A New Device for Deep Vein Thrombosis Prophylaxis in Orthopaedic Surgery: Pneumatic Foot Compression

GEOFFREY H. WESTRICH, M.D., HIP/KNEE FELLOW
THOMAS P. SCULCO, M.D., CHAIRMAN, SURGICAL ARTHRITIS SERVICE
THE HOSPITAL FOR SPECIAL SURGERY, NEW YORK, NEW YORK

Thromboembolic disease is a potentially fatal complication after high-risk orthopaedic surgery such as total joint arthroplasty and major trauma. Without prophylaxis, pulmonary embolism is known to occur in 1% to 2% of hospitalized patients.[1] Pneumatic foot compression devices have recently been developed to increase lower extremity circulation and, as a result, are effective in thromboembolic disease prophylaxis.[2-6] Recent studies in total hip and total knee arthroplasty have documented a statistically significant reduction in deep venous thrombosis using these devices.[7-11] Interestingly, studies utilizing pneumatic foot compression have demonstrated a reduction in lower extremity edema both postoperatively and after significant lower extremity trauma.[12] Pneumatic foot compression appears to be more applicable than the previous mechanical devices, and as a result, compliance appears to have improved.

Thromboembolic disease remains a serious issue in orthopaedic surgery, and the management of deep vein thrombosis prophylaxis is still controversial. While many modalities are available for both prophylaxis and treatment of established thromboembolic disease, each has its own advocates and opponents. Unanswered questions about the epidemiology and natural history of thromboembolic disease prevent a universal consensus on prophylaxis, surveillance, and treatment algorithms.

Current prophylaxis regimens in high-risk orthopaedic surgery patients include two main categories, namely, pharmacological management and pneumatic compression devices. Current pharmacological treatment includes aspirin, warfarin, heparin, and recently, low molecular weight heparins.[13-51] Problems with pharmacological prophylaxis include significant cost, daily phlebotomy, risk of hemorrhage, thrombocytopenia, and difficulty with treatment after discharge. Pneumatic compression devices, however, have been utilized as a safe and simple method of thromboembolic disease prophylaxis with proven efficacy in multiple surgical subspecialties.[25,31-33,36,43,46,50-51] Traditional pneumatic devices have consisted of either calf or calf/thigh compression boots. Recently, impulse foot compression devices have been added to the arsenal of the physician and surgeon to combat deep venous thrombosis, and are quite effective for thromboembolic disease prophylaxis, edema control, and wound healing.[7-12]

THE PATHOGENESIS OF THROMBOEMBOLIC DISEASE

The pathogenesis of venous thrombosis, as described by Virchow in 1846, includes the classic triad: venous stasis, injury (intimal damage to the vessel), and hypercoagulability. Stasis results from a lack of muscular contraction or surgical occlusion which leads to formation of thrombus in the deep veins in the region of the lower extremities. Contributing factors include immobility, heart failure, obesity, varicose veins, and previous thrombosis. Injury to the vessel results in endothelial trauma that can activate the coagulation cascade. The intrinsic pathway can be activated by release of tissue thromboplastin from bone and soft tissue during surgery, while the extrinsic system may be acti-

vated by exposure of subendothelial collagen. Hypercoagulability is observed after excessive blood loss, which results in activation of the clotting cascade.[52]

THROMBOEMBOLIC DISEASE IN TOTAL HIP ARTHROPLASTY

Thromboembolic disease is the most common and dangerous complication following elective total hip arthroplasty. Fatality resulting from massive pulmonary emboli associated with deep vein thrombosis in the lower extremity is considered the single most potentially preventable cause of death in total hip arthroplasty. Without prophylaxis the incidence of deep venous thrombosis is 30% to 70%, that of proximal thrombi 10% to 30%, of pulmonary emboli 10% to 20%, and of fatal pulmonary embolus 2% to 3.5%. Fatal PE accounts for approximately 70% of all deaths following total hip arthroplasty.[53-56]

