



## Comparison of the Forefoot Pressure-Relieving Effects of Foot Orthoses

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**Purpose:** Metatarsal pads are prescribed to decrease forefoot plantar pressure. However, the appropriate metatarsal pad placement location remains a debated issue. We aimed to identify the most effective insole design that reduces forefoot plantar pressure and determine the optimal position for metatarsal pad placement.

**Materials and Methods:** We recruited 16 healthy adult volunteers, and measured their plantar pressure data during walking while using an in-shoe system. The volunteers were randomly assigned to one of four insole conditions: 1/16-inch insole (i.e., control), 1/4-inch soft plastazote (SP) flat insole, metatarsal pad positioned proximal to the metatarsal head (MTH) on the control insole (P0), and metatarsal pad positioned 10 mm distal from the proximal border of the MTH on the control insole (P10). A masking protocol was created by dividing the forefoot into three subareas, distal to the MTH (dMTH), beneath to the MTH (bMTH), and proximal to the MTH (pMTH). The participants reported their comfort level for each insole using a visual analog scale.

**Results:** The SP flat insole and metatarsal pads both had a forefoot plantar pressure-reducing effect and provided insole comfort. Of the three insole designs, the SP flat insole was the most effective. No clear difference existed in efficacy in terms of the location of the metatarsal pad placement.

**Conclusion:** Considering the possibility of discomfort caused by improper metatarsal pad placement, the SP that increases shock absorption may be more clinically useful.

**Key Words:** Metatarsalgia, orthosis, material, plantar pressure

### INTRODUCTION

An increasing number of people enjoy walking, and the inci-

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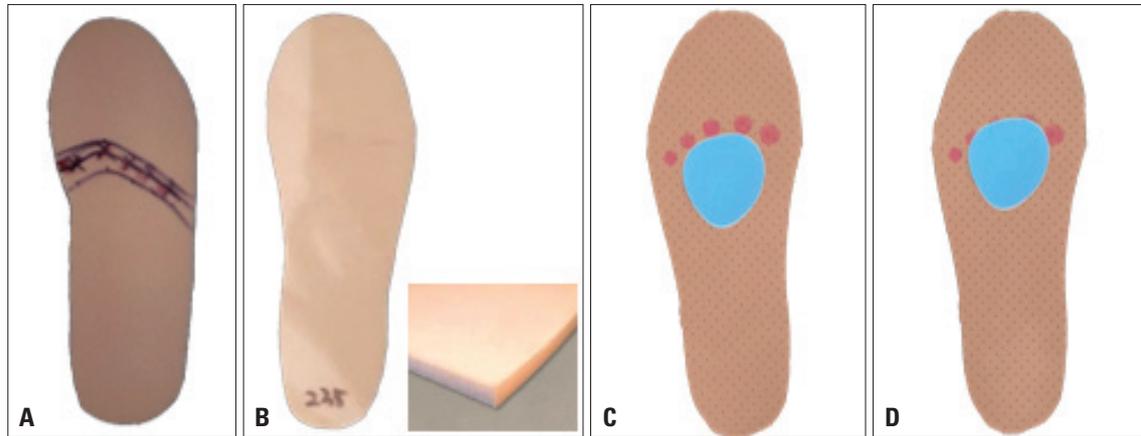
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dence of foot pain and disorders has consequently increased due to the walking-related force applied to the heel and metatarsal area. Repeated pressure accumulation in the metatarsal head (MTH) area during walking can eventually lead to metatarsalgia.

Several studies<sup>1-3</sup> have reported plantar pressure reduction under the MTH, and therefore effective pain reduction, using custom-molded orthoses with a metatarsal dome. Metatarsal pads are used to conservatively treat primary metatarsalgia due to their cost effectiveness and ease of use. However, forefoot pads exert insufficient effects in some patients with metatarsalgia. Furthermore, some patients adhere poorly to treatment due to local pad-induced discomfort.<sup>1,4,5</sup>

Improper metatarsal pad placement affects the plantar pressure-reducing effect, although no consensus exists regarding the most effective and appropriate location for metatarsal pad placement. Some studies<sup>6-8</sup> have reported that metatarsal pad placement in the region just proximal to the MTH is the most



**Fig. 1.** Insole condition. (A) Control: UCOLite insole, 1/16-inch thickness (Multiform). (B) SP: soft plastazote flat insole, 1/4-inch thickness (medium pink; product #7051; Apex). (C) P0: metatarsal pad positioned proximal to the metatarsal head (MTH) on the control insole. (D) P10: metatarsal pad positioned 10 mm distal to the proximal border of the MTH on the control insole.

effective in pain alleviation, while other studies have reported that metatarsal pad placement in the region slightly distal to MTH is more effective.<sup>3,9</sup>

Hähni, et al.<sup>4</sup> revealed a significantly greater forefoot peak pressure reduction by using foot orthoses with forefoot cushioning in asymptomatic marathon runners, compared to the pressure in runners using metatarsal pads which did not provide a pressure-reducing effect. Chen, et al.<sup>9</sup> reported that using an approximately 12.7-mm thick flat insole reduced the pressure nearly as much as a metatarsal pad. In similar manner, using a sufficiently thick insole can potentially reduce metatarsalgia without metatarsal pad placement. However, wearing shoes with pads thicker than 10 mm is difficult due to insufficient space inside the toe box. The purpose of our study was to identify a clinically practical insole design that could reduce MTH pressure. First, we compared the forefoot pressure-relieving effect based on the attachment position of the metatarsal pad in relation to the MTH. Second, we compared the effect of pressure reduction of the forefoot between metatarsal pad and 1/4-inch thick, soft plastazote insole, which is thinner than the thickness of insole which has previously been reported as having a similar effect on the metatarsal pad.

