



Research Paper

Evaluating Satisfaction Factors of Ankle-Foot Orthoses Made by Orthotics and Prosthetics Centers for Stroke Patients in Tehran City, Iran



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Conflict of interest

The authors declare no conflict of interest.

ABSTRACT

Background and Objectives: Stroke is a life-threatening disease that can lead to walking disorders. The orthosis that is generally prescribed for the patients in this situation is ankle-foot orthosis (AFO). For orthotic treatment to be effective, it is important to evaluate the quality of treatment, and one of the most important indicators is the level of patient satisfaction. The present study was conducted to evaluate the level of satisfaction and the factors affecting it in stroke patients who used AFOs made by Orthosis and Prosthesis (O&P) Centers in Tehran.

Methods: The present study was a descriptive-analytical study conducted on 64 stroke patients who were referred to O&P centers and had used AFO in Tehran City, Iran, in 2021. The data were collected through an interview. The level of satisfaction of stroke patients was examined through an opus questionnaire.

Results: The Mean±SD overall satisfaction, satisfaction with services, and satisfaction with the device in patients were 69.3±10.7, 36.7±6.7, and 32.6±6.6, respectively. The results revealed a significant relationship between the number of hours of daily use and satisfaction with the device, service, and overall satisfaction (P=0.038, P=0.041, and P=0.009, respectively). Also, there was a significant relationship between cognitive problems in patients and the level of satisfaction with services and overall satisfaction (P=0.032 and P=0.026, respectively).

Conclusion: Considering the results of this study, it can be stated that the duration of daily use of the orthosis and the presence of cognitive problems can significantly change stroke patients' satisfaction with AFO orthosis usage.

Keywords: Stroke rehabilitation, Patient satisfaction, Foot orthoses



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↑ *What is “already known” in this topic:*

The level of satisfaction in stroke patients during orthotic treatment varies depending on the geographical region and type of orthosis prescribed for the patient. Many factors can change the orthotic treatment experience in these patients.

→ *What this article adds:*

Duration of orthotic usage and having cognitive problems change the level of satisfaction significantly in stroke patients using AFOs made by Orthotics and Prosthetics Centers in Tehran City, Iran.

Introduction

Stroke is a clinically defined syndrome of rapidly developing symptoms or signs of focal loss of cerebral function with no apparent cause other than that of vascular origin, but at times the loss of function can be global. Symptoms last more than 24 h or lead to death [1]. Stroke damage to the motor cortex or corticospinal tract often results in contralateral hemiplegia with significant persistent distal weakness. Patients with this pattern of weakness are often unable to actively dorsiflex the foot during the swing phase of gait, which is referred to as drop foot. This gait impairment can result in compensatory movement patterns, slowed gait velocity, limited functional mobility, and increased risk of falls [2-4]. In Iran, the incidence of stroke is considerably greater than in most Western countries, with a stroke occurring at younger ages [5]. This situation indicates the importance of the quality of treatment and the satisfaction of these patients with the process of medical services.

The orthosis that generally plays a crucial role in treating these patients is a thermoplastic Ankle-Foot Orthosis (AFO) that provides mediolateral stability at the ankle in the stance phase and helps toe clearance during the swing phase, also promoting heel strike [6]. However, this orthosis also has its problems. Based on Zuccarino study, these problems included unpleasant appearance, discomfort, abrasions or irritations, and pain [7]. Given what was stated, AFO, besides many benefits for patients with drop foot, can cause problems and dissatisfaction, so these cases require more attention and investigation. One of the most important and commonly used indicators for measuring the quality of health care is patient satisfaction [8]. Patient satisfaction affects clinical outcomes, patient retention, and medical malpractice claims. It affects the timely, efficient, and patient-centered delivery of quality health care [8]. Studies also suggest a positive

relationship between satisfaction with care and quality of life in patients with chronic disorders [9]. So, it is important to know what factors are important regarding patients' satisfaction.

Ghoseiri's study revealed that in terms of satisfaction with the device, the highest score was related to the fit of the devices and the lowest to the appearance of the devices. Regarding satisfaction with clinical services, the highest score was related to staff behavior and the lowest to the clinic staff coordination with therapists and doctors [10]. Also, Zuccarino showed that in the patients who used AFO, the level of satisfaction with services was higher than the level of satisfaction with the device [7].

