## Clinical Studies Summary

<table>
<thead>
<tr>
<th>Clinical Study Author(s) &amp; Title Abbreviation</th>
<th>IPC Efficacy</th>
<th>Single Chamber vs. Sequential</th>
<th>Knee vs. Thigh Length</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. ACOG Issues Guidelines to Prevent Thromboembolic Events, Obstetrics and Gynecology, 2011; 118718-729 Extract Barclay, Laurie, MD</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CLINICAL STUDIES SUMMARY

Title: Implementing Recommended Practices for Prevention of Deep Vein Thrombosis
Author: SHARON A. VAN WICKLIN, MSN, RN, CNOR, CRNFA, CPSN, PLNC
Source: AORN JOURNAL November 2011, VOL 94, No53
Abstract: One to two people per 1,000 are affected by deep vein thrombosis (DVT) or pulmonary embolism in the United States each year. AORN published its new “Recommended practices for prevention of deep vein thrombosis” to guide perioperative RNs in establishing organization-wide protocols for DVT prevention. Strategies for successful implementation of the recommended practices include taking a multidisciplinary approach to protocol development, providing education and guidance for performing preoperative patient assessments and administering DVT prophylaxis, and having appropriate resources and the facility’s policy and procedure for DVT prevention readily available in the practice setting. Hospital and ambulatory patient scenarios have been included as examples of appropriate execution of the recommended practices.

Title: Recommended Practices for Prevention of Deep Vein Thrombosis
Author: Developed by AORN Recommended Practices Committee was approved by the AORN Board of Directors
Source: AORN 2012 Perioperative Standards and Recommended Practices, p 353-363
Abstract: The purpose of these recommended practices is to guide perioperative RNs by providing a framework for developing a protocol for deep vein thrombosis (DVT) prevention. These recommended practices provide guidance for administering pharmacologic and/or mechanical DVT prophylaxis and patient and health care personnel education. Although the prevention of DVT and pulmonary embolism (PE) should be a priority of the entire health care organization, the particular risks facing perioperative patients makes it imperative that perioperative RNs take an active role in DVT prevention.

Author: Geerts WH, Bergqvist D, Pineo GF, Heit JA, Samama CM, Lassen MR, Colwell CW
Source: Chest. 2008 June; 133(6 Suppl):S38-453S
Abstract: This article discusses the prevention of venous thromboembolism (VTE) and is part of the Antithrombotic and Thrombolytic Therapy: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Grade 1 recommendations are strong and indicate that the benefits do or do not outweigh risks, burden, and costs. Grade 2 suggestions imply that individual patient values may lead to different choices (for a full discussion of the grading, see the "Grades of Recommendation" chapter by Guyatt et al). Among the key recommendations in this chapter are the following: we recommend that every hospital develop a formal strategy that addresses the prevention of VTE (Grade 1A). We recommend against the use of aspirin alone as thromboprophylaxis for any patient group (Grade 1A), and we recommend that mechanical methods of thromboprophylaxis be used primarily for patients at high bleeding risk (Grade 1A) or possibly as an adjunct to anticoagulant thromboprophylaxis (Grade 2A). For patients undergoing major general surgery, we recommend thromboprophylaxis with a low-molecular-weight heparin (LMWH), low-dose unfractionated heparin (LDUH), or fondaparinux (each Grade 1A). We recommend routine thromboprophylaxis for all patients undergoing major gynecologic surgery or major, open urologic procedures (Grade 1A for both groups), with LMWH, LDUH, fondaparinux, or intermittent pneumatic compression (IPC). For patients undergoing elective hip or knee arthroplasty, we recommend one of the following three anticoagulant agents: LMWH, fondaparinux, or a vitamin K antagonist (VKA); international normalized ratio (INR) target, 2.5; range, 2.0 to 3.0 (each Grade 1A). For patients undergoing hip fracture surgery (HFS), we recommend the routine use of fondaparinux (Grade 1A), LMWH (Grade 1B), a VKA (target INR, 2.5; range, 2.0 to 3.0) [Grade 1B], or LDUH (Grade 1B). We recommend that patients undergoing hip or knee arthroplasty or HFS receive thromboprophylaxis for a minimum of 10 days (Grade 1A); for hip arthroplasty and HFS, we recommend continuing thromboprophylaxis > 10 days and up to 35 days (Grade 1A). We recommend that all major trauma and all spinal cord injury (SCI) patients receive thromboprophylaxis (Grade 1A). In patients admitted to hospital with an acute medical illness, we recommend thromboprophylaxis with LMWH, LDUH, or fondaparinux (each Grade 1A). We recommend that, on admission to the ICU, all patients be assessed for their risk of VTE, and that most receive thromboprophylaxis (Grade 1A).
Title: Evidence-Based Compression: Prevention of Stasis and Deep Vein Thrombosis
Author: Rhys J. Morris, PhD; John P. Woodcock, PhD, DSc, CPhys, FInstP, FiPEM
Source: Annals of Surgery 2004; 239(2)
Objective: To summarize the currently published scientific evidence for the venous flow effects of mechanical devices, particularly intermittent pneumatic compression, and the relation to prevention of deep vein thrombosis (DVT).

