Identifying Needs for Ankle-Foot-Orthosis and Orthosis Provision Services Through Interview Analysis of Japanese Stroke Patients

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Abstract
Japan has approximately 1.74 million stroke patients, accounting for 16% of the elderly (age ≥ 65) who are eligible for nursing care. Stroke patients with lower limb disabilities often use a short-foot orthosis as a tool to improve their balance and walking ability. However, some ankle-foot-orthosis users stop using them and suffer a decline in their activities of daily living (ADLs). Therefore, understanding the needs of users is essential; however, only a few studies focused on this aspect have been reported in Japan. The purpose of this study was to interview stroke patients who use an ankle-foot-orthosis and to investigate the needs and difficulties experienced while using orthosis and orthosis services. Semi-structured interviews were conducted and the user's thoughts and opinions were extracted using steps for coding and theorizing. We extracted the benefits that stroke patients hoped to gain from wearing a ankle-foot-orthosis, the areas in which they desired improvements, such as the structure of the orthosis, and the anxieties they experienced while using the orthosis. We believe that by addressing these issues and modifying the orthosis to overcome the limitations of the current design, we can provide better orthosis and services to ankle-foot-orthosis users.

Keywords: Ankle-Foot-Orthosis, Interview Analysis, Stroke Patients

Introduction

Current status of ankle-foot-orthosis for managing the sequelae of a stroke

Stroke is a condition wherein the breakdown or blockage of blood vessels in the brain—cerebral hemorrhage (bleeding) or cerebral infarction (blockage due to blood clots)—impairs the functions of the central nervous system. Japan has approximately 1.74 million stroke patients (Ministry of Health, Labour and Welfare, 2022), accounting for 16% of all patients requiring long-term care in Japan and second only to the number of patients with dementia (Ministry of Health, Labour and Welfare, 2020).

Many stroke patients suffer from spastic paraplegia, or hemiplegia, in which the upper and lower limbs on both sides of the body are paralyzed, affecting the patient's ability to stand and walk smoothly. The patient's impaired mobility is a critical factor leading to their care-dependent condition, and various interventions, including rehabilitation, are being used to improve such conditions. One such intervention is the use of an ankle-foot-orthosis (Figure 1).

Figure 1: An Ankle-Foot-Orthosis

The acute rehabilitation section in the Japanese Guidelines for the Management of Stroke (2021) states that "Active rehabilitation, including early sitting/standing training, early gait training with an orthosis, feeding and swallowing training, and self-care training, be provided as early as possible after the onset of stroke under appropriate risk management." This recommendation for early rehabilitation after the onset of stroke is graded A, that is, it is strongly recommended to be implemented.

The section on Rehabilitation for Gait Disorders states that "It is reasonable to use an ankle-foot-orthosis to improve gait function in hemiplegic patients with hemiparesis due to stroke and a medial apogeotropic foot." This recommendation is graded B, that is, it is moderately recommended and considered reasonable to use. Thus, the use of an ankle-foot-orthosis during rehabilitation is considered an effective treatment method.

Many patients continue to use ankle-foot-orthosis in their daily lives after treatment to overcome the functional decline caused by residual hemiplegia. The use of an ankle-foot-orthosis by stroke patients during their daily activities is effective in improving their walking and balancing abilities, as evidenced by the scores for items other than the sitting position on the Berg Balance Scale (Muraguchi et al., 2013).

Status of the reflection of user intentions for products and services in other areas

In the fields of human factors and Kansei engineering, the importance of a human-centered design, with emphasis on factors such as "what users want" and "how they feel when using a product or service," is growing (Hashida, 2020). Creating a product or service with a human-centered design necessitates investigating the users' requirements and performing a user-centered evaluation. The users' intentions are reflected in their evaluation of the products and can be used for improving the products and services to meet the users' needs.

In the related field of service engineering, making users feel "extremely valued" or creating products and services "beyond their expectations" to promote "customer delight" is essential. In designing and delivering "excellent services" that make users feel delighted, the concept of co-creation, which involves listening to, engaging in dialog with, and reflecting on the voices of users, is indispensable (Ministry of Economy, Trade and Industry, 2021).

