control interface, battery, and charger circuits (in the corresponding model). Also, it allows the user to connect the tool heads by means of special anchor docks and it moves them in linear guide. The external shape of the body was designed to be ergonomic and functional.
b) *Exchangeable tool heads:* Due to the diverse array of attachable tool heads the tip, and therefore the functionality of the device, changes from scissor tool, to small gripper, to tweezers or to whatever small tool is needed. They are all adapted to be mounted on the device. In this way, the same aid could develop a huge variety of tasks that require fine grasping abilities.
c) *Control Interface:* By default, the device is commanded by an embedded touch panel interface, which presents a menu of choices related to the attached tool head. For example, first the user chooses the type of tool connected depending on the task they want to perform, and then the touch-screen presents the right options to perform automatic pre-programmed movements in a suitable way for such tool.

A pilot study to investigate the impressions of individuals using our device in some common activities was conducted at two healthcare facilities. The first trial was carried out at Asociación de Parapléjicos y Personas con Gran Discapacidad Física de la Comunidad de Madrid (ASPAYM-MADRID) where individuals with different levels of spinal cord injury (SCI) participated. The second trial was conducted at Laboratorio de Análisis del Movimiento, Biomecánica, Ergonomía y Control Motor (LAMBECOM) where other individuals participated. Their physical conditions and the inclusion criteria will be detailed in the results section.

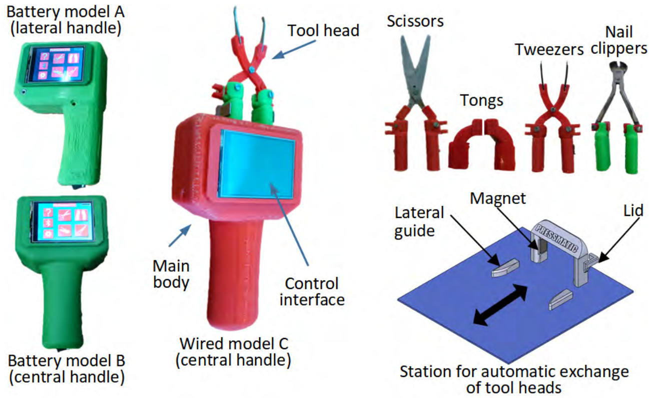

FIGURE 2. **The assistive device's system with complete tool heads set and station for automatic exchange of tool heads.**

III. A QUICK REVIEW OF THE MAIN DESIGN DECISIONS

From the design and specifications defined in [13] and [14], three assistive prototypes which had some morphological differences, but kept the same functionality, were developed (see Fig. 2 left). Models A and B are battery powered and their handle is placed either laterally or in the center, respectively. Model C is mains-powered and it has a central handle. Moreover, there are four tool heads as accessories: scissors, tongs, tweezers, and nail clippers (see Fig. 2 upper right corner). An automated system for exchanging tools (see Fig. 2 lower right corner) has been implemented to facilitate the use of them.

A. MECHANICAL FUNCTIONALITY

On the one hand, one of the main initial design decisions was to achieve a parallel movement for the clamping of the tools attached to the device. The device must be able to imitate the thumb and index finger movement. This type of movement keeps the relative distance between the tools' tips and the object to be manipulated. For example, for the nail clippers, the user only needs to place the device at the initial stage. The device then keeps the relative position of the nail clipper cutting edge with respect to the user's nail tip. In the case of using the scissors, this parallel movement in the attached blades makes it easier to cut due to device maintaining the initial cutting point position. However, other tools require of controlling the percentage of opening or closing of the tip's path. This is the case of both the tweezers and tongs tool heads.

On the other hand, the multi tool approach requires the design of a system to change the tools in an easy way. The user must be able to attach and remove the tools autonomously, moreover the fixation mechanism (anchor dock) has to be passive but strong enough to be functional and avoid undesired detach.

1) PRELIMINARY MODELS

Since the motion of the device tip must be linear, the first option was the use of a solenoid actuator. However, this kind of mechanism is a single-acting device. This option was discarded since the opening or closing movements should be as controllable as possible, allowing to vary the motion speed of the tool heads. Also, because the solenoid stroke is limited.

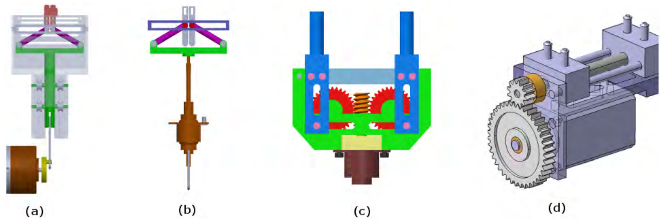

FIGURE 3. **Detail of the development process of the end-effector system: a) Crank-based, b) Linear motor based, c) Endless screw and gears, and d) Bidirectional thread worm screw.**

Several designs were evaluated by means of sketches and preliminary models based on a stepper motor. Among them, a crank-based system (see Fig. 3-a), a system that uses a linear motor as an actuator (see Fig. 3-b), an endless screw with side gear transmission (see Fig. 3-c), and a gear transmission with a bidirectional thread worm screw (Fig. 3-d) were considered. All the alternatives require leading guides for the terminals anchor docks to obtain a linear sliding motion on the device tip. The parallel translational movement desired is achieved in all cases, but with certain disadvantages.

The crank-based system (Fig. 3-a) requires more leading guides than the other models, and this causes jams during movement. This design was also larger. The system based on a linear motor (Fig. 3-b) was discarded because it cannot keep position without the motor being powered. This would imply a higher energy consumption (a shorter autonomy time of the device) because it cannot maintain position mechanically. Although the endless screw and side gear transmission design (Fig. 3-c) could maintain position mechanically, interlocking of moving parts occurred due to the necessary support points which were included to achieve linear movement. Thus, the gear transmission with a bidirectional thread worm screw system (Fig. 3-d) was selected to be implemented in the final prototype, since it is the smaller design and it only uses two leading guides to displace the anchor docks.

2) FINAL MECHANICAL DESIGN AND TOOLS' ATTACHMENT SYSTEM

The mechanical solution chosen to achieve the parallel motion on the tip is shown in detail in Fig. 4-a. Linear displacement (v_d) is obtained by means of the rotary motion of a stepper motor (ω_m) and an intermediary conversion mechanism based on gears and a worm screw (ω_{ws}). A half of the worm screw shaft has a right-hand thread, while the other half has a left-hand thread. This configuration obtains a bidirectional linear movement of the anchor docks.

Also, grippers and similar tool terminals, transmit force perpendicular to the contact surface, while keeping the angle between the contact forces and anchor docks null in the direction of linear movement [15]. Friction estimation is quite

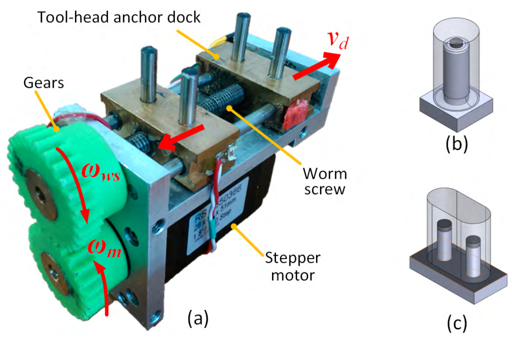

FIGURE 4. a) Detail of the final mechanical design used, b) First anchoring system, and c) Final system for attaching the tool heads.

complex; therefore, the actuator is oversized. A compression test of a spring was performed to estimate the grip force of the device. The displaced distance in the spring is multiplied by the spring constant to obtain the force. A limit in the current has been implement as a safety measure to prevent unintentional pinching. As result, the maximum grip force is close to 40 N.

Regarding the anchoring system, a stable connection is essential for the proper performance of the task intended for the tool. The design must be simple to allow an easy attach and detach of the tool head. The first design was based on cylindrical anchors tips with a magnetic material on the anchor tip as showed in Fig. 4-b. This magnetic knob retains the insertion of the tool head, but has the disadvantage that allows rotation of the tool. In Fig. 4-c the final solution duplicates the dock tips. Therefore, the rotation of the tool head is constrained. Notice that the magnetic knobs are also present in this final design.