## MATERIALS AND METHODS

### Participants

For this study, we recruited 16 healthy adults (representing 26 feet) between the ages of 21–70 years. The study protocol was approved by the Institutional Review Board (IRB) of Bundang Jesaeng General Hospital (Seongnam, Republic of Korea; IRB file Number: DMC 2019-07-008). The data collected included the participants' age, sex, height, weight, body mass index (BMI), and foot size.



**Fig. 2.** Metatarsal pad. An adhesive metatarsal pad with 1/4-inch thickness (4466-PPT; Justin Blair & Company).

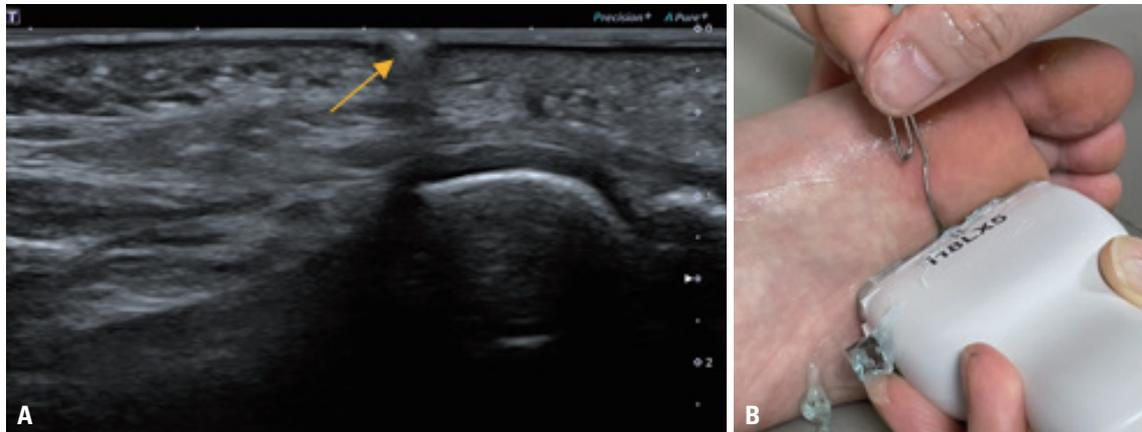
### Interventions

As shown in Fig. 1, we assigned the participants to one of the following four groups, based on the insole conditions:

- 1) Control group: UCOLite insole, 1/16-inch thickness (Multiform, Budapest, Hungary);
- 2) SP group: soft plastazote flat insole, 1/4-inch thickness (medium pink; product #7051; Apex, Mesa, AZ, USA);
- 3) P0 group: Metatarsal pad positioned just proximal to the MTH (P0) on the control insole; and
- 4) P10 group: metatarsal pad positioned 10 mm distal to the proximal border of the MTH (P10) on the control insole.

A teardrop-shaped prefabricated metatarsal pad [metatarsal pad with adhesive [4466]—PPT, 1/4-inch thickness (Justin Blair & Company, Chicago, IL, USA)] was used (Fig. 2).

The MTH location on the insole was marked, using a previously published method.<sup>10</sup> The MTH position was confirmed by an experienced physiatrist with the paperclip technique<sup>11</sup> using ultrasonography (Logiq E9; GE Healthcare, Chicago, IL, USA) (Fig. 3). Based on the MTH location imprint on each of the UCOLite insoles, a metatarsal pad was placed with its anterior margin aligned with the proximal line of the MTH marking in the P0 group and 10 mm distal to the MTH location in the P10 group.



**Fig. 3.** Metatarsal head position, confirmed using the paperclip technique with ultrasonography. (A) Yellow arrow indicates the bright echo with posterior comet tail artifact produced by the paper clip. (B) While scanning over the metatarsal head, an extended paperclip was placed between the transducer and the skin.

### Measurement of plantar pressure parameters

Foot plantar pressures were measured using the Pedar-X in-shoe system (Novel, GmbH, Munich, Germany) with the participant walking at a comfortable speed after putting one of the four test insoles into their own appropriately fitting footwear (i.e., the typical athletic walking shoes with a semi-curved last, medium-density sole, and low collar).

The order of insole testing was randomized to avoid ordering effects. Additionally, participants were blinded to the type of interventions used.

The Pedar-X system comprises 99 capacitive sensors arranged in a grid and embedded within a thin, flexible insole. The Pedar system was calibrated according to the manufacturer's instructions before plantar pressure assessment (Novel GmbH 1995). The sampling frequency of the system was 50 Hz.

A participant was instructed to walk on a 10-m walkway three times at a comfortable speed, after which the acceleration and deceleration steps were excluded from each trial to isolate the middle eight steps for analysis. Then, the average of total steps pressure data was calculated for each condition.

Data on forefoot plantar pressure were assessed using the novel multimask 25.3.27 analysis program (Novel GmbH, Munich, Germany, <https://www.novelusa.com/software>). This mask system divides the forefoot into three subareas based on the anatomic-based forefoot masking protocol proposed by Forghany, et al.,<sup>12</sup> which included subareas distal to the MTH (dMTH), beneath to the MTH (bMTH), and proximal to the MTH (pMTH) (Fig. 4).

