Preliminary investigation on the reduction of plantar loading pressure with different insole materials (SRP – Slow Recovery Poron®, P – Poron®, PPF – Poron® + Plastazote, firm and PPS – Poron® + Plastazote, soft)

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1. Introduction

In Asia, the number of people suffering from diabetes mellitus (DM) is set to balloon from 62 million to 132 million by 2010 [1]. And, Singapore figures in 2004 showed that about 8.2% of adults between 18 and 69 years old were suffering from DM [2].

People with DM are susceptible to the development of plantar foot ulcerations. It is believed widely that such incidences are attributed to a triad of factors namely: presence of sensory neuropathy, ischaemia and an elevated plantar loading pressure [3]. Areas that are susceptible to ulceration are the forefoot region, especially the 1st metatarsal head locality [4]. This is due in part to the bony structures that press on a small area of tissue, limited joint mobility and glycosylation of the collagen fibers [5]. In addition, musculoskeletal and soft tissue composition is altered and hence amounts to an increase in the probability of tissue damage. Atrophy of the intrinsic muscles that control the position of the phalanges is commonly observed in such tissue degradation.

While sensory neuropathy and increased plantar pressure may attribute to ulcer occurrence, Frykberg et al. [6] concluded that both factors are independent of each other, with the latter having the greater magnitude of effect. The direct causal relationship between plantar pressure and neuropathic ulcerations had been shown in both prospective and retrospective studies [7–10]. Parameters of dynamic plantar loading pressure such as length of contact and pressure-time integral (PTI) were determined previously at specific foot regions. Unfortunately, the search for a threshold pressure above which is indicative of ulcer occurrence might prove to be futile [11]. On the other hand, these results may indicate that increased stress at the metatarsal heads is responsible for the occurrence of plantar ulcers compared with other regions of the sole [12].

It was also reported by Abouaesha et al. [13] that plantar tissue thickness displayed a strong inverse relationship with peak pressure measurements. Besides peak plantar pressure exhibited on the skin surface, soft tissue strain in deeper tissues might also play a pivotal role in the development of plantar ulcers [14–16].
studies proposed that ulcer occurrence might not be initiated on the skin surface in the first instance, but rather in deeper tissue layers, and the tissues underlying the distal bony prominences of the medial metatarsals are most vulnerable.

People suffering from DM with elevated peak loading pressure and increased soft tissue strain are therefore at risk of developing foot ulcers, and are recommended to be provided with orthopaedic shoes to prevent foot ulceration [17]. The materials used in such shoes must be effective in reducing the general loading pressure across the whole foot. This effectively will lead to a decrease in the average pressure experienced across a foot step throughout the stance phase of the gait cycle [18–24]. In addition, at specific areas where peak plantar pressure occurs, it is imperative that the strain at that locality be decreased simultaneously. This might potentially serve to dissipate forces and attenuate loading pressure so that deeper tissues will not have to undergo high strain deformation [25].

While Owings et al. [26] had shown that superior pressure reduction was achieved by prescribing and fabricating customised orthotics based on both foot shape and pressure data, these may not always be available in a busy clinical setting. In Singapore whereby there is a marked shortage of qualified podiatrists to care for the diabetic foot, simple flat insoles made of various viscoelastic materials are given to neuropathic patients in the first instance. These flat insoles are often cut-out using the patients’ shoe template as a reference and fitted into their current shoes worn into the clinic.

In the market, there is a plethora of materials used for such simple flat insoles and customised insoles fabrication. While the efficacy of simple flat insoles had been tested to reduce peak plantar pressure in the clinical setting, very little data were available for variants or combinations of these materials in situ [20,23,27–30]. Therefore, this study aims to provide some preliminary data on the effectiveness of different materials and combinations of materials used in the fabrication of simple insoles to reduce the plantar loading pressure. Once such data is ascertained, this will enable the clinician to select the best material for specific purpose when dispensing flat simple insoles to the patients.

2. Methods

2.1. Subjects

A total of 5 healthy volunteer subjects, without any known history of diseases and foot abnormalities, were recruited into this pilot study. All subjects were undergraduate students in a local university and were approached by the author to participate in the study. A small sample size was taken because the nature of the study was exploratory so as to provide some preliminary data for an initial appreciation on the pressure relieving properties of currently used insole materials in the clinics. This study was approved under a larger project by Singapore General Hospital Institution Review Board (SGH IRB) on 6 May 2008, reference number 84/2008. Both written and informed consent were obtained from the volunteers before the commencement of measurement. The inclusion criteria included volunteers with no known disease, had no known foot deformities and were able to walk along a 10-m walkway independently, without assistance or the use of any walking aids. These criteria were assessed independently by a single podiatrist clinically without blinding. Foot deformities excluded were pes planus, pes cavus, plantar heel pain, metatarsalgia, hallux valgus/varus/limitus/rigidus and lesser toe deformities such as hammer toes, clawed toes, and mallet toes. Demographic data such as age, height and weight of the subjects were recorded.

