FACULTY OF MEDICINE
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Influence of Dynamic Orthotic Devices on Medial Tibial Stress Syndrome in Military Personnel

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List of abbreviations

/ = not applicable

µV = microVolt

= = equal

2D = two dimensional

3D = three dimensional

B = better

BF = Musculus Biceps Femoris

BMI = Body Mass Index

Borg = BorgInsole® Custom

BSP = Back Swing Phase

C = control group

Deca = insole Aptonia® Decathlon

DiffPDI_Borg = PDI end - PDI begin of Borg intervention

DiffPDI_Deca = PDI end - PDI begin of Deca intervention

DiffPDI_insole1 = PDI end - PDI begin of intervention period 1

DiffPDI_insole2 = PDI end - PDI begin of intervention period 2

DiffPDI_Gesp = PDI end - PDI begin of Gesp intervention

DiffPDI_RSP = PDI end - PDI begin of RSP intervention

EMG = electromyography

EVA = ethylene-vinyl acetate

FADI = Foot and Ankle Disability Index

FSP = Front Swing Phase

G = Musculus Gastrocnemius

Gesp = insole GesPodo® Custom

GL = Musculus Gastrocnemius Lateralis

GM = Musculus Gastrocnemius Medialis

Hz = Hertz

IIR = Infinite Impulse Response

kg = kilogram

km = kilometre(s)

km/h = kilometre per hour

m = metre

m² = square metre

MHQA = Military Hospital Queen Astrid

ms = milliseconds

MTSS = Medial Tibial Stress Syndrome

MV = missing value

MVC = Maximum Voluntary Contraction

N = number

P = patient group

PDI = Pain Disability Index

PDIdiff = PDI score begin - PDI score end

PL = Musculus Peroneus Longus

Q = Musculus Quadriceps

Q1 = first quartile

Q3 = third quartile

RF = Musculus Rectus Femoris

RMS = Root Mean Square

ROM = Range Of Motion

RSP = Phits® RS Print Custom 3D printed insoles

sEMG = surface electromyography

SENIAM = Surface Electromyography for Non-Invasive Assessment of Muscles

Std. = standard

SP = Stance Phase

SPSS = Statistical Package for Social Science

SSS = Self-Selected Speed

T1 = test moment without insoles; baseline

T2 = test moment when the insoles were just received; pre-insole

T3 = test moment after eight weeks of wearing the insoles; post-insole

TA = Musculus Tibialis Anterior

VL = Musculus Vastus Lateralis

VM = Musculus Vastus Medialis

W = worse

Abstract

Abstract English

Background: Medial Tibial Stress Syndrome (MTSS) is a common overuse injury of the lower limb with incidence rates around 10 to 30%. In literature one can distinguish two main hypotheses, namely tibia fascia-traction theory and bone stress reaction theory. In each theory muscle activity has a different influence on the aetiology and prognosis of MTSS. Insole therapy might be advantageous to reduce the financial and clinical burden MTSS entails.

Objectives: The goal of this study was to investigate the effect of different insoles on muscle activity and Pain Disability Index (PDI) scores in military personnel with MTSS.

Study Design: Observational study.

Methods: The research was conducted in the Military Hospital Queen Astrid, in Brussels. The study included 43 patients with MTSS and 42 controls. Patient group was subjected to two eight-week insole interventions, of which outcome was demonstrated by surface electromyography (sEMG) data and PDI scores. The insole therapy consisted of four insole types: Phits® RS Print Custom 3D printed insoles; BorgInsole® Custom; GesPodo® Custom and Decathlon Aptonia Memory Foam®. Patients were each randomly assigned to two insole interventions. sEMG measurements were performed in all participants during four velocities: 4 km/h, 10 km/h, 12 km/h and self-selected speed. The muscle activity of M. Tibialis Anterior, M. Peroneus Longus, M. Biceps femoris, M. Gastrocnemius Lateralis and Medialis and M. Vastus Medialis and Lateralis was measured at baseline, pre-insole and post-insole. The PDI scores were obtained at the start and at the end of both intervention periods.

Results: Baseline muscle activity without insoles was compared between the patient and control group. This resulted in a trend of significant lower activity in some muscles in the patient group.
Second analysis examined the effect of each insole on the three moments during intervention. In the four different insole conditions the M. Tibialis Anterior, M. Peroneus Longus and M. Gastrocnemius were most affected by the intervention.
Third analysis consisted of PDI score comparison. For both intervention periods, there was no significant difference between the PDI score at the end vs the beginning.

Conclusion: Regardless of the available significant data, it was not possible to draw a generalised conclusion about the influence each insole could have on muscle recruitment in MTSS patients.

Keywords: insoles-dynamic sEMG-military personnel-MTSS-observational study

Abstract Dutch

Achtergrond: Mediaal Tibiaal Stress Syndroom (MTSS) is een veelvoorkomend overbelastingsletsel van het onderste lidmaat met een incidentie van 10-30%. In de literatuur wordt dit verklaard aan de hand van twee theorieën, namelijk tractie ter hoogte van de tibiale fascia en impact ter hoogte van de tibia. Spieractiviteit heeft in beide theorieën een andere invloed op de etiologie en de prognose van MTSS. Zooltherapie zou financieel en klinisch voordelig kunnen zijn bij de behandeling van MTSS.

Doelstellingen: Het doel van deze studie was om te onderzoeken of verschillende zolen een effect hebben op spieractiviteit en Pain Disability Index (PDI) bij militair personeel met MTSS.

Onderzoeksdesign: Observationele studie.

Methode: Dit onderzoek vond plaats in het Militair Hospitaal Koningin Astrid, te Brussel. Deze studie includeerde 43 patiënten met MTSS en 42 controlepersonen. Aan de patiënten werden random twee zolen toegekend, deze werden telkens een periode van acht weken gedragen. Hiervan werden de effecten gemeten aan de hand van oppervlakte elektromyografie en PDI scores. De zolen die werden toegekend konden één van de volgende zijn: Phits® RS Print Custom 3D printed insoles; BorgInsole® Custom; GesPodo® Custom en Decathlon Aptonia Memory Foam®. Bij alle deelnemers werd de spieractiviteit gemeten aan de hand van oppervlakte elektromyografie tijdens 4 km/u, 10 km/h, 12 km/u en een zelf gekozen snelheid. De spieractiviteit van M. Tibialis Anterior, M. Peroneus Longus, M. Biceps Femoris, M. Gastrocnemius Lateralis en Medialis en M. Vastus Medialis en Lateralis werd gemeten op baseline, pre-zool en post-zool. Aan het begin en op het einde van de interventieperiode werden de PDI afgenomen.

Resultaten: Als eerste werd spieractiviteit van patiënten en controlepersonen vergeleken zonder zool. Hieruit kon afgeleid worden dat de spieractiviteit van patiënten in bepaalde spieren lager ligt dan deze van de controlepersonen.
Als tweede werd er gekeken naar het effect van de vier bovenvermelde zolen bij patiënten. Bij de analyse van de vier verschillende zolen werden de M. Tibialis Anterior, M. Peroneus Longus en de M. Gastrocnemius het meest beïnvloed tijdens de interventie.
Als derde werden de PDI-scores vergeleken. Er was geen significant verschil te zien tussen de PDI-scores in het begin en aan het einde van de interventie.

Conclusie: Ongeacht de significante resultaten was het niet mogelijk om een rechtlijnige conclusie te trekken over de invloed van de zolen op spieractiviteit bij patiënten met MTSS.

Trefwoorden: zolen-dynamische sEMG-militair personeel-MTSS-observationele studie

Introduction

Prevalence of overuse injuries is high in a physically active population such as runners and military personnel. When looking at the injury rate in British army recruits during a 26 weeks period of combat training, almost half of the 6608 recruits (48.65%) encountered at least one musculoskeletal injury. [1] This brings a high healthcare cost and has a big impact on both the patients and the organisation, given that these injuries could drag on for a long time. [2]

Medial Tibial Stress Syndrome (MTSS) is one of the most common overuse injuries of the lower limb. Incidence rates of 13.6% to 20% are reported in runners and 7.2% to 35% in military personnel. [2, 3, 4, 5, 6] MTSS is described as exercise-induced lower leg pain. The pain is localized along the posteromedial border of the tibia and is spread over a minimum of five centimetres. [3, 4, 5, 7, 8, 9, 10]

Aetiology is still widely discussed, however two underlying pathologies can be distinguished. Pain is either due to tibia fascia-traction theory or bone stress reaction theory. [3, 8, 9, 11, 12] Risk factors of MTSS have been extensively studied. Through all the research that has been done, different risk factors were suggested. Although more research is necessary, the following aspects on which there seems to be most consensus should be taken into account: increased navicular drop [3, 7, 11, 13, 14], Body Mass Index (BMI) [7, 11, 14], rotational hip Range Of Motion (ROM) [3, 7, 11, 14], female sex [7, 11] and ankle plantar flexion ROM [11, 14].

Insoles have been studied both as prevention and as therapy. The results when used as a preventive method were promising with significant reduction in development of MTSS during a military training period. [15] Literature is rather inconclusive about insoles as therapy in patients with MTSS. Positive effects on kinematics and pain are suggested, but there is a lack of qualitative studies to draw solid conclusions, especially when insoles are used as sole intervention. [5, 16, 17, 18, 19, 20] Even though there is no strong evidence for the use of insoles as treatment, they are frequently used. This brings a high annual refund cost. For Belgian Defence this goes up to €70K.

As discussed previously, kinematic parameters are often described as important risk factors. Gait analysis could therefore be a very interesting tool to observe some of these factors like excessive pronation during heel contact.

Furthermore muscle recruitment can play an important role in pathophysiology. Muscle activity may be examined to determine whether excessive or insufficient muscle activity during the gait cycle has an impact on the development of MTSS symptoms. The tibia fascia-traction theory shows that MTSS can be triggered by hyperactivity of the calf muscles and M. Flexor Digitorum Longus. An alternative concept is that MTSS is caused by hypo-activity of the calf muscles, which can be explained by the bone stress reaction theory. This theory describes that the recovery of bone is negatively affected by lack of muscle strength, which keeps the muscles from absorbing the bending forces. [11, 21, 22]

The impact that muscle activation might have on the predisposing and perpetuating factors, is an important motivator for the use of sEMG measurements. A recent prospective study of 2020 shows that soleus peak sEMG amplitude during propulsion is one of the predictors of MTSS. [21] This raises the question if any significant difference in sEMG activity of other muscles can be found between MTSS patients and controls. Another question is if insoles can influence this muscle activity and therefore change the prognosis.

Research objectives

This study was enabled by researchers of the Military Hospital Queen Astrid (MHQA) in Brussels.

As previously discussed, this topic is highly relevant for Defence, given that the refund cost is high and the morbidity of lower limb overuse injuries can cause a long time away from training and operational activities. Assessing the effectiveness of different insoles could help reduce this high clinical and financial burden.

As there is still no consensus on evidence based prescription of insoles, this study attempted to create more insight in and knowledge of the effect on patients with MTSS. The main goal included assessing the clinical effectiveness of different types of insoles in the management of MTSS.

In the present study, sEMG activity of lower limb muscles and pain disability index (PDI) were analysed. The obtained data was used for further statistical analysis to answer three questions.

- Is relative muscle activity during walking and three running speeds (10 km/h, 12 km/h, SSS) significantly different between patients and controls when no insoles are used?
- Is relative muscle activity within patients significantly different on three test moments (without insoles, with insoles just received and after eight weeks with insoles) during walking and three running speeds?
- Is there a significant difference in PDI score at the end vs the beginning of both eight-week intervention periods?

