Unanticipated Variations Between Expected and Delivered Pneumatic Compression Therapy After Elective Hip Surgery

A Possible Source of Variation in Reported Patient Outcomes

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Abstract: The differences between the pneumatic compression thromboprophylaxis delivered after elective total hip arthroplasties and that was expected were quantified before (49 patients) and after a concerted nursing education program (30 patients) that was designed to ensure maximum compliance and to verify the correct application of the devices. The expected therapy was not delivered to any of the patients monitored. Therapy was delivered only an average of 77.8% of the time during the expected treatment periods. During 99.9% of the expected therapy times, values of key outcomes-related parameters of the therapy delivered to the patients varied by >10% from expected values. These variations were not reduced significantly by medical and nursing education. This variation may be a significant confounding factor in comparatively evaluating thromboembolic disease outcome reports. **Key words:** prophylaxis, deep venous thrombosis, pulmonary embolism, sequential compression, pressure, education.

The provision of prophylaxis against deep venous thrombosis (DVT) and pulmonary embolism (PE) generates considerable debate. In particular, the incidence of fatal PE seems to be changing with time and appears to have been overestimated in the past [1–9]. The overall death rate after total hip arthroplasty (THA) in the European literature is approximately 1% [7,8,10–14] and is an important figure to consider when prophylaxis as pharmacologic methods introduced to decrease the fatal PE rate might increase the death rate from other causes [10,15,16].

The complex balance between the risks and benefits of pharmacologic prophylaxis make other, lower-risk methods of prophylaxis attractive. Pneumatic compression therapy overcomes venous stasis and has a beneficial effect on the fibrinolytic and the coagulation pathways [17–19]. It does not share the hemorrhagic or bleeding complications of pharmacologic prophylaxis [20,21] and should have no

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other inherent risks [22]. The rare reported complications of pneumatic compression therapy have been related to inappropriate use and to device malfunction [23,24].

Many studies support the use of pneumatic limb compression [21,25–29]. After THA, the most commonly used devices are sequential compression (SC) systems, with sleeves with multiple pneumatic chambers positioned along both lower limbs, and intermittent compression (IC) systems, with sleeves with one pneumatic chamber positioned either on the feet or on the lower legs. In some of these studies [26,29], some parameters of the pressure waveforms generated by the pneumatic pressure control devices were given, but the pressure waveforms delivered to the patients by the sleeves over the prescribed period of therapy were not monitored.

The identification of the best mechanical prophylaxis method and the best way to use it may lead to the optimal means of prophylaxis [9,30,31]. To maximize the potential of SC therapy, it is important to identify the variations between the delivered and expected values of key parameters of the pressure waveforms shown in the clinical literature to affect patient outcomes. This study focused on monitoring key parameters of pneumatic limb compression therapy as it was delivered, with the long-term objective of determining how to optimize the delivered therapy and produce the best method of prophylaxis. These parameters included the onset of application of the compression devices along with their actual duration of use as well as the peak pressure generated and the rate of rise of the pressure waveform. In the first phase of the study, the extent of any variations between the expected and delivered values of key outcomes-related parameters of SC therapy generated by a commonly applied device was measured. In the second phase of the study, we attempted to determine the extent to which a concerted nursing education program might reduce variations between expected and delivered therapy.

Patients and Methods

This study was performed in the Division of Reconstructive Orthopaedics at a large teaching hospital. Ethical approval was obtained for the study from the University Clinical Research Ethics Board and the Hospital Research Advisory Committee. Patients were recruited prospectively at random from the population of patients undergoing elective primary or revision THA in the hospital under the care of 1 of 4 orthopaedic surgeons with a major interest in lower limb arthroplasty. Forty-nine patients were entered into the first phase of the study and 30 into the second phase. Informed written consent for inclusion in the study was obtained.

A standard departmental protocol for elective THA was followed for the duration of the study. As part of this protocol, all patients are given pharmacologic and pneumatic SC therapies for the prevention of DVT and PE. Thromboembolic disease stockings were not used in this study. Warfarin is administered on a weight-based protocol on the morning of surgery and continued until discharge from the hospital. For patients weighing <50 kg, the initial warfarin dose was 7.5 mg, and for patients weighing ≥ 50 kg, the initial dose was 10 mg. The target range for the international normalized ratio for this period is 1.6 to 2.3, and subsequent doses are adjusted according to a standard protocol. SC therapy is prescribed for the entire postoperative period until discharge from the hospital. SC therapy was started at the discretion of the recovery nursing staff, then continued on the ward. The pneumatic compression sleeves were identical to sleeves used on nonstudy patients, and the only visible difference was in the recording apparatus that was hidden at the foot of the bed in study patients.

