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Development of simple and portable device for plantar pressure measurement for improvement of foot assessment

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Background : *The most common cause of foot problems is an abnormal plantar pressure distribution. Evaluation of plantar pressure is therefore necessary in management of foot problems. The tool for plantar pressure measurement is; however, expensive, complicated and needs special technicians to operate, so it is not widely used clinically. For this reason, the researchers develop a simple portable device for plantar pressure measurement that is of lower cost and easier to use.*

Objective : *To develop a simple, low cost and easy to use in-shoe pressure measurement and define the correlation with the standard plantar pressure measurement tool (F-scan).*

Design : *Descriptive and analytical study.*

Setting : *Biomedical Engineering, Faculty of Engineering, Chulalongkorn University and Center of Excellence in Gait and Motion, King Chulalongkorn Memorial Hospital.*

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Material and Method : *The researchers developed a simple in-shoe system by using Piezoresistive-insole-sensor to measure plantar pressure at the heel, the 1st and 5th metatarsal head (MTH) during dynamic movement in real-time. We recruited 30 healthy volunteers (10 males and 20 females) to measure their plantar pressure during standing and walking by our developed device and the standard plantar pressure measurement tool which is F-scan. The peak plantar pressures of the heel, 1st and 5th MTH were evaluated. The static pressures were recorded during standing for 30 seconds, and the dynamic pressures were recorded during walking for 5 meters. The average of 3 trials for each session was collected; the data were assessed by the intra-class correlation between the data from our developed device and that of the standard reference tool.*

Result : *The ICCs ($\alpha = 0.05$) of the static plantar pressure measurement of both feet were 0.641 (0.370 – 0.811), 0.466 (0.133 – 0.705), and 0.721 (0.491 – 0.857) for the right heel, 5th and 1st MTH, and 0.727 (0.501 – 0.860), 0.502 (0.179 – 0.727), and 0.545 (0.235 – 0.754) for the left heel, 5th and 1st MTH, respectively. According to the dynamic plantar pressure, the ICCs were 0.884 (0.771 – 0.943), 0.799 (0.620 – 0.899) and 0.878 (0.760 – 0.940) for the right heel, 5th and 1st MTH, and 0.826 (0.666 – 0.913), 0.796 (0.614 – 0.897), and 0.711 (0.476 – 0.851) for the left heel, 5th and 1st MTH, respectively.*

Conclusion : *Our developed device and the standard reference tool were correlated by the ICCs, Therefore, our developed device could be used to evaluate abnormal plantar pressure distribution in clinical foot care.*

