

Excessive Pressure in Multichambered Cuffs Used for Sequential Compression Therapy

Background and Purpose. Pneumatic compression devices, used as part of the therapeutic strategy for lymphatic drainage, often have cuffs with multiple chambers that are inflated sequentially. The purpose of this study was to investigate (1) the relationship between cuff chamber pressure (P_{chamber}) and the pressure on the cuff-skin interface ($P_{\text{interface}}$) and (2) the mechanical interaction of cuff chambers and consequences for device control. **Subjects and Methods.** In this study, we used 3 cylindrical (60-, 80-, and 100-mm-diameter) model limbs and 1 ellipsoidal model of the arm to test a commercially available pressure controller using "target pressures," indicated by the controller, of 30, 60, 80, and 100 mm Hg. We studied the time course of P_{chamber} and $P_{\text{interface}}$ during the inflation sequence and the effect of local curvature on $P_{\text{interface}}$. **Results.** Our data indicated that, overall, $P_{\text{interface}}$ is of the same order of magnitude as P_{chamber} . There was some effect of model diameter and shape, with the smaller curvatures yielding the highest $P_{\text{interface}}$. Cuff chamber interaction led to P_{chamber} and $P_{\text{interface}}$ values in the most distal (first inflated) chamber that were up to 80% higher than the target pressure. For the 80-mm cylindrical model, for instance, pressure in this chamber reached 54, 98, 121, and 141 mm Hg, respectively, instead of the 30, 60, 80, and 100 mm Hg indicated by the controller. **Discussion and Conclusion.** The discrepancy between the target pressure, indicated by the controller, and the pressure measured inside the cuff chambers undermines the therapeutic control and efficacy of the pneumatic compression devices. Because the measured pressures were far beyond the pressure level indicated by the controller, it is recommended that pneumatic compression devices be used at much lower target pressures (<30 mm Hg) than those applied in clinical practice. [Segers P, Belgrado JP, Leduc A, et al. Excessive pressure in multichambered cuffs used for sequential compression therapy. *Phys Ther.* 2002;82:1000-1008.]

Key Words: *Breast cancer, Compression therapy, Deep venous thrombosis, Lymphedema, Mastectomy, Therapy.*

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Arm edema is a complication in approximately 40% (according to US National Cancer Institute data) of patients who undergo axillary radiation and surgery as breast cancer treatment. It can result in substantial impairment and psychological morbidity.¹ Besides pharmacological treatments, physical treatments range from elastic or inelastic bandaging, use of elastic stockings, manual treatment by physical therapists, or sequential compression therapy using pneumatic devices.^{2,3} Pneumatic compression devices are sometimes used as part of the treatment of peripheral edema of venous-lymphatic origin as are techniques for manual drainage via the use of multilayer bandages.⁴⁻⁶

Not all authors agree on whether compression therapy, called "pressotherapy" in some parts of the world, should be part of the treatment.⁷ We contend that this lack of agreement is probably due to the lack of references concerning optimal pressure values and how to apply compression. Methods such as the application of pressure on a limb that are necessary for efficient emptying

of the venous or lymphatic system without increasing the heart load or damaging the vascular parenchyma⁸ are not defined and are in need of scientific foundation and standardization. The optimal pressure for lymphatic drainage to which each chamber of a sequential pressure device is inflated is not clear and may depend on the application of the pressure cuff. Generally, pressures in a relatively wide range between 30 and 100 mm Hg are used.⁹⁻¹¹ During pressure application, patients are usually in a supine position and the pressure in the superficial veins can be assumed not to exceed 20 mm Hg. As such, occlusion of the superficial venous network should be obtained at a compression of about 40 mm Hg, and it can be expected that the application of higher pressures will not further empty the superficial venous network. Pressure over 40 mm Hg raises the load on the heart through an elevation of the intra-auricular and pulmonary capillary pressure.¹² This is not the purpose of compression therapy.