For each subarea, we calculated the mean peak plantar pressure, maximum force, force-time integral, and contact area from three trials in each group.

### Assessment of insole comfort

After completing the experiment with all four insoles, the participants were asked about the level of comfort of each of the tested insoles. Insole comfort was measured using a visual an-

alog scale score ranging from 0 points (i.e., "most uncomfortable") to 10 points (i.e., "most comfortable").

### Statistical analysis

Each parameter was evaluated using a linear mixed model with correlated data match to both feet of a participant using the MIXED procedure in SAS (version 9.4; SAS Institute, Cary, NC, USA), with a restricted maximum likelihood estimation. This analysis used the observed data from each participant, with no imputation for missing data. Age, sex, foot size, and BMI were the adjusted variables, and the least mean square values were estimated. Post hoc adjustment was conducted using the Bonferroni correction method and presented as the adjusted *p*-values. The Shapiro-Wilk test was used to test for the normality of the distribution. These statistical tests were two-sided, and *p*-values < 0.05 were considered statistically significant.

## RESULTS

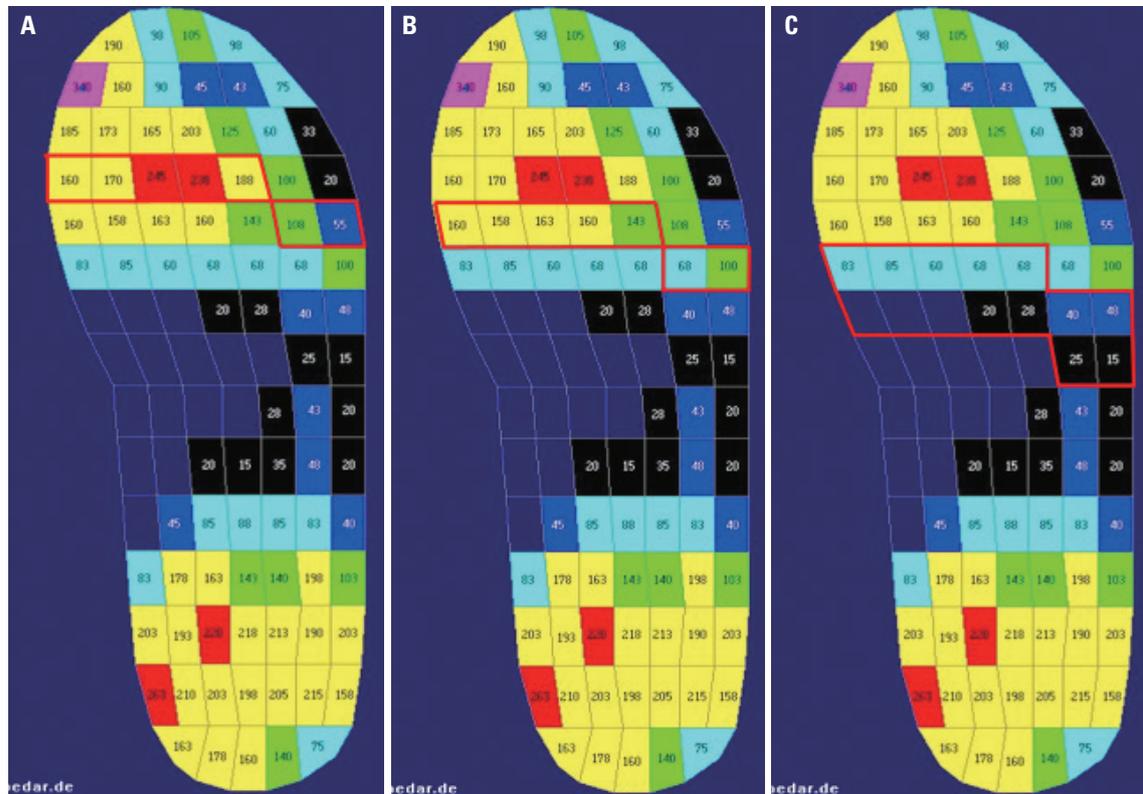
### Participant characteristics

We enrolled 16 healthy participants (representing 26 feet) with a mean age of  $31.9 \pm 7.5$  years. The participants consisted of six male and 10 female, with a mean BMI of  $21.6 \pm 2.1$  kg/m<sup>2</sup>. The participants' characteristics are shown in Table 1.

### Changes in the plantar pressure parameters, based on the foot region and insole condition (Table 2 and Fig. 5)

#### Subarea dMTH

The peak pressure and force-time integral values in the dMTH were significantly decreased in the SP, P0, and P10 groups compared to those of the control group. Moreover, the maximum force in the dMTH was significantly decreased in the SP and P0 groups compared to that of the control group. The contact area was significantly decreased in the SP group.



**Fig. 4.** Anatomic-based forefoot masking protocol. (A) dMTH is the subarea distal to metatarsal head (MTH). (B) bMTH is the subarea beneath the MTH. (C) pMTH is the subarea proximal to the MTH. dMTH, subarea distal to the MTH; bMTH, subarea beneath the MTH; pMTH, subarea proximal to the MTH.

**Table 1.** Demographic Characteristics of Study Participants (n=16)

Characteristics	Values
Foot side (right:left)	11:15
Sex (male:female)	6:10
Age (yr)	31.9±7.5
21–30	8 (30.8)
31–40	1 (3.8)
41–50	2 (7.7)
51–60	6 (23.1)
61–70	9 (34.6)
Weight (kg)	61.8±12.1
Height (cm)	168.3±8.7
BMI (kg/m <sup>2</sup> )	21.6±2.1

BMI, body mass index.

