A Review of Pneumatic Compression Systems: The Science Behind Restep

Prepared by Stryker Sustainability Solutions

Abstract

Scientific literature provides strong evidence that pneumatic compression systems augment blood flow, thereby preventing stasis and resultant blood clots in the leg, and as a result, such systems are effective in reducing the incidence of deep vein thrombosis (DVT). The literature also demonstrates that patient compliance plays a role in successful use of pneumatic compression systems. In laboratory evaluation, the Restep─ system demonstrated augmentation of blood flows of 127-192% in the popliteal vein for calf compression and of 170-550% in the posterior tibial vein for foot compression. When compared with current competitive products, the Restep system is the lightest and among the thinnest, has the lightest pump with the longest battery run time, is one of the few systems made of environmentally friendly PU and has the most complete set of alarms for patient safety. These characteristics are believed to provide a comfortable, mobile system for the patient, which may assist in increased patient compliance.

Literature Review Summary

Published literature provides extensive data which establishes that pneumatic compression systems work by augmenting blood flow in the leg, thereby preventing stasis and resultant blood clots, and that such systems are effective in reducing the incidence of deep vein thrombosis (DVT). The literature also demonstrates that patient compliance plays a role in effective application of pneumatic compression systems.

Augmentation of Blood Flow

Pneumatic compression systems are intended to provide a mechanical means of replacing normal muscle motion in the leg which keeps blood flowing in the veins and thereby prevents the formation of clots that can result in deep vein thrombosis or pulmonary embolism. Thus, in understanding which system might be best to use, it is important to understand the effect of the system on blood flow in the extremity.

Westrich et al[1] performed a crossover study in 10 patients, prior to their having total knee replacement, to evaluate the hemodynamic effects of seven pneumatic compression systems. Included in this study were the following: A-V Impulse System (Kendall Co, Mansfield, MA), PlexiPulse – both foot and foot/calf designs, (NuTech, San Antonio, TX), VenaFlow System 30A (Aircast Inc, Summit, NJ), SCD Sequential Compression System (Kendall Co), Flowtron DVT AC500 (Huntleigh Healthcare, Manalapan, NJ), and Jobst Athrombic Pump (Beiersdorf-Jobst Inc, Charlotte, NC). Hemodynamic parameters assessed were venous velocity, velocity augmentation, and venous volume augmentation. Key outcomes of this study were:

- Enhancement of peak venous velocity occurred primarily in the deep venous system below the level of the saphenofemoral junction.
- All systems augmented both peak venous velocity and venous volume. The greatest effect was with those systems that included calf compression.

Flam et al[2] conducted a cross-over study of 26 healthy patients. Two systems were compared; the Flowtron DVT-10 (Huntleigh Healthcare, Manalapan, NJ) and the SCD Sequential Compression Device Model 5320 (Kendall Co, Mansfield, MA). The Flowtron was a knee-high system while the SCD was a thigh-high system. Femoral vein blood velocity (FVBV) was measured for each patient using Duplex ultrasonography. Key outcomes of this study were:

- Peak compression FVBV was highest with the Flowtron system (39.5 vs. 34.2 cm/s).
- Maximum decompression FVBV was the same for both systems.
- Flow augmentation (velocity decrease between FVBV at peak compression and maximum decompression, divided by the maximum FVBV in decompression) was highest with the Flowtron system (107 vs. 77%).

Clinical Prevention of DVT

Information showing increased blood flow from the use of a system is helpful, but little clinical data exists to show whether enhanced blood flow in the leg is sufficient to prevent DVT from occurring. Thus, it is also important to understand the results of clinical studies which evaluate the occurrence of DVT in clinical applications.

Pidala, et al[3] evaluated 346 consecutive patients who had total hip (THR) or total knee (TKR) replacement using an asymmetrical compression system applied to both legs throughout their hospital stay. Serial duplex ultrasound and impedance plethysmography were used to evaluate the occurrence of DVT through 60 days post procedure. Only 4% of the patients experienced DVT (7.1% THR, 2.6% TKR). Their conclusion was that "IPC is effective in preventing postoperative DVT and may be the preferred approach in prophylaxis."

Ginzburg, et al[4] performed a prospective, randomized clinical study of 442 patients after trauma. An asymmetrical compression (AC) system was evaluated against low molecular weight (LMW) heparin. Duplex imaging was performed through 30 days. There were no statistically significant differences between the 2 groups, although DVT rates were higher in the AC group than the LMW group (2.7% vs. 0.5%), while bleeding complications were lower in the AC group than the LMW group (3.6% vs. 5.9%).