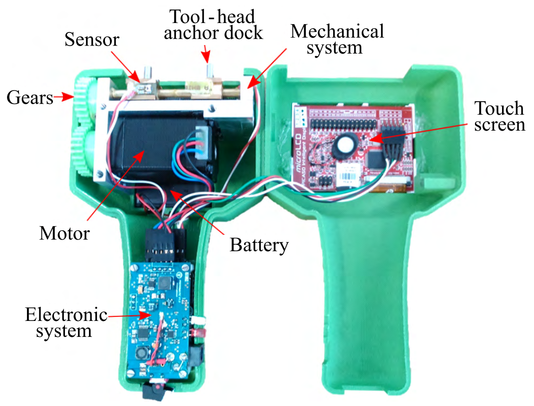

FIGURE 5. Distribution of components in the prototype model B (battery).

The placement of the mechanical transmission and the rest of components within the prototype is shown in Fig. 5.

B. TOOL-ORIENTED CONTROL

As was described in the previous section, a linear movement is obtained from a rotatory movement. Thus, controlling the motor spin translates into the control of the linear motion in the device tip. An Arduino compatible microprocessor

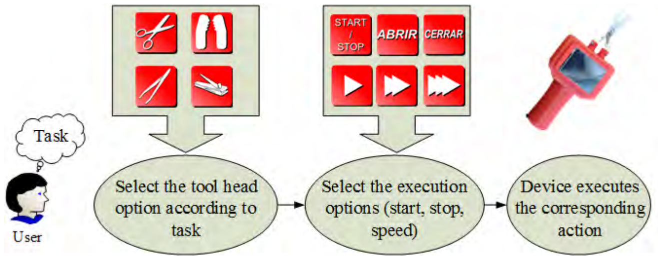

FIGURE 6. Tool-oriented control approach to control the device.

ATmega2560 was chosen to program the motion control system. A motor driver Pololu A4988 is used to supply power to the stepper motor. The control of the linear travel axis is done by means of limit switches. A tool-oriented functionality has been implemented to control the device (see Fig. 6). That is, the user chooses the type of tool head connected depending on the task to perform, and then the device generates automatic pre-programmed movements in a suitable way for such a tool head. No automated tool identification has been implemented to keep the complexity of the system low.

According to the tool heads chosen, three operational modes were implemented: continuous mode for the scissor tool head, simple mode for the nail clipper tool head, and grip mode for both the tweezers and the tongs tool head. The flowchart for the tool-oriented operating modes is shown in Fig. 7. Since the functionality is the same, both the tweezers and the tongs tool heads share the same operation mode.

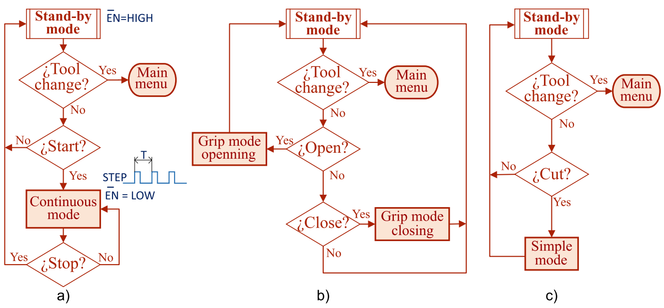

FIGURE 7. Flow-chart for the tool-oriented control modes. a) Continuous mode, b) Grip mode, and c) Simple mode.

1) CONTINUOUS MODE

This mode has been programmed for the scissors tool head to perform full opening and closing cycles indefinitely. The user must signal when to run and to stop the task execution. This operation mode (Fig. 7-a) begins with an idle state in which motor stepping is disabled (EN = '1'), waiting for a tool head exchange or the signal to begin the cutting process. Upon activation of such a signal, Continuous mode is entered, motor stepping is activated (EN = '0'), and a pulse wave with constant period is generated. While this mode is on, the device continuously performs complete opening and closing movements. Micro switches are used to detect the limit of the travel either on opening or closing mode. Their output is connected to two interrupts of the microcontroller that toggle the motor spin direction. When the user activates the signal to stop the cutting process, idle state is restored.

2) GRIP MODE

This mode is programmed to perform small opening or closing motions of the tool heads on user command. To achieve this functionality (Fig. 7-b), two control signals are required for opening and closing motions, respectively. The device is programmed to generate motion (open/close) while the corresponding control signals are activated to allow the user to hold full control over the motions. When there is no signal activation, the device keep position. If either opening or closing travel limit is reached, the motor will stay still until the complementary signal is activated. This is accomplished through the limit switches.

3) SIMPLE MODE

This is used for the nail clipper tool head and executes a full opening and closing cycle, equivalent to a single nail cut. The user would carry out another full cycle when ready. In this mode (Fig. 7-c), the opening motion is limited to one-half of the complete travel, enough to fit the nail in the tool. To maximize the force exerted, velocity change options are not allowed in this mode and the velocity itself is limited to the lowest value.

C. CONTROL CHANNELS

The control interface, intended for commanding the device, must achieve the accessibility and ease-of-use goals. To meet these requirements and reach the highest number of users, two communication channels have been developed: a touch-screen embedded on the device and a smartphone app.

1) EMBEDDED TOUCH-SCREEN

A touch-screen is integrated in the main body, and it displays the graphical interface implemented. The resistive screen uLCD-28PTU was selected due to its 2.8-inch size, suitability for our application, a simple graphic development environment, and serial port communications. A capacitive screen is usually a better choice in terms of touch sensitivity; however, a lower cost resistive screen was preferred to validate this prototype and assess the utility of an integrated screen. Several tool options are visually presented to the user through the touch-screen. To improve intuitiveness, tool-specific pictograms are used. Fig. 8 depicts a flowchart of functionality. Fig. 9 depicts the initial graphical interface design. Web accessibility criteria were considered in the design of the interface to improve icon visibility and make their function easily recognizable.

2) SMARTPHONE APP

The app is for Android OS and can be linked to our prototype via Bluetooth. The graphical design implemented in the touch-screen was preserved in the development of the first mobile app. That is, the same pictograms have been kept, as well as the navigation menus, colors and, primarily, an identical functionality. Moreover, all accessibility criteria from [5] and [16] have been included, too. Fig. 10 shows the menus implemented in the mobile app, which correspond to their counterparts developed for the touch-screen.

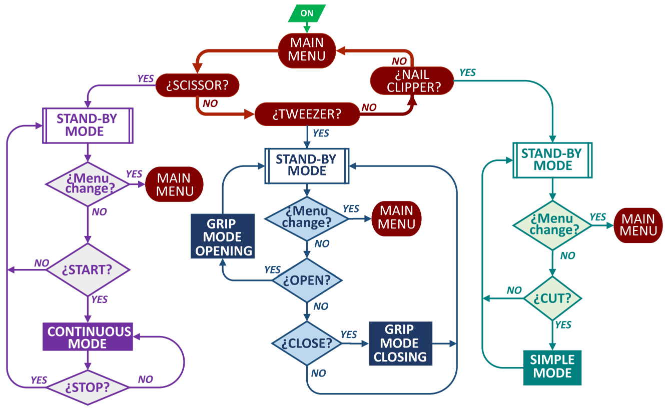

FIGURE 8. Flowchart of the menu window based touch-screen to control the device.

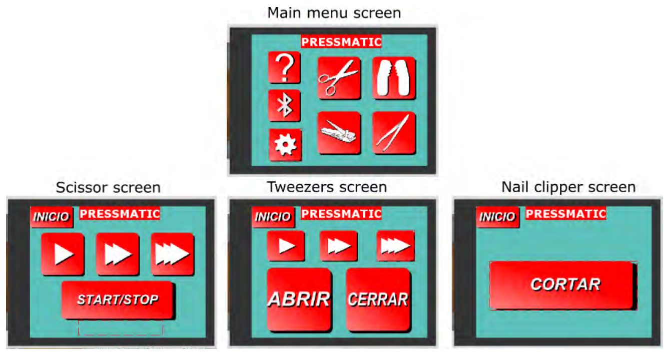

FIGURE 9. Graphic design of the menu window interface in the touch-screen.