Methods

Participants/subjects

Subjects of the Outpatient's Clinic of the MHQA - Centre of Physical Medicine & Rehabilitation were screened on MTSS diagnosis. (table 1) After identification of MTSS the patients were subjected to the selection criteria. (table 2)

Table 1: diagnostic criteria

Criteria for diagnosis of MTSS
• Pain history: the pain is induced by exercise and lasts for a few hours or days after exercise. There is no history of paraesthesia or other symptoms indicative for other causes of exercise-induced leg pain. • Location: the subject identifies pain along the posteromedial border of the tibia. The site has to be spread over a minimum of 5 cm. Focal areas of only 2 to 3 cm are typical for stress fracture. • Palpation: palpation of the posteromedial border of the tibia produces discomfort that is diffuse in nature and confines to the posteromedial border of the tibia. In the areas of discomfort, the bone surface might feel uneven.

Table 2: selection criteria

Inclusion	**Exclusion**
• Male and female with age between 18 and 60 years • Report of a minimum of a three-month history of recurrent lower leg overuse injuries • Medical diagnosis of MTSS • Absence of other illnesses and complaints	• Pre-existing orthotic use • History of surgery to lower extremities and/or lumbar spine • Signs or symptoms suggestive of an acute injury • Consent withdrawal • Running distance of >32 km/week

Injury risk assessment

Participants who met the selection criteria were divided in groups according to the Risk Quantification based on Plantar Pressure Measurement. [15] This plantar pressure measurement was recorded by a plantar pressure plate (Footscan® RSscan International, Paal, Belgium). The subjects had to walk and run barefoot at a SSS across the track. RSscan Footscan system® 9.0 software was used for registration and analysis of time to peak pressure, peak pressure and impact. This temporal data was analysed by the direct three dimensional (D3D®) system to recommend the correction needed in the insole. When one to four corrections were needed, the participant belonged in the medium or high risk group and was included in the study. [23]

Along with the participant's agreement to the study protocol, inclusion was completed. Healthy subjects without a disturbed running/walking pattern were recruited to match as a control group. In this way injured people could be compared with matched healthy controls. This study was approved by the Ethics Committee of the University Hospital Brugmann in Brussels.

Experimental protocol

Materials - orthotic procedure

Four types of insoles were used: Phits® RS Print Custom 3D printed insoles made of ethylene-vinyl acetate (EVA) and polyurethane (Materialise Phits Suite zolen | Phits Insoles, Beringen, Belgium) [24]; BorgInsole® Custom made of EVA (BORGinsole, Rotselaar, Belgium) [25]; GesPodo® Custom made of EVA (GesPodo, Enghien, Belgium) [26] and Decathlon Aptonia Memory Foam® made of polyester foam (Decathlon, Villeneuve d'Ascq, France) [27].

The custom made insoles were manufactured after 3D measurement of the feet and an analysis of the foot pattern during walking and running. The main difference was the measurement position: Borg insoles were assessed while standing on the scanner; RSP insoles were measured while walking and running on a pressure plate and measurements for Gesp insoles were obtained with a 3D application while the participant was lying in a prone position.

Equipment

sEMG is a non-invasive technique that uses surface electrodes. This method made it possible to register the activity of different muscles during movement. The obtained kinetic data allowed a better understanding of the underlying mechanisms of overuse injuries during walking and running. A 16-channel TeleMyo Direct Transmission System (Noraxon Inc, Scottsdale, U.S.A) was used for wireless real time transmission of sEMG. [28] The muscle activity data were amplified with a 10 Hz bandwidth and sampled at 1024 Hz. Signals were digitized by a 12-bit A/D converter and stored on the disk of a personal computer.

Noraxon Myovideo is an integrated 2D high-speed video system that was used during the treadmill walking and running. The Noraxon MR3® software allowed integration of the recording of sEMG and 2D video data.

Testing procedure

Muscle activity of the M. Biceps Femoris (BF), M. Vastus Lateralis (VL) and Medialis (VM), M. Gastrocnemius Lateralis (GL) and Medialis (GM), M. Peroneus Longus (PL) and M. Tibialis Anterior (TA), was measured using sEMG. This sEMG was measured in both lower limbs.

The participant’s skin was carefully shaved, scrubbed and disinfected with alcohol to optimise impedance. The optimal electrode position was determined based on the recommendations according to Surface Electromyography for Non-Invasive Assessment of Muscles (SENIAM) [29]. SENIAM is a European research programme containing a number of guidelines for the selection of the type of electrodes, their location, muscle anatomy and functions, muscle group tests as well as signal processing and equipment conditions. [30] The silver/silver chloride electrodes (Ambu® Blue Sensor M, Ambu A/S, Ballerup, Denmark) with a diameter of two centimetres were attached with an inter-electrode interval of two centimetres parallel to the muscle fibre orientation. Using adhesive tape, the amplifiers were attached and the entire unit was wrapped with bandage gauze. Baseline activity was monitored when the foot was relaxed in a seated position. Measurement was only started when rest potential was less than ten microVolt (µV). Finally, the sEMG signal was verified with contraction of every muscle.

Maximum Voluntary Contraction (MVC) was performed for each muscle. The subject received a short explanation concerning the required movement of the corresponding muscle and was given the opportunity to perform a trial. The investigator verified that the movement was performed with the correct muscle in the proper planes. The MVCs were performed three times for five seconds with a rest period of fifteen seconds between each repetition. The start of the MVC’s measurement was determined by the researcher. As soon as he felt maximal resistance a marker was added to the sEMG recording. Verbal encouragement during maximal contractions was standardized.

Resistance to isometric contraction was given manually, opposite to the specific muscle function. The MVCs of the TA and the PL were executed in a supported long-sitting position with the knee supported on a cushion and the foot over the edge of the table. To test the MVC of GM and GL, the subject was lying in a prone position with both feet over the edge of the table. During this test protocol the manual resistance was applied on both shoulders while the subject was pushing the forefoot of the testing limb against the wall. (figure 1) In the same prone lying position, but with 45° knee flexion, the MVC of the BF was performed. The MVC of VM and VL was measured in supine lying with 20° of knee flexion. Resistance was given against knee extension.

Figure 1: MVC M. Gastrocnemius Medialis and Lateralis

Once all electrodes were attached and the MVCs were measured, the dynamic testing could begin. The dynamic measurements consisted of a walk-part at 4 km/h, a part with running self-selected speed (SSS) (6,5 km/h – 12 km/h) and a part with running at imposed speed of 10 km/h and 12 km/h on the treadmill. When the SSS was the same as the ones imposed, there was no extra recording. Consequently, some subjects had three record measurements instead of four.

During the first test moment, these measurements were done without insoles, with the first pair of insoles and with the second pair of insoles. Participants had the opportunity to adapt the insole when needed before the measurements with insoles started. The measurements were repeated with the first pair of insoles when the first intervention period was succeeded. After the second eight-week intervention with the next pair, the measurements were repeated again with these insoles. Each test moment the subject was requested to wear the same running shoes.

Intervention

The subjects were randomly assigned to two types of insoles. This caused various interventions among the experimental group. Combination of six insole couples resulted in twelve different conditions. (table 3)

Table 3: twelve insole couple conditions

Nr.	Condition (insole1/insole2)	N
1	RSP/Borg	4
2	RSP/Gesp	3
3	RSP/Deca	5
4	Borg/RSP	5
5	Gesp/RSP	3
6	Deca/RSP	4
7	Borg/Gesp	2 (+ dropout: 3)
8	Gesp/Borg	3
9	Borg/Deca	4
10	Deca/Borg	4
11	Gesp/Deca	3
12	Deca/Gesp	3

(Borg = BorgInsole® Custom; Deca = insoles Aptonia® Decathlon; Gesp = GesPodo® Custom; N = number; RSP = Phits® RS Print Custom 3D printed insoles)

Afterwards, the insoles were manufactured according to the measurement as previously described. (cfr. Materials - orthotic procedure) The initial eight-week intervention period with the first pair was set off. During these eight weeks the participants were encouraged to wear the insoles as frequently as possible in all types of shoes. This allowed sufficient adaptation to the walking and running pattern. This phase ended with a retest in which all data of the first insole were obtained.

Delivery of the second pair of insoles induced the start of the second phase with a similar course, including the retesting when the eight-week intervention ended.

The total duration of the procedure was about eighteen weeks.

Outcome measures

The Pain Disability Index (PDI) was used as an outcome parameter for pain and impact on life activities. (annex - figure 2) [31] Participants were asked to complete PDI at the start and end of each eight-week intervention period. These scores allowed the assessment of the evolution of complaints per insole pair. Furthermore this gave the opportunity to differentiate the effect that the first insoles might have had on the second intervention.

Besides the effect of the insoles on PDI, the effect on sEMG muscle activity was also analysed. The sEMG data of each muscle during walking and running was rescaled to the person's maximum capacity which allowed comparison between subjects. Furthermore this relative data created a better understanding of the neuromuscular effort of each muscle that is needed for the task.

Data analysis

Data collection

The variables are summarized per intervention period in Table 4 for both patient and control group. MVC and sEMG data were imported in Noraxon MR3 software. PDI scores were imported in an Excel Sheet.

Table 4: data collection

PATIENTS					
Variables	**Baseline**	**Intervention period 1**		**Intervention period 2**	
	No insole	**Pre-insole**	**Post-insole**	**Pre-insole**	**Post-insole**
MVC	BF/VL/VM/GL/GM/PL/TA	/	/	/	/
sEMG	Walking/running at different speeds: - 4 km/h - 10 km/h - 12 km/h - SSS	Walking/running at different speeds: - 4 km/h - 10 km/h - 12 km/h - SSS	Walking/running at different speeds: - 4 km/h - 10 km/h - 12 km/h - SSS	Walking/running at different speeds: - 4 km/h - 10 km/h - 12 km/h - SSS	Walking/running at different speeds: - 4 km/h - 10 km/h - 12 km/h - SSS
PDI	/	PDI score begin	PDI score end	PDI score begin	PDI score end
CONTROLS					
Variables	**Baseline**	**Intervention period 1**		**Intervention period 2**	
	No insole	**Pre-insole**	**Post-insole**	**Pre-insole**	**Post-insole**
MVC	BF/VL/VM/GL/GM/PL/TA	/	/	/	/
sEMG	Walking/running at different speeds: - 4 km/h - 10 km/h - 12 km/h - SSS	/	/	/	/
PDI	/	/	/	/	/

(/ = not applicable; BF = Musculus Biceps Femoris; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; km/h = kilometre per hour; MVC = Maximum Voluntary Contraction; sEMG = surface electromyography; PDI = Pain Disability Index; PL = Musculus Peroneus Longus; SSS = self-selected speed; TA = Musculus Tibialis Anterior; VL = Musculus Vastus Lateralis; VM = Musculus Vastus Medialis)

Data processing

The MVC data were indicated by three markers at the highest muscle activity. This raw EMG data was processed by smoothing and rectification of the signals. Rectification was applied to convert all negative amplitudes to positive amplitudes. Smoothing ensures the elimination or minimization of non-reproducible contents of the signal. [32] In this case the algorithm Root Mean Square (RMS) with a window of 100 milliseconds (ms) was used. After each marker an interval of three seconds was added so an objective sEMG value could be calculated by the software. The three MVC values were then imported in Excel and the average was calculated for each muscle.

sEMG data of the walking and running procedure was obtained for both legs distinctively. Five strides were analysed by dividing each stride into three moments: initial contact, stance phase and toe off. Initial contact was defined as the moment when the leg was fully extended and the heel had initial ground contact. Stance was defined by the swing leg crossing the stance leg, the moment two knees projected onto each other. The last moment, toe off, was determined by the last foot contact, which was characterized by the first metatarsophalangeal joint standing in neutral position. Marker placement was based on these three moments, which resulted in separation of gait into three phases. Front swing phase (FSP) was defined from toe off to initial contact. Stance phase (SP) started from initial contact and ended with stance. Lastly the back swing phase (BSP) was determined from stance until toe off.

