

Universiteit Hasselt

Faculteit Levenswetenschappen

Academiejaar 2015-2016



Smart compression therapy for venous ulcers

The effect of the positioning of the sensors and the posture of the leg on applied pressures

Lara-Lauren Robben 1335769

3rd Bachelor Biomedical Sciences

Promoter: Prof. dr. ir. Ronald Thoelen

Supervisors: Drs. ing. Marijn Lemmens, Seppe Bormans

Preface

This paper is written as part of my third bachelor year in Biomedical Sciences at the university of Hasselt. It is part of a IMO-IMOMEC research called *Smart Textiles for Wound Healing*. One of the purposes of this research is to design a smart stocking for compression therapy whereby pressures on the lower leg can be monitored and used for therapeutic purposes. My contribution to this research is to see if the positions of the sensors placed upon the leg and the posture of the lower leg will influence these pressures applied by the stocking. The PressCision system, specially designed for this purpose by Seppe Bormans, will be tested. Next on, also the working of compression hosiery will be examined.

This paper wouldn't have been possible without the help of several people. At first, I would like to thank Seppe Bormans for the needed electronic explanations and the overall guidance and help through the weeks I was at IMO. Next, also my supervisor Drs. ing. Marijn Lemmens should be mentioned because of his precious time spend reading and re-reading this paper and giving much appreciated advice and help. Of course I would also like to thank my promotor Prof. dr. ir. Ronald Thoelen for giving me the chance to be a part of his research. I have learned a lot along the way.

*Robben Lara-Lauren
Diepenbeek, Belgium
June 13, 2016*

Abstract

To treat venous ulcers of the lower leg with compression therapy, the right external pressure needs to be applied with the use of compression bandage or hosiery in order to improve the venous return. These days, it is difficult for health practitioners and doctors to know for sure if the right pressure has actually been achieved according to the recommendations, if a pressure gradient is indeed obtained and if these pressure levels are maintained in function of the time. To get a better view on this distribution and magnitude of the pressure, this paper has started with the examination of 16 different positions of the force sensor that will be used to measure the applied pressures. Measurements are done with one type of stocking on one plastic and one human leg. Four different heights along the lower leg have been defined and for every height, four different directions are being used to study the pressures more precisely (anterior, posterior, medial, lateral). Further, this paper has also studied the effect of 3 different movements of the lower leg, namely sitting, standing and lying down. On which height the sensor is placed at and whether the sensor is placed upon bone, fat or muscle is of importance. The placement of the force sensor, and thus the natural shape and consistency of the leg, has an important influence on the measured pressure. The anterior side will show the best results and highest pressures. Also, the movement of the lower leg indeed showed to have an effect on pressure. The standing and sitting position show higher pressures compared to when lying down. The quantization and mapping of the pressure is absolutely necessary for the further improvement of smart compression stockings and the treatment of venous ulcers.

Key words: compression therapy, venous ulcers, force sensors, pressure gradient

Content

Introduction..... 1

Materials and methods 4

 Subjects and stockings 4

 Sensor and electrical circuit used for the tests 4

 Positions and postures used for the measurements 4

 Calibration 5

 Comparison of pucks 5

 Measurements on a plastic leg 6

 Measurements on a healthy subject 6

Results..... 7

 The height and diameter of a puck and its influence on the measured pressure 7

 Comparison of pressures measured on a plastic leg and a human leg 8

 Pressure gradients and the comparison of one and both stockings used on the plastic leg 8

 Different postures of the lower leg and their influence on pressure 9

Discussion 10

Conclusion..... 13

References 14

Introduction

Venous ulcers are among the most common and most difficult to heal wounds of the lower legs. In Belgium, prevalence lies around 1% of the total population and around 3.6% of people older than 65. Each year there are up to 100,000 of new cases. The occurrence of venous ulcers in the adult population is very common with about 40 to 50% for men and 50 to 55% among women [1, 2].

Venous ulcers are – in most of the cases – caused by a malfunctioning venous return. The venous return is taken care of by the superficial and deep veins (according to their anatomical position) in the legs. They are connected to each other by perforator veins. When the deep and superficial veins are normal and healthy, their valves will prevent the reflux of blood. To fulfill that role, the valves are all positioned in the same direction. When the muscles in the leg contract, the superficial veins will empty their blood into the deep veins of the legs and these latter will bring the blood towards the heart. In feet it is the other way around. Here, the blood will flow from the deep to the superficial veins. It is because of this that the region around the ankle is the most vulnerable when there is a disorder in the veins [3]. As mentioned above, the valves play a very crucial role in the maintenance of good blood flow. However, as people grow older and become less mobile, the failure of the valves will be accelerated [4]. When the valves in either the deep, the superficial or the connecting veins aren't working properly, blood in the legs will flow back to the superficial veins and cause the pressure in these veins to rise. In this way, chronic venous hypertension can be developed and will lead to the dilatation of the veins and the accumulation of blood. This will eventually cause edema and inflammation. The inflammatory reaction is caused by ruptures in the endothelium and stasis of blood. White blood cells will be activated to close off these ruptures and will eventually destroy the veins. Proper nourishment and drainage of waste will not be possible [3, 5, 6]. Accumulation of toxins in the tissues will be induced and finally venous ulcers will arise [7].

