Improved venous return by elliptical, sequential and seamless air-cell compression

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Aim. **The risk of deep vein thrombosis (DVT) in the perioperative period is significant, but can be reduced with the use of mechanical intermittent pneumatic compression (IPC). These devices have reached widespread use in hospitals and have been found to be effective prophylactic measures against DVT. This study evaluates the latest design features of one particular IPC device in comparison to current models.**

Methods. **Duplex ultrasound scanning was performed on 40 lower extremities of 20 healthy volunteers before and during the application of the IPC device (VenaFlow System, Aircas, NJ, USA. Two hemodynamic parameters were measured, acceleration time from spontaneous baseline venous flow and peak vein velocity. All measurements were obtained by scanning proximal to the saphenofemoral junction in the common femoral vein in both extremities for each subject. Data were obtained from 3 compression cycles and averaged for each extremity. Results were compared with a recent prospective study form our center using a slow-filling and a rapid-filling sequential IPC devices.**

Results. **The medians for spontaneous average peak velocities at rest of the right and left lower extremities were 26 cm/s and 24.1 cm/s. The median augmented peak velocities during the compression cycle of the device in the right and left side were 79.6 cm/s and 79.0 cm/s. This represented a 306.2% increase in average peak velocity on the right side and a 327.8% increase on the left side. The median acceleration time was 305 ms±40 in the left and 310 ms±50 in the right limb. There was no statistically significant difference in the spontaneous and augmented velocities between the right and left lower extremities in each subject. In comparison to existing slow- and rapid-filling IPC devices the VenaFlow System had superior peak velocities and shorter acceleration times.**

Conclusion. **The use of elliptical, sequential and rapid-filling compression of the leg with overlapping air-cells produces significant hemodynamic changes in the common femoral vein, which are superior to other sequential slow- or rapid-filling IPC devices. Randomized studies should be performed to determine the efficacy of this new device in DVT prevention.**

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Deep vein thrombosis (DVT) has a postoperative prevalence ranging from 19% to 61%, depending on the type of surgery involved.[1] Orthopedic and neurological surgery in particular have high risks for postoperative DVT, and other risk factors, such as age >40 years, obesity, and thrombophilia, have an additive effect on total risk. The major potential complication of DVT is pulmonary embolism (PE). Unfortunately, the signs and symptoms of both DVT and PE are frequently nonspecific or absent, and the 1st clinical manifestation of DVT may be a fatal PE. Significantly, PE is the most common preventable cause of death in hospitals [2] and the 3rd leading cause of death in the United States.[3] Furthermore, once DVT develops, post-thrombotic venous insufficiency may develop over time, leading to skin changes and ulceration, and predisposition of these patients to recurrent DVT.[4, 5] In addition to the detriment to the quality of life in these patients, it is estimated that the annual cost of treating venous ulcers exceeds $1 billion annually.[6] For these reasons, prophylaxis against DVT is essential for surgical patients.

DVT prophylaxis can be generally categorized as pharmaceutical and mechanical. Among mechanical prophylaxis methods, IPC has been found to be especially effective in lowering the incidence of DVT. Intermittent pneumatic compression (IPC) protects against DVT by affecting all 3 aspects of Virchow's triad.[7] First, IPC increases the velocity of venous return and prevents blood stasis. Second, hypercoaguability is avoided by the increased fibrinolytic activity stimulated by IPC. Third, inhibition of venodilatation by IPC may reduce endothelial damage. The efficacy of IPC has been demonstrated persuasively, and the

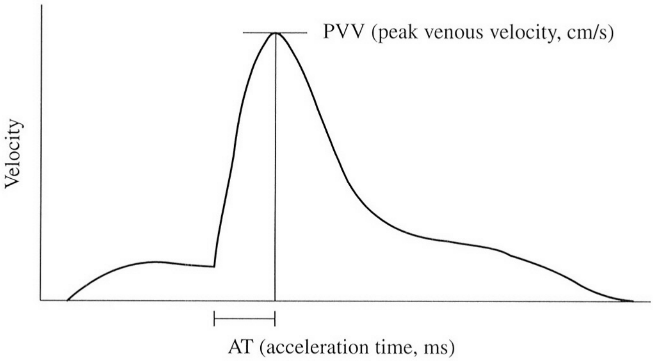

Figure 1.—Diagrammatic representation of the measurements of peak venous velocity (cm/s) and acceleration time (ms).

