Interface Pressures Produced by Two Different Types of Lymphedema Therapy Devices

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Background and Purpose

Sequential compression is used to manage lymphedema, but little is known about pressures delivered to the therapeutic targets. This study characterized actual pressures delivered by a traditional compression pump (Lympha Press [LP]) and one using an alternate compression pattern (Flexitouch [FT]).

Subjects

Ten adults who were healthy volunteered to participate in the study.

Methods

Pressure-time along the forearm was measured using a 256–pressure sensor array during the pressure cycling of each device. Device assessments were separated by at least 48 hours.

Results

Pressure patterns and magnitudes produced by the 2 devices differed considerably. The FT pressure pattern displayed a rapid rise and fall, progressing from the wrist toward the elbow. The LP pressure rose slower and was sustained at a higher level during its inflation cycle. Pressures delivered with the LP were significantly greater than those delivered with the FT.

Discussion and Conclusion

The pressure patterns and magnitudes on treated limbs depend on the device. These differences should be considered before selecting a device for a specific patient.

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Automated sequential compression devices of different types have been reported to be beneficial in treating people with lymphedema in a limb.[1–7] The effectiveness of these devices has been compared with the effectiveness of complete decongestive physical therapy (CDP),[1] and these devices also have been used in conjunction with CDP.[2,8] Most devices consist of multiple contiguous chambers that encircle the limb, which are sequentially inflated and then deflated simultaneously.

Another approach, recently introduced, uses sequential compression patterns that may more closely emulate the pattern used in manual lymphatic drainage (MLD),[6] an integral component of CDP. Two features of this approach would appear to be in contrast to classical automated sequential compression approaches. One feature is its automated preparation phase, in which the region of the trunk proximal to the lymphedematous limb is treated first, under the physiological principle[9,10] that such clearing is efficacious and will permit greater lymph drainage during the subsequent drainage cycle. This concept of clearing truncal and proximal regions first to facilitate drainage is in accordance with experimental findings in which thoracic compression facilitated peripheral lymph transport.[11] This approach also is an essential component of MLD teaching and clinical practice.[10,12]

A second feature that may have relevance encompasses the magnitude, pattern, and timing sequences of the compression-release cycles. According to the manufacturer's claims, these parameters are significantly different from those of classical sequential compression approaches, including applied pressure pulses that are shorter acting and lower in magnitude.

Although both approaches have the common goal of delivering sequential pressures to assist lymphatic drainage, the nature of the pressures may be different in magnitude, pattern, and timing. If one accepts the physiological underpinnings of MLD therapy[9,10] (ie, that successful MLD requires brief application of mild, directional, variable pressure combined with an immediate release or resting phase), then these parameters gain relevance. Thus, differences in delivered pressure may have important implications. It has been reported that, even with manual massage, lymphatic vessels can be damaged if pressures that are too high are used.[13] Measurements of pressures actually applied to limb models showed that pressures provided with sequential compression pumps can far exceed those pressures expected from device settings.[14]

Similar measurements have not been reported with any devices that were applied to human arms. Thus, the main purpose of this initial study was to investigate pressure magnitudes and patterns produced on the forearms of subjects by 2 devices that use different approaches: a traditional sequential compression pump (Lympha Press [LP]*) and a new compression device technology (Flexitouch [FT] lymphedema system†). Although both of these devices have been used clinically to manage lymphedma,[6,7] there have been no reports of the actual pressures that these devices deliver to the target tissue.

Method

Subjects

Ten volunteer subjects (5 male and 5 female) participated in this study after reading, agreeing to, and signing an institutional review board–approved‡ informed consent form. Subjects were recruited by a flyer and word of mouth. To be eligible for participation, subjects needed to be at least 18 years of age and generally in good health without a diagnosis of lymphedema. Subjects with any of the following were excluded: pregnancy, history of peripheral vascular disease, congestive heart failure, chronic renal disease, pulmonary edema or episodes of pulmonary embolism, known active or recurrent cancer or current chemotherapy or radiation therapy, diagnosis of deep vein thrombosis or phlebitis in the last 6 months, open limb wounds or active infection, or prior history of chronic upper-extremity swelling. The study population had the following physical characteristics: mean age=43.2 years (SD=5.3, range=33–48), mean height=1.73 m (SD=0.09, range=1.55–1.85), mean weight=72.7 kg (SD=12.1, range=58.0–96.4), and mean body mass index (BMI)=24.2 kg/m^2 (SD=2.5, range=20.2–28.2). According to BMI criteria, 3 subjects would be classified as overweight (BMI>24.9), with the remainder in the normal range.

Subjects who did not have lymphedema were chosen for this initial study because the goal of the study was to characterize and compare pressures and not to manage lymphedema. Patients with lymphedema already have their own treatment regimens that, on ethical grounds, should not be altered for the purposes of this evaluation. This technical device evaluation used 10 subjects because I believed this number to be sufficient for the intended pressure characterization process.