The most common used treatment for venous ulcers is the compression therapy [7, 8]. We distinguish two types of compression therapies based on either the compression bandage or compression hosiery that is being used. Compression bandage is a strip of fabric that a skilled person must wrap around the leg. This is indeed best performed by trained people because a correct application technique is vital. If the application of the bandage isn't done correctly and safely, it can cause necrosis and maybe even amputation. Here, it is important that the bandage is applied with a constant tension because eventually the natural shape of the lower leg, the circumference, and gravity will cause the pressure gradient [9]. Apart from compression bandages, there also exists compression hosiery. It functions just the same as clothing, a piece of knitted garment that can be put on by the patient him or herself. So here, no skilled applicant is needed.

Another thing to note here, is the use of elastic or inelastic materials (or a combination of both) in compression therapy. Inelastic materials will provide higher stiffness in comparison to elastic materials. Both systems can be used to obtain the correct pressure gradient. A common used term to portray the stiffness of a compression system is the static stiffness index (SSI). If the SSI is high (as in inelastic systems), this means that the compression system will produce a higher pressure

during standing and walking compared to a lower pressure when lying down. When there is a system with a low SSI (like an elastic system) it is the other way around [10]. In this paper there will only be a focus on one hosiery system with a strong SSI.

The application of the bandages or hosiery all aim to reduce the diameter of the veins in the leg in order to enhance and speed up the venous return and to drain the accumulated blood, fluids and waste [11]. By applying the external pressure, which will distribute evenly according to Pascal's Law (see equation 1), the internal pressure will rise [10]. It is therefore once again very important that when these bandages are applied a constant pressure is maintained. If the pressure is too low or too high, treatment won't be effective [12]. The stockings should also display a compression gradient, with a maximum pressure on the ankle. This is because of Laplace's law which states that the smaller the radius (with a constant tension), the higher the pressure. The pressure on the ankle will be an average of 40mmHg (5332.89 Pa) with a strong compression system and the pressure drops towards the knee with an average of 17mmHg (2266.48 Pa) [13]. However, for the medical practitioner it can be a difficult task to achieve the recommended pressure levels, sustain and supervise it [14].

$$P = \frac{F}{A} \quad (1)$$

In order to get a better view on the pressure levels, and to supervise the treatment, the pressures exerted by the hosiery or bandage need to be measured more precisely and in function of time. In this paper a force sensor will be used for the quantization of pressures instead of predicted, calculated values for the sub-bandage pressure [13]. This is done because the Laplace's law offers only a mechanistic view of pressure on curved surfaces and does not consider the deformable, different sizes and shapes a leg can have [15, 16]. The Laplace's law of compression adapted by Thomas (see equation 2) may be a better predictive value but, in reality, the sub-bandage pressure and therefore the effectiveness of compression therapy is dependent on more than just the factors listed in the equation [4, 17]. Hence, to study the pressures in the best way possible, a force sensor is used, namely the FlexiForce® Pressure Sensor (1lb) from Tekscan. This sensor acts as a piezoresistive resistor in an electrical circuit. This means that when a mechanical load is applied, the resistivity of the resistor changes. When a force is applied on the FlexiForce® sensor, the resistance will lower. When this happens, a voltage signal can be detected and related to the applied pressure [18]. To monitor the pressures for a certain period of time, a system was developed that records pressures from six sensors at once.

$$\text{Pressure (mmHg)} = \frac{\text{Tension (KgF)} \times \text{layers of bandage} \times 4620}{\text{Circumference (cm)} \times \text{Bandage width (cm)}} \quad (2)$$

Thus, pressures that are defined by experiment aren't always comparable with the predicted calculated values. This can be examined when a more correct method, namely the force sensor is used. But there is a lot that should be taken into account when pressures are measured, also when

a force sensor is used. The direction or the height a sensor is placed at are just a few parameters that have an impact on the measured pressure. Studies show that when the sensor is placed upon the ankle, pressure will be higher than the pressure measured on the calf. This is because of gravity (in standing and sitting position) and the smaller radius of the ankle. But also in various directions along the ankle (for example posterior, anterior, lateral, medial), the pressure would differ. This can be explained by the anatomical structures of the lower leg. The sensor could be placed on either bone, muscle or fat. Further, one should also keep in mind that the shape of the leg is different for every individual and that this too will influence the pressure [12, 13].

Another parameter worth noting is the posture of the leg. Depending on this posture the leg is in, the venous pressure will change. The movability of a person and thus the use of muscles in the leg will cause the venous pressure to either rise or drop. As a consequence of gravity and a better reflow of blood to the heart when a person is walking, the pressure in the veins will be lower. This occurs for example when a patient is walking. The calf muscles will contract and improve the reflow of blood to the heart. While standing, or walking, gravity will also play a bigger role in the drop of the venous pressure. So if a person is lying down, sitting, standing or walking, this will all have an influence on the venous pressure [10].

All these contributing factors on pressure make it almost impossible for the doctor to know for sure if the bandage or hosiery will indeed produce the right amount of pressure. To know if the therapy that's being used actually works, and to improve the treatment but also to ensure comfort, a better overview of the distribution and magnitude of the pressure measured on the leg needs to be obtained [12]. The experiments exerted for the examination and quantification of these pressures will be done, as mentioned above, with the FlexiForce® sensor.

First, a test will be exerted to see if a puck is necessary for the measurements. Then, further optimization of the pucks' properties (diameter, height) will be determined. Secondly, the differences between the use of a plastic leg and a human leg will be looked at. This will be done by looking at the influence of sixteen different positions of the force sensor on both legs. At four different heights between the ankle and the position under the knee and at each height, four anatomically defined directions along the leg will be studied: anterior, posterior, medial and lateral. This paper will use the position of the four different heights and will define them as the 'ankle', the 'upper-calf' (the widest circumference of the leg), the 'lower-calf' (in the middle between the ankle and the 'upper-calf') and 'under-knee' (for the position right under the knee). Eventually, the changes in pressure for all these 16 different positions will also be tested onto the human leg more deeply. This will be done while holding the leg in three different leg postures: sitting, standing and lying down.

