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Clinical Biomechanics 23 (2008) 1287–1293

CLINICAL BIOMECHANICS

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A comparison of semi-custom and custom foot orthotic devices in high- and low-arched individuals during walking

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Received 21 August 2007; accepted 8 July 2008

Abstract

Background. Orthotic devices can be a successful treatment for lower extremity injuries. However, the high cost of custom devices prevents some patients from purchasing them. Some orthotic companies have begun to offer a less expensive, semi-custom alternative. The purpose of this study was to examine whether the semi-custom devices can provide similar rearfoot control and comfort as custom devices in individuals with excessively high- and low-arches.

Methods. Thirty-seven subjects walked through the motion analysis lab under three conditions: no-orthotic, custom orthotics, and semi-custom orthotics. Rearfoot kinematics and comfort were collected in each device.

Findings. Both devices were effective at reducing eversion velocity and excursion. As compared to the no-orthotic condition, the custom device significantly decreased eversion velocity ($P = 0.03$), while the semi-custom device showed a trend toward decreased eversion velocity ($P = 0.09$). Eversion excursion was significantly reduced in both orthotic conditions ($P < 0.01$). In terms of comfort, high-arched individuals tended to be more comfortable in the semi-custom device in the heel and arch regions. However, the differences in comfort between the devices were generally small (<7%).

Interpretation. Overall, with respect to a comfort and ability to control rearfoot motion, the semi-custom orthotic device is a feasible alternative to the custom orthotic device for high- and low-arched individuals.

Keywords: Orthoses; High-arch; Low-arch; Gait; Kinematics

1. Introduction

Foot orthotic devices have had success rates of up to 75% when used as a conservative intervention for a wide variety of lower extremity problems such as plantar fasciitis, anterior knee pain, and Achilles tendonitis (Eggold, 1981; Gross et al., 1991; Landorf et al., 2004). The success of these devices has been attributed, in part, to their ability to control rearfoot motion. Separate studies by Johanson et al. (1994) and Branthwaite et al. (2004) identified significant changes in peak values of frontal plane rearfoot motion of the foot with the use of foot orthoses during walking. Additionally, several studies of the effect of foot orthoses during running have reported a reduction in some aspect of rearfoot motion such as peak eversion, eversion excursion, and eversion velocity with the use of orthotics (Bates et al., 1979; Mundermann et al., 2003; Smith et al., 1986).

Despite the effectiveness of orthotic devices, the cost can be prohibitive for some patients. A pair of custom orthotics can cost between $100 and $400, and insurance plans often do not cover these costs. This has led many people to purchase off-the-shelf devices which may not fit their foot very well. In addition, they are typically fabricated from soft materials that do not maintain their shape. In response to this, a number of foot orthotic laboratories have begun to develop semi-custom devices. Based upon a range of

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doi:10.1016/j.clinbiomech.2008.07.008

height, length, and width measures from selected landmarks of the foot, a finite number of molds of the foot can be designed. When the laboratory receives a negative impression (cast, foam, etc.), specific measurements are taken and the mold-of-best-fit is chosen from a library of functional orthotic shapes. The device is then made from this mold. These devices are a compromise between cost and fit. This significantly reduces the time and expense of fabrication. This cost savings can then be passed on to the patient.

Foot orthoses are often prescribed to people with excessively high- or low-arches, to help correct abnormal weightbearing and gait conditions. People with excessively high-arches tend to have diminished capacity for shock absorption due to increased stiffness and a smaller area for weight distribution (Franco, 1987; Zifchock et al., 2006). Conversely, people with excessively low-arches tend to collapse into excessive pronation (Mann et al., 1981). This flattening of the foot can disrupt normal weightbearing and cause problems in the ankle, as well as the knee and hip. Further, the excessively flat arch often lacks the rigidity necessary for efficient propulsion during toe-off (Franco, 1987). In fact, people with high- or low-arches appear to be particularly predisposed to injury. Kaufman et al. (1999) reported that those with both high- and low-arched feet are nearly twice as likely to sustain a stress fracture as compared to those with average arch height. Williams et al. (2001a,b) found that runners with high-arched feet have an increased propensity for bony injuries, while those with low-arched feet have a higher rate of soft tissue injuries.

