Human-Centered Design of a Vibrotactile Sensory Substitution Belt for Feet Somatosensation in a Patient with Multiple Sclerosis

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Abstract— **Patients without sensation in their feet due to peripheral neuropathy or spinal cord injury have difficulty with balancing and walking. For patients with sensory loss in other modalities such as vision or hearing, sensory substitution devices have shown to be effective assistive technologies. To support the ethical design and user acceptance of novel assistive systems, the inclusion of patients from the start of the development process is an important factor. In this paper, we present the human-centered design of a sensory substitution device together with a patient lacking somatosensation in the feet. Force distribution during balancing and walking was measured with robotic skin soles and mapped to vibrotactile stimulation through motors integrated into a wearable belt. We discuss how the values and priorities of the patient were included in the system design and present her feedback obtained during a user evaluation session. Using our sensory substitution device, 5 healthy participants were able to distinguish the feedback patterns based on force distributions from 6 different phases of the gait cycle and 3 balancing conditions with 93.2% accuracy.**

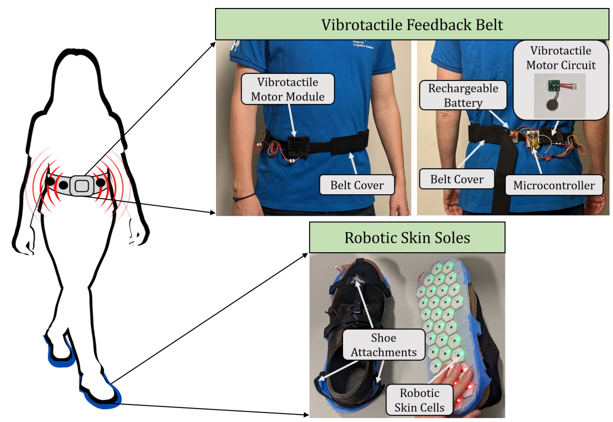

Fig. 1: Force distribution underneath the patient's numb feet during walking and balancing is measured with robotic skin soles and fed back to her through vibrotactile stimulation around the waist.

I. Introduction

Sensory deficits and ataxia of the lower extremities are common signs of neurological disorders and can severely affect patients' sensorimotor control and ability to walk and stand. It is often caused by damage of the peripheral nerves as in polyneuropathy or by a lesion of central somatosensory or cerebellar pathways as it can occur due to CNS demyelination in multiple sclerosis (MS). Patients who have lost their feet sensation permanently tend to substitute the missing information with visual input – a cognitively demanding method that requires them to watch their feet during walking, which in turn results in a forward bent and unstable walk. Moreover, this compensatory method fails in situations where an observation of the feet is not possible [1], e. g. due to lighting conditions, walking down stairs or the deterioration of eye sight, another frequent symptom of MS. The rising numbers of patients with peripheral neuropathy disorder due to demographic change and increasing incidence of diabetes, in combination with falls being the second leading cause of unintentional injury deaths worldwide according to WHO [2], indicates the need to give better assistance to the affected population by providing them with an accessible and reliable substitution signal.

Since the pioneering work of Bach-y-Rita [3], multiple studies have shown that sensory substitution devices can be effective in replacing lost sensory feedback [4][5]. Prior research has proven that vibrotactile sensory substitution can be used in exoskeleton-based brain-machine interface systems to help spinal cord injury patients to walk again [6][7]. Most of these studies, however, focused on the functionality of their systems, but did neglect usability in their design. Research on the abandonment of neuroprosthetics has demonstrated that lack of user-involvement in the development of assistive neurotechnologies can lead to their rejection by the users [8].

In this paper, we present the human-centered design of a sensory substitution device for tactile feedback from the feet, which was developed together with a patient that was diagnosed with MS more than 20 years ago. Based on the needs, values and priorities of the patient, we created a list of engineering design requirements for building a first prototype, which we tested with the patient in an evaluation phase. To verify the objective functionality of the system, we additionally conducted a feedback pattern recognition experiment with 5 healthy subjects.

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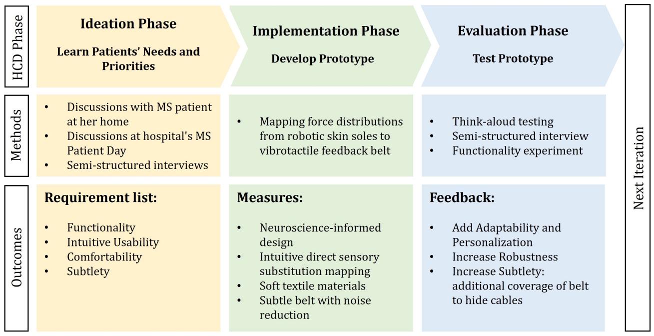

Fig. 2: The human-centered design process applied to the development of a feet sensory substitution device. First, the needs and priorities of patients were gathered and translated into design requirements, which were then implemented into a prototype in a second phase. The prototype was quantitatively tested with healthy subjects and qualitatively evaluated by a patient. The patient feedback starts the next development iteration.

