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Effect of therapeutic insoles on the medial longitudinal arch in patients with flatfoot deformity: a three-dimensional loading computed tomography study

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Abstract

Background—Insoles are frequently used in orthotic therapy as the standard conservative treatment for symptomatic flatfoot deformity to rebuild the arch and stabilize the foot. However, the effectiveness of therapeutic insoles remains unclear. In this study, we assessed the effectiveness of therapeutic insoles for flatfoot deformity using subject-based three-dimensional (3D) computed tomography (CT) models by evaluating the load responses of the bones in the medial longitudinal arch *in vivo* in 3D.

Methods—We studied eight individuals (16 feet) with mild flatfoot deformity. CT scans were performed on both feet under non-loaded and full-body-loaded conditions, first with accessory insoles and then with therapeutic insoles under the same conditions. Three-dimensional CT models were constructed for the tibia and the tarsal and metatarsal bones of the medial longitudinal arch (i.e., first metatarsal bone, cuneiforms, navicular, talus, and calcaneus). The rotational angles between the tarsal bones were calculated under loading with accessory insoles or therapeutic insoles and compared.

Findings—Compared with the accessory insoles, the therapeutic insoles significantly suppressed the eversion of the talocalcaneal joint.

Interpretation—This is the first study to precisely verify the usefulness of therapeutic insoles (arch support and inner wedges) *in vivo*.

Keywords

Insoles; Three-dimensional Image; Flatfoot; Medial Longitudinal Arch; Loading; CT

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1. INTRODUCTION

Flatfoot deformity is characterized by a drop in the medial longitudinal arch, eversion of the hindfoot, and abduction of the forefoot under load (Myerson, 1997; Van Boerum and Sangeorzan, 2003). The standard conservative treatment for symptomatic flatfoot deformity is orthotic therapy with the aid of insoles or ankle foot orthoses (AFOs) or exercise therapy (Wapner and Chao, 1999; Coughlin *et al.*, 2007a). Therapeutic insoles, which are designed to rebuild the arch and stabilize the foot, are commonly used in conservative treatment. However, their reported effectiveness varies (Coughlin *et al.*, 2007b; Alvarez *et al.*, 2006; Lin *et al.*, 2008; Kulcu *et al.*, 2007; Chen *et al.*, 2010) and remains debatable.

A few cadaver studies have used a flatfoot deformity model to evaluate the effectiveness of orthoses based on the load response of the tarsal bones (Imhauser *et al.*, 2002; Kitaoka *et al.*, 2002; Havenhill *et al.*, 2005; Hirano *et al.*, 2009). All of those studies reported improved hindfoot alignment as a result of the orthoses. Recently, *in vivo* studies have been conducted using video images or markers for motion analysis, but these studies have failed to demonstrate any beneficial effects of orthoses (Kulcu *et al.*, 2007; Chen *et al.*, 2010).

Computed tomography (CT) is currently the most useful method for performing a detailed anatomic analysis of the complex tarsal bones. The kinematics of the hindfoot (Imai *et al.*, 2009) during plantarflexion and dorsiflexion have been analyzed *in vivo* using subject-based three-dimensional (3D) CT models. The load responses of the hindfoot (Kido *et al.*, 2011) and the medial longitudinal arch (Kido *et al.*, 2013) in patients with flatfoot deformity were also analyzed using subject-based CT models *in vivo*, and the results indicated that the flat feet dorsiflexed more at the first tarsometatarsal joint and everted more at the talonavicular and talocalcaneal joints under full-body loading in comparison with healthy feet. This method could be powerful for clarifying the effectiveness of therapeutic insoles for flatfoot deformity, based on our hypothesis that therapeutic insoles provide support for the medial longitudinal arch, especially in the first tarsometatarsal, talonavicular, and talocalcaneal joints. The objective of the present study was to quantitatively evaluate the effects of therapeutic insoles for flat feet by analyzing the rotation of the tarsal bones in the medial longitudinal arch in response to load-bearing with and without therapeutic insoles.

