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Comparison of three pressure monitors used to measure interface pressure under compression bandages

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Abstract

Background: Measuring the interface pressure produced by compression therapy devices is essential for research and clinical practice. New user-friendly measuring devices, such as Smart Sleeve Pressure Monitor (SSPM) and Juzo Pressure Monitor (JPM) allow longitudinal pressure measurement. However, their accuracy and agreement with well-established usage of the PicoPress (PP) are unknown. The aim of this study is to investigate measurement accuracy of PP, SSPM, and JPM.

Methods: The three devices were tested in 10 healthy volunteers by applying incrementally increasing pressure from 20 mm Hg to 50 mm Hg using a calibrated sphygmomanometer cuff. The linearity of the response and measurement accuracy were compared among the three devices. In a separate experiment, the three devices were compared by simultaneously recording the interface pressure under bandages immediately after bandaging and after 4 h of wearing the bandage.

Results: PP had the best performance with the reference of sphygmomanometer, while JPM had better linearity and accuracy than SSPM. The mean difference in the interface pressure under bandages was +13.36 mm Hg between SSPM and PP, and +0.50 mm Hg between JPM and PP. The 95% limits of agreement were −13.92 and +40.64 mm Hg, and −19.83 and +20.84 mm Hg, respectively.

Conclusions: JPM showed better agreement with both sphygmomanometer and PP compared to SSPM. JPM is a reasonable alternative for monitoring interface pressure continuously.

Keywords

Compression therapy, wounds, edema, venous disease, interface pressure

Introduction

Compression therapy is widely applied in the prevention and treatment of chronic venous disease. With adequate compression, satisfactory results can include reducing chronic edema, accelerating ulcer healing, and preventing ulcer recurrence.[1–4] Pressure loss beneath compression bandages, however, is a well-known phenomenon and is thought to be related to reduction of leg volume, bandage relaxation, and poor quality of application.[5] The ability to measure interface pressure at the time the bandage is applied can ensure that the desired compression dose is delivered.[6] Moreover, monitoring the pressure under the bandage over time may help to optimize subsequent adjustment or changing of the bandage.[7]

Several measurement devices with varied advantages and limitations have been used in clinical research for years. However, few studies have evaluated or compared the metrological properties of these systems, particularly their accuracy.[8–12] Partsch and Mosti[13] compared PicoPress® (Microlab, Padua, Italy) with Kikuhime® (Meditrade, Soro, Denmark), and SIGaT tester® (Ganzoni-Sigvaris, St. Gallen, Switzerland) and concluded that PicoPress was the most accurate with the least variation and error. Unfortunately, these devices' limitations make them impractical for studying

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change in interface pressure over several days of wearing compression bandages. They cannot be removed and then placed back under the bandage without removing the bandage itself. In addition, the sensor is connected to the measuring device with rigid tubing, which applies excessive pressure to the skin when it is used under a bandage. This can cause skin damages, especially in patients with venous ulcers.

Newer interface pressure measuring devices without such limitations have been recently developed. The Smart Sleeve Pressure Monitor (Carolon, Rural Hall, NC, USA), for example, attaches the pressure sensor to a liner with integrated conductors. This liner can be placed beneath the compression bandage, thus allowing interface pressure measurements to be taken at any time while the bandage is being worn. The Juzo Pressure Monitor (Juzo, Cuyahoga Falls, OH, USA) can be easily inserted under a compression bandage at any time and does not require patients to carry a sensor. However, the accuracy of these new devices has not been reported.

This study investigates the accuracy of PicoPress (PP), Smart Sleeve Pressure Monitor (SSPM), and Juzo Pressure Monitor (JPM) and evaluates the agreement in pressure measurement between the SSPM and JPM and the established standard PP.

Materials and methods

Ten volunteers with no history of vascular disease (five males and five females, aged 31–62 years, mean age 47.3 ± 10.8 years) were enrolled in the study. The health system's Institutional Review Board approved the study, and all volunteers signed informed consent forms. All measurements were performed by specially trained staff in the Jobst Vascular Institute (Toledo, OH, USA) in an air-conditioned room where the temperature was permanently between 20°C and 22°C. The study was performed in two stages: (1) to determine the accuracy of each device and (2) to compare the results of the newer devices (SSPM, JPM) to the established device (PP).