Current situation of orthosis non-use and purpose of this study

In Japan, a doctor's prescription is required to fabricate an orthosis. Therefore, in most cases, the decision on what type of orthosis is appropriate for the user is based on discussions among medical professionals, such as the physician who decides on the overall treatment plan, the physiotherapist who evaluates the physical condition and performs physical therapy, and the prosthetist and orthotist who manufactures and provides the orthosis. This situation is unlike that in other fields such as human factors and service engineering.

It has been suggested that these situations, wherein the users' intentions are not fully considered, are a factor in the non-use of orthosis (Ando, 2020). According to previous reports, approximately 30% of patients discontinue the use of orthosis after being discharged from the hospital (Hanagata & Sone, 2006). Abandonment of assistive devices is an issue that needs to be addressed because it not only causes a decline in the user's activities of daily living (ADLs) but also promotes negative spillover effects in society (Phillips & Zhao, 1993).

In this study, semi-structured interviews of ankle-foot-orthosis users in Japan were conducted to identify the need for improving an orthosis, the array of orthosis provision services currently available, and the factors that need attention and improvement in the provision of orthosis. We also sought to identify the interactions with orthotists and prosthetists and experiences with an orthosis that may have influenced users' needs and impressions of the orthosis and orthosis provision services.

Methodology

Subjects and Ethical Approval

This study included six patients (five female and one male) who lived in Japan and used an ankle-foot-orthosis in their daily lives to manage the sequelae of a stroke. The median age of the subjects was 59 years (52.00–72.75).

Ethical considerations were made in obtaining cooperation for this study. To protect the human rights of the subjects, we explained that participation in the survey was not mandatory, the interview data would not be used for other purposes, individuals would not be identified from the data during and after analysis, and subjects would not be penalized for not answering or stopping questions they did not want to answer.

This study was ethically reviewed and approved by the Hokkaido University of Science (Approval number: 595).

Interviewing and data analysis methods

After informing the subjects that the interview would last approximately 30 min, a semi-structured interview was conducted using an interview guide developed through discussions among researchers.

The subject was asked to freely choose an environment where he/she felt mentally comfortable and where there were few obstacles to the interview. Consequently, one subject was interviewed at home, one at a day service center, one at his/her university, and three were interviewed over the telephone. With the permission of the subjects, all statements were recorded on an Integrated Chip recorder and converted into audio data.

The audio data of the interviews were converted into text and used for data analysis based on the Steps for Coding and Theorization (SCAT). SCAT is a qualitative analysis method that provides theoretical descriptions (what can be said as a result of the analyzed data) after separating the textualized speech data from utterance by performing the following four coding steps (Otani, 2011):

Step 1: Extract words and phrases of interest from the text.
Step 2: Paraphrase the extracted words and phrases.
Step 3: Present concepts not represented in the text that might explain the paraphrased phrases.
Step 4: Describe the constructs (themes) taking into account the context of steps 1 to 3 and the conversation before and after.

Based on the constructs (themes) described in Step 4, a storyline was written out as a series of sentences, which were then re-fragmented to produce a theoretical description.

Results

The median interview time was 30.5 min (27.25–47.25) per person or approximately 222 min for the six subjects in total.

The SCAT-based descriptions of orthosis and orthosis provision services are presented in Tables 1 through 4, grouped by category.

A total of 77 theoretical statements related to orthosis and orthosis provision services were classified into four categories: "perceived effectiveness of an orthosis," "need for an improved orthosis," "need for services," and "impacts of an inadequate professional response."

We obtained 16 theoretical statements related to the "perceived effectiveness of an orthosis" (Table 1), 26 related to the "need for an improved orthosis" (Table 2), 11 related to the "need for services" (Table 3), and 24 related to the "impacts of an inadequate professional response" (Table 4).

