

Clinical effectiveness of customised sport shoe orthoses for overuse injuries in runners – a randomised controlled study

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ABSTRACT

Background and objectives: Treatment of chronic running-related overuse injuries by orthopaedic shoe orthoses is very common but not evidence-based to date.

Hypothesis: Polyurethane foam orthoses adapted to subject's barefoot plantar pressure distribution are an effective treatment option for chronic overuse injuries in runners.

Design: Prospective, randomised, controlled clinical trial.

Intervention: 51 patients with running injuries were treated with custom-made, semi-rigid running shoe orthoses for 8 weeks. 48 served as a randomised control group that continued regular training activity without any treatment.

Main Outcome Measures: Evaluation was made by the validated pain questionnaire subjective pain rating scale (SES), the pain disability index (PDI) and a comfort index in the orthoses group (ICI).

Results: There were statistically significant differences between orthoses and control group at 8 weeks for PDI (mean difference 3.2 (95% CI 0.9 to 5.5) and SES (6.6 (2.6 to 10.6)). The orthoses patients reported a rising wearing comfort (ICI pre 69/100, ICI post 83/100) which was most pronounced in the first four weeks (ICI 80.4/100).

Conclusion: Customised polyurethane running shoe orthoses are an effective conservative therapy strategy for chronic running injuries with high comfort and acceptance of injured runners.

INTRODUCTION

Running injuries, particularly located in the lower limb, are among the most commonly treated sports-related injuries.^[1] Of the latter, overuse injuries are the main pathology to prevent competitive runners from training or competition.^[2-5] In the past 3 decades, the incidence of running-related overuse injuries has continuously increased due to a rising number of recreational athletes and higher training intensity in competitive athletes.^[6-8] Several risk factors appear to be associated with those injuries such as weekly distance, history of previous running injuries, number of years running, training characteristics, surface and footwear.^[1-3]

The most common diagnoses in running injuries are patellofemoral pain syndrome, iliotibial band syndrome, tibial stress syndrome (often referred to as 'shin splints'), low back pain, chronic exertional compartment syndrome, plantar fasciitis and tendinopathies (particularly of the Achilles tendon, patellar tendon, posterior tibial tendon, adductor tendons and upper hamstring tendons).^[9-11]

Treatment consists most commonly of a multi-oriented approach. Conservative treatment is usually based on a combination of training modifications, anti-inflammatories, infiltrations and physiotherapy including soft tissue mobilisation, deep frictions, stretching and strengthening of involved muscles and physical measures (e.g. ultrasound, interferential, cryotherapy and heat).^[12] Insoles are thought to be an efficient tool in the treatment of running-related overuse injuries through correction of biomechanics, modification of afferent input on the foot sole and minimising muscle work.^[13-18]

Patients' satisfaction after orthotic therapy has severally been reported but clear evidence-based data from randomised controlled trials is still rare.^[19-21] Additionally, comparison of studies on foot orthoses as well as transfer to clinical applications is difficult because outcome measures as well as insole constructions are diverse and often not well detailed in the studies. Two recent systematic reviews on foot orthoses in lower limb overuse conditions showed that there is insufficient evidence to support or refute the use of foot orthoses in the treatment of lower limb overuse injuries to date because

methodological quality of the available controlled clinical trials is mostly weak and data is to heterogeneous to pool it.^[19, 21] One high quality randomised controlled study on 179 patients that found foot orthoses to produce earlier and larger improvements than flat inserts in patients suffering from patellofemoral pain syndrome has additionally been published lately.^[22]

The aim of the present study was to evaluate the influence of standardised individually customised foot orthoses on pain and impairment of daily life in runners with unilateral running-related overuse injuries by a randomised controlled trial.

METHODS

This study was conducted at the University Hospital of Freiburg, Germany in compliance with Good Clinical Practice (EC-GCP-Note for Guidance) and CONSORT guidelines for randomised controlled trials.^[23] The study was reviewed and approved by the local University's Ethics Committee.

Orthoses Construction

The sports orthoses used in this study are made out of polyurethane foam material (EVA, compression moulded, semi-rigid) with a bowl-shaped heel, a medial longitudinal arch support and a detorsion wedge (Fig. 1, IETEC GmbH, Fulda, Germany, type "Move Control"). They are individually customised based on the subject's dynamic barefoot plantar pressure distribution. In the study, this was conducted by the same orthopaedic technician (H.T.) using an Emed SF pressure platform (Novel, Munich, Germany).