Device description

Each device was tested separately and its performance was evaluated. The PP device is a portable pneumatic pressure transducer, which also allows dynamic pressure tracing in connection with a software program. It contains a manometer connected to a thin-walled, flexible, circular plastic bladder with a diameter of 5 cm. The battery can be reloaded. This device is widely used in clinical research.[13]

The SSPM device is a component of the Carolon Smart Sleeve multilayer wrap compression system. It is disposable, flexible, and low profile. The sensor attaches to the sleeve to record pressure at any point on the limb. It can be left in place so that compression readings can be taken repeatedly.

The JPM device measures interface pressure under garments that offer variable pressure, bringing greater transparency to applied bandage and wrap pressures. It has a specially designed insertion wand that makes it easy to remove the sensor after bandage application or insert the sensor under existing bandage. An active readout reveals changes between resting and working pressure.

Device accuracy

In all volunteers, the sensors of each device were placed about 10–15 cm above the inner ankle at the medial aspect of the lower leg where the tendon changes into the muscular part of the gastrocnemius muscle, known as the B1 point.[5,14] A blood pressure cuff was fixed around the edge of the leg with its midpoint at the same level as the sensor. Various forces were exerted via the sphygmomanometer, and four different pressure levels (20-, 30-, 40-, and 50-mm Hg) were applied to the leg. Readings of the sensor were then recorded. Measurements were repeated three times for each pressure level.

After each device had been tested separately, two metrological characteristics were evaluated: the linearity of the response and measurement accuracy. The linearity of the response was evaluated by fitting the data giving the measured pressure as a function of the reference one (from mercury sphygmomanometer). The slope and correlation coefficient of the linear model were calculated. Accuracy was evaluated by plotting the difference against the average of the reference (mercury sphygmomanometer) and tested measurements (PP, SSPM, or JPM), which was described by Bland and Altman.[15,16] The mean difference would be the estimated bias (the systematic difference between tested devices and sphygmomanometer), and the standard deviation (SD) of the differences would measure random fluctuations around this mean. The 95% limits of agreement, mean difference plus or minus 1.96 SDs, were used to estimate how far apart measurements by the tested devices and sphygmomanometer were likely to be for most individuals.

Agreement of SSPM and JPM with PP

The second stage of the study compared results of the newer devices with the established device as reference. In addition to using data collected in the previous test, interface pressure values under compression bandages

in the volunteers were also used in the analysis of agreement.

Three bandages commonly used in published articles were selected to achieve compression: Smart Sleeve multilayer wrap compression system (Carolon), Coban 2 two-layer compression system (3M, Saint Paul, MN, USA), and Profore Lite multilayer compression bandage system (Smith & Nephew, London, UK).

In all volunteers, the bandages started at the base of the toes and covered the leg up to the capitulum fibulae. Interface pressure was measured in supine and standing positions after bandage application. Device sensors were placed at the B1 point. Volunteers were then encouraged to walk, and after 4 h interface pressure was measured by the three devices again in supine and standing position. The bandages were then removed.

Evaluation with the remaining two bandages was performed using the same protocol as the first, with an interval of one to seven days for rest. The results of the SSPM and JPM devices were then compared with PP, using a plot of the difference against the average of the reference (PP) and tested measurements (SSPM or JPM), which was similar to that described in the first test. The 95% limits of agreement, mean difference plus or minus 1.96 SDs, were used to estimate how far apart measurements by the tested devices and PP were likely to be for most individuals.

Statistical analysis

Analysis of the results was performed using t-test, analysis of variance, and co-variance analysis. The significance level was 5% (two-tailed without adjusting for multiple testing). All data analyses were conducted with SPSS 20 for Microsoft Windows.

Results

Device accuracy

Linearity. The relation between measured pressures by PP against reference pressure from sphygmomanometer was linear, with a linear correlation coefficient close to 1. The responses of JPM were also linear, with a determination coefficient of 0.9998 (Figure 1). When pressure levels of 40- and 50-mm Hg were applied to the legs, SSPM showed "65+" instead of the exact value in several patients. Therefore, the slope and correlation coefficient of the linear model of SSPM were not available.

