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User-centered Design and Evaluation of Physical Interfaces for an Exoskeleton for Paraplegic Users

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***Abstract*— Over the last decade, the use of wearable exoskeletons for human locomotion assistance has become more feasible. The VariLeg powered lower limb robotic exoskeleton is an example of such systems, potentially enabling paraplegic users to perform upright activities of daily living. The acceptance of this type of robotic assistive technologies is often still affected by limited usability, in particular regarding the physical interface between the exoskeleton and the user (here referred to as pilot). In this study, we proposed and evaluated a novel pilot attachment system (PAS), which was designed based on user-centered design with experienced paraplegic exoskeleton users. Subjective assessments to compare usability aspects of the initial and the redesigned physical interfaces were conducted with two paraplegic and five healthy pilots. The redesigned PAS showed a 45% increase in the system usability scale (SUS), normalized to the PAS of a commercial exoskeleton assessed in the same manner. Pain rating scales assessed with healthy pilots indicated an increased comfort using the redesigned PAS while performing several activities of daily living. Overall, an improvement in usability relative to the initial PAS was achieved through intensified user evaluation and individual needs assessments. Hence, a user-centered design of physical body-machine interfaces has the potential to positively influence the usability and acceptance of lower limb exoskeletons for paraplegic users.**

I. Introduction

Every year, between 250,000 and 500,000 people worldwide suffer from a spinal cord injury (SCI), of which approximately 40% result in incomplete or complete paraplegia [1]. Restoration of walking capacity with assistive devices supporting locomotion can improve the quality of life of SCI patients, as increased access to the environment is positively associated with life satisfaction [2]. Powered lower limb exoskeleton devices are wearable, motorized robots matching the mechanical structure of the human leg to augment, regain or restore motor performance. The user initiates and steers the movement of the robot on his own behalf and is thereby also referenced as a pilot of the assistive device [3]. In the past few years, medical grade lower limb exoskeletons have demonstrated potential to provide task specific overground therapy and training, as well as personal mobility, for individuals with lower extremity complete paralysis [4]–[6]. Likewise, the VariLeg powered lower limb exoskeleton for paraplegic pilots is a research prototype developed at ETH Zurich, Switzerland [7] and which took part in the CYBATHLON 2016 [3].

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As recent reviews on state of the art systems have shown, wearable exoskeletons often provide limited usability, struggling with aspects such as how the users are physically attached to the mechanical frame [6][8]. Often, interface solutions are limited in comfort, operational effectiveness and efficiency. Neatly fitting an exoskeleton to the human anatomical structure is considered essential for a safe and ergonomic usage [9]. Relative motion between the human and the robot can cause interaction forces which may lead to negative physical consequences and decrease the force transmission efficiency [10]. Furthermore, paraplegic patients are known to be susceptible to skin wounds and pressure sores [11]. Therefore, an ideal PAS should strive to provide a safe and comfortable, but simultaneously firm attachment, allowing the human limbs to be moved synchronous to the assistive device. Usability of wearable, robotic exoskeletons is in fact not only limited by the safety and comfort, but also by time-consuming adjustments, high usage complexity and missing consistency of components like the PAS. The absence of clear guidelines and standardized approaches for the design of physical exoskeleton interfaces in literature further underlines the complexity of this problem.

Integrating the target population into the development and evaluation of assistive technologies has proven to increase user satisfaction and usability [12][13]. Moreover, intensified end-user involvement and interaction with research prototypes for competitions such as the CYBATHLON can potentially provide valuable insights and motivation to overcome the usability gap between laboratory testing and clinical or home application [14][15]. It was reported that SCI subjects in powered exoskeleton studies perceived that the respective outcome measures were mostly focused on assessing improved mobility, while neglecting to actually improve the quality of life of the target populations [6]. A paradigm shift towards subjective and qualitative measures aimed to complement clinical scales can help to better represent the user experience with the assistive technologies and consequently promote their user-focused development [16].

Qualitative assessments of comfort and usability have shown to be key in user-centered design (UCD) approaches [17][18][]. As such, traditional comfort evaluations, based on pain rating scales were previously applied in studies involving robotic exoskeletons [19][20]. Also, standardized and validated usability questionnaires like the System Usability Scale (SUS) [21] and the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) [22]