The particularity of those orthoses is the adaptation of the stiffness of the polyurethane material, depending on runners bodyweight and running velocity comparable to midsole material of standard running shoes. It is thought that the resulting combination of orthosis and shoe leads to a proper fit and a synergism of their effects. Furthermore, the relatively stiff material is thought to provide a direct feedback from the running surface and thus enhances proprioception of the foot sole. Evidently, a proper shoe selection and fit of the orthoses are essential. For this type of orthosis, runners are advised to choose a neutral running shoe without additional stabilising elements. The orthoses showed promising results in daily clinical routine and biomechanical testing in healthy runners.^[24]

Recruitment, Participants and Group Assignment

All runners with unilateral, chronic overuse injuries presenting to the Outpatient Clinic between July 2002 and July 2005 were eligible for inclusion. Furthermore, runners from the community with unilateral running-related overuse symptoms responded to publicity measures in local newspapers and at local running events. Male and female subjects were recruited for the study. Inclusion was based on unilateral running-related overuse-injuries, including patellofemoral pain syndrome, iliotibial band syndrome, shin splints, plantar fasciitis and tendinopathies with a duration of > three months, clinically diagnosed by an independent sports medicine physician (orthopaedic surgeon F.M.). Additional inclusion criteria were age-range between 18 and 60 years, a running distance of > 20 miles/week (32 km/week)^[3] and the absence of other illnesses and complaints. Exclusion criteria were history of surgery to lower extremities and lumbar spine, signs or symptoms suggestive of an acute injury, any parallel therapies including physiotherapy, insoles, non-steroidal anti-inflammatory drugs or corticosteroid injections during the previous six months.

Study Procedure

Potential subjects were instructed to contact the study coordinator to review the inclusion criteria of the study. If these were met, the sports medicine physician evaluated them to determine if the physical examination criteria were compliant. If the patient met inclusion criteria and agreed to participate in the study, written informed consent in accordance to the local University's Ethics Committee was obtained. The study coordinator then obtained background demographic data (age, weekly distance, training characteristics and surface, number of years running, shoes worn, amount and distance of competitions per year and aerobic capacity by individual anaerobic threshold determined by an incremental treadmill test^[25]) and measured subject's height and weight. All data were documented in prepared case report forms. A baseline assessment of the study's outcome measurements was then performed.

The outcome measurements were as follows:

(1) Pain disability index (PDI).^[26-30] Assessment of functional disabilities in activities of daily living resulting from running-related injury symptoms.

PDI is a 7-item inventory designed to measure the degree to which pain interferes with functioning across a range of activities. The seven categories include family/home responsibilities, recreation, social activity, occupation, sexual behaviour, self-care and life support activity. Each item can range from 0 (no interference) to 10 (total interference). Thus, total PDI score can range from 0 to 70.^[26-30] For statistical evaluation, sum scores of all categories were calculated. PDI is considered reliable for assessment of functional impairment and chronic diseases.^[30] The validity in overuse-injuries has previously been proven.^[12]

(2) Subjective Pain Experience Scale (SES). Pain quality is described by 24 adjectives including sensory and affective pain qualities using simple descriptive scales.^[12, 31]

SES was used to quantify the course of current symptoms on measurement days as well as during the intervention period. A sum score of sensory and affective qualities as well as a total sum score were calculated with minimum values of 14 points for affective part A (SES-A) and 10 points for sensory part B (SES-B).^{[31], [12]}

(3) Comfort index of orthoses (ICI): Modelled after Mündermann et al., orthosis comfort was rated on 5 independent VAS scales ranging from 0 (=“not comfortable”) to 10 (“very comfortable”).^[32, 33] The 5 items included the quality of heel cup fit, longitudinal arch support, flexibility, combination of orthosis and shoe, and running with orthosis compared to running without orthosis (“much worse” to “much better”). A sum score was calculated analogous to PDI. Total ICI score can range from 0 to 100.

Following baseline evaluation of the outcome measurements, patients were instructed in how to use the training diary. Distance, duration and intensity had to be documented for every training session. SES pain questionnaire as well as ICI comfort questionnaire for orthoses had to be filled out at the end of each week.

Then, runners were randomly assigned to control group or orthoses group by permuted block randomisation (blocks of four), separated according to sex. The randomisation scheme was generated by using the Web Site ‘Randomization.com’

(<http://www.randomization.com>, plan number 19189 and 22219) and kept in a locked cabinet. According to the CONSORT guidelines, a research assistant not involved in outcome assessment revealed group allocation, followed by plantar pressure assessment for patients assigned to the orthoses group.^[23]

The following two weeks were considered habituation and instruction phase for the pain

questionnaires and the training diary. Accuracy of training documentation was checked at a second appointment two weeks later. At that time, orthoses were handed out to the patients of the orthoses group and correct fit in their personal running shoe was evaluated.

The orthoses had to be worn for all physical activities during the intervention phase. This had to be documented in the diaries, as an orthosis use of >80% of training sessions was required. Patients were advised to contact the study coordinator directly in the case of any fitting problems, blisters, bruises or any other new symptoms.

All subjects were advised to continue their regular training activity without modification of training habits. This was controlled by the documentation of distance and duration in the diaries at the end of the study. The outcome measurements were assessed at the end of every week over a period of 8 weeks. After the intervention period, there was another appointment at the study centre including outcome assessment and clinical re-evaluation. If pain was still present in participants of the control group, orthoses were customised for them as well.

