User Satisfaction with Conventional Lower-Limb Orthotic Devices: a Cross-Sectional Survey in Pakistan

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ABSTRACT

Purpose: *Persons with disabilities affecting lower-limb function use ankle-foot-orthoses (AFO) and knee-ankle-foot-orthoses (KAFO) on a regular basis. However, the effectiveness of these devices in daily use is seldom evaluated, especially in the developing world. This study aimed to evaluate user satisfaction with lower-limb orthotic devices while performing a broad spectrum of daily life activities in Pakistan, and to document the desired outcomes.*

Method: *A survey was conducted among orthotic device users in the out-patient departments of three hospitals in Lahore, Pakistan. The survey questionnaire was devised by adapting the Prosthetic Evaluation Questionnaire to suit orthotics evaluation. Fifty-four AFO and KAFO users participated in the study.*

Results: *Most users felt comfortable while walking on even surfaces with their orthoses. However, donning/doffing these, climbing stairs and performing certain routine activities were considered problematic for most people. Energy conservation was the most desired AFO feature, while the KAFO users wanted automatic knee-joint function.*

Conclusion and Implications: *Overall satisfaction with the existing lower-limb orthoses is adequate. Yet, significant improvements are needed in terms of energy efficiency and comfort while walking on different terrains. Further research is required in order to improve the functioning of the existing orthotic devices.*

Key words: *lower-limb orthoses, polio, stroke, AFO, KAFO*

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INTRODUCTION

Around 1 billion people in the world live with disabilities and 80% of these persons live in developing countries in Asia and Africa (World Health Organisation, 2011). This results in lower educational achievements, fewer economic opportunities and higher rates of poverty among people with disability. Pakistan is the sixth most populous country in the world, with around 2.5% of the total population having a disability (Pakistan Bureau of Statistics, 1998). Among these, the largest group (19%) consists of people marked as "crippled" (unable to walk) in the Census. Today, the country has an estimated 5 million people with disabilities, with as many as 1 million unable to walk independently.

A large number of people suffer from neuromuscular diseases such as polio. It is yet to be eradicated completely in Pakistan (World Health Organisation, 2018). Other causes of disability include muscular dystrophy, spinal cord injuries and stroke. All these conditions lead to muscle weakness or paralysis of the legs. People with polio, in particular, have significantly reduced quadriceps muscle strength (Perry, 1992), making the knee joint unstable during walking. In order to improve stability while standing and walking, these persons are commonly prescribed with ankle-foot-orthoses (AFO) or knee-ankle-foot- orthoses (KAFO) (Lusardi et al,2013). These are custom-built wearable orthoses, usually made from thermoplastics. The effectiveness of these devices in restoring user independence is evident from decades of clinical experience and has also been reported in some clinical trials (Pavlik, 2008). The use of such devices is common in many countries including Pakistan.

In Pakistan, orthotic devices are generally provided by the secondary/tertiary level public hospitals and by various charity organisations. Persons with disabilities visit the out-patient department where a physician recommends a consultation with the orthotics department, usually located within the hospital premises. An orthotist chooses a suitable device after examining the client and taking measurements. The cuffs of ankle-foot-orthoses (AFO) and knee-ankle-foot-orthoses (KAFO) are manufactured with thermoplastics, while uprights are made of stainless steel. Once it is ready, the client is invited to train with the device and the necessary adjustments, if any, are made. The client is then advised to make a follow-up visit after one month.

According to some international studies, as many as 54% of AFO users abandon their devices after a while, citing various reasons such as discomfort, pain,

and weight (Gitlin et al,1996; Safaz et al,2015). These issues are generally not obvious in the laboratory and become evident only after prolonged use in daily life. Moreover, many clinical outcome measurement instruments (e.g., Barthel Index, Functional Independence Measure, etc.) do not identify aspects that are important from the user's perspective.