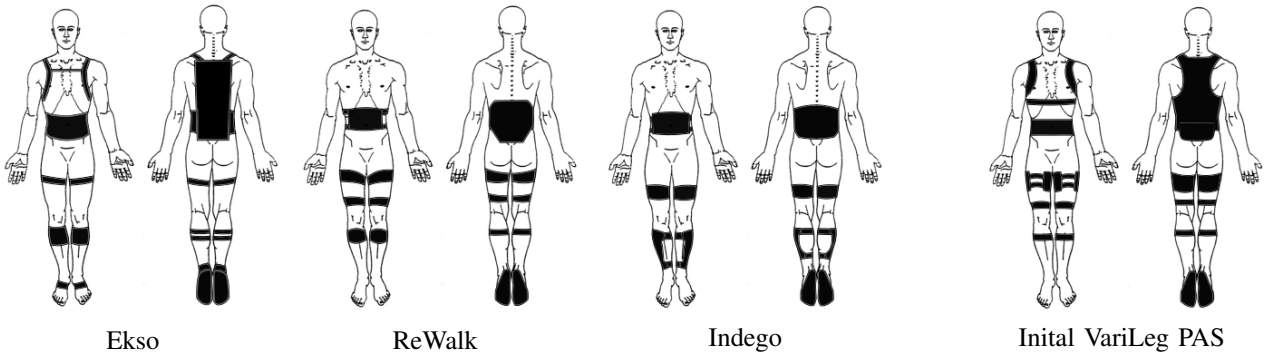

Fig. 1. **Comparison of state-of-the-art solutions from commercial powered lower-extremity exoskeletons for paraplegic users, with the initial VariLeg PAS.** The pilot attachment systems (PAS) of the Ekso GT™ (Ekso Bionics, Berkeley, CA, US), ReWalk™ Personal 6.0 (ReWalk Robotics, Inc, Marlborough, MA, US), Indego Personal® (Parker Hannifin Corp., Cleveland, OH, US) and the VariLeg were schematically drawn on body templates. The representation of the corresponding PAS is based on the respective publications and websites.

were among the subjective assessments used for qualitative comparisons of assistive technologies [23][24]. Although there seem to be a few measures that stand out, more than 65% of assistive technology studies assessing usability have been reported to use non-valid, custom-made and potentially biased measures and questionnaires [25]. This further displays current limitations of existing methods to reliably assess, understand and implement user experience to promote the actual impact on quality of life intended by assistive technologies.

To address this issue on the example of the VariLeg exoskeleton, a user-centered re-design based on user experience and subjective usability evaluation of the PAS was the main objective of this work. By focusing on qualitative feedback in the development and evaluation of new prototypes, we hypothesized that the usability for the end-user could be improved. To specifically assess the change in user satisfaction as well as safety and comfort, evaluations with both paraplegic and healthy subjects were conducted.

II. Pilot Attachment System

A. State of the Art

In this work, the PAS is defined as all physical interfaces required to assure a safe and ergonomic connection between the pilot and the wearable exoskeleton. An optimal solution in the context of lower limb exoskeletons for paraplegic users should neither force the pilot to carry the robot's weight, nor should the attachment prevent the pilot from bearing his/her own body weight. Excluded from this definition are all forms of user displays and control interfaces including crutches, which most pilots of current powered lower limb exoskeletons use to balance, control or initiate the device's movement. This narrow definition of PAS was selected to avoid confusion with the more general terms of physical human-robot-interaction (pHRI) and physical human-robot interfaces (pHRi) with wearable robots [26].

According to the literature, a truly ergonomic physical interface should either be customized to an individual's own anthropometrics and needs [27], or be designed with passive compensatory joint mechanisms to minimize misalignment issues [28][29]. The former of these concepts is incompatible with most research prototypes, as they follow a design-for-all concept with high adaptability to fit a number of different subjects. The latter approach adds substantial complexity and weight to the interface system, often outweighing the ergonomic benefit of misalignment compensation. Nevertheless, minimizing misalignment and optimizing comfort through design considerations in material, size and positioning of the PAS are key to achieve an optimal fit given the mechanical circumstances and limitations.

To understand how the PAS of state-of-the art commercially available lower limb exoskeletons for paraplegic users were designed, simple body sketches representing the corresponding attachment forms and locations were drawn (Figure 1). When comparing type, size, placement and amount of attachment systems such as the upper body interfaces for example, we see that the Ekso GT™ (Ekso Bionics, Berkeley, CA, US)[30] incorporated a rigid back interface with shoulder straps to attach the user very firmly to the prominent structure of the robot. Such a direct fixation of the torso to the mechanical exoskeleton frame also supports users with higher SCI lesions - and thus diminished trunk musculature - to walk and train in the robotic gait orthosis. In contrast, the ReWalk™ Personal 6.0 (ReWalk Robotics, Inc, Marlborough, MA, US)[31] and Indego Personal® (Parker Hannifin Corp., Cleveland, OH, US)[32] focused on a compact hip attachment, while offering more flexibility and freedom in upper body movement.