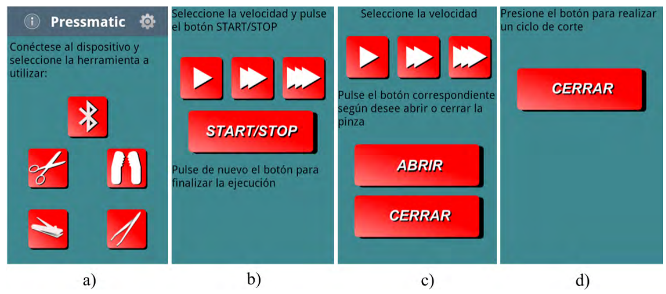

FIGURE 10. Navigation menus in Android app: a) main screen, b) scissors screen, c) pincers screen, and d) nail clipper screen. Note that commands for open (abrir) and close (cerrar) are showed in Spanish.

To link the smartphone with our device, its onboard electronics includes a low-cost HC-05 Bluetooth module. Predefined commands issued by a tap or selection actions are sent from the mobile app. This Arduino compatible Bluetooth module receives these commands and sends them through a serial port to the microcontroller, which executes the appropriate task. This smartphone based graphical interface presents certain advantages over the integrated touch-screen. Both can run simultaneously without interfering with each other, and any change or action applied in one interface will be reflected in the other. Therefore, users may control the device via the mobile app acting as a remote viewer. Also, the end-user is more familiarized with the smartphone device the app will be installed on, thus enabling a smooth and comfortable usage. Additionally, the smartphone's capacitive display greatly improves the touch sensitivity of the integrated resistive screen and makes it easier to use.

IV. PILOT STUDY OF USABILITY AND MANUFACTURING COSTS

A pilot study to investigate the impressions of individuals using the device in some common activities was conducted at two healthcare facilities [17]. A total of nine subjects, with both restricted and manual dexterity problems, were selected by medical professionals to compose the groups. Five individuals who have SCI between level C5 and C6 were selected to compose the Group 1. Four individuals were part of Group 2, three of them had hemiparesis, in two cases caused by a hemorrhagic cerebrovascular accident (CVA) and the other one in the aftermath of brain tumor. The fourth subject had akinetic-rigid syndrome caused by neurodegenerative Parkinson's disease (PD). All participants were eligible in accordance with the following inclusion criteria: a) Affectation of the upper extremity; b) Grabbing ability; c) Spasticity according Modified Ashworth Scale $\leqslant 2$; and d) Ability to understand Mini-mental test instructions $\geqslant 24$.

Demographic data and the expertise level on controlling a smartphone of the participating groups are presented in Table 1. The gender is: (F) for female and (M) for male. The previous experience of the participants regarding the use of smartphones, considering their opinions, was defined as: Beginner (B), Intermediate (I), or Advanced (A).

TABLE 1. Demographics of participants in the study.

		Pathology	Age	Gender	*Exp.
Group 1	P1	SCI on C6 level (complete)	35	M	A
	P2	SCI on C5 level (complete)	30	M	A
	P3	SCI on C6 level (complete)	35	M	A
	P4	SCI on C5/C6 level (complete)	40	M	I
	P5	SCI on C6 level (incomplete)	30	M	A
Group 2	P6	Hemiparesis by CVA	54	F	A
	P7	Hemiparesis by CVA	23	M	A
	P8	Hemiparesis by CVA	55	M	A
	P9	Akinetic-rigid syndrome by PD	58	F	I

*Exp.: Level of expertise on using a smartphone

A. USABILITY TEST RESULTS

Several tasks were proposed to perform, such as picking up small objects, cutting a sheet of paper or exchanging tool heads. All tasks were performed using our device and an appropriated tool head. The device features and its control interfaces were individually evaluated by each user, who expressed their opinions via a range of satisfaction scores, from -2 (strongly disagree) to $+2$ (strongly agree). Regarding the number of users for a proper usability assessment, five is a proper number for usability testing, according to [18] and [19]. Considering these criteria, and since one subject was unable to attend the second trial, the results have been processed as a single group.

TABLE 2. First results for the usability questionnaires.

	Mean	Mode
Utility		
1) Could it gives more independence to you in DLA?	1.33	1
2) Useful for people with your same injury?	0.78	1
3) Would you buy it if you could?	0.78	1
Ergonomy		
4) Is it easy to handle?	-0.44	-1
5) Size and weight adequate?	-1.56	-2
6) Is the device shape user friendly?	-0.56	-2
Use mode		
7) Scissors task completed?	0.56	1
8) Tweezers task completed?	1.11	1
9) Tool heads easily exchanged?	0.56	1
Control options		
10) Touch screen easily used?	0.56	-1
11) Smartphone App easily used?	1.67	2
12) Previous options easily used?	1.33	1

Questions were classified based on four categories and the results are presented in Table 2. The best results were obtained in both Utility and Control options categories. Thus, device was found easy to control by the individuals and that it could be useful in their DLA. Also, a favorable result is achieved for the Use Mode category, and it has an added value, when the fact that all participants could perform the proposed tasks is considered. The Ergonomy category has obtained the worst results. All the participants agreed that the current device weight decreases its usability. The current device weight is 620 grams in A and B models, those that use batteries, though not optimal, allowed proper manipulation of the device. In the case of the wired model C, the weight is 595 grams.

B. IMPROVING THE MOBILE APP BASED ON USER EXPERIENCE

The target was to improve the usability of the mobile app that controls the device. An important requirement is to maintain the functionality that currently exists so that the back of the current development is reusable and only involves changes in the front layer. For this, a specific redesign process based on Ries's Lean Method [20] was followed, and adapted to the characteristics of this project and its starting point. Throughout the process of redesigning the remote-control app of the device, the characteristics of the target users and their satisfaction have been taken into account. The deliverable to be evaluated again, was a navigable model, formed by the final screens and specifications, that will allow any developer to implement the app. Alongside the design improvements, the accessibility and the use mode were improved too. The graphic line of the new version of the mobile application was developed to convey the following values: accessibility, closeness and simplicity.

The user interaction with the control app has been redesigned for simplicity, considering the ability to store previous interactions of the user, choosing predefined speeds and commonly used tools. The colors used for the icons and screens, was also revised, according to these principles. The choice of main colors was somewhat more complex since it was intended to be accessible to all people with some deficiency of color vision (color blindness). The spectrum of colors according to the various deficiencies of the dichromatic colorblind (Protanopia, deuteranopia, and tritanopia) was reduced.

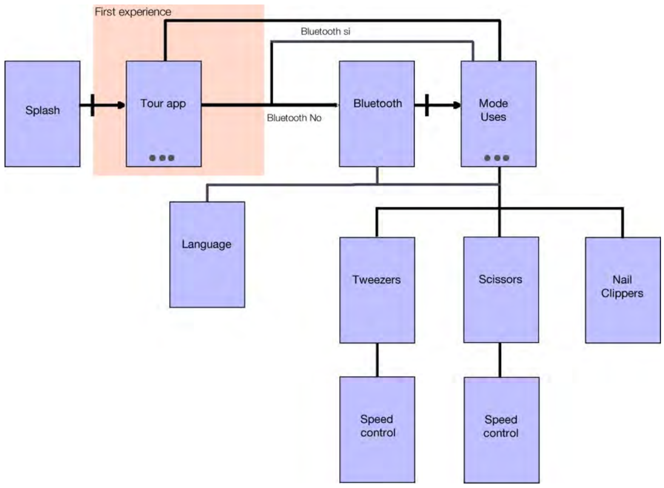

FIGURE 11. New flowchart of the menu window based touch-screen to control the device.