II. Methodology

For the development of our prototype, we used a human-centered design (HCD) approach, which the international standard ISO 9241-210 describes as "an approach to interactive systems development that aims to make systems usable and useful by focusing on the users, their needs, priorities, and requirements, and by applying human factors/ergonomics, and usability knowledge and techniques" [9]. It considers the whole user experience and is characterized by involving the users early on and during the whole design process. Following the HCD process [10] (see Fig. 2), we started with an *ideation phase* by interviewing and observing potential users - in our case patients with MS - to learn about their needs, priorities, tasks and environments, and to formulate design goals together with them. In a following *implementation phase*, we designed a technical prototype based on the user requirements and had a user test it and give feedback during an *evaluation phase*, which can be used to iteratively start the next implementation phase.

A. Ideation Phase: Research on User Needs

1) Visiting Patient at Home: We visited a patient with MS (M.O.) at home to conduct a semi-structured interview about her neurological symptoms, resulting daily struggles, and in which area she would appreciate assistive technology the most. The study plan was approved by the Ethics Commission of the Faculty of Medicine of the Technical University of Munich (2022-206-S-NP) according to the Declaration of Helsinki and the participant gave her informed consent before participation. Besides intentional tremor and medium muscle weakness in her legs, she reported that numbness of her feet is her most limiting physical disability. While she is able to walk by herself at home, using her arms for stability and always looking at her feet for feedback, she relies on a wheelchair when going outside the house. While performing the Romberg Test, she had only little difficulty standing upright when having her eyes open, but once she closed her eyes, she immediately got nervous and had difficulty keeping balance (so called positive Romberg's sign indicating sensory ataxia [1]). During our meeting with M.O., we also talked about which features of assistive technology she considers to be most important. Next to functionality, intuitive usability, and comfortability, she pointed out that the subtlety of the device would be a priority for her as she would like to avoid constantly reminding other people about her condition. Thus, for her to accept and use an assistive technology, it should not be saliently visible nor noticeable noisy.

2) Discussions at Hospital's MS Patient Day: Our resulting hypothesis that artificial sensory feedback to compensate for lower-limb numbness might be a valuable assistive technology for her and other persons with MS was further strengthened by additional discussions with patients and neurologists during the MS Patient Day 2022, organized by the Department of Neurology at the Klinikum rechts der Isar in Munich. Some of the persons with MS reported about similar challenges in walking caused by severe numbness in their feet, even though their muscles where still strong enough to support walking.

B. Implementation Phase: System Design

In the second phase of our development, we built a first prototype which aims to fulfil the requirements that we gathered from our conversations.

1) Functionality: The main function of the system was to map the accumulated force on the fore-, mid- and hindfoot measured with robotic skin soles on both feet to six different vibrotactile motors that are arranged on a waist-worn belt. A schematic of the set-up is depicted in Fig. 1.

Force Distribution Measurements: To record the force distribution underneath the patient's feet during balancing and walking, we used a pair of artificial soles, each made out of 33 silicone-covered robotic skin cells [11] transmitting force measurements with $250\,\mathrm{Hz}$ to a computer (e.g. Raspberry Pi).

Sensory Substitution Mapping: The signal intensity of the vibration motors can be modulated between the subject- and motor-dependent perception threshold ($s_{min,i}$) and maximum intensity ($s_{max,i}$). The sensory substitution mapping was performed by summing up the force values f_c from all cells c for each pre-defined foot region i (fore-, mid- and hindfoot for both feet) and translating them into vibrotactile motor intensities m_i through a normalized linear mapping (see Fig. 3).

Vibrotactile Motor Stimulation: A microcontroller (ESP32) wirelessly receives the stimulation intensities and drives six vibration motors symmetrically positioned around the belt through a custom-designed printed circuit board and a rechargeable battery (see Fig. 1) accordingly. We chose motors with vibration frequencies around $200\,\mathrm{Hz}$ to be close to the preferred stimulation frequency of Pacinian corpuscles in the human skin [12, p. 500]. Considering the *Two-Point Discrimination Threshold* of tactile perception, we chose the waist as the location as it offers a high enough resolution in the horizontal plane, i. a. supported by the results of Cholewiak et al. [13] that found a 95% accuracy when using six equidistant tactors around the waist. To enable users to position the vibration motors in well-differentiable and comfortable locations around their waist,

