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Plantar pressure analysis of accommodative insole in older people with metatarsalgia[☆]

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ABSTRACT

Foot pain frequently reduces physical activity and increases the risk of falls in older people. In current orthotic management of forefoot pain, metatarsal padding is the main strategy to reduce metatarsal pressure. However, pressure reductions are usually diverse and limited. The multi-step accommodative insole is fabricated by sequential foam padding on Plastazote under dynamic accommodation in daily walking. The aims of this study were to investigate the effectiveness and mechanisms of accommodative insole on plantar pressure redistribution in older people with metatarsalgia. The study was conducted on 21 old outpatients with moderate to severe metatarsalgia, using the ethylene vinyl acetate control, 9-mm flat Plastazote, and accommodative insoles with and without metatarsal and arch support. Outcome measures included pressure-related variables measured by a Pedar-X system, and pain scores assessed with a 0–10 Visual Analog Scale. The accommodative insole significantly decreased peak pressure under the metatarsal heads by 47.2% ($p < 0.001$) and the pain scores from 8.2 to 1.1 ($p < 0.001$). Plantar pressure analyses indicated that the effects of dynamic metatarsal contouring and cushioning on reducing peak pressure were greater than those of metatarsal padding. The temporo-spatial relationships between the toe and metatarsal head can assist in explaining an elevated metatarsal pressure and higher risk of falls in older people with toe deformities. The multi-step insole is simple in orthotic fabrication and ensures an even distribution of plantar pressure loading in walking. It can effectively relieve metatarsalgia and help to preserve regular walking activity for older people with metatarsalgia.

1. Introduction

Foot pain affects approximately one-third of community-dwelling people over age 65 [1]. In a prospective cohort study in older adults aged 50 and more, the incidence rate of disabling foot pain is 8.1% at 3-year follow-up and increases with age [2]. Foot pain may increase the risk of falls and decrease physical activity, causing a worse quality of life [3,4]. Reduction of physical activity has been shown to increase the mortality from all causes [5,6]. Regular daily walking is beneficial for health, leading to a longer life [7]. Furthermore, inappropriate footwear is very common in older people and is highly associated with forefoot deformities including hallux valgus and hammer/claw toes [8]. These toe deformities may increase plantar pressure under the metatarsal heads (MTH), resulting in metatarsalgia [9,10]. It has been documented that older adults with foot pain or toe deformities have a higher risk of falls [11,12]. Early comprehensive podiatry intervention has been recommended to prevent falls for older people with disabling foot pain [13].

Plantar pressure reduction with the use of an insole has been demonstrated to effectively diminish the subjective rating of metatarsalgia [14–17]. Metatarsal padding is currently the main strategy for reducing the excessive pressure and thus relieving the pain under the MTH [14–17]. Earlier studies revealed that the insoles incorporated with metatarsal support reduced peak pressure under the MTH by 11.3–21.8% [14–17]. However, the effectiveness of custom-made insole varies greatly with the designs and materials used in orthotic fabrication. The limited pressure reduction and technical variability might account for conflicted reports in randomized controlled trials of foot orthoses for patients with metatarsalgia [18,19].

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Plastazotes have been used to reduce plantar pressure and prevent foot ulcers in neuropathic foot because of their self-molding properties for accommodating plantar contours [20]. However, in a sequential trial of wearing semi-rigid and soft insoles in supporting shoes for 12 weeks, the use of Plastazote did not bring benefits to rheumatoid arthritic patients with metatarsalgia [21]. Recently, we have successfully improved the efficacy of Plastazote and extended their effective life by using multi-step foam padding and successive impression during daily walking. The accommodative insole is superior to a custom molded insole to reduce metatarsal pain in rheumatoid arthritic patients because dynamic impression can obtain more weight-bearing area than static impression under the MTH in walking [22]. However, no study has been conducted to investigate the benefits of using accommodative insoles in older people with metatarsalgia. In addition, very little is known concerning the mechanisms of plantar pressure redistribution during the accommodating process. The purposes of this study were to examine the effectiveness of the new insole for older adults with moderate to severe metatarsalgia, as well as to explore the biomechanical basis for optimizing orthotic management of metatarsalgia.

