Research Paper

Effects of the Custom Mold With a Raised Ridge Around the Perimeter Foot Orthoses on Dynamic Postural Control in Chronic Ankle Instability

Hanieh Khaliliyan[1], Mahmood Bahramizadeh[1*], Reza Vahab Kashani[1], Mohsen Vahedi[2]

1. Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran.
2. Department of Biostatistics, School of Rehabilitation Sciences, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran.

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ABSTRACT

Objectives: Among the foot orthoses prescribed to improve postural control in chronic ankle instability, foot orthoses designed to affect both types of mechanical and functional instability have a limited research background. In the present study, a type of foot orthosis named the custom mold with a raised ridge around the perimeter was designed, and manufactured, and its effect on the dynamic posture control of the subjects was investigated.

Methods: This study was a quasi-experimental type in which 30 active young people with chronic ankle instability were selected from sports clubs and divided into two groups. One of these groups used custom mold foot orthoses (CFO) and the other group used custom mold with a raised ridge around the perimeter foot orthoses (CRFO). Dynamic postural control of the participants was evaluated before and after one month with the star excursion balance test (SEBT). A repeated measured statistical test was used to evaluate the obtained data.

Results: Both types of foot orthoses increased the reaching distance of the SEBT, but the result of CRFO was significant in this field, so that after one month in medial (P=0.045), posteromedial (P=0.002), and anteromedial (P<0.001) directions, significant differences were observed between the two groups.

Discussion: The CRFO can put the subtalar joint in optimal conditions and change the amount of input resulting from the stimulation of the mechanoreceptors in the plantar area of the foot, thus increasing the improvement of dynamic postural control; however, more studies are needed to prove this claim.

*** Corresponding Author:**
Mahmood Bahramizadeh, Associate Professor.
Address: *Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran.*
Tel: *+98 (21) 2218 0010*
E-mail: *ma.bahramizadeh@uswr.ac.ir*

Highlights

• Custom mold foot orthoses (CFO) improve dynamic postural control in chronic ankle instability (CAI).

• Custom mold with a raised ridge around the perimeter foot orthoses (CRFO) improves dynamic postural control in CAI.

• A CRFO can affect both types of functional and mechanical instability in CAI.

Plain Language Summary

Exercise injuries are inevitable and athlete is always exposed to a series of potential risks. A lateral ankle sprain is a common type of these injuries that can cause pain, loss of play, and medical costs. In team sports, the loss of key players caused by lateral ankle sprain can lead to failure in competitions and economic costs. In addition, their long-term complications cannot be ignored. Researchers found that the use of orthoses is effective in preventing lateral ankle sprain. In this study, an orthosis was made to prevent this injury, and positive results were obtained in controlling dynamic posture.

Introduction

Epidemiological literature has shown that ankle sprains or strains are most likely to occur among lower limb injuries [1]. The most common mechanism of injury is a combination of plantar flexion and inversion movements. As a result of this injury, the stabilizing ligaments of the lateral part of the ankle (especially the anterior talofibular ligament) and joint capsule are usually damaged [2].

Research has shown that sprains tend to repeat after an acute one and repeated sprains lead to chronic ankle instability (CAI) [3]. More than 70% of people who have acute lateral ankle sprain experience CAI [4]. The most common problem in CAI is the reduction in the dynamic postural control ability, leading to repeated sprains. In these patients, damage to the ligament and capsule of the lateral part of the ankle joint is manifested in both mechanical and functional instability [5, 6].

Mechanical destruction occurs as a result of stretching and changes in the physical structure of ligaments and capsules. This condition causes ligament laxity and an increased range of motion. Finally, these changes lead to the lateral deviation of the subtalar joint, and the supinator torque is applied to the joint. In this situation, the foot hits the ground with an improper inversion position during fast movements; a large amount of inversion torque is created in the subtalar joint, and the possibility of re-sprain increases [7, 8]. Functional changes occur as a result of damage to the mechanoreceptors of the lateral ligaments and capsule. These receptors are a part of the somatosensory system. They provide sensory messages that in combination with the vestibular and visual sensory messages, help the central nervous system (CNS) in maintaining postural control [9]. Studies believe that a large part of the sensory information of the somatosensory system is provided by mechanoreceptors on the soles of the feet, and in the absence of useful sensory input from mechanoreceptors on the lateral part of the ankle in CAI to the role of plantar foot mechanoreceptors is increasing [10].

