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The effect of computerized custom insole with custom-fit insole on the function of the foot and ankle and quality of life in diabetic elderly

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Abstract

Background: Diabetes alters the distribution of foot pressure and causes foot ulceration and changes the quality of life and function of the foot and ankle. Insole is one of the treatment options to improve the distribution of foot pressure and prevent foot ulcers. The purpose of the present study is to compare the effect of the computerized custom insole with a custom-fit insole on the function of the foot and ankle and quality of life of diabetic elderly.

Methods: 28 Diabetic patients (14 males and 14 females, typeIand II) were included in the study with the approval of a specialist physician if they met the inclusion criteria. The mean and standard deviation of participants' demographic variables for age, weight, height, and BMI for test and control groups were 67.64±5.23 years, 66.79± 4.68 years, 76.44±11.48 kg, 77.24±11.95 kg, and 1.67±8 m, 1.67±5 m, 27.55±5.08 kg/m^2, 26.52±5.33 kg/m^2 respectively. Participants were randomly allocated to the computerized custom insole (test group) and custom-fit insole (control group). Both groups used the insoles for 4-6 weeks. Participants were asked to complete the Persian version of the brief DQOL questionnaire once before using the insoles and once 4-6 weeks after using the insoles. Also, a full version of AOFAS questionnaire was completed by researcher for each patient once before using the insoles and once 4 - 6 weeks after using the insoles.

Results: In the pre-intervention phase, there was no significant difference in the quality of life and function of the foot and ankle of the elderlies in the two groups and the quantitative data in both groups had a normal distribution. After 4 to 6 weeks, there was a significant difference in the quality of life and function of the foot and ankle of the elderlies in the two groups in both groups ($p<0.05$). There was no significant difference between the two groups (the computerized custom insole and custom-fit insole) in terms of the quality of life and function of the foot and ankle ($p>0.05$).

Conclusion: The results showed that there was no significant difference in the effectiveness of these two types of insole on the quality of life and function of foot and ankle; it is recommended to use a custom-fit insole that will cost the patient less.

Keywords: Diabetic elderly, Quality of life, Foot and ankle function, Insole

Conflicts of Interest: *The authors have no conflict of interest in this study.*
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Introduction

Diabetes is a chronic metabolic disorder in which blood sugar level rises due to insufficient insulin use. Diabetes is identified as one of the most important general health problems in the 21st century (1). This disease, especially in the elderly, has debilitating and dangerous effects on the body's vital organs (2). The prevalence of diabetes in the population over 30 years in Iran was 14%, and the prevalence of diabetes in Yazd province was 18% (3).

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↑What is "already known" in this topic:
Medical insole reduces foot pressure by balancing force distribution. The use of orthotic interventions has been shown to reduce foot pressure.

→What this article adds:
The mean score of the quality of life and function of the foot and ankle after intervention for computerized custom insole was only slightly, but not significantly, higher than the custom-fit insole.

Diabetes has several complications, most notably the increased risk of foot ulcers (4). Diabetic foot problems, in addition to reducing mobility and disruption to daily activities, also affect one's mental and social status and lead to a decrease in the quality of life of individuals (5). Increased dynamic foot pressure is one of the important risk factors for diabetic foot ulcers (6,7). Medical insole reduces foot pressure by increasing the area of foot contact (force distribution). For people like diabetic patients, customization has many benefits due to the specific conditions of their feet (8). The review study by de Oliveira et al. (2015), emphasized the effect of orthoses on wound healing and reduction of wound healing time. Still, few studies have indicated the effect of orthoses on improving quality of life by offloading the wounded areas and increasing foot and ankle function (9). Investigating the quality of life and function of the foot and ankle is important because it assesses one's perception and feeling from various aspects, including daily activity, foot-ankle functionality, and biomechanics (10,11). According to what has said, the effect of the orthotic intervention on improving the quality of life and function of the foot and ankle has not received much attention in recent years, of which Davis and Patton studies can be mentioned.

The report by Davis et al. (2000) states that diabetes most affects the physical aspects of the patient, which results in the inability to perform daily activities and decreases quality of life. The orthotic intervention will reduce these physical limitations and subsequently results in significant improvement in health status (12). Also, in another study by Patton et al. (2012) which examined the quality of life and foot pressure in people with diabetes, the use of orthotic interventions has been shown to reduce foot pressure. Still, there was no difference between the quality of life and orthotic interventions (13). Although there are specific questionnaires for assessing the quality of life of diabetic elderlies and their foot and ankle function, there is no study indicating the use of these questionnaires to assess the impact of insole on the variables mentioned. Therefore, the purpose of this study was to compare the effect of the computerized custom insole with a custom-fit insole on foot and ankle function and quality of life in diabetic elderlies. For this purpose, the Persian version of brief DQOL questionnaire was used to assess the quality of life, and full version of AOFAS questionnaire was used to assess the function of the foot and ankle complex. Numerous studies have used these questionnaires to assess the quality of life and function of the foot and ankle, indicating that these questionnaires are suitable tools for measuring the variables mentioned (14- 18). Both questionnaires have good validity and reliability (19, 20).

