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Original research article

Pilot Study: The Effects of Air-Filled Thermoplastic Polyurethane (TPU) in Foot Orthosis

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ABSTRACT

Heel pain is a common foot problem that is often treated by heel cushioning made from a variety of materials. Thermoplastic polyurethane (TPU) is a commonly used material in the medical field, however, studies exploring cushioning performance and plantar pressure reduction of TPU air filled orthosis are limited. The purpose of this study was to evaluate cushioning performance and plantar pressure reduction of the heel while standing, via provision of a TPU heel cushion. This study was divided into two parts: an "egg-drop test" and a heel pressure test. During the egg-drop test, three samples of each experimental material were tested (Pelite®, Plastazote®, PPT®, TPU with air-filled bladders at 5, 10, and 15 kPa) using eggs with controlled weights. The egg was dropped five times to test each material and bouncing of the egg was recorded, as well as the number of broken eggs. Afterwards, 15 participants were recruited to stand on the air-filled orthosis while plantar pressures at the heel were recorded using a force sensing array (FSA). The results from the egg-drop test and clinical trial demonstrated that TPU with air-filled bladders at 5 kPa and 10 kPa had a cushioning property with reduction of plantar pressure at the heel similar to PPT® except for other materials that showed lower performance. However, the other materials resulted in a lower performance. Proper air-filled orthosis should be considered for a range of body weights. Advanced insole material properties along with an appropriate pressure distribution are recommended for further study relating to gait.

Keywords: Egg-drop test; Foot orthosis; Heel cushion; Plantar pressure; Thermoplastic polyurethane

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1. Introduction

The foot is a vital part of the body that stabilizes body posture, transmits body weight to the ground, and adapts to uneven surfaces during gait. Regarding previous studies, the average number of steps per day is around 7,000 to 10,000 steps. While walking and standing, a significant amount of pressure is exerted downwards to the foot, especially at the hindfoot. Around 300 kPa of pressure is exerted during the stance phase in a subject with a normal BMI and normal foot arch. Forces ranging from 50 to 400 % of the body weight are exerted at the hindfoot while running [1- 4].

Feet can tolerate various kinds of stress, however, high stress over time can lead to continuous localized pain, irritation, and can further lead to the progression of heel pain [5]. These common foot problems are usually treated by conservative treatment such as massage therapy, NSAIDs, physical therapy, medical footwear and foot orthoses [6]. In the orthotics field, the heel cushions in foot orthoses are typically made from a variety of materials including silicone, foam, and thermoplastic elastomers. It may reduce irritation while walking depending on the material properties and load deformation characteristics [7].

Thermoplastic polyurethane (TPU) is a type of plastic material that can be either rigid or flexible and has been successfully used with promising results in the footwear industry. The advantages of TPU are its high heat resistance, toughness, excellent abrasion resistance, comfort, flexibility, and that it's made from environmentally friendly polymers. Additionally, it has already been used successfully in medical devices such as vascular prostheses, catheters and has been used to construct air cushions in the footwear industry [8].

However, there is limited research evaluating the cushioning ability of TPU as a part of footwear or insole. TPU has good potential to be used as a heel cushion in foot orthoses to reduce plantar pressure under the heel in people with heel pain. Thus, this study aimed to evaluate the cushioning performance and ability to reduce plantar pressure during standing by a TPU air-filled material. The expectation was that the TPU air-filled material would have similar increased cushioning performance, thus reducing heel pressure during standing similar to PPT®.

2. Materials and Methods

This study consisted of two experimental aspects, the first was a mechanical test done by performing the egg-drop test to evaluate the cushioning performance of TPU with air-filled bladder. The second was a clinical test to compare plantar pressure at the heel area with other experimental materials, including Pelite®, PPT® and Plastazote®.