The data were processed by rectification, smoothing and filtering. A Butterworth IIR bidirectional high pass filter at 20 Hz was used. This procedure resulted in fifteen values for each muscle, representing the means of each phase. Five mean values per phase were imported into Excel. These values were then presented as a percentage of the MVC values to obtain relative sEMG data.

Statistical analysis

Statistical Package for Social Science (SPSS) IBM version 27 was used.
The average EMG activity of the five repetitions was calculated for each muscle and each phase and was used for further statistical analysis. Data distribution was evaluated with boxplots to detect outliers. These were defined as values equalling more than 1,5 times the interquartile range under or above the 25th and 75th percentiles respectively. To avoid too much data loss, all five repetitions were reviewed when such an outlier was detected. When only one or two outliers were found in the five repetitions for one muscle, these were deleted and the rest of the data was used to calculate the mean value. When all five values were extremely high or low, these were deleted and labelled as missing values.

To allow structured and clear comparison it was decided to take only the pathological side into account during analysis. Bilateral complaints occurred in 31 patients. In this case, randomisation decided which side was selected for analysis. The selected sides are presented in Table 5.

Table 5: side distribution for analysis

	Patient group	**Control group**
Right leg	20	21
Left leg	23	21

The statistical analysis started with distribution evaluation, for which the One-Sample Kolmogorov-Smirnov test was used. This test showed that the data was not normally distributed, which implied the use of non-parametric tests.

The Mann-Whitney-U test was used for the comparison of the relative muscle activity without insoles between patients and controls. The alpha value was predetermined at 0.05. All data descriptives were expressed using median, percentiles and interquartile range.

In the second analysis, relative muscle activity during walking and running within the patient population was compared for three different moments: without insoles (baseline), when the insoles were just received (pre-insole test) and after eight weeks of wearing the insoles (post-insole test). To check if there was any significance between the three test moments, the Friedman test was used. When significant p value was obtained, the post-hoc tests checked where the difference was located. Wilcoxon Signed Ranks test served as post-hoc and was executed three times. This allowed comparison between first and second; second and third; and first and third test moments. The Bonferroni correction was performed on the values obtained after the Wilcoxon test. This implied a modification of the alpha value to 0.0167, calculated by the formula: original alpha value/number of pairwise tests.

Third analysis was done for PDI. Wilcoxon Signed Ranks test was used for the questions beneath.
The first objective of this analysis was to check if the first pair of insoles had influence on the PDI score of the second intervention period. When the first insoles had a significant effect on PDI scores, this would bias the treatment effect of the next intervention. The following step was to analyse the effect of both interventions on the PDI scores at the end vs beginning of the eight-week intervention period. Lastly, these two effects were compared to see if one would be significantly larger than another.

Results

Initially, 43 patients were included in the study. During analysis one subject was considered as dropout due to aberrant data. As previously mentioned some outliers were excluded as well.
The analysis started by looking into patient-control differences. The descriptive data of both patient and control group is represented in Table 13 and 14.
Each participant was assigned to different insole conditions which resulted in participants being part of different subgroups. (table 3) This diminished the intervention duration as not every participant needed to wear all four insoles. The descriptive data for each subgroup is given in Table 15-18. As can be seen, the group characteristics differed due to the limited number of total participants and therefore the limited number submitted to each subgroup. This made comparison of the different groups impossible.

The results of the first analysis that looked at the difference between patient vs control group can be consulted in Table 6. The significant results of the second analysis looking at muscle activity at three moments is presented per insole in Table 7-10. In annex the more detailed data can be consulted. (table 20-23) Lastly, the results of the PDI are presented in Table 11-12. The PDI scores were manually compared per patient per insole in the discussion. The tables of this comparison can be consulted in annex. (table 24-27)

Relative muscle activity without insoles in patients versus controls

In the table beneath the significant results per muscle, per phase, per speed are listed. This shows that the relative muscle activity of patients was mostly significantly lower than in controls.

For an extra overview of these significant differences with the medians and interquartile ranges, a more detailed table was added in annex. (table 19)

Table 6: significant differences in relative muscle activity in patient group vs control group

Phase	Muscle	Relative muscle activity	P value (Mann-Whitney U)
Walking			
FSP	PL	P < C	0.025
BSP	BF	P < C	0.035
Running 10 km/h			
FSP	GM	P < C	0.004
Running 12 km/h			
FSP	VL	P < C	0.019
FSP	GL	P < C	0.047
FSP	GM	P < C	0.006
FSP	TA	P > C	0.003
BSP	BF	P < C	0.002
Running SSS			
SP	VL	P < C	0.047
SP	GL	P < C	0.017
BSP	BF	P < C	0.018
BSP	GL	P < C	0.046

(BF = Musculus Biceps Femoris; BSP = Back Swing Phase; C = control group; FSP = Front Swing Phase; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; km/h = kilometre per hour; P = patient group; PL = Musculus Peroneus Longus; SP = Stance Phase; SSS = self-selected speed; TA = Musculus Tibialis Anterior; VL = Musculus Vastus Lateralis)

Relative muscle activity in patients for each type of insole

Deca

During walking there was a significantly higher relative muscle activity during the SP at the baseline testing for the GM (p<0.001), PL (p=0.002) and TA (p=0.01) compared to pre-insole. The values of the post-insole testing in TA (p=0.002) and PL (p=0.01) were higher than during pre-insole tests.

Apart from the test at 10 km/h, the TA showed significantly lower relative muscle activity at pre-insole test compared to baseline or post-insole during all walking and running tests. This occurred in different phases.

The test of running at 12 km/h showed that the values of GL (p=0.003) and TA (p=0.013) significantly differed between baseline and post-insole. The analysis showed a significantly higher baseline value for GL in the SP; the opposite was seen for TA in the BSP.

Table 7: significant differences in relative muscle activity at T1 vs T2 vs T3 - Deca

DECA						
Phase	**Muscle**	**P value (Friedman)**	**Relative muscle activity**	**P value (Wilcoxon)**		
				T1 vs T2	T1 vs T3	T2 vs T3
Walking						
SP	GL	0.047	/	0.03	0.163	0.756
SP	GM	0.003	T1 > T2	<0.001	0.55	0.079
SP	PL	0.007	T1 > T2, T3 > T2	0.002	0.212	0.01
SP	TA	<0.001	T1 > T2, T3 > T2	0.01	0.021	0.002
Running 10 km/h						
FSP	BF	0.024	/	0.1	0.059	0.145
SP	VM	0.011	/	0.37	0.02	0.055
BSP	TA	0.047	/	0.783	0.067	0.1
Running 12 km/h						
SP	BF	0.039	/	0.024	0.379	0.179
SP	GL	0.004	T1 > T3	0.064	0.003	0.061
BSP	TA	0.007	T3 > T1, T3 > T2	0.243	0.013	0.007
Running SSS						
FSP	TA	0.008	T1 > T2	0.013	0.852	0.135
BSP	VM	0.028	/	0.334	0.841	0.149

(BF = Musculus Biceps Femoris; BSP = Back Swing Phase; Deca = insole Aptonia® Decathlon; FSP = Front Swing Phase; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; km/h = kilometre per hour; PL = Musculus Peroneus Longus; SP = Stance Phase; SSS = self-selected speed; T1 = test moment without insoles; T2 = test moment when the insoles were just received; T3 = test moment after eight weeks of wearing the insoles; TA = Musculus Tibialis anterior; VM = Musculus Vastus medialis)

Borg

The post-insole test showed significantly higher values when compared to pre-insole tests for some muscles at different speeds and different phases ($p<0.0167$). This difference was seen during the BSP of VM at 10 km/h ($p=0.005$) and at SSS ($p=0.002$), as well as in GM during the SP when walking ($p=0.016$). TA showed a decrease of muscle activity during the FSP at SSS at pre-insole test compared to baseline testing ($p=0.008$).

Table 8: significant differences in relative muscle activity at T1 vs T2 vs T3 - Borg

BORG						
Phase	**Muscle**	**P value (Friedman)**	**Relative muscle activity**	**P value (Wilcoxon)**		
				T1 vs T2	T1 vs T3	T2 vs T3
Walking						
SP	GL	0.047	/	0.04	0.163	0.831
SP	GM	0.037	T3 > T2	0.026	0.876	0.016
SP	PL	0.013	/	0.445	0.305	0.019
Running 10 km/h						
SP	PL	0.041	/	0.077	0.131	0.149
BSP	TA	0.043	/	0.053	0.247	0.794
BSP	VM	0.047	T3 > T2	0.247	0.062	0.005
Running 12 km/h						
FSP	TA	0.016	/	0.048	0.136	0.852
SP	GL	0.025	/	0.053	0.177	0.679
Running SSS						
FSP	TA	0.031	T1 > T2	0.008	0.322	0.274
BSP	VM	0.012	T3 > T2	0.058	0.376	0.002

(Borg = BorgInsole® Custom; BSP = Back Swing Phase; FSP = Front Swing Phase; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; km/h = kilometre per hour; PL = Musculus Peroneus Longus; SP = Stance Phase; SSS = self-selected speed; T1 = test moment without insoles; T2 = test moment when the insoles were just received; T3 = test moment after eight weeks of wearing the insoles; TA = Musculus Tibialis Anterior; VM = Musculus Vastus Medialis)

Gesp

During walking there was a significant higher relative muscle activity of GL (p=0.003), GM (p=0.001) and TA (p=0.006) during the SP at baseline compared to pre-insole. The TA also showed a higher activity at post-insole compared to pre-insole (p=0.001).

The GL showed a higher pre-insole than post-insole value during the SP in the 12km/h test protocol (p=0.006). During the BSP of the running test at SSS, PL had a significantly higher baseline than pre-insole value (p=0.015).

Table 9: significant differences in relative muscle activity at T1 vs T2 vs T3 - Gesp

GESP						
Phase	**Muscle**	**P value (Friedman)**	**Relative muscle activity**	**P value (Wilcoxon)**		
				T1 vs T2	T1 vs T3	T2 vs T3
Walking						
SP	GL	0.015	T1 > T2	0.003	0.163	0.039
SP	GM	0.002	T1 > T2	0.001	0.023	0.82
SP	TA	0.001	T1 > T2, T3 > T2	0.006	0.438	0.001
BSP	PL	0.022	/	0.408	0.023	0.088
Running 10 km/h						
SP	GL	0.014	/	0.113	0.017	0.163
BSP	VL	0.038	/	0.733	0.026	0.078
Running 12 km/h						
SP	BF	0.022	/	0.069	0.278	0.061
SP	GL	0.015	T2 > T3	0.281	0.02	0.006
Running SSS						
FSP	VL	0.028	/	0.039	0.717	0.148
BSP	PL	0.039	T1 > T2	0.015	0.796	0.102

(BF = Musculus Biceps Femoris; BSP = Back Swing Phase; FSP = Front Swing Phase; Gesp = insole GesPodo® Custom; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; km/h = kilometre per hour; PL = Musculus Peroneus Longus; SP = Stance Phase; SSS = self-selected speed; T1 = test moment without insoles; T2 = test moment when the insoles were just received; T3 = test moment after eight weeks of wearing the insoles; TA = Musculus Tibialis Anterior; VL = Musculus Vastus Lateralis)

RSP

In walking condition, PL had significantly higher muscle activity at post-insole compared to pre-insole during the FSP (p=0.004). The GL (p=0.002) and GM (p<0.001) showed significantly lower muscle activity at baseline than at pre-insole test during the SP. During the BSP the VM showed a higher activity post-insole when compared to baseline (p=0.008). The PL showed a higher muscle activity post-insole vs pre-insole during the BSP (p=0.007).

