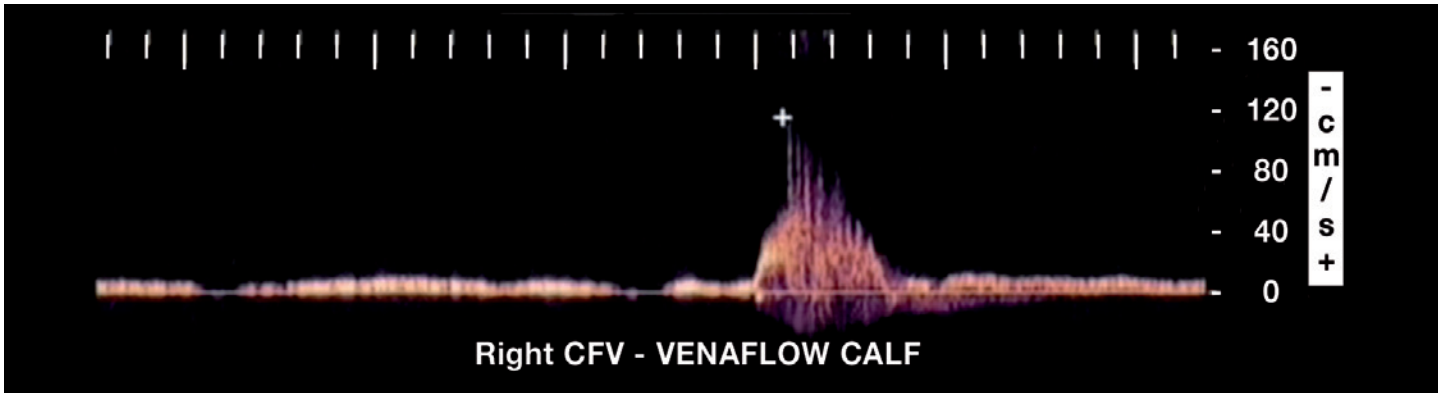
AIRCAST®



Vascular Abstracts

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Key Clinical Excerpts...

"Roberts et al established that devices with a greater rate of inflation produced improved flow augmentation as compared with those with a slower rate of inflation. [VenaFlow] produced the greatest increase in peak venous velocity compared with all the other devices."

– Geoff Westrich, MD

"Research shows that graduated, sequential compression devices are more effective than a nonsequential device in clearing blood from the soleal, tibial and femoral veins and therefore is more effective at preventing deep venous thrombosis proximal to the calf."

– Andrew Nicolaides, MD

"The use of elliptical, sequential and rapid-filling compression of the leg with overlapping aircells produces significant hemodynamic changes in the common femoral vein, which are superior to other sequential slow or rapid-filling IPC devices."

– Nicos Labropoulos, MD

"The use of rapid inflation, asymmetric calf compression gave a significantly lower rate of thromboembolism."

– Paul Lachiewicz, MD

VenaFlow® Research
(VenaFlow Systems Used in these Studies)

Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism in high-risk patients (Review)

Kakkos SK, Caprini JA, Geroulakos G, et al:*Cochrane Database of Systematic Review*, Issue 4. Art. NO.:CD005258, 2008

(Reprint not available at this time)

Randomized controlled trials (RCTs) or controlled clinical trials (CCTs) of combined intermittent pneumatic leg compression (IPC) and pharmacological interventions used to prevent venous thromboembolism (VTE) in high-risk patients were reviewed. Several articles that utilized VenaFlow were included in this Intervention Review.

The authors conclude that combined modalities reduce the VTE incidence significantly compared to compression alone. Compared to anticoagulants alone, combined modalities reduce the DVT rate significantly. As suggested by published guidelines, combined modalities should be used in the prevention of VTE in high-risk patients.

High risk patients should receive multimodal prophylaxis. Reviews of VenaFlow publicwations were included in this Cochrane review.

Rapid-Inflation Intermittent Pneumatic Compression for Prevention of Deep Venous Thrombosis

Eisele R, Kinzl L, Koelsch T:J Bone Joint Surg Am. 89:1050-6, 2007

Over 1800 consecutive inpatients were enrolled in this randomized prospective clinical study. A total of 902 patients were managed with chemoprophylaxis alone and 901 patients received chemoprophylaxis augmented with [VenaFlow] intermittent pneumatic compression (IPC). All patients were Dopplered for evidence of symptomatic and nonsymptomatic deep vein thrombosis (DVT) at discharge. In the chemoprophylaxis-only group, fifteen patients (1.7%) were diagnosed with a DVT; three thromboses were symptomatic. In the IPC group, four patients (0.4%) were diagnosed with DVT; one thrombosis was symptomatic. The difference was significant. In addition, patients who wore the IPC device more than six hours per day had no deep vein thromboses.

The results demonstrate that the multimodal approach of using a rapid inflation intermittent pneumatic compression device as an adjunct to low-molecular-weight heparin is significantly more effective in preventing DVTs than using low-molecular-weight heparin alone.

VenaFlow provides protection to patients at high-risk for DVT. This large, prospective randomized study demonstrates that adding VenaFlow to a chemoprophylaxis regimen significantly lowers DVTs.

Fondaparinux combined with intermittent pneumatic compression vs. intermittent pneumatic compression alone for prevention of venous thromboembolism after abdominal surgery: a randomized, double-blind comparison (APOLLO)

Turpie AGG, Bauer KA, Caprini JA, et al:Journal of Thrombosis and Haemostasis, 5:1854-1861, 2007

(Reprint not available at this time)

In this randomized, double-blind (RCT) comparison study, 1309 patients who were undergoing major abdominal surgery, including surgery for cancer, received either fondaparinux or placebo. All patients received intermittent pneumatic compression (IPC). The rate of venous thromboembolism (VTE) in the intermittent pneumatic compression group with placebo was lower than expected. Use of an anticoagulant further decreased the risk of VTE to 1.7%.There was only one major bleed in the placebo/IPC group (1/650) compared with 10 major bleeds that occurred in the anticoagulant /IPC group (10/635).

This study supports current guidelines that recognize the efficacy of combination modalities of intermittent pneumatic compression with anticoagulant agents in the surgical patient.

Intermittent pneumatic compression plays an important role in reducing the risk of VTE in high risk surgical patients. IPC does not increase the risk of major bleeds.

VenaFlow Plus Lovenox vs. VenaFlow Plus Aspirin for Thromboembolic Disease Prophylaxis in Total Knee Arthroplasty

Westrich GH, Bottner F, Windsor RE, et al: The Journal of Arthroplasty 21(6-2), 139-143, 2006

(Reprint not available at this time)

Prospective, randomized study involving 275 patients undergoing unilateral total knee arthroplasty (TKA). Patients received spinal epidural anesthesia (SEA), VenaFlow calf compression device, and enoxaparin (group A) or SEA, VenaFlow and aspirin (group B).

All patients received ultrasound screening test on postop day 3-5, plus at 4-6 weeks postop. According to the authors, VenaFlow was chosen as the compression device as it produced the greatest increase in peak venous velocity at the common femoral vein and better efficacy compared with other agents such as aspirin and warfarin in recent studies.

Delay of giving anticoagulants until at least two hours after the removal of indwelling epidural catheter was discussed. The PC [pneumatic compression] device bridges the gap to provide effective DVT prophylaxis during the early postoperative period while a patient had the indwelling catheter and thus was unable to receive enoxaparin.

Combination of VenaFlow mechanical compression device and either enoxaparin or aspirin is a safe and efficacious means of preventing DVT and PE (pulmonary embolism) VenaFlow can also "bridge the gap" during the period when anticoagulants can't be given due to surgery or epidural catheters.

Efficacy of Pneumatic Compression Stocking Prophylaxis in the Prevention of Deep Venous Thrombosis and Pulmonary Embolism Following 139 Lumbar Laminectomies with Instrumented Fusions

Epstein NE:J Spinal Disord Tech 19(1):28-31, 2006

(Reprint not available at this time)

Patients undergoing multilevel lumbar laminectomies with instrumented fusions are at high risk for DVT and PE. These same patients cannot afford any hemorrhagic events or the associated risk of neurological deterioration from bleeding. In this study, 139 patients with multilevel lumbar laminectomies with instrumental fusions received pneumatic compression stockings (CS) alone with no unfractionated minidose or low-molecular-weight heparin derivatives. Mechanical pumps [including VenaFlow] were applied intraoperatively and used throughout the average 5 day postoperative course including following ambulation.