Although the device has four heads: large tweezers, small tweezers, scissors, and nail clippers; The operating modes and the control of the large and small clamps are the same, and so they have been grouped into a single option. From the mode selection screen, the user can select the usage head. Fig. 11 illustrates the flowchart of the new app.

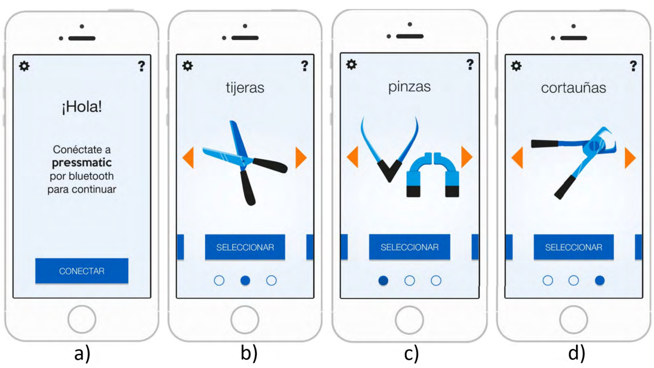

FIGURE 12. Navigation menus in the new Android app: a) main screen, b) scissors screen, c) pincers screen, and d) nail clipper screen. Note that only the name of the tools and selection buttons are shown in Spanish.

To guarantee the contrast between the colors we chose to use: light tones for the background; black and blue for the main elements; and orange tones for minimalist details. The new graphical design is shown in Fig. 12. The user tests were done using the "Thinking Aloud" technique. It consists of asking the user to do a task and the participant is asked to

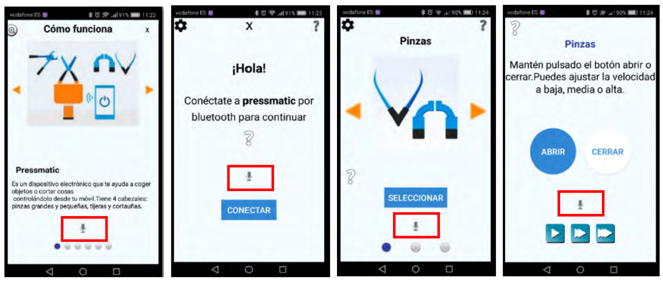

FIGURE 13. Tool-oriented approach to control the device in the new iOS app for the pincers tool head. Note that text is shown in Spanish.

verbalize everything he or she is thinking and explain why he performs the actions he performs. After some interactions and verification with real users of ASPAYM-MADRID veterans in the handle of the device, this design was implemented again in both iOS and Android systems, including HTML5. Considering the participants' suggestions and based on the user experience approach, the design and the usability of the control app was improved. Fig. 13 presents some help menus that presents instructions to use each tool head, according to the tool-oriented approach.

Regarding how the user interacts with the App, the trials with the first app version showed that the participants were able to navigate through the App menus and to activate the buttons without difficulty. The capacitive screen of the smartphone contributes to this fact.

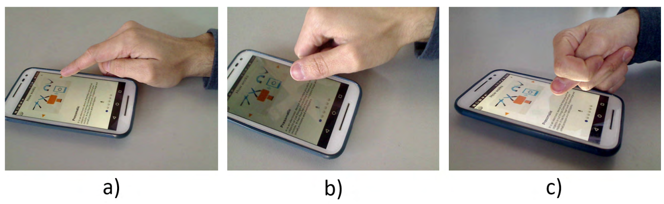

FIGURE 14. Detail of how a user interact with the device app in the new iOS app. Touching the tactile screen with: a) the index finger, b) the thumb, and c) the thumb supported by index finger.

Different ways of how the participants touched the screen were identified. That is, the participants used to touch the screen in several ways such as with the index finger, the thumb finger, the thumb supported by the index finger, or the fist (see Fig. 14). Moreover, a voice control based on the Google talk voice recognition was included in the new version.

Finally, some customization options (language change, text or buttons resizing) were added to increase the App's accessibility.

C. STUDY OF PERFORMANCE

A new trial was carried out in February of 2018 at the same healthcare facilities and with the same participants. This study was focused on testing the new app which was redesigned based on the users' experience. Also, to evaluate the success rate of the device in task performing.

For that purpose, a three-level scale was designed, similar in structure and detail to the feeding and dressing sections of

TABLE 3. Level of autonomy to perform a task and results for the usability questionnaires for each participant. The levels of autonomy were defined as: Independent (I), Needs Help (NH), and Dependent (D).

	Group 1					Group 2				Mean	Mode
	P1	P2	P3	P4	P5	P6	P7	P8	P9		
Autonomy level on											
Using the smartphone	I	I	I	I	I	I	I	I	I	n/a	n/a
Paper-cutting	NH	D	D	D	D	NH	I	NH	NH	n/a	n/a
Nail-cutting	D	D	D	D	D	NH	NH	NH	NH	n/a	n/a
Small objects grabbing	NH	D	NH	NH	NH	NH	I	NH	I	n/a	n/a
Task 1: paper-cutting											
Scissor task completed?	1	1	1	2	2	2	2	2	2	1,67	2
Easy to perform?	1	1	1	1	2	1	2	2	1	1,33	1
Did you use the touch screen?	0	-1	-2	0	-1	0	0	0	0	-0,44	0
Did you use the app?	2	2	1	2	2	2	1	2	1	1,67	2
Was the voice control useful?	1	2	2	2	1	2	1	1	-1	1,22	1
Task 2: pick-up small objects											
Pick&place task completed?	2	1	2	1	2	2	2	2	2	1,78	2
Easy to perform?	1	1	2	1	2	2	1	1	2	1,44	1
Did you use the touch screen?	0	0	0	-1	0	0	0	0	-1	-0,22	0
Did you use the app?	1	2	1	1	1	1	2	2	1	1,33	1
Was the voice control useful?	0	1	1	1	1	2	1	1	0	0,89	1
Task 3: finger nail-cutting											
Nail-cutting task completed?	-1	-2	-1	-2	0	-1	0	1	-2	-0,89	-1
Easy to perform?	-1	0	-1	-1	1	-1	0	-1	-2	-0,67	-1
Did you use the touch screen?	0	0	0	0	-1	0	0	0	-1	-0,22	0
Did you use the app?	1	2	2	2	2	2	2	2	1	1,78	2
Was the voice control useful?	1	1	2	2	2	1	1	2	1	1,44	1
Task 4: tool heads exchange											
Tool heads exchange task completed?	2	2	1	2	2	1	1	2	1	1,56	2
Is this function useful?	1	2	2	2	1	0	0	0	0	0,89	0
Did you use the touch screen?	-1	0	0	0	-1	0	0	0	0	-0,22	0
Did you use the app?	1	1	2	2	1	1	2	2	1	1,44	1
Assessment of app functionality											
Has the app been intuitive to use?	2	2	2	2	2	2	1	1	1	1,67	2
Have you been able to use it without help?	2	1	1	1	2	2	2	2	1	1,56	2
Has the graphic design been adequate?	2	2	1	2	1	1	2	2	1	1,56	2
Is the icons/buttons size appropriate?	2	1	2	1	2	2	2	1	1	1,56	2
Is the voice control useful?	1	2	1	2	2	1	2	2	1	1,56	2
In general, is the app functionality adequate?	2	2	2	2	2	2	2	2	1	1,89	2

the Barthel ADL Index [21]. The design evaluates the degree of autonomy of the participants to perform the tasks proposed in the pilot trial without the device. The levels of autonomy were defined as: Independent (I), Needs Help (NH), and Dependent (D). The responses of the participants are summarized in Table 3, including the results of the tasks being performed. On this basis, the contribution of the assistive device to improve the user independence in the DLA performing can be discussed. Note that for this test, the participants have used the proposed device for the second time.

