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Usability Test of a Smart Textile for Upper-Limb Rehabilitation in Patients with Neurological Diseases

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Abstract

Purpose: (1) To develop a smart jacket with sensors embedded in the sleeve that monitors the upper limb movement through a User Centered Design (UCD) process and (2) to assess by means of a Usability Test whether this tool can be used in upper limb rehabilitation of people with neurological diseases such as spinal cord injuries or strokes.

Methods: 32 participants (aged 25-65), 16 patients with neurological diseases and 16 experts were included in the UCD process for two years of development divided in three parts: (i) focus group, (ii) pilot test and (iii) evaluation of the product, which contains the usability test (UT). During UT the participants performed 10 actions wearing the jacket and assessed it by filling out usability questionnaire with 11 questions that answer eight usability items (satisfaction, effectiveness, easiness of use, safety, comfort, usability, aesthetics and feedback).

Results: User's scores about satisfaction, effectiveness, easiness of use and safety were above 4.5, comfort and usability above 4.0. Expert's scores about satisfaction, usability, effectiveness were below 4.0. Safety, comfort and easiness of use remained above 4. In both groups, aesthetics were the worst rated with a score less than 4.0. Feedback could not be assessed because it was not operational.

Conclusion: Based on inputs, the device showed to be tool for the upper limb rehabilitation because it monitors the patients' movements, it provides a feedback and it collects data for the therapist. However, several aspects such as feedback and aesthetics need to be addressed to improve its usability.

Keywords: Usability test; Smart textiles; Neurorehabilitation; Stroke; Spinal-cord injuries; Traumatic brain injuries; Upper-limb rehabilitation

Introduction

To recover upper extremity both movement and function is a serious challenge in rehabilitation for patients with upper limb dysfunction due to a neurological disease that includes brain injury (BI) such as stroke or traumatic brain injury and spinal cord injury (SCI). The goal of rehabilitation of such patients is to recover lost functions or at least preserve remaining functions to allow autonomy in activities of daily living (ADL's) [1]. Thus, individuals that have sustained stroke or spinal cord injuries will require intensive rehabilitation and several sessions with the physiotherapist or occupational therapist [2,3]. Recent advances in the technology have led to the development of smart textiles that can monitor rehabilitation activities and provide feedback of the therapy and/or of the daily life activities [4].

Smart fabrics are defined as textiles with electrical components [5,6]. These products interact with the environment [7] and can improve the efficiency of the exercise and the compliance of the therapy, because they allow adapting the rehabilitation in real time thank to feedback. Additionally, monitoring the rehabilitation progress introduces the possibility of developing and following up therapeutic programs while providing objective data [8]. This technology will give new insides into rehabilitation and will support clinical decision making in evidence-based rehabilitation.

Hence, in this paper we present a wearable smart textile that has been designed to be a tool for monitoring the upper limb during the rehabilitation or in de ADL's in people with neurological diseases by monitoring the movement of the different upper-limb joints (shoulder, elbow and wrist). Design and development process of a product have to be iterative and user-centered, to address the end-users requirements to increase usability and the acceptability [9-11]. For that reason, the smart textile was designed following a User Centered Design (UCD) process and this was started by both Institut Guttmann and Eurecat. The development process of the device was divided in three parts: (i) Focus Group, (ii) Pilot Test and (iii) Evaluation of the

product that contained two different phases: the first, heuristic evaluation (HE) performed by experienced health professionals such as occupational therapist and physiotherapists and the second, usability test with real users (EU) performed by subjects with neurological disease and upper limb affectation.

The main goals of this study were (1) the development of the device following the UCD process and then evaluate the outcome in terms of usability and end-user satisfaction, (2) testing whether it can be useful in the rehabilitation of the upper limb motor function in people with spinal cord injury and/or stroke/traumatic brain injury with upper-limb dysfunction.

Materials and Method

Smart textile

The smart textile hereafter called Sensing Sleeve (SenS) is a jacket that monitors the upper limb movements in real time and provides a feedback to the user/therapist.