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† Tactile Systems Technology Inc, 4824 Park Glen Rd, Minneapolis, MN 55416.
‡ Sterling Institutional Review Board, 6300 Powers Ferry Rd, Suite 600-351, Atlanta, GA 30339.

Devices

The LP device used in this study was model 103-M, which, according to the manufacturer's documentation, is a multicompartmental, calibrated, gradient pressure pump. It consists of an air compressor unit that distributes pressure through a series of individual regulators at each outflow port and is connected to a garment. Sleeves are designed for both upper- and lower-extremity use. For the purposes of this study, only the arm sleeve was used. The arm sleeve contains 10 overlapping chambers. A shoulder attachment containing one inflatable chamber is available.

Each chamber in the arm sleeve is about 10-cm wide and inflates sequentially, starting at the most distal end of the sleeve. Once a chamber is inflated, it holds the inflation as the remaining, more proximal chambers sequentially inflate and hold pressure. The inflation-deflation cycle is 30 seconds, whereupon the cycle is repeated. For the device evaluated, the pressure in the chambers was adjustable over a range of 30 to 200 mm Hg. For all tests reported in this article, the pressure was set at 45 mm Hg, which is within the middle-to-low end of the range of pressures reported in previous clinical studies.[1,3,5] Figure 1A shows the arm sleeve applied to a subject.

The FT device used in this study was model PD32–120, which, according to the manufacturer, was designed to simulate the effects of optimally performed MLD. The device utilizes a 2-phase lymph preparation and drainage method that is intended to replace MLD performed by the patient at home. The system consists of an electronic controller unit and garments that contain narrow chambers that range from 3.8 to 4.4 cm wide. Garments are designed for use with both the lower extremity and upper extremity, but for the purposes of this study, only the arm garment set was used. The upper-extremity garment set consists of an arm garment (5 chambers over the hand, 4 chambers over the forearm, 5 chambers over the biceps), a chest garment (4 curved chambers over the chest and shoulder), and a trunk garment (8 curved chambers covering the lower trunk).