1) TASKS DESCRIPTION

Four tasks were proposed to be performed by the participants, using the assistive device. Three of them using different tool heads, and the last one to evaluate the automated system for exchanging tool heads. The first proposed task was to cut, using the assistive device with the scissors tool head, several simple geometric figures (circle, triangle or square) printed on a sheet. As second task and using either the tweezers or nippers tool heads, it was proposed to pick up a series of small objects within a box, and then take them out. In this way, both the comfort to manipulate the device and its ease to perform the tasks were assessed. The third proposed task was fingernail cutting by using the nail clippers tool. Finally, the fourth task consisted of tool heads exchange by using the station for automatic exchange.

In the first three tasks, the participants were encouraged to place the tool heads on the device by themselves. If they failed, an evaluator placed the tool heads for them. Regarding the control of the device, the individuals could choose between the touch screen or the new app. The participants were free to use the voice control option when they considered it appropriate.

2) DEVELOPMENT OF THE TASKS AND RESULTS

The results of the questionnaires, to gather the opinion of participants about the development of the tasks, are summarized in Table 3. The participants' opinions were expressed via a range of satisfaction from -2 (strongly disagree) to $+2$ (strongly agree). Some pictures of participants performing the tasks during the trials are shown in Fig 15. At the beginning of the trials, the App was available for the participants to download. They installed the new app in their own smartphones.

In the case of the paper-cutting task, the results were favorable (1.67). All the participants were able to complete the proposed task in different periods of time, according to their motor limitation and dexterity. Note that the participants

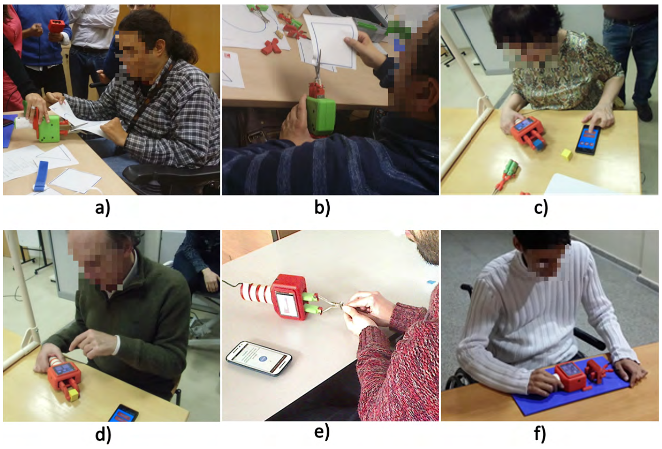

FIGURE 15. Participants performing the tasks proposed. a) P2 in paper-cutting task, b) P1 in paper-cutting task, c) P6 grabbing small object, d) P8 grabbing small object, e) P7 in nail-cutting task, and f) P5 in tool head exchange task.

of Group 1 (quadriparesis), having both arms affected, took more time to complete the tasks than the participants of Group 2 (hemiparesis). It must be highlighted that, the participants from Group 1 have the capacity to adapt their motor limitations to the needs of the task, using the device in the best possible way. For example, Fig. 15-a shows how an user placed the device on the table with the scissor tool head pointing to him. By using the app, the user activated the continuous mode that automatically executes opening and closing cycles. The user is able to hold the paper with both hands and he only has to guide the paper while the scissor blades are automatically cutting. As it is shown in Fig. 15-b, another user leaned the device to the table to cut the paper, safely holding the device with one hand and with the other one holding the paper.

Task 2, picking up small objects, was successfully completed by all participants (1.78). Most of the participants performed the tasks only controlling the device by the smartphone app. Participants of Group 2 were those that more easily used the App, since they have more strength in their arms. The voice control was more useful to Group 1, being able to complete the task by speaking the open and close commands. Due to the way the Grip mode works, that is, a limited displacement of the tool head, the users are required to repeat the voice commands as many times as needed.

The worst results were obtained for the nail-cutting task (−0.89), since only two participants were able to complete the task. This results can be analyzed from two point of view: the use mode and the device capacity. On the one hand, regarding the use mode the participants found that the better way to use the nail-clippers tool head was leaving the device on the table with the tool head pointing to the user (see Fig. 15-e). This method allows the user to be hands free. However, the task could not be completed in all the trials due to the fact the motor power was not enough. In addition, the 3D printed pieces of the tool head suffered undesirable flexion, increasing the losses in power transmission.

In the case of task 4, the station for automatic tool head exchange was positively accepted by all participants, and it was strongly appreciated by Group 1. The tool head exchange was easy for Group 2. This fact is understandable because Group 1 participants' have both arms affected, contrary to Group 2 that still have functionality of one arm.

Regarding the assessment of the new developed app, in general the user experience when using the new app was very satisfactory (1.89). Thus, the new app was useful to perform the tasks designed for this pilot trial. The intuitive graphical design (1.67) and the ease for menu navigation (1.56) were also highlighted. The options to customize the graphical interface (1.56) were appropriate. Besides, the voice control option was reported as useful and it increases the accessibility of the assistive device.

D. REVIEW OF ORIGINAL DESIGN SPECIFICATIONS

The baseline design requirements were in-depth reviewed in [17], according to the impressions and user experience. On this basis, the device components were grouped by the essential ones to maintain the device functionality and the other ones that can be considered optional. A cost point of view analysis was added to the previously mentioned classification (see Table 4), in order to identify the impact of the review of initial requirements of design in the final cost of the device.

A system made up of a main body and exchangeable tool heads is strongly accepted and the multi-tool approach is highlighted by participants.

The tool head set is positively valued but an extension with more tools is requested. The device portability of both A and B models is well appreciated, but the wired condition of model C does not decrease its usability. The central handle models were preferred. With respect to device control, the option of control by cell phone was highlighted to the detriment of control by touch-screen. The idea of controlling the device from their own smartphone increases the device usability, since they are familiar with their mobile phone. Considering the users experience, the embedded touch-screen is not an essential element.

Regarding device weight, all participants ask for its reduction. For that purpose, to remove the touch-screen is a good option, based on the previously mentioned user impressions by using the app. This design modification, involves a weight decrease of 6.5% and a reduction of 8% in the prototype cost. Besides, the mechanical solution to generate a linear movement uses 68.4% of the prototype weight, therefore, an important issue in future developments is improving the current mechanical system. This consideration could induce a remarkable decrease in manufacturing costs since both the motor and the mechanical system are two of the most expensive elements among the essential ones.

V. DISCUSSION

As was shown in [13] and [14], the target population to use our assistive device were people with SCI between

TABLE 4. Device's components and its influence on functionality and manufacturing costs.

	Component	Description	Weight [g]	Used on all prototypes	Utility for the users	Influence on functionality	Cost per prototype [€]
Essential	Mechanical	Transmission system in aluminium 7075	22	Yes	-	H	366.66
	PCB	FR4 two layers	11	Yes	-	H	141.24
	Motor	RS 535-0366 stepper motor	200	Yes	-	H	97.78
	Electronics	Resistors, Capacitors, etc)	12	Yes	-	H	61.79
	Tool heads	3D printing in ABS	30	Yes	H	H	30.00
	Case C	SLS technology printing (central handle)	103	No	H	H	122.00
	Motor driver	A4988 stepper motor carrier	2	Yes	-	H	6.50
	Bluetooth	HC-05 Bluetooth module	3	Yes	H	M-H	5.85
	App	App for smartphone	-	No	H	H	Free
							Subtotal 1 = 831.82 €.
Optional	Case A	3D printed in ABS (lateral handle)	101	Yes	L	M	20.00
	Case C	SLS technology printing (central handle)	103	No	M	M	122.00
	Soldering	SMD components soldering	-	No	-	-	122.00
	Touch-screen	uLCD-28PTU 2.8" LCD module w/ Touch	35	Yes	M	M	72.25
	Battery	DSK for Galaxy Note III	25	Yes	M	M	11.9
							Subtotal 2 = 348.15 €.

Influence on functionality could be: High (H), Medium (M) or Low (L)

C5 and C6 levels (Group 1). However, people with hand motor impairments caused by a neurological disease (Group 2) can also use the device, as it is described in this paper.