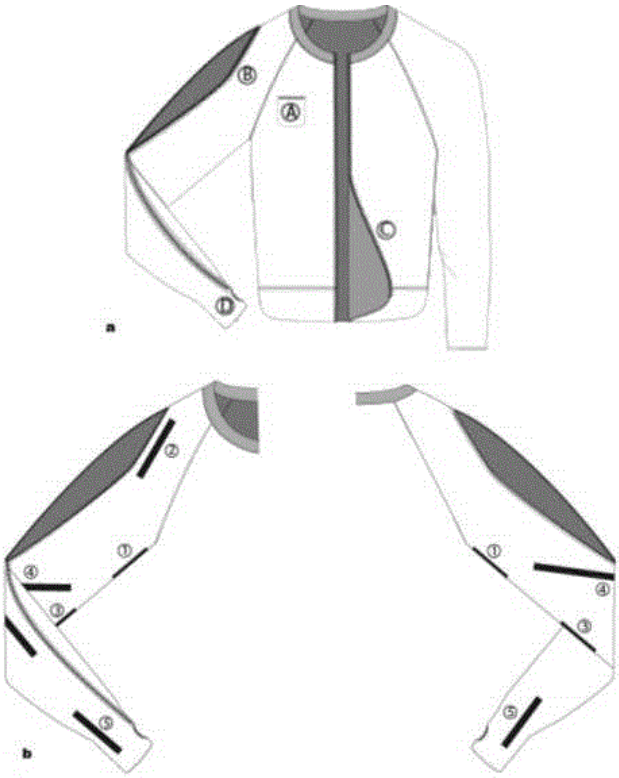

Figure 1: Depicting a) First prototype: [A] Electronic pocket (Battery); [B] and [C] Zippers; [D] Hole thumb. (b) System sensors. Front and back.

Design requirements: The SenS first prototype (Figure 1) was designed in order to meet initial requirements gathered after an analysis of the state of the art, the analysis of the users, their environment and the clinical opinions. The initial requirements were (i) the system has to monitor joints and movements of the upper extremity (ii) the system has to be wearable, light and comfortable (iii) the system has to be elastic, easy to put on/take off, wireless and washable, (iv) The system has to be safe and easy to use for both end users and clinicians. SenS second prototype was modified by participants' feedback of the first usability test.

System description and characteristics: SenS is a tight, plain knit and stretched jacket, 90% of Polyamide and 10% of Elastane that provide breathability and comfort. Five sets of sensors are embedded into the textile surface of the sleeve that sends data through Bluetooth to an external device (smartphone or pc). The weight of the sleeve is 155 gr. These five sets monitor each degree of freedom (Figure 1). The piece is double bottom with different layout of parts in the inner and outer sheet sensors due to the distribution of the forearm pronation and supination sensors (offsite and opposites). All sensors are in the outer face of the sleeve except for forearm pronation, which is found inside.

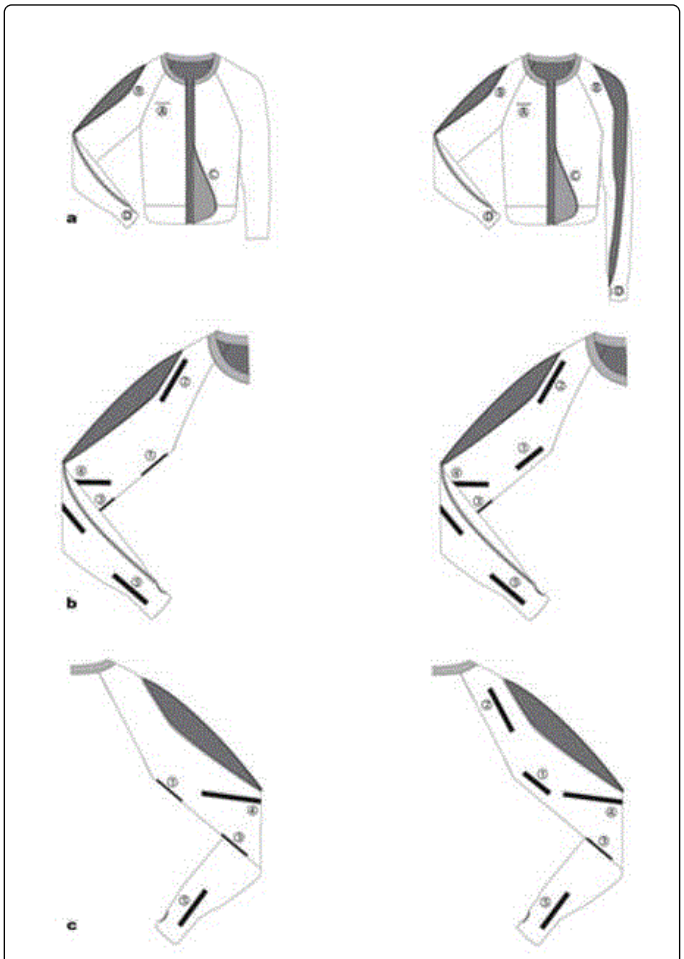

Figure 2: Depicting modifications: (a) Asymmetrical sleeves to symmetrical sleeves with zip, (b) Set of sensors associated to shoulder flex/ext.