Custom mold foot orthoses (CFOs) can place the subtalar joint in a neutral position and prevent the deviation of this joint. Several studies have pointed out the positive effect of this foot orthosis (FO) in improving dynamic postural control in CAI [11-13]. Also, textured FOs have the potential to increase sensory feedback from the soles of the feet, and their use helps improve patient's dynamic postural control [14, 15]. However, it seems that therapeutic devices that can affect both types of mechanical and functional instability compared to interventions that have the potential to affect one type of instability have better results in dynamic postural control of these patients [16].

In 1999, Maki et al. designed and introduced a special type of textured surface. They stated that instead of using an array of indentors that stimulate all the mechanoreceptors of the foot pad, if the raised ridge is used in the perimeter, it will help the CNS more in determining the boundaries of the base of support (BOS) because when the center of mass (COM) approaches to the borders of

BOS, a small concavity is produced in the skin of the foot perimeter, stimulating the mechanoreceptors on the edge of the foot and leading to a change in the afferent information in them [17].

In the following years, researchers created this type of FOs and investigated their effects on the postural control of healthy people and people with postural control disorders caused by sensory damage, and positive results were reported. The researchers introduced the FO with a raised ridge around the perimeter as an intervention to increase balance [17-21].

In previous studies, peripheral ridges were added to shoe soles or prefabricated FOs, but since recent researchers have confirmed the superiority of CFOs over prefabricated types in improving dynamic postural control [13, 16], in this study, to affect both types of mechanical and functional instability in chronic instability, we modified a CFO by creating a peripheral raised ridge, and the immediate and one-month effects of using this type of FO on the dynamic postural control in CAI were evaluated. In addition, we compared the effects of this FO with the CFO to identify the better FO in this field.

Materials and Methods

Study design

This study was a quasi-experimental type and its design was repeated measured within between interactions. The samples were selected non-randomly and available from sports clubs of Mazandaran Province in Iran. After entering the study, the participants were randomly assigned to one of the two groups of CFO and custom mold with a raised ridge around the perimeter FO (CRFO). For this purpose, block randomization was used. Four samples were placed in each block and six blocks were made. Then the blocks were selected by drawing lots and according to their order, the patients included in the study were placed in the desired groups.

Participants and setting

Thirty people with CAI participated in this study. The eligibility criteria for these people were based on the statement of international ankle consortium [22] and included the following criteria: Patients report the feeling of giving way and repeated ankle sprains (at least 2 times in the 6 months before entering the study) and their feeling of instability is confirmed by a score of less than 24 in the Cumberland ankle instability tool (CAIT) questionnaire, a history of at least one significant lateral ankle sprain if the first sprain occurred 12 months or earlier and was associated with symptoms of inflammation, such as pain, swelling and physical dysfunction for at least one day; and score less than 90% in the activity of daily living section, and less than 80% in the sports activities section of the foot and ankle ability measure (FAAM) questionnaire. The information on all questionnaires was provided to the participants in the Persian version. Also, the exclusion criteria included acute injury to one of the joints of the lower limbs in a way that leads to disruption of physical activity for at least one day, history of fracture or surgery affecting balance in one or two lower limbs, and history of disease or taking medicines that affect balance.

Blinding

In this study, different people were responsible for sampling to evaluation, and the treatment process (assessor blinding). Statistical analysis was also performed by a person who did not know about the experiment, intervention, and sampling method.

Intervention

Both types of interventions were made by an orthotist. The CFO was made by impression. This impression was taken in a state where the subtalar joint was neutral. After correcting the positive mold, a 3 mm polypropylene sheet was used to make the CFO. The length of this FO was extended to the metatarsal head, and the depth of the heel cup was considered to be 1 cm for better heel support. The trim line of this FO was medially and laterally under the malleolus to support the medal and lateral longitudinal arch support (Figure 1A). To make a CRFO, first, a layer of soft foam with a thickness of 1 mm was glued on the upper surface of the CFO, then a strip of ethylene-vinyl acetate (EVA) foam (shore A50) with a diameter of 3 mm was attached to the foam with a distance of one centimeter from the plantar sides of the foot (Figure 1B).

Outcomes

Ankle sprains occur in dynamic conditions and during activities. For this reason, the dynamic postural control was evaluated using the star excursion balance test (SEBT) in this study. The validity and reliability of the SEBT to examine dynamic postural control in patients with musculoskeletal injuries, such as CAI was evaluated and confirmed in several studies [8, 23]. This test has 8 directions that are placed to an angle of 45 degrees from each other to the center. The measuring criterion in this test is the distance that each person's limb can travel in any direction while maintaining balance.

