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A randomized controlled trial

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Exercise therapy and custom-made insoles are effective in patients with excessive pronation and chronic foot pain—A randomized controlled trial

Jane Andreasen a, Carsten M. Mølgaard a,*, Marianne Christensen a, Søren Kaalund b, Søren Lundbye-Christensen c, Ole Simonsen d, Michael Voigt e

a Department of Occupational and Physiotherapy Aalborg Hospital, Aarhus University Hospital, Aalborg, Denmark
b Kaalunds Orthopaedic Clinic, Aalborg, Denmark
c Department of Cardiology, Center for Cardiovascular Research, Aalborg Hospital, Aarhus University Hospital, Aalborg, Denmark
d Orthopaedic Research Unit, Aalborg Hospital, Aarhus University Hospital, Aalborg, Denmark
e Center for Sensory-Motor Interaction, Department of Health Science and Technology, Aalborg University, Aalborg East, Denmark

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**A B S T R A C T**

**Background:** Excessive foot pronation is a causal mechanisms described in relation to injuries of the lower extremities. Evidence to support an effective treatment is insufficient.

**Objective:** To investigate the effect of exercise and custom-made insoles to patients with excessive pronation and chronic pain conditions in the foot at short and long term follow-up.

**Methods:** Single blinded Randomized Controlled Trial with 80 subjects randomized: (1) Standard Intervention, (2) Insole, (3) Exercise, and (4) Insole + Exercise. Exercise – 12 week supervised program. Insoles – individually molded and posted. Pain was measured during walking, resting and running. Static and dynamic foot postures were measured as calcaneal angle, navicular drift, drop and height.

**Results:** The average duration of foot pain was 7.3 years. There was a significant pain reduction during walking within all groups at 4 and 12 months follow-up. No differences were seen between groups in any of the pain parameters. Weak correlations between changes in pain and foot postures were observed at baseline and one-year follow-up.

**Conclusion:** A significant pain reduction was seen in all groups, none of the treatment modalities seem to be superior with the number of patients included. Compliance in the standard intervention group was a concern at 12 months.

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1. **Background**

Overuse injuries, also called repetitive strain injuries, are conditions characterized by tissue damage resulting from repetitive demands over the course of time leading to persistent pain and in more advanced cases to weakness and loss of control in the affected muscle groups. Excessive foot pronation is one of the causal mechanisms often described in relation to foot [1,2], lower leg [3–6], knee [7,8] and hip [8] injuries. Leg-length discrepancy is also correlated with abnormal pronation [9].

Excessive pronation may develop from lack of muscle strength and stability or from overuse. Triceps surae, Peronei, Tibialis posterior and anterior muscles are known extrinsic dynamic supporters of the medial longitudinal arch [10–12]. Fatigue of the intrinsic foot muscles has shown increased pronation in the foot measured by navicular drop [10]. Injection of lidocaine in the region of the tibial nerve, posterior and inferior to the medial malleolus, as a nerve block, showed similar results [13]. These studies support the concept of the foot muscles playing an important role in support of the medial longitudinal arch. Furthermore pronated feet are associated with lower EMG amplitude for evertor muscles such as Peroneus longus [14,15] compared to normal or supinated foot posture. Whereas the effect of insoles give some evidence that Peroneus longus and Tibialis anterior EMG amplitude, and the duration of Tibialis anterior activity is greater when wearing foot insoles during walking and running [16].

The effect of exercise on pain or function in the excessive pronated foot is very scarce in the literature. One recent study showed a short term reduced pain and improved function after a three month period of orthoses, stretching and resistive exercise for posterior tibial tendon dysfunction [17].

The use of insoles in treating pain conditions in the excessive pronated foot is widely accepted. Conflicting results are however evident when studying the biomechanical and neuromuscular...
effects of foot insoles [18]. A systematic review from 2007 found evidence to support the use of foot insoles in the prevention of lower limb overuse conditions. However the studies included were characterized by small sample sizes, no control groups, no clinical relevant measures and short follow-up [19].

There is a lack of evidence regarding the treatment of patients with lower extremity injuries related to excessive pronation in order to support professional evidence based treatment decisions [20]. So far the effect of excise therapy has not been sufficiently investigated as a treatment modality for patients with overuse injuries, even though multiple studies, as mentioned above, indicate a reduction in strength and EMG amplitude in the muscles responsible for maintaining a neutral foot posture.