Summary Background Data: While intermittent pneumatic compression is an established method of DVT prophylaxis, the variety of systems that are available can use very different compression techniques and sequences. In order for appropriate choices to be made to provide the optimum protection for patients, the general performance of systems, and physiological effects of particular properties, must be analyzed objectively.

Methods: Medline was searched from 1970 to 2002, and all relevant papers were searched for further appropriate references. Papers were selected for inclusion when they addressed specifically the questions posed in this review.

Results: All the major types of intermittent compression systems are successful in emptying deep veins of the lower limb and preventing stasis in a variety of subject groups. Compression stockings appear to function more by preventing distension of veins. Rapid inflation, high pressures, and graded sequential intermittent compression systems will have particular augmentation profiles, but there is no evidence that such features improve the prophylactic ability of the system.

Conclusions: The most important factors in selecting a mechanical prophylactic system, particularly during and after surgery, are patient compliance and the appropriateness of the site of compression. There is no evidence that the peak venous velocity produced by a system is a valid measure of medical performance.

Title: Thromboembolism After Total Knee Arthroplasty: Intermittent Pneumatic Compression and Aspirin Prophylaxis
Author: Christopher M. Larson, MD, Douglas P. MacMillan, MD, Paul F. Lachiewicz, MD
Source: Journal of the Southern Orthopaedic Association 2001; 10(3)
Abstract: This is a study of two consecutive antithromboembolism regimens after total knee arthroplasty. In group 1, 131 patients were given aspirin prophylaxis alone (650 mg by mouth twice a day). In group 2, 123 patients were treated with aspirin, knee-high compression stockings, and intermittent knee-high pneumatic compression devices, which were started intraoperatively. The prevalence of deep vein thrombosis in group 1 was 15.9% (21 of 131 patients). One patient had a possible symptomatic nonfatal pulmonary embolism, and one patient had a symptomatic calf thrombus. Asymptomatic thrombi were detected in calf veins in 9 patients, popliteal vein in 6 patients, and femoral vein in 5 patients. In Group 2, the prevalence was 7.4% (9 of 123 patients). Asymptomatic thrombi were located in calf veins in 6 patients, popliteal vein in 1 patient, and femoral vein in 2 patients. There was a significant difference in the prevalence of deep vein thrombosis between the two groups. A history of previous thromboembolism was a significant risk factor for a new thrombus. The prevalence after bilateral one-stage knee arthroplasty was 24.3% for group 1 and 12.5% for group 2. Aspirin and knee-high intermittent pneumatic compression together are more effective than aspirin alone for prevention of deep vein thrombosis after primary and revision knee arthroplasty.
**Title:** Deep Vein Thrombosis in Hospitalized Patients: A Review of Evidence-based Guidelines for Prevention  
**Author:** Wendy Kehl-Pruett ARNP, MSN, CCRN  
**Source:** Dimensions of Critical Care Nursing. 25(2):53-59, March/April 2006.  
**Abstract:** Deep vein thrombosis affects many hospitalized patients because of decreased activity and therapeutic equipment. This article reviews known risk factors for developing deep vein thrombosis, current prevention methods, and current evidence-based guidelines in order to raise nurses' awareness of early prevention methods in all hospitalized patients. Early prophylaxis can reduce patient risk of deep vein thrombosis and its complications.