B. Initial VariLeg PAS

The starting point of this work was the PAS of the VariLeg exoskeleton. The unique feature of this research prototype is a variable impedance actuation in the knee joint. This enables the mechanical structure to adapt its stiffness during different phases of the gait cycle, and is expected to more closely mimic adaptive human gait mechanics, compared to commercial solutions [7]. The initial VariLeg PAS, shown in Figure 2, had previously been designed and improved during two years of development. Still, the system showed

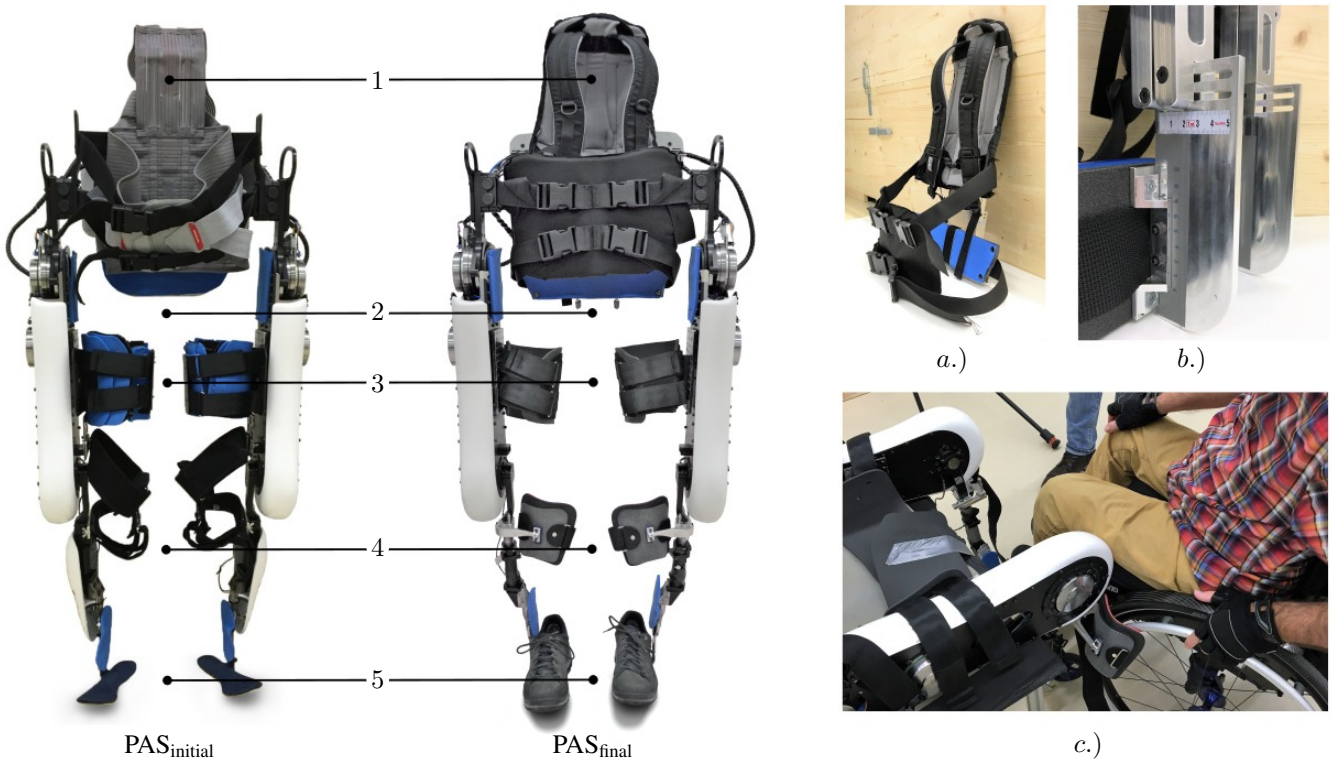

Fig. 2. **Overview and details of the initial and redesigned VariLeg pilot attachment systems (PAS):** For both, the PAS$_{initial}$ and PAS$_{final}$, the local attachment concepts were grouped as follows: 1) upper body , 2) hip, 3) thigh, 4) shank, 5) foot. Detailed concepts of the PAS$_{final}$ are displayed in a.) Upper body and hip combination, b.) anterior-posterior and proximal-distal adjustable pelvic plate, c.) facilitated access and transfer into the VariLeg exoskeleton, with compliant thigh cuffs and laterally rotated shank attachments.

limitations in usability and comfort, as the pilots reported to be not yet satisfied with the user experience provided. Key general limitations of the PAS mentioned by the experienced paraplegic users were (i) lack of individual solutions or adaptability, and (ii) difficulty in transferring in and out of the exoskeleton. The attachment concepts of the initial PAS and their respective drawbacks influencing the PAS usability are listed as follows:

1) Upper Body: An orthotic back brace from Ottobock [33] was used and arranged with two belts onto the aluminum frame of the exoskeleton. The brace mainly functioned as textile coverage and slight padding underneath the belt fixation, and did not provide a sufficient torso stabilization for SCI subjects with lesions affecting trunk muscles. For diverse physiques, an assortment of four brace sizes was available.