Figure 1. A) Custom mold FO, B) Custom mold with raised ridge around the perimeter FO

The way to perform this test is while placing the hands-on hip joints on each side, placing the affected leg in the center of the star, and reaching with the unaffected foot as far as possible along the desired direction. In the modified version of SEBT that is also used in this study, the test was performed only in the anteroposterior, medial, and posteromedial directions because according to Hertel's study, these three directions are more affected in CAI [24]. During the test, the examiner marked the distal part that the foot touched in any direction. The test was repeated three times in each direction and the average of these three attempts was considered as the distance traveled. This distance was in centimeters and was divided by the length of the person's lower limb to normalize the distance obtained [25]. If the participant placed excessive weight on the reaching limb, moved the leg that is in the center, or did any other movement that showed loss of balance, the test was stopped and repeated.

Procedure

In the first session after receiving consent forms from the participants; they were checked for the presence or absence of inclusion and exclusion criteria and were asked to complete two questionnaires of CAIT and FAMM. Then the negative mold was taken from their feet. After making the FOs, in the second session, the participants were first shown a film of how to perform the SEBT, and then they were asked to perform the test six times in each direction according to Hertel's instructions to prevent the learning effect [26]. After learning how to perform the test, they performed the test with short collar shoes and without FOs. They were given FOs and after five minutes of walking with shoes and FOs, the test was repeated. The participants were asked to use FOs for 4-8 hours a day for one month. In the third session, the tests were repeated with and without FOs.

Statistical methods

According to the data of the previous study [16] and hypothesizing α=0.05 and 85% power, the number of samples was calculated at 24 with the G-Power software, version 3.1. With an attrition rate of 25%, 30 people (15 people in each group) were included in this study.

SPSS software, version 25 was used for data analysis. Checking the normality of quantitative data in this study was done using the Shapiro-Wilk test. Independent t-tests were used to compare the demographic and clinical characteristics of the two groups at the beginning of the study. Between and within-group changes were investigated with repeated measured multivariate analysis of variance (MANOVA) and pairwise comparisons statistical tests. $P<0.05$ was considered significant.

Results

Measuring the quantitative data obtained from the SEBT with the Shapiro-Wilk test showed that the data have a normal distribution. Table 1 presents demographic and clinical information. The results of the independent t test showed no difference in these variables between the two groups at the beginning of the study (Table 1).

The results of the repeated measure multivariate analysis of variance (MANOVA) test showed that within- and between-group changes and their interaction are significant. Therefore, the pairwise comparison test was performed to analyze the differences. To compare within-group changes, the immediate effect of the interventions in each of the two groups was first compared (Table 2). In the CFO group, medial (P=0.042) and posteromedial (P=0.046) differences were found, but CRFO was significantly different in all

three directions (P<0.001). Considering the increase in the average reach distance in these directions, it can be concluded that both of these FOs improved dynamic postural control in the mentioned directions (Table 2). After one month of use, in the CFO group, no significant difference was observed in any of the directions. In the CRFO group, a significant difference was observed only in the medial direction (P<0.001), which is due to the increase in the average reaching distance (Table 2).

Comparing the data of the reaching distance without FOs before and after one month in the CRFO and CFO groups showed a significant increase in the reaching distance in all three directions and comparing the data with FOs in both groups of CRFO and CFO showed a significant increase in the reaching distance in the anteromedial and medial directions (Table 3).

This test was performed in two stages before the intervention and after the one-month intervention. Before one month and before the intervention, no significant difference was observed between the CFO and CRFO groups in any of the anteromedial, medial, and posteromedial directions. (The range of P was from 0.701 to 0.961). After using FO, a significant difference was observed in the anteromedial direction (P=0.007), and posteromedial directions (P=0.040), and considering the greater average reaching distance in the CRFO group, it can be concluded that this group's FO was more effective in improving dynamic postural control.

Table 1. Demographic and clinical characteristics differences

Variables	Mean±SD		P
	CFO	CRFO	
Weight (kg)	65.8±5.08	63.8±6.85	0.37
Height (cm)	165.8±8.59	163.06±9.69	0.42
Age (y)	25.73±2.49	26.40±3.18	0.52
CAIT	18.2±3.23	19.0±2.97	0.48
FAMM-sport	21.26±2.81	21.33±2.89	0.93
FAMM-ADL	66.33±7.99	66.53±6.1	0.94

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Abbreviations: CAIT: Cumberland ankle instability tool; FAAM-ADL: Foot and ankle ability measure with activity of daily living; CFO: Custom mold foot orthoses; CRFO: Custom mold with a raised ridge around the perimeter foot orthosis.