Intermittent pneumatic compression devices work by creating pressure on the leg muscles, using air-filled sleeves. This pressure assists in improving venous blood return while decreasing blood pooling and can be applied either in sequential compression devices or longitudinally in rapid inflation, asymmetrical compression devices. Both devices look similar, provide about 45 mm Hg of pressure to the calf muscles, and have been shown to reduce DVT rates from 15% to 6.9% in a prospective, randomized study of 423 orthopedic patients who had total knee replacements. Pneumatic compression is safe with few contraindications and most patients tolerate these devices. Patients with complaints of feeling warm with the use of these devices can often be appeased by using the ventilation mechanism that allows cool air to circulate underneath the plastic sleeves. Other complaints may involve patients with restless leg syndrome who find it difficult to rest with the continuous inflation/deflation mechanism of these devices at night. The ACCP guidelines currently recommend using mechanical prophylaxis measures in all hospitalized patients with anticoagulant contraindications. Use in combination with anticoagulants is also recommended for those patients at high risk for developing DVT without anticoagulant contraindications. Mechanical measures should be used initially in surgical patients with a high risk for bleeding until anticoagulants can be reconsidered. Compression modalities were all found to be safe and effective. However, to be effective, these measures must be used for the duration of bedrest, not just a few hours a day. Nurses must encourage patient use and compliance.

**Title:** Venothrombotic Events: Evidence-Based Risk Assessment, Prophylaxis, Diagnosis, and Treatment  
**Author:** Ruth McCaffrey and Cindy Blum  
**Source:** The Journal for Nurse Practitioners Volume 5, Issue 5, Pages 325-333, May 2009  
**Abstract:** Venothrombotic events (VTE), including deep vein thrombosis and pulmonary emboli, are a common cause of death among community-dwelling, hospitalized, and recently hospitalized outpatients. Nurse practitioners are well positioned to complete a risk assessment, initiate prophylaxis for those at risk to prevent VTE, and provide early diagnosis and treatment if VTE does occur. This article presents information about the incidence and prevalence of VTE, the importance of risk assessment and prevention, and evidence-based guidelines for prophylaxis and treatment.

Intermittent pneumatic compression devices (IPC) provide dynamic compression to promote blood flow in leg veins. Pneumatic compression is safe with few contraindications and most patients tolerate these devices. Patients with complaints of feeling warm with the use of these devices can often be appeased by using the ventilation mechanism that allows cool air to circulate underneath the plastic sleeves. Other complaints may involve patients with restless leg syndrome, who find it difficult to rest with the continuous inflation/deflation mechanism of these devices at night. Impulse technology, a form of IPC known as the “foot pump,” is very effective for prevention of DVT. This device moves blood up the deep calf toward the heart and enhances overall circulation of the limb. The “foot pump” may be even more effective than other more bulky thigh- or knee-high devices. Again, these devices are only effective if used properly and applied for appropriate lengths of time.
Interruption in venous blood flow can be effectively prevented using intermittent compression devices.

Title: *Prevention of Deep Vein Thrombosis and Pulmonary Embolism*
Author: Developed by the ACOG Committee on Practice Bulletins Gynecology with the assistance of Daniel Clarke Pearson, MD, and Lisa N. Abaid, MD, MPH
Source: *The American College of Obstetricians and Gynecologists Clinical Management Guidelines for Obstetrician-Gynecologists, Bulletin 84, August 2007*
Abstract: Despite advances in prophylaxis, diagnosis, and treatment, venous thromboembolism remains a leading cause of disability and death in postoperative, hospitalized patients (1-3). Venous thromboembolism most commonly occurs in the form of a deep vein thrombosis or pulmonary embolism. Beyond the acute sequelae, venous thromboembolism may result in chronic conditions, including postthrombotic syndrome, venous insufficiency, and pulmonary hypertension. The purpose of this bulletin is to review the current literature on the use of thromboprophylaxis in gynecology patients and to provide evidence-based recommendations to guide clinical decision making.

*Interruption pneumatic compression devices reduce stasis by regularly compressing the calf with an inflatable pneumatic sleeve. When used during and after major gynecologic surgery, the devices are as effective as low-dose heparin and low molecular weight heparin in reducing DVT incidence.*

Title: *ACOG Issues Guidelines to Prevent Thromboembolic Events*
Author: Laurie Barclay, MD
Source: *Obstetrics & Gynecology, 2011; 118: 718-729. Extract*
Abstract: "Cesarean delivery is an independent risk factor for thromboembolic events — it nearly doubles a woman's risk," Dr. James said. "Fitting inflatable compression devices on a woman's legs before cesarean delivery is a safe, potentially cost-effective preventive intervention. Inflatable compression sleeves should be left in place until a woman is able to walk after delivery or — in women who had been on blood thinners during pregnancy — until anticoagulation medication is resumed."

