การทดสอบด้วยการบีบอัดวัสดุของขอบตั้งในอุปกรณ์พยุงฝ่าเท้าแบบขอบตั้งสูง (High Profile Insole) เพื่อการควบคุมการบิดตัวของเท้า ในกลุ่มผู้มีอาการเท้าแบนแบบยืดหยุ่นในเด็ก

ธนา เจริญวิทย์วรกุล

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บทคัดย่อ

ความสำคัญของปัญหา: การรักษาเท้าแบนในเด็กโดยการใช้อุปกรณ์เสริม UCBL (University of California Biomechanics Laboratory) เป็นวิธีการรักษาหนึ่งที่ได้ผลดีที่สุด แต่เนื่องจากอุปกรณ์ดังกล่าวมีลักษณะแข็งและมีขอบสูงรอบด้าน ทำให้อาจเกิดรอยกดจนถึงมีอาการเจ็บที่เท้าของผู้ใช้งานได้ จึงมีอัตราการใช้ที่ค่อนข้างต่ำ การรักษาอีกวิธีหนึ่งคือการใช้แผ่นรองในรองเท้า คู่กับรองเท้าที่มีโครงแข็งบริเวณรอบส้นรองเท้า ซึ่งวิธีนี้มีอัตราการใช้อุปกรณ์ที่มากกว่า แต่การหารองเท้าที่มีโครงแข็ง และถูกต้องตามเครื่องแบบนักเรียนนั้นหาได้ยาก และมักมีราคาสูง ทางผู้วิจัยจึงได้ทำการออกแบบอุปกรณ์ใหม่ซึ่งเป็นการรวมจุดเด่นของอุปกรณ์เสริม UCBL และ TCI เข้าด้วยกันเป็นอุปกรณ์ที่เรียกว่า “อุปกรณ์พยุงฝ่าเท้าแบบขอบตั้งสูง” โดยคาดหวังว่าอุปกรณ์นี้สามารถเพิ่มอัตราการใช้และลดผลแทรกซ้อนจากการใช้อุปกรณ์ได้ การทดสอบในงานวิจัยนี้จัดทำขึ้นเพื่อทดสอบความแข็งแรงของวัสดุที่ถูกเลือกมาใช้ในการผลิตอุปกรณ์พยุงฝ่าเท้าแบบขอบตั้งสูง

วัตถุประสงค์: เพื่อทดสอบความแข็งแรงของวัสดุที่ถูกเลือกมาใช้ในการผลิตขอบตั้งสูงของ “อุปกรณ์พยุงฝ่าเท้าแบบขอบตั้งสูง” โดยการวัดความสามารถในการรักษาสภาพต่อแรงที่กระทำต่อขอบตั้งของอุปกรณ์

วิธีดำเนินการวิจัย: ขอบตั้งสูงของ“อุปกรณ์พยุงฝ่าเท้าแบบขอบตั้งสูง”ถูกผลิตขึ้นจากวัสดุสองชนิดประกบกัน คือ Podiaflex® 1.2 mm และ Flexan® series1 0.53mm โดยแรงที่ใช้ในการทดสอบความแข็งแรงของขอบอุปกรณ์เกิดจากการควบคุมแรงดันลมในกระบอกสูบเพื่อสร้างแรงผลักที่ปลายกระบอก เพื่อใช้ในการทดสอบความเปลี่ยนแปลงเปรียบเทียบกันระหว่างรองเท้า และ รองเท้ากับอุปกรณ์พยุงฝ่าเท้าแบบขอบตั้งสูง

ผลการศึกษา: ผลการทดสอบแสดงให้เห็นชัดเจนถึงการลดลงของความผิดรูปของรองเท้าและอุปกรณ์พยุงฝ่าเท้าแบบของตั้งสูง เปรียบเทียบกับรองเท้าเพียงอย่างเดียว โดยจากผลการทดสอบรองเท้าและอุปกรณ์สามารถลดปริมาณความผิดรูปจากแรงที่กระทำในระดับเดียวกันกับรองเท้าอย่างเดียวได้ถึงสองเท่า สรุปผลได้ว่าเป็นผลจากโครงสร้างของอุปกรณ์พยุงฝ่าเท้าแบบขอบตั้งสูงที่เสริมความแข็งแรงให้กับรองเท้าที่ใช้ในการทดสอบ