Keywords : *Plantar pressure measurement, force sensor, in-shoe system, F-scan.*

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- เหตุผลของการทำวิจัย** : สาเหตุหลักอย่างหนึ่งของปัญหาสุขภาพเท้าที่พบมากที่สุด คือ ความผิดปกติของการกระจายแรงกดในฝ่าเท้า ดังนั้นการตรวจวัดแรงกดในฝ่าเท้าจึงมีความสำคัญเป็นอย่างยิ่งต่อการรักษาความผิดปกติของเท้า แต่อุปกรณ์ที่ใช้ในการตรวจวัดแรงกดในฝ่าเท้านั้นมีราคาสูง ทั้งยังมีความยุ่งยากในการทำงานต้องใช้ผู้เชี่ยวชาญในการควบคุมดูแลเครื่องมือ ดังนั้นจึงยังไม่เป็นที่แพร่หลายในการใช้รักษาปัญหาสุขภาพเท้าในทางคลินิก ด้วยเหตุนี้คณะผู้วิจัยจึงได้พัฒนาอุปกรณ์ตรวจวัดแรงกดในฝ่าเท้าชนิดพกพาอย่างง่ายขึ้น ซึ่งมีราคาถูก และใช้งานง่าย
- วัตถุประสงค์** : เพื่อพัฒนาอุปกรณ์อย่างง่าย มีราคาถูก และสะดวกในการใช้งานสำหรับตรวจวัดแรงกดในฝ่าเท้าที่เกิดขึ้นภายในรองเท้า และเพื่อเทียบผลสอดคล้องระหว่างอุปกรณ์ที่พัฒนาขึ้นกับเครื่องวัดแรงกดในฝ่าเท้าประเภทแผ่นรองเท้า (F-scan) ที่ใช้เป็นเครื่องอ้างอิงมาตรฐาน
- รูปแบบการวิจัย** : การวิจัยโดยการพรรณนาเชิงวิเคราะห์
- สถานที่ทำการศึกษา** : วิศวกรรมชีวเวช คณะวิศวกรรมศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย และศูนย์ความเป็นเลิศทางการแพทย์ด้านการเดินและการเคลื่อนไหว แห่งโรงพยาบาลจุฬาลงกรณ์
- ตัวอย่างและวิธีการศึกษา** : คณะผู้วิจัยได้ทำการพัฒนาระบบอย่างง่ายในการตรวจวัดแรงกดในฝ่าเท้าที่เกิดขึ้นภายในรองเท้า โดยใช้แผ่นรองเท้าที่มีเซนเซอร์ชนิดตัวต้านทานแบบเพียโซติดอยู่เพื่อวัดแรงที่เกิดขึ้นตรงตำแหน่งส้นเท้า ปุ่มกระดูกนิ้วหัวแม่เท้า และปุ่มกระดูกนิ้วก้อยเท้าที่เกิดขึ้นในขณะที่เดินแบบ real-time จากนั้นทำการคัดกรองอาสาสมัครสุขภาพดีจำนวน 30 คน (ชาย 10 คน หญิง 20 คน) เพื่อทำการวัดแรงกดในฝ่าเท้าที่เกิดขึ้นในขณะที่ยืนและเดิน ด้วยอุปกรณ์ที่พัฒนาขึ้นและเครื่องอ้างอิงมาตรฐานคือ F-scan และทำการตรวจประเมินแรงกดในฝ่าเท้าสูงสุดตรงตำแหน่งส้นเท้า ปุ่มกระดูกนิ้วหัวแม่เท้า และปุ่มกระดูกนิ้วก้อยเท้า โดยทำการเก็บข้อมูลในขณะที่ยืนเป็นเวลา 30 วินาที และในขณะที่เดินเป็นระยะทาง 5 เมตร แล้วนำค่าเฉลี่ยจากการเก็บผล 3 ครั้ง มาทำการประเมินหาความสัมพันธ์ภายในกลุ่ม (Intra-class correlation coefficients : ICCs) เพื่อเทียบผลสอดคล้องระหว่างอุปกรณ์ที่พัฒนาขึ้นกับเครื่องวัดแรงกดในฝ่าเท้ามาตรฐาน (F-scan)

- ผลการศึกษา :** ค่าสหสัมพันธ์ภายในในกลุ่ม (ICCs; ($\alpha = 0.05$) ของแรงกดในฝ่าเท้า ทั้งสองข้างที่เกิดขึ้น ในขณะยืนได้ค่าเป็น 0.641 (0.370 – 0.811), 0.466 (0.133 – 0.705) และ 0.721 (0.491 – 0.857) จากตำแหน่ง ส้นเท้า ปุ่มกระดูกนิ้วก้อยเท้า และปุ่มกระดูกนิ้วหัวแม่เท้า ของเท้าขวา ตามลำดับ ส่วนเท้าซ้ายได้ค่า ICCs เป็น 0.727 (0.501 – 0.860), 0.502 (0.179 – 0.727), และ 0.545 (0.235 – 0.754) จากตำแหน่ง ส้นเท้า ปุ่มกระดูกนิ้วก้อยเท้า และปุ่มกระดูกนิ้วหัวแม่เท้า ตามลำดับ ในส่วนของข้อมูลของแรงกดในฝ่าเท้าที่เกิดขึ้นในขณะเดิน ได้ค่า ICCs เป็น 0.884 (0.771 – 0.943), 0.799 (0.620 – 0.899) และ 0.878 (0.760 – 0.940) จากตำแหน่งส้นเท้า ปุ่มกระดูกนิ้วก้อยเท้า และปุ่ม กระดูกนิ้วหัวแม่เท้า ของเท้าขวาตามลำดับ ส่วนเท้าซ้ายได้ค่า ICCs เป็น 0.826 (0.666 – 0.913), 0.796 (0.614 – 0.897), and 0.711 (0.476 – 0.851) จากตำแหน่งส้นเท้า ปุ่มกระดูกนิ้วก้อยเท้า และปุ่ม กระดูกนิ้วหัวแม่เท้า ตามลำดับ
- สรุป :** อุปกรณ์ที่คณะของผู้วิจัยได้พัฒนาขึ้นนี้และเครื่องอ้างอิงมาตรฐานมีความสอดคล้องกัน ดังเห็นได้จากการพิจารณาค่า ICCs ดังนั้นอุปกรณ์ ที่พัฒนาขึ้นนี้ควรได้รับการศึกษาเพิ่มเติมในผู้ป่วยผิดปกติที่สามารถ ใช้ในการตรวจวินิจฉัยการกระจายแรงกดในฝ่าเท้าที่ผิดปกติ ในคลินิก สุขภาพเท้าได้
- คำสำคัญ :** การวัดแรงกดในฝ่าเท้า, เซนเซอร์วัดแรง, ระบบการตรวจวัดแรงที่เกิดขึ้นภายในรองเท้า, อุปกรณ์วัดแรงกดในฝ่าเท้าชนิดแผ่นรองเท้า.

