Controlled Trial to compare the Achilles Tendon load during running in flatfeet participants using a customized arch support orthoses vs an orthotic heel lift

CURRENT STATUS: ACCEPTED

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DOI: 10.21203/rs.2.12369/v2

SUBJECT AREAS
Orthopedics

KEYWORDS
Achilles tendon, tendinopathy, flatfeet, runners, orthoses, arch support, heel lift, insole, load
Abstract

Background: Achilles tendinopathy is one of the most common overuse injuries in running, and forefoot pronation, seen in flatfeet participants, has been proposed to cause additional loading across the Achilles tendon. Foot orthoses are one of the common and effective conservative treatment prescribed for Achilles tendinopathy, it works by correcting the biomechanical malalignment and reducing tendon load. Previous studies have shown reduction of Achilles Tendon load (ATL) during running by using customized arch support orthosis (CASO) or an orthotic heel lift (HL). However, there are still little biomechanical evidence and comparative studies to guide orthotic prescriptions for Achilles tendinopathy management. Therefore, this study seeks to investigate the two currently employed orthotic treatment options for Achilles tendinopathy: CASO and HL for the reduction of ATL and Achilles tendon loading rate (ATLR) in recreational runners with flatfeet. Methods: 12 participants were recruited and run along the runway in the laboratory for three conditions: (1) without orthoses, (2) with CASO (3) with HL. Kinematic and kinetic data were recorded by 3D motion capturing system and force platform. Ankle joint moments and ATL were computed and compared within the three conditions. Results: Participants who ran with CASO (p=0.001, d=0.43) or HL (p=0.001, d=0.48) associated with a significant reduction in ATL when compared to without orthotics. There was no difference between the two types of orthoses, the mean peak ATL of CASO was slightly lower than HL. Regarding the ATLR, both orthoses, CASO (p=0.003, d= 0.93) and HL (p=0.004, d= 0.78), exhibited significant lower value than the control but similarly, no significant difference was noted between them in which the use of CASO yielded a slightly lower loading rate than that of HL. Conclusions: Both CASO and HL were able to cause a significant reduction in peak ATL and ATLR comparing to without orthotics condition. There were subtle but no statistically significant differences in the biomechanical effects between the two types of orthoses. The findings help to quantify the effect of CASO and HL on load reduction of Achilles tendon and suggests that foot orthoses may serve to prevent the incidence of Achilles tendon pathologies.

Introduction

Background
Running is a popular exercise with positive effect to physical and psychological health benefits (Ribeiro et al., 2016). Overuse running injuries have become more prevalent, especially for recreational runners (Taunton JE et al., 2003). Achilles tendinopathy is one of the most common overuse running injury, it accounts for 8-15% of all injuries in recreational runners (Lysholm et al., 1987; Van Ginckel et al., 2008). Achilles tendinopathy is a condition marked by heel pain and posterior leg stiffness along with pathological changes within Achilles tendon substance. These symptoms have been found to hinder physical function and subsequently impair athletic performance (Kujala UM et al., 2005).

Regarding the reasons predisposing to the development of Achilles tendinopathy, different intrinsic and extrinsic risk factors have been hypothesized, yet the exact etiology of is still unclear (Mahieu NN et al., 2005). Overuse, altered tissue vascularity, biomechanical imbalance, bacteria and genetic factors have all been linked to Achilles tendinopathy (Courville et al. 2009, Rolf, C.G. et al., 2017).

Excessive abnormal Achilles tendon loading is considered as the key element to an overuse injury. The Achilles tendon is highly vulnerable to overuse injuries due to the repetitive overload it subjected to during walking or running. Previous studies have shown that the Achilles tendon experiences a force approximately 6-8 times of body weight during running, close to the maximum load tolerable by the tendon (Clain MR et al., 1992, Giddings et al. 2000).

