

## **End-user and clinician perspectives on the viability of wearable functional electrical stimulation garments after stroke and spinal cord injury**

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## **Biographical notes:**

Bastien Moineau has been a postdoctoral fellow in the Rehabilitation Engineering Laboratory (KITE, Toronto Rehabilitation Institute – University Health Network), under the supervision of Prof. Milos R. Popovic, since January 2016. His focus is the development of efficient intervention for individuals with spinal cord injury and stroke, through use of functional electrical stimulation. As a trained caregiver, he is particularly sensitive to the health-related quality of life and wish to bring to end-users solutions that can positively affect their functional abilities and independence. As a physiotherapist with a Ph.D. degree, his goal is to bridge the gap between patients' needs, latest research discoveries, and industry. In February 2019, he joined Myant Inc as a post-doctoral fellow of the University of Toronto and an intern of the MITACS program.

Saima Ali is an MASc Candidate in Biomedical Engineering at the University of Toronto, Canada. She previously completed her BSc in Engineering Science, Robotics Engineering Major, also at the University of Toronto. Her interests are in integrating engineering principles with rehabilitative technologies and identifying considerations for clinical translation of engineered healthcare systems and devices. Her goal is to contribute to a field that allows rehabilitation to become more efficient, effective, and easy-to-use, using concepts such as computer vision, machine learning, and neuromodulation. She is excited about the potentialities that the current computing power and large datasets offer, providing opportunities to design intelligent systems that support and augment the abilities of healthcare professionals.

Matthew Myers graduated from the University of Toronto with a degree in mechanical engineering in 2016. Currently, he is a Master's student with the Institute of Biomaterials and Biomedical Engineering at the University of Toronto, under the supervision of Dr. Milos R. Popovic. His research interests include neural interfacing, biosignal processing, and rehabilitative and assistive technology.

Milos R. Popovic is the Director of the KITE Research Institute at the Toronto Rehabilitation Institute - University Health Network. He is also a Professor (Tenured) in the Institute of Biomaterials and Biomedical Engineering at the University of Toronto. Dr. Popovic is a Fellow of the Canadian Academy of Engineering and a Fellow of the American Institute of Medical and Biological Engineering. He is the co-founder and director of (i) MyndTec; (ii) the CentRe for Advancing Neurotechnological Innovation to Application (CRANIA); (iii) the CRANIA Neuromodulation Institute at the University of Toronto; and (iv) the Canadian Spinal Cord Injury Rehabilitation Association. Dr. Popovic is also the founder of the Rehabilitation Engineering Laboratory at KITE - University Health Network and the FabrIc Based REsearch Platform (FIBRE). Dr. Popovic held the Toronto Rehab Chair in Spinal Cord Injury Research appointment from 2007 until 2017.

Sander L. Hitzig is a Scientist at St. John's Rehab Research Program at Sunnybrook Research Institute and an assistant professor in the Department of Occupational Science and Occupational Therapy and the Rehabilitation Sciences Institute at the University of Toronto. Dr. Hitzig uses both quantitative and qualitative methods to examine issues associated with aging with a disability, assessing the impact of primary impairments and secondary health conditions on quality of life, and identifying factors that promote health and well-being in the community.

## **Abstract**

### **Purpose**

Functional electrical stimulation (FES), through repetitive training (FES-therapy) or continuous assistance (neuro-prosthesis), can restore motor function after paralysis due to spinal cord injury or stroke. With current technology, patients are often incapable of independently applying FES, thereby limiting its use. Novel FES-garments with embedded stimulation electrodes were developed in collaboration with Myant, Canada, to address this problem. The purpose of this study was to collect the views of future end-users to inform the refinement of the device design and to obtain insights on subsequent commercialization of this rehabilitation and assistive technology.

### **Methods**

A qualitative study was undertaken to determine the needs of potential users (patients and clinicians; N=19). Participant took part in interviews or focus groups after a presentation of the garments. An inductive content analysis was used to generate the themes from the data and identify data saturation.

### **Results**

The identified themes and sub-themes were: 1) User Perspectives: users' characteristics (needs, limitations), expected benefits (beliefs), and anticipated problems (fears); 2) Device Design: technical features, usability, and disadvantages of the garment, cables, stimulator, software, and interface; 3) Acquisition Process: organizational procedures (acquisition and adoption steps); and 4) Business Model: financial and strategic aspects to facilitate commercialization and support users.

### **Conclusions**

The insights obtained from end-users and clinicians provide guidelines to optimise the development of novel FES-garments, and strategies for bringing the device to the market. The themes identified can serve to inform other rehabilitation and assistive technology developers with processes and ideas on how to meet these groups' needs.

**Keywords:** Design requirements, User-Centred Design, Focus Group, Electrical Stimulation, Neurorehabilitation, Stroke, Spinal Cord Injury

### **Implications for rehabilitation:**

- Participants with neurological paralysis have interest and critical views on new rehabilitation and assistive technology, and the repercussions of using new technologies to address their function, health and wellbeing.
- The FES-garment design presented appeared acceptable to the end-users, pending resolution of certain shortcomings (wiring, operating duration, robustness, easiness to don and doff).
- End-users and clinicians had specific views regarding the acquisition process of new technologies (training, customization, and follow-up/support), which are important to take into consideration to ensure broad stakeholders uptake.

## **Lay abstract (not part of the accepted publication)**

*A new technology has been made to help people who have paralysis, that is, clothing with textile patches that can deliver electricity on the skin (stimulation) to make the muscles underneath contract. This type of stimulation has been used for decades for retraining and/or assisting people with paralysis, but using sticky gel electrodes that have inconvenient (such as being difficult to put by yourself if you have paralysis in your hand(s)).*

*Researchers wanted to know what people who live with paralysis and rehabilitation professionals think about these stimulation clothing, and how it should be used and sold.*

*One-on-one and group discussions have been recorded with a microphone, and then typed on a computer. Four researchers worked on the typed texts of the discussions to identify the topics discussed, and group them by themes. Researchers followed a research method that prevents them from interpreting what has been said based on pre-defined ideas or personal bias.*

*In total, nineteen persons took part in the discussions (11 persons with paralysis, 6 rehabilitation therapists, and 2 caregivers). No more participants were invited for discussions because the last 2 discussions recorded were essentially saying the same thing as what was said and identified before.*

*Four main themes were discussed by the study participants:*

- 1) What people said about themselves (their needs, beliefs, and concerns).*
- 2) What people thought of these stimulation clothing (what it should do, how to make them easy to use, the problems they may have).*
- 3) What the best organization should be to bring these stimulation clothing in people's hands (talk to their doctor to decide if they should get them, work with a therapist to make them well and learn how to use it, have follow-up and support after)*
- 4) What people thought the company who makes the stimulation clothing should do to succeed at selling them (affordable price, realistic advertisement, convince insurances to cover it).*

*What has been learned in this study is going to help researchers and workers make these stimulation clothing in a way that works best for people with paralysis and their therapists and caregivers.*

## **Introduction**

Individuals who have experienced spinal cord injury (SCI) or stroke may deal with a variety of motor disabilities due to paralysis of the upper-limb(s), trunk, and/or lower-limb(s). Less than 1% of patients with SCI have a total recovery [1]. A third of stroke survivors are unable to walk independently at the chronic stage [2] and two thirds of stroke survivors have limited arm function [3]. This impacts their functional capabilities (standing, walking, self-care, object manipulation) [4] and participation in activities of daily living (house-keeping, leisure activities, work) [5].

