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Dynamic impression insole in rheumatoid foot with metatarsal pain

Abstract

Background

Custom molded insoles with metatarsal supports are used to redistribute excessive loading under the metatarsal heads in patients with metatarsalgia. However, these pressure reductions are usually insufficient for the rheumatoid foot with painful deformed metatarsal heads. We developed an effective insole made by sequential foam padding under successive walking impression.

Methods

Seventeen consecutive rheumatoid arthritic outpatients with metatarsal pain participated in this repeated measures study of 7-mm flat Ethylene Vinyl Acetate, custom molded and dynamic impression insoles. Peak plantar pressure, pressure-time integral, contact area and mean force were measured by a Pedar-X mobile system. Pain levels were assessed using a Visual Analog Scale (0–10).

Findings

Compared to the Ethylene Vinyl Acetate control, the metatarsal head peak pressure and pressure–time integral were significantly reduced in dynamic impression insoles by 46.3% ($P < 0.001$) and 48.9% ($P < 0.001$), respectively. Compared to the custom molded insole, the dynamic impression insole significantly reduced 18.3% of peak pressure ($P < 0.001$) and 20.1% of pressure–time integral ($P < 0.001$) by increasing 8.1% of contact area ($P = 0.005$) at the metatarsal heads, but there were no significant differences in all variables at the heel. After using the dynamic impression insole, the mean pain score was significantly reduced from 7.6 to 1.1 ($P < 0.001$), and six participants experienced total pain-relief in walking.

Interpretation

Dynamic impression insoles effectively relieve metatarsal pain because of a larger weight-bearing area. Forefoot shape during walking should be taken into consideration in orthotic designs for maximum pressure reduction. Consequently, we recommend using materials with memory properties to dynamically accommodate painful metatarsal heads.

Keywords

dynamic, metatarsal, foot, rheumatoid, insole, impression, pain

Disciplines

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Dynamic impression insole in rheumatoid foot with metatarsal pain

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Running title: Dynamic Impression Insole for Rheumatoid Arthritis

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1 **Abstract**

2 *Background.* Custom molded insoles with metatarsal supports are used to redistribute excessive
3 loading under the metatarsal heads in patients with metatarsalgia. However, the pressure reductions
4 are usually insufficient for rheumatoid feet with painful deformed metatarsal heads. We developed
5 an effective insole made by sequential padding of foams with different compressibility under
6 successive walking impression.

7 *Methods.* Seventeen consecutive rheumatoid arthritic outpatients with metatarsal pain participated
8 in this repeated measures study of 7-mm flat Ethylene Vinyl Acetate, custom molded and dynamic
9 impression insoles. Peak plantar pressure, pressure-time integral, contact area and mean force were
10 measured by Pedar-X mobile system. Pain levels were assessed using a Visual Analog Scale (0-10).

11 *Findings.* Compared to the Ethylene Vinyl Acetate control, the metatarsal heads peak pressure and
12 pressure-time integral were significantly reduced in dynamic impression insoles by 46.3% ($P<0.001$)
13 and 48.9% ($P<0.001$), respectively. Compared to the custom molded insole, the dynamic impression
14 insole significantly reduced 18.3% of peak pressure ($P<0.001$) and 20.1% of pressure-time integral
15 ($P<0.001$) by increasing 8.1% of contact area ($P=0.005$) at the metatarsal heads, but no significant
16 differences in all pressure-related variables at the heel. After using the dynamic impression insole,
17 the pain score was significantly reduced from 7.6 to 1.1 ($P<0.001$), and six participants experienced
18 total pain-relief under the metatarsal heads in walking.

19 *Interpretation.* Because of a larger weight-bearing area, dynamic impression insoles are effective
20 to relieve metatarsal pain. Forefoot shapes during walking should be taken into considerations in
21 orthotic designs for maximum pressure reduction. Consequently, we recommend using the materials
22 with memory properties to dynamically accommodate the painful metatarsal heads.

23
24 *Key words:* rheumatoid arthritis; metatarsalgia; pressure measurement; insole.