Additionally, altered foot biomechanics, especially excessive foot pronation, have been shown by numerous studies to increase the risk of Achilles tendinopathy through two mechanisms. Firstly, excessive foot pronation generates greater hindfoot eversion motion. When the hindfoot goes from a varus position at heel strike, to a valgus position in midstance, and then back during the running gait cycle, a “whipping” action on the Achilles tendon is created resulting in increased tensile forces over the medial aspect of Achilles tendon. Repetitive whipping action may result in microtears in the tendon, initiating an inflammatory response (Clement et al., 1984, Kvist M, 1994). Ryan et al. have found that subjects with Achilles tendinopathy showed greater hindfoot valgus during barefoot running in midstance than controls (Ryan M et al. 2009). Secondly, excessive pronation contributes to asynchronous movement between ankle and foot segment during stance phase, this wrings out vessels in the tendon and peritendon causing vascular impairment as well as degenerative changes
on Achilles tendon. These implicates that runners with a planus foot would have a higher chance of developing Achilles tendinopathy (Clement et al., 1984).

Foot orthoses have long been considered as an effective intervention to conservative treatment and prevention of Achilles tendinopathy in clinical setting, with a success rates as high as 75% in runners reported from case studies and retrospective surveys (Gross M et al., 1991; Donoghue et al., 2008; Mayer et al., 2007). Mayer et al. 2007 investigated the effect of semi-rigid, individual fitted arch support orthoses in runners with Achilles tendinopathy, there was significant symptomatic relief after orthotic intervention as reported through the pain scores. Similar to Mayer et al’s study, Donoghue et al. showed an improvement in pain symptoms with the use of custom foot arch support orthoses were reported from chronic Achilles tendinopathy runners. Rabusin et al. also reported that an orthotic heel lift had the same effectiveness as calf muscle eccentric exercise for Achilles tendinopathy management in a randomized controlled trial (Rabusin et al., 2018).

Although previous studies indicated that foot orthoses are an effective treatment towards Achilles tendon pathologies, there is currently insufficient evidence to explain the mechanism by which foot orthoses exert their effects when used to treat Achilles tendinopathy. The hypothesized effect of arch support orthotics in decreasing the Achilles tendon stress is the correction of biomechanical malalignment. It serves to reduce hindfoot valgus and align the calcaneus in the vertical position, thus relieving the shear stress over the Achilles tendon, particularly in the pronated foot (Schepsis et al., 2002, Mayer et al., 2007, Donoghue et al., 2008, Ryan et al., 2009). Besides, orthoses elevating heel height may cause plantar flexion of the ankle joint which shortens the muscle-tendon unit, thus relieving the force over Achilles tendon during gait. More recently, different biomechanical hypotheses have been proposed, including the increased of hindfoot movement variability by orthoses resulting in decreased ATL (Donoghue et al., 2008) and alteration of the neuromotor activity of Triceps surae towards subjects with Achilles tendinopathy (Wyndow et al., 2010).

Load management plays a crucial role in preventing overuse Achilles tendinopathy.. In general, there are two commonly used foot orthoses for studying changes in ATL; these are the foot orthotic with medial arch support (Figure 1) and orthotic heel lift (Figure 4) (Sinclair et al., 2014; Wulf et al. 2016;
Dixon et al., 2002; Farris et al., 2012).

Sinclair et al first investigated the effect of a commercially available arch support insole on ATL of 12 runners, the result showed a significant reduction in ATL for runners using arch support insole. While Farris et al. evaluated the different heel lift height on ATL in female runners which showed that an 18mm heel lift yield a better outcome in reducing ATL and strain during running than that of using 12mm one (Farris et al., 2012). A similar result was found by Wulf et al (Wulf et al. 2016), the tensile load in Achilles tendon was examined through ultrasound transmission speed, the ATL was lower with the addition of a 12mm heel lift in 12 male runners. In view of this, it showed that both foot orthotic with medial arch support and orthotic heel lift have the ability to alter the ATL in running.

However, there are still limitations of previous studies that warrant further consideration. First, there is no consensus or guidelines on the types of foot orthoses to be prescribed for Achilles tendinopathy management. Second, the foot types of subjects have not been standardized, as the degree of pronation is one of the risk factors affecting the ATL, so orthotic customization for variable foot types is required to accommodate the different of foot pronation among subjects. Third, there are presently no comparative studies evaluating foot orthotics as the management options for Achilles tendinopathy. Moreover, there are still little biomechanical evidences regarding the alteration in ATL through orthotic intervention and comparative studies to guide orthotic prescriptions for Achilles tendinopathy management.