2.1 Material preparation

TPU with a 0.012 mm thickness was used to fabricate the heel cushion by attaching two sheets of TPU and ironing at a temperature of 135 to 140° C with a plastic cover. Each TPU sheet was peeled off the plastic cover and filled with air using a pressure gauge with an air pump at pressures of either 5, 10 or 15 kPa. Three other materials commonly used in prosthetic and orthotic clinics, available at the Sirindhorn School of Prosthetics and Orthotics (SSPO), were used in the experiment. The materials were cut into ovals the same shape and size as the TPU air-filled bladders (7 cm. width and 5.5 cm. Height). Pelite® (Jin supplies shop, Thailand) was 5 mm. thick, with 40 - 50 Shore A, thermoformable and commonly used as a soft liner and cushioning in orthosis. PPT® (Ottobock, Thailand) was 6 mm. thick, with 15-22 Shore A, and memory foam characteristics commonly used as a cushioning for orthotics. Plastazote® (Ortocentrum Co., Ltd, Thailand) was 5 mm. thick, with 15-20 Shore A, and is thermoformable. Clinical trial footplates, made from ethylene-vinyl-acetate (EVA) foam was cut into an insole shape with the oval channel at the heel to fit the experimental material inside as shown in Fig. 1.

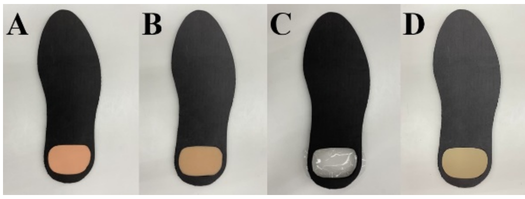

Fig. 1. The footplate with experimental materials (A) Pelite® (B) Plastazote® (C) TPU with air filled and (D) PPT®.

2.2 Mechanical test

Six experimental materials, including Pelite®, PPT®, Plastazote®, and TPU air-filled bladders filled at pressures of 5, 10, and 15 kPa (Fig. 2) were tested by performing an egg-drop test to evaluate the cushioning performance of each material. The egg-drop test apparatus consisted of a transparent tube 120 cm in height held up by a retort stand (Fig. 3) in order to make each egg drop consistent. To prevent potential errors during the test, only eggs weighing 60 ± 5 grams were selected. Moreover, three samples of each experimental material were prepared for this test. The procedure was to drop an egg 5 times on each sample (each egg was dropped only once). For each material, the egg-drop test was performed 15 times for a total of 90 times. Observations on the characteristics of each egg after impact with the material were recorded [9].

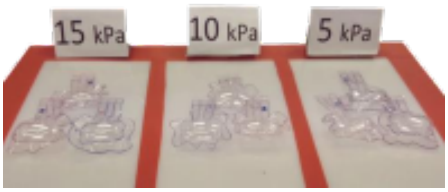

Fig. 2. TPU with air filled 5, 10 and 15 kPa and ironing the air pathway to close the system.

Fig. 3. The egg-drop test apparatus.

2.3 Clinical test

A total of 15 participants, 12 females (80%) and 3 males (20%), above 18 years old, with no severe foot deformity and weighing between 40-80 kg were recruited from the Sirindhorn School of Prosthetics and Orthotics, Faculty of Medicine Siriraj Hospital, Mahidol University. There have been no studies on air-filled TPU cushions as a part of foot orthosis or heel cushions done at this institute before. Although the authors recognize the limitations associated with using a small sample size, previous research has reported that sufficient statistical power can be accomplished when using a sample size of 10 [10-11] However, to avoid an insufficient sample size and accounting for potential drop-outs during study that may occur, the researchers set the number of participants at 15. The focus of this study was to compare the plantar pressure reduction ability of commonly used and available heel cushion materials with different body weights. Thus, the authors did not consider gender to be an issue in this current study. Additionally, the authors decided to do a pilot study prior to perceiving trends and apply the results to calculate a larger sample size for clinical trials in a future study. Participants with severe foot deformities, heel ulcers, balance problems or unable to communicate in Thai were excluded.