It is possible that people with these extreme arch types may have difficulty accommodating to a semi-custom device. They may require a more custom device to provide maximum comfort and rearfoot control. On the other hand, the semi-custom device is partially customized to the individual, and may be an acceptable alternative to the custom device. Therefore, there were two purposes of this study. The first was to examine the rearfoot kinematics in individuals with excessively high- or low-arches in a custom, semi-custom, as well as no-orthotic condition during walking. Compared to the no-orthotic condition, both the custom and semi-custom were expected to reduce the peak rearfoot eversion angle, peak eversion velocity, eversion excursion, and eversion duration to a similar degree. The second purpose was to evaluate the individuals' comfort in the custom compared to the semi-custom device. No differences were expected between devices in heel, forefoot, edge, arch, or overall comfort.

2. Methods

An a priori power analysis was conducted for a two-way, repeated measured ANOVA using the equations of Park and Schutz (1999). Assuming an expected effect size of 0.6 and correlation of 0.7 between orthotic conditions, as derived from pilot rearfoot eversion angle, velocity, and excursion data, a minimum of 18 subjects were necessary to adequately power this study. Therefore, 37 individuals (18 high-arched and 19 low-arched) were recruited to participate in the study. None of the subjects were wearing orthotics when they entered the study. The subjects were 23.6 ± 6.4 years, 1.7 ± 0.1 m, and 66.5 ± 10.2 kg; 17 males and 20 females. All subjects were also recreational runners, logging at least 10 miles/week. Subjects were excluded if they had any injury at the time of the study, any history of a neurological or orthopedic condition, or surgical procedure that would affect their gait pattern. In addition, subjects with a leg length discrepancy greater than 1.5 cm were excluded due to the inability to adequately compensate for this difference with the orthosis.

Individuals were identified as having high- or low-arches during standing using the arch height index measurement system (see Fig. 1) (Zifchock et al., 2006). This device has a series of precise sliding calipers that allows for accurate, repeatable anthropometric measurement of the foot. The arch height index (AHI), described by Williams and McClay (2000) was used to characterize the arch height as follows:

$$\mathrm{AHI} = \text{Dorsum height}/\text{Truncated foot length},$$

where dorsum height was measured at 1/2 of the total foot length (measured from the posterior heel to the longest toe), and the truncated foot length was measured from the posterior heel to the first metatarsal phalangeal joint.

Individuals whose AHI was at least 1.5 standard deviations above and below the mean of a reference population, 0.34 ± 0.03 arch height units (Zifchock et al., 2006), were considered high- or low-arched, respectively. Subjects provided written consent prior to participation in the study. All procedures were reviewed an approved by the University Human Subjects Review Board.

Subjects were told that the study was comparing two different types of foot orthotics. During their first visit, all subjects had molds taken of their feet while lying prone. This was performed by an experienced physical therapist using a neutral position, slipper cast technique. Once the casts were obtained, measures of leg length, forefoot to

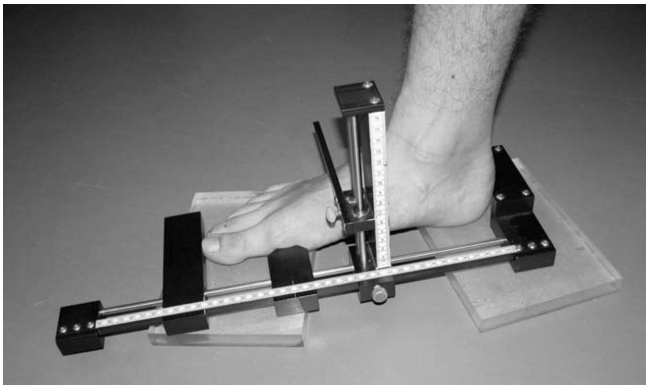

Fig. 1. Measurement of arch height was accomplished using the arch height index measurement system.

rearfoot position, and standing calcaneal angles were obtained. These measures were used to determine the individualized prescription for the devices. All forefoot deformities were balanced intrinsically to neutral. Any leg length discrepancies were accommodated to 50%. The amount of rearfoot posting was determined by the resting calcaneal stance position (RCSP) in the following manner:

$\leq 0^\circ$ (varus) = 0° post
$1\text{–}4^\circ$ (valgus) = 3° medial post
$5\text{–}8^\circ$ (valgus) = 5° medial post
$> 8^\circ$ (valgus) = 7° medial post

Low-arched individuals tended to have a more valgus RCSP than high-arched individuals (1.1° versus 0.1°, on average). Therefore, they also tended to have more medial posting (2.8° versus 0.7°, on average).