Feedback: The software provides a visual feedback in real time. In the first version; the feedback was represented by color bars that represent the intensity and the direction of the movements' joints. In the second prototype the feedback was represented by the same color bars and an avatar mimicking the movements of the different degrees of freedom of each joint (Figure 2). The software also recorded sessions for later analysis.

Experimental equipment: Additionally to the SenS: A test station (pc, table, chair and screen) was used, and to assess usability participants had to fill out questionnaires. Different objects such as glass and key.

User centered design/usability test

UCD is the process of designing a usable and safe product influenced by the users' needs, wants, requirements, abilities and limitations. The process involves users throughout the design and development process and it is iterative («ISO 9241-210:2010(en), Ergonomics of human-system interaction-Part 210: Human-centred design for interactive systems», s. f.) [12]. According to ISO 9241-210:2010 the UCD process consists of three main stages that are repeated until a user-adapted product can be released: (i) specification of user requirements; (ii) production of design solutions to meet user requirements; (iii) evaluation of the design solutions versus user requirements by means of a usability test («ISO/NP 9241-11-Ergonomics of human-system interaction-Part 11: Usability: Definitions and concepts», s. f.) [13].

Participants of the evaluation

A total of 32 participants (mean age=40; age range=25÷65; 17 female) were included in the evaluation. The participants were 16 professionals (mean age=36, 31; age range=25÷57; 12 male) from the Institut Guttmann, with different backgrounds (i.e., physiotherapy and occupational therapy, that were not involved in the focus group and pilot test explained later), named Experts and 16 patients (mean age=43.63; age range=27÷65; 5 female) from Institut Guttmann with SCI or BI named End-users (Table 1), whom were recruited according to the following inclusion criteria: (i) reduced mobility on the upper limb due to neurological disease (ii) at least 3 months after injury (iii) over age of 18 (iv) a written informed consent, stating that they voluntary agreed to participate in the study; and to the following exclusion criteria: (i) spasticity>3 on Ashworth scale, (ii) <6 on Level of Cognitive Functioning Scale, (iii) skin injuries or fractures on the upper limb, (iv) allergy to textile components, (v) other medical restrictions that not allow to perform the test. The study was approved by the Local Ethics Committee of the Institut Guttmann.

Characteristics	Round 1	Round 2
Experts		
Gender		
Male	2	2
Female	6	6
Total	8	8
Mean Age	37,13	35,50
End-Users		
Gender		
Male	5	6
Female	3	2
Total	8	8
Mean Age	43,63	43,63
Pathology		
Stroke	2	4
TBI	2	1
SCI C c	1	0
SCI L i	1	0
SCI C i	2	1
Other	0	2

Table 1: Participant characteristics, TBI (Traumatic Brain Injury); SCI (Spinal Cord Injury); C (Cervical); L (Lumbar); c (Complete).

Study design

The study consisted of three stages: (i) Focus group, (ii) Pilot Test; (iii) Evaluation by means of a usability test.

Focus group

Three engineers from Eurecat and four clinics (physiotherapists and occupational therapists) from the IG participated in the meetings to give their opinions, ideas and experiences. The discussions in the focus group addressed the motivation of patients and their needs, the patients' requirements, potential patients' profile (inclusion and exclusion criteria) and the potential context of use. Additionally, patients' needs were analyzed and the work plan for the usability test was defined.