The SC systems used in the study were the Kendall Model 6325 and Model 5325 SCD pneumatic pressure control devices connected to 2 full-leg, thigh-high Model 5330 plastic sleeves (Kendall Company, Mansfield, MA). The Model 5325 is no longer manufactured, having been replaced by the Model 6325, but the performance specifications published by the manufacturer for both devices are identical. Each sleeve incorporates 3 pneumatic chambers that are connected individually to the SCD pneumatic pressure control device: The first chamber is intended to be located over the ankle and lower calf; the second chamber, over the upper calf; and the third chamber, over the thigh. Clinicians' expectations about key parameters of the pressure waveforms produced by the SC systems used in the study were based partly on information supplied by the manufacturer [32–34], partly on clinical literature cited by the designer [35], and partly on other clinical and technical literature on the subject [25,28,36,37].

The expectation was that SC therapy should start as soon as possible after surgery, ideally within 1 hour in the postanesthetic recovery room, and should continue until the patient is discharged from the hospital. During that period, it was expected that SC therapy could be discontinued whenever the patient was ambulant or undergoing specific treatment, such as physiotherapy; dressing changes; or investigations. It was expected that any single

interruption of SC therapy should not be >2 hours and that the total time resulting from interruptions of SC therapy should not be >10% in the early postoperative period and not be >20% in the later postoperative period. The patient would be expected to receive at least 21 hours of therapy in each of the first 2 days after surgery and at least 19 hours/d each subsequent day. It was also expected that the operated and unoperated limbs should be subjected to the same pressure waveforms and that the maximum pressures and rate of pressure rise of the pressure waveform should not vary by >10% from the values of the parameters given in literature supplied or cited by the manufacturer. Ten percent was arbitrarily chosen as a reasonable variation because we were able to achieve this small degree of variation in testing on volunteers under idealized circumstances.

The following specific variables were included in the study because of their suggested effect on patient outcomes regarding the incidence of DVT, PE, and death: delay from surgery to the onset of therapy [28,38,39], number and duration of any interruptions in therapy after its onset [22,30,40], total cumulative time during which pneumatic pressure waveforms were delivered [22,30,41], maximum values of the delivered pressure waveforms [35,42,43], rates of rise of delivered pressure waveforms [35,42,43], and periods of delivery of unilateral limb therapy only [44–46]. Table 1 summarizes the information excerpted from manufacturer-related sources [32–35] about the expected values of key parameters of the pressure waveforms generated cyclically by the SC systems used in the study. There is good evidence that variations in the rate of pressure rise in the chambers of pneumatic sleeves produce variations in peak venous blood flow velocities [35,42,43]. Higher rates of rise of pressure in the pressure waveforms delivered to patients are related to higher peak venous blood flow velocities and more effective DVT prophylaxis [42].

Table 1. Values of Key Parameters of Pressure Waveforms Generated by the Systems Used in the Study*

Parameter of Pressure Waveforms	Expected Value of Parameter From Manufacturer and Literature
Maximum pressure (mm Hg)	
In ankle chamber of sleeve	45
In calf chamber of sleeve	40
In thigh chamber of sleeve	27
Rate of pressure rise (mm Hg/s)	
In ankle chamber of sleeve	13.6
In calf chamber of sleeve	9.7
In thigh chamber of sleeve	4.8
Cycle time (s)	
Total duration of 1 pressure waveform cycle	71
Pressure rise/inflation portion of cycle	11
Pressure decrease/deflation portion of cycle	60

*As stated in information from the system manufacturer and in clinical literature cited by the manufacturer.