The relative muscle activity of TA was higher at baseline than at pre-insole test in BSP at 10 km/h (p=0.006) and also at SSS (p=0.012).

Table 10: significant differences in relative muscle activity at T1 vs T2 vs T3 - RSP

RSP						
Phase	**Muscle**	**P value (Friedman)**	**Relative muscle value**	**P value (Wilcoxon)**		
				T1 vs T2	T1 vs T3	T2 vs T3
Walking						
FSP	PL	0.001	T3 > T2	0.03	0.04	0.004
SP	GL	0.011	T1 > T2	0.002	0.145	0.433
SP	GM	0.002	T1 > T2	<0.001	0.048	0.433
SP	PL	0.004	/	0.007	0.398	0.573
BSP	TA	0.047	/	0.017	0.737	0.017
BSP	VM	0.006	T3 > T1	0.506	0.008	0.058
BSP	PL	0.004	T3 > T2	0.039	0.26	0.007
Running 10 km/h						
BSP	TA	0.022	T1 > T2	0.006	0.765	0.247
Running 12 km/h						
FSP	VL	0.03	/	0.654	0.022	0.199
BSP	PL	0.03	/	0.629	0.363	0.017
BSP	VM	0.047	/	0.126	0.133	0.071
Running SSS						
SP	VL	0.029	/	0.548	0.07	0.036
BSP	TA	0.019	T1 > T2	0.012	0.794	0.04
BSP	VM	0.034	/	0.17	0.421	0.025

(BSP = Back Swing Phase; FSP = Front Swing Phase; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; PL = Musculus Peroneus Longus; km/h = kilometre per hour; RSP = Phits® RS Print Custom 3D printed insoles; SP = Stance Phase; SSS = self-selected speed; T1 = test moment without insoles; T2 = test moment when the insoles were just received; T3 = test moment after eight weeks of wearing the insoles; TA = Musculus Tibialis Anterior; VL = Musculus Vastus Lateralis; VM = Musculus Vastus Medialis)

PDI

The PDI at the start of the second intervention period was significantly lower than the PDI at the start of the first intervention period (p=0.025). When the PDI scores at the end of the eight-week intervention were compared with the PDI scores at the beginning, neither the first (p=0.083) nor the second (p=0.320) pair of insoles caused a significant difference. The changes that did occur in the PDI score were not significantly different between the two intervention periods (p=0.244).

Table 11: descriptives PDI

Variable	N	Median	Q1 - Q3
PDI score begin 1	36	8.5	3.3 - 12.0
PDI score end 1	34	4.0	0.0 - 7.0
DifPDI_Insole1	34	-2.5	- 8.0 - 0.3
PDI score begin 2	27	6.0	0.0 – 14.0
PDI score end 2	23	2.0	0.0 – 4.0
DifPDI_Insole2	23	0.0	- 12.0 – 0.0

(DifPDI_Insole1 = PDI end - PDI begin of intervention period 1; DifPDI_Insole2 = PDI end - PDI begin of intervention period 2; N = number; PDI = Pain Disability Index; Q1 = first quartile; Q3 = third quartile)

Table 12: significant differences in PDI variables

Comparison		P value (Wilcoxon)
Variable 1	Variable 2	
PDI score begin 1	PDI score begin 2	0.025
DifPDI_Insole1	DifPDI_Insole2	0.244
PDI score end 1	PDI score begin 1	0.083
PDI score end 2	PDI score begin 2	0.320

(DifPDI_Insole1 = PDI end - PDI begin of intervention period 1; PDI = Pain Disability Index)

Discussion

Result clarification

The purpose of this study was to examine the effect of different types of insoles in military personnel with MTSS. In order to do so, three hypotheses were stated. The questions behind the three hypotheses were restated and discussed below.

Patient vs control

Before the effect of different types of insoles could be analysed, the first question that arose was whether the relative muscle activity would be significantly different between patient and control groups. This muscle activity was analysed at walking speed and at the three running speeds.

After examining the patient and control group, almost all significant differences showed a lower relative muscle activity in the patient group. This means that the military personnel with MTSS in this study showed hypoactivity of some muscles. Whether this hypoactivity is cause and/or effect in MTSS is still unclear. However the most remarkable differences and those that seemed to be clinically relevant will be discussed.

Significant decreased activity in patients was seen in BF during the BSP at the speed of 4 km/h, 12 km/h and SSS. Although not significant, the control group had a higher BF activity at 10 km/h as well. The question that arises in this case is whether there is clinical relevance of these small differences in MTSS.

Although following differences were only found significant during one velocity, they might be relevant in the pathogenesis of MTSS. Patients showed a lower relative VL activity during the FSP than the control group when running at 12 km/h. The M. Quadriceps (Q) has an important role in shock absorption through its function of eccentric control. [33] Hypoactivity could lead to less shock absorption, which might be an important issue when looking at the bone stress reaction theory in the pathogenesis of MTSS. [21, 22] During SSS, a lower relative muscle activity was seen for GL in both the SP and the BSP. The M. Gastrocnemius (G) has an important role during unipodal stance and during the active heel lift right before toe off, so hypoactivity during these two phases might be important to consider. [33] However, both hyper- and hypoactivity of the calf muscles are described in the pathogenesis, so the exact mechanisms of G activity in developing and perpetuating MTSS could be a question for further research.

The TA was the only muscle with significantly higher activity in the patient group. The relevance of this phenomenon should be considered carefully as the hyperactivity was only seen when running at 12 km/h and only during the FSP. This muscle is known to be important during this phase in order to keep the foot in dorsiflexion. The explanation why patients show a higher activity is yet to be researched.

Analysis within patient group per insole

The second question that was explored was whether the relative muscle activity within patients significantly differed on the three test moments (baseline, pre-insole and post-insole) during walking and the three running speeds. Differences, ought to be clinically relevant, were discussed below.

Deca

It was remarkable that all significant effects at walking speed occurred during the SP. To understand this, the biomechanical background of the SP should be exploited. The SP is initiated by the heel making contact to the ground. The ground reaction force induces a plantar flexion moment, resulting in the ankle to range from dorsiflexion to relative plantar flexion. [34] During heel contact the joint forms a rigid lever, supporting absorption of the impact and transfer of these forces upward the kinetic chain in an energy sustainable way. This initial contact requires activity of TA, M. Extensor Digitorum Longus and M. Extensor Hallucis Longus. [35] During the SP the ankle evolves from a rigid lever to a more loose packed position which allows reduction of impact and adaptation to the underground. [36] In the beginning of the BSP the patient is in a single leg position, which demands a stable ankle joint. This stability is partly acquired by the GM and GL.

Although Deca was the only prefabricated insole used, it did not show less significant results. Patients showed a significant decrease in PL activity during pre-insole test compared to baseline test, nevertheless the activity significantly increased with 12% post-insole vs pre-insole. The GM showed a similar trend, despite having only significant differences between baseline and pre-insole tests. During the SP these muscles play an important role in the stabilisation of the ankle joint. The results in this study suggest that Deca insoles might have an enhancing effect on the muscle recruitment of the G and PL.

At the speed of 10 km/h no statistical significance was found, however the seen differences might be of clinical value. The VM activity decreased by almost 20% during the SP at baseline compared to post-insole. This lowered activity might add to a heightened force impact on the limb, hence an increase in odds to the bone stress reaction theory.

Additionally, the GL had a significant decrease of 70% post-insole compared to baseline during the SP at 12 km/h. The GL is an important muscle during the SP because it provides eccentric deceleration of dorsiflexion and during unipodal stance**.** Hypo-activity of the G has an influence in the bone stress reaction theory. In this case it is questionable that a decrease in muscle activity will have a positive effect on the MTSS complaints. When looking at the tibia fascia-traction theory, in which hyperactivity of the G is mentioned to be a predisposing factor, this decrease could have positive effects.

The TA activity increased with 15% post-insole vs baseline during the BSP. In literature the last part of this phase shows preparation of the TA for foot control. (figure 4) [35] The increased input of the TA post-insole implies the support of Deca insoles in muscle activation. This effect did not occur immediately upon wearing the insoles, but only after habituation to the insoles for eight weeks.

Borg

In the results a greater muscle activity of the PL at post-insole test versus baseline was observed in the SP during both walking speed and 10 km/h. Together with other plantar flexors the function of the PL in the SP is deceleration of the foot dorsiflexion. It could be questioned if this increased muscle activity influences the contribution of PL's synergists and what the effect on MTSS is.

Nevertheless the PL has an important role in initiating supination, which contributes to decrease the navicular drop. As an increased navicular drop is a risk factor for developing MTSS, the change in PL activity could be considered clinically relevant.

During the FSP the TA has an important contribution to keep the foot in dorsiflexion for foot clearance and to prepare for heel contact. This muscle showed inconsistent differences between baseline test and/or pre- and post-insole tests both when running at 12 km/h and at SSS.

Gesp

The G has its role both during the SP and the BSP. A contribution of the G is needed during the BSP to actively lift the heel. During the SP, the G also has an eccentric function when body weight is transferred anteriorly.

At walking speed, both GL and GM showed a significantly lower relative muscle activity at pre-insole test compared to baseline. Post-insole test also revealed a lower relative activity compared to baseline activity, but this difference was not significant. This non-significant difference was also seen when running at 10 km/h and running at 12 km/h. At 12 km/h there was a significant decrease when comparing post-insole with pre-insole.

As the G is mentioned to be involved in the pathogenesis of MTSS, these differences could be important. However both hyperactivity and hypo-activity are mentioned in the tibia fascia-traction theory and the bone stress reaction theory respectively. Therefore it cannot be concluded what effect this lowered relative muscle activity with insoles has on the injury. [21]

During the SP of walking, the TA showed a significant difference at baseline vs pre-insole and at pre-insole vs post-insole. Both differences were approximately 1% with the lowest relative muscle activity at pre-insole test in both comparisons. Although the TA has an important role during the SP in controlling the plantar flexion after heel contact, the question whether this difference is clinically relevant could be asked. [34]

RSP

This insole showed a lot of significant differences in the relative muscle activity of various muscles in various phases of the gait cycle. However, these differences were often too little to be clinically relevant.

Significant differences were found for GL and GM during the SP at walking speed. The pre-insole test showed lower activity than the baseline test. These differences were also seen in the Gesp insole group and were discussed above.