On the one hand, the contribution of the developed assistive device to the autonomy of participants in DLA performing can be analyzed from the conducted tests. The level of autonomy of participants to perform the proposed tasks in daily living was measured through questionnaires. First, all the participants declared they are self-reliance to use a smartphone. The expertise of each participant was summarized in Table 1. It can be seen, that all of them have an intermediate or advanced level. Thus, the management of the new app for controlling the assistive device could not be a barrier.

On this basis, the participants of Group 1 were dependent to perform task 1 without the device, while Group 2 needed help to accomplish it. By using the assistive device, all the participants were able to complete the paper-cutting task without help, giving them more autonomy. For the case of task 2, most of the participants told they needed help to grab small objects, while two individuals of Group 2 told they were able to handle little objects by themselves. Thus, it can be seen that the tweezers tool head was more valued for participants of Group 1, that are able to hold the device by mass flexion of fingers but they are not able to grab little objects that require fingers dissociation. Related to task 3, Group 1 expressed they were dependent for nail-cutting task, while Group 2 individuals need help to hold the nail-clippers with the affected arm.

On the other hand, it is not only important the assistance provided, but safety should also be considered. In the case of paper-cutting task, some users suggested to increase the cutting speed of the scissors blades. This fact highlights the users' impression of the reliability of our device, being appreciated as a non dangerous device. Note that engine speed for the scissors tool heads was reduced by software before the trials were conducted, with the aim of keeping the user safe while interacting with the device. If needed, this speed could be easily setup by software increasing the commutation speed of the steeper motor.

Knowledge of the user is as important as system functionality, since without the user's cooperation, functionality may be ineffective [22]. On this respect, after the last trial in February, it can be noted that the acceptance for the new app is good, both in the front end design and in its functionality. Due to their reduced manual dexterity, Group 1 have much more appreciated the improvements on the app usability with respect to the older app.

Also, note that the functionality of voice control was very valued for all the participants. Nevertheless, also it has been noticed that for task executing commanding by voice, some issues arise, that allow space for improvements. First, the usability of voice control could depend on the task to be performed, as for the case of paper-cutting that requires one command to start and another one to stop the cutting motion. For the case of grip mode, several voice commands will be required according to the size of the target object. Additionally, some failures in voice recognition processes were generated because of the noisy engine actuation, especially with the device leaning on the table. In these cases, the user had to repeat the voice commands on several occasions.

Regarding the ability of using smartphones in people with SCI, the Kim *et al.* study [23] shows that when the SCI patients use smartphones with the appropriate guiding devices, they are expected to access mobile cellular devices faster and with more satisfaction. However, users with SCI between C5 and C6 levels chose universal cuff with stylus or bare hands to interact with smartphone.

In our study, the participants from Group 1 were individuals with SCI on C5 and C6 levels. The trials show that they were able to use the smartphone with bare hands, but with different ways of touching the screen as it was previously described in Fig. 14. Besides, a variety of smartphone applications to assist individuals living with a SCI are currently available on the market [24]. This fact supports the use of an app for controlling the device presented in this paper.

VI. CONCLUSIONS

This paper presents a systematic approach to analyze and review an assistive device. For that purpose, the hardware development and functionality description of a novel assistive device were presented. Three functional prototypes with ergonomic differences were implemented. Several commonly used electronic devices, such as touch-screen, stepper motor, microcontroller, etc., were used to obtain a novel application. A tool-oriented control to increase the device usability was developed. The device functionalities and control channels and modes were analyzed by means of performing usability trials, and then it was discussed their contribution to the final cost of the prototype. Additionally, a two stages pilot study, focused on the design considerations and user experience, is presented.

It is highlighted that the proposed device covers a real need and its functionality is adequate according to the user experience in pilot trials. However, some considerations must be taken into account to improve the usability of the device, such as tool head set extension, weight reductions, and touch-screen removal. Besides, a new version of the App, that was more considerate of the user experience, was developed and tested. This version has been rebuilt, taking into account the principles of User Experience (UX) design to drastically improve its usability. Also, the new control app includes the Android speech recognition to control the device by voice commands. This fact increases the device usability.

Based on the user experience and the cost of the device's components, the original design specifications were evaluated. Thus, the device components were classified according to their influence on device functionality. It must be highlighted, that participants think that the embedded touch-screen could be removed, and the better way for controlling the device is through the App. This consideration could reduce size and weight of the device, as well as an 8% reduction in prototype cost.

This study has also developed a proper method to quickly capture the acceptance by target users of the proposed functionalities, such are intended to help them to recover their autonomy in DLAs. Besides, the required improvements to boost the user adherence to the device have been remarked. The results presented, and the evaluation by target users, further support the development of a newer and lighter device, to obtain an affordable system to assist people with reduced manual dexterity to improve their autonomy in DLA.

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Part III

Conclusions

CHAPTER 10

Final Remarks

10.1 Introduction

This section summarises the main conclusions derived from the research conducted in this thesis. The conclusions are grouped according to the global objectives stated in Chapter 1. The principal contributions of this doctoral dissertation are also set out. Finally, the prosperous research lines that suggest this work are described.

10.2 Conclusions

Neurological rehabilitation is a challenging field with a growing research interest that aims to reduce the functional limitations caused by a neurological deficit; for instance, stroke, Parkinson's Disease (PD), spinal cord injury, among others. The functional problems derived from a neurological disorder are diverse and very complex, leading to a loss of autonomy in the performance of the activities of daily living (ADL). Among the typical functional problems, those related to motor functioning are the more disabling ones, usually reflected on impairments of upper, lower, or both limb motions. Hence, one of the principal aims of neurological rehabilitation is the recovery of motor function, which is fundamental to perform the ADL as independently as possible. According to the principles of clinical practice, the process of rehabilitation involves various phases denoted as assessment, assignment, intervention, and evaluation. Despite the latest technological advances, this process is still performed manually by clinicians, presenting some issues in terms of labour-intensive administration, susceptibility to errors, difficult data management, human resource burden and cost, among others. These issues aggravate those expected and well-known ones as the high demand for assistance and care due to the growing ageing of the population.

On account of the above, the primary motivation of this thesis was to develop a conceptual framework of rehabilitation, which based on the clinical significance of rehabilitation cycle, that integrates robotics and automated systems in the same paradigm towards a more autonomous and intelligent process of functional recovery. This innovative approach was successfully carried out and resulting in a distributed rehabilitation strategy based on three automated elements denoted as (1) automated assessment systems (AAS), (2) rehabilitation robotic systems (RRS), and (3) decision support systems (DSS). Each one aims to boost the efficiency of the rehab cycle in stages as assessment and evaluation, intervention and assignment, respectively.

After the definition of the conceptual framework, the thesis focused on the development and validation of a core component, this is, the AAS. The relevance of this component relies on two aspects: (1) the importance in order to determine the therapy effectiveness and goals, and (2) the repetitive phases of assessment along the treatment.

10.2.1 Systems for automatic assessment

In the case of automated assessment systems, the most suitable approach is to automate the traditional clinical tests commonly used in clinical practice or design systems based on them. This requirement is due to the "traditional scales are still the golden standard for measuring outcomes and determine the effectiveness of treatment" [22].

Thereby, this part of the research work resulted in the development and validation of an automated version of the Box and Blocks Test (BBT). The achieved system is denoted as the Automated Box and Blocks Test (ABBT) and aims to measure manual dexterity similarly to its manual version. In contrast to the manual BBT, the ABBT automates the whole process of assessment according to the rules stated in the BBT. The ABBT uses a graphical user interface (GUI) to guide and interact with the patient in a friendly manner, additionally serving as automatic storage method of performance-based data. The latter is a relevant feature of the ABBT since, in addition to the traditional outcome (number of cubes), the automated system can provide further indicators about the user performance, such as the partial times, the colour of cubes, hand trajectories and its derived metrics (speed or smoothness). The results of piloting the ABBT demonstrated that all the obtained metrics strongly correlate with the manual counting and suggest this innovative assessment method is an objective and reliable alternative to the traditional one.