To this end, user survey is an effective tool. A few studies have used qualitative and quantitative surveys to evaluate the users' satisfaction with the orthoses. Fisher and McLellan (1989) conducted a survey in England, using a questionnaire to assess clients' satisfaction with lower-limb orthoses. The survey questionnaire focused largely on the comfort and fit of the device, along with provision delays and general satisfaction. Overall, 16% of the AFO users revealed dissatisfaction with the weight of their device and its failure to improve mobility. However, information associated with pain, energy expenditure, and ability to perform activities of daily life was not covered by the questionnaire. Similarly, Phillips et al (2011) did a qualitative study with 15 AFO users living with Charcot-Marie-Tooth (CMT) disease in the UK. The study ranked the top advantages and drawbacks of the AFOs, based on user opinion. More recently, O'Connors et al (2016) interviewed 15 AFO and KAFO users from the NHS service in England. They assessed the clinical effectiveness of orthotic management for an unstable knee following neuromuscular and central nervous system (CNS) diseases. The study also went a step further and inquired about the prime desired outcomes and valued features in their devices. Similarly, surveys assessing user satisfaction have been carried out in countries such as Italy (Vinci and Gargiulo,2008), with insights into the factors affecting the compliance of orthotic devices with the users.

However, these studies were all limited in scope, either in terms of the type of device (mostly involving only AFO users) or in evaluating only a few aspects of daily life (e.g., the fitting or pain/fatigue or falls). Moreover, these were conducted in advanced countries and usually carried out a qualitative assessment. To the author's knowledge, no such studies have been carried out in the developing world to quantify the satisfaction and expectations of both AFO and KAFO users.

Objective

To address this gap, a pilot survey of AFO and KAFO users was conducted in three different hospitals in Pakistan. The purpose of the survey was two-fold:

- To evaluate user satisfaction with lower-limb orthotic devices while performing a broad spectrum of daily life activities in Pakistan, and
- To identify users' desired outcomes and features related to the orthotic devices.

METHOD

Study Setting

From June to August 2018, surveys were conducted among clients in the outpatient departments of three hospitals (Pakistan Society for the Rehabilitation of the Disabled (PSRD) Hospital, Ghurki Trust Teaching Hospital, and Shahbaz Sharif Indus Hospital) in Lahore, Pakistan. A single interviewer interacted with the clients in person, and asked them questions from a questionnaire in the local language (Urdu). Interviews were conducted in the presence of a healthcare professional.

Study Sample

Using convenience sampling, study participants were directly recruited from the out-patient departments. Participants were screened on the basis of age, types of device used and the experience level.

Inclusion criteria:

- Persons at least 15 years of age,
- Only AFO and KAFO users, and
- Those who had used the orthotic device for 1 year at the minimum.

The survey participants comprised 41 male and 13 female users, from 15 - 60 years of age. All the users currently employed a custom-moulded orthosis made of thermoplastics, as prescribed by the doctor of physiotherapy and fabricated in the in-house facility.

Survey Questionnaire

Although a validated Prosthetic Evaluation Questionnaire (Legro et al,1998) has been developed and used extensively to evaluate functional outcomes of lower-limb prostheses (Boone and Coleman, 2006), no questionnaire exists for

evaluating orthoses. Proebsting et al (2017) recently adapted the PEQ to compare the effectiveness of the C-brace (a microprocessor-based KAFO device) with a traditional KAFO device. Using a similar approach, the current author adapted the Prosthetic Evaluation Questionnaire. While reducing its size from 9 domains to the 4 most relevant domains, a few questions were added relating to the local community (e.g., the use of an Indian toilet seat) and users' desired outcomes from their orthotic devices. The survey was reviewed by all the collaborators who were physiatrists and engineers. The questions were analysed for their relevance to the objectives of this study and their proper construction.

