

Comparison of Venous Blood Flow in the Lower Leg Using Standard Pneumatic Compression and Portable Pneumatic Compression

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Disclosures

- This study was sponsored by BioCompression Systems, Inc., Moonachie, NJ

Background

Prevention and treatment of deep venous thrombosis (DVT) is achieved mainly using drugs that affect clot formation or clot dissolution (e.g., heparin, warfarin, apixaban, enoxaparin etc.). Mechanical devices also play an important role in the prevention of blood clots. Pneumatic compression devices (PCD) are approved under the U.S. Food and Drug Administration's (FDA's) 510(k) process for the prevention of DVT. They are classified as Class II devices. PCDs are used to simulate muscle action in the extremities of individuals with reduced mobility to encourage blood circulation with the goal of preventing formation of a thrombus.

Introduction

- One of the main concerns associated with the use of PCD's is compliance
- A systematic review published in 2012 found that 25% of individuals prescribed PCDs for DVT prevention during their post-op hospital stay were non-adherent.
- The ACCP* guidelines recommend that the device be used for at least 18 hours in a day.
- Traditional PCD's need to be connected to an external power source, are heavy, cumbersome and are designed to be used while the patient is in bed

Craigie S, Tsui JF, Agarwal A, et al. Adherence to mechanical thromboprophylaxis after surgery: A systematic review and meta-analysis. *Thromb Res.* 2015; 136(4):723-726.

*American College of Chest Physicians

Objective

- The objective of this evaluation was to measure and compare the effects of a commonly used traditional PCD and a portable PCD on the velocity and volume flow in the popliteal vein in healthy volunteers

Methods

Devices:

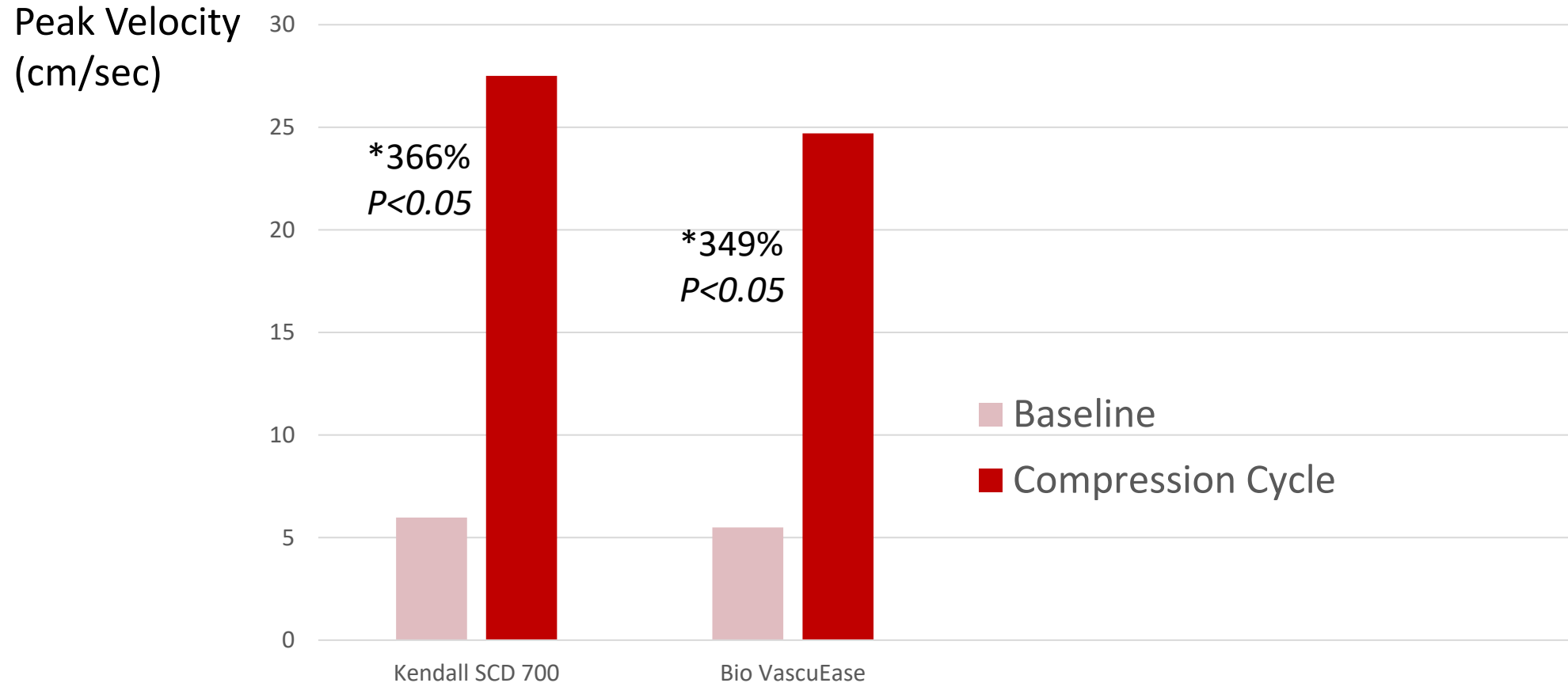
- Kendall SCD™ 700 (Covidien, Plainfield, IN) is a standard plug-in sequential compression system with leg sleeves. It is a prescription device indicated for DVT and pulmonary embolism (PE) prophylaxis
- VascuEase™ (BioCompression Systems Inc, Moonachie, NJ) is a portable rechargeable battery-operated sequential compression system with leg sleeves. It is also a prescription device indicated for the prophylaxis of DVT and stimulation of venous and arterial circulation
- Both PCDs are approved under the U.S. Food and Drug Administration's (FDA's) 510(k) process and are classified as Class II devices, cardiovascular therapeutic devices, and compressible limb sleeves

