Primary metatarsalgia: the influence of a custom moulded insole and a rockerbar on plantar pressure

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Abstract

The effects of a custom moulded insole and a rockerbar on peak pressure and force impulse as well as on pain scores in subjects with a history of metatarsalgia were studied. In addition the subjects' preference for the type of intervention was determined. Forty-two subjects with a history of primary metatarsalgia were selected. They were all provided with the same brand of extra depth shoes with a ready made insole. The effect of custom moulded insoles, a rockerbar and the interaction between the two interventions were studied by testing the four possible combinations: ready made insole without a rockerbar, ready made insole with a rockerbar, custom moulded insole without a rockerbar and custom moulded insole with rockerbar.

At the most important region, the central distal forefoot, a rockerbar caused a decrease in force impulse of 15.1% and a decrease in peak pressure of 15.7%.

The custom moulded insole produced a decrease of 10.1% in force impulse and of 18.2% in peak pressure.

Pain scores were significantly lower for interventions with a custom moulded insole, while the rockerbar showed no influence on pain scores. Subjects with pain preferred a custom moulded insole more often than subjects without pain.

Decrease of peak pressure or force impulse was not correlated to pain scores.

The use of either a custom moulded insole or a rockerbar produced an important decrease of peak pressure and force impulse at the central distal forefoot and, therefore, either is suitable in any situation which a decrease of pressure is vital.

Introduction

Foot pain is a highly frequent problem in older adults. Benvenuti *et al.* (1995) claimed a prevalence of 83% in a survey of 459 subjects 65 years or older. In females the prevalence was significantly higher than in males. They suggested that this gender difference is related to both biological characteristics and womens' use of shoes with high heels and a triangular shaped anterior portion. More specifically, pain in the forefoot was the problem most frequently mentioned in a survey of foot-shoe problems among older adults in the Netherlands. Sixty percent of the females and 30% of the males reported having foot problems in general (Herschel and Meel, 1978).

Reynolds (1988) described metatarsalgia as 'pain in and around the head of the metatarsal or the metatarsophalangeal joint and adjacent soft tissue structures'. It is thought of as a syndrome with causes being described as either primary or secondary. Primary metatarsalgia is idiopathic and mostly due to degenerative changes or to ageing. Secondary metatarsalgia is associated with metabolic, neurologic, postsurgical, or traumatic events. The pain might also be related to plantar pressure at the forefoot (Holmes, 1992).

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The treatment of primary metatarsalgia generally aims at redistributing the plantar pressure. The following methods to achieve pressure reduction or redistribution are discussed: flat shoe inserts, metatarsal pads, custom moulded inserts, and rockerbars.

- Flat shoe inserts. Ready made flat shoe inserts have shock-absorbing capacities. With a polymeric foam rubber of 6.5mm thickness in the shoe, the loading peak of the ground reaction force is 11% less than in the same shoe without an insert (Shiba *et al.*, 1995). The level of comfort which subjects score for shoe inserts is clearly related to the softness and shape of the inserts (Chen *et al.*, 1994; Hennig *et al.*, 1993). Softer insert materials result in lower peak pressure at the metatarsal head regions (Hennig *et al.*, 1993).
- Metatarsal pads. An easy and frequently used treatment for metatarsalgia is the application of metatarsal pads (Silverskiold, 1991). The pads can differ in shape, thickness, hardness, and location. The use of pads results in a considerable reduction of plantar pressure, mainly at the heads of the metatarsalia II, III, and IV and an increase of pressure at the metatarsal shaft region (Chang *et al.*, 1994; Flot *et al.*, 1995; Holmes and Timmerman, 1990).
- Custom moulded insert. A custom moulded insert, made from a plaster cast, resulted in a reduction in plantar pressure of 7% to 9% at the region of the metatarsal heads (Bennett *et al.*, 1994). Total contact casting can result in a large reduction of pressure at the region of the metatarsal heads. Wertsch *et al.* (1995) found values as high as 32% for metatarsal head 5 (MTH-V) 63% for the MTH-IV and 69% for the MTH-I. Birke *et al.*, (1985) even found reductions upto 84%. Comparing the effect between ready made flat inserts and custom moulded inserts, Lord and Hosein (1994) found statistically sugnificant lower peak pressures with custom moulded inserts.
- Rockerbar. During normal roll off, in a normal step, the line of gravity is shifted from the heel to the metatarsal heads; then the heel is lifted and the foot rotates over the metatarsal heads. The progression of the line of gravity is slowest during this rotation, resulting in relatively long acting ground reaction forces at the metatarsal heads. At push off, when the line of gravity is applied to the region of the metatarsal heads, the ground reaction force shows a high peak. In order to reduce the duration and the amount of plantar pressure, the rotation point can be shifted in the proximal direction by a rockerbar fixed to the sole of the shoe. At the rockerbar, two main aspects can be distinguished: the rotation point and the height. The rotation point is the point around which the shoe rotates forward. Nawoczenski *et al.* (1988) described the position as the distance in percentage of the total length of the shoe with the distance to the rockerbar being measured from the heel of the shoe. The height is considered to be the perpendicular distance from the front edge of the sole to the floor. With a rockerbar proximal to the metatarsal region, the rotation point will, thus, also be proximal to the metatarsal region. This position leads to significant reduction of the plantar pressure and impulse (intergral of pressure) at the forefoot region. The tratitional rocker, without curvature, is even more effective than a rocker with curvature (Coleman, 1985; Nawoczenski *et al.*, 1988; Novick *et al.*, 1991b; Peterson *et al.*, 1985; Schaff and Cavanagh, 1990).