The survey comprised 46 questions in total. After the basic biodata questions, there were a few questions pertaining to the disability (the type, duration, etc.) and the rest were related to users' perceptions of their existing devices, categorised into four domains: general satisfaction, bodily discomforts, ability to move around, and daily activities. The selected domains reflected the focus of this study on the functional aspects of these devices. For most questions, users rated their satisfaction with different aspects and their ability to perform certain activities with their existing orthoses on a symmetric Likert-type Scale of 1-5. A higher rating indicated a more favourable condition (more happiness, ease of performing an activity, etc.), except for the frequency-related questions (pain, falls, etc.). A few questions required a simple binary response, such as, for the weight of the device 'bearable vs. unbearable'. (The survey questionnaire has been included as an Appendix.)

An important objective of this study was to identify users' preferences in terms of their device features. To achieve this, in the last section, the users were asked to suggest 3 improvements they would like to have in their devices. They could either choose from a list of 12 features related to the form and function of the device or could suggest any feature of their own. The choices were presented to the participant in no specific order and were explained by the interviewer wherever necessary.

Data Analysis

The collected data was entered into the SPSS® (IBM SPSS Statistics, version 25) for further analysis. Descriptive statistical analysis was performed on the data from all categories, collectively as well as separately, for both user groups (AFO and KAFO users). The responses to the final question regarding the desired features were grouped together and ranked accordingly.

Ethics Approval

Ethics approval was granted by the departmental Ethics Review Committee at the University of Central Punjab in Lahore, Pakistan. Many of the participants could not read or write, so their verbal consent was taken on the spot to ensure a uniform protocol throughout the survey.

RESULTS

Out of a total of 54 participants, 37 individuals (26 males, 11 females) used a KAFO device with a locked knee version, while 17 individuals (15 males, 2 female) used an AFO device. A large majority of participants lived with either polio (38) or stroke (14). Two users had orthoses following a traumatic injury (1 AFO and 1 KAFO user). Of the 38 people living with polio, 33 had weakness in one leg only. All people with polio (except for 2) used KAFO, while all the 14 people with stroke used an AFO.

The mean age of the participants was 33.5 ± 9.9 years. Two-thirds of the participants belonged to the 26 – 45 years age bracket. Though the average age of the participants was similar for both user groups, there was a large difference between the mean numbers of device-use years (4.4 years for AFO users vs. 13 years for KAFO users). The users' level of experience with their device varied greatly, ranging from a minimum of 1 year to a maximum of 37 years.

Table 1: Profile of the Orthotic Device Users in the Study

Attribute	AFO users	KAFO users
Age (years) Mean ± s.d.	34.8 ± 10.3	32.9 ± 9.8
No. of years since using the device, Mean ± s.d.	4.4 ± 7.0	13.1 ± 11.0
Reason of disability:	Stroke: 14 Polio, one affected leg: 02 Trauma: 01 Total: 17	Polio-one affected leg: 31 Polio-both legs affected: 05 Trauma: 01 Total: 37

While 89% of all study participants used their device for 6 hours or more during the day, 65.4% wore it for more than 8 hours. All the users employed the device regularly while walking.

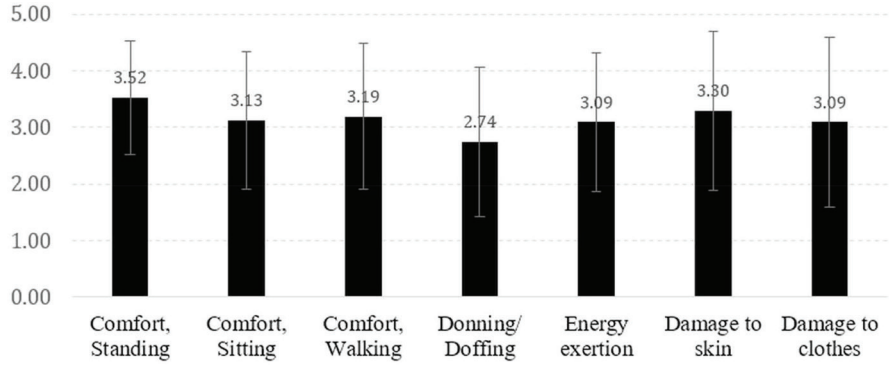
Perceived Comfort and Overall Satisfaction

Questions regarding perceived comfort and wearability of the device resulted in mixed responses. Figure 1 shows the mean ratings for some of these criteria. As a whole, the comfort in standing, sitting and walking had a mean rating of over 3 out of 5. The donning/ doffing of the device received the least mean rating (2.74±1.32) in this category. Moreover, the energy exertion received a mean rating of 3.1 (±1.2), corresponding to a 'moderate' level of exertion.