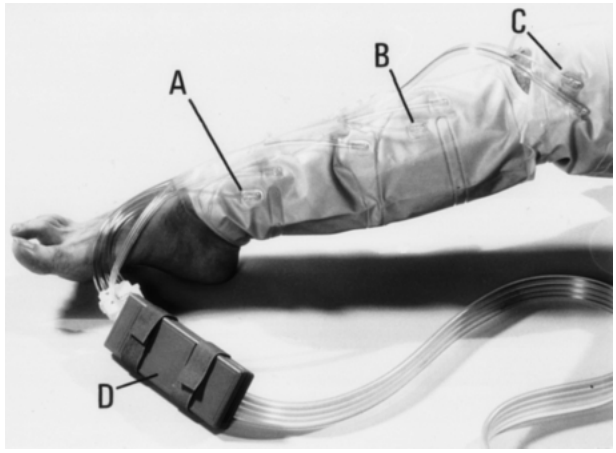

Fig. 1. Apparatus used to monitor the pressure waveforms delivered to patients by each 3-chamber sleeve of a Kendall SCD sequential pneumatic compression system. Shown are the extra monitoring ports added to each of the ankle (A), calf (B), and thigh (C) chambers of the sleeve, together with extra tubing connecting each of these monitoring ports to the therapy monitor (D). One therapy monitor was attached to each of 2 sleeves attached to the legs of each patient enrolled in the study to monitor key parameters of the delivered pressure waveforms over a 5-day period of prescribed therapy.

To monitor and record the maximum pressures and rate of pressure rise delivered in all 3 chambers of the SC sleeves, 3 additional pressure monitoring ports were added to each sleeve (Fig. 1). A new set of modified sleeves was made and used for each patient enrolled in the study. The addition of these monitoring ports in the modified sleeves enabled direct monitoring of the pressures produced in each of the ankle, calf, and thigh chambers of each sleeve and delivered to the limb beneath each chamber during therapy. The miniature therapy monitors (Fig. 1) were capable of monitoring and recording pressure waveform data continuously from each of the 3 sleeve chambers at 15 Hz [47]. The small size of the therapy monitors (6 cm × 18 cm × 2.5 cm) allowed them to be positioned on the tubing normally connecting the sleeves to the pressure con-

troller unit, with minimal physical interference. The uncertainty in the pressure measurements owing to the pressure transducers and the sampling rate was tested at the start of the study and was determined to be ±1 mm Hg for measurement of pressure values and ±0.3 mm Hg/s for measurement of rate of pressure rise in each pressure waveform. Each monitor was calibrated thoroughly and tested by technical staff before each connection to a sleeve for therapy monitoring, and the testing included pressure checks at ambient room pressure and at 50 mm Hg. The SC devices were not tested on control subjects to simulate ideal conditions.

At the time of discharge of each patient from the hospital, each associated set of 2 therapy monitors was retrieved, and all recorded data in the monitors were downloaded into a computer for subsequent analysis. Data analysis for all patients was completed using only the data from the first 120 hours of expected SC therapy to provide a standardized basis of analysis and comparison between patients. In the analysis, the pressure data for each patient first were scanned by computer to identify all the pressure cycles delivered to the patient during the expected period of SC therapy. The time and duration of interruptions in SC therapy also were identified. Observed interruptions in therapy <0.1 hour (6 minutes) were not counted as actual interruptions in the analysis.

From each compression cycle monitored and recorded, the values of 3 parameters of the delivered pressure waveform were derived: i) time-stamp data, from which the time at which the cycle was delivered could be determined, ii) the maximum pressure produced within each chamber of each sleeve during the cycle, and iii) the rate of pressure rise produced within each chamber during the cycle. Using all derived values for the maximum pressures and the rate of pressure rise, the maximum pressure in each chamber and the rate of pressure rise in each chamber were averaged from all the pressure cycles delivered to each patient.

Tests were done in which the same parameters of the delivered pressure waveform were derived under idealized conditions: It was determined that the manufacturer's specifications generally could be achieved to within 10% by monitoring delivered pressure cycles and by having 1 of the authors, an experienced biomedical engineer (J.A.M.), iteratively reapply and adjust the sleeves on the limbs of volunteer subjects using feedback from the monitored pressure cycles.

All pressure cycles delivered to all patients were scanned to count the number of cycles that the maximum pressures and rates of pressure rise delivered varied by <10% from the expected maximum pressures and rates of pressure rise shown in Table 1. Pressure data were scanned for comparisons of pressures in the ankle, calf, and thigh chambers separately as well as for comparisons of pressures in all 3 chambers simultaneously (ie, for cycles in which all 3 chambers varied simultaneously by <10% from the expected maximum pressures). The scanning process was repeated twice: to allow for variations of 20% between expected and delivered values and to allow for variations of 30% between expected and delivered values. Using the time-stamp data recorded by the therapy monitors, along with the times for the start and duration of surgery and the ward arrival time obtained from patient records, the following data were derived: i) the delay from surgery to the start of SC therapy, ii) duration of SC therapy (calculated as the total duration of monitored therapy minus the total duration of detected interruptions), and iii) the average and longest interruptions during SC therapy.