1. Introduction

The prevalence of rheumatoid arthritis (RA) is approximately 0.8%, ranging from 0.3% to 2.1% of the population (Fauci et al., 2008). Involvement of metatarsophalangeal joints has been reported to be as high as 80% to 92% during the course of the disease (Vainio et al., 1975; Speigel et al., 1982). The most common forefoot deformities are hallux valgus and claw/hammer toes with dorsal subluxation or dislocation of the lesser metatarsophalangeal joints (Jeng et al., 2008). Toe deformities may cause prominence of the metatarsal heads (MTH) and distal displacement of fat-pad cushion beneath the MTH, resulting in the metatarsal pain in RA patients (Sumpio, 2000). Foot pain frequently leads to limitation of activities of daily life and deterioration of life quality (Kerry et al., 1994; van der Leeden et al., 2006).

Plantar pressure analyses have been widely applied to biomechanical research and orthotic evaluation in rheumatoid foot (Otter et al., 2004; Hodge et al., 1999). In RA with forefoot pain, metatarsophalangeal subluxation and erosion have been related to increased pressure under the forefoot (van der Leeden et al., 2006). Even though RA patients with metatarsal pain may not have particularly high peak pressure, a decrease in plantar pressure still reduces subjective ratings of pain in their walking (Hodge et al., 1999). Foot orthoses have been commonly used in clinical practice to reduce plantar pressure and subsequent pain in management of rheumatoid feet (Clark et al., 2006). The main strategies are to shift the excessive MTH forces by custom insoles with a metatarsal dome or a metatarsal bar placed proximal to MTH (Postema et al., 1998; Hodge et al., 1999; Chalmers et al., 2000; Jackson et al., 2004). Nevertheless, both types of metatarsal pads need to be appropriately positioned to achieve their effectiveness (Clark et al., 2004). Previous studies of RA with metatarsalgia (Hodge et al., 1999; Jackson et al., 2004) reported that the metatarsal padding provides 11.3% to 21.8% peak pressure reduction at the MTH. However, the force redistribution with the use

of metatarsal support may cause a discomfort in the area proximal to MTH, affecting patient acceptance (Clark et al, 2004). Therefore, the therapeutic efficacies of custom molded insoles with a metatarsal support vary widely with their designs and materials for the rheumatoid foot with metatarsalgia (Conrad et al., 1996; MacSween et al., 1999; Novak et al., 2009).

A Plastazote foam is generally used in neuropathic foot because of the excellent self-molding properties and therapeutic effectiveness, but it has a very short life due to high compressibility (Bertram et al., 1997). The Plastazote combined with less compressible foam Aliplast has been reported to relatively increase its longevity, but it still limits the effective use within a few months (Bertram et al., 1997). Furthermore, an insufficient toe-box space of shoes would have restricted the initial thickness for sufficient pressure reduction. We designed a simple and effective method that a dynamic impression insole was made by sequential padding of foams with different compressibility under successive dynamic impression in daily walking. Very few studies have provided the plantar pressure analysis in the accommodative insole for the RA subjects with metatarsalgia. The purposes of this study were to investigate the biomechanics of dynamic impression insole in plantar pressure reduction, as well as to compare with custom molded insole among seventeen RA adults with metatarsal pain.

2. Methods

2.1. Participants

Nineteen consecutive RA patients with metatarsal pain, who were diagnosed by rheumatologists according to American College of Rheumatology criteria (Arnett et al., 1988) were recruited from the podiatry outpatient clinic of Taipei Veteran General Hospital. Seventeen participants (15 females and 2 males, 16 bilateral feet and 1 unilateral foot involvements) completed this study without interruption of using dynamic impression insoles. One of the dropouts was due to an insufficient

toe-box space for the severely deformed forefoot with the Plastazote in walking, and the other was due to difficulty following the schedule required by this study. The participants were active in walking without any aids for plantar pressure measurement. There were no flexible flat feet in all participants. The demographic characteristics of participants are given in table 1. The locations (% morbidity) of metatarsal pain were the first MTH (8.8%), the second MTH (76.5%), the third MTH (70.6%), the fourth MTH (20.6%), and the fifth MTH (2.9%). The metatarsal pain was complicated with toe deformities including hallux valgus (76.5%) and claw/hammer toes (58.8%). All subjects were instructed to wear extra-width and extra-depth shoes that could accommodate deformed forefoot and minimal 10-mm thick insole. This study was approved by the Ethics Committee of the Taipei Veterans General Hospital, and informed consent was obtained from all participants.

2.2. *Dynamic impression insole*

The procedures of fabricating the dynamic impression insole were divided into four steps in four visits to the podiatry clinic.