Values are expressed as the mean±standard deviation or n (%).

#### Subarea bMTH

The peak pressure, maximum force, and force-time integral values in the bMTH were significantly decreased in the SP, P0, and P10 groups compared to those of the control group ( $p < 0.0001$ ). In the P0 and P10 groups, the contact area in the bMTH was significantly reduced compared to that of the control group ( $p < 0.0005$ ), although it was unchanged in the SP group.

#### Subarea pMTH

The peak pressure and maximum force in the pMTH were not

significantly different in the SP, P0, and P10 groups than those of the control group, while the contact area was significantly increased in these groups compared to that of the control group ( $p < 0.0001$ ). The force-time integral value was significantly decreased in the P0 group compared to that of the control group ( $p = 0.0155$ ).

#### Comparison of the forefoot plantar pressure-reducing effect of the three insole conditions (Table 3 and Fig. 6)

##### Subarea dMTH

Compared to the P0 and P10 groups, the SP group had a decrease of 11% ( $p < 0.0001$ ) and 9% ( $p = 0.0002$ ), respectively, in the least mean square peak pressure, which indicated a significantly decreased peak pressure in the SP group. The differences in the decrease in peak pressure between the P0 and P10 groups were not significant (1% change,  $p = 0.5521$ ). No significant differences existed in the decrease in maximum force among the SP, P0, and P10 groups.

The decrease in the least mean square force-time integral values was significantly greater in the SP group than in the P0 and P10 groups (P0 vs. SP: 27% change,  $p < 0.0001$ ; P10 vs. SP: 14% change,  $p = 0.0214$ ). The difference in the least mean square force-time integral value between the P10 and P0 groups was a 13% change, which indicated that the P10 condition reduced the force-time integral value of the dMTH more effectively

**Table 2.** Pressure Data for Each Foot Region and Insole Condition

	Least mean square estimate				Difference					
	Control	SP	P0	P10	SP-control	p value	P0-control	p value	P10-control	p value
Visual analog scale	3.66	7.23	5.79	5.52	3.57	<0.0001	2.13	<0.0001	1.87	0.0004
Peak pressure (kPa)										
dMTH	171.76	134.31	154.82	151.22	-37.45	<0.0001	-16.95	0.0001	-20.55	<0.0001
bMTH	184.55	148.08	164.26	164.60	-36.47	<0.0001	-20.29	<0.0001	-19.94	<0.0001
pMTH	171.21	164.50	178.60	174.16	-6.70	0.9840	7.39	0.8430	2.95	>0.9999
Maximal force (%BW)										
dMTH	135.08	121.91	123.41	126.50	-13.17	0.0096	-11.66	0.0262	-8.58	0.1699
bMTH	113.95	92.15	92.16	102.10	-21.80	<0.0001	-21.79	<0.0001	-11.85	<0.0001
pMTH	269.50	272.77	270.83	278.29	3.27	>0.9999	1.33	>0.9999	8.79	0.8274
Force time integral (nsec)										
dMTH	15.80	9.56	12.85	11.52	-6.24	<0.0001	-2.95	0.0363	-4.27	0.0014
bMTH	12.88	9.07	9.87	9.35	-3.80	<0.0001	-3.01	0.0010	-3.52	0.0001
pMTH	62.65	62.23	58.45	62.76	-0.43	>0.9999	-4.20	0.0466	0.11	>0.9999
Contact area (cm <sup>2</sup> )										
dMTH	10.19	10.02	10.16	10.16	-0.17	0.1257	-0.02	>0.9999	-0.03	>0.9999
bMTH	9.90	9.90	9.52	9.51	0.01	>0.9999	-0.37	0.0055	-0.38	0.0053
pMTH	9.82	10.86	11.29	11.16	1.03	0.0004	1.47	<0.0001	1.34	<0.0001

SP, 1/4-inch soft plastazote flat insole; MTH, metatarsal head; dMTH, subarea distal to the MTH; bMTH, subarea beneath the MTH; pMTH, subarea proximal to the MTH; P0, metatarsal pad placed proximal to the MTH; P10, metatarsal pad placed 10 mm distal to proximal border of the MTH; %BW, percent body weight. The adjustment covariates were age, sex, foot size, and body mass index.

than in the P0 condition ( $p=0.0392$ ). The contact area decreased in the three experimental groups compared to the control group, although no significant difference was observed between the groups in terms of pressure decrease.

*Subarea bMTH*

Compared to the P0 and P10 groups, the SP group showed a 9% ( $p<0.0001$ ) and 10% ( $p<0.0001$ ) change, respectively, in the least mean square peak pressure in the bMTH. Therefore, the SP group showed a greater bMTH peak pressure decrease compared to the P0 and P10 groups ( $p<0.0001$ ). No significant difference existed between the P0 and P10 groups regarding the bMTH peak pressure decrease (-1% change,  $p=0.7733$ ).

Compared to the P10 group, the SP group showed an 11% change ( $p=0.0009$ ) in the least mean square maximum force in the bMTH; moreover, the P10 group showed a -11% change compared to the P0 group ( $p=0.0006$ ). Therefore, the SP and P0 groups had significantly greater reductions in the maximum force than did the P10 group. No significant difference existed in the maximum force reduction in the bMTH between the SP and P0 groups ( $p=0.8946$ ). No significant difference existed in the force-time integral reduction in the bMTH in all three experimental groups.

