Preliminary Results from Functional and Usability Assessment of the WiGlove - a Home-based Robotic Orthosis for Hand and Wrist Therapy after Stroke

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***Abstract*—Robotic orthoses have emerged as a promising tool to provide an opportunity for supporting therapy at home for post-stroke hand and wrist rehabilitation. Despite their benefits, usability issues have hampered the acceptance of such devices. To overcome this, the WiGlove was designed following a user-centred approach that involved user evaluations to validate the prototype in an iterative process. This article presents the methodology and early findings of the WiGlove's first co-design iteration involving functional and usability evaluation by two-stroke survivors. The findings offer initial evidence for meeting the user requirements while identifying areas for improvement to enhance its usability and acceptance. Additionally, the article highlights the challenges encountered in conducting such long-term usability evaluations conducted at stroke survivors' homes.**

***Keywords*—Stroke rehabilitation; Robot-aided rehabilitation; Home-based therapy; Hand-wrist orthosis; user-centred design.**

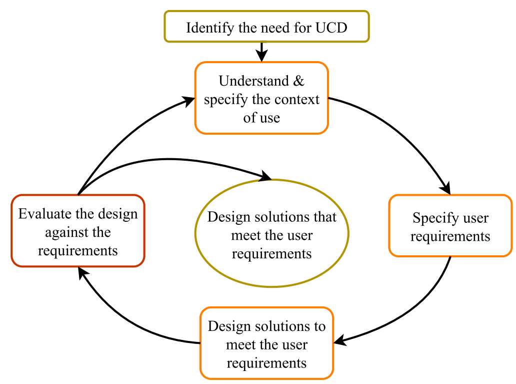

Figure 1. Iterative User-Centred design (ISO 9241-210:2019) [8].

I. INTRODUCTION

Hand impairments in stroke survivors significantly impact their ability to perform the Activities of Daily Life (ADL). With the prevalence of stroke increasing [1], traditional one-to-one therapy lacks scalability and creates excessive demand on the healthcare systems, which can be further exacerbated in periods of extreme pressure as seen during the COVID-19 pandemic. Therefore, home-based rehabilitation approaches with a remote monitoring opportunity by therapists have gained interest in recent years. Robotic devices that allow the user to train at home without any external assistance have the potential to act as valuable instruments to support additional doses of therapy in the comfort of patients' homes. Patients are free to train for as long as needed, whenever they want. Integrating computer games in therapy has the potential to further enhance motivation and adherence to training independently at home [2]. Current solutions for the distal arm segment that provides the aforementioned benefits are typically designed to train either the wrist or fingers separately but not together, disregarding the synergy between these two segments. Given the significance of coordinated use of both segments for several functional tasks such as drinking from a cup or picking up objects, this approach could hinder functional recovery. While there are devices available (Table I) that allow training of both segments simultaneously, usability issues often limit their suitability for independent use in a home environment.

To address this, the following objectives were set for our work:

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.

Fulfilling some of the above (points 1-3), the state-of-the-art SCRIPT Passive Orthosis (SPO) [6] is a wired device, which uses elastic cords to passively assist with flexion/extension exercises of the wrist and fingers. Its sensors allow interaction with therapeutic games on a computer and remote monitoring by therapists. Although it demonstrated the feasibility of such a system, it suffered from various functional and

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TABLE I. ORTHOTIC DEVICES USED FOR THE REHABILITATION OF THE WRIST AND FINGERS TOGETHER

Device Name	Mode of Operation	Assisted DoF	Suitable for home-based	Wireless/ Wired	Interaction with games
Hand Mentor [3]	Active	2 (1 for fingers + 1 for wrist)	The peripherals of the actuation mechanism makes it unsuitable	Wired	No
HWARD [4]	Active	3 (1 for fingers, 1 for thumb, 1 for wrist)	The peripherals of the actuation mechanism makes it unsuitable	Wired	No
SCRIPT Active Orthosis [5]	Passive	6 (1 per finger + 1 for wrist)	Study showed that the bulky size, unsafe and complicated appearance prompted the user's to deem it less suitable [5]	Wired	Yes
SCRIPT Passive Orthosis [6]	Passive	6 (1 per finger + 1 for wrist)	Studies showed that it was suitable home environment [6]	Wired	Yes
[7]	Active	18 (3 per finger + 4 for thumb + 2 for wrist)	Active actuation with multiple motors could lead to potential risk factors and therefore require supervision, complicated and unsafe appearance	Wired	Yes (VR)

usability issues such as time decay of sensors, difficulty with donning/doffing, and tethers that prevent stroke survivors from training while performing ADL [9]. Using the learning from the SPO, the WiGlove advances this state-of-the-art through a User-Centred Design (UCD) approach.