Foot is the important organ that bears the body weight, and affects locomotion.⁽¹⁾ Thus, when there are foot problems; such as pain from diseases or foot deformities from abnormal structures, weight bearing, walking, and their activities of daily life are all disturbed.⁽²⁻⁴⁾

Abnormal foot distribution is one of the most common foot problems which can lead to foot ulcer because of the high pressure will damage tissue of the foot, especially the tissues under the bony prominent areas.⁽⁵⁻⁷⁾ Then, foot orthosis or insole is generally used to relieve the abnormal plantar pressure,⁽⁸⁾ as insole making is based on the principle of foot biomechanics.⁽⁹⁾ Thus, the information of abnormal plantar pressure measurement is necessary for the diagnosis and management of foot problems, especially the consideration of the effectiveness of insole.⁽¹⁰⁻¹²⁾

At present, the commonly used measurement applications are divided into two types: force plate and in-shoe system. The force plate is used to assess the plantar pressure in barefoot, whereas, the in-shoe system is used to assess the pressure while wearing shoe. The latter is more useful for foot care because people spend more time with shoes. Moreover, the in-shoe system is used to evaluate the effect of insole design. Thus, the foot-care team can deal with foot problems in the right situation.^(13,14)

However, these two methods have the main drawback that they tend to be too expensive and complicated. Moreover, they are the large and only set in labs, and need special technicians to use. Therefore, they are unpopular in public health care.

It is much better to get a proper plantar pressure measurement device. Therefore, the aim

of this study is to improve an in-shoe pressure's measurement device which is portable, low cost, and easy for clinical use, as well as to prove the other one is to prove the correlation between the results from our developed device and that of the standard reference tool.

Materials and Methods

This descriptive and analytical study has been approved by the Institutional Review Board, Faculty of Medicine, Chulalongkorn University. The setting of this study is the Excellence Center for Gait and Motion, King Chulalongkorn Memorial Hospital.

Subjects

After the development, the correlation between the result from our developed device and that of the F-scan were studied. This study was conducted on 30 healthy volunteers. All subjects had no history of foot problems for at least 1 year before the start of the study. Subjects were excluded from the study, if they had the clinical signs of instability, pathologic gait and problems related to locomotion. Informed consent was given by all participants.

Measurement devices

This study used two devices for plantar pressure measurement, i.e., our developed device and the standard reference tool (F-scan). F-scan (Tekscan Inc., Boston, MA) is the in-shoe system, which consists of a pair of thin-polyester film with hundreds of force sensors inside. It is used for accessing the plantar pressure, which appears in shoes while moving. The developed device (Figure 1) is an in-shoe system which has three force

sensors on the important zones of foot biomechanics for the plantar pressure measurement at the heel, the 1st and 5th MTH during dynamic movement in real-time. The concept of this measurement system is to use the piezoresistive-insole-sensor to measure the localized forces on the sole of foot.^(15, 16) The collected data from both left and right feet are sent to the left and right waist boxes that contain the measuring and low-pass filter circuits inside.⁽¹⁷⁾ Then, the data from both waist boxes are sent to the middle waist box that helps to convert the analog signals into digital. After several processes the outcomes of the measurement system are still the digitalized data that they will be linked wirelessly to a personal computer via Bluetooth communication.