2) Hip: The mechanical frame of the VariLeg exoskeleton hip structure was limited to a horizontal dual-pipe system on lower back height. To prevent an undesired hip flexion and subsequent slippage of the pelvis under the hip frame, an aluminum plate was used to apply sufficient counteracting force on the pelvic region. As the position of this pelvic plate was fixed, no adaptation possibilities to varying spine curvatures were given.

3) Thigh: To assure a high fixation stability on the mid-thigh region, carbon-fiber reinforced plastic (CFRP) cuffs were used on the mid thigh region. By providing sufficient foam material, the intentionally oversized circumference of the carbon shell was padded to fit the thigh volumes of different subjects. Due to their size and stiffness, these attachment solutions further increased the complexity of the transfer from a wheelchair into the exoskeleton. Additional to the CFRP cuffs, an off-the-shelf assortment of cuffs from the LOKOMAT® gait orthosis [34] were used to stabilize the knee more distally.

4) Shank: By the use of the same off-the-shelf cuff on the lower thigh as on the upper shank, a high knee fixation stability was intended. The anterior, load bearing part of these cuffs consists of a hock-and-loop fastening system and therefore offered a slightly compliant hold to minimize physical abrasions or pressure points. Unfortunately, this compliance occasionally allowed for a small misalignment between the robotic and human knee joint during the sit-to-stand motion.

5) Foot: As a well-distributed ground contact force was desired, a CFRP footplate module was used in combination with an unilateral passive ankle joint [33]. The footplate could be inserted in any shoe type, as it was simply placed underneath the insole of the corresponding footwear. The desired shoe used was then chosen two sizes bigger than the size before injury, aiming to minimize the risk of pressure sores. This simple solution, in use with running footwear, unfortunately acted like a shoehorn allowing the foot to slip out of the shoes especially when walking on inclines.

III. User-Centered Design and Evaluation

To be able to generate an improved user experience within the target population, a UCD approach was applied

to redesign the PAS. The individual attachment concepts of the initial VariLeg (see Section II-B) were first assessed in terms of usability (see section III-C), then progressively redesigned and subsequently implemented into the VariLeg exoskeleton to eventually form a completely renewed PAS. The incremental changes of the attachment concepts were thereby grouped into three specific configurations to be compared: the initial system ($PAS_{initial}$), was compared with a intermediate ($PAS_{intermediate}$) and final (PAS_{final}) configuration to group certain attachment concepts and differentiate their effect in usability. Changes in upper body, hip and foot attachments were first addressed, forming an intermediate PAS configuration. The changes addressed for the $PAS_{intermediate}$ were prioritized and separated from the thigh and shank attachments, which then were part of the PAS_{final} redesign. The prioritization of the listed changes was based on a compromise between development effort and expected usability impact.

The development of each new attachment solution followed a clear, iterative design process, as proposed for UCD by Abras et al. [35]. The feasibility of promising ideas was assessed with rapid prototyping, and after proof of concept including further consulting with the paraplegic users, the prototypes were manufactured with material that could withhold the expected forces. Once the mechanical safety was assured, a new attachment concept was then carefully examined with healthy pilots. Only if healthy subject testing sessions proved to be safe, tests with the paraplegic pilots were conducted, if their consent was obtained for each change in attachment or configuration. After assessing the single changes of the PAS with a think aloud protocol [36], the prototype development cycles were iterated until satisfying new attachment concepts were designed.

A. Evaluation with Parplegic Subjects

For the purpose of previous research and participation at the CYBATHLON in 2016 [3], two male, paraplegic pilots were recruited and trained with the VariLeg exoskeleton [7]. Thanks to their agreement to proceed as testing pilots after the event, they were included as experienced paraplegic exoskeleton users. The two pilots display an adequate spectrum of user needs representing the target population, as their specifications (Table I) and preferences differed strongly.