Statistics

Baseline data from the case report forms were manually entered into a prepared database and crosschecked twice. All evaluated data were first analysed for plausibility. Implausible values were compared to the raw data and recalculated, if necessary. In addition, 10% of all values were recalculated from the original data and compared with the values in the database (> 95% of the values had to agree).

Change in SES sum score, PDI and ICI over eight weeks was analysed using descriptive statistics (means and standard deviation). The mean difference between the two treatment groups after the 8-week period was compared by using 95% confidence intervals. The primary outcome measures (PDI sum score and SES sum score) were statistically analysed by a two-factor repeated measure's ANOVA ($\alpha=0.05$). The independent variable was the intervention group (orthoses/control) and the dependent variable was PDI/SES sum score. All statistical analyses were performed with JMP Statistical Discovery Software package version 5.0.1.a (SAS Institute, Cary, USA).

RESULTS

1) Before Treatment

Subjects:

63 male and 62 female runners were initially evaluated for the study. After orthopaedic examination and checking of the inclusion criteria, 50 male and 49 female were included and randomised to the two intervention groups (orthoses n=51, control n=48, Fig. 2).

Baseline Data:

Patients ranged from 19 to 52 years of age (37.2 ± 8.3) and were running a mean weekly distance of 44 kilometres. Most of the participants were experienced runners (regular running activity > 3 years, mean 8.1 years) and high-level athletes (mean training speed 5:40 min/km, individual anaerobic threshold > 12km/h). There was no statistically significant difference in any of the baseline criteria between groups ($p>0.05$, Tab. 1).

TABLE 1

**Subject Characteristics at Baseline for Orthoses and Control Groups.
Values are presented as mean \pm SD.**

	Control Group (n =48)	Orthoses Group (n=51)
Age [y]	37.1 \pm 8.3	37.3 \pm 8.2
Height [cm]	174.4 \pm 9.1	172.5 \pm 9.3
Weight [kg]	68.8 \pm 13.6	66.8 \pm 11.6
Competitions [no/year]	5.2 \pm 4.5	5.8 \pm 8.3
Running experience [y]	8.1 \pm 1.0	8.1 \pm 1.0
Training sessions [u/week]	3.9 \pm 1.2	4.2 \pm 1.7
Training volume [h/week]	4.9 \pm 2.1	4.6 \pm 2.2
Training speed [min/km]	5.6 \pm 0.9	5.7 \pm 0.8
Distance [km/week]	43.7 \pm 21.3	44.1 \pm 23.4
Individual anaerobic threshold [km/h]	12.3 \pm 1.7	12.0 \pm 1.4

The most common diagnosis in the 99 patients was Achilles tendinopathy (26 patients), followed by patellar tendinopathy (18 patients), patellofemoral pain syndrome (14 patients), iliotibial band syndrome (13 patients), plantar fasciitis and periostitis tibiae (each in 7 patients). Table 2 shows the distribution of the diagnoses in the groups.

**TABLE 2
Distribution of diagnoses in Orthoses and Control Group**

	Achilles tendinopathy	Patellar tendinopathy	Patellofemoral pain syndrome	Iliotibialband syndrome	Plantar fasciitis	Periostitis tibiae	Others
Control group	14	8	7	7	3	3	6
Orthoses group	12	10	7	6	4	4	8
Sum	26	18	14	13	7	7	14

Disability and Pain:

Mean PDI sum score as well as mean SES sum score at baseline were similar in the two

intervention groups. As presented in table 3 baseline values of PDI were 4.1 (\pm 5.6) in the control group and 4.0 (\pm 5.5) in the orthoses group, baseline values of SES were 31.6 (\pm 9.6) in the control group and 29.9 (\pm 8.2) in the orthoses group, respectively ($p>0.05$, Tab. 3).

TABLE 3
Group mean values and group mean differences of PDI and SES
at baseline and post treatment

	PDI			SES		
	Control group	Orthoses group	Mean diff. (95% CI)	Control group	Orthoses group	group mean diff (95% CI)
Baseline	n=48	n=51		n=48	n=51	
Mean \pm SD	4.1 \pm 5.6	4.0 \pm 5.5	0.1	31.6 \pm 9.6	29.9 \pm 8.2	1.7
95% CI	2.3 to 5.9	2.3 to 5.7	-2.1 to 2.3	28.5 to 34.8	27.4 to 32.5	-1.9 to 5.3
Post treatment	n=39	n=42		n=39	n=42	
Mean \pm SD	4.8 \pm 7.2	1.6 \pm 2.1	3.2	29.9 \pm 8.2	25.9 \pm 3.3	6.6
95% CI	2.5 to 7.1	0.97 to 2.3	0.9 to 5.5	27.4 to 32.5	24.9 to 27.0	2.6 to 10.6

2) After Treatment

During the intervention period of 8 weeks, there were 18 drop-outs recorded (Fig. 1). Six suffered from acute injuries/illnesses, including 1 forearm fracture, 1 ankle sprain and 1 borreliosis infection in the orthoses group and 1 meniscal injury, 1 ankle sprain and 1 acute low back pain in the control group. 4 in each group withdrew from the study without specification of causes and 4 were excluded due to non-compliance (arbitrary side therapy, inadequate documentation of questionnaires or training habits or reduction of training volume and/or intensity). The drop-out rate was equivalent in both intervention groups (17.6% in the orthoses group and 18.6% in the control group), none of the subjects changed between groups. Thus, there remained 39 athletes in the orthoses group and 42 athletes in the control group for final evaluation (Fig. 2).