The same protocols and procedures were followed in the second phase of the study after a period of concentrated institutional and manufacturer-based nursing education on the wards and in the postanesthetic recovery rooms. This education comprised supplementary training, in groups and individually, led by a clinical nurse specialist and approved by the manufacturer's representative, in the correct use of the SC devices and sleeves. This training included a 15-minute presentation with pictorial material and a handout, which the nurses were encouraged to keep for later reference. A detailed patient care guideline describing the correct use of the SC devices and sleeves was drawn up to supplement the standard protocol. This procedure included a statement that the SC devices and sleeves should be applied as soon as possible after patients left the operating room. The manufacturer's representative reviewed the educational data supplied to the nursing staff and approved them. Standardization in service staff training was undertaken before and during the study period as per the representative's standard practice. Key written instructions were posted on the unit for the duration of the study. During the study period, the clinical nurse specialist was available on a 1-on-1 basis to discuss any patient or nursing queries and to ensure that the protocol and supplementary procedure were being followed correctly. The authors were available to address any technical problems.

All statistical analyses were performed using SSPS for MacIntosh. The primary outcome measure analyzed was the duration of the longest interrup-

Table 2. Patient Characteristics in the 2 Phases of the Study

	Phase 1	Phase 2	*P* Value	Statistical Test
No.	49	30		
Sex*	17 M, 32 F	10 M, 20 F	.90	Chi-square
Age*	61.7 ± 15.5 y (range, 24–90 y)	60.0 ± 16.2 y (range, 21–83 y)	.64	Student's *t*-test
Weight*	73.7 ± 16.6 kg (range, 34–122 kg)	71.7 ± 14.3 kg (range, 52–111 kg)	.59	Student's *t*-test
Intervention*	40 primary THA 9 revision THA	20 primary THA 10 revision THA	.22	Chi-square

*$P > .05$.
THA, total hip arthroplasty.

tion of therapy. To determine the number of patients required for the second phase of the study, a power analysis was performed for a 1-tailed *t*-test, with α set at 0.05 and β at 0.2 (power = .80). A 1-tailed *t*-test was used because nursing education had to improve the outcome for it to be effective. Based on this power analysis, it was determined that a sample size of 22 patients would be sufficient to test whether a 50% reduction in the duration of longest interruption of therapy could be achieved as a result of a concerted staff educational program.

Results

Data from 49 patients were used in the primary analysis and from a further 30 patients in the second phase of the study to assess the effects of nursing education. There were no significant differences between the 2 groups. The basic demographics and characteristics of the 2 groups are summarized in Table 2. The analysis showed that during the first phase of the study, the mean and SD of the delay between the end of surgery and the start of SC therapy was 5.2 ± 2.1 hours (range in individual subjects, 2.3–12.2 hours). Interruptions of therapy reduced the duration of therapy to 78% ± 17% of the expected therapy time. The average duration of therapy was 67 ± 28 hours (range, 5.1–107.0 hours), the average interruption of therapy was 3.6 ± 3.0 hours (range, 0.0–15.9 hours), and the longest interruption of therapy for each patient averaged 9.3 ± 8.6 hours (range, 0.0–39.6 hours). Of the 49 patients in the first phase of the study, 19 had at least 1 interruption in SC therapy lasting >10 hours. Comparative data between the 2 phases of the study are summarized in Table 3. The primary key parameter in our analysis was the duration of the longest interruption. This duration averaged 10.1 ± 11.6 hours (range, 0.7–40.0 hours) and showed no statistically significant effect of nursing education ($P = .64$).

A further analysis of the time-related data compared interruptions during the first 48 hours of therapy with interruptions after the first 48 hours. The percentage of time that interruptions occurred increased as the postoperative period progressed: 16.3% ± 15.5% during the first 48 hours and 30.3% ± 20.3% after 48 hours. The duration of the average interruption increased from 2.7 ± 3.1 hours during the first 48 hours to 4.3 ± 4.3 hours after the first 48 hours of therapy. This finding was reflected in the data from both phases of the study. Throughout the study, there were no recorded instances when SC therapy was delivered to only 1 limb for a duration >10 minutes, the approximate time required to attach sleeves to limbs, and there was no notable difference in the values of pressure-related parameters delivered to operative and nonoperative limbs, as described and summarized subsequently.