2. Methods

2.1. Participants

Twenty-three old adults were consecutively recruited from our podiatry outpatient clinic in 2010–2011. The inclusion criteria were: (1) age range 65–85; (2) with moderate to severe metatarsalgia (VAS = 5 and more; see 2.3 Evaluation of the insoles); and (3) who were able to walk in the community. We excluded those who walked with walking aids because of requirement of plantar pressure measurement. Twenty-one participants (13 males and 8 females; 18 bilateral feet and 3 unilateral right foot involvement) completed this study. The demographic characteristics of participants are given in Table 1. The location of metatarsalgia (% morbidity), in descending morbidity rate, was as follows: the third MTH (78.6%), the second MTH (66.7%), the fourth MTH (33.3%), the fifth MTH (16.7%), and the first MTH (16.7%). The metatarsalgia was complicated with heel pain (14.3%), hallux valgus (66.7%) and claw/hammer toes (33.3%). To minimize the influence of footwear on gait characteristics and ground reaction forces, all participants were instructed to wear same kind of wide extra-depth shoes that could accommodate the minimum 10-mm thick insole. The project was approved by the Ethics Committee of the Taipei Veterans General Hospital, and informed consent was obtained from all participants.

2.2. Accommodative insole

The materials necessary to fabricate the accommodative insole included 9-mm Plastazote (15 Shore A hardness, Schein orthopädie service KG. Remscheid, Germany), 2-mm Multiform (30 Shore A hardness, Schein orthopädie service KG.), 7-mm EVA (Ethylene Vinyl Acetate, 40 Shore A hardness, Schein orthopädie service KG.), 6.5-mm P-cell (21 Shore A hardness, Acor orthopedic Inc. Cleveland, Ohio, USA), and double-sided adhesive tape for multiple layers adhesion. The procedures involved 4 steps of sequential foam padding under daily walking impression as we previously described [22].

Table 1
Characteristics of participants ($N = 21$).

Characteristics	Mean (SD)	Range
Age (years)	75.0 (6.5)	65–84
Body weight (kg)	60.4 (11.7)	35–87
Body height (cm)	160.0 (8.3)	143–171
Body mass (kg/m^2)	23.5 (3.4)	14.6–30.1
Walking speed (m/min)	54.9 (12.0)	29.5–75.9

2.3. Evaluation of the insoles

The subjective pain levels were recorded using a horizontal 10 cm Visual Analog Scales (VAS) pain score marked at the left end 0 (no pain) and at the right end 10 (the worst pain) [23]. The pain levels were assessed before treatment with insoles, after using 9-mm Plastazote, and one month after the final step of accommodative insole fabrication. The plantar pressure analysis was performed using a Pedar-X mobile in-shoe system (Novel gmbh, Munich, Germany) to evaluate 4 different insoles including 7-mm flat EVA control (40 Shore A hardness), 9-mm uncompressed Plastazote (15 Shore A hardness), accommodative insole with, and without MAS. An immediate effect of walking on plantar pressure only occurred in Plastazote. As reported by Hurkmans et al. [24], the 1.9 mm flexible Pedar-X insole, consisting of 84–99 capacitance-based sensors, is reliable to measure vertical force during a short-time period. The plantar pressures were recorded at a frequency of 100 Hz in the middle 5-meter path of an 8-meter walkway. Participants were instructed to walk 5 laps for each insole at their comfortable and stable walking speed. Since walking velocity has been demonstrated to influence plantar pressure [25], the walking trial would be adjusted and repeated if speed was not within 5% of the mean velocity measured in 4 different insoles. To overcome high variability of walking speed in older people for speed adjustment and minimize day-to-day variation error [24], the plantar pressure measurement of all insoles was performed in random order on the same day after wearing accommodative insoles one month. The Pedar insoles were calibrated according to the manufacturer's instructions before plantar pressure measurement. All pressure data were processed with the Novel-Win Multimask analysis software (Novel gmbh, Munich, Germany). Outcome measures included peak pressure, pressure–time integral, maximal force, contact area, and time process of peak pressure and contact area. Since relative shortness of toe length was noted in subjects with toes deformities, we slightly adjusted plantar region division from normal setting, especially between toes and MTH. The plantar area was divided into 4 regions that were heel (0–30% of foot length), midfoot (30–60%), metatarsal heads (60–85%), and toes (85–100%). Only the right foot was chosen for statistical analysis because of data independence.