Dopplers were performed on all patients on the second postoperative day, with repeat Doppler upon onset of symptoms of DVT or PE.

Results of 2.8% DVT, 0.7% PE were comparable with those achieved with low dose heparin in other series. By using only CS, risk of hematomas and their neurologic sequelae were avoided.

VenaFlow provides a safe alternative to low-dose-heparins in the high-risk lumbar spinal surgical patient. Risk of bleeding and associated neurological complications is avoided. Pumps can be applied intraoperatively and be used until discharge, even after the patient is ambulating.

Comparison of two intermittent pneumatic compression systems. A hemodynamic study

Kakkos SK, Nicolaides AN, Griffin M, et al:International Angiology 24(4), 330-335, 2005

(Reprint not available at this time)

Using 12 volunteers, four hemodynamic measurements were measured at the level of the common femoral vein. Compared with the Kendall Express, VenaFlow had superior Total Volume Flow, Peak Volume Flow, Peak Velocity and Peak Volume expelled per hour. Single Cycle Volume was similar for the Kendall 11 second cycle vs. VenaFlow six seconds. [Note: Measuring for 11 seconds on VenaFlow would have yielded even higher volume, as each respiration produces cycle volume.]

VenaFlow's compression ejected most of the blood in half the time compared with Kendall Express. Calculation for blood ejected per hour was based on mathematical hypothesis, three cycles [minutes] and not an actual 60 minute measurement. For blood ejected per hour, Kendall Express was calculated with 40-45 second cycle vs. VenaFlow's 60 second cycle. [Kendall Express can range from 31 seconds (116 cycles per hour) to 72 seconds (50 cycles per hour). The cycle cannot be adjusted by staff. The study does not include calculations from the Kendall Express default 72 second cycle. Calculating a 72 second cycle with the Total Volume Flow as noted in Table II would have yielded significantly lower volume per hour mathematical estimate for Kendall Express.]

In addition, refill time by VenaFlow was faster. [Note: Vascular experts have verified that faster refill time indicates that the blood in the vein was ejected, the vein was emptied, and therefore the vein has the opportunity to refill more quickly which is in contrast with the author's hypothesis.] The authors noted that potential errors can occur in the estimation of duplex scan-derived refill time due to extreme variations in the respiratory efforts of the subjects.

VenaFlow demonstrated superior total volume flow, peak volume flow, peak velocity and peak volume enhancement and refill time compared with Kendall Express. VenaFlow's pump and cuff design produces superior hemodynamics to maximize blood movement, allowing patients to "Walk Away From Risk."

Intermittent Pneumatic Compression Stocking Prophylaxis Against Deep Venous Thrombosis in Anterior Cervical Spinal Surgery; A Prospective Efficacy Study in 200 Patients and Literature Review

Epstein NE: SPINE 30 (22): 2538-2543, 2005

(Reprint not available at this time)

In two hundred cervical spine surgeries, a single modality of intermittent pneumatic compression (IPC) was used to avoid deep venous thrombosis (DVT) and pulmonary embolism (PE). Because of the high risk (2-4%) of major bleeding in the neurosurgical patient, no anticoagulants were prescribed. All patients were Dopplered. If DVT was documented, patients underwent spiral CT angiography to screen for PE. In addition, patients were screened for at-risk factors.

Without prophylaxis, DVT rates in the combined cranial and spinal series approached 43%. In these high risk patients with lengthy surgical time, the rates of DVT (1% and 7%) and PE (1% and 2%) were much less. These rates are comparable to frequencies using mini-heparin and/or low-dose heparin regiments.

By not utilizing anticoagulants, 2%-4% major postoperative hemorrhage and complications were nonexistent. IPC prophylaxis proved to be as effective as existing therapies for prophylaxis against DVT/PE but avoided the risk of postoperative hemorrhage.

IPC [including VenaFlow] is proven to be an equally safe and attractive alternative to mini-heparin or low-dose heparin-based therapies in the neurosurgical patient. Bleeding complications that can be precipitated from anticoagulants

Thromboembolic Disease Prophylaxis in Patients with Hip Fracture. A Multimodal Approach

04374

Westrich GH, Rana AJ, Terry MA, et al: Journal of Orthopaedic Trauma, 19(4): 234-240, 2005

This prospective cohort study determined the effectiveness of VenaFlow® in conjunction with warfarin (Coumadin) or ASA (aspirin). Color flow duplex scans were conducted on all 200 patients with hip fractures to determine the presence or bsence of deep venous thrombosis (DVT). All patients were followed for three months. DVT was diagnosed in 7 patients (3.5% overall.) This is one of the lowest rates ever demonstrated for this high-risk patient population.

"We chose to use the VenaFlow device because of its excellent augmentation of peak venous blood flow." The authors discuss other papers that indicate that VenaFlow increases peak venous flow by over 200% of baseline (the same range that active or passive dorsiflexion of the ankles increases peak venous velocity).

The two mechanisms of action for sequential compression devices are to increase plasma fibrinolytic activity by stimulating the blood vessels walls to release plasminogen activator and by secondly, mechanically decreasing the transit time of venous blood. This prevents stasis and the accumulation of coagulant materials. In addition, PCDs (pneumatic compression devices) are safe, inexpensive, and are not contraindicated for patients who may be at increased risk for bleeding.

VenaFlow demonstrates one of the lowest rates of DVTs (3.5% overall) in high-risk patient group. Multimodal approach of VenaFlow and chemoprophylaxis is ideal for high-risk patients.
For patients who tolerate anticoagulants, VenaFlow is used as primary approach.

Two mechanical devices for prophylaxis of thromboembolism after total knee arthroplasy; a prospective, randomised study

Lachiewicz PF, Kelley SS, Haden LR: J Bone Joint Surg (BR) 86-B(8):1137-1141, 2004

04368

The ideal operating parameters of IPC devices for the prevention of DVT following total knee arthroplasty have not been proven. This prospective, randomized study compared an asymmetrical calf compression device providing rapid impulse inflation (Device V) to a circumferential calf compression device (Device S) using gradual inflation.

The hypotheses maintained that the device providing the greater increase in peak venous velocity would result in a lower incidence of thromboembolism. The study included 423 patients totaling 472 knees who had primary or total knee arthroplasty across two surgeons at one institution. Sealed envelopes were used to randomize the patients and experienced technicians utilized duplex ultrasonography to detect the presence of thrombi. The technicians were unaware of the device used.

In total, 206 patients (232 knees) were treated with Device V and 217 patients (240 knees) with Device S. The incidence of venous thromboembolism was 6.9% (16 thrombi in 232 knees) with Device V as opposed to 15% (36 thrombi in 240 knees) with Device S. This difference was statistically significant (p=.005). There were no deaths or pulmonary embolisms with Device V compared to one death (.2%, myocardial infarction) and one pulmonary embolism (.2%) with Device S.

In unilateral primary knees the incidence of thrombi was 8.4% with Device V compared to 15.8% with Device S (p=.032). In bilateral knee patients, the incidence of thrombi was 4% with Device V compared to 22.7% with Device S (p=.096 per patient; p=.05 per knee).

Overall, there is a low incidence of death and pulmonary embolism using intermittent pneumatic compression and aspirin. However, the device utilizing rapid impulse inflation and asymmetric compression had significantly lower incidence of thromboembolism than the device utilizing circumferential compression and gradual inflation.

VenaFlow, utilizing rapid, impulse inflation and asymmetric compression, had approximately 50% reduction in the incidence of thromboembolism compared with the Kendall device utilizing circumferential compression and gradual inflation.

Prevention of deep-vein thrombosis after total hip and knee replacement: low molecular weight heparin in combination with intermittent pneumatic compression

Silbersack Y, Taute BM, Hein W, et al: J Bone Joint Surg [Br], 86-B(6):809-812, 2004

04371

This prospective, randomized study examined the efficacy of Low Molecular Weight Heparin (LMWH) with VenaFlow vs. LMWH with graduated compression stockings (GCS) in 131 patients. Authors also assessed the conditions for the optimal use of intermittent pneumatic compression (IPC) for the maximum reduction of thrombosis. Total hip replacement (THR) and total knee replacement (TNR) patients had no (0%) incidence of clots when VenaFlow was utilized with LMWH. The group utilizing LMWH with stockings experienced a 28.6% incidence of deep vein thrombosis (40% after TKR and 14% after THR).