Table 3. Duration of Therapy and Interruptions in the 2 Phases of the Study

	Phase 1	Phase 2
Total duration of therapy	67 ± 28 h (range, 5.1–107.0 h)	72.7 ± 23.2 h (range, 41.2–105 h)
Duration of therapy, as percentage of time from start to finish	78% ± 17%	80.6% ± 14.0%
Duration of average interruption	3.6 ± 3.0 h (range, 0.0–15.9 h)	2.6 ± 2.7 h (range, 0.4–12.8 h)
Duration of longest interruption	9.3 ± 8.6 h (range, 0.0–39.6 h)	10.1 ± 11.6 h (range, 0.7–40.0 h)

Table 4. Some Key Parameters of Sequential Compression Therapy

	Manufacturer's Parameters	Phase 1	Phase 2	*P* Value (Student's *t*-test)*
Average maximum pressure (mm Hg)				
Ankle	45	43.4 ± 4.7	44.9 ± 6.3	.23
Calf	40	39.3 ± 3.0	38.7 ± 5.2	.52
Thigh	27	20.0 ± 3.0	18.9 ± 4.1	.17
Average rate of pressure rise (mm Hg/s)				
Ankle	13.6	12.6 ± 3.6	8.5 ± 4.5	<.001
Calf	9.7	5.9 ± 1.3	5.2 ± 2.8	.14
Thigh	4.8	3.3 ± 1.2	3.9 ± 5.2	.44
Percentage of channels within 10% of expected values for maximum pressure				
Ankle	100	76.9	45.5	.004
Calf	100	80.7	67.1	.19
Thigh	100	14.9	9.8	.49
Percentage of channels within 10% of expected values for rate of pressure rise				
Ankle	100	26.4	4.6	.003
Calf	100	8.5	1.0	.09
Thigh	100	3.7	11.2	.24

*Comparing phase 1 and phase 2 results.

The average values of the maximum pressure and rate of pressure rise of the pressure waveforms monitored in all ankle, calf, and thigh chambers are summarized in Table 4. The maximum pressures in all chambers of the sleeves were within 10% of the expected values during only 9.9% of the overall SC therapy time (Fig. 2). The rates of pressure rise in all chambers of the sleeves were within 10% of the expected values during only 0.1% of the overall SC therapy time (Fig. 3). Consequently, both parameters of the pressure waveform were simultaneously within 10% of the expected values in all chambers of the sleeves only 0.1% of the time (Fig. 4). If variations of 30% between delivered and expected values were considered to be clinically acceptable, variations >30% occurred during 94.7% of periods during which delivered SC therapy was monitored in the study (Fig. 4). In Fig. 4, the expected maximum pressure generated and the rate of pressure rise are compared with the average maximum pressure and average pressure rise seen in these patients. The function of these devices depends on a regular cyclic pattern to maintain venous blood flow. A few inadequate cycles cannot be compensated for by a cycle that generates pressures above what is expected, and comparing averages may be misleading.

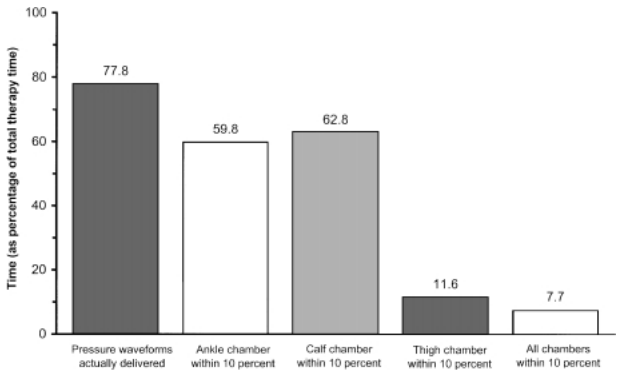

Fig. 2. Percentage of time that the maximum pressures of the pressure waveforms delivered to 49 patients during 5-day periods of therapy varied by <10% from the expected maximum pressures.

