Effects of Arch Support Insole versus Standard Insole on Balance and Strength in Bilateral Flexible Flatfoot

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ABSTRACT

Background: Custom-made arch support insoles (ASI) are commonly described for flexible flatfoot (FFF) patients. Whether using of ASI has similar effects compared to standard foot insoles needs to be explored. **Purpose:** to compare custom-made ASI added to strengthening exercise of foot muscles versus standard insole added to strengthening exercise of foot muscles on dynamic balance, and ankle muscles strength in patients with bilateral FFF. **Materials and Methods:** Thirty-four patients with FFF recruited to participate in this study; age 18 to 30 years old. All patients' evaluation included balance by means of star excursion balance test (SEBT), and hand-held dynamometer (HHD) for ankle muscles strength. They were randomized into two groups, A and B. Group A used custom-made arch support insole (ASI) combined with strengthening of foot muscles, while group B used standard insole combined with the same strengthening exercises of foot muscles applied in group A. **Results**: A significant improvement in means of SEBT values has been detected in comparing groups in favor of Group A in both limbs. On the other hand, no significant difference was noticed in reported means of muscle strength among groups in dorsiflexion, plantar flexion, and inversion in both limbs. Evertors were the only muscles group showing marginal significant difference in muscle strength between groups in both limbs in favor of group A (P=0.048). **Conclusion:** in the current study it could be concluded that custom-made ASI was more effective than standard insole in terms of dynamic balance, and foot evertors' strength.

Keywords: arch support insole, flexible flatfoot, hand-held dynamometer, star excursion balance test.

INTRODUCTION

Flexible flatfoot (FFF) is the most common form of flatfoot. It is marked by an arch that disappears in weight-bearing and reappears when the foot is non-weight bearing. FFF is highly widespread between participants globally; with 37.95% and 55.55% prevalence ratio in females and males respectively **[1].**

When the medial longitudinal arch (MLA) has declined or been totally lost, resulting in functional disorders, patients will lose the ability to absorb impacts and will lose the sense of balance, resulting in decreased stability while walking, resulting in walking problems, and decreased endurance **[2]**.

It has been reported that FFF was associated with decreased muscle activity of abductor hallucis (AbdH), peroneus longus (PL), and tibialis posterior (TP) during walking **[3].** The dynamic stability of the MLA is exerted by the AbdH and TP muscles and lower EMG activity in these muscles can result in decreased biomechanical ability, bad absorption of external impacts, and postural instability which can lead to injuries **[4].**
Orthotic insoles supporting the MLA are a conservative treatment for FFF **[5]**. Customized arch support insoles (ASI) were better than prefabricated insoles to correct malalignment of the foot, provide plantar pressure distribution and greatly improve comfort in patients with FFF **[6]**.

Most of the previous studies had investigated the effect of using insole alone or exercise programs alone or comparing between them on FFF patients. Therefore, this study aims to compare custom-made ASI versus standard insole when either insoles is used with strengthening of foot muscles. Comparing their outcomes will be in terms of dynamic balance, and ankle muscles strength.

MATERIALS AND METHODS

Study design:

This was a pre- post two groups study conducted at physical therapy outpatient clinic, Horus University, New Damietta, Egypt in the period from September 2021 to January 2022. Prior to data collection, ethical approval was obtained (No: P.T.REC/012/ 003374), and the study protocol was registered on clinical trials.gov with approval number (NCT05056298).

Participants:

Thirty-four patients (males and females) with bilateral FFF were recruited for the study. Sample size calculation was carried out using G Power and Sample Size Calculations software, type 3.0.11 for MS Windows (Walton D and William D. DuPont., Vanderbilt University, Tennessee, USA). Based on a report by a previous publication, using 80% power at $\alpha = 0.05$ level and effect size = 1.12 **[2]**. A random number generator(www.randomization.com) was used to randomly assign the patients to one of the two groups. Randomization was done by a research associate not engaged in the study.