Authors determined that IPC should be used in the early postoperative period and "the longer it is used the better". The authors recommend the additional use of IPC to peri-and post-operative thromboembolic prophylaxis with LMWH since LMWH and GCS provides insufficient prophylaxis.

VenaFlow with LMWH provides significant reduction in DVTs over stockings with the identical LMWH. VenaFlow can be utilized with or without stockings and is a vital component in combination therapy. In addition, VenaFlow gives protection during the early post-op window when anticoagulants can not be given due to risk of bleeding.

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

Labropoulos N, Oh DS, Golts E, et al: International Angiology 22(3): 317–321, 2003

04356

VenaFlow's rapid-filling, sequential inflation cycle and seamless, overlapping, elliptical designed cuffs are essential for producing peak velocities that are superior to other sequential devices. In this study, the author compared the Kendall Thigh SCD and VenAssist (ArtAssist) hemodynamics to the VenaFlow (calf) System.

"Two hemodynamic parameters were measured, acceleration time from spontaneous baseline venous flow and peak vein velocity. Measurements were taken proximal to the saphenofemoral junction in the common femoral vein in both extremities for each subject." In 20 subjects, VenaFlow produced peak velocities that averaged 328% above baseline, more than the other devices. "Peak velocity and sheer stress have been shown to increase in sequential compression models, decreasing stasis and increasing fibrinolytic activity, including activation of tPA." The authors conclude that the design of the cuffs and the rapid acceleration of the system correlates with the greater velocity. Velocity is regarded as the most important performance indicator of all the hemodynamic parameters.

VenaFlow's superior design incorporating elliptical, sequential, and rapid-filling compression of the leg with overlapping aircells produces significant hemodynamic changes. The peak velocity average of 328% over baseline maximizes potential for creating shear stress on the endothelial wall and subsequent release of fibrinolytics.

Prophylaxis Against Venous Thromboembolic Disease in Patients Having a Total Hip or Knee Arthroplasty

Sculco TP, Colwell CW, Pellegrini Jr. VD, et al: J Bone Joint Surg 84–A(3): 466–477, 2002

This Instructional Course Lecture conducted at the American Academy of Orthopaedic Surgeons meeting explored mechanical and chemical prophylaxis for patients undergoing total joint replacement. Rates and locations of DVT and caveats associated with specific procedures are described. The advantages of rapid, multi-chamber, asymmetric calf compression over thigh and foot compression is discussed in-depth.

The ideal device is described. "On the basis of in vivo flow studies, it appears that a calf compression device (with or without sequential foot compression) with and asymmetric multichamber system that applies at least 50 mmHg of sequential external pressure at a frequency of at least once per minute with an inflation time of less than one second is the ideal device for prophylaxis against deep venous thrombosis in patients undergoing elective orthopaedic surgery."

The role and safety measures required for intraoperative use of IPC are also discussed by the panel in this in-depth paper and lecture.

VenaFlow® is described as the ideal device for prophylaxis against DVT in patients undergoing elective orthopaedic surgery.

The Role of Nitric Oxide in Vasodilation in Upstream Muscle during Intermittent Pneumatic Compression

Chen LE, Liu K, Qi WN, et al: Journal of Applied Physiology 92(2):559–566, 2002

(Reprint not available at this time)

This study examined the effects of intermittent pneumatic compression on uncompressed upstream muscles. Subjects were divided into two groups. Group 1 examined what effect L-NMMA (a nitric oxide synthase inhibitor) had on the IPC-induced vasodilation of the uncompressed cremaster muscle. Group 2 examined the effects of IPC application on the expression of eNOS mRNA and eNOS protein of the cremaster muscle.

IPC on the legs resulted in vasodilation of the uncompressed cremaster muscle. It also caused an increase of 2 and 2.5 times its normal levels of eNOS mRNA in the uncompressed cremaster muscle. IPC induced vasodilation was significantly reduced, abolished or reversed with the concurrent infusion of L-NMMA (NOS inhibitor).

Nitric oxide from eNOS can create vasodilation, reduce leukocyte adhesion, and inhibit platelet activation and aggregation, thereby increasing blood flow and enhancing fibrinolysis and antithrombotic activity. Authors speculate that one source of NO generation by IPC application could be a result of external compression causing elevated shear stress in the blood vessel's walls due to increased blood flow velocity in the deep veins. This stimulates endothelial cells lining the blood vessel walls to release NO, which then modulates blood flow. Another possible source of NO is that it is produced by compression of the skeletal muscles by IPC cuffs, since eNOS is present in skeletal muscle fibers.

This is the first study to connect IPC induced vasodilation and eNOS expression in skeletal muscles. Study results suggest that the increased release of NO (and related compounds) is a major pathway for vasodilation induced by IPC.

IPC use results in vasodilation and also in an increase in nitric oxide's chemical precursors in uncompressed muscles. This suggests that NO plays an important role in the regulation of microcirculation during IPC use. The IPC system used for this study had the same parameters as VenaFlow®.

Effect of Mechanical Compression on the Prevalence of Proximal Deep Venous Thrombosis as Assessed by Magnetic Resonance Venography

Ryan MG, Westrich GH, Potter HG, et al: J Bone Joint Surg 84–A(11):1998–2003, 2002

04349

This randomized prospective study examined the efficacy of VenaFlow in preventing pelvic and proximal deep vein thrombosis (DVT) after total hip arthroplasty. Magnetic resonance venography (MRV), the most sensitive technology currently available for detecting pelvic and proximal and extremity thrombi was used on all study patients.

The 100 participants (50 study, 50 control) received hypotensive epidural anesthesia and 325 mg. of aspiring (ASA) twice daily. The control group wore elastic stockings while the study group utilized the VenaFlow calf device. Statistically significant results were found: 22% (11) in control group developed DVT while only 8% (4) in the VenaFlow study group. In addition, the rate of occlusive clots which obstruct blood flow was significantly higher (10% stocking group) vs. only 2% in the VenaFlow group. No clinically symptomatic DVT or pulmonary embolism were noted in either group.

MRV visualizes clots that are not seen on less sensitive tests like venography or duplex Doppler ultrasound. Clots near the hip and pelvis can be detected even if the patient has undergone a total hip arthroplasty. Many of the clots that are visualized on MRV would not be visualized on traditional venography or ultrasound. Authors note in two previous studies IPC showed a decrease in distal DVT but an increase in proximal DVT. The authors feel this may be attributed to older forms of pneumatic compression with lower stroke volumes as well less sensitive screening techniques.

The authors conclude, "The VenaFlow mechanical compression device used in the present study provides a rapid impulse inflation compressing the calf veins through two overlapping air cells every sixty seconds. The asymmetrical compression maximizes blood velocity and total blood flow, which results in greater venous ejection compared with that provided by circumferential compression. Additionally, the inflation rate has a profound effect on venous velocity. In a previous comparative study of venous hemodynamics after total joint arthroplasty, the VenaFlow was noted to increase peak venous velocity at the level of the common femoral vein by almost 300% above the baseline, which was the greatest increase offered by the devices that were studied."

VenaFlow significantly reduces occlusive proximal thrombi as assessed by sensitive magnetic resonance venography.

Evaluation of Intermittent Pneumatic Compression Devices

Whitelaw GP, Oladipo OJ, Shah BP, et al: Orthopedics 24(3): 257–261, 2001

04337

Six different pneumatic compression devices (VenaFlow calf, Jobst calf, Jobst thigh, Kendall thigh, Venodyne calf, and PlexiPulse foot) were compared for their effect on venous blood flow and the results were compared to that of active and passive dorsiflexion. Doppler measures were taken proximal to the greater saphenous vein-femoral vein junction. The Aircast® VenaFlow produced venous velocity rates most similar to those of active or passive dorsiflexion. The venous velocity achieved with the other devices was significantly lower than active or passive dorsiflexion and the Aircast VenaFlow. "The relative effectiveness of pneumatic compression devices, particularly with respect to increasing venous blood flow in the lower extremity, may correlate well with how closely the device simulated the physiologic contraction of the calf muscles."