Method

In the initial test, we used the developed device to measure the plantar pressure during walking. In our test, a volunteer was asked to walk

5 m with natural walking cadence.

The results of the test (Figure 2) showed the relationship between weight (kg) and time (s). We can observe the plantar pressure graphs of 4 steps of walking in 6.00 s. The maximum force at the right and left heels, the right and left 1st MTHs, the right and left 5th MTHs are 1.78 kg, 1.87 kg, 0.74 kg, 0.82 kg, 0.18 kg and 0.21 kg, respectively. These results are related to the load distribution in the foot based on the foot biomechanics; therefore, we can measure the higher force at the heel more than any other parts. During each step, we can observe that the plantar pressure change started from the heel to the 5th MTH and the 1st MTH, respectively. These are consistent with the walking rhythm, in which the heel is the 1st part to touch the floor. After that, the graph of the plantar pressure at the 1st MTH was changed because the 1st MTH was the last part to contact the floor before the push off.

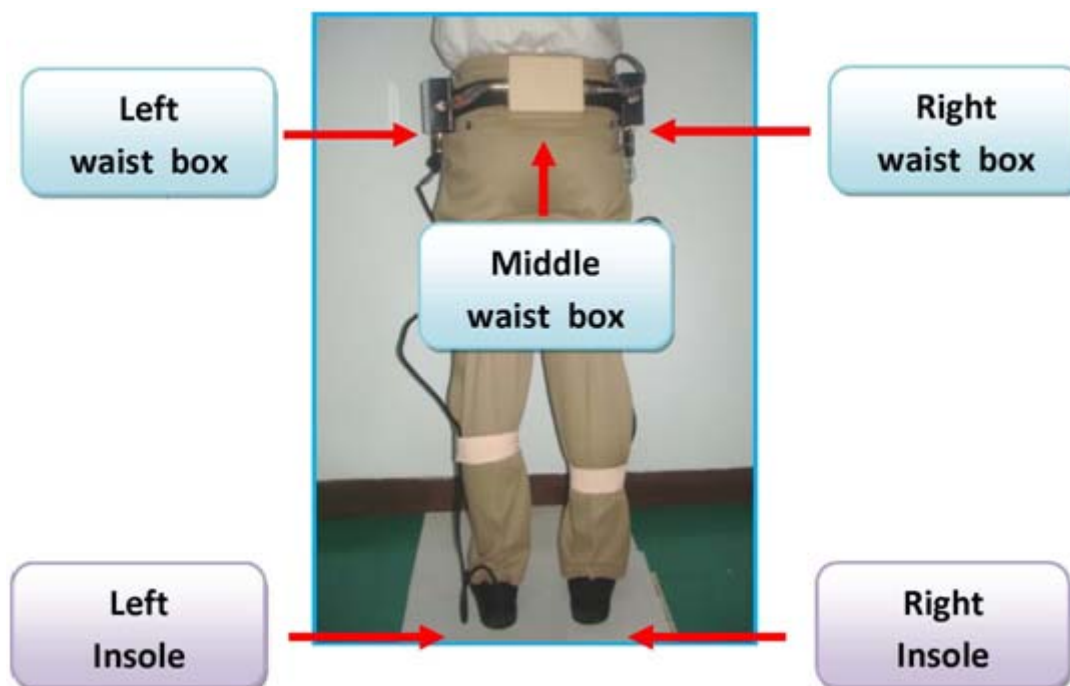


Figure 1. A simple portable device for plantar pressure measurement.