In this study, at first, we tried to evaluate the level of stroke patients' satisfaction with the device and service in O&P clinics in Tehran, Iran, through a questionnaire. Then we discussed the effect of 5 variables of Body Mass Index (BMI), physical disorders in the upper limbs, the amount of physical activity, cognitive problems, months of using the device, and hours of using the device during the day, on the level of stroke patients' satisfaction with AFO devices, and clinical service in O&P clinics in Tehran City, Iran.

Holtkamp's study revealed that females and users living alone had relatively high levels of dissatisfaction, especially in dimensions, comfort, weight, safety, and effectiveness. Also, people with a higher body mass index were more dissatisfied with orthotic services [11]. Gonzalez's study revealed that patients with a higher body mass index had a lower level of satisfaction, but this effect was not significant ($P=0.132$) [12].

In Chen's study, the patients with less severe disorders, who used pressure garment and wore it for less than 1 year, had the highest level of satisfaction with the orthosis and orthotic services [13]. In Cramm's study, it was

reported that the level of physical disorder in a stroke patient on hospitalization day has a great impact on the quality of life of a person after hospitalization, and the level of satisfaction with care, is an important indicator in the quality of life of the patient [14].

On the other hand, Swigchem's study showed that the walking speed and activity level of stroke patients were similar in both cases of wearing AFO and Functional Electrical Stimulation system (FES). However, the quality of activity and patient's satisfaction with using the AFO and FES is much higher, and there is a direct relationship between the walking pattern, walking distance, effort of walking, and stability during gait and the level of satisfaction in the patients who use the functional electrical stimulation system [15]. Bouffioulx's study states that in stroke patients, the level of physical activity, in addition to the level of satisfaction, has a significant impact on the environmental conditions, physical performance, and cognitive states of the patient [16].

Based on the results of Baumann's study, a significant relationship was found between cognitive problems and functional disorders and the quality of life in stroke patients. According to the results, various quality of life domains were strongly related to dissatisfaction with the help received and coordination between services [17]. Based on the results of Kariyawasam's study, the quality of life of stroke patients had a significant relationship with the level of cognitive problems like speech problems [18].

Baghbanbashi's study revealed a significantly higher satisfaction with service in the patients who received service for less than one year. Although satisfaction with the device was higher among the patients who wore devices for more than one year, the difference was insignificant [19]. Also based on the results of Chen C-L study, the highest satisfaction score was related to the patients who wore the orthosis for less than 1 year [13].

According to the results of DeZeeuw's study, orthosis comfort scores had a fairly positive correlation with the duration time of orthosis use (hours per week). The patients who wore AFO orthosis for longer hours during the week had a significantly higher orthosis comfort score than the other patients [20]. According to the results of Unes's study, the patients who wore AFO for 6-12 hours had significantly higher satisfaction than patients who wore it for 12-24 hours [21].

Based on Rubin's study findings, if the patients have the opportunity to evaluate the hospital care they receive,

the answers regarding the level of satisfaction with the care can provide many ways to improve the hospital's services. Similarly, marketing specialists can help attract and retain clients of hospitals by reporting information about the satisfaction level of patients [22]. This study aimed to evaluate the level of satisfaction and the factors affecting it, in stroke patients who used AFO made by orthotics and prosthetics centers in Tehran.

Materials and Methods

Study participants

The present study was descriptive-analytical research. The study's statistical population included people suffering from stroke referring to orthosis and prosthetics centers in Tehran, Iran. The inclusion criteria were suffering from one type of stroke in which a person has weakness in the muscles of the lower limbs that led to weak ankle dorsiflexion (drop foot) and walking disorder [2, 3], have passed at least three months since the prescription of orthosis [11], the use of AFO and the patient's consent to participate in the research. A convenience sampling method was used. The sample size was estimated at 64 people using G*Power software and considering $\alpha=0.05$, power of 0.8, and effect size of 0.5 [23]. During this study, informed consent was obtained from all the participants, and they were allowed to withdraw from cooperating with the researchers at any study stage.