The specific aim of this study is to acquire insight into the redistribution of pressure under four regions of the forefoot in patients with a history of primary metatarsalgia. All selected subjects were provided with the same brand of extra depth shoes with a ready made insole. A custom moulded insole was also made, and on both conditions a rockerbar was also placed in the sole. The second aim was to investigate the effect of a custom moulded insole and a rockerbar on pain at the region of the metatarsal heads and to determine the subjects' preferences for these two treatment methods.

It was expected that the most important pressure points and the largest effects of the interventions would be at the central distal forefoot.

Materials and methods
Subjects
Subjects had a history of primary metatarsalgia and no other walking problems. The inclusion and exclusion criteria for the study were chosen to prevent inclusion of subjects

with other problems than primary metatarsalgia. Three orthopaedic shoe technicians, in different regions of the Netherlands, selected patients with metatarsalgia who came to visit them. The final selection was performed by a physician for rehabilitation.

Inclusion criteria:
- pain or a history of pain at the metatarsal region, the primary reason for visiting the orthopaedic technician;
- a walking distance of at least 500 metres without a walking aid;
- a splay foot (forefoot becomes wider when weight bearing);
- prominent heads of the metatarsalia.

Exclusion criteria:
- hallux valgus > 40° (angle between os metatarsale I and first toe);
- hallux limitus; dorsiflexion in the first metatarsal joint < 45° when the subject stands (weight bearing);
- hammer and claw toes with pain;
- toe contact with the floor is lost when standing (mostly due to subluxation of the metatarsal joints);
- valgus or varus of the hindfoot > 20°;
- dorsiflexion < 10° with knee extended;
- plantarflexion < 30°;
- problems which could result in secondary foot problems, such as rheumotoid arthritis, diabetes mellitus, and circulatory problems;
- problems with knees and/or hips;
- metabolic diseases which could cause problems in walking and/or secondary metatarsalgia;
- neurologic diseases which could possibly influence walking.

Forty-two subjects were selected, 41 females and only 1 male. All subjects gave written informed consent. Due to technical problems, the data of the gait analysis for 11 subjects could not be used. A 'non-response' analysis

Table 1. Description of the 42 subjects

	Mean (s.d.)	mimimum	maximum
age (years)	58.6 (20.4)	41	81
height (cm)	166 (8)	150	183
weight (kg)	75.6 (10.4)	46.6	95.4

showed no differences in relevant characteristics in participants and 'drop-outs'. Other information from these 'drop-outs' is used in further analysis, as indicated. Table 1 summarises the descriptions of the subjects.

Study design and data analysis
Design
The study was designed as a double blind, randomised trial. Neither the investigator nor the subjects were informed which intervention was applied at what moment. Although subjects could not be kept totally blind to the intervention, they were not informed about the expectations of the different interventions.