Materials and methods

Subjects and stockings

To study and quantify the influence of the positioning of the sensor and the posture of the leg, this study started with measurement on a plastic leg and continued with measurements on a healthy human subject (age 21 years, height 169 cm, weight 55 kg, body mass index 19.4 kg/m²). For the ready to wear medical compression garments, small- and medium-sized therapeutic Medical Stocking without a zipper (on top) and small- and medium-sized Compression Liner (applied first) of JOBST® Medical LegWear was used (with a reference number for the small stocking: 73630-41 and for the medium stocking: 73630-42). According to the legs circumferences and the manufacturer's recommendation, a small or medium hosiery was used. The top stocking consists of 76% Nylon/polyamide and 24% Spandex/Elastane. The Compression Liner is made of 79% Nylon/Polyamide, 16% Spandex/Elastane and 5% Silk. According to the manufacturer's labeling, a pressure gradient will be applied with an average pressure on the ankle of 40 mmHg when both stockings are worn. Also according to the manufacturer, the bandage has a Static Stiffness Index (SSI) above 10. The stockings are always applied by the same person to limit considerable variations due to possible, different applications.

Sensor and electrical circuit used for the tests

For the experiments a force sensor was used, namely the FlexiForce® sensor A201. The sensor is a 191 mm long and 0.203 mm thick flexible sensor with at the end a round sensing area of 9.53 mm diameter [19]. The sensor is attached to an electrical circuit (see figure 1) to read out a voltage value and to choose a range between which this value will be situated. On the sensing area of the FlexiForce® sensor, a puck was taped with a 9.3 mm diameter and a height of 1 mm. The puck is a disc made out of Plexiglas, a polymer.

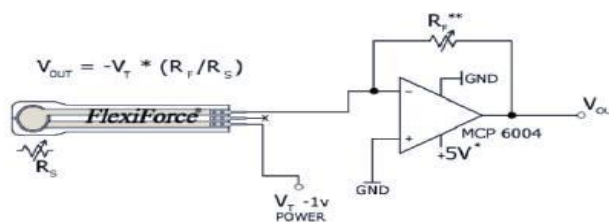


Figure 1 FlexiForce® A201 sensor with the attached electrical circuit.

Positions and postures used for the measurements

To get a good overview of the distribution of the pressures, the four different anatomical directions were chosen. The anterior, posterior, lateral and the medial side of the leg (see figure 2) will all be studied and this at four different heights along the lower leg (see figure 6). This will give a total of 16 different positions that will be studied on both plastic and human leg. The human lower leg will also be studied at these 16 different positions while holding different postures, namely while sitting, standing and lying down.

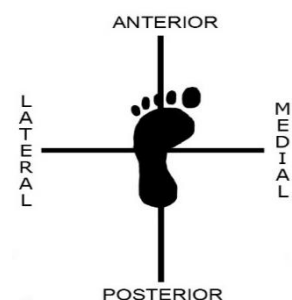


Figure 2 The universally defined anatomical directions on the left leg.

Calibration

Before the calibration of the sensor began a weight of 110 g was placed upon a puck (diameter of 9 mm and a height of 1 mm) which in turn was placed on the force sensor (see figure 3). The manufacturer recommended to start the calibration like this in order to condition the sensor [20]. After two minutes, the 110 g was put aside to start the calibration. First, no weight was placed on the sensor. A new weight of 10 g was placed every two minutes till the weight of 100 g was reached. For every weight, a voltage was measured. These measurements were then plotted against each other with weight (in grams) on the x-axis and voltage (in volt) on the y-axis. From the resulting graph, the equation could be used in the calculations for the corresponding mmHg-value.



Figure 3 FlexiForce® A201 sensor with a 9 mm puck on its sensing surface.

After trying out these calibrations according to the manufacturers' recommendations, eventually a sphygmomanometer was used to do the calibrations. With this, a known pressure was applied instead of a known weight. Before the calibration of the sensor began a pressure of 130 mmHg for the plastic leg (and 80 mmHg for the human leg) was applied on the force sensor with a 9.3 mm puck in order to condition the sensor (see figure 4). The sphygmomanometer was always placed upon the subject that would be tested. So for this paper, two calibrations (one on a plastic and one on the human leg) were done. The voltage was measured with a Keithley 2000 multimeter for every 10 mmHg drop until the value of zero was reached. This was done three times in order to ensure the measurements were correct and stable. Then, with the obtained mean equation, the pressure exerted by the stockings on the leg could be calculated.



Figure 4 The calibration of the plastic leg with the help of a sphygmomanometer.

Comparison of pucks

First off all, experiments were done to see if the use of a puck was indeed necessary. Later on, the use of the most suitable puck was tested. For this, pucks with different diameters (8 and 9 mm) were compared to the use of a sensor with no puck. The measurements were made on the medial side of a plastic leg at the 'upper-calf'-position and with a small-sized Compression Liner of JOBST® Medical LegWear. Thereafter the influence of the height was examined by comparing pucks with a 1 mm and 0.4 mm height. This was also done on the medial side of the plastic leg at the four different heights with the same stocking used as for the plastic leg.