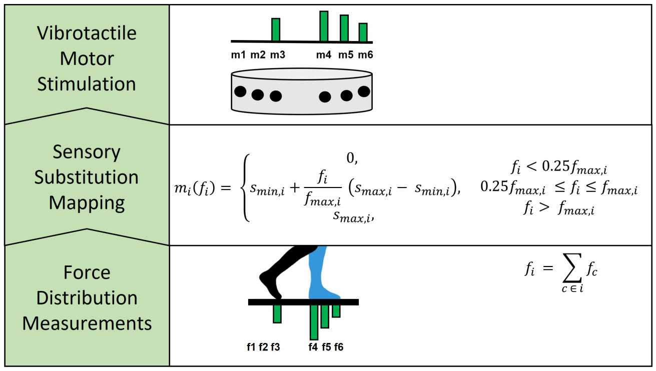

Fig. 3: Force distribution underneath the patient's numb feet during walking and balancing is measured with robotic skin soles for the fore-, mid- and hindfoot and fed back to her through vibrotactile stimulation around the waist. f_i refers to the accumulated forces f_c from all cells c of the three foot regions i on each side and $f_{max,i}$ is the maximal force on each foot region during a normal gait cycle and obtained through initial calibration with a user. $s_{min,i}$ and $s_{max,i}$ are subject- and motor-dependent calibration parameters for the feedback intensity.

we integrated the motors into small textile modules that are movable throughout the belt. The modules provide an additional protection layer to the vibration motors and their connections, but they also increase the maintainability of the belt, as a broken module can just be disconnected and replaced. Hence, the whole belt can be disassembled quite easily, which allows to wash the different parts of the belt after removing the electronic parts. The modules were slid onto a stretchable textile belt, whose outside fabric can be utilized to flexibly attach components using Velcro.

2) Intuitive Usability: Concomitant to the patient's priority for us to create a functional and maintainable design, she also emphasized the value of intuitive usability. To achieve this, we decided for a direct force distribution mapping between foot regions and individual vibration motors, maintaining their symmetric anterior-to-posterior order. I. e. the vibration motor substituting sensory information from the left forefoot was placed on the frontal left body side of the user and vibrated proportionally to the force put on the left forefoot. Choosing the waist as the location for feedback has the advantages that only one compact device must be donned, in contrast to two separate devices at the ankles or hands, and that it would not interfere with performing tasks in everyday life.

3) Comfortability: To make the belt a feasible accessory in daily living, it must be comfortable to wear. Therefore, we chose a flexible textile material (41% latex, 59% polyester) which is stretchable, soft, and skin-friendly. Using textile bags instead of stiff attachments for the motor modules had the advantage that they do not heat up during prolonged vibrations and do not lead to cross stimulation. We found that they still transmit a strong enough signal to the skin, are inexpensive to produce, easily movable, lightweight and protect the vibration motors well.

4) Subtlety: Finally, M.O.'s last design priority was the subtlety of the belt. Prior research on user requirements for vibrotactile feedback systems showed that it is not only a personal opinion of our patient, but a frequent priority of users [14][15]. Choosing the waist minimizes the visibility of the device, since regardless of season and weather, it is mostly covered by clothes where the tight-fitting belt can be hidden underneath. Furthermore, we only chose black, uniformly coloured fabrics and hid flashy components with an additional belt cover, as shown in Fig. 1. The vibrotactile stimulation provides subtle and thus private feedback compared to auditory feedback alternatives. Placing the vibrotactile motors inside textile modules further reduced their noise during stimulation.

III. Results and Discussion

A. Evaluation Phase: Testing & User Feedback

1) Qualitative Evaluation: After finalizing the first prototype, we arranged another visit at M.O.'s home to show her the system and get feedback and input for our next prototype iteration. Employing the *speak aloud* and *semi-structured interview* methods from HCD, we asked her to express her thoughts while exploring the system during sitting and walking. We noted down her impressions, reactions, comments, and suggestions and substantiated her thoughts with a questionnaire in the end. Shortly after putting the device on, M.O. was already able to control the vibrations with her feet and to fully understand the functionality of the system. After feeling no tactile sensation from her feet for multiple years, the sensation of some kind of feedback, even just of such substitutional manner, seemed to have a strong positive emotional impact on her. She offered many suggestions, such as the implementation of an app to adjust the intensity of vibration or ideas for the design of the next generation of the robotic skin sole. The former is necessary as it turned out that due to different attention levels, vibrations should be weaker during periods of sitting and stronger while walking. Regarding the robotic skin soles, she suggested that we develop insoles that can fit in her normal shoes. With that and some additional design-related improvements, such as the hiding of the cables in an additional covering for increased subtlety, she emphasized that she could imagine herself to wear such a sensory substitution belt every day. Furthermore, she said that the sensory substitution device might enable her to walk outside her house again with the additional help of a walker, increasing her level of independence. While she did not yet feel more secure during walking, she hypothesized that training and adaption could lead to that outcome. Moreover, she thought that the vibrotactile feedback was neither haptically nor auditively annoying. She had the feeling that the belt was very comfortable and that the modules were at the right position. In the questionnaire, she fully agreed that it is intuitive and agreed that it is helpful.

