WiGlove : A Passive Dynamic Orthosis for Home-based Post-stroke Rehabilitation of Hand and Wrist

By

VIGNESH VELMURUGAN

School of Physics, Engineering and Computer Science

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Abstract

Stroke survivors often experience varying levels of motor function deficits in their hands affecting their ability to perform activities of daily life. Recovering their hand functions through neurorehabilitation is a significant step in their recovery towards independent living. Home-based rehabilitation using robotic devices allows stroke survivors to train at their convenience independent of factors such as the availability of therapists' appointments and the need for frequent travel to outpatient clinics. While many robotic solutions have been proposed to address the above concerns, most focus on training only the wrist or the fingers, neglecting the synergy between the two. To address this, the WiGlove was co-designed to allow hemiparetic stroke survivors to train both the wrist and fingers in the comfort of their homes.

The central hypothesis of this work is to investigate if a device designed using user-centred methods featuring aspects of usability such as easy donning and doffing and wireless operation, can act as a feasible tool for home-based rehabilitation of the hand and wrist following stroke. In order to aid this investigation, we tackled this task in three stages of usability and feasibility evaluations.

Firstly, healthy participants tried the current state of the art, the SCRIPT Passive Orthosis, as well as the WiGlove, in a counterbalanced, within-subject experiment and attested to WiGlove's improvement in several aspects of usability such as ease of don/doffing, suitability for ADL, unblocked natural degrees of freedom, safety and aesthetic appeal. Subsequently, a heuristic evaluation with six stroke therapists validated these improvements and helped identify issues they perceived to potentially affect the device's acceptance. Integrating this feedback, the updated WiGlove was subjected to a six-week summative feasibility evaluation with two stroke survivors, with varying levels of impairment, in their homes without supervision from the therapists. Results from this study were overwhelmingly positive on the usability and acceptance of the WiGlove. Furthermore, in the case of the first participant who trained with it for a total of 39 hours, notable improvements were observed in the participant's hand functions. It showed that even without a prescribed training protocol, both participants were willing to train regularly with the WiGlove and its games, sometimes several times a day. These results demonstrate that WiGlove can be a promising tool for home-based rehabilitation for stroke survivors and serve as evidence for a larger user study with more participants with varying levels of motor impairments due to stroke.

The findings of this study also offer preliminary evidence supporting the effectiveness of training with the WiGlove, particularly in the case of the first participant, who exhibited a significant reduction of tone in the hand as a result of increased training intensity. Owing to the participant's satisfaction with the device, it was requested by him to extend his involvement in the study by using the WiGlove for a longer duration which was facilitated.

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AUTHOR'S DECLARATION

I declare that the work in this dissertation was carried out in accordance with the requirements of the University's Regulations and Code of Practice for Research Degree Programmes and that it has not been submitted for any other academic award. Except where indicated by specific reference in the text, the work is the candidate's own work. Work done in collaboration with, or with the assistance of, others, is indicated as such. Any views expressed in the dissertation are those of the author.

SIGNED: VIGNESH VELMURUGAN DATE: 31st MAY, 2023

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ABBREVIATIONS

RAT	Robot-Assisted therapy/Robot-Aided therapy
SCRIPT	Supervised Care and Rehabilitation Involving Personal Tele-robotics
MCP	Metacarpo phalangeal joint
SPO	SCRIPT Passive Orthosis
ROM	Range Of Motion
DoF	Degrees of Freedom
ADL	Activities of Daily Life
IMU	Inertial Measurement Unit
FDM	Fused Deposition Modeling
SUS	System Usability Scale
IP	Interphalangeal joint
DIP	Distal Interphalangeal joint
FM	Fugl-Meyer
UCD	User-Centred Design
SoA	State of the Art
RQ	Research Question
QUEST 2.0	The Quebec User Evaluation of Satisfaction with Assistive Technology
FES	Functional Electrical Stimulation
PNF	Proprioceptive Neuromuscular Facilitation
CTE	Cognitive Therapeutic Excercise

CHAPTER 1

INTRODUCTION

Stroke is a medical condition that results in a loss of local or global cerebral function due to a rupture or an occlusion in the cerebral blood vessels [9]. Based on the location and extent of this damage, it could impair cognition, vision, sensation, language and motor function [10]. Motor impairments may range from paresis to plegia, wherein paresis is characterised by muscle weakness leading to impaired motor functions, and plegia or paralysis represents an advanced stage of paresis, where the affected body part loses complete functioning [11]. Notably, stroke is the second leading cause of death and the third leading cause of disability worldwide [12, 13]. In a study involving 680 stroke survivors, it was observed that 88% of them experienced varied levels of motor function deficits [14], significantly impacting their ability to perform activities of daily living (ADL).

1.1 Post-stroke rehabilitation

Spontaneous neurological recovery by recruiting redundant neural pathways and salvaging undamaged ones ensues in the initial hours after stroke and can last up to 3 months [15–17]. The extent of recovery during this phase varies from person to person. Motor recovery post this spontaneous phase, can either occur through compensatory behaviours developed by the user or through neural plasticity. In the early stages of their recovery, stroke survivors develop compensatory strategies such as moving the trunk and scapula to perform reaching tasks [17, 18]. Over-reliance on such compensatory behaviours might inhibit the generation of more normal motor patterns while performing daily tasks. In the long term, this learned non-use could potentially limit the recovery and result in a reduced range of motion in the impaired limb [19, 20]. On the other hand, recovery can also be achieved through learning-related neural plasticity mechanisms where cortical reorganisation or vicariation is mediated by repetitive movements and sensory

stimulation. This leads to the formation of new neural pathways in the surviving undamaged region that take over the functions of the damaged ones [17]. This is the neurophysiological basis for conventional post-stroke rehabilitation.

Post-stroke rehabilitation is a cyclic process involving the assessment of motor capabilities, setting improvement goals, and intervention [21]. While conventional interventions involve the physical exercise of the impaired limbs with the help of a therapist, a multi-disciplinary approach tailored to the survivor, including techniques such as constraint-induced movement therapy (CIMT), bilateral training, and electrical stimulation of muscles, has proven to be effective [22–24]. The intensity and large repetitions of training are important factors contributing to the recovery of arm functions [25]. However, with the increasing incidence of stroke, there is a limit to the intensity of training that conventional therapy can deliver, putting further stress on the available rehabilitation services [26]. A study shows that only 31% of the patients continue their recommended training at home after discharge [26]. The reasons for the low adherence to training include fatigue, depression, pain, and lack of motivation, which have been shown to affect the patient's performance in training [27].

The present discourse posits that home-based training may yield a promising avenue for enhancing patient motivation and reducing fatigue, thereby augmenting the potential for recovery. By facilitating training in familiar surroundings, patients can overcome the dependence on external factors such as therapist appointments, which may impede training duration and frequency. This approach can be facilitated through the development of remote supervision systems, as studies have shown that such systems lead to improvements in Fugl-Meyer scores ranging from 7.86 to 8.36, above the minimum clinically important difference for FM in stroke [28]. Fugl-Meyer is a widely used measure of post-stroke motor impairments detailed later in section 2.1.1.1. This technique is especially advantageous for stroke survivors in remote locations with limited access to medical facilities, who can undergo post-stroke rehabilitation without the burden of commuting [29]. In times like the COVID-19 pandemic, this approach helps to alleviate the stress on a strained healthcare system by allowing stroke survivor's to continue their training in the safety of their home, while also ensuring the safety of the therapists who can remotely monitor the progress of the training. An effective home-based rehabilitation system should require a means to assist the participant in the absence of the therapists, allow for remote monitoring and motivate the participant to adhere to training. With their ability to offer all the above, robotic devices prove very useful in this context.

Robot-aided rehabilitation or Robot-Aided Therapy (RAT) has gained impetus in this context due to its ability to deliver repetitive physical training for long durations while allowing remote monitoring of progress by clinicians through sensors in the robot [30]. Such systems

offer additional benefits such as quantitative assessment measures that are objective, unlike the subjective conventional assessment scales currently in use [18, 30]. Furthermore, it allows patients to spread practice sessions at their convenience, potentially improving performance and retention of learned tasks [31]. The presence of sensors also allows for the possibility to interact with therapeutic computer games to improve motivation and promote training engagement. The autonomy and control that this approach provides, might contribute to improvement in the outcome of the therapy [32].

1.2 Motivation and research goals

In a stroke patient's recovery towards regaining their ability to perform activities of daily life, recovering the functions of the wrist and fingers play a significant role. This is due to their significant influence on the functional use of the arm (example: grasping). However, the conventional post-stroke rehabilitation approach of initiating training from the proximal parts of the upper limb and moving to the distal segments may potentially result in a missed opportunity to leverage the synapses of the distal segments and prevent hypertonia [33]. A study observes a lack of research in rehabilitation systems to train the distal segment of the upper arm [34]. This has been attributed to be one of the reasons for the improvement in motor assessment scores not translating to functional recovery [33]. While there have been several attempts [35–38] at addressing this with robot-aided therapy (RAT) approaches, a recent survey found that only two robotic devices were designed to allow the user to train both the wrist and the fingers together in order to account for the synergy between them [39].

Of these devices, only SCRIPT Passive Orthosis (2014) [32] was deemed ideally suitable for home-based therapy due to the inherent safety of the passive actuation and the absence of bulky and noisy peripherals such as the compressors used in pneumatic devices. Given the unique requirements and design challenges of such a device, SPO serves as the state-of-the-art for this research area. SPO is a passive orthosis that allows stroke survivors to perform hand and wrist exercises. Developed in a European Framework 7 project, it is a part of the SCRIPT system that includes interactive games and a back-end system for clinical monitoring. While a study involving 23 stroke survivors validated SPO's feasibility, it also identified several functional and usability shortcomings [7, 32]. Usability is one of the significant user requirements that affect the acceptance of such devices [40, 41]. These limitations in the state-of-the-art highlight a research gap and opportunity to innovate.

Therefore, the overarching aim of the research presented in this thesis aims to design and develop a home-based rehabilitation device for the hand and wrist that addresses the limitations of SPO through a user-centred design approach (UCD). Thus, in this work, a passive dynamic

orthosis called the WiGlove was developed from scratch to:

1. Facilitate safe home-based therapy.
2. Provide the ability to interact with games to improve engagement and motivation.
3. Allow the fingers and wrist to be trained together, accounting for their synergy.
4. Provide support in performing ADL activities using the orthosis's ability to counter abnormal synergies.

The term orthosis refers to a device used to support or modify the structural and functional characteristics of a movable part in conformity with ISO 8549-1:1989 [42]. A dynamic orthosis, also known as an articulated orthosis provides support and helps in the movement of a body part while wearing it [43]. Unlike an active orthosis, a passive one does not guide the user's joints throughout the entire range of motion while training but rather provides assistive or resistive forces using passive actuators such as extension springs or elastic cords [44]. It requires the active participation of the user in the initiation and movement during training which has been shown to increase functional recovery [45].

1.2.1 Hypothesis and research questions

The central hypothesis of this work is:

"**The design of a passive orthosis for hand and wrist rehabilitation, following a user-centred design approach will lead to a feasible home-based system demonstrated by evidence of adherence, usability and effectiveness.**"

The investigation of this hypothesis involves addressing the following three research questions.

RQ1: **What are the user requirements for a home-based rehabilitation orthosis that allows hemiparetic stroke survivors to independently train their fingers and wrist ?**
Previous research [46] highlights the significance of identifying the requirements and ensuring that they are fulfilled in a user-centred design of medical devices. Accordingly, the first step involved in addressing the research gap is to define the user requirements that can guide the design process. This is achieved by extending the work done by the SCRIPT project through original work carried out in this PhD in the form of a review of the literature including existing usability analyses and clinical trials of various rehabilitation devices. In answering this research question, a comprehensive list of user requirements for an ideal home-based hand rehabilitation orthosis was formulated.

RQ2: **Can the WiGlove, which was designed using a user-centred approach to meet specific requirements, result in better functionality and usability compared to the current state-of-the-art?**
Given the objective of this work is to improve the state-of-the-art, it is essential to comparatively evaluate the prototype's design features to ensure that they satisfy the requirements better than SPO (SoA). While most similar works focus on testing functionality, usability is often neglected at the formative stage. Given the significance of usability in the device's acceptance and usage, it is very significant to this aspect of the device.

RQ3: **Is it feasible to use the WiGlove as an orthosis for rehabilitation by hemiparetic stroke patients, in a home environment, without requiring assistance from therapists and is there evidence of its effectiveness?**
After verifying the functionality and usability improvements of the WiGlove, the next stage involves evaluating its suitability for unsupervised use by hemiparetic stroke survivors with motor function impairments. Given its intended application, it is crucial to assess the device's suitability for use in a home environment and the engagement it offered. Finally, this study attempts to evaluate the primary function of the WiGlove by assessing the effects of the intervention it delivered on the recovery of hand functions in stroke survivors. Various objective and subjective measures are used to evaluate the orthotic (with assistance) and restorative (without assistance) effects of training with the WiGlove.

1.3 Thesis outline

This thesis presents the different stages involved in the user-centred design of the WiGlove (Figure 1.1). It is organised as follows:

Chapter 2 of this thesis provides background information and motivation for the research. It begins by discussing the best practices and principles of using robots and home-based methods for stroke therapy and describes various studies examining their effectiveness. The chapter then looks at the challenges in designing a robotic orthosis for the hand and presents a detailed survey of the different rehabilitation devices that aim to train the distal segment of the upper limb.

Chapter 3 of this thesis presents the user-centred methodology used in this study to design and develop the WiGlove from scratch. Beginning with an analysis of the requirement, it highlights the various design features of the WiGlove that addresses these specifications. Finally, this chapter discusses the methodology and results of the technical evaluation to validate that the WiGlove fulfils the functional requirements identified earlier. This chapter addresses **RQ 1** and partially covers **RQ 2**.

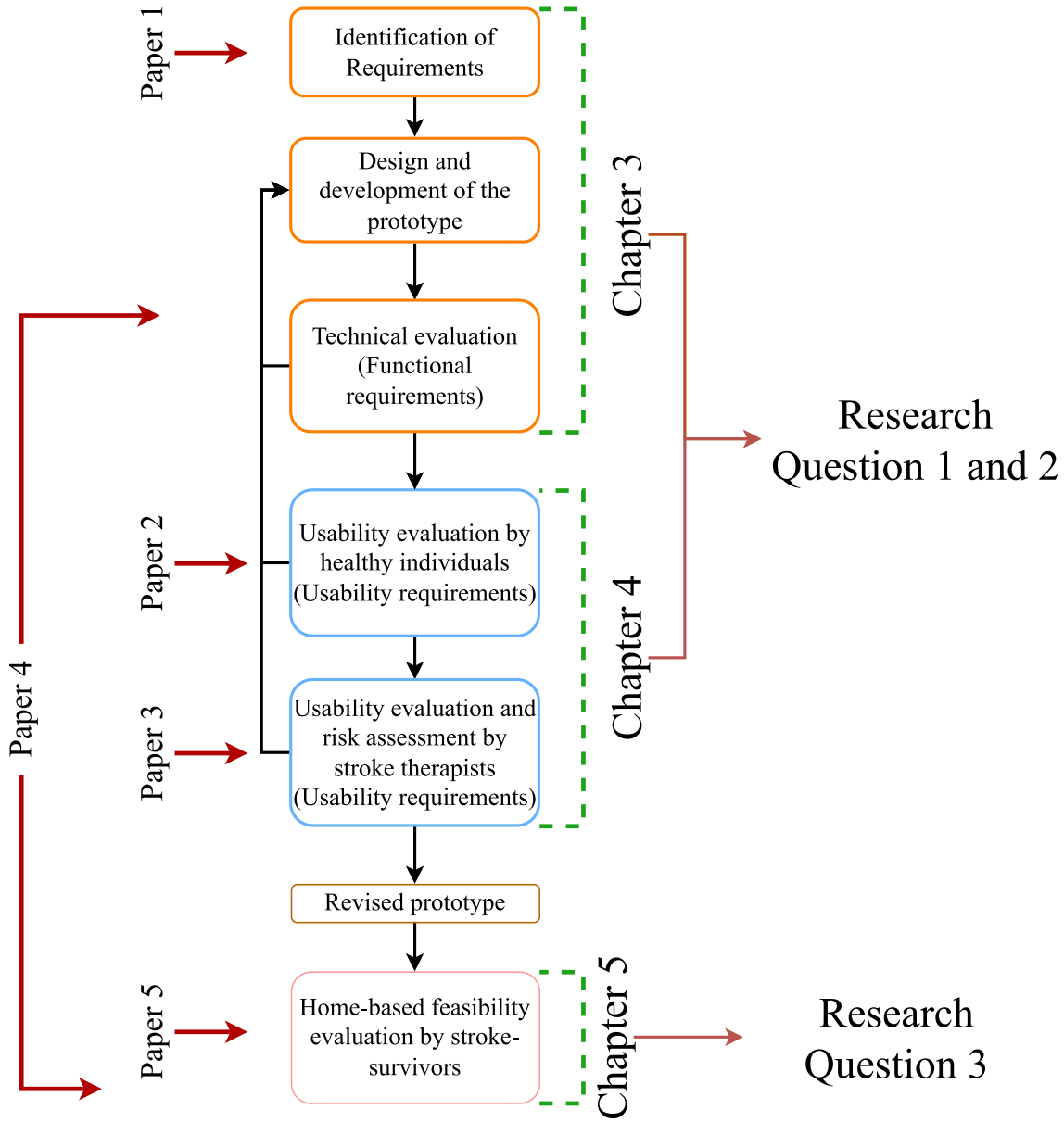


Figure 1.1: The WiGlove's design stages and chapters mapped to the research questions of this study and the corresponding publications listed later in this chapter and in section 6.1.3

As part of the user-centred design approach, **Chapter 4** presents the methodology and results of the two formative usability evaluations of the WiGlove involving healthy participants and physiotherapists with experience in post-stroke rehabilitation. While most similar works focus on testing functionality, usability is often neglected at the formative stage. Hence this chapter focuses on the evaluation of WiGlove's usability and provides preliminary evidence of its improvements in several elements over the current state of the art, thereby answering the rest of **RQ 2**. Due to the unique functional and usability challenges that arise with the design of such a device, SPO acts as the only ideal state-of-the-art for this application and therefore we benchmark our device against it. Firstly, twenty healthy participants evaluated the usability and safety of the WiGlove compared to its predecessor, the state-of-the-art SPO. In this within-subject experiment, they performed various tasks such as donning/doffing, adjusting the tension, grasping, etc., with both gloves and rated them using a Likert scale-based questionnaire. The results showed improvements in several aspects of usability and safety. Building on this preliminary validation, the subsequent phase of this formative evaluation involved obtaining feedback from 6 stroke therapists from the Luton and Dunstable Hospital, UK who interacted with the WiGlove and assessed its usability with a focus on the aspects discussed in the previous study. The results of this study largely validated the improvements and helped identify the areas of improvement for the next iteration. This chapter elucidates how the insights obtained from these evaluations were utilised to enhance the design of the WiGlove.

Having undergone the formative evaluations, **Chapter 5**, presents the summative feasibility analysis of the revised WiGlove. It presents the methodology and results of this home-based assessment to address **RQ 3**. In this study, two hemiparetic stroke survivors used the WiGlove to train at their homes without assistance from the therapists. Their training involved using the WiGlove to do flexion/extension exercises of their wrist and fingers while performing ADL or while playing therapeutic games on the tablet. Results from this study were overwhelmingly positive on the usability and acceptance of the WiGlove. Furthermore, in the case of the first participant who trained with it for a total of 39 hours, notable improvements were observed in the participant's hand functions. These findings serve as preliminary evidence supporting the feasibility of the WiGlove for home-based therapy thereby positively answering the following third and final research question of this study. Although the duration of the study was six weeks, encouraged by the improvements in his hand, the first participant expressed his desire to continue using the device for an extended period and thereby prolonged his training with it.

In conclusion, **Chapter 6** presents an overview of the research undertaken in this thesis involving the design and development of the WiGlove. It summarises the results of the different experiments to validate the WiGlove's functionality and usability and details how they contributed to its iterative development. Furthermore, it identifies the limitations of this study and highlights

the scope for future work.

The work presented in these chapters contributed to the publication of three peer-reviews research papers in international conferences and is pending the acceptance of two more listed below.

Chapter 3

Paper 1 - **V. Velmurugan**, L. Wood, and F. Amirabdollahian, “Requirements for a home-based rehabilitation device for hand and wrist therapy after stroke,” in UKRAS21: The 4th UK Robotics and Autonomous Systems Conference, July 2021, p. 23.http://doi.org/10.31256/Xw5Aj7Q

Chapter 4

Paper 2 - **V. Velmurugan**, L. Wood, and F. Amirabdollahian, “Formative usability evaluation of WiGlove – a home-based rehabilitation device for hand and wrist therapy after stroke,” In Companion of the 2023 ACM/IEEE International Conference on Human-Robot Interaction, March 2023, https://doi.org/10.1145/3568294.3580087

Paper 3 - **V. Velmurugan**, L. Wood, and F. Amirabdollahian, "A User-centred Design and Feasibility Analysis of the WiGlove - A Home-based Rehabilitation Device for Hand and Wrist Therapy after Stroke," ACHI 2023, The Sixteenth International Conference on Advances in Computer-Human Interactions,p 134 to 139, April 2023. article here

Chapter 3 and 5

Paper 4 - **Submitted** - The paper titled "Preliminary Results from Functional and Usability Assessment of the WiGlove - a Home-based Robotic Orthosis for Hand and Wrist therapy after Stroke." submitted to IEEE International Conference on Robot & Human Interactive Communication (RO-MAN 2023).

Chapter 5

Paper 5 - **V. Velmurugan**, L. Wood, and F. Amirabdollahian, "Preliminary Results From A Six-Week Home-based Evaluation of a Rehabilitation Device for Hand and Wrist Therapy after Stroke," In 2023 IEEE-RAS-EMBS 18th International Conference on Rehabilitation Robotics (ICORR).

CHAPTER 2

BACKGROUND

Stroke is a medical condition arising from disrupted blood supply to the brain, with two main causes: hemorrhagic stroke due to a ruptured brain blood vessel, and ischemic stroke due to a clot in the cranial blood vessels [47]. The World Health Organization designates stroke as the primary cause of global disability and the second leading cause of death [48]. This complex condition yields diverse effects contingent upon the location of the affected blood vessel, resulting in varying levels of brain damage. Impaired cognition, vision, sensation, language, and motor function can manifest based on the severity and site of damage [10]. These impairments significantly disrupt independent living and daily activities. Motor deficits in the upper limb are prevalent in 80% of stroke survivors [49]. Immediate post-stroke recovery initiates spontaneous neurological restoration by utilising alternative neural pathways and preserving undamaged ones [16]. During early recovery, survivors adopt compensatory strategies like trunk and scapula movements for reaching tasks [17, 18]. Over-reliance on such behaviours may hinder the development of normal motor patterns. Distinguishing true recovery, driven by enhanced voluntary motor control, from compensatory behaviours is crucial. Physical rehabilitation is crucial to restoring functions not reclaimed during spontaneous recovery. Numerous post-stroke rehabilitation approaches have emerged to guide this process.

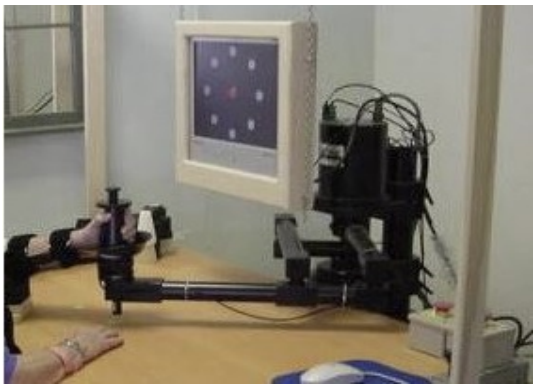
Proprioceptive neuromuscular facilitation (PNF) is a widely used approach by physiotherapists which is defined as 'methods of promoting or hastening the response of the neuromuscular mechanism through stimulation of the proprioceptors' [50]. This method of improving muscle elasticity involves repetitions of stretching the target muscle by the therapist followed by its contraction by the user to achieve an increase in the RoM of a joint [51]. Autogenic and reciprocal inhibition has traditionally been accepted as the neurophysiological explanations for the superior

ROM achieved by PNF stretching [52]. While short-term positive effects on the passive RoM are documented, the long-term benefits remain insufficiently explored. Furthermore, the heterogeneity in the PNF practices as pointed out by several researchers precludes generalisation of the benefits and drawbacks [50].

On the other hand, Carlo Perfetti proposed the Cognitive Therapeutic Excercise (CTE), a motor learning model that involves the cognitive system in traditional motor-system-centred physical rehabilitation [53]. It occurs by integrating afferent proprioceptive and tactile information in the training activity [54]. This activates the brain's cognitive process and allows it to engage and train brain regions necessary for performing ADL [53]. This approach has been shown to result in improved performance compared to traditional treatment approaches.

Among the neurophysiological approaches, according to [55], the Bobath concept is one of the most widely used approaches in stroke rehabilitation in the Western hemisphere. Initially proposed by Bertha and Karl Bobath, it is based on a hierarchical model of motor control involving a problem-solving approach with a focus on the release of abnormal tone to regain normal movement patterns [56]. With recent developments in the understanding of the neurophysiological basis of neuroplasticity, the Bobath concept has evolved into its current form still used by therapists. Studies have shown that high-intensity physical training involving large repetitions significantly improves the recovery of motor functions [22–24]. Delivering such rigorous therapy through conventional one-to-one interaction with the therapists is a labour-intensive task [34]. This difficulty is further compounded by the increasing incidence of stroke which increases the burden on the available resources.

2.1 Robot assisted therapy (RAT)



(a) MIT-MANUS [57]

(b) GENTLE/S [58]

Figure 2.1: Devices used in robot-assisted therapy

Repetitive tasks can be automated with the help of robots and can act in conjunction with clinicians and therapists. This can act as a tool that allows for efficient use of their expertise [59]. Besides this, the use of robotic devices in stroke rehabilitation offers further benefits such as:

- The use of sensors to measure various kinematic parameters that could result in objective measures of outcome [18, 60, 61].
- Greater user engagement when integrated with games and virtual reality [10, 62, 63].
- Ability to automate the process of adapting the parameters of the therapy based on the user's performance [44, 64, 65].

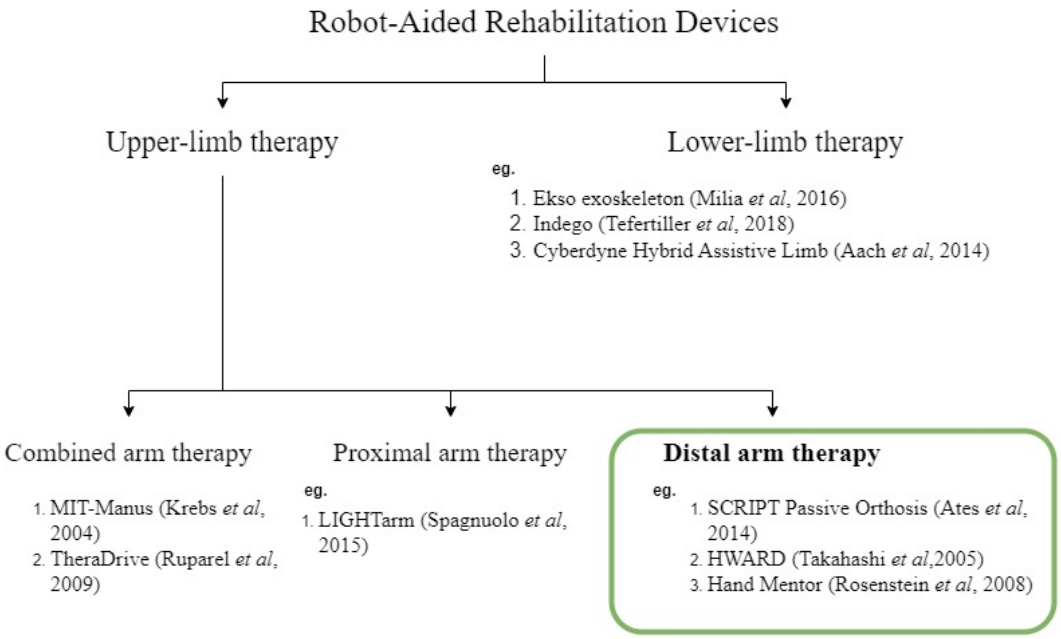


Figure 2.2: Classification of robot-aided rehabilitation devices

Figure 2.2 illustrates various rehabilitation robots designed to target different body parts following neurological injuries. Notably, robots such as Ekso Exoskeleton [66] and Indego [67] are designed to support and assist the lower limb in performing rehabilitation and gait training. Similarly, several devices have been proposed for the rehabilitation of the upper limb such as MIT- Manus [61, 68], InMotion Shoulder-Elbow Robot [69], Bi-Manu Track (focused on the distal segment of the upper arm) [70], SCRIPT Passive orthosis [32], etc. MIT-Manus is one of the most well-known and clinically studied robots that allow the user to train their arm in performing reaching tasks against the stiffness and damping parameters defined by the therapist. Studies have reported improved recovery as a result of training with the device for an additional 4 to 5 hours a week than conventional training [10]. To integrate sensory stimulation with robot-aided rehabilitation, the GENTLE/S system employs a 3 DOF haptic device in the form of the Haptic

Master robot and a VR technology [58]. This system focuses on neuro-physical rehabilitation by increasing the sensory input and the brain's relearning stimulations to improve coordination [10].

The upper-limb rehabilitation robots can broadly be classified into three categories as shown in figure 2.2. From robots that target the whole arm like MIT-Manus, there exists devices that target only the proximal joints separately and the distal joints separately. Devices like the LIGHTarm focusses on the shoulder rhythm and elbow singularity which is in the form of a fixed wearable device [71]. Such devices help in training the gross positioning of the arm. However, training the distal segment which involves the wrist and hand is highly significant to perform fine manipulations required to perform activities of daily life. Consequently, this PhD focuses on the rehabilitation of the wrist and fingers. Section 2.6 and appendix 7 present a comprehensive survey of the rehabilitation devices aimed at this part of the upper limb.

2.1.1 Efficacy of robot-assisted therapy

A dose-matched trial comparing the effects of RAT and conventional therapy on stroke patients reported no significant differences in the outcomes between the two groups [72]. However, this disregards the significant benefit of RAT's ability to offer higher-intensity training than conventional face-to-face therapy with a therapist. Such high-intensity training has shown evidence of resulting in an enhanced recovery in stroke patients [73]. A meta-analysis of the effects of RAT on upper-limb recovery of stroke survivors concluded that it resulted in significant motor recovery [60]. Stroke patients who received RAT were more likely to recover their ability to perform ADL than those who received conventional therapy [74]. In agreement with this, a systematic review [34] that included 11 clinical trials, reports a mean increase in the FM score of 3.7 points. This represents a statistically significant 6% increase in motor control where improvements in muscle activation pattern, selectivity and speed of movement were observed as a result of RAT. Fugl-Meyer (FM) scale used to qualitatively measure post-stroke impairment is discussed in detail in section 2.1.1.1. However, it was also observed that this increase in motor assessment scores did not translate to clinically relevant functional recovery [75]. Similar results with mixed outcomes were reported by [60] where improvements in motor assessment scores did not translate to functional recovery. This could be attributed to the use of the Fugl-Meyer score for quantification of the outcome as explained below.

The clinical trials included in this systematic review involved robot-aided rehabilitation that focused only on the proximal parts of the upper limb. Its authors suggest that the use of the upper-limb portion of the Fugl-Meyer scale that includes the assessment of both proximal and distal segments of the arm might have underestimated the functional outcomes of robot-aided rehabilitation [34]. This shows the significance of recovering the functions of the distal segment of the arm (wrist and fingers), in improving the stroke survivor's ability to perform activities of

daily life (ADL).

2.1.1.1 Measures of motor impairment

Several standardised measures of motor impairments can be found in literature such as Motor Assessment Scale (MAS) [76], Barthel Index (BI) [77], Action Research Arm Test (ARAT) [78], Fugl-Meyer (FM) [75] etc. Among them, Fugl-Meyer is the most widely used quantitative measure of post-stroke motor impairments. It is a 226-point Likert scale tool that assesses the user's motor impairments along the following 5 domains: motor function, joint range of motion, sensory function, balance and joint pain. These items are scored on a 3-point Likert scale where 0 = cannot perform the movement, 1 = partially performed the movement, and 2 = performed the movement fully. The overall score ranges from 0 (hemiplegia) to 100 (normal motor performance). Although the upper limb portion of the scale corresponds to 66 points out of 100, the authors of [75] highlight the FM scale's lack of sensitivity to detect changes due to its 3-point scoring scheme. The authors also underscore the under-representation of distal fine motor functions. Improvements in motor impairment levels as measured using FM, often not translating into functional recovery could be ascribed to the above-mentioned limitations. Nevertheless, FM is still widely used in clinical trials that evaluate the effectiveness of post-stroke rehabilitation intervention. Since the scope of this PhD is to only demonstrate the feasibility, the Fugl-Meyer scale is not used as an outcome measure or baseline measurement in this work.

Alternatively, ARAT is a test that is designed to account for the functional capabilities of the stroke survivor. The user is evaluated across 19 tasks spread across the following 4 subscales: grasp, grip, pinch and gross movement using the test kit shown in figure 2.3. However, since the therapists in the Luton and Dunstable Hospital had not been trained to administer this and due to this PhD focus being demonstrating the feasibility, ARAT was not included in this work. Instead, two functional tests of fine and gross motor dexterity known as the Nine Hole Peg test (NHPT) and the Box and Block Test were employed as discussed in section 5.1.

Figure 2.3: Action Research Arm Test kit [1]

2.2 Limitations of robot-aided therapy

Most of the existing robot-aided rehabilitation devices are limited to operating in a clinical environment due to factors such as complicated mechanical structure, large size, safety concerns related to the actuation mechanism and therefore the necessity of supervision. This requires the stroke survivors to travel to and from the clinic, leading to fatigue. Fatigue has been shown to hurt the stroke survivor's performance during training and in activities of daily life (ADL) [27]. Furthermore, training in a clinical environment limits the number of hours that a patient can train thereby effectively countering one of the main advantages of RAT which is its ability to permit training for long durations at a high frequency that increases the stimulation of functional recovery [32]. Home-based approaches help to overcome this limitation.

2.3 Home-based rehabilitation

The limitations of conventional therapy and in-clinic RAT approaches were exacerbated during the COVID-19 pandemic and the resulting social distancing-related lock downs. This severely affected the ability of stroke survivors in receiving adequate conventional one-to-one therapy since it could compromise the health safety of both the patient and the therapists [79]. Increased stress was placed on the already strained healthcare system and therapists. A global observation study that studied 124 centres of rehabilitation reported an overall decline in the quality of stroke care during the pandemic [80]. Ensuring regular and continuous therapy is essential to harness the opportunity to regain motor functions in stroke survivors' recovery towards independent living. To address this concern, the integration of home-based tele-rehabilitation approaches that allow remote monitoring and autonomous training is essential [79].

This approach allows stroke survivors to train at any time and place of their choice. They could train multiple times a day which results in an increase in the total training duration. Such distributed training sessions have been reported to improve the overall performance during the sessions. It was observed that this leads to greater retention of the learned tasks compared to the bulked training approach [81]. This form of training is difficult to achieve in the conventional one-to-one rehabilitation methods due to a multitude of factors such as the availability of therapists, transportation, etc. Home-based rehabilitation techniques permit stroke survivors in remote locations with inadequate transportation or medical resources to avail themselves of invaluable therapy [29]. Training at home without constant supervision could provide a sense of autonomy which would result in improved outcomes. With increasing stroke incidence and the resulting stress on the available healthcare resources, there is a need for new home-based rehabilitation strategies for stroke survivors and their caregivers [82]. Although several home-based rehabilitation systems have been proposed, only a few have been subjected to extensive home-based studies by installing them in stroke survivors' homes [83].

A randomized controlled trial [82] comparing the effectiveness of home-based video conferencing mediated therapy and conventional rehabilitation for stroke patients, showed significant improvement in both groups. Both groups underwent physical exercise and EMG-triggered neuromuscular stimulation and showed an increase in the Modified Barthel Index and Berg Balance Scale. However, no significant difference between the groups was observed. Another such randomized trial [28] comparing home-based telerehabilitation and in-clinic therapy reports both the group showing an increase in FM scores of 7.86 to 8.36, which is significantly higher than the 5.25 MCID as per [84]. Similar studies have explored the approach of home-based therapy for post-stroke rehabilitation and reported that it results in improved functioning of the upper limb [85–87] and it is a reliable and feasible approach [83, 88–90]. Furthermore, a review of telerehabilitation trials for stroke found it not inferior to face-to-face therapy and was observed to be cost-effective [91]. This approach was deemed to be a viable alternative to traditional rehabilitation during the height of the pandemic for stroke survivors [92].

2.4 State of the art in home-based rehabilitation

Different approaches to home-based post-stroke rehabilitation can be found in the literature. The authors of [93] have classified the different approaches into six different groups based on the primary technology involved in them. The groups are as follows:

- Computer-based games
  High-intensity training in the traditional approach could be considered tiresome and exhaustive [94]. Adherence to such fatigue and pain-inducing training requires high motivation from the patient[95]. Gamification of this training has the potential to enhance the patient's motivation due to their competitive nature [94]. A survey reports 90% of its participants agreed that therapy involving games was less confusing and easy to track their improvements. To take advantage of the ability of computer games to entertain and engage, researchers have explored both adapting commercial games [89, 96, 97] and developing novel games to suit the needs of rehabilitation therapy[32]. Although existing commercial games enjoy the benefits of greater acceptance and affordability they do not meet the needs of a rehabilitation system. Since stroke survivors who experience motor function deficits in their hands, have a reduced range of motion there is a need for the games to have a calibration method to allow them to train within their available range. Furthermore, they are unable to measure various kinematic parameters that help inform clinicians to track the progress of training. This has been addressed in [83, 98], by developing a system consisting of a device to interact with the game while measuring the kinematic parameters. There is a need for custom games that are focused on training stroke survivors to perform activities of daily life.

- Tele-rehabilitation
  In this approach, therapists use telephone or video conferencing to supervise the training remotely, thereby eliminating the need for the patient or the therapist to commute. This reduces both time and cost involved in therapy [93]. This method requires the users to have technical proficiency with conferencing software and hardware. According to [93], there is a need for further work on aspects such as privacy and system security in telerehabilitation.

- Virtual Reality based therapy
  The integration of Virtual Reality technology with computer games is gaining impetus in the context of home-based rehabilitation [63, 96]. VR adds to the entertainment and engagement aspect of computer game-based therapy. Since most existing VR systems are not designed for rehabilitation, it is hard to verify their clinical effectiveness [93]. However, it is easy to customize it to rehabilitation by developing scenarios that involve performing tasks of activities of daily life such as handling a cup, opening the door, etc. Furthermore, it also allows for easily adapting and modifying the training scenarios based on the user's needs.

  Although the integration of haptic devices with VR is increasingly common [44, 99], the absence of an assistive component is a limitation of this method. This makes it unsuitable for stroke survivors with moderate to extreme motor impairments. Furthermore, [93] postulates that even though some training scenarios that require the user to move real-world objects imitating the virtual ones exist, this approach could reduce the overall sensory feedback that impacts recovery.

- Neuromuscular electrical stimulation
  Unlike physical rehabilitation discussed so far, this approach uses electrical stimulation of the neuromuscular system to induce muscle movement. A controlled electrical current is delivered to a target muscle which induces a depolarisation of the peripheral neurons and as a result cause muscle contraction. Such systems broadly fall into the following two categories according to [100]. One uses this in a therapeutic role where the electric currents are used to stimulate lasting physiological changes facilitating neuroplasticity with the aim of improving voluntary motor control. The other approach is known as functional electrical stimulation where the electric stimulus is used to supplement lost motor functions and help achieve functional movements such as holding a book. Devices that employ this technique to elicit movements are known as neuroprosthesis. Some commercially available neuroprostheses include MyoTrack Infiniti [101] and NeuroMove NN900 [102]. Given the observed evidence of the positive effects of FES on motor function recovery [103], recent works have proposed the integration of both FES and an orthosis. Since FES systems largely do not involve an orthosis, they are not explored further within the scope of this thesis.

- Device with integrated sensors
  Most of the devices and studies in robot-assisted therapy are focused on operating in a clinical setup. However, there are few commercial devices for home-based post-stroke rehabilitation, such as Saebo Mobile Arm Support [104], Hand Mentor [105], Hand mentor Pro [106] and Myomo mPower 1000 [107]. The most common limitation among these devices is their requirement for technical expertise and large space. Furthermore, home-based devices with actuators have the risk of causing injury to the user due to malfunction. They could cause large undesirable forces on the joints forcing them to move beyond their natural range of motion causing pain and injury. This is overcome through the use of passive orthosis such as the SCRIPT passive orthosis [32]. It uses a suite of sensors (Bending sensors, IMU and visual sensors) to measure the position of the hand and the joint angles of the fingers and wrist.

2.5 Rehabilitation of the hand

The human hand is a sensorimotor apparatus with a complex kinematic structure (Figure 2.4). It consists of 27 bones including 8 carpals and 5 metacarpals. The thumb and the fingers are made of two and three phalanges respectively [108]. Twenty-nine skeletal muscles operate the joints of this skeletal system to offer a total of 19 degrees of freedom(DOF) at the hand and 2 at the wrist. The carpometacarpal and metacarpophalangeal joints offer 2 DOF each: flexion/extension and abduction/adduction. The remaining fingers and thumb joints offer 1 DOF each, bringing the total to 19 DOF in hand. Additionally, the wrist offers two degrees of freedom along the flexion/extension and abduction/adduction axes.