Stone, et al[5] performed a prospective, randomized clinical study of 50 patients after total hip replacement. An asymmetrical compression system was evaluated against Enoxaparin. DVT rate was the same between the two groups (one in each), but the Enoxaparin group required blood transfusions more frequently (7 vs. 3 patients).

Proctor, et al[6] clinically compared five pneumatic compression systems, evaluating rates of DVT, hours of use, patient satisfaction and nursing acceptance. The five systems compared were: Venodyne (Microtek Medical, Inc. Columbus, MS), NuTech (KCI Co, San Antonio, TX), Kendall (Kendall Co, Mansfield, MA), Huntleigh (Huntleigh Healthcare, Eatontown, NJ), and Aircast (Aircast Inc, Summit, NJ). Key conclusions from this study were:

- Length of sleeve did not have a statistically significant effect on the DVT rate (3.6% - calf length; 3.4% - thigh length).
- Number of hours of use did not have a statistically significant effect on DVT rate.
- An asymmetrical compression system provided greatest patient satisfaction and nursing acceptance.

The United Kingdom's National Institute for Health and Clinical Excellence (NICE)[7] developed a clinical guideline for venous thromboembolism prophylaxis. Several key statements from this document are:

- There is a lack of strong evidence available to suggest one method of mechanical prophylaxis is better than any other, or to suggest thigh length of stockings or intermittent pneumatic compression devices are better than knee length.
- Encourage patients on the ward who have foot impulse or intermittent pneumatic compression devices to use them for as much of the time as is possible and practical, both when in bed and when sitting in a chair.

Patient Compliance

Although there is some disagreement in the literature, generally speaking, most authors believe that patient compliance with an intermittent pneumatic compression protocol yields better results than lack of compliance. Thus, those devices which are comfortable for the patient and encourage more consistent usage should perform better in preventing DVT.

Vanek[8] conducted a meta-analysis of all articles from 1966 to June 1996 to examine the clinical effectiveness of intermittent pneumatic compression (IPC). His key point from this analysis was:

- In one study, 35% of patients were either not started on intermittent pneumatic compression until postoperatively, taken off the IPC in less than 72 hours, or both. This group had a 40%

DVT incidence, whereas those who complied with the IPC protocol had a 32% DVT incidence.

Morris et al[9] conducted a literature review covering 1970-2002, examining the effect of intermittent pneumatic compression as it relates to the prevention of DVT. The conclusion of his review was that "intermittent compression prevents DVT and prevents venous stasis. The precise way in which that stasis is prevented appears to be of much less relevance than ensuring that systems are applied properly. The most important factors in selecting a mechanical prophylactic system, particularly during and after surgery, are patient compliance and the appropriateness of the site of compression."

Colwell et al[10] clinically evaluated a mobile sequential compression device (Active Care + SFT; Medical Compression Systems, Or Akiva, Israel) randomized against LMW heparin in 395 total hip arthroplasties. The compression system is mobile as it incorporates a lightweight pump and functions on battery power for up to 6 hours. The compression devices were placed bilaterally on the patient's calves. All patients were treated for 10-12 days post procedure, at which time they were evaluated for DVT using bilateral duplex ultrasonography. Bleeding events were also captured. Compliance was measured using an internal timer on the pump unit. Key findings from this evaluation included:

- Rate of bleeding events was significantly less in the compression device group (0% vs. 6%).
- Rate of DVT was similar in the two groups (5% in both groups)
- The mobile compression device was used 83% of the time over the course of the 10-12 day treatment. This compares favorably to the rate of compliance with other compression devices, which is typically 49-59%.

Hemodynamic Assessment of Restep

A hemodynamic assessment was performed to determine the increase in blood flow in the leg resulting from use of the Restep system. With calf compression, augmentation of blood flow velocity in the popliteal vein was increased by 127-192%, whereas with foot compression, augmentation of blood flow velocity in the posterior tibial vein was increased by 170-550%.

Objective

To determine whether the maximum blood flow velocity into the femoral vein is increased by more than 50% when the Restep garments are inflating; compared to a maximum flow when not using the garments (the baseline flow).

Methods

The maximum blood flow velocity at rest, when not using garments, was measured to establish the baseline flow. All measurements were made with the subject prone, using a 4MHz ultrasound probe at 45 degrees to the vein. Measurements to evaluate the calf garment were taken on the rear of the leg, on the popliteal vein, while those to evaluate the foot garment were taken on the side of the ankle, over the posterior tibial vein.