สรุป: โครงแข็งบริเวณรอบส้นรองเท้าและขอบตั้งสูงของ“อุปกรณ์พยุงฝ่าเท้าแบบขอบตั้งสูง” ให้ความสามารถในการควบคุมการบิดตัวของเท้าในแบบเดียวกัน งานวิจัยนี้ใช้ในการทดสอบวัสดุที่ถูกเลือกมาใช้ในการผลิตขอบตั้งสูงของอุปกรณ์ ซึ่งผลการทดสอบแสดงให้เห็นว่าขอบของอุปกรณ์ที่ติดตั้งในรองเท้าสามารถเสริมความแข็งแรงของโครงสร้างรองเท้าเพื่อต้านทานต่อแรงที่อาจเกิดขึ้นต่อขอบด้านในของรองเท้าและอุปกรณ์ได้เป็นอย่างดี

Keywords: เท้าแบนแบบนิ่ม, เท้าแบนแบบยืดหยุ่น, แผ่นรองในรองเท้า, อุปกรณ์พยุงฝ่าเท้า

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The Compression Testing Apparatus of Border Material of Novel High Profile Insole to Control Pronation in Children with Flexible Flatfeet

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Abstract

Background: The gold standard of non-surgical treatment for flexible flatfeet is the UCBL (University of California Biomechanics Laboratory). However, children often times feel uncomfortable, such as skin redness pressing by high and hard border of device. Thus, the UCBL is less often prescribed because of the lowered compliance. An alternative treatment is an insole with arch support and appropriate supportive shoe. The problem of uniforms shoe is missing of firm heel counter and hard to find in the market. Even the good support one will be the high price. The researcher developed foot orthosis with a high border around the heel area call "High profile insole (HPI). The principle of HPI is the combination feature of total contact insole (TCI) and UCBL together in one device. This combo treatment might provide acceptable user compliance and corrective properties, combining both comfort and corrective properties.

Objectives: The objective of this study is to evaluate stiffness of chosen materials for HPI's border by evaluate deformation properties of this device configuration while loaded in a compression testing apparatus.

Materials and Methods: The HPI's border made by Podiaflex® 1.2 mm thickness attached together with Flexan® series1 0.53mm thickness. To test stiffness of device border in this study the pneumatic cylinder was connected to an air pressure regulator and air pump to perform pushing force to a paddle at the end of cylinder. To compare deformation volume at each corresponding force applied to the model shoe with HPI as well as deformation with the model shoe without the HPI.

Results: Results is clear that a reduction deformation volume at medial side of shoe occurred in the HPI when force was applied, therefore the device had a reduction of more than 2 times that of deformation volume of model without HPI. This could be as a result of the material's hardness and extra layers at the border areas reinforcing the heel part of model shoe to be stronger.

Discussion and Conclusion: The heel counter of shoe and border of the HPI was designed to provide the same support to control over pronation of foot. The chosen materials were tested via mechanical testing to evaluate stiffness of the medial border of the device and observe changes of deforming volume. Result of this study evidenced an acceptable performance of the model shoe combined with the HPI, with an ability of the combo to tolerate various loading forces.

Keywords: Flexible flatfeet, Insole, Foot orthosis

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Introduction

Feet are important structures, which promote proper movement and ambulation of our body. Unfortunately, there are a number of people who have problems with their feet[1] The primary function of the foot is to bare body weight, relieve shock of the ground and adapt itself to provide whole body balance in a variety of terrains. When feet have a deformity, disease or misalignment, this can disrupt the mechanism of feet and create a chain of events, the overloading mechanism resulting from foot deformity is transferred to proximal area such as knees, hip, and lower back. There are a number of foot issues for children but, flatfeet are quite common.[1-4] There are a number of methods to evaluate feet in children such as Foot Posture Index (FPI), Resting Calcaneal Stance Position Angle (RCSPA), plantar pressure, Arch Index, and the Navicular drop test. These tests can help understand the presence and the severity of flatfeet. Flatfeet or pes planus, has two components: first is a sagging of the longitudinal arch and second is the heel going into a valgus position. Flat feet can be classified into two types, flexible flatfeet and rigid flatfeet. These are understood by determining whether the calcaneus or heel can be return to a normal position under a non-weight bearing position.[2] Flat feet is an issue because it leads to a flattening of arch and calcaneus valgus as a result of weakened feet.[1]