Periodic external compression for emptying the venous system of the limb is best performed in a nonuniform,

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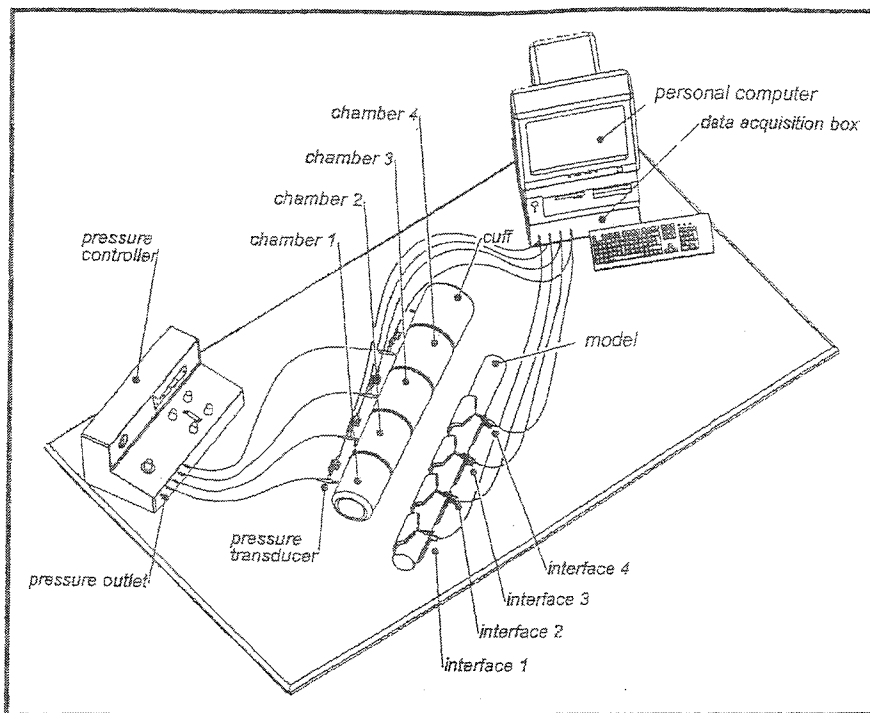


Figure 1. Schematic drawing of the setup showing the pressure controller device, the cuff, and the instrumented, cylindrical limb model. For the cylindrical model, chamber pressures were measured in the 4 most distal chambers. Interface pressures were measured at 4 different locations on the limb model.

graded way, with maximal pressure at the extremity of the limb.^{9,13-16} This can be achieved by using specially designed cuffs, consisting of multiple chambers, which are inflated in a sequential order from the extremity of the limb toward the torso. Compression devices, in our experience, have simple controls, and only the air pressure inside their internal air reservoir is controlled. Cuff chamber pressures, in our experience, are not monitored during the entire inflation sequence of the cuff and the pressure exerted on the patient's limb is not measured. We conducted this study for 2 purposes. First, we wanted to verify whether the pressures applied in the cuff chambers are actually transferred to the patient's limb. Second, we wanted to monitor the pressures in different cuff chambers during inflation and to assess the interaction of adjacent cuff chambers and the consequences for the pressure control of these pneumatic devices.

Materials and Methods

Multichamber Cuff and Pneumatic Control

The cuff and pneumatic control device used throughout this study, provided by a company specializing in physical therapy devices,* are shown in the schematic drawing

of Figure 1. The cuff (Lympha-mat type) has 5 chambers, is designed for application on the arm and, in our opinion, is representative of the type of multichamber cuffs used in the field. With this type of cuff, the partition is between chambers in such a way that an inflated chamber "leans" over onto its adjacent noninflated chamber. This "overlapping" design creates what we believe is a wavelike compression, generating a smooth flow-driving pressure gradient over the limb. The pneumatic controller houses a compressor, an internal pressure reservoir with a pressure sensor, and 5 valves and outlet ports, which can be connected to the cuff. The working pressure is preset on the device. An inflation sequence starts with the opening of the first valve. The first chamber (ie, the most distal chamber) is inflated until the working pressure (measured in the internal pressure reservoir) is reached. The first valve is then closed, and the second valve is opened. This second chamber is then inflated until the working pressure is reached, and this is repeated for all chambers. Chamber deflation depends on the control settings, but deflation is initiated only after the last chamber has been pressurized.

Model of the Arm

For our study, we used 3 cylindrical model limbs consisting of polyvinyl chloride tubes, 1 m in length, with outer diameters of 60, 80, and 100 mm, respectively. In order to further test the effect of local curvature on the transition of the pressure chamber to the cuff-model interface, we deformed a cylindrical 100-mm-diameter tube so as to obtain an ellipsoidal model with a 112-mm long axis and an 86-mm short axis.