The plaster casts were then sent to a commercial orthotic manufacturer (KLM Orthotic Laboratories; Valencia, CA, USA). Custom and semi-custom devices were fabricated out of semi-flexible graphite with vinyl covers per technical standards established by The Board for Accreditation of Prescription Foot Orthotic Laboratories. The semi-custom device was made from the mold-of-best-fit chosen for each subject. The decision was based upon measurements taken from the cast. Contour measurements of the medial and lateral arches and heel, and discrete measurements of the foot length (from the most posterior point of the heel to the first metatarsal phalangeal joint), heel width, and medial and lateral arch height were considered. Subjects received both pairs of devices, however the investigators and subjects were blinded to whether they were semi-custom or custom.

Subjects returned to the lab to be fitted with the orthotic devices and were given an 18-day accommodation schedule that included a gradual schedule of increased walking and running in both devices. The schedule specified an alternating period of wear for each device so that subjects had equal opportunity to accommodate to both. By the end of the accommodation period, the subjects were running their typical distance in both devices. This schedule is similar to that used in previous literature, with slightly more time afforded to account for the fact that these were high- and low-arched individuals (Davis et al., 2008). Comfort in the areas of the heel, arch, forefoot, and edges, as well as overall comfort were assessed in each orthotic condition using a 100 mm visual analog scale (VAS) after the subjects had walked a full day in a given orthotic device (as specified in the accommodation schedule). The scale ranged from 0% to 100%, where a score of 0% was completely uncomfortable and 100% was completely comfortable. Previous work has suggested that a difference in comfort scores as small as 10% could lead to a preference for one orthotic device over another (Davis et al., 2008). A similar scale has been used in and validated in previous studies of comfort of orthotic devices (Mundermann et al., 2002).

Once fully accommodated, subjects returned to the motion analysis lab. Retroreflective markers were placed on the pelvis, thigh, lower leg and foot segments of the lower extremity (see Fig. 2). The side with the most extreme deviation from average arch height was tested. Markers on the foot were placed directly on the heel and projected out through holes in the heel counter of the shoe. All subjects were tested in a pair of neutral running shoes (Nike Air Pegasus; Beaverton, OR, USA). Five trials were collected for each of the three footwear conditions: custom, semi-custom, and no-orthotic device. In order to minimize order effects, the conditions were randomized. Subjects traversed a 75 ft walkway within 5% of 2.0 m/s, striking a force plate (Bertec Corp., Worthington, OH, USA) at its center with the foot of interest. Gait speed was monitored using photoelectric cells and a timer. Kinematic data were collected at

Fig. 2. Retroflective markers were places on the pelvis, thigh, shank, and rearfoot. Rearfoot markers were placed directly on the heel through holes in the heel counter of the shoe (inset picture).

120 Hz with a 6-camera, VICON motion analysis system (Oxford Metrics Ltd., Oxford, UK). The force plate data were used to determine heel-strike and toe-off using vertical force thresholds. All kinematic data were analyzed during stance period only.

Data were processed using Visual 3D software (C-Motion, Inc., Rockville, MD, USA). Kinematic data were low-pass filtered at 8 Hz with a fourth-order zero lag Butterworth filter. Variables of interest included peak eversion angle and velocity, eversion excursion, and eversion duration. Eversion excursion was defined as the range in motion measured from heel-strike to peak eversion. Eversion duration was defined as the time from heel-strike to the point of resupination and was normalized to stance time to yield units of % stance. Variables were extracted from each trial and averaged within each condition.