- 1) A 9-mm thick Plastazote (15 Shore A hardness, Schein orthopädie service KG, Remscheid, Germany) was inserted into wide extra-depth shoes in each RA participant. The Plastazote in the MTH region would be compressed more than one half of the original thickness about 2-3 weeks, depending on the level of walking activity.
- 2) The Plastazote in the toes area was fattened to the same thickness as the deepest toe impression. A 6.5-mm thick P-cell (21 Shore A hardness, Acor orthopaedic Inc. Cleveland, Ohio, USA) was adhered to the bottom of the impressed Plastazote with double-sided adhesive tape. The P-cell in the forefoot region was ground to the thickness that patient's forefoot could accommodate.
- 3) After walking compression for about 2-3 weeks, a piece of metatarsal pad and arch support made of Ethylene Vinyl Acetate (EVA) of 40 Shore A hardness was attached to the bottom of impressed insole just proximal to the first, second, and third MTH according to the foot impression.

4) After further walking for about 2-3 weeks, a 2-mm thick Multiform (30 Shore A hardness, Schein orthopädie service KG, Remscheid, Germany) was adhered to the top of the impressed insoles.

The EVA was also used to adjust unequal thickness between medial and lateral side (figure 1).

2.3. Custom molded insole

1) Foot impression was taken in an impression box while holding the subtalar joint at a neutral position as possible.

2) A 3-mm Multiform was used as a top layer and cork as a bottom layer. The middle layer was P-cell at the forefoot, EVA at the midfoot and hindfoot. A metatarsal support was incorporated 5-mm proximal to all MTH in the cork layer (figure 1).

3) All layers were sequentially added on the positive plaster cast in vacuum former after gluing and heating in the oven.

2.4. Evaluation of the insoles

The pain levels of using the dynamic impression insoles at different stages were recorded from 0 (no pain) to 10 (the worst pain) according to the Visual Analog Scales (VAS) pain score. Pain levels were assessed on the first visit (before treatment with insoles), on the second visit (2-3 weeks after using the 9-mm thick Plastazote), and on the day for the plantar pressure measurements (1 month after the final step of fabricating the dynamic impression insole). The custom molded insoles were prescribed to the participants at their second visits. The pain levels of using the custom molded insole were recorded on the day for the plantar pressure measurements. The participants had about half day of time of using the custom molded insoles before assessing the pain levels and plantar pressure. Plantar pressure analysis was performed using the Pedar-X mobile in-shoe system (Novel gmbh, Munich, Germany). Three kinds of insoles including 7-mm flat EVA control (40 Shore A hardness), dynamic impression insole and custom molded insole were randomized in the plantar

pressure measurements. The measurements were carried out under a comfortable and stable walking speed preferred by the participants one month after the dynamic impression insoles were fabricated. The Pedar system was calibrated according to the manufacturer's instructions before plantar pressure assessment. Plantar pressures were measured at a frequency of 100 Hz in the middle 5-meter path of an 8-meter walkway. All participants walked 5 laps without any walking aids for plantar pressure measurements on the same day. Since the walking velocity has been demonstrated to influence plantar pressure (Zhu et al., 1995; Kang et al., 2008), walking trials would be adjusted and repeated if the speed was out of 5% from the mean velocity of three different insoles. All pressure data were processed with the Novel-Win Multimask analysis software (Novel gmbh, Munich, Germany). The plantar area was divided into 4 regions that were heel (0-30% of foot length), midfoot (30-60% of foot length), metatarsal heads (60-85% of foot length), and toes (85-100% of foot length). Only the left foot was chosen for statistic analysis due to the requirement of data independence.

2.5. Statistical analysis

The required sample size was estimated by GPower 3.1.2 (Faul et al., 2007), assuming a power of 0.8 and an alpha level of 0.05. From the data of previous study in RA with metatarsalgia (Jackson et al., 2004), we calculated the sample size required as minimal 13 subjects to detect a statistical difference of 15% in peak plantar pressure between two dependent means. All statistical analyses were performed using SPSS 17.0 (SPSS Inc, Chicago, Illinois). One-way ANOVA with repeated measures was undertaken to determine significant differences in peak pressure, pressure-time integral, contact area and mean force among the three insoles, and post-hoc Bonferroni test to perform pair-wise comparisons among the three insoles. Two-tailed paired t-test was used to compare the VAS pain scores before and after treatment with insoles. The differences were considered significant if $P < 0.05$.

