In vitro protocol for validating interface pressure sensors for therapeutic compression garments: Importance of sphygmomanometer placement and initial cuff diameter

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Abstract

An optimal protocol is needed to validate the performance of future interface pressure sensors for compression garments when using a sphygmomanometer.

PicoPress® was used on a rigid plastic cylinder (r=4 cm). An FDA-cleared aneroid sphygmomanometer was used to apply pressures from 10-60 mmHg with a diameter of 8 cm or 12 cm placed either beneath the sphygmomanometer's airbag or fabric cuff. A two-tail t-test was performed ($P<0.05$ for significance) for all applied pressures.

PicoPress® outputs vary with sensor placement (airbag *vs* fabric cuff) and the initial cuff diameter. Sensor placement overlying the sphygmomanometer's fabric cuff compared to the airbag led to significantly higher pressures (37%-135%) depending on the cuff diameter size. These differences were nearly all statistically significant ($P<0.05$).

Validation of new interface pressure sensors deploying a sphygmomanometer for calibration should specify the location of sensor placement location and initial diameter with a preference for placement under the airbag.

Introduction

Compression garments represent the standard of care for numerous venous and lymphatic diseases.[1] Although compression stockings and bandages have a well-established safety and efficacy profile, numerous groups have suggested the opportunity of interface pressure measurements to improve clinical practice by ensuring adequate therapeutic pressure delivery to the limb.[2-5] The International Compression Club (ICC), a group of experts in the field, have identified PicoPress® (Microlabitalia, Padua, Italy) as the gold-standard interface pressure sensor due to superior measurement accuracy and repeatability.[6] However, PicoPress® is limited to research settings given the bulk of the base unit, high cost that prohibits routine use in clinical settings, and lack of wireless communication underscoring the need for wearable technologies capable of providing accurate pressure measurements.[7] Prior works validating new interface pressure sensors often use an FDA-cleared sphygmomanometer to apply graduated amounts of pressure for calibration and characterization purposes. Currently, there remains a need for interface pressure sensors amenable to routine clinical use. Although the ICC has established guidelines for *in vitro* testing procedures,[6] there is limited detail on the best protocol for sphygmomanometer use.

Materials and Methods

As outlined by the International Compression Club (ICC) working group,[6] we performed all *ex vivo* measurements using a rigid cylinder (r=4 cm) with low interface friction. An Optimax Labtron Adult Sphygmomanometer (Graham-Field) with the Blue Accumax™ nylon cuff was used to apply pressures from 10 mmHg to 60 mmHg in 10 mmHg increments. A sphygmomanometer employs an airtight airbag with a hand-held pump. There is an integrated pressure gauge that measures the internal pressure within the airbag. The airbag itself is composed of an inner and outer nylon fabric layer with a component that wraps circumferentially around a limb. We refer to this nylon fabric layer as the fabric cuff component of the sphygmomanometer. We tested the pressure outputs of PicoPress® by alternating the placement of the sensor at the center of the airbag compartment or the fabric cuff of the sphygmomanometer (Figure 1). We conducted the experiment for an initial, un-inflated sphygmomanometer diameter at both 8-cm and 12-cm. All measurements were done in triplicate. A two-tail t-test were performed across all comparisons with significance set at $P=0.05$. Pearson's correlation coefficients were determined for pressures underlying the airbag and fabric cuff for a sphygmomanometer at 8-cm and 12-cm in diameter (significance set at 0.05). We propose a theoretical explanation based on Laplace's law to explain the experimental results.

Results

For an initial sphygmomanometer cuff diameter of 8 cm, pressure sensor place-

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Contributors: IJ, ZX contributed equally. IJ, SX, and ZX conceived, and designed the experiment. QH, JK, JL, BJ performed the experiment. All authors composed the manuscript, and provided critical revisions of the manuscript. SX completed the statistical analysis. SX obtained funding for the experiment. Guarantor: IJ and SX.

Conflict of interest: SX, IJ report royalty interest related to a patent application assigned to Northwestern University concerning an interface pressure sensor.