PDI

Finally the third topic that was researched included several questions concerning the PDI scores.
The PDI score at the start of the second intervention was significantly lower than at the start of the first intervention. This could mean that the first pair of insoles had an effect on the PDI score of the second intervention period. However, the PDI data at the start of the second intervention period was only obtained from 27 patients, so this should be interpreted carefully. The PDI data at the start of the first intervention period was not complete either.
Furthermore there was no significant difference in the PDI change between the end and the beginning of neither the first nor the second intervention period. The change that did occur during the intervention periods, did not significantly differ from one another. Therefore the significant effect that the first pair of insoles had on the PDI score of the second intervention period is supposed to be rather small.
The individual scores at the end and beginning of the eight-week period were manually compared to see if there was any clinical effect of the insoles on the PDI.
The first intervention period showed a trend among Borg and Gesp insoles. A positive evolution of PDI was seen in 63.64% of the subjects with Borg intervention. Among the participants who were assigned to Gesp insole, 66.67% showed an improvement in PDI scores. This suggests that these insoles might have a positive effect on the PDI for some patients.
The second intervention period had too many missing values, as a consequence it was impossible to deduce a conclusion. (table 24-27)

Strengths and limitations

Testing and intervention

One of the strengths of this study was that it looked at the impact of insoles at different speeds rather than selecting one speed. [38] Using SSS was a good choice as this enhances natural biomechanics in each subject. An intervention period of eight weeks gave the body adequate time to adapt to the insoles. In literature a period of six to eight weeks is often mentioned to achieve neuromuscular and proprioceptive adaptations, although there is no clear explanation stated. [39, 40, 41]

One could consider that sEMG might not be the most exact measurement tool as a lot of influential factors are known such as subcutaneous fat tissue, the skin type, the temperature of the lab environment, movement artifacts etc. Artifacts were countered by various strategies like thorough preparation of the skin, fixation of the electrodes, filter application, normalisation to MVC etc. However the crossover electromyography (EMG) of surrounding muscles could not be ruled out. [32] Needle and fine wire EMG are more accurate methods, but these are not preferable as they are painful for the subjects. Especially in functional movement, this can be restrictive and interrupt normal gait. Furthermore sEMG gives a more global representation of the muscle activity, whereas needle and fine wire EMG only show activity of a small part of the muscle. [42]

Since many variables can influence sEMG measurement, MVC data should be obtained at every test moment in order to calculate objective relative sEMG muscle activity. In this study, the MVCs were only measured at the first test moment. Relative data of the post-insole tests could therefore be aberrant.

Furthermore, the MVC data should be appraised critically as supramaximal EMG data was seen in the results. This aberration can be explained by various factors. First, valid MVC data can only be produced with healthy subjects who were trained for MVC test series. An additional training of the subjects would have made the testing protocol too long. Secondly, different muscle length during the MVC testing protocol vs the walking and running protocol might have had an influence on the percentages. Lastly, there might occur motor unit synchronization and an increased electrical superposition within submaximal movements as these are performed over a longer period of time. [32]

The study of Naderi et al. has shown that M. Soleus hyperactivity might be a cause of MTSS. [21] Furthermore the M. Flexor Digitorum Longus was not included in this study, even though research suggests these muscles could have an influence on developing MTSS. [11] These muscles were not included in this study as the 16-channel TeleMyo Direct Transmisson System could only capture eight muscles bilaterally. More superficial muscles were chosen to be analysed.

One could question the relevance of analysing muscle activity without considering kinematics. Kinematics, e.g. hip stability, overstriding, cadence etc., often play an important role in the development of running injuries. Insoles might influence some of these kinematic parameters in a positive way. Nevertheless the complaints may shift to other areas when the insole causes a change in movement and posture. Although the VM, VL and BF might not seem closely related to MTSS, these were analysed because of their importance in the kinematics and the kinetic chain.

Muscle activity is dependent on gait pattern and this will be different in each individual. [43] Furthermore custom-made insoles are designed for the individual biomechanical needs. This individuality in gait pattern and the custom made insoles make it hard to draw conclusions about the general effect of one brand of insoles, as the biomechanics and muscle activity will be influenced in a different way.

When observing the PDI, this might not have been the most relevant tool to use in this research protocol. This questionnaire focuses on the influence of pain symptoms in different daily activities. It is questionable if MTSS has a highly aggravating impact on e.g. self-care, family responsibilities, sexual behaviour or life-support activities. Compliance, pain and comfort were not questioned, which are important outcome parameters to evaluate insoles. [39] To measure specifically the pain, the VAS score could be an alternative for future research. Another scale that might be useful to determine the functional interruption is the Foot and Ankle Disability Index (FADI) Score and Sports Module. (figure 5) [37]. In addition the MTSS score could be used to evaluate the severity of the complaints. (figure 6) [8, 44]

Lastly, during this study it was opted that all participants who met the inclusion criteria tested two types of insoles. This led to restraints during analysis of the results. The limited number of participants caused small sample sizes, which brought about group descriptives that did not match. The differences between groups constricted the comparison between insoles.
Testing all four insoles would have created a more complete and profound insight. Unfortunately, this was not possible due to the high cost, lack of participants and prolonged duration of the study. The Deca insole, which was the only prefabricated insole, could have been used as control if comparison of the four insoles was possible.

Data analysis

During the analysis of the sEMG and video footage, some problems were encountered. The measurements were not always registered correctly, some values were extremely high and for some patients recordings were missing. These defaults can be attributed to an altered contact of the electrodes. As a consequence some data was lost and had to be labelled as a missing value.

Result interpretation

The method used to obtain the different phases caused some difficulties in interpretation. The key moments of gait were chosen as markers. As a consequence the relevant muscle activity could not be assigned to one phase only. For example initial contact was both the end point of the FSP and the beginning of the SP.

The gait cycle is often differently divided in the literature than in this study. Most frequently the stance phase and the swing phase are described as the main subphases. The stance phase is further separated in contact, midstance and propulsion phase. In this study the stance phase was subdivided in only two phases, SP and BSP, instead of three. The FSP, as previously described, equals three subphases reported in literature - initial, mid and terminal swing. (figure 7) [36] Therefore comparing the muscle activity in this study with findings of other research was difficult.

The expertise of the researchers is another limitation in the result interpretation. Although physiotherapy students are well equipped with knowledge of gait, kinetic chain and muscle recruitment, there is lacking expertise about insoles and the effect on the kinetic chain.

Level of evidence

B2

Conclusion

Relative muscle activity and PDI were analysed for four types of insoles. All four showed some significant differences in relative muscle activity. Nevertheless these did not show consistency in muscle, gait phase or velocity. For every pair of insoles, some positive effects were noted. However it was impossible to draw a generalised conclusion for the use of insoles in the treatment of MTSS. On a global level the insoles did not have a significant positive effect on the PDI scores. When appraised individually, some patients did seem to benefit from insoles. However the sample size with complete PDI data was too small to draw meaningful conclusions.

Researchers concluded that insole therapy might not be recommended as sole therapy. Nevertheless, insoles could be combined with other treatment options such as exercise therapy, manual techniques, compression stockings etc. Considering the pathogenesis, selective muscle training of weaker muscles and/or relaxing techniques for tensed muscles could be of added value in treating MTSS. Further research is needed in order to support this.

Disclosure statement

The authors report no conflict of interest.

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Abstract in layman's terms

Achtergrond: Scheenbeenvliesontsteking is een veelvoorkomend overbelastingsletsel. Spieractiviteit heeft in de verklaringen voor het ontstaan telkens een andere rol. Zolen zouden een positief effect kunnen hebben op de klachten van dit letsel en op het financiële plaatje.

Doelstellingen: Het doel van deze studie was om te onderzoeken of verschillende zolen een effect hebben op spieractiviteit en de scores op vragenlijsten.

Methode: Deze studie van het Militair Ziekenhuis Koningin Astrid bevatte 43 patiënten en 42 gezonde personen. De patiënten droegen elk twee zolen voor een periode van telkens acht weken. Vier verschillende zolen werden gebruikt. De spieractiviteit van verschillende kuit- en dijspieren werd gemeten tijdens wandelen en lopen. In het begin en op het einde van de behandelperiode werd telkens een vragenlijst afgenomen in verband met pijn.

Resultaten: Uit het onderzoek bleek dat de spieractiviteit zonder zool bij patiënten lager is dan deze bij gezonde personen. Daarnaast werden enkele belangrijke spieren in het ontstaan van scheenbeenvliesontsteking het meest beïnvloed door zolen bij patiënten. In de vragenlijst was er geen verschil te zien tussen de scores.

Conclusie: Ongeacht de bekomen resultaten, was het niet mogelijk om een algemene conclusie te trekken over de invloed van de zolen op spieractiviteit.

Trefwoorden*: zolen-spieractiviteit-militair personeel-scheenbeenvliesontsteking-observationele studie*

Ethics committee

C H U - U V C
B R U G M A N N

Réf. : CE 2017/54

COMITE D'ETHIQUE HOSPITALIER
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Secrétariat
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Mr Eric Bernard

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14/03/2017

Cher Mr Bernard,

Concerne :
Influence of dynamic orthotic devices on lower limb overuse injuries of the military personnel.
B077201731826

Le Comité d'Ethique Hospitalier du C.H.U. BRUGMANN a pris connaissance du protocole d'étude dont l'intitulé est repris sous rubrique.

Formulaire de demande interne
Protocole
Document d'information et de consentement éclairé
CV Damien Van Tiggelen – Eric Bernard

Le comité d'éthique marque son accord.

Nous vous prions de croire, Monsieur, en l'assurance de nos sentiments les meilleurs.

Docteur P. VERBANCK,
Secrétaire

Docteur J. VALSAMIS,
Président

Le Comité d'Ethique rappelle que les amendements substantiels et les notifications de sécurité, comme décrites dans la loi du 7 mai 2004, doivent lui être soumis.

Annex

Tables

Table 13: descriptive data patient group

Variable	N	Minimum	Maximum	Mean	Std. Deviation
Age (years)	43	18	46	24.5	6.56
Length (m)	43	1.55	1.91	1.749	0.0900
Weight (kg)	43	55	97	71.4	9.72
BMI (kg/m^2)	43	19.59	32.05	23.338	2.7623
SSS (km/h)	43	7.0	11.5	8.68	1.160
DifPDI_Insole1	34	-17	24	-1.9	8.67
DifPDI_Insole2	23	-22	19	-2.2	9.55
Female	15				
Male	28				

(BMI = Body Mass Index; DiffPDI_insole1 = PDI end - PDI begin of intervention period 1; DiffPDI_insole2 = PDI end - PDI begin of intervention period 2; kg = kilogram; km/h = kilometre per hour; m = metre; m^2 = square metre; N = number; PDI = Pain Disability Index; SSS = self-selected speed; Std. = standard)

Table 14: descriptive data control group

Variable	N	Minimum	Maximum	Mean	Std. Deviation
Age (years)	42	18	50	28.1	8.40
Length (m)	42	1.53	1.92	1.725	0.0979
Weight (kg)	42	50	100	69.3	11.48
BMI (kg/m^2)	42	19.43	28.39	22.460	2.1795
SSS (km/h)	42	7.0	15.0	9.68	1.452
Female	15				
Male	27				

(BMI = Body Mass Index; kg = kilogram; km/h = kilometre per hour; m = metre; m^2 = square metre; N = number; PDI = Pain Disability Index; SSS = self-selected speed; Std. = standard)

Table 15: descriptive data Deca group

Variable	N	Minimum	Maximum	Mean	Std. Deviation
Age (years)	22	18	40	24.6	6.15
Length (m)	22	1.55	1.90	0.736	0.0931
Weight (kg)	22	58	88	71.0	8.13
BMI (kg/m^2)	22	20.24	32.05	23.648	3.1503
SSS (km/h)	22	7.0	10.5	8.43	1.072
DifPDI_Deca	15	-10	17	1.8	7.08
Female	10				
Male	12				

(BMI = Body Mass Index; Deca = insole Aptonia® Decathlon; DiffPDI_Deca = PDI end - PDI begin of Deca intervention; kg = kilogram; km/h = kilometre per hour; m = metre; m^2 = square metre; N = number; PDI = Pain Disability Index; SSS = self-selected speed; Std. = standard)