A T-junction was inserted in the tubes connecting the pressure controller to the cuff chambers (Fig. 1). This allowed us to use piezoelectric pressure transducers (DTX/Plus Pressure Transducer[†]) of the type routinely used in hospitals for cardiovascular pressure measurements. We continuously monitored the pressure inside the cuff chamber (P_{chamber}). To measure the contact pressure between the model and the compression cuff, we filled 500-mL infusion bags with about 50 mL of water and deaerated the bags by manually squeezing out the

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air. A connector was glued into the bag to allow coupling to a 3-way stopcock and the piezoelectric pressure transducers. When inflated, the cuff pressure is transferred onto the infusion bag, and the pressure measured inside the bag is thus representative of the pressure exerted by the cuff on the cuff-model interface ($P_{\text{interface}}$). Four of these bags were attached to the limb models at different measuring locations (Fig. 1), and the instrumented model was then inserted into the cuff.

The maximum deviation of the pressure transducers, due to the total effects of nonlinearity, hysteresis, and sensitivity variation, is no more than 2% of the reading (minimum value of 1 mm Hg) according to the product specifications provided by the manufacturer. The pressure transducers were calibrated before and after each measurement series by connecting the sensors to a water column, with water level controlled over a range of 0 to 115 cm (corresponding to pressures of 0–85 mm Hg). No drift of pressure transducer offset or gain was observed. The response of the transducers is high (natural frequency in the order of 200 Hz), but the frequency response of the complete measurement setup strongly depends on the properties of the tubes (length, stiffness, diameter, and density of medium in the tubes) connecting the transducer to the location where pressure is being monitored. In our study, the transducers were connected directly to the infusion bag (to measure $P_{\text{interface}}$) or to the T-junction (P_{chamber}) on the pressure line. When measuring P_{chamber} , air is present in the connection to the pressure transducer, lowering the frequency response of the system. Our main interest, however, was the (quasi-static) maximum pressure level reached within the cuff or at the cuff-model interface, which depends on the low-frequency contents of the signal only.

We were able to simultaneously capture the analog signals of 4 pressure transducers (National Instruments A/D card[†]). Data were sampled at 5 Hz and visualized on a computer screen using customized software (Labview[†]).

Measurement Protocol

Data were gathered for preset working pressures of 30, 60, 80, and 100 mm Hg. Preset working pressures were the same for all chambers. For the 3 cylindrical models, we measured both P_{chamber} and $P_{\text{interface}}$ in a successive way. For a given working pressure, P_{chamber} was first measured in the 4 most distal chambers. The pressure transducers were then connected to the infusion bags, and the cuff was inflated. The model was placed horizontally on a laboratory table.

For measurements with the ellipsoidal model, the model was placed in a vertical position. Four infusion bags were attached to the 4 vertices of the ellipsoidal model at the same height in order to eliminate gravity pressure differences among the 4 sensors. Only $P_{\text{interface}}$ was measured. The model was inserted into the cuff, with the measurement location under chamber 2. The model was moved such that the instrumented bags were located in the middle of the cuff (under chamber 3), and the measurements were repeated.

Data Analysis

For each measurement series, measurements were obtained during 3 complete inflation/deflation cycles. We believe that during such an inflation sequence, pressure (P_{chamber} as well as $P_{\text{interface}}$) reaches different levels (indicated as A, B, C, and D in Fig. 2), corresponding to the inflation of the different chambers. We calculated an average pressure value for each level from data gathered during at least 15 seconds over 3 inflation/deflation cycles. From the 3 inflation/deflation cycles, we calculated one average cycle (which is displayed in Figs. 2, 3, and 4).

In order to assess the interaction among the chambers, we performed a 3-way analysis of variance (ANOVA), using SigmaStat 2.0,[‡] on the calculated mean pressure levels measured during the plateau phase (A–D), the preset target pressures (30, 60, 80, and 100 mm Hg), and the pressure measurement locations (1–4). When the ANOVA test reached statistical significance ($\alpha=.05$), a Tukey test was used for pair-wise *post hoc* analysis. Measurements were considered statistically significant at $P<.05$. Similar analysis was used to assess differences in measurement location on the ellipsoidal model, taking into account the data from the 2 series of measurements. The effect of diameter on $P_{\text{interface}}$ was determined by performing a 3-way ANOVA at each measurement location, with pressure plateau, preset target pressure, and model diameter as independent factors.