method was endorsed as an effective prophylactic measure in 1986 by the NIH consensus, the American College of Chest Physicians and an international consensus.[6, 8, 9] Despite its clear efficacy, IPC design can be improved and made more effective by optimizing its hemodynamic effects.[10] Additionally, the design of the IPC sleeve may be improved to increase patient comfort.

This study was designed to evaluate the performance of a new sequential IPC pump and sleeve design that utilizes elliptical and overlapping air-cell compression.

Materials and methods

This device was evaluated by measuring 2 hemodynamic parameters: 1) acceleration time based on change of velocity from spontaneous baseline flow and 2) peak velocity (Figure 1).

The hemodynamic effect of the VenaFlow device (Aircast, Summit, NJ, USA) was studied in 20 healthy volunteers, mean age 24±5 years, range 22 to 34 years (19 males and 1 female), through the use of duplex scanning. With the subject in the supine position, duplex scanning was performed proximal to the saphenofemoral junction in the common femoral vein in both the right and left lower extremities. All measurements were obtained by imaging the long axis of the common femoral vein with a 4-7MHz linear array transducer (ATL, HDI 3000, Bothel, WA, USA). The angle of insonation was set at 60°. Measurements were taken before, during, and after compression and were recorded on film and video. Data were obtained from 3 compression cycles and averaged for the further analysis for each lower extremity separately. A recent study from our center using a slow- (SCD model 5325 Kendal Healthcare Products, Co., Mansfield, MA, USA) and a rapid-filling (VenAssist, ACI Medical, San Marcos, CA, USA) sequential IPC devices on 30 limbs of 15 healthy volunteers with comparable age (28±3.7 years) were used for comparison.[11] All subjects were asked specifically about pain, discomfort, increased heat and perspiration during the application of the device using an analog scale from 1 to 10.

Results

Due to the nonparametric distribution of the data of the average peak velocities, comparisons of the median values were performed using the Mann-Whitney rank sum test.

The median acceleration time for the left limb was 305 ±40 ms and for the right 310 ±50 ms. The median for spontaneous average peak velocities in the right lower extremities of the volunteers was 26 cm/s (interquartile range 21.7-29.6 cm/s). The lowest average spontaneous peak velocity was 13.7 cm/s and the highest was 48.1 cm/s. The median augmented peak velocities in the right lower extremities of the volunteers were 79.6 cm/s (interquartile range 71.2-93.3 cm/s). Augmented peak velocities ranged from 132 to 511 cm/s. This represented 306% increase in the average peak velocity (range from 115% to 653%). When compared by the Mann-Whitney rank sum test the difference was statistically significant with p value less than 0.0001.

The median for spontaneous average peak velocities in the left lower extremities was 24.1 cm/s (interquartile range 18.5-29.2 cm/s). The lowest average spontaneous peak velocity was 13.7 cm/s and the highest was 48.1 cm/s. The median augmented peak velocity in the left lower extremities of the volunteers was 79.0 cm/s (interquartile range 59.2-101.3 cm/s). The numbers ranged from 47.4 to 125.3 cm/s. This represented a 328% change in the mean peak velocity (range from 175% to 698%). The results were statistically significant with p value less than 0.0001. An example of the effect of VenaFlow on the peak venous velocity and acceleration time is illustrated in Figure 2.