Disability:

There was a statistically significant difference in the group mean values of the orthoses and the control group at the second measurement day for both, SES and PDI ($p<0.05$, Tab 3). In the orthoses group, mean PDI sum score decreased from 4.0 to 1.6 after the 8 weeks ($p<0.05$), whereas it slightly increased from 4.1 to 4.8 in the control group ($p>0.05$, Tab. 3). When calculated as intra-individual percentages of the baseline values (PDI sum score at the first measurement day =100%), there was a mean reduction of 58% in the orthoses group (95% CI -74% to -43%) and a mean increase of 23% in the control group (95% CI -16% to +62%), respectively ($p<0.001$, Fig. 3).

Pain:

Mean SES sum score analogously decreased from 29.9 to 25.9 in the orthoses group ($p < 0.05$) and again slightly increased from 31.6 to 32.5 in the control group ($p > 0.05$, Tab. 3). The statistically significant reduction of SES mean values in the orthoses group were seen in both parts of the questionnaire with affective part values reducing from 17.2 (95% CI 15.6 to 19.0) to 14.9 (95% CI 13.4 to 15.5) and sensory part values reducing from 12.6 (95% CI 11.6 to 13.7) to 10.9 (95% CI 10.5 to 11.6).

In the control group, the increase was only observable in the affective part of the questionnaire: affective part mean sum score at baseline was 18.3 (95% CI 16.3 to 20.8) vs. 19.9 (95% CI 17.2 to 21.0) after the 8 weeks, sensory part mean sum scores were 13.3 (95% CI 12.0 to 14.6) at baseline vs. 13.3 (95% CI 11.9 to 14.8) after the 8 weeks.

Pain course:

Fig. 4 shows the course of the mean SES sum scores values in control and orthoses group during the intervention phase. After a slight increase at the end of the first week in both groups, there was a continuous decrease in the orthoses group the following seven weeks. Mean values of the control group remained almost constant for five weeks and increased again slightly towards the second measuring day. For some individuals in the orthoses group, a longer time passed before they reported a decrease of pain level.

Orthoses Comfort:

Overall, patients reported high comfort when wearing the orthoses. All except one of the participants judged the orthoses very comfortable and, after the eight weeks, preferred running with the orthoses rather than without. Only one runner rejected the orthoses and one runner used an additional viscoelastic heel cup, so that he had to be excluded from the study. Mean comfort index values of the comfort questionnaire raised by 14% during the intervention phase. There was a 10% increase in the first four weeks with mean values rising from 69.0 (95% CI 61.0 to 77.0) to 80.4 (95% CI 75.6 to 85.1), which was most pronounced in the second to third week. No substantial further increase was noted during the second 4-week period (80.4 to 83.0 (95% CI 75.0 to 91.2, Fig. 5). When analysing the individual diaries of the patients, in quite a few cases pain reduction was already apparent in the second week of treatment, whereas satisfaction concerning the comfort of the orthoses took longer.

Side Effects:

There were no adverse effects of the orthoses recorded at all, neither local foot problems nor symptoms in localisations other than the initial ones. One patient rejected the orthoses because he “did not like” them. All patients who retired from the study were also asked for side effects and none of them reported any.

DISCUSSION

The present study is one of the first randomised controlled studies on foot orthoses in lower extremity overuse injuries showing a statistically significant pain reduction in runners after a standardised orthoses therapy of eight weeks. Results revealed statistically significant differences between intervention and control group at the second measurement day for both questionnaires, SES and PDI. The pain reduction after the intervention phase was seen in the sensory and the affective part of the SES, with post-treatment values of 14.9 in affective part and 11.0 in sensory part, respectively. As minimum scores (14 points for affective part and 10 points for sensory part) were almost

reached, this result can be considered not only statistically significant but also highly clinically relevant.

The pain decrease proved in the SES questionnaire was accompanied by a significant reduction of the impairment in activities of daily living, expressed by a 58% decrease in PDI sum score, which must be considered a relevant reduction.

Nevertheless, compared to the maximum value of 96 for SES and 70 for PDI, respectively, the mean values of the injured runners at baseline as well as the absolute improvement during the intervention phase were rather low. As floor effects are very likely when investigating sport specific injuries that do not highly affect every day living, the use of more specific pain questionnaires and functional disability measures, e.g. the VISA questionnaire in Achilles and Patellar tendinopathy, should be implemented in further therapy studies.