It is well-established that rehabilitation enhances neurological and functional recovery after SCI [6–9] and stroke [10–12]. Among the existing modalities to augment rehabilitation is functional electrical stimulation (FES) [13,14], a therapeutic technique that produces movements to stimulate recovery. FES has been shown to provide benefits for improving voluntary command, muscle and bone composition, and function after SCI [15–19] and stroke [20–24]. Conventionally, FES-therapy is administered via adhesive disposable gel electrodes secured with adhesive tape or wrap. This setup requires knowledge of where to place the electrodes and bimanual dexterity, which is limited in most individuals with paralysis due to SCI or stroke. Thus, FES-therapy cannot be applied independently and is limited to a clinical setting. Moreover, the lack of feasible home- or community-based FES interventions deters physical therapists from using FES [25].

FES is also used as an assistive technology [26]. Unlike FES-therapy, assistive-FES requires wearing a device during the execution of daily-living activities such as grasping [27] or walking [28]. The available commercial solutions are characterized by their relative bulkiness while lacking versatility [29], which hinders adoption and function and call for the development of new assistive devices that would benefit a wide range of needs [30].



**Figure 1:** Functional electrical stimulation garment prototypes for lower-limbs and upper-limbs motor rehabilitation.

To facilitate use of FES by both patients and clinicians, new solutions are desired [31]. Our team developed wearable FES-garments (i.e., shirts and stockings embedded with fabric electrodes and wires; Figure 1 [32]) that demonstrate potential for bridging this clinical gap [33,34]. The garment prototypes are form-fitting, elastic clothing with conductive electrodes woven seamlessly into the fabric. The electrodes are positioned such that specific muscles are targeted, with the caveat that the electrodes must be sufficiently moist (e.g. with the addition of tap water) to ensure consistent electrical contact. Initial prototypes have been tested in able-bodied individuals [32,33], and customised prototypes are presently under clinical testing with neurologically impaired participants [34] (clinicaltrials.gov: NCT03658798).

The proposed solution requires the feedback of end-users to optimise its design and enable future commercialization. Knowing the attitudes and needs of end-users is critical to generate appropriate designs early in the development process of assistive technology [35–38]. The concept of “user-centred design” [39] is used to enhance the ergonomics of human-system interaction, which can be obtained using qualitative data (i.e., interviews) [40–42]. Hence, the objective of this study was to obtain the perspectives of end-users to inform the refinement of a wearable-FES garment and to obtain insights on strategies for commercialization.

## **Methods**

### ***Study design***

Fundamental qualitative description methodology as previously proposed [43] was employed to provide a comprehensive summary of an event or phenomenon, in the everyday terms of the event, organised in a way that best fits the data and that will be most relevant to the target audience. This approach was chosen to limit interpretation of the content and ensure descriptive validity of the topic discussed. Study approval was given by the University Health Network's Research Ethics Board.

Focus group methodology was chosen [31,39,44] to stimulate discussion among participants and obtain insights about which points they agreed or disagreed upon. It has been suggested that there is potential methodological advantage of using focus groups over individual interviews for this type of study [45].

### ***Participants***

Study participants were recruited from a tertiary rehabilitation hospital or from the community via referrals and online flyers. The inclusion criteria were English-speaking adults who were at least one-year post-SCI or stroke, or who were formally (i.e., clinicians) or informally (e.g., family members) caring for these individuals. Recruitment efforts ceased as the study approached the point of data saturation, which is when successive interviews become repetitive and no new responses or themes emerge [46].

### ***Procedure***

After informed consent was obtained, key socio-demographics were obtained from the sample (i.e., age, sex, etc.) and end-users with paralysis completed the Functional Independence Measure [47] and the short form of the World Health Organization Quality Of Life questionnaire [48]. Data on knowledge of and previous experience with FES was also collected.

Prior to the group discussion, a 10-minute presentation about current FES technology, the FES garments, experimental results, and possible applications was given. Participants were allowed to visually and tactilely inspect FES-garment prototypes without donning or using them. Some participants were invited to join another study to test the garments' usability and efficacy [34].

A set of semi-structured interviews was conducted to identify the internal and external factors that are favorable and unfavorable to garment use (Appendix 1). The interview guide was first refined through mock interviews (used to train the moderator), and then via interviews of two pilot-participants (one SCI end-user and one SCI clinician) to verify its appropriateness.

The focus groups were conducted by one moderator (BM) who had designed and tested the FES-garment prototype, assisted by two co-investigators (SA and/or MM). This moderator choice was made to ensure participants' technical questions could be answered. The discussion was recorded with a microphone (ProCon Series1-AC-404-USB) connected to a laptop.

### **Data analysis**

Interviews and focus groups were transcribed by one of the co-investigators (SA or MM) using Microsoft Word and Express Scribe, and reviewed by BM.

An inductive content analysis [46] with initial open coding process was used: two co-investigators (BM and SA or MM) independently read each transcript, and assigned codes to text selections that contained information relevant to the objective. Across several meetings, findings were compared, discrepancies easily resolved, and a final coding framework (codes and their definitions, Appendix 2) established and re-applied to all transcripts. The final step involved the identification of themes, defined as a recurring category or connection made between categories [49]. Themes and sub-themes were developed through consensus among investigators (BM, SA, MM, SLH). Iterative investigator triangulation (separate coding, in parallel, followed by comparison and discussion) was used at each stage of the analysis process to ensure the trustworthiness of the data [49].

### **Results**

Eleven end-users living with paralysis, six rehabilitation clinicians, and two caregivers were recruited (Table 1). All but two participants knew of FES, 14 had received FES previously (e.g., during treatment, research, or training), and 10 had used FES previously (operated on themselves and/or somebody else).