Average peak spontaneous velocities in right lower and left lower extremities were compared for each volunteer. No statistically significant difference was

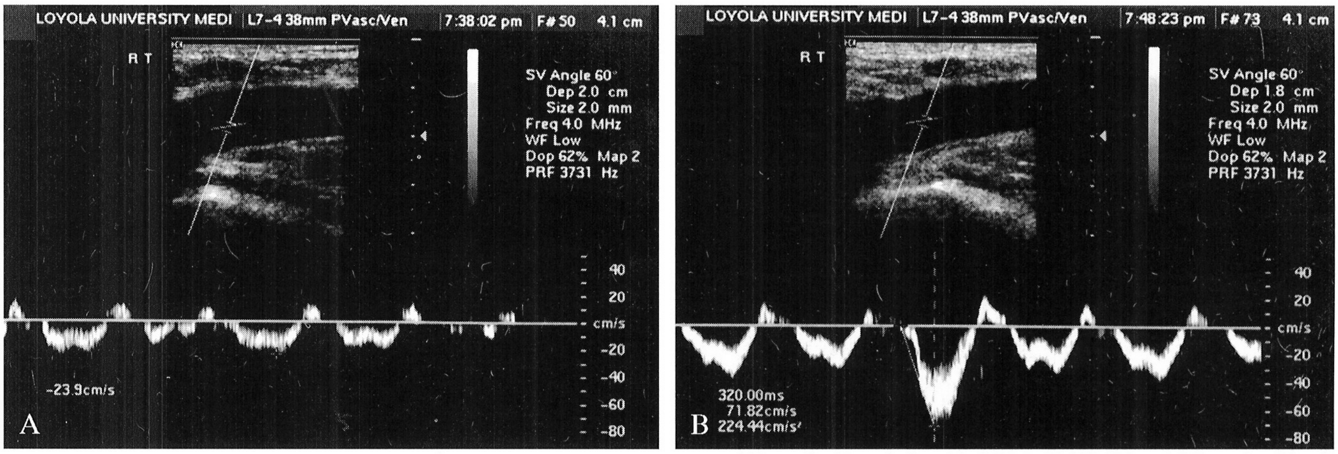

Figure 2.—Duplex scanning of the common femoral vein before (A) and during the application (B) of intermittent pneumatic compression. The peak venous velocity is significantly increased with application of IPC compare to baseline (from 24 to 72 cm/s, 300%). The time taken to reach the peak vein velocity (acceleration time 320 ms) is very short due to rapid and elliptical, seamless air-cell compression.

found with p=0.37. Likewise, no statistically significant difference was found when comparing the augmented peak spontaneous velocity in right lower and left lower extremities with p=0.95.

All subjects tolerated very well the application of this device. There were no complaints about pain, increased heat or perspiration. Two subjects noticed some discomfort but their score on the analogue scale was only 2 and 3, respectively.

Discussion

The device in the current study is a newer IPC that incorporates design changes claimed to improve IPC efficacy in preventing DVT. This study was intended to verify these claims and to examine whether or not this particular model is a significant improvement over designs currently in use, such as the Kendall 5325 and the VenAssist. These models have been compared against each other previously at our institution.[11] That study showed the peak venous velocity of the Kendall to be 37.4 ±6.9 cm/s and the VenAssist to be 55.1±17.8 cm/s. Acceleration times were 370±93.4 ms in the VenAssist and 560±83.5 ms in the Kendall model. The results of the VenaFlow model in the present study indicate a superior peak venous velocity and a shorter acceleration time than these other models.

IPC devices function by mimicking the effects of the physiological calf muscle pump that returns venous blood through a "wavelike milking action".[12] It has been found that optimal performance is obtained by designs that utilize sequential or graduated compression from the distal to proximal aspect of the lower limb, as opposed to uniform compression.[12-14] Peak velocity and shear stress have been shown to increase in sequential compression models, decreasing stasis and increasing fibrinolytic activity, including activation of tPA.[8, 15, 16] The enhancement of fibrinolytic activity is still a matter of debate since recent studies have not shown significant changes with the IPC application.[17,18] Among sequentially inflating designs, moreover, the IPC device in this study has a seamless transition between chambers, whereby the distal and proximal air-cells overlap, producing better venous flow than a segmented transition. This seamless air-cell design is applied together with a combination of sequential and graduated compression. The Kendall and VenAssist models also utilize sequential compression, but these models feature segmented air-cells only.