VenaFlow® is the only device to replicate the physiologic contraction of the calf muscles, as shown with venous velocity measurements

A clinical comparison of pneumatic compression devices: The basis for selection

Proctor MC, Greenfield LF, Wakefield TW, et al:Journal of Vascular Surgery 34(3), 461-464, Appendix A-E, 2001

(Reprint not available at this time)

Five devices were compared in this non-randomized, non-blinded study. Each device was assigned a month and depending on the patient population and the configuration of the device (calf, thigh or foot if available), the groups were assigned (but not matched). A total of 1350 patients received IPC during the five month period. Approximately 35% of the patients included in the study figures and treated with pneumatic compression devices consented to full study participation. VenaFlow (124 patient group) had approx 75% less patients than the W group (432 patients).

Approximately 82% of the study patients were not screened for DVTs, even though many DVTs are "silent". The percentage of screening varied widely from over 58% screening (V) to significantly less than 20% for some groups. According to the author, pump readings were not conducted on many patients as patients were not admitted to the hospital after outpatient surgery or were admitted for less than 48 hours, which did not provide sufficient time for enrollment. However, those patients were included in the data for diagnosis of thromboembolism. In the W group, only 18% of the patients were screened for DVT. Over 58% of the V group were screened and some were screened twice which is in contrast to other groups. (See published Addendum A-E.) Over 60.4% of the DVTs in this study were asymptomatic and were found during screening.

VenaFlow achieved the lowest rate of proximal DVT out of all 5 devices tested. VenaFlow patients had longer length of stay indicating that VenaFlow was not applied to the lower risk patients, potentially due to the knee only configuration of VenaFlow and the lack of outpatient and low risk surgeries during the trial month.

VenaFlow ranked #1 in compliance. The authors were unable to show a difference in DVT incidence based on the length of the device or the method of compression. "Randomized studies are needed to confirm our findings and evaluate hypotheses derived from this study."

VenaFlow achieved a low rate of proximal DVT. Proximal DVTs are documented to be the most dangerous and fatal. VenaFlow ranked #1 in compliance. Randomized controlled studies (RCTs) are needed to evaluate hypotheses derived from this "non matched groups" study. The study demonstrated that DVTs are often asymptomatic. Matched groups are needed

Venous Hemodynamic Characteristics of Pneumatic Compression Devices

Proctor MC, Zajkowski PJ, Wakefield TW, et al:The Journal of Vascular Technology 25(3): 141-145, 2001

(Reprint not available at this time)

This observational hemodynamic study was conducted using fifteen (healthy) volunteers and nine pumps. According to the author(s): "VenaFlow demonstrated the greatest increase over baseline in all variables." Doppler illustration on the paper shows the same evidence. [Note: The scale on the Dopplers and total size of the Doppler illustration for each product varies. The box/scale for VenaFlow is approximately 25% larger than the next largest, Product B. Larger box maximizes the Doppler scale and minimizes the VenaFlow peak.]

"The rapid gradient compression (device V) demonstrated the greatest increase over baseline in all variables. "VenaFlow increased all three elements of blood movement: peak systolic velocity (PSV), mean velocity (MV) and peak volume flow (PVF). "Compression devices are thought to work by increasing blood flow from the lower extremities and thus preventing stasis, a major cause of DVT. There is also some suggestion that they may exert a fibrinolytic effect."

The goal of the paper was to form hypotheses for future studies attempting to associate these variables with product efficacy. The author is currently reviewing her hypothesis on rapid inflation. Note: Continual use has failed to confirm the suggested outcome in the study pump or similar pumps with higher pressures.

VenaFlow demonstrated greatest increase over baseline in three important blood movement parameters necessary for prevention of clots. Scientific and clinical evidence has demonstrated that VenaFlow's and ArterialFlow's rate of inflation and pressures promote healing, which is the opposite of endothelial injury or damage.

Pneumatic Compression Hemodynamics in Total Hip Arthroplasty

04335

Westrich GH, Specht LM, Sharrock NE, et al: Clinc Ortho and Rel Research 372:180–191, 2000

Seven different pneumatic compression devices (foot: A-V Impulse and PlexiPulse, foot/calf combo: PlexiPulse, calf: VenaFlow, thigh: Kendall, Flowtron, Jobst) were evaluated on ten total hip arthroplasty patients in order to examine the effects on venous velocity and venous volume. Use of VenaFlow resulted in "the best increase in peak venous velocity... [and] has great potential for prophylaxis of thromboembolic disease." Since nursing and patient compliance are essential to the success of mechanical prophylaxis for thromboembolic disease, "the more simple, yet efficacious, devices that are easier to apply and less cumbersome appear to have a greater likelihood of success."

VenaFlow® surpasses other pneumatic compression devices in terms of venous velocity.

An in vitro cell culture system to study the influence of externalpneumatic compression on endothelial function

(Reprint not available at this time)

Dai G, Tsukurov O, Orkin RW, et al: Journal of Vascular Surgery 977–987, 2000

A simple three-dimensional in vitro system was designed to simulate the vessels and blood flow in the leg. This system models hemodynamic shear stress and vessel wall strain associated with blood flow. Human endothelial cells were used to line the system's "vessels" and the vessels were subjected to intermittent pulsatile flow (rapid acceleration of flow for 4 seconds followed by 56 seconds of "rest" by air pump), vessel collapse, or a combination of the two.

Both t-PA and eNOS mRNA expression are up-regulated by pulsatile flow, "increased levels of t-PA can decrease the baseline level of fibrin formation, which might contribute to the decreased incidence of DVT. Upregulation of eNOS suggests increased nitric oxide production, causing vasodilation and inhibiting platelet adhesion and aggregation."

Compression only group (50% vessel collapse with steady flow rate) caused little or no change in any of the genes considered, suggesting that it is "pulsatile shear stress, not vessel compression that is responsible for these changes. This has important implications for the design of EPC systems; the objective should be to increase shear stress above a certain level rather than to achieve vessel collapse." In previous studies (Dai 1999), both asymmetric and circumferential pressure at 50 mmHg generated the same degree of vessel collapse and vessel wall strain; however, the difference in shear stress level was considerably higher with asymmetric compression.

VenaFlow provides asymmetric pulsatile compression, which generates sufficient shear stress in the blood vessels, enhancing fibrinolytics and vasomotor function.

The Effects of External Compression on Venous Blood Flow and Tissue Deformation in the Lower Leg

Dai G, Gertler J, Kamm RD: Journal of Biomechanical Engineering 121:1–8, 1999

04339

Finite element analysis was used to examine the stress distribution within the tissues, and the corresponding venous blood flow and intravascular shear stress with different external compression modalities. Circumferentially symmetric (C) compression was compared to asymmetrical (A)compression, with axial distribution being either uniform or graded sequential. "The results show that A compression produces greater vessel collapse and generates larger blood flow velocities and shear stresses than C compression." Elevated levels of shear stress can influence the release of fibrinolytic agents, demonstrating that fluid dynamic effects might modulate fibrinolysis.

Asymmetric compression, as used in VenaFlow, produces greater vessel collapse and generates larger blood flow velocities and shear stresses than circumferentially symmetric compression.

Influences of Inflation Rate and Duration on Vasodilatory Effect by Intermittent Pneumatic Compression in Distant Skeletal Muscle

(Reprint not available at this time)

Liu K, Chen LE, Seaber AV, et al: Journal of Orthopaedic Research 17(3): 415–420, 1999

This study examined the influences of inflation rate and peak-pressure duration on the vasodilatory effects of intermittent pneumatic compression (IPC). Asymmetrical compression was applied to the legs (rat cremaster model), with inflation to 55 mmHg. Inflation rate and peak inflation time were adjustable. The data demonstrated that "intermittent pneumatic compression with a faster inflation rate [less than 1 second] caused a much greater increase in vessel diameter than did compression with a slower inflation rate.

Once the peak pressure is attained, increasing the duration of inflation does not facilitate this [vasodilatory] effect. The mechanism for this phenomenon appears to be related to the magnitude of shear stress during rapid inflation of the compression, which stimulates the vascular endothelium to release nitric oxide, causing systemic vasodilation."

Intermittent pneumatic compression devices with an inflation rate of less than one second cause a much greater increase in vessel diameter compared with slower inflation rates. The best inflation parameters for performance are the same as those found in VenaFlow (inflation to 55 mmHg in less than one second).