Results

The data shown in Figure 2 are the pressures recorded for the cylindrical 80-mm model, but they are similar for all measurements. Upon inflation of the first (most distal) chamber, P_{chamber} reached a plateau (A), with a value slightly above the preset target pressure. During inflation of chambers 2, 3, and 4, the pressure in chamber 1 continued to rise (the pressure reached plateaus B, C, and D, respectively), although the effects were more attenuated upon inflation of chambers 3 and 4. The same pattern of pressure increase was observed for chambers 2 and 3 when the more proximal chambers

[†] National Instruments Corp, 11500 N Mopac Expressway, Austin, TX 78759.

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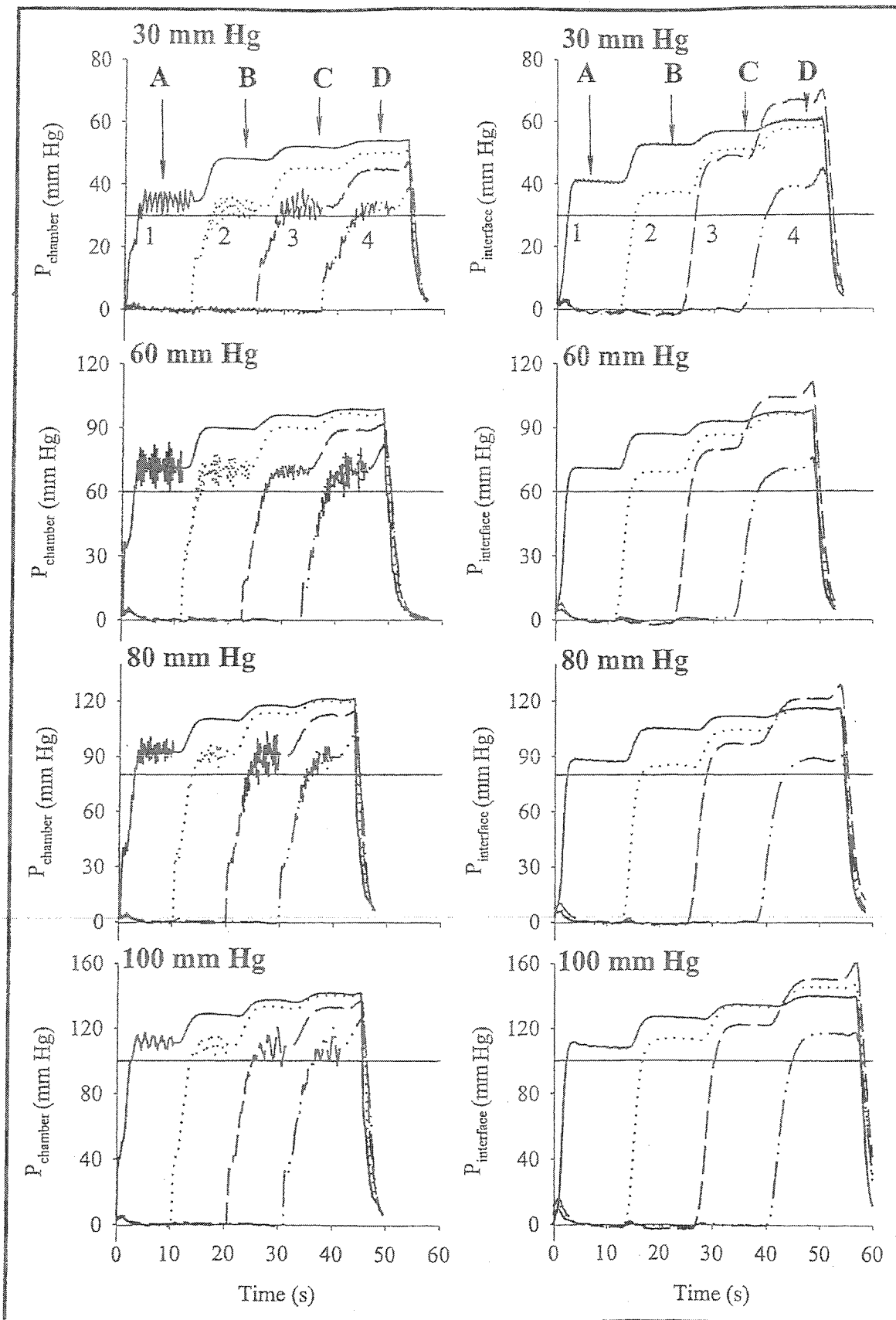


Figure 2. Measured chamber pressure (P_{chamber}) and interface pressure ($P_{\text{interface}}$) in the 4 most distal chambers (1, 2, 3, and 4) during an inflation sequence of the pneumatic compression device for the 80-mm cylindrical model and for preset working pressures of 30, 60, 80, and 100 mm Hg. A typical pressure pattern is observed, with pressure reaching a new plateau value (A–D) upon inflation of a new chamber.