The unique natural history of deep venous thrombosis in total hip arthroplasty is such that isolated proximal thrombosis occurs commonly without evidence of more distal thrombi.[53-56] Kinking of the common femoral vein is known to occur during total hip arthroplasty and results in venous stasis as well as intimal injury. Intraoperative and cadaveric venographic studies have demonstrated severe distortion of the common femoral vein secondary to manipulation of the limb.[57-58] Hypercoagulability is observed intraoperatively with increasing blood loss; however, new techniques of hypotensive epidural anesthesia appear to maintain less blood loss and prevent initiation of the hypercoagulable state.[59-60]

THROMBOEMBOLIC DISEASE IN TOTAL KNEE ARTHROPLASTY

Patients undergoing elective total knee arthroplasty also remain in a high risk group for the development of thromboembolic disease. Without prophylaxis after total knee arthroplasty, the overall incidence of deep venous thrombosis is between 40% and 84%, while proximal thrombosis is observed in 8% to 23% of patients.[11,20,22,25,32,34,38,40,42,45,49,60-62] Without prophylaxis, furthermore, the incidence of pulmonary embolus is documented in 1.7% to 4.5% of patients, with fatal pulmonary embolus occurring in 1% to 2%.[34] Some form of prophylactic treatment, therefore, is paramount to the success of the knee arthroplasty to avoid or decrease the associated morbidity and mortality from thromboembolic disease.

The unique natural history of deep venous thrombosis in total knee arthroplasty differs from that observed in total hip arthroplasty. After total knee arthroplasty, deep venous thrombosis occurs commonly in the calf region, and is observed more often after bilateral total knee arthroplasty (75%) than after unilateral total knee arthroplasty (50%).[34] In contrast to total hip arthroplasty, isolated proximal vein thrombosis in the popliteal or femoral veins is infrequent after total knee arthroplasty. When fatal pulmonary embolus does occur after total knee arthroplasty, however, it is rarely from the calf region and most likely from proximal vein involvement. Propagation of calf thrombosis proximally into the popliteal and femoral venous system is well documented, and it is the causative factor for the majority of fatal pulmonary emboli after total knee arthroplasty.[22,52,63]

Prevention of deep venous thrombosis and subsequent pulmonary embolus is crucial due to the difficulty in clinical diagnosis, problematic forms of treatment, significant associated morbidity and mortality, and late sequelae such as the postphlebitic syndrome.

INFLUENCE OF REGIONAL ANESTHESIA

Regional anesthesia is beneficial in prevention of deep venous thrombosis when compared to a general anesthesia.[50,60] The main effects of hypotensive epidural anesthesia are the reduction in blood loss and the increase in blood flow to the lower extremities. Also, the reduction in intraoperative blood loss with regional anesthesia may preserve the normal coagulation profile and prevent the hypercoagulable state. In total

Table 1. Clinical Trials with Pneumatic Foot Compression

		Pneumatic Foot Compression		Control	
		Overall	Proximal	Overall	Proximal
Total Hip Arthroplasty					
Bradley et al.	Venogram	6.6%	0.0%	27.3%	2.3%
Fordyce et al.	Venogram	10.3%	5.1%	40.0%	7.5%
Santori et al.	Doppler	4.5%	1.5%	23.0%	3.0%
Total Knee Arthroplasty					
Wilson et al.	Venogram	50.0%	0.0%	68.7%	19.0%
Westrich et al.	Venogram	27.6%	0.0%	60.6%	15.5%

hip arthroplasty Sharrock et al. have demonstrated a reduction in DVT formation, and this effect is increased when epinephrine was used in addition to hypotensive epidural anesthesia.[47]

During total knee arthroplasty, Sharrock et al. have also demonstrated venographically a reduction in both the overall and proximal rates of deep venous thrombosis utilizing regional anesthesia (overall: 48%; proximal: 4%) instead of a general anesthetic (overall: 64%; proximal: 9%). They stated that some form of postoperative prophylaxis for thromboembolic disease is still required, however, since the incidence of proximal and distal thrombosis was quite significant.[60]

It should be noted that contraindications to regional anesthesia include severe mitral or aortic stenosis and carotid artery occlusive disease.