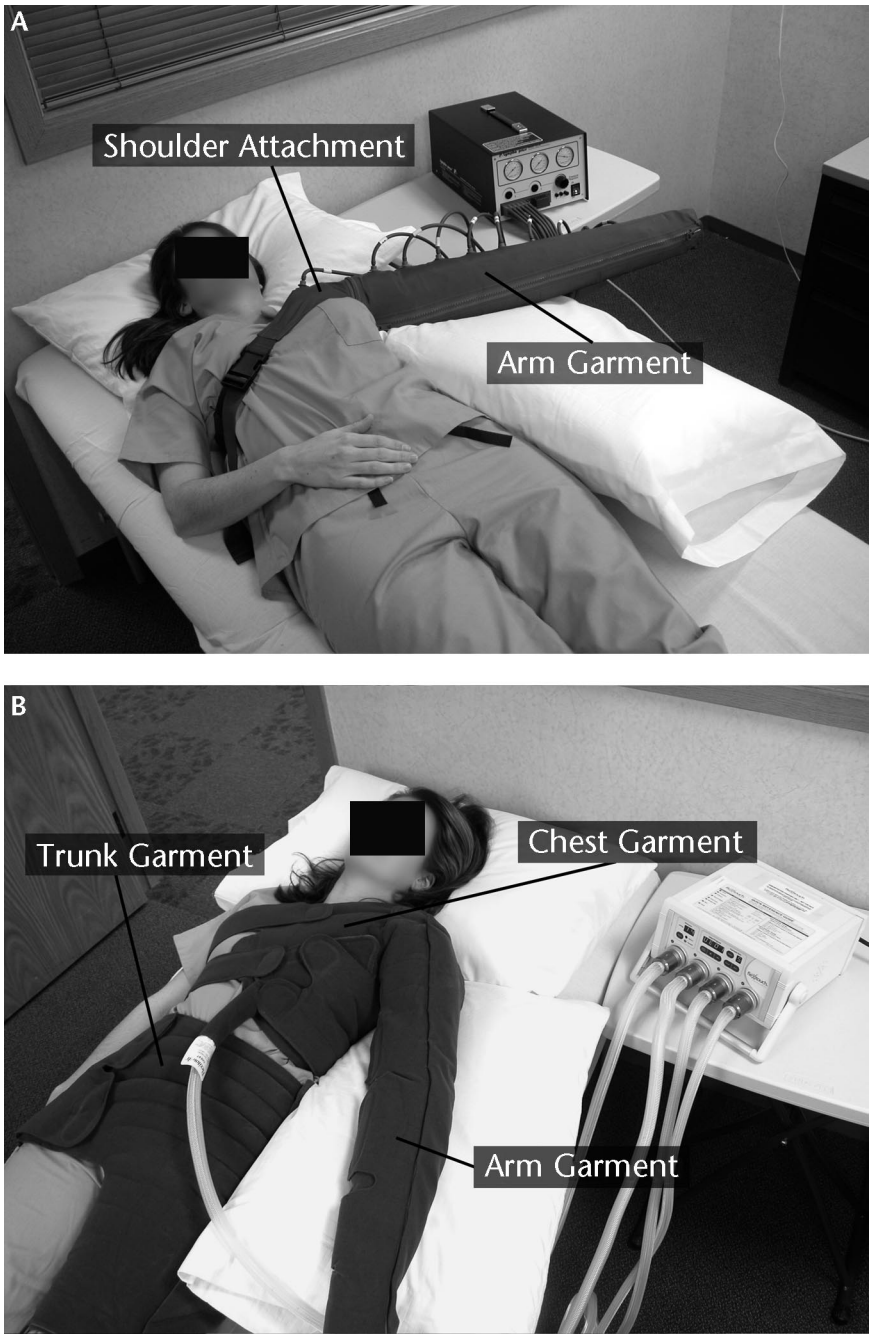

Figure 1.
The devices in position on a test subject. (A) Lympha Press and (B) Flexitouch.

The preparation phase initiates in the trunk and is then applied to the chest, biceps, forearm, and finally the hand. The drainage phase ini-

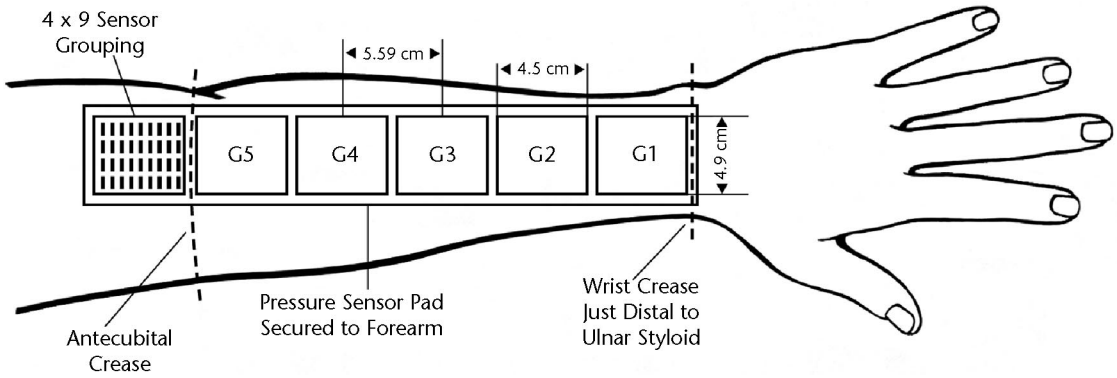

Figure 2.
Pressure sensor arrangement on arm.

tiates in the hand and then moves proximally, ending its cycle at the trunk. The individual chambers are automatically inflated and then rapidly deflated, with no 2 chambers remaining fully inflated at the same time. Figure 1B shows the device applied to a subject.

Protocol

Subjects were evaluated in the supine position with 1 of the 2 devices applied to the left arm. The order of evaluation was random, with a minimum of 48 hours between evaluations on the same individual. After the subject assumed a supine position, a 256-pressure sensor array (XSensor Pressure Mapping System, model X2)[§] was affixed to the left arm as described below to measure interface pressures along the forearm. Garments then were applied to the subject according to manufacturers' directions. The FT or LP device then was activated, and pressures were recorded for at least 2 full cycles of each device.

Pressure Sensors and Measurement

Pressures along the left posterior forearm were measured using the 256-pressure sensor array with the sensors embedded in a 33- × 4.9-cm cloth strip as shown in Figure 2. Each rectangular sensor was 1.1 × 0.4 cm with the long dimension oriented across the arm. The full array consisted of 64 sets of 4 sensors, with each set of 4 sensors monitoring an arm width of 4.9 cm and length of 0.4 cm. Spacing between adjacent sensors up the arm was 0.10 cm, and spacing between sensors across the arm was 0.16 cm.

To determine the pressure profile along the forearm, 5 standardized areas were defined, with each area corresponding to a group of 4 × 9 sensors encompassing an arm surface area of about 22 cm^2. These groups were designated as G1 through G5 and are shown in Figure 2. The distance between midpoints of consecutive groups was 5.59 cm, making the distance measured from the wrist to the midpoint of each group approximately equal to 2.8, 8.4, 14.0, 19.6, and 25.2 cm for groups G1 through G5, respectively. Pressures measured by all sensors were automatically sampled and recorded at 0.1-second intervals over at least 2 full inflation cycles of each device. The stored pressure data were subsequently processed with dedicated software provided with the sensor array system.