2.4. Statistical analysis

The required sample size was estimated by GPower 3.1.2 [26], assuming a power of 0.8 and an alpha level of 0.05. Based on the data of a preceding study in older people with metatarsalgia [11], the sample size was calculated to be a minimum of 21 persons 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) and the pressure data were checked for normality using the Kolmogorov–Smirnov test with Lilliefors correction. A general linear model with repeated measures analysis was used to evaluate the effects of multi-step padding on redistribution of peak pressure, pressure–time integral, maximal force and contact area among different foot regions. One-way repeated measures ANOVA and post hoc Bonferroni test were undertaken to examine the significance of differences among 4 different insoles for each measured variable and plantar region. The two-tailed paired *t*-test was performed to test the significance of differences in means VAS pain scores before and after treatment with insoles. The differences were considered significant if $p < 0.05$.

3. Results

After using 9-mm thick Plastazote for 2–3 weeks, the mean VAS pain score significantly decreased from 8.2 (range 5–10, SD = 1.7) to 4.2 (range 2–8, SD = 1.3, $p < 0.001$). One month after wearing accommodative insoles with MAS, the mean VAS pain score was further decreased to 1.1 (range 0–4, SD = 1.2, $p < 0.001$). Eight participants experienced total pain-relief (VAS = 0) under the MTH in their walking. All participants were satisfied with the use of insole for their daily walking at an additional 6-month follow-up. Analysis of the general linear model indicated the presence of significant interactions between insole types and plantar regions in each pressure-related variable (all $p < 0.001$). One-way ANOVA also revealed significant differences among 4 insoles in each pressure-related variable and plantar region (Table 2).

At the MTH, pairwise comparisons between the EVA control and other 3 insoles showed significant differences in all measured variables (all $p < 0.001$). Compared to the EVA control, the accommodative insole with MAS caused significant reductions in peak pressure (−47.2%, $p < 0.001$), pressure–time integral (−48.9%, $p < 0.001$) and maximal force (−17.8%, $p < 0.001$), but a significant increase in contact area (+18.0%, $p < 0.001$). In 9-mm uncompressed Plastazote, the magnitude of pressure and force reduction was lower than those of accommodative insole with MAS (all $p < 0.001$). However, no significant difference was demonstrated in contact area.

At the midfoot, the maximal force and contact area increased progressively and significantly during the multi-step padding process (all $p < 0.001$). But, no significant differences were noted in peak pressure and pressure–time integral.

Similar to those of the MTH, the heel peak pressure and pressure–time integral reduced progressively and significantly during serial padding process (all $p < 0.001$) (Fig. 1). At the MTH and heel, MAS intervention caused significant reductions in peak pressure ($p < 0.001$, $p < 0.001$), pressure-time integral ($p < 0.001$, $p < 0.001$) and maximal force ($p < 0.001$, $p = 0.005$), but no significant differences in contact area.

Assuming the effect difference between the EVA control and accommodative insole with MAS as 100%, the contribution percentage of 9-mm Plastazote to the final accommodative insole at the MTH were 69% in peak pressure, 71% in pressure–time integral, 65% in maximal force and 82% in contact area, respectively (Fig. 2).

4. Discussion

The pain reductions after using 9-mm Plastazote and final accommodative insole were compatible with their MTH pressure

Table 2
Peak pressure, pressure–time integral, maximal force and contact area for 4 different insoles ($N = 21$).