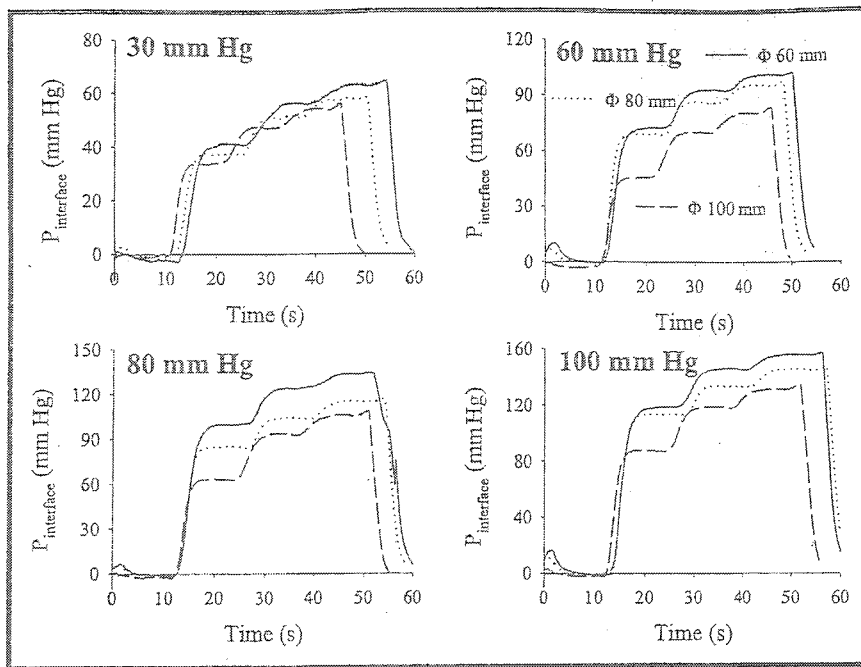


Figure 3. Effect of 3 different model diameters (cylindrical 60-, 80-, and 100-mm models) on interface pressure ($P_{\text{interface}}$) measured at location 2 during an inflation sequence for preset working pressures of 30, 60, 80, and 100 mm Hg.

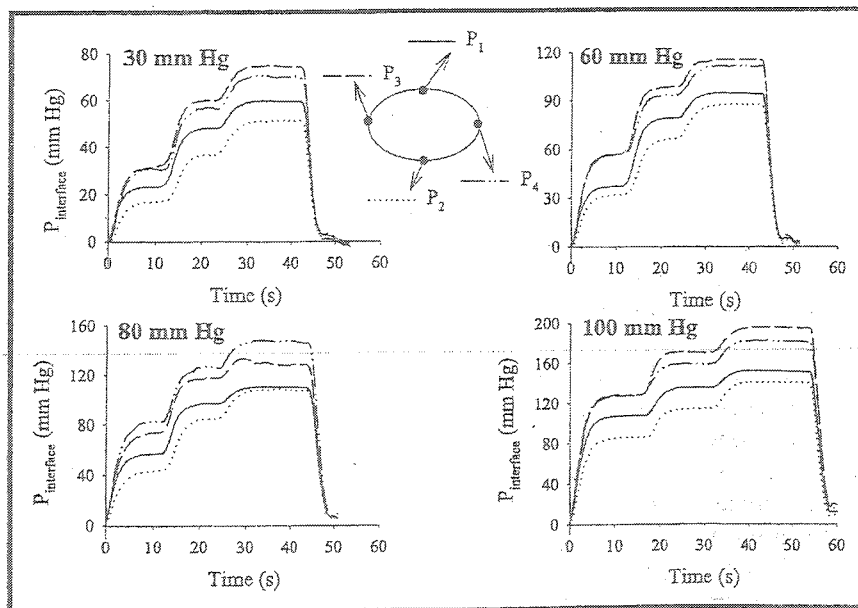


Figure 4. Pressures measured along 4 sides of the ellipsoidal model (P_1 , P_2 , P_3 , and P_4) during an inflation sequence of the pneumatic compression device for preset working pressures of 30, 60, 80, and 100 mm Hg. Measurements were done at location 2.

were inflated. As a result of this interaction, for target pressures 30, 60, 80, and 100 mm Hg, maximal pressure in chamber 1 reached 54 (80% increase in pressure over the target pressure), 98 (63% increase), 121 (51% increase), and 141 mm Hg (41% increase), respectively.