The question regarding overall satisfaction with the existing device received a mean rating of 4.07 (±0.866). The majority of the users (38 or 70%) gave a rating of 4 or above for this criterion (corresponding to the word choices of 'happy' and 'extremely happy').

A majority of users (51 out of 54) rated the weight of their device as 'bearable'. Questions regarding damage to the skin and clothes by the device received a mean rating of 3.3 and 3.1 respectively, with large standard deviation among subject responses.

Figure 1: Results regarding Comfort and Satisfaction with the Orthoses



Bodily Discomfort and Falling

The survey included five questions regarding sweating and leg and back pains. Forty-one users (76%) reported 'moderate' to 'extreme' sweating inside their orthoses during summer. The mean rating was 2.81 (±1.06).

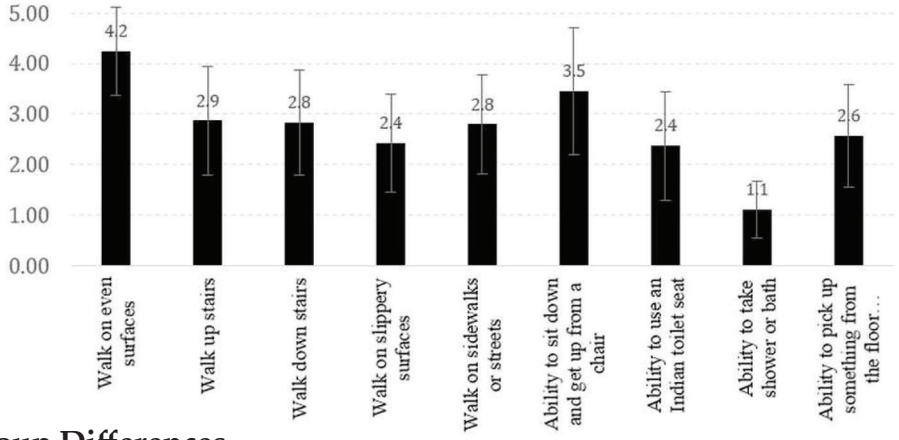
Between 30-70% of the users reported the occurrence of leg and back pain (once per week or more) while using their devices. However, the intensity of pain

ranged from 'mild' to 'moderate' in most cases. Among the participants, 31 users (14 AFO and 17 KAFO) experienced at least one fall while wearing their device, while 23 reported very frequent falls (once a week or more).

Locomotion and Other Daily Activities

There was a clear distinction between walking on even and rough surfaces, and stair ascent/descent. While walking on flat ground was deemed to be easy for most individuals (mean rating of 4.24 ± 0.867), walking outdoors and climbing/descending stairs were difficult for most of them, reflected by their mean ratings between 2.4 and 2.9 for these activities (Figure 2). Most users reported difficulty in performing other tasks, such as using a toilet or taking a bath, with very low mean ratings.

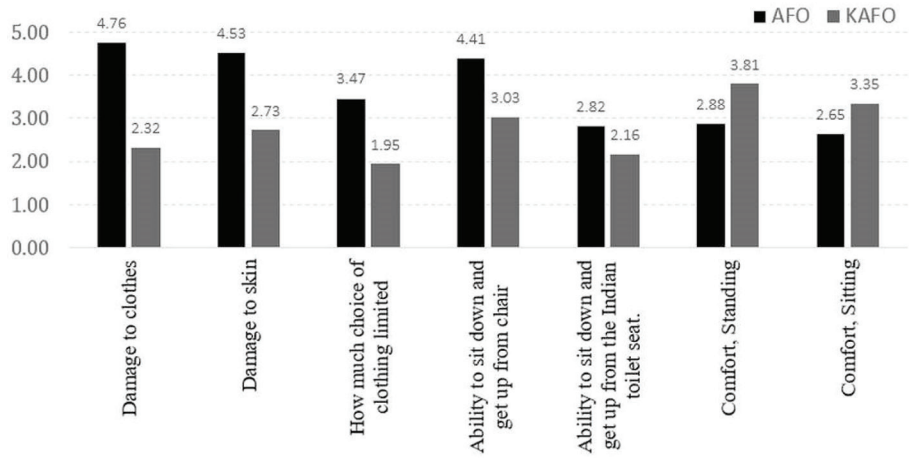
Figure 2: Results regarding Walking and Other Activities of Daily Life