Measurements on a plastic leg

To make the comparison with a normal, human leg, measurements were first done on a plastic leg. To get a good overview of the distribution of the pressure, the earlier discussed four different directions were used. The anterior, posterior, lateral and the medial side of the leg were all studied and this at the four different heights along the lower leg (see figure 6). The sensor was attached to the leg with tape to ensure its position (figure 5). The circumference of the ankle was 19.4 cm, the upper-calf valued 32.25 cm, under the knee 28.6 cm and the lower-calf 27.6 cm. The stocking was always applied by the same person to avoid any differences in pressures that could come from different applying methods. For the first measurements a time of 5 minutes was chosen to record the pressures in order to examine the stability of the sensor simultaneously. Later on, when a constant value was achieved on the Keithley 2000 multimeter, this value was immediately used instead of waiting for 5 minutes. At the ankle area, the application of the sensor had to be adjusted to fit a rather horizontal surface in order to measure properly. A small-sized Compression Liner (73631-71) and a small-sized Medical Stocking were used on the plastic leg. The room's temperature varied between 20 and 23°C.

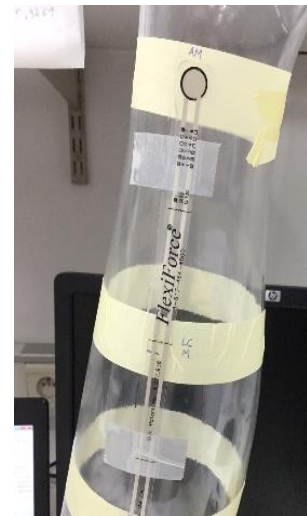


Figure 5 Set up of the plastic leg with the force sensor placed upon ankle height. Bandages were used to ensure the same measurement points.

Measurements on a healthy subject

With a puck of 9.3 mm diameter and 1 mm height taped onto the sensor and the sensor taped onto the human leg, measurements were exerted. Here, the influence of different leg postures on the measured pressure was studied. Three different postures were examined: standing, sitting and lying down. For this subject, a medium-sized Compression Liner of JOBST® Medical LegWear (73631-72) and a medium-sized Medical Stocking were used. The circumferences of the leg of the first subject (see figure 6) were 21.3 cm for the ankle, 28 cm for the lower-calf, 35.6 cm for the upper-calf and 31.7 cm for the position right under the knee. The same sixteen positions that were studied on the plastic leg, were also used for the healthy subject. Once again, for every position, measurements were made when the value on the Keithley had stabilized. The temperature at the four different heights on the lower leg were 24.7°C on the ankle, 26.7°C on the lower calf, 28.4°C on the upper-calf and 27.9°C under the knee. The room's temperature, again, varied between 20 and 23°C. Once again, the same person applied the bandages.

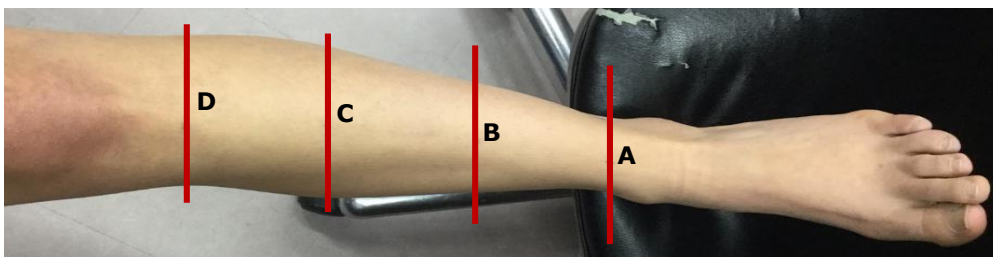


Figure 6 An overview of the positions and their defined names according to the height. A: Ankle, B: defined as 'Lower-Calf' (LC), C: defined as 'Upper-Calf' (UC) and D: defined as 'Under Knee' (UK)

Results

The height and diameter of a puck and its influence on the measured pressure

In order to find the most suitable puck for further measurements and to examine if a puck is indeed necessary to do measurements an analysis was carried out with different pucks on the medial side of the plastic leg at the upper-calf position. Changes in diameter as well as the height of the puck were studied.

First, the influence of the diameter of a puck was tested. This was done by comparing a puck with a diameter of 8 mm to another puck of 9.3 mm. The use of no puck at all was also looked at (see figure 7). The puck of 8 mm showed a higher pressure than the puck with a 9.3 mm diameter. When no puck was used, the measured pressure was far lower and even reached the value of zero. The experimental results thus show that there is indeed an influence of diameter on the measured pressure and that the use of a puck is necessary.

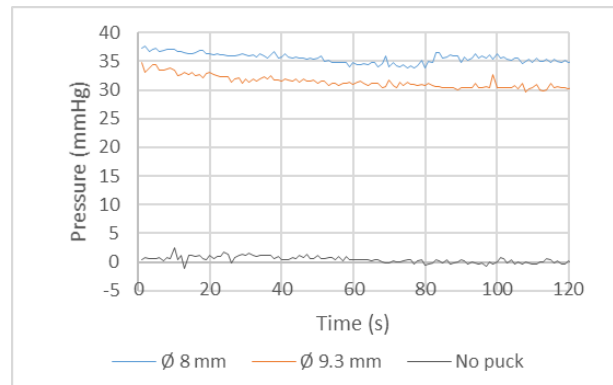


Figure 7 Comparison and influence on the pressures of pucks with different diameters (8 mm and 9.3 mm) and the use of no puck. The pressure in mmHg can be found on the y-axis in function of the time in seconds.

