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Can a new design of pneumatic compression device reduce variations in delivered therapy for the mechanical prophylaxis of thromboembolic disease after total hip arthroplasty?

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Background: Compression devices have been shown to prevent thromboembolic disease. However, the pressures generated may not be the same as the ones recommended by the manufacturer. The purpose of this study is to investigate a new sequential compression device with feedback to maintain optimal therapy, and to determine whether therapy is improved with this new device. **Patients and method:** A series of 50 patients undergoing elective total hip arthroplasty at a major tertiary-care hospital with a special interest in joint replacement were enrolled prospectively. In addition to pharmacological prophylaxis for thromboembolic disease, all patients received compression from a modified device. Maximum pressures generated and the rate of pressure rise in each of the 3 compartments within the device sleeves were measured and the results compared with data from historical controls. **Results:** We considered therapy to be ideal when in a particular compression cycle all chambers of both right and left sleeves reach within 10% of their target pressures at within 10% of their target pressure rise rates. The average patient received this ideal therapy 88% of the time that the new trial sequential compression device was operating. This represents a dramatic improvement over previous devices. **Conclusions:** The new device allows dramatically improved pressures within the device because of a feedback loop that allows dynamic control of each chamber's pressure. Improved consistency of delivery should make it easier to accurately assess the true benefits of mechanical prophylaxis with a sequential compression device.

Contexte : Il est prouvé que les dispositifs de compression préviennent la thromboembolie. Les pressions produites peuvent toutefois différer de celles que recommande le fabricant. Cette étude vise à analyser un nouveau dispositif de compression séquentielle avec rétroaction pour maintenir la thérapie à son niveau optimal et à déterminer si ce nouveau dispositif améliore le traitement. **Patients et méthode :** On a inscrit de façon prospective une série de 50 patients subissant une arthroplastie totale de la hanche élective à un grand hôpital de soins tertiaires qui s'intéresse spécialement à l'arthroplastie. Outre la prophylaxie pharmacologique contre la thromboembolie, tous les patients ont été soumis à une compression au moyen d'un dispositif modifié. On a mesuré les pressions maximales produites et le taux de montée de la pression à l'intérieur de chacun des compartiments du dispositif, y compris les résultats comparés aux données provenant de témoins historiques. **Résultats :** Nous avons considéré que la thérapie est idéale lorsqu'au cours d'un cycle précis de compression, la pression à l'intérieur de tous les compartiments des deux côtés se situe en deçà de 10 % de la pression visée et en deçà de 10 % de la vitesse cible de hausse de pression. Le patient moyen a reçu cette thérapie idéale 88 % du temps pendant lequel le nouveau dispositif de compression séquentielle à l'essai fonctionnait. Ces données représentent une amélioration spectaculaire par rapport aux dispositifs précédents. **Conclusions :** Le nouveau dispositif permet d'augmenter de façon spectaculaire les pressions à l'intérieur du dispositif à cause d'une boucle de rétroaction qui permet d'assurer le contrôle dynamique de la pression à l'intérieur de chaque compartiment. L'uniformité améliorée de la pression produite devrait aider à évaluer avec exactitude les avantages réels de la prophylaxie mécanique au moyen d'un dispositif à compression séquentielle.

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Thromboembolic prophylaxis after total hip arthroplasty (THA) remains a controversial area. Pharmacological agents are widely used but have their own inherent risks, which need to be balanced against their benefits. It has even been suggested in 2 large meta-analyses[1,2] that no significant benefit in overall death rate was seen with any of the prophylactic agents studied. While pharmacologic methods continue to be considered as the criterion standard for prophylaxis in many centres, mechanical prophylaxis with pneumatic compression also exists as an alternative or adjunctive treatment. Pneumatic compression has been shown to be both effective and efficacious for prophylaxis of thromboembolism after major surgery.[3–11]

Pneumatic compression therapy can be intermittent or sequential. In intermittent compression, 1 or more inflatable chambers applied to the limb inflate and deflate simultaneously at regular intervals. In sequential compression, multiple chambers inflate in a distal-to-proximal sequence, with normally a pressure gradient from higher at the distal chambers to lower at the proximal chambers.