Objectives

The aim of this study was to compare two clinically applied treatment options: Customized arch support orthoses (CASO) and orthotic heel lift (HL) on the effect of ATL in recreational runners with pronated feet. It implicated to provide a better understanding of the types of foot orthoses for flatfeet runners and additional biomechanical evidence for the clinical field to guide orthotic prescription as well as selection for Achilles tendinopathy management.

Methods

* Trial design and hypothesis*
This was a controlled laboratorial, within subject, repeated measures study. It was hypothesized that both orthoses would lower the ATL when compared with the orthotic intervention. It was also hypothesized that CASO would have a larger ATL reduction than that of HL for flatfeet runners.

**Participants**

12 recreational runners of age greater than 18 years who trained regularly for running at least once per week and with running experience for 1 year or more (Cheung et al., 2007), with excessive foot pronation and with hind-foot strike landing pattern were recruited.

Foot Posture Index (FPI) was used as evaluating pronated foot posture. FPI is a non-invasive method of assessing the degree of standing foot posture with the scores reflecting highly supinated (−5 to −12), supinated (−1 to −4), neutral (0 to +5), pronated (+6 to +9) or highly pronated (+10 to +12). This is a validated instrument, which is adequately reliable as a screening tool standing foot posture (Evans et al., 2018; Keenan et al., 2018). Subjects with FPI scores of 6-12 were recruited in the current study.

All participants should be free of Achilles tendinopathy and triceps surae injury for 6 months with no previous surgery as well as not previously attempted any foot orthoses intervention before this study. All subjects were clinically assessed by the same Prosthetist and Orthotist for the range of motion, strength and flexibility of the lower extremities. Subjects exhibiting leg-length discrepancy, rigid forefoot varus deformity, gastrocnemius equinus, structural hallux limitus, or rigidus were excluded. Any musculoskeletal or neurological disorders, which would affect normal running gait, were also excluded.

**Sample size**

The sample size was based on previous similar studies (Donoghue et al., 2008, Kelly et al., 2011; Sinclair et al., 2014). Also, according to a priori power analysis, 12 participants were considered to be sufficient for minimal statistical power ≥ 0.8 and α=0.05.
Foot orthoses

Customized arch support orthoses (CASO)

The CASO (fig 1-3) was made from the traditional hand-made method, all subjects were asked to lie prone with both feet as a non-weight bearing position and the foot plantar surface was casted by using the Plaster of Paris bandages bilaterally in a subtalar neutral position manipulated by the same Prosthetist and Orthotist. The negative casts were placed in a calcaneal vertical position and a positive mold was created from the negative cast by filling Plaster. Custom-molded orthoses were then fabricated from the positive mold with 3-mm polypropylene (Polystone ® P copolymer, from Röchling) using a vacuum press method with an extrinsic ethyl vinyl acetate (EVA) standard rearfoot posting, cut at 50% of the length of the heel cup. A 3mm multiform cover was added at last according to the shape of shoes.

Orthotic heel lift (HL)

The HL was made by high-density ethyl vinyl acetate (EVA), it was wedge-shaped which tapered over its 8.2 cm length from a height of 18 mm posteriorly to finish flush anteriorly. It was added underneath to the insole of the rearfoot of each shoe by double-sided adhesive tape in order to prevent any sliding movement during running. (fig 4)

Data collection

Kinematic data

Kinematic data was captured by an 8-camera motion capturing system (Vicon 370, Oxford, UK). Kinematic analysis and a calculation of the position of the center of mass were performed using the lower body Plug-in-Gait model. 16 Retroreflective markers were positioned onto the posterior superior iliac spine, anterior superior iliac spine, lateral thigh, lateral femoral epicondyle, lateral shank, lateral malleolus, calcaneus and second metatarsal head (on shoes) bilaterally following anatomical landmark for defining anatomical frames of the right foot and shank. (fig 5) The foot segment was tracked using the metatarsal and calcaneus markers. Before data collection, static calibration trials
Kinetic data

Piezoelectric force platform (AMTI force plates) was used for capturing kinetic data once subjects striking with their right (dominant) foot. The stance phase of the running cycle was identified at the time over which ≥20 N of vertical force was applied to the force platform (Sinclair et al., 2011).