Regarding the course of the pain level during the 8 weeks, it was interesting to see that SES sum score initially slightly increased. Transferring these results to clinical practice, it seems important to prepare patients for a possible pain increase at the beginning of an orthoses therapy so that they do not immediately stop using the orthoses.

Concerning possible mechanisms for the effect achieved by the orthoses, it is currently speculated that neuromuscular adaptations and reduction of muscle fatigue play the most important role.^[15, 19, 24, 39, 40] Mündermann et al. showed changes in EMG variables as an expression of neuromuscular changes related to different insoles.^[15, 24, 39, 40] To support the hypothesis of sensorimotor effects of the orthoses used in this study, a pilot study including electromyography and plantar pressure measurements was conducted before. Using the same type of orthoses, Baur et al. showed an increasing electromyographic activity of the peroneus longus muscle accompanied by higher peak pressure values under the midfoot when wearing orthoses with a longitudinal arch support.^[24, 39] As higher EMG activity of the peroneal muscle might imply enhanced joint stability in the stance phase of running, this leads to the conclusion that modification of the sensory input to the sole can considerably influence neuromuscular response patterns and that neuromuscular adaptations may be more important than mechanical corrections.^[24, 39, 41]

The fact that the adaptation to the orthoses seems to be almost completed after four weeks of therapy supports this hypothesis of a mainly sensorimotor effect as it is well known that the results of sensorimotor training show within four weeks.^[42]

In addition to the improvement in pain and functional disabilities, participants showed very good compliance in wearing the orthoses. All except one runner reported a high satisfaction concerning wearing comfort. This is probably due to a good fit of the customised orthoses as it is postulated that orthoses fit when running is essential to provide comfort and to not hamper the natural roll-over process of the foot.^[43, 44] In this study, this was allowed by customising the orthoses to runner's individual dynamic barefoot plantar pressure distribution and by using polyurethane material similar to the midsole of running shoes. The polyurethane does not provide additional cushioning so that proprioception is not altered. Robbins and Gouw showed a reduction of afferent input from the foot sole when wearing soft shoes or walking on soft ground and concluded that soft materials negatively influence feedback.^[45]

An additional important reason for the high satisfaction and compliance to the orthoses therapy certainly is that runners usually prefer therapies that do not imply a reduction of running distance and do not require any additional training time. As orthoses generate their effect when running, it is even important for their effectiveness that patients continue their running activity.

Some limitations of the study have to be considered when interpreting the results. A lack of the study certainly is that therapy was not blinded and that only one orthoses type was tested. As there was no comparative “sham orthosis”, it cannot be proven that the sports-specific model used in the study is more effective than standard models or prefabricated ones. Due to the fact that all patients included in this study were still able to continue their regular training activity with a weekly distance of at least 32 kilometres, transfer of the study results to other populations with more severe symptoms is limited. As repetitive loading of the orthoses seems to be the most important factor for their effectiveness, this type of therapy can only work as long as the runner is able to run. Additionally, all types of overuse running injuries were included in the study. Thus, the results are not diagnoses-specific and may not apply to all diagnoses to the same degree.

CONCLUSION

The results of this study indicate that individually customised foot orthoses are an important effective treatment strategy for running-related overuse injuries. In contrast to the widespread opinion that “orthoses are only one facet of treatment and should be combined with rest, training modification, a change in the running surface or shoe and a proper conditioning and stretching programme” (Gross et al. 1991), the results of our study justify the prescription of orthoses as a single-measure approach for runners that are still able to continue their training activity as the majority of participants responded well without any side treatments and reported high comfort wearing the orthoses.^[13, 37]

WHAT IS ALREADY KNOWN ON THIS TOPIC:

Running-related overuse injuries are among the most frequent reasons for consulting a sports medicine practitioner. Foot orthoses are often prescribed for those injuries despite a lack of high quality evidence from randomised controlled trials as highlighted by two recent systematic reviews.

WHAT THIS STUDY ADDS:

The results of this randomised controlled study show that foot orthoses are an effective treatment strategy for overuse injuries with a high acceptance by injured runners.

FIGURE LEGENDS

Figure 1: Running shoe orthosis (Polyurethane material with bowl-shaped heel, medial longitudinal arch support and detorsion wedge individually customised by dynamic barefoot plantar pressure distribution measurements)

Figure 2: Flowchart of patient recruitment, randomisation, treatment, and follow-up

Figure 3: Intra-individual percentage of PDI sum score at M2 ($M2/M1*100$) for Control group and Orthoses group (mean/95% CI).