2. METHODS

The protocols for this study were all approved by the Institutional Review Board (IRB) (ERB-C-127). Eight subjects were recruited. All of the participants provided written informed consent. Sixteen feet with symptomatic mild flatfoot deformity (four men, age range 29-38 years; four women, age range 26-38 years; mean age 32.1 years (SD 4.8 years)) were studied. Flatfoot deformity was diagnosed by two board certified orthopedic surgeons (specializing in foot and ankle surgery) on the basis of clinical examinations and X-ray images taken under load-bearing conditions. The talo-first metatarsal angle was measured on the lateral projection of the X-ray images. Mild flatfoot was defined as a foot with a talo-first metatarsal angle greater than 4° and less than 15° (mean 8.0° (SD 2.2°), range 5.6-14.0°) (Karasick *et al.*, 1993; Supple *et al.*, 1992).

The shoes used in the study were commercially available standard sneakers. The therapeutic insoles were made using a CAD system (Pedcad Insole Designer; Pedcad, Oberkochen, Germany) to make the product quality as uniform as possible (Fig. 1a, 1b). A licensed orthotist supervised the production of the insoles, which were designed to raise the medial longitudinal arch by 10 mm with a 5-mm inner wedge, particularly reducing the burden of the posterior tibial tendon (Fig. 1a).

Each subject underwent axial foot CT scanning under non-loaded and full-body-loaded conditions using a custom loading device (Fig. 2) (Kido *et al.*, 2011, 2013). CT images of 0.5-mm thickness were scanned from the sole of the foot to a position 5 cm proximal to the tibiotalar joint. The CT system used was an Aquilion CX64 (0.5 s $\times$ 0.5 mm $\times$ 64 rows, 120 kV $\times$ 45 mA, volume EC, 512 $\times$ 512 matrix; Toshiba, Tokyo, Japan). A total of four CT scanning sessions were performed, first with accessory insoles (Condition A) with and without loading and then with therapeutic insoles (Condition B) with and without loading.

The resulting CT images were converted to Digital Imaging and Communication in Medicine (DICOM) format and reconstructed using 3D image reconstruction software (Mimics; Materialise, Inc., Leuven Belgium). The threshold level for cortical bone was selected for the tibia segments and each of the individual bones of the medial longitudinal arch (first metatarsal bone, cuneiforms, navicular, talus, and calcaneus).

The rotation of each medial longitudinal arch bone associated with loading was measured using a validated volume merge method (Imai *et al.*, 2009; Kido *et al.*, 2011, 2013; Ochia *et al.*, 2006; Watanabe *et al.*, 2012). A validated volume merge method was used for 3D-3D registration of the tarsal and metatarsal bones. In the volume merge method, a tarsal bone or a metatarsal bone in the unloaded position (the moving bone) was virtually rotated and translated toward the same bone in a loaded position (the stationary target). These rotations and translations of the bone were conducted with 0.1° and 0.1 mm increments, respectively, until the moving bone merged with the stationary target in the loaded position. The degree of volume merging was calculated at each transformation using an algorithm previously described, and the transformation was repeated until the maximum degree of volume merging was obtained. The accuracy of the volume merge method was reported to be 0.1 mm in translation and 0.2° in rotation (Ochia *et al.*, 2006).

The rotation of the following bones was assessed: the first metatarsal bone relative to the cuneiforms at the first tarsometatarsal joint; the cuneiforms relative to the navicular at the cuneonavicular joint; the navicular relative to the talus at the talonavicular joint; the calcaneus relative to the talus at the talocalcaneal joint; the talus relative to the tibia at the tibiotalar joint; the first metatarsal bone relative to the talus; and the first metatarsal bone relative to the tibia. The amount of bone rotation between the tarsal bones while wearing accessory (Condition A) and therapeutic (Condition B) insoles was compared. A global X-Y-Z coordinate system corresponding to anatomical axes was used to describe the orientation of the tarsal bones in the unloaded condition (Fig. 3). The Z-axis ran along the tibial shaft through the center of the ankle, and the Y-axis ran parallel to the projection of a line connecting the center of the heel and the second metatarsal head on a plane perpendicular to the Z-axis. The X-axis was determined according to a right-hand rule from

the Y-axis and Z-axis. The coronal (XZ) plane, sagittal (YZ) plane, and transverse (XY) plane were defined from these X-Y-Z axes. A local coordinate system was defined for each tarsal bone with its origin at the centroid of each bone and the same orientation as the X-Y-Z axes. The rotations of the tarsal bones and metatarsal bones under loading were expressed using Eulerian angles in a transverse plane-sagittal plane-frontal plane (Z-X-Y) sequence (Glasoe *et al.*, 2014). Dorsiflexion, eversion, and abduction were designated by a plus sign, and plantar flexion, inversion, and adduction were designated by a minus sign (Imai *et al.*, 2009; Kido *et al.*, 2011, 2013). The results are expressed as the mean $\pm$ standard deviation (SD). Differences in the load response between flat feet with accessory insoles (Condition A) and those with therapeutic insoles (Condition B) were analyzed using an unpaired t-test with Bonferroni's adjustment with a p value of 0.017. A p value of less than 0.05 was considered to be statistically significant.