Although mechanical prophylaxis avoids the increased hemorrhagic risks associated with pharmacological agents,[12] these methods have been associated with complications resulting from device malfunction or inappropriate use. Such complications have included compartment syndrome (from problems with pressure control),[13] skin ulceration, blistering, common peroneal nerve palsy and increased intraoperative blood loss.[14–16] It is therefore important that the pressure delivered is accurately and reliably controlled.

The purpose of this study was to determine if a new device could deliver a more reliable and consistent sequential compression therapy than a widely used and previously reported system.[17] Improved consistency of delivery should make it easier to assess accurately the benefits of mechanical prophylaxis using a sequential compression device.

Patients and methods

Ethics approval was obtained from the university clinical research ethics board and the hospital research advisory committee. On the basis of previous work, we determined that a sample size of 50 patients was required for this study. Fifty-three patients undergoing elective primary or revision THA (roughly a quarter of those at our centre during the study period) were approached at random and prospectively recruited; those who agreed were entered into the study with informed written consent.

At the time, the standard departmental protocol[17] for thromboembolic prophylaxis included both warfarin and mechanical therapy using a 3-chamber (ankle, leg and thigh) thigh-high sequential compression device applied to both lower limbs (Model 5330, Kendall Company, Mansfield, Mass.). An initial dose of 7.5–10 mg of warfarin, based on the weight of the patient, was administered 90 minutes before surgery, with subsequent doses adjusted to achieve a target international normalized ratio (INR) of 1.6–2.3. Sequential pneumatic compression was applied via thigh-length compression sleeves postoperatively until discharge from hospital.

A new sequential compression device was developed at the study centre in an effort to correct the variations in pressure waveform delivery found in our previous study.[17] This device uses a dedicated pressure-monitoring line and flow-control valve for each individual chamber, providing a feedback loop allowing dynamic control of each chamber's pressure and rate of pressure rise during each cycle. This enables accurate and precise delivery of a predetermined pressure waveform under changing conditions (such as compression sleeve snugness and position on the limb) during therapy.[18]

The new device was used for the initial 48-hour period following surgery, after which it was exchanged for a traditional compression device (Kendall SCD models 5325 and 6325, Kendall Healthcare, Mansfield, Mass.). This allowed data collection for the first 2 days, during which time patients are least ambulatory.

Table 1 shows the average maximum pressure expected in each of the 3 chambers, the average rate of pressure rise for the 3 chambers, and the cycle time specified in the manufacturer's literature for the pneumatic pressure-control devices normally used in the department (Kendall SCD models 5325 and 6325).[19,20] The new device was programmed to deliver these same waveforms.

Equipped with an internal data recorder, this experimental device is capable of monitoring and recording pressure-waveform data from each of the 3 sleeve chambers, at a rate of 15 Hz.[21] Accuracy for the pressure measurements had previously been calculated at ± 1 mm Hg for pressure values and ± 0.3 mm Hg/s for rate of pressure rise in each pressure waveform.[17] The recorders were calibrated and tested by the technical staff including pressure checks at ambient room pressure and 50 mm Hg before use.

After about 48 hours of therapy, data recorded for each patient were downloaded into a computer for analysis, and the recorder was recalibrated and retested before being used again. Data were analyzed by identifying all delivered pressure cycles and subsequently recording, from each pressure waveform, the time at which the cycle was delivered and the maximum pressure and rate of pressure rise within each individual chamber.

The primary outcome measure used, upon which a sample size calculation was made, was a variation of < 10% from the expected maximum pressures; a secondary outcome measure was variation of < 10% from the

expected rate of pressure rise (both according to manufacturer's data, shown in Table 1). This was compared using Student's *t* test to data from recent work from our department to provide a historical control.[17] The percentage of recorded waveforms with both pressure and rate of rise simultaneously within 10%, 20% and 30% of target values in all chambers for both limbs was calculated for each patient. The average percentages across all patients were then calculated to represent the quality of therapy the average patient could expect.