Title: *Blood Flow Augmentation of Intermittent Pneumatic Compression Systems Used for the Prevention of Deep Vein Thrombosis Prior to Surgery*
Author: Eric Flam, PHD, Piscataway, Silvia Berry, MSc, RVT, Amy Coyle, VT, Herbert Dardik, MD, Englewood, Loretta Raab, RPh
Purpose: To compare, using Duplex ultrasonography, different intermittent pneumatic compression (IPC) systems to augment venous blood flow for deep venous thrombosis (DVT) prevention during and after surgery and during periods of immobility.
Methods: This cross-over study randomly assigned 26 young, healthy, adult subjects, without history of DVT, hypertension, diabetes, stroke, vascular or cardiac pathologies, to an order of knee-high, foam, single pulse IPC device and thigh-high, vinyl, sequential-pulse pneumatic compression systems. Prior to making the flow measurement, the girth of the calf and thigh and length of the leg of each subject were determined. The right leg was used in this evaluation.
Results: The average flow augmentation, which is a direct measure of the amount of femoral vein blood flow velocity increase over the base, was 107% x,49 "h with the knee-high system, and T7Y" t 35% with the thigh-high tPC system (p <0.002). Augmentation was higher for 62% of the subjects with knee-high IPC, and for 23% of the subjects with the thigh high system. Overall, the blood was actively moving through the vein during the decompression phase. On occasion, the velocity during the decompression phase would fall to zero for short intervals with both systems, indicating complete emptying of the vessel. Variation in limb anatomy did not significantly affect blood-flow augmentation with the kneehigh IPC, but augmentation decreased with increase in girth with the thigh-high tPC.
Conclusions: The study indicates that the knee high, foam, single-pulse IPC device produces a significantly higher venous blood-flow augmentation than the thigh-high, vinyl, sequential pulse system.
**Title: Effects of Intermittent Pneumatic Compression in Normal and Postphlebitic Legs**
**Author:** Salvian, A.J., Baker, J.D.
**Source:** The Journal of Cardiovascular Surgery, 1988 pp. 37-41

**Abstract** The changes in common femoral vein flow produced by three different intermittent pneumatic compression devices were recorded with a Doppler velocity detector in 20 normal legs and 20 with postphlebitic syndrome. Mean and peak velocity increases were measured and expressed as a percent of resting baseline values. There was no significant difference in the peak velocity increase produced by the three devices in normals and normals; however, there were differences in the mean velocity increases. The devices worked as well on postphlebitic legs as on normal ones. Correct cuff application was more critical than indicated by the manufacturers, suggesting that some of the failures of intermittent pneumatic compression may have resulted from improper cuff placement. The results show that different designs of intermittent pneumatic compression equipment accelerate venous flow in the leg.

‘Overall, the results show that different designs of compression equipment (sequential and intermittent pneumatic compression) provide satisfactory acceleration of venous blood for the prevention of venous thrombosis.’

**Title: A clinical comparison of pneumatic compression devices: The basis for selection**
**Authors:** Mary C. Proctor, MS, Lazar J. Greenfield, MD, Thomas W. Wakefield, MD, and Paul J. Zajkowski
**Source:** Journal of Vascular Surgery, 2001

**Purpose:** The five pneumatic compression devices (PCDs) that are marketed provide mechanical protection from deep venous thrombosis (DVT). They differ with respect to patterns of compression and the length of the sleeve. Evidence linking differences to clinical outcomes is lacking. Our purpose was twofold: to evaluate each of the marketed PCDs with respect to effectiveness, compliance, and patient and nursing satisfaction and to determine whether there is a clinical basis for the selection of one device over another.

**Methods:** Each of the marketed devices was used exclusively for a 4-week period. Patients participated in an evaluation including venous duplex ultrasound scan, DVT risk assessment, and device evaluation. Vascular laboratory records were used to document DVT. Compliance was measured by meters installed on all pumps. A ranking matrix was stratified by compression pattern: rapid graduated sequential compression, graduated compression, and intermittent compression, and each device was rated by patients and nurses.

**Results:** The PCDs were used in 1350 cases with a DVT rate of 3.5% ranging from 2% to 9.8% depending on the method of compression. Patients with DVT were older (58 vs 54 years), had better compliance (67% vs 50%), and had more compression days (11 vs 7.2). When thigh-length sleeves were used, a greater proportion of DVT occurred in the proximal segments (71%) as compared with the number of proximal DVT when the calf-length devices were used (52%; P = .21). Devices W, X, and Y had comparable rates of DVT, which were lower than those for V and Z. Compression device Y, with calf and thigh sleeves, achieved the best overall ranking largely because of high scores for patient and nurse satisfaction.

**Conclusion:** Our data appear at odds with commonly held beliefs. We 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.