Furthermore, in a similar line of research, other technological alternatives were explored in order to enhance the features of the ABBT. On one side, the success rate in cube counting had a room for improvement since the developed algorithm uses computer vision techniques; consequently, the susceptibility to environmental lighting conditions is not entirely solved yet. In this sense, the use of a proximity sensing bar placed in the central partition of the physical BBT can help to improve cube detection via a hybrid vision-sensing strategy. The feasibility of the sensing-based approach was demonstrated; however, the implementation of the hybrid strategy is an ongoing research topic. On the other side, the fully-automation level of the ABBT is limited due to minimal participation of third-party assistant is mandatory in order to arrange the physical setup before each assessment stage. The use of a robotic assistant can ameliorate this limitation. Nevertheless, this thesis also explored the use of emerging technology in healthcare and automation; that is, virtual reality (VR).

The research on the proper use of VR for the automation of the BBT led to the implementation of fully-immersive VR-based system for the assessment of manual dexterity, denoted as the VR-BBT. The use of gaming technology provides useful capabilities for automation, such as absolute freedom in modelling the environment and interactions, markerless tracking of user's movements or entertaining features to promote user's adherence. The mindful combination of such features made it possible for the VR-BBT to address the automatic test administration, outcome measurement in terms of the number of cubes, and capture further data based on performance. More importantly, the shapeable characteristics of the virtual environment allow for design novel assessment strategies in order to facilitate an advanced movement analysis (healthy patterns of motion). Overall, the results of pilot trials support the feasibility of this VR-based strategy as a deployable tool in clinical settings that is friendly-to-use for both therapists and patients, and with motion analysis capabilities that are yet to explore fully.

On account of the above, the researcher also explored the suitability of VR for the automation of the Fugl-Meyer Assessment (FMA) test. Some critical drawbacks of the FMA are the labour-intensive and time-consuming administration of the test, the reduced resolution in the impairment measurement and the observation-based rating of items. Thus, the understanding of such limitations led to the development of a VR-based version of the FMA, denoted as the Automated Fugl-Meyer Assessment (AFMA). The AFMA uses the virtual environment to encourage the patient to perform the items of the FMA in a stand-alone manner. A Kinect sensor replicates the movements of the user into the virtual scenario by reliable joint's tracking. As a result, the AFMA can provide objectively a 3-point based indicator similar to the traditional outcome, as well as the biomechanical information gathered by Kinect sensor. Automatic acquisition of kinematic data is especially crucial in order to address motion analysis for expanding the outcome and significance of the outcome provided by the AFMA. The preliminary result of evaluating this approach suggests the viability in order to address an analysis of the motion quality based on smoothness analysis. More importantly, the proper use of the virtual elements can allow for increasing the resolution of the provided metric by defining performance areas. This hypothesis requires further research, but it is promising.

10.2.2 Systems for intervention

This block of the research focused on the development of robot-based rehabilitative and assistive systems, as part of the second component of the conceptual framework, namely, the robotic rehabilitation systems (RRS). Additionally, the strong relationship of the central topic of thesis with functional assessment also motivated the development of systems to promote changes in motor functioning in order to evaluate the feasibility of the assessment systems.

In this regard, this thesis presented two strategies (robot- and gaming-based) developed for upper limb functional rehabilitation which promotes active mobilisation of limbs. Both strategies were built under the assumption that optimal rehabilitative procedures must involve proper task-oriented exercises combined with proper stimuli of cognition, perception and action factor of the individual associated with a life-like context of tasks. On one side, the robot-based strategy aims to promote a better acquisition of gains from therapy by including cognitive factors into the same paradigm. The strategy used a robotic arm to encourage the user to perform active arm movements of reaching associated with object identification and grasping. These motor capabilities are commonly assessed by the clinical tests of neurorehabilitation, suggesting significant participation in the user's autonomy. The robot-based approach was not sufficiently evaluated, requiring further research to consolidation. On the other side, serious gaming technology was useful to develop an innovative method for active arm training. The flexibility in modelling of virtual scenario allowed for integrating into gameplay proper elements to stimulate motor, cognitive and perceptive factors. The results of piloting this system in patients with PD probed the efficacy of mindfully-designed video games in the improvement of upper limb functioning. This fact is consistent with related work founded in literature and support the viability of this approach in rehabilitation and healthcare. However, one limitation of the implemented VR-based system is the lack of capability to perform therapy other than active (without physical support). In this regard, the combination of the robot- and gaming-based training paradigms can lead to overcoming the drawbacks of each strategy towards a more enriching process. Additionally, an overall conclusion is that not only practice is enough for functional recovery, but principles of motor learning must be included in the same rehabilitative paradigm towards increasing the benefits of the intervention.

Finally, contrary to the recovery-oriented approach of the previous systems, the development of an assistive device for compensating the lack of manual dexterity was also conducted in this thesis. This device generates opening and closing movements automatically in order to assist the user when performing dexterous tasks like cutting, nail-clipping or fine grasping. The results from clinical trials highlighted that some issues reduce the device's usability. However, the user experience and therapist's opinions support the viability of the proposed assistive approach in order to cover an apparent demand for a large population sector.

10.2.3 Final remarks of thesis

In order to investigate the feasibility of the framework proposed in this thesis, and under the guidance of medical professionals, several clinical trials with individuals with a neurological disease were conducted. As a result, this research work also offers a methodology for the validation of systems with clinical applicability and guidelines for designing autonomous systems for such environments. On this basis, this study suggests an adaptive environment in which therapist can organise the rehabilitation session with more effective support of robotic rehabilitation systems (RRS) and advocates the use of automated assessment systems (AAS) to build a holistic rehabilitation ecosystem that is more autonomous and objective.

Furthermore, the analysis of limitations of robot-aided treatments and performance of gaming-based training resulted in the identification of essential requirements of prosperous rehabilitation systems. These requirements include self-adaptation for personalising the treatments, safeguarding and enhancing of patient–system interaction towards training essential factors of movement generation into the same paradigm, and the use of life-like environments for increasing the assimilation of motor gains.

10.3 Key contributions

The key contributions of this research are:

- The design and development of a conceptual framework of rehabilitation with hospital-oriented perspective using robotic and automated systems, including a description of the framework components and the technical requirements needed for its implementation and, particularly, the definition of the main requirements to develop automated systems for assessment and intervention.

- The *Automated Box and Blocks Test (ABBT)* - An automatic evaluation system of hand motor function. The ABBT entails the development and validation of an automated assessment system (AAS) based on a clinically-validated test using in the automation process various complementary technologies. This system illustrates the practical application of the proposed framework and the potential of using robotics and automation-related technology to improve the clinical procedures manually performed.

- The development and clinical validation of a set of serious games focused on improving the upper limb motor function and mindfully designed to promote motor gains and its transference to the performance of activities of daily living. The clinical validation probes the applicability of this strategy in the treatment of Parkinson's Disease (PD), but feasible in other collectives.

10.4 Suggested future lines of research

The future lines of research derived from this work include:

- Further piloting of the ABBT is necessary towards building a database of correlated metrics related to manual dexterity. The centralisation of performance-based data can lead to a better understanding of the motor impairment progress and, thereby, to improved management of treatments.

- To develop hybrid-methods for the assessment of manual dexterity by combining the best features of the technologies used during the implementation of the ABBT.

- The robot-based training in lifelike environments is a clear need for current rehabilitation robotics. In this sense, the implementation of health strategies that combine virtual reality and robot assistance can help to reduce the limitations of both approaches.

- The implementation of robot-based strategies for the assessment of motor impairments is a field of interest due to the broad diversity of functional impairments. The evaluation of muscle spasticity is a clear example of the feasibility of robotics due to the inherent physical interaction and subjectivity during the current clinical procedures. Note that this is an ongoing research topic arising from work conducted in this thesis and resulting in the ROBOESPAS project funded by the Spanish Ministry of Economy and Competitiveness.