An "interruption" in therapy was defined as a gap 5 minutes or longer in the data, indicating that the sequential-compression device was turned off. It is obviously important to know if the device still functions accurately after sleeves are reapplied, to demonstrate its robustness in the normal clinical environment. To determine if the quality of therapy changes over such an interruption, the half-hour periods before and after each interruption were compared (paired *t* test, 2-tailed). Note that the half-hour before and after periods must be uninterrupted; interruptions occurring within half an hour of another or within half an hour of the beginning or end of therapy could therefore not be analyzed.

Conversely, it is also important to determine if the quality of therapy changes during long unattended periods, to ensure that the sleeves do not need frequent adjusting for optimal results. To look at this, the first and last hours of each patient's longest uninterrupted period of therapy were compared (paired *t* test, 2-tailed), and the last hour was also compared with the patient's overall result (paired *t* test, 2-tailed).

Patient tolerance was subjectively assessed with a questionnaire they filled in. They were asked to report on a 5-point scale on the levels of discomfort, inconvenience, and disruption to sleep that they experienced, and their willingness to wear the device again if undergoing a similar surgery.

Table 1

Manufacturers' recommended average values for Kendall SCD model 5325 and 6325 pneumatic pressure–control devices

Pressure waveform parameter	Value
Maximum pressure, mm Hg	
Ankle chamber	45
Calf chamber	40
Thigh chamber	27
Rate of pressure rise, mm Hg/s	
Ankle chamber	13.6
Calf chamber	9.7
Thigh chamber	4.8
Total duration of 1 cycle, s	71
Inflation portion of cycle	11
Deflation portion of cycle	60

Information taken from Kendall Healthcare Products Company's *Operation and service manuals*, model 5325 (1994) and model 6325 (1995). Mansfield, Mass.

Results

Among the 53 patients enrolled, no complications were noted related to use of compression devices. Two were withdrawn because of nursing shortages, which necessitated termination of the SCD therapy at 2.1 and 2.2 hours, respectively. Another patient was withdrawn when the data recorder failed. This left data from 50 patients for analysis, as required by our preoperative sample-size calculation. Patient demographics are summarized in Table 2.

The device was applied and data collected for an average of 46 hours (range 9–114, standard deviation [SD] 20.4 h); patients received therapy for an average of 82.7% of this time (range 18%–100%, SD 19.0%) or 36.6 hours (range 7.9–83.3 h, SD 14.5 h). This was similar to the overall proportion of therapy time in the controls in our previous study.[17] In the current study, 26 of 50 patients received therapy for longer than 90% of the monitored period; these people were monitored for an average of 38 hours (range 9–68 h, SD 14.3 h), indicating that the device is well tolerated by most patients for periods of up to 3 days.

For both limbs in each patient, an average of 3769 waveforms (range 812–8568, SD 1493) were recorded. Mean percentages of waveforms within 10%, 20% and 30% of the target values are shown in Table 3. The primary outcome measure of pressures achieved within 10% of expected values in all chambers was achieved for a mean of 97.7% of the cycles recorded.

The average number of interruptions longer than 5 minutes was 5 per patient (of the 23 patients) who had such an interruption of therapy (range 0–37 interruptions, SD 6), for a total for analysis of 116 interruptions with uninterrupted half-hour periods before and after. The mean duration of interruption was 2.4 hours (range 0.09–30.2 h, SD 4.8 h). On average, the difference in a patient's percentage of waveforms with pressure and rate errors < 10% between the half-hour before and the half-hour after an interruption was not significant (paired *t* test, 2-tailed, for 116 pairs, $p = 0.077$).