In the bMTH, no significant difference existed in the least mean square contact area between the P0 and P10 groups ( $p=0.9326$ ). Moreover, the contact area decrease in the SP group was significantly less than those of the P0 and P10 groups (P0 vs. SP: -4% change,  $p=0.0005$ ; P10 vs. SP: -4% change,  $p=0.0005$ ).

*Subarea pMTH*

No significant difference was found in the changes in peak pressure, maximum force, and contact area between the SP, P0, and P10 groups. The force-time integral value decrease was significantly greater in the P0 group than in the SP group (P0 vs. SP: -6% change,  $p=0.0381$ ) and the P10 groups (P0 vs. P10: -7% change,  $p=0.0209$ ). However, the force-time integral value was not different between the SP and P10 groups ( $p=0.7671$ ).

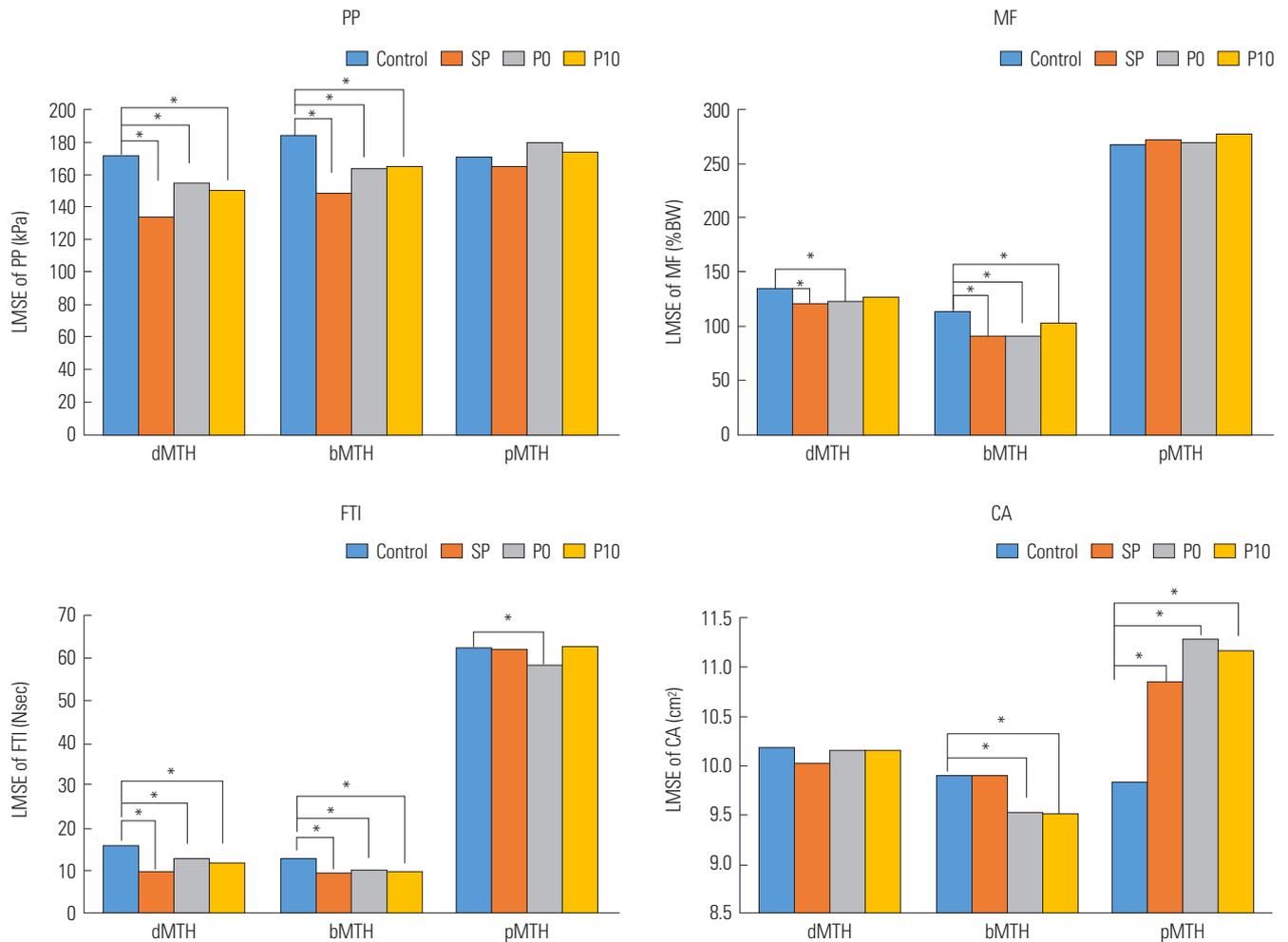
**Insole comfort**

The insole comfort level was significantly higher in all three experimental groups than in the control group (Table 2). The SP group had a significantly higher insole comfort level than did the P0 (-55% change,  $p=0.0035$ ) and P10 (-43% change,  $p=0.0199$ ) groups. The insole comfort level was not significantly different between the P0 and P10 groups ( $p=0.5147$ ).

**DISCUSSION**

This study showed that the 1/4-inch SP flat insole and metatarsal pad, regardless of the pad placement location, exert plantar pressure-reducing effects. In addition, the use of the 1/4-inch SP flat insole was more effective than metatarsal pad application.