Figure 4: Course of SES sum score during eight-weeks' therapy for Control group and Orthoses group (mean/SD)

Figure 5: Course of orthoses comfort index (ICI) during eight-weeks' therapy (mean/SD)

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COMPETING INTERESTS

None to declare

LICENCE FOR PUBLICATION

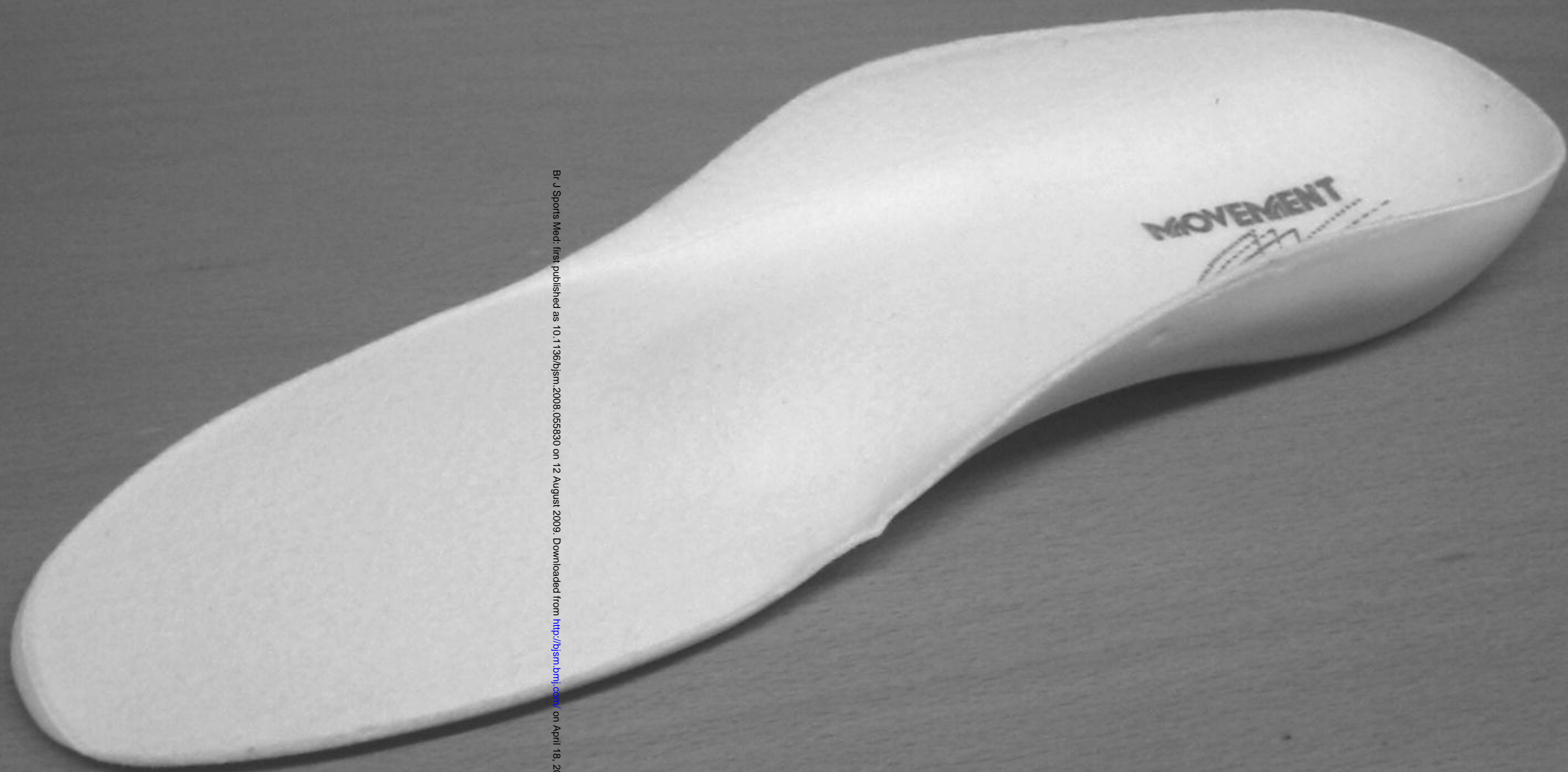
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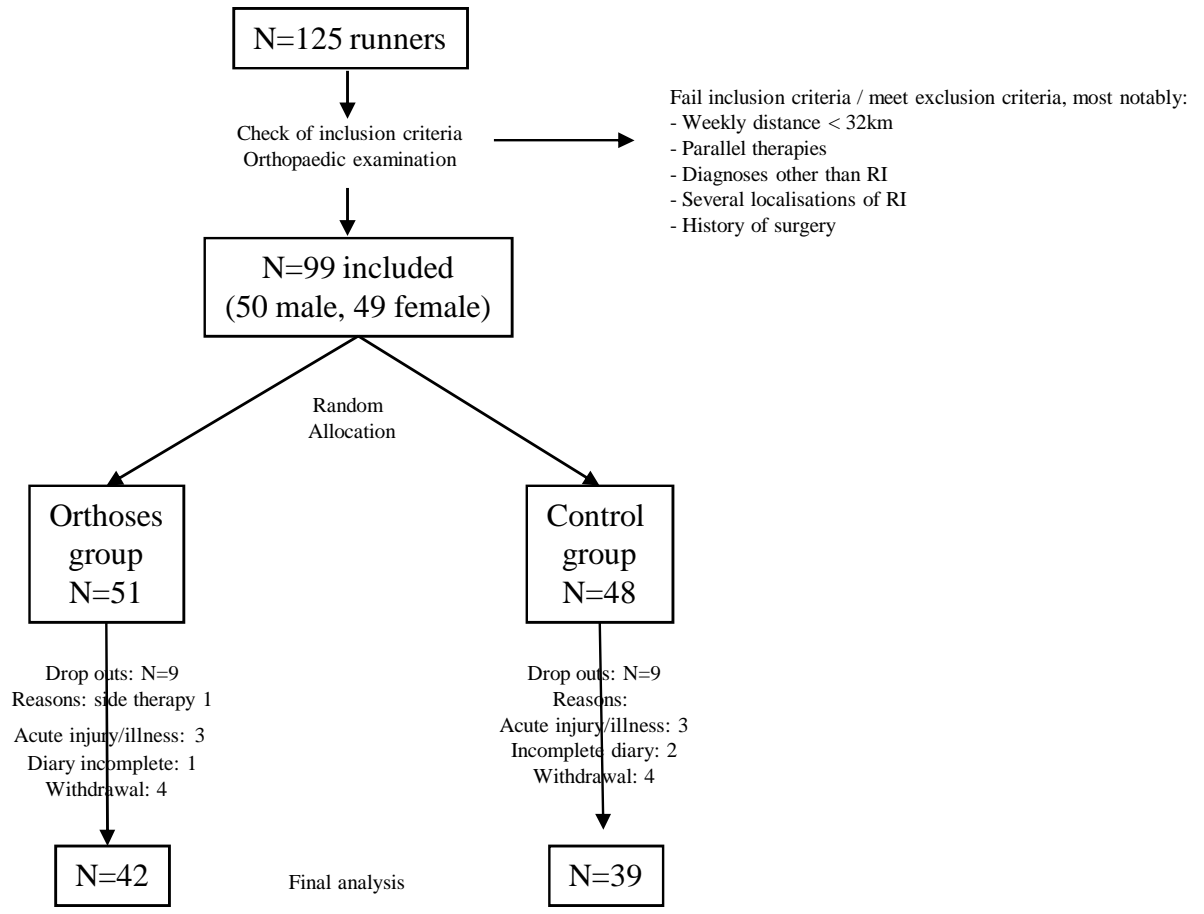