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ment overlying the fabric cuff leads to higher pressure ratings by an average of 60% for all pressures measured (range: 54%-61%) compared to pressure readings from sensor placement overlying the sphygmomanometer's airbag. These differences were statistically significant (P<0.05) for the applied pressures of 30 mmHg, 40 mmHg, 50 mmHg, and 60 mmHg (Figure 2). For an initial sphygmomanometer cuff diameter of 120 mm, pressure sensor placement overlying the fabric cuff versus the airbag led to higher mean differences of 125% (range: 111%-135%) for all pressures measured. All applied pressures (20 mmHg, 30 mmHg, 40 mmHg, 50 mm Hg, 60 mmHg) were statistically significant (P<0.05) (Figure 3). In Table 1, we show that the measured pressures from PicoPress® was only statistically different between an 8 cm and 12 cm cuff when the sensor was placed at the center of the cuff fabric. A sphygmomanometer with an initial diameter of 12 cm yielded a greater mean difference of 50% (range: 41%-65%) compared to pressure measurements from an 8 cm sized cuff. All applied pressures were statistically significant (P<0.05) with the exception of 50 mmHg (P=0.069). PicoPress® measurements agreed with the sphygmomanometer gauge pressure only when the sensor was placed underneath the airbag. Although the absolute values of pressure measurements differed with sensor placement and sphygmomanometer diameter, Pearson's correlation coefficients indicate that these pressure measurements are all highly correlative. The correlation coefficients of pressure measurements underlying the fabric (8-cm *vs* 12-cm sphygmomanometer) and underlying the airbag (8-cm *vs* 12-cm sphygmomanometer) were both 0.99 (P<0.001). The correlation coefficients of pressure measurements underlying the fabric and airbag for an 8-cm diameter sphygmomanometer cuff size, and the fabric and airbag for an 12-cm diameter sphygmomanometer cuff

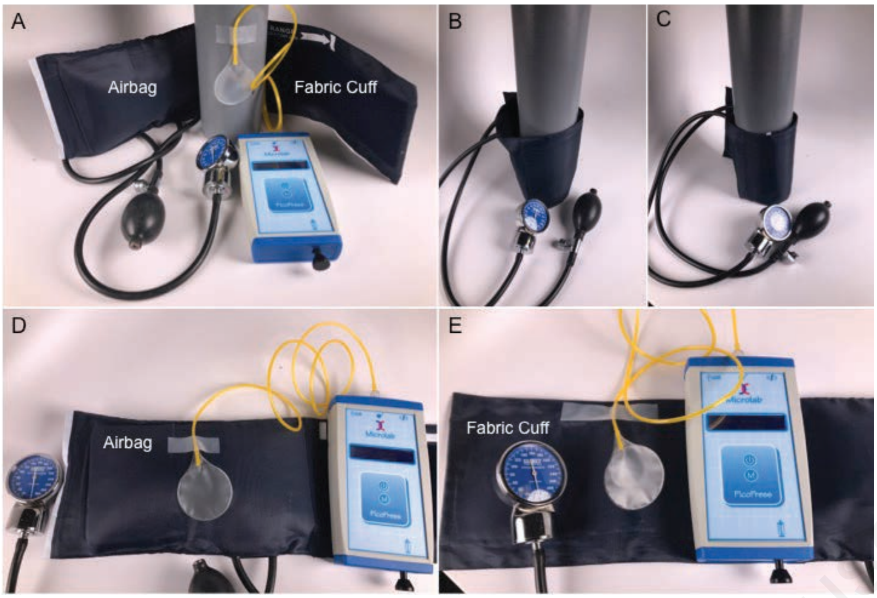

Figure 1. Experimental of set-up. A) A rigid 8 cm diameter cylinder with low surface friction is used for all experiments. Clear, scotch tape is used to secure the PicoPress sensor. All pressures are applied with an Optimax Labtron Adult Sphygmomanometer (Graham-Field) with the Blue Accumax™ nylon cuff from 20 mmHg to 60 mmHg (10 mmHg intervals). B) The initial cuff diameter is set at 8 cm; and C) 12 cm. The PicoPress® sensor is then placed either on the center of the sphygmomanometer's airbag (D) or overlying the fabric cuff (E).