Intermittent Pneumatic Compression of Legs Increases Microcirculation in Distant Skeletal Muscle

(Reprint not available at this time)

Liu K, Chen LE, Seaber AV, et al: Journal of Orthopaedic Research 17(1): 88–95, 1999

The effects of intermittent pneumatic compression (IPC) on microcirculation were examined using a rat cremaster-muscle model. The IPC device applied rapid asymmetrical compression to the legs at 55 mmHg within 1 second, with a 5 second hold time*, and caused "a marked and rapid increase of blood-flow velocity in the lower extremities, thereby creating strong shear stress on the venous wall." The results showed that the application of intermittent pneumatic compression with the same parameters used in this study "can significantly increase the diameter of both arterial and venous vessels in rat cremaster muscle at the microcirculation level. Because the inhibition of nitric-oxide production completely eliminates vasodilation induced by IPC, an explanation of the compression's effectiveness may be related to increasing nitric-oxide release as a result of hemodynamic changes during the compression." This suggests that rapid leg inflation IPC may be beneficial for the improvement of microcirculation. *These are the same inflation parameters as found in VenaFlow.

VenaFlow®'s rapid asymmetric inflation increases blood velocity by increasing vessel diameter through hemodynamic changes resulting from shear stress on the vessel walls.

Evaluation of Pneumatic Compression Devices and Compression Stockings

Boegli S, Fennell C: Middleton Regional Hospital, Ohio, 1998

(Unpublished data)

This study examined the effectiveness of various intermittent pneumatic compression (IPC) devices, on healthy subjects and high risk patients, in mimicking the body's normal blood flow achieved with dorsiflexion. It also quantified the increase in blood flow with compression stockings alone and in combination with various IPC devices. Results showed that the Aircast VenaFlow system most closely approximated dorsiflexion. Compression stocking combined with IPC calf or thigh devices did not increase blood flow when compared to IPC alone. Stockings did increase blood velocities when combined with the foot pump device when compared to the foot pump without stockings. There was no difference in performance of the IPC devices when tested on healthy patients compared to testing on high-risk patients

VenaFlow outperformed other IPC devices and most closely matched the increase in blood velocity achieved with dorsiflexion. The additional use of compression stockings did not affect the blood velocities achieved with the calf or thighlength IPC devices.

Venous Haemodynamics After Total Knee Arthroplasty

Westrich GH, Specht NE, Sharrock RE, et al: JBJS (British) 80(B):1057–1066, 1998

A variety of pneumatic compression devices (PlexiPulse foot, AV Impulse foot, Plexipulse foot-calf, VenaFlow calf, Kendall SCD thigh, Flowtron thigh, and Jobst thigh) were tested on total knee arthroplasty (TKA) patients in order to determine the effect of different devices on venous velocity in postoperative applications. "VenaFlow produced the greatest increase in peak venous velocity compared with all the other devices" in measures both above and below the greater saphenous-common femoral junction and in both patient groups. VenaFlow provides impulse calf compression. The authors state that foot pump devices "have a small stroke volume of 30 mL, and thus the increase in peak venous velocity in the common femoral vein was considerably less than in devices which pump the calf and soleal sinus, giving a much greater stroke volume." When compared to the results of the thigh-length compression systems, the authors "doubt whether the addition of thigh compression is necessary."

VenaFlow produces the greatest increase in venous velocity compared to other tested devices.

Using Duplex Ultrasound Imaging to Optimize the Inflation Characteristics of an Intermittent Compression Device

Needham TN, Ort ST, Johnson GW, McVicker J: The Journal of Vascular Technology, 19(2):63-66, 1995

Reviewing early work on the VenaFlow system, this paper describes how duplex ultrasound imaging was employed to establish optimum inflation characteristics. VenaFlow's design parameters and the benefits of increased velocity plus patient compliance are also discussed.

Performance was affected by cuff configuration, type of compression, cuff pressure, rate of pressure rise, sequence, duration and interval. The effects of flow velocities were independent of leg size and the age of the subject. Measurements were recorded just proximal to the saphenofemoral junction, as optimal movement of blood through the thigh was considered vital.

VenaFlow's superior design parameters are based on goals to reduce venous stasis while enhancing fibrinolytic activity. This study confirms VenaFlow's design which optimizes inflation sequence, timing, pressures, intervals and duration of compression.

Mechanical DVT Prophylaxis (General)

Intermittent pneumatic compression and pharmacologic thrombosis prophylaxis

Caprini JA:Current Opinion on Pulmonary Medicine,15(5):439-442, 2009

(Reprint not available at this time)

In this review article, the author concludes that new data regarding the value of IPC alone and in combination with anticoagulants support the use of these devices particularly in the highest-risk patients. "It is important not to use GCS (graduated compression stockings) interchangeably with IPC since no venographic data are available for stockings." In addition, there is no data to suggest that adding stockings to IPC improves efficacy achieved by IPC alone.

IPC has been proven venographically to dramatically reduce the incidence of VTE. No venographic data is available to support the use of stockings.

Duration and magnitude of the postoperative risk of venous thrombo-embolism in middle aged women: prospective cohort study

Sweetland S, Green J, Liu B, et al:BMJ 339:b4583, 2009

(Reprint not available at this time)

This prospective cohort study (Million Women Study) examined the duration and magnitude of increased risk of VTE after different types of surgery. Using questionnaires and NHS data, 947,454 middle aged women were followed for an average of 6.2 years. The postoperative risk of VTE varied considerably by surgery type, with highest relative risks after inpatient surgery for hip or knee replacement and for cancer.

The risk of DVT and PE after surgery is substantially increased in the first 12 postoperative weeks, and varied considerably by type of surgery. Compared with not having surgery, women in this study were 70 times more likely to be admitted with VTE in the first six weeks after an inpatient operation and 10 times more likely after a day case operation.

"Million Women Study" demonstrated that the postoperative risk of VTE was substantial and varied by specialty. The risk of VTE continued for an extended period after surgery.

Cost benefit of intermittent pneumatic compression for venous thrombo-embolism prophylaxis in general surgery

Nicolaides A, Goldhaber SZ, Maxwell GL, etal:International Angiology, 27(6):500-506, 2008

(Reprint not available at this time)

Systemic reviews comparing IPC with no prophylaxis have recently demonstrated a 60%-69% reduction in DVT in the IPC groups. Using costs of prophylaxis from the English medical literature and Medicare, the cost effectiveness of using IPC with stockings vs. no prophylaxis was examined.

In 1,000 moderate to high risk general surgical patients, in the absence of prophylaxis, the cost of investigating and treating 72 patients with clinical suspicion of DVT and 32 with PE is calculated to be $263,779. This corresponds to $263 per surgical patient. The cost of IPC combined with stockings in 1,000 similar patients would be $66,760, and the cost of diagnosis and treatment of the reduced numbers (69% reduction) of clinical VTE is $83,574 making a total of $150,344. This means a savings of $113,435 ($263,779-$150,344) per 1,000 patients. This corresponds to a saving of $113 per surgical patient and clearly demonstrates that IPC prophylaxis is a cost beneficial modality.

For moderate to high-risk patients undergoing general surgery, IPC is a cost beneficial modality.

Prevention of venous thromboembolism: American College of Chest Physicians Evidence – Based Clinical Practice Guidelines (8th Edition)

Geerts WH, Bergqvist D, Pineo GF, et al:CHEST 133:3815-4535, 2008

(Reprint not available at this time)

The conference guidelines, which include extensive review of the clinical literature, form the basis for many other articles for DVT prevention. The authors also review pathophysiology and risk factors for deep vein thrombosis. Risk factors vary depending on the patient's history, previous illness, current illness, current procedures and other factors. Risk stratification and plan of prevention is discussed at length. Multimodal therapy is discussed. Prophylactic protocols are vital to reduce the risk of DVTs.

Guidelines for risk assessment and DVT prophylaxis often include intermittent pneumatic pumps. Guidelines should be individualized for patients and are a medical decision.

Direct Medical Costs of Venous Thromboembolism and Subsequent Hospital Readmission Rates: An Administrative claims Analysis From 30 Managed Care Organizations

Spyropoulos AC, Lin J: Journal of Managed Care Pharmacy (13)6, 475-486, 2007

(Reprint not available at this time)

This retrospective analysis quantified the cost burden to the health plan by examining annual DVT and PE related payments made by the health plan to providers for inpatient and outpatient care. Over 5 million discharges were analyzed. The total health care cost for a VTE ranged from $7,594 to $16,664, depending on the type of event and whether it was primary or secondary diagnosis. The hospital readmission rates of DVT of PE within 12 months were 5.3% for primary and 14.3% for secondary diagnoses. The recurrent DVT event was associated with a 21% greater cost compared with the initial DVT event.