Four interventions were tested:
1. ready made insole without rockerbar;
2. ready made insole with rockerbar;
3. custom moulded insole without rockerbar;
4. custom moulded insole with rockerbar.

After each measurement session, only one intervention was changed (insole or rockerbar). The order of interventions was randomly assigned to each subject. Only the orthopaedic shoe technician was informed of the schedule, to allow him to provide the shoe with the correct intervention. He did not perform any assessment regarding pain or plantar pressure.

To compare the last intervention with the initial one, the first intervention was repeated at the end of the trial. The results from questionaire and gait analysis from this latter measurement were used for subsequent calculations. The subjects were not aware of this. At the start of the trial each subject was fitted with standard shoes for a 4 week habituation period. During this period the orthopaedic shoe technician was allowed to change the upper leather of the shoe to prevent pressure points at the medial, dorsal, and lateral sides of the foot. After this period, the scheduled intervention for each subject was followed. An habituation period of 2 weeks was given to allow the subject to adjust to the intervention. At the end of this period, a gait analysis was performed and the questionnaire was filled in. After these measurements, the next scheduled shoe modification was carried out. This procedure was repeated for the remaining three interventions.

Orthotic devices
All subjects were provided with the same brand of extra depth shoes.

Ready made insole

The only difference between the ready made insole and the custom moulded insole is the shape. Therefore, standard ready made insoles were not used, rather the ready made insoles were produced according to a standard model with the same materials as the custom made ones. The heel raise was kept the same as for the custom made insoles.

Custom moulded insole

Measurements of the feet were made according to a fixed protocol. Since the form of the nonweight bearing foot is different from the weight bearing foot, particularly in splay feet, the cast for the insert was made during weight bearing (Novick *et al.,* 1991a). The plaster of Paris cast was made using vacuum cushions with the subject standing. The custom moulded insoles were made according to the following protocol:

- heel raise: 25mm;
- heel socket and medial support according to cast;
- metatarsal (MT) pad directly proximal to the metatarsal heads with height at the level of MT-I of 2mm; MT-II/III: 5mm; and MT-V: 1mm. Length in sagittal plane: 40mm;
- insole model at MT-level is oval in frontal plane, according to cast.

Rockerbar

The rockerbar was designed in such a way that it was usable in daily practice. It was placed perpendicular to the sagittal plane, 40mm proximal to the normal bending point (MT-level). The height, perpendicular distance from the front edge of the sole to the floor, was 20mm. The rockerbar slowly curved to the front edge of the sole. To prevent the shoe from tumbling backwards, the heel height was increased by 10mm.

Questionnaire

A short questionnaire was constructed to obtain information about pain and comfort. The subjects were asked only to consider pain at the plantar side of the forefoot region. A score 0 means no pain and a score of 5 indicates extreme pain. At every measurement the subject was also asked to give a preference for the shoe in use relative to the foregoing one. The subjects were urged to consider only 'function'

of the shoes and not cosmetic aspects. If the preferences of a subject did not consistently refer to the same intervention for either one type of insole intervention and one type of rockerbar intervention, the preference was treated as 'no preference'.

Gait analysis

For this project 4 regions of the foot were defined (Fig. 1):
1. medial distal forefoot, MTP-I;
2. central distal forefoot, MTP-II + III;
3. lateral distal forefoot, MTP-IV + V;
4. central proximal forefoot, proximal to MTP-II + III.