Achilles tendon loading (ATL)

Ankle joint kinetics were computed using the Newton–Euler inverse-dynamics. Net external ankle joint moments were then calculated which has been shown to give a relevant approximation for internal joint loading (Zhao et al. 2007).

An algorithmic model was used as a predictive technique to determine ATL. This technique has been shown to be sufficiently sensitive to resolve differences in ATL during running with different footwear (Kulmala et al., 2013; Sinclair et al., 2014).

Achilles tendon load (ATL) is determined by dividing the plantarflexion moment (MPF) by the estimated Achilles tendon moment arm (MA):

\[
\text{ATL} = \frac{\text{MPF}}{\text{MA}}
\]

The moment arm was quantified as a function of the ankle sagittal plane angle (SAK) using the procedure described by Self and Paine (Self and Paine, 2001), the equation is calculated by Rugg et al. using magnetic resonance imaging (MRI) (Rugg et al., 1990).

\[
\text{MA} = -0.5910 + 0.08297 \times \text{SAK} - 0.0002606 \times (\text{SAK})^2
\]

ATL was normalized to body weight (B.W.) and Achilles tendon loading rate (ATLR) (B.W. s⁻¹) was also calculated as a function of the change in ATL from initial contact to peak ATL divided by the time to peak ATL.

Study settings
There were totally two face-to-face appointments for each subject. In the first appointment, initial screening and assessment based on the inclusion and exclusion criteria by Prosthetists and Orthotists were done. For the assessment for flatfeet by FPI, subjects were required to stand in a relaxed position; the rearfoot was first assessed through palpation of the head of the talus, observation of the curves above and below the lateral malleoli and the degree of the inversion/eversion of the calcaneus. Scores would be summed according to the six parameters. Subjects with FPI scores of 6-12 were recruited. Then for the forefoot, the bulge in the region of the talonavicular joint, the extent of abduction/adduction of the forefoot on the rearfoot and the congruence of the medial longitudinal arch. Subjects fulfilling research requirement were casted for the CASO by the method mentioned above and demographic data were collected. Data collection was done in the second appointment. The second appointment was arranged once the CASO and HL were ready (which was ~2-3 weeks). (fig 6)

The experimental procedure was conducted in a 10m long gait lab. Before testing commenced, there was 15 minutes acclimatization period for each subject to walk or run on runway. During this period, the subject walked or ran with orthoses at their comfortable speed and gait pattern to adjust to the surroundings and to make sure the orthoses were comfortable and the running gait was consistent. After this period, subjects were asked if they needed more time. If they asked for more time, additional familiarization was given until they feel accustomed to the condition. There were 3 minutes rest before testing to avoid muscle fatigue (Garcia-Perez et al., 2014).

Interventions

For the testing condition, subjects were asked to run on the runway at a self-selected speed in threes conditions: (1) run without orthoses, (2) run with HL and (3) run with CASO. The test sequence was randomized. Recording began once subjects ran with their comfortable running pace. The eight-camera system and the force platform were used to record the kinematic and kinetic data synchronously at 250 and 1000 Hz respectively. Subjects were required to complete five acceptable trials (completely contacted the force plate with the right leg with acceptable speed and without
targeting) running at a self-selected speed at each condition. To minimize the effect of speed on biomechanical parameters, all actual trials were required to be within ±5% of the determined average self-selected speed (Queen et al., 2006), while the running speed was monitored by mobile phone positioned 1.5 m from the force plates using a video radar application (SpeedClock, Sten Kaiser, version 3.1) (Sobhani et al., 2015).