Pressure Profile Analysis

The average pressure recorded within each of the 5 sensor groups was determined at 0.1-second intervals. This was done by calculating the average value of the pressures recorded by each of the 36 sensors for each 0.1-second pressure sample. Figure 3 shows examples of average pressure-time plots for the FT drainage cycle (Fig. 3A) and the LP cycle (Fig. 3B). The maximum values of the average pressure-time graph are referred to as the average peak pressure.

In addition to the average and peak pressures, the integrals of the pressure-time curves were obtained for each sensor group. This parameter reflects the exposure of the arm to the combined effects of instantaneous pressure and its duration of action. The pressure-time integration was carried out over a time window of 30 seconds, which corresponds closely to the drainage cycle period of the LP and FT devices. The pressure-time integral was calculated by determining the area under each of the 5 pressure-time curves (curves 1–5 in Fig. 3). The average pressure of each pressure pulse was determined by dividing the area under each pressure-time curve by its duration of action. For the LP analysis, the duration was taken as 30 sec-

[§] Xsensor Technology Corp, Suite 111, 319-2nd Ave SW, Calgary, Alberta, Canada T2P 0C5.

onds; for the FT analysis, the duration was determined for each individual pressure pulse because duration varied slightly with both the individual and the arm site.

Data Analysis

All statistics were determined using the statistical package SPSS, version 9.0.[‖] A general linear model for repeated measures was used to test for overall differences between pressures. In this analysis, the site (G1–G5) was used as the within-factor variable, and LP pressures, FT preparation phase pressures (FT-P), and FT drainage phase pressures (FT-D) were used as independent between-factor variables. *Post hoc* tests of pressure differences at each site were done using a one-way analysis of variance among the LP pressures, FT-P pressures, and FT-D pressures. In all cases, differences were considered statistically significant if the applied test resulted in $P<.05$. Data are presented as mean±SD unless otherwise noted.

Pressure System Validation

Pressure system validity was evaluated using a specially designed chamber illustrated schematically in Figure 4A. The sensor pad was placed in the chamber with the sensor array over a foam surface. A rubber bladder was placed over the sensor pad. The bladder was connected to a calibrated pressure manometer and a valved air bulb to allow bladder inflation and deflation. Inflation of the bladder resulted in increases in measured chamber pressure (Pc) that were then compared with average pressures recorded by the 4 × 9 sensor grouping (Px). Measurements were done by increasing Pc in progressive steps from 0 mm Hg to 10, 20, 40, 60, 80, and 100 mm Hg. The bladder then was deflated and the sequence was repeated 5 additional times (total of 6 cycles), with 60 seconds between cycles. The average sensor group pressure and its standard deviation at each value of Pc were determined. The entire procedure then was repeated at 24 hours and at 48 hours.

The composite relationship, combining data for all 3 days, is shown in Figure 4B. The overall linear regression equation was Px = 1.026 Pc + 3.92 mm Hg, with an R^2 value of .997. The standard deviation of repeat measurements for any day did not exceed 1.0 mm Hg at any chamber pressure setting. The largest difference in sensor pressures between any 2 days for each chamber pressure ranged from 1.5 to 4.9 mm Hg, with the largest average difference (mean±SD) being 3.3±1.2 mm Hg.