The subjects were asked to walk barefoot at a comfortable speed on a walkway that is approximately 12 metres long. A pressure platform (EMED-SF pressure platform, with 62 by 32 pressure sensors ($\pm$ 2/cm^2), data collection frequency 70 Hz) hidden under a thin black sheet, was used to obtain a dynamic pressure print of the foot. The regions were determined according to a fixed protocol, in which 6 points
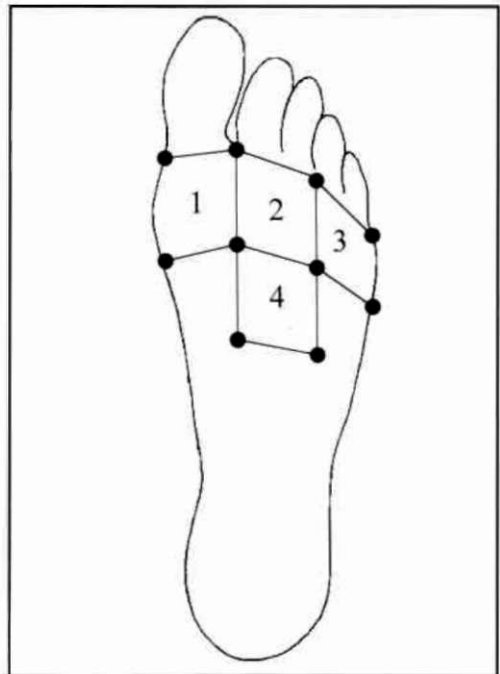

Fig. 1 Foot regions.
1. medial distal forefoot, MTP-I. 2. central distal forefoot, MTP-II+III. 3. lateral distal forefoot, MTP-IV +V. 4. central proximal forefoot, proximal to MTP-II+III.

(A-F) and a permanent length of the regions (fixed proportion of the foot length) are specified, as is seen in Figure 1. The regions are, interactively placed over the insoles.

During the trial, the pressure under the foot was measured with the Mikro-EMED system with Pedar insoles. This system consists of an insole with 99 capacitive pressure sensors. Data were collected with a frequency of 80 Hz and were transferred to a datalogger which is worn around the belt. Three insole sizes are available: 38, 40 and 42 (European sizing system). These sizes correspond to insole lengths of 245mm, 259mm, and 271mm respectively. The insole has a thickness of 2mm. To avoid a volume problem resulting from the measurement insole, a 2mm layer of cork is put under the custom moulded or ready made insole. This extra layer is taken out during the measurements.

The whole system is portable, and, therefore, the measurements were carried out at several locations to avoid long travel distances for the subjects.

Subjects were asked to walk at comfortable speed over a walkway of approximately 15 metres during the different measurements speed differences up to 10% were accepted.

For analysis of the data, 5 steps were selected and data for these were averaged. 'Good' steps were assumed to have approximately the same stance time, to have comparable curves of the vertical ground reaction force and to be consecutive.

For every foot region, peak pressure and force impulse were calculated. The latter yields the force-time intergral which quantifies the 'total' load of the foot during the stance phase.

Results of the measurements for one foot of a subject could influence the results of the other foot. To avoid this kind of dependency of measurements, the results of only 1 foot were processed, for all subjects. The results of the foot for which the subject reported most pain were used for calculations. When no pain was reported a random choice was made.

Statistics

To establish differences produced by the type of intervention, either custom insole or rockerbar, all measurements with a specified intervention were compared with those measurements without this intervention. For analysis the paired T-test was used.

A repeated measures multivariate analysis of variance with difference contrast was used to determine possible interactions between both interventions, and between the interventions and the pain scores. The within-subjects factor was the type of intervention. For analysing pain scores, only subjects who reported pain for at least one intervention were involved. To study the relation between pain and intervention preference, the one-sided Fisher exact test was used. The applied level of significance for all statistic calculations was 0.05.

Results
Gait analysis

Table 2 displays for a rockerbar and the custom moulded insole the force impulse and the peak pressure.

Type of rockerbar and force impluse: the regions 1 and 4 show no statistically significant difference for this variable. Regions 2 and 3 show statistically significant decreases of 15.1% and 10.5% respectively.

Type of rockerbar and peak pressure: again the peak pressure shows no significant difference in the regions 1 and 4. Regions 2 and 3 show a statistically significant decrease of 15.7% and 7.6% respectively.

Type of insole and force impluse: in the proximal forefoot, region 4, where the custom moulded insole provides extra support, there is a statistically significant increase of the force impluse of 82.3%. At the central distal forefoot, region 2, there is a statistically significant decrease of 10.1% while the lateral distal forefoot, region 3, shows a statistically significant increase of 13.8%. Under the medial distal forefoot region 1, no significant differences are measured.

Type of insole and peak pressure: the influence of the type of insole on peak pressure is statistically significant at the central and lateral distal forefoot (regions 2 and 3), where the decrease is respectively 18.2% and 10.8%. At the medial distal forefoot and the central proximal forefoot there is no dignificant difference.