This approach is characterised by an iterative design process (Figure 1) with user evaluation at various stages of development and has been shown to result in enhanced usability and user acceptance [10],[11]. Furthermore, identification of the user requirements and ensuring their fulfilment forms the core of the UCD of medical devices [12]. This paper discusses a similar approach to how the WiGlove's design addresses the user requirements and their validation through functional and usability evaluation with stroke survivors. WiGlove is a wearable, wireless, passive dynamic, robotic orthosis, which allows hemiparetic stroke survivors to train their wrist and fingers independently at their homes.

Beginning with a detailed discussion of the user requirements for an ideal home-based hand rehabilitation device and the different features of the first prototype of WiGlove designed to address them in Section II, this paper presents the evaluation methodology (Section III) and its initial findings (Section IV). It also discusses the challenges involved in conducting an unsupervised, long-term, user evaluation in the homes of participants experiencing motor impairments (Section VI).

II. USER-CENTRED DEVELOPMENT OF WIGLOVE

Firstly, a review of the literature that also included the findings of SCRIPT's focus groups and in-depth interviews[13] were used to compile a list of user requirements (**RQs**) that are broadly classified into functional and usability elements.

A. *Functional requirements*

RQ1: **Adjustable functional assistance.**
Hand impairments in stroke survivors often manifest in the form of hyperflexion that results in a clenched fist and a fully flexed wrist. Shortening and elongation of the flexor and extensor muscles of the hand respectively, which affects the wrist and finger flexion has been observed after long periods of hyperflexion. To offset this the WiGlove (Figure 3) provides assistance with extension using extension springs that passively open the hand allowing them to actively perform flexion exercises against the springs' resistive forces (Figure 2a). Active initiation and movement have been shown to enhance functional recovery [14]. The therapists can choose from a range of springs with different stiffness to ensure optimal assistance and challenge while training. Throughout its operation, the device remains passive, relying on a motorised adjustment mechanism only to allow easy adjustment of the tension controlled with a tablet interface.

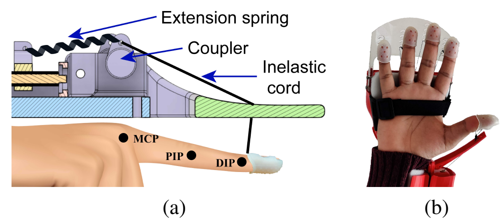

Figure 2. Images showing the extension assistance mechanism and the open palm design of the WiGlove.

RQ2: **Does not hinder any of the natural Range of Motions (RoM) of the joints.**
Although only the joint extension is assisted, 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 torque and flexible interconnection between the forearm and hand modules ensures that ab/adduction of the fingers and the wrist is unrestricted.

RQ3: **Self-aligning centre of rotation (CoR).**
The use of a base-to-distal mechanism where the only point of interaction with the fingers is at the fingertips using inelastic cords eliminates the concern of injury and discomfort due to the misalignment between the device and finger joint axes prevalent in exoskeletal devices.

RQ4: **Measurement of finger and wrist motion.**

The WiGlove measures the flexion angles of the fingers and the wrist to allow the therapists to monitor the progress of training. This is achieved using a potentiometer for each finger and the wrist. 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 are estimated. The analogue output is interpreted using a microcontroller that transmits them via Bluetooth. It also permits playing therapeutic computer games to enhance motivation while capturing performance metrics.

RQ5: **Accommodate different hand dimensions.**
To guarantee comfort, 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 wrist's width using a parametric design approach.

RQ6: **Visual and tactile transparency.**
The WiGlove's open-palm design and silicone fingercaps preserve the user's haptic experience by ensuring that tactile perception is maintained while grasping objects. The finger mechanism's extension structure, which directs the inelastic cord to the fingertips, is constructed of transparent material, providing visual feedback during training. This visual and tactile transparency adds to this sensory stimulation and neural modulation potential.