Table 2. Within-group comparison of the reaching distances of the SEBT with and without foot orthosis

Direction		Beginning			After 1 Month		
		Mean±SD		P	Mean±SD		P
		Without FO	With FO		Without FO	With FO	
CFO	Anteromedial	0.8±0.04	0.82±0.05	0.158	0.85±0.04	0.87±0.05	0.225
	Medial	0.88±0.06	0.91±0.07	0.042	0.94±0.07	0.95±0.07	0.152
	Posteromedial	0.85±0.07	0.89±0.07	0.046	0.91±0.06	0.093±0.05	0.377
CRFO	Anteromedial	0.79±0.06	0.87±0.05	0.000	0.94±0.07	0.95±0.05	0.682
	Medial	0.89±0.04	0.96±0.05	0.000	0.99±0.05	1.02±0.05	0.000
	Posteromedial	0.84±0.07	0.95±0.07	0.000	0.99±0.05	1.02±0.04	0.064

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Abbreviations: CFO: Custom mold foot orthoses; CRFO: Custom mold with a raised ridge around the perimeter foot orthosis; FO: Foot orthosis.

Table 3. Within-group comparison of the reaching distances of the EBT before and after one month of using each of foot orthoses

Direction		Without FO		P	With FO		P
		Mean±SD			Mean±SD		
		Before 1 Month	After 1 Month		Before 1 Month	After 1 Month	
CFO	Anteromedial	0.8±0.04	0.85±0.04	0.005	0.82±0.05	0.87±0.05	0.000
	Medial	0.88±0.06	0.94±0.07	0.000	0.91±0.07	0.95±0.07	0.008
	Posteromedial	0.85±0.07	0.91±0.06	0.002	0.89±0.07	0.93±0.05	0.101
CRFO	Anteromedial	0.79±0.06	0.94±0.07	0.000	0.87±0.05	0.95±0.05	0.000
	Medial	0.89±0.04	0.99±0.05	0.000	0.96±0.05	1.02±0.05	0.000
	Posteromedial	0.85±0.07	0.99±0.05	0.000	0.95±0.07	1.02±0.04	0.064

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Abbreviations: CFO: custom mold foot orthoses; CRFO: custom mold with a raised ridge around the perimeter foot orthosis; FO: foot orthosis

After one month of using the FOs in the case without FO, differences were observed in three anteromedial (P<0.001), medial (P=0.045) and posteromedial (P=0.002) directions. Also, in the case where the FOs were used significant differences were observed in all three directions (P range was from 0.000 to 0.008), which shows that CRFO has performed better in improving dynamic postural control (Table 4).

Discussion

In frequent ankle sprains, the amount of ankle joint muscle activity and the range of motion of the joint change, which decreases the ability to maintain dynamic postural control in these patients. Based on the results of this study, both CFO and CRFO showed significant immediate and four-week effects on reaching the distance of SEBT; however, after one month, only CRFO led to increased reaching the medial direction. In the comparison between the groups, it was also found that CRFO was more successful immediately and after four weeks of use.

The primary result of this study is the increase in the reach distance of SEBT due to the use of CFOs immediately and after one month of use. These results confirmed the results of previous research. The studies conducted by Orteza et al. and Guskiewicz et al. emphasized the positive effect of the immediate use of CFOs on postural control [13]. In 2008, Sesma et al. evaluated the effect

Table 4. Between-group comparisons of the reaching distances of the SEBT with and without FO and before and after one month

Direction		Without FO		P	With FO		P
		Mean±SD			Mean±SD		
		CFO	CRFO		CFO	CRFO	
Before 1 month	Anteromedial	0.8±0.04	0.79±0.06	0.719	0.82±0.05	0.87±0.05	0.007
	Medial	0.88±0.06	0.89±0.04	0.701	0.91±0.07	0.96±0.05	0.061
	Posteromedial	0.85±0.07	0.84 ±0.07	0.961	0.89±0.07	0.95±0.07	0.040
After 1 month	Anteromedial	0.85±0.04	0.94±0.07	0.000	0.87±0.05	0.95±0.05	0.000
	Medial	0.94±0.07	0.96±0.05	0.045	0.95±0.07	1.02±0.05	0.008
	Posteromedial	0.91±0.06	0.99±0.05	0.002	0.93±0.05	1.02±0.04	0.000

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of one month using CFOs on dynamic postural control by SEBT and found that this type of FO was effective to improve dynamic postural control. The evaluation methods of Orteza et al. and Guskiewicz et al. were using a digital balance evaluation device and the Chetex balance system, respectively. Despite the difference in the evaluation method and characteristics of patients with ankle sprains in these studies, all three mentioned studies confirmed the results of the present study [11-13].