3. Results

After using the 9-mm thick Plastazote with the extra-width and extra-depth shoes, the mean VAS pain score was significantly decreased from 7.6 (range 5-10, SD=1.7) to 4.1 (range 2-6, SD=1.2) in daily walking ($P < 0.001$). One month after the dynamic impression insoles were well fabricated, the mean VAS pain score was further significantly decreased to 1.1 (range 0-4, SD=1.1, $p < 0.001$), and 6 of 17 participants experienced no pain under the MTH in their walking. In addition, all participants did not feel any discomfort or pain under the region proximal to MTH when using dynamic impression insoles. The pain score (mean=2.5, range 0-6, SD=1.7) with the use of custom molded insole was significantly higher than that of dynamic impression insole ($p < 0.001$). Fourteen participants preferred using the dynamic impression insoles, but only three participants considered no differences between two insoles. The mean walking speed in the pressure measurement was 57.7 m/min (range 42.9-89.3, SD=12.1 m/min), which was slower than mean normal walking speed of 77 m/min in people of similar age group (Kang et al., 2008).

At the MTH, one-way ANOVA with repeated measures revealed significant differences among the three insole in peak pressure ($P < 0.001$, table 2), pressure-time integral ($P < 0.001$, table 3), mean force ($P < 0.001$, table 4) and contact area ($P < 0.001$, table 5). Compared to the 7-mm flat EVA control, the peak pressure and pressure-time integral were reduced by 46.3% ($P < 0.001$) and 48.9% ($P < 0.001$) along with an 18.1% reduction in mean force ($P < 0.001$) and a 15.1% increase in contact area ($P = 0.002$) with statistical significances in the dynamic impression insole. Compared to the custom molded insole, the dynamic impression insole provided an 18.3% reduction in peak pressure ($P < 0.001$), a 20.1% reduction in pressure-time integral ($P < 0.001$), an 8.1% increase in contact area ($P = 0.005$) with significance, but no significant difference was found in mean force ($P = 1.000$).

At the midfoot, ANOVA revealed significant differences in mean force ($P < 0.001$) and contact area ($P < 0.001$) among three insoles, but no significant differences in peak pressure ($P = 0.097$) and

pressure-time integral ($P = 0.909$). Compared to the EVA control, the dynamic impression insole significantly increased the mean force by 2.6 times ($P < 0.001$) and the contact area by 2.0 time ($P < 0.001$), while the custom molded insole significantly increased the mean force by 2.1 times ($P < 0.001$) and the contact area by 1.9 times ($P < 0.001$). The dynamic impression insole had significantly greater mean force than custom molded insole ($P = 0.004$), but no significant difference in contact area ($P = 0.130$).

Repeated measures ANOVA also showed significant differences among three insoles in four pressure-related variables at the heel (all $P < 0.001$, table 2 to 5). However, post-hoc Bonferroni test revealed no significant differences between dynamic impression insole and custom molded insole in peak pressure ($P = 0.124$), pressure-time integral ($P = 0.999$), contact area ($P = 0.058$) and mean force ($P = 1.000$).

In pair-wise comparisons between the three insoles at the MTH, the post-hoc power analysis of peak pressure revealed statistical powers from 0.81 to 1, which were larger than 0.8 of priori power analysis.

4. Discussion

Rheumatoid arthritis is three times more common in females than in males (Fauci et al., 2008). Furthermore, metatarsal pain frequently occurs in women who like to wear fashion shoes with restricted toe-box. These could account for the fact that most of our participants were females in gender distribution. The RA participants with metatarsal pain had very high morbidity of hallux valgus and claw/hammer toes in this study. Most participants were bilateral foot involvements including metatarsal pain, which was consistent with clinical manifestation of symmetric arthritis in the RA. The mean VAS pain score after using 9-mm Plastazote in walking was decreased to 4.1, which was very close to a similar study (Chalmers et al., 2000). The walking pain score with the use

1 of the dynamic impression insole was lower than that with the custom molded insole. It was hard to
2 ensure that each participant used the same amount of time in using the custom molded insoles and
3 the dynamic impression insoles. However, the pain score with the use of our custom molded insole
4 was comparable to those reported in previous studies (Postema et al., 1998; Hodge et al., 1999). The
5 participants were given about half day of time of getting accustomed to the custom molded insoles,
6 before assessing the pain levels and plantar pressure.