Data processing

VICON Nexus v2.6, Oxford Metrics software (Plug-in-Gait model) was used to compute joint kinematics and kinetics. Data were exported to MatLab software (R2019a) for further processing. Kinematics and kinetics data were time normalized (0-100%) of the stance phase and averaged across five trials to get individual mean curves. Joint angles and internal joint moments (N.m.kg⁻¹) during the stance phase of running were determined across five successful force plate contacts of the right leg. Marker trajectories and kinetic data were low-pass filtered using a fourth-order Butterworth filter with cutoff frequencies of 12 and 50Hz respectively. Kinetic variables were all normalized for body mass.

Statistical Analysis

Normality distribution analysis was carried out by the Shapiro Wilks test, considering a normal distribution when P > 0.05. Demographic characteristics such as age, height and weight were included. Mean and standard deviation (SD) were applied to the data set to describe quantitative data. For the normality of the variables, One-way repeated measures ANOVA was conducted in order to examine the differences in primary outcomes: peak Achilles tendon load (B.W.) and Achilles tendon loading rate (B.W. s⁻¹) , as well as secondary outcomes include peak plantarflexion moment, time to peak Achilles tendon force and peak dorsiflexion angle among the three conditions. Post-hoc comparisons with Bonferroni correction was used as a follow-up analysis.

All statistical tests were conducted by means of the IBM SPSS Statistics software (SPSS, v22, Inc, Chicago, Illinois). Statistically significant differences were considered at P < 0.05 with a 95% confidence interval (CI). Effect sizes in terms of Cohen’s d were calculated in order to quantify the
differences between the three conditions (https://www.socscistatistics.com/effectsize/). The effect is regarded as small, medium and large when Cohen’s d is 0.2, 0.5 and 0.8 respectively (Laknes., 2013).

Results
Totally, 12 subjects (10 males and 2 females) were recruited (Table 01). The ankle kinetics and kinematics with respect to the three testing conditions were presented in Figure 5.

Peak plantarflexion moment
There was significant a difference among the three conditions, F (2, 22) = 21.29, P<0.001. Post-hoc comparison showed that there was significant reduction in peak plantarflexion moment when running with CASO (p=0.001, d= 0.44) and HL (p=0.001, d= 0.39) compared with no orthotic intervention. Although there is no significant difference between the two orthoses, the peak plantarflexion moment from using CASO was slightly lower than using HL in running (p>0.05, d=0.04). (fig 8)

Peak Achilles tendon load
Significant difference was found among the three conditions, F (2, 22) = 25.02, P <0.001. The Post-hoc comparison revealed that the Peak ATL was significantly reduced when using CASO (p=0.001, d=0.43) and HL (p=0.001, d= 0.48) during running than the control having no orthotic intervention in the post-hoc test. There was no significant differences (p>0.05, d=0.05) between CASO and HL while the Peak Achilles tendon load of using HL was slightly lower than that of CA. (fig 9)

Time to peak Achilles tendon force
Significant difference was found within the three conditions, F (2, 22) =4.90, p=0.001, in which the difference between CASO (p= 0.56, d= 0.13) and the control was marginally significant, but no significant difference (P > 0.05) was shown between the two orthotic interventions (p= 0.83, d= 0.28) and between control and HL(p=0.24, d= 0.87) in the post-hoc comparison. When compared with the control, both CASO and HL intervention demonstrated a slightly longer time required from initial contact to peak Achilles tendon force. (fig 10)
Achilles tendon loading rate

Repeated measures ANOVA indicated a significant difference within the three conditions, F (2, 22) = 15.38, p<0.001. Running with CASO (p=0.003, d= 0.93) and HL (p=0.004, d= 0.78) resulted in significantly lower ATLR when compared with the control group (table 02). While the difference between CASO and HL was insignificant (p>0.05, d=0.09), the use of CASO yielded a slightly lower loading rate than that of HL. (fig 11)

Peak dorsiflexion angle

There was a significant difference found between the three conditions, F (2, 22) = 69.76, p<0.001. Post-hoc comparison also demonstrated significant difference within the three conditions in which CASO and HL resulted in an increase (p= 0.042, d=0.14) and a decrease (p<0.001, d=0.72) in peak dorsiflexion angle respectively while the peak dorsiflexion angle (p<0.001, d=0.87) of using CASO was higher than that of HL (Table 02). (fig 12)