All participants read and signed a consent form which was approved by Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University before participating in this experiment. The procedure was explained to the participants by a researcher.

To measure plantar pressure at the heel area, participants were asked to stand on the footplate with the experimental materials. The data was collected using a Foot Sensor Array (FSA, USA) at sensors C12, C13, D12, D13, E12 and E13 (Fig. 4) representing the hind foot and center of the material, while participants stood on the footplate, with the material fixed in a comfortable position. Each experimental material was tested three times and the pressure was recorded for 7 seconds. The statistical data was analyzed from each participant across each material.

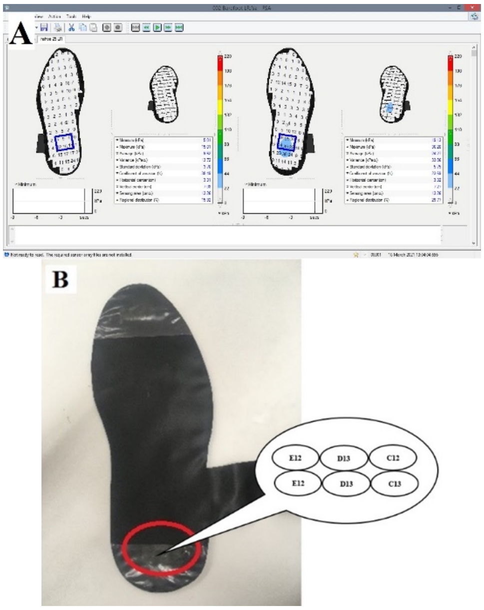

Fig. 4. (A) Foot sensor array device at sensor C12, C13, D12, D13, E12 and E13 show in software. (B) location to put experimental material (red circle) underneath Foot sensor array device.

3. Results

3.1 Mechanical result

In the egg-drop test, results are presented as % non-broken eggs, indicating the cushion success rate (Fig.5). The results of the egg-drop test revealed that all the eggs were broken when dropped over Pelite® and Plastazote® (0%). Whereas, when the PPT®, TPU 5 kPa and TPU 10 kPa were tested, the eggs did not break (100%). Lastly, TPU 15 kPa had a success rate of 87 % (13/15). As mentioned above, this reveals trends and possibilities for applications in practical use.

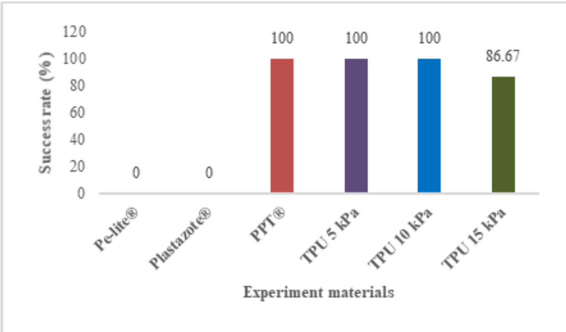

Fig. 5. Success rate from egg-drop test.

3.2 Clinical result

From individual consideration in each cushion material across 3 rounds, peak pressure in each round has a similar value, meaning data were reliable.

As shown in Fig. 6. And Table 1, Pelite® had the highest mean plantar pressure, followed by Plastazote®, TPU 15 kPa, PPT®, TPU 10 kPa, and finally TPU 5 kPa. Clinical results showed good cushioning properties with similar trends as seen in mechanical testing with PPT®, TPU 5 kPa, and TPU 10 kPa.