All iterative PAS changes were progressively integrated into weekly training sessions. The initial training period consisted of isolated ADL execution, namely repeated sit-to-stand transition and 30m level walking. During these initial movements, the stability, retention and general performance of the PAS was carefully observed to spot any potentially occurring issues and adapt the attachments respectively. The full testing session then consisted of continuous gait training, with parallel thinking aloud exchanges and eventual structured usability evaluations (see section III-C) on the defined distinct configurations. The average time of these sessions was two hours with at least 45 minutes of active training with the exoskeleton.

TABLE I
DEMOGRAPHICS OF THE SPINAL CORD INJURED SUBJECTS

Attributes	Pilot 1	Pilot 2
Sex	male	male
Age [y]	57	40
Height [m]	1.77	1.83
Weight [kg]	85	77
SCI since [y]	3	7
Lesion Height	Th 12	Th 4
Classification*	ASIA A	ASIA B

*American Spinal Injury Association [37]

B. Evaluation with Healthy Subjects

Due to the reduced or diminished sensory feedback, the paraplegic subjects could hardly assess inconveniences and pressure points below lesion level. To further evaluate ergonomics of the PAS, tests with healthy pilots were conducted. A healthy sensory, especially nociceptive, system allowed for more detailed evaluations of possible discomfort. Moreover, including more subjects of varying sizes and weights increased the safety procedure and eventual risk awareness before testing new prototypes with paraplegic pilots. The five subjects, all male candidates (age: 25 ± 2.3 years; height: 1.82 ± 0.03 m; mass: 76.6 ± 5.2 kg), were untrained on the VariLeg and had no previous experience using robotic gait orthoses.

Each pilot performed the same testing routine of approximately 60 minutes duration with each of the three different PAS configurations. Before donning the exoskeleton, the subjects were presented with a body diagram and asked to specify their current sensory responsiveness. By marking numb or highly sensitive body regions, such influences on the perceived discomfort were registered. The healthy subjects were then asked to minimize their muscle activity below lumbar level while executing a defined movement protocol with the VariLeg exoskeleton. The protocol consisted of isolated ADL executions, including repeated sit-to-stand transition, level walking, as well as static standing and sitting. After each isolated movement execution, comfort evaluations were assessed.

C. Outcome Measures

To specifically assess the users subjective opinion in user experience, a combination of summative and formative measures were used [38]. The aim was thereby to show, that an evaluation solely based on qualitative measures, namely a customized questionnaire, a standardized usability scale as well as pain rating scales can be sufficient to capture and assess usability differences in pilot attachment systems. As all included subjects were native German speakers, all evaluations and discussions were translated and/or assessed in German.

1) Paraplegic User Experience Questionnaire: For an extended evaluation and formative measure of the user experience with the PAS, a custom-made questionnaire focusing on the long-term use of the VariLeg was designed. The use of open-ended questions allowed the experienced

paraplegic exoskeleton users to reflect on the tested system and state their opinions on different attachment configurations. Also, specific wishes and ideas could be further elaborated in writing. Additionally statements concerning ergonomics, repeatability, safety, adaptability, ease of use as well as consequential physiological aspects of the PAS were evaluated in form of 7-point Likert scales [39], similar to previously used evaluations by Bortole et al. [40]. For example, the paraplegic subjects were asked to state their level of agreement with statements such as *"I feel safe transferring from the wheelchair into the exoskeleton"*, or *"The tested PAS is a clear limiting factor preventing daily usage of the VariLeg exoskeleton"*.

As the performance of the PAS can not be completely segregated from the whole exoskeleton, many of the questions regarding user experience automatically integrated several other aspects outside of the scope of this work, such as general mechanical design and control of the VariLeg. The questionnaire was assessed at the start and very end of the study, such that the $PAS_{intermediate}$ and PAS_{final} could be compared thoroughly.

2) System Usability Scale: As a summative measure to quantify and compare the usability of the different PAS, the System Usability Scale (SUS) [21] was used with the paraplegic subjects. The SUS includes 10 statements rated by means of a 5-point Likert scale, from 1 (strongly disagree) to 5 (strongly agree), so each statement contributes with 0-4 points. The sum of all contributions is then multiplied by 2.5 such that the final score ranges between 0 (no satisfaction) and 100 (extreme satisfaction). To simplify the original SUS to the context of assessing the PAS as a subsystem of the VariLeg exoskeleton, the word "system" was replaced by "PAS" and three statements (namely number 5, 7, 10) of the original work were adapted as follows: *5.) I found the time needed to mount the PAS satisfying, 7.) I found the PAS convenient and comfortable to use, 10.) I thought the PAS aggravates the transfer into the exoskeleton substantially.*

Each of the three PAS configurations mentioned in section III was assessed twice per subject, with a temporal distance of two weeks. As a SUS reference, the pilots also rated the PAS of the commercially available Ekso GT™ exoskeleton, after testing the device in a single training session at the Swiss Paraplegic Centre, Nottwil, Switzerland.