Combination of interventions: custom moulded insole and rockerbar

The effects of the combinations of both interventions and their possible interaction was examined for the central distal forefoot, region

Table 2. Force impulse (N s) and peak pressure (N/cm²) for shoes with rockerbar and shoes without a rockerbar and also for shoes with a custom moulded insole and shoes with a ready made insole, with standard deviation (s.d.), t-value, and p-value. Degrees of freedom = 30 for all tests (N=31).

ROCKERBAR								
	force impulse (N.s)				peak pressure (n/cm²)			
Region	with rockerbar (s.d.)	without rockerbar (s.d.)	t-value	p-valve	with rockerbar (s.d.)	without rockerbar (s.d.)	t-value	p-value
1	39.0 (12.9)	40.3 (14.4)	-1.3	.20	29.8 (9.2)	31.2 (8.7)	-1.24	.22
2	53.4 (16.4)	62.9 (20.7)	-5.7	.00	30.6 (11.5)	36.3 (14.1)	-6.49	.00
3	20.5 (8.0)	22.9 (10.1)	-3.2	.003	19.4 (7.8)	21.0 (8.3)	-2.29	.03
4	12.8 (11.4)	11.2 (9.5)	1.6	.12	12.5 (5.6)	13.5 (6.7)	-1.45	.16
INSOLE								
	force impulse (N.s)				peak pressure (n/cm²)			
Region	custom moulded (s.d.)	ready made (s.d.)	t-value	p-valve	custom moulded (s.d.)	ready made (s.d.)	t-value	p-value
1	40.2 (12.8)	39.1 (15.5)	0.57	.57	30.0 (9.7)	31.0 (9.5)	-0.55	.58
2	55.1 (16.2)	61.3 (21.4)	-2.97	.006	30.1 (10.9)	36.8 (15.2)	-4.68	<.000
3	23.1 (9.9)	20.3 (8.5)	3.04	.005	19.0 (7.8)	21.3 (8.7)	-2.35	.03
4	15.5 (11.7)	8.5 (9.7)	5.34	<.000	13.3 (6.1)	12.6 (7.3)	0.65	.52

2, using the force impluse. The averaged force impulses, for the 4 configurations, for the central distal forefoot are as follows:-
custom moulded insole with a rockerbar:
50.4 N s (s.d. 15.1);
custom moulded insole without a rockerbar:
59.8 N s (s.d. 18.3);
ready made insole with a rockerbar:
56.5 N s (s.d. 19.2);
ready made insole without a rockerbar:
66.1 N s (s.d. 25.1).

A multivariate analysis of variance showed that there was an intervention effect (within-subject factor = intervention, Pillais (3.28) = 0.640, exact F (3.28) = 16.61, p < .00).

The force impluse of the ready made insole is greatest. The value of the custom moulded insole without a rockerbar equals the value of the ready made insole with a rockerbar. In order to detect a different influence of the rockerbar on the effects of the 2 insoles and *vice versa* a multivariate analysis within-subject factors (insole and rockerbar) was performed. This analysis showed no interaction (F (1.30) = 0.01, p = .92).

Questionnaire

Twenty-five subjects reported pain with one or more interventions. The individual scores varied for all interventions between 0 and 3. The averaged scores are as follows:
custom moulded insole with a rockerbar:-
0.56 (s.d. 0.92);
custom moulded insole without a rockerbar:
0.76 (s.d. 1.01);
ready made insole with a rockerbar
1.68 (s.d. 1.07);
ready made insole without a rockerbar:
1.72 (s.d. 1.24).

A multivariate analysis of variance showed that there was an intervention effect (within subject factor = intervention, Pillais (3.72) = 0.616, exact F (3.72) = 10.43, p < .00).

The scores for custom moulded insole with and without rockerbar do not show a statistically significant difference. The same applies to the scores for ready made insole with and without rockerbar. The scores for both interventions with the custom moulded insole are statistically significantly lower (p-values are lower than .00) than both interventions with the ready made insole.