The average of the longest uninterrupted therapy periods in patients who had interruptions of therapy was 17.9 hours (range 4.5–43.2 h, SD 5.9 h). On average the difference in a patient's percentage of therapy with pressure and rate errors < 10% between the first and last hours of their longest uninterrupted therapy period was not significant (paired *t* test, 2-tailed, $p = 0.48$). Similarly, the difference between the last hour of the longest uninterrupted period for a patient and that patient's overall result was not significant (paired *t* test, 2-tailed, for 50 pairs, $p = 0.052$). This suggests that the device functions well for as long a period of time as is required, and it continues to function well even after interruptions.

Of the 53 patients entered into the study, 51 completed questionnaires assessing their subjective tolerance;

results are shown in Table 4. Forty-three patients (84%) said they would use the system again. The largest problem was sleep disruption caused by the noise of the new device. The noisiness was mainly due to the prototype nature of the device, which can be addressed with improved sound insulation in the future.

Discussion

The incidence of fatal pulmonary embolism (PE) appears to be less in more recent reports than older papers.[22] During the 1970s, fatal PE rates of 2.3%[23] and 3.4%[24] were reported in patients without prophylaxis. More recent single-centre series without routine pharmacological prophylaxis have reported lower fatal PE rates of 0.34%[25] and 0.38%,[26] whereas a regional hip register from the United Kingdom showed an 0.19% incidence of death from PE.[22] The reasons for this decrease are likely to be a combination of a true reduction due to current medical practice and a possible overestimate in the past.

Freedman and colleagues[2] performed a meta-analysis of thromboembolic prophylaxis in 10 929 patients after elective THA. This analysis demonstrated that compared with placebo, pneumatic compression significantly reduced the risk of distal and proximal deep-venous thrombosis (DVT) and symptomatic PE. Review of their data reveals that the 3 prophylactic agents with the lowest risks of distal or proximal DVT were low-molecular-weight heparin, pneumatic compression and warfarin. These were also the only 3 agents that significantly reduced the risk of symptomatic PE. Pneumatic compression was associated with the lowest risk for major-wound and total major bleeding. They concluded that the best prophylactic agent for efficacy and safety was warfarin, followed by pneumatic compression.

In the orthopedic literature the greatest attention is generally paid to the incidence of fatal PE. While it is not possible to extrapolate from a reduction in rate of DVT rate to that of fatal and nonfatal PE, thromboembolic disease has other serious sequelae, the avoidance of which has long-term importance for patients undergoing THR.[27] These include venous outflow obstruction in the lower limbs and (more chronically) postphlebitic or postthrombotic limb syndrome with venous hypertension, swelling, pain and sometimes ulceration. Postthrombotic syndrome has been estimated to occur within 5 years in 60%–70% of patients who develop a proximal DVT, and within 2 years in 16% of patients who develop a distal DVT.[28] If mechanical prophylaxis could safely reduce these local complications, it would be worthwhile in the long term even with no proven effect on the incidence of fatal PE.

The efficacy of pneumatic leg compression in significantly reducing the risk of DVT, if not the risk of PE, has been demonstrated previously. The first reductions in DVT rates were reported in general surgical patients and subsequently in urological and neurosurgical patients.[3–7] More recently, its efficacy in orthopedic patients has been proven in several studies[8–11] where the rate of DVT has been more than halved (50%–65% reductions, $p < 0.05$) in fractures of the hip or acetabulum and elective arthroplasty of the hip and knee. Significant reductions in DVT rate com-

Table 2

Current patient characteristics compared with historical control paper[17]

Characteristic	Current study	Control paper	*p* value	Test
Patients, no.	50	49	—	—
Men:women	20:30	17:32	0.44	χ^2
Mean age (and SD), yr	63.4 (6.4)	61.7 (15.5)	>0.50	*t*
Range	20–86	24–90		
Mean weight (and SD), kg	78.1 (18.0)	73.7 (16.6)	0.21	*t*
Range	43–123	34–122		
Type of total hip arthroplasty	19 primary 31 revision	40 primary 9 revision	<0.0001	χ^2
Mean length of interruption (SD), h	2.4 (4.8)	2.7* (3.1)	0.71	*t*
As % of monitored time (and SD)	17.3 (19.0)	16.3* (15.5)	0.78	