B. Usability requirements

RQ7: **Ease of donning/doffing.**
SPO's user trials reported that stroke survivors found it difficult to slide their hand through the forearm shell and to pass the velcro straps through loops of the finger caps while donning. To avoid that, elastic straps with hooks are used to don/doff the forearm and hand module of the WiGlove. The inherent elasticity of the silicone fingercaps helps them cling to the fingertips eliminating the need for velcros. This allows users with one unimpaired arm to independently use the device at home with ease.

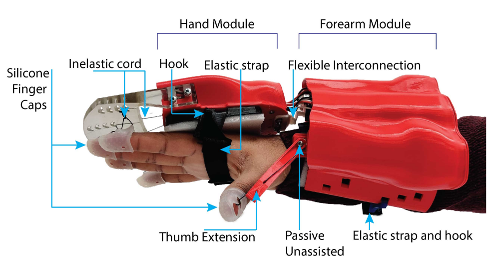

Figure 3. WiGlove.

RQ8: **Safe to use at home.**
Given the absence of a clinician's supervision, the WiGlove's passive operation and design eliminates excessive forces, or any potential pinch points and lack of 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.

RQ9: **Smaller space requirement and increased mobility.**
The WiGlove-tablet system's compact size and wireless operation provide stroke survivors with the flexibility to train in different areas of their homes without being tethered to a computer or power supply. This location flexibility can help provide access on demand, allowing duration and repetition flexibility.

RQ10: **Require relatively less technical proficiency to operate.** The WiGlove has a simple control interface involving two push-button switches one for turning the glove on/off and one for adjusting the tension. Apart from this, it does not require the users to perform any maintenance tasks making it easy to learn and use.

III. Evaluation Methodology

The resulting prototype was subjected to the following technical and usability evaluations to ensure the fulfilment of the above-mentioned user requirements.

A. Evaluation of the functional requirements

The previous section discusses how **RQ1, RQ3, RQ5** and **RQ6** 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.

1) Joint angle sensors: To evaluate the repeatability of the joint angle sensing mechanism, a method akin to the one employed in SCRIPT [9] is used. Repetitions of flexing the fingers to a closed fist followed by an extension to a flat position were performed for 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 = $84\text{mm}\phi$, Medium = $60\text{mm}\phi$, Small = $50\text{mm}\phi$), inline with the dimensions utilised in SCRIPT.

2) Range of Motion: The joints' achievable natural range of motion differs from person to person and depends on the individual's physical characteristics [9]. Since this 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.

B. Evaluation of the usability requirements

The user-centred methodology strives to ensure this is designed into the system through usability evaluations with the end-users in the formative stages [11]. Accordingly, evaluation with physiotherapists with experience in stroke rehabilitation was used to iteratively improve WiGlove's usability [15].

TABLE II. 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.

Subsequently, this section presents a preliminary usability evaluation conducted to validate **RQ8-RQ10** as a part of UCD involving stroke survivors.

Custom-fit WiGloves were provided to two hemiparetic stroke survivors who experienced hand impairments to train at home without the assistance of the therapist. They were also provided a touchscreen tablet that can be used with the WiGlove to play therapeutic games. that Box and Block Test (BBT)[16] and Nine Hole Peg Test (NHPT)[17] were administered at the beginning of the study to record their baseline fine and gross manual dexterity. As evident from the performance in these tests, **participant A** suffered from significant impairments in the arm resulting in a fully flexed wrist and fingers without any voluntary RoM in extension (Table II). Before the participation, his hand therapy was restricted to three five-minute sessions per week with a therapist. On the other hand, the impairments of **participant B** were moderate with a significantly reduced tone allowing him to perform relatively better in the baseline assessments. Although previous therapy involving functional electric stimulation resulted in a reduction in the hand's spasticity, he still suffers from a reduced voluntary RoM in finger and wrist extension. Henceforth, participants A and B are referred to as **pA** and **pB** respectively.

