

VenaFlow® Research

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

04356

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

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.

Prospective, Randomized Study of Two Intermittent Pneumatic Compression Devices for DVT Prophylaxis After Total Knee Arthroplasty

(Reprint not available at this time)

Lachiewicz PF: Presented at AAOS, Hip and Knee Society, Specialty Day, San Francisco, CA, 2004 and at the Knee Society, Chicago, Illinois, 2003

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 hypothesis 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 a 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 device utilizing circumferential compression and gradual inflation.



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Abstract

Aspirin plus venaflow vs. lovenox plus venaflow for DVT prophylaxis in TKA patients

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Introduction

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The purpose of this study is to compare the combined efficacy of aspirin with pneumatic compression (PC) vs. low molecular weight heparin (LMWH) with PC for deep vein thrombosis (DVT) prophylaxis in unilateral total knee arthroplasty (TKA) patients.

Methods

TOP

Two hundred twenty-nine patients were prospectively randomized to receive aspirin plus PC (Group A) or LMWH plus PC (Group B). VenaFlow® calf pumps (PC) were applied bilaterally to both groups in the recovery room and remained on while the patient was non-ambulatory. Group A received aspirin (325 mg BID for 4 weeks postoperatively). Group B received Lovenox®, (a LMWH), initiated 2 hours after epidural catheter removal approximately 48 hours postoperatively, 30 mg BID until hospital discharge; upon discharge, 40 mg QD for three weeks. The incidence of DVT was monitored twice by Doppler Ultrasound; POD 3–5 and 4 weeks postoperatively. Any patient with a positive ultrasound on POD 3–5 was removed from the study and treatment protocol was initiated.

Results

POD 3–5, 219 patients underwent ultrasounds revealing a 16.9 percent (37/219) DVT incidence; Group A-17.9 percent (19/106) and Group B- 15.9 percent (18/113). Postoperative week 4, 150 patients underwent ultrasounds revealing a 3.3 percent (5/150) incidence of secondary DVT; Group A- 5.5 percent (4/72) and Group B- 1.3 percent (1/78). (No significant differences in DVT incidences.) No complications were reported due to the Aspirin, Lovenox® or PC device.

Discussion and conclusion

TOP

This is the study to demonstrate the efficacy of combining modalities for DVT prophylaxis. For instance, both groups demonstrated lower DVT rates relative to historical controls using LMWH (38 percent) or aspirin plus plantar PC (27 percent).

Publishing a Reprint Information

TOP

PAPER #29

**ASPIRIN PLUS VENAFLW VS. LOVENOX PLUS VENAFLW FOR DVT
PROPHYLAXIS IN TKA PATIENTS**

Geoffrey H. Westrich, MD, Thomas Sculco, MD, Richard Laskin, MD, Russell Windsor, MD,
Steven Haas, MD

Introduction: The purpose of this study is to compare the combined efficacy of aspirin with pneumatic compression (PC) vs. low molecular weight heparin (LMWH) with PC for deep vein thrombosis (DVT) prophylaxis in unilateral total knee arthroplasty (TKA) patients.

Methods: Two hundred twenty-nine patients were prospectively randomized to receive aspirin plus PC (Group A) or LMWH plus PC (Group B). VenaFlow® calf pumps (PC) were applied bilaterally to both groups in the recovery room and remained on while the patient was non-ambulatory. Group A received aspirin (325 mg BID for 4 weeks postoperatively). Group B received Lovenox®, (a LMWH), initiated 2 hours after epidural catheter removal approximately 48 hours postoperatively, 30 mg BID until hospital discharge; upon discharge, 40 mg QD for three weeks. The incidence of DVT was monitored twice by Doppler Ultrasound; POD 3-5 and 4 weeks postoperatively. Any patient with a positive ultrasound on POD 3-5 was removed from the study and treatment protocol was initiated.

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Discussion and Conclusion: This is the first study to demonstrate the efficacy of combining modalities for DVT prophylaxis. For instance, both groups demonstrated lower DVT rates relative to historical controls using LMWH (38 percent) or aspirin plus plantar PC (27 percent).

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

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.

(Reprint not available at this time)

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

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 aspirin (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."