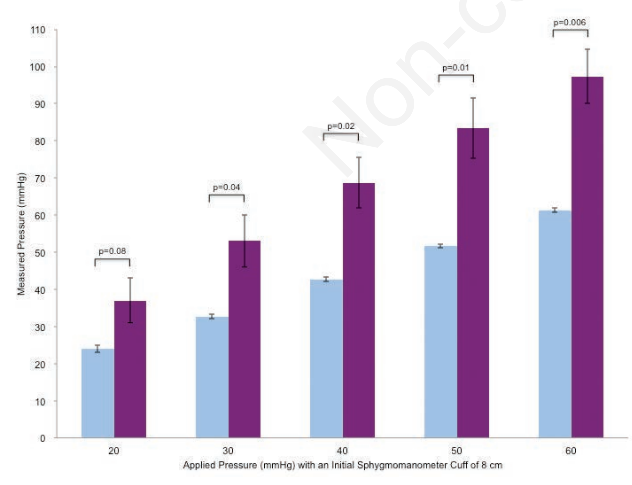

Figure 2. Differences between measured pressures by an air-bladder sensor based on placement underneath the airbag or fabric of a sphygmomanometer (diameter: 8 cm). Across all applied pressures (20 mmHg to 60 mmHg) for a cuff of an initial diameter of 8 cm, PicoPress displayed significantly higher pressures when placed underneath the cuff fabric. This result was statistically significant (P<0.05) for all applied pressures except 20 mmHg.

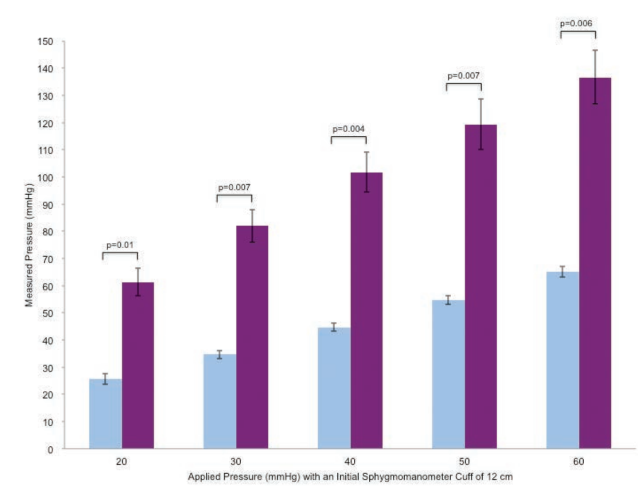

Figure 3. Differences between measured pressures by an air-bladder sensor based on placement underneath the airbag or fabric of a sphygmomanometer (diameter: 12 cm). Across all applied pressures (20 mmHg to 60 mmHg) for a cuff of an initial diameter of 12 cm, PicoPress displayed significantly higher pressures when placed underneath the cuff fabric. This result was statistically significant (P<0.05) for all applied pressures.

size were again both 0.99 (P<0.001). We present an experimental model using LaPlace's law to explain the observed differences (Figure 4).

Discussion

Although there are published reports describing the features of an ideal interface pressure sensor for compression garments[7,8] and useful protocol suggestions for *in vitro* validation such as the use of an 8 cm rigid cylinder,[6] this is the first report - to the best of our knowledge - that illustrates the importance of sensor placement and sphygmomanometer diameter for measurement output of interface pressure. Previous published works validating and testing interface pressure sensors employ sphygmomanometers but provide limited details on cuff placement and initial cuff diameter.[7,9-12] Our results, both experimental and a new theoretical model, illustrate that both initial cuff diameter and sensor placement make a significant difference in measured interface pressures. The high correlation between these various pressure measurements (Pearson's >0.99) suggesting a physical relationship and offset between the values. The clinical implications for this work relates to the validation of future interface pressure sensors that can improve the real-world effectiveness of compression stockings and bandages.