2.2. Pressure measurement

Dynamic loading pressure data were collected using the F-Scan in-shoe system (Tekscan, Inc., Boston, MA). The in-shoe sensor for each foot was thin (0.18 mm thick) and consisted of 960 resistive sensing elements arranged in a rectangular grid with a spatial density of 4 elements per cm². The in-shoe sensors were first checked for any "dead-cells", by placing them into the subjects’ sports shoes with double sided adhesive tape on top of the shoe inlays, and having them walked along a 10 m walkway randomly. Before pressure data was collected, calibration of the sensors was done for each subject with respect to their weight, according to the manufacturer’s recommendation of the “step calibration” function in the software. Although there had been reports suggesting that the sensor was sensitive to surface conditions, loading speed, temperature and lacked durability, F-Scan® is still recommended for relative comparisons of plantar pressure distributions under constant condition and calibration before use [31–34].

Initially, all 5 subjects had both feet tested without any padding or insoles in their sports shoes. These measurements were denoted as barefoot measurements (BF). Thereafter, all subjects were fitted with 6.2 mm thick simple insoles cut-out from the following 4 commonly used materials in the podiatry clinic:

1. SRP – Slow Recovery Poron® (extra soft 4790-92),
2. P – Poron® (soft 4708-blue),
3. PPF – Poron® (soft 4708-blue)+Plastazote (firm 30 shore A durometer),
4. PPS – Poron® (soft 4708-blue)+Plastazote (soft 15 shore A durometer).

In addition, the subjects were also tested with a piece of 7 mm semi-compressed felt (SCF) padding with an aperture cut-out at the 1st metatarsophalangeal joint (MTPJ) locality so as to simulate an active ulcer location, see Fig. 1. The SCF was adhered onto the plantar surface of the foot of both feet directly. SCF padding was tested because it is a very common clinical practice for podiatrist to use such padding to off-load an area of the foot as a short-term measure. This would provide some preliminary data on how well this modality is effective as an off-loading strategy.

All in-shoe sensors were firmly attached to the top surface of the simple insoles and shoe inlays with the use of double-sided adhesive tape. All subjects were instructed to walk at their usual walking speed during pressure measurement along the 10m walkway. A total of 8 pressure stances per foot were collected each for the above 6 conditions.

![Fig. 1. 7 mm semi-compressed felt padding with aperture cut-out.](image-url)
Table 1
Demographics of the 5 healthy volunteer subjects.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age/years</th>
<th>Height/m</th>
<th>Weight/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>26</td>
<td>1.75</td>
<td>70.6</td>
</tr>
<tr>
<td>2</td>
<td>32</td>
<td>1.70</td>
<td>75.3</td>
</tr>
<tr>
<td>3</td>
<td>31</td>
<td>1.75</td>
<td>75.6</td>
</tr>
<tr>
<td>4</td>
<td>27</td>
<td>1.80</td>
<td>80.5</td>
</tr>
<tr>
<td>5</td>
<td>28</td>
<td>1.75</td>
<td>72.9</td>
</tr>
<tr>
<td>Mean (2sd)</td>
<td>29 (3)</td>
<td>1.75 (0.04)</td>
<td>75.0 (3.7)</td>
</tr>
</tbody>
</table>

2.3. Data analysis

Since the aims of the study were to investigate on the pressure reduction capabilities of the insole materials clinically, pressure data on both feet were analysed collectively as one entity. The effects of variability during the gait cycle were often enhanced during the first few steps and last few steps, owing to the acceleration and deceleration when a person walks. As such, only the mean pressure value for the middle six stances per foot in each condition had been entered for statistical analysis [23].

The minimum, maximum and mean peak contact pressures for each condition, except SCF, were compared with BF measurements. Thereafter, the peak pressures derived from the timing analysis module (TAM) at the 1st MTPJ, 2nd MTPJ, 3rd/4th MTPJ, 5th MTPJ and Hallux localities for all condition were compared with BF measurements. Repeated measures analysis of variance with post hoc Bonferroni paired wise comparison was used to test for any statistical significance at the 95% confidence level for all pressure data.

3. Results

All 5 volunteer subjects had a mean age of 29 ± 3 years, weight of 75.0 ± 3.7 kg and height of 1.75 ± 0.04 m (see Table 1). The minimum, maximum and mean peak contact pressures, presented as mean ± standard deviation and the 95% confidence interval, were greatest under BF condition (see Table 2). The least minimum and mean peak contact pressures occurred under SRP condition, while the least maximum was with PPF. However, significant differences were only noted between BF and PPF for minimum (p < 0.005; 23.56 ± 8.30 kPa vs. 30.17 ± 9.45 kPa) and mean (p < 0.03; 47.91 ± 8.37 kPa vs. 60.73 ± 11.31 kPa) peak contact pressures, see Fig. 2a and b. This accounted for approximately 28% and 27% pressure reduction in minimum and mean pressure, respectively.