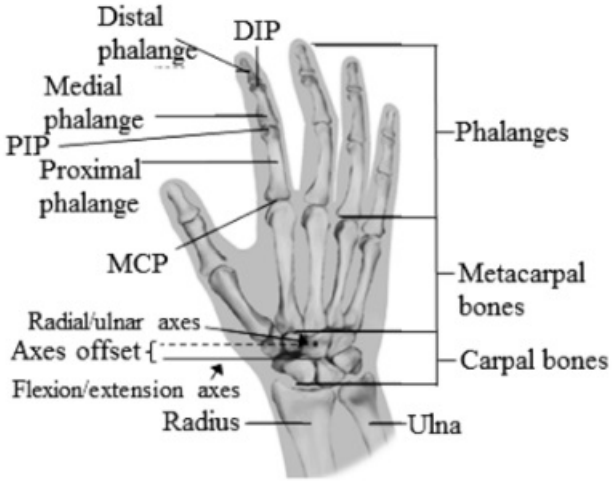


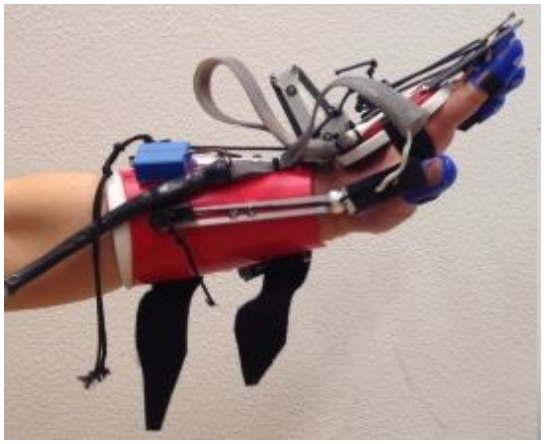
Figure 2.4: Anatomy of Hand [2]

The hand's dexterity is controlled by an intricate neural network that consists of various cortical and sub-cortical structures [109, 110]. This dependence on such extensive cortical resources

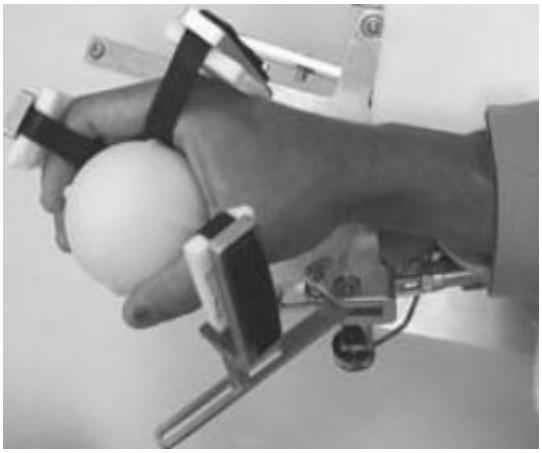
makes the hand's function extremely vulnerable in the event of a stroke often resulting in severe impairment and loss of dexterity. A reduction in the flexion of the proximal interphalangeal joint (PIP), the extension of the metacarpophalangeal joint (MCP) and finger abduction were observed in stroke survivors [111]. 60% of stroke survivors suffer from impairments of the hand that affects functional activities of daily life such as grasping and holding an object, buttoning a shirt, etc [109]. Stroke survivors experiencing hemiparesis in their hand, tend to use excess forward movement while reaching towards an object and use its wind resistance to coil the fingers around it [17]. To compensate for the impaired feedforward control, they tend to rely on visual feedback [17, 111]. Hence a regular functioning hand's strength and dexterity are essential to perform grasping and manipulation. Therefore rehabilitation is essential to restore the stroke survivor's ability to independently perform activities of daily life (ADL) [34].

Rehabilitation of the hand involves exercises to strengthen the muscles and reduce muscle tone if the impairment is ascribed to problems with motor execution. On the other hand, if the problem is with motor learning and planning, rehabilitation involves task-oriented therapy with techniques such as bi-manual training [110]. The conventional post-stroke rehabilitation approach involves initiating training from the proximal parts of the upper limb and moving to the distal segments, potentially resulting in a loss of opportunity to harness the synapses and prevent hypertonia in the distal segment [33]. Study shows that there is a higher skill transfer to the proximal segments when the training starts at the distal end of the upper arm compared to starting from the proximal end [33]. Taking advantage of the robot-aided rehabilitation technique to train the distal segment of the upper limb is the focus of this research.

2.6 Survey of robotic devices designed for the rehabilitation of the hand



(a) SCRIPT Passive Orthosis [6]



(b) HWARD [99]

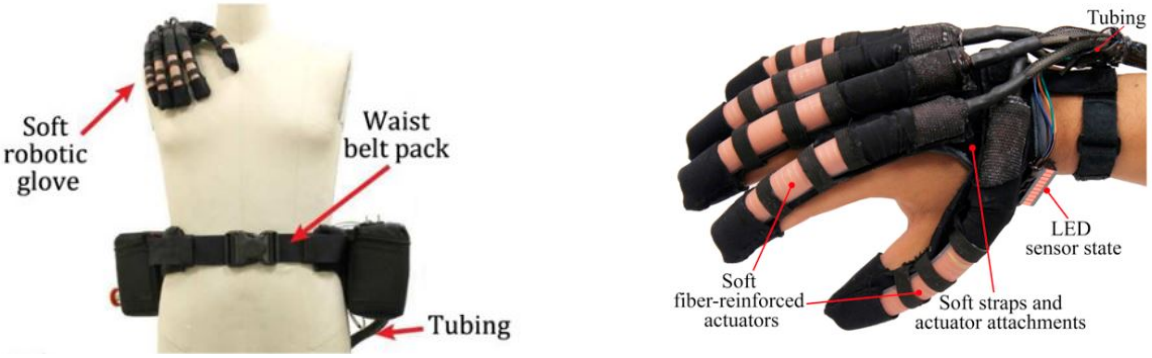
Several works have attempted at creating an orthosis for the rehabilitation of wrist/fingers such as Gloreha [35], Hand of hope [112], Saebo Flex [113], HandSOME [114], SCRIPT SPO [32], HWARD [99], etc. In this study, the term orthosis refers to a device used to support or modify the structural and functional characteristics of a movable part in conformity with ISO 8549-1:1989 [42]. A comprehensive survey of 67 existing devices targeting the distal segment of the upper limb was conducted in our research (Appendix 7, Table 1). The survey focused exclusively on robotic orthoses that were specifically designed for the purpose of rehabilitation, rather than assistive devices. In addition, orthotic devices that were part of an extended system aimed at training the proximal segments of the arm were excluded from the analysis due to their distinct design specifications. The survey highlighted a wide variety of design concepts, modes of operation and mechanisms that were adopted in existing orthoses that rendered them suitable for different scenarios. Subsequently, to analyse the best practices that help achieve the objectives of this work, in the upcoming sections, we delve into the current state-of-the-art for various aspects pertaining to these devices.

2.6.1 Mechanical structure

Two major categories of mechanical structures can be identified in the literature: End-effector structures and Exo-skeleton structures.

The end-effector type rehabilitation robots are attached to the most distal segment of the user's limb that is undergoing training [115–118]. For example, in the case of upper-limb rehabilitation, the user grabs the end-effector with their hand or is strapped to it. These robots are less complicated in terms of mechanical design and control since it does not require the alignment of the robot and the user's joint. It is independent of the body dimensions and therefore easy to configure for different users. The end-effector trajectory is carefully planned according to the therapy requirements of the joints. However, since the robot is attached to the hand, training the shoulders cannot be done independently of the other joints. This design makes it very difficult to isolate and target a specific set of joints or muscles.

Exoskeletons, on the other hand, have the ability to administer targeted training to specific parts of the upper limb. This renders it the ideal solution for an orthosis aimed at training only the distal segment of the arm. Accordingly, most existing devices aimed at training the distal segment of the upper limb are exoskeletons [32, 35, 36, 112, 114, 119–125]. Exoskeletons can be either wholly wearable or partly fixed. The interaction between the device and the body is higher than in the case of end-effector robots. The design of such a structure needs to ensure that the joints of the device coincide with the biological joints. Misalignment in the joint axes might lead to discomfort due to undesirable forces. Additionally, due to the large variability in body dimensions, the design should be easy to adapt. These requirements and the complex kinematic structure of



(a) (b)

Figure 2.6: Soft robotic glove [3]

the hand and wrist often lead to very complex mechanical design and control algorithms.

Exoskeletons in the literature aimed at hand rehabilitation fall into two major categories namely soft and rigid [126]. Soft exoskeletons use flexible compliant structures to transmit force and torque to the finger joints (Figure 2.6). Although they are lightweight, they have a significant limitation to their suitability for home-based rehabilitation due to their peripherals. Soft exoskeletons are usually pneumatically actuated and they require a compressor and an FRL (Filter-Regulator-Lubricator) unit which is noisy and occupies space.

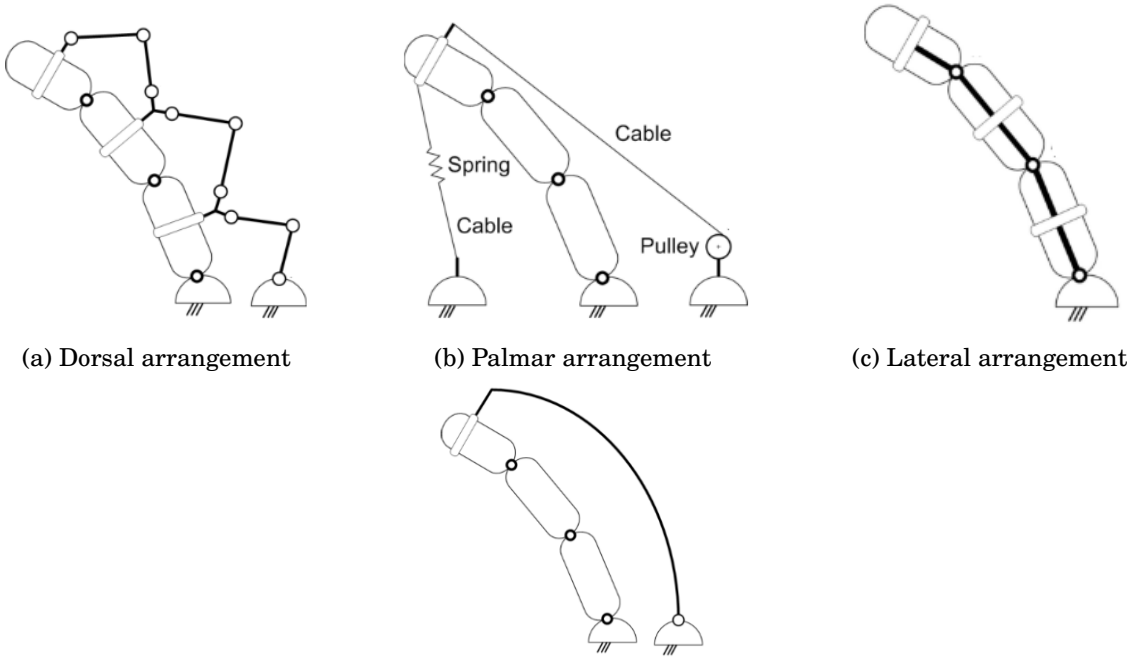
On the other hand, rigid exoskeletons, use mechanical linkages to transmit the force and torque to the phalanges. Based on the arrangement of these linkages relative to the hand, they can be classified into the following three categories.

2.6.1.1 Palmar arrangement

In this architecture (Fig 2.7b), the linkages or parts of the mechanism such as tendons and cables are located on the palmar side of the hand. This mechanism suffers a significant limitation due to the interference with objects being grasped. Most such devices are in the form of a glove made of fabric to allow for cables to run through them. This completely blocks any tactile sensation with the objects being grasped during training.

2.6.1.2 Lateral arrangement

Also known as matched axis design [126], this architecture (Fig 2.7c) overcomes the joint misalignment concern by positioning the linkages on the side of each finger such that the joint axes coincide [127]. This, however, prevents ab/adduction of the fingers due to the limited space



(a) Dorsal arrangement (b) Palmar arrangement (c) Lateral arrangement

(d) Base-to-distal mechanism

Figure 2.7: Common mechanical architectures in hand exoskeletons [4]

between the fingers. Blocking this degree of freedom could lead to non-use which results in hypertonia or excessive stiffness.

2.6.1.3 Dorsal arrangement

The linkages are arranged on the dorsal side of the hand (Fig 2.7a). This permits a palm that is free of any linkages that interfere with objects being manipulated. Since the linkages are on one side of the hand, these mechanisms use a remote centre of rotation to avoid misalignment between the finger and robot joints [36, 128–130]. Misalignment between these joint axes could cause physical discomfort and injury. This design results in a complex mechanical structure that is often bulky.

One way to overcome this is by the use of flexible base-to-distal (Fig 2.7d) mechanisms where the exoskeleton is in contact with the finger only at the fingertip. This eliminates the concern of misalignment while staying on the dorsal side of the hand. This approach overcomes the limitations of all the other two types of arrangements and hence is ideal for this work.

2.6.2 Mode of operation

The interaction between the user and the robot in robot-aided rehabilitation has been categorised into several types using different approaches. Different works in the literature use terms such

as active, active-assisted and passive training modalities to describe the status of either the subject or the robot. For example, from the perspective of the status of the user's involvement, active training modality refers to when the user actively performs all the motions without any assistance from the robot. On the contrary, some literature refers to this as a passive approach owing to the passive status of the device in this interaction. Hence, [45] proposed an alternative approach to categorise the training modalities based on the specific technical features involved in the interaction such as *spring against movement*, *damper against movement*, *tunnels*, etc. In this work, the term, *"mode of operation"* is used to describe the status of the device and hence broadly classified the robot-aided rehabilitation devices into active and passive devices.

2.6.2.1 Active

Active devices perform the movements completely on their own or partially assist, based on the user's requirement. The device guides the subject's hand and the user is not required to exert any effort. This approach is ideal for users with acute stroke who have very limited motor control in their hands. The partial assist or active-assist approach is ideal for stroke survivors with partial motor control who can initiate movements but require assistance with completing them. This approach has been reported to be the most consistent among the different training modalities in showing improvement in body functions [45]. This systematic review identified that this method showed significant improvements in the body functions in 58% of the groups and significant improvements in activity level in 36% of the participant groups analysed in their review.

Owing to their active participation in training, these devices contain active actuators to control the movements in each degree of freedom. Researchers have explored different sources of power to actuate these devices. Based on the power source, the actuators used in these devices are classified into three major groups.

Electromagnetic Actuators are the most common choice of actuator found in 70% of rehabilitation robots [39]. DC motors are mostly used due to their high mechanical bandwidth, bi-directional actuation and smaller size [115, 116, 118, 120, 122, 130–137]. In the form of rotary or linear actuators [112], electric motors are used to control each finger through mechanical linkages or Bowden cable mechanisms. Despite their relatively smaller size, when used to individually actuate each finger on an exoskeleton, they increase the weight acting on the distal segment of the arm. To avoid user fatigue due to this added weight, many works use dorsally placed motors with linkages that transmit torque to each finger. Additionally, the torque-to-speed ratio of DC motors is too low making them unsuitable for the higher ratios required for human movements [138]. Although gearheads are used to increase the torque-to-speed ratio, they introduce backlash and affect back-drivability. With the help of modern compact drivers, they can be controlled with

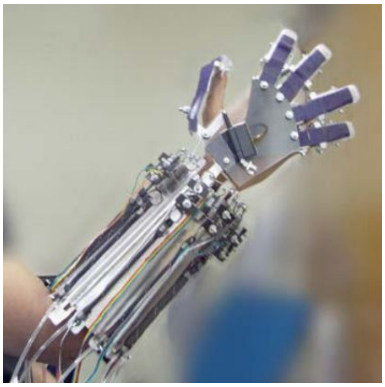
high precision and accuracy. Despite this, it is reported that the impedance of electric actuators is too high to be used in rehabilitation orthoses [139]. Some researchers have adopted series elastic actuators to overcome this limitation of electric motors [128, 129, 140, 141].

Series Elastic Actuators (SEA) use an elastic element such as a spring in series with the electric motor to lower the stiffness of interaction and provide shock absorption which increases the safety [126, 139, 142]. Although they allow accurate and stable force control, they increase the complexity of the mechanical structure and power requirement while delivering an overall lower force output.

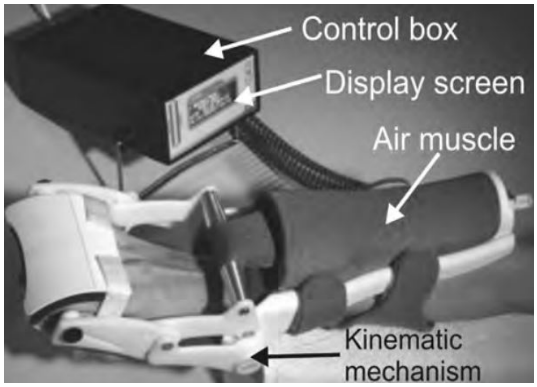
Pneumatic Actuators convert the energy of compressed air into motion. Lower impedance and higher power-to-weight ratio compared to electric actuators make them an ideal candidate for rehabilitation orthosis. Different implementations of pneumatic actuation such as piston-cylinder linear actuators, variable stiffness bending actuators and pneumatic air muscles have been attempted in rehabilitation orthoses (Figure 2.8).

Pneumatic linear actuators consist of a piston and cylinder mechanism. Such devices [35, 99, 112, 122, 143, 144] have a system of linkages and joints that convert this linear motion into a turning moment and transmit to the different joints of the fingers. Another approach is the use of pneumatic bending actuators that stretches from a bent position to a straight one when air is pumped in. These actuators [145] run along the length of the finger dorsally and have variable stiffness at different sections to achieve bending similar to that of the human finger. The third class of devices use McKibben muscles or Pneumatic Artificial Muscles (PAM). It consists of an elastomeric tube which when inflated, expands radially and contracts axially [146]. By inflating and deflating, the length of the tube can be controlled. This tube is covered by a braided sheath that adds to the strength of the artificial muscle and controls the magnitude of the length when inflated. They are used for their lightweight and flexible nature [147] that can be tailored to suit complicated exoskeleton designs. Although pneumatic actuators are considered to have a high power-to-weight ratio, they do not include the weight of the peripherals such as the compressor and FRL (Filter Regulator and Lubricator) units that are essential for its operation. The weight, noise and safety issues that accompany these peripherals limit them to fixed devices that operate in a rehabilitation facility.

Hydraulic Actuators are similar to pneumatic ones but use pressurised oil instead of compressed air to move the finger joints. They have the ability to generate higher force than pneumatic ones. However, they suffer from significant limitations such as difficulties in preventing leakages, and bulky peripherals that render them less suitable for home-based rehabilitation. [3] attempts to overcome this by mounting the peripherals and the hydraulic storage units on the body to enable the subject to move around. However, it poses safety concerns such as leakage and fatigue



(a) [146]



(b) Hand Mentor[148]

Figure 2.8: Hand orthosis with Pneumatic Artificial Muscles

due to the added weight acting on the body.

Apart from these three classes of actuators, few works have attempted to employ shape memory alloys as the actuator in rehabilitation robots [149, 150]. These alloys are used in the form of rods or wires that contract or expand based on the temperature [126]. It is heated or cooled by controlling the current passing through it. Despite their high power-to-weight ratio, they are known to be highly non-linear and produce a lower maximum force [39]. Additionally, the heat produced in the shape memory alloy creates a safety hazard for the user when used in exoskeleton robots [39, 126].

The increase in weight of the robotic device due to these actuators renders them less suitable for an exoskeleton and more for end-effector-type devices. Exoskeleton devices with active actuators use various methods like underactuated mechanisms and remotely located cable-driven mechanisms to reduce the weight of the device [112, 133, 151]. Remotely located actuators require the user to be located near them thereby restricting their mobility. Furthermore, with the device actively controlling the movements of the hand, there is a potential for malfunctioning that could cause injury to the user by performing undesired movements. Due to this potential hazard, the presence of professional supervision is essential while training with the device making it unsuitable for home-based applications.

2.6.2.2 Passive

The passive mode of operation overcomes the above-mentioned limitations of active devices through the use of passive actuators. In this approach, the user is required to initiate and perform the movements while the device provides passive assistance. Active initiation and involvement of the users during training have been shown to improve cortical stimulation and therefore func-

tional recovery [45]. The passive involvement of the device in training significantly reduces the risk of injury making it safer for home-based environments compared to their active counterparts. The absence of active actuators and their peripherals results in a lower overall weight of the device and permits wireless operation. This allows the user to move freely while training which could reduce the mental/emotional fatigue resulting from being restricted to a specific location. Moreover, they occupy less space making them suitable for home-based rehabilitation.

The assistive or resistive forces in these devices are provided by passive actuators such as extension springs and tension cords [44]. This mode of operation is suitable for stroke survivors who experience hyperflexion in their joints but have some residual motor control. SCRIPT Passive orthosis (SPO) uses elastic tension cords to assist with extension for the fingers and wrist [32]. This device was aimed at stroke survivors experiencing hyperflexion who require assistance to open their hands and extend their wrists. The user is then able to perform flexion exercises against the resistive force of the elastic cord. The amount of assistance is adjusted using cord stops to adjust the length of the cord. Home-based studies where 24 stroke survivors used this orthosis for six weeks found that these cords frequently failed due to wear from the cyclic loading [7]. They had to be replaced which required additional external support from a technician. The use of elastic cords also eliminates the possibility to measure or estimate the magnitude of assistive force required by the user to monitor their progress. This is overcome by the use of extension springs as the passive actuator.

The magnitude of assistive force required by the user can be estimated and monitored during training with the use of extension springs of known stiffness. SaeboFlex uses individual extension springs to offset the hyperflexion of each finger [113]. Extension springs are more resistant to wear compared to elastic cords and therefore require less frequent changes. Based on the user's requirement, the magnitude of assistance can be easily adjusted by using the extension spring of appropriate stiffness.

A clinic-based study of SCRIPT Active orthosis (SAO-i3), involving nine stroke survivors observed that the performance was slower while wearing the SAO than while wearing a passive orthosis [120]. SAO-i3 is an exoskeleton-type orthosis that uses electric actuators for training the wrist and fingers. The users found the device to be bulky and preferred to use the passive orthosis instead. The study concluded that the active version of their orthosis was not suitable for home-based training. It is evident from the literature that a passively operating design is the most suitable for a home-based rehabilitation environment due to its inherent safety. Given that its users will have some degree of residual motor control in their joints, this provides an adequate amount of assistance to their training as shown in [32].

Finally, to transmit the forces/torques from these actuators to the joints of the hand, different types of transmission systems have been adopted in literature based on the type and location of the actuators. Studying their merits and demerits helps us inform WiGlove's design.

2.6.3 Transmission

Actuators located on the distal segment of the hand exoskeleton make the design less complicated and allow to directly drive the joint mechanisms [126]. However, this increases the weight acting on the hand making it difficult to perform the movement. Many devices avoid this by proximally placed actuators that use a transmission mechanism to transmit the torque to the joints. This approach reduces the inertia of the distal segments consequentially making it easier for the user to control the movements. The different types of transmission mechanisms used in rehabilitation orthoses are discussed as follows:

The most common approach is to use rigid mechanical linkages to transmit torques to the phalanges [33, 99, 121, 144] or cables [124, 125, 130, 134, 152–154]. They permit direct measurement of all the finger's joint (MCP, PIP, DIP) angles. However, a significant limitation with linkages is the alignment between the exoskeleton's joints and the corresponding finger joints as discussed earlier in section 2.6.1.3. Misalignment between these joints causes discomfort and pain to the user, which is avoided by complex mechanical design[41]. This also increases the friction in the system and the complexity of the control system. This is avoided by the use of cables to transmit power due to their low friction and the complexity of the design.

Two types of cable-based transmission systems were found in the literature. The most commonly used approach of these is the Bowden cable mechanism [124, 130, 154]. It consists of a cable co-axially covered by an outer sheath. The outer sheath is attached to the actuator and the inner one is attached to the joint. Movement is caused by the relative movement of the inner cable with respect to the outer sheath. However, they suffer from backlash which requires complex feedback controllers to ensure accuracy.

Alternatively, few devices use the tendon-driven mechanisms that involve cables that are routed through channels in the gloves [155, 156]. They are designed to mimic the anatomy of the hand's natural tendons [126]. They run through the glove and are usually connected to the distal part of the finger that bends when the cables are pulled. However, this only allows uni-directional control with one cable and hence requires two cables for bi-directional control of each finger. This results in a complex network of cables running through the dorsal and palmar sides of the hand. This covers the palmar side of the hand preventing tactile feedback with the interacting objects. Tactile feedback has been shown to be significant to promote sensory stimulation that improves recovery. The use of a base-to-distal mechanism that uses a flexible transmission element was

identified as the ideal approach to augment the advantages of all the mechanisms mentioned above and overcome their limitations.

The final significant part of robot-aided home-based rehabilitation is the ability to remotely monitor progress. As briefly discussed earlier (Section 2.3), the sensors play a major role in implementing any such system and their choice depends on their application.

2.7 Sensory and bio-mechanical feedback

Two types of sensors can be found in home-based rehabilitation robots based on their purpose. The first type includes position sensors (optical and hall-effect encoders) that provide feedback for the control system of actively actuated devices [126]. On the other hand, the second type of sensor is used to provide the user and the therapist feedback on the performance. This helps to analyse the progress and prepare a plan for therapy.

Motor learning theory shows that feedback stimulates cortical reorganisation and is one of the key factors that affect motor learning and motivation [157]. Authors of [158] suggest that the lack of quality feedback in a home-based therapy compared to clinical therapy might result in insufficient motivation. Quality feedback helps in sustaining motivation according to [159] which plays a significant role in the success of a rehabilitation program. Furthermore, the authors of [30, 160] stress the need for objective outcome measures to overcome the limitations of subjective clinical outcome measures such as the Fugl-Meyer scale. Measures such as movement smoothness, speed, efficacy, etc., require the measurement of various kinematic parameters during training. Such feedback helps in identifying subtle changes in terms of movement and muscle activation that would otherwise be difficult to observe [161].

The most common feedback involves measuring geometric parameters such as joint angles and positions using various sensors to derive the above-mentioned parameters [32, 99, 105, 118, 162]. Different types of sensors that have been used to measure joint angles in the literature are as follows.

2.7.1 Electromagnetic motion tracking

This consists of an electromagnetic transmitter and receiver. By comparing the transmitted and received signal the relative position and orientation between them are calculated [163]. This system has been successfully used in a miniaturised form to track the motion of the hand in [164]. However, this system is sensitive to the electromagnetic field due to any conductive material in its surroundings. Hence it is not suited to a function in a home environment with considerable ambient electromagnetic disturbance.

2.7.2 Inertial measurement unit (IMU)

An IMU is a combination of an accelerometer, gyroscope and magnetometer. Although IMUs can be used to track the orientation of an object, they suffer from drift over a period of time [165]. Computer vision-based tracking can be integrated with the IMU to compensate for the drift in tacking the device[6]. Tracking the different joints of individual fingers would require multiple IMUs and this will lead to accumulation of drift and integrating computer vision will require the user to use the device at a specific location. This could lead to emotional fatigue and prevent training for a longer duration. However, IMUs can be used along with other sensors to provide gross movement information.

2.7.3 Optical motion tracking

This system uses markers positioned on the fingers and palm. These markers are tracked by a network of cameras connected to a motion tracking system [166]. This system requires a large and complicated setup and therefore not suitable for a home-based system.

2.7.4 Resistive flex sensors (RFS)

The working of these sensors is based on the principle of variable resistance of a bending conductive material. This variation of resistance is proportional to the magnitude of bending and hence the angle of bend can be calculated by interfacing it with a micro-controller. Their miniature size and low electric footprint make them an interesting option for WiGlove. However, they have been shown to exhibit a decay in response to time. Studies have shown decays of more than 30% and 22% after 30 seconds [165]. Another study showed that after 60 minutes of usage commercial sensors took approximately 15 minutes to attain stability. A significant decay was reported over a period of 6 weeks. [7] who used Spectra Symbol (SEN-10264, 55 [mm]) reported significant decay in the step response within 20 seconds of its operation. This decay varies with the manufacturer and type of sensor. Another limitation of flex sensors is their non-linear resistance *Vs* bending angle relationship [167] which makes it difficult to account for drift. High decay makes these sensors befitting to detect angular changes rather than measuring their magnitude [165]. Furthermore, they need to be directly attached to the bending surface (fingers and wrist in our case). Hence it is difficult to maintain minimal and comfortable physical interaction between the body and the device.

2.7.5 Rotary potentiometer

A rotary potentiometer consists of a shaft that when rotated, moves an attached conductor along a resistance coil. This acts as a variable resistor. Potentiometers that exhibit both linear and logarithmic responses are commercially available. An experiment comparing it with a flex sensor shows that the latter undergoes significant decay relative to the former. Its miniature

size, stability, and compatibility for a home environment make it an ideal choice for joint angle measurement [6]. They do not suffer from the drawbacks of the other sensors discussed here and are ideal for WiGlove.

Furthermore, the gripping force is another parameter that helps the therapist judge stroke survivors' recovery [105, 117, 118, 168]. This is commonly accomplished using resistive force sensors on the tip of the finger. EEG [169–172] and EMG [105, 112, 121, 132, 135] are also used as a feedback in the literature for detection of intent and movement. They are used to initiate and control the movements in the case of actively actuated devices.

2.8 Affordability

The incidence of stroke has been on a rapid rise in low and middle-income countries (LMICs), witnessing a staggering 100% increase in the past four decades [173]. Projections suggest that by 2050, over 80% of all stroke cases will occur in these LMICs [174]. However, the challenging scenario is compounded by the fact that these countries suffer from a severe shortage of rehabilitation professionals, with less than 0.5 therapists available for every 10,000 individuals [175]. This scarcity places a significant burden on the healthcare system, resulting in inadequate access to rehabilitation services. While robot-aided rehabilitation has the potential to alleviate this burden, its implementation in LMICs remains limited due to the prohibitively high costs involved. For instance, a study highlights the case of a Chennai-based hospital in India that operates three rehabilitation robots (a total cost of 1 million dollars), charging patients up to $667 for a complete therapy course. This places an immense financial burden on individuals in a country where the estimated per capita gross national income stands at $1,120 [175]. Therefore, the need of the hour lies in the development of affordable rehabilitation robots that can leverage the advantages of robotic therapy and bridge the gap between technological advancements and accessibility to such devices [176]. Although many experimental devices of low cost have been proposed, many of available devices in the market follow a more expensive trend, for example, the hand such as Hand of Hope is reported to cost €20,000 according to [177].

2.9 General observations

A multitude of robotic devices has been developed for neuro-rehabilitation of the distal segment of the upper limb. Each device exhibits unique characteristics in terms of mode of operation, actuation system, transmission, and bio-feedback, offering specific advantages and disadvantages that render them suitable for particular use cases, such as assistive or rehabilitative purposes for fingers, wrist, or both simultaneously. Table 2.1 summarises the key learnings from the survey regarding the best practices in each attribute.

Table 2.1: A summary of the best practices and design choices for robotic devices aimed at the home-based rehabilitation of the hand

Attribute	**Observation**
Mechanical structure	The wearable nature of exoskeletons and their capacity to provide targeted assistance to specific joints make them an ideal structural solution
Mechanism	To address concerns of discomfort and pain from joint misalignment in exoskeletons, the base-to-distal mechanism was determined to be the preferred choice for providing assistance with joint extension.
Mode of operation	The passive mode of operation was found to be the safest and most suitable option for home-based use. Additionally, it encourages active initiation from users, which has been shown to enhance recovery.
Actuator	Among the passive actuators used to provide assistance, Extension springs are considered the most durable and reliable passive actuators for providing assistance, as they allow for precise estimation and control of the level of assistance.
Sensory feedback	Effective remote monitoring of training progress requires a significant focus on tracking the range of motion (RoM). In this regard, potentiometers are considered the most suitable sensing method for accurately measuring joint angles.

2.10 Research gap

In the survey of robotic devices for hand rehabilitation conducted in this study (Appendix 7), it was observed that 57 of these devices focus on training the fingers alone while 5 focus on just the wrist. Only 5 devices were found to focus on training both the fingers and wrist together and are listed in Table 2.2.

The most significant observation from this review of the literature was the lack of devices that allows rehabilitative training of both the fingers and wrist simultaneously. Most existing devices [35–38] are designed to train only the fingers or target solely the wrist disregarding the synergy between these two segments. [179] notes that motor impairments in the hand are mostly studied in isolation, without considering the synergy with the proximal joints. The authors postulate that failure to account for this is the reason for results in studies focusing on the devices training the hand not translating to functional recovery.

The intricate musculoskeletal structures of the distal upper limb segment, spanning multiple segments, render them kinematically and dynamically coupled [180]. Consequently, the position of the wrist has a significant effect on the force generated by the fingers during a grasp. Research indicates that finger forces are greater when the wrist is extended as opposed to when it is flexed; the maximum gripping force from the fingers is achieved at a 20-degree extension of the

Table 2.2: Orthotic devices used for the rehabilitation of the wrist and fingers together

Device Name	Exoskeleton/End-effector	Mode of Operation	Assisted DoF	Actuation	Transmission	Suitable for home-based	Wireless/ Wired	Interaction with games
Hand Mentor[119]	Exoskeleton	Active	2 (1 for fingers + 1 for wrist)	McKibbon muscle	Linkage	The peripherals of the actuation mechanism makes it unsuitable	Wired	No
HWARD [99]	Fixed - Exoskeleton	Active	3 (1 for fingers, 1 for thumb, 1 for wrist)	Pneumatic	Linkage	The peripherals of the actuation mechanism makes it unsuitable	Wired	No
SCRIPT Active Orthosis[120]	Exoskeleton	Passive	6 (1 per finger + 1 for wrist)	DC-motor	Whipple tree mechanism	Study showed that the bulky size, unsafe and complicated appearance prompted the user's to deem it less suitable [120]	Wired	Yes
SCRIPT Passive orthosis[32]	Exoskeleton	Passive	6 (1 per finger + 1 for wrist)	Elastic cords		Studies showed that it was suitable home environment [32]	Wired	Yes
[178]	Fixed-Exoskeleton	Active	18 (3 per finger + 4 for thumb + 2 for wrist)	DC-motor	Timing belts	Active actuation with multiple motors could lead to potential risk factors and therefore require supervision, complicated and unsafe appearance	Wired	No

wrist.[181]. Furthermore, both [180] and [182] highlight that most activities of daily life involving the distal segment of the upper limb require the coordination of the hand and wrist. The authors, therefore, stress the significance of the combined training of these joints to regain coordination which could lead to improved rehabilitative outcomes and help them recover their ability to do ADL. [180] points out that these anatomical, biomechanical and functional couplings are often overlooked in the design of rehabilitation robots.

A recent survey of exoskeletal devices aimed at rehabilitation of the hand by [39] noted that only 2 devices were found to train the fingers and wrist. In addition, the survey conducted in this study that included both exoskeleton and end-effector-type devices further highlights this research gap. To the best of our knowledge, SCRIPT Passive Orthosis (SPO) [7] was found to be the only device that allows simultaneously training the wrist and fingers while being ideally suitable for home-based therapy due to the inherent safety of the passive actuation and the absence of bulky and noisy peripherals such as the compressors used in pneumatic devices (Table 2.2). Given the unique requirements and alignment of design challenges of such a device, SPO serves as the state-of-the-art for this research.

2.10.1 SCRIPT passive orthosis

Designed as a part of the European Project Framework 7. It is a passive dynamic orthosis that allows stroke survivors to exercise flexion/extension of the joints of the distal segment of the upper limb. It includes a custom-developed user interface that allows both the patient and the therapist/clinician to monitor the progress of training. It also allows the user to play interactive games while training. They subjected this device to a feasibility evaluation involving 23 patients for 6 weeks. It showed the feasibility of their system with an average score on the system usability scale of 69% [32]. However, their study also pointed out several limitations with the functionality and usability aspects such as frequent failure of the elastic cords, difficulty in donning using velcro straps, potential pinch point in the double parallelogram mechanism, degradation in the flex sensors etc. Consequently, to address this gap in the literature on post-stroke home-based rehabilitation of wrist and fingers by overcoming the limitations of SPO warrants the need for this research.

2.10.2 Scope for innovation

This research gap presents a unique opportunity to innovate with a completely new design. Therefore, the overarching aim of this work is to develop a prototype that satisfies the following attributes as discussed in (Section 1.2, Chapter 1):

1. Facilitate safe home-based therapy.

2. Provide the ability to interact with games to improve engagement and motivation.

3. Allow the fingers and wrist to be trained together, accounting for their synergy.
4. Provide support in performing ADL activities using the orthosis' ability to counter abnormal synergies.

This is achieved by following a user-centred approach involving the end-users in different stages of the design process, directly or indirectly in various capacities. This entails answering the research questions mentioned in the previous chapter (Section 1.2.1) in an iterative process beginning with identifying the requirements for this device, followed by the design and evaluation of the prototype to ensure that it meets these requirements. The following three chapters of this thesis will describe each stage of this process in detail.

2.11 Summary

This chapter provides a brief background on the advantages and effectiveness of robot-assisted and home-based rehabilitation techniques. Home-based robot-aided rehabilitation systems have the potential to allow stroke survivors to train independently at a significantly higher intensity for longer durations without the constraints of resources such as the availability of therapists' appointments. They can act as a valuable companion to therapists in assisting them to efficiently use their expertise to supervise more patients, thereby reducing the stress on the currently strained healthcare system. The challenge involved in home-based rehabilitation is to provide a means to assist the user while training and allow remote monitoring by the therapist while ensuring safety for the user and other members of the family. Furthermore, this discussion highlights the significant benefits of gamification of training with robotic devices in improving stroke survivor motivation which could result in longer engagement in training.

Following an overview of the notable robot-aided rehabilitation devices documented in the literature, this chapter zeroes in on the training of the distal segment of the upper limb as the core focus of this doctoral research. Training the hand and wrist is essential for stroke survivors to regain their ability to independently perform activities of daily life, given the significance of this segment in performing functional tasks such as grasping.

This chapter presents a comprehensive survey of the different mechanisms, sensors and modes of operation adopted in robotic devices aimed at training or assisting the distal segment of the upper arm and discusses their advantages and disadvantages. Notably, it identifies the passive mode of operation as ideal for a home-based rehabilitation system given its inherent safety.

In conclusion, the survey of 57 robotic devices for hand rehabilitation presented in this chapter highlights the research gap in devices that train both the wrist and the hand simultaneously

taking into account the synergy between them. It identifies SCRIPT Passive Orthosis (SPO) as the state of the art, being the only device that allows hand and wrist training while being ideally suitable for home-based rehabilitation. However, it also highlights several usability and functional limitations observed in SPO. These findings show a research gap, underscoring the need for the development of a hand rehabilitation device that trains both the fingers and the wrist while being safe and suitable for a home environment and is devoid of the limitations observed in the state-of-the-art. This presents an opportunity to innovate within the scope of this doctoral work through a from-the-scratch design using a user-centred approach. The next chapter discusses the first stage of the user-centred design of the prototype called the WiGlove.

CHAPTER 3

USER-CENTERED DESIGN OF WIGLOVE

The term user-centred design (UCD) describes an approach that involves incorporating input from end-users in the design of a device. This design methodology has been shown to have the potential to enhance usability in medical devices [183, 184]. It is essential to ensure that usability is an integral part of the system's design, particularly in rehabilitation devices, as this encourages prolonged and frequent training which has been shown to improve recovery [185].

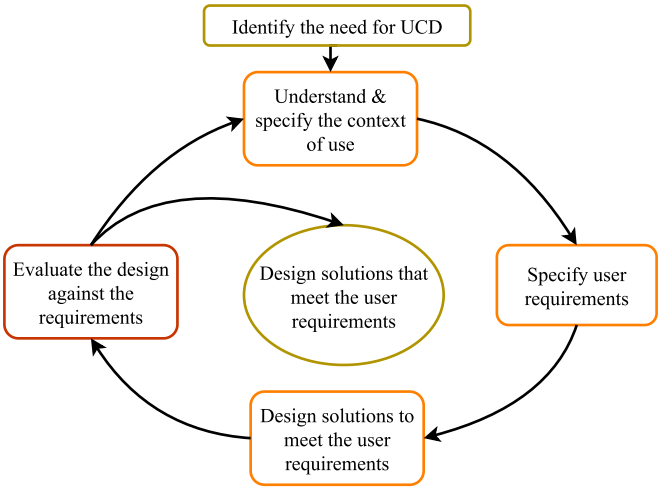


Figure 3.1: Iterative User-Centred design (ISO 9241-210:2019)[5]

ISO 9241-210:2019 outlines the significant stages of user-centred design that involve an iterative process of identifying user requirements and ensuring that the resulting device meets those requirements through usability evaluations, as shown in Figure 3.1. The significance of this approach in the design and development of medical devices is underscored by [46]. This

thesis presents a similar approach in the development of the WiGlove, demonstrating how the device's design addresses user requirements and validates them through functional and usability evaluations.