Apart from the diameter, also the height of the puck should be tested (see figure 8). For this, an analysis (in arbitrary units) was conducted at the four different positions along the medial side of the plastic leg. One small-sized stocking was used. The puck with a height of 1 mm showed higher pressures and a better pressure gradient ($R^2=0.955$) than the puck of 0.4 mm. The difference in measured pressure was the highest at the ankle. These results show that the height of the puck also plays a role, especially at the ankle and lower calf position.

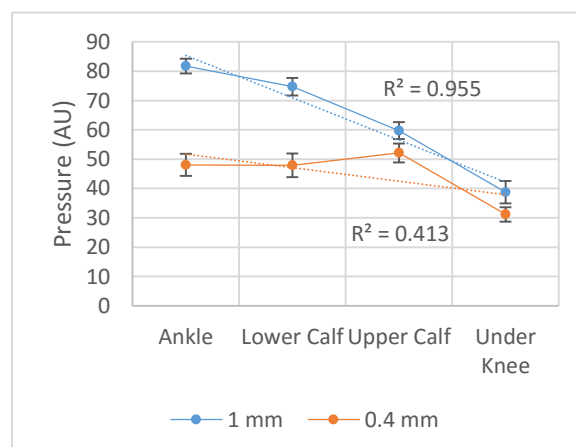


Figure 8 Comparison of pucks with different heights on the four positions of the lower leg and their influence on pressure. Pressures are shown on the y-axis in function of the four positions along the heights of the lower leg (on the x-axis)

Comparison of pressures measured on a plastic leg and a human leg

One may deduce that the pressures measured on a hard, plastic leg (as often done in experiments) will surely differ from those of a real human leg. In order to check if there is a difference, measurements on both human and plastic leg were made in the sixteen different positions. The pressures measured on the plastic leg were overall higher than those of the human leg. The gradient of the pressure was also more visible on the plastic leg.

Pressure gradients and the comparison of one and both stockings used on the plastic leg

To examine the pressures and pressure gradients on a lower plastic leg an analysis was exerted. The findings of the experiment show that pressures measured on the plastic leg have an overall good pressure gradient, especially on the anterior, lateral and posterior side of the leg (see figure 9). It's clear that the second stocking is obviously needed to obtain the right pressures. The overall pressures on the posterior side are lower than on the other sides. The performance of the hosiery at the ankle region doesn't meet the recommended level of pressure, except at the anterior side.

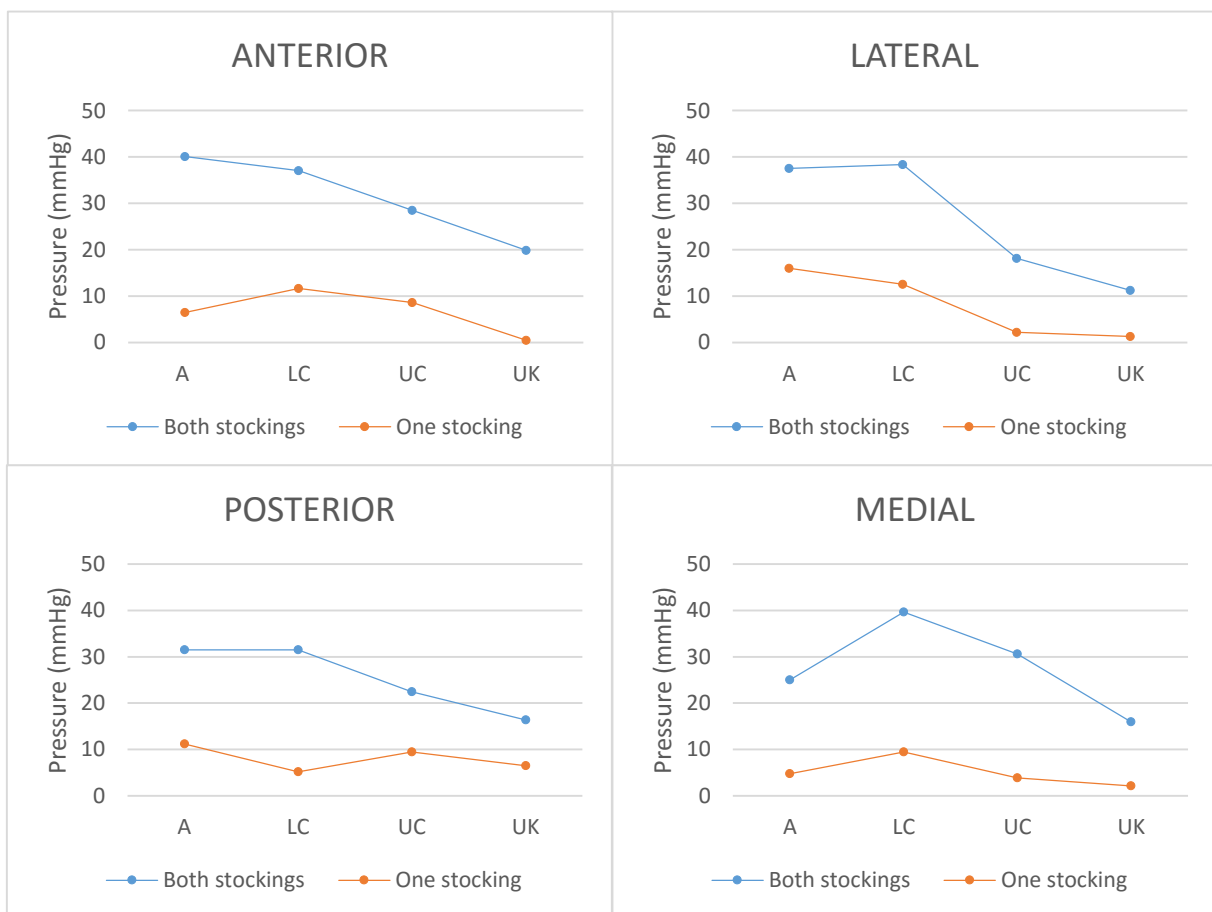


Figure 9 Measurements made on the anterior, posterior, medial, and lateral side of the plastic leg with both stockings. 'A' stands for the ankle, 'LC' the lower-calf, 'UC' the upper-calf and 'UK' for the position right under the knee. On the y-axis the measured pressures are shown in function of the four heights (on the x-axis).