Discussion

The current study aimed to investigate the effectiveness of the Customized arch support orthoses (CASO) and orthotic heel lift (HL) on the reduction of ATL for flatfeet runners during running activities. Previous studies mainly focused on the treatment outcomes of orthotic devices towards Achilles tendon pathology, while only a few studies examined the changes in ATL and the results were quite diverse. To the best of our knowledge, this represents the first study to quantify the two currently employed orthotic treatment options for Achilles tendinopathy which are CASO and HL in terms of the effect on ATL.

Our results showed that ankle kinetics in the sagittal plane was reduced by using orthotic interventions. The primary outcomes from the current study, peak ATL and peak ATLR, were significantly reduced with the two presence testing orthoses, by 9.1% and 10.3% for CASO and HL respectively when compared to running with shoe only. While the difference between CASO and HL on ATL as well as the loading rate were statistically insignificant, HL presented a slightly higher
reduction on peak loading when compared to that of CASO. Whereas CASO just showed a relatively lower peak ATLR than that of HL, which was attributed to a longer time from the initial contact to peak Achilles tendon force being recorded.

**CASO**

In addition to the main reduction in ATL and ATLR, the mean peak plantarflexion moment was reduced by 9.3% and the peak dorsiflexion angle was increased by 6.0%. These were consistent with the result of previous studies (Sinclair et al., 2014, Chen et al., 2010) where a decrease in peak plantarflexion moment, as well as an increase in peak dorsiflexion angle were found during stance phase when using foot orthoses comparing to the control group. This indicated that CASO had a significant effect on the angle and moment of the ankle joint in the sagittal plane during the stance phase of running. Comparing to a normal foot, Hunt et al., 2004 found out that people with midfoot pronation exhibit a greater peak plantarflexion ankle moment in the stance phase of the gait cycle because of their abnormal biomechanical changes. In view of this, Mundermann et al., 2003 and Stacoff et al., 2000 have already demonstrated in their studies that by using appropriate orthotics design, these features could be corrected. These findings were similar to our current results which indicated CASO had the efficacy to improve the flat foot running gait pattern.

The reduction of ATL parameters from CASO was not only attributed to the decrease in peak plantarflexion moment but also the increase in dorsiflexion angle according to our algorithm model. It is hypothesized that it was caused by the additional midfoot support and midsole cushioning from CASO. Runners would select to increase dorsiflexion angle at heelstrike and throughout the stance phase owing to the increased in midsole support (Lieberman et al., 2010), this, in turn, lengthened the moment arm of the Achilles tendon, thus reducing the loading of Achilles tendon (Sinclair et al., 2014). Moreover, people with the pronation problem would suffer from reduced ankle flexibility because of the tightness in gastrocnemius or soleus, which increase the risk of Achilles tendinopathy. This was due to the prolonged contraction of the gastro-soleus complex in order to control pronation (Cook et al., 2002). Accordingly, through correcting the midfoot pronation by the use of CASO might
help relieve the tightness of the gastroc-soleus complex to improve the flexibility in the ankle, giving rise to the increase in dorsiflexion angle in the present finding. Limited ankle joint dorsiflexion also induced gait changes of shorter midstance period, this indicated that increased in joint dorsiflexion angle by CASO in relation to the increased in the timing of peak loading. However, since only the immediate effect of the orthotic intervention was reflected in our investigation, the long-term effect of CASO should be explored to confirm such relation.