Accuracy. As described previously, any value higher than 65 mm Hg would be displayed as "65+" instead of the exact value in SSPM; therefore, these values were not used in the analysis of SSPM's accuracy. SSPM showed a bias of +27.27 mm Hg, and the SD of differences was 9.79 mm Hg. Hence the lower 95% limit was $27.27 - 1.96 \times 9.79 = 8.08$ mm Hg and the upper 95% limit was $27.27 + 1.96 \times 9.79 = 46.47$ mm Hg. Thus, we estimated that for 95% of individuals the SSPM measurement would be between 8.08 mm Hg and 46.47 mm Hg above the actual pressure from sphygmomanometer (Figure 2). JPM had better agreement with sphygmomanometer, with a mean difference of −6.97 mm Hg and an SD of 5.10 mm Hg. Therefore, for 95% of individuals, the JPM measurement would be between 16.96 mm Hg below the sphygmomanometer value and

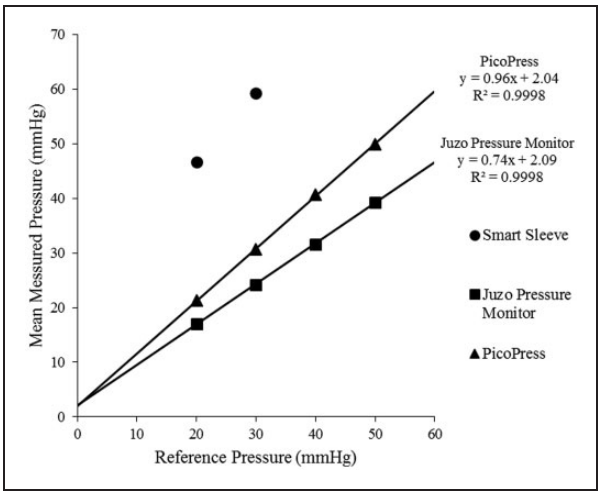

Figure 1. Measured pressures versus reference pressures for the three devices. Measured pressure by Smart Sleeve at reference pressure levels of 40- and 50-mm Hg were not available.

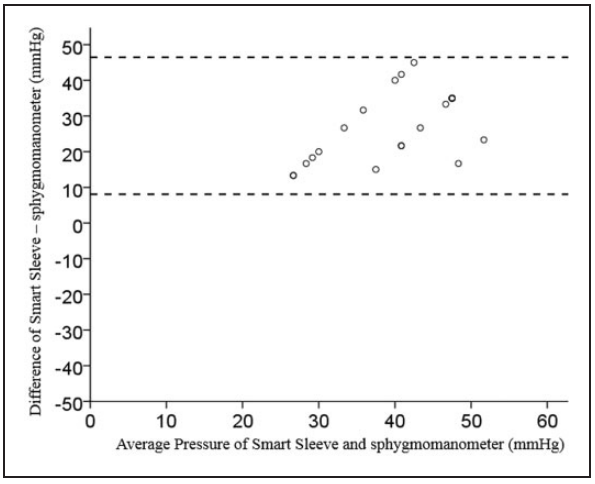

Figure 2. Difference against average of Smart Sleeve and sphygmomanometer values, with 95% limits of agreement (broken lines).

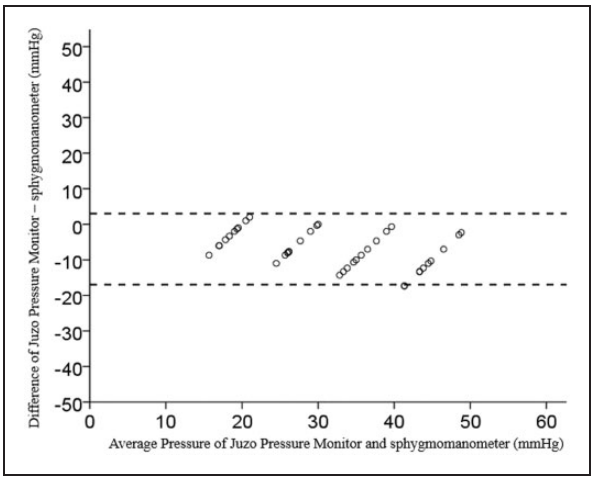

Figure 3. Difference against average of Juzo Pressure Monitor and sphygmomanometer values, with 95% limits of agreement (broken lines).

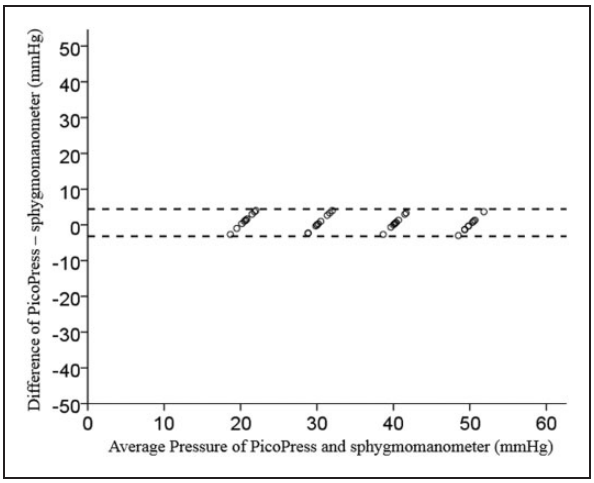

Figure 4. Difference against average of PicoPress and sphygmomanometer values, with 95% limits of agreement (broken lines).