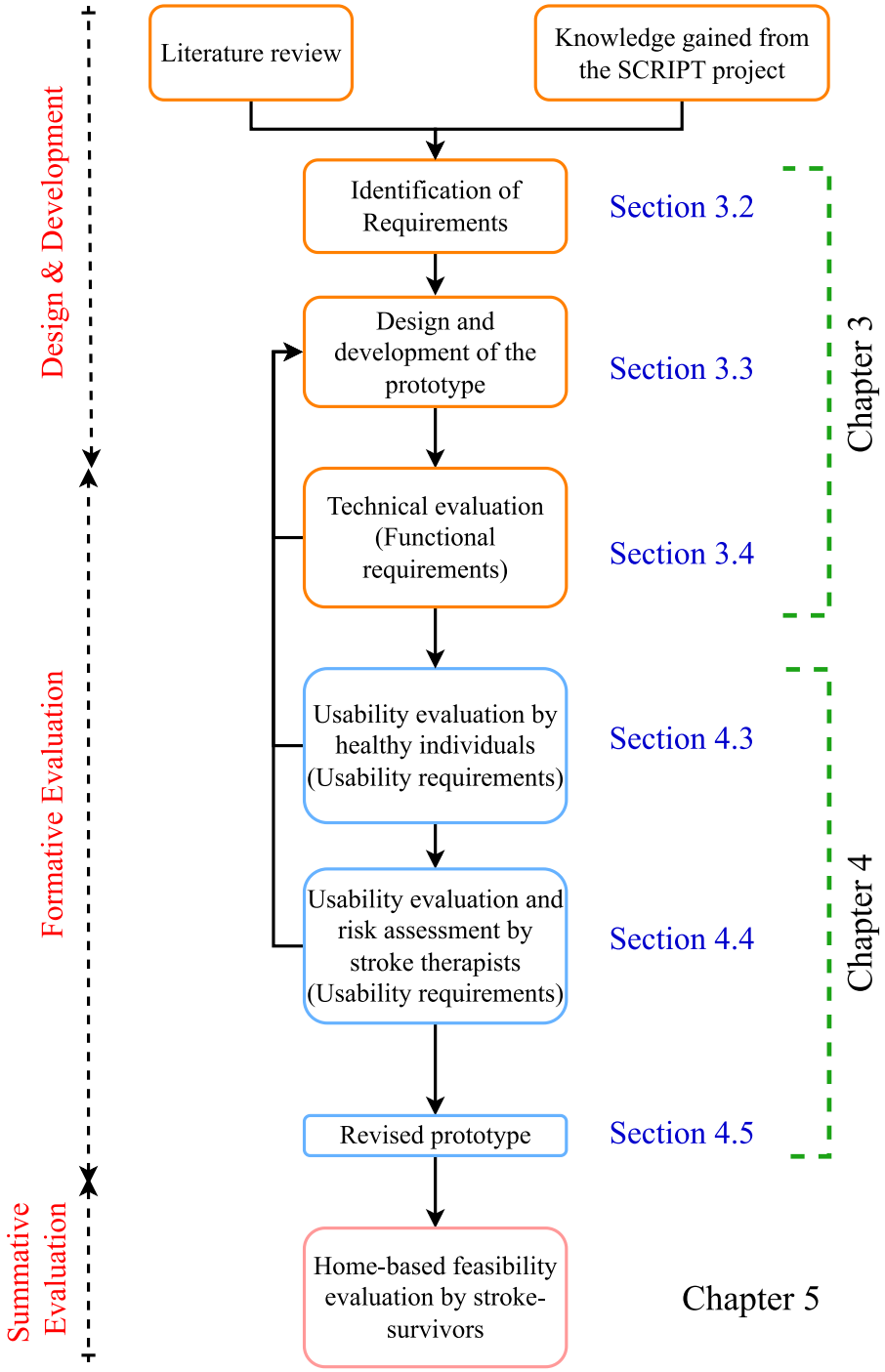


Figure 3.2: Design methodology

3.1 Design methodology

In this work, the WiGlove was designed and developed from scratch using this UCD methodology that incorporated feedback from both stroke survivors (primary users) and stroke therapists (secondary users) in its design as illustrated in figure 3.2. To begin with, the prototype developed based on the identified user requirements was subjected to a technical evaluation to ensure that it satisfies the functional requirements. After ensuring this, in subsequent stages the WiGlove's design was evaluated against the usability requirements through several evaluations involving healthy participants, stroke therapists and stroke survivors. The WiGlove's design was iteratively revised based on the observations and outcomes of each evaluation.

3.2 Requirement analysis

As discussed in the previous paragraph, the first stage of the WiGlove's user-centred design process involved the identification of the requirements for a post-stroke home-based rehabilitation device designed for hand and wrist therapy. This was achieved by leveraging the knowledge gained from the development of the SCRIPT Passive Orthosis (SPO) and the user evaluations of other rehabilitation orthoses for hand and wrist. During the development of SCRIPT, a thorough user study was conducted by the researchers to gain an understanding of the experience and preferences of stroke survivors living with technology [32, 186]. To achieve this, cultural probes such as personal diaries and self-recorded photographs were utilised to identify cues which were then used in subsequent stages to facilitate in-depth interviews with stroke survivors. The insights gained from this process helped in the creation of persona-based scenarios that informed the user preferences and requirements for a robotic device used for hand rehabilitation. From these studies, a comprehensive set of user requirements for such a device was formulated and discussed below. These requirements formed the fundamental framework for the design and development of the first iteration of the WiGlove.

3.2.1 Functional requirements

Req 1 : Adjustable functional assistance.

Hand impairments in stroke survivors often manifest themselves in the form of hyperflexion that results in a clenched fist and a fully flexed wrist (Figure 3.3)[187]. Continuation of this posture affects the function of agonist-antagonist pairs of muscles responsible to articulate finger joints and wrist, with shortening of the flexors and elongation of the extensors observed after long periods of hyperflexion. They require assistance with extension to overcome the hyperflexion. The magnitude of the assistive forces required depends on the user's motor deficit and varies with training due to the underlying recovery. If the difficulty is very high, they could get frustrated and quit while if it is very low, they could get bored

[188]. Hence the ability to change the magnitude of assistance allows them to train within their operational range while also providing them with the opportunity to keep themselves adequately challenged. Since the users suffer from reduced dexterity it is imperative to be easy to make this adjustment according to their needs without external assistance.

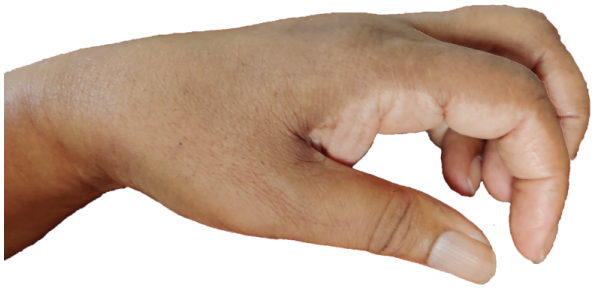


Figure 3.3: Hyperflexion of a stroke survivor's wrist and fingers

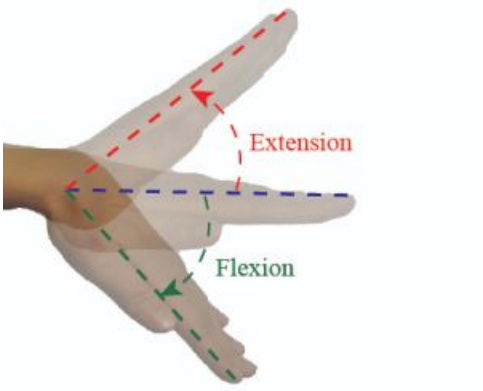


Figure 3.4: Flexion and Extension of the wrist

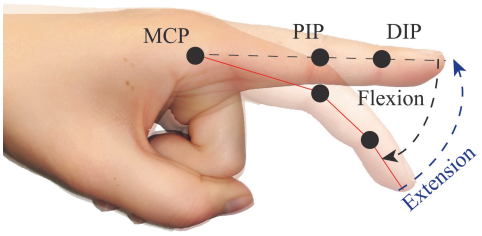


Figure 3.5: Flexion and Extension of the fingers

Req 2 : Range of Motion (RoM) required for Activities of Daily Life (ADL).
Given that the objective is to allow stroke survivors to regain their ability to perform activities of daily life, the range of motion required to achieve this is a significant factor in the design of the orthosis. The device should allow for training over the entire range of motion (RoM) required to perform ADL as established from the literature [189–191] (Table. 3.4). In the below table, the metacarpophalangeal, proximal interphalangeal and distal interphalangeal joints are abbreviated as MCP, PIP and DIP respectively (Figure 3.5).

Req 3 : Does not hinder any of the natural range of motions of the joints.
Most of the existing hand rehabilitation devices, block one or more degrees of freedom to simplify the design. These blocked degrees of freedom mean that while training with the device to perform ADL, the user never performs these movements. This non-use could lead to muscle atrophy [192]. Therefore it is essential that the device should not block

any of the natural degrees of freedom of the fingers (flexion/extension of all the joints and abduction/adduction of the metacarpophalangeal joint) and wrist (flexion/extension, pronation/supination, abduction/adduction).

Req 4 : Self-aligning centre of rotation (CoR).
As discussed earlier (Chapter 2, Section 1.6.1) the centre of rotation of the joints varies with hand movements and a misalignment between the axes of the device's joints and that of the hand would result in discomfort and pain that could lead to injury [4]. Therefore, ensuring that the orthosis accommodates for or compensates for this misalignment is a critical design requirement in wearable devices.

Req 5 : Measurement of finger and wrist motion.
Since home-based rehabilitation involves training in the absence of therapists, it is essential to allow the therapists to remotely monitor the progress of training. This requires a mechanism to measure the flexion and extension joint angles. These measurements can also be used to control therapeutic interactive games which have been shown to enhance users' motivation and engagement in training [32, 62].

Req 6 : Accommodate different hand dimensions.
A mismatch between the size of the hand and the device could lead to pain while training and render it bio-mechanically inefficient. Therefore it is imperative that the device adapts to different hand dimensions/sizes.

Req 7 : Visual and tactile transparency.
Wearable hand devices often block the fingers' tactile sensing and restrict the visibility of the hand. According to [44], providing tactile feedback to the flexor and extensor surfaces could improve the clinical outcomes of training by promoting naturalistic movements. The ability to observe grasping and movement of the fingers and wrist and feel the tactile features of the interacting object adds to this sensory stimulation and neural modulation potential. Tactile and visual feedback act as a reafference to the central nervous system and hence it is essential that the device allows this sensory feedback while training with it [193].

3.2.2 Usability requirements

Req 8 : Ease of donning/doffing.
A device intended to be used for home-based therapy should be usable with minimal external assistance. Given that the users experience motor deficits in their hands, it is necessary that the device is easy to don and doff with the help of one unimpaired hand without assistance.

Req 9 : Safe to use at home.
Given the absence of a clinician/therapist's supervision in home-based therapy, the device should not pose any risk to the user due to malfunction or incorrect usage. Similarly, it is imperative that it poses no risk also to the other members of the user's home.

Req 10 : Smaller space requirement and increased mobility.
Most of the existing rehabilitation devices are not designed to operate in a home environment due to their large size. It is therefore essential that the ideal device occupies less space to ensure use as needed. Additionally, they require the user to be present in a specific place since they are tethered to a power supply and/or a computer. Facilitating location flexibility by eliminating the tethers could reduce mental and emotional fatigue which in turn could lead to longer training durations. Furthermore, to allow the users to train while performing ADL, the device should not be heavy. A study by [194] identified that a maximum weight up to 500g and 200g acting on the forearm and hand was deemed acceptable based on interviews with clinicians and participants with hand impairments.

Req 11 : Require relatively less technical proficiency.
Ensuring that the users do not require extensive and complicated training to operate the device is essential to allow independent training. Easy and short procedures for setting up, operating and troubleshooting help maintain the user's motivation levels.

The WiGlove's design features that address these usability requirements are detailed in sections 3.3.2.7, 3.3.2.8, 3.3.2.9, 3.3.2.10. Usability evaluations with healthy individuals (Chapter 4), stroke therapists (Chapter 4) and stroke survivors (Chapter 5) are used to validate that the WiGlove satisfies these requirements.

Req 12 : The cost of the robotic orthosis should be affordable.
Given the expensive nature of most commercially available robotic devices for rehabilitation, it is imperative to ensure that the design of the robotic orthosis is cost-effective to make it affordable and accessible as discussed earlier in section 2.8. (Chapter 2).

Identifying these requirements answers the first research question of this work. Table 3.1 briefly presents the user requirements and how the WiGlove's design aims to address them and the methods used to validate them as discussed in the following sections of this chapter. The following section presents the first functional prototype of the WiGlove and its various design features that aim to satisfy the above requirements. A set of target product design specifications were established based on these requirements to guide this design process (Appendix 7, Table 3)).

Table 3.1: The validation methodology of the user requirements in the WiGlove's development

User requirement		**Addressing/Validation method**
Req 1	Adjustable functional assistance	Through design, using a passive assistance mechanism (Section 3.3.2.1)
Req 2	Range of Motion (RoM) required for Activities of Daily Life (ADL).	Goniometric measurements (Section 3.4.2)
Req 3	Does not hinder any of the natural range of motions of the joints	
Req 4	Self-aligning centre of rotation (CoR)	Through design, using a base-to-distal architecture (Section 3.3.2.3)
Req 5	Measurement of finger and wrist motion	Repeatability experiment (Section 3.4.1)
Req 6	Accommodate different hand dimensions.	Through design, using customised dimensioning (Section 3.3.2.5)
Req 7	Visual and tactile transparency.	Through design, using an open palm concept (Section 3.3.2.6)
Req 8	Ease of donning/doffing	Usability Evaluation (Chapter 4,5)
Req 9	Safe to use at home.	
Req 10	Smaller space requirement and increased mobility.	
Req 11	Require relatively less technical proficiency.	
Req 12	The cost of the robotic orthosis should be affordable.	Through design (Section 3.3.2.11)

3.3 Design of the WiGlove

3.3.1 Design concept

A significant observation from the review of the literature (Chapter 2, section 2.6), is that passive devices were found to be more suitable and safe in the context of home-based rehabilitation compared to their active counterparts. The inherent features of the former such as the reduced

risk of injury due to malfunction and the absence of large/heavy peripherals such as compressors and battery packs that are either wired or attached to the body render them safe to use independently without the supervision of a professional. SPO demonstrated the feasibility of this approach to partially assist hemiparetic stroke survivors in the rehabilitation of the fingers and the wrist. Following in its footsteps, the WiGlove's mode of operation is inspired by SPO's concept of a passive dynamic orthosis.

A dynamic orthosis, also known as an articulated orthosis provides support and also helps with the movement of a body part while wearing it [43]. Unlike an active orthosis, a passive one does not guide the user's joints throughout the entire range of motion while training, instead provides assistive or resistive forces during a partial or complete range of motion [44]. It requires the active participation of the user in the initiation and movement during training which has been shown to increase functional recovery [45].

The WiGlove uses passive actuators to assist stroke survivors with motor impairments in the hand with the extension of the fingers and wrist thereby allowing them to actively initiate and perform flexion/extension exercises. Although it is designed for stroke survivors experiencing hyperflexion, it can also be used by individuals with flaccid wrists and fingers due to any neurological injury as a resistive exercise device. Although they do not require the assistive component of the WiGlove, with the appropriate choice of spring stiffness, they can perform flexion exercises against the resistive forces of the spring. However, this use case has not been explored in the scope of this PhD. The structural components of the prototype were fabricated through 3D printing to facilitate rapid iterative development minimising the lead times between the concept stage and the first functional prototype. Additionally, the versatility of 3D printing approach allows the customisation of the aesthetics of the device according to the user's preferences. Figure 3.6 illustrates the metamorphosis of the WiGlove's design from the initial concept of a passive dynamic orthosis to the first full prototype (Mark 14) that was tested against the user requirements later in this chapter and this thesis. Here "Mark" refers to the iteration of the design.

3.3.2 Detailed design

The WiGlove consists of two modules - a forearm and a hand module (Figure 3.7). The assistance mechanism for the wrist and the thumb are situated on the forearm module while those of the fingers are on the hand module. Each finger is independently assisted to facilitate isolated use while performing certain grasps such as a palmar pinch. Therefore it passively assists 6 DoF (flexion/extension of the five digits and wrist) of the distal segment of the upper arm. This section discusses the different design features of the WiGlove's design.

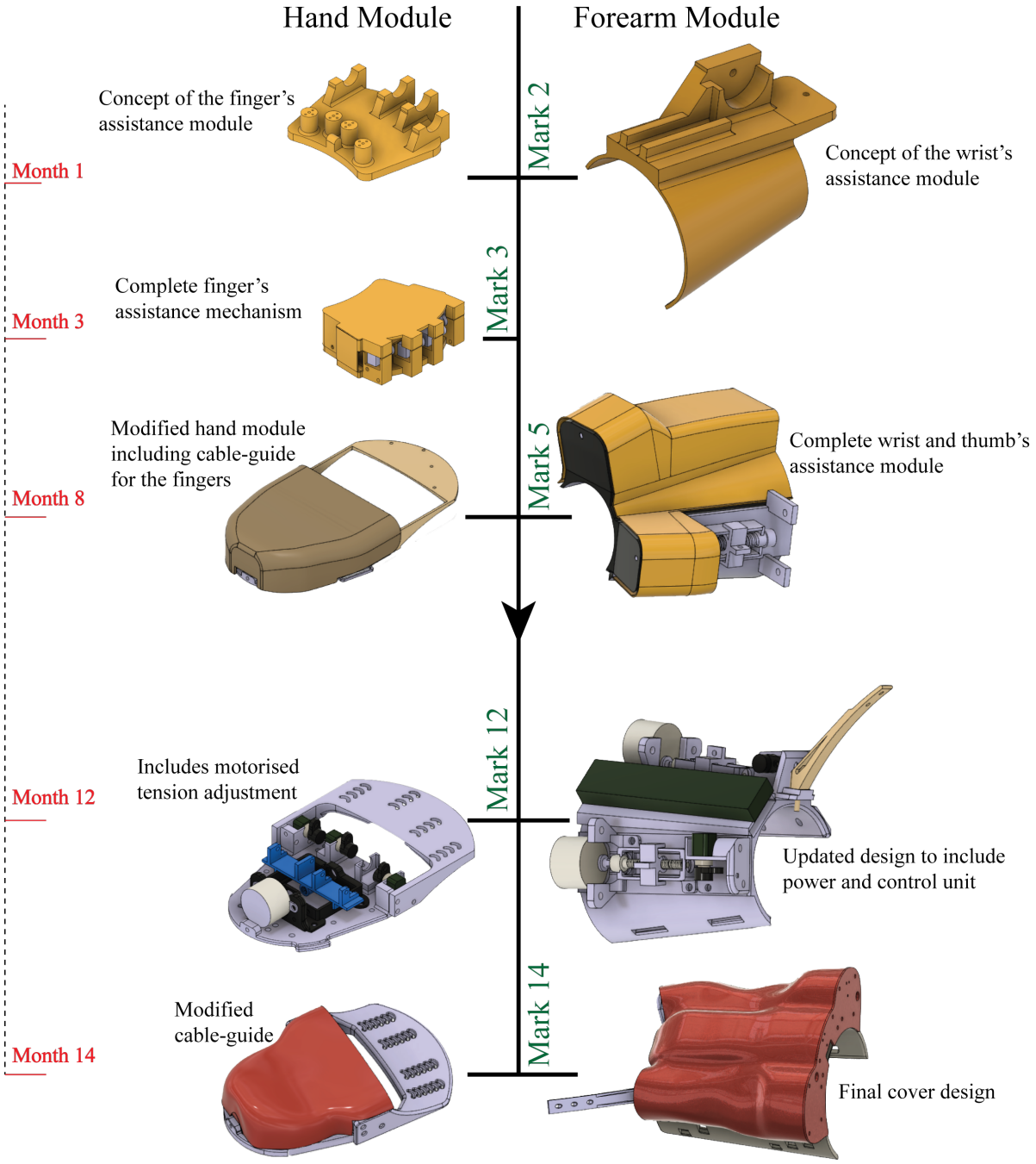


Figure 3.6: Metamorphosis of the WiGlove's design.

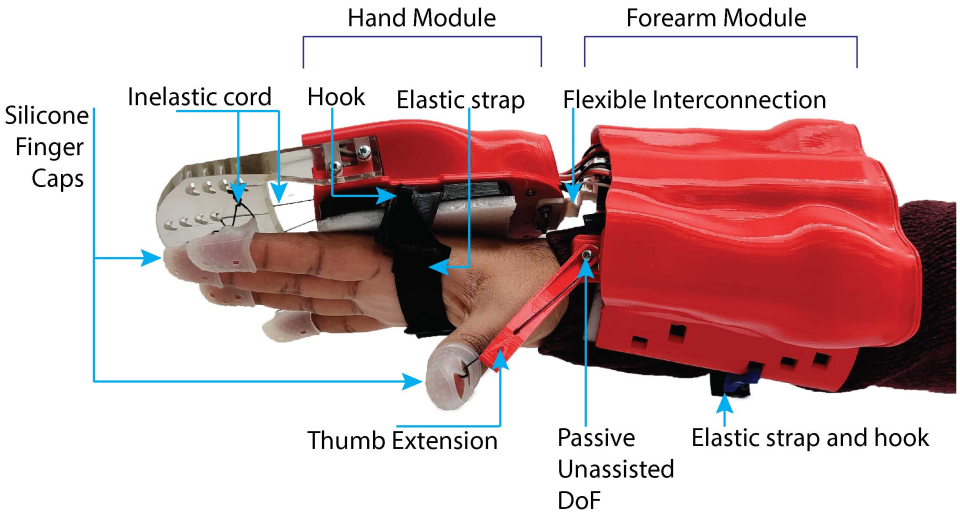


Figure 3.7: WiGlove.

3.3.2.1 Adjustable extension assistance mechanism. (Req 1)

Among the passive finger rehabilitation devices, the following two assistance mechanisms emerge as potential candidates: a combination of extension springs and nylon cords employed by SaeboFlex, and a combination of leaf springs and elastic cord utilised by SPO.

SaeboFlex uses extension springs as a passive actuator which is in turn connected to an inelastic cord that is attached to the fingers through a fixed and rigid guide (Figure 3.8). During finger flexion, the assistive force vector is no longer normal to the longitudinal axis of the fingers when approaching the maximum flexion angles. The authors of [195] postulate that this deviation from the perpendicularity could lead to discomfort arising from the increasing pressure on fingertips induced by the lateral component of the assistive force. Moreover, they argue that this leads to an undesirable reduction in the effect of the assistive force at the extreme positions. However, such a reduction is not necessarily detrimental since this reduced effect also ensures that it is not very difficult to overcome the spring force by the hemiparetic fingers of stroke survivors while performing flexion. Since the flexion forces required are the highest at maximum flexion angles, this slightly reduced effect of the assistive force allows for a trade-off between being adequately assisted and adequately challenged.

Meanwhile, SPO aims to maintain the normality of the force vector by employing a mechanism where the assistive extension force is provided by a leaf-spring and elastic cord combination (Figure 3.8). Unlike in the case of SaeboFlex, the leaf-springs bend along with the fingers to ensure that the force vector does not deviate too far from normal to the fingers. However, this mechanism suffers from the limitation of being unable to accurately estimate the magnitude of assistive force due to the non-linear nature of the leaf-springs' bending and the elasticity of

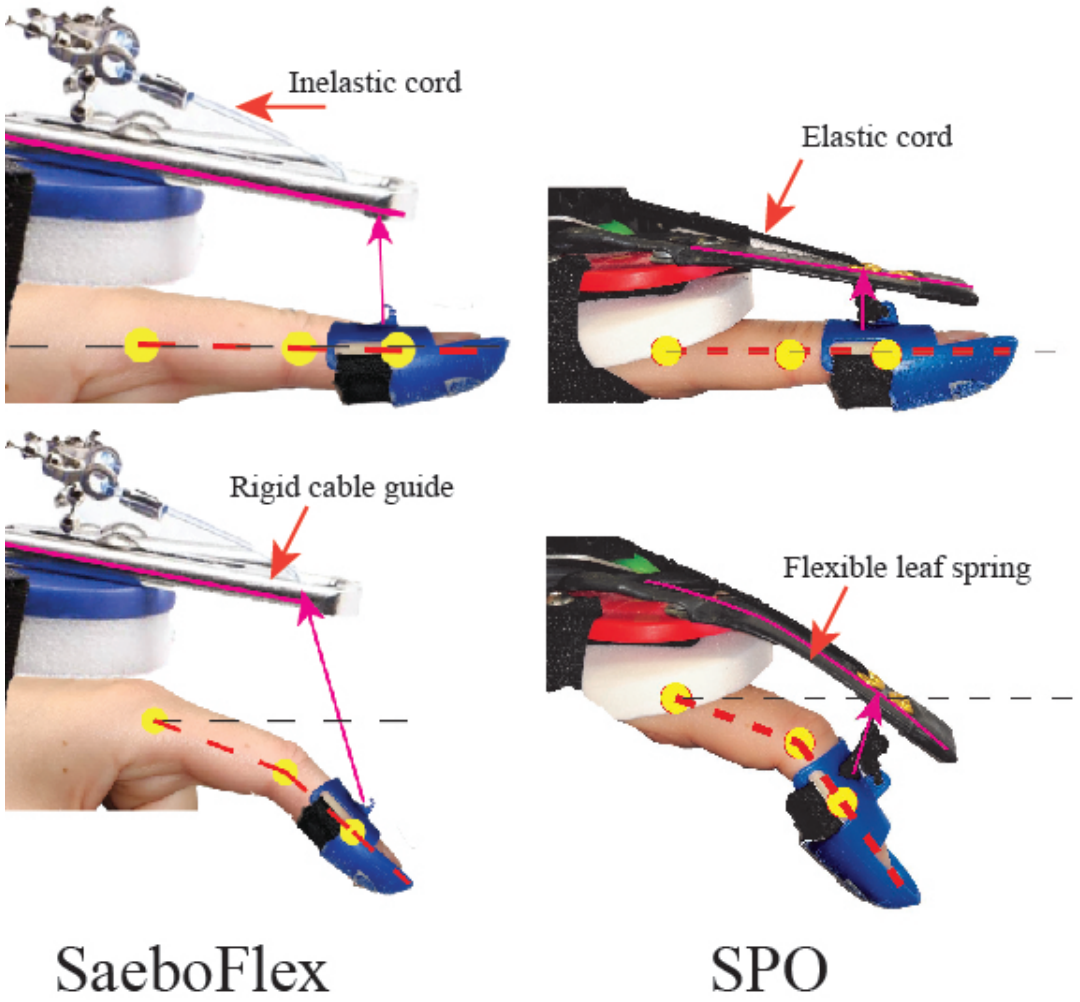


Figure 3.8: Finger assistance mechanisms employed in SaeboFlex and SCRIPT Passive Orthosis (SPO) where the pink arrow represents the assistive extension force vector

the cords. This limitation is further exacerbated by the findings of SPO's feasibility studies that reported excessive wear of the elastic cords and frequent snapping. Based on the observations of this analysis, this work proposed a novel assistance mechanism to encompass the advantages and address the disadvantages of these two approaches in a trade-off to be used in the WiGlove.

The WiGlove uses extension springs as passive actuators to assist with the extension of the wrist and fingers to a more neutral position from a fully flexed position (Figure 3.9). This allows the stroke survivors to voluntarily perform flexion against the resistive force of the springs. The spring force is transmitted to the fingers by means of inelastic nylon cords that are attached to the fingertips by means of silicone fingercaps. The nylon cords are guided to the fingertips by a fixed extension structure. Although, even in this mechanism the assistive force deviates from being normal to the fingers at extreme flexion, it provides an adequate trade-off between

adequate challenge and assistance as described above. Furthermore, unlike the rigid fingercaps used in SaeboFlex and SPO, the elastic nature of the WiGlove's fingercaps ensures compliance with the lateral component of the force discussed above thereby preventing any discomfort or pain.

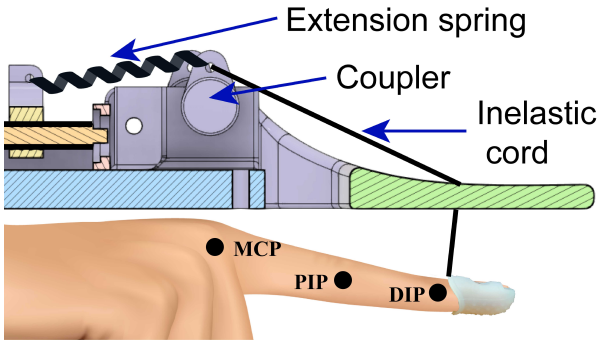


Figure 3.9: The WiGlove's extension assistance mechanism.

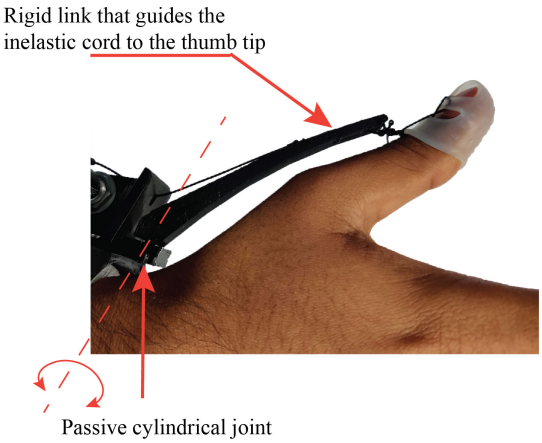


Figure 3.10: Thumb assistance mechanism

Extension assistance for the thumb uses the same approach with an additional passive DoF to facilitate the thumb's ab/adduction, which is essential for its opposing action while grasping (Figure 3.10). A rigid extension structure that is free to rotate about this passive joint axis guides the inelastic cord to the thumb's digit cap. The WiGlove employs a similar mechanism located on the forearm module to assist the wrist from which the spring force is transmitted to the joints using an inelastic cord that is attached to the hand module.

The magnitude of assistive forces required depends on the user's motor deficit and varies with training due to the underlying recovery. To adjust the tension, SPO requires the user to adjust the length of the individual elastic cords using cord stops. Stroke survivors could find it difficult to perform this, especially in the cramped hand module and therefore the WiGlove's design aims to overcome this difficulty.

Based on the degree of hyperflexion experienced by the user, the therapists can choose from a range of springs with different stiffness to ensure optimal assistance and challenge while training. This allows the WiGlove to offer extension assistance to even severely impaired participants by using an appropriate spring, compared to the elastic cords used in SPO whose elasticity was deemed insufficient in such cases [7]. Furthermore, the WiGlove has a motorised tension adjustment system (Figure 3.11) that increases or decreases the free length of a given spring. This allows the user and the therapists to easily modulate the assistance so that the user is adequately challenged during training using a slider interface on a touchscreen tablet (Figure 3.12), thereby satisfying **Req 1**.

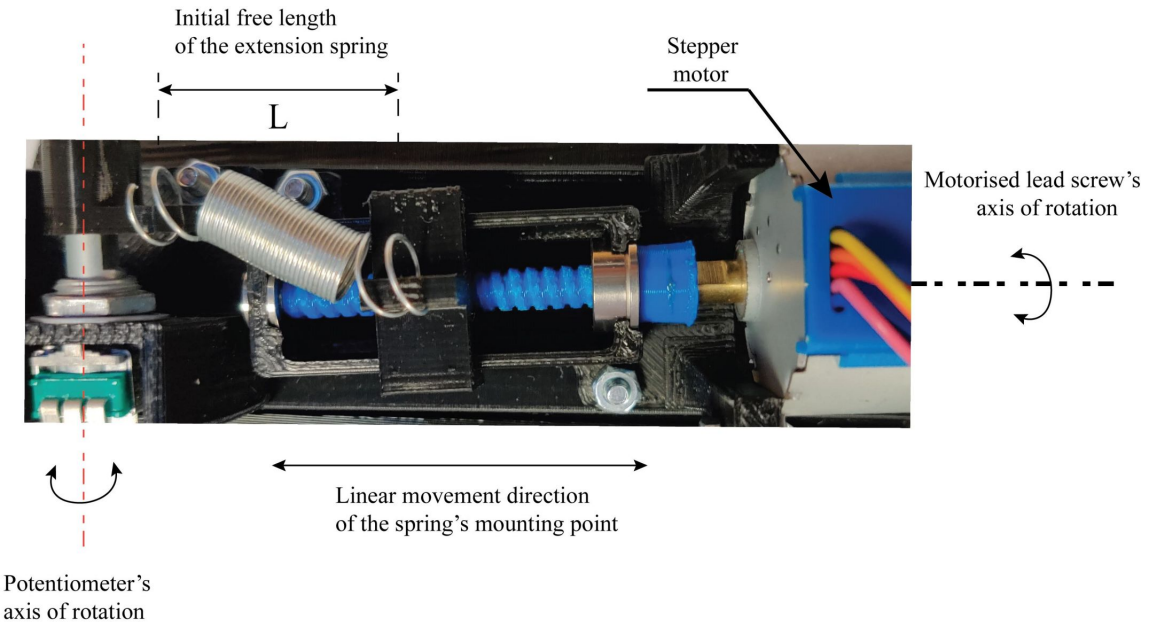


Figure 3.11: Tension adjustment mechanism

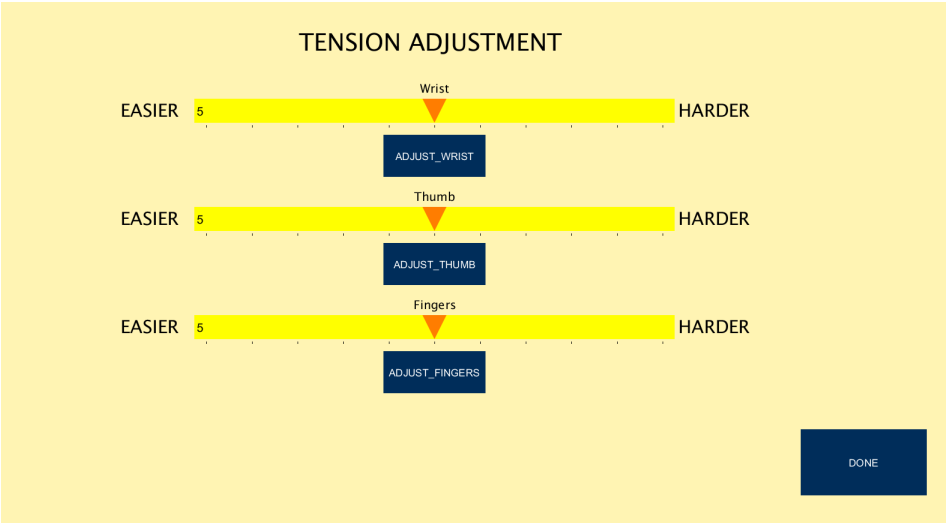


Figure 3.12: Tension adjustment interface on a touch screen tablet

3.3.2.2 Range of motion achievable with the WiGlove (Req 2 & Req 3)

Although the WiGlove only assists the joint extension, it is designed to ensure that it does not hinder any of the natural RoM required to perform ADL. The use of inelastic cords to transmit the force/torque ensures that ab/adduction of the fingers is unrestricted. However, this alone is not sufficient to ensure the freedom of this DoF in the wrist as demonstrated in SPO's design. A double parallelogram mechanism is used in SPO's wrist mechanism to ensure compliance with different hand dimensions. However, this design completely blocks the ab/adduction of the

wrist. To overcome this, the WiGlove uses a 3D printed flexible interconnection element between the forearm and hand modules which combined with the inelastic cord allows the user to freely perform ab/adduction of the wrist (Figure 3.13).

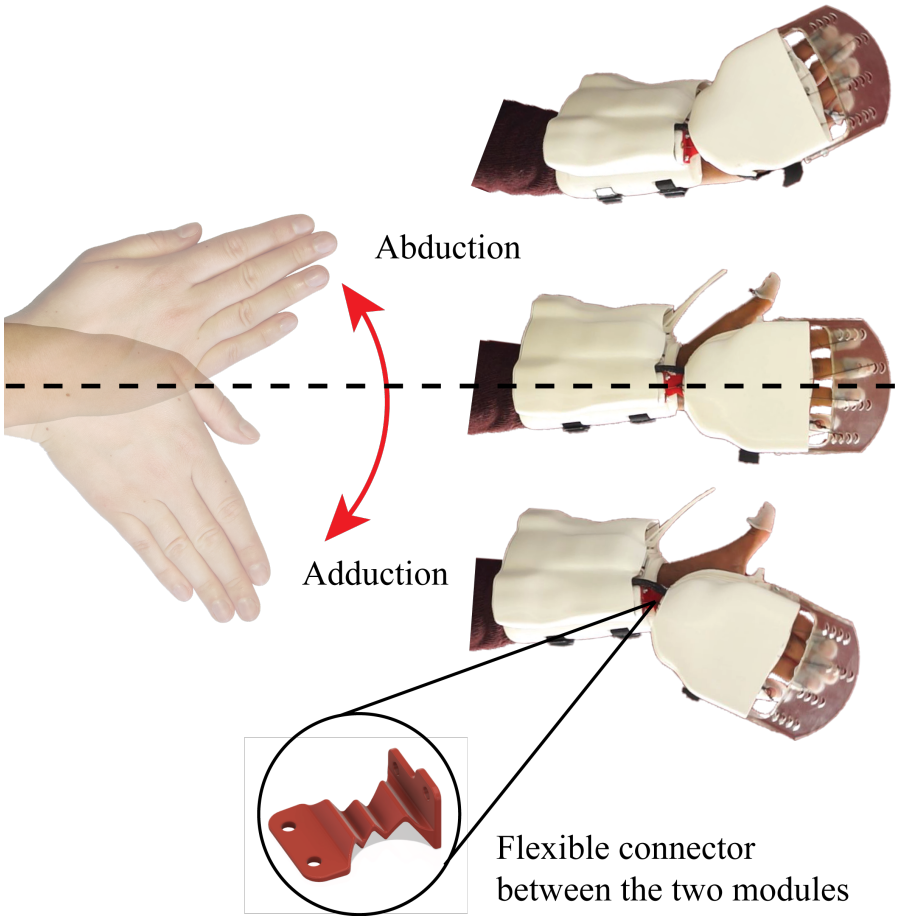


Figure 3.13: Wrist abduction/adduction with the WiGlove

3.3.2.3 Accommodating the changes in the centre of rotation. (Req 4)

The finger's assistance mechanism explained earlier follows a base-to-distal architecture where the wearer's MCP joint and the fingertips are a part of the mechanism. The only two points of interaction are at the base of the fingers in the form of an elastic strap and at the fingertips using inelastic cords and fingercaps. As discussed earlier in section 2.6.1.3 (Chapter 2), due to the absence of any other rigid links that interact with the finger, this design accommodates the changing CoRs and eliminates the concern of injury and discomfort due to the misalignment between the device and finger joint axes prevalent in most exoskeletal devices, thereby satisfying **Req 4**.

3.3.2.4 Joint angle measurement system (Req 5)

As discussed earlier in section 2.7.5 (Chapter 2), rotary potentiometers were identified as the ideal sensors of choice for the measurement of joint angles in a wearable home-based orthosis. However, these sensors typically require two rigid links that rotate around a common axis. As discussed earlier (section 3.3.2), the WiGlove uses a base-to-distal mechanism that does not have these rigid links, making it difficult to use potentiometers conventionally. As a result, the state-of-the-art SPO system, which also employs the base-to-distal mechanism, uses resistive bending sensors attached to leaf springs instead of potentiometers (Figure 3.14). This approach suffered from poor repeatability discussed earlier in section 2.7.4 (Chapter 2). In contrast, the WiGlove design overcomes this limitation by proposing a novel mechanism that uses potentiometers while still utilising the base-to-distal mechanism that offers comfortable interaction.

The spring in each assistance module is attached to the respective inelastic cord through a coupler that rotates about the shaft of a rotary potentiometer (Figures 3.9 & 3.15). When a finger or the wrist is flexed, the inelastic cord exerts a torque on the coupler which rotates the potentiometer's shaft. Since the mechanism only generates a single flexion value per finger, accurate and direct measurement of the intra-digit angles (metacarpophalangeal (MCP), proximal interphalangeal (PIP) and distal interphalangeal (DIP)) is challenging and therefore can only be estimated by an approach similar to [7]. In this approach, the intra-digit angles are calculated by interpolation between the ADC output values at the fully flat and fully flexed positions for each joint as shown in equation 3.1. Here $ADC_{norm}(k)$, $\theta_{joint}(k)$, $\theta_{joint_{max}}$ correspond to the normalised value from the arduino's ADC, desired joint angle and the maximum angle that the specific joint can achieve respectively.

$$\theta_{joint}(k) = \theta_{joint_{max}} |ADC_{norm}(k) - 1| \tag{3.1}$$

In addition to the joint angles, the posture of the arm is estimated by an inertial measurement unit (IMU). The LSM9DS1 IMU module consists of a 3-axis digital accelerometer, 3-axis digital gyroscope and a 3-axis magnetometer and is integrated into the Arduino Nano microcontroller. The microcontroller interprets the sensor values and transmits them to the tablet via Bluetooth. It also permits playing therapeutic computer games to enhance motivation while capturing performance metrics.