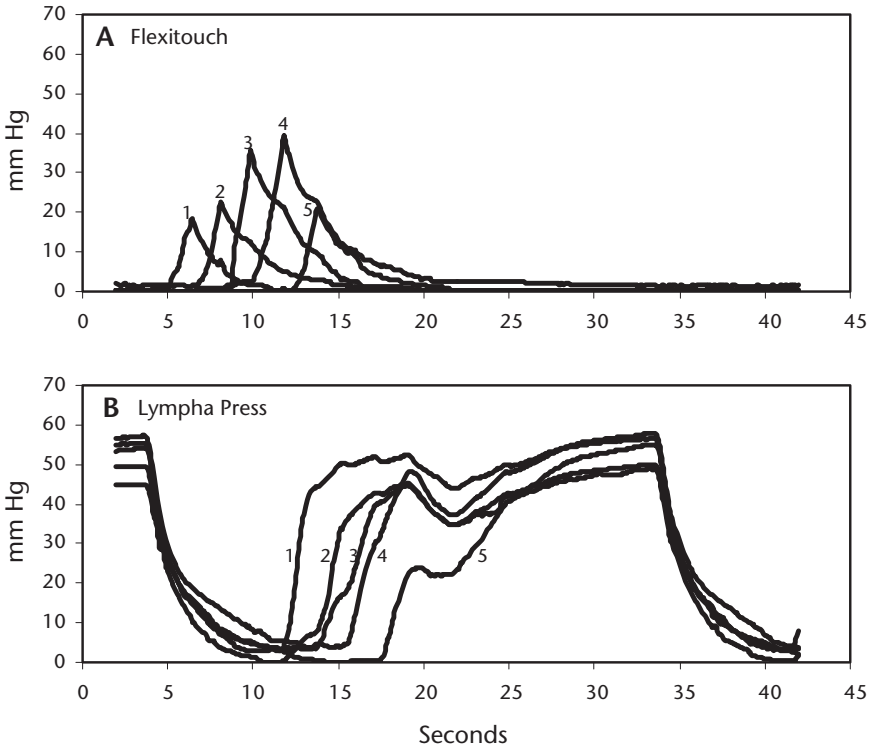

Figure 3.
Typical pressure-time recordings. Numbers (1–5) correspond to the 4 × 9 sensor groupings (G1–G5), with grouping 1 being closest to the wrist. Values shown are the instantaneous average pressures within each grouping. (A) Flexitouch drainage cycle, (B) Lympha Press cycle.

Results

Pressure Pattern Comparisons

There were several differences in the pressure patterns produced by these 2 devices, as shown by the typical pressure characteristics illustrated in Figure 3. Although the initial pressure rise accompanying inflation of both devices to its peak (for the FT device) or to an initial plateau (for the LP device) was rapid, it occurred significantly more rapidly with the FT device (1.48±0.31 seconds versus 4.12±1.66 seconds, $P<.001$). Furthermore, the FT device started its pressure release immediately after this time, whereas the LP device maintained the inflation pressure for the remainder of its cycle. Thus, the duration of the actual inflation component of the FT device at all arm sites was significantly shorter (about

[‖] SPSS Inc, 233 S Wacker Dr, Chicago, IL 60606-6307.

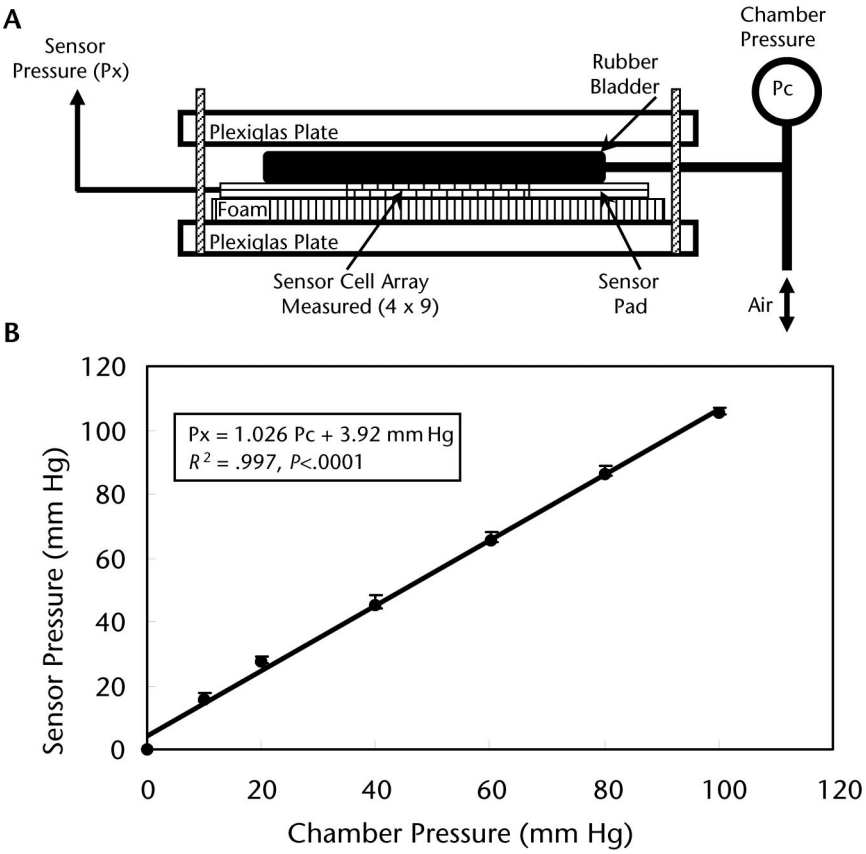

Figure 4.
Pressure system validation. (A) Pressure system test setup. (B) Comparison of chamber pressures (Pc) and sensor pressures (Px). Data points are mean±SD of values obtained for Px at each independent Pc setting for all measurements obtained on 3 separate consecutive days. The solid line is the linear regression with the associated equation shown in the inset of the figure.

1.5 seconds) compared with the LP device (up to 22 seconds).