3.03 mm Hg above it (Figure 3). PP, with a mean difference of +0.61 mm Hg and an SD of 1.94 mm Hg, showed the best agreement with sphygmomanometer. The lower 95% and higher 95% limits were −3.20 mm Hg and 4.42 mm Hg, respectively (Figure 4).

Agreement of SSPM and JPM with PP

When comparing SSPM with PP (Figure 5), the mean difference, SSPM minus PP, was +13.36 mm Hg, which was significantly different from zero ($p < 0.001$). The SD was 13.92 mm Hg. Hence the lower 95% limit was $13.36 - 1.96 \times 13.92 = -13.92$ mm Hg and the upper 95% limit was $13.36 + 1.96 \times 13.92 = 40.64$ mm Hg. Therefore, we estimated that for 95% of subjects the SSPM measurement would be between 13.92 mm Hg below the PP measurement and 40.64 mm Hg above it. The correlation between difference and average was 0.323 ($p < 0.001$), suggesting that the difference increased with the magnitude of the measurement, although the relation was weak.

For JPM (Figure 6), the mean difference, JPM minus PP, was +0.50 mm Hg, which was not significantly different from zero ($p = 0.562$). The SD was 10.37 mm Hg. Hence the lower 95% limit was –19.83 mm Hg and the upper 95% limit was 20.84 mm Hg. We therefore estimated that for 95% of subjects the JPM measurement would be between 19.83 mm Hg below the PP measurement and 20.84 mm Hg above it. Correlation coefficient between difference and average was 0.014 ($p = 0.865$), suggesting that there is no marked difference in the variability between volunteers for the two methods.

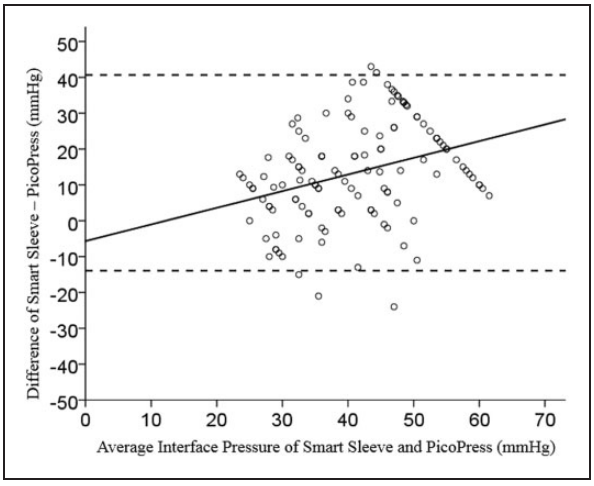

Figure 5. Difference against average of Smart Sleeve and PicoPress measurements, with 95% limits of agreement (broken lines) and regression line.

Discussion

This study demonstrated that PP had the best measurement performance with the reference of sphygmomanometer, while JPM had better linearity and accuracy compared to SSPM. When measuring interface pressure under different bandages, JPM had good agreement with PP, with a mean difference of +0.50 mm Hg. However, the agreement between SSPM and PP was poor, with a mean difference of +13.36 mm Hg.

The effectiveness of compression therapy depends on adequate interface pressure. In the management of venous ulcers, several studies have demonstrated that an interface pressure of 30–40 mm Hg was safe and

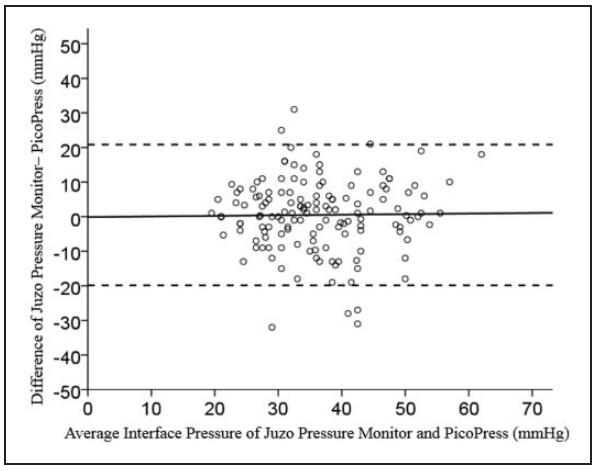

Figure 6. Difference against average of Juzo Pressure Monitor and PicoPress measurements, with 95% limits of agreement (broken lines) and regression line.