Patients were allowed to get involved in the study if they had the subsequent criteria: 1) Navicular drop tests (NDT) 1cm or greater difference in the heights of the navicular tubercle from sitting to standing positions **[7].** 2) Age ranges from 18 to 30 years from both sexes **[8]**. 3) BMI ranges from 18 to 25 **[9].** While patients were excluded from the study if they exhibited one of the subsequent criteria: 1) past history of lower limb injuries or fractures, congenital deformities, or surgery disturbing foot muscle strength and balance. 2) any neurological disorder like cerebral concussions and/or visual or vestibular deficits, disturbing foot muscle strength and balance **[10].** Patients who met inclusion criteria were given a detailed information of the study objectives. Patients who allowed to get involved were requested to sign an informed consent form, then inclusion in either groups was revealed to the patients.

Patients in both study groups were evaluated for 1) MLA height assessment for patient selection and inclusion using navicular drop test (NDT). Outcome parameters were (2) dynamic balance evaluated by star excursion balance test (SEBT), and (3) ankle muscle strength evaluated by hand-held dynamometer (HHD).

Measurement Procedures

1) Navicular Drop Test

The patients sat with their feet flat on a hard surface, their knees flexed to 90 degrees, and their ankle joints neutral. While preserving neutral position of the subtalar joint, it was established when depressions of the talus were similar on the medial and lateral edges of the ankle. Navicular tuberosity was recognized and marked with a pen and its height from the ground was measured by a standard ruler **figure (1)**. Another measurement was done in normal standing. Then, the difference of the height of the navicular tuberosity between sitting and standing positions was calculated rendering the ND amount in centimeters. The criteria to determine flatfoot is ND of ≥ 1cm **[7].**

Fig. (1): measuring navicular height in sitting position with subtalar neutral position

2) Star Excursion Balance Test (SEBT):

The SEBT was carried out as described by **Robinson & Gribble, (2008) [11].** Patients stood in the center of a grid on the ground with eight lines extending at right angles from the grid's center, which is labelled with the direction of excursion in reference to the standing leg just as anterior, medial, anteromedial, lateral, anterolateral, posterior, posteromedial, and posterolateral. Patients undertook the testing barefoot, with their foot in the grid's center and great toe with the anteriorly extended line. Patients were requested to sustain a single limb support on the tested leg while reaching the other leg to touch as far as feasible over the selected line with the most distal segment of their feet **figure (2)**. The foot was permitted only to touch gently in order to avoid balance assistance. The maximum reaching distance was measured manually using tape measurement. Four trials are necessary as a practice. On each limb, three trials were done in each direction separated by ten seconds of rest. Reaching lengths were adjusted to each patients' limb length as evaluated from the anterior superior iliac spine (ASIS) to the medial malleolus.

Fig. (2): the lateral reach of SEBT of the right limb

3) Hand-Held Dynamometer (HHD):

The Lafayette® HHD was used to assess the isometric strength of the extrinsic foot muscles. It was calibrated before testing each patient. All testing was done with the participants in a subtalar neutral position. To prevent any accessory movement during testing, the lower leg was strapped. Patients were directed to pull or push as hard as they could on the device in each direction, while the investigator countered that force with both hands for 3 seconds per trial, with a 10-second rest between trials. The patient peak force was calculated using the maximal force (newton) **[12].**

- For eversion and inversion: patients were in a side-lying position and the dynamometer was placed at the lateral and medial border of the forefoot respectively **(figure 3. A, B)**.

- For dorsiflexion and plantar flexion: patients were in supine lying position dynamometer was placed against dorsum and sole of the foot respectively **(figure 3. C, D)**.

Fig. (3): positions for isometric testing of extrinsic foot muscle strength using HHD
a. Evertors, b. Invertors, c. Dorsiflexors, d. Plantar flexors

Treatment procedure:

All treatment sessions were done by the same therapist. Group (A): received custom-made arch support insole (ASI). Group (B): received standard insole. Patients in both groups alike received intrinsic and extrinsic foot muscle strengthening **[13]**. Patients in both groups received the treatment program for 3 sessions per week for 8 weeks.