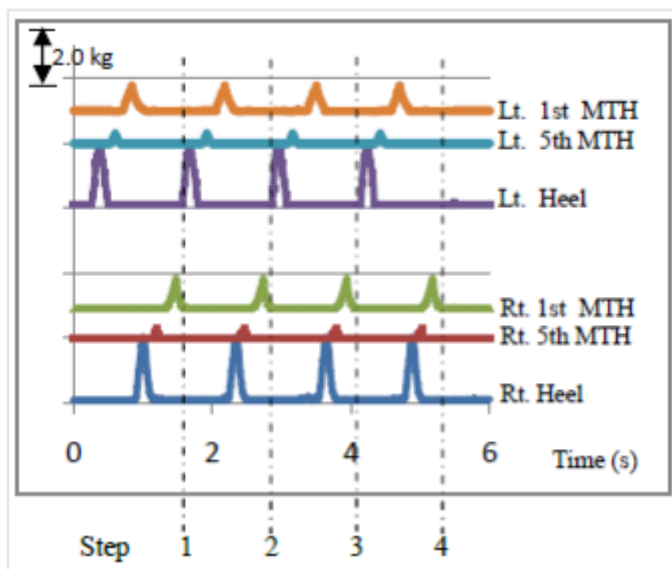


Figure 2. The relationship between force and time.

Based on the initial study, it is confirmed that our developed device can evaluate the plantar pressure in real-time. The comparison of correlation coefficients of plantar pressure measurement between our developed device and F-scan were determined by two separate training-sessions, which are standing and walking ones. The plantar pressure data of the heel, the 1st and 5th MTH were collected during standing and walking. All subjects used the same brand and design of shoes to avoid the differences in personal foot wears.

During the standing session, the volunteers stood in an anatomical position for an equal weight balance, and then the data were recorded in 30 seconds. During the walking session, pressures were recorded in 5 m that the collected data were excluded the 1st step and the last step to avoid the steps that were not natural. The average of 3 trials for each session was recorded, and the plantar pressures from both sessions were evaluated by the developed device and the reference tool.

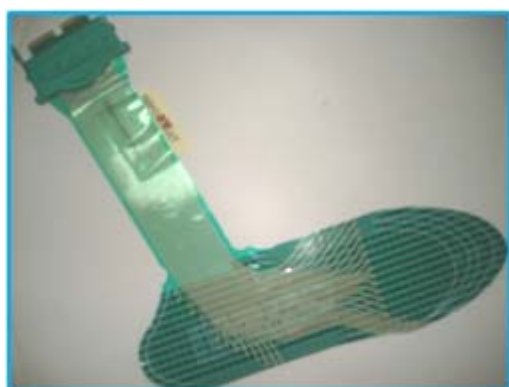


Figure 3. The standard reference tool (F-scan).



Figure 4. The measuring insole.

Statistical analysis

The general data such as weight, age and shoe sizes were expressed as mean \pm standard deviation. Then the plantar pressure measurement data were analyzed by using the SPSS version17 program. The comparison of the correlation between the developed device and the F-scan were analyzed as the ICCs with 95% confidence interval. *P*-value of less than 0.05 was defined as significant.

Result

The subjects mean age was 25.87 ± 2.60 years (range: 22 – 32), mean weight was 55.87 ± 11.73 (range 42 – 76); mean BMI was 20.28 ± 2.17 kg/m^2 (range: 17.63 – 27.75); and the mean shoe size was 33.77 ± 2.39 (range: 35 – 43). The study drew a comparison between the average plantar pressure from our developed device and F-scan in standing session (Table 1), percent of the total average were 34.71%, 35.69%, and 25.89% for the right heel, 5th and 1st MTH, and 33.63%, 39.51%, and 26.81%

for the left heel, 5th and 1st MTH, respectively. In walking session (Table 2), percent of the total average were 30.19%, 37.98%, and 30.83% for the right heel, 5th and 1st MTH, and 29.87%, 35.51%, and 31.89% for the left heel, 5th and 1st MTH, respectively.