PHARMACOLOGICAL PROPHYLAXIS

Historically, prophylactic regimens have been initiated postoperatively and have included pharmacological forms of prophylaxis such as aspirin, warfarin, and, recently, low molecular weight heparin. Pharmacological prophylaxis with aspirin was popular in the past; however, the incidence of deep venous thrombosis after total knee arthroplasty has ranged from 40% to 75%, and its effectiveness appears to be less than optimal.[13,17,25-26,41,48] Warfarin therapy has been utilized for thromboembolic disease prophylaxis after total hip arthroplasty with documented efficacy; however, its use after total knee arthroplasty is now in question. It is associated with bleeding complications, routine phlebotomy, significant cost, and inconvenience after discharge.[20,26,36,46] Low molecular weight heparins have recently become a popular alternative method of thromboembolic disease prophylaxis due to the fixed subcutaneous dosing regimens without daily clotting factor surveillance. While they were developed to provide equivalent or increased antithrombotic activity without associated bleeding complications, low molecular weight heparins still reveal significant untoward effects such as thrombocytopenia, hemorrhage, after-discharge dosing only by injection.[20]

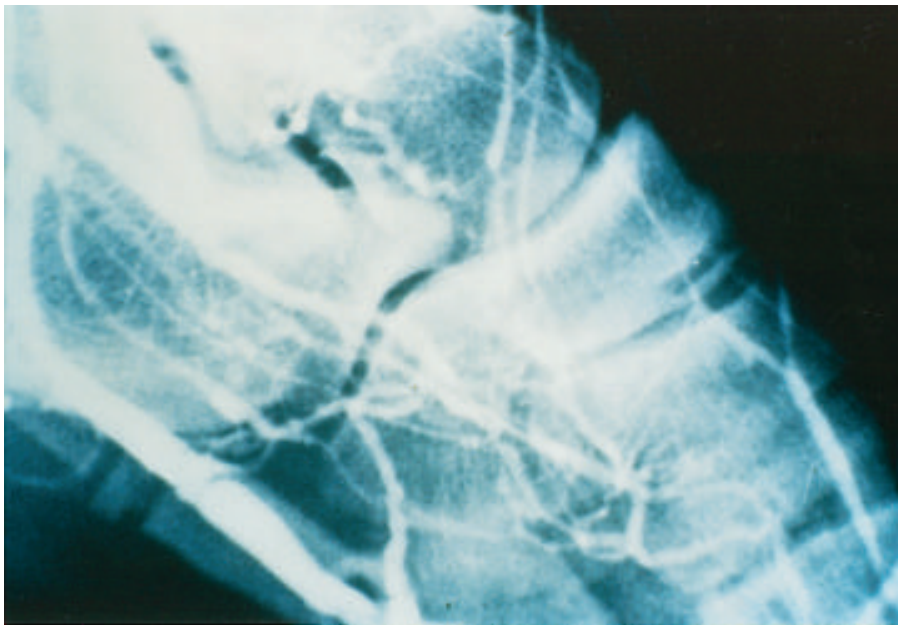

Figure 1a. Venogram of a non–weight-bearing foot demonstrating the plantar plexus filled with venous blood. Note the course of the plantar venous plexus surrounding the lateral plantar artery.