04349

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

Evaluation of Intermittent Pneumatic Compression Devices

04337

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

Six different pneumatic compression devices (VenaFlow calf, Jobst calf, Jobst thigh, Kendall thigh, Veno-dyne 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® was the only device to replicate the physiologic contraction of the calf muscles, as shown with venous velocity measurements.

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

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."

(Reprint not available at this time)

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

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.

Evaluation of Thromboembolic Disease Using the VenaFlow Mechanical Compression Device in Orthopedic Surgery Trauma Patients

04334

Westrich GH: Presented at Eastern Orthopaedic Association, 31st Annual Meeting, Lake Buena Vista, FL, October, 2000

Three hundred trauma or lower extremity injury patients were prospectively studied to evaluate the efficacy of the VenaFlow pneumatic compression device for the prevention of deep venous thrombosis (DVT). VenaFlow was applied immediately following surgery to both lower extremities. Patients also received chemical prophylaxis (either warfarin or aspirin). On postoperative day 4-7, patients were examined for presence of DVT by non-invasive color duplex imaging. Results were compared to a matched historical control group (warfarin or aspirin only) at same institution. Overall DVT rate with VenaFlow was 2.7% (compared with 12.5% for control). VenaFlow plus aspirin showed a 3.2% rate (17.0% control - aspirin only). VenaFlow plus warfarin resulted in a 2.1% DVT rate (8.0% control - warfarin only). No clinical PE were noted.

This prospective study showed that VenaFlow plus aspirin or warfarin resulted in a DVT rate of 2.7%. VenaFlow is a safe and effective device for the prevention of thromboembolic disease in the orthopaedic trauma population.

Pneumatic Compression Hemodynamics in Total Hip Arthroplasty

Westrich GH, Specht LM, Sharrock NE, et al: *Clin 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."

04335

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

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

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.

04339

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

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".

(Reprint not available at this time)

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

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.

(Reprint not available at this time)

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

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.

(Unpublished data)

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 thigh-length 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.”

04302

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

Mechanical DVT Prophylaxis

Prevention of Venous Thromboembolism in the ICU

04361

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

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 reviewed daily 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.

Selection and policies for prophylaxis for ICU patients is critical. To minimize pulmonary embolism, sequential prophylaxis combined with anticoagulation (when appropriate) is suggested in this high-risk group.

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

04348

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 an 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 Mechanical and Other Adjuncts

04366

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.

Prevention of Venous Thromboembolism

International Consensus Statement (Guidelines According to Scientific Evidence)
London, Med-Orion Publishing Company, 1997

04287

This review of published studies on DVT prophylaxis states that "PE continues to be a major cause of death in hospital patients in developed countries... In medium and high risk patients the cost of screening, diagnosis and treatment of thromboembolism are so high that the currently used recommended methods of prophylaxis are cost-effective (i.e. optimize the use of available resources)." Intermittent pneumatic compression devices provide safe and proven prophylaxis, either alone or in combination with pharmacological methods, for many different levels of risk in surgical, gynecological and obstetric, orthopedic surgery, and trauma patients.

IPC devices provide safe and effective DVT prophylaxis that is cost-effective compared to screening, diagnosis, and treatment of DVT.

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

15023

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.

Current Recommendations for Prevention of Deep Venous Thrombosis

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

04286B

This chapter identifies risk factors for venous thromboembolism (VTE) and provides an overview of the efficacy 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]."

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.

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."

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.

**Prevention of Venous Thromboembolism:
Fourth ACCP Consensus Conference on Antithrombotic Therapy**

04288

Clagett GP, Anderson FA, Heit JA, et al. *Chest* 108(4 Suppl): 312S-334S, 1995

Recommendations made in this consensus paper are based on published clinical studies. The authors state that "[I]ntermittent pneumatic compression (IPC) is an attractive method of prophylaxis because there is no risk of hemorrhagic complications... it is effective in reducing leg DVT in most general surgical patients and in high-risk surgical patients with malignant disease. It is also moderately effective in patients undergoing major orthopedic surgery... In moderate-risk patients who are older than 40 years of age and are undergoing major operations, but who have no additional clinical risk factors... IPC would be a good alternative." The use of IPC is recommended in most types of surgery with patients from low to very high risk. "IPC would also be a good choice in higher-risk patients, particularly if they are prone to wound problems... In very-high-risk general surgical patients with multiple risk factors, combining the most effective pharmacologic methods with IPC offers excellent protection."