3. RESULTS

The subjects voiced no complaints of discomfort throughout the experiments.

The notable differences included less eversion of the calcaneus in the coronal plane relative to the talus at the talocalcaneal joint (Condition A: 3.6° (1.5°); Condition B: 2.4° (1.4°), $p = 0.0003$) in the therapeutic insoles group (Condition B) compared with the accessory insoles group (Condition A) under loading conditions (Table 1).

4. DISCUSSION

The present study investigated the effect of therapeutic insoles on the changes in the medial longitudinal arch bone associated with loading *in vivo*. We found that therapeutic insoles significantly suppressed the eversion of the talocalcaneal joint compared with accessory insoles. Kulcu *et al.* (2007) and Chen *et al.* (2010) performed gait analyses on flatfoot patients using optical surface marker systems on the feet to investigate the effect of insoles on flatfoot deformity during gait; however, neither study demonstrated the effectiveness of insoles. Several cadaveric studies have been conducted to verify the effectiveness of orthoses in a severe flatfoot deformity model produced by resecting almost all of the soft tissue around the talus (Imhauser *et al.*, 2002; Kitaoka *et al.*, 2002; Havenhill *et al.*, 2005; Hirano *et al.*, 2009). These studies confirmed that some parameters, such as arch and hindfoot alignment, were improved by orthoses in the severe flatfoot deformity model.

Our study investigated custom therapeutic insoles with an additional 5-mm inner wedge for treating patients with mild flatfoot deformity. This is the first study to verify the usefulness of insoles (arch support and inner wedge) *in vivo*. The results of the present study indicated that the insoles suppressed the eversion of the talocalcaneal joint, which may be the most important problem for flexible flat feet. In this study, the patients experienced an improvement in the deformity, represented by reductions in the rotational angles in 1.2° eversion. The change in the rotational angles attributable to the therapeutic insoles was less than the results reported by Hirano *et al.* (2009) and Imhauser *et al.* (2002) using the cadaveric severe flatfoot deformity model. The inclusion of patients with mild flatfoot deformity in the present study and the inherent differences between cadaveric studies and *in*

vivo studies, such as the lack of muscle forces in the cadaveric studies, may have caused the differences in the effectiveness of the orthoses.

Regarding the clinical significance, the reduction in the rotational angles was only slight by 1.2°. Considering the extremely large number of steps or motions other than axial loading that a human takes in daily life, a small amount of bone rotation at each single transition from non-loaded to full-body loaded condition may develop gradually and finally result in a significant change over time. Therefore, the improvements of the deformity observed in this *in vivo* study, although small, may still have value in the clinical treatment for symptomatic flatfoot deformity.

The measurements in this study were performed on subject-based 3D CT models created by CT images taken under unloaded and loaded conditions. The 3D measurement technique was able to demonstrate the subtle movements of the tarsal bones caused by weight bearing. The present study used the coordinates with orientations corresponding to the conventional anatomical planes. Several studies on the 3D alignment of tarsal bones and metatarsal bones used the local coordinate systems based on the 3D orientation of the individual tarsal bone or metatarsal bone determined by inertial axes of each bone (Ledoux et al., 2006; Glasoe et al., 2013; Glasoe et al., 2014). While these coordinate systems provide refined relative motions at each joint in the foot, the 3D orientation of an individual tarsal bone or metatarsal bone may not always correlate with the anatomical planes, which makes interpreting the results difficult in such cases. Another study defined a local coordinate system using anatomical landmarks set at each tarsal bone or metatarsal bone (Gutekunst et al., 2013). Although this coordinate system provides segmental motion at each joint in the foot in a more clinically relevant manner, determination of the anatomical landmarks appears to require manual selection. A future study will utilize a local coordinate system set at individual joint surfaces of the foot in a standardized manner for better understanding of the segmental motions in the foot.