Inter-group Differences

The combined responses from both the ankle-foot-orthoses users and the knee-ankle-foot-orthoses users (presented in Figure 2) gives a holistic picture of the satisfaction levels of users in Pakistan. However, the two user groups reported different pain points in some aspects of their devices. Figure 3 shows separate mean ratings for questions where the maximum variation between the two groups was observed. The largest difference in mean ratings was observed for the questions related to damage to skin and clothes. The KAFO users reported much lower rating to their orthoses in terms of damage to skin and clothes and their choice in clothing. Similarly, the ability to sit down and get up from a chair and the Indian toilet seat was also reportedly much more difficult for the KAFO users. However, in terms of standing and sitting with the orthoses, KAFO users rated their comfort higher than the AFO users.

Figure 3: Mean Ratings given by AFO (black) and KAFO (grey) Users for Key Areas of Difference between the AFO and KAFO Groups

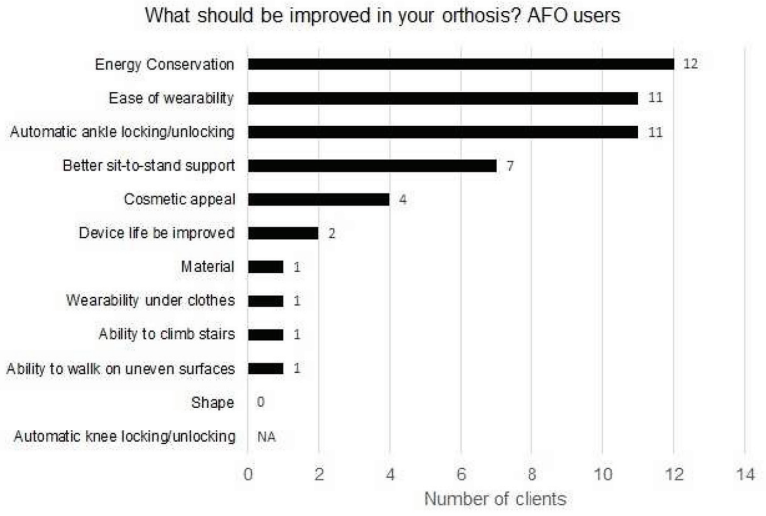


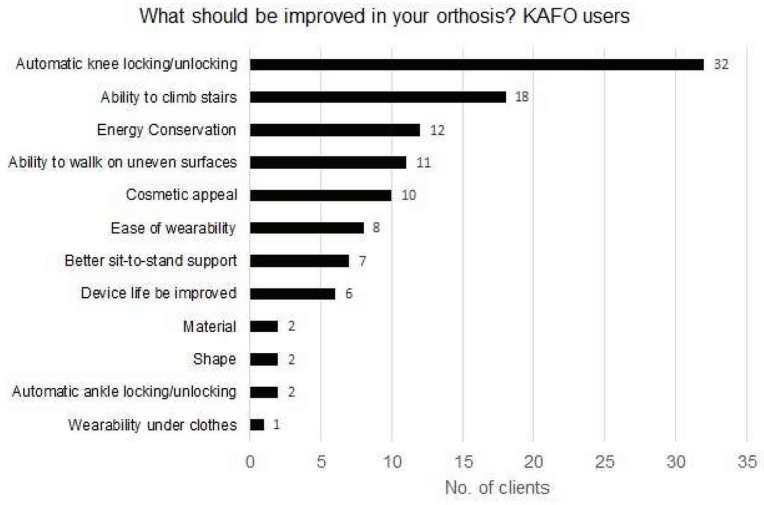
Difference was also observed in terms of falls and trips. Among the AFO users, 14 out of 17 (82%) reported a fall or trip while walking with their orthoses, as compared to 46% of KAFO users.