Garments were applied as per the User Instructions; a baseline measurement was taken (with the pump turned off). The pump was turned on, allowed to run for two cycles, and then retesting took place on an inflation cycle. The results were compared.

Results

Table 1. Popliteal Baseline Testing
(No garments; measurements on the popliteal vein)

Patient #	Baseline 1 Max velocity (cm/s)	Baseline 2 Max velocity (cm/s)	Average baseline Max. velocity (cm/s)
001 – F	13	15	14
002 – M	12	12	12

Table 2. Calf Garments
(Measurements on the popliteal vein)

Patient #	Baseline Max velocity (cm/s)	Calf Garment Inflating Max. velocity (cm/s)	Augmentation (max-base/base) (%)
001 – F	13	38	192
002 – M	11	25	127

Table 3. Foot Garments
(Measurements on the posterior tibial vein)

Patient #	Baseline Max velocity (cm/s)	Foot Garment Inflating Max. velocity (cm/s)	Augmentation (max-base/base) (%)
001 – F	8	52	550
002 – M	10	27	170

Conclusions

- Published clinical data on ten subjects shows baseline flow in the popliteal vein to be in the range of 4.0 – 15.0 cm/s[11]. The measured flows in this test are also in that range and are therefore valid.
- Published clinical data shows popliteal vein maximum blood velocity flows around 30cm/s with a standard deviation around 10 for a well respected IPC system running at 50mmHg[12]. The results for the calf garments in this study are in the 25 – 38cm/s range, and therefore equivalent.
- Published clinical data for peak velocity flow in the popliteal and femoral veins showed very little difference in the peak systolic venous flow of 18 femoral and 18 popliteal veins, at rest and when using IPC systems[13]. Therefore the measurement site may be the popliteal or the femoral vein with similar results of relative augmentation.
- The Restep DVT System is showing augmentation for calf compression of 127 – 192% in the popliteal vein, well within the range expected[9].
- The Restep DVT system is showing augmentation for foot compression of 170 – 550% in the posterior tibial vein, well within the range expected[14].
- The longer, slightly slower inflation time of the Restep DVT System means that the velocity augmentation lasts for a longer time than most systems, and increased blood flow velocity over a longer time means that more volume of blood is being pushed towards the heart. This helps avoid blood stasis, which is the aim of any DVT prophylaxis therapy.
- It is concluded therefore that the Restep DVT System may achieve a similar clinical effect to other IPC systems on the market today.

Feature Comparison with Competitive Product

Table 4 below provides details on how the Restep DVT System compares and contrasts with current competitive products.

Several key differences are observed from table 4. The Restep system is the lightest and among the thinnest. In addition, the Restep system has the lightest pump and the longest battery run time. The convenient carrying strap assures that mobile patients can easily transport and use the system for longer periods of time. Together, these features provide a product which can assist in improving patient compliance. The Restep system is one of the few systems made of polyether urethane (PU) rather than polyvinyl chloride (PVC). PU is an organic thermoplastic polymer that is considered much more environmentally friendly than PVC, a synthetic thermoplastic polymer. For instance, when burned, PVC releases an environmentally hazardous gas. In addition, PVC is not biodegradable. Lastly, the Restep system has a more complete set of alarms, including alarms for high pressure and garment not deflating. This provides safe and effective treatment for the patient.