SD = standard deviation

*in the first 48 h of therapy

Table 3

Average quality of therapy delivered (*n* = 50) in percentage of waveforms delivered (with 95% confidence interval)

	All chambers within this % of expected value:		
	10%	20%	30%
Pressures	98 (97.5–98.8)	99 (98.7–99.2)	100 (99.9–100.1)
Rates	89 (87.7–90.9)	96 (95.4–96.8)	97 (96.6–97.6)
Both	88 (86.7–89.9)	95 (94.4–95.8)	97 (96.6–97.6)

Table 4

Results from 51 self-assessments on patients' tolerance of the new pressure–control device

Variable	None	Mild	Moderate	Severe	Intolerable
Discomfort	16	19	11	5	1
Inconvenience	20	18	9	4	0
Disruption to sleep	19	7	9	8	8

pared with controls or heparin have also been shown with intermittent pneumatic compression using foot pumps.[29,30]

The incidence of fatal PE, even in patients who received no prophylaxis, is very low, reported at 0.1%–0.2%.[1,2] This means that clinical studies to show a reduction in fatal PE are difficult because of the huge numbers of patients required. It has been calculated that a future randomized prospective trial to demonstrate a 50% reduction in the risk of fatal PE from 0.1% to 0.05% would require almost 100 000 patients.[2]

Data from the literature on the benefits of pneumatic compression devices need to be interpreted with care, as there are differences in patient tolerance and device design that can alter the therapy actually delivered. Foot pumps may only be worn for as little as 60% of the time, because of poor patient tolerance.[31] Noncompliance rates for thigh-length sequential compression devices are reported to be much lower (5%–6%),[8,11] but unavoidable breaks in therapy occur when the sleeves are removed for washing, nursing care or physiotherapy. Previous work from our department[17] has shown that thigh-length sequential compression appears to be well tolerated: therapy was delivered for 77.8% of the time during the first 5 postoperative days after THA. Unfortunately, although well tolerated, the pressures actually delivered were >10% less than expected for 99.9% of the time.

A great deal of work has already gone into identifying the ideal parameters for delivered pneumatic compression. Bioengineering studies on a simulated leg have been used to investigate the effects of external compression on 3 hemodynamic criteria: degree of vessel collapse, level of fluid velocity and level of shear stress.[32] This model had advantages with sequential and graded compression over uniform compression. The report also described how the wave speed and gradient of applied external pressure could alter key hemodynamic parameters. The authors concluded that a combination of sequential and graded compression might be the most effective means of mechanical prophylaxis against DVT.

In vivo studies have subsequently been performed to optimize indices of external pneumatic compression for prophylaxis against DVT.[33,34] In 10 volunteers, Nicolaides and associates[33] analyzed mean and peak blood-flow velocities, detected by Doppler ultrasound, in the femoral vein during sequential compression. They recommended pressures of 45, 40 and 25 mm Hg for the ankle, calf and thigh, respectively. They also recommended a decompression period of 1 minute, as they calculated that 45 seconds were required for the veins to refill, and thought that the fuller the veins were, the better activated clotting factors would be cleared from the soleal veins and axial valve pockets. Kamm and coauthors[34] monitored blood flow with radioactive labelling in 23 volunteers. For optimal performance they suggested a quicker rate of pressure rise and a sequencing time of 0.5 seconds, compared with Nicolaides' group's 1 second.

From this data, manufacturers have produced recommended values for the key pressure waveform parameters generated by pneumatic compression devices. Table 1 shows these parameters for the system currently used at our institution.[19,20] Although there is not yet any direct evidence to link accurate achievement of these parameters to a reduction in DVT rates, the *in vitro* and *in vivo* studies outlined suggest that reproducible achievement of these key parameters should optimize the hemodynamic factors important in resisting clot formation and propagation.