Future Improvements

The results from the last question regarding the users' desired outcomes are summarised in Figure 4 for AFO and KAFO users separately.

Figure 4: Desired Improvements based on Opinions of (a) AFO users and (b) KAFO users





'Energy conservation' was considered the most desired aspect by the AFO users, with 12 out of 17 participants selecting it among their top three choices. This was followed by 'ease of wearability' and 'automatic ankle joint function' options. For the KAFO users, the most desired feature was 'automatic knee locking/unlocking', with 32 out of 37 participants picking this option. It was followed by the 'ability to climb stairs' and 'energy conservation' aspects.

DISCUSSION

The main purpose of this study was to evaluate the performance of low-cost orthotic devices from the perspective of users in Pakistan. The majority of users expressed overall happiness while using their existing device. However, wearability of the device (putting on and taking off) was considered a difficult aspect. Other areas of dissatisfaction included walking on uneven surfaces, toileting, sweating and skin damage.

Comparison of mean scores between ankle-foot-orthoses users and knee-ankle-foot-orthoses users revealed a few differences in areas of concern. The issue of skin and clothes damage, which is a key concern for KAFO users, could be attributed to the design of the device and would require resolution at that level. However, some other aspects are a result of the users' underlying disease condition and should be taken into consideration in order to fully understand their dynamics. For example, it is possible that stroke-related gait deficits (Weerdesteijn et al,2008) were responsible for more frequent falls among AFO users. Nevertheless, these results give an insight into the key areas that orthoses designers need to focus on.

A major contribution of this article is the identification of desired outcomes from the users' perspectives. A large majority of the KAFO users wanted to automate their knee joint function in order to free-up their knee joint when needed (e.g., during the swing phase of walking). It is well known that locking the knee joint during walking results in abnormal gait pattern involving compensatory movements (hip hike, leg circumduction) and high energy expenditure (Waters and Mulroy,1999; Zissimopoulos et al,2007). Rehabilitation specialists have long recognised the need to remove this constraint (Michael and Bowker,1994). Moreover, as this survey result demonstrated, this constraint also prevented the users from effectively performing certain activities such as kneeling on the floor or using the Indian toilet. In order to address this issue, the Stance Control KAFO (SC-KAFO) has been developed which unlocks the knee joint during swing, using a mechanical switching mechanism (Irby et al,2005; Yakimovich et al,2009) or by an onboard computing unit (e.g., the C-Brace by Ottobock). While these innovations have demonstrated improved gait function and reduced energy expenditure, several design and cost challenges need to be addressed before these devices may be used on a mass scale (Bernhardt et al,2006; Yakimovich et al,2009). Local research into the design of Stance Control knee joints which can be retrofitted into the existing KAFO versions would be of value in this context.

On the other hand, AFO users predominantly selected energy conservation as the top desired outcome from their device. It can be speculated that while existing AFO devices improve the walking efficiency of stroke clients, users expect even better energy efficiency. Keeping in view these results and existing literature that reported an increased energy cost per meter for stroke survivors (Zamparo et al,1995; Waters and Mulroy,1999), research towards reducing this cost by using elastic elements (Collins et al,2015) in the orthoses may be of interest in this regard.

The results of the current study highlighted some challenges specific to the local society. Due to the hot climate, both user groups reported considerable sweating inside their orthoses. Similarly, they reported difficulty in using the squat-type Indian toilet which requires extensive knee-bending. To the best of the author's knowledge, these aspects have not been highlighted in earlier survey studies.