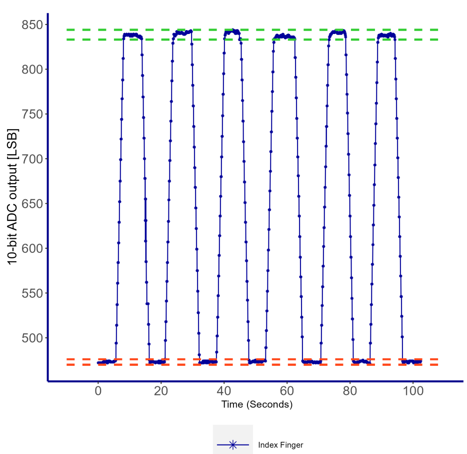

Figure 4. Repeatability of the index finger's joint angle measurements during repetitions of finger flexions (green region) to a closed fist followed by an extension to a flat position (red region).

The various aspects involved in using the device were demonstrated to the participants. They were encouraged to use the glove for exercises, play games on the tablet, or wear the glove while performing ADL. During the first week, both participants required support in the form of specific doubts about the donning method and adjustments of the assistance mechanism beyond which they trained on their own. They were not prescribed an exercise schedule; rather, they were encouraged to train at their convenience. The study was aimed at a duration of 6 weeks with an intermediate assessment at 3 weeks. In line with literature that demonstrated the efficacy of using qualitative assessments to evaluate the usability of orthoses [11], this study used a semi-structured interview with open-ended questions to record the participants' feedback in separate 25-minute sessions evaluating if **RQ8-RQ10** are met. The audio responses during this interview were recorded, transcribed using Microsoft Word's built-in transcription tool and analysed. Additionally, QUEST 2.0 questionnaire [18] and System Usability Scale (SUS) [19], were used to qualitatively evaluate satisfaction with the device. This study serves to demonstrate WiGlove's initial proof-of-concept, paving the way for subsequent large-scale feasibility assessments. Having undertaken measures to ensure participants' safety and privacy, this study was approved by the University's Ethics Committee (Ethics protocol number: aSPECS/ PGR/ UH/ 05084(1)).

IV. RESULTS

A. Technical evaluation

Since the sensing mechanism employed is the same across all fingers, the readings from the index finger's sensor expressed in Lease Significant Bit (LSB) are presented here to demonstrate its repeatability (Figure 4). The standard deviation of the readings at fully flexed and fully extended positions were 1[LSB] and 2[LSB] respectively. Similarly, the results of other repeatability experiments corresponding to the grasping tasks are presented in Table III. With respect to **RQ2**, the measured maximum achievable joint angles with and without the WiGlove are presented in Table IV. The labels "Flex", "Ext", "Abd", "Add" and "P Abd" correspond to Flexion, extension, abduction, adduction and palmar abduction, respectively.

TABLE III. 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

B. Usability evaluation

The results discussed in this manuscript correspond to the data gathered at the end of the first 3 weeks of a 6-week study. **pA** and **pB** offered a SUS rating of 75 and 70 out of 100 respectively and the same QUEST 2.0 score of 3.75 out of 5. These scores reflect a level of satisfaction ranging from "more or less satisfied" to "quite satisfied" on the former scale, and a rating of "OK" to "good" on the SUS scale. Furthermore, Table V presents a summary of the participants' remarks and specific quotes pertaining to the usability requirements from the interview.

TABLE IV. 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°	10°
		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°

V. DISCUSSION

Beginning with the functional requirements, excellent repeatability was observed in the sensor readings without any time decay, presenting marked improvements compared to SPO[9]. However, examining the individual flexion and extension instances reveals 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. The results of the grasping tasks serve to corroborate further the remarkable repeatability of the sensing mechanism, as well as its capacity to differentiate between various grasp sizes. 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 **RQ4**.

Similarly, Table IV 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. These results support that the WiGlove's design satisfies **RQ2**.

The participant's feedback during the interview confirms the safety (**RQ8**) and the general ease of use (**RQ10**) of the WiGlove. They did not encounter any safety issues for the user or the other members of the family in the 3 weeks of use. Furthermore, apart from **pA** requiring a change of size for one of the finger caps in the first week, both participants did not require any technical assistance with its operation.

pB demonstrated the WiGlove's ease of independently donning and doffing. Despite this not being the case with the first participant who experienced severe impairments in the arm, this shows a promising sign towards supporting **RQ7** for moderately impaired hemiparetic stroke survivors. Given that the major obstacle for **pA** was the weakness in the shoulders, in the next stage, we aim to explore the use of arm supports (such as SaeboMAS used with SPO) while doffing for stroke survivors with severe impairments in the proximal joints of the arm. **pB** reported occasional challenges in coordinating the two modules during donning due to the flexible interconnections. He proposed that incorporating a stiffer connecting element would enhance usability. Given the significance of maintaining wrist ab/adduction freedom, further investigation is necessary to strike an optimal balance.