"The economic burden of DVT and PE in direct medical cost is large, due not only to the initial hospitalization event, but also to the high rate of hospital readmission (5%-14%), over half of which occurs within 90 days."

Economic burden of DVT and PE is large. Effective prevention by VenaFlow can help patients and facilities "Walk Away from Risk" of DVTs and the associated economic burden.

An audit of intermittent pneumatic compression in the prophylaxis of asymptomatic deep vein thrombosis

Illingworth C, Timmons S:Journal of Perioperative Practice, 2007

(Reprint not available at this time)

Noninvasive mechanical methods to prevent DVT are included in prevention guidelines. Using a questionnaire this study audited the use of IPC. While the standard states that IPC devices are effective in prophylaxis of asymptomatic DVT in surgical patients, only 15% of the respondents say that IPC was used on every patient in their department. In addition, according to the participants in the study, approximately half of the patients returned to the floor without the IPC [Flowtron].

Compliance with VenaFlow can improve outcomes. The unique design of the VenaFlow pump and cuffs promotes nursing and patient compliance.

AORN Guideline for Prevention of Venous Stasis

AORN Journal, 85(3):607-624, 2007

(Reprint not available at this time)

The purpose of the guideline is to provide a framework that perioperative team members and others can use to develop polices, procedures, and protocols for prevention of venous stasis and DVT/PE. Definitions, prevalence, pathophysiology and pathogenesis of DVTs are explored. Assessing for risk factors section and sample risk assessment protocol is included in this thorough review.

The choice of therapy is a medical decision, but the perioperative nurse should collaborate with the team regarding initiating the established protocol orders. According to the guidelines, IPC devices should be turned on before the beginning of induction of general anesthesia or before regional anesthesia has been administered. Plan of care should be considered for procedures lasting longer than 30-45 minutes.

DVT prevention protocols based on AORN Guidelines include pumps such as VenaFlow. Decisions based on guidelines should be a collaboration among entire team in the hospital or surgery center

Risk factors and clinical impact of postoperative symptomatic venous thromboembolism

Gangireddy C, Rectenwald JR, Upchurch GR, et al:Journal of Vascular Surgery, 45(2):335-342, 2007

(Reprint not available at this time)

In surgical patients, symptomatic venous thromboembolism (VTE) is associated with significantly increased 30-day mortality. In addition to previously recognized risk factors, patients who have postoperative complication of an infectious nature, bleeding or myocardial infarction (MI) are at particular risk for VTE.

Risk factors for VTE continue to expand. Correlation between infection and DVT is still being explored.

Prevention of Venous Thromboembolism in the ICU

04361

Geerts W, Selby, R: CHEST 124(6):357S–363S, 2003

Risk factors for VTE continue to expand. Correlation between infection and DVT is still being explored.

The risk of venous thromboembolism (VTE) is high in the ICU. Screenings are difficult and may be less reliable in this group due to the complexities of the illness and the critical state of the patient. Many pulmonary embolisms are undetected in the ICU patient.

This systematic review of the literature discusses the published trials of ICU thromboprophylaxis and suggests strategies to reduce the incidence of this complication in critical care patients. In the usual risk (normal risk of bleeding) critical care admission the combination of anticoagulant and mechanical prophylaxis is suggested. In the high risk (increased bleeding risk) group the authors state, "Sequential prophylaxis, with the use of mechanical devices during an initial high bleeding risk phase followed by anticoagulant prophylaxis should be considered in relevant critical care patients." In addition, prophylaxis should be revieweddaily and changed if necessary, taking into consideration each patient's overall clinical status on that particular day. The authors suggest that policies for thromboprophylaxis should be developed by critical care units.

Patient Safety in Office-Based Surgery Facilities: I. Procedures in the Office-Based Surgery Setting

Iverson RE, and the ASPS Task Force on Patient Safety in Office-based Surgery Facilities
Plastic and Reconstructive Surgery 110(5):1337-1342, 2002

(Reprint not available at this time)

DVT prevention practice guidelines for ASPS facilities include intermittent pneumatic compression for moderate and high-risk patients. Application before the induction of general anesthesia and continued until the patient is awake and moving in the recovery room is recommended.

This document if one of four "practice advisories" written to assist decision-making in areas of patient care for plastic surgery in the office setting. The author and task force looked into a variety of safety issues common to most plastic surgery procedures. The goal was to produce this comprehensive practice principal to help establish a national standard on patient care and safety for this setting. Attention was given to several safety issues including prevention of deep vein thrombosis.

For procedures lasting longer than 30 minutes, implementing necessary measures based on risk for DVT prevention are detailed. These measures are based on diagnostic patient history, physical exam and subsequent risk assessment. For moderate-risk and high-risk patients … "intermittent pneumatic compression devices of the calf or ankle and frequent alteration of the operating room table are recommended. The devices should be in place before the induction of general anesthesia, and their use should be continued until the patient is awake and moving in the recovery room."

A Comparison of Two Different Prophylactic Dose Regimens of Low Molecular Weight Heparin in Bariatric Surgery

Scholten DJ, Hoedema RM, Scholten SE:Obesity Surgery, 12:19-24, 2002

(Reprint not available at this time)

DVT poses a significant risk for patients undergoing surgery for morbid obesity. In this retrospective review study, a multimodal protocol including intermittent compression device, stockings, early ambulation and anticoagulant was used by all participants. Two different doses of enoxaparin were given to the study groups. All 481 patients were followed for at least six months postoperatively.

The multimodal risk reduction protocol and strategy for this high risk group was beneficial. Essential parts of the protocol included venous thrombosis risk assessment plus application of IPC.

IPC is valuable component of a multimodal risk reduction protocol for Bariatric patients.

04286B

Current Recommendations for Prevention of Deep Venous Thrombosis

Heit JA. Handbook of Venous Disorders 2nd Edition Chapter 23:224–234, 2001

This chapter identifies risk factors for venous thromboembolism (VTE) and provides an overview of theefficacy and safety of prophylaxis regimens for DVT prophylaxis. Intermittent pneumatic compression (IPC) is "useful as either primary prophylaxis or as an adjunct combined with anticoagulant prophylaxis... IPC is an attractive prophylaxis option for multiple trauma patients or medical patients in whom anticoagulant-based prophylaxis is contraindicated due to active bleeding, or surgery in which even minimal bleeding could be catastrophic (i.e., neurosurgery or spinal surgery)." Moderate, high and very high risk general and vascular surgery recommendations included IPC as primary defense or component of combination therapy. "IPC is the most effective nonpharmacological prophylaxis for total knee replacement patients. IPC may provide a risk reduction that is similar to LMWH [low molecular weight heparin]."

As for timing of IPC application, it is recommended that "IPC should be initiated preoperatively if possible, and continued until the patient is fully ambulatory."

IPC is often recommended as primary or component of combination therapy. In some cases, IPC can provide risk reduction comparable to LMWH. IPC is a safe, attractive option for patients in whom anticoagulant-based prophylaxis is contraindicated.

04366

The Role of Mechanical and Other Adjuncts

Westrich G: American Journal of Knee Surgery 12(1):64–71, 1999

A meta-analysis was performed on all published total knee arthroplasty (TKA) studies that included routine screening for deep vein thrombosis (DVT) and pulmonary embolism (PE). Twenty-five studies met this criteria. The meta-analysis divided prophylaxis into 4 groups: aspirin warfarin, low molecular weight heparin (LMWH), and intermittent pneumatic compression (IPC). This review of the literature indicated that IPC devices were the most effective modality in preventing the occurrence of DVT after TKA. Mechanical prophylaxis for DVT using IPC devices "is safe and efficacious, and may be more cost-effective" than pharmacologic prophylaxis.

Intermittent pneumatic compression devices, such as VenaFlow, provide safe and efficacious prophylaxis against DVT.

15023

Blood-Flow Augmentation of Intermittent Pneumatic Compression Systems Used for the Prevention of Deep Vein Thrombosis Prior to Surgery

Flam E, Berry S, Coyle A, et al. Am J Surgery 171:312–315, 1996

Peak venous blood velocity was measured using Duplex ultrasonography in order to compare flow augmentation achieved by different intermittent pneumatic compression (IPC) systems. The knee-high single pulse intermittent pneumatic compression system (IPC) produced a significantly higher venous blood-flow augmentation than the thigh-high vinyl sequential pulse system.