Limitations

This study has several limitations. First of all, only orthoses users were recruited at follow-up appointments in hospitals. Hence, there was no possibility of

interaction with the dissatisfied users who had stopped using their devices. This may have positively skewed the overall satisfaction rating for the study sample. Moreover, the surveys took place in Lahore, a predominantly urban area in the plains. Future studies are needed, with a larger and more diverse sample, for confidence in generalising these results to samples that are demographically and geographically different.

The survey questionnaire for this study was derived from the Prosthetic Evaluation Questionnaire, and its validity in the case of orthoses users is not known. However, complete validation of a questionnaire requires rigorous development and statistical testing (Boone,2006) which was not the purpose of this study. There is a need for a validated questionnaire to make the results of future studies comparable and more reliable.

CONCLUSION

The conventional ankle-foot-orthoses and knee-ankle-foot-orthoses for people living with polio and stroke in Pakistan need improvement in terms of energy efficiency and walking on uneven terrain. In contrast to the previous studies indicating less weight and cosmetic appeal as prime desired outcomes for AFO user groups, the users in this study seemed more concerned about the functionality of their devices. Only about one-fourth of the surveyed users chose cosmetic appeal as their preference (see Figure 4).

These results will help researchers in user-centric decision-making in the design of these devices and can guide future research activities. The results are also useful for designing rehabilitation services for persons with disabilities.

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Appendix

Serial Number: US_____

Date _____

Location _____

A survey on the effectiveness of conventional lower-body orthoses

BioMechatronics Lab,
University of Central Punjab, Lahore

QUESTIONNAIRE

Patient information:	**Disability information:**
Name: _____	(i) Reason of disability:
Gender: □ Male □ Female	□ Multiple Sclerosis □ Muscular Dystrophy
Age: _____years	□ Stroke □ Spinal Cord Injury
City of residence: _____	□ Polio (□ One Leg (□ Left □ Right) □ Two Leg)
Occupation: _____	□ Other_____
Income: _____	(ii) Time since disability: _____ years
	(iii) Using any assistive device: □ Yes □ No
	(iv) Type of device used: □ AFO □ KAFO
	(v) Using since: _____years
	(vi) Name of brand/manufacturer: _____
	(vii) Cost paid:_____

Section 1: General

Q1: For how many hours do you use the device?	0-2 □ 1	2-4 □ 2	4-6 □ 3	6-8 □ 4	8+ □ 5
Q2: How often do you use this device during walking?	Rarely □ 1	Occasionally □ 2	Often □ 3	Usually □ 4	Always □ 5

Q3: How do you categorize the weight of your device?	Un-bearable □ 1	Bearable □ 2			
Q4: How would you rate your comfort while standing using your orthosis?	Not at all Comfor-table □ 1	Somewhat uncom-fortable □ 2	Neutral □ 3	Somewhat Comfortable □ 4	Very Comfortable □ 5
Q5: How would you rate your comfort while sitting using your orthosis?	Not at all Comfor-table □ 1	Somewhat uncom-fortable □ 2	Neutral □ 3	Somewhat Comfortable □ 4	Very Comfortable □ 5

Q6: How would you rate your comfort while walking using your orthosis?	Not at all Comfortable □ 1	Somewhat uncomfortable □ 2	Neutral □ 3	Somewhat Comfortable □ 4	Very Comfortable □ 5
Q7: How would you rate the ease/ difficulty of donning and doffing of your orthosis?	Extremely difficult □ 1	Difficult □ 2	Neither Easy nor Difficult □ 3	Easy □ 4	Very Easy □ 5
Q8: How would you rate the energy exertion during walking with your orthosis?	Extreme □ 1	Significant □ 2	Moderate □ 3	Small □ 4	Negligible □ 5
Q9: How would you classify the damage done by the orthosis to your <u>skin</u>?	Extreme □ 1	Significant □ 2	Moderate □ 3	Small □ 4	Negligible □ 5
Q10: How would you classify the damage done by the orthosis to your <u>clothes</u>?	Extreme □ 1	Significant □ 2	Moderate □ 3	Small □ 4	Negligible □ 5
Q11: Overall, how happy are you with your device?	Extremely Unhappy □ 1	Unhappy □ 2	Neutral □ 3	Happy □ 4	Extremely Happy □ 5