3) Local Discomfort Heat Map: To assess the wearing comfort during the execution of different ADL assisted by the VariLeg exoskeleton, an assessment for healthy subjects was designed on the basis of simple pain rating scales [41]. Body schematics (ventral and dorsal view) were separated into 13 distinct body regions to split for example the dorsal trunk into: shoulders, upper back, lower back, pelvic area and buttocks. The tasks included sitting, standing and level walking. The healthy subjects were asked to state their local level of discomfort during each ADL task execution. The pain rating was scaled from 0-10, with 0 representing no pain at all and 10 representing unbearable pain. The mean pain values per body segment during all tasks was calculated for each subject. These individual mean values were then combined to obtain one pain value per body region representing all subjects. By mapping the resulting combined mean per body region to a green-to-red color bar, comfort heat maps of each PAS configuration were created. Additionally, the general comfort during each ADL was rated on a 7-point Likert scale.

IV. Results

A. Re-desinged Pilot Attachment System

The configuration of the new upper body, hip and foot attachments together with the initial PAS concepts formed the $PAS_{intermediate}$. All new concepts and design changes combined formed the PAS_{final}, shown in figure 2. The design considerations and attributes of each concept are listed as follows:

1) Upper Body: The new upper body concept allows the use of different attachment combinations depending on the SCI lesion height. For a high lesion requiring a firm connection of the torso to the exoskeleton, a harness system reinforced with foamed PVC sheets can be arranged and connected with a lower torso belt to the buckles on a belly cushion. For a lower and less restricting concept, the system can be used without the harness, such that only the lower torso is fixated with the belt and belly cushion in combination with the hip concept (Fig. 2a). This allows a user with a lower lesion level to more actively use the remaining torso control for maintaining balance. Different sizes and forms of cushions can be chosen to accommodate varying physiques and assure fixation stability.

2) Hip: In combination with the upper body concept, an adjustable pelvic plate was designed. A belt around the waist, which is connected from the pelvic plate to the lower buckles on the belly cushion, allows a stable hip fixation. The aluminum backbone can be adjusted in the anterior-posterior as well as proximal-distal direction to accommodate to different spinal curvatures (Fig. 2b). To assure comfort, the aluminum frame is connected to a hip-wide foam plate which can then be further cushioned with orthopedic-grade pads.

3) Thigh: On the mid-thigh region, compliant thermoplastic cuffs equipped with orthopedic-grade padding form a compact fixation. Due to their softness and structure, the cuffs can be deformed and held down to build a flat surface on the seating area to simplify the transfer in and out of the exoskeleton.

4) Shank: An increased compliance in the thigh concept was thought to interplay with a firm and stable fixation on the anterior shank area. Double-layered thermoplastic shells with sufficient padding provide a large contact area on the upper tibia to distribute the acting forces. A spring supported hinge system allows the opened cuffs to rotate outwards, laterally away from the exoskeleton's frame, to facilitate the access with a wheelchair (Fig. 2c).

5) Foot: The new attachment concept allows for the shoes to be donned outside of the exoskeleton, and - after transfer - to be mounted on to the exoskeleton leg structure. A connection rod from the ankle joint was bent and reshaped, such that it can be inserted into a steel tunnel, which itself was integrated into the sole of a firm trekking shoe - also oversized relative to the actual user's foot size.

B. Outcome Measures

1) User Experience Questionnaire: Derived from the user experience statements collected from the open-ended questionnaire, the PAS_{final} seems to no longer be a main restricting point to fully exploit the VariLeg exoskeleton's functions. General statements on comfort and attachment consistency reflected a positive effect of the implemented PAS changes. Both pilots now recommend to approach other weaknesses of the device and felt appropriately considered in the PAS solutions. Although the transfer in and out of the exoskeleton was simplified with less spatially restricting lower limb fixations, and independent usage in, e.g. daily life, seems not yet feasible as fastening and loosening the attachment of the PAS_{final} still requires assistance. The feeling of safety and level of trust into the PAS and general usage of the VariLeg exoskeleton was not changed between the $PAS_{initial}$ and PAS_{final}.

2) System Usability Scale: As shown in figure 3, the combined mean SUS score of the $PAS_{initial}$ was 22.5/100 points. The Ekso GT™ was rated with a mean of 83/100 and subsequently used as relative value representing a good PAS usability to compare to [42]. The $PAS_{intermediate}$ was rated with a combined mean of 52/100 and the PAS_{final} with 59.5/100 points respectively. Normalizing these scores to the Ekso GT™, a 36% improvement with the $PAS_{intermediate}$ and a 45% improvement with the PAS_{final} were measured compared to the $PAS_{initial}$.