Methods

The present study is quasi-experimental. Twenty-eight diabetic elderly patients who were referred to technical orthopedic centers in Yazd city were selected by random sampling. Initially, the purpose and method of the study were described for patients. Individuals who agreed to participate in the study completed the written consent form and were enrolled (Ethical code: IR.IUMS.REC. 1398.496). They were also allowed to drop out at any time. In this study, patients' information was kept confidential, and patients did not incur any costs. Selection criteria included 60-75 years of age, confirmation of diabetes (The average history of diabetes was 6.5 years) and no neuropathy and deformity by a specialist physician, confirmation of specialist physician to receive medical insole, absence of diabetic ulcer, ability to walk, minimum literacy to answer questionnaires. The full Persian Version of the American Orthopedic Foot and Ankle Society Score (AOFAS) was used to evaluate the function of the mid/hind foot and ankle in diabetic elderlies (19). Cronbach's alpha coefficient is 0.696, and the intra-class correlation (ICC) is 0.853, which indicates good reliability and validity of this questionnaire (19). The brief Persian version of the Diabetes Quality of Life Questionnaire (DQOL) was used to evaluate the quality of life in diabetic Elderlies. Cronbach's alpha coefficient is 0.77 for all questions and is 0.77 for intra-class correlation (ICC), indicating good reliability and validity of this questionnaire (20).

Specialist physician approval and monofilament 5.07 at three points in the foot were used to confirm that a person had no diabetic neuropathy (21). DQOL and AOFAS questionnaires were used after confirmation of the absence of diabetic neuropathy. Then the first ten subjects who completed the questionnaire were divided into two groups of 5 test and control subjects according to the use of computerized custom insole or custom-fit insole, respectively. Individuals were randomly divided into two groups. The sample size was calculated using the pilot method after examining five samples for each group using SPSS software version 25, Formula 1 and, Table 1 information. Eventually, 28 individuals in two groups of 14 people formed the study population. According to a similar article in evaluating the effect of orthotic interventions in these patients, the period of orthotic interventions was considered 4-6 weeks (22). For all patients in the test group, computerized custom insole was fabricated (Fig. 1). For this purpose, a PS-320 scanner (made in Iran, Danesh Salar Iranian company) was used to perform a foot scan. Patients were asked to remove their shoes and socks, to stand up on the scanner, to look forward, and to distribute their weight normally on both feet (Fig. 2). Their profiles were stored on the computer and CAD-CAM software. Then a skilled expert- designed proper insole based on the foot pressure was obtained using the appropriate modeling machine. The software allows independent management of materials and covers, permits to draw, modify and customize the various

Formula 1. Sample Size Calculation Formula

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^{2} (\delta_1^2 + \delta_2^2)}{(\mu_1 - \mu_2)^2}$$

Table 1. The effect of pre- and post-intervention of the computerized custom and custom-fit insoles on foot and ankle function and quality of life

Variable	Partial eta squares	F (1.26)	(P)
Time (Quality of life after the intervention)	0.750	78.104	0.002
Time (Quality of function of the foot and ankle after the intervention)	0.893	217.667	0.000

Fig. 1. Computerized Custom insole

Fig. 2. The patient is undergoing a compression scan

Fig. 3. Custom-fit insole

templates in all sizes. As the pressure of more than 200 kPa causes foot wounds, areas of the foot in which the foot pressure exceeded this threshold were offloaded (6).Custom-fit insoles were made in two layers by a skilled expert based on the size of each patient's foot. The top layer was made of 5 mm thick Plastazote and the bottom layer was made of 5 mm thick Ethylene-vinyl acetate (23-25). Based on the size of the patient's foot, the internal longitudinal arch of 15 mm thick Ethylene-vinyl acetate, from the talus bone to the first metatarsal head, and the superior portion of this arch was placed under the navicular bone. The metatarsal pad, made of Ethylene- vinyl acetate, was placed 10 mm behind the metatarsal heads (24, 26). To absorb the impact, the undersole was made of hard material and for greater comfort, the upper sole was covered with soft material (Fig. 3) (26, 27). This type of insole with vibration has been used in the study by Bagherzadeh et al (28). Also the shore of Ethylene-vinyl acetate used in both types of insole were 30 (29). Participants were not aware of the insoles (single-blind) and because the insoles fitted into the ordinary shoes of the participants which used it daily, it was not possible to match the shoes (12). Then, SPSS v. 25 was used for data analysis. For descriptive statistics, quantitative variables, measures of central tendency (mean and median), and dispersion indices (range and standard deviation) were calculated. Shapiro-Wilk test was used to check if the data distribution is normal. After confirming the normality of the data distribution, analysis of variance was used to compare the results before and after using insole (intra-group comparison), and also between two groups (inter-group comparison). A test error of 0.05 and a test power of 80% was considered.