Plantar regions	7-mm flat EVA (40 Shore A)	9-mm flat Plastazote (15 Shore A)	Accommodative insole without MAS	Accommodative insole with MAS	F value	p-Value
Peak pressure (kPa)						
Heel	211.4 (26.4)	164.6 (21.8)	143.3 (20.7)	135.1 (22.6)	119.5	<0.001
	0%	−22.2%	−32.2%^{a}	−36.1%^{a,b}		
Midfoot	113.2 (33.4)	98.5 (15.4)	100.8 (17.9)	96.9 (13.9)	3.5	0.038
	0%	−13.0%	−11.0%	−14.4%		
MTH	268.4 (41.2)	181.2 (39.0)	156.9 (22.4)	141.8 (18.5)	236.7	<0.001
	0%	−32.5%	−41.5%^{a}	-47.2%^{ab}		
Toes	185.6 (66.2)	132.6 (37.9)	146.7 (54.9)	147.7 (54.3)	9.2	0.001
	0%	−28.6%	−20.9%	−20.4%		
Pressure-time integral (kPa s)						
Heel	73.2 (23.5)	56.9 (17.6)	50.8 (15.4)	46.9 (13.8)	25.4	<0.001
	0%	−22.3%	−30.6%^{a}	−36.0%^{a,b}		
Midfoot	45.4 (16.3)	41.8 (12.0)	44.5 (11.5)	44.5 (10.7)	4.2	0.021
	0%	−8.0%	−1.9%	−1.9%		
MTH	97.1 (23.7)	63.5 (18.3)	55.6 (11.3)	49.6 (12.2)	228.7	<0.001
	0%	−34.6%	−42.8%^{a}	−48.9%^{a,b}		
Toes	52.1 (19.4)	38.9 (10.6)	45.4 (14.0)	44.1 (12.6)	6.1	0.005
	0%	−25.5%	−12.9%	−15.4%		
Maximal force (Newton)						
Heel	374.1 (83.5)	338.9 (85.1)	324.9 (87.4)	308.3 (83.7)	29.4	<0.001
	0%	−9.4%	−13.2%	−17.6%^{a,b}		
Midfoot	77.7 (38.5)	106.2 (43.0)	141.8 (45.4)	173.3 (48.7)	52.5	<0.001
	0%	36.7%	82.5%^{a}	123.0%^{a,b}		
MTH	434.4 (79.2)	383.7 (74.5)	377.8 (73.1)	357.2 (68.3)	31.5	<0.001
	0%	−11.7%	−13.0%	−17.8%^{a,b}		
Toes	90.2 (42.5)	95.9 (41.1)	107.9 (39.1)	114.8 (40.5)	10.4	<0.001
	0%	6.3%	19.7%	27.3%^{a}		
Contact area (cm^{2})						
Heel	33.0 (5.9)	35.3 (5.8)	35.7 (5.5)	35.8 (5.2)	15.8	<0.001
	0%	6.8%	8.1%	8.4%		
Midfoot	19.2 (8.1)	26.8 (8.1)	34.9 (8.9)	42.9 (7.7)	87.7	<0.001
	0%	39.9%	82.2%^{a}	123.7%^{a,b}		
MTH	39.4 (7.4)	45.2 (6.2)	46.3 (5.8)	46.5 (5.7)	33.8	<0.001
	0%	14.6%	17.6%	18.0%		
Toes	12.3 (3.6)	15.8 (4.6)	16.4 (4.1)	16.7 (4.1)	16.3	<0.001
	0%	28.3%	33.0%	35.7%		

Values are expressed as mean (standard deviation) and % change of mean values compared to EVA control.

[a] $p < 0.05$, accommodative insole with and without MAS compared to 9-mm Plastazote (Bonferroni test).

[b] $p < 0.05$, compared between the accommodative insole with MAS and without MAS (Bonferroni test).

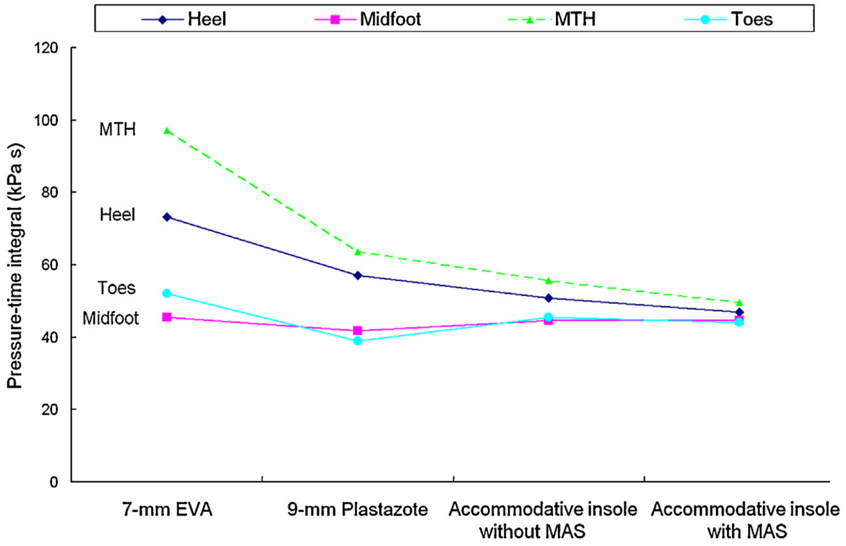

Fig. 1. The heel and the MTH displayed similar changes in pressure–time integral during the multi-step padding process. The final accommodative insole reduced pressure–time integral at the MTH and the heel, ensuring an even distribution of pressure loading under the foot.