Calf cuff may augment blood flow better than thigh cuff.

Prophylaxis against Deep Venous Thrombosis after Total Knee Arthroplasty

Westrich GH, Sculco TP: J Bone Joint Surg 78-A(6):826–834, 1996

15025

The efficacy of pulsatile pneumatic compression combined with aspirin was compared to the use of aspirin alone for DVT prophylaxis after total knee arthroplasty. This article "supports the use of mechanical compression for prophylaxis against deep venous thrombosis and for the reduction of edema in patients who have had a total knee arthroplasty." In addition to increased venous return, rapid (pulsatile) inflation may "increase turbulence around venous valves, thus decreasing the formation of thrombi... hemodynamic studies have confirmed increased blood flow and tissue perfusion with the release of endothelial-derived relaxing factor [EDRF] and prostacyclin."

Rapid inflation devices provide effective DVT prophylaxis through increased venous return, increased turbulence around the venous valves, and increased blood flow due to release of EDRF.

The Return of Blood to the Heart: Venous pumps in health and disease

Gardner AMN, Fox RH. Second Edition. London, John Libbey and Company Ltd., 1993

15019

In this text, the authors discuss the role of EDRF (endothelial-derived relaxing factor or nitric oxide) and impulse inflation in the prevention of venous thrombosis. EDRF is produced "in response to rapid velocity changes (shear-stress) in the vascular system and is a most powerful relaxant of vascular smooth muscle... The ability of EDRF both to increase blood flow and disaggregate platelets, helps to explain how both muscular activity and impulse pumping are effective in preventing venous thrombosis." The slow inflation rate of intermittent compression devices does not mimic the calf pump action in normal ambulation. Rapid inflation produces turbulence in valve pockets where thrombosis commonly originates. They conclude that rapid impulse compression may be a more effective form of mechanical DVT prophylaxis since it "can mimic the effect of exercise on the circulation by producing pulsatile venous flow and thus causing endothelial shear-stress, generating locally the natural antithrombotic agents prostacyclin and EDRF that also increase arterial flow."

Rapid impulse inflation mirrors calf pump action resulting in turbulence in valve pockets.

Rapid inflation causes endothelial shear stress, which generates natural antithrombotic agents.

Why Does Prophylaxis with External Pneumatic Compression for Deep Vein Thrombosis Fail?

15026

Comerota AJ, Katz ML, White JV. Am J Surgery 164:265–268, 1992

Due to the risk of bleeding complications with pharmacologic prophylaxis for DVT, mechanical devices are an attractive alternative since they have no inherent risk. When examination of possible reasons for reduced efficacy of external pneumatic compression devices (EPC) was conducted, they found that "improper use (of EPC) is frequent and failure of DVT prophylaxis with EPC devices many be due to improper use, rather than failure of the method itself... This can be partly explained by patients removing the devices because of discomfort and inconvenience..."

Patient compliance and overall efficacy of EPC can be improved with a comfortable cuff design.

Effect of Optimization of Hemodynamics on Fibrinolytic Activity and Antithrombotic Efficacy of External Pneumatic Calf Compression

Salzman EW, McManama GP, Shapiro AH, et al. Ann Surgery 206(5):636–641, 1987

15018

A comparison of the hemodynamics of uniform compression vs. graded sequential compression was conducted using a custom-designed cuff to meet optimal parameters for graded sequential compression. They found that "a system for external pneumatic compression in which the pressure was applied in a gradedfashion, milking the blood from ankle to knee, was more effective hemodynamically, and in the clinical trial it proved to be more effective in enhancement of fibrinolytic activity than uniform compression..."

Graded sequential compression is better than uniform for blood flow and fibrinolysis.

Optimisation of Indices of External Pneumatic Compression for Prophylaxis against Deep Vein Thrombosis: Radionuclide Gated Imaging Studies

15020

Kamm R, Butcher R, Froelich J, et al. Cardiovascular Research 20(8):588–596, 1986

Healthy human subjects with radionuclide-labeled blood were examined for the effect of external pneumatic compression in order to determine the optimal parameters necessary for DVT prophylaxis. They found that the optimal cycle has "some combination of gradation and sequencing... (and) the optimal values of Δp were in the range of 5–10 mmHg and of Δt in the range of 0–0.5 s." Most blood ejection occurred in 2–4 s from the start of the compression cycle and 30–50 s was needed for the blood vessels to refill. They also found that the maximum proportion of venous blood ejected was directly related to the degree of collapse of the vessel, and the square of the maximum velocity is directly proportional to turbulent shear stress. Shear stress is important since it can mechanically strip seeds of thrombi off the endothelium.

Optimal parameters for IPC:
- Graded and sequential
- Δp = 5 – 10 mmHg
- Δt = 0 – 0.5 s
- Comp. cycle = 2 – 4 s
- 30 – 50 s refill time

Bioengineering Studies of Periodic External Compression as Prophylaxis against Deep Vein Thrombosis — Part I: Numerical Studies

15021

Kamm RD. J Biomech Engineering 104(I):87–95, 1982

The author states that "external compression in its present form may not be providing the greatest possible level of protection" for the prevention of DVT formation. This is the first in a series of investigations designed to examine the hemodynamic events associated with external limb compression and to determine which procedure for compression may be most effective. The goal of external pneumatic compression is to empty the entire length of the veins "as fully and as rapidly as possible." Computer simulation of flow produced by periodic external compression showed that "uniform compression expels only about 70 percent of the blood volume contained in the large veins... The effectiveness of uniform compression is severely compromised by the formation of a flow-limiting throat at the proximal end of the compression cuff that reduces both the rate at which blood is discharged from the lower leg and the total blood volume removed. Both of these detrimental effects can be avoided by the use of either wavelike or graded compression."

Uniform compression is not as effective in emptying veins as graded or wavelike compression.

Bioengineering Studies of Periodic External Compression as a Prophylaxis against Deep Vein Thrombosis — Part II: Experimental Studies on a Simulated Leg

Olson DA, Kamm RD, Shapiro AH. J Biomech Engineering 104(II):96–104, 1982

15022

Second part of investigational series examines the effect of alternative modes of compression performed on a simple leg model on hemodynamic parameters that are relevant to DVT prophylaxis. This study concludes "either sequential or graded compression, or perhaps a combination of the two, would be more effective than uniform compression in prophylaxis against deep vein thrombosis." With sequential compression, a firing delay of 0.5 s was determined to be optimal for shear stress and blood velocity changes.

Graded or sequential compression is superior to uniform for DVT prophylaxis.

Intermittent Sequential Pneumatic Compression of the Legs in the Prevention of Venous Stasis and Postoperative Deep Venous Thrombosis

Nicolaides AN, Fernanades e Fernandes J, Pollock AV. Surgery 87(1):69–76, 1980

15016

This early study of graduated sequential compression devices determined that "peak and mean velocities in the femoral vein during compression with the sequential device were higher than when a single chamber of equal length was used." In addition to superior velocities, sequential compression devices appear to provide better emptying of the veins since." The high flow in the femoral vein at the beginning of the non-compression period using the single-chamber legging suggests that a considerable amount of blood was trapped in the veins distally." A clinical trial that followed demonstrated that "the sequential compression device was as effective as small-dose subcutaneous heparin during the period it was used. The sequential compression device may become the method of choice... in order to avoid the risk of hemorrhage and wound haematoma associated with small-dose subcutaneous heparin."

Blood velocities and vein emptying for sequential compression are superior to uniform compression.

The Effect of Intermittently Applied External Pressure on the Haemodynamics of the Lower Limb in Man

Roberts VC, Sabri S, Beeley AH, et al. Brit J Surg 59(3):223–226, 1972

15017

Study results showed that peak femoral blood flow increases proportionally with the rate of pressure application. When examining the effect of compression intervals on peak flow, results indicated that the "maximal values occur when the interval between successive compressions is about 60 seconds, a finding which appears to be related to the time required for the venous system to refill following release of leg compression..."

Rate of pressure application is proportional to peak flow.

Improving limb salvage in critical ischemia with intermittent pneumatic compression: A controlled study with 18-month follow-up

Kavros SJ, Delis KT, Turner NS, et al: Journal of Vascular Surgery: 47(3)543-549, 2008 **00-0774**

The objective of this retrospective, controlled study was to evaluate the clinical efficacy of IPC [ArterialFlow] in patients with chronic critical limb ischemia, tissue loss, and nonhealing wounds of the foot after limited foot surgery (toe or transmetatarsal amputation).