2) Quantitative Evaluation:

a) Functionality: We evaluated the functionality of the system by assessing the accuracy with which healthy participants could distinguish sensory feedback mapping from different phases of the gait cycle and during balancing. The subjects stood on one side of the table in front of a computer wearing the vibrotactile belt and the conductor who had the robotic soles on their feet was standing outside of the participant's view. In every trial of the experiment, the

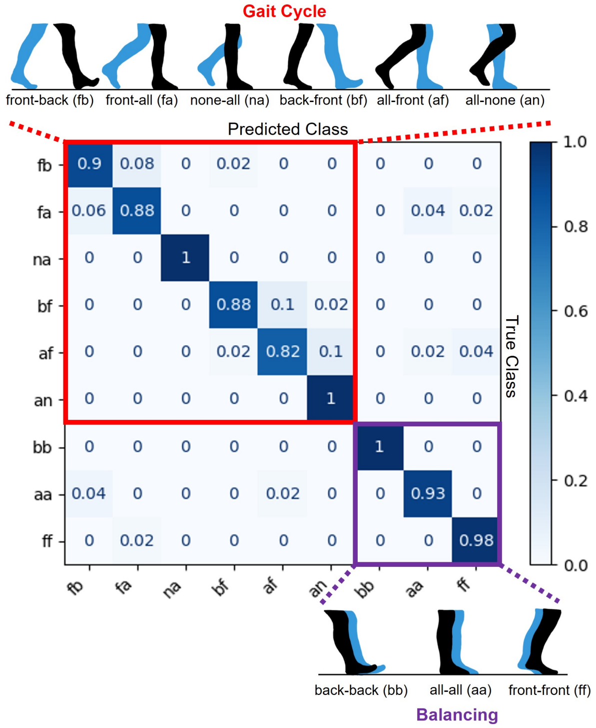

Fig. 4: Confusion matrix for the recognition accuracy of 9 feedback patterns related to the foot force distribution during 6 gait cycle phases and 3 balancing conditions. The average recognition accuracy across 5 healthy participants was 93.2%.

conductor took pose of one of the six gait cycle phases or one of three balancing phases (see Fig. 4), thus simulating their typical force distribution on either the front (f), back (b) or all (a) of the feet. The participants received the force distribution information as mapped vibrotactile stimulation and had to guess the respective phase. After an introduction to the system and a training session (ca. 30 min), each subject performed 90 trials by testing each of the 9 classes 10 times in a random order, resulting in a total of 450 trials from which 7 errors trials were discarded. The average recognition accuracy across all 5 participants was 93.2% (std: 5.3%). In Fig. 4 we show the confusion matrix across all participants. Importantly for the prevention of falls, the recognition accuracies for the balancing conditions are close to 100%. Our static experiment only evaluated the recognition accuracies based on sensory feedback, however during walking we expect even higher accuracies as users would also employ their internal models for forward prediction of the next gait phase based on sequence learning and their efferent signals to their leg muscles.

b) Noise Subtlety: To evaluate the noise level of our vibrotactile feedback belt, we measured its average noise levels during three minutes of different feedback conditions from a distance of $1\,\mathrm{m}$ using a volume recording app on a smartphone. Setting all six motors to vibrate at full intensity resulted in an equivalent continuous sound pressure level (LAeq) of $35.9\,\mathrm{dB}$, whereas vibrating them at the averaged minimum intensity $\overline{s_{min}}$ resulted in LAeq of $35.0\,\mathrm{dB}$. In contrast, the baseline noise level of the room was measured as $34.5\,\mathrm{dB}$. According to [16], a $3\,\mathrm{dB}$ change in noise is just discernible. Therefore, fitting to our own perception, even vibrating all motors at full intensity should not be noticeable by other people.

IV. Conclusions

In this paper, we presented a human-centered design approach for the development of a vibrotactile device that provides sensory substitution feedback for patients who lost their feet somatosensation. Based on the needs and priorities of a person with MS, we created a list of design requirements including functionality, intuitive usability, comfortability, and subtlety for the system and described technical approaches for implementing them. The sensory substitution device was evaluated based on a mixed method approach, by utilizing quantitative measures to test its functionality with 5 healthy subjects who could recognize gait and balancing phases successfully with 93.2% accuracy as well as conducting a qualitative usability evaluation with the patient.

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