To explain the experimental results, we propose the following mechanical model. Laplace's law relates the tension applied by a compression garment (T) with the interface pressure (P) at the surface of a perfect cylinder with a radius of r: P = T / r. The differences in interface pressure can be explained as follows (Figure 4). The radius of the airbag at the outermost layer of the sphygmomanometer (R_2) is larger than the radius of the cylinder (r). R_1 is the radius that describes the transition between the fabric and airbag where there is a discontinuity between the two components of the sphygmomanometer. The pressure within the airbag (P_{sph}) itself is outputted directly by the pressure gauge. This can also be equated as an internal pressure of $P_{sph} = T_{in} / R_1$ where T_{in} is the tension of the internal fabric layer of the airbag. This is, in turn, also equal to T_{out} / R_2 where T_{out} describes the tension of the external fabric layer of the airbag. We can observe that T_{fabric} and T_{out} are almost in same straight line in the experiment, so $T_{fabric} \approx T_{out} >> T_{in}$. Since the P_{sph} is equivalent throughout the entire airbag, then we can assume that T_{out} must be proportionally larger than T_{in} to maintain the same P_{sph}. Thus $T_{out} >> T_{in}$ yields $R_2 >> R_1$. Here we can get $R_2 > r >> R_1$. The interface pressure between the inner fabric layer of the airbag and the cylinder is $P_{airbag} = P_{sph} + T_{in} / r$ or expressed in another way as $P_{sph}(1+ R_1 / r)$. Since r is >> R1, the interface pressure beneath the airbag (P_{airbag}) is largely reflective of the P_{sph}, which is measured

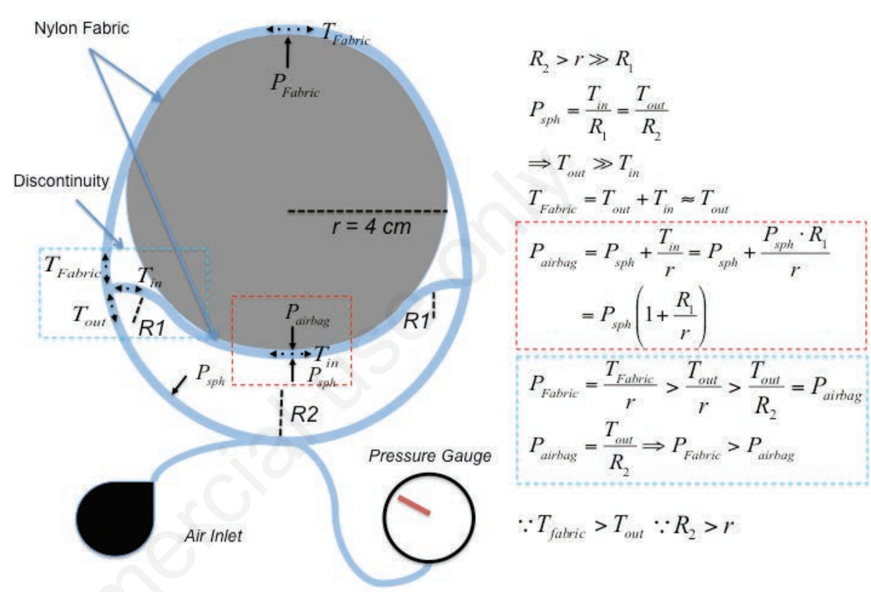

Figure 4. Experimental model of interface pressure sensing underlying a sphygmomanometer. Laplace's Law relates the interface pressure as P = T / r where T is the tension of the fabric and r is the radius of the cylinder. In the case of pressure application from a sphygmomanometer, placement of the sensor makes a significant difference in measured interface pressure. The radius overlying the stiff fabric of the sphygmomanometer is significantly lower than the radius of the outer fabric layer overlying the airbag of the sphygmomanometer (R_2 >> r) leading to a differential interface pressure where P_{Fabric} >> Pairbag even with a cylinder of the same radius (r = 4 cm). T_{Fabric} is the vector sum of T_{out} and T_{in}. Friction is assumed to be zero between the sphygmomanometer and the cylinder.

Table 1. Influence of initial cuff size, sensor pressure and measured pressure on PicoPress® outputs.