Different postures of the lower leg and their influence on pressure

To determine if different postures of the lower leg will have an influence on the pressure, an analysis was exerted on a healthy subject. Again, the sixteen different positions were used to make the measurements. At each anatomical direction, each position was studied (see figure 10). The anterior and posterior side display a pressure gradient while at the medial and lateral side deviations are noticed at the ankle and lower-calf. Pressures measured at the lateral and medial sides of the leg turn out to be generally less than the mean pressure at the ankle region. The standing and sitting position always have the highest pressures. These experimental findings show that there is indeed an influence of leg posture on pressure which, according to our findings, can even make a difference to about 35 mmHg.

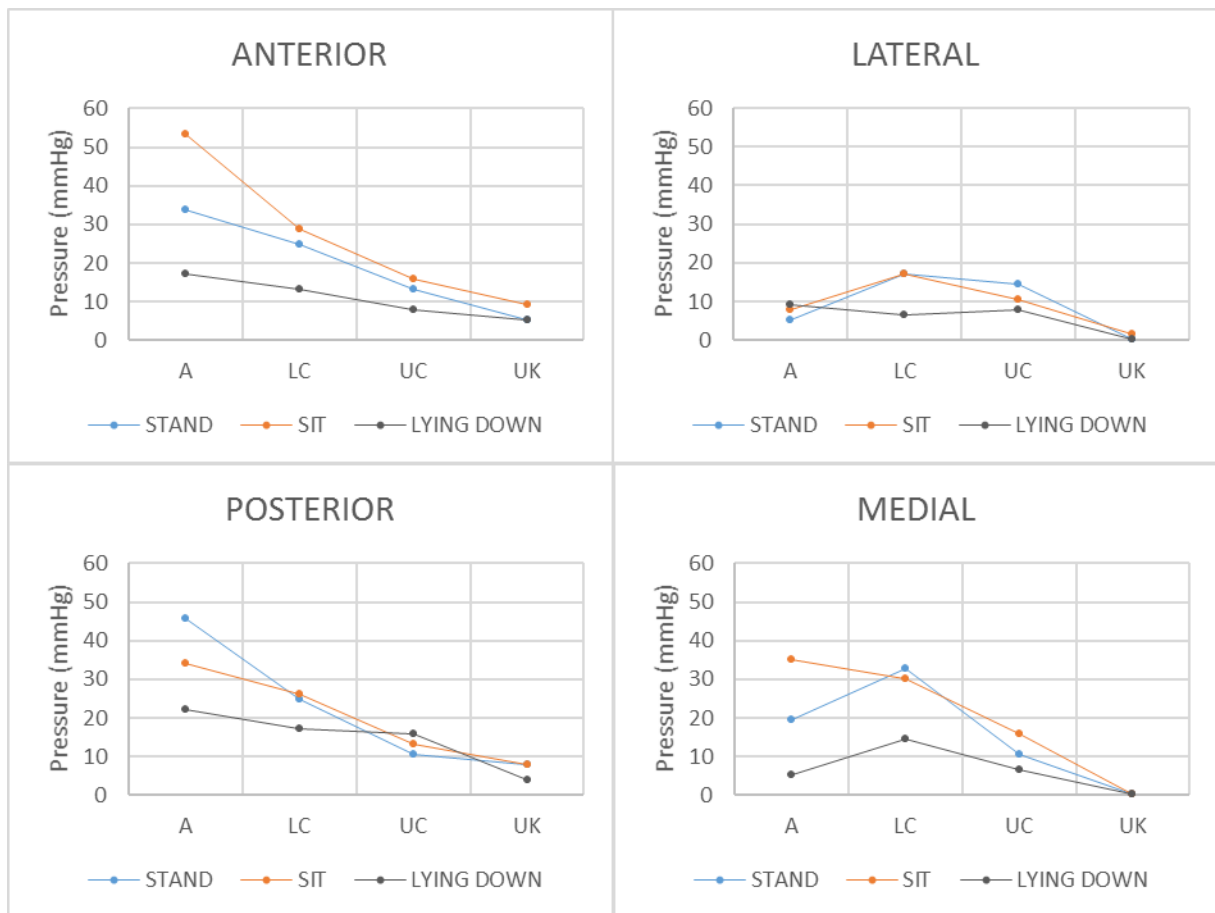


Figure 10 An overview of the influence of the posture of the lower leg (while standing, sitting or lying down) on the pressure. Measurements were made in the four directions (anterior, posterior, lateral, and medial) and at the four different heights whereby 'A' is the ankle, 'LC' the lower-calf, 'UC' the upper-calf and 'UK' under the knee. The y-axis shows the pressures in function of these four different heights (on the x-axis)

Discussion

The puck with a diameter of 9.3 mm was used for further measurements because this value was closest to the actual diameter of the force sensor (9.53 mm) so that an almost one-to-one relationship was achieved. It is obvious that the diameter of the puck has an influence on the measured pressure when the force is held constant. This is because of the formula (see equation 1) where the pressure will rise if the diameter gets smaller [21]. The use of no puck led to less stable measurements and the pressure measured was far lower than the pressures measured with the use of a puck. It is clear that the use of a puck will help concentrate the force onto the surface area of the sensor to avoid inaccurate measurements of the force.