#	Session	Age	Gender	FIM	QOL	Year	Role	Words	Quotes (coded)
1	Pilot 1	46	M	83	88	23	End-User, traumatic incomplete T8 SCI	6507	215 (140)
2	Pilot 2	47	W	-	-	17	Occupational therapist in SCI rehab. center	6396	268 (132)
3	Group 1	34	W	80	71	8	End-User, traumatic incomplete C6 SCI	2217	118 (72)
4	Group 1	44	W	72	74	2	End-User, traumatic incomplete T4 SCI	3187	148 (75)
5	Group 1	76	M	31	65	14	End-User, traumatic incomplete C3 SCI	7807	238 (110)
6	Group 2	53	M	80	68	1	End-User who had a stroke	900	70 (35)
7	Group 2	56	M	78	54	6	End-User who had a stroke	3588	250 (135)
8	Group 2	38	W	-	-	13	Physiotherapist in stroke rehabilitation clinic	7254	235 (139)
9	Group 2	52	W	-	-	30	Physiotherapist in stroke rehabilitation clinic	3466	164 (91)
10	Group 3	45	W	49	76	21	End-User, traumatic complete C6 SCI	5082	94 (75)
11	Group 3	63	M	17	79	3	End-User, traumatic incomplete C3 SCI	925	37 (25)
12	Group 3	55	W	-	-	3	Caregiver, spouse of #11	3113	85 (55)
13	Group 3	45	W	-	-	20	Physiotherapist and researcher in SCI rehab	2349	36 (25)
14	Group 3	42	W	-	-	10	Physiotherapist and researcher in SCI rehab	2901	35 (31)
15	Group 4	65	W	79	84	21	End-User who had a stroke	694	61 (22)
16	Group 4	49	W	82	86	8	End-User who had a stroke	5288	139 (77)
17	Group 4	83	M	74	78	34	End-User who had a stroke	1178	105 (28)
18	Group 4	39	M	-	-	8	Caregiver, personal support worker of #17	3312	55 (39)
19	Group 4	56	W	-	-	14	Kinesiologist and researcher in stroke rehab	3244	134 (46)

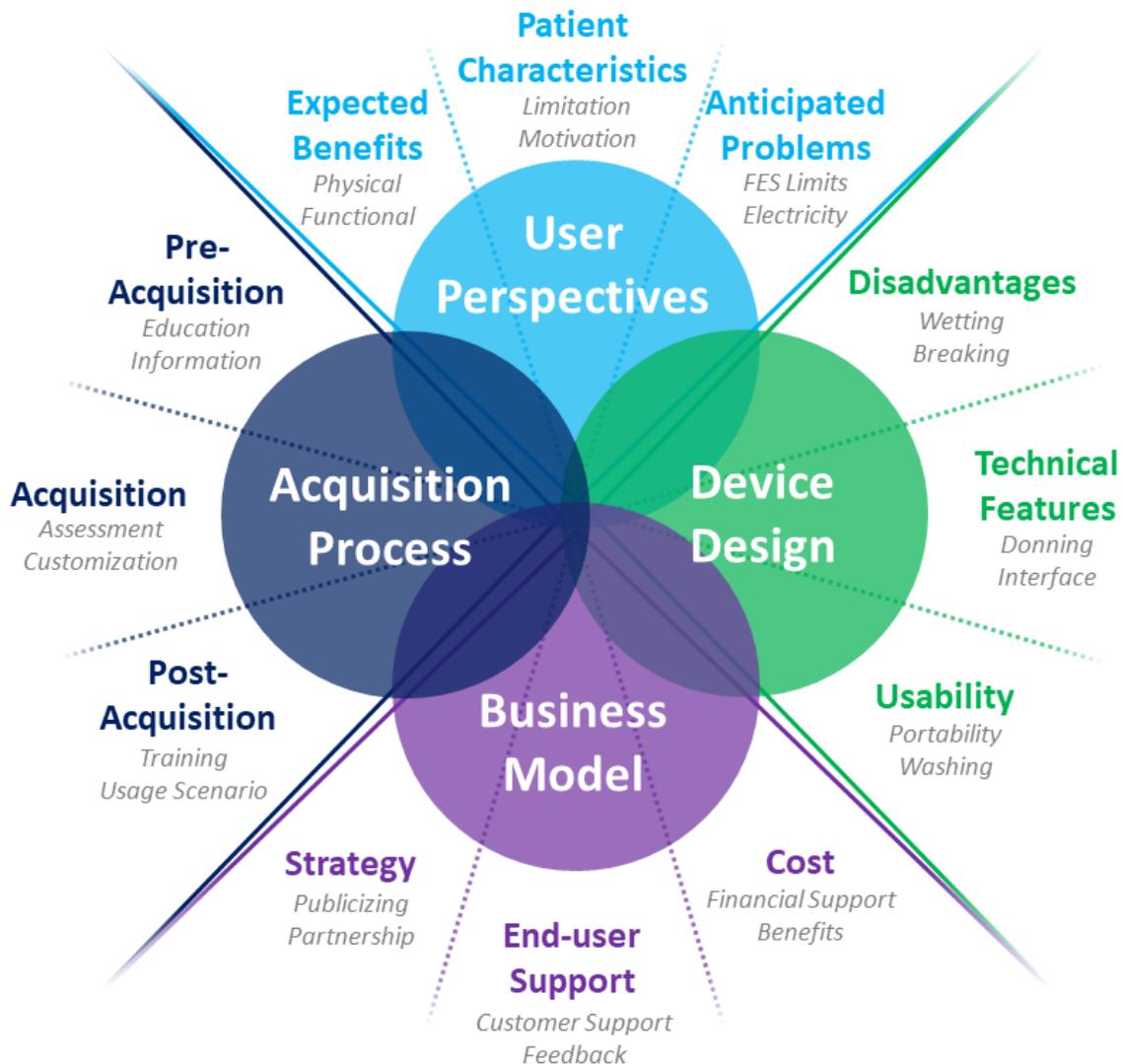
*M: Man. W: Woman. FIM: Functional Independence Measure questionnaire (12-84 points). QOL: World Health Organization-Quality Of Life-BREF questionnaire (20-100%). Year: duration since injury, or experience as clinician/caregiver. Words: total speech in transcript. Quotes (coded): number of quotations and (number of quotations that were assigned one or several codes).*

**Table 1.** Participants' information

From the transcripts of the interviews, 40 codes and definitions were identified, which were subsequently reduced to 32 codes and definitions. No new codes were obtained from the last two focus groups (saturation, i.e., redundancy in the discussions' content). Investigator triangulation was used at each stage of the analysis, and the 32 codes were classified into four main themes:

- (1) User Perspectives:** Information about specific needs, expectations, fears, beliefs, and medical limitations of end-users.
- (2) Device Design:** Considerations of the technical features of the final products (garment, cable, stimulator, software, and interface).
- (3) Acquisition Process:** Organizational procedures aimed to facilitate acquisition and adoption of the device as well as optimise user experience.
- (4) Business Model:** The financial and strategic aspects that a company producing these devices should consider to facilitate successful commercialization.

Three sub-themes were identified in each theme to help structure the information collected (Figure 2). There is a partial overlap between the themes as some aspects of the coding framework informed multiple themes. The “quotations” reproduced below, identified with a participant number [#] referring to Table 1, are only a fraction of the 1,384 coded quotations, and were selected to illustrate the points raised by participants.