Furthermore, misalignment of feet can affect the knee and hip in the future by creating knee valgus and hyperextension which leads to hip internal rotation.[2-3] Flatfoot occurring in children is mostly the flexible flatfeet type, however, flat feet rarely cause pain or deformity in children.[2] Some known causes are ligament laxity, neurological muscular abnormalities, and genetics.[2-3] The flat feet typically occur in school-aged children.[4-5]

The gold standard treatment of flexible flatfeet is UCBL, which provides maximum control of heel valgus (calcaneus hyper pronation) and arch support.[2,6-9] The UCBL is a rigid material, usually plastic that is custom made to stabilize a flexible foot deformity. it fully encompasses the heel with a molded high heel cup along midfoot to hindfoot, medial to lateral. While correcting and holding the heel in a neutral position, and provide arch support[7] However, the UCBL provides total correction to the calcaneus, which often results in decreased adherence in children[6]. Anecdotally, in our foot clinic there is a reduced compliance in kids because in some cases, depending on the degree of flatfeet, pain might occur at the medial border of device. Children typically find a restrictive orthosis uncomfortable and do not like tight fitting shoes or devices. Thus, UCBL is prescribed less because of poor compliance.[8] In Thailand the price of UCBL per 1 side is around 2,700 THB.

Figure 1 UCBL (University of California Biomechanics Laboratory)

An alternative treatment is the insole with an arch support or total contact insole (TCI) to realign calcaneus valgus combined with an appropriate supportive shoe. Good supportive shoe is an enclosed shoe may provide structural support to the skeletally immature foot such as firm heel counter to hold calcaneus in proper position, firm shoe sole to prevent the compressing from over pronation of foot and should comfortably support an orthotic device. The advantage of this intervention is that children can chose a design of shoe that prefer.[10-12] In Thailand the price of TCI is around 2,000-4,000 THB per pair.

From the cost perspective, the price of both devices (UCBL/TCI) is around 2 times different in the Thailand market, this is one of many barriers to accessing the gold standard UCBL does not include a lower use rate of it.

In Thailand, about 33.33% of male children and 15.83% female children (4-10 years old) have flatfeet and school aged children are required to wear uniform shoes to attend school with approximately 82 percent of Thai children using uniform shoes [8]. The problem of uniforms shoe is missing of firm heel counter and shoe sole to support mid foot and hind foot over pronation cause of this reason an appropriate supportive shoe for children with flexible flat feet is quite hard to find in the market. Even the good support one will be the high price about 5 times the price of uniform shoes (DR.KONG: Model “Back to school” series). It is posited that a foot orthosis with a high border around the heel area coined the “high profile insole” (HPI), could offer similar control properties seen in the UCBL, yet with added comfort and a shoe heel counter feature in the form of a foot orthosis. This combination treatment might provide an acceptable user compliance and corrective properties with comfort and corrective properties. The fabrication technic that has been used in HPI is modified from a normal TCI fabrication that less expensive than the plastic negative pressure suction of UCBL fabrication technic. Therefore, the cost price can be controlled better than the aforementioned production.

Figure 2 Thai uniform shoe

Research question

Is design of High profile insole (HPI) structure is firm enough to control foot pronation in children with flexible flatfeet?

Research hypothesis

We hypothesize the chosen material of HPI structure can created counter force to control midfoot and hindfoot pronation.

Objective

Non-surgical treatments of flexible flat feet have many devices available and start with prefabrication device such as prefabrication insole, arch support, custom devices such as foot orthosis, orthopedic shoe also full control orthotic device such as UCBL (University of California Biomechanics Laboratory), SMO (Supra-malleolar orthosis). All of the devices for flexible flatfeet provide the same thing for plantar aspect to collect fallen medial arch or misalignment of calcaneus by using arch support or medial wedge, for sagittal aspect to provide reaction force for control foot pronation by using firm (heel counter of shoe) or rigid (border of UCBL or SMO) border.

The devices that are available in the market are manufactured by various materials such as silicone gel, PU (Polyurethane) injection foam, EVA (Ethylene vinyl acetate) form, rigid plastic such as PP(Polypropylene). The properties of material provide specific advantages for each material such as silicone or PU foam for good shock absorption EVA foam for super light weight PP for full function of control.