The advantages of the WiGlove's wireless operation were evident as it provided the flexibility of training location, which also extended to the workplace in the case of **pB**. Along with their remarks on its ease of storage, both participants validated **RQ9**. Unlike **pA**, whose mobility was restricted, we anticipated that the WiGlove's location flexibility would allow **pB** to train while performing ADL. Despite it allowing him to grasp different everyday objects such as a cup, TV remote, key, etc., **pB** was restricted by the limited RoM with forearm pronation. Furthermore, we identified that the extension structure was a hindrance while picking small objects from a flat surface. This will be addressed in future design iteration through custom length extension that does not come in the way.

VI. CHALLENGES

Considering the advantages of user evaluations in the User-Centred Design (UCD) process, this study's long-term duration and home-based nature present unique challenges. Compounded by the participants' motor function impairments, this section discusses the challenges encountered in conducting this study.

It was observed that the unsupervised nature of the training resulted in the participants developing distinct practices based on individual comfort levels concerning donning and doffing methods, training duration, and other factors. While this can be seen as a positive feature, such inter-individual variability precludes straightforward comparisons of behaviour between participants. Similar variability in users' behaviours prompted the researchers to not follow specific task completion protocols in a user evaluation of a tele-manipulated echo device in a clinical setting [10] which supports our study's similar approach.

In the case of **pB**, he was also undergoing functional electrical stimulation therapy concurrent to participating in this study. While this precludes a direct evaluation of the efficacy of the intervention utilising the device, withholding secondary therapy poses an ethical dilemma by potentially depriving the participant of beneficial treatment. Additionally, prior exposure to different devices and techniques could introduce a unique bias in their feedback (**pB**) compared to other participants. Therefore, the variability introduced by such factors necessitates the analysis of each participant's feedback and performance as individual case studies.

Given that the study is being conducted within the homes of stroke survivors, the influence of other family members cannot be disregarded. Our observations indicate that, in both cases, spousal encouragement was reported to significantly

TABLE V. SUMMARY OF THE PARTICIPANTS' FEEDBACK ON THE WIGLOVE'S USABILITY

Requirement	Participant A	Participant B
RQ7	Unable to independently don and required assistance due to excessive tone in the shoulders. But was able to doff. "**Ease to remove finger caps and fore arm**"	Was able to independently don/doff. "**it takes in a few sessions for me to wear it, So now like I'm doing it by myself, I don't need anyone's help.**"
RQ8	Did not perceive any safety issues	Did not perceive any safety issues "**there is no safety issues and it has small battery in the glove which is charged. There are no safety concerns.**"
RQ9	Found it easy to store and train at different parts of the house. "**When kids are coming, its not a problem hiding it**"	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**", ""
RQ10	Perceived it to be straightforward and easy to use.	Had some difficulty with donning the hand module in the beginning but otherwise found it easy to use

enhance participant adherence to training as demonstrated by the quote below. Therefore, it is crucial to consider this aspect and its impact on the intervention while assessing participant engagement at the end of the study's duration.

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*"

VII. CONCLUSION AND FUTURE WORK

This paper presents the design methodology for WiGlove as a home-based passive dynamic orthosis used for post-stroke rehabilitation of the hand and wrist. Part of a user-centred design approach, this study performed a combination of laboratory-based technical evaluation and a 6-week home-based usability evaluation involving two hemiparetic stroke survivors. The early findings provide promising evidence towards the fulfilment of the user requirements and helped to identify potential areas of improvement to be addressed in the next iteration of this UCD process. Although promising, these findings should be interpreted with caution as these correspond to the first 3 weeks of a 6-week study and only involved two stroke patients. The results from the complete duration of the study will be used to further improve its design and provide evidence to support further user evaluation involving a larger number of participants with varying levels of impairments. Furthermore, this paper also reports on the unique challenges posed by the unsupervised and long-term nature of the study for the consideration and discussion of the greater research community.

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