7
8 In dynamic impression insole, both mean VAS pain score and peak pressure were further reduced
9 after sequential padding and successive walking compression. Approximate one third of the
10 participants experienced total pain-relief under MTH in their daily walking. Compared to the custom
11 molded insole, the dynamic impression insole apparently reduced the peak pressure, pressure-time
12 integral and increased the contact area at the MTH. However, there was no significant difference in
13 mean force at the area. Since both the dynamic impression and custom molded insoles have been
14 incorporated in the metatarsal region with similar metatarsal supports and the same P-cell material
15 (figure 1), their comparable force-shifting and force-absorbing effects could account for no
16 significant differences in mean force. Therefore, the contact area is a main determining factor that
17 causes the different effectiveness between two insoles in reducing peak pressure and pressure-time
18 interval at the MTH. Although the MTH peak pressure was reduced by 34.4% after incorporating the
19 P-cell into the forefoot region in custom molded insole, the pressure reduction was still lower than
20 that of dynamic impression insole as a result of smaller contact area. These could explain the
21 dynamic impression insole was superior to custom molded insoles in pain relief. Since RA subjects
22 with metatarsal pain have 20-40% lower pain pressure threshold (Hodge et al., 2009), these patients
23 require more plantar pressure reduction to diminish their pain sensation.

24 Previous studies have reported 11.3% to 21.8% of pressure reductions at the MTH after using

1 custom molded insoles (Hodge et al., 1999; Jackson et al., 2004). The magnitudes of these
2 reductions were lower than the reductions (46.3%) made by the dynamic impression insole. Some
3 other studies reported that a custom molded insole could not reduce plantar pressure (Novak et al.,
4 2009) and did not bring any clear benefits to patients with foot pain (Conrad et al., 1996; Novak et
5 al., 2009). Different designs and materials used in the insoles leading to different ability to reduce
6 plantar pressure could explain these conflicted results.

7 Although the dynamic impression insole requires the persistent walking compression in a period
8 of time, it is very simple and low cost in orthotic fabrication. Since all the layers are adhered
9 together with double-sided adhesive tape, it is easy to adjust or renew for extending their effective
10 life to one-year or longer. It is extremely important that no organic solvent will be evaporated in all
11 the procedures. Furthermore, the metatarsalgia due to multiple forefoot deformities is very
12 individualized in subjects with rheumatoid foot. The dynamic impression insole can be customized
13 to accommodate plantar contour by their own impression. The pressure from the patient's weight and
14 dynamic forces in walking could optimize the shape of the multilayer insoles to reduce plantar
15 pressure by increasing contact area and force-absorbing capacity after sequential padding and
16 dynamic impression. In addition, metatarsal padding could further reduce metatarsal pressure by
17 redistributing force loading from the MTH to the proximal area without a pressure discomfort.

18 In fabricating custom molded insoles, a plantar mold is taken from a static impression when the
19 foot is put in a neutral subtalar and horizontal forefoot position. However, the metatarsophalangeal
20 joint is situated at a dorsiflexion position and experiences higher pressure than the static state during
21 heel-rise of the gait. Thus, the plantar mold taken from the static impression is incompatible to the
22 dynamic shape of the forefoot in walking. This could explain that custom molded insole has a less
23 contact area and higher pressure at the MTH than dynamic impression insole. In orthotic
24 management of metatarsal pain, the majority of strategies are to shift the excessive MTH force

loading with a metatarsal support proximal to MTH (Hodge et al., 1999; Jackson et al., 2004). The metatarsal pad utilizes only a small area to shift the excessive force from the MTH to the metatarsal shaft, leading to a decrease in mean force without obvious increase in contact area. In contrast, the dynamic impression insole utilizes all available area around the MTH to reduce the pressure at the painful plantar areas, which corresponds to the deeper indentations on the top surface of insole (figure 2). It also explained why the MTH pressure reduction in dynamic impression insole was twice as those reported in previous studies for custom insoles with metatarsal support (Postema et al., 1998; Hodge et al., 1999).