The HPI contain arch support and high border around the heel area could be an inroad for research evaluating stiffness of chosen materials in this design. Hardness of various layers and border tolerances should be explored. These features are designed to create a reaction force against the applied forces and to stop over pronation of midfoot to hindfoot. The objective was to evaluate deformation properties of medial border of this device configuration while loaded in a compression testing apparatus.

Scope of study

This study was focus on structure design of HPI's border with chosen combination of material to control foot pronation by applied force from air pressure system thru pneumatic valve to test reaction force that HPI's border can created.

The Result of this study is predicting the proper materials of HPI structure to create great reaction force and give more information for developing design of HPI in clinical application.

Research method

The principle of HPI is the combination feature of TCI and UCBL together by bring the total surface pressure distribution of TCI and rigid high border structure from UCBL and combine it together in one device. To decide the element of HPI researcher divide the consideration in two aspects. Pressure distribution and comfort by using the TCI principle in material selection. Stiffness and design of border by using UCBL principle in material selection and testing the hardness by mechanical testing.

The study was an experimental test of specific material for HPI structure. The main purpose of testing is to choose the proper material for control of foot pronation. The study preformed by pneumatic valve with air pressure to provide specific force at medial border of HPI and compare deformation volume at each corresponding force applied to the model shoe with HPI as well as deformation with the model shoe without the HPI.

Materials and Methods

High profile foot orthosis (HPI) Developing design in foot orthosis

The principle of UCBL can provide good control for bone deformities in flexible flat feet case. Control of UCBL can minimize misalignment of unstable subtalar joint when patient on the device.[6]

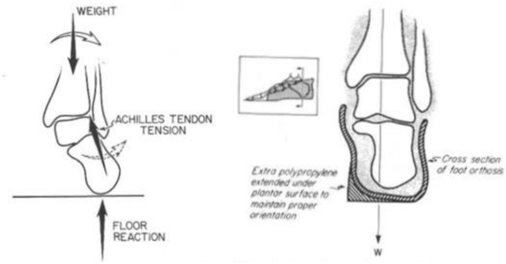


Figure 3 Principle design of UCBL [6]

The insole (foot orthosis) is made by using Total contact foot orthosis principle to provide comfort to user by distributing pressure from main weight baring area to other area of foot (30-40% pressure reduction) [15]

Shoe has an important part to control or support foot, many research found heel counter could improve stability of foot significantly. Heel counter and border of UCBL provide same support and control for the foot.

The good structure of custom orthopedic high-top shoe can support and improve stability of flexible flatfeet patient in same level as regular shoe with rigid functional FO. A Reason for this study is Orthopedic custom shoes (medical shoes) has been made with good structure shoe criteria and including firm heel counter between upper and liner of upper part of shoe. Functional foot orthosis with regular shoes and arch support from FO can control heel valgus and improve stability of subtalar joint. To control misalignment of foot in flexible flatfeet case, the good properties of novel FO combine advantage points from these two cases.[16]

Material selection

The component of HPI consist of 3 layers top cover, Mid layer and base layer.

Top cover of HPI: Top cover is a layer on the top surface of the foot orthosis or layer that contacts the plantar surface of the foot. The principle of total contact foot orthosis is to distribute the plantar pressures of the foot and provide comfort at the same time. A number of research articles has found that low density EVA can redistribute pressures across the plantar surface of the foot and can be a good cushioning material. Nora Lunairmed was chosen as the top layer of HPI because of good moisture absorption properties inherent in low density EVA.[16] In Thailand, high humidity climate is suit for using in daily life for children in school age.

Mid layer (Border): Materials available in the foot clinic at Siriraj Hospital have shore hardness ranges of 53- 63D, a range of hardness that suggested to use as heel counter for control subtalar joint.[18] PODIAFLEX (Shore A90, Podiatech Sidas Medical, Vairon, France)[14] is widely used in heel counter shoe modification.

Previous research[18] that used variety of heel counter in basketball shoe and divide shoe counter into 3 levels by using shore hardness durometer (shore D) to stiffness regular (53D), stiffer (63D), stiffest (63D+). According to this research regular to stiff heel counter should to have shore hardness type D around 53D - above 63D.[18]

Shore hardness is often used as indication of flexibility or stiffness. Shore has many types to evaluate hardness of difference kind of material such as shore OO for super soft material such as marshmallow like material, foam, gel insole (silicone). Shore A for material stiffer such as bottle nipple and every kind of form that we use in Prosthesis and Orthotic field are in these categories.