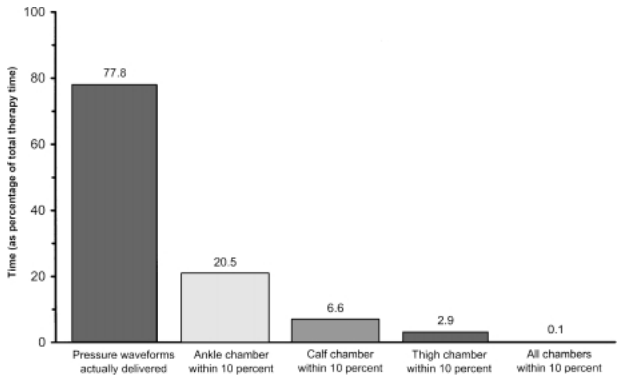

Fig. 3. Percentage of time that the *rate of pressure rise* of the pressure waveforms delivered to 49 patients during 5-day periods of therapy varied by <10% from the expected rate of pressure rise.

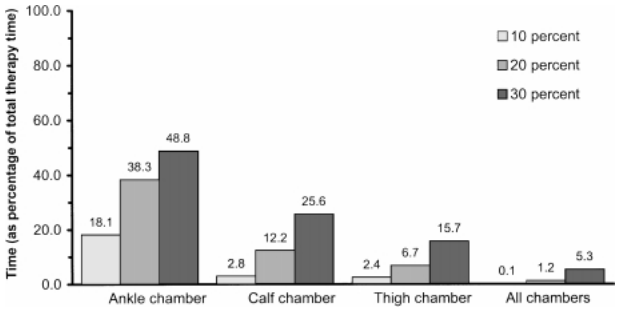

Fig. 4. Percentage of time that both values of 2 key parameters (maximum pressure and rate of pressure rise) of the pressure waveforms delivered to patients varied from the expected values by <10%, <20%, and <30%. The data were collected from 49 orthopaedic patients over 5-day periods of prescribed pneumatic compression therapy after hip arthroplasty surgery. □, 10%; ▨, 20%; ■, 30%.

Discussion

To the best of our knowledge, this is the first study to monitor the pneumatic compression therapy delivered to patients throughout the prescribed period of therapy. Only 4 previous studies assessed the parameters of delivered pneumatic compression therapy to any extent. The methodology of these studies varied widely: One reported intermittent nursing checks of operation [22], and the others reported only cumulative periods of therapy [29,30,41]. The wide and unanticipated variations that were found in this study as a result of continuous monitoring suggest that such detailed monitoring should be performed routinely and reported in the future as part of any study in which parameters of pneumatic compression therapy are compared with other forms of DVT prophylaxis or related to the patient outcomes, including the incidence of DVT, PE, and death. In any such comparative studies, if such detailed monitoring is not performed routinely and the consistency of delivered pressure therapy is not known, the validity of any conclusions may be questioned.

Detailed monitoring of the prescribed periods of therapy may provide orthopaedic surgeons and hospital staff with a sensitive tool to improve compliance with protocols and clinical practice guidelines aimed at the prevention of DVT and PE and the improvement of patient outcomes. Such monitoring would help to ensure that sleeves are applied correctly and consistently to reduce variations in the delivered therapy [48]. We anticipate that these improvements are possible because it was confirmed in the study that the manufacturer's specifications could be achieved to within 10% by monitoring delivered pressure cycles and by iteratively reapplying and adjusting the sleeves using feedback from the monitored pressure cycles.

Patient compliance and nursing compliance with mechanical prophylaxis methods contribute to difficulties with the implementation of these methods. In a prospective randomized comparison of the use of foot pumps or low-molecular-weight heparin in the prevention of DVT after THA, an internal compliance meter was used in 124 patients to assess patient compliance [49]. The investigators found that the pumps were used for a mean total of 101 hours (60% of the time) during the first 7 postoperative days. These investigators ascribed this finding to poor patient tolerance of the device. In a prospective study by Comerota et al [22], the Kendall model 3520 SC device was applied and functioning properly only 48% of the time on routine nursing units. In 15% of these cases (50 of 330), the sleeves were applied, but the pump was not functional. Nursing education programs did not increase the proper application and use of these devices. Comerota et al [22] attribute this problem partly to patient discomfort or annoyance with the SC devices. Our results reinforce their finding that nursing education does not improve the overall duration of therapy. We also have shown that education and reinforcement do not improve the performance of SC devices with reference to the key parameters assessed. We believe this lack of improvement is because these key parameters primarily depend on the design of the SC devices and sleeves and not on education and vigilance and because the SC devices do not provide meaningful audiovisual feedback to staff with respect to these key parameters.