Methods

Participants and Procedure

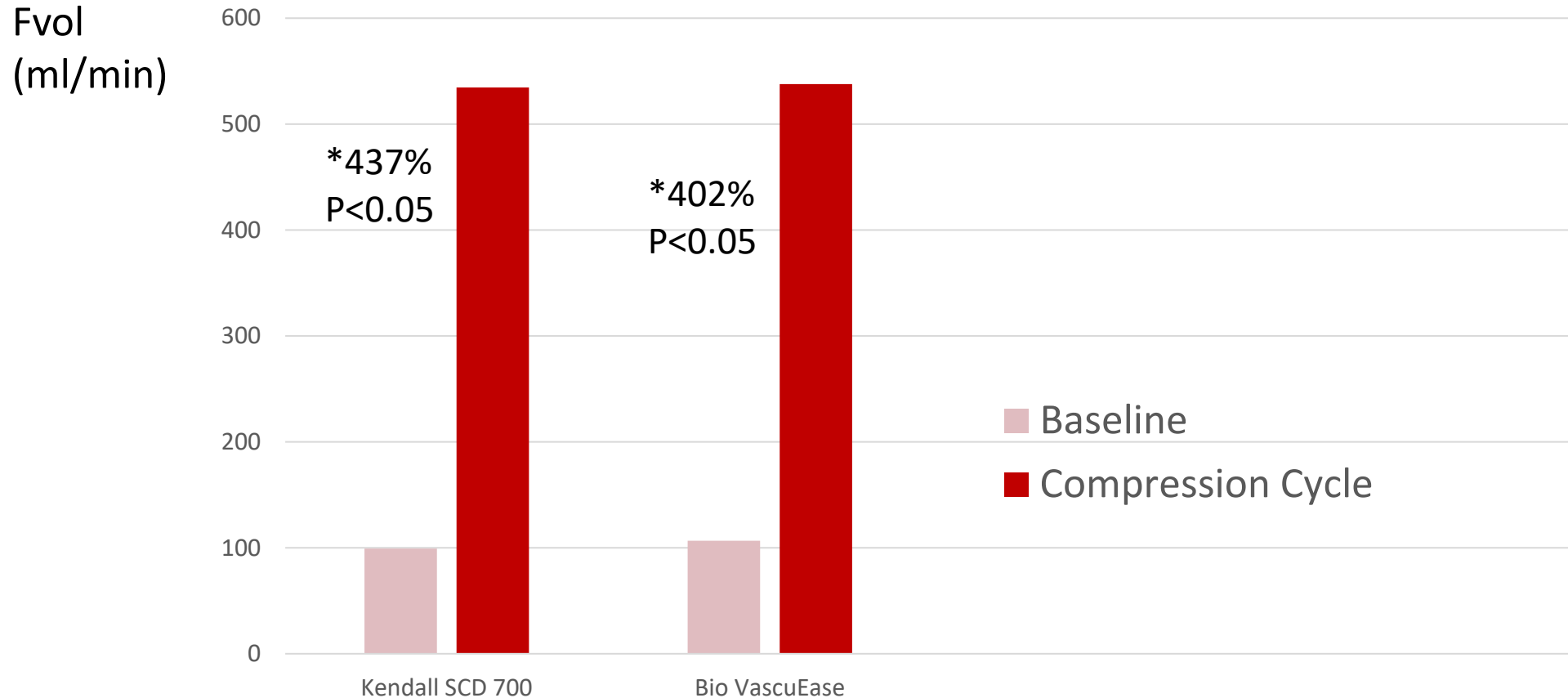
- Three (3) normal male volunteers age range 50-81 participated
- One leg per volunteer was examined and prepared as per manufacturers instructions
- Volunteers were in the supine position and left for 5 minutes to establish venous and arterial equilibrium
- Blood velocities and volume flow were measured in popliteal vein at rest during the non-compression cycle (Baseline) and during active compression (Compression Cycle)
- Popliteal vein was imaged in a longitudinal section using the SONIMAGE HS2 and L18-4 and L11-3 Linear Array Transducers (Konica Minolta Inc., Wayne NJ)
- Peak velocity (PV) (cm/sec), diameter of the vein at the point of sampling and duration of the Doppler waveform at rest and during compression were measured
- Ultrasound measurements were repeated 3 times on each subject