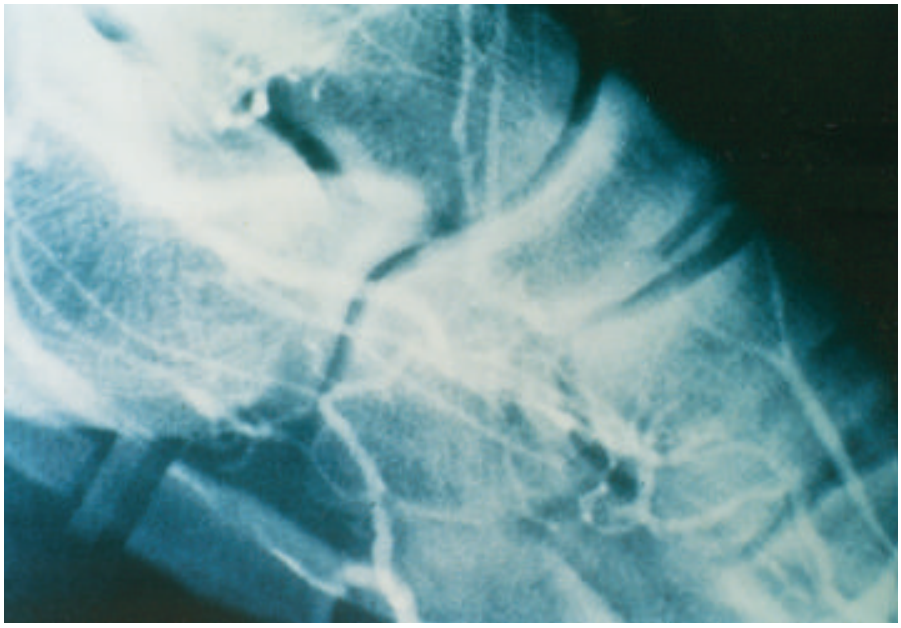

Figure 1b. After activation of a Plexipulse™ pneumatic foot compression device, a venogram of the foot demonstrates emptying of the plantar venous plexus. This pneumatic impulse compression by the foot pump simulates weight-bearing activation of this venous system.

EXTERNAL PNEUMATIC COMPRESSION DEVICES

Mechanical compression has been utilized as a safe and simple method of thromboembolic disease prophylaxis with proven efficacy in multiple surgical subspecialties. Intermittent pneumatic compression devices accelerate venous emptying with decreased venous stasis and have proven fibrinolytic effects.[64] Multiple studies have documented the safety and efficacy of intermittent pneumatic compression after total joint arthroplasty.[25,31-33,36,43,46,50-51] A major criticism of pneumatic compression devices, however, has been the lack of compliance resulting in treatment failure. Recently, a lack of compliance was documented by Comerota et al., noting a functional application of only 33% of patients using an external pneumatic compression device. The authors stated that failure of deep venous thrombosis prophylaxis with external pneumatic compression devices may be due to improper use rather than failure of the method itself.[65]

PNEUMATIC FOOT COMPRESSION

In 1983, Gardner and Fox described a physiologic venous foot pump mechanism in the sole of the foot involving the

venae comitans of the lateral plantar artery.[2] This "pump" has a 20-cc stroke volume that empties only through the deep venous system and is activated solely upon weight bearing.[2] From this description, a pneumatic plantar compression device was developed to activate this pump in patients that are nonambulatory. In contrast to the traditional external pneumatic compression devices that produce only a 20- to 30-mm Hg slow rise in venous pressure, pulsatile pneumatic plantar compression devices produce a forceful ejection of blood from the foot into the calf in excess of 100 mm Hg. This pulse wave of venous blood that originates in the plantar venous plexus is demonstrable both by venography and Doppler ultrasound to flow proximally into the popliteal vein and more proximally into the femoral vein (Figs. 1, 2).[2-6]

Pneumatic compression devices prevent thromboembolic disease by primarily increasing venous return. Similar to traditional external pneumatic compression, pulsatile pneumatic plantar compression results in decreased venous stasis with accelerated venous emptying.[2-6] It is hypothesized, however, that plantar impulse pumping may prevent deep venous thrombosis by several other factors. First, high flow states create increased turbulence around venous valve pockets, thus decreasing thrombus formation. Second, hemodynamic studies have confirmed increased blood flow and tissue perfusion with the resultant release of EDRF (endothelial derived relaxing factor) and prostacyclin.[6] Lastly, Allenby et al. have documented enhancement of fibrinolysis after tissue compression using standard external pneumatic compression devices,[64] and fibrinolytic activity with foot compression is thought to exist as with other pneumatic devices.[6]

Pulsatile pneumatic plantar compression has the added advantage of ease of applicability (since the foot is readily available) and hopefully improved compliance.