At the midfoot, the mean force and contact area were simultaneously increased in the dynamic impression insoles, resulting in no significant differences in plantar pressure among the three different insoles. The results were compatible with our clinical observations that all participants experienced effective pain relief under their MTH without any discomfort or pain at the midfoot when using the dynamic impression insole. Patients with rheumatoid feet may suffer from progressive flattening or collapse of the plantar arch due to tarsal joints involvement (Bouysset et al., 1987). The dynamic impression insole increased the mean force at the midfoot by 2.6 times and the weight-bearing area by 2.0 times. However, as this force is only supportive rather than corrective due to the compressibility of the insole, it is not recommended for RA subjects with flexible flat foot. The dynamic impression insole had a more flattened arch contour than the custom molded insole (figure 1). This explained why the custom molded insole has caused discomfort under the midfoot in some participants, but the discomfort was not seen in patients using the dynamic impression insole. The discomfort at the midfoot was similar to the initial discomfort caused by wearing the rigid molded orthoses (Woodburn et al., 2002). This was resulted from a force resisting the downward movement of longitudinal plantar arch at the midfoot in the stance phase of walking (Hunt et al., 2001). It is interesting that the dynamic impression insole has a significantly greater mean force but

1 a lower pressure at the midfoot compared to the custom molded insole.

2 At the midfoot, the mean force and contact area were simultaneously increased in both custom
3 molded and dynamic impression insoles, resulting in no significant differences in plantar pressure
4 among the three different insoles. The results were compatible with our clinical observations that all
5 participants experienced effective pain relief under their MTH without any discomfort or pain at the
6 midfoot when using the dynamic impression insole. Patients with rheumatoid feet may suffer from
7 progressive flattening or collapse of the plantar arch due to tarsal joints involvement (Bouysset et
8 al.,1987). The dynamic impression insole could also provide an arch support with 2.6 times the mean
9 force and 2.0 times the weight-bearing area at the midfoot. Since the force is only supportive rather
10 than corrective, the insole is not recommended for RA subjects with flexible flat foot. Similar to the
11 initial discomfort caused by wearing the rigid molded orthoses (Woodburn et al., 2002), our custom
12 molded insole also caused a plantar discomfort under the midfoot in some participants. The pressure
13 discomfort was resulted from a rigid force to resist the downward movement of longitudinal plantar
14 arch at midfoot in the stance phase of walking (Hunt et al., 2001). This downward movement of
15 plantar arch could also explain that dynamic impression insole had a more flattened arch contour
16 than custom molded insole in the study (figure 1). It is interesting that the dynamic impression insole
17 has a greater mean force but a lower pressure discomfort at the midfoot compared to the custom
18 molded insole.

19 The dynamic impression insole possessed a superior pressure reduction due to a larger
20 weight-bearing area at the MTH compared to the custom molded insole, but no significant
21 differences were found in all pressure-variables at the heel between two insoles. These findings
22 indicate that custom-made insoles will be same effective in heel pressure reduction regardless of
23 using static impression or dynamic impression. This hypothesis is supported by the fact that tarsal
24 joints are in a relatively stationary status in walking as compared to the most mobile

metatarsophalangeal joints. The foot joints motion in gait cycle could also explain that dynamic impression insole had a greater contact area than custom molded insole only at the MTH, but no significant differences at the heel, midfoot and toes.

5. Conclusions

In the custom molded and dynamic impression insoles, the MTH pressure was reduced due to the increase of contact area with a concomitant decrease of loading at the forefoot. However, the dynamic impression insole is superior to custom molded insole to reduce pressure because it provides a larger weigh-bearing area from an optimal forefoot contouring on the insole. In contrast to the less contour change at the heel during walking, the dynamic status of forefoot is an important factor that should be taken into consideration in orthotic designs for reducing the MTH pressure. In orthotic management of metatarsal pain, we recommend using the materials with memory properties to dynamically accommodate the painful MTH for maximum pressure reduction. Since this study is a preliminary evaluation in repeated measures design, further investigations can be carried out on a large scale for randomized controlled trials.

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1 Table 1

2 Demographic characteristics of subjects (n=17)

Characteristics	Mean (SD)	Range
Age (years)	58.6 (10.1)	42-74
Body weight (Kg)	54.6 (9.9)	35-73
Body height (cm)	155.6 (6.7)	143-168
Body mass (Kg/m ²)	22.5 (3.6)	14.6-28.9
Disease duration (years)	16.3 (7.1)	6-32

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1 Table 2
2 Peak pressure (kPa) for three different insoles (n=17)