The setting was a community and referral orthopedic surgical and multidisciplinary wound care clinic. The study groups received wound care for tissue loss and nonhealing amputation wounds of the foot due to critical limb ischemia. Group 1 consisted of 24 patients, median age 70, who started using IPC as an adjunct therapy between 1998 and 2004. Patients were typically asked to use the ArterialFlow pump at home on the affected limb three times daily for two hours each session (six hours total per day). This was for both the pre and postoperative periods. Group 2 (control group) consisted of 24 consecutive patients, median age 69 years, who received wound care and biologicals, but no pump.

In the control group, foot wounds failed to heal in 20 patients (83%) and they underwent a below knee amputation. In the IPC group, 14 patients (58%) had complete wound healing and limb salvage. On study completion, TcPO2 on sitting was higher in the IPC group than in the control group.

Patients with severe and critical limb ischemia may benefit from the use of an intermittent compression pump [ArterialFlow] as adjunctive therapy when considering a local foot amputation. In these high risk individuals, limb preservation and function can often be achieved, or the level of the lower extremity amputation reduced. IPC [ArterialFlow] provides an effective method of leg inflow enhancement and amelioration of claudication in patients with peripheral arterial disease. This controlled study adds to the momentum set by previously published case series and other reports for ArterialFlow use in critical limb ischemia.

ArterialFlow, used preoperatively and postoperatively, is proven to be an effective adjunctive therapy and dramatically reduced the incidence of lower extremity amputations in high-risk individuals.

Use of Intermittent Pneumatic Compression for Treatment of Upper Extremity Vascular Ulcers

Pfizenmaier DH, Kavros SJ, Liedl DA, et al: Angiology 56(4):417-422, 2005

04377

ArterialFlow® is a viable therapeutic option to improve healing of upper extremity ulcers when added to standard therapy. Patients who healed also reported pain reduction.

Limited data exists regarding the natural history of upper extremity vascular ulcers. Most ulcers involve the fingers and are secondary to trauma in the setting of underlying ischemia. Arteriosclerosis obliterans and, especially, autoimmune disorders such as scleroderma, MCTD, and vasculitis comprise the most common predisposing diseases. Standard medical therapy includes protection with dressings or mitts, optimal wound hygiene, topical agents, systemic vasodilators, and occasionally surgical/chemical sympathectomy. Management is often complicated by the fact that digits are frequently injured despite the best attempts at protection. Pain control is also a common difficulty. Based on the Mayo Clinic Wound Care Center experience, over one-half to three-quarters of these ulcers do not heal with standard medical therapy. Subsequent digital amputation is often required.

The intermittent pneumatic pump is a novel therapy involving external compression of an extremity that results in improved distal laser Doppler blood flow. Use of the device in critical ischemia of the lower extremities has resulted in complete wound closure and limb preservation (Montori VM. Int Angiol 2002). In order to study and attempt to improve therapeutic outcomes in treating upper extremity ulcers, the Aircast ArterialFlow pump was added to the regimen of standard medical therapy.

In a retrospective chart review, 27 upper extremity ulcers in 26 patients were identified. Since most of these patients presented with more than one ulcer, the largest ulcer was chosen as the index lesion. Inclusion criteria were: 1) documented measurements of index ulcer were obtained at the initial visit, 2) the intermittent compression pump was instituted after the initial visit, and 3) documented follow-up was required.

Eighty one percent of patients were female (21/26) and 96% were Caucasian (25/26). The average age at ulcer onset was 53 years (SD = 11 years). Autoimmune disorders were underlying etiologies in 88% (23/26) of patients, with scleroderma representing 65% (17/26). Arteriosclerosis obliterans was involved in 12% (3/26) of patients. Mean ulcer size was 1.0 cm2 (SD=0.3 cm2). All patients received topical treatments and drug therapies — mostly cadexomer iodine gel (in 85%) and calcium-channel blockers (in 78%), respectively.

Out of 27 upper extremity ulcers, 26 (96%) healed with the use of the ArterialFlow pump. One digit required amputation. The mean age of ulcers prior to the use of the device was 31 weeks (SD=37 weeks). Mean time to heal after the use of the ArterialFlow pump was 25 weeks (SD=31 weeks); or 19 weeks (SD=11 weeks) if one outlier was removed. All patients tolerated use of the device for a mean of 5 hours (SD=1.5 hours) per day. Two patients (8%) reported worsening of pain with initiation of pump use that subsequently improved after several days of continued pumping. No standard evaluation or measurement of pain was recorded over the duration of pump use, but all patients that healed reported improvement of pain.

Effect of Intermittent Pneumatic Soft-tissue Compression on Fracture-Healing in an Animal Model

Park S-H, Silva M: Journal of Bone and Joint Surgery 85(8):1446–1453, 2003 **04364**

This randomized, controlled study evaluated the effect of intermittent pneumatic compression on fracture-healing following a transverse tibial osteotomy in an animal model. Intermittent pneumatic compression, utilizing the Aircast ArterialFlow System, was applied for one hour daily for a period of 25 days, starting on the fourth postoperative day. Applying arterial pressure may facilitate venous emptying and prevent stasis by allowing the lower extremity veins to have increase in arterial-venous gradient, "ultimately resulting in an increase in the arterial blood flow. Blood circulation especially arterial blood flow, is recognized as an important factor in fracture-healing. Therefore, an increase in arterial blood flow to the fracture site, especially in the lower limb, may improve healing".

As early as four weeks, radiographs showed faster callus formation and mineral content with a more uniform bridging of the defect in the study group. Computerized tomography revealed significantly higher mineralized callus area and mineral density in the study group compared with the control group.

At eight weeks, superior biomechanical properties were evident in the ArterialFlow group for maximum torque, stiffness, angular displacement at maximum torque, and energy required for failure. "The clinical implication of this finding is that the use of intermittent pneumatic compression in patients with an acute fracture, especially in the lower limb, may improve the fracture-healing."

The Aircast® ArterialFlow® System produced superior healing, including callus formation, mineral content and strength, when applied post-operatively in lower limb fracture study group.

Intermittent compression pump for nonhealing wounds in patients with limb ischemia. The Mayo Clinic experience (1998 – 2000)

Montori VM, Kavros SJ, Walsh EE, et al: International Angiology, 21(4):360–366, 2002

04357

"The aim of this retrospective observational study was to review the use of an intermittent pneumatic compression device on nonhealing wounds in patients with critical limb ischemia at Mayo Clinic Rochester." The ArterialFlow device is designed to "augment arterial flow and microcirculation with pulsatile compression of the limb."

One hundred seven patients were instructed to use the device at home on the affected limb(s) for a minimum of six hours per day daily. To accomplish this goal, patients were requested to use the device for three, two-hour sessions in the morning, afternoon, and evening. Patients were encouraged to use the pump for extended periods at night when ambulatory requirements were minimal. Data collection included history of diabetes, hypertension, renal impairment, dyslipidemia, previous cardiovascular disease, previous revascularization or amputation. Wound etiology, complications, $TcPO_2$ levels before initiating pump use were documented. Strict adherence to outcomes was determined by complete wound healing and limb preservation. Patients with unfavorable outcomes had either amputation of the limb bearing the wound or a persisting wound at the last follow-up visit.

"In patients with nonhealing multifactorial wounds and limb ischemia treated with an intermittent compression device, we observed complete wound healing and limb preservation in 40% of patients with $TcPO_2$ levels below 20mmHg; 48% with osteomyelitis or active wound infection; 46% with diabetes treated with insulin; and 28% with any previous amputation. These unexpectedly high rates suggest that the device may have affected the clinical course of nonhealing wounds in patients at high risk of limb loss." The strict and explicit definition of a favorable outcome (complete wound healing with limb preservation) was easily verified in the patient medical history. However, its strict character left out many more patients experiencing a "favorable" outcome including wound reduction (partial wound healing) with limb preservation and improvement of ischemic limb pain. This factor cannot be minimized with regard to the overall quality of life for the patient and associated families.

ArterialFlow favorably influenced wound healing in patients with critical limb ischemia. It is designed to augment arterial flow and microcirculation using rapid, pulsatile compression of the limb. Using the ArterialFlow System may affect the clinical course of nonhealing wounds in patients at high risk of limb loss.

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