IPC provides DVT prophylaxis with no risk of bleeding complications and is recommended in most types of surgery with patients from low to very high risk.

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

15019

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

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 may 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

15018

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

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 graded fashion, 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 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
- $\Delta p = 5 - 10$ mmHg
- $\Delta t = 0 - 0.5$ s
- Comp. cycle = 2 – 4 s
- 30 – 50 s refill time

Prevention of Venous Thrombosis and Pulmonary Embolism

15024

National Institutes of Health Consensus Development Conference Statement.

JAMA 6(2): 744–749, 1986

The consensus panel concluded that “deep venous thrombosis and pulmonary embolism constitute major health problems... (and) can be significantly reduced by prophylactic regimens, which should be used more extensively.” Both mechanical and pharmacological regimens have been successfully used, alone or in combination, to decrease DVT formation. External pneumatic compression devices have been shown to be efficacious and safe for most patients, and are highly recommended for certain groups of high-risk patients where the increased risk of bleeding could result in serious complications.

Guidelines for use of mechanical regimens for DVT prophylaxis

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

15021

Kamm RD. *J Biomech Engineering* 104(1): 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

15022

Olson DA, Kamm RD, Shapiro AH. *J Biomech Engineering* 104(11): 96–104, 1982

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 "[T]he 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.

ArterialFlow® Research

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

04357

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

“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, TcPO₂ 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 TcPO₂ 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.

The Effect of Lower Extremity Amputation Level with the use of an Intermittent Compression Pump in the High Risk Foot, The Mayo Clinic experience (1998 – 2003)

Kavros SJ, Turner NS, Voll AE, et al: Mayo Clinic, Rochester, MN

(Reprint not available at this time)

The objective of this retrospective, observational study was to review the results of surgical amputations of the forefoot with the use of an intermittent pneumatic compression device (pump). Patients evaluated had non-healing wounds, osteomyelitis, and severe to critical limb ischemia at Mayo Clinic Rochester.

The setting was a community and referral orthopedic surgical and multidisciplinary wound care clinic. The authors analyzed 24 patients, median age 72, with severe to critical limb ischemia and active ulcer, osteomyelitis or gangrene started using a compression device between 1998 and 2003. Seventeen percent of patients had a history of amputation (contralateral limb), 67% had diabetes, 100% with severe to critical limb ischemia, 17% with chronic renal failure on hemodialysis, 70% with osteomyelitis, and 58% had previous vascular reconstructive surgery. Of all the wounds, 70% were multifactorial in etiology, and 60% had associated transcutaneous oxygen tension levels below 20 mmHg. Patients were typically asked to use the pump at home on the affected limb for 6 hours daily (this was for both the pre and postoperative periods).

The median follow-up after initiation of treatment was 12 months. Primary intention healing with limb preservation was achieved by 62% of patients. Secondary intention healing was achieved in an additional 17% with limb preservation. Twenty one percent of the patients went on to below knee amputation after failure of the initial local foot amputation. Seventy percent of the patients had active osteomyelitis and 33% with TcPO₂ levels below 20 mmHg. Of the patient subgroup (17%) that had a previous contralateral below knee amputation prior to the study, none went on to a below knee amputation of the effected study limb. All patients used the intermittent compression pump preoperatively and postoperatively until healed of further surgical intervention.

Patients with severe and critical limb ischemia may benefit from the use of an intermittent compression pump as adjunctive therapy when considering a local foot amputation. Limb preservation and function can be achieved in the high-risk individual by using an intermittent compression device and reduce the level of lower extremity amputation.

ArterialFlow[®], used preoperatively and postoperatively, proved to be effective adjunctive therapy and dramatically reduced incidence of lower extremity amputations in high-risk individuals.

The Use of an Intermittent Pneumatic Compression Pump in the Treatment of Upper Extremity Ulcers

Pfizenmaier DH, Kavros SJ, Liedl DA, et al: *International Angiology*, 23-1, 2004

(Reprint not available at this time)

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.

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.

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 Air-cast 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.

The intermittent pneumatic compression pump is a viable therapeutic option to improve healing of upper extremity ulcers when added to standard therapy.

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

04364

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

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 postoperatively in lower limb fracture study group.

