CLINICAL RESEARCH

Micro-mobile Foot Compression Device Compared with Pneumatic Compression Device

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Abstract

Background   A combination mechanical-pharmacologic regimen is an accepted prophylactic treatment against symptomatic venous thromboembolism for patients undergoing total hip and knee arthroplasties. Foot pumps have been recognized as effective mechanical devices. Research suggests pharmacologic prophylaxis for venous thromboembolism is associated with complications and foot pumps offer an adjunct or alternative approach. Presumably the effectiveness of foot pumps relate to enhancement of venous flow.

Questions/purposes   We compared an established foot pump system with a new mobile foot pump for their ability to influence mean peak venous velocity in the common femoral, popliteal, and posterior tibial veins.

Methods   We evaluated 60 healthy subjects with the established and the novel foot-pump systems. Ultrasonography was used to measure baseline and peak venous velocity with mechanical compression. We constructed 95% confidence intervals (CI) on the mean differences between the two devices to establish equivalence limits. We compared ratios of peak velocity to resting velocity. Subjects subjectively rated the two foot pumps with respect to size, fit, and comfort.

Results   The 95% CI test for equivalence of the mean differences between the two devices was inconclusive. The novel device augmented the venous velocity 11 times greater than the resting velocity in the posterior tibial vein and three times greater than the resting velocity in the popliteal vein. The established foot pump augmented the venous velocity 15 times greater than the resting velocity in the posterior tibial vein and four times greater than the resting velocity in the popliteal vein. The novel device rated better for size, fit, and comfort when compared with the established device.

Conclusions   The established foot pump tended to be associated with greater peak velocities; the novel device produced more consistent mean peak venous velocities and may be more acceptable to patients and caregivers.

Level of Evidence   Level II, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Introduction

Deep vein thrombosis (DVT) is a relatively common and potentially serious complication of prolonged bed-confining inpatient hospital stays. Symptomatic venous thromboembolism is most prevalent after invasive neurosurgical procedures and THA [26]. Prophylactic measures are recommended to prevent thromboembolic complications in hip and knee arthroplasties [11, 14, 15, 18]. The American Academy of Orthopaedic Surgeons consensus for the prevention of thromboembolic events in total hip and knee

arthroplasties is a combination of pharmacologic and mechanical methods [15]. Mechanical devices include elastic support hose, foot pumps, foot-calf pumps, calf pumps, and calf-thigh pumps. The foot pump evolved after Gardner and Fox showed there is a powerful physiologic venous pumping mechanism in the sole of the foot, the venous plexus [12]. The foot pump relies on cyclical compression of the venous plexus in the sole of the foot to augment venous flow, reducing stasis. This system enhances venous return and supports venous endothelial fibrinolysis when a patient is not ambulatory [1, 21]. The various devices developed for this purpose differ in the frequency and magnitude of compression. The minimum venous velocity or venous volume augmented by mechanical compression necessary to prevent thromboembolic events is unknown [18, 19, 24, 25]. Several studies suggest the degree of increase in flow velocity is a good hemodynamic measure of device efficacy [9, 24, 25]. Nevertheless, clinical studies suggest patient compliance and consistent application of compression devices throughout each 24-hour period are imperative to ensure DVT prophylaxis [5, 18, 22]. A well-designed mechanical device should incorporate augmentation of peak venous velocity, augmentation of venous volume return, ease of device application, and patient comfort, which are essential for user compliance to ensure continuing use throughout the day.

We compared the novel foot pump with a FDA-approved foot pump regarding: (1) the ability to increase venous return flow velocity with each cycle of foot compression, (2) the degree of velocity augmentation, (3) the effects of body habitus, age, and gender on the difference in mean peak velocity, and (4) the ratings on comfort and acceptability.