effective, leading to reduced pain, pigmentation, and swelling.[17–19] Inadequate interface pressure is usually caused by inappropriate size of compression devices, incorrect or unskillful application, unfixed bandages, and overworn stockings.[20–22]

For these reasons, measurement of interface pressure is essential to obtain and maintain adequate pressure in compression therapy. As described previously, PP was accurate with relatively small variation and error. However, it is not convenient for patients to carry the sensor around and is not ideal for pressure monitoring. A reasonable alternative, therefore, is of great value.

Chi et al.[9] compared and examined the accuracy between a piezoresistive sensor and PP using the cylinder cuff model to measure in vitro interface pressure. A piezoresistive sensor might represent a viable alternative to PP in interface pressure measurement, but the standard deviation was larger for the piezoresistive sensors than PP at any given pressure, especially in the higher pressure range.

Both JPM and SSPM are new tools to measure interface pressure. To our knowledge, no article comparing these two devices has been published. In the current study, we compared the performance between them, using a sphygmomanometer and PP as reference in two tests, respectively.

In clinical measurement, comparison of a new technique with an established measurement is often needed to see whether they agree sufficiently for the new to replace the old. A plot of the difference against the standard measurement is sometimes suggested, but this will always appear to show a relation between difference and magnitude when there is none. Therefore, for assessing agreement between two methods of clinical measurement, plotting difference against standard method is misleading.[15] An alternative approach, a plot of the difference against the average of the standard and new measurements, is unlikely to mislead in this way.[16]

Measurement performance of PP, SSPM, and JPM was compared as the first step, using a mercury sphygmomanometer as the standard. PP and JPM exhibited a linear response in the tested pressure range, which corresponds to the common range of pressures exerted by compression bandages. Systematic error of PP and that of JPM were +0.61 mm Hg and −6.97 mm Hg, respectively. SSPM, however, could only show values not higher than 65 mm Hg, and any value higher than 65 mm Hg would be displayed as "65+," which meant the mean measured pressure of 10 volunteers cannot be calculated correctly in pressure levels of 40- and 50-mm Hg. Even though such values were excluded, SSPM still had a much greater systematic error of +27.27 mm Hg, suggesting that PP and JPM were more accurate devices.

Secondly, in the presence of compression bandages, we compared SSPM and JPM in terms of agreement with PP. When compared with PP, JPM showed a smaller mean difference (0.50 mm Hg vs. 13.36 mm Hg) as well as a smaller SD (13.92 mm Hg vs. 10.37 mm Hg) than SSPM did, suggesting that JPM provided a better agreement with PP. In addition, difference between the measurements by SSPM and PP was related to the magnitude of the measurement ($p < 0.001$), while there was not a significant difference in the variability between JPM and PP ($p = 0.865$). Part of the reason of relatively inferior performance of SSPM is its increment of 5 mm Hg, while PP and JPM were more precise, with the same increment of 1 mm Hg.

Moreover, SSPM is a single-use device and needs to be replaced with every bandage changes, whereas the JPM can be used with multiple patients because of its single-use protective sleeves, which makes a single-device sufficient for a busy wound clinic. Therefore, JPM seemed to be a better choice in continuous monitoring of interface pressure.

Conclusion

When compared with SSPM, the JPM showed better agreement with both sphygmomanometer and PP. Considering the intrinsic limitations of PP, the JPM was a reasonable alternative for monitoring interface pressure continuously.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethical approval

ProMedica Health System Institutional Review Board approved this study.

Guarantor

FL.

Contributorship

Conception and design: JN and FL. Analysis and interpretation: JN, JF, FT, JA, AS, and FL. Data collection: NJ and FL. Writing the manuscript: NJ and FL. Critical revision: JN, JF, FT, JA, AS, and FL. Approval of the manuscript: JN, JF, FT, JA, AS, and FL. Agreement to be accountable: JN, JF, FT, JA, AS, and FL. Statistical analysis: JN and FL. Obtaining funding: FL.

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