Peak pressure on the 1st MTPJ locality showed significant reduction of 37% and 29% with the use of SCF and PPF respectively when compared to BF. The peak pressure at the 1st MTPJ locality was greatest in BF and least in SCF (p < 0.004; 191.45 ± 25.00 kPa vs. 119.68 ± 37.34 kPa), see Table 3. However, even though the peak pressure for PPF was not the lowest, it appeared significantly lower than BF (p < 0.004; 135.70 ± 23.36 kPa vs. 191.45 ± 25.00 kPa), see Fig. 3.

It was also noted that under SCF condition, there appeared a non-significant resultant increase in peak pressure at the 3rd/4th MTPJ and 5th MTPJ localities compared to BF measurement (230.85 ± 113.86 kPa vs. 207.41 ± 88.29 kPa and 160.09 ± 76.71 kPa vs. 133.84 ± 57.81 kPa), see Table 2.

Table 2
Minimum, maximum and mean peak pressure across both feet.

<table>
<thead>
<tr>
<th></th>
<th>SRP</th>
<th>P</th>
<th>PPF</th>
<th>PPS</th>
<th>BF</th>
</tr>
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<tbody>
<tr>
<td>Maximum</td>
<td>74.55 ± 14.53 (56.51–92.60)</td>
<td>74.11 ± 9.18 (62.71–83.51)</td>
<td>71.70 ± 9.66 (58.71–83.96)</td>
<td>72.69 ± 8.45 (62.20–83.18)</td>
<td>92.57 ± 18.58 (69.50–115.64)</td>
</tr>
<tr>
<td>Mean</td>
<td>46.69 ± 4.00 (41.71–51.66)</td>
<td>48.72 ± 6.58 (40.53–56.89)</td>
<td>47.91 ± 7.44 (38.67–57.15)</td>
<td>48.36 ± 7.64 (38.88–57.85)</td>
<td>60.73 ± 10.32 (47.93–73.54)</td>
</tr>
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</table>

* p < 0.005; † p < 0.03.

Fig. 2. Comparison of different simple insole materials in reducing (a) minimum peak pressure and (b) maximum peak pressure across both feet.

4. Discussion

The use of insoles to reduced plantar loading pressure for people with diabetes has been well documented in several studies. While some studies looked into the efficacy of simple flat insoles [20,27–30], others investigated on the finished products of contoured insoles and footwear [18,19,23,35–38]. An earlier study that was conducted quasi-quantitatively evaluated the shock absorbing characteristic of Plastazote, Spenco, Sorbothane, Poron and ViscoLas. Poron was rated the best insole material for shock absorption [39].

Over the years, it has been well accepted by podiatrists, orthotists, prosthetists, certified pedorthists, and physical therapists that Poron was rated as one of the most popular materials used in the fabrication of foot orthoses. It is resilient and able to...
Table 3

<table>
<thead>
<tr>
<th>Material</th>
<th>Peak pressure/kPa (mean ± sd; 95% CI)</th>
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<tr>
<td>SC</td>
<td>185.76 ± 123.20 (72.89–338.73)</td>
</tr>
<tr>
<td>SRP</td>
<td>184.23 ± 96.88 (110.94–257.44)</td>
</tr>
<tr>
<td>P</td>
<td>182.68 ± 70.46 (94.00–267.74)</td>
</tr>
<tr>
<td>PPF</td>
<td>179.56 ± 62.93 (89.53–269.59)</td>
</tr>
<tr>
<td>PPS</td>
<td>178.34 ± 50.84 (89.53–269.59)</td>
</tr>
<tr>
<td>BF</td>
<td>186.54 ± 123.20 (72.89–338.73)</td>
</tr>
</tbody>
</table>

Fig. 3. Comparison of SCF with aperture cut-out and other simple insole materials in reducing peak pressure at 1st MTPJ.

Table 3 shows the peak pressure at the hallux, 1st MTPJ, 2nd MTPJ, 3rd/4th MTPJ, 5th MTPJ timing analysis module (TAM).

The ability of Poron to attenuate pressure is partly related to its hardness measurement according to INESCOP (Technological Institute for Footwear and Related Industries). The hardness meter Asker C is in turn dependent on the elastic modulus and viscoelastic properties of the material. Poron is an open cell polyurethane foam with a hardness of 15–35° Asker C, whilst Plastazote is a closed cell polyethylene material with hardness between 40° and 75° Asker C [41]. Naturally, Poron with a softer Asker index would be more accustomed to cushion the loading foot for a greater pressure reduction when used as a simple insole. However, Plastazote being more resilient would be ideal for durability and contouring to the shape of the foot for sustained reduction over time [30].