**HL**

The results of recent findings of the efficacy of HL were relatively similar to those of CASO. Besides reducing the ATL and ATLR, the mean peak plantarflexion moment was reduced by 8.7%, the peak dorsiflexion angle was decreased by 28.2%. When looking at the previous studies about the effect of HL on ATL, the results were quite diverse and varied among individuals. Dixon and Kerwin found an increase in ankle joint moment and Achilles tendon forces when patients wore 7.5 mm and 15 mm heel lifts in comparison to the barefoot condition but the time to peak force and rate of loading were found lower in the follow-up study (Dixon et al., 2002). It was contrary to our results in which a decrease in mean ankle joint moment and Achilles tendon force was resulted. When comparing individually, only 1 out of 12 subjects demonstrated a slightly higher peak Achilles tendon force with respect to the control condition. One of the reasons leading to these variations might due to the different thickness and the material used for HL. Concluding the previous researches giving positive results in loading reduction, the magnitude of HL required is greater than the HL used for reducing pain and injury (Low et al., 2015). Thickness of 18mm HL was used in the current study, according to the study done by Farris and coworkers, 18mm heel lift significantly reduced both the force and strain in the Achilles tendon during running which reduce the strain in the tendon even better than that of 12mm heel lift (Farris, D.J. et al., 2012). In addition, Reinschmidt et al showed that with the increase in heel height, there were 2 out of 5 subjects resulted in a decrease in plantarflexion moment during running (Reinschmidt et al., 1995) which was similar to our current findings. This indicated that different heel height had an influence on ankle kinetics. Besides, the difference in density and
material of HL between the present and previous studies might affect the shock absorption property, thus affecting the plantarflexion moment and loading rate. Therefore, the large variations of materials and thickness for HL in previous studies might account for the inconsistent of tendon loading as well as outcomes of the current study.

Although the positive outcomes of using HL in Achilles tendinopathy management are controversial, there was one theory suggesting that heel inserts change the orientation of the foot by raising the heel relative to the forefoot, which helps lower the maximum dorsiflexion angle during the mid-stance phase of gait. It was hypothesized to lessen the eccentric force, which used to control the downward movement of the center of mass to the tendon (Clement et al., 1984). Our result showing a decrease in mean maximum dorsiflexion angle when using HL was in line with that theory, suggesting for the mechanism of reducing Achilles tendon force.

**CASO and HL**

As mentioned above, both CASO and HL demonstrated positive results in the primary outcome, ATL and ATLR, with respect to the control. When comparing the two orthotic interventions, it was statistically insignificant for both ATL and rate, 1.3% reduction for HL and 2.2% reduction for CASO respectively. The small differences might be explained by only sagittal plane kinetic and kinematic was considered due to the current method used in ATL calculation, this regardless the fact that the use of CASO and HL would also influence frontal plane parameters like the rearfoot angle and the inversion/eversion moment. Besides, the subtle difference might be owing to the sample size. A post hoc sample size analysis for the ATL parameter indicated that a sample size of 22 subjects was required to power the study which might explain the insignificant result.

The small difference indicated that no relative superiority between these twoorthoses could be proved in the present study. In other words, prescriptions of these two orthoses for Achilles tendinopathy management can be considered for individual accommodation so that subjective feedback such as comfort, footwear and sports adaptation can be taken into account for better clinical outcomes. In future studies, in order to further address the differences between CASO and HL,
long-term effect and the corresponding muscle activities of triceps surae in related to CASO and HL intervention during running are suggested to investigate.

Limitations

There are several limitations of this study that warranted to address in the future study. First of all, despite our results showed quite a positive outcome of orthotic intervention towards the reduction of ATL, it is only limited to the immediate effects of these two orthoses. It is not clear whether these effects will persist or change over a longer accommodation period. Hence, further study is needed to investigate the long-term effects and the consistency of the efficacy of current orthoses in ATL. Besides, assumptions are made for the calculation of the Achilles tendon force in current analysis such that all other structures inducing the internal moment are neglected. Of which, the muscle activity of triceps surae during running have not taken into account. However, triceps surae generates most of the net force during dorsiflexion which applies across the Achilles tendon to control ankle movement. Therefore, the force from triceps surae also has an effect on the ATL (Reinschmidt et al., 1995). Recent studies also suggested that altered neuromotor control from triceps surae would be one of the underlying mechanisms leading to Achilles tendinopathy (Wyndow et al., 2010). In view of these, further investigation including the EMG signals from triceps surae together with ankle kinetic and kinematic measured would provide more comprehensive information about the effectiveness and difference of CASO and HL on the reduction of tendon loading.