Consequently the aim of this study was to investigate the effect of exercise and insoles to patients with excessive pronation and chronic pain conditions in the foot at one year follow-up.

2. Methods

2.1. Study design

The study was designed as a single-blinded randomised controlled trial with follow-up at four and 12 months. The research physiotherapists, responsible for the outcome measures at follow-up were masked to the randomisation. It was not possible to mask either participants or physiotherapists participating in the interventions.

2.2. Participants

The participants were recruited from the orthopaedic outpatient clinic at Aalborg Hospital or from orthopaedic specialists in the local community; the intake and follow-ups were completed in a four-year period. Participants meeting the inclusion criteria were contacted by the project staff. Prior to inclusion, all participants were informed of the project orally and in writing as stipulated by the Local Ethics Committee.

2.3. Eligibility criteria

Inclusion criteria were excessive foot pronation measured as calcaneal valgus angle greater than 6° in a relaxed bilateral standing [21] and overload related pain conditions in the foot or below the knee for at least three months. Aged between 18 and 70. When included, participants gave their informed consent in writing. Exclusion criteria were rheumatic diseases, infections or foot fractures or fractures below the knee, previous foot surgery, cavus foot and if the participant did not have the physical or mental capability to participate in the study.

2.4. Randomisation

Participants were randomised into four groups. The randomisation was carried out after informed consent was obtained and baseline examinations were completed. A secretary, who was not otherwise involved in the project, accomplished the randomisation. Opaque sealed envelopes containing treatment allocation were used. The project physiotherapists involved with the participants were informed of the randomisation by telephone. The assessors at baseline, short and long term follow-up were two experienced physiotherapists throughout.

2.5. Interventions

The physiotherapists involved in examination and interventions had previous training sessions to secure protocol compliance and minimize variation. The four groups were a standard intervention group (SI), a custom-made insole group (IG), an exercise therapy group (EG) and a combined insole and exercise therapy group (IEG). The SI were handed a folder on overuse injuries and exercise, which is standard procedure at the hospital. However patients included in the SI were informed not to buy or use insoles at anytime without consulting the project leader.

Each participant in the IG and the IEG received custom made insoles made by an orthotist. The primary aim of the insole was to decrease excessive pronation by supporting the medial longitudinal arch and the calcaneus. A pedograph was used to assess the foot size and degree of pronation and eventual problems related to the forefoot arch. The insoles were made of ethylene-vinyl acetate (E.V.A. shore A 35) and moulded and posted individually to the participant and adjusted if necessary. Insoles were adjusted or remade if patients experienced any discomfort wearing them.

The intervention for the EG and the IEG consisted of individual exercise guided by a physiotherapist, 30 min twice a week for a period of 12 weeks (24 sessions). The sessions included exercises targeting muscle strength and stability, balance, range of motion related to the chronic pain condition and the excessive pronation of the foot. The exercise program was standardized: however individual adjustments due to pain- and functional level were possible. The participants received a home exercise program with continuous progression as regards to frequency, intensity and load.

2.6. Outcome measures

The following outcome measures were assessed at baseline, 4 and 12-month follow-up.

The participants reported changes in their pain level while walking (primary outcome), and while running and resting using a VAS scale. The VAS scale assesses pain on a single-dimensional scale with end-points marked as “no pain” and “worst pain possible”. The scale is a reliable and valid measure of self-reported pain intensity [22,23]. Compliance to physiotherapy sessions was measured by the physiotherapist responsible and the record was returned to the project leader for each patient.

In order to assess the biomechanics of the foot both static and dynamic measures were used (Fig. 1). A test retest reliability study was conducted for both static and dynamic measurements of the foot and the two tests did not reveal overall test retest difference [24].

2.7. Static evaluation

Navicular height unloaded and loaded, calcaneal angle and truncated foot length were measured by photographic examination. Anatomical landmarks were marked at the navicular tuberosity and the 1st metatarsal head (Fig. 1A). The truncated foot length [25] was measured as the length from the anterior aspect of the first metatarsal head to the posterior aspect of the calcaneus (Fig. 1A, top). Calibrated digital photographs (Canon EOS300) of the navicular height (sagital plane) and calcaneal angle (frontal plane) were taken and printed and the static measures were extracted from the photographs (Fig. 1A).