3) Local Discomfort Heat Map: No considerable deficits in sensory responsiveness were reported, such that all healthy subjects were able to rate any perceived discomfort caused by PAS usage. In figure 4, the overall mean pain values of the segregated body regions are displayed in a discomfort heat map, represented with color mapping. Since none of the mean pain values reached higher than 5 on the 0 to 10 scale, the green-to-red color bar was refined from 0 to 5 to enhance the coloring contrasts.

V. Discussion

The pilot attachment system (PAS) of the VariLeg exoskeleton was identified as one of the main components affecting usability and comfort of the assistive device, and was redesigned based on a user-centered design and subjective evaluation approach. An increase in usability for the target population can be concluded, as an overall improvement of comfort and usability was observed with the different evaluation measures assessed with experienced paraplegic, and novice neurologically intact exoskeleton pilots.

The two paraplegic pilots agreed that the usability has improved, but showed disagreement with the actual amount

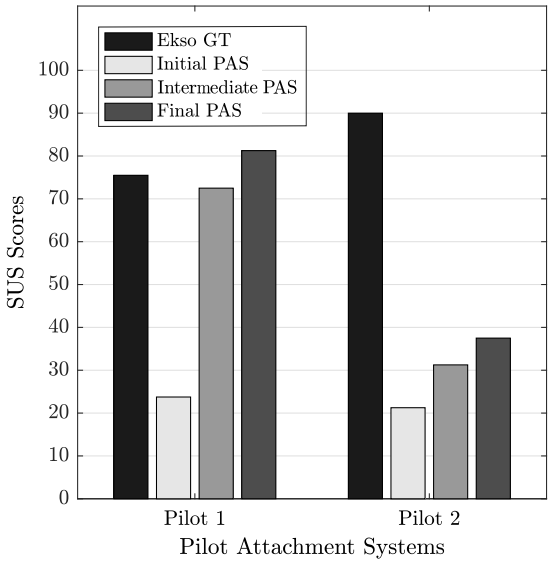

Fig. 3. **System Usability Scale scoring of the paraplegic pilot testing.** No standard error of the mean applied, as the total number of evaluations is n=2 for all shown PAS configurations.

of change. Pilot 2 still seemed not fully satisfied with the PAS_{final}, by rating comfort and safety lower than for the initial configuration in both, the individual SUS statements as well as in the user experience questionnaire. On the other hand, pilot 1 rated the final configuration with a SUS score exceeding the Ekso GT™ used as reference. The reference value should however be interpreted with caution, as this was the only exoskeleton tested aside from the VariLeg, and was used in a brief, single session. Also, the rating of the different PAS could have been influenced by the timing of the Ekso GT™ testing session, as it was assessed between the assessment sessions of the $PAS_{intermediate}$ and PAS_{final}.

Changes implemented in the $PAS_{intermediate}$ showed the expected strong impact on comfort and usability of the PAS. This was observable in the 36% increase in the mean SUS score (Fig. 3), as well as in a decreased regional discomfort illustrated in the heat-map (Fig. 4). Interestingly, the thigh and shank pain points reported in the $PAS_{initial}$ were almost completely removed without changing those attachment concepts for the $PAS_{intermediate}$ configuration. This might have resulted from the new, adaptable pelvic plate, as hip flexion angles could now be supported more individually, allowing for a more upright posture. The stabilizing force on the pelvis was perceived as less comfortable than in the initial solution, also due to the fact that the interface padding was not yet optimized. Additionally, an increased complexity of use and preparation time was the consequence of the implemented adjustment options, which represented the general difficulty in balancing maximal joint alignment with optimal comfort. Although there were still minor drawbacks in the current solution, the adaptable pelvic plate represented a great example of a novel user interface concept, offering high adaptability to improve usability for a wide range of users.