Perceived Effectiveness of an Orthosis
• The user feels anxious about removing an orthosis and feels that the orthosis is necessary for walking and is indispensable for his/her life. • The user feels that an orthosis is an indispensable tool for living with a disability because it provides stability when standing and walking. • Wearing the orthosis indoors results in a smooth indoor gait. • The reduced gait speed and stability associated with not using an orthosis makes the user choose to wear the orthosis at all times, except when sleeping, even during a leisurely day. • The ability to walk faster and stand on their feet with the help of an orthosis gives the user a sense that the orthosis is useful and can lead to a higher degree of independence. • Smooth walking with the help of an orthosis gives the user the freedom to walk in various environments. The feeling of "I have to have the orthosis" leads to continued use of the orthosis outside of leisure activities and makes the user independent in performing most household chores. • The feeling of dependence on the orthosis when going out creates an opportunity to wear the orthosis in proportion to the opportunity to go out. • The user feels useful and satisfied with the orthosis when going outside. • The user feels satisfied with the orthosis when going outside. • Fear of going outside without the orthosis limits the user to a very limited range of activities. • The use of the orthosis in daily life allows the user to go out for a variety of purposes, participate in routine household chores, and socialize for pleasure. • The reduced gait speed and stability associated with not using an orthosis limits the user to a limited range of indoor activities. • Fear of not being able to walk to the best of one's ability leads the user to choose an orthosis to reduce anxiety. • Ankle instability in non-orthotic situations may lead the user to choose orthotics to reduce anxiety. • The reduction in anxiety and the perceived benefit of the orthosis for standing and walking will give the user a sense of the orthosis's efficacy.

Table 1: Theoretical Descriptions Categorized as the "Perceived Effectiveness of an Orthosis"

Need for an Improved Orthosis
• The user is dissatisfied with the lack of freedom to choose footwear. • The experience of being deprived of the freedom of footwear choice due to an orthosis that makes the foot appear larger than the bare foot can cause significant discomfort to the user and may lead to envy toward other people's footwear. • The user's desire for freedom of footwear choice may be related to frustration over the time and effort required to put on footwear over the orthosis. • The user has a problem with not being able to choose footwear due to the orthosis and feels most uncomfortable with the lack of footwear that fits the orthosis. • The user has a desire for good-looking shoes and is reluctant to go out in shoes that lack design. • The lack of available footwear for the user's needs accelerates the user's indifference to the appearance of the footwear because the user places the highest priority on footwear that fits the orthosis. • Users who wear orthosis that are difficult to accommodate inside standard footwear have a desire for orthotic designs that offer a choice of footwear. Complaints about the fashion implications of clothing choices that tend to hide the orthosis. The user's desire not to be noticed while wearing the orthosis leads to the choice of clothing that can easily hide the orthosis. • Users are dissatisfied with the negative impact of the orthosis on their clothing choices, especially the reduced variety of pants that can be worn over an orthosis. • The user's experience of difficulty putting on and taking off shoes while wearing the orthosis leads to a desire to use orthosis that allow freedom of clothing choice. • The user has the desire to use a variety of orthosis, including less glamorous orthosis for everyday use and more fashionable orthosis for going out. • They believe that the appearance of their orthosis is important to their use. • The user has a positive impression of the appearance of the orthosis he or she is wearing and wants to be able to use the orthosis without having to hide it. • The weight of the orthosis when the user wears it for the first time makes the user think that lightness is important for daily use of the orthosis and gives the user the impression that the orthosis is "light" for his/her use. • The user feels that the orthosis is too heavy to handle. • The user feels that the weight of the orthosis makes it difficult to handle, even though he/she has learned to put on and take off the orthosis in a short time through years of use. • The user has a desire for greater independence in wearing the orthosis. • The ability to wear and manage the orthosis independently leads to less stress for the user. • The ability to use the orthosis without pain leads to a greater sense of satisfaction with the use of the orthosis. • The ability to wear an orthosis helps reduce the amount of time and effort required to use the orthosis. • Simple orthosis gives the user the impression that the orthosis is light and easy to put on and take off. • Simple orthosis will make the user want to use a lightweight orthosis. • The user may be able to detect damage to a simple orthosis but may not be able to detect damage to a complex orthosis. • The user is not aware of the risk of breakage of a complex orthosis. • Dissatisfaction with the "lifespan" of the orthosis can lead to the user's habit of regular orthosis fabrication and a feeling of resignation and compromise about the durability of the orthosis.