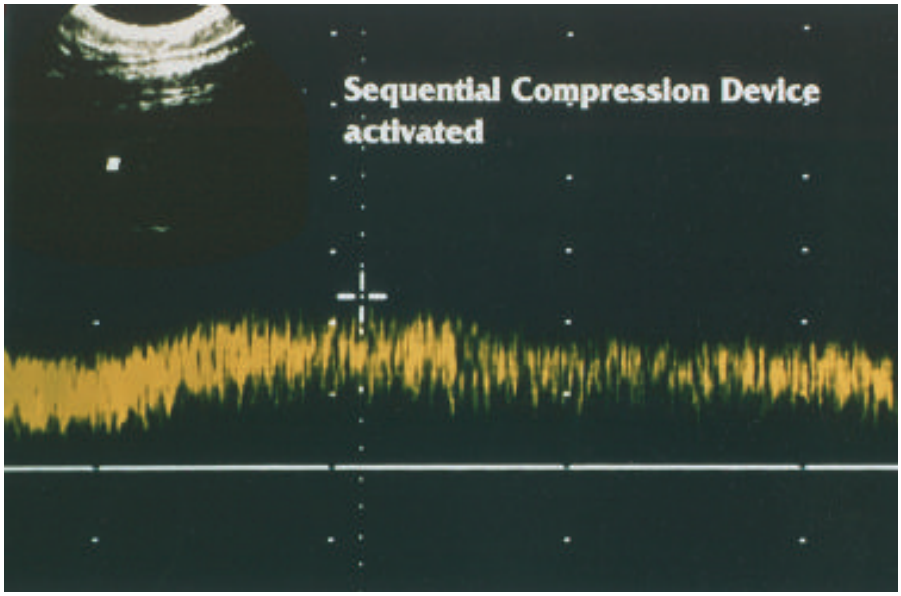

Figure 2a. Venous Doppler examination of the popliteal vein during inflation of a standard external pneumatic sequential compression device. Note the slow increase in venous peak flow utilizing this sys-

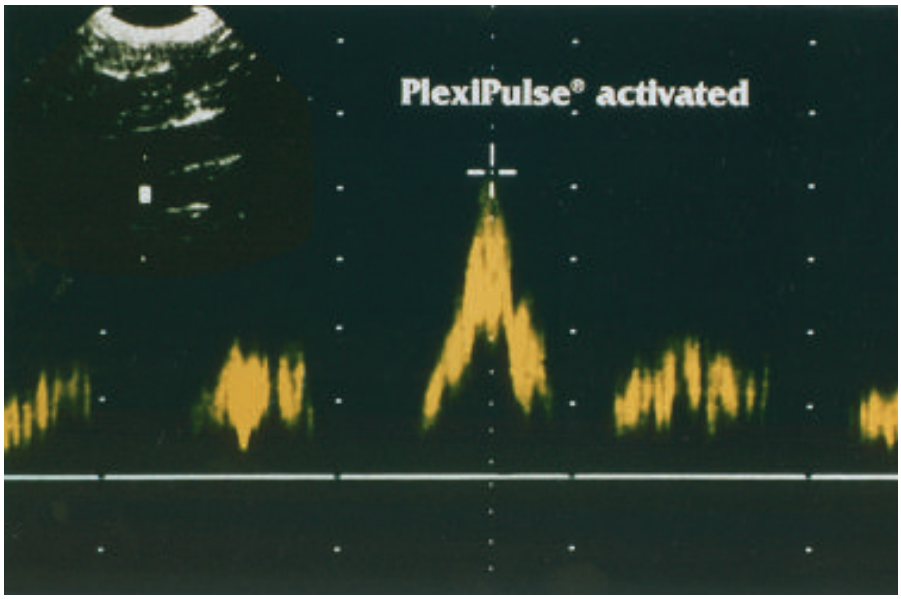

Figure 2b. After activation of a Plexipulse™ pneumatic foot compression device, a venous Doppler examination at the popliteal vein demonstrates a significant increase in venous peak flow.