The preference of the 42 subjects for an intervention, in relation to the existence of pain accompanying each intervention, are found in Table 3. Twenty-five subjects reported pain with one or more interventions. Nineteen of these subjects preferred a custom moulded

insole. Of the 17 subjects who reported no pain, only 6 preferred a custom moulded insole. Therefore, subjects with pain prefer statistically significantly (p = .00) more often a custom moulded insole.

Only 12 of the 25 subjects who reported pain, preferred a rockerbar while 6 of the subjects who did not experience pain prefered a rockerbar. There is no statistically significant preference for a rockerbar (p = .23) between the 2 groups.

Check for two possible confounders

Two effects were checked which could act as confounder: speed and overweight. Speed could act as confounder since it is known to influence force impulse and peak pressure (Kernozek and LaMott, 1995). The average speed in the different situations is as follows (n=31):-
custom moulded insole with a rockerbar: 1.265 m/s;
custom moulded insole without a rockerbar: 1.287 m/s;
ready made insole with a rockerbar: 1.257 m/s;
ready made insole without a rockerbar: 1.270 m/s.

The differences are so small that it is assumed that there is no influence on force impulse and peak pressure.

Overweight could also possibly act as a confounder. The Quetelet Index (QI) was used as measure for overweight and the correlation QI and peak pressure and force impluse were analysed for the ready made insole without a rockerbar. A subject with a QI of 20 to 25 is considered to be not overweight, while one with a QI greater than 30 has a clinically significant obesity.

The mean QI was 26.77 (s.d. = 3.82, n = 42). There was no statistically significant correlation between the QI and peak pressure (r = 0.328; p = .071) or between the QI and force impulse (r = 0.185; p = .3180). When only the subjects with a QI greater than 30 (n=6) were analysed there was still no correlation.

Therefore, the results do not support the idea that for subjects with a Quetelet Index < 30, overweight is a factor of risk for high peak pressures and force impluses. This is in agreement with the results of Cavanagh *et al.* (1991) who concluded that body mass is a poor predictor of peak plantar pressure in diabetic men.

Discussion

Redistribution of pressure under the foot as a result of a custom moulded insole and a rockerbar was investigated as the primary aim of this study. Since it is assumed that pressure and the duration of pressure are important in relation to the causes of foot problems, two parameters were selected: peak pressure and force impluse. The force impluse (intergral of pressure) is equally dependent on pressure and loading time.

The peak pressure and force impulse under the central distal forefoot, assumed to be the most important region, decreased considerably with the use of a custom moulded insole. With the use of a rockerbar it also decreased. The effect of the custom moulded insole with and without the rockerbar is of the same order. Further there was no interaction between the use of the custom moulded insole and the rockerbar, that is the use of one intervention did not influence the use of the other intervention.

Table 3. Preference of intervention for the subjects who reported pain (n=25) and those who reported no pain (n=17).

INSOLE				
Pain	Custom moulded	ready made	no preferance	total
present	19	0	6	25
absent	6	5	6	17
ROCKERBAR				
	with rockerbar	without rockerbar	no preference	total
present	12	9	4	25
absent	6	4	7	17

Effect of a rockerbar

A rockerbar, proximal to the metatarsal region, produced a statistically significant decrease of peak pressure (15.7%) and force impulse (15.1%) on the central distal forefoot and 7.6% and 10.5% on the lateral distal forefoot. This is in agreement with the results which are described in literature by Coleman (1985), Nawoczenski *et al.* (1988), Novick *et al.* (1991b), Peterson *et al.* (1985), and Schaff and Cavanagh (1990). These results do not indicate to what extent the decrease of force impulse was due to decrease of pressure and to what extent it was due to shorter loading time.

Contrary to the expectations, there was no statistically significant decrease at the level of the medial distal forefoot. Two possible reasons for this finding are the small number of subjects and a slight external rotation of the foot, which often occurs. The external rotation might alter the effect of the rockerbar, which was placed perpendicular to the sagittal plane of the shoe. Probably it should have been placed perpendicular to the roll off direction. The rockerbar should shift the line of gravity during the push off in the proximal direction. Therefore, at the proximal central forefoot an increase of peak pressure and force impulse were expected. However, there were no statistically significant changes. Force impulse tended to increase, while peak pressure tended to decrease. Possibly the smaller moment arm (Moment = F of calf musculature × perpendicular distance calf musculature to loading point) during the push off leads to smaller push off forces and a decrease of peak pressure. Two opposite mechanisms, longer loading period and decrease of pressure, can be responsible for eliminating changes in the force impulse.