The same tendency was observed for $P_{\text{interface}}$ (Fig. 2). The effect of inflation of chambers 2 to 4 was clearly observed in the pressure recordings at location 1. During most of the inflation sequence (inflation chambers 1–3), the highest pressure was at location 1, with a pressure gradient from the extremity of the limb toward the body. When chamber 4 was inflated, however, pressure at location 3 became the highest, and there was no longer a continuous distal-proximal pressure gradient. Overall, $P_{\text{interface}}$ had about the same order of magnitude as the corresponding P_{chamber} . For instance, at location 1 and for the 4 target pressures, maximal $P_{\text{interface}}$ values were 60, 97, 116, and 140 mm Hg, respectively, and maximal P_{chamber} values were 54, 98, 121, and 141 mm Hg, respectively.

Analysis of variance revealed that, for both P_{chamber} and $P_{\text{interface}}$, the pressure plateau values, as we expected, were dependent on the target pressure level ($P < .001$), the measurement location ($P < .001$), and the plateau identification (A–D) ($P < .001$). This means that, within one inflation sequence and at one measurement site, pressure was different at plateaus A through D, indicating an interaction among chambers. This was the case for all model measurements.

There was little effect of the diameter of the model on P_{chamber} . $P_{\text{interface}}$, in contrast, showed marked effects, as shown in Figure 3, for measurement location 2. The smaller the diameter, the higher the pressure. There was an effect of diameter at measurement locations 1 ($P < .001$), 2 ($P < .001$), 3 ($P < .05$, with the only statistically significant difference between 80 and 100 mm), and 4 ($P < .001$).

We found an effect of limb geometry and measurement location on the pressure exerted on the cuff-skin interface (Fig. 4). For the ellipsoidal model, there was an effect of measurement location ($P < .001$). Pressure at measurement locations 3 and 4 (opposite of the long axis; see Fig. 4) were not different, but were higher ($P < .05$) than pressures at measurement locations 1 and 2 (opposite of

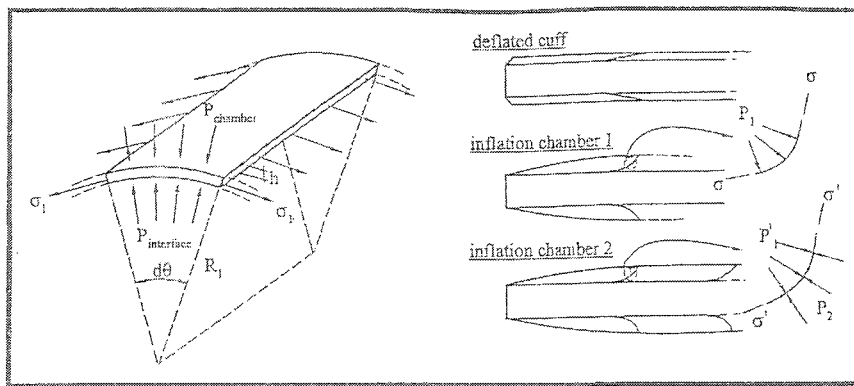


Figure 5.

In the left panel, consider an infinitesimal segment of a curved surface with an opening angle ($d\theta$), radius (R_1), and wall thickness (h). Local equilibrium of stresses yields Laplace's law: $P_{interface} = P_{chamber} + \sigma_1 h / R_1$, where $P_{interface}$ is the pressure exerted by the cuff on the cuff-model interface, $P_{chamber}$ is the pressure inside the cuff chamber, and σ_1 is the stress in the cuff material. The right panel shows the deformation of the cuff upon inflation of chamber 1 and chamber 2. After inflation of chamber 1, pressure becomes P_1 and stress (σ) is built up in the wall separating chambers 1 and 2. Inflating chamber 2 to P_2 , a new equilibrium is reached, with stress (σ') in the wall and P_1 increasing to P_1' . P_1' is maximally equal to $P_1 + P_2$ if wall stress (σ) remains constant.

the short axis; see Fig. 4). Pressures at measurement locations 1 and 2 were not different from each other.