Therefore, when reducing an area of focal pressure such as the 1st MTPJ, it might be better to use a combination of Poron and firm...
Plastazote (PPF). This is because the Poron layer will absorb the initial impact whilst the more resilient Plastazote backing would conform to the shape of the 1st MTPJ so as to increase the surface area over time. This study demonstrated a peak pressure reduction of 29% at the 1st MTPJ which is 8% and 1% more than a finite element modeling study that utilized pure Poron and pure Plastazote respectively as a plug embedded in a microcell puff midsole [46].

As for semi-compressed felt (SCF) padding with an aperture cut-out, previous literature reported about 34–68% pressure reduction at the aperture site depending on the location of the foot and the combination thickness of felt and foam [47–49]. The 37% pressure reduction achieved in this study at the 1st MTPJ pure felt cut-out design is comparable. However, it should be noted that increased pressure at the periphery of the aperture site could be harmful to the insensitive foot [47]. The inclusion of SCF padding comparing alongside flat simple insoles in this study might be useful since most podiatrists would use such a modality as a “chair-side” padding for short-term off-loading. Although such padding can reduce pressure effectively at the aperture site, it should be noted that this might not be sustainable after 1 week unless a new SCF padding was re-applied [49,50].

It seemed logical thus to suggest that the best material for off-loading a focal area of pressure in a busy clinical setting is to use Poron/Plastazote (PPF) as the simple insole base, followed by a layer of SCF with an aperture cut-out, as shown in Fig. 4. The placement of the SCF directly onto the skin or on the insoles would have no implication of its efficacy to off load the 1st MTPJ [50]. This combination would suffice for dispensing on the 1st visit of a neuropathic ulcer consult. Thereafter, the patient should return for a follow up to have total contact insoles prescribed and made because these have shown to reduce peak pressure more dramatically [21].

It will also be important to discuss on the ability of these insole and padding materials in maintaining pressure reduction over successive wear time. Bench top laboratory studies had been conducted to show how well these materials continue to provide pressure reduction over cyclic compressions [41,51,52]. In particular, after 100,000 compression cycles with a pressure of 700 kPa and a frequency of 60 cycles per minute (approximately 4.5 days of wear time assuming 6 h/day), ethyl vinyl acetate and polyethylene with low hardness range emerged as superior to provide sustained compression after the test when compared with polyurethane foam [41].

In clinical trials with subjects, a previous report suggested that SCF should be replaced every 3 days when applied to off-load an area of ulceration before losing its efficacy [49]. When this recommendation was adopted, the average healing days of neuropathic ulcers appeared to be even more effective than conventional plantar ulcer treatment with the pressure relief half-shoe in a 10-week trial period (75 days vs. 85 days) [53]. Poron/Plastazote combination simple insoles had also shown to have a sustained peak pressure reduction on the forefoot area after 30,000 steps wear time [30]. Similarly, sustained pressure relief was achieved with Plastazote and Aliplast/Plastazote customised orthoses over a period of 2 months wear time among elderly persons with diabetic neuropathy [45]. However, the authors reported that the subjects might not have worn the orthoses regularly, thereby preserving the sustained pressure relieving properties of the orthoses upon measurement. Therefore, further studies should also collect data on the actual wear time of the orthoses by the subjects, so that the actual “life span” of such insole materials can be ascertained.

Unfortunately, this study failed to analyse the ability of these materials to reduce pressure-time integral (PTI). PTI is an important variable because brief, transient pressures exceeding normal values might not result in ulceration [54–56]. Instead, the duration of any high pressure on the plantar aspect of a foot might be more hazardous than the high pressure itself [57]. Another limitation to this study is that tests of the materials were performed on healthy individuals, where the results presented herein might not be extrapolated for diabetic patients with neuropathy, foot deformities and ulceration. It is acknowledged by the investigators that pressure relieving data reported in this study is not transferrable to people with diabetes who wear insoles made of the materials tested.

5. Conclusion

It had been shown that most materials used in the podiatry clinic were able to cushion the loading foot, thereby reducing mean pressure across the whole foot. However, the combination of Poron and firm Plastazote (PPF) seemed significantly superior to other materials tested. This material was also equally effective in reducing a focal area of pressure such as the 1st MTPJ where most neuropathic ulcers would develop. Alternatively, semi-compressed felt (SCF) with an aperture cut-out can be added onto the PPF simple insole base to enhance the total off-loading capabilities. However, it should be noted that SCF padding would require weekly changes since it could bottom out quickly. Finally, the results of this study should not be transferred to diabetic patients since all tests were done on healthy individuals.

Conflict of interest

None.

Acknowledgements

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