Metatarsal dome or bar placement can alleviate metatarsal pain by reducing excessive plantar pressure in the bMTH or dMTH, and by shifting excessive force from the MTH to the metatarsal shaft.<sup>1,6,13</sup> This study similarly confirmed that metatarsal pad placement increases the contact area in the pMTH



**Fig. 5.** Pressure data for each foot region and insole condition. \* $p < 0.05$ . MTH, metatarsal head; dMTH, subarea distal to the MTH; bMTH, subarea beneath the MTH; pMTH, subarea proximal to the MTH; LMSE, least mean square estimate; PP, peak pressure; MF, maximal force; FTI, force time integral; CA, contact area; SP, soft plastazote; %BW, percent body weight; P0, metatarsal pad placed just proximal to the MTH; P10, metatarsal pad placed 10 mm distal to the proximal border of the MTH.

and decreases pressure in the bMTH and dMTH by redistributing the plantar pressure, thereby alleviating metatarsalgia.

The methodology of this study was different from that of previous studies. First, musculoskeletal ultrasonography was used to confirm the MTH location. Previous studies<sup>12</sup> were limited in that they identified the anatomical landmark of the MTH by palpation during metatarsal pad placement. The thickness and flexibility of the plantar fat pad under the MTH can differ among individuals. Therefore, a 5-mm margin of error may result if the external landmark of an internal bony structure is palpated, even if the palpation is conducted by a certified podiatrist. In a previous study, computed tomography conducted after palpation-based metatarsal pad placement showed that the actual pad locations were somewhat consistent with the intended location, although high patient-based variability existed in the placement positions.<sup>7</sup> In some instances, the placement position differed by up to 10 mm from the mean position.<sup>7</sup> Therefore, conflicting results in previous studies were likely caused by an inherent lack of accuracy in metatarsal pad place-

ment. In our study, we minimized this error by using musculoskeletal ultrasonography and the paperclip technique<sup>11</sup> to confirm the MTH location.

Second, plantar pressure parameters measured with an in-shoe sensor were analyzed by subarea by using an anatomic-based forefoot masking protocol,<sup>12</sup> which can potentially produce different results, depending on the area from which the parameter is measured. Most previous studies that examined plantar pressure analyzed the peak pressure in the entire forefoot.<sup>3,14</sup> The traditional masking protocol used to assess forefoot pressure defines the forefoot area in terms of a certain percentage of the foot length. However, this percentage may be misleading as it is not well established. Furthermore, in the presence of foot deformities or a shod condition, the length of a pressure-measuring insole often differs from that of the actual foot. Additionally, using the entire forefoot pressure is disadvantageous since the foot area in relation to the MTH reflected by using a given percentage is unclear.<sup>12</sup> To alleviate forefoot plantar pain, plantar pressure reduction in the bMTH and

**Table 3.** Comparison of the Forefoot Plantar Pressure-Reducing Effect among the Three Insole Conditions

A vs. B (A/B ratio)*	P0 vs. SP		P10 vs. SP		P0 vs. P10	
	Ratio (% change)	p value	Ratio (% change)	p value	Ratio (% change)	p value
VAS score	-55	0.0035	-43	0.0199	-12	0.5147
PP (kPa)						
dMTH	11	<0.0001	9	0.0002	1	0.5521
bMTH	9	<0.0001	10	<0.0001	-1	0.7733
pMTH	4	0.2665	3	0.5118	2	0.6642
MF (%BW)						
dMTH	2	0.6077	5	0.2029	-3	0.4376
bMTH	0	0.8946	11	0.0009	-11	0.0006
pMTH	-1	0.7366	1	0.7864	-2	0.5489
FTI (nsec)						
dMTH	27	<0.0001	14	0.0214	13	0.0392
bMTH	11	0.0591	1	0.9004	11	0.0847
pMTH	-6	0.0381	1	0.7671	-7	0.0209
CA (cm <sup>2</sup> )						
dMTH	1	0.0816	1	0.0933	0	0.9808
bMTH	-4	0.0005	-4	0.0005	0	0.9326
pMTH	6	0.0669	3	0.3644	3	0.3675

MTH, metatarsal head; dMTH, subarea distal to the MTH; bMTH, subarea beneath to the MTH; pMTH, subarea proximal to the MTH; SP, 6-mm soft plastazote flat insole; P0, metatarsal pad placed just proximal to the MTH; P10, metatarsal pad placed 10 mm distal to the MTH; PP, peak pressure; MF, maximum force; %BW, percent body weight; FTI, force-time integral; CA, contact area; VAS, visual analog scale.

The adjustment covariates were age, sex, foot size, and body mass index.

\*A vs. B [A/B ratio (%change)] is the difference of the least mean square estimate (A)/the difference of the least mean square estimate (B).

dMTH is important. Thus, pressure change analysis by subarea, rather than in the entire forefoot, may be more accurate. We used the anatomic-based masking protocol proposed by Forghany, et al.<sup>12</sup> and found that neither the 1/4-inch SP flat insole nor the metatarsal pads significantly changed the pressure in the pMTH. However, both devices decreased the peak pressure in the bMTH and dMTH, thereby demonstrating their clinical efficacy.

Third, plantar pressure may vary based on the participant's age, weight, and foot length. Therefore, we conducted our analysis after adjusting for age, sex, foot length, and BMI. Furthermore, our results may have differed from those of a previous study that compared the mean differences of the aforementioned parameters,<sup>15</sup> since we analyzed the pressure change ratios between the control group and each of the three insole groups.

Data from participants' feet were interrelated. Hence, we conducted a mixed covariate analysis to adjust for this interrelationship.