Discussion

Our results showed that for the tested pressure controller and multichamber cuff, which were used for sequential compression therapy, there was a mechanical interaction between adjacent cuff chambers. In and beneath the most distal (first inflated) chamber, pressure continued to rise upon inflation of the other adjacent chambers, leading to $P_{chamber}$ and $P_{interface}$ values exceeding the preset working pressures by 40% to 80% for working pressures of 30 to 100 mm Hg. The typical pressure pattern was observed for all models studied and at all levels of preset target pressure. The actual $P_{interface}$ is a function of target pressure, model diameter, and geometry. The smaller the diameter or local curvature, the higher the pressure. We believe that these results are representative for other devices and cuffs with similar pressure controllers and multichamber cuff designs.

The effect of diameter and curvature, we believe, can be explained on the basis of Laplace's law (Fig. 5). Given $P_{chamber}$ and $P_{interface}$, the local radius (R_1), the stress in the cuff material (σ_1), and the wall thickness (h), equilibrium of stresses yields $P_{interface} = P_{chamber} + \sigma_1 h / R_1$. Thus, theoretically, $P_{interface}$ is always higher than $P_{chamber}$, except on flat contact surfaces ($R_1 = \infty$) or when the wall material does not bear any stress ($\sigma_1 = 0$). Our data are consistent with Laplace's law: $P_{interface}$ values were higher for the smaller model diameters and for those measurement locations on the ellipsoidal model with the smallest curvature.

The diameter of the model and curvature influenced the pressures measured, as did the fluid-filled infusion bags. The pressure sensors were as small as we could make them. We tried to measure contact pressure using miniature (1-mm-thick, about 4-mm-diameter) pressure sensors (EPL series¹¹) embedded in the model. Results were poor, with very low reproducibility. We believe that these problems were due to the fact that pressures were measured under a cuff, rather than under an elastic stocking. The inner diameter of the cuff is larger than the model. Thus, when the cuff is inflated, the inner wall folds, and the cuff-sensor contact may be very different for different experiments. These problems can be avoided using larger fluid-filled bags, as it is expected that the cuff "folds" around the model and the bag, providing overall good contact.

Under ideal conditions, $P_{chamber}$ is fully transferred to the infusion bags, with $P_{chamber}$ being equal to $P_{interface}$. In most conditions, however, $P_{interface}$ was slightly higher than $P_{chamber}$. This also indicates that, conforming to the Laplace formula, some tension (σ_1) may be absorbed in the inner cuff wall. The exact value of σ_1 is difficult to estimate, as it depends on cuff material properties, on friction between the cuff and the model, and on the folding pattern of the cuff.

Due to the large size of the infusion bags, measured $P_{interface}$ represents an average pressure exerted over a relatively wide area. The disadvantage is that it is difficult to measure strictly underneath individual cuff chambers. We believe that the high pressure measured at location 3 for the 80-mm cylindrical model (Fig. 2) was due to the fact that the infusion bag was not well centered underneath chamber 3, where we might have captured some influence of the stiffer stitching seam. Nonetheless, these high pressures actually occur and may be important, as they can reverse the pressure gradient. Overall, we believe that the disturbing effect of the presence of the infusion bags is limited for the uniform model data. Cuff pressures and measured $P_{chamber}$ were of the same order of magnitude and followed the same "typical" pattern with a progressive increase in pressure upon inflation of adjacent cuff chambers. The effect is probably more important for the ellipsoidal model, as 4 bags are connected at the same level under the cuff.

¹¹ Entran Devices Inc. 10 Washington Ave, Fairfield, NJ 07004.

Both the $P_{\text{interface}}$ and P_{chamber} data showed an interaction between adjacent cuff chambers. This interaction caused the most distal pressure to rise continuously, ultimately reaching values 40% to 80% higher than the preset working pressure for working pressures of 30 to 100 mm Hg. The increase in pressure is explained by simple mechanics (Fig. 5). Upon inflation of the first chamber to pressure P_1 , the partition between chambers 1 and 2 takes a "rounded" shape, and a steady state, with equilibrium between P_{chamber} and wall stresses, is obtained. With zero pressure in chamber 2, the transmural pressure difference is P_1 . Inflating the adjacent chamber to pressure P_2 , the shape of chamber 1 is more or less maintained, together with the coexisting stresses in the wall. If the shape and stresses are completely maintained, equilibrium requires a constant transmural pressure difference of P_1 , and pressure in chamber 1 therefore would rise to $P_1 + P_2$. Measurements show that P_2 is not entirely added to P_1 , suggesting that the shape of chamber 1 is probably not entirely maintained upon inflation of the other chambers.