Shore D that we mentioned before is for real solid material such as plastic rubber PVC pipe Etc. For previous research that use variety of heel counter stiffness by measure hardness with shore D because researcher try to check rigidity of counter. Material in PO field do test material in shore D except real hard plastic PP, PE

Design of HPI is combination of total contact foot orthosis and UCBL together, base layer and border of HPI will connect together. Materials that available in foot clinic siriraj hospital have many kinds of material but materials that have shore hardness in range 53-63D is PODIAFLEX (Shore A90, Podiatech Sidas Medical, Vairon, France). Other material that available in market now is reinforcing paper that formal use in shoe manufacturing have more cost efficient but hard to fabricate because paper need to use with thinner as solvent and take time before setting. Plastic PP or PE are common use in PO field is hard and rigid but as research “Use of UCBL” found that hard and fully control of UCBL can made skin redness on patient feet.[8]

Other reason that researcher choose PODIAFLEX as base layer of HPI is common material that used in heel counter shoe modification because easy to fabricate strong and firm structure in only 1.2 mm. of thickness.

Proper materials for functional FO were thermoforming resin polycaprolactone on a textile base (PODIAFLEX) for firm structure of FO, soft EVA such as NORA for comfort, provide cushion and moisture absorption at same time.[13-14,16]

Base layer: Base layer of HPI was made from ethylene-vinyl acetate (EVA) with a high density to make the insole structure firm.

The HPI was custom made from a foot model out of soft EVA material (Nora) with a thickness of 3mm at the top layer and posterior section of the metatarsal head (mid-rear foot area) of the insole (including the medial and lateral border of insole) was made from resin polycaprolactone (PCL) on a textile base (PODIAFLEX) and Fluxan[13-14,21] in order to create rigidity and offer a bit of flexibility in the border areas (heel counter area) of the mid-layer of the insole. The medial border began proximally from the 1st metatarsal head and lateral border will to the 5th metatarsal base. The base layer of insole was made from ethylene-vinyl acetate (EVA) of a high density to make the insole structure firm.

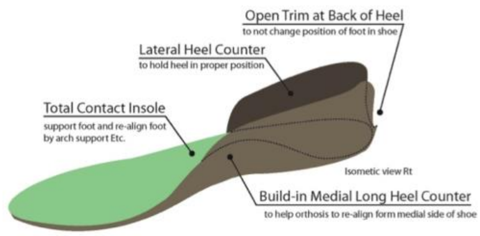
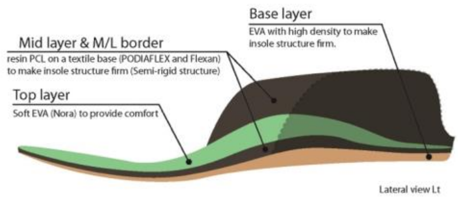


Figure 4 Detail of High profile insole (Isometric view)



Detail of High profile insole
(Lateral side view)

Figure 6 High profile insole (HPI)

Device fabrication

Casting

HPI will cast in non-weight bearing position and extend patient toe to get fully height of longitudinal arch. This principle of casting technic is similar to UCBL casting technique.

Model modification

Remove excessive plaster from plaster model, add medial heel wedge on plaster. (Add more arch support in case if need) Extend plaster from metatarsal head to end of toe plus 2 cm.

Figure 7 Plaster model modification

Thermoforming

Thermoform materials layer-by-layer starting from 1st layer is top cover of device (Nora 3mm.) to provide cushion and comfort. 2nd layer is mid-layer (structure reinforcement) and HPI border made by double layers of polycaprolactone (PCL) on a textile base (PODIAFLEX) and Fluxan. 3rd layer is base of device to fill under surface of HPI and make device stable.

Trimming/ Finishing

Design trim line of HPI by trim medial border start proximally from 1st metatarsal head for 1 centimeter. Lateral border starts proximally from 5th metatarsal head for 2 centimeters. Height of border is cover subtalar joint or depend on height of topline of shoe that user use.