Data collection

After obtaining legal permits, all clients' information in 15 public and private O&P centers in Tehran was accessed. By checking the medical records, stroke patients who used any AFO orthoses (posterior leaf spring, hinged, etc.) were identified. To evaluate research variables, three methods were used. Interviews with the patients or caregivers were conducted to obtain information regarding AFO wearing time (or duration of use), rate of AFO use (in months), and the amount of physical activity during the day. Based on the frequency and range of changes in findings, the rate of orthosis usage was divided into 4 groups: less than 6 months, 6 months to one year, one year to 2 years, and more than 2 years. Also, the patient's daily use of orthosis was divided into 4 groups: less than 2 hours, 2 to 6 hours, 6 to 12 hours, and more than 12 hours. The amount of activity was determined based on the hours that patient was in a non-rest state during the day and similarly according to findings divided into 4 groups: less than 2 hours, 2 to 4 hours, 4 to 8 hours, and more than 8 hours. To access the health-related and clinical variables, the patient's medi-

Table 1. Determining the mean satisfaction with the devices and services among the participants (n=64)

Variables	%	Mean±SD
Satisfaction with the device	59.2	32.6±6.6
Satisfaction with the service	73.4	36.7±6.7
Overall satisfaction	66.01	69.3±10.7

cal records were used. The BMI variable was measured by both asking patient's height and weight and checking medical records. By checking the patient's medical records, the presence of any type of complication in the patient's upper limbs that caused problems in using the orthosis was determined. Physical disorders of stroke in the upper limbs mainly include muscle contracture, sen-

sory problems, muscle weakness, and difficulties with voluntary production of movement [24]. By checking the patient's medical record, the presence or absence of these cognitive problems in patients was determined. Common cognitive problems in stroke patients generally include problems with memory, orientation, language, and attention [25].

Table 2. Relationship between the study variables and the level of satisfaction in patients (n=64)

Variables	n	Mean±SD			
		Satisfaction with Device	Satisfaction with Services	Overall Satisfaction	
Physical disorder in upper limbs*	With	51	32.07±6.3	36.2±6.4	68.3±9.9
	Without	13	34.6±7.6	38.6±7.3	73.3±13.01
	P		0.209	0.253	0.136
Physical activity**	Less than 2 hours	13	30.9±7.1	36.4±8.5	67.3±13.7
	Between 2 and 4 hours	30	31.8±6.6	37.06±6.09	68.9±9.6
	Between 4 and 8 hours	15	33.4±6.3	36.2±7.4	69.7±11.7
	More than 8 hours	6	37.8±4.4	36.6±3.6	73.5±6.05
	P value		0.160	0.983	0.613
Cognitive problems*	With	41	31.7±7.1	35.3±7.1	67.09±11.7
	Without	23	34.2±5.3	39.08±5.01	73.3±7.3
	P value		0.149	0.032	0.026
Rate of use (months)**	Less than 6 months	13	29.6±5.9	34.01±7.6	63.6±11.01
	Between 6 months and 1 year	22	33.4±6.8	39.04±6.1	72.5±10.3
	Between 1 year and 2 years	9	31.4±8.8	34.4±5.6	65.8±10.6
	More than 2 years	20	34.1±5.5	36.9±6.3	71.1±9.9
	P		0.230	0.113	0.067
Duration of daily use (hours)**	Less than 2 hours	20	30.1±6.5	33.3±7.05	63.4±11.3
	Between 2 and 6 hours	31	32.7±6.7	37.7±6.5	70.6±10.2
	Between 6 and 12 hours	9	33.8±5.3	39.6±4.2	73.5±3.8
	More than 12 hours	4	40.01±3.1	38.7±4.7	78.7±5.1
	P		0.038	0.041	0.009

The results are reported as mean±standard deviation, *The Independent t-test was used, **The analysis of variance test was used, Significance is determined at the P<0.05 level.