Group (A) 1) Arch support insole (ASI):
The casting method was used to fabricate the Custom-made ASI with semi-rigid arch support. A specialized orthotist took a plaster cast of both feet in neutral position of the subtalar joint. The negative castings were positioned in vertical position of the calcaneus, and the positive molds taken from the negative casts was utilized to fabricate a custom-molded orthosis **(figure 4).** If patients complained about pain while wearing them, they would be refitted or refabricated **[14].**

Fig. (4): custom-made arch support insole (ASI)

Patients were asked to wear the customized ASI inside their shoes during the treatment period of
(8 weeks), 6 to 8 hours each day, to keep the orthoses on when walking outside, and during
strengthening exercise of extrinsic foot muscles **[4].**

2-Intrinsic foot muscle training (short foot exercise) (SFE)

Patients were requested to stand barefooted against wall, raise their toes off the floor and then depress their toes while preserving the MLA height to develop a subtalar neutral position. Hold it for 10 seconds while attempting to keep the MLA as stable as possible during the period without any compensating extrinsic foot muscular activation. Allow the foot to pronate and the MLA to drop to a relaxed condition gently and with eccentric control after the 10-seconds. After 1-2 seconds of rest, actively resupinate and repeat the exercise. Perform this concentric, isometric, and slow eccentric SFE exercise up to 30 times each day for two months. The exercise was done every day at home and in the clinic under the observation of the examiner to progress the exercise every two weeks **[15].**

The sequence of progression of intrinsic foot muscle training:

Phase 1: The exercise was done in a bilateral standing with the patient's fingertips on the wall.

Phase 2: The exercise was done in a unilateral standing with the patient's fingertips on the wall.

Phase 3: The exercise was done in a unilateral standing, with fingers off the wall while opening his eyes.

Phase 4: The exercise was done in a unilateral standing, with fingers off the wall while closing his eyes.

3) Extrinsic foot muscle strengthening:

For eight weeks, participants did strengthening exercises with both ankles for dorsiflexors, plantar flexors, invertors, and evertors three times every week for 20 minutes each session. Thera-Band elasticated bands were used in a progressive resistance program and patients were advanced during the training sessions according to the progressive resistance protocol**.** Regardless the color (resistance) of the band, all strength training was performed with the band elongated to 70% of the resting length of the doubled Thera-band. As the color of the band progresses, the tension force generated by each color increases; graduated from red, green, blue, and then black. Each band color for 2 weeks over 4 sets per session, of 10 repetitions each. The mean kilogram-force units are used to describe the tension force produced by each color of the band **[16,17].**

Group (B)

1-Standard Insole: the patient was directed to wear a standard flat rubber insole **figure (5)** inside his shoes for 8 weeks, 6 to 8 hours every day, and during outside walking.

Fig. (5): standard flat insole

2-Intrinsic foot muscle training: same as Group (A).

3-extrinsic foot muscle training: same as Group (A).

Data analysis:

SPSS for Windows, version 26 (SPSS, Inc., Chicago, IL) was utilized to perform Statistical analysis. Data were checked for normality, homogeneity of variance, and the existence of outliers prior to the final analysis. This was carried out as a requirement for the study of differences of parametric difference. Preceding assumption testing found that all tested variables were normally distributed, as determined by the Shapiro-Wilk test (p 0.05). Levine's test evaluated homogeneity of variances ($p > 0.05$) and covariances ($p > 0.05$). As a result, parametric statistics were utilized. The un paired t-test was used to determine if the dependent variable differed between the two independent groups. A paired t-test was conducted to determine if there was a difference between the two groups. The pre-treatment demographic features of the 2 groups were compared using an unpaired t-test to see if there was a difference. The alpha level was set at 0.05.

RESULTS

Patients' demographic and clinical features:

As demonstrated in Table 1, the baseline features of the patients revealed no significant differences between the right and left foot groups (P>0.05). Also, there

was no significant difference in gender
among the two groups (P>0.05).

Table 3. General features of patients in both groups

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	Group A $\bar{x}$ ± SD	Group B $\bar{x}$ ± SD	*P-value*
Age (Years)	26.5 ± 2.34	29.2 ± 8.09	0.200
Height (cm)	174.76 ± 9.51	175.73 ± 8.34	0.754
Weight (kg)	74.99 ± 7.93	76.94 ± 9.27	0.516
BMI (kg/m^2)	24.32 ± 0.50	24.38 ± 0.70	0.803
Gender			
Male	9 (53 %)	7 (41.17 %)	0.732
Female	8 (47 %)	10 (58.8 %)	

P-value: probability value; *Significant at *P-value* <0.05

Comparison of the both groups' dna-erp post-treatment outcomes:

There were no statistically significant differences in pre-treatment observed between the 2 groups. for right and left foot in balance and ankle muscles strength (P>0.05), as shown in Tables 2 &3. On the contrary, in all evaluated variables, both groups showed statistically significant improvement for right and left foot (P>0.05) in favor of group A. The exception was in the Posterolateral direction, lateral, Anterolateral directions of SEBT, and dorsiflexion, plantarflexion, and inversion muscle strength, where there were no significant differences between patients in both groups as seen in Tables 2 &3

Each group's dna-erp post-treatment comparison:

As seen in Tables 2 and 3, there was a statistically significant improvement in all evaluated variables (P<0.05) for the right and left foot in both groups.