**Figure 2:** Model of the themes and sub-themes obtained by content analysis of the views of end-users and clinicians on functional electrical stimulation garments

## 1. User Perspectives

### 1.1. Expected benefits

A salient theme from the users was the expected benefits of the device for improving or restoring function in their limbs. For instance, participants stated that manipulating objects

with their upper-limbs was meaningful for them (e.g., drinking, cutting food, opening Ziploc bags, keyboard typing, reaching elevator buttons, fishing, etc.). The promise of restored function was equated with independence (e.g., toileting, feeding), acknowledging that *“even just small changes are huge”* [#19]. Similarly, benefits for lower-limb functions highlighted by respondents included standing and sitting down, walking, stairs, and transfers. As well, issues related to improving trunk stability were noted, which would lead to better balance, improved bowel movements, or *“just to stimulate the abdominal wall”* [#4] to help support the organs and to result in a *“stronger core”* [#1].

Some physiological benefits were expected to address secondary health conditions associated with paralysis, such as improved blood circulation and reduced swelling (e.g., while sitting in a plane), increased bone density, decreased muscle spasticity, reduced muscle atrophy and fatigue, and reduced risk of pressure sores. Some end-users expected aesthetic benefits (desire for their *“arm to look normal”* [#15], e.g., shoulder symmetry that will also make it *“so [their] clothes don’t fall off [their] shoulder”* [#16]). Finally some expected benefits were psychological: confidence and motivation to try new things, happiness, and awareness of their abilities (*“patients were seeing their hand as more functional”* [#2]).

Participants desired the continuous orthotic assistance (use FES when needed) and/or the intermittent therapeutic training (*“our goal is they don’t, hopefully, need it for the rest of their life”* [#8]). It seemed that the more able the participants were, the more their interest was focused on immediate functional benefits and increased autonomy (*“I was thinking more about the function”* [#3]); while more severely impaired participants stated: *“even if I don’t [benefit out of it], I’ll probably keep going”* [#11]. One clinician believed that to obtain the therapeutic effect, people should use FES as an orthosis: *“for FES to really have an impact in terms of motor learning, people need to be able to [...] use [it] all day, every day”* [#9].

End-users and clinicians partly disagreed on the desired therapeutic approach for FES, with some end-users noting it should be simple in execution (*“keep it to single motions, not multiple”* [#7]), while therapists stressed that movements elicited by FES should mimic natural movements (*“a pattern of movement because that’s how we’re wired naturally”* [#9]). However, they agreed that simpler exercises may be done independently, while complex ones could be done with a therapist.

### 1.2. Patient characteristics

Participants pointed out a number of users' physical and mental characteristics that could affect their experience with the garments. End-users' paralysis results in reduced strength, dexterity, and range of motion (e.g., shoulder subluxation, tight fingers, and spasticity), which may limit their ability to use such garments (*"a whole shirt that's this tight, I just don't know that you'd ever actually get it on this man, he's, without seriously causing some pain in his shoulders" [#2]*). Less obvious limitations are their performance variability, the mental concentration required to use the affected limb, and a possible hypersensitivity (*"some days you're more sensitive than others" [#9]*). A major consideration for using the device would be that the benefits would outweigh the inconveniences of using it (*"meaningful enough that somebody's willing to do certain things around" [#13]*, *"most of us would let go of minor inconveniences, just to have that function again" [#7]*). However, it was acknowledged that this balance would be really known only through trying the device.

The initial motivation may come from the immediate FES action *"because people like to see their limb moving" [#2]*. For continued use, providing a concrete feedback on performance would create awareness of their progress and maintain motivation (*"to measure improvement is probably the most important thing" [#16]*). For individuals with stroke, bimanual tasks might be more motivating to use FES because they can use their unaffected hand for simple tasks (*"if it's just a one-handed thing, [you would] just take your functioning hand" [#19]*).

It is also critical to temper expectations on the capabilities of the technology, which could be achieved through appropriate advertisement and discussion with a prescriber (*"they want too much, right?" [#2]*, *"I can see people thinking they're gonna have a bionic arm after they put this on" [#2]*). For example, some expectations related to cure should be clearly discussed (*"I wanna rebuild muscle in my legs, so that when whatever fixes my spinal cord and I can walk again, then I don't have to start from ground zero" [#4]*).

### 1.3. Anticipated problems

Some participants expressed negative concerns about wearing the FES garment. Some worried they would *"get a shock" [#15]* if a wire breaks or if the garment gets wet (e.g., from rain), and several others were worried about getting burned (*"I don't want to catch on fire!" [#3]*). To that end, they required an *"emergency off" [#7]* button easily accessible in case of

undesired stimulation, an integrated automatic stop mechanism (e.g., if stimulation goes on for too long or electrodes dry out), and an upper limit to the stimulation current. Additionally, users expressed concerns that they would experience skin breakdowns from prolonged moisture exposure or develop pressure sores due to seams or zippers resting on a denervated area, bony area, or any area they lie on.

Throughout the discussions, participants identified limitations inherent to FES which, although not specific to the garments, may inform their development: it may be difficult to generate certain movements (*“They spent hours digging for [the motor points] on me”* [#7]), some cannot tolerate FES (*“weren’t able to do the FES bike upstairs because of the pain they felt”* [#1]), and not all patients benefit equally from FES (*“There was some additional movement, but no functional improvement. [...] I have too much tone.”* [#16]).

## **2. Device design**

While participants generally approved of the rationale for the garments (*“it’s got a future for me”* [#5], *“lots of potential there”* [#13], *“the concept is amazing”* [#16]), they had a number of critical insights on how the device should be designed.

### **2.1. Technical features**

Since the garment must be worn close to the skin to ensure a stable contact of the electrode on the skin (a gap in between skin and electrode during stimulation would create discomfort and/or discontinuation of the stimulation), a paramount issue from the participants was the need to be able to *don* the garment quickly and safely. A number of viable suggestions were provided, which were grouped across three categories.

The first solution category was the selection of the overall shape of the garment. For the upper limbs, the suggested designs were: forearm sleeve, arm sock, sling-wrap style sleeve, bolero/shrug-style (double sleeve without trunk cover), jacket, or shirt. For lower limbs, the suggested design was pants that covered both legs, but it was imperative that the final product provide easy access for bladder catheterisation for voiding in people with SCI, and be easily removable for toileting. In rarer instances, the garment should also be able to accommodate for stomas and associated equipment (ileostomy or tracheotomy).

The second solution category was the addition of openers and fasteners to allow for easily loosening, closing, or tightening of the garment (Velcro, zipper, magnetic or snap buttons,

or elastic straps, selected depending on user ability). Velcro straps typically require less dexterity but may result in more position variability, which might be resolved by detailed instructions and anatomical markers on the garment.