To evaluate user satisfaction, the Orthotics and Prosthetics User's Survey (OPUS) questionnaire was used. The OPUS questionnaire is a self-report questionnaire that Heinemann designed in America in 2003 [26]. This questionnaire has good consistency and reliability and is well suited for evaluating satisfaction with the orthosis and related services in clinical environments [26, 27]. The OPUS questionnaire contains 21 questions, the first 11 of which are related to satisfaction with the assistive device and the next 10 questions are related to satisfaction with the service. For each question, there are 6 responses (strongly agree, agree, neither agree nor disagree, disagree, strongly disagree, do not know/not applicable) [26]. In this study, after gathering the information, the score for satisfaction with the device will be between 11 (the lowest possible score) and 55 (the highest possible score), and for satisfaction with service, it will be between 10 and 50. For general satisfaction, these two scores summed together resulted in a score between 21 to 105. The Persian version of this questionnaire, translated by Mohammad Hadadi, has a Cronbach alpha of 0.71 for satisfaction with the device and 0.89 for satisfaction with clinic services. Also, the intra-class correlation coefficient of this questionnaire is 0.76 for satisfaction with devices and 0.90 for satisfaction with service, so it has good reliability and validity [28].

Statistical analysis

After collecting data, SPSS software, version 26 was used for the final analysis. At first, the Kolmogorov-Smirnov test was used for testing data normality. Then, a correlation test was used to check the research results, and the independent t-test and an analysis of variance test were used to compare them.

Results

In general, 64 people participated in this study, and the information of these people was evaluated based on the study's aims. Table 1 presents the mean satisfaction with the devices and services among the study subjects. Results are reported in this Table 1.

Table 2 examines the relationship between the non-demographic variables of the study (BMI, physical disorder in upper limbs, physical activity, cognitive problems, duration of daily use, and rate of use) and the level of satisfaction with the device, services, and overall satisfaction in patients measured through OPUS questionnaire. Based on the study's results, a significant relationship was found between cognitive problems and service satisfaction and overall satisfaction ($P=0.032$, $P=0.026$, respectively). Also, a significant relationship was found between the duration of daily use and satisfaction with the device, services, and overall satisfaction in patients ($P=0.038$, $P=0.041$, and $P=0.009$, respectively).

Table 3 also showed no significant relationship between Body Mass Index (BMI) and patient satisfaction ($P=0.067$, $P=0.454$, and $P=0.110$, respectively).

Discussion

In this study, the information of 64 stroke patients referred to Orthotics and Prosthetics Centers in Tehran and AFOs were prescribed for them was evaluated. According to the results of the study, the Mean \pm SD overall satisfaction of the patients was 69.3 ± 10.7 . Also, the Mean \pm SD satisfaction with services was 36.7 ± 6.7 , and the Mean \pm SD satisfaction with the device was 32.6 ± 6.6 . According to the study's results, there was a significant relationship between cognitive problems in patients and the level of satisfaction with services and overall satisfaction ($P=0.032$, $P=0.026$, respectively). So the people with cognitive problems had lower mean satisfaction with service and overall satisfaction. Moreover, the study's results revealed a significant relationship between the duration of daily use of orthosis and the level of satisfaction ($P=0.038$, $P=0.041$, and $P=0.009$, respectively). So the people who used orthosis for less than 2 hours had the lowest level of satisfaction with services, devices, and overall satisfaction compared to other ones.

In this study, there was no significant relationship between the mean body mass index and patient satisfaction ($P=0.067$, $P=0.454$, and $P=0.110$, respectively). This result is consistent with the studies by Cristina Gonzalez-

Table 3. Determining the correlation between BMI and patient satisfaction (N=64)

Variable	Satisfaction with Device	Satisfaction with Services	Overall Satisfaction
Body mass index	Correlation coefficient	-0.231	-0.202
	P	0.067	0.11

The results are reported as correlation coefficients; Significance is determined at the $P<0.05$ level.

Martin [12] and inconsistent with the study by Holtkamp FC [11]. Gonzalez's study revealed that patients with a higher body mass index had a lower level of satisfaction, but this effect was not significant ($P=0.132$). Based on the results of Holtkamp's study, people with a higher body mass index were more dissatisfied with AFO. The effect of body mass index on patient satisfaction can differ in different studies. Also, increasing the number of samples in a higher volume can provide researchers with more accurate information about the relationship between the physical index and the level of satisfaction with the orthosis.