Also the height or the thickness of the puck influences the pressure that is measured. When the puck is thicker, higher pressures are measured. This is because the force exerted from the stocking on the leg will be higher in order to compensate for the higher force exerted from the thicker puck on the stocking. In line with our experiments and findings, and to ensure an accurate measuring system, a puck with a height of 1 mm was used. Other research shows that the height of the sensing area should be 0.5 mm maximum but according to our results, it is best to use a 1 mm puck to get a good view on the pressure gradient [22].

At first the calibration was done on the surface of a table. With different weights placed upon the sensor, a calibration curve was formed. When measurements were then done on the plastic and human leg, it showed unreal high and low pressures, not corresponding to the pressures that should be achieved. We concluded that when the calibration was done on the hard surface of the table and the measurements on the soft surface of the human leg, the measured pressure will not correspond to the real pressure due to different types of underground. Because of this and also because the known weight placed upon the sensor couldn't be transformed to the right corresponding pressures, the calibration performed with the manufacturer's instructions couldn't be used. Calibrations need to be done on the surface whereupon the measurements are made. This led us to using a sphygmomanometer where the plastic and human leg could be calibrated with. So from our experiments, we conclude that – in order to get the right pressures – the calibration needs to be done for every patient individually and for every position the sensor would be placed on. This can be done with a sphygmomanometer. However, when a sphygmomanometer is used, one should keep in mind that there are a lot of parameters that further will influence the calibration. Hardness of the material, stiffness of the underground and the technique used to calibrate will all contribute to different measurements.

The overview of the pressure gradient along the lower plastic leg shows differences depending on the side on which the measurements were made. At the medial and lateral side, pressures that are measured at the height of the ankle are lower than the pressures at the lower-calf. This is due to the bones that protrude at the ankle, namely the lateral malleolus of the fibula (at the lateral side) and the medial malleolus of the tibia (at the medial side). These bones will cause the stocking to not fully exert its pressure on the medial and lateral ankle region. The sensor should also be placed on a

rather horizontal surface on the plastic leg because a deformed or bended sensor will falsely experience a pressure.

On the human leg, the anterior side also displays the most accurate pressure gradient. This could be explained by the tibia bone that's underneath the sensor. The static underground will provide a better force measurement than for instance at the posterior side. Here the muscle and fat under the now more dynamic skin will sink in and distribute the force when the sensor and the bandages are applied. So there exist unevenly distributed pressure levels at each height with the highest pressures on the anterior side. When this pressure on the anterior side becomes too high, the patient could at that region eventually develop ischemia, artery injury and after a longer period of time even ulceration [23]. Because of this, the anterior side should be used for the positioning of most sensors to ensure these too high pressures will not be achieved. Contrary to what the manufacturer says, a pressure of 17 mmHg isn't always achieved at the height of the knee. The circumference of the leg also plays a role. Measured pressures are influenced by the circumference of the leg. However, most legs do not show circular cross sections. This will cause the pressures to vary along the leg and at particular places on the leg, namely on bone or fat. Overall, the bigger the circumference, the lower the measured pressure [24]. Some studies suggest padding the most risky regions where there is a very high pressure (for example at the malleolus of the ankle) to avoid damage, to get more similar pressures at each height and a better pressure gradient [10]. For the human leg, also the room temperature should be looked at and controlled. A change in temperature will affect the measured pressures. High temperatures will make the pressure rise. [14].

Different positions of the leg also influence pressure and this will make the interpreting of the data more difficult if one does not know the posture the leg is in. Here, our results do not exactly match our expectations. We expected that the standing position would display the highest pressure because of the gravity that will accumulate blood in the legs and because of the calf muscle that is more contracted. But because the subject here is not walking, and not fully using the calf muscles, pressures will not differ much from the pressures while sitting. Also with the human leg, the medial and the lateral side of the leg show lower pressure values at the ankle region. This is, as discussed above with the plastic leg, due to the protruding bones at the ankle. The lying down position shows almost always the lowest pressures because gravity doesn't play a role anymore.

Normally, bandages with a Static Stiffness Index above 10 (SSI is the pressure measured underneath the stockings in standing position minus the pressure measured underneath the stockings when lying on the back) will provide higher pressures on the leg while standing and lower pressures while lying down [10]. It will make sure there will be an efficient compression and so the use of the bandage will lead to an improvement of the venous ulcer. From our experiments, this statement is correct for the compression system used in this paper. The pressures reached when standing are indeed greater than the pressures in the supine position [25].

Further it should be noted that the application of a compression system and the resulting pressures are strongly influenced by the person who applies it, even with hosiery. Pressures can vary depending on the pulling power and the exact right placement of the stocking. So it is very important that the application is always done correctly. The same goes for the calibration done with the sphygmomanometer.

Conclusion

Various pressure levels will be measured according to the different anatomical structures of the lower leg, the positioning of the sensor, the stocking that is used and the application of it, the characteristics of the puck that is used, temperature, the calibration that was done... and it will all cause differences in pressure gradient distribution. Our findings show that with the human leg, the anterior side of the leg almost always shows the most accurate pressure gradient and also the highest pressures because of the tibia bone underneath. We conclude that most sensors should therefore be placed on that side of the leg. This is in line with the findings of Liu et al [12]. We can further conclude that depending on the positioning of the sensor and the posture the leg is in, pressure will also differ. One should keep in mind that there are indeed several parameters that influence the measured pressures, and that this could make the interpreting of the data difficult.