Table 16: descriptive data Borg group

Variable	N	Minimum	Maximum	Mean	Std. Deviation
Age (years)	23	18	46	22.9	6.43
Length (m)	23	1.59	1.89	1.741	0.0845
Weight (kg)	23	55	90	70.0	7.69
BMI (kg/m²)	23	20.38	28.34	23.109	1.9699
SSS (km/h)	23	7.0	10.0	8.42	1.011
DifPDI_Borg	15	-17	12	-4.1	8.78
Female	7				
Male	16				

(BMI = Body Mass Index; Borg = BorgInsole® Custom; DiffPDI_Borg = PDI end - PDI begin of Borg intervention; kg = kilogram; km/h = kilometre per hour; m = metre; m² = square metre; N = number; PDI = Pain Disability Index; SSS = self-selected speed; Std. = standard deviation)

Table 17: descriptive data Gesp group

Variable	N	Minimum	Maximum	Mean	Std. Deviation
Age (years)	17	19	36	25.6	5.43
Length (m)	17	1.55	1.91	1.762	0.1041
Weight (kg)	17	57	97	74.1	12.51
BMI (kg/m²)	17	19.59	32.05	23.915	3.8604
SSS (km/h)	17	7.0	11.5	9.00	1.250
DifPDI_Gesp	11	-9	19	-0.4	8.18
Female	7				
Male	10				

(BMI = Body Mass Index; DiffPDI_Gesp = PDI end - PDI begin of Gesp intervention; Gesp = insole GesPodo® Custom; kg = kilogram; km/h = kilometre per hour; m = metre; m² = square metre; N = number; PDI = Pain Disability Index; SSS = self-selected speed; Std. = standard deviation)

Table 18: descriptive data RSP group

Variable	N	Minimum	Maximum	Mean	Std. Deviation
Age (years)	23	18	46	25.6	7.59
Length (m)	23	1.59	1.91	1.761	0.0839
Weight (kg)	23	55	97	71.2	10.77
BMI (kg/m²)	23	19.59	27.77	22.849	2.0697
SSS (km/h)	23	7.0	11.5	9.01	1.195
DifPDI_RSP	15	-15	24	-3.7	9.60
Female	5				
Male	18				

(BMI = Body Mass Index; DiffPDI_RSP = PDI end - PDI begin of RSP intervention; kg = kilogram; km/h = kilometre per hour; m = metre; m² = square metre; N = number; PDI = Pain Disability Index; RSP = Phits® RS Print Custom 3D printed insoles; SSS = self-selected speed; Std. = standard deviation)

Table 19: significant differences in relative muscle activity in patients group vs control group with descriptives

Phase	**Muscle**	**Relative muscle activity**	**Descriptives patient group (relative muscle activity)**		**Descriptives control group (relative muscle activity)**		**P value (Mann-Whitney U)**
Walking			Median	Q1-Q3	Median	Q1 - Q3	
FSP	PL	P < C	12.49	8.63 - 22.43	17.11	13.02 - 24.15	0.025
BSP	BF	P < C	4.16	2.42 - 5.99	5.20	3.50 - 7.16	0.035
Running 10 km/h							
FSP	GM	P < C	20.75	14.56 - 34.02	29.42	23.43 - 48.25	0.004
Running 12 km/h							
FSP	VL	P < C	14.18	9.72 - 26.41	23.80	14.90 - 42.20	0.019
FSP	GL	P < C	24.99	18.55 - 44.92	45.04	21.96 – 58.86	0.047
FSP	GM	P < C	34.28	18.06 - 47.70	57.35	33.04 - 77.20	0.006
FSP	TA	P > C	73.12	57.16 - 93.47	57.52	40.68 - 73.27	0.003
BSP	BF	P < C	11.84	7.91 - 18.88	18.33	13.65 - 22.17	0.002
Running SSS							
SP	VL	P < C	29.38	20.18 - 48.40	46.96	29.40 - 61.68	0.047
SP	GL	P < C	94.59	68.70 - 149.95	120.28	96.59 - 173.98	0.017
BSP	BF	P < C	11.11	8.79 - 15.35	13.94	10.42 - 18.81	0.018
BSP	GL	P < C	10.02	6.37 - 18.48	13.48	8.74 - 25.36	0.046

(BF = Musculus Biceps Femoris; BSP = Back Swing Phase; C = control group; FSP = Front Swing Phase; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; km/h = kilometre per hour; P = patient group; PL = Musculus Peroneus Longus; Q1 = first quartile; Q3 = third quartile; SP = Stance Phase; SSS = self-selected speed; TA = Musculus Tibialis Anterior; VL = Musculus Vastus Lateralis)

Table 20: significant differences in relative muscle activity within patients with Deca at T1 vs T2 vs T3 with descriptives

DECA												
Phase	**Muscle**	**P value (Friedman)**	**Relative muscle activity**	**Descriptives T1**		**Descriptives T2**		**Descriptives T3**		**P value Wilcoxon**		
				Median	Q1 - Q3	Median	Q1 - Q3	Median	Q1 - Q3	T1 vs T2	T1 vs T3	T2 vs T3
Walking												
SP	GL	0.047	/	29.62	21.98 - 40.21	26.51	20.40 - 33.88	26.51	18.82 - 34.61	0.03	0.163	0.756
SP	GM	0.003	T1 > T2	41.69	29.15 - 56.79	34.29	27.00 - 45.93	45.86	30.92 - 57.01	<0.001	0.55	0.079
SP	PL	0.007	T1 > T2, T3 > T2	24.40	19.49 - 35.82	19.98	11.85 - 35.07	32.23	14.55 - 43.03	0.002	0.212	0.01
SP	TA	<0.001	T1 > T2, T3 > T2	6.02	4.96 - 8.05	4.25	3.84 - 8.89	7.97	5.22 - 11.95	0.01	0.021	0.002
Running 10 km/h												
FSP	BF	0.024	/	44.14	35.16 - 50.08	39.81	28.72 - 48.88	28.89	22.81 - 53.37	0.1	0.059	0.145
SP	VM	0.011	/	77.51	55.55 - 135.69	75.81	56.04 - 99.39	57.28	31.34 - 98.36	0.37	0.02	0.055
BSP	TA	0.047	/	29.38	23.74 - 35.97	29.55	19.59 - 36.73	29.95	22.17 - 47.39	0.783	0.067	0.1
Running 12 km/h												
SP	BF	0.039	/	30.05	14.07 - 48.72	36.85	20.70 - 62.00	26.68	21.35 - 35.85	0.024	0.379	0.179
SP	GL	0.004	T1 > T3	136.40	91.82 - 186.17	138.00	90.81 - 177.57	66.10	8.44 - 167.41	0.064	0.003	0.061
BSP	TA	0.007	T3 > T1, T3 > T2	29.32	26.55 - 39.28	30.74	22.34 - 39.65	44.46	28.58 - 71.32	0.243	0.013	0.007
Running SSS												
FSP	TA	0.008	T1 > T2	53.18	40.15 - 65.01	52.31	34.76 - 64.49	49.15	41.27 - 74.58	0.013	0.852	0.135
BSP	VM	0.028	/	4.11	2.65 - 8.38	3.31	2.11 - 7.32	5.12	2.46 - 7.92	0.334	0.841	0.149

(BF = Musculus Biceps Femoris; BSP = Back Swing Phase; Deca = insole Aptonia® Decathlon; FSP = Front Swing Phase; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; km/h = kilometre per hour; PL = Musculus Peroneus Longus; Q1 = first quartile; Q3 = third quartile; SP = Stance Phase; SSS = self-selected speed; T1 = test moment without insoles; T2 = test moment when the insoles were just received; T3 = test moment after eight weeks of wearing the insoles; TA = Musculus Tibialis Anterior; VM = Musculus Vastus Medialis)

Table 21: significant differences in relative muscle activity within patients with Borg at T1 vs T2 vs T3 with descriptives

BORG												
Phase	**Muscle**	**P value**	**Relative muscle activity**	**Descriptives T1**		**Descriptives T2**		**Descriptives T3**		**P value Wilcoxon**		
				Median	Q1 - Q3	Median	Q1 - Q3	Median	Q1 - Q3	T1 vs T2	T1 vs T3	T2 vs T3
Walking												
SP	GL	0.047	/	28.70	18.44 - 48.26	29.86	18.33 - 40.15	26.94	21.34 - 37.11	0.04	0.163	0.831
SP	GM	0.037	T3 > T2	40.62	26.37 - 57.20	36.34	21.93 - 44.65	40.00	25.42 - 66.33	0.026	0.876	0.016
SP	PL	0.013	/	27.00	17.26 - 46.63	26.65	18.17 - 38.79	34.98	23.23 - 45.13	0.445	0.305	0.019
Running 10 km/h												
SP	PL	0.041	/	75.45	56.43 - 94.02	74.83	55.77 - 94.86	83.68	62.78 - 101.22	0.077	0.131	0.149
BSP	TA	0.043	/	30.20	26.51 - 45.72	28.96	22.26 - 38.49	28.52	22.64 - 35.98	0.053	0.247	0.794
BSP	VM	0.047	T3 > T2	2.93	1.87 - 7.52	2.74	1.69 - 7.31	5.46	2.57 - 16.77	0.247	0.062	0.005
Running 12 km/h												
FSP	TA	0.016	/	75.29	55.76 - 91.28	64.82	53.69 - 82.30	64.36	50.87 - 76.62	0.048	0.136	0.852
SP	GL	0.025	/	129.44	87.43 - 153.62	112.59	74.74 - 158.05	117.80	45.67 - 141.38	0.053	0.177	0.679
Running SSS												
FSP	TA	0.031	T1 > T2	49.81	40.89 - 76.69	41.46	35.12 - 60.95	52.84	34.36 - 65.23	0.008	0.322	0.274
BSP	VM	0.012	T3 > T2	2.84	2.11 - 7.23	2.44	1.72 - 4.17	3.67	2.21 - 9.42	0.058	0.376	0.002

(Borg = BorgInsole® Custom; BSP = Back Swing Phase; FSP = Front Swing Phase; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; km/h = kilometre per hour; PL = Musculus Peroneus Longus; Q1 = first quartile; Q3 = third quartile; SP = Stance Phase; SSS = self-selected speed; T1 = test moment without insoles; T2 = test moment when the insoles were just received; T3 = test moment after eight weeks of wearing the insoles; TA = Musculus Tibialis Anterior; VM = Musculus Vastus Medialis)

Table 22: significant differences in relative muscle activity within patients with Gesp at T1 vs T2 vs T3 with descriptives