Kinematic and comfort variables were analyzed separately using two-way (arch type × orthotic condition), mixed ANOVAs. Interactions were further tested using Tukey pairwise comparisons. Statistical significance was set at $P < 0.05$. A trend was operationally defined as $0.05 < P < 0.10$. All analyses were performed using SPSS 14.0 (SPSS Inc., Chicago, IL, USA).

3. Results

Mean eversion angle and velocity curves are presented for each orthotic condition in Fig. 3. The results of the analyses of the discrete kinematic variables showed no interactions between orthotic condition and arch type. In terms of the main effects, eversion velocity and excursion were significantly different among orthotic conditions (Fig. 4). Post-hoc testing showed that eversion velocity was significantly decreased in the custom device as compared to the no-orthotic condition ($P = 0.03$). There was also a trend toward decreased values for the semi-custom device as compared to the no-orthotic condition ($P = 0.09$). Eversion excursion was significantly decreased in both the custom and semi-custom device conditions as compared to the no-orthotic condition ($P < 0.01$ for both). There was also a main effect of arch type for eversion duration, which was decreased in the low-arched individuals as compared to the high-arched individuals.

In terms of comfort, there were significant interactions for the heel and arch regions (Fig. 5). Post-hoc testing showed that the high-arched individuals were significantly more comfortable in the semi-custom device condition with respect to the heel region ($P = 0.01$). This equated to a 12% difference between conditions (79% for semi-custom and 67% for the custom condition). Further, there was a trend to suggest that the high-arched individuals were also more comfortable in the semi-custom device condition with respect to the arch region ($P = 0.07$). The low-arched individuals did not exhibit significant differences between conditions for either region. For the forefoot and edge regions, there were trends to suggest that both the high- and low-arched individuals were more comfortable in the semi-custom device condition. Comfort ratings were generally higher than 75% for both orthotic conditions. Only the arch region yielded lower values, which were approximately 66%.

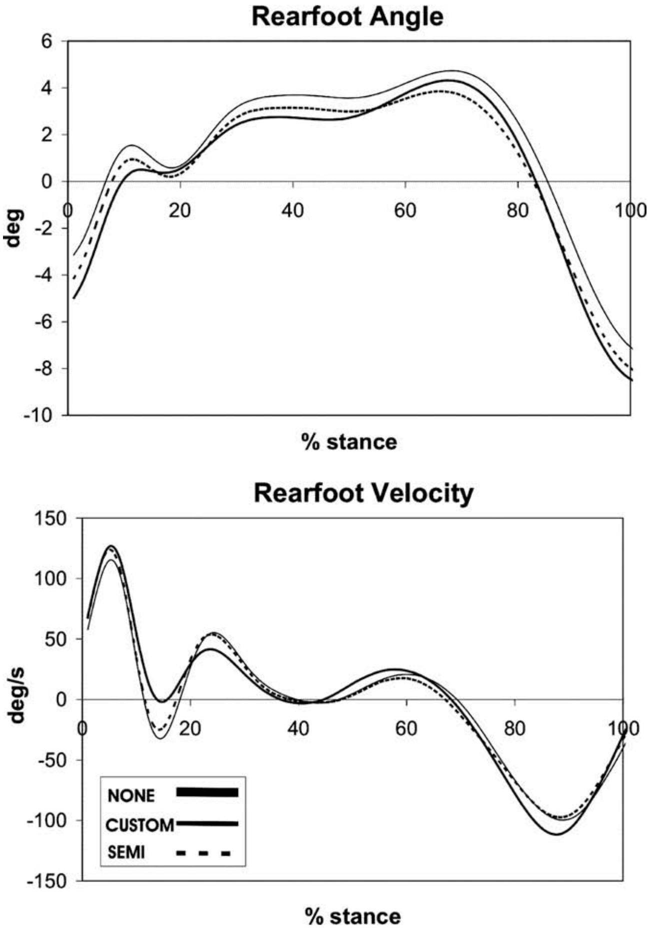

Fig. 3. Average rearfoot eversion angle and velocity curves, combined for all high- and low-arched individuals. *Note:* Eversion is positive, and inversion is negative.