The third solution category was the use of facilitators, such as a fabric that is stretchy and easy to slide in and on (*“rash guard”* style [#10]), fabric loops positioned along the garment and on the fasteners/zippers (*“finger pulls”* [#5] allowing users with limited dexterity to hook), a thumb hole or heel stirrup to align electrodes and maintain the garment, a large head-hole, a waistband to keep the pants up, and the absence of fingers on the sleeve. An accessory *“that’s holding the garment open”* [#19], similarly to a stocking donner, was also suggested.

Participants also discussed how to ensure appropriate positioning of electrodes, particularly through customization of garment size and electrode positions. Specifically, clinicians working in private clinics expressed a desire for generic garments that could fit different patients (mass-produced and then individually adjusted). Even for individually customised garments, the possibility to adjust the positions afterward would allow to accommodate for daily variations, progress (*“muscle migration”* [#8]), and new objectives (*“not growing out of it as quickly”* [#10]). For long-term therapeutic use, participants stated that having more options is desired (*“make a sleeve that will [stimulate] 20 muscles and then only use the ones you need”* [#13]).

The aesthetic appearance of the garment was of varying importance to end-users (*“do you wanna look cool and technological and bionic, or do you want to just kind of blend in?”* [#3]): some suggested to make it fun (*“like an astronaut [...] or a Stormtrooper”* [#2]); others advised to focus on function (*“you’re [not] gonna make it stylish for everyone”* [#7]), and some wanted the device to be discrete (*“If they look like Robocop, generally people don’t want to wear it”* [#9]). It was reported that being visibly using rehabilitation technology generates word of mouth and attention (desired or not). Specifically after stroke, individuals typically need stimulation on one arm only but some said they would like to have both arms covered for aesthetic reasons (symmetry), while others advocated for a practical single-sleeve design.

In general, participants had high expectations from the technology (e.g., stimulator in a flat lightweight watch), with some expectations being beyond the scope of present technology: *“connect it to the brain [with a] helmet”* [#18], *“connect with my spinal cord”* [#1], *“have the*

*computer trigger the motion with the camera” [#12], “send electricity wirelessly” [#1], or have a “biofeedback where you see that the electrodes are doing 40% of the work but you are doing 60%” [#19].*

## 2.2. Usability

While some desired a wireless system, the present technology requires a separate stimulator. The stimulator should be as small as possible to fit in a back or coat pocket, a purse, a fanny pack, *“a little pouch underneath [their] chair” [#1]*, a holster on the leg, or around the neck. Its battery should sustain at least a full day of use. The stroke groups debated having the stimulator on the upper-limb like a phone or a watch: although it could be convenient, it might impede their functional arm or worsen the function of their weaker arm. A single connection cable was preferred (*“plug and go. Plug and zap!” [#5]*), likely sticking out through the bottom of the shirt (front-side of the pelvis), although some situations might require a customised cable position. A long cable would give more choice as to where to put the stimulator and a retractable cable was suggested.

The stimulator should allow for the selection of stimulation intensity, sequence, and channels (muscles, with corresponding numbers on the garment electrodes), by the prescriber or directly by the end-user (with safety limitations set by the therapist, depending on user’s objectives and understanding). The stimulator could be made remotely accessible to the prescriber, although it would require safety measures to prevent electronic intrusion (*“grade 12 [guy] who says: « Hey, look what I hacked into! »” [#1]*).

Interaction with the stimulator could be done through a smart-phone application (*“Anything that you can put in an app, put in an app” [#3]*), although one disagreed: *“I’m not a techie person” [#10]*) and/or with a separate hand controller (wired or wireless) to trigger the beginning and end of stimulation sequences. The interface should also provide feedback on device performance. Individuals might use pre-existing interfaces from powered wheelchair (chin command or sip-and-puff) or information technology (eye-tracker or voice command).

Because the proposed device is made of fabric, there was concern about the ability to wash it (washing machine vs. hand wash), the *“need [for] more than one garment [...] because it has to be washed”*, and the ability of the fabric to be cleaned (*“those wicking fabrics are pretty stinky cause they [...] hold the moisture” [#2]*).

### 2.3. Disadvantages

Having to wet the electrodes to use FES was considered a significant deterrent to the orthotic use on a daily basis (*"Is there any way to get it away from having to wet it" [#10]*) but *"maybe not such an issue in therapy" [#9]*. The setup time, cold feeling from wetness, and limited duration of use before drying out could also act as deterrents. It was expressed that the electrodes should remain functional for as long as possible (wet in that case), while the rest of the garment should remain dry and breathable for comfort. It was suggested to use oil instead of water (the greasy discomfort would be balanced by the longer time of use). Any dry electrodes alternatives should slide easily on the skin (no stickiness) so it remains easy to don.

The risk of fabric tearing and wires breaking was repeatedly indicated as a potential issue, particularly if the wires are loose, so having the wires embedded or protected between two layers of fabric could improve the durability of the garment. Other concerns were being warm and sweaty from wearing long-sleeved garments during the summer (*"Gonna be hot in the summertime" [#6]*), potential incompatibility with airport security checks (*"nobody's gonna believe that at an airport" [#8]*), and being disheartened when taking the garment off and losing its temporary assistive functional benefits (*"you can't do that function [...] you have to switch back" [#16]*).

## 3. Acquisition Process

### 3.1. Pre-acquisition

Adoption of the device requires appropriate education of the health care specialists and of the end-users. For clinicians, there is a legal obligation to be trained to use a technique, as defined by their supervising body (e.g., College of Physiotherapists). This training should emphasise the eligibility criteria and the potential benefits and risks, making them *"certified" [#4]* therapists (*"at no cost to them" [#5]*) so to increase engagement). Participants opined that not all clinicians would know enough but that it should not be difficult for them to learn. To train these clinicians, *"in-service would be ideal" [#14]* to give clinicians a first-hand demonstration (*"wow factor" [#14]* when they see what FES does). Conferences, certification courses, or online training (*"help desk [...] E-learning module" [#9]*) could be alternative options.

Information for end-users should (i) disseminate awareness of the device (*"cause if you don't know it exists..." [#3]*), and (ii) give sufficient information about the expected benefits

(*“give me three-four things that I can actually do with this”* [#16]). Information could be provided by being exposed during regular care (*“information session”* [#16]), or through advertising (see Business Model). Detailed information should be available through clearly identified resources (customer support, website, prescriber contact).