The unloaded position was performed with the subjects seated with a 90° knee angle, placed vertically above the ankle and the feet in a relaxed parallel position. The loaded position was relaxed one-legged standing [26]. The navicular drop was defined as the difference between the navicular height in mm, between the unloaded and loaded position [26]. The calcaneal angle was defined as the angle between the midline of the calcaneus in the frontal plane and the bisection line of gastrocnemius as described by Root et al. [27,28] and was measured in the earlier described loaded position.

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Navicular drift was measured as the distance in mm through which the navicula tuberosity was displaced horizontally in the frontal plane, again from the unloaded to the loaded position [29]. A custom-made plate with a groove, in which a measurement unit could be moved across a ruler was used. (ICC\textsubscript{intra}rater 0.76 (95\%CI: 0.48;0.89), Unpublished data) (Fig. 3).

2.8. Electrogoniometric evaluation

Calibrated digital photographs were taken of the loaded foot during upright standing from the dorsal side in the frontal plane and from the medial side in the sagittal as a reference for the dynamic electrogoniometric measures. Two flexible wire goniometers (Bio- metrics) were skin mounted, one measuring the angle of calcaneus in relation to the shank in the frontal plane and one measuring the angle between the calcaneus and the first metatarsal bone in the sagittal plane (medial longitudinal arch). The goniometers were attached as illustrated in Fig. 1B following the red lines depicted in Fig. 1A. This angle was translated into the navicular height using basic trigonometry. Additionally, two switches were placed under the heel (posterior on the heel fat pad) and the forefoot (below head of 1. Metatarsal) to measure temporal gait parameters. Data were collected at a self-selected walking speed on a treadmill. All signals were sampled at 1000 Hz with a PC-based data acquisition system and processed in Matlab. The maximal change in navicular height (maximal navicular drop) and the maximal calcaneal angle during the gait cycle were used as outcome measures.

2.9. Ethics

The project was approved by the local Ethic Committee in Region North, Denmark, VN 2003/107. Clinical trials no. NCT01587612.

2.10. Statistical analysis

Sample size was based on a clinical improvement of 20 mm [30] on a 100 mm visual analogue scale for pain when walking. A
standard deviation of 20 mm, a power at 0.80 and a significance level at 0.05 estimated 16 participants in each group. This was increased to twenty participants in each of the four groups due to potential drop-outs.

Baseline: The endpoints were self-reported pain during resting, walking and running. The associations between pain and calcaneal angle, navicular drift, navicular height unloaded and loaded, navicular drop and truncated foot length were analysed by linear regression, normality of pain scores were tested by QQ-plots and normal distribution was assumed. The analyses were adjusted for age, gender, weight and truncated foot length using multiple regressions. Model assumptions were checked by visual inspection of residuals and found adequate. Spearman correlation coefficients were calculated for bivariate correlations.

Intervention: The absolute changes from baseline to 4 or 12 month follow-up in calcaneal angle, navicular drift, navicular height unloaded and loaded, navicular drop, and self-reported pain during resting, walking, and running were analysed. The relative changes were also analysed for the endpoints: Calcaneal angle, navicular drift, navicular height unloaded and loaded. Within and between groups effects were analysed by One-way analysis of variance, assuming the endpoint variables to be normally distributed with time and group as factors, respectively. A posthoc Bonferroni analysis was carried out to define group effects.

The effects of insoles and training were also analysed by two-way analysis of variance, assuming the endpoint variables to be normally distributed. The analyses were adjusted for age, gender, weight, truncated foot length and compliance using a univariate analysis of covariance model.

A drop-out analysis was performed. Model assumptions were checked by visual inspection of residuals and found adequate. All analyses were performed by SPSS 15.0 for Windows.

### 3. Results

Of the 146 adults screened for inclusion over three years, 80 (55%) were enrolled in the trial, with 20 randomly allocated to each of the four groups (Fig. 2). The baseline characteristics of the participants were very similar among groups except for the calcaneal angle (Table 2), and there were no differences in foot pain scores ($P>0.05$) (Table 2).

Of the 80 patients included in the present study 65 were women (81%). The average age was 43 years (95%CI: 40; 46) and 71% were sports active. The average duration of foot pain symptoms were 7.3 years (95%CI: 5.2; 9.4) and according to Brighton's test [31] 20% were hypermobile (Table 1).