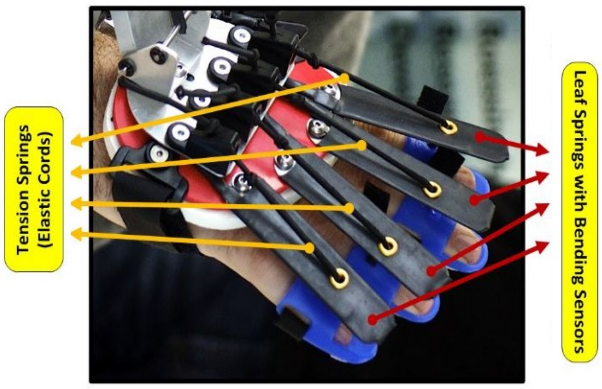


Figure 3.14: Image of the SCRIPT orthosis, showing the assistance mechanism [6]

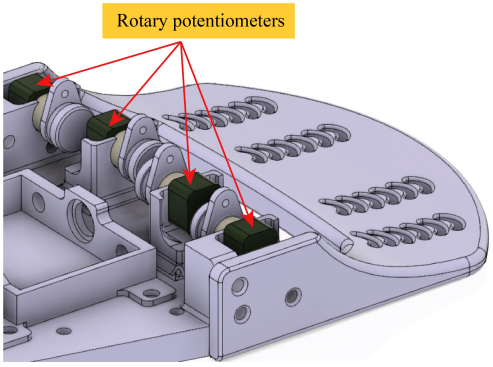


Figure 3.15: Image of the WiGlove, showing the assistance mechanism

3.3.2.5 Sizing of the WiGlove (Req 6)

SPO uses an off-the-shelf forearm shell and hand plate from Saebo Flex which exists in five standard sizes chosen based on two of the user's hand dimensions (dorsal hand width and wrist circumference). However, selecting the size only based on these two dimensions could lead to a mismatch in the other parts of the device that come in contact with the arm. Therefore, in satisfying **Req 6** to avoid discomfort and pain due to this mismatch the WiGlove is customised according to the user's hand dimensions by adjusting the length of the inelastic cord, choosing the appropriate guide slot on the finger extension structure and custom printing the forearm module based on the participant's hand dimensions using a parametric design approach.

3.3.2.6 Visual and tactile transparency (Req 7)

SPO's rigid fingercaps made of plastic, block tactile contact in the fingertips while interacting with objects. The absence of tactile feedback makes it difficult to grasp small objects and prevents sensory stimulation that could affect recovery [44]. This is compounded by its smooth surface finish that offers a very low coefficient of friction while grasping. WiGlove overcomes these issues with silicone finger caps that offer a high coefficient of friction and partial tactile transparency. The WiGlove's open palm design preserves visual transparency and maintains the user's haptic experience in the palm while grasping objects (Figure 3.16). The finger mechanism's extension structure, which directs the inelastic cord to the fingertips, is constructed of transparent material, providing visual feedback during training. Furthermore, unlike SPO, WiGlove's finger caps do not block the DIP (distal interphalangeal) joint, allowing for easy grasping of large objects. This visual and tactile transparency adds to this sensory stimulation and neural modulation potential thereby satisfying **Req 7**.

Figure 3.16: Images showing the open palm design of the WiGlove

3.3.2.7 Donning and doffing mechanism. (Req 8)

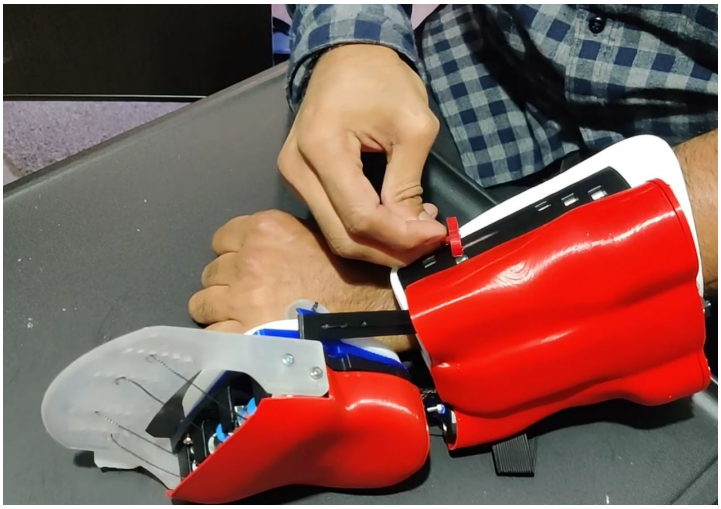


Figure 3.17: Image showing a hemiparetic stroke survivor using the elastic strap and hook to independently don the WiGlove

An earlier study reported that stroke survivors with reduced dexterity found it challenging to slide their arms into the SPO's shell and pass the Velcro straps through its loops [7]. Being a home-based device, it is imperative that the user can don/doff the WiGlove easily without assistance. Hence in WiGlove's design, SPO's donning mechanism is replaced by an elastic strap and hook approach whose tension can be adapted to suit the user. Unlike SPO, the WiGlove's forearm shell is designed with sufficient access to easily place the arm rather than sliding in and hooking the elastic straps with the unimpaired hand. It contains multiple mounting points to allow for further minute adjustments in the tension of these straps to ensure comfort. These points are situated on the ventral side of the device to ensure an unobstructed view while

donning/doffing the device with the unimpaired hand (Figures 3.7 and 3.17).

Similarly, SPO's finger caps, required strapping individual Velcro straps for each finger that often get entangled due to their proximity and require separation before donning. This would be difficult for stroke survivors with one free hand [7]. This has been overcome in WiGlove's design using silicone finger caps that cling to the fingers by virtue of their inherent elasticity, thereby eliminating the need for straps.

3.3.2.8 Safety (Req 9)

Given its home-based application in the absence of a clinician's supervision, several potential risk factors were identified in SPO such as pinch points in the double parallelogram, entanglement, and tripping hazards from the wire. On the contrary, the WiGlove's passive operation and design eliminates excessive forces, and is devoid of any pinch points and sharp edges ensuring the safety of the user and the family members. Bluetooth communication and the built-in power supply eradicate any tripping hazard due to wires and tethers. Furthermore, both modules are lined with thermoplastic polyethylene foam on all the surfaces that come in contact with the arm. This layer makes sure that the interaction is soft and comfortable by preventing contact with hard components.

3.3.2.9 Portability and space requirement of the system (Req 10)

Most of the WiGlove's components such as the assistance mechanism for the wrist and thumb, power unit, signal processor and transmitter are situated on the forearm module so as to reduce the weight acting on the hand module. The total weight of the device is 570g while the forearm and hand modules weigh 390 g and 180 g respectively. Since this is a wearable device, its weight was a significant design constraint and was maintained below the 500g (on forearm) + 200g (on hand) limit that was identified as satisfactory according to users [194].

In addition, the microcontroller mentioned earlier transmits all the sensor data to a touch-screen tablet through Bluetooth 4.0. This allows both therapists and users to monitor the performance including the range of motion (RoM), number of repetitions, training duration, etc. It also allows the user to interact with therapeutic games on the tablet while training with the WiGlove to enhance motivation. On the other hand, SPO required it to be connected to a desktop computer for data acquisition and playing games. Compared to this, the WiGlove - tablet system is significantly smaller, occupies less space and is easy to store. We hypothesise that these features render the WiGlove more suitable and easy to use in a home environment.

The WiGlove is a wireless device with a dedicated inbuilt rechargeable power unit, data acquisition and control units. Given that one of the objectives of the device is to allow the user to train while performing different activities of daily life, the WiGlove's wireless operation poses no

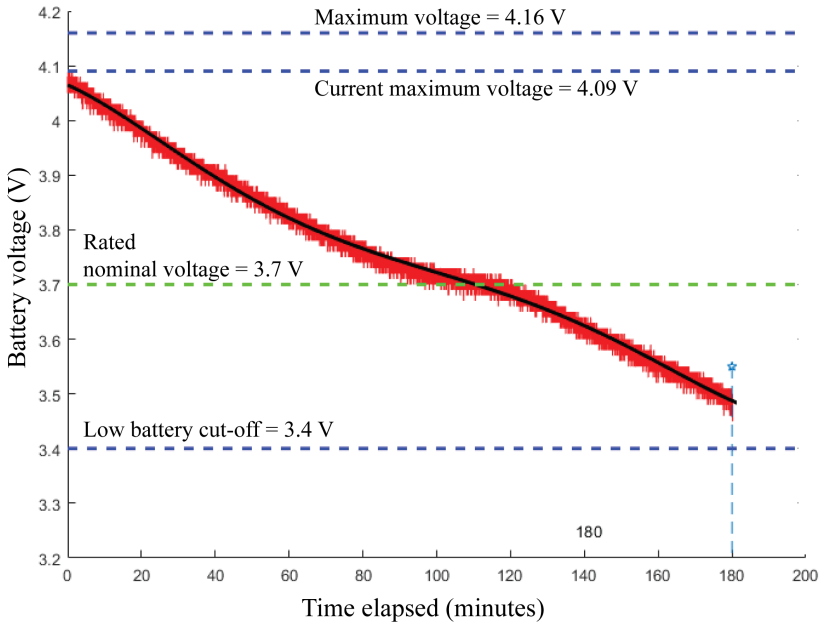


Figure 3.18: The WiGlove's battery capacity while logging all sensors

restriction while performing different tasks. Unlike the SPO's tethered operation, the WiGlove allows the users to train in different parts of the house which has the potential to alleviate the mental fatigue of training in one place as discussed earlier (Req 10). This location flexibility can help provide access on demand, allowing duration and repetition flexibility. Battery stress tests showed its capacity to last for more than 180 minutes while logging all the sensors and transmitting them via Bluetooth before requiring a recharge. The power management unit was designed to maximise the operation time on a single charge, even when the tension adjustment system is used at the beginning of a session. In figure 3.18, the voltage data stops approximately at 3.5V since the test was stopped before it reached the cut-off value to protect the battery's health. Both the WiGlove and the tablet can be charged using a microUSB cable.

3.3.2.10 Learnability (Req 11)

The WiGlove has a simple control interface involving two push-button switches one for turning the glove on/off and one for turning on the tension adjustment mechanism. An intuitive slider interface on the tablet is used to individually adjust the tension (extension assistance) for the wrist, thumb and fingers. Apart from this, it does not require the users to perform any maintenance tasks making it easy to learn and use without professional support.

3.3.2.11 Cost (Req 12)

Given that this work aimed to achieve a cost-effective design, cost played a significant role in every design decision. To begin with, the selection of PLA as the material and utilising 3D printing as the fabrication method significantly contributed to reducing the overall expenses. Moreover, all other components, including sensors, microcontrollers, cushion pads, and inelastic cord, were carefully chosen from off-the-shelf options. This approach eliminated the need for custom procurement and manufacturing, resulting in further cost reduction. The cost breakdown presented in Table 3.2 shows that the total cost of the WiGlove amounted to £840 or $ 1046.06. The current clinical standard for dynamic hand orthosis is SaeboFlex, which costs £972 including value-added taxes in the United Kingdom [196]. It is important to note that, it only allows the exercise of fingers while also not possessing any sensors to provide feedback or a gaming interface to motivate the patient while training. On the other hand, a commercially available fully robotic hand orthosis called the "Hand of Hope" is reported to cost €20,000 according to [177] which is considerably higher than the threshold of $9,040 set by WHO-CHOICE for affordability [175]. Therefore, in comparison to the existing devices, the cost of $ 1046.06 WiGlove - tablet system can be characterised as affordable, thereby satisfying **Req 12**. Furthermore, being a home-based glove, it helps the patient avoid the expense of travelling to and from a therapy centre.

Table 3.2: Cost breakdown of the WiGlove

Component	**Cost (£)**
Potentiometers	15
Motors	10
Motor drivers	25
Springs	10
Fingercaps	10
Nylon cords	10
PCB manufacturing and delivery	25
Microcontroller	30
Bluetooth module	20
Battery	10
Charging module	15
Charging adapter	15
PCB components	15
Wires	10
buckles	10
hand foam	35
Forearm foam	35
3D printing materials	40
Touch screen tablet	500
Total	**840**

3.4 Technical evaluation

The previous section discusses how **Req 1, Req 4, Req 6** and **Req 7**, were addressed by virtue of specific design features. The following experiments were performed to evaluate if the WiGlove satisfied the remainder of the functional requirements.

3.4.1 Joint angle sensors

Given the significance of the feedback on performance during training, it is imperative to validate the measurement system. Accordingly, to evaluate the repeatability of the joint angle sensing mechanism, a method akin to the one employed in SCRIPT [7] is used. Repetitions of flexing the fingers to a closed fist followed by an extension to a flat position were performed for approximately 5 seconds each. The corresponding digital sensor output is logged to analyse the repeatability. Similar experiments were also performed while grasping 3D printed cylinders of varying diameters (Large = 84mm ϕ, Medium = 60mm ϕ, Small = 50mm ϕ), inline with the dimensions utilised in SCRIPT. Since the sensing mechanism employed is the same across all fingers, the readings from the index finger's sensor expressed in Least Significant Bit (LSB) are presented here to demonstrate its repeatability (Figure 3.19). The standard deviation of the readings at fully flexed and fully extended positions were 1[LSB] and 2[LSB] respectively.

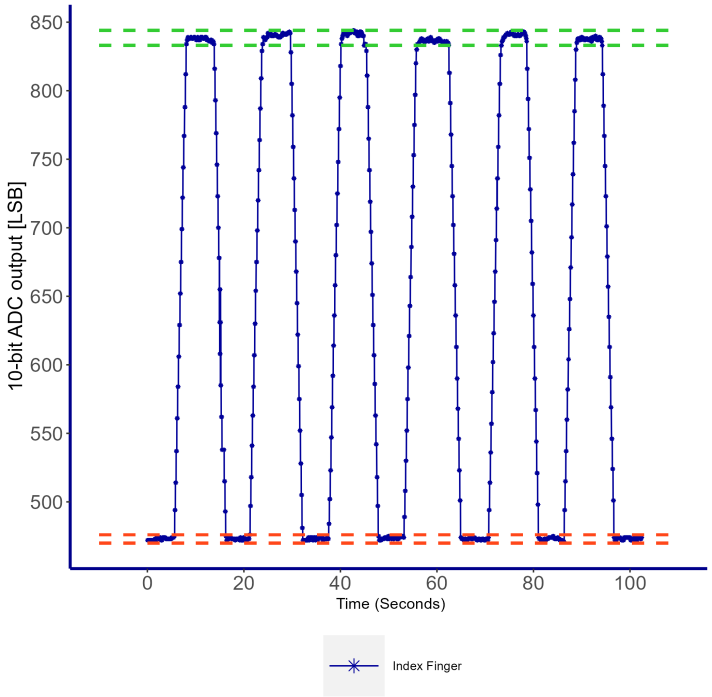


Figure 3.19: WiGlove - Repeatability of the index finger's joint angle measurements during repetitions of finger flexions to a closed fist followed by an extension to a flat position. It demonstrates excellent repeatability at fully flexed (green region) and fully extended positions (red region).

On the contrary, a study to demonstrate the repeatability of SPO observed high repeatability at maximum extension when the fingers are flat, however, when they are flexed, the sensor readings reach the corresponding value but start to decay slowly as shown in Figure 3.20 [7]. Excellent repeatability was observed in the sensor readings of the WiGlove without any time decay, presenting marked improvements compared to SPO. However, examining the individual flexion and extension instances reveal a higher intra-individual variability during flexion. This can be attributed to the tremors in the fingers that occur when held at maximum flexion, where the resistive forces of the spring are at their highest.

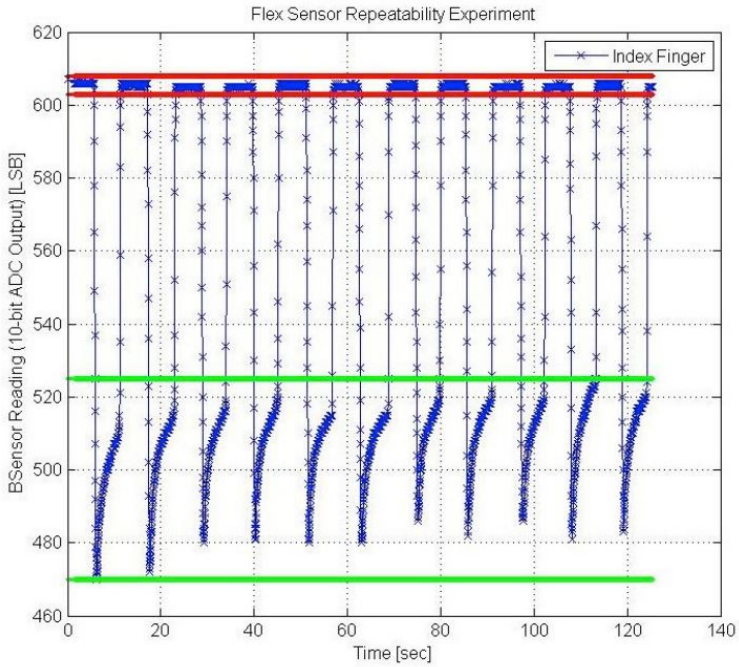


Figure 3.20: SPO = Step response of the index finger's joint angle sensor at maximum flexion (green region) and extension conditions (red region) [7]

The results of the grasping tasks (Table 3.3) serve to corroborate further the remarkable repeatability of the sensing mechanism, as well as its capacity to differentiate between various grasp sizes based on the corresponding values at flexion. Despite not measuring the intra-digit angles as mentioned earlier, the excellent repeatability of these sensors would be adequate to enable the therapists to keep track of changes in the overall range of motion of each finger and for interacting with the games thereby satisfying **Req 5**.

Table 3.3: Mean and Standard deviations of the ADC output at different conditions expressed in Least Significant Bit (LSB).

		Closed fist	Large grasp	Medium grasp	Small grasp
Flexion	Mean	839	783	745	657
	SD	1	1	1	1
Extension	Mean	473	473	473	473
	SD	1	1	1	1

3.4.2 Range of motion

The joints' achievable natural range of motion (RoM) differs from person to person and depends on the individual's biometrics [7]. Since the RoM is further reduced in stroke survivors with impaired hands, to validate this requirement, the measurements are performed on a healthy individual using a clinical goniometer. The measured maximum achievable joint angles with and without the WiGlove are presented in Table 3.4.

Table 3.4: Range of motion measurements

			Natural RoM	With SPO	With WiGlove	ADL
WRIST		Flex	76°	40°	74°	70°
		Ext	-58°	-20°	-52°	-60°
		Abd	28°	0°	25°	20°
		Add	31°	0°	31°	30°
THUMB	MCP	Flex	100°	60°	100°	100°
		Ext	0°	0°	0°	0°
		P Abd	50°	50°	50°	50°
	PIP	Flex	80°	15°	80°	80°
		Ext	-40°	0°	0°	-10°
FINGERS	MCP	Flex	90°	60°	90°	90°
		Ext	-10°	0°	0°	-11°to -14°
		Abd	25°	25°	25°	25°
		Add	0°	0°	0°	0°
	PIP	Flex	100°	80°	100°	100°
		Ext	0°	0°	0°	-10°
	DIP	Flex	80°	15°	80°	80°
		Ext	0°	0°	0°	0°

The labels "Flex", "Ext", "Abd", "Add" and "P Abd" correspond to flexion, extension, abduction, adduction and palmar abduction respectively. The column titled "Natural RoM" presents the

available RoM of this experiment's healthy participant. The negative sign convention is followed to denote the extension angles that are measured in the direction opposite to that of flexion. It shows that while wearing the WiGlove, the healthy individual was able to perform most of the natural RoM without any restrictions. Even in cases where the natural RoM is slightly restricted, it is still above that required to perform ADL. However, the 10° extension of MCP, PIP and DIP required to perform ADL is blocked by WiGlove's finger extension structure. Since it is used without any supervision, this is essential to mitigate the risk of over-extension. Such undesirable movements can lead to pain and injury and therefore its prevention is imperative. These results support that the WiGlove's design satisfies **Req 2** and **Req 3**.

3.5 Summary

The WiGlove's development began with addressing the first research question.

RQ1: What are the user requirements for a home-based rehabilitation orthosis that allows hemiparetic stroke survivors to independently train their fingers and wrist ?

Consequently, the first part of this chapter details the various user requirements identified in this work based on the knowledge gained from a comprehensive survey of the literature up to date including but not restricted to the in-depth user study performed during the development of SPO (state-of-the-art). These identified requirements were classified into two distinct categories: functional and usability, based on the specific aspects of the device they pertain to. This requirement analysis highlighted the significance of wearability and usability in user acceptance and hence gained a major part of our focus. As a result, this answers the first research question of this work.

Furthermore, starting with an overview of the WiGlove's design process, this chapter comprehensively discusses its various design features and the design choices made to cater to the aforementioned user requirements. The subsequent stage of a user-centred design approach entails validating the design to ensure its alignment with the user requirements and to validate the improvements over SPO in order to answer **RQ 2**.

RQ 2 : Can the WiGlove, which was designed using a user-centred approach to meet specific requirements, result in better functionality and usability compared to the current state-of-the-art?

To begin with, this chapter demonstrates the WiGlove's validation of all the functional requirements through various design decisions and through experimental validation. This validation answers the functionality part of **RQ 2** in the affirmative. The subsequent chapter will address the verification of the usability of the WiGlove to completely answer **RQ 2**.

CHAPTER 4

FORMATIVE USABILITY EVALUATION

4.1 Introduction

Having ensured that the WiGlove satisfies the functional requirements, the next step was to evaluate its wearability and usability. A study highlights that during the prototyping stage, most works on assistive devices focus solely on the technical evaluation, neglecting their wearability and usability [197]. Evaluating usability, which depends not only on the device but also on its interaction with the human body, can help identify potential shortcomings that could hinder user adoption. These two factors play a significant role in the acceptance of the device. Therefore, it was imperative to conduct a formative evaluation to ensure the safety and usability of the WiGlove before introducing it to stroke survivors.

This formative usability evaluation consisted of three stages, during which the WiGlove's design was reviewed and revised based on feedback from healthy individuals and stroke therapists who interacted with the glove (Figure 4.1). This chapter outlines the methodology and results of this formative evaluation, including the resulting design changes.

4.2 Background

According to ISO 9241-20:2021(en) [198], usability is defined as the extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use. Unidentified usability issues have been credited as a significant reason for most devices where the performance in a laboratory environment does not transfer to the real-world scenario [40]. This highlights the significance of conducting usability evaluations in the formative stages of developing medical devices. The

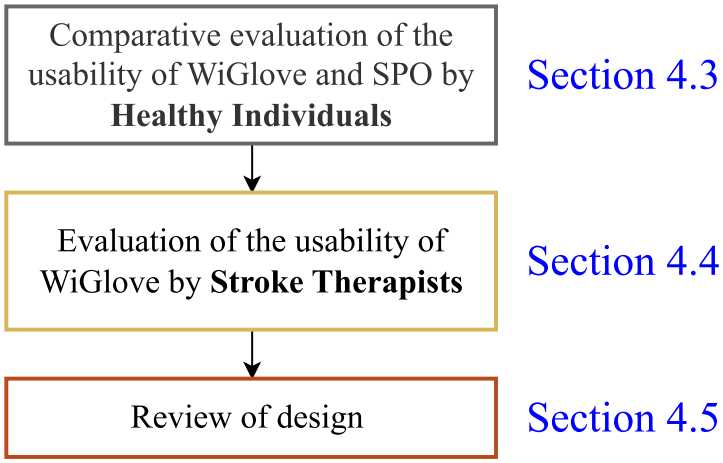


Figure 4.1: Stages of the Formative Evaluation

authors of [199] highlight that the field of usability evaluation in medical devices is relatively underdeveloped with research focusing on this aspect has been slowly increasing only in the last five years.

The traditional protocol followed in most studies that evaluate the usability of upper limb prostheses involves developing a custom-made framework tailored to the device and to its features that are being evaluated [200, 201]. During the evaluation process, participants are asked to perform specific tasks while wearing the device and provide their feedback. These tasks are designed according to the elements of the device that are of interest. Both quantitative and qualitative methods have been employed in evaluating the usability of medical devices, including heuristic evaluation [202], cognitive walkthroughs [203], interviews, focus groups [204], benchmarking [205], and questionnaires [206] based on the elements that are studied.

Heuristic evaluation involves several experts examining the device to identify potential usability issues based on their knowledge and experience. This approach is ideal for use in the formative stages of device development. On the other hand, cognitive walkthroughs are task-specific, with each task being decomposed into a sequence of events that participants perform and record potential issues. This approach helps to contextualise each usability issue thereby making them easier to address.

Interviews and focus groups are also commonly used methods in usability evaluation where the participants are asked a series of questions and their responses are recorded in the form of interaction. However, while interviews are conducted one-on-one with participants, focus groups involve multiple participants simultaneously, which could result in redacted outcomes if some participants are uncomfortable about discussing their opinion in public.

Benchmark testing is used to establish a baseline usability performance against which future redesigns can be evaluated. This quantitative approach helps to both evaluate the holistic usability to identify potential areas of improvement. This method is also done to evaluate the device under development against an industry standard, competitor or state-of-the-art.

Finally, of all the methods, questionnaires were observed to be the most commonly used approach in usability testing. The Agency for Healthcare Research and Quality recommends questionnaires as the ideal approach to assess the usability of medical systems and devices due to their inexpensive and easy-to-use nature [197, 207]. Owing to these advantages, this study adopts questionnaires to evaluate the usability of the WiGlove. Several standardised usability questionnaires such as System Usability Scale (SUS), Perdue Usability Testing Questionnaire (PUTQ), Computer System Usability Questionnaire (CSUQ), etc., were identified in the literature. However, these questionnaires are designed to be answered by the end-users of a system, which in our case would be stroke survivors. However, in this study, the participants were healthy individuals; therefore, the existing questionnaires cannot be used. Therefore, as observed to be common practice in literature [206], a custom questionnaire to suit the specific needs of this study was used as detailed in section 4.3.2 and appendix 7.

Furthermore, [40] highlights the significance of involving caregivers as secondary users in the usability evaluation of medical devices. Through the use of both quantitative and qualitative methods, they demonstrated that the feedback from secondary users was valuable in identifying and addressing usability issues. Akin to this, in the evaluation of the WiGlove's usability, a Retrospective Think-Aloud (RTA) approach was employed to record the thoughts and feedback of stroke therapists. This method involves the participant interacting with the device, followed by them providing their thoughts based on their experience. In the subsequent sections, the two stages of the formative usability evaluation are discussed in detail.

4.3 Formative evaluation involving healthy participants

Given the unique functional and usability challenges that arise with the design of a passive dynamic orthosis that trains both the wrist and fingers, SPO stands as the ideal state-of-the-art for this application and therefore we benchmark our glove against it. The WiGlove was designed to better satisfy the user requirements detailed in chapter **3** than the SPO. The objective of this stage was to conduct a preliminary evaluation with healthy individuals to verify this by testing the following hypotheses.

H_1 **Donning and Doffing the WiGlove is easier than the SPO.**
The WiGlove is to be used by stroke survivors at home by themselves. Therefore, it is imperative that it is easy to don and doff without external assistance. The WiGlove is designed

to address the issues identified in SPO that made this difficult (Section 3.3.2.7). Such difficulties could potentially lead to frustration and affect the stroke survivors' motivation to train. Hence, evaluating this aspect against the SPO is essential.

H_2 **The WiGlove does not restrict any natural range of motions of the wrist and fingers.**

Restricted range of motion while using the glove could lead to muscle atrophy due to non-use [192]. SPO uses a double parallelogram at the wrist to prevent misalignment between the joints and the device. This mechanism blocks the abduction/adduction of the wrist to a large extent [32]. The WiGlove was designed to prevent joint misalignment without blocking abduction/adduction of the wrist (Section 3.3.2.2).

H_3 **Adjusting the magnitude of assistance is easier in the WiGlove than the SPO.**

Since the amount of assistive force required for extension depends on the severity of the stroke and varies with recovery, SPO requires the user to adjust the length of the elastic cord using cord stops. Stroke survivors with reduced dexterity could find it difficult to perform this and therefore, the WiGlove uses a slider interface on a touchscreen tablet to make it easier. It controls an actuator that modifies the assistance. Difficulties in modifying the tension could lead to frustration and emotional fatigue that negatively affect training (Section 3.3.2.1).

H_4 **Performing activities of daily life(ADL) is easier while wearing the WiGlove than the SPO.**

Being a home-based rehabilitation device, it is desired that the user is able to perform activities of daily life while wearing the device. The WiGlove was designed to be non-invasive and non-restrictive and facilitate the user to perform these activities without causing hindrance. Hence, we evaluate the WiGlove on aspects such as ease of performing different grasps, user's perception of the weight of the gloves and their suitability for ADL against SPO.

H_5 **The WiGlove is safer and aesthetically more appealing than the SPO.**

The aesthetics of an exoskeleton has been shown to affect its user acceptance [208]. Researchers who studied the influence of the aesthetic appeal of a scoliosis brace on the psychology of users observed that aesthetically pleasing design increases user compliance and acceptance. They suggest that it has a positive influence on psychology during treatment [209]. Therefore, we evaluated the WiGlove's aesthetic appeal against SPO's bare robot-like appearance. Making sure that training with the WiGlove does not pose any potential risk to the user and the other members of the house are imperative since it was designed to be used at home without the supervision of a therapist. The user's perception of this aspect was also evaluated against that of SPO in this study.

4.3.1 Participants and ethical considerations

This study involved twenty healthy participants over eighteen years of age. It was ensured that they were not suffering from any injuries to the fingers, hands and wrist at the time of their participation. All interested participants were sent a "participant information sheet" that briefly explains the procedure and the tasks involved. It also informs them about the steps taken for data protection and storage. Furthermore, only the participants whose hands fit the glove's size were recruited. Those interested in participating in the study placed their hand on a piece of paper that contained the layout of the maximum hand size that could fit both gloves. This check was performed at the beginning of each session and only those individuals who fit this criterion were recruited. Voluntary participants from the staff of the University of Hertfordshire were recruited for this study. The demographics of the participants are presented in table 4.1.

This study was approved by the University of Hertfordshire Ethics Committee before participants were recruited (Ethics protocol number: SPECS/ PGR/ UH/ 04896). Age and gender were the only personal information obtained from each participant. All the data gathered from the participants were anonymised before storage to protect the identity of the participant. It is stored securely with access to it restricted to the research team. Prior to their participation, each participant was provided with a participant information sheet that provides an overview of the experiment's procedure, data gathered and data handling. Each session only commenced after obtaining their consent through a consent form. Similar to the participant information sheet, this form contains an overview of the experiment.

Participants	Number	Average Age (Years)
Female	5	31.8 (SD = 4.9)
Male	15	26.6 (SD = 4.0)
Total	20	27.9 (SD = 5.2)

Table 4.1: Demographics of the study's participants

4.3.2 Data acquisition

A customised questionnaire was developed for the purposes of this study to test the hypotheses discussed earlier in this chapter. Separate but identical questionnaires were designed for both gloves. The questionnaire also contained images and video clips to guide the participants in performing various tasks. Each question is scored on a 7-point Likert scale. For example, the first question shown below deals with donning the forearm module. The participants were asked to rate the ease with which they can don this part of the glove on a scale of 1 to 7 (1 - Very Difficult and 7 - Very Easy).

How easy is it to put on (donning) the forearm module of the glove ?

	1	2	3	4	5	6	7	
Very Difficult	○	○	○	○	○	○	○	Very Easy

The usability and aesthetics questionnaires are included in their entirety in appendix 7. These questionnaires were presented to the participants in the form of a Google Form. Each questionnaire begins with the participants entering their age and gender after which it proceeds to the following sections on usability and wearability. The participants' scores were exported into separate spreadsheets for quantitative analysis.

4.3.3 Experimental setup and procedure

This study was conducted at the Assistive and Rehabilitation Robotics Laboratory of the University of Hertfordshire, UK. The experimental setup can be seen in figure 4.2. Both gloves were placed on opposite sides of a table. The participant was seated on a chair in front of the table. A laptop with a mouse was present on the table for the participants to record their feedback. A browser is opened on the laptop with the appropriate questionnaires. The questionnaire contains terminology referring to different parts of the glove and therefore a labelled image of the glove was present for their reference. Furthermore, a touchscreen tablet which is a part of the WiGlove system was also present on the table. Additionally, during each session, at specific times, the principal investigator introduced certain other objects by placing them on the table for the participant to interact with. These objects that are a part of the study are discussed in section 4.3.3. Apart from these, given the COVID-19 pandemic, hand sanitiser and sanitising wipes were present on the table for the participants to use before and after each session.

Figure 4.2: Experimental setup

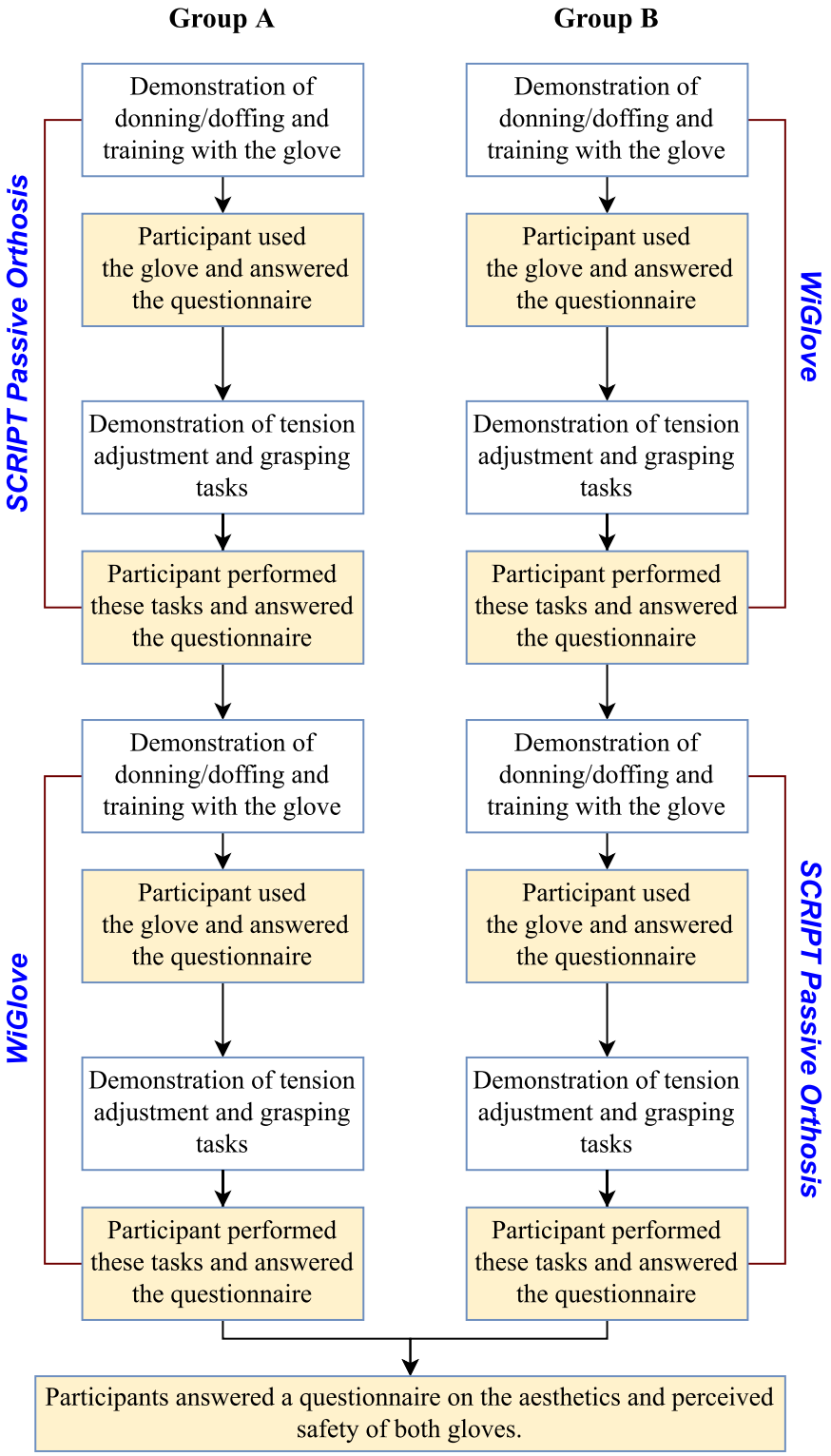


Figure 4.3: Experimental flow - usability evaluation by healthy participants

Overview and counterbalancing

Each participant used both gloves and comparatively evaluated the two gloves in a within-subject experiment. The experimental protocol involved the participants performing a series of tasks designed to test the hypotheses while wearing the two gloves. Each session involved one participant and lasted for a duration of 60 minutes during which they performed the tasks and provided their feedback using questionnaires. A counterbalancing approach was adopted to allow for evaluation with and without the effect of the order in which the participants tried the two gloves. At the beginning of each session, the participants were asked to randomly choose a folded piece of paper from a bowl of many with either **A** or **B** written on them. This decided the order in which the participants tried the two gloves. Participants who chose group **A** interacted with the SPO first and answered the corresponding questionnaire. They then performed the same tasks with the WiGlove. Out of 20 participants, ten participants chose group **A** and the remaining ten started with the WiGlove. Figure 4.3 illustrates the order of events in groups A and B at each stage.

Tasks to evaluate the donning and doffing mechanism and the device's DoF (H_1,H_2)

The study began with the principal investigator demonstrating donning, doffing and using either the SPO or the WiGlove based on the group that the participant chose. As a standard procedure, the participants were asked to start by donning the forearm module first since it is the heaviest. Once this part is supported by the forearm, it is easier to don the remaining modules. Subsequently, the hand module should be donned and then finally the finger caps. Following these instructions, the participants donned the glove and then answered a set of questions regarding the ease of donning (Appendix 7, questions 3-5). Subsequently, the questionnaire prompted them to perform abduction/adduction of the wrist and fingers one after the other and rate the ease with which they were able to perform them. It contained videos demonstrating these tasks. Afterwards, they were requested to doff the glove and then answer the corresponding questions. Similar to donning, the participants were requested to doff the glove in the order opposite to that of donning (Appendix 7, questions 9-11).

Tasks to evaluate the tension adjustment and grasping (H_3, H_4)

Next, the principal investigator demonstrated the procedure to adjust the magnitude of assistance of the glove that they were using at that stage. The participants then donned the glove again and attempted to change the amount of tension. In the WiGlove this can be done by moving a slider in a graphical user interface running on a tablet(Figure 4.4). In SPO, this is accomplished by manually pushing or pulling the elastic cord to readjust its tension using cord stops.

Afterwards, the questionnaire prompted the participants to evaluate the ease with which they can grasp a key, bottle and ball. These objects helped assess the ease with which the participants were able to perform a cylindrical, spherical and palmar pinch grasp while wearing the glove (Appendix 7, questions 13-15). To account for both power and precision grasps, cylindrical grasp

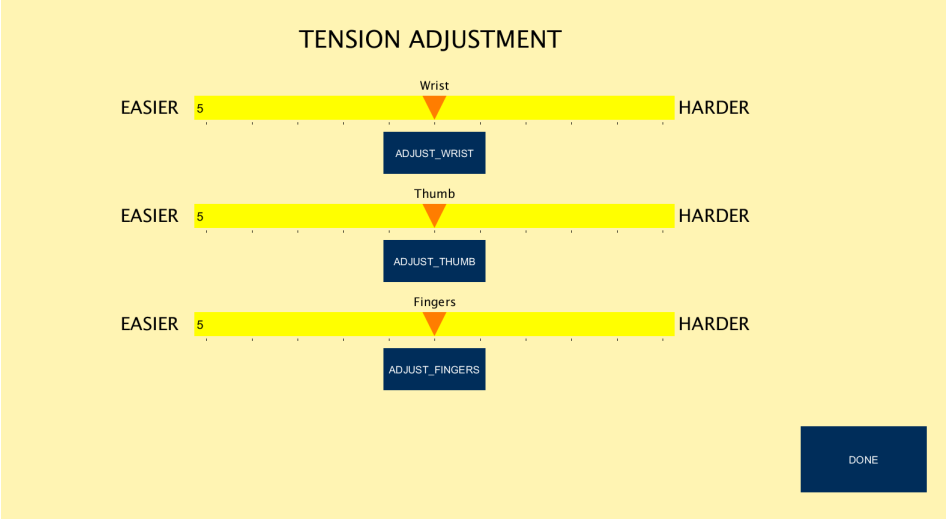
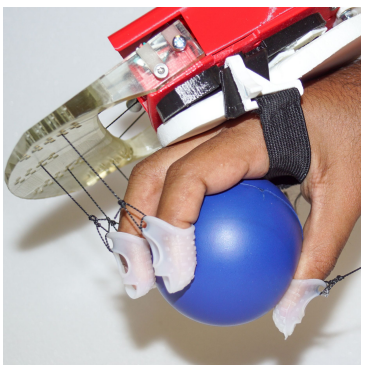


Figure 4.4: Tension adjustment screen

and palmar pinch were included in this study. Cylindrical and spherical grasps are categorised as a power grasp while the palmar pinch is a precision grasp [210]. These grasps were shown to be important in performing some of the most important activities of daily life such as eating with a spoon, combing hair, drinking from a bottle or glass etc [211]. For the palmar pinch, the participants were asked to hold a steel key that was approximately 50 mm in length and 20 mm in thickness between the tips of their thumb and index finger. The questionnaire contained a picture of all the grasps to help the participants.

(a) Palmar pinch (Key)

(b) Cylindrical grasp (Bottle)



(c) Spherical grasp (Ball)

Figure 4.5: Grasping tasks involved in the study

Similarly, a picture of a cylindrical grasp was also present to help the participants. The participants were asked to grasp a cylindrical bottle made of glass. A study shows that the magnitude of the gripping force produced decreases with an increase in the diameter of the object in cylindrical grasps [8, 212]. Its authors characterise, objects of diameter greater than 58 mm as large. While grasping such large objects, the gripping forces are concentrated at the fingertips

and require the flexion of all the joints of the fingers [212, 213] (Figure 4.6). It was observed that for the hand sizes included in this study, cylindrical objects of smaller diameters can be grasped by using the flexion of just the MCP and IP joints of the fingers to support the object against the palm and an opposing thumb. Hence a bottle that is 75 mm in diameter was chosen to evaluate the ease with which a cylindrical grasp involving all the joints can be performed. Therefore, the chosen size and material of the bottle help to evaluate the ease of performing a grasp at such an extreme condition while wearing the glove.