Pad-related discomfort reduces adherence in patients using metatarsal pads for pain alleviation. Factors affecting pad fitness sensation include the presence of an adequate shoe width

for metatarsal pad placement and the discomfort felt by a patient due to an improperly placed metatarsal pad.<sup>4</sup> If a metatarsal pad is positioned too distally, it can cause discomfort by interacting with plantar tissues near the MTH, such as the plantar fascia.<sup>8</sup> Therefore, the metatarsal pad placement position in reference to the MTH is clinically critical.

Furthermore, the possibility of a change in the relative positions of the metatarsal pad and MTH during walking should be considered as feet move inside the shoes. The relative positions created when a metatarsal pad is placed in a stationary foot position may change during gait movement. Furthermore, the relative positions of the metatarsal pad and the anatomical structures of a patient's foot may change in the shod foot condition due to the size difference between the shoe and the insole. A pressure difference as large as 63% can occur, even with just a 5-mm metatarsal pad displacement.<sup>9</sup> A previous study demonstrated that a metatarsal pad placed 1.8 mm distal and 6.1 mm proximal to the second MTH center and 10.6–16.8 mm in the proximal line reduced the overall peak pressure.<sup>7</sup> Nonetheless, a large degree of interindividual variability occurred. What is important is that the location that produces the highest pain alleviation effect may vary across patients.

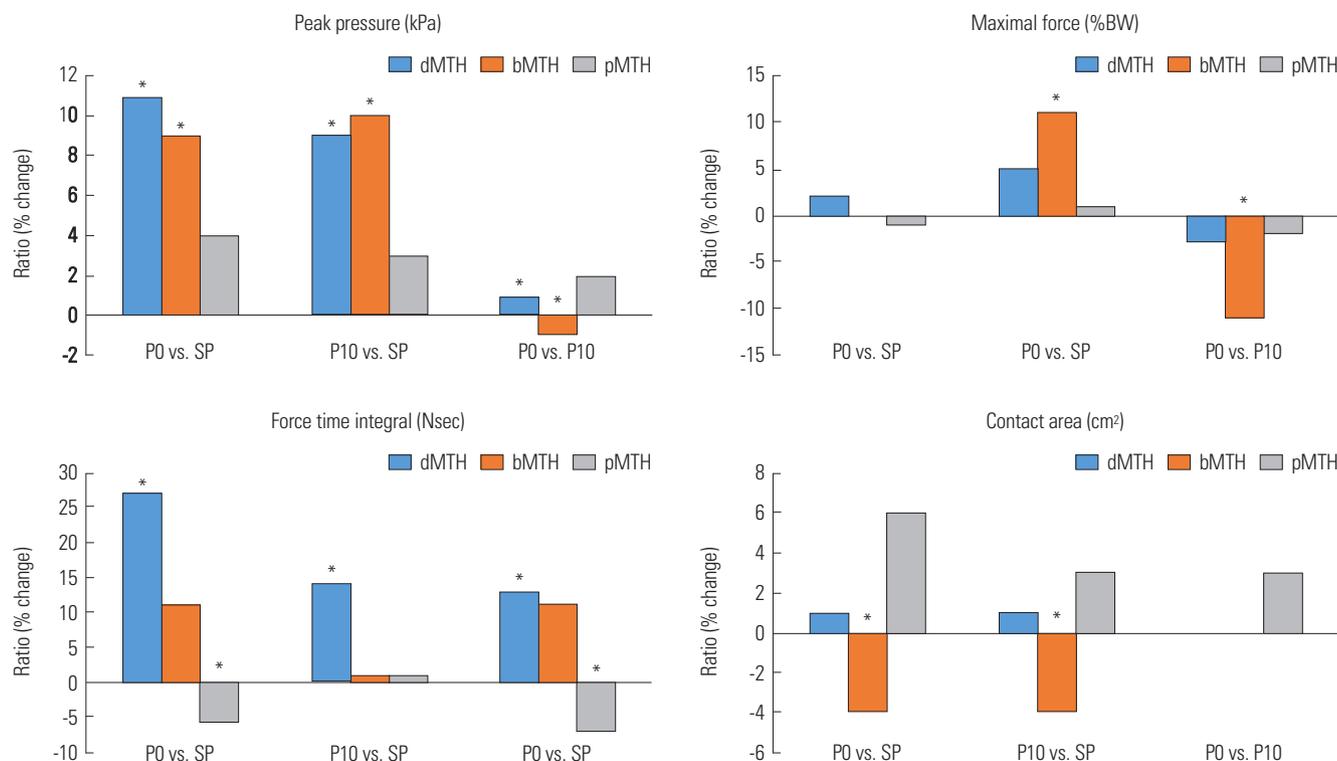
We found that the P0 and P10 conditions exhibited a forefoot pressure-reducing effect, but with no difference between the two insole conditions. Therefore, a more effective pad location may differ among patients.

The maximum force in the bMTH decreased the most in the P0 group, whereas the force-time integral in the dMTH was decreased the most in the P10 group. Thus, the greatest maximum force-reducing effect may have occurred at a location just distal to the metatarsal pad placement area. To minimize pain and maximize insole comfort, the area needed for pressure relief should consequently be considered when deciding the appropriate metatarsal pad placement location for each patient. Moreover, insole fitting should be customized for each patient.