Figure 2. Flowchart of patient recruitment, randomisation, treatment, and follow-up

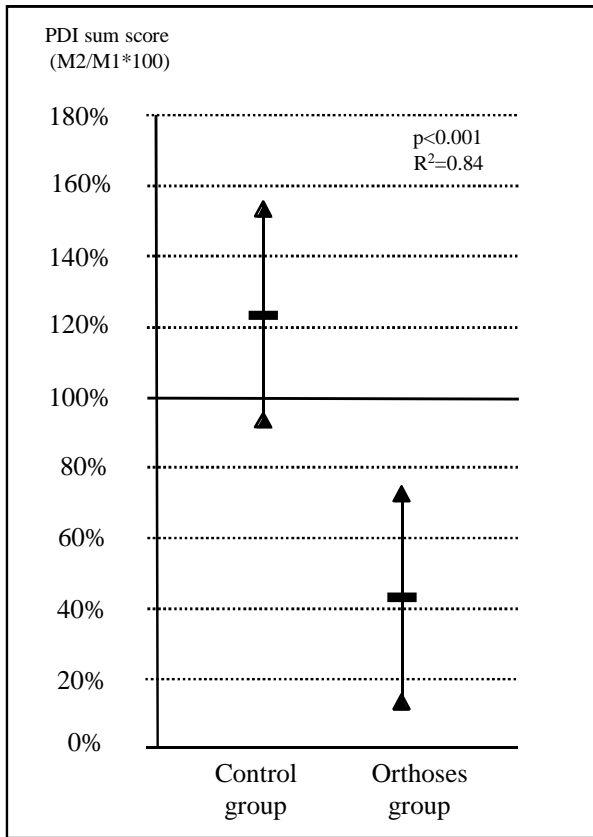


Figure 3: Intra-individual percentage of PDI sum score at M2 (M2/M1*100) for Control group and Orthoses group (mean/95% CI).