Average Pressure Magnitude Comparisons

Results of the general linear model analysis that included the FT-P pressures, the FT-D pressures, and the LP pressures showed significant differences among overall pressures. Mean pressures and their respective 95% confidence intervals (95% CIs) were: 32.6±6.5 mm Hg (95% CI=30.3–34.9) for the LP pressures, 13.7±4.9 mm Hg (95% CI=11.4–16.0) for the FT-P pressures, and 9.0±4.2 mm Hg (95% CI=6.7–11.3) for the FT-D pressures. *Post hoc* testing (Bonferroni test) showed that the overall LP pressures were significantly ($P<.001$) greater than both the FT-P and FT-D pressures, but the FT-P pressure was significantly greater than the FT-D pressure ($P=.017$). A site-by-site comparison (Fig. 5) showed that, at every site (G1–G5), the LP pressure was greater than either the FT-P or FT-D pressure ($P<.001$). The difference between FT-P and FT-D pressures was not significant ($P>.05$) at any site except site G3 (mid forearm), where the FT-P pressure was significantly ($P<.01$) greater than the FT-D pressure.

Peak Pressure Magnitude Comparisons

Results of the general linear model analysis showed significant differences among overall peak pressures. The mean peak pressures and the respective 95% CIs were: 52.4±7.9 mm Hg (95% CI=47.8–57.0) for the LP pressure, 37.3±9.2 mm Hg (95% CI=32.7–41.9) for the FT-P pressure, and 28.6±13.2 mm Hg (95% CI=23.9–33.2) for the FT-D pressure. *Post hoc* testing showed that the overall LP pressures were significantly ($P<.001$) greater than both the FT-P and FT-D pressures, but the FT-P pressure was greater than the FT-D pressure ($P=.031$).

Pressure-Time Comparisons

Results of the general linear model analysis also showed significant differences among pressure-time integrals. The mean pressure-time integral values and the respective 95% CIs were 978±197 mm Hg × second (95% CI=918–1,038) for the LP pressure, 411±146 mm Hg × second (95% CI=352–471) for the FT-P pressure, and 99±74 mm Hg × second (95% CI=40–159) for the FT-D pressure. *Post hoc* testing showed that the overall LP pressure-time integral was significantly ($P<.001$) greater than the values for both the FT-P and FT-D pressures and that the FT-P pressure-time integral was greater than the FT-D value ($P<.001$). A site-by-site comparison (Fig. 6) showed that, at every site (G1–G5), the LP pressure-time integral was greater than either the FT-P or FT-D values ($P<.001$) and that the FT-P values were greater than the FT-D values ($P<.01$).

Discussion

The main goal of this study was to measure, characterize, and compare the pressures produced by a traditional pneumatic sequential compression pump that has been available for a long time and a new type of pneumatic compression device that is claimed to have features that more closely emulate MLD techniques. Devices that use traditional pumping methods have been used

clinically with some success.[3,5,7,15–18] More recently, good clinical results were reported using the newer approach embodied in the FT device.[6]

Both types of devices have been evaluated in a clinical setting by the same group.[5,6] These researchers used a traditional sequential compression-type pump, similar in function to the LP device evaluated in the present study, in combination with standard CDP therapy. Their results indicated a significantly greater reduction in arm volumes with the combined approach than with CDP alone in the initial treatment of women with postmastectomy lymphedema in the arm.[5] Subsequently, these researchers compared the FT device as a maintenance therapy with self-massage in patients previously treated for unilateral lymphedema related to breast cancer treatment. They reported a significant benefit of the FT device with respect to arm volume reduction, quality of life, and weight loss.[6] The LP device characterized in the present study also has shown clinical utility,[7,15] but there have been no reports of the pressures that these different types of devices impart to treatment areas.

The specific devices discussed in this report both provide treatment beyond the forearm. The LP garment covers the hand, biceps brachii muscle, and shoulder. The FT covers the hand, biceps brachii muscle, chest, and lower trunk. For the purposes of this report, data acquisition and analysis were limited to the subjects' forearms. This was a practical consideration because the length of the pressure sensor strip closely matched the part of the arm below the elbow. Although absolute pressure values may differ at the hand and biceps brachii muscle from those measured on the forearm, it is likely that differences between the 2 devices would be in the same direction as found on the forearm. Furthermore, because therapy is not