### 3.2. Acquisition

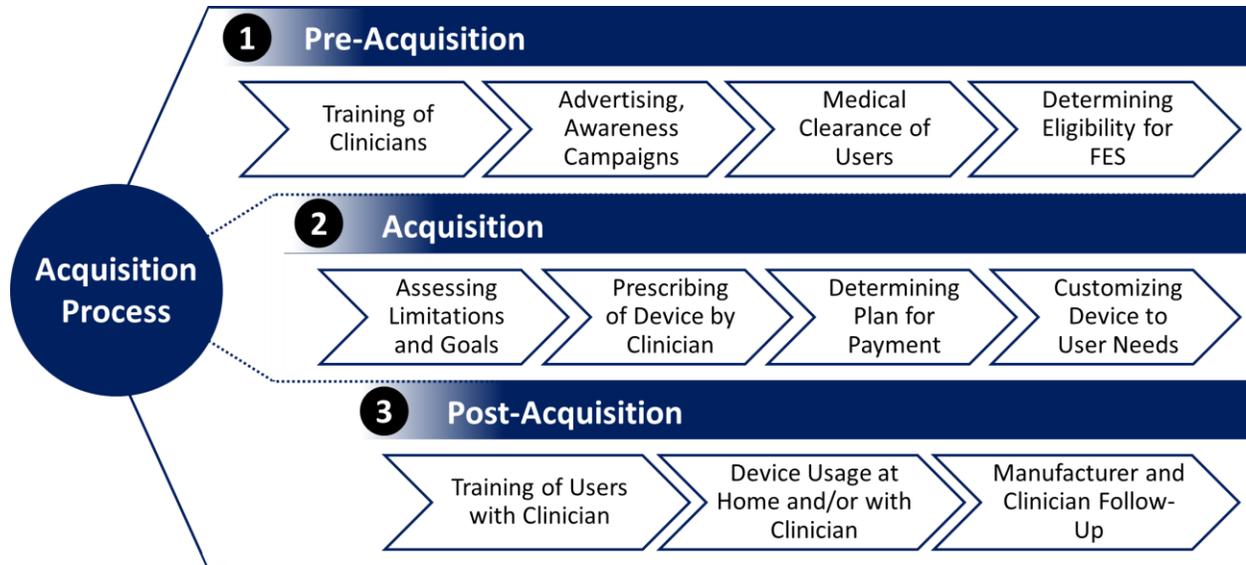
It was suggested that garments could be adopted during hospitalization (*“Earlier the better, right?”* [#3]) and continue to be used at home, with clinical supervision where and when necessary. Some end-users wanted direct access to the device as they feared *“a bump-up in prices because it’s gone through a therapist”* [#7], while others wanted to go through a therapist (*“because they’re only going to want me to use this if they think I’m going to benefit from it”* [#4]). Similarly, clinicians did not *“like to be involved in the selling of stuff”* [#8] but reported that they sometimes assist with new medical device explanations and set-up.

The steps necessary to bring the device to users’ hands were synthesised in Figure 3 (*“collaboration between the user, the therapist, and the vendor”* [#2]). Of importance was the necessity to test early on if the potential user is eligible (*“get the doctors’ clearance”* [#2], absence of *“hypersensitivity”* [#1], and *“Are they even stim-able?”* [#1]), which could be done by having them try FES. It would then be the clinician’s role to do an assessment to define the needs, limitations, and goals with the user (so to customise the garment as necessary), as well as having a conversation on the cost-benefit balance of getting such device. To that end, they would have to be trusted by the end-user (e.g., no financial incentives for selling the device).

### 3.3. Post-acquisition

After the garment is made, the end-user would need some continued follow-up (*“From the manufacturer’s perspective in terms of liability, they would probably want at least one session, an hour session, with someone to set it up [...], and then maybe a follow up to make sure that all the settings are ok”* [#3]). The initial session(s) should involve the end-user and their primary caregiver. The users’ training should focus on how to (i) don the garment (*“you wouldn’t know if it works for you if you put it incorrectly”* [#18]), (ii) use FES, (iii) measure performance, and (iv) plan their use (*“people put their pre-stroke situation on a pedestal [...] constantly looking at that as your go-to, as opposed to sort of the next step in front of you”*

[#16]). Then, they should still have access to instructional resources (online videos, handout reminders, booklet, or CD).



**Figure 3:** Flow chart of the proposed step-by-step acquisition process of the functional electrical stimulation garments

Unsupervised use of the device in the home should have some guiding parameters (e.g., limited duration and intensity built into the device) to ensure safety (“*you know how sometimes people think more is better, and then let’s say they end up with soreness*” [#8]). Their progression should be overseen by a clinician (“*regular follow-ups are a must*” [#14]). The need for regular supervision is supported by examples of experienced or anticipated misuse by users: modification of the garment or use of baby powder to facilitate donning, damaging fabric by hauling and pulling, ironing, wearing it in the shower or while doing dishes, increasing stimulation too much (“*Oh yeah I used to juice it up!*” [#7]), loss of components, accidental damage to the stimulator or cable during transfer, and imprudent continuation of FES if facing change in health status (e.g., skin wound) (“*some people might not be as responsible as others, so they’ll start playing [...] improperly*” [#1]).

Some participants imagined exercising at a specific frequency and duration. (e.g., “*2 sets of 10-15 minutes each with 20 minute break*” [#5], “*one or two hours, [...] after I take it off*” [#6]), although a practical asset is to use it “*whenever you have the energy [...] any time during the day as opposed to an assigned time*” [#16]. There could be a complementarity between

simple functional benefits in daily life (*“even a simple open, close”* [#13]), and more *“complex protocol that [therapist] might do [with] shoulder, elbow, wrist”* [#13].

#### **4. Business Model**

Based on their previous positive and negative experiences with medical devices, participants gave suggestions to support the translation to the commercial market and improve the customer experience.

##### **4.1. Cost**

Cost was seen as a likely major barrier to accessing the device (*“something that is new, and that works: often the price is skyrocketed”* [#17]). The decision to purchase it or not will depend on the expected outcomes (*“if people see the benefits, they’ll pay for it”* [#10]) and on the easiness to use the system (*“if it’s really time-consuming and slow and cumbersome [...] it’s not worth the investment of their time and energy, or money”* [#9]).

The cost might be reduced by mass-production (economy of scale), competing devices, durability and versatility of the device, and compatibility with various third-party systems (e.g., stimulator or FES-bike). Having a range of devices (from the simplest and cheapest to the most expensive) could allow more people access to this technology.

Conversely, the cost could increase through multiple therapist visits (for assessment, training), intermediate vendors, customization, aesthetic options, and additional features (phone application, multiple stimulators, and motion sensors). Suggestions that might help users overcome a high price included offering a *“payment plan”* [#1], a *“30 day warranty or return period”* [#5] (i.e., trial period which cost contributes to the final payment), and giving direct access to replacement components (i.e., not going through the prescriber).

Resources to support that cost could include public programs, private insurances (health, motor vehicle, or work-related), personal savings, payment plans, and crowdfunding. Participants advised to involve private and public institutions early on to get reimbursement approval, either on a case-by-case basis (with a streamlined procedure for the end-user to follow) or systematically (through arguments on cost-saving and benefits to patients). Patient organizations might be useful to advocate for more reimbursement or subsidies.