Foot pain was bilateral in 80% of the cases, and common diagnoses included shin splint, Tibialis posterior insufficiency, plantar heel pain, and midfoot pain assessed by an experienced physiotherapist or orthopaedic surgeon. Etiology was classified as idiopathic for all patients. Overall, 70 participants (88%) were followed up at 12 months. Compliance to foot training was moderate, with 70% participating in approximately one session per week during the 12 week intervention from the training group and 65% from the training and insole group. The number of subjects using insoles in the SI and the EI groups from 4 to 12 months was not systematically recorded. A drop-out analysis showed no differences between the drop-outs and the participants in the study on baseline parameters.

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No significant associations were observed between any of the baseline parameters and the primary outcome, pain during walking. The analyses were adjusted for age, gender and weight using multiple regressions.

3.1. Pain

There was a significant pain reduction during walking within all four intervention groups at both 4 and 12 months follow-up. However, no significant differences were seen between groups in any of the pain parameters (Table 2). Baseline navicular drop during standing was significantly related to pain during running. One percent elevated navicular drop increased VAS score with 4.5 mm. (P = 0.035) and when data were adjusted for age, gender and weight each percent increase in navicular drop increased VAS score with 3.7 mm (P = 0.036). Pain during walking was not correlated to foot posture measures at baseline.

The adjusted analysis comparing SI-IG (no exercise) with EG+IEG (exercise) and likewise by comparing SI+EG (no insole) with IG+IEG (insole) revealed no significant effect on pain during walking (no data presented).

3.2. Effects in static foot posture

Significant changes in static foot posture were observed with a decrease in navicular drift within the EG and the IEG at 4 months follow-up, but the changes were only present in the IEG at twelve months follow-up. There was a significant difference between SI and

<table>
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<td>Baseline description of all subjects and evaluation of randomization divided by each group individually.</td>
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<td><strong>Gender (%)</strong></td>
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<td><strong>Long. Arch</strong></td>
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<td><strong>Shin Splints</strong></td>
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<td>Baseline measures are reported, whereas only differences from baseline are reported at follow-up. Bold indicate a significant change within groups. ΔNH= difference between unloaded and loaded navicular height. Calcaneal Angle= Angle between bisection line of M. Gastrocnemius and calcaneus– measured in the frontal plane. *Indicate a significant difference between the Standard Intervention and Insole groups in baseline static calcaneal angle – a more pronated foot posture was seen in the insole group.</td>
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<td><strong>Baseline</strong></td>
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<td><strong>Static</strong></td>
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<td><strong>ΔNH (mm)</strong></td>
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<td><strong>Calcaneal angle (°)</strong></td>
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<td><strong>Navicular drift (mm)</strong></td>
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<td><strong>Dynamic</strong></td>
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<td><strong>Navicular drop (mm)</strong></td>
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<td><strong>Calcaneal angle (°)</strong></td>
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The training program primarily consisted of recommended and generally accepted exercises addressing both the intrinsic and extrinsic foot muscles such as ‘short foot’, quadriceps, gluteus and hamstring exercises. Wong [33] concluded that the abductor hallucis muscle was a dynamic elevator of the medial arch of the foot, which suggests a greater focus on this in the treatment of pes planus.

It has been proposed that the concept of “aligning the skeleton” with shoes, inserts, and orthotics should be reconsidered, because only small, non-systematic, and subject-specific changes of foot and leg movement can be observed [20]. This could explain the lack of kinematic changes in the present study. Possible changes in the forces acting on the foot during the stance phase, can act as an input signal producing a muscle reaction, but this has not been investigated in the present study. However, the limited effect of insoles on pain during walking support the idea that changes in forces or “aligning the skeleton” are of less clinical importance.

The compliance to physiotherapy sessions was relatively low in both exercise groups, which may have reduced the potential effect of exercise therapy.

A potential bias in this study was that some of the participants in the standard intervention group and in the exercise group used insoles after the four-month intervention period, which may have underestimated a possible follow up effect. The results at 12 months follow-up should be viewed with caution due to the fact that the number of participants in each group that had decided to wear insoles was not systematically recorded.

The prevalence of foot problems lasting one day or more during a one month period is 30% in the Danish population [34], which emphasize the importance of research in effective treatment modalities in daily clinical practice.

5. Conclusions

A significant pain reduction was seen in all four groups at both short term and long term follow-up. The results at 12 months follow-up should be viewed with caution due to the risk of cross-contamination. None of the treatment modalities seem to be superior with the number of patients available in this study and therefore different approaches seem to have an effect in treating orthopaedic outpatients in daily clinical practice. Only a weak correlation between changes in pain scores and changes in structural and biomechanical outcome measures of the foot was seen.

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