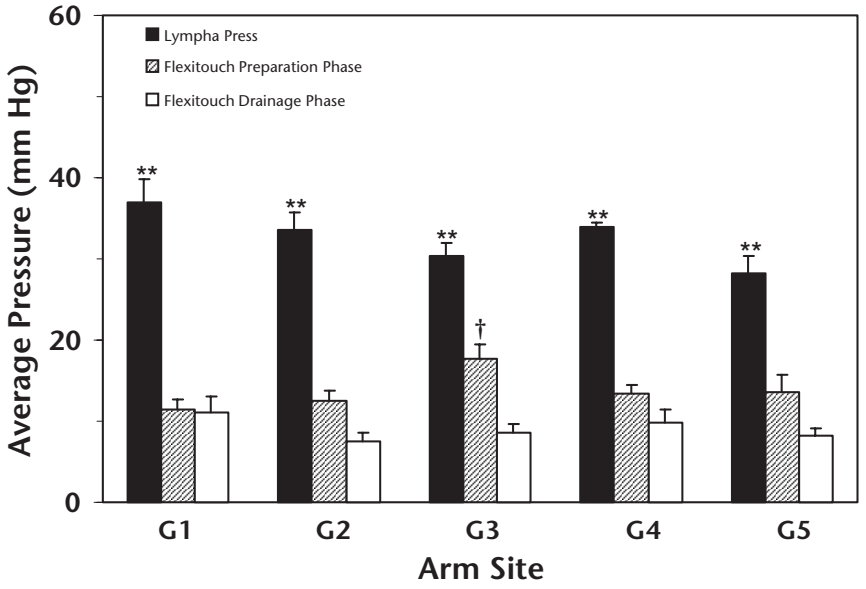

Figure 5.
Average pressures in the forearm. ** Lympha Press pressures greater than Flexitouch preparation and drainage phase pressures ($P<.001$). † Flexitouch preparation phase pressure greater than drainage phase pressure ($P<.01$). G1 to G5 are the 6 cm^2 areas specified in the text, with G1 being closest to the wrist. Bars are standard error of the measurement (SEM).

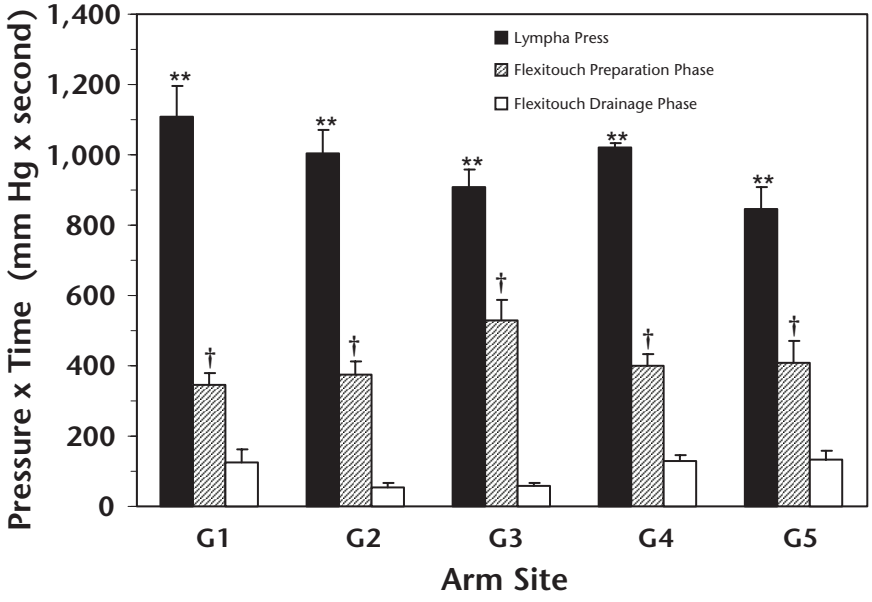

Figure 6.
Pressure-time integrals over a full activation cycle. ** At all forearm sites, the Lympha Press device had pressure-time integrals that were significantly greater ($P<.001$) than those for the Flexitouch device. † Flexitouch preparation cycle pressure-time integral greater than Flexitouch drainage cycle value ($P<.01$). Bars are standard error of the measurement (SEM).

applied to the trunk or chest with the LP device, no device comparison would be possible for these regions. The temporal patterns of compression-relaxation would be the same at all sites.

A related aspect is that the present results were obtained from nonlymphedematous arms, for reasons previously described. This fact raises the question about the differences that might be expected when either device is used with patients with limb lymphedema. It is suspected that the absolute pressures would vary for each patient depending on the specifics of his or her limb contour and tissue properties. For example, a patient with significant fibrosis would likely experience a higher pressure than one with softer tissue; however, such changes would likely affect pressures of both devices. It is not known whether the variation among lymphedematous arms would be greater than the interindividual variation found for nonlymphedematous arms.

One main result of the present study was that significant quantitative differences in applied pressures were observed between devices. These differences were demonstrated as differences in the pattern, timing, and magnitude of pressures in the treated areas.

For the 2 devices evaluated, one primary difference was the presence of a preparation phase in the FT device. This phase precedes the drainage phase, initiates in the trunk region, and then progresses to the chest, biceps brachii muscle, forearm, and hand. The therapeutic basis and potential value of this preparatory sequence are premised on some animal experimental evidence,[11] and this preparatory phase is a widely taught and applied principle in the use of MLD therapy.[10,12] An analogy that is sometimes used to teach this concept is that if you want to put water into a full glass, then it is best to remove some of the water from the glass first. Although there are no randomized controlled trials comparing MLD with and without clearance, the principle makes good physical and physiological sense in the case of MLD. Furthermore, the premise on which this truncal clearance and preparation is based is so rooted in the scientific understanding of the lymphatic system that ethical considerations might preclude such a study.