Table 2. Comparisons of means between and within both groups in Star Excursion Balance Test before and after treatment.

Variable		Time	Group (A) $\bar{x}$ ± SD	Group (B) $\bar{x}$ ± SD	*P-Value*
Anterior direction	**Right foot**	Before	0.77 ± 0.05	0.74 ± 0.07	0.177
		After	0.88 ± 0.04	0.84 ± 0.04	***0.022****
		P-Value	***0.0001****	***0.0001****	
	Left foot	Before	0.74 ± 0.05	0.75 ± 0.08	0.553
		After	0.90 ± 0.04	0.85 ± 0.04	***0.007****
		P-Value	***0.0001****	***0.0001****	
Anteromedial direction	**Right foot**	Before	0.74 ± 0.1	0.67 ± 0.14	0.108
		After	0.91 ± 0.06	0.80 ± 0.05	***0.0001****
		P-Value	***0.0001****	***0.0001****	
	Left foot	Before	0.72 ± 0.08	0.7 ± 0.16	0.450
		After	0.91 ± 0.06	0.78 ± 0.05	***0.0001****
		P-Value	***0.0001****	***0.0001****	
Medial direction	**Right foot**	Before	0.67 ± 0.05	0.66 ± 0.08	0.528
		After	0.93 ± 0.05	0.79 ± 0.06	***0.0001****
		P-Value	***0.0001****	***0.0001****	
	Left foot	Before	0.72 ± 0.09	0.69 ± 0.11	0.394
		After	0.91 ± 0.04	0.76 ± 0.04	***0.0001****
		P-Value	***0.0001****	***0.0001****	
Posteromedial direction	**Right foot**	Before	0.74 ± 0.04	0.71 ± 0.09	0.408
		After	0.93 ± 0.05	0.84 ± 0.07	***0.0001****
		P-Value	***0.0001****	***0.0001****	
	Left foot	Before	0.75 ± 0.04	0.71 ± 0.1	0.199
		After	0.93 ± 0.03	0.83 ± 0.07	***0.0001****
		P-Value	***0.0001****	***0.0001****	
Posterior direction	**Right foot**	Before	0.75 ± 0.04	0.73 ± 0.08	0.470
		After	0.94 ± 0.04	0.88 ± 0.07	***0.023****
		P-Value	***0.0001****	***0.0001****	
	Left foot	Before	0.77 ± 0.06	0.76 ± 0.12	0.738
		After	0.93 ± 0.04	0.88 ± 0.07	***0.017****
		P-Value	***0.0001****	***0.0001****	
Posterolateral direction	**Right foot**	Before	0.77 ± 0.04	0.74 ± 0.1	0.390
		After	0.92 ± 0.06	0.90 ± 0.07	0.352
		% of change	19.48 %	21.62 %	
		P-Value	***0.0001****	***0.0001****	
	Left foot	Before	0.72 ± 0.05	0.74 ± 0.08	0.320
		After	0.92 ± 0.06	0.90 ± 0.07	0.398
		P-Value	***0.0001****	***0.0001****	
Lateral direction	**Right foot**	Before	0.74 ± 0.09	0.78 ± 0.08	0.176
		After	0.90 ± 0.12	0.86 ± 0.06	0.350
		P-Value	***0.0001****	***0.0001****	
	Left foot	Before	0.68 ± 0.05	0.73 ± 0.14	0.262
		After	0.89 ± 0.06	0.89 ± 0.06	0.979
		P-Value	***0.0001****	***0.0001****	
Anterolateral	**Right foot**	Before	0.70 ± 0.04	0.71 ± 0.07	0.462
		After	0.89 ± 0.07	0.85 ± 0.05	0.146
		P-Value	***0.0001****	***0.0001****	
	Left foot	Before	0.71 ± 0.04	0.74 ± 0.07	0.196
		After	0.86 ± 0.04	0.87 ± 0.07	0.871
		P-Value	***0.0001****	***0.0001****	

$\bar{x}$: Mean; SD: Standard deviation P-value: probability value; *Significant at P<0.05

Table 3. Comparison of means between and within both groups in Hand-Held dynamometer before and after treatment in both groups.