We have shown that the expected SC therapy was not delivered to any of the 79 subjects monitored. In the first phase of the study, SC therapy was delivered only an average of 77.8% of the time during the prescribed 5-day periods of therapy, and the longest interruptions of SC therapy in individual subjects averaged 9.3 hours. During 99.9% of the prescribed therapy times for all the subjects in the study, values of key parameters of the pressure waveforms delivered to the patients varied by >10% from expected values. These findings were not improved by nursing and paramedical education.

The variations found within individual patients may be just as important. The delay from surgery to the application of the SC devices was 2.3 to 12.2 hours, with interruptions of SC therapy in individual subjects ranging from 0.0 and 39.6 hours, and the duration of therapy lasting between 5.1 hours

and 107.0 hours (or 17.1%–100% of the total therapy time). Similarly, wide variations were found within individual subjects for the maximum pressures and rates of pressure rise in the pneumatic pressure waveforms delivered.

The increase in the average duration of interruptions after the first 48 hours of therapy was seen throughout the study and probably is indicative of longer periods of patient mobilization, but it also may reflect increasing patient dissatisfaction or annoyance with the SC device. After THA, patients in this institution are transported to and from a central rehabilitation facility that is off the inpatient unit. With more aggressive mobilization, the patients tend to spend more time in bed awaiting transport to and from the rehabilitation facility—hence the longer interruptions. Had the patients been completely mobile during these interruptions, it would have been less important to measure and document these interruptions. Patients are not as mobile as one might have hoped otherwise because they are discharged as soon as they can mobilize without assistance. Because the importance of the application of these devices throughout the inpatient stay was stressed strongly to the nursing staff and the physiotherapists before the second phase of the study, these interruptions are unlikely to represent a lack of compliance based on nursing advice.

Although the variations in the therapy delivered by only 1 type of SC system were studied, variations are likely to occur in the therapy delivered by other types of SC and IC systems, and this possibility is being studied currently. In view of our results and their implications, manufacturers of systems for SC and IC therapy may wish to consider adapting the design of existing SC and IC systems to incorporate direct monitoring of therapy as was done in this study or designing new SC and IC systems with integral monitoring of the key parameters identified in the literature as affecting patient outcomes. If such expanded monitoring shows that variations in the values of key parameters of SC therapy cannot be maintained within clinically desirable limits over the duration of therapy in individual patients and among patients, the claimed benefits of SC therapy relative to simpler and lower-cost forms of pneumatic compression therapy, such as single-chamber IC therapy, may be questioned and re-examined.

This study was designed to determine the variation between the expected and observed parameters of SC therapy. It was not our intention to assess physiologic indices, such as femoral vein blood flow, or clinical outcomes, such as the rate of DVT, PE, or sudden death, in this cohort. There is, to our knowledge, no clearly documented quantifiable relationship between the key parameters studied and clinical outcome measures. It is these same parameters, however, that underlie the basis for the design of this type of therapy, and we can hypothesize that the failure of the therapy to meet expected values implies that it is not providing optimal prophylaxis. A large-scale clinical outcome study that includes measurements of the key parameters defined in this study, preferably in comparison with a group in which a feedback loop or warning device ensures that expected values are reached, is necessary to determine the importance of achieving the key parameters of SC therapy. Having said that, there were no cases of symptomatic DVT, PE, or sudden death in our patient cohort. We did not screen for asymptomatic DVT, however, because this was not a part of the study protocol and is not our routine clinical practice.

The key parameters of pneumatic compression therapy include the delay to onset of therapy, the duration of therapy, the timing and duration of interruptions of therapy, the maximum pressure of pneumatic pressure waveforms, and the rate of pressure rise in pneumatic pressure waveforms. These have all been shown in the clinical literature to affect the incidence of DVT and PE [27–29,35–37,40,46]. The unanticipated magnitude of variations between expected and delivered pneumatic compression therapy, within individual subjects and among all subjects, may be an important source of variations in patient outcomes with regard to the incidence of DVT, PE, and death. This may be an important confounding variable in comparatively evaluating reports of such patient outcomes. The variation between the delivered and anticipated pressure waves within the thigh, calf, and ankle chambers probably is related to the accuracy of the fit of the sleeves on the patients' extremities, with the most variability occurring in the thigh, followed by the calf and the ankle. This variability probably accounts for the better results in the ankle compartment, followed by the calf and the thigh compartments.

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