Results

In this study, data on 28 diabetic patients were analyzed. The mean and standard deviation of participants' demographic variables for age, weight, height, and BMI for test and control groups were calculated (*Table 2*). Mean and standard deviation of DQOL questionnaire

Table 2. Descriptive statistics of demographic variables

Variable	Group	Mean	SD	Minimum	Maximum
Age	Test (n=14)	67.64	5.23	60.00	75.00
	Control (n=14)	66.79	4.68	61.00	74.00
Height	Test (n=14)	1.67	0.08	1.55	1.80
	Control (n=14)	1.67	0.05	1.58	1.74
Weight	Test (n=14)	76.44	11.48	57.80	95.20
	Control (n=14)	77.24	11.95	53.60	92.30
BMI	Test (n=14)	27.55	5.08	22.13	32.76
	Control (n=14)	26.52	5.33	19.93	31.94

Table 3. The effect of pre- and post-intervention the computerized custom and custom-fit insoles on foot and ankle function and quality of life

Variable	p	F(1,26)	partial eta squares
Time *(Quality of life after the intervention)*	0.002	78.104	0.750
Time *(Quality of function of the foot and ankle after the intervention)*	0.000	217.667	0.893

before and after the intervention for computerized custom insole were 48.07±4.02 and 58.36±1.53, and for custom-fit insole before and after intervention were 45.36±5.68 and 59.50±7.10, respectively. Mean and standard deviation of AOFAS questionnaire before and after intervention for computerized custom insole were 62.79±11.34 and 82.71±7.94 and for custom-fit insole before and after intervention were 59.79±13.48 and 73.93±12.27 respectively. In the pre-intervention phase, there was no significant difference in the quality of life and function of the foot and ankle of the elderlies in both groups, and the two groups were homogeneous. After 4 to 6 weeks, there was a significant difference in both groups ($p<0.05$) (Table 3). There was no significant difference between the two groups (the computerized custom insole and custom-fit insole) in terms of the quality of life and function of the foot and ankle ($p>0.05$) (Table 4), also, the interaction effect of intervention type and time was significant for foot and ankle function ($p<0.05$) (Table 5) and that means that caution should be exercised when interpreting the relevant results. The judgment of function before and after the intervention is influenced by the type of insole used.

Discussion

Since it is important to look at an elderly period like other periods of life, chronic diseases such as diabetes can have a great impact on the quality of life and function of these people, which affects the physical, mental, and social aspects of the individual (30). No study has simultaneously examined the variables of quality of life and function of foot and ankle along with insole interventions. In the study of Devis et al. (2000), only the quality of life variable with one type of insole intervention was investigated, which stated that diabetes affected most of the physical aspects of the patient, which in turn resulted in an inability to perform daily activities and decreased quality of life. The results of orthotic interventions reduce these physical limitations, thereby improving the health status and the quality of life of the patient. The positive effect of orthotic interventions over 12 months is also evident between the intervention and comparison (no insole group) groups. Therefore, orthotic treatment should be considered as one of the important stages of treatment (12). The results of this study are in line with the results of Davis's study on quality of life before and after the intervention, which indicates that diabetes has negative effects on the quality of life of diabetic elderlies, and orthotic interventions can improve their quality of life compared to pre-orthotic use. In the study by Paton et al. (2000), only the quality of life variable with the intervention of two types of insoles was investigated. This study states that orthotic interventions do not affect the quality of life before and after the intervention, as well as in the two groups of the computerized custom insole and prefabricated insoles (13). The results of the present study are inconsistent with the results of Patton's study of quality of life before and after the intervention. They are in line with the improvement of quality of life between intervention and control groups. The results of Patton's study and the present study show that orthotic intervention is a low-cost, safe, and affordable treatment that has positive effects on quality of life. Prefabricated insoles, however, cost less than computerized custom insole. These results suggest that health centers that do not have the equipment to design and manufacture computerized custom insole can also provide valuable and effective services in the treatment of diabetic patients.