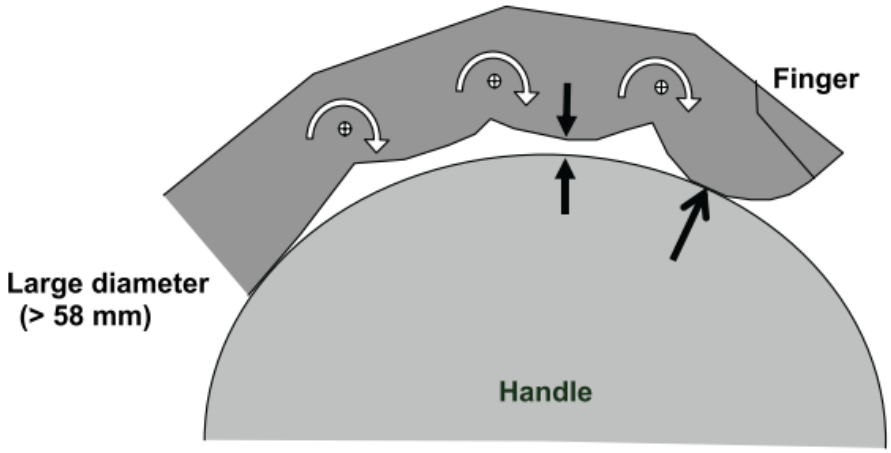


Figure 4.6: Grasping a large diameter cylindrical object that requires the flexion of all finger joints [8]

Although a power grasp (cylindrical grasp) had already been included, it was decided to also include the spherical grasp. Unlike a cylindrical grasp, the spherical grasp requires the abduction/adduction of the fingers, especially the fourth the fifth digits. This allowed us to evaluate the ease of performing a grasp that requires both the flexion and abduction of the fingers while wearing the glove (Appendix 7, questions 6 and 7). After each of the above-mentioned tasks, the participants answered questions about the ease of performing them while wearing the glove. After answering all the questions, they are requested to doff the glove and answer a set of questions on the ease of donning and doffing for the second time (Appendix 7, questions 19-24). This concluded the participant's interaction with the first glove. Each participant donned and doffed the glove twice over the duration of the study to allow for some familiarity. This familiarisation allowed the participants to exclude any difficulties that arose during their first try and also allowed them to notice any difficulties that they might have missed. Subsequently, the same steps detailed above are repeated for the second glove. Once the participants provided feedback on the usability of both gloves, it concludes the usability part of the study.

Aesthetics and perceived safety (H_5)

The third and final stage of the study corresponds to the aesthetic appeal and the perception

of safety. The participants were requested to answer a questionnaire on the aesthetic appeal and perceived safety of both gloves. It contained three questions (Appendix 7, question 3) where the participants rated both gloves on a scale of 1 to 7 similar to the ones used to evaluate the usability. Both gloves were present on the table and to prevent the participants from confusing their names, labelled pictures of the gloves were included in the questionnaire.

Playing a game with the glove on the tablet

The WiGlove has built-in sensors to monitor and record joint angle data. This data is transmitted to the tablet via Bluetooth. In addition to it assisting in monitoring the recovery, it can act as a controller that allows the user to play games on the tablet. At the end of their interaction with the WiGlove, the participants played a game on the tablet while wearing the WiGlove. In this game, the participants controlled the movement of a spaceship with flexion/extension of their wrists (Figure 4.7). Before the start of the game, there was a calibration phase where the participants were asked to keep their hands flat on the level with their arms and then perform maximum flexion. They were asked to repeat this at least three times in order to adapt the game to their available range of motion.

The objective of the game was to navigate the arena without crashing against the moving obstacles. When they successfully pass each obstacle, their score increases by one. If the spaceship crashes, the game ends and it gives the user the option to play again. Subsequently, they rated their perception of the sensitivity of the glove while playing the game. This stage was to help improve the experience of gaming with the WiGlove. During the study, it was observed that the participants tended to be competitive in trying to beat the top score set by one of the previous participants. Eleven of the twenty participants played the game multiple times until they eventually obtained the highest score. This showed the potential for improving user engagement with an improved and more diverse set of games.

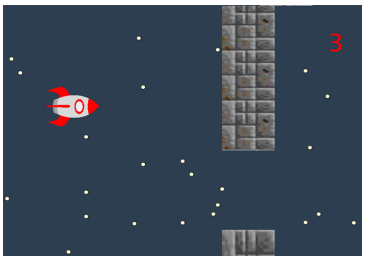


Figure 4.7: Wrist exercise game

4.3.4 Results and discussion

The participant's responses were recorded on an ordinal scale ranging from 1 to 7 where 1 corresponds to the most negative experience and 7 to the most positive. The results of this study

comparing the participants' judgement of the two gloves and their analysis are discussed in this section.

4.3.4.1 Statistical analysis

Being a within-subject experiment, a paired sample test was conducted to analyse if there were any statistically significant differences between the participants' scores for the two gloves. IBM's SPSS software was used to perform the statistical analysis. In this test, the type of the glove (the WiGlove or SPO) was the independent variable while the participants' responses to each were the dependent variable. Firstly, a test for normality showed that the samples were not normally distributed. Therefore, as a non-parametric alternative to the paired sample t-test, Wilcoxon signed rank test was chosen as the test to verify statistical significance [214, 215]. The results of this test reported here include the p-value, which is used to test the null hypothesis. A p-value of 0.05 or lower shows a statistically significant difference between the two samples. Additionally, the effect size (r) of the difference is calculated using the equation 4.1 [216].

$$r = |Z|/\sqrt{N} \tag{4.1}$$

where Z refers to the test statistics value or Z-score and N refers to the sample size. The effect sizes are categorised based on Cohen's classification: 0.1 (small effect), 0.3 (moderate effect) and 0.5 and above (large effect) [217]. Wilcoxon signed-rank test was also used to test for statistically significant differences between the participants' scores for donning/doffing between their first and second attempts. Mann-Whitney U test was performed to analyse the order effects between the two groups. The dependent variables for this test were the participants' scores for each category while the group that they belonged to was the independent variable. This test was chosen since the sample was not normally distributed as discussed before. The summary of all the statistical results is included in the appendix 7 (Table 6). The results of the Mann-Whitney U test exploring the order effects are included in (Appendix 7, Tables 9 and 10)

4.3.4.2 Ease of donning and doffing - H_1

The gloves used in this study have three parts that need to be donned and doffed: the forearm module, the hand module and the finger caps. The participants of this study rated the ease with which they were able to don/doff these parts on a scale of 1 to 7 as explained in section 4.3.2. As detailed earlier, the experiment involved the participants donning and doffing each glove twice. They were asked to rate the gloves after both instances to account for a change in perception due to familiarisation with the gloves. The boxplots of these scores for both the WiGlove and SPO show insignificant differences between the first and the second attempts (Figures 4.8 and 4.9). Wilcoxon signed-rank test shows that the participants overall felt it slightly easier to don the hand module of SPO during the second attempt with a statistically significant difference between

the scores ($Z = -2.588$, $p = 0.01$, $r = 0.579$). This notwithstanding, statistical analysis showed no statistically significant differences between the two attempts in every other category for both gloves. The summary of the results of this statistical analysis is included in the appendix (Tables 7 and 8). Hence, moving forward we base our discussions on the participants' scores after their second donning/doffing attempt.

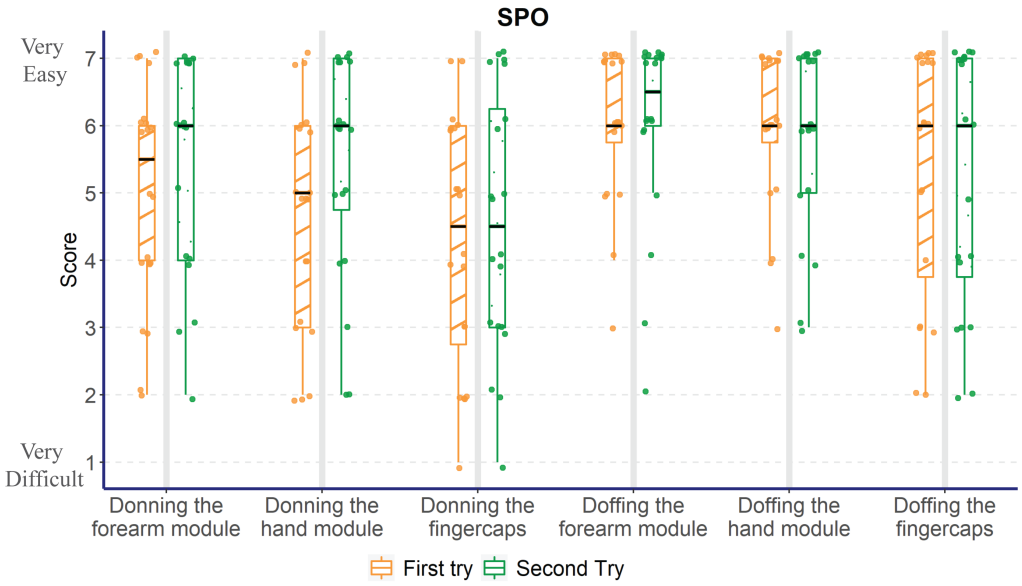


Figure 4.8: Boxplot of participants' scores for the ease of donning and doffing different parts of SPO in their first and second tries.

Figure 4.9: Boxplot of participants' scores for the ease of donning and doffing different parts of the WiGlove in their first and second tries.

In analysing the participants' scores on the ease of donning the finger caps, a statistically significant difference was observed between their scores for the WiGlove and SPO ($Z = -3.337$, $p =< 0.001$, $r = 0.746$). Overall, they found it easier to don the finger caps of the WiGlove than the other. This can be seen in the boxplot from figure 4.10 where the median score for the WiGlove is higher than that of SPO. The finger caps of SPO (Figure 4.12b) are made of plastic and contain a velcro strap to prevent them from sliding off the fingers. A prior study by the SCRIPT researchers observed that participants found it difficult to don these finger caps [7]. The individual straps from the four fingers' caps had a tendency to get entangled due to their proximity and required the user to separate them before donning. Meanwhile, the silicone finger caps of the WiGlove are flexible and do not require any straps while donning (Figure 4.12a). The users had to simply pull the finger caps slightly towards the finger and insert the fingers into them. The cap's size is chosen to suit the size of the finger and its inherent elasticity helps them to cling to the finger preventing any sliding off. We hypothesise that this explains the observed improvement in the score of the WiGlove for this aspect. The median scores for the ease of donning the forearm and hand modules were the same for both gloves showing no difference between the two gloves. However, comparing the corresponding scores based on the order in which the participants tried the two gloves helped us understand the reason (Figure 4.11).

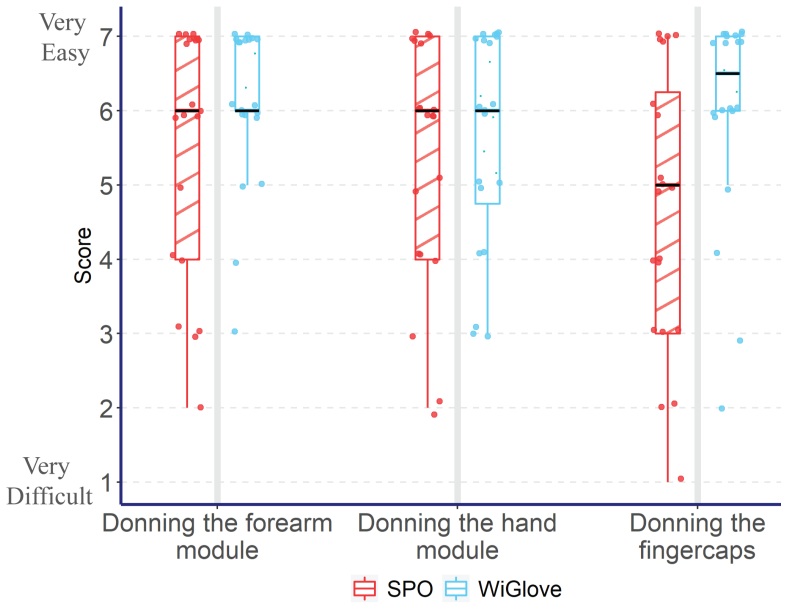


Figure 4.10: Boxplot of the participants' scores for the ease of donning different parts of the two gloves

In both groups, SPO's forearm and hand modules received the same median score of 6 against a maximum of 7. Researchers who studied the usability of the SPO observed that stroke patients found it challenging to slide their arm and hand into the shell, pass the Velcro straps through the loop and strap it [7]. This requires dexterity at levels that stroke survivors lack. This, however, is

not the case for healthy individuals who were the participants of this study. Although there was no statistically significant difference between the groups, this could explain the higher scores for SPO.

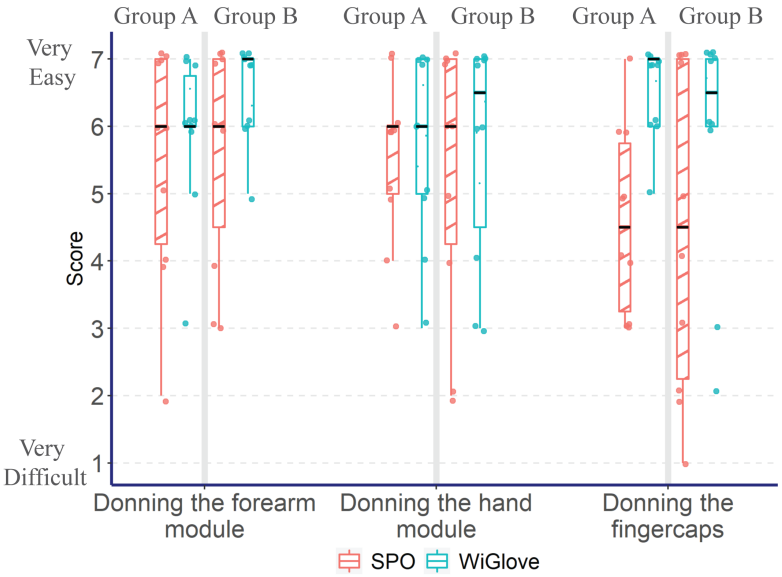
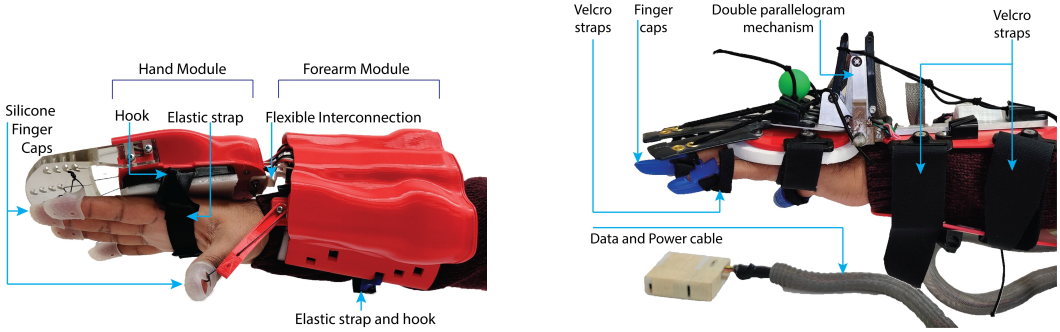


Figure 4.11: Boxplot of the participants' scores for the ease of donning different parts of the two gloves categorised according to the counterbalanced groups

However, participants in Group B who tried the WiGlove first and then evaluated SPO had the former as a reference. The forearm and hand modules of the WiGlove received a higher median score by them than SPO. We further hypothesise that stroke survivors would find the hook and elastic strap solution (Figure 4.12a) of the WiGlove to be easier than SPO. This is evaluated during the summative evaluation involving stroke survivors. Furthermore, it is noteworthy that, figure 4.11 also shows that the participants from both groups consistently rated the WiGlove's finger caps as easier to don than that of the SPO. This further stands testament to the improvement in the design of the finger caps of the WiGlove.



(a) The WiGlove

(b) SCRIPT Passive Orthosis (SPO)

Figure 4.12: Labelled figures of the two devices showing the differences in their design attributes

After performing all the tasks with each glove, the participants doffed the glove in a sequence starting with the finger caps followed by the hand module and finishing with the forearm. Following this, they rated the ease of doffing on a scale similar to the ones discussed in donning. A boxplot of these scores can be seen in figure 4.13. The WiGlove's forearm module and the finger caps were rated easier to doff than those of the SPO with a statistically significant difference ($Z = -2.145$, $p = 0.032$, $r = 0.48$; $Z = -2.958$, $p = 0.003$, $r = 0.661$). It can be seen from the figure that both the modules of the WiGlove scored a median score of 7 (Very Easy) which is higher than those of SPO. This can be attributed to the same factors that influenced the donning.

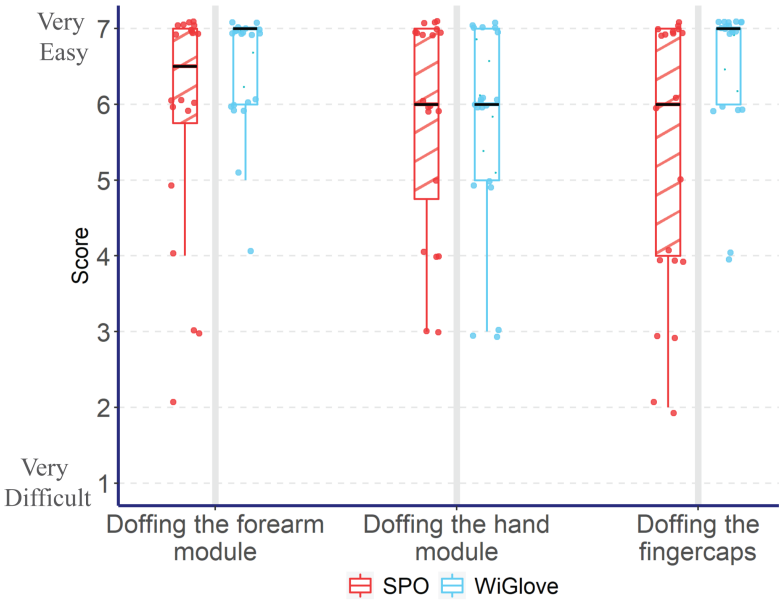


Figure 4.13: Boxplot of the participants' scores for the ease of doffing different parts of the two gloves

However, doffing the hand modules of both gloves was found to be similar in difficulty with a median score of 6. To analyse this further, these scores were split based on the experiment groups similar to the one performed in donning. In figure 4.14, it can be seen that overall, participants from group A, who tried the SPO first, rated its hand module to be easier to doff. This could be attributed to healthy participants finding it easier to doff the SPO than stroke patients. However, this does not explain the fact that the WiGlove received the same median score in both groups. During the study, it was observed that some participants found it a little hard to release the hook due to the tension from the elastic strap. This could be the reason for the scores not being higher. This could be adjusted by adjusting the length of the straps using the attached buckle according to the user's choice. This will be investigated in the next evaluation phase. Overall, these results confirm the first hypothesis (H_1) of this study.

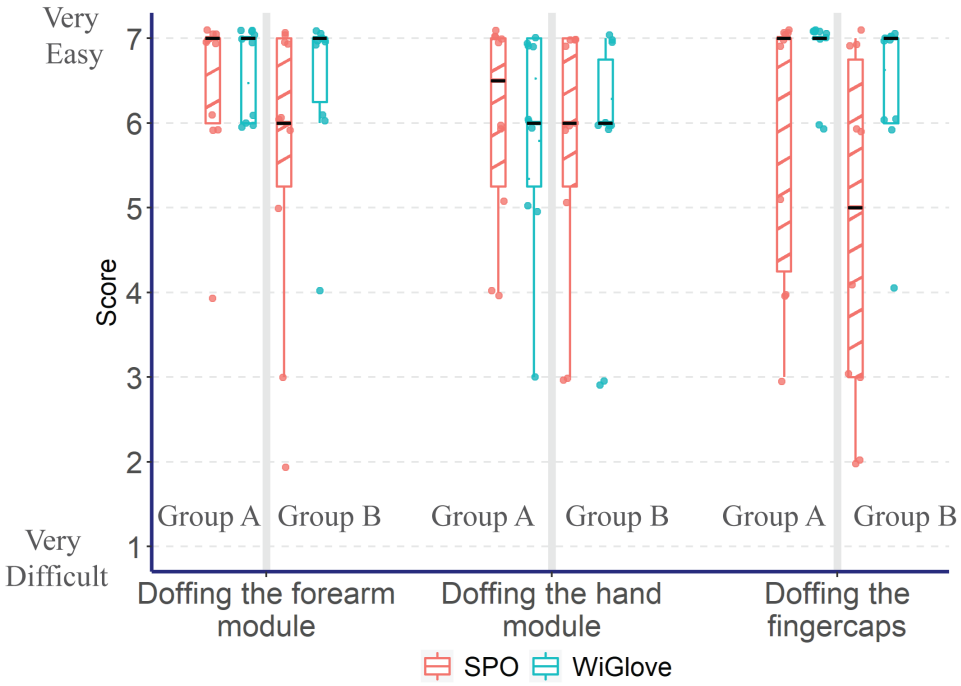


Figure 4.14: Boxplot of the participants' scores for the ease of doffing different parts of the two gloves categorised according to the counterbalanced groups

4.3.4.3 Freedom of natural degrees of motion - H_2

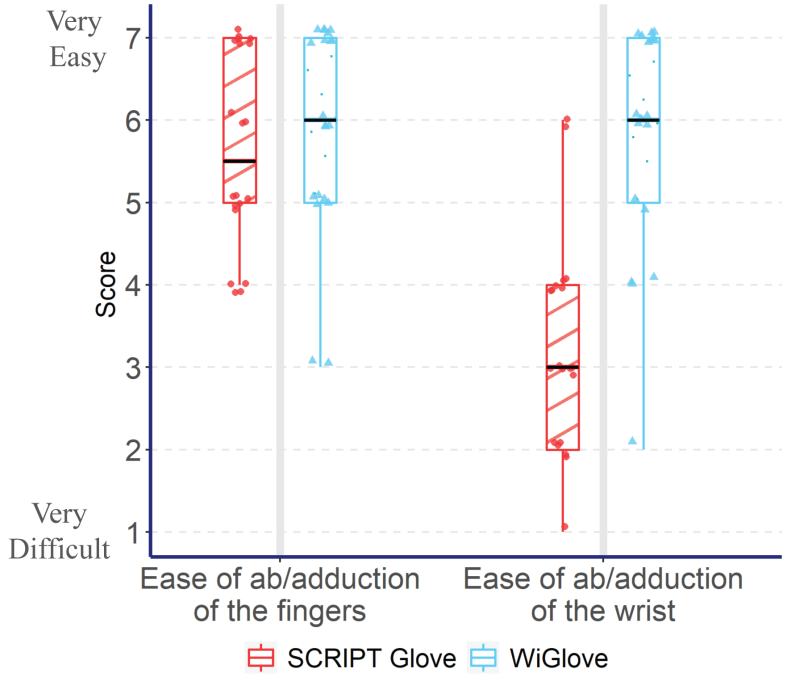


Figure 4.15: Boxplot showing the participants' scores for the ease of performing abduction/adduction while wearing the two gloves

One of the requirements was that the WiGlove should not hinder any of the natural degrees of freedom of the hand (refer to a previous chapter). The boxplot in figure 4.15 shows that with a median score of 6, the participants found it slightly easier to perform ab/adduction of the fingers while wearing the WiGlove compared to SPO. However, the difference of only 0.5 in the median score shows that the participants predominantly found it similarly easy with both gloves. This could be explained due to the fact that both gloves use flexible strings attached to the finger caps that allow the fingers to move freely in directions other than the assisted direction (flexion/extension) (Figures 4.12a and 4.12b).

On the contrary, this is not the case with the wrist. The participants found it significantly easier to perform abduction/adduction of the wrist while wearing the WiGlove compared to SPO($Z = -3.543$, $p =< 0.001$, $r = 0.792$). The WiGlove received a median score of 6 compared to 3 for SPO. The double parallelogram mechanism (Figure 4.12b) in SPO significantly restricts this degree of freedom. The results of this study showed that the flexible interconnection between the forearm and hand modules of the WiGlove facilitates easy wrist ab/adduction. This is further confirmed by the fact that the WiGlove was rated higher by participants from both the counter-balanced groups as can be seen in figure 1 attached in the appendix 7. These results verify this study's second hypothesis (H_2).

4.3.4.4 Ease of tension adjustment - H_3

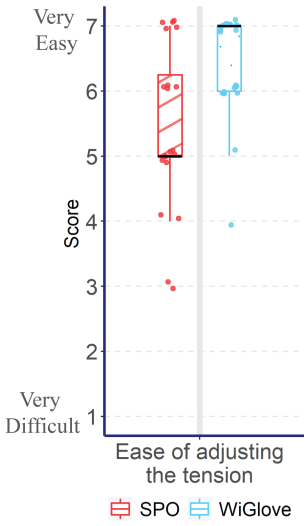


Figure 4.16: Boxplot showing the participant's scores for ease of adjusting the tension on the two gloves

A statistically significant difference with a large effect size ($Z = -2.583$, $p = 0.01$, $r = 0.578$) was observed in the participants' responses for the two gloves. With a median score of 7 (Very Easy), they judged that it was easier to adjust the amount of assistance with the WiGlove's touch screen interface than with SPO's cord stops (Figure 4.16). Although the healthy participants of

this study rated SPO's approach also as relatively easy, we hypothesize that stroke survivors with reduced dexterity would find it difficult to reposition the cord stops. This can be difficult, especially in the hand module where the user needs to identify the right cord from among the other cords and make the adjustment in a cramped space. Analysing the scores based on the order in which the participants tried the two gloves shows that both groups gave the WiGlove a higher rating than SPO with the greatest difference observed in the group that tried the WiGlove after having tried SPO (Fig 5). This shows an improvement in this usability aspect of the WiGlove confirming hypothesis H_3.

4.3.4.5 Suitability for activities of daily life - H_4

Figure 4.17 shows the boxplots of participants' scores for the ease of performing the three grasps discussed earlier (Section 4.3.3). To begin with, it can be seen that overall, there is no difference between the two gloves while performing a spherical grasp. Along with the flexion of fingers, this grasp involves holding the spherical object (ball) against the palm using an opposing thumb and the abduction of the fingers, especially that of the fourth and fifth digits. A median score of 6, shows that performing this grasp is easy with both gloves.

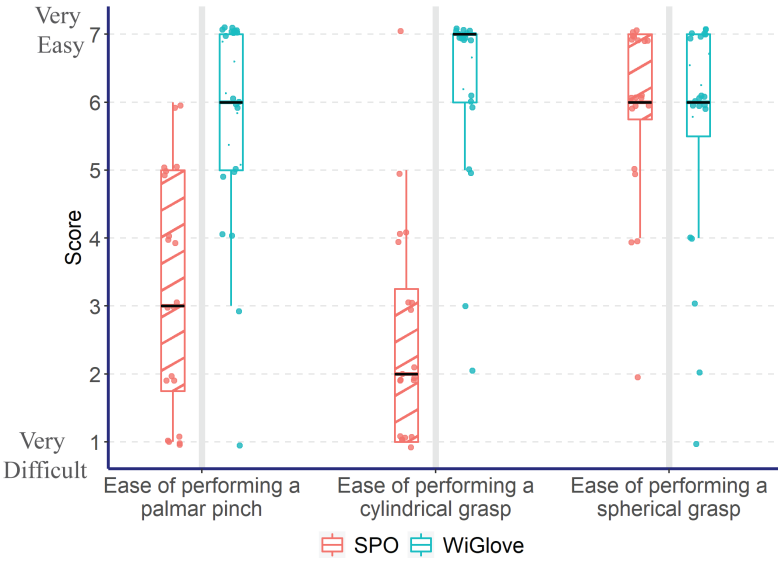


Figure 4.17: Boxplot showing the participants' scores for the ease of performing different grasps with the two gloves

On the contrary, significant differences can be observed in the palmar pinch ($Z = -3.396$, $p =< 0.001$, $r = 0.759$) and cylindrical grasp ($Z = -3.698$, $p =< 0.001$, $r = 0.827$) categories. The boxplots show that the participants found it easier to perform both grasps with the WiGlove than with the SPO. Performing a pinch grasp requires the abduction of the thumb and the flexion of the index finger (in some cases also the middle finger). Given that the degrees of freedom

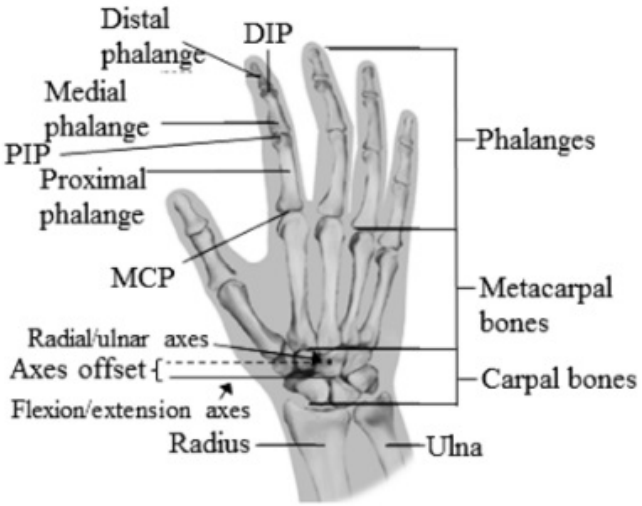


Figure 4.18: Anatomy of Hand

offered to the fingers by both gloves are the same, this improvement in the WiGlove's scores can be attributed to the increased tactile sensation offered by the silicone finger caps of the WiGlove, than the plastic ones of SPO.

Similarly, significant improvement can be observed in performing the cylindrical grasp with the WiGlove. The median score of 7 for the WiGlove shows that overall, the participants found it very easy to perform this grasp with the WiGlove. This improvement over SPO (Median score - 2) could be due to two factors.

1. While grasping the bottle, the high coefficient of friction of the WiGlove's silicone finger caps prevents slipping. This along with the increased tactile feedback offered by the finger caps made it easier to grasp the bottle compared to the rigid plastic finger caps of SPO.

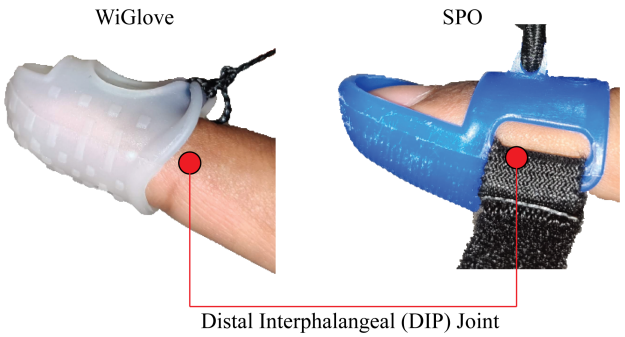


Figure 4.19: Image showing the DIP joints unblocked and blocked in the WiGlove and SPO respectively

2. As discussed earlier, a bottle of this size requires the flexion of all three phalanges of the fingers. Finger caps of SPO prevent the flexion of the DIP (distal interphalangeal) joints

(Figure 4.18) since it extends until the centre of the medial phalange. On the other hand, the finger caps of the WiGlove do not block this joint which allows the fingertips to exert maximum gripping force (Figure 4.19).

Boxplot of the scores grouped based on the groups are attached in the appendix (Figure 2). It can be seen from that boxplot that the participants who rated the WiGlove after having tried SPO, almost unanimously found it easier to perform the palmar pinch and cylindrical grasp with the WiGlove (Median score - 7) than with SPO with a statistically significant difference. This supports the inferences from the combined scores discussed previously.

The additional weight of the exoskeleton could have physiological and bio-mechanical effects that could lead to physical fatigue. The WiGlove weighed 570 g compared to SPO which weighed 600 g without the cables. The three actuators on the WiGlove used to adjust the tension of the extension springs weigh 120 g. The location of the two actuators on the forearm leads to an asymmetric distribution of the weight. It was suspected that this asymmetry might give it a heavier perception despite it being lighter than SPO by 30 g.

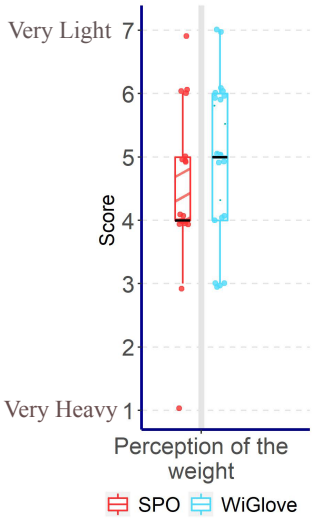


Figure 4.20: Boxplot showing the participants' perception of the weight of the two gloves

However, figures 4.20 and 3 (Appendix 7), shows that this was not the case and that the participants still perceived the WiGlove to be the lighter of the two. Notwithstanding this, the median score of 5 shows the scope for further improvement in this aspect of the WiGlove's design. This weight reduction could enhance the suitability of the glove for activities of daily life.

Finally, the participants were asked about their overall opinion on the two gloves being suitable to wear while performing activities of daily life such as having a hot drink and preparing food. They recorded their responses on a scale of 1 to 7 where 7 stands for **Strongly Agree**, and

1 stands for **Strongly disagree**. A statistically significant difference with a high effect size was observed in the participants' scores for the two gloves ($Z = -3.504$, $p =< 0.001$, $r = 0.784$).

The WiGlove received a median score of 6 compared to 3 for SPO (Figure 4.21). It can be seen in figure 4 in the appendix, that the participants from both groups scored the WiGlove higher. This could be due to multiple factors including the improvements in finger cap design discussed above, open palm design, lack of tethering cables and relatively lighter weight. The participants predominantly judged the WiGlove to be more suitable to perform the activities of daily life, thereby confirming the hypothesis H_4.

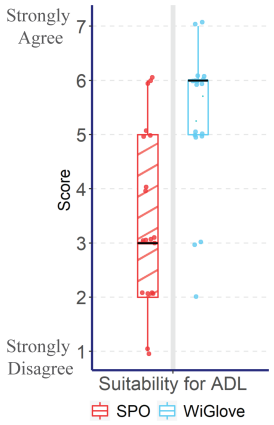


Figure 4.21: Boxplot showing the participants' opinion on the suitability of the two gloves for performing activities of daily life

4.3.4.6 Aesthetics and safety perception - H_5

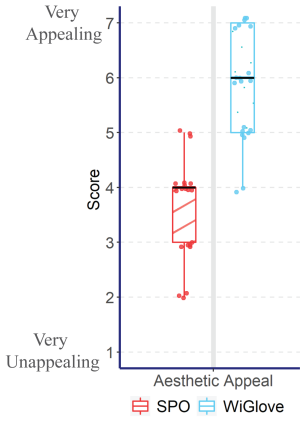


Figure 4.22: Boxplot of the participants' perception of the gloves' aesthetics

It can be seen from figure 4.22, that the participants judged the WiGlove to be more aesthetically pleasing than SPO. The SPO received a neutral median score while the WiGlove received a median score of 6. The Wilcoxon's signed-rank test shows a statistically significant difference in the responses ($Z = -3.79$, $p = 0.001$, $r = 0.847$).

Similarly, a majority of the participants perceived, the WiGlove to be safer for the user ($Z = -2.393$, $p = 0.017$, $r = 0.535$), and other members of the family ($Z = -3.093$, $p = 0.002$, $r = 0.692$). In both cases, a statistically significant difference of high effect size was observed in favour of the WiGlove. Potential risk factors in SPO such as the pinch point in the double parallelogram, and tripping hazard from the wire could harm the user.

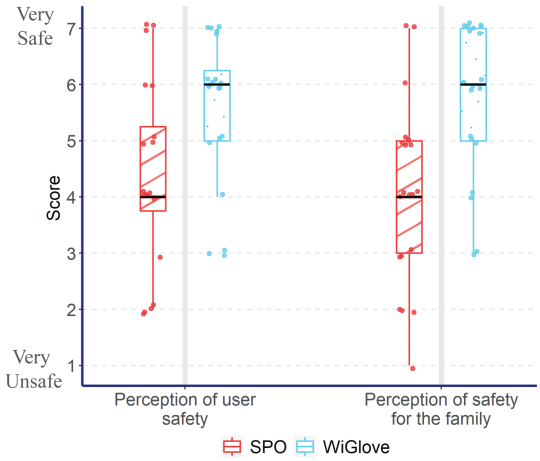


Figure 4.23: Boxplot of the participants' perception of the gloves' safety

Being a home-based device, these factors could also potentially harm other members of the family. These factors were taken into consideration in the WiGlove's design process by eliminating pinch points, wireless operation, absence of sharp edges etc. The results of this study confirm this improvement and thereby hypothesis H_5 of this study.

4.3.5 Limitations

The WiGlove was designed to be used by stroke survivors to train their hands and wrist at home. These results serve as a preliminary validation of the glove's wearability and usability. However, since the participants of this study were healthy individuals, these results might not translate to stroke survivors. Since the participants were not end users, standardised measurements of usability such as the System Usability Scale and User Experience Questionnaire could not be used. This precludes benchmarking this glove at this stage of development. Furthermore, the ease of donning and doffing was evaluated in this study only based on subjective feedback from the participants. Objective measures such as the time taken to don/doff were not measured in this study for the following two reasons. Firstly, since the end users are stroke survivors, the time taken by healthy participants to don/doff the whole device will not accurately reflect the experience of the former. Secondly, given that it is intended to be used as per convenience at the user's home, we hypothesise that the effort required to don/doff would be more significant than the time taken to do so and therefore recorded their subjective data. Additionally, since only one WiGlove of a given size was used in this study, the participants were only recruited if their

hand's dimensions fit the WiGlove. Therefore, this rendered it difficult to conduct gender-balanced recruitment in this study.

4.3.6 Conclusion

In this comparative formative evaluation, healthy individuals interacted with SPO and the WiGlove to evaluate certain aspects of their usability and wearability. The WiGlove's design to address these aspects was formulated into five hypotheses that were tested in this counterbalanced within-subject study. The results confirm all the hypotheses, that overall, the WiGlove performed better than SPO in the categories such as donning/doffing, suitability for activities of daily life, freedom of abduction/adduction, ease of adjusting the assistance and perception of aesthetics and safety. A significant learning from this study was the importance of adjusting the tension of elastic straps. It was observed that two individuals with identical hand dimensions preferred different amounts of tension in the strap to easily don and doff them. This will be considered while customising the device during the evaluation with stroke survivors.

4.4 Formative evaluation involving stroke therapists

Having verified by healthy individuals that the WiGlove's design choices resulted in higher levels its usability compared to SPO, the next phase of the formative evaluation involved conducting an assessment by stroke therapists. The objective of this experiment is to leverage the therapists' experience in stroke rehabilitation to ensure that the WiGlove is ready to be used by stroke survivors independently at home by verifying the following hypotheses.

H_A The WiGlove would be judged by stroke therapists to be easy to independently use by stroke survivors.

H_B The WiGlove would be judged by stroke therapists to be safe to wear while performing ADL.

H_C The WiGlove would be judged by stroke therapists to be safe to use at stroke survivor's home without supervision

This study aims to incorporate their knowledge to identify and improve potential areas of concern in the WiGlove's design enhancing its safety and usability.

4.4.1 Participants and ethical consideration

The study involved six participants over the age of eighteen. All the participants were clinicians working at the Luton and Dunstable Hospital, UK, with experience in post-stroke rehabilitation. Prior to their participation, all the participants were sent a participant information sheet that

briefly explained the procedure and tasks involved along with the steps taken for data protection and storage. It was ensured that they were not suffering from any injury to their fingers, hands and wrist at the time of their participation.

This study was approved by the University of Hertfordshire Ethics Committee before participants were recruited (Ethics protocol number: aSPECS/ PGR/ UH/ 04896(1)). Participants'consent was obtained using the consent forms before their participation. No personal information other than their name (Consent form) was obtained from the participants. The same procedures that were followed in the previous study were followed here to ensure data protection.

4.4.2 Data acquisition

Akin to the previous study, traditional usability questionnaires were rendered unsuitable since the participants of this study were not the primary users of the WiGlove. Hence the custom Likert scale questionnaire used in the previous study for the WiGlove was used in this study to evaluate the same aspects (Appendix 7, Questions 1 - 14). Additionally, open-ended questions (Appendix 7, Questions 15 - 18) were also used to record their thoughts in a more detailed and descriptive manner on the WiGlove's suitability of ADL, don/doffing and safety. For example, the following question prompts the user to comment on the safety of the glove.

Please add any additional comments regarding the perceived safety of training with the device.

The complete questionnaire is included in appendix 7. Each participant took approximately 15 minutes to answer the questionnaire. This approach provided invaluable context to their Likert scale scores and helped to better address their concerns in improving the WiGlove's design.

4.4.3 Experimental setup and procedure

This study was conducted at the Stroke Unit of Luton and Dunstable Hospital, UK. The setup primarily involved the right-hand version of the WiGlove and the accompanying tablet. Additionally, the three items used to study the ease of grasping in the previous study were also present on the table for the participants to interact. Apart from these, hand sanitisers were present since all the participants interacted with the same glove and tablet. All the items involved were sanitised with wipes after each use.

Given the objective of this study and having already compared the WiGlove and SPO with healthy individuals, the participants of this study only interacted with the WiGlove. This approach consumed less time than the previous study thereby having minimal impact on the busy and overwhelmed schedule of the therapists. The study (Figure 4.24) began with the principal investigator demonstrating donning, doffing and using the glove to perform the same tasks

discussed in the previous study for all six therapists at the same time. Following this, each therapist used the WiGlove to perform the same tasks described in the previous study and also to play the game on the tablet. After the completion of all the tasks, they answered the questions on the questionnaire.