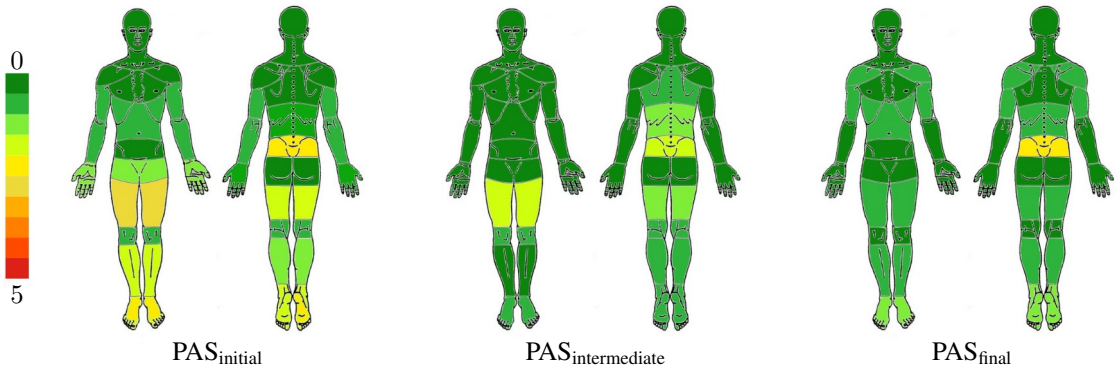

Fig. 4. **Results of the healthy pilot discomfort evaluation of specific body regions.** The heat maps of the three defined PAS configurations are displayed. From left to right: Initial, intermediate and final PAS. The overall mean pain value for each body region is represented by color mapping. The range of values from 0 to 5 is represented in a green-to-red color bar, with increments of 0.5 for each basic color. Dark green represents areas of no discomfort with mean pain values < 0.5, dark red represents areas of substantial discomfort with mean pain values > 4.5

The comfort evaluation with healthy subjects clearly helped understanding, identifying and tackling local pain points. However, these findings need to be interpreted with caution, as a notable difference in muscular tissue and bone density leads to highly diverging physiques between healthy and chronic spinal cord injured subjects. For example, healthy subjects reported the initial thigh cuffs to be too tight, likely due to the fact that they were designed for atrophied thighs. Also, relaxing the lower body muscles to mimic functional deficits is still quite different to the usage with paraplegic subject. Nonetheless, one can conclude that integrating healthy subjects into comfort evaluations as part of assistive device development can potentially increase to usability for the target population user.

From the assessed measures and thinking aloud responses, one can conclude that the PAS_{final} needs further optimization. Still, changes implemented additional to the $PAS_{intermediate}$ configuration further increased the mean SUS ratings by 9%, leading to a total improvement of 45% from the $PAS_{initial}$. The thigh attachment of the $PAS_{initial}$ was initially observed to substantially decrease the comfort and safety of transferring in and out of the exoskeleton and therefore had been highlighted as main safety concern to be addressed. The more compliant thigh concept in the PAS_{final} was appreciated during the transfer, but observably increased the load on the anterior shank cuffs causing an unstable fixation in the anterior-posterior direction during sit-to-stand transfer. A less compliant thigh attachment or different interplay to the shank concept should be implemented, such that a better knee fixation stability could be achieved. In conclusion, lower limb attachment concepts for paraplegic users should be designed such that firm fixation during usage is provided, but that the transfer in and out of the exoskeleton generates minimum safety risks. It is important to note that long-term usability aspects such as robustness and repeatability are yet to be assessed for the novel configurations compared to the $PAS_{initial}$.

The rather scarce availability of validated and standardized measures for the specific context of this study led to the expected difficulties in assessing the needs of the intended end-users and implementing such evaluations into incremental PAS development. Due to the high intra- and inter-rater variability and limited number of subjects in the SUS responses (Figure 3), statistical tests to assess the significance of changes were considered inappropriate. In addition to high variability, the SUS responses might be biased, as co-designing subjects tend to rate an implemented change that is based on their suggestion as beneficial, while it may not necessarily improve the usability for other users. Nonetheless, it has previously been shown that the SUS can be used for any kind of system usability evaluation and leads to interpretive results even with a test population of two subjects [42][43]. Furthermore, it appears that slight adaptions to and translations of the SUS do not affect reliability and validity measures assessing the intended aspects of system usability [42][44]. Still, the small sample size as well as the missing inclusion of independent target population subjects clearly limit the generalization of the obtained results.

In conclusion, this work should be interpreted as case study with the purpose of applying a user-focused, qualitative evaluation protocol to the PAS development to increase the integration of the target populations' needs. For future work, a more in-depth investigation of the evaluation context should help identifying standardized measures, which will then be assessed in their original, validated form. Nonetheless, the practically oriented application of customized, subjective measures has demonstrated the potential for improving the usability of an assistive device; in this case the usability of the PAS of the VariLeg lower limb exoskeleton.

VI. Conclusion

An overall increase in comfort and user experience of the VariLeg powered lower limb exoskeleton was achieved by realizing a user-centered redesign of the physical interface system. We could show that qualitative usability evaluations, improved needs assessments, and the resulting design improvements favorably impacted the device and its intended application. Integrating the target population into each stage of assistive technology development could help overcoming acceptance limitations and to more significantly improve the quality of life of people living with functional disabilities.

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