Figure 8 Trim line of HPI

Model shoe

The model shoe for testing in this study was made from Surlyn® using the thermoforming method 6mm thickness and was attached sole by using high density EVA. The HPI was placed directly into the model shoe and trimmed to match the desired wall and border heights.

Figure 9 Model shoe (Surlyn®)

Information for Mechanical testing

Shoe testing protocol is depending on purpose to test specific properties of shoe. We can classify shoe testing into 3 main categories physical testing, chemical testing and microbiological testing. In this study we focus on physical shoe testing in this group we have many kinds of testing protocol such as Flex and fatigue resistance, Impact resistance, Cushioning and shock absorption, cut resistance, Longitudinal and Torsional stiffness of footwear, Slip resistance. However, a lot of physical testing that we have still lack of heel counter stiffness testing. (Main outcome of this study)

Heel counter testing protocol

Many of research use subjective testing to check structure of shoe that made by The American Academy of Podiatric Sports Medicine utilizes by 3 steps of checking call 3-point testing procedure. The test consists of flexion stability, torsional rigidity and heel counter rigidity. "Heel counter rigidity" testing is a way to test stiffness of heel counter of shoe by use hand grab shoe over shoe sole and use finger to squeeze rear part of shoe (heel counter) to check rigidity of heel counter.[23]

Mechanical testing system

A guilded rod type pneumatic cylinder was connected to an air pressure regulator and air pump (0.8 HP tank size 24 litre) to perform foot loading testing using an open air pressure regulator gauge from 0 bar (totally close) to 1bar, 2bar, 3bar, 4bar and 5bar (max pressure from air pump compressor). Air pressure passed through the air pipe to the pneumatic cylinder ("SMC" Code: CXSM 10-75 ,diameter 10 mm) to generate a pushing force to a paddle at the end of cylinder. This paddle at the end of piston rod cantered pressure on the model shoe @ 0 bar prior to performing the test.

The objective was to compare deformation volume at each corresponding force applied to the model shoe with HPI as well as deformation with the model shoe without the HPI. The test was performed 3 times at every air pressure level and mean values were calculated to avoid errors in result.

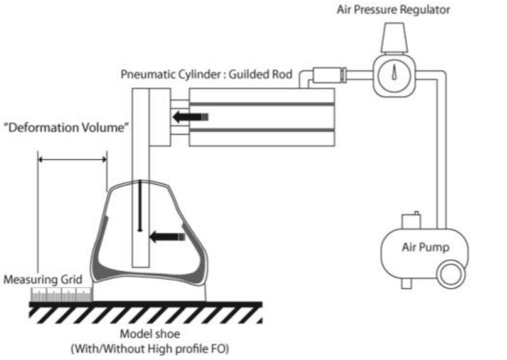


Figure 10 System diagram of study

The "Pascal's Law" equation was used to calculate paddle force at each level of air pressure, whereas pressure is equal to force divided by area. [19] Pressure was controlled by adjusting the amount of air pressure regulator gauge (in "bar" units,1 bar = 105 N/m2). Furthermore, the pneumatic cylinder had a diameter of 10 mm, thus to calculate the area of the cylinder, the formula "πr^2"was used in order to determine the force occurring at the end of the paddle.

$F = P \times A$

$F = P\ (N/m^2) \times A\ (m^2)$

$F = P\ (10^5) \times 3.14\ (\text{Cylinder Radius})^2$

$F = P\ (10^5) \times 3.14\ (0.05)^2$

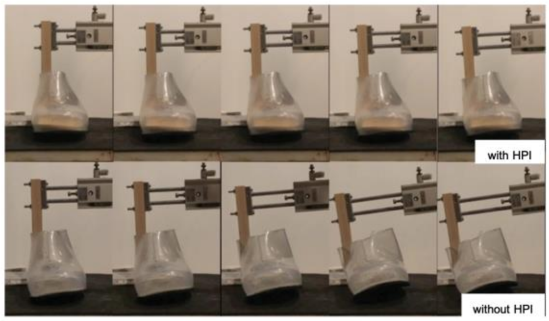


Figure 11 Deforming volume of shoe when provide force

Result

The test was performed 3 times at every air pressure level with an increase level of air pressure starting from 1-5 bar. The model shoe with HPI could create a counter force and hold original form well at 1 bar (7.85 N) with a deforming volume is just only 8 mm.. Compared with model shoe without HPI a deformation of around 25 mm. occurred with the same paddle force applied. At 2 bar (15.7 N) of pressure the model with HPI could tolerate force and deformed at 14 mm., whereas in the model without HPI there was a deformation of 33 mm.. At 3 - 4 bar (23.55 N, 31.40 N) of air pressure a similar HPI deformation trend was observed, 18 mm and 21 mm. respectively. See Table 4.1 additional testing results. A deforming volume ratio from 3-4 bar by 2 times can observed with the device beginning to deform at this level. For model without HPI at this level was higher deformed at similar levels.