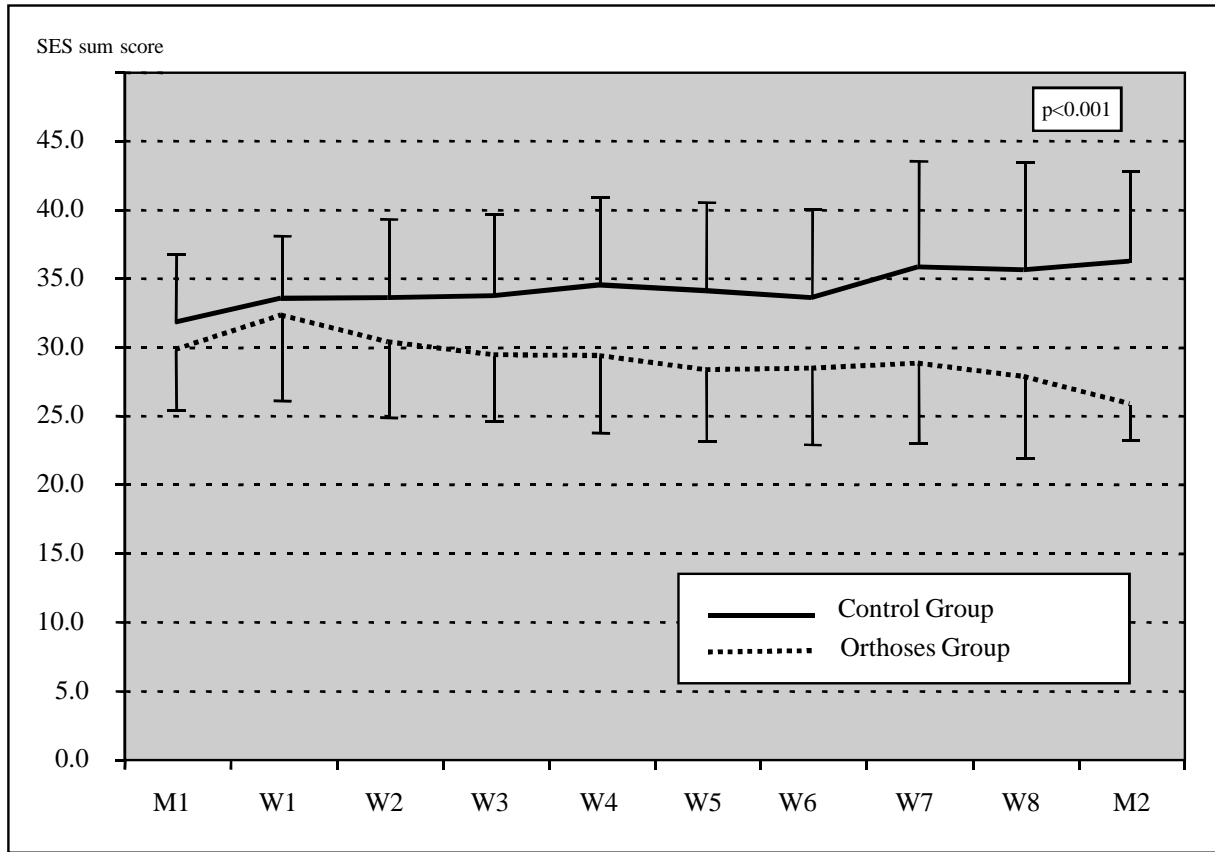


Figure 4: Course of SES sum score during eight-weeks therapy for Control group and Orthoses group (mean/SD)

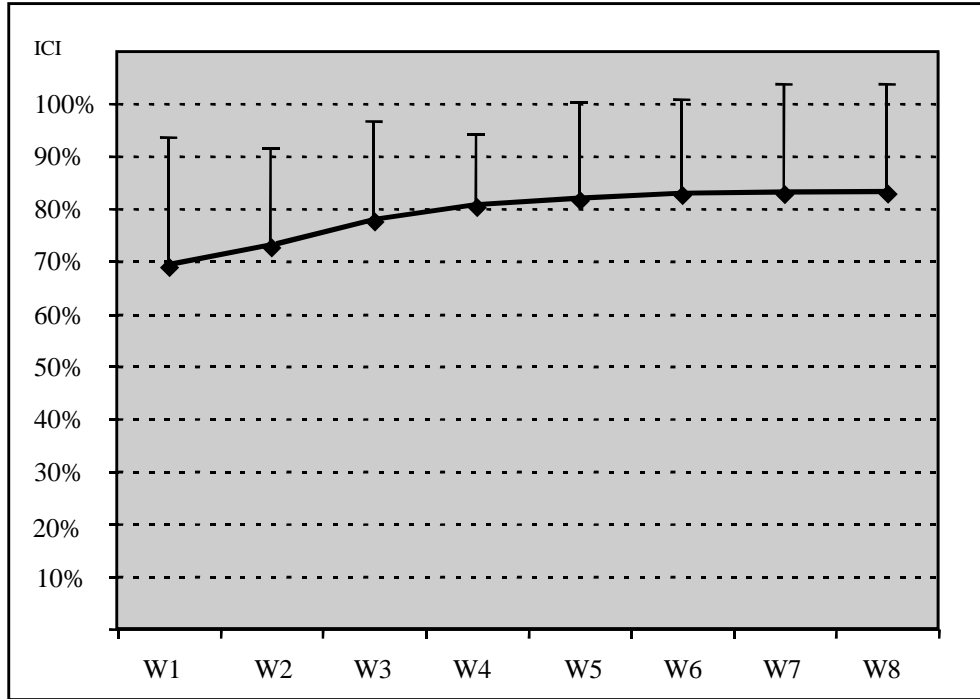


Figure 5: Course of orthoses comfort index (ICI) during eight-weeks therapy (mean/SD)