Table 2: Theoretical Descriptions Categorized as the "Need for an Improved Orthosis"

Need for Services
• The user has a desire for better orthosis design suggestions from prosthetists and orthotists and a desire for orthosis fabrication that meets his or her needs. • The user feels it is important to have the opportunity to meet with a prosthetist or orthotist to obtain information about the orthosis. • Long-term use of an orthosis with the same shape may trigger a desire for suggestions on making functional modifications to the orthosis. • The lack of access to information about the orthosis from an orthotist and the fact that the specifications of the orthosis have not changed since the start of use may lead to a desire to know which orthosis option is right for the user. • The user has a sense that the orthosis can be improved, even after the user has become familiar with it, and has expectations for new orthosis that will be created in the future. • The user wants the orthosis to be repaired as it wears out due to the hazards associated with wear and tear. • The user has a desire for follow-up care, such as home repairs by a prosthetist and orthotist. • The user is aware of the need for regular maintenance of the orthosis. • The follow-up services, such as mold making and home visit repairs, give the user a positive impression of the orthosis company and a reason to recognize it as a responsive orthosis company. • Contacting an orthotics and prosthetics company through a therapist may create a situation where the user does not have access to an orthotics and prosthetics company on their own or can only communicate with an orthotics and prosthetics company in a hospital setting, which may lead to a desire for the services of an orthotics and prosthetics company in a setting other than a hospital. • The user's desire for contact with an orthotist regarding the orthosis is based on the apparent problem with the orthosis and not the frequency of contact.

Table 3: Theoretical Descriptions Categorized as the "Need for Services"

Impacts of an Inadequate Professional Response
• Lack of opportunity to compare the user's orthosis to other orthosis can lead to the perception that there is only one type of orthosis. • Lack of expectation of what an orthosis should look like. • Lack of explanation of the need for orthosis by the prosthetist and orthotist can lead to negative feelings about the use of an orthosis. • Lack of explanation of the orthosis-related system by the prosthetist and orthotist makes it necessary to contact the prosthetist and orthotist through a third party. • Lack of a clear explanation of the purpose of the orthosis makes it difficult for the patient to understand the details of the purpose of the orthosis. • Physical therapists and prosthetists who do not respond sincerely to consultations about the patient's physical condition break the patient's trust such that even if the patient has a contact person for consultations about the orthosis, he/she may not want to discuss it with them. • The patient may mistrust the prosthetic company due to poor fitting or fitting by an injured prosthetist or orthotist. • The experience of being turned down for follow-up makes the prosthetist angry that the orthotist is not following up, leading to a feeling of resignation about follow-up by the prosthetist and orthotist, and a reason to fabricate the orthosis themselves. • If the patient is unable to contact a prosthetist or orthotist for an extended period of time, he/she may be concerned about orthosis failure or damage to the orthosis. • Contacting an orthotist or prosthetist through a third party may result in the patient not contacting the orthotist or prosthetist. • The user's understanding of the orthosis payment system is inadequate due to the lack of explanation of the orthosis payment system by the prosthetist and orthotist. • The user's understanding of the orthotic supply system is poor due to a lack of explanation of the system by the prosthetist. • Prosthetists and orthotists who do not suggest functional modifications may prescribe the same orthosis even when the deformity has progressed, leading to a sense of resignation that an ill-fitting orthosis is okay. • The user is unable to visualize the effect of the orthosis, leading to a sense that the orthosis is not as good as expected. • The user does not communicate directly with the prosthetist and orthotist, which may cause the user to seek orthosis repair services. • Lack of direct contact with the prosthetist and orthotist may cause the user to feel that they are not getting the follow-up care they need to continue using their orthosis. • The user's memory of the orthosis is vague, and without the opportunity for input into the specifications of the orthosis, the user may not be able to visualize the benefits of the orthosis. • The lack of direct communication between the user and the prosthetist and orthotist makes the user want to address orthosis problems before they occur. • The user is unfamiliar with and unaware of the orthosis fabrication process. • The user's weak relationship with the prosthetist or orthotist may result in the use of the orthosis beyond the end of its useful life. • The user's weak connection with the prosthetist and orthotist will result in an inability to deal with orthosis problems. • A weak connection between a prosthetist and an orthotist makes it impossible to contact the orthotist. • Lack of connection to a prosthetist and orthotist means that there is no follow-up on orthotic issues. • A lack of connection to an orthotist or prosthetist can leave the user uncertain about the continued use of the orthosis.