In this study, there was no significant relationship between the mean physical disorder ($P=0.209$, $P=0.253$, and $P=0.136$, respectively) and patient satisfaction, which was not consistent with the results of the Cramm JM study [14] and Chen C-L study [13]. In Cramm's study, it was reported that the level of physical disorder in a stroke patient on hospitalization days has a great impact on the quality of life of a person after hospitalization, and the level of satisfaction with care is an important indicator of the quality of life of the patient. Based on the results of a Chen Ling study, the severity of the disorder in patients significantly affected the satisfaction level of orthotic treatment. The patients with fewer physical disorders had higher orthotic treatment satisfaction. In our study, the presence of physical disorder in the upper limbs has been studied, but the level of disorder was not considered. Medical records in orthotic and prosthetics centers often do not include the level of physical disorder, leading to lower reliability in measuring the physical disorder severity.

In this study, the mean physical activity had no significant relationship with patient satisfaction ($P=0.160$, $P=0.983$, and $P=0.613$, respectively). This result is consistent with the result of Van Swigchem's study [15], and it is inconsistent with the results of Bouffoulx's study [16]. The Van Swigchem study considers the quality of the walking pattern, the walking distance, effort of walking, and stability during gait while using AFO and FES as determining factors in patient satisfaction. In other words, according to Van Swigchem, the determining factor in patient satisfaction was not the amount of activity but the quality of the activity. The Bouffoulx study states that in stroke patients, in addition to the level of satisfaction, the level of physical activity has a significant impact on the environmental conditions, physical performance, and cognitive states of the patient. In the present study, people's activity level was evaluated based on the activity hours during the day. The reason for not finding its relationship with the level of satisfaction may

be attributed to the impact of the quality of activity and other environmental factors on the level of satisfaction.

Based on the present study, the mean cognitive problems had a significant relationship with the level of satisfaction with services and overall satisfaction ($P=0.032$ and $P=0.026$ respectively), which was consistent with Baumann's studies [17] and Kariyawasam [18]. According to Baumann's study, cognitive-functional problems, like memory problems and sensory problems, showed a significant and direct relationship with low levels of quality of life. Also, based on the results of this study, various quality of life domains were strongly related to dissatisfaction with the information about stroke and its consequences/changes over time, the accuracy of information obtained, help received, coordination between services, and the possibility of receiving help when necessary. Based on the results of the Kariyawasam study, the level of quality of life of stroke patients had a significant relationship with the level of speech problems in the patients.

In this study, mean satisfaction with the device, service, and overall satisfaction had a significant relationship with the duration (hours) of the patient's daily use of AFO ($P=0.038$, $P=0.041$, and $P=0.009$, respectively). This result was consistent with Katrina G's study [20] and inconsistent with Unes's study [21]. According to Unes's study results, a significant relationship was found between wearing time and satisfaction in cerebral palsy patients who used AFO orthosis. Patients who wore AFO for 6-12 hours had significantly higher satisfaction than patients who wore it for 12-24 hours. Nevertheless, a study by Katrina G revealed that the orthosis comfort score had a significant and positive relationship with the patient's satisfaction with the orthosis. According to these two studies, orthosis wearing time during the day can significantly affect patient satisfaction, but based on the type of disease and patient's age, its effect can be positive or negative.

The results of the study showed no significant relationship between the rate of orthosis use (months of use) and satisfaction ($P=0.230$, $P=0.113$, and $P=0.067$, respectively), which is in contrast to the results of Chen C-L studies [13] and Baghbanbashi [19]. Based on the results of Chen C-L's study, a significant and inverse relationship was found between patient satisfaction and the duration of using orthosis, so the highest satisfaction score was related to patients who wore the orthosis for less than 1 year. Also, the results of the Baghbanbashi study showed significantly higher satisfaction with service in patients who used O&P services for less than one year.

Nevertheless, it is important to know that there was no significant relationship between satisfaction with the device and the rate of O&P services use. The reason for the difference in the results of our study with the results obtained in two other mentioned studies may be attributed to the age difference, type of disorder, and their different lifestyles. In our study, the mean age of stroke patients was 64 years old. Due to the high mean age and higher rate of unemployment, and also higher amount of disability in the majority of these people, they spend most of their time resting. So, the way of orthotic use and its duration may be different, considering the living conditions of these patients.