4. Discussions

The aim of this study was to compare the effectiveness of a semi-custom to a custom device in individuals with abnormal arch height. In terms of rearfoot control, individuals with both high- and low-arches had similar responses to the orthotic conditions. Both devices appeared to control the motion to a similar degree as compared to the no-orthotic condition. Eversion velocity and excursion were reduced in both devices, while peak eversion angle was not. This is supported by Smith et al. (1986) who found that orthotics were more effective in controlling eversion velocity than peak eversion. However, the reduction in eversion velocity (15°/s) and eversion excursion (1°), demonstrated in the current study, represent changes of less than 11% and are smaller than noted in previous literature (Bates et al., 1979; Mundermann et al., 2003; Smith et al., 1986). The discrepancy may be due, in part, to the fact that

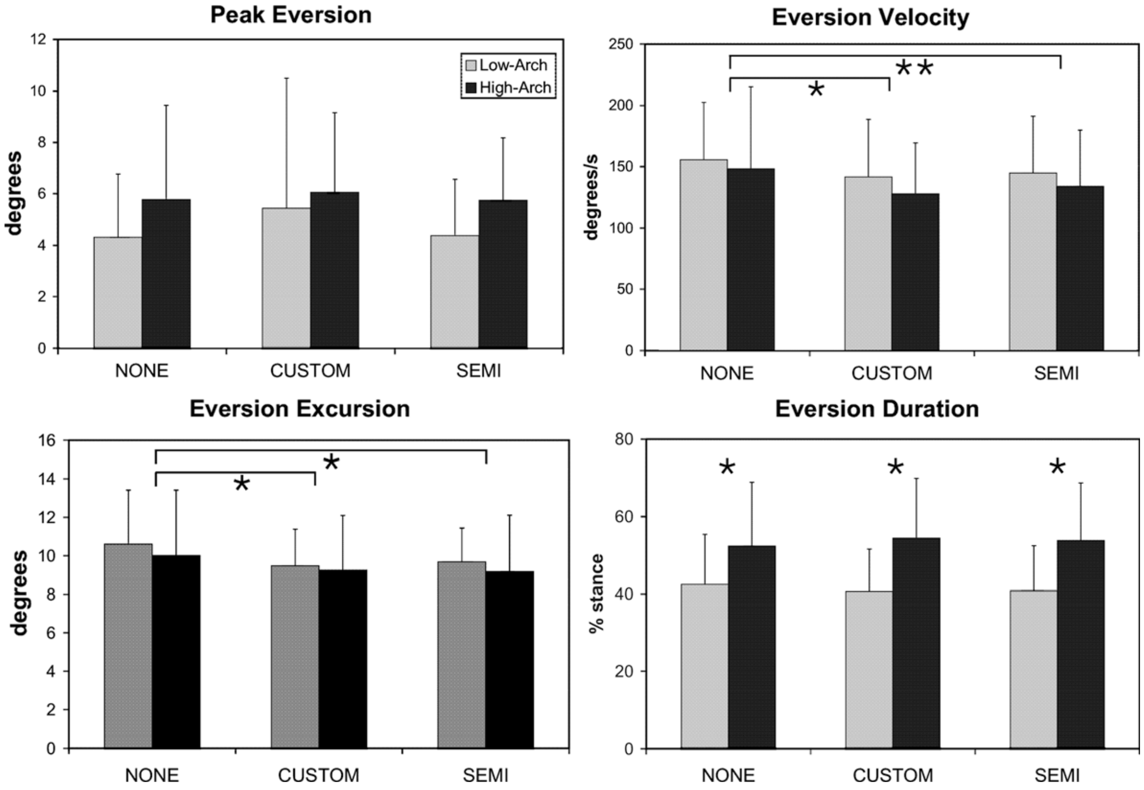

Fig. 4. Comparisons of the effect of the no-orthotic, custom, and semi-custom device conditions on rearfoot kinematics of all high- and low-arched individuals (* indicates a significant relationship, and ** indicates a trend).

the current study examined motion during walking, while much of the previous work has described the effects of orthoses during running. Additionally, the discrepancies may be related to the definition of foot eversion. Mundermann et al. (2003) described whole-foot eversion whereas the present study specifically examined calcaneal eversion. Additionally, the present study, as with others, may be missing crucial information concerning their effect upon the motion of the midfoot. Measurement of midfoot motion using standard motion analysis techniques may be inaccurate due to the relative skin movement over the small bones (Davis, 2004).