Table 4: Theoretical Descriptions Categorized as the "Impacts of an Inadequate Professional Response"

Conclusion

Theoretical descriptions in the "perceived effectiveness of an orthosis" category indicate that the perceived benefits for orthosis users are their improved ability to stand and walk, decreased anxiety in performing daily activities, and an increase in the range of activities that they can perform.

A user's sense of efficacy is important for the continued use of an orthosis (Ishiguro et al., 2011). The results of this study suggest that the use of an ankle-foot-orthosis may provide the users with a sense of efficacy by contributing to their ability to walk and stand, reducing their anxiety, and expanding the range of activities they can perform.

Theoretical descriptions in the "need for an improved orthosis" category indicate that users mainly value the minimal influence of an orthosis on their choice of clothes and shoes and prefer an orthosis with an impressive design. However, we cannot exclude the possibility that this factor was characteristically extracted because most of the subjects in this study were women. Other descriptions in this category suggested that users preferred an orthosis that is lightweight, easy to put on and take off, causes no pain or discomfort, has a simple structure that is easy to understand, and is durable and low maintenance.

Applying the theoretical descriptions extracted from "perceived effectiveness of an orthosis" and "need for an improved orthosis" to service quality items (Johnston & Clark, 2005) demonstrated that many of them can be categorized as hygiene factors. From the user's point of view, the satisfaction of these factors is taken for granted. The improvement of the orthosis structure and materials in addition to considering the user's physical functions and requirements, as recommended by a medical professional, will lead to a reduction in dissatisfaction and complaints by focusing on the elements in which the user is aware of the effectiveness of the orthosis and the needs of the orthosis itself.

The theoretical descriptions in the "needs for services" category indicate a desire to exchange information with an orthotist and prosthetist before and after orthotic services. Further examination of the descriptions revealed a desire to have their needs reflected in the orthosis and a desire to receive suggestions from the prosthetist and orthotist regarding functional modifications to the orthosis in light of their current physical condition. Therefore, it can be concluded that the reason users seek information exchange with the prosthetist and orthotist is to make the orthosis more suitable for their use. Other service needs include follow-up services such as repair and maintenance. Respondents also expressed a desire for more flexible service locations, such as home visits, instead of being limited to hospitals.

Similar to the two categories described above, applying the theoretical descriptions extracted as "needs for services" to service quality items (Johnston & Clark, 2005) confirmed that they include a large number of satisfaction factors. We believe that satisfying these needs will lead to increased user satisfaction with orthosis provision services.

The "impact of inadequate professional response" category, which encompassed factors that are thought to influence the impression and perception of the orthosis itself and the orthosis provision services, highlighted the issues of inadequate comparison of orthosis and inadequate explanation of the purpose of an orthosis by the prosthetist and orthotist. This can negatively impact the user's perception of the orthosis, what the orthosis will be like, and how it will benefit them, which can be detrimental to the co-creation of value between the user and the prosthetist and orthotist. Many of these problems can be resolved through a close exchange of information between the user and the

prosthetist and orthotist. We conclude that time-consuming communication before and after the provision of the orthosis is important and useful, both in terms of meeting the user's needs and in terms of eliminating problems related to the use of an orthosis.

Furthermore, as previously mentioned, five of the subjects in this study were women and only one was a man, and the possibility of gender bias in the theoretical descriptions obtained in this study cannot be ruled out. In addition, the subjects in this study have been wearing the ankle-foot-orthosis for a long time, and we were not able to interview those who decided not to use the orthosis. Therefore, in the future, we plan to conduct a similar study with more male subjects and former ankle-foot-orthosis users who decided to discontinue its use.

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