IPC devices are typically found with either knee-high cuffs or thigh-high cuffs. In an effort to compare the efficacy of the 2 design modalities, Flam *et al.* compared a knee-high single compression device with a thigh-high sequential compression system.[19] Overall, it was found that the knee-high single compression device produced significantly higher venous peak velocity than the thigh-high sequential compression model. This is reflected in the superior performance of the knee-high VenaFlow and VenAssist models in comparison with the thigh-high Kendall model.

The pattern of compression by the cuff around the calf is another variable in IPC design that has been found to be significant in its hemodynamic effects. It has been shown experimentally that asymmetric or anterior-posterior compression is more efficient in augmenting venous return than circumferentially uniform compression.[20] A device that compresses the calf into an elliptical shape produces greater vessel collapse and generates larger flow velocities and shear stresses than one that uniformly compresses the calf around its circumference. Furthermore, it was found that asymmetric compression could operate with less pressure than a circumferential compression device to give the same results.[21] The VenaFlow model is the only one in this study that incorporates this design feature. Both the Kendall and VenAssist devices rely on circumferential compression. The VenaFlow model and the Kendall model both inflate their air-cells to similar pressures (VenaFlow 53 and 45 mmHg, Kendall 45 mmHg), but the VenaFlow model has superior results. In comparison, the VenAssist model inflates to 80 mmHg and while it performs better than the Kendall, it is less effective than the VenaFlow model.

The time required for individual chamber inflation as well as the temporal relationship between chamber inflation in sequential compression is significant in the efficacy of venous return. Kamm *et al.* have found that a faster rate of inflation of air-cells correlates with greater peak velocity.[20] Since peak velocity occurring during compression is regarded as the most important performance indicator of all the hemodynamic parameters,[14] the rate of inflation would seem to have the greatest influence on the performance of the 3 IPC devices. In the VenaFlow model, the distal air-cell first inflates to 53 mmHg over 0.5 seconds followed 0.3 seconds later by the proximal air-cell, which inflates to 45 mmHg over 1 second. The air-cells remain inflated for 6 seconds. In comparison the Kendall model inflates its single air bladder to 45 mmHg over 12 seconds. The VenAssist model inflates the distal air-cell to 80 mmHg over 0.3 seconds and 1 second later the proximal air-cell inflates to 80 mmHg over 0.3 seconds. Both air-cells remain inflated for 3 seconds. All 3 models cycle through their respective compression patterns once every minute. The Kendall model had the poorest performance of this group, and it may be concluded that its slow inflation rate is a significant reason. By contrast, the VenaFlow and VenAssist models inflate similarly, both reaching their peak inflation in less than 1/2 second. Although the proximal air-cells inflate differently in these 2 models, it is the distal air-cell that has the greatest contribution to the velocity of venous return. The proximal cells merely supplement and extend the action of the distal air-cell. This is reflected in the waveform of venous velocity, which rises rapidly initially, decreases a little, plateaus and then decreases gradually to baseline.

The VenaFlow device shows superior performance characteristics in comparison to the Kendall 5325 and VenAssist models. These 3 devices have differing design features from one another, making it difficult to pinpoint which feature makes the VenaFlow more effective. It utilizes a graduated, sequential design with 2 overlapping air-cells that inflate rapidly. The air-cells are incorporated in a sleeve that utilizes eccentric compression in a knee-high design. The VenaFlow's closest competitor in this comparison is the VenAssist. Both utilize sequential compression, rapid inflation time, and knee-high cuffs. The differences are that the VenAssist does not utilize graduated compression, seamless air-cells, or asymmetric pressure. Significantly, the VenAssist actually has higher inflation pressures with a similar inflation rate, yet its performance is lower than that of the VenaFlow. It is possible that the higher efficacy of the VenaFlow may be due to the graduated compression, eccentric compression design, as well as its seamless air-cells.

Conclusions

The IPC device evaluated in this study produces a statistically significant increase in the peak venous flow velocities of the common femoral vein. In comparison with 2 other IPC models, the current device has better hemodynamic parameters that may be attributed to the graduated compression delivered asymmetrically to seamless, overlapping air-cells.

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