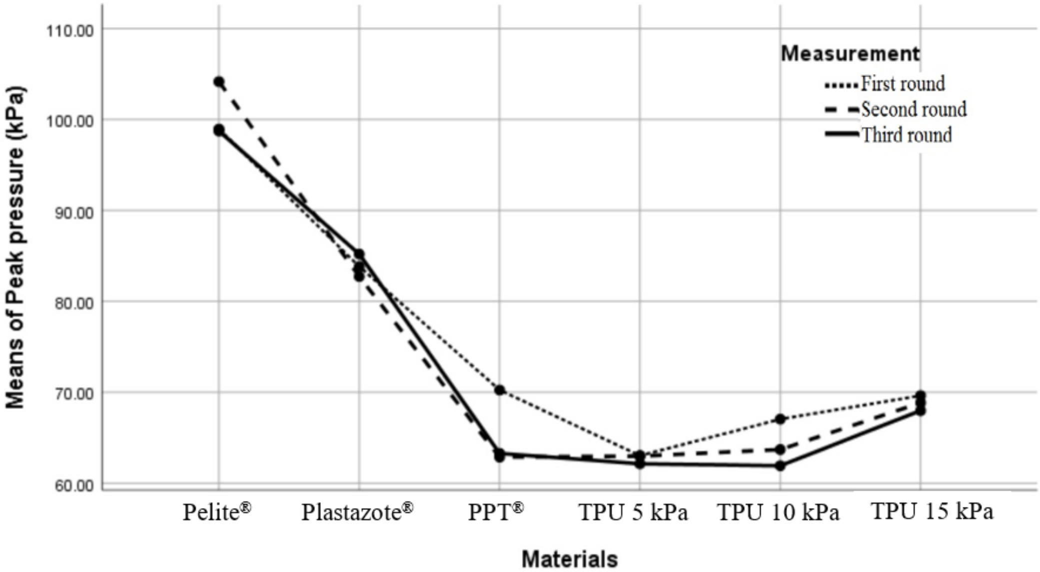

Fig. 6. Three round peak pressure in each cushion material.

Table 1. Mean plantar pressure (kPa) at heel in experimental material.

Material	Mean ± SD.	% Change of mean value compared with PPT®*
Pelite®	100.65±26.89	53.96
Plastazote®	83.91±19.93	28.18
PPT®	65.31 ±14.86	0.00
TPU with air filled 5 kPa	62.71±14.52	-4.20
TPU with air filled 10 kPa	64.22±14.46	-1.90
TPU with air filled 15 kPa	68.81±14.85	5.13

Note: *Negative mean less mean value of plantar pressure Statistically significant P-value < 0.05.

One-way repeated measures ANOVA was undertaken to determine if there were significant differences in peak pressure among the six heel cushion materials. A *post-hoc* Bonferroni Test was used to perform pairwise comparisons (Table 1) if significant differences were found in the repeated measures ANOVA. Two-tailed paired t-test was used to compare the peak pressure between the six heel cushion materials. The differences were considered significant if $P < 0.05$.

Significant differences were found with Pelite® when compared with the other five materials: Plastazote® ($p = 0.208$), PPT®, TPU 5 kPa, 10kPa, 15kPa ($p = 0.000$). Plantar pressure with Plastazote® compared with TPU 5 kPa also shown significant difference ($p = 0.030$).

As mentioned, the purpose of this study was to evaluate the cushioning performance and ability to reduce plantar pressure during standing by using TPU air-filled bladders compared to common cushioning materials, especially PPT, which was a good shock absorber. The results showed no statistically significant difference between PTT and TPU at all air pressures. This finding was in line with our hypothesis. As seen in Table 1, percent change of mean was calculated based on PPT compared with the five heel cushion materials, with results revealing that TPU 5 kPa and 10 kPa have a smaller mean value of plantar pressure than PPT, -4.20 % and -1.90%, respectively. Meanwhile, other cushion materials showed a higher mean value of plantar pressure compared to PPT®, with the biggest differences being with Pelite® 53.69 %, Plastazote® 28.18% and TPU 15 kPa 5.13%. This might indicate that TPU had a similar cushioning performance to PPT® in terms of heel cushion while static.