reductions measured in this study. Our short-term effect of Plastazote was contrary to a previous report using 6.5-mm Plastazote although both final pain scores were the same [21]. Because our study recruited the participants with moderate to severe metatarsalgia (VAS pain score 5 and more), the pain score was reduced significantly from a higher initial level. Since Plastazotes are highly compressible, the effectiveness in reducing plantar pressure and pain is usually of limited duration. After further padding and walking impression for 3 or 4 months, the MTH pressure reduction was twice those previously reported for custom insoles with metatarsal padding [14–16].

Plastazotes had an immediate effect on MTH pressure reduction because of the synergistic interaction between an increased contact area and a decreased maximal force. In contrast, the metatarsal pad utilized a small area to shift the excessive force from the MTH to the metatarsal shaft with no obvious increase in contact area, resulting in a limited pressure reduction under the MTH. Moreover, the effectiveness of the metatarsal pad can be influenced by their size, shape, positioning and materials [15,17,27,28]. It is not surprising that customized insole may have controversial results in several clinical trials for subjects with metatarsalgia [18,19].

At the MTH, 9-mm Plastazote could contribute more than 65% of total effects of a final accommodative insole in all measured variables (Fig. 2). Since Plastazotes possess unique self-molding properties, most of metatarsal area can be immediately available for weight bearing in walking. The metatarsal contouring could not merely increase the weight-bearing area but also shift the loading force from MTH to the proximal area. Since Plastazotes will concurrently lose cushioning properties after a short-term walking compression, further padding with less compressible foam is necessary to maintain their force-absorbing capacity. It is important to older people with metatarsalgia because progressive loss of tissue elasticity resulting from the aging process may decrease the force-absorbing ability under the foot [29]. We also found that further padding with P-cell and Multiform produced a

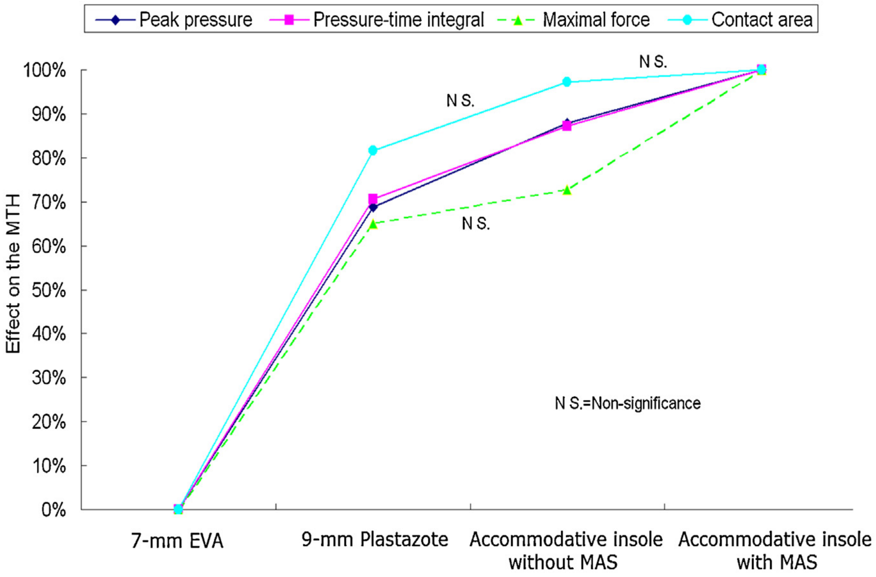

Fig. 2. Assuming the total effect of accommodative insole with MAS as 100%, 9-mm Plastazote contributed more than 65% of the total effects on the MTH in all 4 pressure-related variables. After further padding on Plastazote, the contact area showed a slight increase but this change was not significant.

non-significant decrease in maximal force and a non-significant increase in contact area at the MTH. However, their synergistic instead of additive effect could still reduce peak pressure and pressure–time integral significantly.