- To explore the feasibility of using electromyogram (EMG) sensors for improving the assessment and training capabilities of the video games implemented in this thesis. The results obtained from only using unobtrusive sensors as the leap motion controller (LMC) were successful. However, the addition of EMG sensors into the same VR-based paradigm of training can enhance the scope of target impairments to treat and even extending the usage of our video games in therapies with persons with a hand amputation.

- Testing of the extended assessment modalities of the VR-BBT is relevant towards the definition of healthy patterns of hand motor function. It is also interesting to explore the feasibility of these modalities in order to reduce the difference in the outcomes from the physical and virtual BBTs.

- Further testing of the AFMA system is necessary in order to clinical validation of the provided high-resolution outcome and analysing the level of correlation with other outcome measures.

Part IV

Appendices

APPENDIX A

Mapping of publications and systems

A.1 Publications related to the conceptual framework

1. E. D. Oña, R. Cano-de la Cuerda, P. Sánchez-Herrera, C. Balaguer, A. Jardón. A Review of Robotics in Neurorehabilitation: Towards an Automated Process for Upper Limb. *Journal of Healthcare Engineering*, vol: 2018, number: 9758939, pages: 1 - 19. 2018. DOI: `https://doi.org/10.1155/2018/9758939`.

2. E. D. Oña, J. M. Garcia-Haro, A. Jardón, C. Balaguer. Robotics in Health Care: Perspectives of Robot-aided Interventions in Clinical Practice for Rehabilitation of Upper Limbs. *Applied Sciences*, 9 (13), 2586, 2019. DOI: 10.3390/app9132586.

3. E. D. Oña, P. Sánchez-Herrera, A. Jardón, C. Balaguer. Review of Automated Systems for Upper Limbs Functional Assessment in Neurorehabilitation. *IEEE Access*, vol: 7, pages: 32352-32367. 2019. DOI: 10.1109/ACCESS.2019.2901814.

A.2 Publications related to the ABBT

1. E. D. Oña, P. Sánchez-Herrera, A. Cuesta-Gómez, S. Martinez, A. Jardón, C. Balaguer. Automatic Outcome in Manual Dexterity Assessment Using Colour Segmentation and Nearest Neighbour Classifier. *Sensors*, vol: 18, number: 2876. 2018. DOI: 10.3390/s18092876.

2. E. D. Oña, A. Jardón, C. Balaguer. Feasibility of Automated Assessment of Manual Dexterity in Parkinson's. 2017 IEEE/RSJ International Conference on Intelligent Robots and Systems

(IROS), ISBN: 978-1-5386-2682-5, pages: 5508, IEEE. 2017-09-27, Vancouver, BC, Canada. 2018. (Poster). URL: Online.

3. E. D. Oña, A. Jardón, C. Balaguer. The Automated Box and Blocks Test an Autonomous Assessment Method of Gross Manual Dexterity in Stroke Rehabilitation. 18th Towards Autonomous Robotic Systems (TAROS). Lecture Notes in Artificial Intelligence 10454, ISBN: 978-3-319-64106-5, pages: 101 - 114, Springer. 2017-07-20, Guildford, UK. 2017. DOI: 10.1007/978-3-319-64107-2_9.

4. E. D. Oña, A. Jardón, C. Balaguer. Toward an Automated Assessment Method of Manual Dexterity. International Workshop on Assistive and Rehabilitation Technology IWART. December 14-16, 2016, Elche, Spain, ISBN: 978-3-319-46668-2, pages: 1 - 2, Limencop S.L.. 2016-12-14, Elche, Spain. 2016. URL: Online.

5. E. D. Oña, A. Jardón, C. Balaguer, A. Cuesta, M. Carratalá, E. Monge. El "Automatizado Box & Blocks Test" Sistema Automático de Evaluación de Destreza Manual Gruesa. XXXVII Jornadas de Automática. ISBN: 978-84-617-4298-1, pages: 619 - 626, CEA-IFAC. 2016-09-07, Madrid, Spain. 2016. URL: Online.

A.3 Publications related to the VR-BBT

1. E. D. Oña, J.A. Garcia, W. Raffe, A. Jardón, C. Balaguer. Assessment of manual dexterity in VR: Towards a fully-automated version of the Box and Blocks Test. *Studies in health technology and informatics*, vol: 266, pages: 57-62. 2019. DOI: 10.3233/SHTI190773.

2. E. D. Oña, A. Cuesta-Gomez, J.A. Garcia, W. Raffe, P. Sanchez-Herrera, R. Cano de la Cuerda, A. Jardón. Evaluating A VR-based Box and Blocks Test for Automatic Assessment of Manual Dexterity: A Preliminary Study in Parkinson's Disease. IEEE 7th International Conference on Serious Games and Applications for Health (SeGAH), ISBN: 978-1-7281-0300-6, pages: 1 - 6, IEEE. 2019-08-6, Kyoto, Japan. 2019. DOI: 10.1109/SeGAH.2019.8882472.

A.4 Publications related to the AFMA

1. E. D. Oña, A. Jardón, E. Monge, F. Molina, R. Cano and C. Balaguer. Towards Automated Assessment of Upper Limbs Motor Function Based on Fugl-Meyer Test and Virtual Environment. In: Masia L., Micera S., Akay M., Pons J. (eds) Converging Clinical and Engineering

Research on Neurorehabilitation III. ICNR 2018. Biosystems & Biorobotics, vol 21, pages: 297-301. Springer, Cham. 2018. DOI: 10.1007/978-3-030-01845-0_60.

2. E. D. Oña, C. Balaguer, A. Jardón. Towards a Framework for Rehabilitation and Assessment of Upper Limb Motor Function Based on Serious Games. IEEE 6th International Conference on Serious Games and Applications for Health (SeGAH), ISBN: 978-1-5386-6298-4, pages: 1 - 7, IEEE. 2018-05-16, Vienna, Austria. 2018. DOI: 10.1109/SeGAH.2018.8401346.

A.5 Publications related to the Serious Games for rehabilitation

1. E. D. Oña, C. Balaguer, R. Cano-de la Cuerda, S. Collado-Vázquez, A. Jardón. Effectiveness of Serious Games for Leap Motion on the Functionality of the Upper Limb in Parkinson's Disease: A Feasibility Study. *Computational Intelligence and Neuroscience*, vol: 2018, number: 7148427, pages: 1 - 17. 2018. DOI: 10.1155/2018/7148427.

2. P. Fernandez, M. Carratalá, E. Monge, S. Collado, P. Sánchez-Herrera, A. Cuesta, E. D. Oña, A. Jardón, F. Molina, C. Balaguer, J.C. Miangolarra, R. Cano de la Cuerda. Leap motion controlled video game-based therapy for upper limb rehabilitation in patients with Parkinson's disease: A feasibility study. *Journal of NeuroEngineering and Rehabilitation*. 2019. [Accepted on 9 Sep 2019, pending publication]

A.6 Publications related to Pressmatic

1. E. D. Oña, G. Barroso, C. Balaguer, A. Jardón. Towards an Affordable Assistive Device for Personal Autonomy Recovery in Tasks Required of Manual Dexterity. *IEEE Access*, vol: 6, pages: 26338 - 2634. 2018. DOI: 10.1109/ACCESS.2018.2834377.

2. E. D. Oña, A. Jardón, C. Balaguer, A. Martínez, P. Sánchez-Herrera, J.C. Miangolarra. A pilot study on the design consideration and user impressions of an assistive affordable device. RoboCity16 Open Conference on Future Trends in Robotics. ISBN: 978-84-608-8452-1, pages: 19 - 28, CSIC. 2016-05-26, Madrid, Spain. 2016. URL: Online.

3. E. D. Oña, A. Jardón, G. Barroso, C. Balaguer. Control orientado a la herramienta para dispositivo asistencial en tareas que requieren capacidad de pinzado. XXXVII Jornadas de Automática. ISBN: 978-84-617-4298-1, pages: 635 - 641, CEA-IFAC. 2016-09-08, Madrid, Spain. 2016.

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