Moreover, results of both the mechanical test and clinical test reveal a correlation between cushioning properties and decreased plantar pressure during standing while using TPU air- filled bladder as a heel cushion. However, consideration and more clinical application will be further discussed.

4. Discussion

TPU composite has been used in various shapes and in various industries; one of its uses is in the footwear industry, used to improve the energy return effect, shock attenuation and performance. TPU composite footwear claims to enhance energy return by reducing energy cost at low speeds and improved running efficiency compared to minimalist shoes [12]. Most TPU composites in the midsole are usually in the form of expanded foam, which is different from the transparent TPU sheet that was used in this study. The kinetic and kinematic effects of expanded TPU composite midsole in running shoes compared to EVA in conventional running shoes was studied by J. Sinclair et al. who found greater kinetic and kinematic effects from the boost energy return design of TPU midsoles. But it was also found that boost energy return footwear itself may increase the risk of chronic injury in runners [13].

Meanwhile in this study, TPU was used in sheet form, which is similar to medical catheter material which is thin, transparent, flexible, and also skin- and soft tissue-friendly. However, the main properties remain, which can also be found in the footwear industry as mentioned in a U.S. Patent [8], stating that TPU was selected to provide cushioning for the outsole structure. As mentioned, TPU was a newly available material at the Sirindhorn School of Prosthetics and Orthotics. It was fabricated as transparent check shoes and has a variety of thicknesses, flexibilities and heat-sealing abilities, which lead to this study. Accordingly, this research was designed to apply TPU within foot orthoses and compare the results to other commonly used materials. One of the materials was PPT®, which has shown good shock absorption and durability in several studies [14, 15]. This study uses PPT® which meets certain quality standards for materials in terms of shock absorption and compares it to TPU air-filled bladder. Mechanical properties measured by the egg-drop test demonstrated that 5 and 10 kPa materials provided cushioning similar to PPT® with a 100 % success rate.

Meanwhile, TPU at 15 kPa showed an 87% success rate. The clinical test was performed with 15 participants and demonstrated that TPU 5 kPa and 10 kPa provided a low pressure, similar to PPT®. Increasing air pressure increased plantar pressure as was shown in Table 1. TPU 15 kPa showed the highest mean pressure, due to the increased air within the bladder, which created more tension on the TPU sheet causing it to become rigid at the surface.

In the production process of TPU air-filled bladders, this study used manpower with adjustable temperature. Ironing may cause air leaking due to a poor seaming area and waste some of the TPU material. Furthermore, the development of a TPU sealing tool or machine would be beneficial as it would allow manufacturing to be more precise and avoid fabrication errors.

This study focused on heel pressure via provision of a variety of heel cushion materials. Plantar pressure distribution in other areas such as the midfoot and forefoot also need to be considered, as pressure transference may occur. Farzadi et al. found that adding medial arch support creates higher pressure at the midfoot than without medial arch support, and results in pressure reduction at the forefoot and hindfoot in patients with Hallux valgus [16].

Regarding the findings of the clinical experiment, this study was conducted in only static positions. However, movement also affects plantar pressure distribution as well as body mass, foot deformity and pathology. Additional experimental aspects including increased sample size, plantar pressure during dynamic movement, effects of weight on TPU air-filled selection, and foot pathologies which require heel cushion treatment are recommended for further study.

5. Conclusion

This study demonstrated that the novel TPU air-filled bladder construction at 5 kPa and 10kPa were able to provide cushioning effects similar to PPT®. Meanwhile, an 87 % success rate was achieved using a pressure of 15 kPa. In addition, the static clinical trial revealed the effectiveness of lower pressures at the heel area with TPU air-filled bladders at 5 kPa, 10 kPa, and 15 kPa as compared to other common cushion material in the clinical trial. However, advanced testing of material behavior, invention of advanced fabrication tools, more clinical trials, larger sample size, effect of weight change and material relation, as well as long-term cushioning effects are recommended for further study.

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