Conclusion

Based on the results of this study, the duration of using orthosis and cognitive problems in stroke patients can significantly change the satisfaction level of these patients in orthotic treatment. Longer use of the orthosis during the day increases user satisfaction. Therefore, in the patients who used orthosis for more than 12 hours, the highest level of satisfaction with the devices, services, and overall satisfaction was comparable to the other patients. It means that the acceptance of the device by the patients will increase over time. Also, a cognitive impairment that is related to stroke in the patients has a great impact on the level of satisfaction with services and overall satisfaction, so patients with cognitive problems have lower service satisfaction and overall satisfaction.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Ethics Committee of the [Iran University of Medical Science](#) (Code: IR.IUMS.REC.1400.264).

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Authors' contributions

Conceptualization, Supervision: Behshid Farahmand, Hassan Saeedi, Mohammad Kamali; Methodology and Writing—original draft: Behshid Farahmand and Ehsan Rahmani; Investigation, Writing—review &

editing: All authors; Funding acquisition and Resources: Ehsan Rahmani, Behshid Farahmand.

Conflict of interest

The authors declare no conflict of interest.

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مقاله پژوهشی

بررسی عوامل رضایت بیماران سکنه مغزی از ارتوزهای مچ-کف پای ساخته شده توسط مراکز ارتوز و پروتز تهران، ایران

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چکیده

مقدمه سکنه مغزی یک بیماری مرگ‌آور است که می‌تواند باعث اختلالات راه رفتن شود. ارتوزی که عموماً برای این بیماران تجویز می‌شود، ارتوز مچ-کف پای (AFO) می‌باشد. برای این که درمان ارتوزی موثر واقع شود، لازم است تا کیفیت درمان ارزیابی شود و یکی از مهمترین نشانگان برای این مهم، میزان رضایت بیمار می‌باشد. تحقیق حاضر جهت بررسی میزان رضایت و عوامل موثر بر آن در بیماران سکنه مغزی که از ارتوزهای مچ-کف پای ساخته شده در مراکز ارتوز و پروتز تهران ساخته شده بودند، انجام شد.

مواد و روش‌ها مطالعه حاضر یک تحقیق توصیفی-تحلیلی بود که در سال ۲۰۲۱ بر روی ۶۴ بیمار سکنه مغزی که به مراکز ارتوز و پروتز تهران مراجعه کردند و از ارتوز مچ-کف پای استفاده کردند، انجام شد. اطلاعات از طریق مصاحبه جمع‌آوری شد. سطح رضایت بیماران سکنه مغزی از طریق پرسشنامه اپاس صورت گرفت.

یافته‌ها میانگین رضایت کلی، رضایت از خدمات و رضایت از وسیله در بیماران به ترتیب $36/7 \pm 6/9$ ، $69/3 \pm 10/7$ و $32/6 \pm 6/6$ بودند. نتایج تحقیق نشان داد که یک رابطه معنی‌دار میان میزان ساعات روز که بیمار ارتوز را می‌پوشد و میزان رضایت از وسیله ($P=0.038$)، رضایت از خدمات ($P=0.041$) و رضایت کلی ($P=0.009$) وجود دارد. همبستگی رابطه‌ی معنی‌داری بین وجود مشکلات شناختی در بیماران و میزان رضایت از خدمات ($P=0.022$) و رضایت کلی ($P=0.026$) وجود داشت.

نتیجه‌گیری با توجه به نتایج تحقیق، می‌توان گفت میزان استفاده روزانه از ارتوز و همبستگی وجود مشکلات شناختی در بیماران سکنه مغزی می‌تواند به مقدار معنی‌داری میزان رضایت آنها از ارتوز مچ-کف پای را تحت تأثیر قرار دهد.

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کلیدواژه‌ها:

توانبخشی سکنه مغزی، رضایت بیمار، ارتوزهای پا، مراکز توانبخشی، نظرسنجی‌ها و پرسشنامه‌ها



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