Table 1 Results of model pneumatic pressure testing (Deformation volume unit = millimeter, Applied force unit = Newton)

Force(N)	Air pressure (Bar)	Deformation volume (mm.)		Volume difference(mm)
		Shoe with HPI	Shoe only	
7.85 N	1	80	258	-178
15.70 N	2	140	334	-194
23.55 N	3	182	448	-266
31.40 N	4	212	586	-374
39.25 N	5	282	586	-304

To be easy to understand, we can convert result from numerical data to graph and it will show slope from 0 bar to 1 bar, 1 bar to 2 bar, 2 bar to 3 bar, 3 bar to 4 bar, 4 bar to 5 bar in control and intervention group. Deforming volume at first bar pressure have about 3 times difference in slope ratio. At 2nd bar slope start decrease rising and keep slope rising until 4th bar, be opposed to shoe with HPI slope rising as same accelerate from 1st to 5th bar of air pressure.

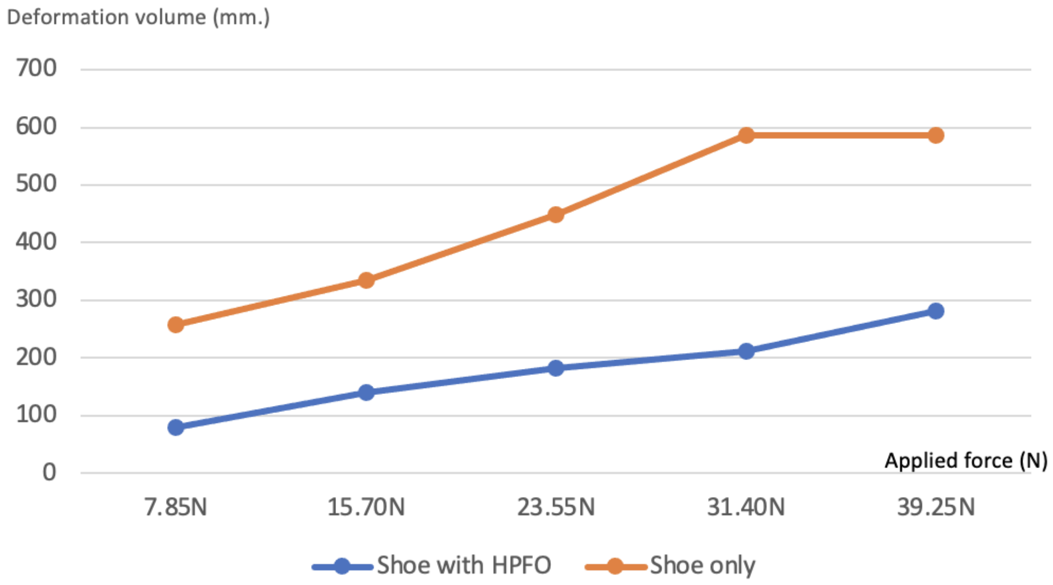


Figure 12 Results of model pneumatic pressure testing (graph) (Deformation volume unit = millimeter, Applied force unit = Newton)

Discussion and conclusion

Discussion

Mechanical testing of this study researcher adapted from testing protocol of shoe heel counter. Like we mentioned earlier HPI is device that combine foot orthosis and control of UCBL together. Previous research[24] already proved rigid foot orthosis can improvement of foot posture at hind foot, but still lack some support at mid foot. Testing in this study is to test stiffness of added part of orthosis (border). Testing protocol to check stiffness of counter is pushing posterior part of shoe and see displacement of heel part but this testing is quite subjective because we can not control amount of force that we apply to shoe.[22-24]

To know force exactly that we applied to part of HPI we developed testing system by using air pressure pump to pneumatic cylinder. Position that paddle of cylinder place in testing protocol is medial border of device and pushing from inside to out side.