Table 4. Feature Comparison with Competitive Product

FEATURE	Restep DVT System	Huntleigh Flowtron Universal	CTC Vasopress	Covidien SCD Express	Aircast VenaFlow
Indications					
Prevention of Deep Vein Thrombosis	Yes	Yes	Yes	Yes	Yes
Garment Design & Construction					
Bladder Construction	RF welded PU	RF welded PVC	RF welded PVC	RF welded PVC	RF welded PU
Bladder Type	Single compartment	Single compartment	Single compartment	3 compartment circumferential	Double compartment
Garment Outer Material	Hook compatible brushed polyester	Hook compatible brushed polyester	Hook compatible brushed nylon	Hook compatible brushed polyester	Hook compatible brushed polyester
Garment Inner Material	Non-woven polyester	Polyester foam	Nylon tricot covered foam	Non-woven polyester	PU
Garment Thinness	0.876mm	4.69mm	8.81mm	0.927mm	0.401mm
Garment Weight	58.9g	68.4g	107g	105.2g	69.39g
Inlet	Single tube	Single tube	Single tube	Multi tube	Double tube
Garment Attachment Method	Hook & loop	Hook & loop	Hook & loop	Hook & loop	Hook & loop
Pump Attachment Method	Snap lock air	Snap lock air	Snap lock air	Custom air	Twist lock air
System Operating Features					
Pump Cycle – Leg	12 sec inflated; 48 sec deflated	12 sec inflated; 48 sec deflated	12 sec inflated; 48 sec deflated	11 sec inflated; Vascular refill detection for deflation time *	6 sec inflated; 54 sec deflated
Pump Cycle - Foot	12 sec inflated; 48 sec deflated	3 sec inflated; 27 sec deflated	12 sec inflated; 48 sec deflated	5 sec inflated; Vascular refill detection for deflation time *	6 sec inflated; 54 sec deflated
Leg Inflation Pressure	40mmHg	40mmHg	40mmHg	Gradient 30-45mmHg	Gradient 45-52mmHg
Foot Inflation Pressure	80mmHg	130mmHg	80mmHg	130mmHg	140mmHg
Pump Features					
Garment Operational Mode	Dual and single leg modes	Dual and single leg modes	Dual and single leg modes	Dual and single leg modes	Dual leg mode only
Mains Operated Mode	Yes, via power adaptor	Yes, built-in power adaptor	Yes, pump runs on AC mains voltage and frequency	Yes, built-in power adaptor	Yes, pump runs on AC mains voltage and frequency
Battery Operated Mode	Yes, battery replaceable	Yes, battery is an option	No	Yes, battery custom	N/A
Battery 'Run' Time	8 hours min	4 hours	N/A	6 hours	N/A
Charge Method	External power adaptor	Built-in/or external power adaptor	No	Built-in power supply	N/A
Pump Control	Software driven controls & alarms	Software driven controls & alarms	Mechanical rotor driven cycle and pressure switch alarms	Software driven controls & alarms	Software driven controls & alarms
Air Distribution	Solenoid valve	Stepper motor driven rotary valve	Continuously driven rotary valve	Solenoid valve	Via a bladder to create a "burst of air" effect
Garment Attachment	Snap lock connector	Snap lock connector	Snap lock connector	Custom system	Twist lock connector
Indicators	LED power & alarms	LCD power & alarms	LED power & alarms	LED power & alarms	LED power & alarms
Pump Weight	1.0lb	8.5lb	6.4lb	3.5lb	9lb
Power (max)	9 Watt	25 Watt	15 Watt	50 Watt	40 Watt
Safety/Alarms					
High Pressure	Yes	Yes	No	No	Yes
Low Pressure	Yes	Yes	Yes	Yes	Yes
NO Garment	Yes	Yes	Yes	Yes	Yes
Garment NOT Deflating	Yes	Yes	No	No	Yes
Low Battery	Yes	Yes	N/A	Yes	N/A
Audible/visual	Yes	Yes	Yes	Yes	Yes
UL60601-1 Approved	Yes	Yes	Yes	Yes	Yes

Conclusions

- Published literature provides extensive data which establishes that pneumatic compression systems work by augmenting deep venous flow in the leg, and that the greatest effect is seen with systems that include calf compression.
- Published literature demonstrates that pneumatic compression systems prevent stasis and resultant blood clots, and that such systems are effective in reducing the incidence of deep vein thrombosis (DVT). When compared with heparin or Enoxaparin, pneumatic compression systems experienced similar DVT rates, but less bleeding complications.
- Published literature generally demonstrates that patient compliance plays a role in effective application of pneumatic compression systems. Devices which are lighter and more comfortable for the patient and encourage more consistent use should perform better.
- Hemodynamic assessment of the Restep system demonstrates augmentation of maximum blood flow velocity in the popliteal vein using calf compression of 127-192% and augmentation of maximum blood flow velocity in the posterior tibial vein using foot compression of 170-550%.
- The longer, slightly slower inflation time of the Restep system means that the velocity augmentation lasts for a longer time than most systems, and increased blood flow velocity over a longer time means that more volume of blood is being pushed towards the heart.
- Several key differences are observed between the Restep and competitive products.
    - The Restep system is the lightest and among the thinnest.
    - The Restep system has the lightest pump and the longest battery run time. The convenient carrying strap assures that mobile patients can easily transport and use the system for longer periods of time. Together, these features provide a product which can assist in improving patient compliance.
    - The Restep system is one of the few systems made of PU rather than PVC. PU is environmentally friendly while PVC is not.
    - The Restep system has a more complete set of alarms, including alarms for high pressure and garment not deflating. This provides safe and effective treatment for the patient.

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