Section 2: Bodily Discomforts

Q1: How much do you sweat inside orthosis in summer?	Extreme □ 1	Very □ 2	Moderate □ 3	Slight □ 4	Not at all □ 5
Q2: How often have you experienced back pain?	□ Never	□ 1-2 Times per Week	□ 3-6 Times per Week	□ Several times everyday	□ Almost all the time
Q3: If yes, what is the intensity of the pain?	Extremely Intensive □ 1	Intensive □ 2	Moderate □ 3	Mild □ 4	Negligible □ 5

Q4: How often have you experienced pain in the leg?	□ Never	□ 1-2 Times per Week	□ 3-6 Times per Week	□ Several times everyday	□ Almost all the time
Q5: If yes, what is the intensity of the pain?	Ex-tremely Intensive	Intensive	Moderate	Mild	Negligible
	□ 1	□ 2	□ 3	□ 4	□ 5

Section 3: Ability to move around

On a scale of 1-5, how would you rate your ability…

	Ex-tremely difficult	Difficult	Neither Easy nor Difficult	Easy	Very Easy
Q1: To walk on even surfaces?	□ 1	□ 2	□ 3	□ 4	□ 5
Q2: To walk upstairs?	□ 1	□ 2	□ 3	□ 4	□ 5
Q3: To walk downstairs?	□ 1	□ 2	□ 3	□ 4	□ 5
Q4: To walk on slippery surfaces?	□ 1	□ 2	□ 3	□ 4	□ 5
Q5: To walk on sidewalks or streets?	□ 1	□ 2	□ 3	□ 4	□ 5
Q6: To stand for a long time?	□ 1	□ 2	□ 3	□ 4	□ 5

Q7: Have you tripped or slipped during walking while wearing orthosis?	□ Yes	□ No			
Q8: If yes, how often have you experienced fall down?	□ Once a Month	□ Once a Week	□ 2-3 Times per Week	□ 4-6 Times per Week	□ Several Times Everyday

Section 4: Daily Activities

On a scale of 1-5, How would you rate your ability…

	Ex tremely difficult	Difficult	Neither Easy nor Difficult	Easy	Very Easy
Q1: To sit down and get up from a chair?	□ 1	□ 2	□ 3	□ 4	□ 5
Q2: To sit down and get up from the Indian toilet seat?	□ 1	□ 2	□ 3	□ 4	□ 5
Q3: To take shower or bath safely?	□ 1	□ 2	□ 3	□ 4	□ 5
Q4: To kneel down to pick up something off the floor?	□ 1	□ 2	□ 3	□ 4	□ 5

Q5: How limited is your choice of clothing due to your orthoses?	Ex-tremely Limited □ 1	Limited □ 2	Some-what Limited □ 3	Slightly Limited □ 4	Not at all □ 5
Q6: Do you drive any conveyance?	□ Yes	□ No			
Q7: If yes, which one you are using for travelling?	□ Bicycle	□ Motorbike	□ Rickshaw	□ Car	□ Other
Q8: Rate your ability to drive this vehicle?	□ 1	□ 2	□ 3	□ 4	□ 5

Section 5: Future Design

In your opinion, what should be IMPROVED in conventional knee braces/ orthoses? (tick 3 most applicable)	□ Ability to walk on uneven surfaces
	□ Ease of wear ability
	□ Better sit-to-stand support
	□ Automatic knee locking / unlocking
	□ Automatic ankle locking / unlocking
	□ Energy conservation
	□ Ability to climb stairs
	□ Device life be improved
	□ Cosmetic appeal
	□ Wearability under clothes
	□ Shape, please elaborate _____
	□ Material, please elaborate _____
	□ Other, please specify _____

Additional comments/suggestions:

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_____

_____

Thank you for your time