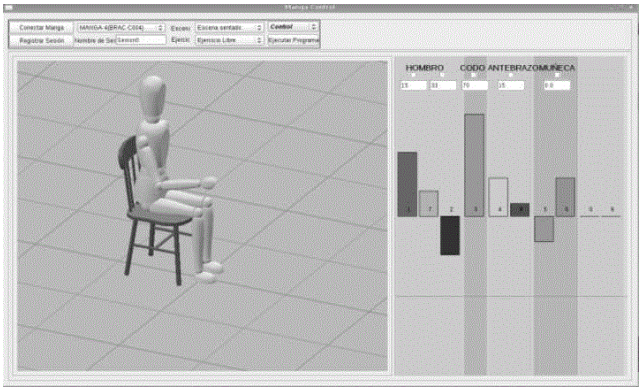

Figure 3: Depicting visual feedback of the prototype, on the right side of the window the color bars that show the movements, on the left side the avatar shows the arm movement.

Pilot test

In the pilot test the clinicians of the Institut Guttmann tested the first version of the SenS in order to know whether it achieves all the requirements and whether it was save to test it in patients. Also, the pilot test was useful to test the usability test for the next step.

Evaluation

Once the first version was ready, the usability test was carried out in the IG. The evaluation was divided in two phases: the heuristic

evaluation (HE) made by experienced health professionals (experts in rehabilitation) and the usability test with end-users (EU) (patients with ND and upper limb dysfunction). Both phases were performed two times, divided by one year of development of the device Each phase contain a 35 minutes long sessions for each participant which included a short introduction about the test and the execution of the 10 actions wearing the SenS (Figure 3). At the end of each session questionnaires different for experts and for end-users were filled by the participants. All sessions were supervised by technicians who guaranteed the correct functioning of the SenS.

Heuristic evaluation

During the HE phase the experts wore the SenS and performed 10 different arm movements (see section E). Each movement was performed six times, 3 quick and 3 normal, in order to know if the sensors are able to detect the movement with both velocities.

End-users usability uest (EU)

In this phase the SenS was tested by end-users with neurological diseases. Users performed the same arm movements but only three times with their preferred velocity to avoid fatigue.

Arm movements and activities of daily living

Ten different movements were chosen to assess the SenS functionality. These movements were divided in two categories: (A) arm movements that include (1) shoulder flexion/extension, (2) shoulder rotation, (3) shoulder abduction/adduction, (4) wrist flexion/extension, (5) Elbow flexion/extension, (6) forearm prono-supination, and (B) actions typically performed in basic ADLs. These were selected according to different experts' opinion. These actions were: (7) drink with a cup, (8) place an object to a higher place, (9) brushing the hair and (10) use a key. During each session the correct performance of the movements were supervised by a therapist.

Questionnaires

Questionnaires were adapted from other usability test called SUS [14] that we modified it to be more understandable for patients and easy to fill it for all. The Expert's Questionnaire was a short battery of questions for the experts and the end-users questionnaire was a battery of easy and short questions to be answered by end users with neurological disorders without the assistance from a third person.

Both questionnaires had 11 questions (in the first round only 10 were used hence aesthetic aspects were not considered), that were classified into eight categories (i.e., comfort, easiness of use, safety, usability, satisfaction, feedback, effectiveness and aesthetic) in the Expert Questionnaire and seven (all except feedback) in the End-User Questionnaire (Annexure). Each questionnaire had an extra part of open questions to pick, according to them, what were both the best and the worst aspects of the SenS.

All questions were ranked by a 6-point Likert scale [15] because it forces to respondents to choose a positive or negative option. Due to the 5 options, a score of 2.5 was chosen as the sufficiency threshold. Scores were presented in the table 2 by the mean (MS) and the standard deviation (SD).

Results and Discussion

In total, 32 subjects participated in the evaluation. Table 2 summarizes the mean score (MS) and standard deviation (SD) for both questionnaires in each round.

Expert (Heurisctic evaluation)					End-user				
	HE1		HE2			EU1		EU2	
Items	N	Mean (SD)	N	Mean (SD)	Items	N	Mean (SD)	N	Mean (SD)
Satisfaction					Satisfaction				
I1	7	3.71 (0.76)	8	3.50 (1.31)	I1	8	4.50 (0.53)	8	4.50 (0.53)
Comfort					Comfort				
I2	8	4.00 (0.76)	8	4.00 (1.41)	I2	8	4.50 (0.53)	8	4.38 (0.52)
I3	8	3.75 (0.46)	8	3.75 (0.71)	I3	8	4.38 (0.74)	8	4.38 (0.52)
Effectiveness					Effectiveness				
I4	7	3.38 (1.34)	8	3.75 (0.89)	I4	7	4.57 (0.53)	8	4.25 (0.89)
I8	8	4.13 (0.64)	8	4.50 (0.76)	I8	8	4.63 (0.52)	8	4.88 (0.35)
Easiness of use					Easiness of use				
I5	8	4.13 (0.64)	8	4.13 (0.83)	I5	8	4.63 (0.52)	8	4.63 (0.52)
I6	8	4.29 (0.49)	8	4.50 (0.55)	I6	8	4.50 (0.53)	8	4.63 (0.52)
Safety					Safety				
I7	8	4.00 (0.58)	7	4.43 (0.53)	I7	8	4.63 (0.52)	8	4.13 (0.99)
Usability					Usability				