GESP												
Phase	**Muscle**	**P value**	**Relative muscle activity**	**Descriptives T1**		**Descriptives T2**		**Descriptives T3**		**P value Wilcoxon**		
				MEDIAN	Q1 - Q3	MEDIAN	Q1 - Q3	MEDIAN	Q1 - Q3	T1 vs T2	T1 vs T3	T2 vs T3
Walking												
SP	GL	0.015	T1 > T2	34.54	27.48 - 48.70	27.94	23.96 - 38.05	29.93	24.14 - 45.33	0.003	0.163	0.039
SP	GM	0.002	T1 > T2	58.57	39.80 - 81.96	43.99	32.67 - 59.16	45.09	33.37 - 62.11	0.001	0.023	0.82
SP	TA	0.001	T1 > T2, T3 > T2	6.55	5.11 - 10.25	5.59	3.33 - 7.75	6.83	4.44 - 15.27	0.006	0.438	0.001
BSP	PL	0.022	/	9.10	5.02 - 12.87	7.80	6.40 - 13.05	9.75	5.04 - 17.88	0.408	0.023	0.088
Running 10 km/h												
SP	GL	0.014	/	132.88	97.92 - 179.87	122.95	88.93 - 155.59	107.98	83.31 - 133.28	0.113	0.017	0.163
BSP	VL	0.038	/	5.71	4.34 - 9.56	5.21	4.37 - 10.85	7.46	5.56 - 13.05	0.733	0.026	0.078
Running 12 km/h												
SP	BF	0.022	/	37.46	25.64 - 58.44	46.61	30.39 - 59.54	36.59	24.09 - 52.10	0.069	0.278	0.061
SP	GL	0.015	T2 > T3	169.18	91.06 - 183.95	160.95	104.03 - 207.68	100.43	16.75 - 133.69	0.281	0.02	0.006
Running SSS												
FSP	VL	0.028	/	18.94	9.12 - 30.27	21.22	11.70 - 40.18	16.73	10.18 - 30.22	0.039	0.717	0.148
BSP	PL	0.039	T1 > T2	17.50	10.81 - 26.98	13.90	9.74 - 24.68	16.93	11.26 - 31.50	0.015	0.796	0.102

(BF = Biceps Femoris; BSP = Back Swing Phase; FSP = Front Swing Phase; Gesp = insole GesPodo® Custom; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; km/h = kilometre per hour; PL = Musculus Peroneus Longus; Q1 = first quartile; Q3 = third quartile; SP = Stance Phase; SSS = self-selected speed; T1 = test moment without insoles; T2 = test moment when the insoles were just received; T3 = test moment after eight weeks of wearing the insoles; TA = Musculus Tibialis Anterior; VL = Musculus Vastus Lateralis)

Table 23: significant differences in relative muscle activity within patients with RSP at T1 vs T2 vs T3 with descriptives

RSP												
Phase	**Muscle**	**P value**	**Relative muscle activity**	**Descriptives T1**		**Descriptives T2**		**Descriptives T3**		**P value Wilcoxon**		
				MEDIAN	Q1 - Q3	MEDIAN	Q1 - Q3	MEDIAN	Q1 - Q3	T1 vs T2	T1 vs T3	T2 vs T3
Walking												
FSP	PL	0.001	T3 > T2	11.14	7.79 - 15.37	10.06	6.74 - 14.99	13.74	6.41 - 32.47	0.03	0.04	0.004
SP	GL	0.011	T1 > T2	27.36	20.35 - 40.14	23.61	18.46 - 31.83	24.00	18.92 - 35.10	0.002	0.145	0.433
SP	GM	0.002	T1 > T2	46.65	31.83 - 57.10	37.05	25.83 - 47.77	39.22	21.94 - 48.74	<0.001	0.048	0.433
BSP	TA	0.047	/	15.02	10.22 - 20.52	14.17	9.07 - 18.91	13.64	10.46 - 24.08	0.017	0.737	0.017
BSP	VM	0.006	T3 > T1	1.30	0.60 - 2.64	1.37	0.68 - 2.38	1.52	0.88 - 2.21	0.506	0.008	0.058
BSP	PL	0.004	T3 > T2	6.34	4.57 - 8.36	6.26	3.89 - 10.14	7.69	3.31 - 14.23	0.039	0.26	0.007
Running 10 km/h												
BSP	TA	0.022	T1 > T2	27.99	18.29 - 45.08	25.38	17.20 - 38.48	28.06	17.99 - 36.01	0.006	0.765	0.247
Running 12 km/h												
FSP	VL	0.03	/	14.08	8.10 - 30.07	15.02	8.38 - 25.91	20.46	12.28 - 46.52	0.654	0.022	0.199
BSP	PL	0.03	/	14.34	11.20 - 27.45	16.20	12.84 - 27.82	16.84	8.58 - 31.48	0.629	0.363	0.017
BSP	VM	0.047	/	4.35	2.76 - 8.89	4.96	2.45 - 15.61	6.03	2.47 - 32.41	0.126	0.133	0.071
Running SSS												
SP	VL	0.029	/	27.53	18.55 - 50.46	31.77	16.51 - 52.19	35.93	29.45 - 52.98	0.548	0.07	0.036
BSP	TA	0.019	T1 > T2	26.27	18.62 - 42.37	26.11	18.40 - 37.14	31.39	18.86 - 42.78	0.012	0.794	0.04
BSP	VM	0.034	/	3.70	2.21 - 4.68	3.13	2.12 - 4.25	3.07	2.03 - 7.74	0.17	0.421	0.025

(BSP = Back Swing Phase; FSP = Front Swing Phase; GL = Musculus Gastrocnemius Lateralis; GM = Musculus Gastrocnemius Medialis; km/h = kilometre per hour; PL = Musculus Peroneus Longus; Q1 = first quartile; Q3 = third quartile; RSP = Phits® RS Print Custom 3D printed insoles; SP = Stance Phase; SSS = self-selected speed; T1 = test moment without insoles; T2 = test moment when the insoles were just received; T3 = test moment after eight weeks of wearing the insoles; TA = Musculus Tibialis Anterior; VL = Musculus Vastus Lateralis; VM = Musculus Vastus Medialis)

Table 24: PDI scores and PDI differences with Deca

DECA			
Deca used as first pair (N = 11)			
PDI score begin	**PDI score end**	**PDI diff**	**Better / worse**
0	MV	/	/
2	2	0	=
MV	MV	/	/
1	0	1	B
13	12	1	B
19	MV	/	/
11	1	10	B
10	27	-17	W
4	5	-1	W
9	5	4	B
0	0	0	=
Deca used as second pair (N = 10)			
PDI score begin	**PDI score end**	**PDI diff**	**Better / worse**
3	2	1	B
5	MV	/	/
MV	MV	/	/
1	3	-2	W
MV	MV	/	/
0	7	-7	W
10	27	-17	W
0	0	0	=
0	0	0	=
0	0	0	=

(B = better; Deca = insole Aptonia® Decathlon; MV = missing value; N = number; PDI = Pain Disability Index; PDI diff = PDI score begin - PDI score end; W = worse; / = not applicable; = = equal)

Table 25: PDI scores and PDI differences with Borg

BORG			
Borg used as first pair (N = 11)			
PDI score begin	**PDI score end**	**PDI diff**	**Better / worse**
20	17	3	B
8	4	4	B
21	4	17	B
22	34	-12	W
11	3	8	B
5	0	5	B
0	7	-7	W
10	0	10	B
MV	MV	/	/
16	0	16	B
6	13	-7	W
Borg used as second pair (N = 11)			
PDI score begin	**PDI score end**	**PDI diff**	**Better / worse**
MV	MV	/	/
MV	MV	/	/
10	MV	/	/
14	2	12	B
6	9	-3	W
17	4	13	B
3	3	0	=
8	MV	/	/
6	4	2	B
MV	MV	/	/
MV	MV	/	/

(B = better; Borg = BorgInsole® Custom; MV = missing value; N = number; PDI = Pain Disability Index; PDI diff = PDI score begin - PDI score end; W = worse; / = not applicable; = = equal)

Table 26: PDI scores and PDI differences with Gesp

GESP			
Gesp used as first pair (N = 9)			
PDI score begin	**PDI score end**	**PDI diff**	**Better / worse**
12	3	9	B
6	4	2	B
12	7	5	B
1	4	-3	W
3	0	3	B
14	22	-8	W
MV	MV	/	/
9	0	9	B
10	4	6	B
Gesp used as second pair (N = 9)			
PDI score begin	**PDI score end**	**PDI diff**	**Better / worse**
16	MV	/	/
0	0	0	=
22	0	22	B
MV	MV	/	/
3	22	-19	W
6	MV	/	/
0	0	0	=
MV	MV	/	/
MV	MV	/	/

(B = better; Gesp = insole GesPodo® Custom; MV = missing value; N = number; PDI = Pain Disability Index; PDI diff = PDI score begin - PDI score end; W = worse; / = not applicable; = = equal)

Table 27: PDI scores and PDI differences with RSP

RSP			
RSP used as first pair (N = 11)			
PDI score begin	**PDI score end**	**PDI diff**	**Better / worse**
6	6	0	=
7	MV	/	/
0	0	0	=
9	1	8	B
4	10	-6	W
15	1	14	B
MV	MV	/	/
4	2	2	B
0	0	0	=
14	7	7	B
6	30	-24	W
RSP used as second pair (N = 12)			
PDI score begin	**PDI score end**	**PDI diff**	**Better / worse**
MV	MV	/	/
MV	MV	/	/
16	4	12	B
17	3	14	B
MV	MV	/	/
6	0	6	B
15	0	15	B
0	0	0	=
0	0	0	=
MV	MV	/	/
MV	MV	/	/
7	6	1	B

(B = better; MV = missing value; N = number; PDI = Pain Disability Index; PDI diff = PDI score begin - PDI score end; RSP = Phits® RS Print Custom 3D printed insoles; W = worse; / = not applicable; = = equal)

Figures

Figure 2: PDI questionnaire [31]

Pain Disability Index
Pollard 1984

Geautoriseerde vertaling Pijn Kennis Centrum, academisch ziekenhuis Maastricht
1999

De onderstaande vragen zijn gemaakt om de invloed van uw pijnklachten op uw leven te meten. We willen graag weten in welke mate de pijn u beperkt in het uitvoeren van allerlei dagelijkse activiteiten, die u normaliter zou willen doen. Beantwoord elke vraag door de gemiddelde invloed van de pijn op de activiteit in te vullen. Dus niet als de pijn het hevigste is of juist het minste.
Voor elke vraag moet u het cijfer omcirkelen wat voor de mate van beperking of hinder bij het uitvoeren van deze activiteit het beste weergeeft. Een score van 0 betekent dat u helemaal geen beperkingen of hinder bij het uitvoeren ervaart, en een score van 10 betekent dat het onmogelijk is om de activiteit uit te voeren.

1. **Familiare en huishoudelijke verantwoordelijkheden**
   Deze categorie houdt activiteiten in die te maken hebben met huishoudelijke werkzaamheden in en rond het huis (b.v. tuinieren e.d.) en verplichtingen ten aanzien van andere familieleden (b.v. kinderen naar school brengen e.d.).

   0 1 2 3 4 5 6 7 8 9 10
   geen beperkingen — volledig beperkt

2. **Recreatie**
   Deze categorie omvat activiteiten zoals hobby's, sport en andere vrije tijdsbestedingen.

   0 1 2 3 4 5 6 7 8 9 10
   geen beperkingen — volledig beperkt

3. **Sociale activiteiten**

   Deze categorie heeft te maken met samen met vrienden en/of familie uit te voeren activiteiten, zoals feestjes, theater of concertbezoek, uit eten gaan en andere sociale gelegenheden.

   0 1 2 3 4 5 6 7 8 9 10
   geen beperkingen — volledig beperkt

4. **Beroep**
   Deze categorie omvat activiteiten die geheel of gedeeltelijk te maken hebben met uw beroep. Ook niet-betaald werk, zoals huishouden of vrijwilligers werk, hoort hierbij.

   0 1 2 3 4 5 6 7 8 9 10
   geen beperkingen — volledig beperkt

5. **Sexuele activiteiten**
Deze categorie vraagt naar de invloed op de frequentie en de kwaliteit van uw sexleven.