Variable			Time	Group (A) $\bar{x} \pm SD$	Group (B) $\bar{x} \pm SD$	*P-Value*
Hand-Held dynamometer - Right	**Foot**	**Dorsi flexors**	Before	126.64 ± 2.73	130.94 ± 23.81	0.466
			After	160.52 ± 6.41	158.0 ± 14.89	0.525
			P-Value	*0.0001**	*0.0001**	
		Planter flexors	Before	128.7 ± 2.73	140.05 ± 32.04	0.156
			After	170.88 ± 7.88	175.75 ± 18.81	0.337
			P-Value	*0.0001**	*0.0001**	
		Invertors	Before	128.17 ± 4.54	125.41 ± 12.15	0.386
			After	160.05 ± 4.43	160.05 ± 9.50	1.00
			P-Value	*0.0001**	*0.0001**	
		Evertors	Before	131.17 ± 17.50	127.94 ± 3.96	0.463
			After	167.41 ± 16.93	160.64 ± 3.95	0.119
			P-Value	*0.0001**	*0.0001**	
Hand-Held dynamometer - Left	**Foot**	**Dorsi flexors**	Before	126.82 ± 2.6	131.82 ± 23.39	0.388
			After	157.05 ± 3.19	160.70 ± 9.94	0.160
			P-Value	*0.0001**	*0.0001**	
		Planter flexors	Before	128.29 ± 5.44	135.0 ± 16.39	0.119
			After	172.70 ± 8.85	178.47 ± 14.70	0.176
			P-Value	*0.0001**	*0.0001**	
		Invertors	Before	127.23 ± 4.3	125.47 ± 13.06	0.600
			After	163.35 ± 4.32	162.41 ± 8.03	0.764
			P-Value	*0.0001**	*0.0001**	
		Evertors	Before	127.29 ± 12.53	127.64 ± 2.78	0.910
			After	169.05 ± 17.83	160.52 ± 4.14	*0.048**
			P-Value	*0.0001**	*0.0001**	

DISCUSSION

The result of the study revealed that: star excursion balance test (SEBT) means values of group (A) were significantly improved in comparison with group (B) post-treatment in both limbs. There was no statistically significant difference in the mean values at post-treatment ankle muscles strength measured by hand-held dynamometer (HHD) between the two groups in both limbs except for eversion isometric muscle strength.

In relation to SEBT reaching distances, there was a statistically significant improvement in group (A) and group (B) in favor of group (A). This was supported by the findings of **Kim et al., (2016) [2]** who found improvement in dynamic balance as evaluated by SEBT using customized ASI for five weeks. Also, our result regarding SEBT was augmented by a previous study **[18]** which evaluated several types of insoles to see whether insole improved balance during standing on the ground in normal and FFF patients and discovered that ASI was more efficient in improving standing balance in both FFF patients and normal subjects.

Group (A) improvement on SEBT might be explained that the insole supported the MLA, increased somatosensory input to the sole of the foot, realigned the foot into neutral posture, and promoted center of mass alignment and displacement within the base of support **[19].**

In contrast to our finding, **Percy & Menz, (2001) [20]** indicated that there was no significant improvement of dynamic balance using two different types of insoles on male athletes but the insole used in the study was prefabricated insoles not customized.

Another interesting conclusion was that, with the exception of evertors, isometric foot muscle strength values were non-significant between both groups post-treatment. however, the finding of the study was not in agreement with **Telfer et al., (2013) [19]** who evaluated the impact of customized ASI on selected lower limb muscles' EMG activity and he found that there was no significant effect of ASI on EMG activity of extrinsic foot muscles.

Our finding regarding HHD means values came in agreement with the result of **Murley, Menz, et al., (2009) [21]** who performed a systematic review about the influence of foot orthoses on lower limb muscle activity. They indicated that wearing ASI has increased activation of the peroneus longus (PL) muscle during gait. furthermore, this finding was augmented by **Murley & Bird, (2006) [22]** who indicated that customized insole produced improvement in PL muscle EMG maximum amplitude throughout walking in comparison with shoe-only.