For reliability analysis of 3 times of plantar pressure in both feet in standing posture (Table 3), the intra-class correlation coefficients (ICCs) with 95% CI were 0.641 (0.370 – 0.811), 0.466 (0.133 – 0.705), and 0.721 (0.491 – 0.857) for the right heel, 5th and 1st MTH, and 0.727 (0.501 – 0.860), 0.502 (0.179 – 0.727), and 0.545 (0.235 - 0.754) for the left heel, 5th and 1st MTH, respectively. In walking (Table 4), the intra-class correlation coefficients (ICC) with 95% CI were 0.884 (0.771 – 0.943), 0.799 (0.620 – 0.899) and 0.878 (0.760 – 0.940) for the right heel, 5th and 1st MTH, and 0.826 (0.666 – 0.913), 0.796 (0.614 – 0.897), and 0.711 (0.476 – 0.851) for the left heel, 5th and 1st MTH, respectively. These results showed high agreement of data.

Table 1. Comparison between the average plantar pressure from our developed device and F-scan during standing session.

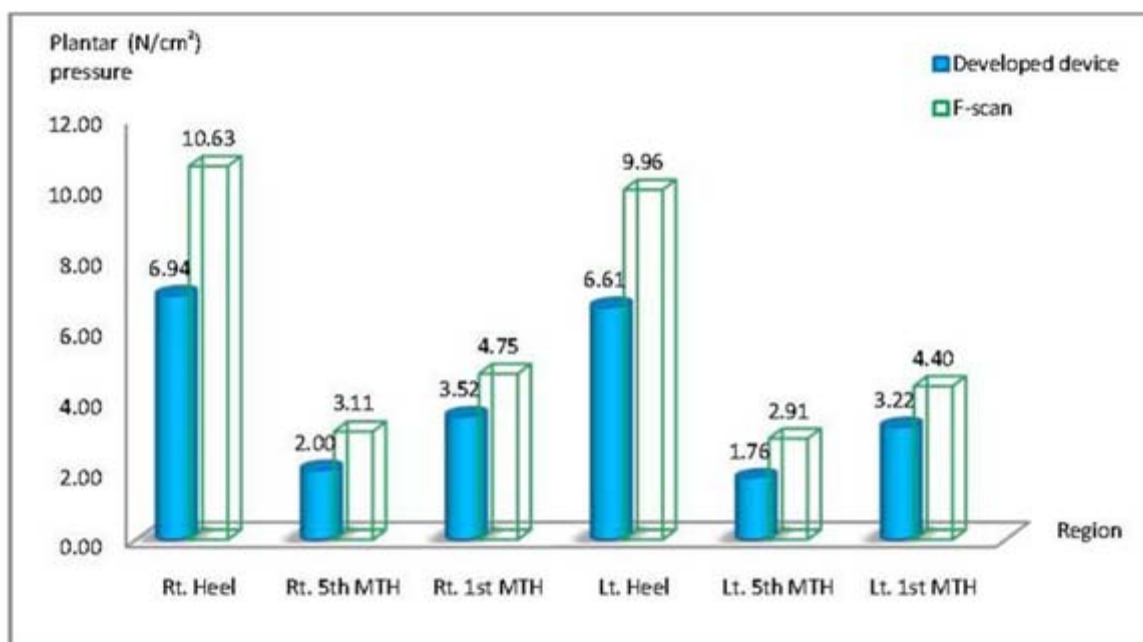


Table 2. Comparison between the average plantar pressure from our developed device and F-scan during walking session.