Table 4. Comparison of quality of life and foot and ankle function between the computerized custom and custom-fit insoles

Variable	F (1.26)	Significant value (P)	partial eta squares
Quality of life	0.221	0.642	0.008
Quality of function of the foot and ankle	1.998	0.169	0.071

Table 5. Interactive effect of time and orthosis intervention on quality of life and foot and ankle function

Variable	Significant value p	F (1.26)	partial eta squares
Interactive effect of time and orthosis intervention (Quality of life)	0.930	1.947	0.070
Interactive effect of time and orthosis intervention (Quality of function of the foot and ankle)	0.019	6.277	0.194

Conclusion

In the present study, the mean score of the quality of life and function of the foot and ankle after intervention for computerized custom insole was only slightly, but not significantly, higher than the custom-fit insole. Since this study did not address the effect of subsets of the questionnaires used specifically, further clinical trials are needed to determine the effect of each of these subsets on appropriate insole prescriptions. Since the results of this study showed that there is no significant difference in the efficacy of these two types of insoles, it is recommended to use a custom-fit insole that imposes less cost on the patient.

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Conflict of Interests

The authors declare that they have no competing interests.

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مقايسه اثر كفي سفارشي ساخت كامپيوتري با كفي سفارشي فيت شده بر عملكرد پا و مچ پا و كيفيت زندگي سالمندان مبتلا به ديابت

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چكيده مقدمه: ديابت باعث تغيير توزيع فشار كف پا و عاملي بر ايجاد زخم كف پا و تغيير كيفيت زندگي و عملكرد پا و مچ پا است. كفي، يكي از روش‌هاي درماني براي بهبود توزيع فشار كف پا و جلوگيري از زخم كف پا است. هدف از مطالعه حاضر مقايسه اثر كفي سفارشي ساخت كامپيوتري با كفي سفارشي فيت شده بر عملكرد پا و مچ پا و كيفيت زندگي سالمندان مبتلا به ديابت است.

روش‌ها: 28 بيمار مبتلا به ديابت (14مرد و 14زن، نوع يك و دو) با تأييد پزشك متخصص در صورت دارا بودن معيارهاي ورود به مطالعه وارد مطالعه شدند. مقادير ميانگين و انحراف معيار متغيرهاي زمينه اي شركت‌كنندگان براي سن، وزن، قد و شاخص توده بدني به‌ترتيب براي گروه آزمون و كنترل برابر 5/23±67/64 سال، 4/68±66/79 سال، 11/48±76/44 كيلوگرم، 11/95±77/24 كيلوگرم، 8.1±67 متر، 5±67.1 متر و 5/08±27/55 كيلوگرم بر متر مربع، 5/33±26/52 كيلوگرم بر مترمربع بود. شركت‌كنندگان به‌طور تصادفي به دو گروه استفاده‌كننده از كفي سفارشي ساخت كامپيوتري (گروه آزمون) و كفي سفارشي فيت شده (گروه كنترل) تقسيم شدند. هر دو گروه كفي را براي مدت 4 – 6 هفته، استفاده كردند. از شركت‌كنندگان هر دو گروه خواسته شد تا سؤالات نسخه خلاصه شده فارسي پرسشنامه DQOL را يك بار قبل از استفاده از كفي و يك بار در 4 – 6 هفته بعد از استفاده از كفي، تكميل نمايند. همچنين نسخه كامل پرسشنامه AOFAS بوسيله محقق، يك بار قبل از استفاده از كفي و يك بار در 4 – 6 هفته بعد از استفاده از كفي براي هر بيمار كامل شد.

يافته‌ها: در مرحله قبل از مداخله تفاوت معناداري در ميزان كيفيت زندگي و عملكرد پا و مچ پا سالمندان در دو گروه وجود نداشت و داده هاي كمي در دو گروه از توزيع نرمال برخوردار بودند. پس از 4 تا 6 هفته، در هر دو گروه نسبت به قبل تفاوت معنادار مشاهده شد ($p<0/05$). در مقايسه نمره كيفيت زندگي و عملكرد پا و مچ پا بين دو گروه استفاده‌كننده كفي سفارشي ساخت كامپيوتري و فيت شده، تفاوت معناداري مشاهده نشد ($p>0/05$).

نتيجه‌گيري: در ميزان اثر بخشي اين دو نوع كفي بر كيفيت زندگي و عملكرد پا و مچ پا، تفاوت محسوسي وجود ندارد، پيشنهاد مي‌گردد از كفي فيت شده كه هزينه كمتري به بيمار تحميل مي‌كند، استفاده شود.

كليدواژه‌ها: سالمندان ديابتي، كيفيت زندگي، ارزيابي عملكرد پا و مچ پا، كفي

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