0 1 2 3 4 5 6 7 8 9 10
geen beperkingen volledig beperkt

6. **Zelfverzorging**
Deze categorie omvat activiteiten op het gebied van persoonlijke verzorging en onafhankelijke kunnen uitvoeren van allerlei dagelijkse activiteiten (b.v. douchen, aankleden, autorijden)

0 1 2 3 4 5 6 7 8 9 10
geen beperkingen volledig beperkt

7. **Basale levensbehoeftes**
Deze categorie omvat activiteiten die de vitale levensfuncties omvatten, zoals eten, slapen en ademhalen.

0 1 2 3 4 5 6 7 8 9 10
geen beperkingen volledig beperkt

Figure 3: EMG activity of plantar flexor muscles [35]

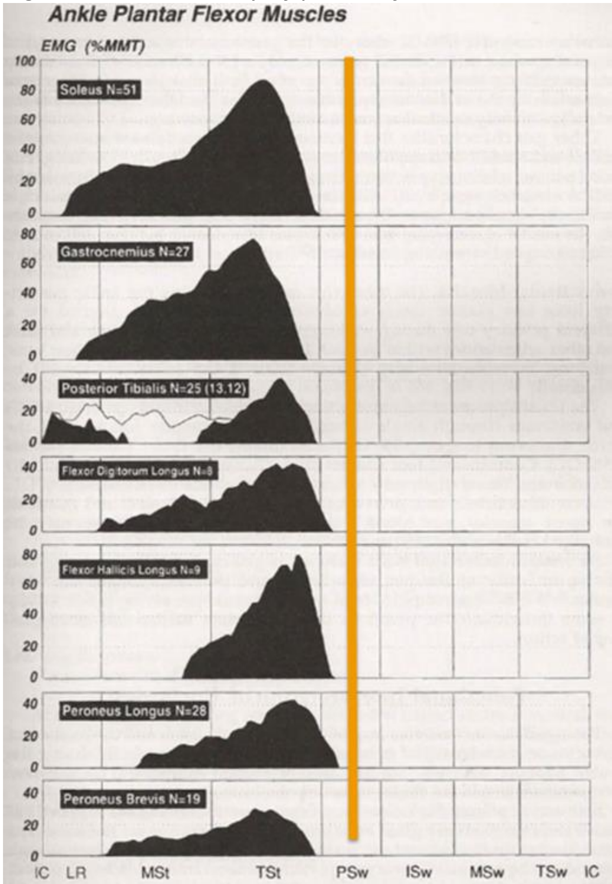

Figure 4: EMG activity of dorsiflexor muscles [35]

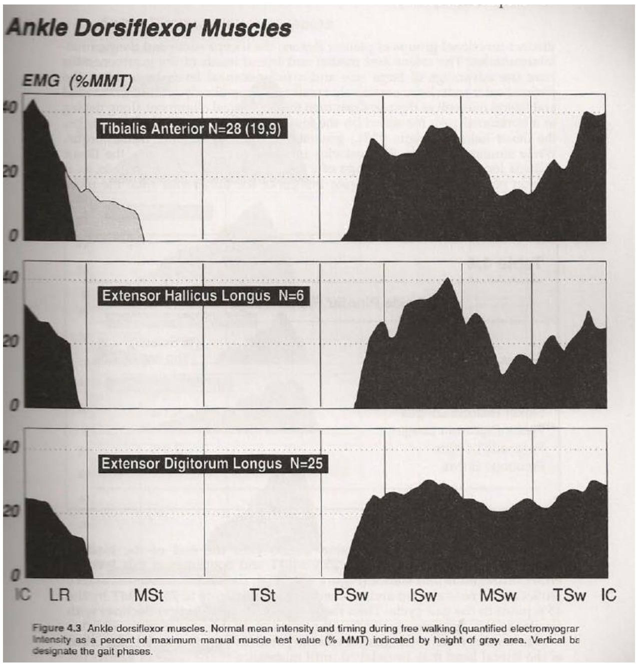

Figure 5: The Foot and Ankle Disability Index Score and Sports Module [37]

The Foot and Ankle Disability Index (FADI) Score and Sports Module

Patient Name: ____ Date: __________

Please answer every question with one response that most closely describes your condition within the past week by marking the appropriate number in the box. If the activity in question is limited by something other than your foot or ankle, mark N/A.

0 Unable to do
1 Extreme difficulty
2 Moderate difficulty
3 Slight difficulty
4 No difficulty

Standing		Walking up hills	
Walking on even ground		Walking down hills	
Walking on even ground without shoes		Going up stairs	
Walking on uneven ground		Going down stairs	
Stepping up and down curves		Squatting	
Sleeping		Coming up to your toes	
Walking initially		Walking 5 minutes or less	
Walking approximately 10 minutes		Walking 15 minutes or greater	
Home responsibilities		Activities of Daily Living	
Personal Care		Light to moderate work (standing, walking)	
Heavy work (push/pulling, climbing, carrying)		Recreational activities	

Sports Module:

Running		Jumping	
Landing		Squatting and stopping quickly	
Cutting, lateral movements		Low-impact activities	
Ability to perform activity with your normal technique		Ability to participate in your desired sports as long as you would like	

Pain related to the foot and ankle:

0 Unbearable
1 Severe Pain
2 Moderate Pain
3 Mild Pain
4 No Pain

General level of pain		Pain at rest	
Pain during your normal activity		Pain first thing in the morning	

Office Use Only: Score: ____/136 points (FADI 104 points & SPORTS 32 points; No Disability 136)
Number of PT Sessions: _____ Gender: M F Age: _____
ICD-9 Code: PT Initials:

Figure 6: MTSS score [8, 44]

APPENDIX 1: Item set in Dutch as generated by the Delphi Study

Sportactiviteiten:

Voor militairen: Marsen en marcheren zijn sportactiviteiten.

1) Momenteel:
- Beoefen ik al mijn gebruikelijke sportactiviteiten ☐
- Kan ik, door mijn scheenbeenklachten, minder dan mijn gebruikelijke sportactiviteiten doen ☐
- Kan ik, door mijn scheenbeenklachten, alleen alternatieve sportactiviteiten doen ☐
- Kan ik, door mijn scheenbeenklachten, geen enkele sportactiviteit doen ☐

2) Deze vraag gaat over de hoeveelheid van uw sportactiviteiten:
- Ik heb het aantal keer dat ik sport per week niet aangepast ☐
- Ik heb het aantal keer dat ik sport per week teruggebracht met 1-25% ☐
- Ik heb het aantal keer dat ik sport per week teruggebracht met 26-50% ☐
- Ik heb het aantal keer dat ik sport per week teruggebracht met 51-75% ☐
- Ik heb het aantal keer dat ik sport per week teruggebracht met 76-100% ☐

3) Deze vraag gaat over de inhoud van uw sportactiviteiten:
- Ik heb mijn sportactiviteiten niet aangepast ☐
- Ik heb mijn sportactiviteiten een beetje aangepast (±25%), bijvoorbeeld een beetje minder sprintwerk/sprongwerk, een beetje minder lang sporten ☐
- Ik heb mijn sportactiviteiten behoorlijk (±50%) aangepast, ik sport minder intensief; bijvoorbeeld veel minder sprintwerk/sprongwerk, minder lang achter elkaar hardlopen ☐
- Ik heb het merendeel (±75%) van mijn training aangepast, ik sport veel minder intensief; bijvoorbeeld geen sprintwerk/sprongwerk, niet lang achter elkaar hardlopen, alleen kort durende lichte belasting ☐
- Ik kan geen enkele sportactiviteit doen vanwege mijn scheenbeenklachten ☐

4) Tijdens het sporten:
- Heb ik geen pijn in mijn scheenbeen ☐
- Heb ik enige pijn in mijn scheenbeen ☐
- Heb ik veel pijn in mijn scheenbeen ☐
- Ik kan niet sporten vanwege de pijn in mijn scheenbeen ☐

5) Hoe lang, nadat u gestart bent met sporten, voelt u pijn aan het scheenbeen?
- Ik heb geen pijn tijdens het sporten ☐
- Langer dan 15 minuten nadat ik gestart ben ☐
- Binnen 15 minuten nadat ik gestart ben ☐
- Direct nadat ik gestart ben ☐
- Ik kan niet sporten vanwege de pijn aan mijn scheenbeen ☐

6) Als u pijn heeft tijdens het sporten, en u gaat door met sporten, wat gebeurt er dan met de pijn?
- Ik heb geen pijn tijdens het sporten ☐
- De pijn neemt af ☐
- De pijn blijft hetzelfde ☐
- De pijn neemt toe ☐
- Ik kan niet sporten vanwegede pijn aan mijn scheenbeen ☐

7) Als de pijn aanwezig is wanneer u begint met sporten, en u gaat door met sporten, wat gebeurt er dan met de pijn?
- Ik heb geen pijn tijdens het sporten ☐
- De pijn verdwijnt binnen 10 minuten ☐
- De pijn verdwijnt na 10 minuten ☐
- De pijn verdwijnt niet ☐
- Ik kan niet sporten vanwege de pijn aan mijn scheenbeen ☐

8) Na het sporten:
- Heb ik geen pijn ☐
- Verdwijnt de pijn binnen 12 uur ☐
- Verdwijnt de pijn tussen de 12 uur en 2 dagen ☐
- Blijft de pijn langer dan 2 dagen aanwezig ☐
- Ik kan niet sporten vanwege de pijn aan mijn scheenbeen ☐

9) Tijdens staan:
- Heb ik geen pijn in mijn scheenbeen ☐
- Heb ik enige pijn in mijn scheenbeen ☐
- Heb ik veel pijn in mijn scheenbeen ☐
- Ik kan niet staan vanwege de pijn in mijn scheenbeen ☐

10) Tijdens lopen:
- Heb ik geen pijn in mijn scheenbeen ☐
- Heb ik enige pijn in mijn scheenbeen ☐
- Heb ik veel pijn in mijn scheenbeen ☐
- Ik kan niet lopen vanwege de pijn in mijn scheenbeen ☐

11) Tijdens trap op- of aflopen:
- Heb ik geen pijn in mijn scheenbeen ☐
- Heb ik enige pijn in mijn scheenbeen ☐
- Heb ik veel pijn in mijn scheenbeen ☐
- Ik kan niet traplopen vanwege de pijn in mijn scheenbeen ☐

Gewone dagelijkse activiteiten: bijvoorbeeld staan, wandelen, lopen, traplopen of fietsen.

12) Tijdens gewone dagelijkse activiteiten:
- Heb ik geen pijn in mijn scheenbeen ☐
- Heb ik enige pijn in mijn scheenbeen ☐
- Heb ik veel pijn in mijn scheenbeen ☐
- Ik kan geen gewone dagelijkse activiteiten doen vanwege de pijn in mijn scheenbeen ☐

Pijn in rust: bijvoorbeeld zitten of liggen.

13) In rust is mijn scheenbeen:
- Niet pijnlijk ☐
- Gevoelig ☐
- Pijnlijk ☐
- Heel pijnlijk ☐

14) 's Nachts:
- Heb ik geen pijn ☐
- Is mijn scheenbeen soms gevoelig ☐
- Word ik wakker van de pijn in mijn scheenbeen maar ik val snel weer in slaap ☐
- Kan ik door de pijn in mijn scheenbeen delen van de nacht niet slapen ☐

15) Pijn bij aanraking:
- Ik heb geen pijn bij aanraking van mijn scheen ☐
- Ik heb alleen pijn wanneer ik de scheen stoot ☐
- Ik heb pijn wanneer ik op de scheen druk én wanneer ik de scheen stoot ☐
- Ik heb pijn wanneer ik over de scheen wrijf, er op druk én de scheen stoot ☐

Figure 7: Classification of walking in phases [36]