#### 4.2. Strategy

A successful business model would require good partnerships, in particular with clinicians. It is not possible to train all clinicians, so they suggested having some local representatives certified by the manufacturer (e.g., “assessment centers” [#9]). Most agreed that a therapist would be better than a vendor (“you want someone that can harness the knowledge” [#12], “trust is very important” [#16]). On that matter, it was discussed that users in remote communities might be particularly interested but would have difficulty accessing the device if it requires specialised clinicians (“for people that don’t have access to therapy places in the far north, this could be part of the tele-health program” [#7]).

Potential users need to know that the devices exist, which could be done through word of mouth (people who “brag about it on Facebook” [#10]), magazines, websites used by their community, search engines, clinics identified as “knowledge center[s]” [#12], fairs and trade shows, patient and clinician association newsletters, presentations in medical schools, exposure during hospital care, main stream media (“the news loves big stories” [#10]), pioneer clinics (“there’s always a physio clinic that’s willing to experiment” [#4]), and knowledgeable motion specialty stores. To build trust in the product, the device should be endorsed by institutions or personalities (“high profile spokesperson” [#4], testimonials), it should not be seen akin as a gadget with dubious benefits (i.e., infomercial device), and should be supported by scientific papers.

The commercial launch of the device should come promptly (“there’s lots of things that you need to continue to work on, but that shouldn’t keep you from getting it out there” [#13]), although not prematurely (“I have seen when the product was launched when it wasn’t quite ready, [...] because there’s a lot of frustration on the part of patients and families if it doesn’t.” [#14]). It was advised to launch the device progressively: use in clinics should precede home-use, use for training should precede use as an orthosis, and simple stimulation functions should precede integration of complex closed-loop control (“probably in the initial stages it’s going to be more of a therapy in-house” [#10]).

Regarding industrial partnerships, working with a big corporation with a diverse set of products and/or that is specialised in the field could provide established space and staff for people to access and might help the device remain on the market longer (because bigger

companies “*tend to survive*” [#2]). However, participants believed such partnership would increase the price due to the profit-driven approach.

Finally, there was some discussion about the legal aspects of selling and using such devices, as people might conduct legal suits against the manufacturer or the prescriber (“*we are such a litigious society*” [#7], “*that’s why I have lawyers, they throw the net as far as they can to see what they can catch*” [#7]). To protect their liability, it is suggested the manufacturer enforces the acquisition through a trained therapist. However the clinicians expressed firmly that they will not take the risk to be sued (“*it’s not worth my livelihood*” [#9]). Solutions to this threat, beyond a rigorous acquisition process and clear written instructions about how to use the system, include “*look[ing] at [clinician’s] college guidelines about selling products or endorsing products*” [#8]. Of note, resale of the device is also a risk (“*If people are buying it as a device, they may sell it later*” [#2]), so liability should also be clarified for such cases.

#### 4.3. End-user support

Participants expressed a desire for a customer support service (“*someone buys their device and all of a sudden all communication stops [...] if things go wrong, will you help us?*” [#2]). This could be a simple phone contact to somebody who can answer questions and help troubleshoot issues, and having access to “*online instructional videos because people forget*” [#2]. For clinicians, continuous training and demonstration to new staff is expected (“*sometimes they’ll need to come onsite and problem solve that way*” [#2]).

Patients and therapists should be able to give feedback to the manufacturer, whom should actively follow up on how their clients are doing during the first years of commercialization. Indeed, certain information will appear only during use (“*people at the user end [...] have got a totally different analysis than the one that developed it*” [#11]).

## Discussion

Our goal was to obtain end-user perspectives on the development of novel wearable FES-garment to restore physical function, and to identify strategies that would support its commercialization. We gathered knowledge from 19 participants with lived experience of having or treating stroke- or SCI-related disabilities, then analysed and synthesised it in four themes: User Perspectives, Device Design, Acquisition Process, and Business Model. Overall,

the content analysis generated several important considerations for developing a new assistive and rehabilitation device for people with paralysis, with some issues being generalizable to medical device development in general.

With regard to the manufacturing aspects of the device, a number of technical recommendations emerged: (i) make the fabric electrodes functional without applying water, or significantly prolong the time it remains functional after applying water (particularly for assistive use); (ii) make the fabric and wires durable, particularly by incorporating the wires in the fabric, while keeping the garment easy to wash and not too warm; (iii) make the system as versatile and adaptable as possible (initial customization and possibility to change the position of electrodes as necessary), and by adding finger loops and fasteners adapted to users' ability; (iv) develop a small, portable and versatile user-friendly stimulator unit (for therapeutic and assistive use, with various possible user interfaces) that has a sufficient failsafe to prevent user-misuses; and (v) offer a measurement system to track progress. These guidelines are consistent and complimentary with previous explorations of user expectations [31,44] and researchers analysis of other FES devices [50,51]. However, a major concern with the device of respondents was skin damage by pressure, electrical burn, or moisture. These issues could be mitigated by avoiding seams and fasteners on sensitive areas, implementing an electrical failsafe, and having dry electrodes, respectively.

The guidelines for the distribution aspects were to: (i) follow a rigorous delivery process led by a network of trained clinicians, (ii) launch devices in more controlled environments first (e.g., in clinics, then at home); (iii) make the system affordable through a controlled price and reimbursement by insurances; (iv) set up a customer support base able to answer questions and seek feedback from patients and clinicians; (v) implement a publicizing strategy fostering realistic expectations and supported by organizations trusted in the communities; and (vi) clarify all liability matters.

Although patients are eager for solutions that can increase their function and independence [52], the implementation of sophisticated rehabilitation and assistive technology into mainstream clinical practice has been low [25,51,53,54]. User-centred design aims to create interfaces, artefacts, products, and services that are applicable, appropriate, and

accessible to as many users as possible [39], which is critical for their commercial success. Without commercial success, no new interventions can be made available to these populations.

Guidelines extracted from the present study will help avoid the typical gaps of assistive technology development. Beyond the specific insights for the proposed garments, this study highlighted several procedures and criteria that may help other groups aiming to bring technological solutions to a population with particular needs. It would seem that people living with motor impairment want easy-to-use, comfortable, and durable solutions that they can use independently, reliably, and safely; with sufficient guidance and support. Despite high expectations, designing affordable solutions with simpler functions, even if less versatile, might be the best approach.

### ***Limitations***

It is possible that the 10-minute presentation and choice of moderator introduced bias to the study. However, it is arguably justified considering the many questions posed by the participants. The moderator only answered questions on basic science and current technical implementations of the garment, paraphrasing the specific questions in an open-ended manner to the participants to obtain their views.

Despite the moderator's efforts to avoid unequal participation by prompting the quieter participants to express their views, the contribution of participants during focus groups was unequal (Table 1). Although more time-intensive, undertaking individual interviews may have allowed these participants to be more comfortable in sharing their thoughts and perspectives about the device with the interviewer.