PNEUMATIC FOOT COMPRESSION: DVT PROPHYLAXIS IN TOTAL HIP ARTHROPLASTY

Pulsatile pneumatic plantar compression, therefore, appears to be a useful modality for deep venous thrombosis prophylaxis after total joint arthroplasty and has been studied after total hip arthroplasty with documented efficacy.[7-11] Bradley et al. performed a randomized prospective study of 74 patients undergoing total hip arthroplasty. All the patients received TED stockings and half of the patients received a pneumatic plantar compression device. Venography revealed only 2 femoral vein clots in the pump group compared to 1 calf vein and 11 femoral clots in the control group.[7] Furthermore, Fordyce and Ling also evaluated pneumatic plantar compression after total hip arthroplasty in 84 patients. Using venography, they documented clinically significant deep venous thrombosis in 5% of the pump-treated group and 40% of the control group.[8] After total hip arthroplasty in 132 patients, Santori et al. have recently demonstrated by Doppler ultrasound the effectiveness of pneumatic plantar compression compared to unfractionated heparin for thromboembolic disease prophylaxis, and noted deep venous thrombosis in 13.4% (9/67) and 35.4% (23/65), respectively (Table 1).[9]

PNEUMATIC FOOT COMPRESSION: DVT PROPHYLAXIS IN TOTAL KNEE ARTHROPLASTY

Limited information exists, however, in total knee arthroplasty patients as to the efficacy of such a device. Wilson et al. studied a small series of 60 total knee arthroplasty patients comparing a first-

generation pneumatic plantar compression device to a control group without any prophylaxis and only noted a reduction of proximal deep venous thrombosis (from 19% to 0%). This study lacked statistical power and failed to control for many variables such as type of anesthetic (regional vs. general), risk factors, and objective compliance.[11]

In our preliminary study of 149 total knee arthroplasties performed under regional anesthesia, we noted a statistically significant reduction ($p<0.05$) of deep venous thrombosis in patients utilizing the pulsatile pneumatic plantar compression device (Plexipulse™, NuTech, San Antonio, Tex.) with aspirin–from 60.6% only with aspirin to 27.6% with both compression device and aspirin. In addition, no evidence of proximal thrombosis was noted in any patient using the pneumatic foot compression device, while proximal thrombosis was observed in 15.5% of the patients with aspirin alone ($p<0.001$). Furthermore, we demonstrated by objective compliance with an internal hour meter, that the patients who reliably used the pneumatic plantar compression device postoperatively (102 hours or 19.5 hours per day) did not demonstrate deep venous thrombosis, while the patients that were not as compliant (72 hours or 13.7 hours per day) developed a deep venous thrombosis ($p<0.001$) (Table 1).

Since some surgeons after total knee arthroplasty either apply a large bulky dressing or utilize a brief period of extension splinting postoperatively, the former external pneumatic compression devices are less applicable and compliance suffers. As mentioned earlier, ease of applicability and improved compliance are the added advantages of pulsatile pneumatic plantar compression (Fig. 3).

EDEMA REDUCTION WITH PNEUMATIC FOOT COMPRESSION

Edema reduction as well as a decrease in compartment pressure has been documented using impulse compression of the foot by Gardner and Fox in 1990.[6] In a multicenter international clinical trial, they demonstrated a reduction in posttraumatic and postoperative swelling and pain. In addition, they presented evidence that suggests it is possible to reduce dangerously high compartment pressures to an acceptable level by artificially activating the venous foot pump.[6]

Figure 3. Patient in recovery room after one-stage bilateral total knee replacements with the Plexipulse™ pneumatic foot compression device applied to each foot. Note the bulky dressing and plaster splints that would not allow application of a standard thigh-high sequential compression device.

In addition, Myerson et al. demonstrated a reduction in foot and ankle swelling with volumetric analysis utilizing pneumatic foot compression devices in patients after elective or posttraumatic foot and ankle surgery. After foot and ankle trauma or surgery, they concluded that foot compression devices were effective in the control of both acute and chronic swelling.[12]

CONCLUSION

We conclude that pulsatile pneumatic foot compression is a safe and effective method of mechanical prophylaxis for thromboembolic disease in both total hip and total knee arthroplasty patients. In addition, pneumatic foot compression has been shown to decrease swelling in the lower extremity after surgery and trauma. Effective mechanical prophylaxis, however, necessitates proper compliance to achieve optimal treatment. STI

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