The LP device does not provide a preparation treatment phase. As such, comparisons of pressure timing, magnitude, and pattern between the devices could only be completed for what will be referred to as a drainage therapy sequence. Because one of the purposes of this report is to provide technical device data, however, this report includes data regarding pressure timing, magnitude, and pattern for the preparation phase of the FT device.

Timing differences between devices were most apparent in the inflation-deflation sequence of the individual chambers. Although during the drainage sequence chambers of both devices inflated first in the most distal area and progressed centrally, the inflation of the LP device was sustained until all chambers were fully inflated. For the model evaluated, this resulted in the most distal part of the forearm receiving inflation pressure for about 22 seconds and the most proximal segment receiving inflation pressure for about 16 seconds. In contrast, the timing of the inflation-deflation of the FT device resulted in chamber inflation for about 1.5 seconds, after which deflation was initiated, with no 2 chambers beginning to inflate at the same time. The shorter duration of pressure pulses resulted in a crisper, progressive pressure wave that may facilitate fluid movement in part because their timing more closely resembles respiratory movement timing and arterial pressure pulses, both of which are thought to stimulate lymphatics.[10,19,20]

In addition to the pattern and timing differences between devices, there were significant differences in the pressure magnitudes in the arm tissues. Average pressures, peak pressures, and the pressure-time integral were all significantly greater for the LP device. The use of pressures higher than those needed for therapeutic efficacy may have detrimental effects on treated tissues and vessels. Keeping in mind that a main goal of this form of therapy is to move lymphatic and interstitial contents out of the affected limb, the question of what constitutes optimal pressure levels is of great interest.

Some authors[12,21,22] have questioned the utility of compression pumps based on limited evidence that pressures applied by traditional compression pumps exceed clinically acceptable levels and may injure superficial lymphatics. Other authors[2,14] have suggested that standard pneumatic pump device pressure settings may be used, but pressure settings should not exceed 30 mm Hg. Some researchers have clinically set devices between 40 and 60 mm Hg[3,5,23] and as high as 80 to 90 mm Hg.[4] In the present study, I used single pressure settings for both the FT and LP devices. For the LP device, which has a range of possible pressure settings, I chose a setting of 45 mm Hg, which is toward the lower end of those settings used in most clinical studies.[3,5,23] In addition, communications with prescribing physicians and therapists indicate that a setting of 45 mm Hg is widely prescribed.

The FT device has 2 pressure settings: "standard" and "intense." I chose to set the device to the "stan-

dard" setting, which reflects the most frequently prescribed setting and follows the manufacturer's recommendations. Thus, the present results with respect to pressure magnitudes strictly apply for these settings. The magnitude of the maximum delivered pressure, at least for the LP device, would most likely depend on the pressure setting, but this aspect was not evaluated in this study. A more detailed parametric characterization over the full pressure range would be informative and could form the basis of a future research study.

Despite the preceding limitations, the pressure parameters that I measured would appear to be representative of those that are routinely experienced by many patients treated with the LP device or other similar pump devices. These pressure settings are well in excess of pressures measured within normal skin lymphatic vessels, which are reported to range from about 4 mm Hg[24,25] to 8 mm Hg,[26] depending on measurement method and site. At present, there does not seem to be a scientifically sound basis for choosing a specific pressure level. It is logical to argue that the pressure must be sufficient to overcome the resistive forces present within the tissue being treated, but these are unlikely to exceed 20 mm Hg if judged on the basis of pressure measurements in edematous lymphatics and tissues, which range from 15 to 18 mm Hg.[26,27]

Based on such measurements, one may speculate that pressure pulses with peak inflation pressures of about 25 to 30 mm Hg might be sufficient for most patients in the absence of significant fibrosis. From the point of view of minimizing possible injuries from externally applied pressures, it would seem that pressures should be not greater than those needed to produce the desired therapeutic result.

Conclusion

Pressures applied during lymphedema treatment remain an area of interest in part because the success of MLD, a mainstay of lymphedema therapy, is conceptually and physiologically rooted in precise application of manual pressure techniques. For the first time, pressure profiles of 2 sequential compression devices have been evaluated with a specific goal of measuring pressures applied to target tissue. Significant differences between devices in applied pressure timing and pattern have been clearly identified. In addition, significant differences in pressures delivered by the devices were evident when pressures for the FT device were set as recommended by the manufacturer and when pressures for the LP device were set as commonly used. This information provides a quantitative basis that clinicians can use to choose a device for the management of lymphedema. Further research to better define the delivered pressure over a wider range of pressure settings would be useful.

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