Effects of a custom moulded insole

As expected, with a custom moulded insole the peak pressure and the force impulse of the central distal forefoot were both deceased, 18.2% and 10.1% respectively. At the lateral distal forefoot only the peak pressure decreased, while the force impulse did not change. It is not likely that the loading time increases as a result of the use of a custom moulded insole, and probably therefore, the averaged pressure did not decrease.

At the level of the medial distal forefoot there were no changes in peak pressure and force impulse. Two mechanisms might act in opposition: the oval shape of the custom moulded insole and the metatarsal pad. The oval shape of the insole is more likely to increase the pressure at the medial and lateral distal forefoot than to decrease it, while the metatarsal pad, on the other hand, is likely to decrease the pressure.

At the proximal central forefoot, the force impulse increased by more than 80% while the peak pressure did not change. This must be the result of a longer loading period. There findings support the idea that, due to the influence of time, the force impulse is an important parameter with more impact than pressure.

Interaction between custom moulded insole and rockerbar

No significat interaction of the effects of the custom moulded insole and the rockerbar were found. For practical use this conclusion means that the effects of the custom moulded insole and the rockerbar on pressure distribution can be added and therefore, in daily practice, it is useful to prescribe both interventions simultaneously.

Peak pressure, force impulse, pain and preference

Peak pressure and force impulse, at the central distal forefoot, are significantly lower with the use of a custom moulded insole. Pain scores are also significantly lower. It might be assumed that the differences of peak pressure and force impulse, with and without a custom moulded insole, could be related to the differences of the pain scores for both interventions. In order to analyse this relation a correlation analysis was performed for 18 subjects (from 31 subjects with usable data 18 reported pain), but no statistically significant correlation was found (r-value varies from 0.06 to 0.26, p-value varies between .06 and .83).

Although there is no correlation between peak pressure, force impulse and pain scores, subjects who reported pain during the trial had a clear preference for the custom moulded insole and subjects who did not report pain did not have this preference.

The effects of the rockerbar on the peak pressure and force impulse are approximately the same as the effects of the custom moulded insole. However there is no effect of the

rockerbar on pain scores. This means that decrease of peak pressure and force impulse, produced by a rockerbar, could not be related to a decrease of pain scores. Hence, it is not surprising that there is no relation between pain scores and preference for rockerbar. The patients who expressed a preference for the rockerbar could possibly be influenced by such aspects as comfort, stability during walking and the cosmetic appeance of the footwear.

In daily practice it is often presumed that decrease of pressure is the most important factor to prevent pressure sores and to provide relief from pain. The results in this study do not confirm this hypothesis. Several factors might play a role:

- The subjects were asked to give a score for pain at the forefoot region, without distinguishing between medial, central and lateral forefoot. The values of peak pressure and force impulse, used for the calculations, are only for the central distal forefoot. Therefore, some pain scores might not have any relation to these values.
- The experience of pain is influenced by many other factors, which are not likely to be equal in all subjects. This might result in confounding and masking the relationship between pressure and pain.
- The way in which pain is interpreted. Do the subjects experience less pain when walking with a custom moulded insole, or do they experience more comfort, which they then refer to as less pain?
- The increase of force impulse at the proximal central forefoot could possibly provide a sensation of comfort which suppresses the pain sensation at the distal forefoot. This last hypothesis would be supported by the findings of Chen *et al.* (1994) who reported that a shift of pressure from forefoot to midfoot was found in the most comfortable insoles.

Overall it may be concluded that the custom moulded insole and the rockerbar both result in a substantial redistribution of pressure, as expressed by the peak pressure and force impulse, in particular by decreasing the load on the central distal forefoot. Since there is no interaction between the 2 interventions, both should be used together. The subjects who reported pain at the forefoot preferred the custom moulded insole more often, but showed no preferance for the rockerbar. The custom moulded insole and the rockerbar are important tools in the management of foot problems.

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