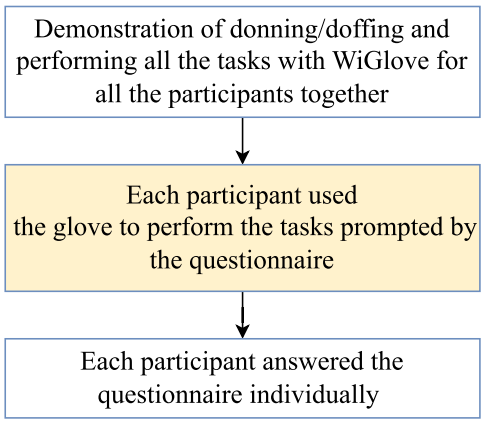


Figure 4.24: Experimental flow - usability evaluation by stroke therapists

4.4.4 Results and discussion

The statistical results obtained from the participants' scores in the questionnaire are presented in Table 4.2.

Table 4.2: Results of therapists' feedback (1 - Very Difficult, 7 - Very Easy)

	Median	**Inter Quartile Range**
Ease of donning the forearm module	4.5	1
Ease of donning the hand module	5	0.75
Ease of donning the fingercaps	5	1.5
Ease of doffing the forearm module	5	1.5
Ease of doffing the hand module	5	0.75
Ease of doffing the fingercaps	5	0.75
Ease of performing the ab/adduction of the wrist	4.5	2.5
Ease of performing the ab/adduction of the fingers	3.5	1
Perception of the weight	4.5	2
Ease of performing a palmar pinch (key grasp)	4	1.5
Ease of performing a cylindrical grasp(bottle)	6.5	1.75
Ease of performing a spherical grasp(ball)	5.5	1.75
Suitability for ADL	4	2
Aesthetic appeal	5	0.75
Perception of user safety	5	0.75
Perception of safety for the family	5	0

4.4.4.1 Ease of Donning and Doffing - (H_A)

The WiGlove received a positive response regarding the ease of donning/doffing all its modules indicated by median scores of 4 and above. The scatter plot overlayed on the boxplot (Figure 4.25) shows that all the therapists except one gave a score of 4 and above for all the categories. Their responses to the open-ended question on the donning/doffing mechanism were positive with a few stressing that it would be easy and only limited by the cognitive ability of the stroke survivors. The comments shown below stressed the significance of cognitive ability in the stroke survivor's ability to don/doff the WiGlove easily without assistance. They also point out the need for clear written instructions to help the user during the first few sessions until they get familiar with the glove.

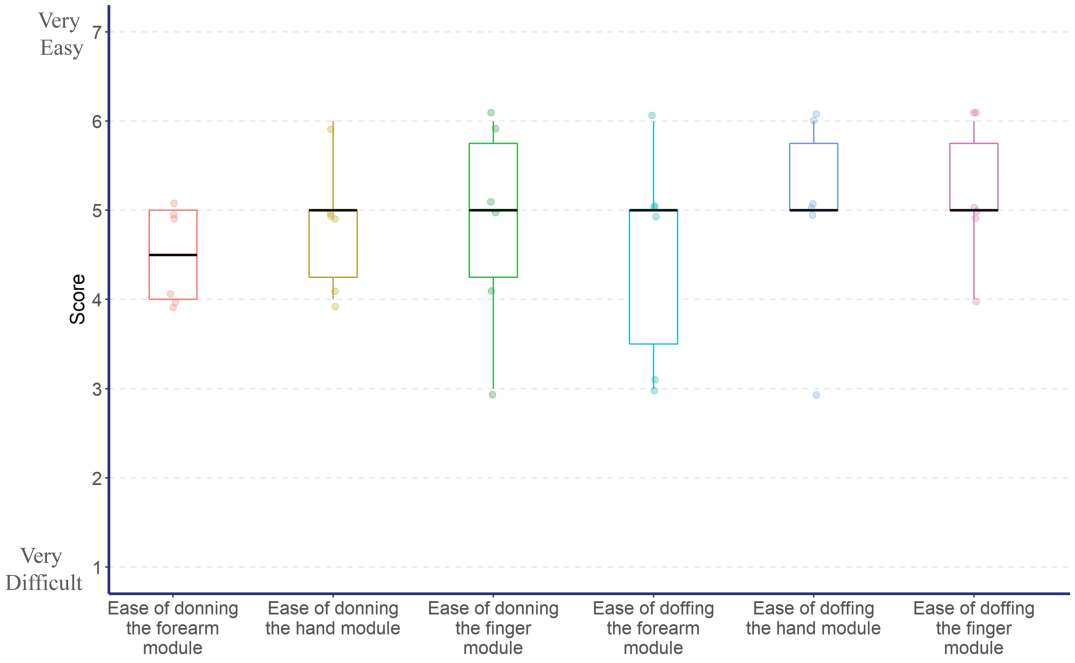


Figure 4.25: Boxplot of the therapists' scores for the ease of donning and doffing different parts of the WiGlove

Therapist 1 - "*Appears suitable for patients to do. However, would be limited to those cognitively able to do so*"

Therapist 3 - "*Would need a good level of cognitive ability. Can be a bit fiddly the first few times*"

Therapist 4 - "*Written instructions required to show participants how to use table and support for putting device.*"

These results show that the therapists judged that the stroke survivors experiencing reduced dexterity will be able to don/doff the WiGlove verifying H_A. This reaffirms the improvement of the WiGlove's donning/doffing mechanism.

4.4.4.2 Suitability for activities of daily life - (H_B)

The participants' score indicates a neutral opinion on the weight of the WiGlove. The median score of 4.5 is similar to the median score given by healthy participants who tried the WiGlove first in the previous study. On the contrary, the participants of the previous study who tried the WiGlove after having tried SPO overwhelmingly rated the WiGlove to be light with a median score of 6. Hence, this could indicate that the low scores by the therapists were due to a lack of reference since they only tried the WiGlove. Overall, the scores show that the therapists found it easy to perform the three grasps discussed earlier (Table 4.2). Of the three grasps, it can be seen that ease of performing palmar pinch received only a neutral score which is the lowest of the three. This could be explained by some of the therapists' answers to the open-ended questions on the WiGlove's suitability for ADL shown below.

Therapist 2 - "*I found that the nuts of the glove was resisting my normal movement.*"

Therapist 3 - "*Difficult to get natural movements - it limits MCP joints.*"

Given that performing the palmar pinch requires the flexion of the index finger and the thumb, the position of the nuts above the MCP joints of each finger could have restricted their flexion. This could explain the low scores for the ease of performing this precision grasp. This could also explain the below-neutral median score (4.5) for the ease of performing ab/adduction of the fingers. Furthermore, the thumb's mechanism extended beyond the level of the wrist which had the potential to limit the abduction of wrists of larger size. These are areas of concern to be addressed in the following design revision stage. This and the ease of performing a palmar pinch could explain the neutral score for the WiGlove's suitability for performing ADL rendering it unable to verify H_B. We anticipate that the design changes discussed in section 4.5 will ensure that stroke survivors will not face the above issue faced by therapists and find it easy to perform activities of daily life while wearing the WiGlove.

Notwithstanding this, the median scores for ease of performing grasps, in general, follow a similar trend to those given by healthy participants of the previous study who rated the WiGlove without SPO as a reference. Healthy participants who tried WiGlove first tended to rate it slightly lower compared to those who tried the WiGlove after using SPO. The median scores for the ease of performing the cylindrical and spherical grasps were the same as the corresponding ones from

group B in the previous study confirming the improvement in this aspect of the WiGlove's design.

4.4.4.3 Perception of aesthetics and safety - (H_C)

The median score of 5 shows that the therapists judged the WiGlove to be safe for both the user and the other members of the household. The only point of concern raised by one of the therapists in the open-ended questions was a potential point of pressure through the following statement.

Therapist 3 - "*Potential for pressure area around the wrist joint*"

Given that this was not a concern raised by the other therapists, this could be due to a mismatch with the glove's size where the person's wrists were bigger than the glove's. Unlike this study, where a glove of standard medium size was used, the succeeding formative evaluation with stroke survivors will use custom-sized gloves to account for this. Table 4.2 shows that the WiGlove was predominantly judged to be aesthetically pleasing in line with the corresponding results from the previous study. These scores and comments from the stroke therapists helped to verify H_C.

4.4.5 Limitations

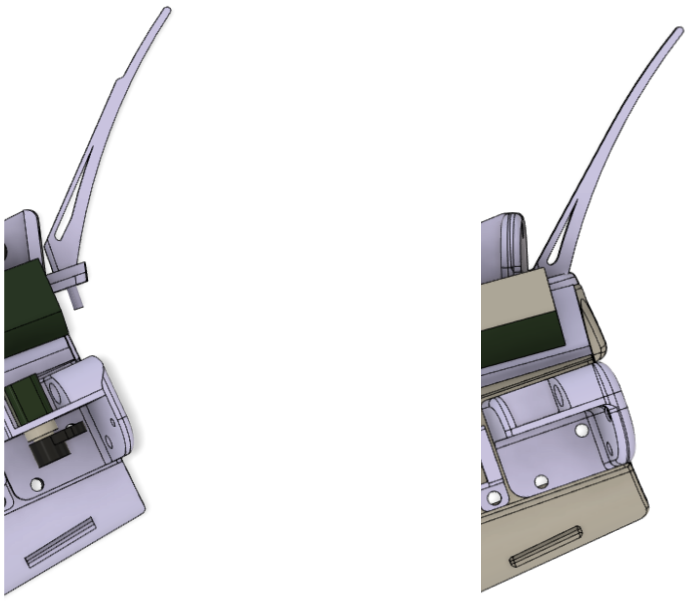
Although the results of this study were positive, the participants were still healthy individuals and their experience might not translate to stroke survivors with reduced hand functions in one hand and one healthy hand. Therefore, these findings were interpreted with care as formative results and used to further improve the WiGlove's usability.

4.4.6 Conclusion

The therapists overall positively rated the WiGlove's usability and their feedback helped to identify areas to improve the WiGlove's usability. The following section details the changes to the WiGlove's design to address the above-mentioned areas of improvement.

4.5 Review of the design

A noteworthy outcome of the evaluation by the therapists was that some participants reported difficulties in achieving the entire range of motion of the joints. Given that the WiGlove was designed to allow training over the range of motion required for performing activities of daily life which is a subset of each joint's complete natural range of motion, this feedback was expected and is in line with the design requirements. While this applies to the assisted degrees of freedom, it is essential to ensure that all the unassisted degrees of freedom remain unrestricted. However, during the study, it was observed that the glove partially restricted the abduction of the wrist for some participants. The structure of the passive joint that allows wrist ab/adduction, extended beyond the line of the wrist and impinged on the thumb of some participants while performing



(a) Before revision (b) After revision

Figure 4.26: Evolution of the thumb's mechanism based on the feedback from formative evaluation

abduction thereby restricting it. The thumb mechanism was therefore redesigned by moving the passive joint proximal to the line of the wrist to avoid interference with the thumb.

Furthermore, the therapist's scores for performing a palmar pinch with the key indicate that they judged that stroke survivors would find it difficult to achieve the necessary range of motion with the WiGlove. This could be attributed to the following factor.
Plastazote LD60, which is a thermoplastic foam was used to provide padding on surfaces where the arm comes in contact with the rigid parts of the glove. However, based on the therapist's feedback, it was evident that this did not provide adequate isolation from the nuts present in the hand module directly above the MCP joints. During flexion, the knuckles came into contact with the protrusions from the nuts and this caused resistance and physical discomfort. This could contribute to the difficulties reported during flexion. Hence in the revised design, a custom-made foam found in SaeboFlex was used in the WiGlove to provide isolation and ensure comfortable interaction. This foam was used in SPO where no such issues were reported in user trials. This revision was implemented in the WiGlove before the next phase of evaluations. Furthermore, this design change also addresses the following concern about cleanliness that was raised by one of the therapists.

Therapist 5 - "*It actually needed cleaning after each trial.*"

When used for long durations, the foam is covered with perspiration from the skin in contact with it. These foams can be easily cleaned with wet wipes and are attached to the glove in such a way that they can also be swapped easily without the requirement of professional assistance.

Given the changes implemented, we anticipate that stroke survivors will not face the above issue faced by therapists and find it easy to perform activities of daily life while wearing the WiGlove.

4.6 Summary

This chapter discussed the methodology and findings of the two formative usability evaluations of the WiGlove. The first evaluation involved healthy participants who tried both gloves and rated different aspects of their usability in a counterbalanced within-subject experiment. Having answered the functionality aspect of **RQ 2** in the previous chapter, this experiment aims to answer the second part of this research question corresponding to the WiGlove's usability.

RQ 2: Can the WiGlove, which was designed using a user-centred approach to meet specific requirements, result in better functionality and usability compared to the current state-of-the-art?

The results of this comparative evaluation indicate that overall, the WiGlove performed better than Script Passive Orthosis (SPO), in aspects such as donning/doffing, suitability for activities of daily life, freedom of abduction/adduction, ease of adjusting the assistance and perception of aesthetics and safety. These findings along with the functional aspects validated in the previous chapter confirm the WiGlove's enhanced functionality and usability compared to SPO (state-of-the-art) and thereby answering **RQ 2** affirmatively. Building on this preliminary validation, in the subsequent evaluation, stroke therapists positively rated the WiGlove's usability.

The therapists concluded that stroke survivors with sufficient residual motor function in their hands would find it easy to independently don and doff the WiGlove. They advised providing detailed instruction manuals to aid users in the initial stages of becoming familiar with the device. Additionally, the therapists helped to identify areas of concern that could limit certain ranges of motion in stroke survivors. Consequently, changes were made to specific features of the WiGlove, including the positioning of the thumb mechanism and the choice of foam material, to address these issues.

Significantly, the therapists did not observe any risk factors in training with the WiGlove and reaffirming the WiGlove's readiness and suitability for unsupervised use at a stroke survivor's home thereby allowing it to proceed to the next evaluation phase. The findings of the two studies serve as a preliminary validation of the glove's wearability and usability. However, to assess whether these findings extend to the intended end-users of the WiGlove, the next phase of the evaluation will focus on further testing with hemiparetic stroke survivors.

CHAPTER 5

SUMMATIVE FEASIBILITY EVALUATION

The next stage of the WiGlove's development is to evaluate the feasibility of the WiGlove to act as a viable home-based rehabilitation at stroke survivors' homes. In the preceding stage, physiotherapists specialising in stroke rehabilitation verified the safety of the WiGlove for stroke survivors to use at their homes and provided feedback to enhance its usability. This chapter presents a comprehensive account of the methodology and results obtained from a long-term feasibility evaluation conducted in the homes of two-stroke survivors.

5.1 Background

Various quantitative (questionnaires) and qualitative (semi-structured interviews) approaches have been identified by [218] for evaluation in a user-centred design of exoskeletal devices. A systematic review of existing measures to evaluate rehabilitation and assistive devices highlights a lack of standardised usability evaluation methods [206]. This makes it difficult to benchmark similar devices against each other. The most commonly used standardised outcome measure for usability was the System Usability Scale (SUS)[219] and QUEST 2.0 [220] scale coming in at second place. SUS is a standardised questionnaire that uses 10 five-point Likert scale items to gauge the perceived usability of a system [184, 221]. With alternating positive and negative tone questions, it provides a final score ranging between 0 (Very poor perceived of usability) and 100 (excellent perceived usability). QUEST 2.0 questionnaire is used to record satisfaction with assistive technology on a 5-point Likert scale [184, 221]. Therefore a combination of QUEST 2.0, System Usability Scale and semi-structured interviews were used in this study to evaluate the usability of the WiGlove.

Furthermore, very few works propose a methodology for systematically evaluating the feasibility of rehabilitation orthosis designed to operate in a home environment without supervision. A user study of a lower limb exoskeleton demonstrated employing a combination of qualitative and quantitative methods to evaluate its usability as a part of its user-centred development [184]. However, this was a short-term study conducted in a supervised laboratory environment and therefore does not provide sufficient time for the user to become familiarised with the device. This limitation is addressed in a recent study [221] that analysed the feasibility of hand exoskeleton for patients with spinal cord injury, by including five one-hour sessions in the presence of a therapist for familiarisation. Following this, the participants used the device at home to perform a set of predefined exercises prescribed to them for one day. Very few studies in the literature were found to explore the feasibility and engagement of assistive devices at home without a prescribed training program. Such predefined protocols limit the flexibility and autonomy that home-based rehabilitation could provide to stroke survivors. This was demonstrated in the feasibility analysis of SPO, which showed that despite the lack of such a defined training program, participants regularly used the device to train [32]. We hypothesise that this autonomy would enhance their engagement towards training and therefore did not prescribe any pre-defined protocol for training with the WiGlove in this study. Moreover, contrary to most feasibility studies of assistive devices in the literature that were conducted for short periods (< 1 week), the WiGlove was subjected to a 6-week evaluation at stroke survivors' homes that allowed analysis of the usage patterns and engagement over longer durations.

Finally to measure the participants' motor impairment in the upper limb and to monitor the effects of using the assistive device, the most commonly used standardised scale is the upper limb portion of the Fugl-Meyer scale (FM) [99, 112, 113, 131]. However, improvements in motor assessment scales such as FM have been observed to not translate to functional recovery, due to a lack of skill transfer [60]. Therefore to evaluate the participants' functional ability, several studies [99, 221, 222] used measures such as Box and Block test (BBT) and Nine Hole Peg Test (NHPT) along with FM. As measures of fine and gross manual dexterity, BBT and NHPT respectively allow monitoring of the functional ability of the participants to perform and complete tasks. NHPT requires the participant to pick nine cylindrical pegs (ϕ 9mm, 32 mm length) one by one and place them into a 9-hole grid and the time taken to complete the test, or the number of pegs placed in a second with a maximum limit of 300 seconds is reported as its outcome [223]. In the BnB test, the participant is required to pick cube-shaped blocks (2.5 cm) one at a time from one side of the test platform to the other by crossing over a partition. The number of blocks carried over the partition in 60 seconds is reported as the outcome measure. Therefore, this study employs only BBT and NHPT to monitor the effect of training with the WiGlove.

5.2 Methodology

The Mark-15 version of the WiGlove is based on an updated design that incorporates the design revisions discussed in the previous chapter. This phase of the user-centred design (UCD) entailed the assessment of this updated WiGlove's design by stroke survivors in its intended use environment, who represent the intended user group, and within the intended use environment, patient's home. This study was conducted at two-stroke survivors' homes for a period of six weeks without any assistance from the therapist. The duration of the study was chosen to align with the feasibility study conducted with SPO, enabling meaningful comparisons with existing and previous state-of-the-art. The objective of this study was to assess the adherence, usability, and effectiveness of the WiGlove, thereby establishing its feasibility as a rehabilitation tool [221]. By examining these crucial aspects, this study aimed to shed light on the potential of the WiGlove in supporting the recovery process of stroke survivors, particularly within the home environment. The study's protocol is illustrated in figure 5.1.

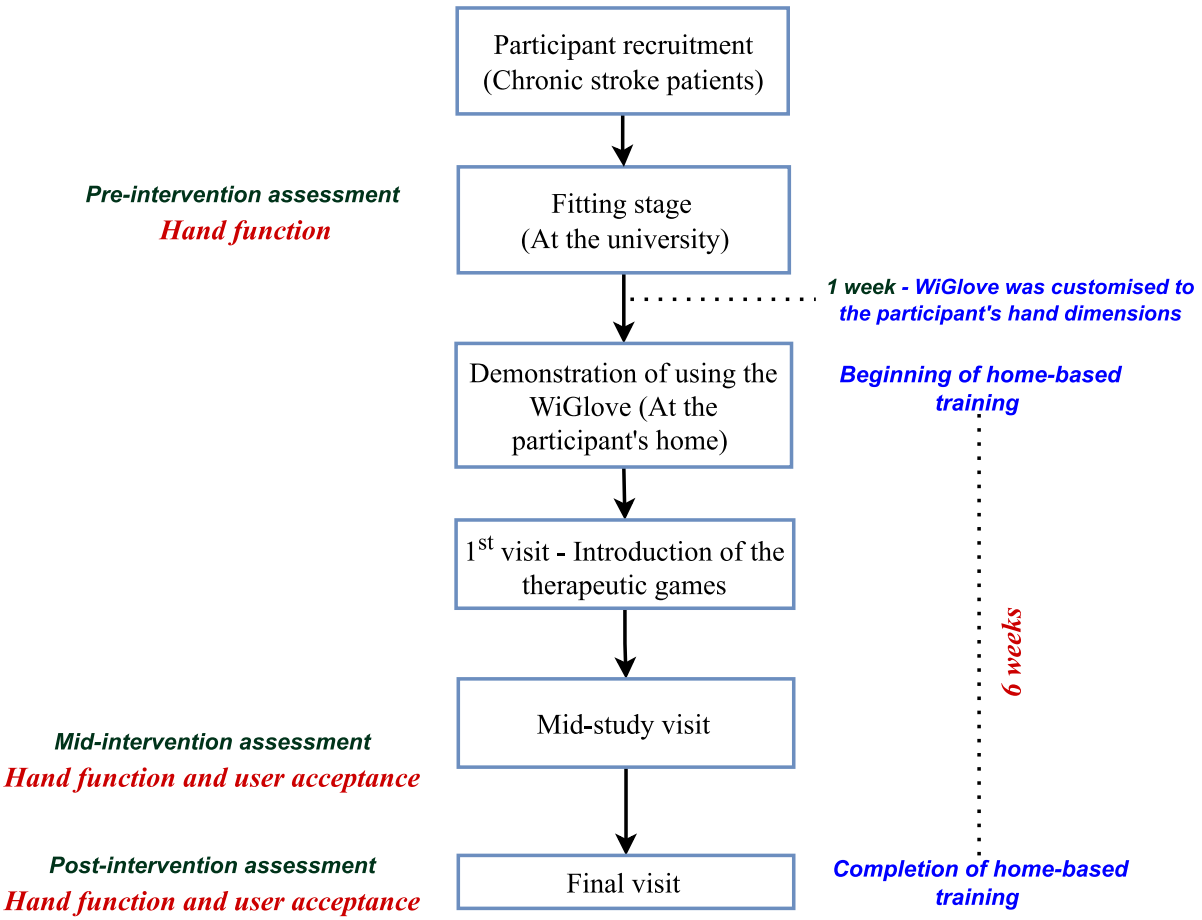


Figure 5.1: Stages of the summative feasibility evaluation

5.2.1 Outcome measures

5.2.1.1 Effectiveness and adherence of the WiGlove

As widely accepted measures, of fine and gross manual dexterity, the Nine Hole Peg Test (NHPT) [223] and Box and Block Test (BBT) were respectively administered at the beginning, midway and at the conclusion to monitor the effects of this intervention [221]. As per [222], the time required to place all 9 pegs in the grid and to return them back into the container, or the number of pegs placed in a second with a maximum limit of 300 seconds is reported as its outcome. Performing these tests with and without the device would permit the evaluation of the orthotic (with assistance) and restorative (without assistance) effects of training with the WiGlove. Moreover, while training with the device, the tablet logged and stored the training data such as joint angles, training duration and game statistics such as scores. The training duration allowed for the assessment of the participant's adherence to training with the WiGlove.

5.2.1.2 Usability of the WiGlove

To evaluate the usability of the WiGlove, this study employed the following quantitative and qualitative measures to obtain both subjective and objective user feedback in the middle of the study's duration (after 3 weeks) and at its conclusion (after 6 weeks).

Quantitative Usability Assessment

Consistent with literature [184, 221], this study utilised the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) questionnaire (Appendix 7) and the System Usability Scale (SUS)(Appendix 7) to record the user's satisfaction and thoughts on WiGlove's usability. Similar to [224], only 8 out of its 12 items of QUEST 2.0 pertaining to the assistive device were used in this study since the remainder evaluated the quality of service. Similarly to adapt SUS for this study, the term "system" in every item was replaced with "WiGlove". [184] demonstrated that this approach did not affect the validity of the scale. This was used only at the end of this study.

Qualitative Usability Assessment

Despite being widely used, the above scales do not consider the user's perceptions about how it fits their environment and its effectiveness. Hence semi-structured interview was also used with open-ended questions on aspects such as how the WiGlove fits their environment, motivation and ergonomics (Appendix 7, Section 7). The interview lasted for 25 minutes during which the participant's responses were recorded and transcribed later using Microsoft Word's built-in transcribe tool. This approach complemented the scores in the aforementioned scales by providing valuable context. The participants were visited at their homes by the investigator a total of three times during the study to collect the training data from the tablet and to conduct

the interviews. The conversations conducted during visits to participants' homes revealed a noteworthy phenomenon: the significant influence exerted by other household members on the participants' performance. Considering the home-based nature of the device under study, this presented a unique opportunity to investigate the impact of this factor on the acceptance of the device. To address this, a semi-structured interview was conducted with the other family members, using a questionnaire included in the appendix. The questions were designed to evaluate their perception of the WiGlove's suitability for the home environment and their role in the participant's training (Appendix 7, Section 7). As with the participant's feedback, the responses were meticulously recorded and transcribed using Microsoft Word's transcribe tool.

5.2.2 Participants and ethical considerations

The participants were recruited for this study using flyers placed at the stroke unit of Luton and Dunstable Hospital. The inclusion criteria for selecting the participants were as follows:

- The participant should be above 18 years of age.
- The participant is experiencing hemiparesis as a result of a stroke. Hemiparesis results in weakness or loss of motor functions in only one side of the body. This criterion was employed since the WiGlove is designed to be worn independently by the user with the help of one unimpaired hand.
- The participant should have some residual voluntary movements in their fingers. This is essential to initiate and perform movements since the WiGlove is a passive device that only partially assists (with extension) during training.
- The participant should have no cognitive or psychological impairments that would prevent them from giving their informed consent to participate in this study and provide feedback based on their experience of using the WiGlove.

Incorporating the design revisions proposed in the previous chapter, two prototypes of the WiGlove (version - Mark 15) were developed and therefore two-stroke survivors were recruited as participants for this study according to the above criteria. The number of participants in this study is in line with a similar study [184] that demonstrated the effectiveness of two participants in the evaluation of an assistive exoskeleton. Upon their interest in participation, they were sent a participant information sheet that detailed all the steps involved in the study, the duration, the type of data that will be collected from them and the steps taken to protect their privacy. A consent form was used prior to the commencement of their participation to obtain their consent to gather all the data discussed earlier including a video of them using the glove and performing the tests. This study was approved by the University's Ethics Committee (Ethics protocol number: aSPECS/ PGR/ UH/ 05084(1)).

The participants differed vastly in terms of their age, social environment and their performance in the baseline assessments. They had noticeably different levels of impairments in their hands, residual voluntary range of motion and mobility. Consequently, in an approach similar to [225] this chapter treats the two participants as two distinct case studies allowing for a thorough analysis of their performance and feedback taking into account their unique circumstances and appropriate context.

Table 5.1: Participant characteristics

Characteristics	Participant A	Participant B
Gender	Male	Male
Age (years)	78	43
Time post-stroke (months)	15	27
Impaired hand	Left (Non-dominant)	Left (Non-dominant)
Baseline BBT (no. of blocks/60 secs)	0*	6
Baseline NHPT	0 pegs in 300 seconds	3 pegs in 300 seconds

* Modified version only counting the number of blocks picked and dropped.

5.2.2.1 Participant A

Henceforth referred to as **participant A** or **pA**, the first participant was a 78-year-old male, who experienced two incidences of stroke 15 months ago, leading to hemiparesis on his left side. As evident from his performance in BBT and NHPT (Table 5.1), his hemiparesis manifested as excessive tone and significant impairments in both the proximal and distal joints of his left arm. He experienced hyperflexion resulting in a fully flexed wrist and closed fist without any voluntary RoM in the extension of both these joints. Using his dominant (unimpaired) hand, was able to move 34 blocks in 60 seconds during the BBT and complete NHPT in 35 seconds. However, the weakness in his left shoulder and elbow (impaired arm) prevented him from executing the reaching movements required to complete BBT, leading to an alternative measure of performance: recording the number of blocks he could pick and drop within a minute, without necessitating their transfer over the partition. **pA** lacked the sufficient voluntary range of motion in his left hand to grasp the box or pegs in both BBT and NHPT. Furthermore, he suffered from severe weakness in his left leg, necessitating the assistance of a caregiver and a wheelchair for mobility. The participant's wife was the only other household member present during the study, which was conducted at their residence. Prior to participation, the participant had been undergoing hand therapy limited to three five-minute sessions per week with a therapist for the past six months. Apart from this conventional one-on-one physiotherapy, he had no prior exposure to robotic rehabilitation therapy, telerehabilitation, or computer games.

5.2.2.2 Participant B

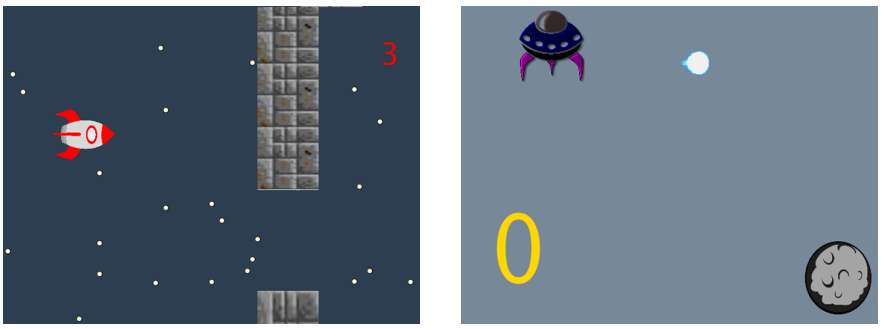
The second participant (**participant B** or **pB**) on the other hand, only experienced moderate impairments in his left arm with no mobility issues. Following his discharge, he underwent long-duration in-patient physiotherapy at a rehabilitation centre in India involving a multitude of training programs such as conventional one-to-one therapy, and functional electrical stimulation (FES). As a result, the tone in his shoulder and elbows had reduced considerably. Similarly, his hand therapy involved FES and occasionally robot-aided therapy using an active pneumatic glove called Syrebo. It is a finger rehabilitation device that is worn like a normal glove which actively guides the fingers through flexion/extension exercises while the user remains passive [226]. Although this had helped in some reduction of the tone, he still was not able to voluntarily extend his fingers and wrist to a neutral posture at the beginning of this study. The reduced tone in the proximal and distal joints is evident in his performance in the BBT and NHPT where, unlike the first participant, he was able to grasp and transfer 6 blocks in BBT and 3 pegs in NHPT (Figure 5.2). Notably, two weeks before the commencement of this study, **participant B** rejoined his full-time employment. His wife who is also employed is the only other member of this participant's household.

Figure 5.2: Participant B performing BBT during the fitting stage

5.2.3 Experimental procedure

Firstly, upon recruitment, both participants visited the assistive and rehabilitation robotics laboratory at the University of Hertfordshire for a fitting stage (Figure 5.1). The dimensions of

the participant's hand were measured and the WiGlove was customised accordingly to ensure proper fit by adjusting the length of the interconnection, length of finger extension structure, etc. Since the WiGlove's structures are 3D printed, the participants were given the choice of its colour. Subsequently, a bespoke WiGlove was delivered to the participant's home along with a tablet with which the device communicates. A comprehensive demonstration was provided, covering the various aspects of using the WiGlove such as don/doffing, performing flexion/extension exercises, charging, operating the tablet's graphical interface, and so forth. For the first week, the participant was encouraged to become acquainted with the device by performing flexion/extension exercises with their fingers and wrist while wearing it. Technical support was available on-call during this period. Following the acclimation phase, the participant was introduced to two therapeutic games that were provided to offer additional interaction context (Figure 5.3).



(a) Wrist exercise game (b) Fingers exercise game

Figure 5.3: Therapeutic games for training

The first game entailed the users controlling the position of a virtual spaceship to avoid collision with obstacles by flexion/extension of their wrist with the WiGlove. The second game requires the users to flex all their fingers to fire a virtual bullet and hit a moving target. The bullet is triggered when the user flexes all their fingers to 90% of their respective maximum RoM. Due to the inter-individual variability, at the start, there is a calibration phase that records their maximum available RoM. This ensures that the game is tailored to each participant's capabilities and that they are adequately challenged. It is expected that these games help the user to train their neuromuscular system to plan ahead and coordinate their flexion movements which have been shown to promote neural plasticity and learning [227].

As in [32], no explicit therapy protocol was prescribed, apart from introducing the games and encouragement to try performing ADL while wearing the device. The time and duration of training were left to the participant's choice.

5.3 Results and discussions

5.3.1 Participant A

5.3.1.1 Adherence to training

In contrast to the three five-minute sessions per week dedicated to the rehabilitation of hand that the participant underwent prior to the participation, during the first six weeks of this study, he trained with the device for an average of 48 minutes per day (SD = 41 minutes). Figure 5.4 shows the duration for which the participant trained with the WiGlove each day during the study. The data logged on the tablet indicated that the WiGlove allowed him to split the training into multiple sessions which on one particular day allowed him to train for up to 175 minutes in total by spreading them over 5 sessions. Despite not being prescribed a specific training protocol or being monitored, demonstrates the participants' willingness to train with the WiGlove to perform regular exercises. This observation aligns with SPO's previous studies [32], reinforcing the argument for integrating home-based devices into post-stroke rehabilitation. Compared to the average training duration of 15 minutes per day with the SPO (23 participants), the increased adherence to training with the WiGlove could be due to the improvements in its usability discussed in the previous chapters.

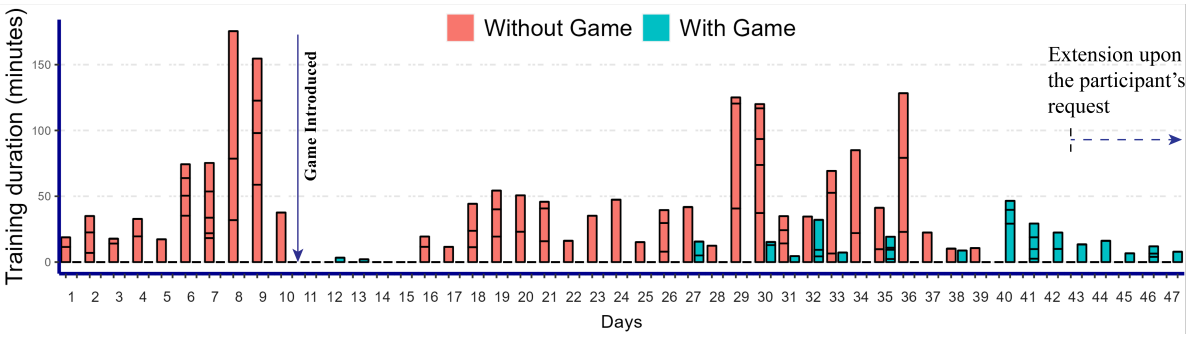


Figure 5.4: Participant A's daily training duration with the WiGlove. Stacked chart shows the number of sessions attempted in a day. The period between day 10 and 16 present the duration of an unrelated secondary illness that hampered physical activity for this participant. At 6-week, he requested to continue using the device for a further 6-weeks due to their perceived benefits of the system to their recovery.

Although the games were introduced after the first 10 days, he did not train with them until Day-27 due to an unrelated secondary health complication resulting in an overall reduction in training. However, after his recovery, the participant familiarised himself with the games and increasingly trained while playing during the remainder of the 6 weeks as shown in figure 5.4. An interesting observation while looking at days where sessions include both with and without game use of the WiGlove was that they performed an average of five times more repetitions during game play (5.7 reps/min) compared to interaction without games (1.04 reps/min) (Fig 5.5). Also as

the participant familiarity with the system increased (day 40 onwards), they exclusively trained with the games.

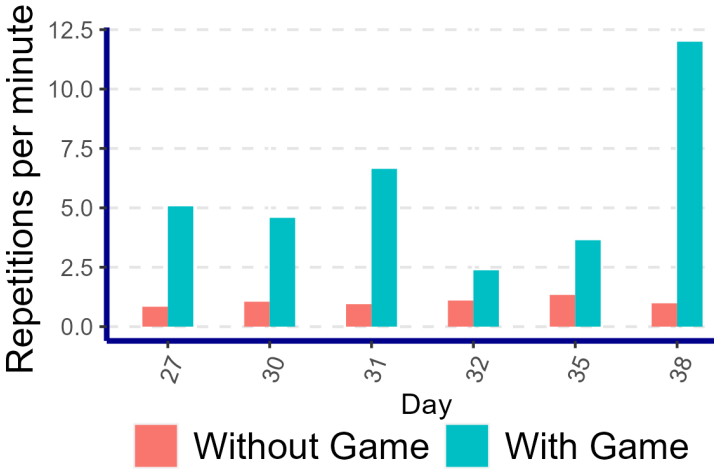


Figure 5.5: The number of repetitions per minute performed by participant A with the WiGlove while playing the game and not playing the game.

Furthermore, we hypothesise that the lower average training duration with the games compared to without them is due to the participant being fatigued earlier from the five times more repetitions performed during the former. These indicate that using a game with robotic orthosis has motivated and stimulated the participant to train at a higher intensity. Such high-intensity training with high repetitions has been shown to improve recovery [185].

Table 5.2: Participant A's average and maximum duration (in minutes) of training per day with and without the game.

	Mean	**SD**	**Maximum**
Without Games	52	42	175
With Games	15	11	46

5.3.1.2 Effect of the intervention

During the baseline assessments at the beginning of the study, the participant was unable to grasp any block (BBT) or pegs (NHPT) with the impaired left hand due to the closed fist from hyperflexion. The results of the BBT with the left hand are summarised in Table 5.3. When

administered after 3 weeks of training with the WiGlove, the participant was able to pick and drop 11 blocks in 60 seconds while wearing the device compared to 2 blocks at the beginning of this study. Performing the same test without wearing the device, he was able to pick and drop 5 blocks in 60 seconds compared to zero blocks at both the beginning and half-time of the study. An improvement in the BBT score while not wearing the device was observed with the increase in training intensity discussed in the previous section. The participant's improved performance both with and without the device , highlights the orthotic and restorative benefits of the device. At the end of 6 weeks, he was able to regain some voluntary RoM for extending his fingers from the flexed position which allowed him to partially open the hand and grasp the blocks (Figure 5.6). On the contrary, the participant had not yet gained adequate finger dexterity to grasp any pegs to perform NHPT thereby underscoring the necessity for more extended and sustained rehabilitation to attain the requisite fine motor control.

Table 5.3: Results of participant A's Box and Block test showing the number of boxes picked and dropped in 60 seconds)

	Baseline	**After 3-weeks**	**After 6-weeks**
With the WiGlove	2	9	11
Without the WiGlove	0	0	5

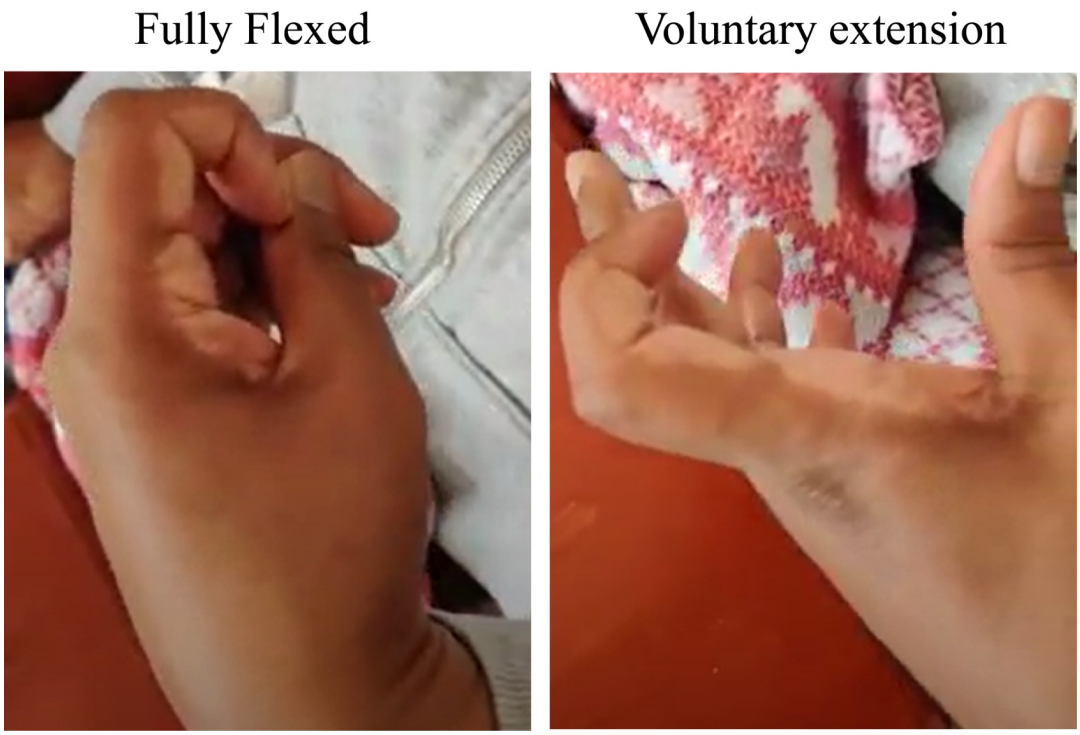


Figure 5.6: Image showing participant A's regained RoM for a voluntary extension at the end of 6 weeks

5.3.1.3 Assessment of Usability

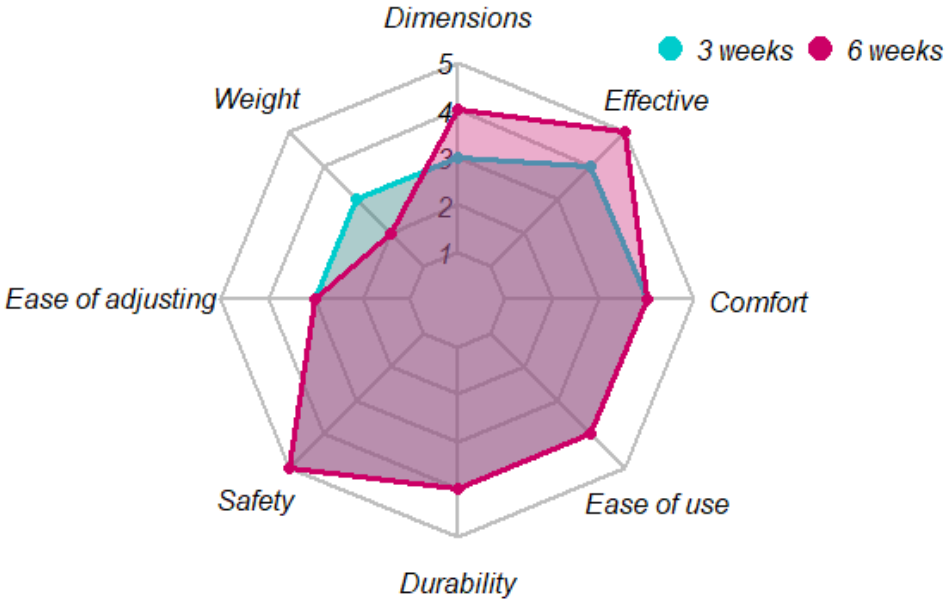


Figure 5.7: Participant A's responses to the QUEST 2.0 questionnaire after 3 weeks and 6 weeks respectively

The participant's scores in the QUEST 2.0 questionnaire are illustrated in figure 5.7. The participant rated the device 3.75/5 and 3.875/5 during the mid-study and post-study assessments, respectively, indicating a range from being mostly satisfied to quite satisfied. Similarly, the WiGlove received an SUS score of 75/100 during the 6-week assessment which is classified as "good to excellent" according to [228].