CFOs can create a neutral subtalar position, maintain heel position, support medial and lateral longitudinal arches, distribute foot pressure, and control movements. The deep heel cup of this type of FO maintains bone integrity in the subtalar joint and this bone stability improves postural control [16, 27]. Unlike ankle supports, FOs do not restrict movement in the ankle joint, that is why people are more inclined to use them [28, 29].

The therapeutic devices that have been studied in CAI often seek to affect mechanical instability and maximize motor output, ignoring the wide range of sensory disorders and their effects on movement [27]. Because all the features of the two FOs in this study are the same and only one of them has a peripheral raised ridge, it seems that the improvement in dynamic postural control when using CRFO is due to the existence of a peripheral raised ridge and its effect on CNS for better recognition of the BOS boundaries. This result also confirms past research on this type of textured surface in patients with postural control disorders [17- 21]. To maintain postural control, COM should move within BOS. The complexity of COM fluctuations in time series is the result of the interaction between the feedback mechanisms of the somatosensory, vestibular, and visual systems [30, 31].

Mechanoreceptors on the plantar surface of the feet are the vital receptors involved in the evaluation of BOS. Previous researchers believed that these receptors play a role in the constant control of continuous shifts of COM. The possible mechanism of the raised ridge on the complexity of postural control can be due to the stronger sensory stimulation of the mechanoreceptors. This strong stimulation is caused by the pressure difference between the raised ridge and the depressed area in the textured sole pattern of CRFO [32]. It seems that when this FO is used for some time, slowly adapting receptors encode the continuous pressure on the foot plantar surface [33]. In this way, they increase body awareness and improve the special representation of pressure distribution in the soles of the feet, and convey more accurate information [34-36].

The results of the present study emphasized that when SEBT is repeated after one month, the CFO no longer immediately helps increase reach in any of the three directions. No study has investigated the immediate effect of this type of FO on postural control after one month of use in CAI; therefore, the results cannot be compared with the previous studies. A possible cause of this issue can be the habituation process, which leads to a decrease in muscle response as a result of repeated stimulation. In this process, changes occur in the synapses of the nervous system, which leads to a decrease in the reaction [37]. However, after one-month CRFO was able to immediately create a significant difference in increasing the reach distance in the medial direction. This result confirms the results of Perry et al. They investigated the effect of 12 weeks of using FOs with the peripheral raised ridge on dynamic postural control in healthy elderly adults and by examining the immediate effect of FOs after 12 weeks of use; they found its effect to be positive [18]. Sensory stimulation that this FO exerts with gentle pressure on the peripheral receptors of the plantar area of the foot does not seem to become a habit, but more research is needed to confirm this claim.

For this reason, we aimed to affect both types of mechanical and functional disorders in CAI; we have added the peripheral raised ridge to the CFO. Because prefabricated FOs are available and cheaper, in future studies, by adding a peripheral raised ridge to prefabricated FOs and examining its effect on dynamic postural control, the effect of this type of FO can also be investigated in CAI. Also, based on the results of one study, it is not possible to make a definite opinion about CRFO. It is suggested that in future studies, the effect of this type of FO on the rehabilitation process of people with CAI will be investigated and compared with different types of FO. Also, the authors have some other suggestions for further study in this area, including investigating the impact of the CRFO on other variables related to the rehabilitation process, such as quality of life, comfort, the possibility of return sprains, and the kinetics and kinematics of the lower limb joints and designing clinical trial studies to investigate the long-term effect of the introduced foot orthosis.

This study had limitations, such as the participants of this study were young people in the age range of 18-30 years, and the effect of this FO cannot be generalized to people of other age groups or people who have frequent sprains due to an underlying disease, such as Charcot. Also, in cases where proprioception changes in the short term due to factors, such as fatigue, the results of using the desired FO are not obvious.

Conclusion

In this study, after examining the effect of CFO and CRFO on dynamic postural control of patients with CAI, it was found that both types of FOs lead to improvements in dynamic postural control but CRFO performs better in this regard .In this study, CRFO immediately increased the reaching distance in anteromedial and posteromedial directions of SEBT compared to CFO and after one month of use, a significant difference was observed between CFO and FO in all three directions, and considering the greater reach distance in the CRFO group, CRFO seems to be more effective in improving postural control.

According to the results of the present study, it seems FOs that are made to influence mechanical and functional instabilities work better than the FO that are made to influence mechanical instability in the rehabilitation process of people with CAI.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Ethics Committee of the University of Social Welfare and Rehabilitation Sciences (Code: IR.USWR.REC.1400.301). All participants read and signed the consent form before entering the study.

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Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

The authors declared no conflicts of interest.

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