Effect of a Portable PCD and a Traditional PCD on the Velocity of Blood Flow in the Popliteal Vein

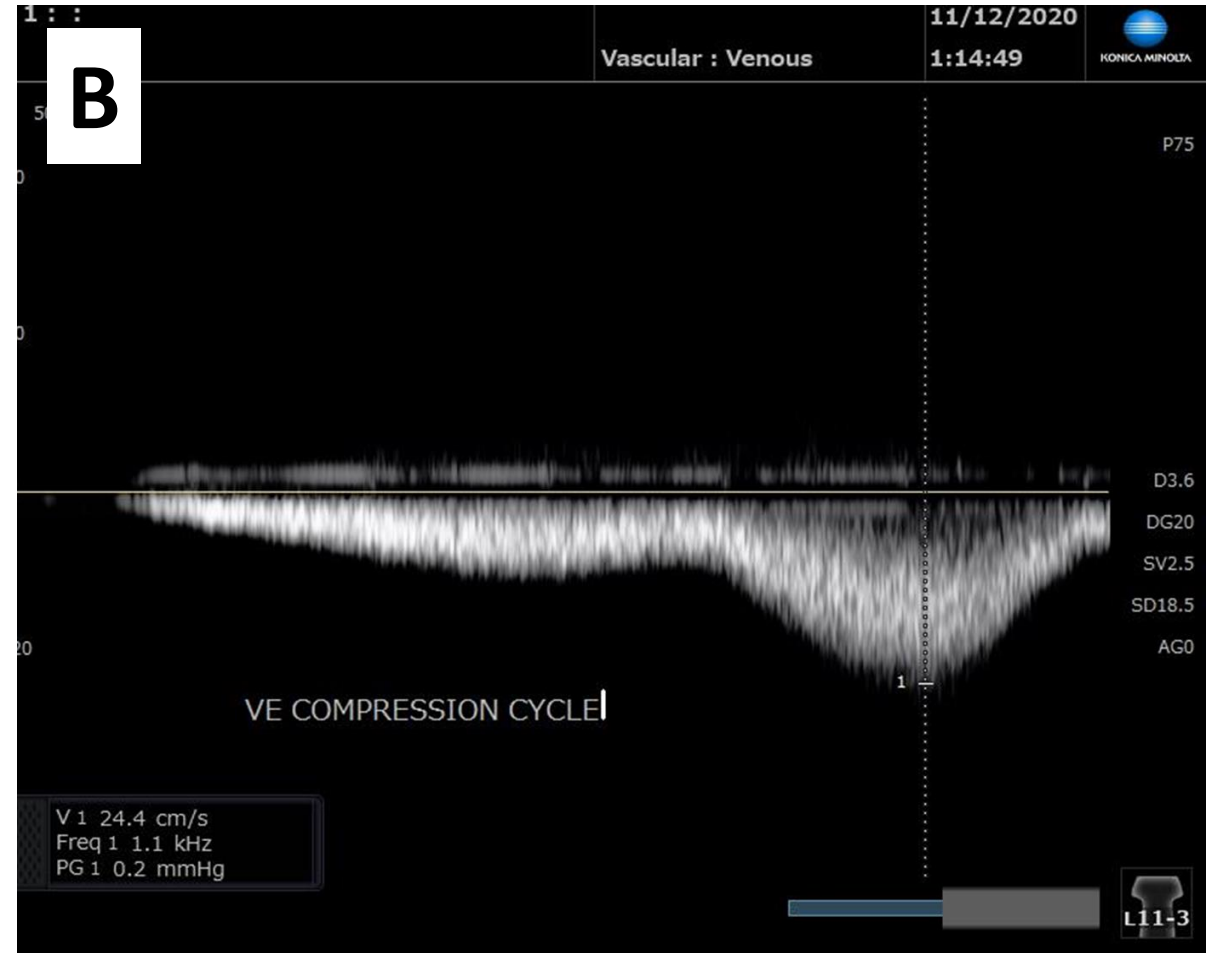
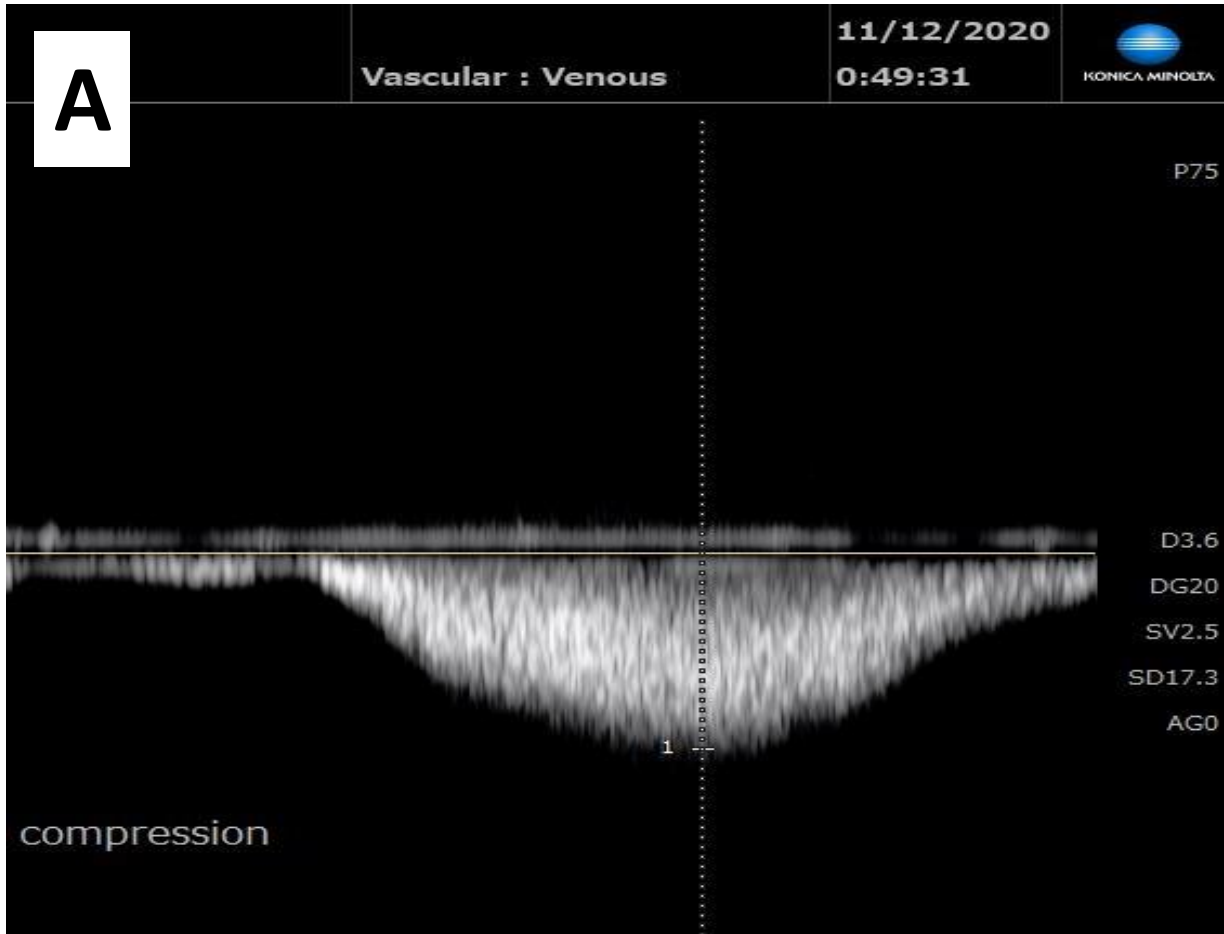


* % increase and p-value in peak velocity at baseline (resting cycle) and during compression

Effect of a Portable PCD and a Traditional PCD on Volume Blood Flow in the Popliteal Vein



* % increase and p-value in volume flow at baseline (resting cycle) and during compression



Venous flow in the popliteal vein during the compression cycle of: Kendall 700 (A) and Vascu-Ease (B)

Results

- Peak velocity was increased by 366% with the Kendall-700 PCD and 349% with the VascuEase PCD
- Flow volume also increased with the Kendall (437%) and VascuEase (402%) PCDs during the compression cycle
- The increase from baseline in peak velocity and volume flow was statistically significant ($p < 0.05$) with both PCDs
- From the results of this pilot study, it appears that both the Kendall and VascuEase PCDs have similar effects on venous blood flow
- The Vascular Refill Detection feature of the Kendall device regulates the time between compression (20-60 seconds), whereas the VascuEase PCD provides a constant cycle (15 seconds during compression and 45 seconds during rest).