Since further padding on Plastazote did not cause significant changes in MTH contact area, the maximal force would be a major factor determining further metatarsal pressure and pain reduction in the following multi-step padding (Fig. 2). In mechanics, the maximal force can be attenuated by using force-absorbing and force-shifting approaches. Both P-cell and Multiform were primarily used as force-absorbing layers due to their cushioning properties. Alternatively, the MAS was used to shift the force from MTH and heel to midfoot for arch support. Because the MAS was affixed to the midfoot, MAS intervention increase the weight-bearing area only at the midfoot. Since maximal force and contact area were simultaneously increased in the same proportion during serial padding procedures, both peak pressure and pressure–time integral did not elevate at the midfoot (Fig. 1). These results were compatible with our clinical observations that all participants experienced metatarsalgia relief with no pressure discomfort under their midfoot during the trial.

The mechanism of MAS function can be recognized from the time process of peak pressure and contact area during stance phase (Fig. 3). The instant of heel peak pressure appeared after the toes began to contact the ground in stance phase of gait. Because the walking foot was in a foot-flat position, the arch support could shift the loading force from heel to midfoot for heel peak pressure reduction. In contrast, the instant of MTH peak pressure appeared very close to the end of midfoot contact in late stance phase. Since the metatarsophalangeal joint was in a dorsiflexed position during the heel-rise, the MTH peak pressure could be reduced by metatarsal support rather than arch support. Theoretically, the plantar contours of longitudinal arch and heel obtained from custom molded insole make a trivial contribution to the MTH peak pressure reduction. Since MTH and toe were very close to each other in the instant of peak pressure, the toe dysfunctions resulting from toe deformities might increase MTH functional loading in walking. Structurally, the hammer/claw toes may cause MTH prominence and distal displacement of fat-pad cushion beneath the MTH, resulting in metatarsalgia. The temporo-spatial relationships between the toe and MTH could account for the fact that most of participants suffered from toe deformities in the study. The mechanisms also assist in explaining why older people with toe deformities have an elevated metatarsal pressure and a higher risk of falls than those without deformities [10,12,30]. However, no differences in static balance or gait characteristics have been demonstrated between older people with and without toe deformities [30]. It has been proposed that metatarsal pain and altered weight-bearing patterns may affect the foot function of mechanical stability and thereby increase the risk of falls in more challenging locomotor tasks [30]. The accommodative insoles possess excellent self-molding and force-attenuating properties to dynamically accommodate plantar contours and uniformly redistribute plantar pressure loading for high-grade locomotion skills.

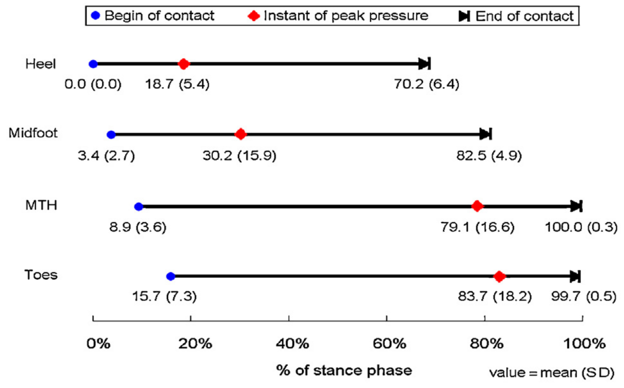

Fig. 3. The time process of peak pressure obtained from all insoles indicated temporal relationships between the heel and midfoot, and between the MTH and toes. Since the instant of MTH peak pressures is very close to the end of midfoot contact, metatarsal support instead of arch support contributed to the reduction in peak pressure reduction under the MTH.

5. Conclusions

In contrast to the traditional concept of orthotic management of metatarsalgia, dynamic metatarsal contouring and cushioning is more important than metatarsal padding for MTH pressure reduction. Using a Plastazote or metatarsal pad alone is usually inadequate for patients with severe metatarsalgia. Nevertheless, the force-absorbing capacity and effective life of Plastazotes can be easily enhanced by further padding with less compressible materials. The metatarsal and arch support provides an additive force-shifting function to increase the supporting force at the midfoot and thus reduce the loading force at the MTH and heel. Furthermore, the accommodative insole can utilize all available plantar areas for weight bearing and ensure an even distribution of plantar pressure loading throughout the stance phase. The total contact insole is simple in orthotic fabrication and is useful to older people with metatarsalgia in preserving daily walking activity.

Conflicts of interest

There are no conflicts of interest related to this study and no professional relationships between the authors and manufacturers of materials utilized in this study.

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