I9	8	3.38 (0.92)	8	4.38 (0.52)	I9	8	4.50 (0.76)	8	3.63 (2.00)
Feedback					I10	8	4.13 (1.13)	8	3.88 (1.73)
I10	0		0		Esthetic				
Esthetic					I11	0		8	3.63 (1.06)
I11	0		8	3.19 (0.98)					

Table 2: Results of the two rounds (first and second) of the expert questionnaire and end-user questionnaire.

First round

A total of 16 participants tested the SenS, eight in each phase.

Heuristic evaluation 1 (HE1)

XQ scores showed that in general the SenS has a good acceptation since all the answers were above the sufficiency threshold. In terms of satisfaction and comfort the experts were satisfied with the SenS (Q1; MS: 3.71; Q2, MS: 4.00). The dimensions, material and composition of the SenS seemed to be good enough (Q3, MS: 3.75). Additionally, experts felt that SenS allowed moving the upper limb without restrictions (Q8, MS: 4.11). The system was easy to use (Q5, MS: 4.13), easy to understand and to remember (Q6, MS: 4.25). According to experts' opinion, this version of the SenS was not ready enough to be a tool for the rehabilitation of the upper limb and it would need some modifications (Q4 and Q9; MS: 3.38 and 3.38). Finally, at R1, feedback was not configured yet and therefore scores could not be given (Q10, MS: N/V).

End-user 1 (EU1)

Main results of the UQ showed a good acceptability in this new product. End-users appreciated the SenS in specific terms of satisfaction and comfort (Q1; Q2; Q3 and MS: 4.50, 4.50 and 4.38 respectively). For them, the SenS was easy to use and their instructions were easy to understand and remember (Q5 and Q6, MS 4.63 and 4.50 respectively). The patients felt save when using the SenS. (Q7; MS: 4.57). Users opined that they could normally perform all the activities with the SenS (Q8; MS: 4.63) and it could be an effective tool for the rehabilitation of the upper limb (Q4, MS: 4.57). Finally, they opined that they would like to do some rehabilitation with the SenS either in the hospital or at home (Q9 and Q10: MS 4.50 and 4.13, respectively).

Second round

A total of 16 participants participated, eight at HE2 and eight EU.

Heuristic evaluation 2 (HE2)

In this round, the general acceptation and satisfaction of the SenS was similar to the HE1 (Q1; MS: 3.50.). In HE_R1, the general comfort (Q2, MS: 4.00), the dimensions, material and the composition (Q3, MS: 3.75) and easiness of use (Q5, MS: 4.13) showed no changes with respect to HE_R1. However safety score (Q7, MS: 4.43) was higher. This version of the system was more easy to use, understand and remember (Q6, MS: 4.50) than the previous one. According to experts' opinion, this new version of the SenS was better, and allowed moving the upper limb without restrictions little bit better if compared to HE1 (Q8, MS: 4.50), however experts kept on scoring low its applicability as a tool for the rehabilitation both at hospital and home (Q4 and Q9; MS: 3.75 and 4.38). As it happened in the previous round, both the interface and the feedback were not accurate enough and thus the experts did not answer the question (Q10, MS: N/V). Aesthetically, experts agreed that the SenS was fashionable (Q11, MS: 4.00).