Limitations of the current study include: the study evaluated only the short-term effects of the ASI and did not evaluate its long-term effects.

CONCLUSION

In the current study it could be concluded that custom-made ASI was more effective than standard insole in terms of dynamic balance, and foot evertors' strength.

Conflict of interest

The authors state that there is no conflict of interest concerning the publication of this paper.

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تأثير نعل دعم القوس الطولي مقابل النعل القياسي على التوازن والقوة في ثنائية القدم المسطحة المرنة :**محمد رمضان إبراهيم؛** المشرفون **:د /محمد شوقي عبد السلام** .استاذ مساعد بقسم العلاج الطبيعي لاضطرابات الجهاز العضلي الحركي وجراحتها كلية العلاج الطبيعي جامعة القاهرة . **ا.د /إيناس فوزي يوسف** .أستاذ ورئيس قسم العلاج الطبيعي لاضطرابات الجهاز العضلي الحركي وجراحتها كلية العلاج الطبيعي جامعة القاهرة . **د /محمد عزت محمد شلبي** .مدرس العلاج الطبيعي لأمراض الجهاز العضلي الحركي وجراحتها كلية العلاج الطبيعي جامعة القاهرة .رسالة ماجستير -قسم العلاج الطبيعي لاضطرابات الجهاز العضلي الحركي وجراحتها(. **2022**)

المستخلص

الخلفية :عادة ما يتم وصف نعال دعم القوس الطولي المصنوعة خصيصاً للمرضى الذين يعانون من القدم المسطحة المرنة .نبحث في هذه الدراسه ما إذا كان استخدام نعل دعم القوس الطولي المصنوعة خصيصاً له تأثيرات مماثلة مقارنة بنعل القدم القياسية .**الغرض من البحث :**أجريت الدراسة لمقارنة نعل دعم القوس الطولي المصنوع حسب الطلب والذي تم إضافته لتمرينات تقوية عضلات القدم مقابل النعل القياسي والذي تم إضافته لتمرينات تقوية عضلات القدم على التوازن الديناميكي وقوة عضلات الكاحل في المرضى الذين يعانون من ثنائيه القدم المسطحه المرنه .**مواد البحث و اساليبه :** شارك أربعة وثلاثين مريضاً يعانون من ثنائيه القدم المسطحه المرنه في هذه الدراسة وتراوحت اعمارهم من 18 إلى 30 عا م ا .تم تقييم جميع المرضى من اجل التوازن الديناميكي عن طريق الاختبار النجمي للتوازن الازاحي و قوه عضلات الكاحل عن طريق مقياس القوة المحمول باليد .تم تقسيمهم عشوائيا إلى مجموعتين أ و ب .تلقت المجموعة أ نعل دعم القوس الطولي المصنوع خصيصاً بالإضافة إلى تقوية عضلات القدم بينما تلقت المجموعة ب نع لا قياسي ا بالإضافة إلى نفس تمارين تقوية عضلات القدم المطبقة في المجموعة أ .**النتائج :**كان هناك تحسن كبير في متوسط قيم الاختبار النجمي للتوازن الازاحي في مقارنة المجموعات لصالح المجموعة أ في كلا الطرفين .من ناحية أخري لم يلاحظ أي فروق ذات دلاله احصائيه في متوسط قوة العضلات بين المجموعات في العضلات الرافعة والباسطة للكاحل وعضلات انقلاب الكاحل للداخل في كلا الطرفين .كان هناك فرق ا هامشي ا في قوة العضلات المسؤله عن انقلاب الكاحل للخارج بين المجموعتين لصالح المجموعة أ في كلا الطرفين (0.048P =)

الخلاصة:

في الدراسة الحالية يمكن الاستنتاج أن نعل دعم القوس الطولي المصنوع خصيصا كان أكثر فاعلية من النعل القياسي من حيث التوازن الديناميكي وقوة عضلات انقلاب الكاحل للخارج.

الكلمات الدالة :القدم المسطحة المرنة، نعل دعم القوس الطولي، الاختبار النجمي للتوازن الازاحي، مقياس **القوة المحمول باليد.**