The present study investigated changes in the medial longitudinal arch under loading. However, this loading condition with a neutral ankle position only mimics a standing condition. Although the evaluation of the effects of the insoles using the subject-based 3D CT model may be limited to semi-static conditions, future studies of different loading conditions, such as the simulated toe-off position in the gait cycle, may be helpful to understand the effectiveness of the insole during gait in patients with flatfoot deformity.

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Highlights

- ▶ We investigated the effect of therapeutic insoles in patients with mild flatfoot.
- ▶ We examined tarsal bone rotational angles with accessory and therapeutic insoles.
- ▶ CT scans were performed on both feet under unloaded and full-body-loaded conditions.
- ▶ The CT scans were performed with accessory insoles and with therapeutic insoles.
- ▶ The therapeutic insoles suppressed the eversion of the talocalcaneal joint.

a

b

Figure 1. Production of therapeutic insoles. a) Therapeutic insoles were mechanically produced using CAD software. The plantar geometry was raised in the medial longitudinal arch by 10 mm with a 5-mm inner wedge by a licensed orthotist (left; before processing, right; after processing). b) Appearance of a therapeutic insole.

Figure 2.
CT scans in the loading condition. Loading was performed with an original loading device as reported in the previous studies.

Figure 3.

X-Y-Z axes. A global X-Y-Z coordinate system corresponding to anatomical axes was used to describe the orientation of the tarsal bones. The rotation of each medial longitudinal arch bone associated with loading was measured.

Table 1

Comparison of the load response between flat feet with accessory insoles (Condition A) and those with therapeutic insoles (Condition B) at the first tarsometatarsal, cuneonavicular, talonavicular, talocalcaneal, and tibiotalar joints and the talo- and tibio-first metatarsal relationships.

		Condition A	Condition B	Difference	p value
First tarsometatarsal Joint	df+/pf-	0.9 (1.0°)	0.7 (0.9°)	-0.2°	0.7704
	ev+/iv-	0.0 (1.0°)	-0.3 (0.9°)	0.3°	0.999
	abd+/add-	-0.1 (1.4°)	0.0 (0.8°)	0.1°	0.999
Cuneonavicular joint	df+/pf-	0.8 (1.0°)	0.7 (0.8°)	-0.1°	0.999
	ev+/iv-	-0.7 (0.9°)	-0.6 (0.9°)	0.1°	0.999
	abd+/add-	0.1 (1.3°)	0.0 (1.1°)	-0.1°	0.999
Talonavicular joint	df+/pf-	2.1 (1.1°)	2.0 (1.3°)	-0.1°	0.999
	ev+/iv-	5.0 (2.5°)	4.0 (2.7°)	-1.0°	0.0519
	abd+/add-	4.3 (3.5°)	3.6 (2.4°)	-0.7°	0.999
Talocalcaneal joint	df+/pf-	2.1 (1.2°)	1.8 (1.2°)	-0.3°	0.6015
	ev+/iv-	3.6 (1.5°)	2.4 (1.4°)	-1.2°*	0.0003
	abd+/add-	2.2 (1.7°)	2.0 (1.5°)	-0.2°	0.999
Tibiotalar joint	df+/pf-	-2.0 (1.2°)	-2.2 (1.4°)	-0.2°	0.999
	ev+/iv-	-0.1 (0.7°)	0.0 (0.6°)	0.1°	0.999
	abd+/add-	-0.6 (2.2°)	-1.1 (1.4°)	-0.5°	0.6558
Talo-first metatarsal Relationship	df+/pf-	3.9 (2.1°)	3.4 (2.0°)	-0.5°	0.5367
	ev+/iv-	4.3 (2.5°)	3.1 (2.5°)	-1.2°	0.0498
	abd+/add-	4.1 (3.2°)	3.4 (2.5°)	-0.7°	0.8064
Tibio-first metatarsal Relationship	df+/pf-	1.8 (1.5°)	1.2 (1.2°)	-0.6°	0.2082
	ev+/iv-	4.4 (2.8°)	3.2 (2.5°)	-1.2°	0.1221
	abd+/add-	3.5 (2.7°)	2.3 (2.4°)	-1.2°	0.2310

df: dorsiflexion +/- pf: plantarflexion - ev: eversion +/- iv: inversion - abd: abduction +/- add: adduction -

The data are expressed as the mean (SD).

* Significant difference: *p* value < 0.017