End-user 2 (EU2)

In the EU2, users expressed the same good acceptation as the EU1 in specific terms of satisfaction and comfort (Q1 and Q3 and MS: 4.50 and 4.38 respectively), however, with respect to comfort the score was lower (Q2, MS: 4.38). Regarding efficacy, end users believed that SenS could be could be an efficient tool for rehabilitation, nevertheless the score was lower than the previous round (Q4, MS: 4.25). The SenS was easy to use and their instructions were easy to understand and to remember (Q5 and Q6, MS 4.63 and 4.63 respectively). The patients felt safe when using the device; however the score was lower than the previous round. (Q7; MS: 4.13). Users opined that they could still perform normal arm movements with the sleeve (Q8; MS: 4.88). Despite the score of the Q9 and Q10 were above the threshold, this time the users scores were lower than the EU1 (Q9 and Q10: MS 3.63 and 3.88 respectively). Regarding the aesthetic aspect, they opined that is fashionable enough (Q11; MS: 3.63).

Conclusion

The purpose of this study was first, to evaluate the smart textile, in terms of usability and end-user satisfaction during a UCD process and second, to determine whether the SenS can be an useful tool in the rehabilitation of the upper-limb motor function in people with neurological diseases.

The smart textile is a rehabilitation tool that could provide valuable objective data of rehabilitation process, as well as, it provides feedback for the patients during rehabilitation. However, these kinds of approaches are still new and they have little scientific evidence. Recent review found only 20 studies with intelligent fabrics and neurological diseases [5] and only one of the 20 studies tested the fabric in patients with neurological diseases [16] with a good acceptance. McLaren et al., in their review, conclude that this kind of technology could be helpful for neurological rehabilitation and could have the ability to measure gross movement [5]. However, nowadays there is no substantial evidence to support the use of e-textiles in neurological rehabilitation. As a rehabilitation tool, our results of the SenS obtained significant good scores and acceptation.

During the evaluation we collected feedback from both users and experts. The most commented point by the experts in both rounds was the difficulty of donning and doffing the jacket as well as its proper adjustment due to spasticity of the upper limb. Some experts experienced the donning of the SenS first version as difficult and as

well as doffing it. This was due to the fact that it had asymmetrical sleeves, meaning that one of the sleeves (the one with sensors) had a zipper that enabled to don and doff the SenS easily; whereas the other sleeve was normal and that hindered the action. For this reason the experts from Eurecat together with experts from IG decided to change the design, in a way that the second prototype had symmetrical sleeves (both sleeves with arm zipper).

Despite of the changes is still difficult to donning the device without help. Regarding to the general satisfaction both, patients and experts were satisfied. The device showed to be a good tool for rehabilitation; hence it measures objectively the movement of the patient's upper limb and collects all data to be analyzed by the therapist. However, comments showed that the SenS should monitor and interpret with more precision the patients' movements. For this reason, between rounds, Eurecat modified the sensors format in order to improve the sensibility of the smart textile.

With respect to the feedback, both experts and end-users, found it difficult to understand and follow in the first round, because it was represented only by color bars as it explained before. For that, in the second round of the SenS the feedback was an avatar that mimicking the user's movement. Regarding to the participant's comments, this representation of feedback was better understood than the previous one; however the accuracy of the movements between the sleeve and the avatar movements were not precise enough. This accuracy depends on the textile sensor, which requires individually calibration for little differences of arm lengths and shapes. The same problem happened in the Tognetti's prototype [17] there were a lack of synchronization between the prototype and the avatar. Further resources and more interaction between engineers and clinicians are needed to agree on feedback more clinically valuable. According the results, the smart textile seemed easy to use however it could not be assessed it integrated to the software because it was not configured.

Patient safety is one of our most important goals; the SenS was designed in the safest way possible. Participants 'scores showed that they felt safety using the smart textile.

According to both experts and end user scores, aesthetically, the device seemed modern and fashionable; however an expert suggested designing it in neoprene. We had already considered this material; however it was discarded because neoprene is not as elastic as the polyamide, so it would make difficult the process of donning and doffing the device. In addition, neoprene is significant less breathable and comfortable compared to polyamide, which would have an impact on usability. When asked by usage of this technology, end users think that this technology has the potential to help improving the rehabilitation during the hospital stance and even at home.

In conclusion, developing a smart textile following the UCD process guarantee that it will meet in the users 'requirements and this increase the acceptability of the device. These smart technologies have the potential to be a usable tool for upper limb rehabilitation, although, some aspects such the feedback, wearability and aesthetic need to be addressed in order to improve the usability. Further tests with both patients and clinicians are needed to improve and integrate these new technologies to clinical daily practice.

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Disclosure Statement

The authors do not have any financial or personal relationship with other persons or organizations that could inappropriately influence the work presented here.

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