Despite these challenges, it was determined that we achieved data saturation from the interview and focus group data based on the pre-established criteria (no new codes required to classify the quotes in the transcripts) and did not require further participant recruitment. After several team discussions (triangulation), we are confident the key insights on design and commercialization considerations for the FES-garments were identified, based on the aforementioned data saturation.

## **Conclusion**

We identified four dimensions within the user views on the development of the FES-garment and formulated synthetic guidelines for the design of this new type of assistive technology. These guidelines might improve the usability, use, and thus successful commercialization of the proposed assistive devices, and could inspire other researchers and industries focused on the development of technologies for individuals with motor impairment.

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Bastien Moineau is a MITACS intern at Myant Inc., the company manufacturing the textile-based technologies discussed here, as part of his post-doctoral fellowship with Dr. Milos R. Popovic at the University of Toronto.

Milos R. Popovic is CTO of MyndTec Inc., a company manufacturing stimulator for functional electrical stimulation.

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## **Appendix 1: Interview framework**

1. *Thank you for agreeing to participate in this study about these F.E.S. garments.*

*We are not audio-recording yet: if you want to, tell briefly to the group who you are, and what viewpoint you are bringing to the discussion. I will start the round table:*

*My name is Bastien, I am a physiotherapist and I'm doing research since 2010. I worked in stroke rehabilitation previously and now I'm focused on spinal cord-injury rehabilitation.*

### **[Participants and researchers introduction]**

2. *As you see, we purposefully made a diverse group, with various perspectives. We want this to be a safe place to talk: here everybody's opinion matters!*

*I am now going to give you a brief presentation about the project.*

*Please refrain from asking questions for now: we will have lots of time to discuss after.*

### **[Presentation of the slides and videos on the technology]**

3. *Before we begin taping the discussion, here is how we would like things to work today.*

**First**, *as you know, this discussion is going to be audio-recorded.*

*So, please let each person finish without interrupting.*

*This will help us when listening to the tapes afterwards.*

*Don't worry, we will ensure that everyone has the opportunity to have their say.*

**Second**, *please remember that whatever is discussed today should not be shared outside.*

*Since this is for research, we want to make sure everyone's privacy is respected.*

**Third**, *if at any time anyone wants to stop participating, please just signal it and feel free to leave. Additionally, you can say "pass" if you don't want to discuss a certain topic.*

4. *Does anyone have questions or concerns before we begin taping?*

### **[Recording begins – few seconds of silence for filtering]**

5. *Here we go! Now here are the wearable devices, please feel free to examine them.*

*What are your spontaneous comments or questions based on the presentation and on those prototypes?*

6. *What features of these wearable devices do you like?*

- i. What do you think of the texture? Of the look?*
  - ii. What features appeal you the most?*
- 7. What features do you think could be improved or changed?*
- iii. What can be done to make it easier to use?*
  - iv. What would make it more attractive to use?*
  - v. How could it be safer to use?*
- 8. How do you think this type of device can be used to help someone with a SCI/Stroke?*
- vi. If science was not limited, what activities would you do with it?*
  - vii. Where would it be used? (hospital, at home, in the community, etc.)*
  - viii. When would you use it? How often? For how long?*
  - ix. Realistically, what muscle or function could be exercised or compensated with it?*
- 9. What could be the negative consequences of using this type of device?*
- x. What safety issues can you imagine when using it?*
  - xi. How could this negatively impact your social life?*
- 10. What could affect its adoption by patients and clinicians?*
- xii. If it was on the market tomorrow, what would help you get them?*
  - xiii. If it was on the market tomorrow, what would prevent you using them?*
  - xiv. What role does insurance, medical store, network, etc. should play to access it?*
  - xv. What characteristic or organization would be the decision-maker?*
- 11. In your experience with assistive devices, how could this technology become available to you?*
- xvi. Who should we partner with? companies, government, advocacy groups...*
  - xvii. How would you advertise it to patients and clinicians?*
- 12. Is there anything else you would like to add that we may not have discussed?  
Thank you for participating and sharing your insights, that was very helpful!*
- [Recording ends]**
- 13. Feel free to use the comments section to write down things that you forgot to speak about.*

## **Appendix 2: Final coding framework**

Code	Definition
Acquisition-financial	Any means or barriers to purchase such FES device; insurance, private/public/personal funds, procedure to obtain such funds, how to organize/schedule payment.
Acquisition-Process	Any sequence, events, facts, actions, procedures that ultimately leads to the patient (not) having device in their hands and using it, including (re)assessment by a professional of the state, health, needs and (non-)eligibility criteria of the end-user.
Benefit-functional	Any type of benefits resulting from using the garments (or FES in general) regarding function, daily life, possibility to do things... whether FES is delivered during the function or not (result of physical changes or result of using the assistance).
Benefit-health	Any type of benefits resulting from using the garments (or FES in general) regarding body composition, organs functioning, disease, health, prevention of complication.
Benefit-psychological	Any type of benefits resulting from using the garments (or FES in general) regarding mood, motivation, pleasure, excitement, self-esteem, social engagement, behavior.
Business-model	Elements regarding the purchase, rent, ownership of the devices/services, and also opportunities of (not) collaborating with other institutions, individuals, companies, to bring devices to end-users and to have a sustainable business, or examples of business that could be a (counter)example for us.
Cost	Anything affecting or pertaining to the final price of the product.
Customer-support	About anything organized by the manufacturer/retailer to provide support, information, technical assistance, to end-users (clinicians, patients, caregivers), excluding education of users and prescribers.

Customization-garment	Any type of modification/customization of the garment itself (size, fabric, electrodes position, leads) in order to adjust to a patient's specificities, needs, requests.
Customization-stimulation	Any choice (not) to customize stimulations, by whom, how much, which muscles, in what pattern, duration, intensity, frequency, to conform to end-users needs, specificities, objectives, evolution, .
Design-aesthetic	Any considerations regarding the visual appeal of the device/garment (colors, appearance, shape, and so on).
Design-donning/fastening	Any choice (not) to be made before commercialization regarding how to facilitate donning, fastening, wearing, doffing the garment by end users (patients, caregivers, clinicians).
Design-garment	Any choice (not) to be made before commercialization regarding the shape, composition, position of the garments in general, the electrodes and/or the wires, that would affect efficacy, safety, comfort, usability... except information better coded by design-aesthetic and design-donning/fastening.
Design-stimulator	Any choice (not) to be made before commercialization regarding what the stimulator (hardware and software) should look like, its features, size, shape, abilities (including type and means to provide feedback to user) that would affect efficacy, safety, comfort, usability.
Disadvantage	Any (potential) inconvenience or problems coming from wearing, using, owning, showing the garment and/or FES, to the exception of things coded by the "safety" codes.