Plantar regions	7-mm flat EVA (40 Shore A)	Custom molded insole	Dynamic impression insole	ANOVA	
				F value	p value
Heel	238.8 (50.8) 0%	138.9 (30.0) -41.8%**	146.5 (28.1) -38.6%**	61.9	<0.001*
Midfoot	108.1 (40.7) 0%	102.9 (22.7) -4.8%	95.2 (18.9) -11.9%	2.7	0.097
MTH	275.5 (57.6) 0%	180.9 (51.4) -34.4%**	147.9 (32.0) -46.3%** [†]	144.3	<0.001*
Toes	174.3 (71.3) 0%	147.9 (59.8) -15.2%	147.9 (44.8) -15.1%	3.1	0.074

3 Values are expressed as mean (standard deviation) and % change of mean values normalized to those of
4 EVA,

5 *= $P < 0.05$, compared among three insoles using one-way ANOVA with repeated measures,

6 **= $P < 0.05$, dynamic impression insole and custom molded insole compared to 7-mm flat EVA,

7 [†]= $P < 0.05$, compared between dynamic impression insole and custom molded insole.
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1 Table 3
2 Pressure-time integrals (kPa s) for three different insoles (n=17)

Plantar regions	7-mm flat EVA (40 Shore A)	Custom molded insole	Dynamic impression insole	ANOVA	
				F value	p value
Heel	79.6 (17.4) 0%	48.0 (11.0) -39.7% **	49.1 (11.0) -38.3% **	43.7	<0.001*
Midfoot	43.7 (18.6) 0%	45.0 (11.8) 2.9%	44.2 (11.0) 1.1%	0.1	0.909
MTH	88.7 (21.4) 0%	56.8 (16.1) -36.0% **	45.3 (11.8) -48.9% ** [†]	86.0	<0.001*
Toes	50.0 (26.5) 0%	45.8 (23.0) -8.4%	41.1 (16.1) -17.8%	2.6	0.109

3 Values are expressed as mean (standard deviation) and % change of mean values normalized to those of
4 EVA,

5 *= $P < 0.05$, compared among three insoles using one-way ANOVA with repeated measures,

6 **= $P < 0.05$, dynamic impression insole and custom molded insole compared to 7-mm flat EVA,

7 [†]= $P < 0.05$, compared between dynamic impression insole and custom molded insole.

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2 Table 4
3 Mean force (Newton) for three different insoles (n=17)

Plantar regions	7-mm flat EVA (40 Shore A)	Custom molded insole	Dynamic impression insole	ANOVA	
				F value	p value
Heel	168.9 (33.5) 0%	131.6 (33.5) -22.1% **	129.2 (32.7) -23.5% **	45.2	<0.001*
Midfoot	42.4 (33.1) 0%	89.8 (43.0) 111.6% **	110.6 (43.4) 160.7% ** [†]	83.2	<0.001*
MTH	162.9 (63.8) 0%	131.2 (57.3) -19.5% **	133.4 (50.6) -18.1% **	21.0	<0.001*
Toes	26.2 (14.0) 0%	37.4 (19.0) 43.1% **	36.0 (16.4) 37.5% **	9.7	0.002*

4 Values are expressed as mean (standard deviation) and % change of mean values normalized to those of
5 EVA,
6 *= $P < 0.05$, compared among three insoles using one-way ANOVA with repeated measures,
7 **= $P < 0.05$, dynamic impression insole and custom molded insole compared to 7-mm flat EVA,
8 [†]= $P < 0.05$, compared between dynamic impression insole and custom molded insole.

1 Table 5

2 Contact area (cm²) for three different insoles (n=17)

Plantar regions	7-mm flat EVA (40 Shore A)	Custom molded insole	Dynamic impression insole	ANOVA	
				F value	p value
Heel	33.0 (5.4) 0%	37.0 (5.4) 12.1%**	35.7 (5.0) 8.2%**	30.6	<0.001*
Midfoot	22.1 (11.9) 0%	40.8 (10.5) 84.6%**	44.7 (7.3) 102.5%**	48.6	<0.001*
MTH	38.5 (7.7) 0%	41.0 (8.3) 6.5%**	44.3 (6.3) 15.1%** [†]	21.5	<0.001*
Toes	11.7 (4.9) 0%	15.1 (5.9) 28.5%**	15.3 (4.7) 30.0%**	13.8	0.001*

3 Values are expressed as mean (standard deviation) and % change of mean values normalized to those of
4 EVA,

5 *= $P < 0.05$, compared among three insoles using one-way ANOVA with repeated measures,

6 **= $P < 0.05$, dynamic impression insole and custom molded insole compared to 7-mm flat EVA,

7 [†]= $P < 0.05$, compared between dynamic impression insole and custom molded insole.

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