Regarding the current findings, statistical insignificant as well as a large confidence interval were found between the two orthotic intervention in ATL and ATLR, the underlying reason behind might due to insufficient sample size used in current study. A larger sample size is required in future study and as mentioned above at least 22 subjects are needed to give a larger statistical power.

For the measurement of kinematic data, owing to some of the attached to the vamp of the shoe instead of directly onto the skin, it is difficult to ensure the trajectories acquired from the externally-mounted reflective markers coincide with those of the internal foot structure accurately and consistently, thus certain of errors might be resulted.
Conclusions
The findings from the current study showed that both CASO and HL were able to significantly reduce the ATL and ATFR for runners with flatfeet in running. While there are subtle differences in the Achilles tendon kinetic parameters, no relative superiority of between the two types of orthoses could be concluded. Owning to the proposed correlation between ATL and Achilles tendinopathy, the use of CASO and HL may attenuate the risk of developing running related pathologies in AT.

Clinical relevance
Flatfeet is recognized as a contributing factor in various lower limb musculoskeletal pathologies in running sports including Achilles tendinopathy. Foot orthoses such as CASO and HL have been commonly used for the management of Achilles tendinopathy which yield a positive clinical outcome. Although the underlying reasons for the efficacy of foot orthoses on Achilles tendinopathy are still unknown, load reduction on the tendon is one of the proposed mechanisms. By quantifying the effectiveness of CASO and HL in terms of ATL in the present study, the positive results were found when compared to the control. This provides better insight and evidence of the efficacy for commonly used orthotic intervention in Achilles tendinopathy management. In other words, the use of CASO and HL in running activities may be considered as a preventive measure for flatfoot runners who are at a higher risk predisposed to Achilles tendinopathy. At the same time, the findings may also act as a practice guideline for orthotic prescriptions in clinical settings.

Abbreviations
ATL – Achilles tendon load
ATLR – Achilles tendon loading rate
CASO – Customized arch support orthoses
FPI – Foot posture index
HL – Orthotic heel lift

Declarations
This study adheres to CONSORT guidelines
Ethics approval and consent to participate

Ethical approval was obtained from for The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee, CREC Ref.No.: 2018.589 (The Joint CUHK-NTEC CREC). Written consent was obtained from all subjects.

Consent for publication

Not Applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

Funding

No conflict of interest will arise from any of the authors involved in this paper.

Authors' contributions

All the authors were involved in the design and conception of the work within this paper. KKWL drafted the manuscript and performed the study procedures with critical revision and ongoing support and advice from SKKL and PSHY. All authors read and approved the final manuscript.

Acknowledgements

The author would like to thank Dr. Samuel KK Ling and Mr. Chan Kwok Chu for their guidance and comment as well as all the subjects who took part in this study.

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Tables
Table 1. Demographics of the subjects (n=12).

Table 2. Achilles tendon kinetics and kinematics as a function of orthotic interventions.

Due to technical limitations, tables 1 and 2 are only available as a download in the supplemental files section.

Figures
Figure 1
The CASO fabricated from the negative plaster cast.

Figure 2
The CASO (left) and the CASO with 3mm multiform added (right).
Figure 3
CASO intervention to foot pronation (left in barefoot condition, right in CASO).

Figure 4
The HL with maximum height of 18mm.
Figure 5

Retroreflective markers including anterior superior iliac spine, lateral thigh, lateral femoral epicondyle, lateral shank, lateral malleolus
Figure 6

The flow of the experimental procedure
Figure 7

Ankle kinetics and kinematics in the three conditions during stance phase of running (a= sagittal ankle angle, b= sagittal plantarflexion moment, c= Achilles tendon load).
* indicates significant differences

Figure 8

Peak Plantar Flexion moment in the three conditions.
Figure 9

Peak Achilles tendon load in the three conditions.
Figure 10

Time to peak Achilles tendon force in the three conditions.
Figure 11

Achilles tendon loading rate in the three conditions.

* indicates significant differences
Figure 12

Peak dorsiflexion angle in the three conditions.

Supplementary Files
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Table 2.pdf
Table 1.pdf