Cuffs have been designed to generate a more wavelike compression, proceeding from the extremity of the limb toward the heart. This compression mode is much more effective than uniform compression in evacuating fluid.^{13,14} We argue, however, that it is unacceptable for pressures to rise far above the desired working pressures. There are several possible ways to prevent these excessive pressures. A simple method could be to use different target pressures for each chamber, with lower target pressures for the more proximal chambers. Another solution may consist of better control algorithms in the pressure controller: instead of measuring pressure only during inflation of each chamber, repetitive measurements in each chamber could allow better control of target pressures. Other alternative cuff designs such as those with controllable pressure valves mounted on each cuff chamber might prevent pressures from rising above a desired value.

In clinical practice, compression therapy and lymphatic drainage are used for the prophylaxis of deep venous thrombosis.^{9-11,17,18} Target pressures depend on the application, but range from 30 to 100 mm Hg or higher. Especially for the prevention of deep venous thrombosis, working pressures of 100 mm Hg or higher are used.¹⁰ The prophylactic effect of pneumatic compression on deep venous thrombosis is attributed to the intermittent application of high flows and shear stresses, thereby—at least in theory—also preventing stasis. Nicolaidis et al¹¹ found that pressures higher than 35 mm Hg did not increase venous peak flow in the limb. Generally, for the treatment of lymphatic edema, lower target pressures (around 30 mm Hg) are used.⁹ Nevertheless, cuff interaction causes the pressures to rise to 50 mm Hg or

higher. Such high pressures may be detrimental to the lymphatic circulation.⁸

Limitations

Our study has some limitations. Only one device was used during the experiments. We believe, however, that the apparatus and its control algorithm are representative for this type of device. The model we used consisted of a simple, rigid structure. We contend, however, that the $P_{\text{interface}}$ values we recorded are representative of the pressures exerted on the soft tissues of the limb for 2 reasons. First, the perimeter of the inside of the cuff is larger than the perimeter of a limb, and upon inflation, the cuff folds itself around the object inside, creating what we believe is perfect contact, with P_{chamber} fully transferred to the contact surface. Although this is our contention, we have no data to support this hypothesis. Second, by using fluid-filled bags to measure $P_{\text{interface}}$, we believe a deformable soft tissue-like layer is induced, making the cuff-model interface less rigid.

Our measurements do not give information on the pressure distribution inside the limb (which depends on the exact geometry and constitution of the limb) or information on the effect of compression therapy on venous or lymphatic flow. In addition, the reproducibility of the measurements, particularly with respect to $P_{\text{interface}}$, depends on the exact positioning of the model inside the cuff. Although we did not do a thorough repeatability study, we believe the observation that there was an interaction among cuff chambers was not attributable to measurement error. The reported data were measured on 4 different models that were taken apart and instrumented between measurement sessions. The typical pressure pattern was present in all measurements (both P_{chamber} and $P_{\text{interface}}$), and there was an interaction. Within one measurement sequence (ie, different inflation/deflation sequences without removing the model), data are highly reproducible. The maximum standard deviation of measured plateau pressure was less than 2 mm Hg. In addition, for the same target pressure level, P_{chamber} was—as we expected—independent of cylindrical model diameter, and the anticipated effect of diameter on $P_{\text{interface}}$ could be demonstrated.

Conclusion

We demonstrated that the mechanical interaction in a multichambered cuff made by one manufacturer for pneumatic sequential compression therapy leads to $P_{\text{interface}}$ values up to 80% higher than the preset target value indicated by the manometer of the apparatus. We believe that this discrepancy between target and effective pressures can interfere with treatment and may have detrimental effects on the lymphatic circulation. In anticipation of the development of appropriate measures by the manufacturers, therefore, we recommend

that pneumatic compression devices be used with much lower than target pressures than those used in clinical practice. What is necessary, however, is research to determine whether our results could be found in testing other devices and other cuffs.

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