As already pointed out, it is very important to map out the distribution and magnitude of the pressures in order to improve the treatment of venous ulcers with compression therapy. In the future, these pressure differences along the height of the leg and according to the position of the patients' leg should be precisely mapped out with the use of smart stockings that track and evaluate the pressure data. Also – in order to get the right pressures – the calibration needs to be done for every patient individually and for every position the sensor would be placed on. Only then, doctors will be able to correctly interpret these data and – if necessary – adjust the used compression therapy for the best results.

References

- [1] L. Gryson. (2006). *Prevalentie van wonden in Europa en België*. Available: <http://www.hubrussel.net/wound-ex-site/Wound/Wound-ex-Bestanden-en-afbeeldingen/Wound-ex-Bestanden-en-afbeeldingen-Documenten/Prevalentie-van-wonden-in-Europa-en-Belgi---presentatie.pdf>
- [2] L. P. Abbade and S. Lastoria, "Venous ulcer: epidemiology, physiopathology, diagnosis and treatment," 20050608 DCOM- 20051025.
- [3] S. S. Chatterjee, "Venous ulcers of the lower limb: Where do we stand?," *Indian Journal of Plastic Surgery : Official Publication of the Association of Plastic Surgeons of India*, vol. 45, pp. 266-274, May-Aug 2012.
- [4] S. Barrett, "Providing optimal sub-bandage pressure in compression therapy."
- [5] J. T. Trent, A. Falabella, W. H. Eaglstein, and R. S. Kirsner, "Venous ulcers: pathophysiology and treatment options," *Ostomy/wound management*, vol. 51, pp. 38-54; quiz 55-6, 2005/05// 2005.
- [6] J. A. Caprini, H. Partsch, and R. Simman, "Venous Ulcers," *The Journal of the American College of Clinical Wound Specialists*, vol. 4, pp. 54-60, 12/04.
- [7] KCI. (2013). *Veneuze beenwonden*. Available: http://www.kci-medical.nl/cs/Satellite?c=KCI_Condition_C&childpagename=NL-DUT%2FKCILayout&cid=1229635468982&p=1229625444138&packedargs=locale%3Dnl_NL&pagenamename=NL-DUTWrapper
- [8] T. Wu, "Compression Bandage Pressure Measurement," 2003.
- [9] A. Finnie, "Bandages and bandaging techniques for compression therapy," 20020320 DCOM- 20020625.
- [10] W. International, "Principles of compression in venous disease: A practitioner's guide to treatment and prevention of venous leg ulcers," 2013.
- [11] D. R. D. Mariën C., Vercauteren S., Mertens M., Van Thielen J. *Een Open Oog Voor Het Open Been*.
- [12] R. Liu, Y. Kwok YI Fau - Li, T. T. H. Li Y Fau - Lao, X. Lao Tt Fau - Zhang, X. Q. Zhang X Fau - Dai, and X. Q. Dai, "Objective evaluation of skin pressure distribution of graduated elastic compression stockings," 20050705 DCOM- 20050802.
- [13] S. Thomas. (2003). *The use of the Laplace equation in the calculation of sub-bandage pressure*. Available: <http://www.worldwidewounds.com/2003/june/Thomas/Laplace-Bandages.html>
- [14] B. Kumar, J. Hu, and N. Pan, "Smart medical stocking using memory polymer for chronic venous disorders," *Biomaterials*, vol. 75, pp. 174-181, 1// 2016.
- [15] J. R. Basford, "The Law of Laplace and its relevance to contemporary medicine and rehabilitation," 20020805 DCOM- 20020828.
- [16] J. Schuren and K. Mohr, "The efficacy of Laplace's equation in calculating bandage pressure in venous leg ulcers," *WOUNDS UK*, vol. 4, p. 38, 2008.
- [17] K. M. J. Schuren, "De dynamiek van compressietherapie: de wetten van Laplace en Pascal," 2009.
- [18] S. Electronics. (2016). *Flexiforce Pressure Sensor - 1lb*. Available: <https://www.sparkfun.com/products/8713>
- [19] Tekscan. (2016). *FlexiForce A201 Sensor*. Available: <https://www.tekscan.com/products-solutions/force-sensors/a201>
- [20] Tekscan, "Calibration Quick Start Guide for FlexiForce Sensors," 2011.
- [21] J. M. Melhuish, R. Clark M Fau - Williams, K. G. Williams R Fau - Harding, and K. G. Harding, "The physics of sub-bandage pressure measurement," 20020405 DCOM- 20021030.
- [22] M. W. Ferguson-Pell, "Design Criteria for the Measurement of Pressure at Body/Support Interfaces," *Engineering in Medicine*, vol. 9, pp. 209-214, October 1, 1980 1980.

- [23] R. Liu, X. Guo, T. T. Lao, and T. Little, "A critical review on compression textiles for compression therapy: Textile-based compression interventions for chronic venous insufficiency," *Textile Research Journal*, p. 0040517516646041, 2016.
- [24] S. Thomas, "Compression bandaging in the treatment of venous leg ulcers," *World Wide Wounds*, 1998.
- [25] G. Mosti, "Elastic or inelastic compression in patients with leg ulcer and restricted mobility?," *2013*, 2013-11-11 2013.