In this study, the 1/4-inch SP insole had a greater plantar pressure-reducing effect and provided greater insole comfort than did the insoles with metatarsal pad attachment. This finding corroborates those of previous research, wherein a pad covering the entire plantar surface<sup>3</sup> and forefoot cushioning<sup>4</sup> reduced the forefoot peak pressure more significantly compared to a metatarsal pad.

Chen, et al.<sup>8</sup> stated that for the highest reduction in peak pressure in the bMTH when using metatarsal pads, the insole thickness should be 12.7 mm. Our study was significant as it demonstrated that the 1/4-inch SP flat insole, which has a smaller thickness than that suggested by Chen, et al.,<sup>8</sup> exerted a greater pressure-reducing effect than did the insoles with metatarsal pad attachment.

The extent of plantar pressure reduction correlates with the extent of pain alleviation.<sup>2</sup> However, the extent of pressure relief sufficient for pain alleviation remains unclear. Our study was



**Fig. 6.** Comparison of the forefoot plantar pressure-reducing effect among the three insole conditions. \* $p < 0.05$ . MTH, metatarsal head; dMTH, subarea distal to the MTH; bMTH, subarea beneath to the MTH; pMTH, subarea proximal to the MTH; P0, metatarsal pad positioned proximal to the MTH on the control insole; P10, metatarsal pad positioned 10 mm distal from the proximal border of the MTH on the control insole; %BW, percent body weight; SP, soft plastazote.

conducted only on healthy volunteers; therefore, future studies should evaluate whether the plantar pressure reduction achieved using a 1/4-inch SP insole is sufficient to produce a clinically meaningful metatarsalgia alleviation effect.

Several studies<sup>1-3</sup> have demonstrated that metatarsal pad application reduces pressure in the bMTH and, therefore, effectively relieves metatarsalgia. The 1/4-inch SP flat insole showed a greater pressure-reducing effect than did metatarsal pads, and thus may potentially exert a greater pain-relieving effect.

The shear force of the forefoot should be decreased to alleviate metatarsalgia, although the pressure measurement system currently used in clinical practice cannot measure the shear force. We hypothesize that the SP had a shear force-decreasing effect due to its physical properties. Studies should be conducted to test this hypothesis by using a device that accurately measures the shear force.

Our study demonstrated an effective plantar pressure decrease and insole comfort level increase by using a 1/4-inch SP, which is thinner than that suggested by Chen, et al.<sup>8</sup> Thus, the SP insole may be useful in clinical practice. Moreover, it is easily applied to routinely worn shoes. Future research should investigate whether the coapplication of a 1/4-inch SP insole with a metatarsal pad will produce additional pressure-reducing and pain-relieving effects.

This study had some limitations. First, the sample size was small, and the study was conducted only on healthy volunteers.

Therefore, the results cannot be generalized to patients with metatarsalgia, diabetes, or peripheral neuropathy. However, in the absence of sensation loss or permanent foot deformity, a person with foot pain will change gait speed or weight load distribution to avoid pain or discomfort during walking, which may influence changes in plantar pressure parameters. Thus, we conducted this study on participants without pain. Additionally, interindividual variability should be considered when interpreting foot plantar pressure study results. Second, this study measured only the immediate effect after insole application. Therefore, the long-term effects were not confirmed. Third, markings were created using musculoskeletal ultrasonography to determine the metatarsal pad placement location accurately. Nonetheless, the possibility of error around the marking for a precise location cannot be excluded. Because of unclear border of lipstick mark for metatarsal head position on the insole can be made during stepping several steps. In that case, we tried to repeat the marking procedure to lessen the possibility of error. Fourth, pressure measurements obtained using the Pedar system carry an inherent degree of error owing to the limited spatial resolution of the system's in-shoe sensor. Finally, only the force perpendicular to the sensor surface can be measured using the in-shoe plantar pressure measurement system. Hence, it was impossible to examine the effect of the insoles on the shear force.

Our study found that the 1/4-inch SP flat insole and meta-

tarsal pads exert a forefoot plantar pressure-reducing effect and provide additional insole comfort. Of the three experimental insole designs, the 1/4-inch SP flat insole was the most effective. However, efficacy differences based on the metatarsal pad placement location were unclear. Considering the possibility of discomfort caused by improper metatarsal pad placement, the SP that increases shock absorption may be more clinically useful. This also suggests that when manufacturing sneakers, adding a soft insole to increase the cushioning effect can increase the forefoot pressure load-reducing effect.

Future studies on the role of good shoes and foot orthoses are needed to reduce forefoot pressure during standing and walking. Moreover, further biomechanical studies are warranted to investigate the immediate and long-term effects of foot orthoses on metatarsalgia.

## AUTHOR CONTRIBUTIONS

**Conceptualization:** Tae Im Yi. **Data curation:** Tae Im Yi, Eun Chae Lee, and Nak Hoon Son. **Formal analysis:** Tae Im Yi and Nak Hoon Son. **Investigation:** Tae Im Yi and Eun Chae Lee. **Methodology:** Tae Im Yi and Eun Chae Lee. **Project administration:** Min Kyun Sohn. **Resources:** Tae Im Yi and Eun Chae Lee. **Software:** Eun Chae Lee. **Supervision:** Min Kyun Sohn. **Validation:** Tae Im Yi, Nak Hoon Son, and Min Kyun Sohn. **Visualization:** Tae Im Yi and Eun Chae Lee. **Writing—original draft:** Tae Im Yi and Eun Chae Lee. **Writing—review & editing:** Tae Im Yi and Min-Kyun Sohn. **Approval of final manuscript:** all authors.

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