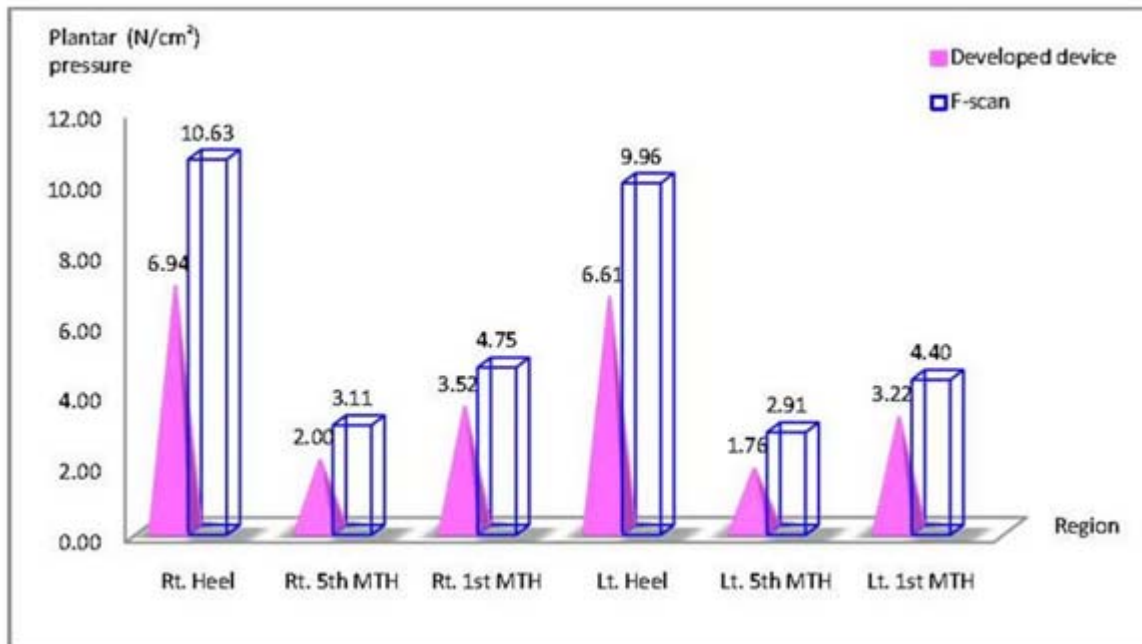


Table 3. Comparison between measuring data from our developed device and F-scan during standing session (statistical significant $\alpha = 0.05$).

Parameter	Right Foot			Left Foot		
	ICC	95% Confidence Interval		ICC	95% Confidence Interval	
		Lower bound	Upper bound		Lower bound	Upper bound
		Heel	0.641		0.370	0.811
5 th MTH	0.466	0.133	0.705	0.502	0.179	0.727
1 st MTH	0.721	0.491	0.857	0.545	0.235	0.754

Table 4. Comparison between measuring data from our developed device and F-scan during walking session (statistical significant $\alpha = 0.05$).

Parameter	Right Foot			Left Foot		
	ICC	95% Confidence Interval		ICC	95% Confidence Interval	
		Lower bound	Upper bound		Lower bound	Upper bound
		Heel	0.884		0.771	0.943
5 th MTH	0.799	0.620	0.899	0.796	0.614	0.897
1 st MTH	0.878	0.760	0.940	0.711	0.476	0.851

Discussion

As a result, the average plantar pressure from our developed device is observed to be lower than the standard reference tool because the different from the measuring insoles. The developed insoles are thicker and softer than the F-scan's insole; therefore, loads are distributed over the developed insoles more than the F-scan's insoles. Since our developed device measures only 3 parameters at the heel, 5th MTH and 1st MTH, but F-SCAN can measure all area of the foot so that the ICCs might not well correlate. Nevertheless, the ICCs during standing is 0.466 – 0.727. The ICCs during walking is 0.711 – 0.884, which trends toward good reliability,⁽¹⁸⁾ particularly during walking. The preliminary testing indicates that our developed device may be can used to measure the plantar pressure in the clinical situation without any standard reference tool. Additionally, our developed device which spent 35,000 baht on expenses of the invention is up to 17 times cheaper than F-scan. So far, it saves up for the low-income countries. In clinical uses, everyone will generally benefit by occasionally using our developed devices. Therefore, it is portable, light and easy to use, whereas F-scan is complicated tool which only set in labs, and needs special technicians to use.

However, the reliability and the accuracy of our developed device need further improvement to reach the level of the standard reference tool. Furthermore, we will be continuing this study in the pathologic gait. These plans are likely to result in lasting benefit to the whole of clinical foot care.

Conclusion

Based on the study, the developed device

trends toward in a good reliability to the standard reference tool. Thus, there is a good possibility that our developed device is appropriates for foot screening in clinical foot care. Moreover, our developed device can achieve the aim of this study at lower cost and easier for use.

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