Interestingly, only eversion duration was significantly different between high- and low-arched individuals. This finding is contrary to those of Williams et al. (2001a,b) who found that low-arched individuals had increased eversion excursion and velocity as compared to high-arched individuals. Nevertheless, that study focused upon rearfoot motion during running, where higher levels of loading may exaggerate the differences between the groups. It is surprising that eversion duration was increased in the high-arched individuals. The larger range of pronation that was expected in the low-arched individuals, along with the flexibility of their arches, was expected to result in extended eversion duration (Williams et al., 2001a,b; Zifchock et al., 2006). Nevertheless, eversion duration is a timing variable that has not been widely investigated with respect to high- and low-arched individuals. Extended eversion duration (delayed supination of the foot) could be related to a difference in the coupling relationship of the rearfoot and tibia between different arch structures. In fact, Nawoczenski et al. (1998) suggested that arch structure does play a role in the coupling of tibial rotation and rearfoot motion.

In terms of comfort, the two arch types did exhibit some differences. The high-arched individuals tended to be more comfortable in the semi-custom device for the heel and arch regions. In fact, both arch types exhibited slightly more comfort in the semi-custom device for the forefoot and edge regions. It is very surprising that either group would find the semi-custom device to be more comfortable since the custom device is made specifically for their foot. However, the custom device also provided slightly more rearfoot control, and therefore less freedom of movement. Therefore, despite any benefits of the reduced motion, it may have been perceived as less comfortable. The high-arched individuals were particularly less comfortable in the custom device for all four regions of interest. This may be due to the fact that they tend to have stiffer feet (Butler et al., 2007), and were less able to adapt to the added control of that device.

Nevertheless, it is important to point out that the average difference in comfort between the devices was generally 7% or less for both arch types. The only difference in comfort that may approach clinical relevance is the preference of the high-arch individuals for the semi-custom device by