Clinicians have previously utilized resin PCL as "Podiaflex" and "Flexan" to create borders at the heel to hold and realign the midfoot to prevent arch collapse and hind foot for calcaneus valgus. Both of these materials are being widely used to reinforce the base of functional insole because the material itself is strong thin and hard to crack.[13-14] Moreover, some orthopaedic shoe makers use this "podiaflex" to fabricate heel counters or heel counter fabrication in shoe modification and "Flexan" for toe boxe s. Thus, this was the rationale for this researcher to utilize the aforementioned materials in the HPI design.

The position of medial part of HPI that we applied force is at peak of navicular or the point that previous research use to radiological measurement to analyse change of anteroposterior talocalcaneal angle. (APTCA) [20,27] The reason that we choose this position to test stiffness of HPI because many research did not mention about shoe that they use in their study. Some of study that they mention about shoe such band or type of shoe in study but did not show detail in component of shoe such as stiffness of shoe heel counter. In this study we applied force by calculated from weight distribution area on target group of this device (7-12 year olds children with flexible flatfeet). Average body weight of target group is 21.6–37.3 kg. and weight distribution of medial side of feet is 7% on static.[25-26] The medial border of HPI should tolerate body load at medial side around 1.512 kg for minimum and 2.611 kg for maximum case. The applied force to medial border of HPI in this study is maximum at 39.25 N or about 4 kg. of weight and force that border re-act to hold original shape against applied force.

From these results it is clear that a reduction deformation volume at medial side of shoe occurred in the HPI when force was applied, therefore the device had a reduction of more than 2 times that of deformation volume of model without HPI. This could be as a result of the materials' hardness and extra layers at the border areas reinforcing the heel part of model shoe to be stronger.

On the other hand, the UCBL that made from PP 5 mm. of thickness have a very strong and rigid structure and able to tolerate the applied force in every pressure level. However, regarding to result of use of UCBL[8] using foot orthosis overtime can reduce pain significantly but problem is rigidity of UCBL can lead to skin redness, pain or ulcer because UCBL force patient foot to neutral position with hard and rigid material. Result of this study can proved flexibility of material and provide enough force to control foot pronation at acceptable deformation volume in target group region, its may avoid reason of poor compliance that rigid border of UCBL made skin redness to user.

Result of this testing can proved, the border of HPI that made from chosen material can provide reaction force against medial side of midfoot to control pronation in children with flexible flatfeet.

Study limitation

This study is not without its limitations, a single HPI and model with only a single size was used in testing. A larger shoe could have longer medial longitudinal arch and higher topline of the shoe and create a larger border of the device. All of which could necessitate additional layers of material, which were not evaluated in this current study. The HPI is designed for the adolescent with flexible flat feet between 7-12 years of age, various shoe sizes (devices) and multi-layer combinations should be further explored.

The force applied in this study is also a limitation which should be further evaluated in future studies that explore various pressures corresponding with various known body weights and ground reaction forces during gait. We were limited to a force no more than 40 N, which is suitable to represent smaller patients, but certainly a higher body weight will create more force against medial border of the HPI so further studies should upgrade the air presser pump and pneumatic cylinder to allow additional and increased levels of pressure and force.

Conclusion

This study is aimed to create a unique HPI which could facilitate a higher border and higher profile insole to augment foot control for the flat foot adolescent. The device was created and evaluated for deformation under pressurized testing conditions. In flexible flatfeet cases, clinicians often suggest patients to find a good structure shoe for use with the prescribed foot orthosis. In Thailand, this can be a problem. Still, a good structure shoe may reduce excessive motion of foot during walking, offer comfort through shock absorption, and offer a heel counter to control over pronation and hold the orthosis in a proper location in the shoe. For all of these aforementioned reasons, the heel counter of shoe and border of the HPI was designed to provide the same support to control over pronation of foot. The chosen materials were tested via mechanical testing to evaluate stiffness of the medial border of the device and observe changes of deforming volume. Result of this study evidenced an acceptable performance of the HPI, with an ability of the combo to tolerate various loading forces. Future studies could begin to perform more mechanical evaluation and ultimately clinical trials to truly understand the clinical efficacy of the HPI.

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