Previous work from our department[17] has highlighted the unexpected variations that can occur with the delivery of sequential pneumatic compression. Using a widely used system, the maximum pressures in all chambers of the sleeves were within 10% of expected values during only 9.9% of the therapy time, and the rates of pressure rise in all chambers of the sleeves were within 10% of expected values during only 0.1% of therapy time. Overall variations exceeded 30% during 94.7% of the delivered therapy time.

We considered therapy to be ideal when in a particular compression cycle all chambers of both right and left sleeves are within 10% of their target pressures and rates of pressure rise. Our results show that with the new trial sequential compression device, the average patient received this ideal therapy 88% of the time that it was operating. This represents a dramatic improvement over the 0.1% achieved during our previous study using the conventional device.[17] On average, all parameters were within 30% of target values in 97% of the compression cycles.

The current results also indicate that the new device is robust both to long periods of unattended use and also to the normal variety of interruptions and sleeve reapplications that occur with the typical patient. The high rates of ideal therapy persist over long uninterrupted periods, and, on average, the last hour of a patient's longest uninterrupted therapy period is ideal for 91% of the compression cycles. Therapy did not change significantly due to interruptions of 5 minutes or longer (during which sleeves may have been reapplied or adjusted). Previous studies may have underestimated the effectiveness of pneumatic compression, as it is likely that, as in Haddad and coworkers' report,[17] the compression delivered was suboptimal. It is interesting to note that Haddad's group showed that it was particularly in the thigh chamber that both the correct maximum pressure and correct rate of pressure rise was achieved least frequently (2.4% of the time). This may explain why some studies have shown a decrease in distal DVT but an increase in proximal DVT with

pneumatic compression compared with warfarin.[35–37] It is important not to dismiss pneumatic compression prophylaxis without ensuring that the devices tested actually deliver the therapy they are designed to.

Timing when thromboprophylaxis starts is also important. Warfarin is difficult to use intraoperatively, and manufacturers of low-molecular-weight heparin do not recommend its intraoperative use.[38] It is thought that the high proportion of isolated femoral thrombi identified after total hip replacements develop during the operation.[38] It has also been shown that external pneumatic compression can cause blood to flow through the kinked femoral vein that occurs during intraoperative extreme rotation of the lower extremity,[39] which should help reduce the risk of femoral thrombosis. Although in this study we did not use intraoperative pneumatic compression, previous authors have,[38] and we feel that if the issues of sterile application of the devices can be addressed, then mechanical prophylaxis should begin at the time of surgery.

The current study has some limitations. A historical control was used. However, both groups were from the same wards at the study centre, with largely the same staff members attending. The current study group had a significantly higher proportion of revision patients than the historical control; however, the pattern of interruption and tolerance was similar, as indicated by the insignificant differences in interruption frequency and average duration between the 2 groups (Table 2). In both the current study and the historical control, patients and nursing staff were not blinded; it is therefore possible that patient tolerance of the therapy and the care and effort in applying the compression sleeves were greater than normal. Because of the limited number of prototype devices available in the current study, patients were monitored for approximately the first 48 hours only, not the entire prescribed therapy time.

This study demonstrates how a new design of device to deliver sequential compression therapy with built-in monitoring and a corrective feedback loop can accurately achieve the target parameters, reduce variations in delivered therapy, and independently monitor the therapy delivered. This self-monitoring capability may further assist in reducing the complications reportedly associated with compression therapy. In this era of evidence-based medicine, it is important to establish therapeutic parameters and verify consistency of application in order to determine the effectiveness of treatment modalities such as sequential compression therapy.

It was not within the scope of this study to assess physiological indices such as femoral-vein blood flow, or clinical outcomes such as the rate of DVT or PE. Now that we have demonstrated that accurate and reliable pneumatic compression can be delivered, clinical outcome studies can be performed with the new device. This will ensure that future studies on the clinical effectiveness of sequential compression therapy can be accurately related to the actual therapy delivered in each individual case.

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