His qualitative feedback from the semi-structured interview (Table 5.4) reflects an overwhelmingly positive experience of WiGlove's usability and effectiveness. The device was perceived to be easy to use and learn, making it highly suitable for home use. Due to the excessive tone in his shoulder and elbow, a carer's help was required to don/doff the device. We hypothesise that a user with moderate impairments would be able to don/doff independently. A summary of the participant's remarks from the semi-structured interview on the usability and perception of the WiGlove, including a few notable quotes, is presented in Table 5.4. However, one area of concern

Table 5.4: Participant A's user experience feedback (The text in red and blue are the participant's quotes from the interviews conducted after 3 weeks and 6 weeks respectively.)

Usability Aspects	**Comments**
Ease of donning/doffing	Due to substantial tone in the elbow and shoulder, the participant was unable to independently don the device and required the caregiver's help. On the other hand, he was able to doff the finger caps and forearm module without help. **"Ease to remove finger caps and fore arm"**
Safety	The participant did not find or experience any safety concerns.
Suitability for the home environment	Due to its small size the participant found it easy to store away from the reach of children. Being wireless, the WiGlove allowed him to train in different rooms including while lying in the bed. It was deemed very suitable for the home environment.
Learnability	Operating the device was perceived to be straightforward and easy to learn.
Battery	No concerns of battery life were raised. It was charged for 30 minutes every day.
Games	The participant found the games very interesting and was very satisfied with the WiGlove's sensitivity for playing them. **"Felt very happy even when I hit just twice"**. He suggested that games involving musical triggers and multiplayer games where other members of the family like the grand children also can be involved would be even more stimulating. **"The grand kids, yeah, they always want to win, yeah that motivating factor"**
Comfort	It was perceived to be very comfortable
Weight	The participant felt that the device could be lighter. **"It's not heavy, but it could be lighter"**
Feedback on WiGlove's effectiveness	The participant reported observable improvements in his hand with a noticeable reduction in the finger's stiffness. **"It was not supple enough, but over the last two weeks, the mornings, it is very relaxed and soft"**, **"How long will, I need, I don't know, but, Definitely, the glove makes a difference"**."**Good improvement in flexing. think it is positive that I have made this improvement after such a long time. 100% definitely there is positive."**

raised by the participant was that he felt that the device could be lighter to allow for longer use. Excessive weakness in the shoulder and elbow could have impacted the perception of the weight of the device. While we note that SPO's use was assisted by an arm support, (the SaeboMAS), which provided support to counter the weight of the device, this approach was not chosen here due to the intervention aiming at evaluating a wireless and mobile device, with expected use during ADL activities. Nevertheless, this concern will be noted during further evaluations and potential design revisions. Despite this, the overall scores from the QUEST 2.0 and SUS indicated that this patient was highly satisfied with the WiGlove's performance and usability.

5.3.1.4 Feedback from the participant's wife

The participant's wife played a significant role in encouraging the participant to perform regular training with the WiGlove. Although the participant found it easy and comfortable to use, external motivation in the form of reminders and encouragement was needed in the absence of scheduled therapy appointments.

" **He doesn't initiate it himself really. So, we have to guide him and encourage him. Prompt him. But once we start doing it, he is fine.**"

Despite finding the games to be interesting, she stressed the need for custom games according to the participant's interest by saying:

" **I think maybe. Something that he can use with the music because I thought that would be more helpful, some kind of movements which corresponds to the music that is being played.**"

The interview with the participant's wife provided further insights into the WiGlove's feasibility as a home-based rehabilitation. It was perceived to be easy to use and suitable for the home environment. She found it safe to use in the presence of children and highlighted that the only limiting factor was the loss of concentration while training in such circumstances. Similar to the participant, she also felt that a slightly lighter version would further enhance the usability.

5.3.1.5 Overall perception

Overall the feedback indicates the participant's positive experience after using the device for six weeks. He reported feeling safe using the WiGlove and did not perceive any risk for other household members. As evidenced by remarks in Table 5.4, the participant was very pleased with the intervention it delivered as he was able to realise marked improvements in his hand. The participant's wife also agreed on the positive impact of training with the WiGlove, as evident

from her following quotes:

"His dexterity has improved tremendously from how it was to how it is now. Even though we are not there yet."

"There is a great difference in the way he used to clench his fingers, fingers all the time. Now he's much more relaxed automatically."

"Yeah, the first time when we came, you asked him to pick up things he couldn't do it at all. But now he can move it and he can pick it up with a bit of help. His grip has improved greatly."

As a result, this positive experience prompted him to request to retain and continue training with the WiGlove beyond the study's intended duration of six weeks. Consequently, with an amended ethics approval, his participation was extended for an additional six weeks. Figure 5.8 shows the WiGlove's usage by the participant after the six weeks. It shows a largely regular training of the WiGlove with the exception of a temporary break when the participant fell ill with COVID-19, the participant used the glove regularly. It is noteworthy that, the total number of training days and training intensity decreased compared to that of the first six weeks potentially due to illness-induced fatigue according to the participant and due to the complacency arising from the study ending.

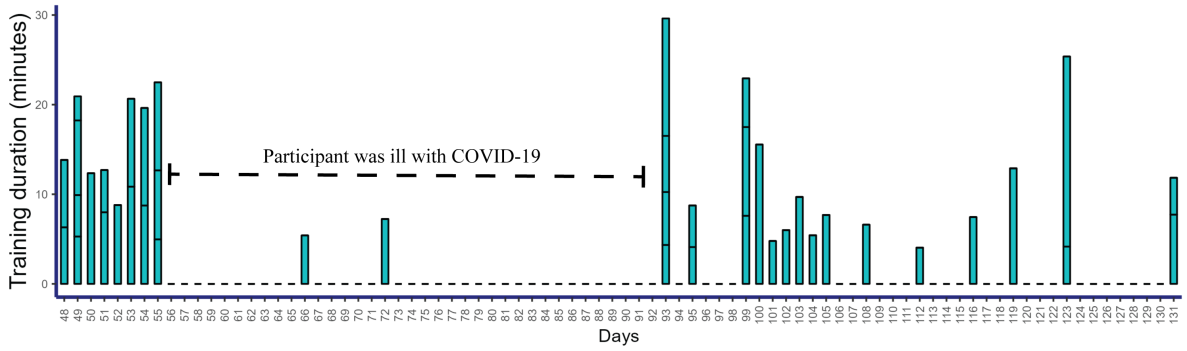


Figure 5.8: Participant A's daily training duration with the WiGlove in the extended period of the study. The stacked chart shows the number of sessions attempted in a day. The period between day 55 and 90 present the duration of an unrelated secondary illness that hampered physical activity for this participant.

In this extended period, the participant trained with the WiGlove for a total of 25 days at an average training duration of 12.9 (SD = 7) minutes compared to 48 minutes in the first 6 weeks. This could be the reason for a lack of improvement in their performance in BBT and NHPT which was the same as that at the end of 6 weeks. While this emphasises the importance

of consistent and intensive training with the WiGlove, the research team decided to conclude their participation after 131 days. This was done to analyse the findings and make improvements to the design of the WiGlove, as discussed in detail later in this chapter.

5.3.2 Participant B

5.3.2.1 Adherence to training

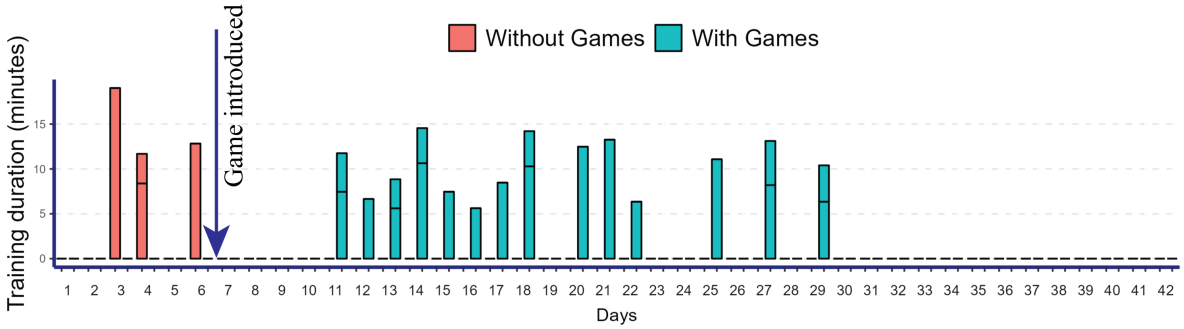


Figure 5.9: Participant B's daily training duration of participant B with the WiGlove. Stacked chart shows the number of sessions attempted in a day.

Mirroring the protocol followed by the first participant, **pB** was provided with the bespoke WiGlove along with a comprehensive demonstration of its usage at his house. Initially, they performed simple flexion/extension exercises before being introduced to the games. The utilisation pattern of the WiGlove by pB, as depicted in Figure 5.9, draws a contrast to that of the first participant. **Participant B** did not train regularly with the device, training only for a total of 16 days at an average of 11.2 minutes per day (SD = 3 minutes) performing 5 repetitions per minute on average. The participant ascribed the infrequent training due to hectic work commitments while mentioning the following.

"Definitely less workload will help me to use it for long term."

Participant B, unlike the first participant who was retired and predominantly home-bound, had increasingly longer work hours throughout the study's duration, thereby impinging upon the availability of time for training with the WiGlove.

5.3.2.2 Effect of the intervention

As previously discussed in Section 5.2.2.2, the participant exhibited a moderate level of impairment in their arm, evident from their comparatively superior baseline performance when compared to Participant A. The post-intervention assessments of Box and Block Test (Table 5.5) and Nine-Hole Peg Test (Table 5.6) conducted after a span of 3 weeks exhibited a discernible yet

marginal enhancement in performance relative to the baseline. However, it is important to note that this improvement cannot be solely attributed to the influence of the WiGlove intervention. Concurrently with this study, the participant also perfomed intermittent Functional Electrical Stimulation (FES) sessions, which renders it challenging to isolate the restorative impact solely attributable to the WiGlove. Furthermore, during the latter half of the study, wherein the participant significantly reduced his training activities (both the WiGlove and FES), no discernible improvements were observed. This decline in performance can potentially be attributed to the sudden decrease in training intensity due to increased work-related commitments, as discussed in the preceding section.

Table 5.5: Results of participant B's Box and Block test showing the number of boxes picked and dropped in 60 seconds)

	Baseline	**After 3-weeks**	**After 6-weeks**
With the WiGlove	10	14	13
Without the WiGlove	6	9	9

Table 5.6: Results of participant B's Nine Hole Peg Test showing the number of pegs placed in 300 seconds)

	Baseline	**After 3-weeks**	**After 6-weeks**
With the WiGlove	5	6	6
Without the WiGlove	3	3	2

5.3.2.3 Usability

A comprehensive summary of the qualitative feedback pertaining to the usability and feasibility of the WiGlove along with some notable quotes are presented in Table 5.7. The text in red and blue are the participant's quotes from the interviews conducted after 3 weeks and 6 weeks respectively.

The participant expressed a high level of satisfaction in terms of safety and suitability for home use. However, this perception did not extend to the work environment. Due to his demanding work commitments, the participant resorted to carrying the WiGlove to his workplace for training purposes. Regrettably, he encountered challenges as the device attracted unwarranted attention from curious colleagues, resulting in distractions and discouraging its usage at work.

"Everyone looking at me. I did try a couple of times. Both times the disappointment was you know people are looking at it as if it's a new toy and they are too curious now about my glove rather than the meeting itself. "

"So I stopped taking it to work and I only do it at home and that was one of the reasons why my usage of the glove is not that great."

Table 5.7: Participant B's user experience feedback (The text in red and blue are the participant's quotes from the interviews conducted after 3 weeks and 6 weeks respectively.)

Usability Aspects	**Comments**
Ease of donning/doffing	Was able to independently don/doff. "**it takes a few sessions for me to wear it, So now like I'm doing it by myself, I don't need anyone's help.**". However, it was suggested that making the joints between the forearm and hand modules stiffer could make the donning much easier. "**I was able to do it, but I expect that to be seamless**"
Safety	Did not perceive any safety issues "**there is no safety issues and it has small battery in the glove which is charged and there are no safety risk.**"
Suitability for the home environment	Very portable. Trained at different parts of home and also took it to the office to train. "**You know storage is easy because that comes in two parts. You can always fold it**"
Learnability	Had some difficulty with donning the hand module in the beginning but otherwise found it easy to use. "**I did learn, but once I learned it, I sustained the learning.**"
Battery	No concerns were reported about the battery life of the WiGlove.
Games	Initially found it difficult to understand the calibration process but was able to understand and found it interesting. Suggested that the option to increase the levels of difficulty would motivate further use. "**maybe moving forward Level 3 could be more objects coming from different places and you have to shoot.**". The participant also felt integrating additional objects into the game would help practice grasping while playing the game. "**If you have to play badminton, you had, you know, racket in hand and you're playing as if you're holding a real racket, I can just be more engaging into that**"
Comfort	The participant felt comfortable wearing it. However, he reported feeling anxious that they might break some parts of the device like the inelastic cords that are open and exposed.
Weight	It was perceived to be slightly heavy.
Feedback on WiGlove's effectiveness	The participant was happy with the performance and effectiveness of the WiGlove's intervention. "**As I said just it's really good. It does what you need especially with extensions it gives you know all the facility.**" However, he was unable to regularly train with it owing to work commitments and also had no noticeable improvements in their recovery.

To mitigate this issue, the participant suggested that a more inconspicuous form factor would be advantageous, as it would attract less attention and potentially foster usage in the workplace. In terms of donning the device, although the participant initially faced difficulties, he was able to independently don it with ease after receiving a further demonstration of the donning technique. Drawing upon his prior experience with the Pneumatic Syrebo glove, which necessitated assistance for donning, the participant appreciated the WiGlove's open design and its user-friendly clips and hooks interface that enabled independent use.

"I definitely liked it. Especially the design and usability. It's not that difficult. As such, I have seen both gloves. With Syrebo Glove the way it is designed, especially when my fingers flex someone need to keep them straight where the glove to onto my fingers. Whereas in your glove it's only the cap."

"In your case, the glove that you designed. I can wear it by myself."

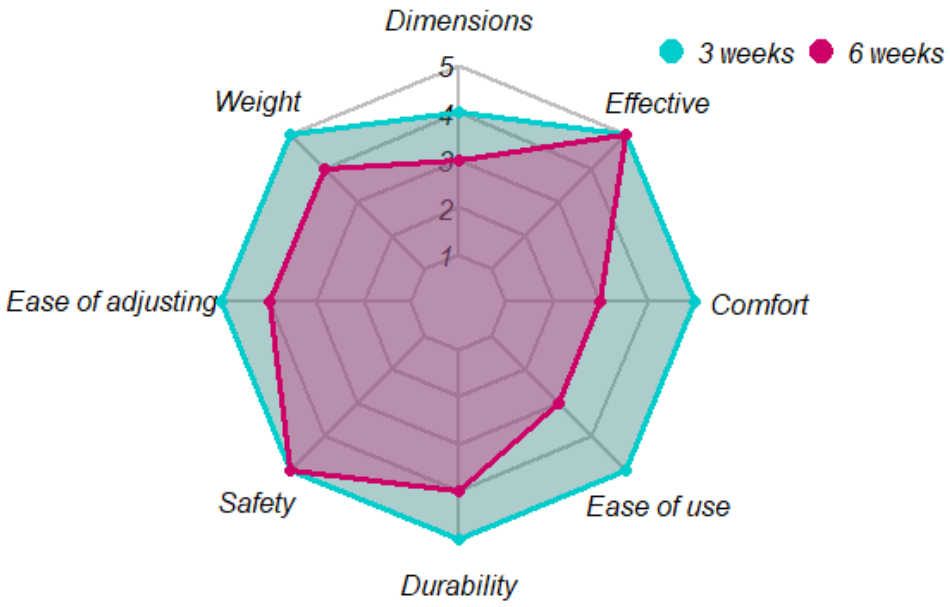


Figure 5.10: Participant B's responses to the QUEST 2.0 questionnaire

However, the participant did encounter occasional challenges in coordinating the two modules during the donning process due to the flexible interconnections. He proposed that incorporating a stiffer connecting element would enhance usability. Nevertheless, given the significance of maintaining wrist ab/adduction freedom, further investigation is necessary to strike an optimal balance. In addition, a noteworthy observation during the visits was that the transparent extension structure sometimes was a hindrance while picking small objects from flat surfaces. This was also reported by the participant as affecting the performance of some daily tasks. It was possible to complete these tasks by performing pronation/supination which avoided the structure's hindrance. However, this was not possible in the participant's case since the spasticity in his wrist prevented him from performing this motion and the WiGlove also does not assist with this motion. Therefore, this design constraint needs to be considered in future design revisions. Notwithstanding this, the participant provided an overall positive assessment of the WiGlove's usability, as evidenced by his scores on the QUEST 2.0 (3.875) (Figure 5.10) and SUS (70) scales. These scores reflect a level of satisfaction ranging from "more or less satisfied" to "quite satisfied" on the QUEST 2.0 scale, and a rating of "OK" to "good" on the SUS scale. This positive evaluation indicates that the participant found the WiGlove to be user-friendly and effective in fulfilling its intended purpose.

5.3.2.4 Feedback from the participant's wife

The participant's spouse, a practising physiotherapist, expressed satisfaction with the WiGlove's intervention, despite their unfortunate inability to utilise it for an extended period.

"**Job and so much demanding the job. So he was not able to do that much.**"

Notably, the spouse emphasised the device's advantageous features, such as its compact size and lightweight construction, which facilitated convenient storage and portability during travel. Similarly, echoing the participant's sentiments, they acknowledged that while the WiGlove seamlessly integrated into their home environment, its usage in the presence of others depended on the level of familiarity to avoid undue attention. Moreover, the spouse reaffirmed the participant's occasional struggle in independently donning the device, requiring assistance. This further underscores the participant's earlier suggestion regarding the stiffness of the connecting element, necessitating careful consideration in future iterations. Lastly, the spouse reported taking on the responsibility of encouraging the participant to engage in regular training sessions, given their role as the sole support in the household.

"**Stroke survivors. They don't have that level of patience, so that is the reason. If other person would be next to him. Then they will definitely do more.**"

5.3.2.5 Overall perception

In contrast to the experiences of **pA**, this particular case highlights the capability of the WiGlove to enable independent donning and doffing for a hemiparetic stroke survivor with moderate impairments, while also identifying areas for further improvement in terms of ease of use. Despite considering the WiGlove as easy and safe to train with, **pB** encountered challenges in maintaining regular training sessions for extended durations, primarily due to increased work commitments. Unfortunately, this hindered the comprehensive analysis of the intervention's impact, which could have provided valuable insights into the potential restorative benefits of the WiGlove for stroke survivors with moderate impairments.

5.3.3 Common observations

Having discussed the case studies of the two participants separately, despite their differences, certain common observations were made between the two.

1. During the study, it was observed that both participants exhibited a significantly higher number of repetitions while engaging in game-based training compared to unstimulated flexion/extension exercises, with the former yielding approximately three times more repetitions. This outcome underscores the efficacy of the WiGlove's games in motivating users to train at a heightened intensity. This observation confirms the perceived benefits of improved motivation as a result of gamified stroke rehabilitation using socially assistive robots reported in a recent study [229]. Notably, despite variations in the participants' impairment levels, they performed a similar number of repetitions per minute during gameplay. This finding suggests that the level of difficulty of the games served as the limiting factor. It emphasises the necessity for an adaptive gaming model that can dynamically adjust training intensity, as well as the importance of developing customised games tailored to the user's individual interests. Such approaches would enable users to maximise their training potential and further enhance the effectiveness of the WiGlove intervention.

2. Despite finding the games interesting, the interviews showed that both participants required external motivation in the form of encouragement from their spouses to regularly train with the WiGlove as demonstrated by the following quote.

   pB - "*Had it not been (my wife), I wouldn't have used the glove more often the way I have used it over the last few weeks. So she has always encouraged me to wear the glove and help me initially to wear the glove*"

   Multiplayer games were shown to increase the training intensity in a study involving stroke survivors [230]. It is imperative to incorporate this motivating factor to augment

the benefits of home-based rehabilitation approach, through multiplayer games that allow other members of the family to be involved in the training.

3. The improved performance of both participants in BBT while wearing the WiGlove provides compelling evidence of its positive orthotic effect, effectively assisting in performing movements. However, their suboptimal performance in the Nine-Hole Peg Test (NHPT), which evaluates fine motor dexterity, aligns with the feedback received from therapists discussed in the previous chapter. The therapists emphasised the significance of the available range of motion (RoM) in leveraging the WiGlove's orthotic effect. Due to insufficient strength, neither participant could overcome the resistive force of the springs and achieve the necessary palmar pinch to grasp the pegs effectively. It is hypothesised that continued training with the WiGlove would contribute to improvements in this aspect. This will be further analysed in future studies.

4. Both participants perceived the WiGlove to be safe to use at home and found no safety concerns for the other members of the family.

5. The small size and portability of the WiGlove allowed them to train at different parts of their homes and found it easy to store.

6. Both participants voiced their preference for a slightly lighter device that would enable extended periods of use. While the WiGlove's weight is already lower than the design specification derived from user feedback, this aspect warrants further investigation, particularly with a larger sample size during subsequent design revisions to achieve a trade-off between weight reduction and functionality. The major part of the WiGlove's weight is accounted for by the motors of the tension adjustment system and therefore designing a custom lightweight actuator or a combined drive system where one actuator is used to adjust the tension of more than one joint should be considered for the next iteration of the WiGlove.

7. The feedback from the interviews suggests that the WiGlove was well-received by both participants. They perceived it to be safe and were satisfied with its usability and the quality of intervention it delivered. This is also evident from their average QUEST 2.0 scores which is a measure of the user's satisfaction with assistive devices like the WiGlove. These observations show a promising trend towards the acceptability of the WiGlove. However, this has to be interpreted with caution given the small sample size.

5.3.3.1 Durability

During the six-week feasibility study, the SPO exhibited a recurring issue of frequent snapping of elastic cords. To mitigate this problem, each participant was given up to three spare cords for the duration of the study. Additionally, the velcro straps displayed a tendency to sag, impeding the ease of donning for users with one unimpaired hand thereby requiring replacements. Furthermore,

the researchers noted that the positioning of the potentiometers rendered them susceptible to collisions, therefore also requiring replacements. In contrast, the six-week study of the WiGlove demonstrated remarkable reliability. Throughout the study, totalling 39 hours and 3 hours of usage for the two WiGloves by participants A and B respectively, no reliability issues were reported. Participant A did encounter a minor problem with the thumb fingercap becoming loose, but successfully resolved it following instructions provided via phone. Despite the limited sample size, these findings offer promising evidence regarding the reliability of the WiGlove.

5.4 Summary

This chapter presents the 6-week, home-based feasibility evaluation of the WiGlove by two hemiparetic stroke survivors without the supervision of a therapist. The findings demonstrate that both participants perceived the WiGlove as safe, durable, easy to store, and capable of independent operation, making it suitable for home-based training without therapist supervision. While the participant with severe arm impairments faced difficulties in independently donning the device, the primary challenge was extending the shoulder joint to position the arm within the WiGlove's forearm module. However, once the arm was in place, the participant successfully engaged the hooks and completed the glove's donning process. Meanwhile, the second participant, who exhibited considerably reduced tone in the proximal joints, was able to independently don and doff the device. These findings provide valuable insights for the development of a more modular inclusive device that allows stroke survivors with varying levels of impairments to independently don/doff the WiGlove. Achieving this inclusivity could involve designing a fixture to assist with donning and doffing the WiGlove and carefully considering the stiffness of the interconnection element. However, the challenge lies in striking a balance between facilitating ease of donning and doffing while satisfying other user requirements, such as compactness and maintaining unrestricted wrist ab/adduction.

Although the evaluation of training effectiveness with the WiGlove was not feasible for participant B, the improvements observed in participant A's performance provide promising evidence of the device's restorative effect. This discrepancy in outcomes can be attributed to the disparity in training intensity, as participant A trained with the WiGlove for a total of 39 hours, while participant B only used it for 3 hours. This finding aligns with the findings of a recent meta-analysis [231], which reported that clinically significant improvements in robot-aided therapy were observed when the total training duration exceeded 15 hours. Despite this discrepancy, both participants expressed satisfaction with the effectiveness of the WiGlove intervention, as indicated by their responses on the effectiveness component of the QUEST 2.0 scale. This was more pronounced, especially in the case of participant A where it prompted him to request for an extension of their participation in this study. The following quote illustrates their encouragement

induced by the noticeable reduction in the hand's tone during their participation in this study.

"**It's also has focused us on what he has been lacking because initially our priority has been to make him stand up, and being able to transfer from one position to another and the hand was not given priority and now we realise that it's also a very big priority. That has shifted the focus.**"

Furthermore, the participants' feedback on the comfort and safety of using the WiGlove validates the design revisions made in this regard as discussed in the previous chapter. This demonstrates the significance of involving secondary users such as therapists in the evaluation of home-based robotic stroke rehabilitation devices.

Although the results of this study are positive, one must be cautious in interpreting these findings as they are based on quantitative and qualitative measures recorded from only two stroke survivors and they may not generalise to different participants with varying levels of motor impairment. It is therefore imperative to recruit participants of diverse ages, genders, and levels of motor impairment in future studies to further enhance the device's design. Similar to [184] this chapter should be construed as a case study of the feasibility of a rehabilitation orthosis designed using a UCD approach at the home of two severely impaired hemiparetic stroke survivors.

These findings about the WiGlove's usability, suitability for home and the effectiveness of its intervention serve as preliminary evidence supporting the feasibility of the WiGlove for home-based therapy thereby positively answering the following third and final research question of this study.

RQ 3 : Is it feasible to use the WiGlove as an orthosis for rehabilitation by hemiparetic stroke patients, in a home environment, without requiring assistance from therapists and is there evidence of its effectiveness ?

CHAPTER 6

CONCLUSION

6.1 Review of research hypothesis and research questions

The review of the literature shows a lack of robotic devices that allow stroke survivors to train both their fingers and wrist simultaneously in the comfort of their homes. The ability to practice at home, given the pressure on healthcare systems and especially given the impact of COVID-19 in the past three years, is considered an important and unmet need. This work aims to address this research gap and exploit this opportunity to innovate solutions for improving stroke survivors' quality of life.

The overarching objective of this research work was to design and develop a robotic rehabilitation device that allowed stroke survivors to independently perform flexion/extension exercises of their hand and wrist while playing therapeutic computer games and while assisting them with performing activities of daily life. It aimed to achieve this in a user-centred design and validation approach by involving the intended users throughout the development process to overcome the functional and usability limitations present in previous designs such as the SCRIPT Passive orthosis.

The central hypothesis of this work was:

"**The design of a passive orthosis for hand and wrist rehabilitation, following a user-centred design approach will lead to a feasible home-based system demonstrated by evidence of adherence, usability and effectiveness.**"

The work entailed in this thesis conveyed by investigating the three research questions provides a positive and supportive answer for this hypothesis, as discussed below.

6.1.1 User centred design, design novelty and user requirements

The first research question considered in this thesis provides the necessary input for designing a home-based rehabilitation device for use in stroke patient's home:
RQ 1 : What are the user requirements for a home-based rehabilitation orthosis that allows hemiparetic stroke survivors to independently train their fingers and wrist ?

In addressing this research question, chapter 3 of this thesis delves into the formulation of a comprehensive list of user requirements, derived through a meticulous analysis of up-to-date literature on rehabilitation devices, as well as insights gained from previous user studies conducted during the development of SPO. Classified into functional and usability requirements, these serve as a guide to designing the first fully functioning prototype. The list of usability requirements identified highlights the significance of usability evaluations in designing a robotic orthosis in line with a similar observation made by a recent review of evaluation practices in wearable hand orthosis [232]. This answers the first research question (**RQ 1**) of this study.

Based on these requirements, the first prototype called the WiGlove was developed from scratch in this PhD work. It is a wireless dynamic orthosis that passively assists stroke survivors to perform flexion/extension exercises while performing activities of daily life. Equipped with integrated sensors, the WiGlove records crucial training information, including joint angles, duration, and repetitions, thereby enabling remote monitoring of progress by clinicians. This also allows the patient to train while playing therapeutic games on a tablet to enhance their motivation and increase the therapy time. In achieving this design, this work makes the following contributions to the body of knowledge.

Contributions to the body of knowledge – novelty in the design

This work strives to better satisfy the user requirements than SPO through novel design features that are applicable to wearable rehabilitation devices in general.

- The amount of assistance needed to extend a limb after a stroke depends on the severity of the stroke and can vary throughout the recovery process. As a result, to adjust the tension, SPO necessitates the user to adjust the length of the elastic cord by utilising cord stops. However, stroke survivors with impaired hand functions may encounter difficulty in performing this task. In light of this, a novel electro-mechanical mechanism has been developed in this work to adjust the tension in the WiGlove. This new mechanism uses a

slider interface on a touchscreen tablet to modify the tension, allowing stroke survivors with impaired hand functions to easily adjust the device.

- Given its home-based use, the joint angle sensing mechanism is necessary for the therapists to remotely monitor the progress. However, SPO's mechanism suffered from poor performance exhibiting a gradual decay with time. This study addresses this limitation by proposing a novel mechanism that uses potentiometers in the WiGlove which has demonstrated good repeatability.
- The WiGlove offers a significant usability improvement over the state-of-the-art (SoA) by enabling wireless operation through Bluetooth communication and an onboard power unit. Unlike other existing wireless robotic orthoses that require additional hardware to be worn on the body, the WiGlove is an all-in-one unit that only weighs 570 grams and is designed to be compact. This feature allows stroke patients to train in different parts of their homes while performing daily activities without being hindered by bulky hardware.
- The WiGlove proposes several usability improvements over SPO such as improved ease of donning/doffing, and unblocking the natural degrees of freedom.
- This work proposes a design with improved durability for the WiGlove compared to the state-of-the-art by addressing its issues such as frequent snapping of elastic cords, sagging velcro straps, and vulnerable positioning of potentiometers, resulting in improved reliability and long-term usability.

As shown in Table 6.1, various technical and usability evaluations involving healthy individuals, stroke therapists and stroke survivors verified that the WiGlove's design satisfied the user requirements, thereby validating these novel design features proposed in this work.

Table 6.1: The validation methodology of the user requirements in the WiGlove's development

User requirement		**Remarks**
Functional requirements - Addressed through design and validated through experiments		
Req 1	Adjustable functional assistance.	Proposed a novel assistance mechanism using extension springs and motorised tension adjustment system.
Req 2	Range of Motion (RoM) required for Activities of Daily Life (ADL).	Goniometric measurements validated that the WiGlove allowed training flexion/extension over the essential RoM
Req 3	Does not hinder any of the natural range of motions of the joints.	Goniometric measurements validated that the WiGlove does not block the unassisted ab/adduction of the fingers and wrist.

Req 4	Self-aligning centre of rotation (CoR).	The base-to-distal architecture of the assistance mechanism, eliminates the concern of misalignment.
Req 5	Measurement of finger and wrist motion.	Experiments verified excellent repeatability of the sensing system that can allow the therapists to monitor progress.
Req 6	Accommodate different hand dimensions.	The device is customised to the participant's hand dimensions.
Req 7	Visual and tactile transparency.	The WiGlove uses an open-palm design, a transparent finger extension structure and silicone fingercaps to maximise tactile and visual transparency.
Usability requirements - Two hemiparetic stroke survivors evaluated the WiGlove's usability		
Req 8	Ease of donning/doffing.	Although the first participant with severe impairments was unable to independently don the device, he was able to doff by himself. Meanwhile, the second participant with moderate impairments was able to independently don and doff.
Req 9	Safe to use at home.	Two stroke survivors rated the WiGlove to be safe to use at home and found no risks for the other members of the family.
Req 10	Smaller space requirement and increased mobility.	Two-stroke survivors verified its portability, ease of storage and suitability for home. • Weighs 570 g < (500 g (on Forearm) + 200 g (on hand)) threshold identified in the literature to be satisfactory • Wireless operation for portability
Req 11	Require relatively less technical proficiency.	Two stroke survivors verified the learnability and ease of use

Req 12	The cost of the robotic orthosis should be affordable.	The total cost of the WiGlove is $ 1046.06 which is less than the threshold of $9,040 set by WHO-CHOICE to be classified as cost-effective.

As highlighted by **RQ 1**, usability is a significant factor that influences the acceptance of rehabilitation orthosis, especially robotic devices aimed at operating independently in a home environment. Therefore the second research question focuses on this.

6.1.2 Usability evaluation and comparative assessment

A second line of inquiry in the thesis corresponded to the assessment of usability improvements over SoA and clinical validity of the passive dynamic orthosis, supporting the following research question:

RQ 2 : Can the WiGlove, which was designed using a user-centred approach to meet specific requirements, result in better functionality and usability compared to the current state-of-the-art?

In addressing this, chapter 4 presents a two-stage formative evaluation conducted in this study to verify the WiGlove's usability improvements. Firstly, in a counterbalanced, within-subject study, twenty healthy participants comparatively evaluated the WiGlove's usability against that of SPO (state-of-the-art). The findings validated the WiGlove's usability improvements with statistical significance in 11 out of the 17 aspects that were evaluated relating to donning/doffing, suitability for activities of daily life, freedom of abduction/adduction, ease of adjusting the assistance and perception of aesthetics and safety.

Building upon these encouraging outcomes, a subsequent usability study was conducted with therapists with experience in stroke rehabilitation to ensure that the WiGlove is safe and suitable for use by stroke survivors at home. Six stroke therapists extensively tested the WiGlove and reaffirmed its usability and safety through descriptive comments and Likert-scale scores. Their feedback helped to identify areas of concern. Subsequent evaluations involving stroke survivors validated the revisions made to address these concerns, with no reported issues. This underscores the significance of involving the secondary users in the user-centred development of rehabilitation robots, which agrees with the observations of a similar study [40]. Furthermore, this study also demonstrates the effectiveness of using qualitative data in identifying usability issues as pointed out by [232].

The findings derived from the two formative usability evaluations verify that the user-centred design approach employed in developing the WiGlove has yielded significant usability improve-

ments compared to the state-of-the-art, thereby answering **RQ 2** in the affirmative.

Having validated the WiGlove's design by healthy participants and stroke therapists, the next research question strives to verify if the usability improvements validated in the previous stages transfer to stroke survivors who are its intended end-users.

6.1.3 Usability, adherence and effectiveness at home

Our final research question relates to the assessment of the device for suitability for its intended use as formulated by the following research question:

RQ 3: Is it feasible to use the WiGlove as an orthosis for rehabilitation by hemiparetic stroke patients, in a home environment, without requiring assistance from therapists and is there evidence of its effectiveness?

To address this, two prototypes of the WiGlove were developed based on the revised design incorporating therapists' feedback. Two hemiparetic stroke survivors were recruited and during an initial fitting stage the WiGlove's dimensions, magnitude of assistance and colour were personalised to their respective requirements. This was then deployed for an initial duration of six weeks in their homes. These participants utilised the WiGlove to independently perform flexion/extension exercises both with and without therapeutic games provided on a touchscreen tablet.

Overall, both participants expressed positive opinions regarding the WiGlove's usability and safety, affirming its suitability for home-based use. This was supported by their ratings on the QUEST 2.0 and SUS scales which were (3.87, 3.87)/5 and (70, 75)/100, respectively, indicating a level of satisfaction ranging from "more or less satisfied" to "quite satisfied" and a rating of "good to excellent". This serves to verify the validity of the user requirements identified in this work, based on which the WiGlove was designed. Notably, the second participant who suffered from moderate impairments, was able to independently don/doff the WiGlove, validating the design improvements in this regard, aligning with the findings of earlier evaluations. However, severe impairments experienced by the second participant hindered his ability to independently don/doff the device reflecting a trend observed in a similar study of a hand (only fingers) rehabilitation device which reported independent don/doffing to be possible only for users with moderate impairments [221]. This highlights the scope for future improvements.

Their positive usability experience allowed them to use the device more than once a day, especially in the case of the first participant who trained for an average of 48 minutes per day for a total of 39 hours with the WiGlove. Additionally, the training data revealed that engaging

in therapeutic games on the tablet while using the WiGlove enabled the first participant to train at a higher intensity, performing five times more repetitions compared to sessions without the games. This observation strengthens the argument for the integration of serious games in rehabilitation which has been shown to enhance recovery [233]. Unfortunately, lack of time due to work commitments, the second participant was unable to regularly train. Nevertheless, the data gathered from the first participant provides promising evidence of adherence to training with the WiGlove.

The effect of the distinct adherence pattern between the participants is reflected in their performance improvements. The first participant showed significant improvements in his hand functions evidenced by improved performance in the box and block test after six weeks, along with a noticeable reduction of tone. This allowed him to voluntarily open his hand at the end of six weeks compared to having a completely closed fist at the beginning. Such improvements were only observed in the first participant who trained with the WiGlove for more than 39 hours while the second participant who only used it for a total of 3 hours did not show any improvements. This finding aligns with a recent meta-analysis [231], which reported that significant improvements in robot-aided therapy were observed only when the total training duration exceeded 15 hours. This reaffirms the effect of increased training intensity on recovery as pointed out by [185].

Encouraged by these positive results and a noticeable reduction in wrist and finger tone, the first participant expressed a desire to extend his participation beyond the initial six-week study period and used the glove for an additional 12 weeks. The findings of this study establish the WiGlove's usability, safety, and ability to enhance patient adherence, ultimately leading to positive outcomes. These results offer preliminary evidence supporting the feasibility of the WiGlove for effective hand rehabilitation in the homes of stroke survivors, thus providing an affirmative response to **RQ 3**. In addressing this research question, this work makes the following contributions to the body of knowledge.

Contributions to the body of knowledge - User-centred development of rehabilitation robotics

Although a user-centred design approach is increasingly popular in the field of medical robotics, it is a relatively young field in the development of rehabilitation robots. This work demonstrates a multi-stage evaluation methodology in the development of a rehabilitation robot:

- This study introduces a methodology for evaluating and validating the usability improvements of an assistive device during its formative design stages with non-end users. This is accomplished by conducting a counterbalanced within-subject study to compare the hypothesised improvements of the device with another device or the state-of-the-art.

- This study emphasises the importance and effectiveness of involving secondary users, such as stroke therapists, in the user-centred design process of assistive devices. This process demonstrates the use of a heuristic evaluation that incorporates their expertise and feedback to identify potential usability issues during the development process, ultimately ensuring the safety of the device for end-users.

- Given that the summative usability studies were conducted at the patient's home, it highlighted the significance of the influence of other members of the household. In the case of both participants, spousal encouragement was found to be a contributing factor that enhanced the participants' adherence to training. Therefore, this study proposes and demonstrates the inclusion of qualitative feedback through semi-structured interviews in the usability evaluation of home-based rehabilitation devices.

Contributions to the body of knowledge - Home-based rehabilitation robotics

The study highlights the importance of empowering stroke survivors with user-friendly tools in home-based independent robot-aided rehabilitation. By using these tools, the first participant of the study was able to perform regular and repeated training, without the need for a prescribed protocol or therapist. These findings suggest that robotic rehabilitation devices that prioritise ease of use and motivation can have a positive impact on the independence and rehabilitation outcomes of stroke survivors strengthening the early evidence provided in [32].

Publications

The work done in this PhD contributed to the publication of three peer-reviewed research papers in international conferences and is pending the acceptance of two more. The research reported in these publications was carried out by the first author with the guidance of the co-authors.

1. **V. Velmurugan**, L. Wood, and F. Amirabdollahian, "Requirements for a home-based rehabilitation device for hand and wrist therapy after stroke," in UKRAS21: The 4th UK Robotics and Autonomous Systems Conference, July 2021, p. 23.http://doi.org/10.31256/Xw5Aj7Q

   This paper discusses the different user requirements of an ideal home-based hand rehabilitation device and the methods of evaluation to verify that the prototype iterations meet these requirements.