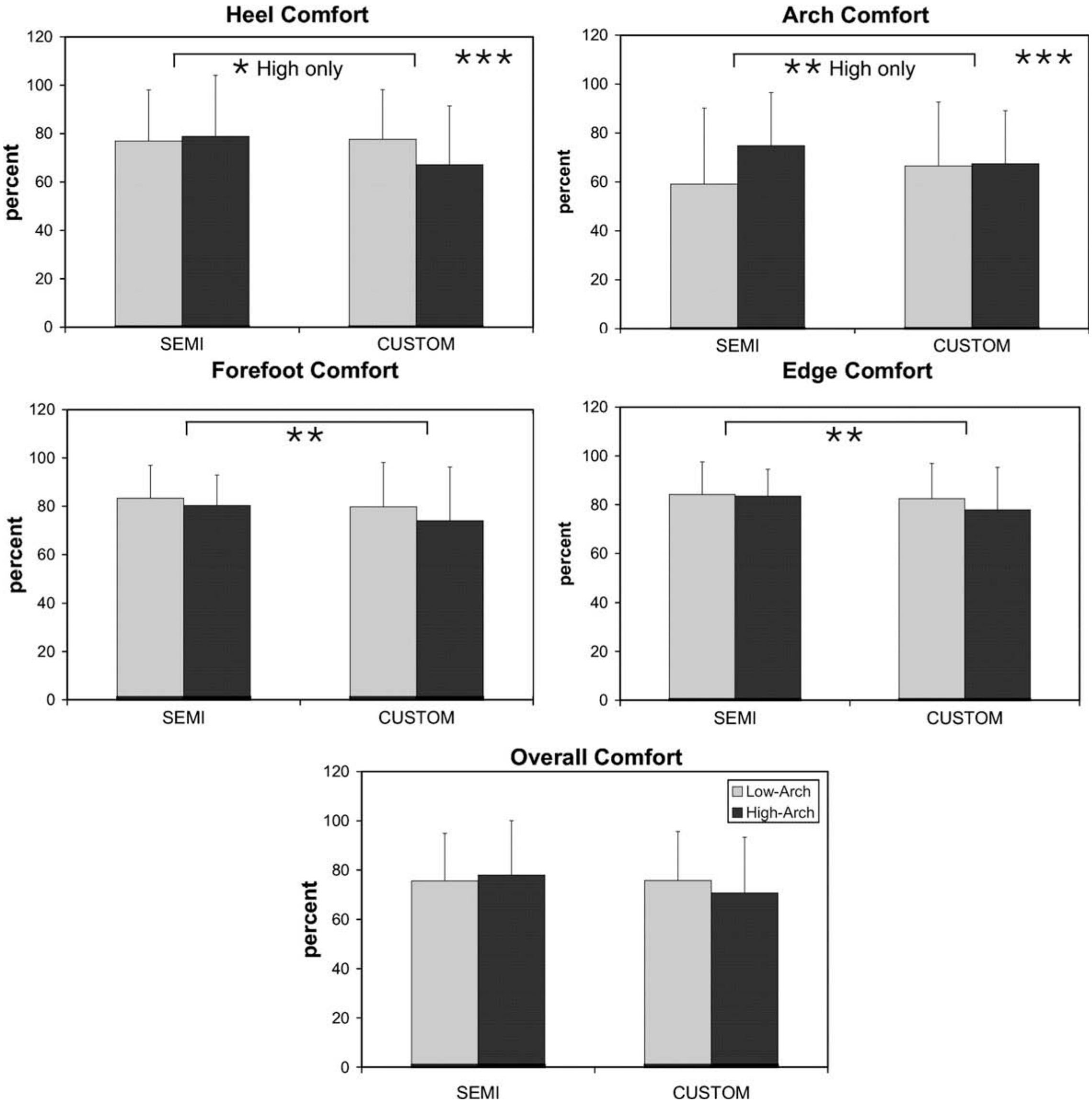

Fig. 5. Comparisons of the effect of the semi-custom and custom device conditions on comfort of all high- and low-arched individuals (* indicates a significant relationship, ** indicates a trend, and *** indicates an interaction where simple main effects are displayed).

almost 12%. This is larger than the value of 10%, which has been previously established as a clinically meaningful difference (Davis et al., 2008).

Comfort is an extremely important factor to consider when assessing the effectiveness of an orthotic, as Finestone et al. (2004) found that people are unlikely to use a device they find uncomfortable. While comfort ratings were reasonably high for both orthotic devices, they were slightly reduced in the arch region. This may be related to the fact that these individuals exhibited abnormal arch structure and suggests that further customization may be necessary in both types of orthotic devices for this population.

Ultimately, this study shows that the semi-custom device is a reasonable alternative to the custom device in terms of it comfort and ability to control rearfoot motion. The cost savings associated with this option make this orthosis a feasible option for many patients who may not have purchased them otherwise. It is important to note that this study focused upon individuals with excessively high- or low-arches. This group was identified since orthotic devices are often prescribed to people with structural abnormalities (Eggold, 1981). However, none of the individuals were experiencing an injury related to excessive rearfoot motion that may have been resolved with the use of orthoses. The next step in this research is to examine the effectiveness of these devices in an injured population. One limitation of this study is in the inability to assess the effect of the devices on midfoot motion. Improvements in technology, such as dynamic MRI and fluoroscopy, may provide more accurate methods of examining the effects of orthoses on this important function of the foot.

In summary, these results suggest that both devices were similarly effective at reducing eversion velocity and excursion. The semi-custom device appeared to be slightly more comfortable, particularly for the high-arched individuals. Overall, however, both devices received very similar comfort ratings. Therefore, the semi-custom device seems to be a feasible alternative to the custom device, when rearfoot control is desired.

Conflict of interest statement

This work was supported by a grant from the Pauline Marshall Research Foundation. The funding source did not play a role in the design, collection or interpretation of the data, nor did they help influence the writing or decision to submit the manuscript. However, the owners of KLM, Inc are the founders of the Pauline Marshall Research Foundation and did provide the foot orthoses for the study, thus constituting a conflict of interest.

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