Applied pressure (mmHg)	80-mm sphygmomanometer	120-mm sphygmomanometer	Difference (%)	P-value
	Mean measured pressure - mmHg (SD)			
Fabric cuff placement				
20	37 (6.0)	61 (5.1)	65%	0.042*
30	53 (7.0)	82 (6.0)	55%	0.007*
40	69 (6.8)	102 (7.4)	48%	0.027*
50	83 (8.1)	119 (9.3)	43%	0.069
60	97 (7.2)	137 (9.8)	41%	0.018*
Airbag placement				
20	24 (1.0)	26 (2.1)	8%	0.423
30	33 (0.6)	35 (1.5)	6%	0.074
40	43 (0.6)	45 (1.5)	5%	0.225
50	52 (0.6)	55 (1.5)	6%	0.095
60	61 (0.6)	65 (2.0)	7%	0.128

*Indicates a statistically significant result (P<0.05). The variation in sensed pressure from a commercially available air-bladder device shows significant differences only when the sensor is placed beneath the sphygmomanometer's Fabric cuff.

directly via the pressure gauge of the sphygmomanometer and demonstrated by our experimental results. The final P_{airbag} can be expressed as $P_{airbag} = T_{out} / R_2 * (1 + R_1 / r)$. If we assume that R_1 / r approaches zero since R_1 is $<< r$, $P_{airbag} = T_{out} / R_2$. Thus, the interface pressure $P_{fabric} = T_{fabric} / r > P_{airbag}$ since $T_{fabric} \approx T_{out}$ and $R_2 > r$. The above theoretical model, which assumes no friction between the sphygmomanometer and the cylinder, is verified by our experimental results.

Furthermore, this experimental model also explains the differences in interface pressure with initial cuff size overlying the fabric component alone. With a larger initial diameter for the sphygmomanometer, the airbag must be inflated more to register on the pressure gauge of the sphygmomanometer. Thus, R_1 does increase slightly as there is a greater discontinuity between the airbag and the fabric component. However, R_1 is still significantly smaller than r (4 cm in our case). This explains why the P_{airbag} remains largely unchanged with a mean increase of only 6% increase between cuffs with an initial diameter of 8 cm versus 12 cm. This may not hold true if R_1 does become more comparable with r as in the case where r is a smaller cylinder. The initial cuff size affects P_{Fabric} to a greater degree because nylon itself is a highly stiff material. The nylon material quickly reaches maximum stretch. With incremental increases in airbag pressure, the stiff fabric applies greater tension.

Ultimately, the higher pressures sensed by PicoPress® when placed under the fabric cuff should not be construed as sensor error. Rather, the sphygmomanometer is applying differential interface pressure at the points beneath the airbag and the fabric cuff alone. Our theoretical model demonstrates interface pressure varies because of differential fabric tension and cylinder radii. Furthermore, PicoPress® placement beneath the airbag of the sphygmomanometer is malleable and soft. This likely leads to only a direct normal pressure with minimal tangential force (T_{Fabric}) contributions. In contrast, the stiff nylon fabric of the sphygmomanometer delivers higher tangential forces (T_{airbag}) leading to higher interface pressures for the same cylinder radius. With a higher initial sphygmomanometer diameter, the airbag must inflate more to reach the same pressure gauge value. Thus, this will yield greater T_{Fabric} as the material itself will have already reached maximum stretch at a lower pressure gauge value.

Although the interface pressure measured underneath the fabric cuff is intuitively more consistent with *in vivo* conditions, the wide variation in outputs with initial sphygmomanometer diameter suggests against sensor placement in this region for testing purposes. Our experimental model explains that a looser cuff size requires more air to be pumped into the airbag leading to a greater tensile force exerted by the fabric even at the same pressure gauge value. The interface pressure underneath the airbag enables relatively stable outputs regardless of cuff size. One important limitation of the study is that we used the sphygmomanometer output as the true applied pressure rather than using a National Institute of Standard and Technology certified manometer. However, as an FDA-cleared device, the sphygmomanometer must meet ±3 mmHg accuracy. Thus, this potential source of error would be unlikely to influence the implications of our findings. In addition, future work should validate whether these findings are consistent on irregular surfaces (*e.g.* mannequin leg) and *in vivo*.

Conclusions

Future *ex vivo* testing of interface pressure sensors should be explicit in describing sensor placement and initial sphygmomanometer diameter. We propose the placement of all interface pressure sensors to be underneath the airbag with a set sphygmomanometer diameter as close to 8 cm as possible to circumferentially wrap around a cylinder with a radius of 4 cm as suggested by the International Compression Club.[6] In conclusion, a commercially available interface pressure that is accurate, wearable, wireless, and low-cost remains elusive. Thus, there is a continued need for optimized testing protocols to ensure adequate performance for new sensors.

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