2. **V. Velmurugan**, L. Wood, and F. Amirabdollahian, "Formative usability evaluation of WiGlove – a home-based rehabilitation device for hand and wrist therapy after stroke," In Companion of the 2023 ACM/IEEE International Conference on Human-Robot Interaction,

March 2023, https://doi.org/10.1145/3568294.3580087

This paper presents the methodology and results of this first formative evaluation of the glove with twenty healthy participants. It provides preliminary evidence of the WiGlove's usability improvements in several elements over the current state of the art (SPO).

3. **V. Velmurugan**, L. Wood, and F. Amirabdollahian, "A User-centred Design and Feasibility Analysis of the WiGlove - A Home-based Rehabilitation Device for Hand and Wrist Therapy after Stroke," ACHI 2023, The Sixteenth International Conference on Advances in Computer-Human Interactions,p 134 to 139, April 2023. article here

   Beginning with the features of the WiGlove, this paper focuses on discussing the methods and findings of its formative usability evaluation with stroke therapists and presents preliminary results from the feasibility study conducted at a stroke survivor's home.

4. **Submitted** - The paper titled "Preliminary Results from Functional and Usability Assessment of the WiGlove - a Home-based Robotic Orthosis for Hand and Wrist therapy after Stroke." discusses the WiGlove's design approach on how it addresses the user requirements and their validation through functional and usability evaluation with stroke survivors. This has been submitted to IEEE International Conference on Robot & Human Interactive Communication (RO-MAN 2023).

5. **Submitted** - The paper titled "Preliminary Results From A Six-Week Home-based Evaluation of a Rehabilitation Device for Hand and Wrist Therapy after Stroke" submitted to the International Consortium for Rehabilitation Robotics, 2023 (ICORR).

   This paper presents a case study of a 6-week feasibility evaluation of the WiGlove conducted at a stroke survivor's home without assistance from the therapists. The results of this study show overwhelmingly positive outcomes in terms of its acceptance, usability and effectiveness in offering home-based rehabilitation of the wrist and fingers.

6.2 Limitations and future work

Although the results presented in this research are overwhelmingly positive in favour of the proposed WiGlove's design, it should be interpreted with care and knowledge of the following limitations of this research.

1. The formative evaluation conducted with stroke clinicians involved a restricted sample size of only six therapists due to their busy schedules. Each therapist interacted with the device for 15 minutes and therefore involving additional participants was difficult given their

availability. Consequently, the statistical significance of the findings regarding the various aspects of the WiGlove's usability could not be firmly established. Therefore in future work, involving a larger cohort of stroke therapists would offer more comprehensive insights into the WiGlove's performance and potential advancements in usability.

2. The evaluation of the WiGlove's feasibility included the participation of two hemiparetic stroke survivors who exhibited very distinct levels of motor impairment in both proximal and distal joints of the upper limb. They also varied significantly in their training pattern and overall training duration. Consequently, the generalisability of the findings, particularly the impact of the WiGlove's intervention, should be approached with caution as they may not extend to individuals with varying levels of impairment and at different stages of their recovery. It is imperative to recruit more participants of diverse ages, genders, and levels of motor impairment in a large-scale clinical trial to assess the overall effectiveness and usability and to further enhance the device's design.

3. Moreover, the participants were introduced only to the WiGlove due to the end of the SCRIPT project in 2017, which rendered the SCRIPT system to be inaccessible. This precludes direct comparison of the two orthoses. In future, this could be addressed by an evaluation of the WiGlove following a comparable profile to that of SPO with 21 participants with similar impairment levels, similar study durations, a similar number of interactive games with remote monitoring and regular feedback by therapists [32].

4. In the home-based phase of the WiGlove's evaluation, participants were provided with a limited selection of two therapeutic games. Expanding the range of available games, and allowing participants to choose those that align with their specific interests, could have potentially heightened their motivation levels. Both the participants expressed a desire for custom games based on their interests. Furthermore, the games remained fixed at a constant difficulty level throughout the evaluation. This lack of adaptive difficulty adjustment, based on the individual participant's performance, may have failed to challenge them consistently and subsequently impacted their overall engagement during the training sessions. A study with SPO, observed that during a training session, the performance initially increased (due to learning) and then decreased due to fatigue [64]. This has been addressed in SPO, by developing a performance-based adaptation module to adjust the difficulty of the games [64]. Therefore, incorporating a similar dynamic difficulty adaptation mechanism that tailors the game's challenge to the participant's abilities could be beneficial in sustaining their interest and optimising the effectiveness of the WiGlove as a training tool.

5. Both participants expressed their preference for the device to be lighter in weight. Since the WiGlove only weighs 570 g, which is less than the combined weight of three iPhone 14 pro devices, it is necessary to determine if this is isolated to these two participants and

their level of impairments. If this finding is supported by the findings of future large-scale feasibility trials, this needs to be addressed. The major part of the WiGlove's weight is accounted for by the motors of the tension adjustment system and therefore designing a custom lightweight actuator or a combined drive system where one actuator is used to adjust the tension of more than one joint should be considered for the next iteration of the WiGlove.

6.3 Concluding remarks

The research presented in this thesis through the investigation of the three research questions, presents evidence that unequivocally supports the following central hypothesis:

"**The design of a passive orthosis for hand and wrist rehabilitation, following a user-centred design approach will lead to a feasible home-based system demonstrated by evidence of adherence, usability and effectiveness.**"

This has been evidenced by answering RQ 1, related to designing a system by establishing user requirements aligned with user-centred design methodology, but also aligned with accepted engineering design methods. It is further substantiated by a comparative assessment with the state-of-the-art (SPO) providing supportive evidence for the WiGlove's design improvements (RQ 2), and also affirmative and supportive evaluation by the clinicians (RQ 2). This led to two individual case studies confirming the device's usability, adherence and effectiveness where the device was used for a duration that is expected to create a significant impact (RQ 2, RQ 3). The contribution of this work is extending the state-of-the-art in post-stroke home-based rehabilitation orthosis for hand and wrist through novelty in design developed using a user-centred approach.

Furthermore, the improvements observed in the first participant and their (the participant and his wife) enthusiasm in continuing their use of the WiGlove has kindled our efforts to pursue further development of the WiGlove starting with a search for funding opportunities to support a large-scale feasibility trial. This trial will enable us to systematically assess the potential of the WiGlove on a broader scale. I hope that the WiGlove could become an invaluable companion to therapists by allowing them to efficiently use their expertise in helping stroke survivors regain their ability to live independently. Its affordability has the potential of increasing access to stroke survivors while alleviating the stress on the healthcare system. It is important to note that while the primary focus of the device lies in stroke rehabilitation, its potential extends to the rehabilitation of spastic hands following various neurological injuries, opening avenues for broader application and impact.

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APPENDIX - A SURVEY OF DYNAMIC HAND AND WRIST REHABILITATION ORTHOSIS

Table 1: Hand and Wrist rehabilitation orthosis - Overview

Reference	Year	Device Name	Mechanical Structure	Actuation Type	Transmission
Wrist and Hand orthosis					
[119]	2010	Hand Mentor	Exoskeleton	McKibbon Muscle (PAM)	Mechanical Linkage
[178]	2011		Fixed Exoskeleton	DC Motors	Mechanical Linkage and timing belts
[99]	2005	HWARD	Fixed Exoskeleton	Pneumatic	Mechanical Linkage
[120]	2015	SAO	Exoskeleton	DC Motors	Whipple Tree mechanism and cable
[32]	2014	SCRIPT-SPO	Exoskeleton	Passive	Elastic cable
Wrist orthosis					
[152]	2008	RICEWRIST	Fixed Exoskeleton	DC Motors	Steel Cables, Capstan Arc
[121]	2013		Exoskeleton	Servo Motors	Mechanical Linkage

[234]	2013		Fixed Exoskeleton	DC Motors	Mechanical Linkage
[33]	2007	MIT-MANUS Extension	End Effector	DC Motors	Mechanical Linkage
[235]	2021		Exoskeleton	McKibben Muscle (PAM)	4-SPS Mechanical linkage
Hand orthosis					
[236]	2019	HERO	Exoskeleton	Linear Servo	Cables
[113]	2007	SAEBO-FLEX	Exoskeleton	Passive	Extension Springs
[122]	2014	FINGER	Exoskeleton	Servotube Actuators (Linear Motors)	8-bar curling mechanism
[123]	2009		Exoskeleton (Index Finger)	Servo Motors	Wire driven 4-bar mechanism
[114]	2011	HANDSOME	Exoskeleton	Passive	Elastic cable
[36]	2016	HANDSOME-II	Exoskeleton	Passive (Extension spring)	Mechanical Linkage
[124]	2009	HANDEXOS	Exoskeleton	DC Motors	Bowden cable
[237]	2014		Exoskeleton (Index finger and thumb)	DC Motors	Mechanical Linkage
[131]	2010	HEXORR	Exoskeleton	DC Motors	Mechanical Linkage and gear train
[132]	2005		Exoskeleton	Servo motors	Mechanical Linkage, cables and spring return

[238]	2008		Exoskeleton	DC motors	Flexible cables
[130]	2007		Exoskeleton	DC motors	Bowden cable
[154]	2004		Exoskeleton	DC Motors	Bowden cable
[239]	2010		Exoskeleton	McKibbon Muscle (PAM)	Mechanical Linkage and cable
[240]	2014	ASSISTON-FINGER	Exoskeleton	DC Motors	Mechanical Linkage
[133]	2011	iHANDREHAB	Fixed Exoskeleton	DC Motors	Mechanical Linkage
[241]	2011		Exoskeleton	Braided Pneumatic Actuators	Bowden cable and MechanicalLinkage
[125]	2012	CAFE(Cable Actuated Finger Exoskeleton)	Exoskeleton (Index finger)	DC Motors	Cable
[242]	2009		Exoskeleton	DC Motors	Extension springs, cables
[243]	2014		Exoskeleton	DC Motors	Bowden cable and circuitous joint
[162]	2007	Gentle/G	Exoskeleton	DC Motors	Direct Drive
[153]	2015		Exoskeleton	DC Motors	Cables
[244]	2015		Exoskeleton	DC Motors	Cables and Mechanical Linkage
[146]	2013		Exoskeleton	McKibbon Muscle (PAM)	Cables

[134]	2014	BIOMHED (Biomimetic Hand Exoskeleton Device)	Exoskeleton	DC Motors	Cables
[35]	2016	Gloreha	Exoskeleton	Pneumatic	Cables
[112]	2011	HAND OF HOPE	Exoskeleton	Pneumatic	Mechanical Linkage
[3]	2015		Exoskeleton	Hydraulic	Soft reinforced fibres
		Saebo Glove	Exoskeleton	Passive	Elastic straps
[245]	2013		Exoskeleton	DC Motors	Mechanical linkage and lead screw
[246]	2014		Exoskeleton	Servo Motors	Cables
[145]	2015	ExoGlove	Exoskeleton	Pneumatic variable stiffness actuator	
[247]	2015	handExo	Exoskeleton	DC Motors	Direct Drive
[248]	2015	ExoHand	Exoskeleton	Linear Servo Motors	Mechanical Linkages
[249]	2015		Exoskeleton	DC Motors	Bowden Cables
[128]	2015		Exoskeleton (Index finger)	DC Motors	Bowden cables and serial elastic element
[143]	2014		Exoskeleton	Pneumatic	Cam/Follower
[250]	2013		Exoskeleton	Linear servo	Connecting rod mechanism

[251]	2015		Exoskeleton	Servo Motors	Cables
[252, 253]	2016,2015		Exoskeleton	DC Motors	Cables
[116]	2016		Exoskeleton	Servo Motors	Mechanical Linkage (crank and slider)
[254]	2016	ExoK'ab	Exoskeleton	DC Motors	Direct Drive
[255]	2013		Exoskeleton	DC Motors	Cables
[135]	2015	BRAVO	Exoskeleton	DC Motors	Direct Drive
[137]	2015		Exoskeleton	DC Motors	Cables
[136]		WaveFlex 6000X hand CPM	Exoskeleton	DC Motors	Flexible Link
[144]		Festo Exo Hand	Exoskeleton	Pneumatic	Mechanical Linkage
[115]	2012	AMADEO	End Effector	Linear Actuator	Direct Drive
[117]	2007	Haptic Knob	End Effector	DC Motor	Parallelogram mechanism
[118]	2008	Hand CARE	End Effector	DC Motor	Cables
[256]	2023		Exoskeleton	Servo motors	Direct drive
[257]	2023		Exoskeleton	DC motors	Cables
[258]	2020		Exoskeleton	DC motors	Cables
[259]	2022		Exoskeleton	Linear Actuator	Sliding springs
[260]	2019		Exoskeleton	Linear Actuator	Sliding springs

[261]	2019		Exoskeleton	Pneumatic bladder	Pneumatic bladder
[262]	2019	DexoHand	Exoskeleton	Servo motor	Cables and mechanical linkage
[263]	2018		Exoskeleton	DC Motors	Cables

Appendix - Design specification analysis

Product design specifications that address the user requirements are detailed in Table 3. The third column of this table corresponds to the priority/weight of each specification that represents their significance in designing a user acceptable device that best satisfies the user requirements. The method of determination of these priority ratings is discussed in this section. The different functional and usability requirements that have been discussed in chapter 3 are cross-referenced with the product design specifications to determine the effect of these specifications on each of the requirements (Tables.4,5). When a specification is determined to influence a requirement it is marked with "Y" for "yes" in the corresponding column and row. Based on the degree of influence, each specification is given a weight or priority rating ranging from 1 to 3 (Table 2). A rating of 1 informs us that the corresponding specification is not as important and a failure to meet it will have minimal effect on the user's acceptance of the device. A rating of 3 shows that the corresponding specification is highly essential for the acceptance of the device. A specification is given a weight of 1 and 2 if they affect one or two requirements respectively. A rating of 3 is given to a specification that addresses three or more requirements. The high correlation between the requirements is illustrated by the fact that all specifications have a priority rating of more than or equal to 2 due to their relevance to more than one requirement.

Table 2: Rating scheme for the specifications

Weight/priority rating	**Importance**
3	Very important
2	Fairly important
1	Slightly important

Table 3: Product design specification

Specification	**Technical descriptors/Value**	**Priority**	**Requirement**	**Validation method**

Assistance	Provide assistance with the extension of the wrist and the fingers.	3	Req 1, 2	Through Design (Section - 3.3.2.1)
Assisted DoF	Range of motion in Flexion / Extension required to perform activities of daily life	3	Req 1, 2	Goniometric measurements (Section -3.4.2)
Unassisted DoF	Freedom of ab/adduction of the wrist and fingers.	3	Req 2, 3	
Feedback on the performance	Measurement of the flexion/extension angle for the fingers and wrist.	3	Req 3, 5	Repeatability experiment (Section - 3.4.1)
Tactile transparency	Ensuring maximum tactile feedback while interacting with objects.	2	Req 7	Through design (Section - 3.3.2.6)
Visual transparency	Ensuring that the device does not block the visual during exercise.	3	Req 7,8	
Weight	• < 200g on the hand • < 500g on the forearm	2	Req 8,10	Usability Evaluation (Chapter 4,5)
Material	Lightweight, strong and 3D printable.	3	Req 10	Through design using PLA (Polylactic Acid)
Size	Ensure that it is not bulky enough to prevent any joint motions and to make donning easy	2	Req 8,10	Through design (Section - 3.3.2.5)

Ease of use	• Easy to independently don/doff with one hand. • Easy to adjust the tension of assistance with one hand. • Operation is easy to learn	3	Req 1,8,9	Usability evaluations (Chapter 4,5)
Comfort of interaction	• Device fits the hand's dimensions. • Prevent misalignment of joint axes. • Does not cause any discomfort or pain while training.	3	Req 4,6,9	
Safety	• Avoid any pinch points and sharp edges. • Avoid any device malfunctions that could lead to injury. • Avoid any tripping hazard.	3	Req 4,6,9	
Portability	Ensure that the system is easy to store and easy to move while training.	3	Req 8, 10	

Table 4: Product design specifications - determination of the weight/priority

		Product design specifications								
		Assistance with joint extension	Assisted DoF	Unassisted DoF	Feedback on performance	Tactile transparency	Visual transparency	Weight	Size	Material
User Requirements	Adjustable functional assistance	Y	Y							
	Range of motion for Activities of daily life	Y	Y	Y						
	Does not hinder any natural range of motion of the joints			Y	Y					
	Self aligning centre of rotation (CoR)									
	Measurement of finger and wrist motion				Y					
	Accommodate different hand dimensions									Y
	Visual and tactile transparency					Y	Y			
	Ease of donning/doffing						Y	Y	Y	
	Safe to use at home									
	Smaller space requirement and increased mobility.							Y	Y	Y
	Require relatively less technical proficiency to operate.									
	The cost of the robotic orthosis should be affordable.	Y	Y	Y	Y	Y	Y			Y
Priority rating		3	3	3	3	2	3	2	2	3

Table 5: Product design specifications - determination of the weight/priority

		Product design specifications			
		Ease of use	Comfort of interaction	Safety	Portability
User Requirements	Adjustable functional assistance	Y			
	Range of motion for Activities of daily life				
	Does not hinder any natural range of motion of the joints				
	Self aligning centre of rotation (CoR)		Y	Y	
	Measurement of finger and wrist motion				
	Accommodate different hand dimensions		Y	Y	
	Visual and tactile transparency				
	Ease of donning/doffing	Y			Y
	Safe to use at home		Y	Y	
	Smaller space requirement and increased mobility.				Y
	Require relatively less technical proficiency to operate.	Y			
	The cost of the robotic orthosis should be affordable.	Y	Y	Y	Y
Priority rating		3	3	3	3

Testing for statistically significant difference between the participants' scores for the two glove

Table 6: Statistical results of both gloves

	WiGlove			SPO			Wilcoxon signed-rank test results		
	Median	SD	IQR	Median	SD	IQR	Z	p	r
Ease of donning the forearm module	6	1.005	1	6	1.637	3	- 1.754	0.079	0.392
Ease of donning the hand module	6	1.525	2.75	6	1.635	2.75	- 0.712	0.476	0.159
Ease of donning the fingercaps	7	1.386	1	4.5	1.932	3.75	- 3.337	0.001*	0.746
Ease of doffing the forearm module	7	0.759	1	6.5	1.45	1	- 2.145	0.032*	0.48
Ease of doffing the hand module	6	1.361	1.75	6	1.387	2	- 0.051	0.959	0.011
Ease of doffing the fingercaps	7	0.754	1	6	1.916	3.75	- 2.958	0.003*	0.661
Ease of performing ab/adduction of the wrist	6	1.399	2	3	1.292	2	- 3.543	< 0.001*	0.792
Ease of performing ab/adduction of the fingers	6	1.293	2	5.5	1.182	2	- 0.8	0.424	0.179
Perception of the weight	5	1.316	2	4	1.276	1	- 1.107	0.268	0.248
Ease of adjusting the tension	7	0.82	1	5	1.273	1.75	- 2.583	0.01*	0.578
Ease of performing a palmar pinch	6	1.657	2	3	1.765	3.75	- 3.396	< 0.001*	0.759
Ease of performing a cylindrical grasp	7	1.436	1	2	1.605	2.75	- 3.698	< 0.001*	0.827
Ease of performing a spherical grasp	6	1.791	2.5	6	1.333	1.75	- 0.642	0.521	0.144
Suitability for ADL	6	1.308	1	3	1.605	3	- 3.504	< 0.001*	0.784
Aesthetic appeal	6	1.005	2	4	0.94	1	- 3.79	0.001*	0.847
Perception of user safety	6	1.356	2	4	1.663	3	- 2.393	0.017*	0.535
Perception of safety for the family	6	1.372	2	4	1.638	2	- 3.093	0.002*	0.692

* Statistically significant difference.

Testing for statistically significant difference between the participants' scores for don/doffing in the first and second attempts

Table 7: Statistical results - SPO

	1^{st} Try			2^{nd} Try			Wilcoxon signed-rank test results		
	Median	SD	IQR	Median	SD	IQR	Z	p	r
Ease of donning the forearm module	5.5	1.654	2	6	1.637	3	- 1.642	0.101	0.367
Ease of donning the hand module	5	1.694	3	6	1.635	3	- 2.588	0.010*	0.579
Ease of donning the fingercaps	4.5	1.867	4	4.5	1.932	4	- 0.916	0.360	0.205
Ease of doffing the forearm module	6	1.146	2	6.5	1.451	1	- 0.322	0.748	0.072
Ease of doffing the hand module	6	1.191	2	6	1.387	2	- 0.552	0.581	0.123
Ease of doffing the fingercaps	6	1.843	4	6	1.916	4	- 0.520	0.603	0.116

* Statistically significant difference.

Table 8: Statistical results - WiGlove

	1^{st} Try			2^{nd} Try			Wilcoxon signed-rank test results		
	Median	SD	IQR	Median	SD	IQR	Z	p	r
Ease of donning the forearm module	6	0.887	2	6	1.005	1	- 1.095	0.273	0.245
Ease of donning the hand module	6	1.603	2	6	1.525	3	- 1.442	0.149	0.322
Ease of donning the fingercaps	6	1.182	2	7	1.387	1	- 1.192	0.233	0.267
Ease of doffing the forearm module	7	0.688	1	7	0.759	1	- 0.277	0.782	0.062
Ease of doffing the hand module	6	1.732	3	6	1.361	2	- 0.823	0.410	0.184
Ease of doffing the fingercaps	7	0.761	1	7	0.754	1	- 0.575	0.565	0.129

* Statistically significant difference.

Order effects

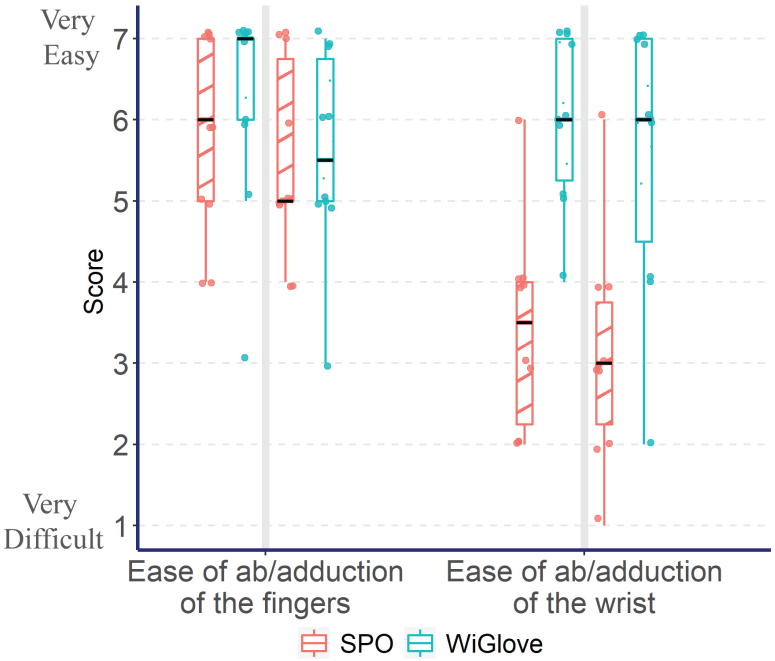


Figure 1: Boxplots showing the participants' scores for the ease of performing abduction/adduction while wearing the two gloves categorised according to the counterbalanced groups

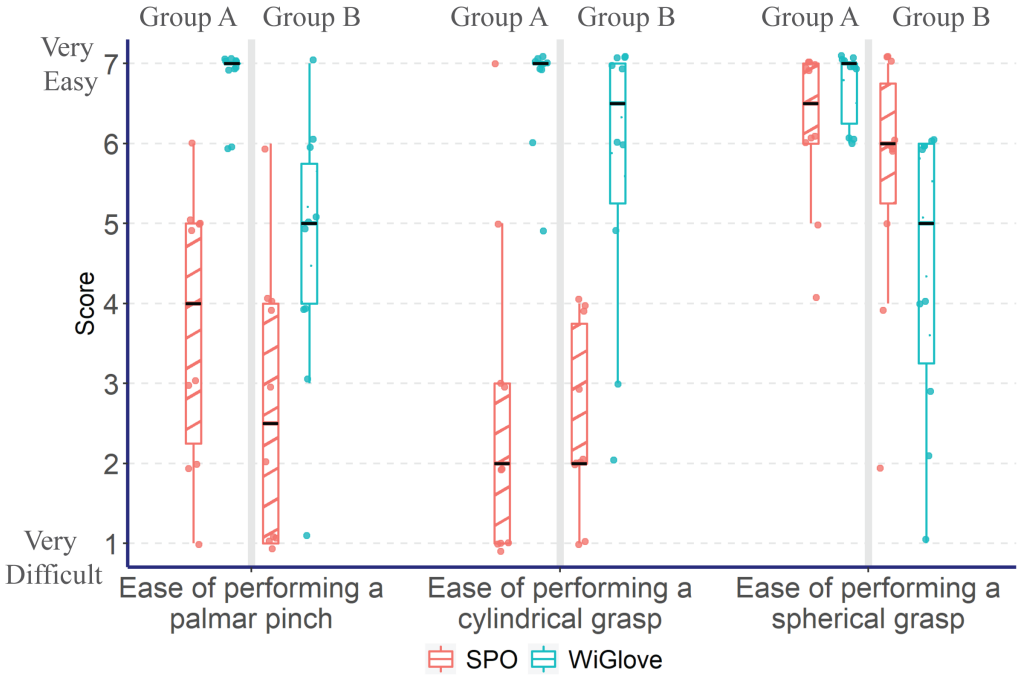


Figure 2: Boxplots showing the participants' scores for the ease of performing different grasps with the two gloves categorised according to the counterbalanced groups

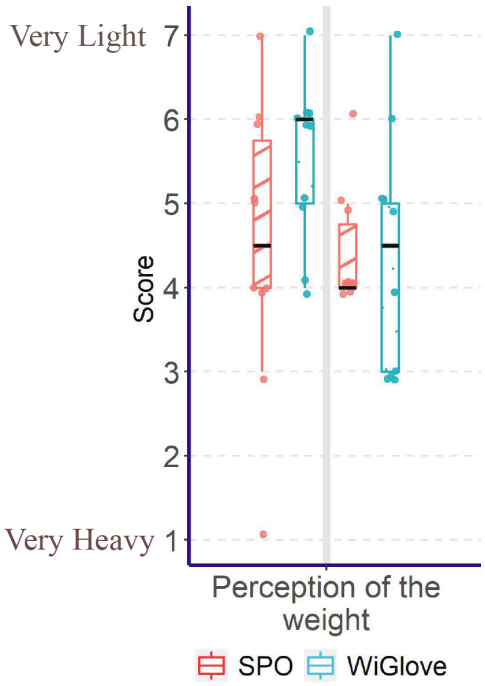


Figure 3: Boxplot showing the participants' perception of the weight of the two gloves categorised according to the counterbalanced groups

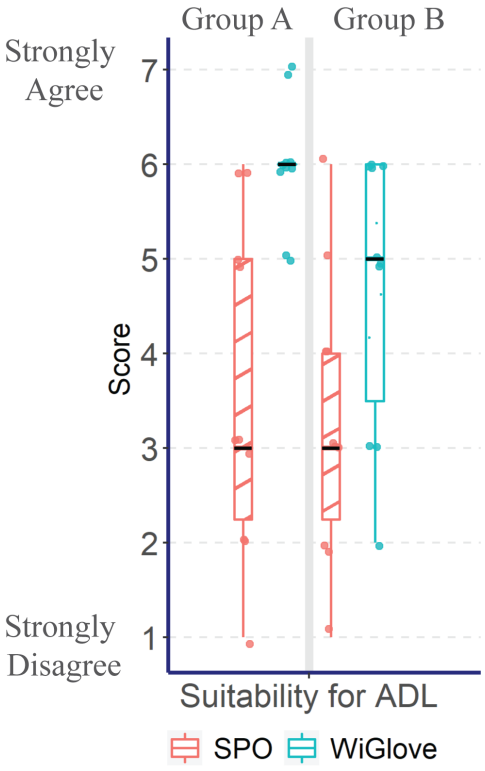


Figure 4: Boxplot showing the participants' opinion of the suitability of the two gloves for performing activities of daily life categorised according to the counterbalanced groups

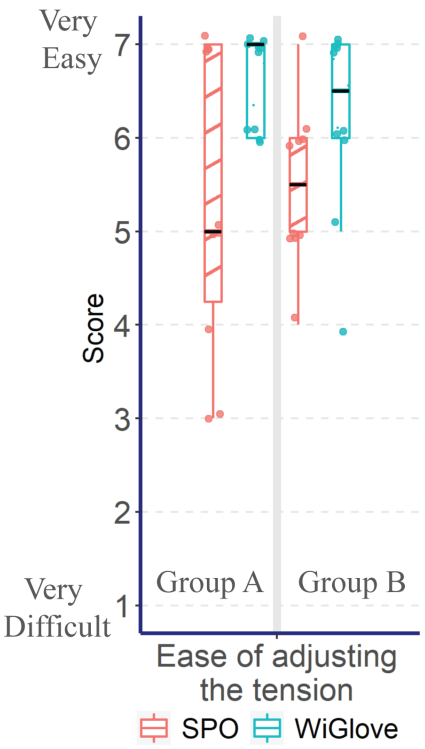


Figure 5: Boxplot showing the participant's scores for ease of adjusting the tension on the two gloves categorised according to the counterbalanced groups

Testing for statistically significant differences between the scores of the participants from the two groups

Table 9: SPO - Statistical results of order effects

	Group A			Group B			Mann-Whitney U test results		
	Median	SD	IQR	Median	SD	IQR	U	p	r
Ease of donning the forearm module	6	1.716	3	6	1.647	3	49	0.971	0.04
Ease of donning the hand module	6	1.269	2	6	2.003	4	47.5	0.853	0.044
Ease of donning the fingercaps	4.5	1.43	3	4.5	2.415	5	49.5	0.971	0.008
Ease of doffing the forearm module	7	0.966	1	6	1.776	3	36.5	0.315	0.248
Ease of doffing the hand module	6.5	1.247	2	6	1.567	3	44.5	0.684	0.098
Ease of doffing the fingercaps	7	1.619	3	5	2.111	4	32	0.19	0.32
Ease of performing the ab/adduction of the wrist	3.5	1.265	2	3	1.37	2	42.5	0.579	0.131
Ease of performing the ab/adduction of the fingers	6	1.229	2	5	1.179	2	43	0.631	0.123
Perception of the weight	4.5	1.716	2	4	0.699	1	44.5	0.684	0.1
Ease of adjusting the tension	5	1.636	3	5.5	0.85	1	47.5	0.853	0.044
Ease of performing a palmar pinch	4	1.703	3	2.5	1.767	3	32.5	0.19	0.301
Ease of performing a cylindrical grasp	2	2.011	3	2	1.179	2	45	0.739	0.087
Ease of performing a spherical grasp	6.5	1.033	1	6	1.578	2	38.5	0.393	0.206
Suitability for ADL	3	1.776	3	3	1.494	2	46	0.796	0.069

* Statistically significant difference.

Table 10: WiGlove - Statistical results of order effects

	Group A			Group B			Mann-Whitney U test results		
	Median	SD	IQR	Median	SD	IQR	U	p	r
Ease of donning the forearm module	6	1.197	1	7	0.707	1	34	0.247	0.294
Ease of donning the hand module	6	1.418	2	6.5	1.703	3	47.5	0.853	0.044
Ease of donning the fingercaps	7	0.707	1	6.5	1.814	2	42.5	0.579	0.141
Ease of doffing the forearm module	7	0.516	1	7	0.972	1	47	0.853	0.061
Ease of doffing the hand module	6	1.287	2	6	1.494	2	47.5	0.853	0.045
Ease of doffing the fingercaps	7	0.422	0	7	0.966	1	39	0.436	0.232
Ease of performing the ab/adduction of the wrist	6	1.054	2	6	1.713	3	46.5	0.796	0.062
Ease of performing the ab/adduction of the fingers	7	1.317	1	5.5	1.265	2	33.5	0.218	0.296
Perception of the weight	6	0.972	1	4.5	1.43	2	26	0.075	0.417
Ease of adjusting the tension	7	0.516	1	6.5	1.033	1	41	0.529	0.171
Ease of performing a palmar pinch	7	0.422	0	5	1.713	2	8	<0.001*	0.749
Ease of performing a cylindrical grasp	7	0.675	0	6.5	1.829	3	33.5	0.218	0.328
Ease of performing a spherical grasp	7	0.483	1	5	1.897	3	7.5	<0.001*	0.76
Suitability for ADL	6	0.667	1	5	1.494	3	23	0.043*	0.492

* Statistically significant difference.

formative evaluation questionnaire - healthy participants

Usability evaluation questionnaire

1. **Please state your age** _____
2. **Please state your gender** _____

Wearability

Please answer the following questions based on your experience of wearing the device.

3. **How easy is it to put on (donning) the forearm module of this glove?**

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

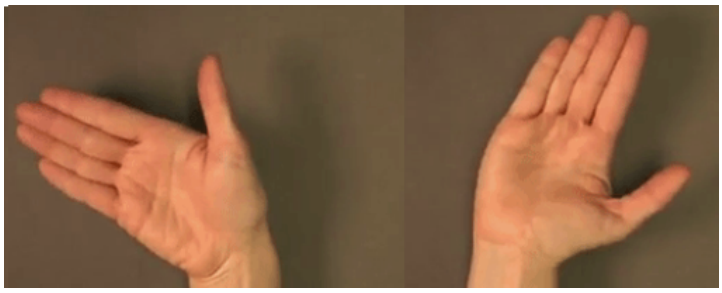
4. **How easy is it to put on (donning) the hand module of this glove?**

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

5. **How easy is it to put on (donning) the fingercaps of this glove?**

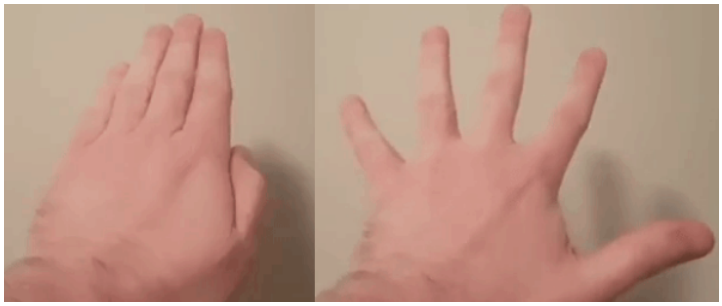
	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

6. **How easy is it to perform abduction/adduction of the wrist while wearing this glove?**



	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

7. **How easy is it to perform abduction/adduction of the fingers while wearing this glove?**



	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

8. **How would you characterise the weight of this glove?**

	1	2	3	4	5	6	7	
Very Heavy	□	□	□	□	□	□	□	Very Light

9. How easy is it to remove the forearm module of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

10. How easy is it to remove the hand module of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

11. How easy is it to remove the fingercaps of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

Usability

Please answer the following questions based on your experience of using the Wi glove and interacting with the tablet and performing the tasks detailed below.

12. How easy is it to adjust the amount of assistance for extension in this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

13. How easy is it to grasp a key while wearing this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

14. How easy is it to grasp a bottle while wearing this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

15. How easy is it to grasp a ball while wearing this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

16. I think that the activities of daily life such as having a hot drink, moving around the house and personal hygiene can be performed while wearing this glove.

	1	2	3	4	5	6	7	
Strongly Disagree	□	□	□	□	□	□	□	Strongly Agree

17. Please state your thoughts on performing activities of daily life such as having a hot drink, preparing food and personal hygine while wearing this glove?

_____

18. How would you characterise the sensitivity of the joint angle sensors on the glove while playing the game?

	1	2	3	4	5	6	7	
Not Sensitive	□	□	□	□	□	□	□	Very Sensitivity

Repeat Donning and Doffing

Please answer the following questions about donning/doffing again

19. How easy is it to put on (donning) the forearm module of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

20. How easy is it to put on (donning) the hand module of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

21. How easy is it to put on (donning) the fingercaps of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

22. How easy is it to remove the forearm module of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

23. How easy is it to remove the hand module of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

24. How easy is it to remove the fingercaps of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

Aesthetics and perception questionnaire

25. How would you characterise the aesthetic appeal of both gloves?

		1	2	3	4	5	6	7	
WiGlove	Unappealing	□	□	□	□	□	□	□	Appealing
SPO	Unappealing	□	□	□	□	□	□	□	Appealing

26. How would you characterise the safety of both gloves to the user?

		1	2	3	4	5	6	7	
WiGlove	Unappealing	□	□	□	□	□	□	□	Appealing
SPO	Unappealing	□	□	□	□	□	□	□	Appealing

27. How would you characterise the safety of both gloves to the other family members?

		1	2	3	4	5	6	7	
WiGlove	Unappealing	□	□	□	□	□	□	□	Appealing
SPO	Unappealing	□	□	□	□	□	□	□	Appealing

Usability questionnaire

Please try the glove and answer the following questions based on your opinion

1. How easy is it to put on (donning) the forearm module of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

2. How easy is it to put on (donning) the hand module of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

3. How easy is it to put on (donning) the fingercaps of this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

4. How easy is it to perform abduction/adduction of the wrist while wearing this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

5. **How easy is it to perform abduction/adduction of the fingers while wearing this glove?**

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

6. **How would you characterize the weight of this glove?**

	1	2	3	4	5	6	7	
Very Heavy	□	□	□	□	□	□	□	Very Light

7. **How easy is it to remove the forearm module of this glove?**

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

8. **How easy is it to remove the hand module of this glove?**

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

9. **How easy is it to remove the fingercaps of this glove?**

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

10. **How easy is it to grasp a key while wearing this glove?**

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

11. **How easy is it to grasp a bottle while wearing this glove?**

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

12. How easy is it to grasp a ball while wearing this glove?

	1	2	3	4	5	6	7	
Very Difficult	□	□	□	□	□	□	□	Very Easy

13. I think that the activities of daily life such as having a hot drink, moving around the house and personal hygiene can be performed while wearing this glove.

	1	2	3	4	5	6	7	
Strongly Disagree	□	□	□	□	□	□	□	Strongly Agree

14. How would you characterise the sensitivity of the joint angle sensors on the glove while playing the game?

	1	2	3	4	5	6	7	
Not Sensitive	□	□	□	□	□	□	□	Very Sensitivity

Comments

Please add any additional comments regarding the following:

15. Putting on the glove - Donning

16. Removing the glove - Doffing

17. Performing activities of daily life while wearing this glove.

18. Perceived safety of training with this device.

APPENDIX - SUMMATIVE EVALUATION SEMI-STRUCTURED INTERVIEW QUESTIONS

Questions for the participant

1. **What are your thoughts about the Wi glove and the intervention it delivered?**
2. **Did you require any help while using this glove? Could you please explain why?**
3. **Did you feel that the Wi glove-system fit your physical and social environment? Which part of the house did you use feel most comfortable in to use this glove?**
4. **What are your thoughts about exercising with the glove in a familiar place without the presence of your therapist compared to performing this in a clinical setting?**
5. **What everyday activities did you perform while wearing this glove**
6. **Were you satisfied with the sensitivity/responsiveness of the glove while interacting with the tablet?**
7. **What did the members of your family feel about the WiGlove? How did they react to it?**
8. **Was the WiGlove easy to learn? How long did it take to get used to the glove?**
9. **What do you think about the reliability of the system?**
10. **Would you be willing to use the system for a longer period?**
11. **Would you like to add anything else?**

Questions for members of the participant's household

1. **What are your thoughts about the WiGlove and the intervention it delivered?**
2. **Did you feel that the WiGlove-system fit your physical environment.**
3. **Did you feel that the WiGlove-system fit your environment when you have visitors?**
4. **What were your thoughts about training while playing therapeutic games that were given on the tablet?**

5. **Did you need to help the participant in any aspect of using the WiGlove?**
6. **Could you talk about your role in the participant training with the WiGlove?**
7. **What were your expectations about the WiGlove, and did it satisfy them?**
8. **Do you have any other comments for us to improve the WiGlove's design?**

Appendix - Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0)

QUEST
(version 2.0)

1	2	3	4	5
not satisfied at all	not very satisfied	more or less satisfied	quite satisfied	very satisfied

ASSISTIVE DEVICE ***How satisfied are you with,***					
1. the **dimensions** (size, height, length, width) of your assistive device? *Comments*:	1	2	3	4	5
2. the **weight** of your assistive device? *Comments*:	1	2	3	4	5
3. the **ease in adjusting** (fixing, fastening) the parts of your assistive device? *Comments*:	1	2	3	4	5
4. how **safe and secure** your assistive device is? *Comments*:	1	2	3	4	5
5. the **durability** (endurance, resistance to wear) of your assistive device? *Comments*:	1	2	3	4	5
6. how **easy** it is to use your assistive device? *Comments*:	1	2	3	4	5
7. how **comfortable** your assistive device is? *Comments*:	1	2	3	4	5
8. how **effective** your assistive device is (the degree to which your device meets your needs)? *Comments*:	1	2	3	4	5

Appendix - System Usability Scale (SUS)

System Usability Scale (SUS)

Sl. No		Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1	I think that I would like to use the WiGlove frequently.	☐	☐	☐	☐	☐
2	I found the WiGlove unnecessarily complex.	☐	☐	☐	☐	☐
3	I thought the WiGlove was easy to use.	☐	☐	☐	☐	☐
4	I think that I would need the support of a technical person to be able to use the WiGlove.	☐	☐	☐	☐	☐
5	I found the various functions in the WiGlove were well integrated.	☐	☐	☐	☐	☐
6	I thought there was too much inconsistency in the WiGlove.	☐	☐	☐	☐	☐
7	I would imagine that most people would learn to use the WiGlove very quickly.	☐	☐	☐	☐	☐
8	I found the WiGlove very cumbersome to use.	☐	☐	☐	☐	☐
9	I felt very confident using the WiGlove.	☐	☐	☐	☐	☐
10	I needed to learn a lot of things before I could get going with the WiGlove.	☐	☐	☐	☐	☐