Patients and Methods

We designed an equivalence study to evaluate the hemodynamic parameters of a novel foot pump compared with an accepted foot pump. We randomized 60 healthy subjects to receive either the established or the novel foot pump system. Ultrasonography was used to measure a baseline and peak venous velocity with mechanical compression. Inclusion criteria were: (1) age greater than 21 years, (2) availability for study visit, (3) ability to understand the risks and benefits of participation in the study, and (4) ability to comply with the protocol requirements. The exclusion criteria were: (1) bleeding disorder or any active systemic disease, (2) active cancer, (3) history of prior DVT or pulmonary embolism, (4) body mass index (BMI) greater than 35, (5) congestive heart failure, (6) pregnancy, (7) history of peripheral vascular disease, (8) history of saphenous vein stripping, (9) vasculitis, (10) varicose

Table 1. Demographic data for patients

Variables	All patients n = 60	Equivalence zone n = 20	Test cohort n = 40
Men (n)	20	7	13
Women (n)	40	13	27
Age (years) (SD)	46.14 (13.42)	47.0 (13.77)	45.69 (13.40)
BMI (SD)	26.56 (4.20)	27.35 (3.86)	26.01 (4.32)

veins, and (11) clinically apparent venous insufficiency. We recorded the age, height, and weight for all subjects. Of 68 patients screened, 60 met the inclusion criteria and agreed to participate. There were 40 women and 20 men, with a mean age of 46 years (range, 24–74 years), the average BMI was 26.56 (range, 18–35) (Table 1). The study plan was approved by the Western Institutional Review Board (WIRB) before recruiting the study subjects. The WIRB designated the novel device a nonsignificant risk for the purpose of this study.

The sample size was justified on the basis of a power analysis, in which the power was set at 0.80; alpha 0.05; the true difference in the two devices is assumed to be 0, and the equivalence limit was 0.50 standard deviation (SD) of the mean difference in the devices [7]. This analysis suggested 36 subjects were adequate. We randomly abstracted 40 subjects to construct the 95% CI and used 20 subjects to construct the zone of indifference or establish the venous return velocity range considered equivalent with use of random number tables. Independent researchers recruited and enrolled subjects via mass media and social networking. The researchers and subjects were not blinded to the interventions.

The novel foot pump, the Frogg Dynamic Compression System (FDC; Leap Frogg LLC, Grand Junction, CO, USA) consists of three components: the Frogg, a compliance monitor, and the footwear (Fig. 1). When the two-step actuation process is initiated, an 18.61 cm^3-compression pad firmly presses into the arch of the foot every 20 to 30 seconds and compresses. This action moves a bolus of blood up the deep veins of the leg, eliminating blood pooling. The compliance monitor controls and displays device functions, tracks subjects' compliance regarding wear time, tracks ambulation, and displays battery status. The compliance record indicates: (1) the amount of time the patient was active and ambulating during the last 24 hours, (2) the amount of time the FDC actively compresses the patients' feet, and (3) the amount of time the device was turned off or inactive. The battery powered micromotor footwear secures the actuator to the arch of the foot, houses the Frogg, and contains a flexible sole to enable walking. The comparative foot pump was the A-V Impulse System (AVI) (The Kendall Company, Mansfield, MA, USA).

Two certified vascular ultrasound technicians (BH, BS) performed all ultrasonography assessments. We used a standardized assessment protocol to minimize the known sources of error [13]. We performed the ultrasonography studies using a Philips HDI 5000 (Philips, Bothell, WA, USA) duplex ultrasound device with a variable high-frequency linear array transducer (5–7 MHz). During the examinations, we placed the subjects in a 30°-reverse Trendelenburg position with the leg externally rotated to minimize active dorsal or plantar flexion. The literature suggests that the use of venous impulse foot pumps while subjects are in a reverse Trendelenburg position may increase the thromboprophylactic effect [10].

The FDC and AVI devices each have two user-selectable pressure settings: 314 mm Hg and 395 mm Hg, and 130 mm Hg and 180 mm Hg, respectively. The
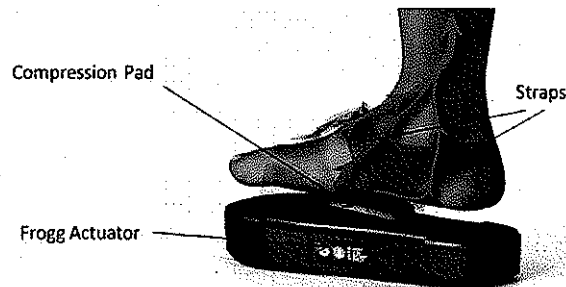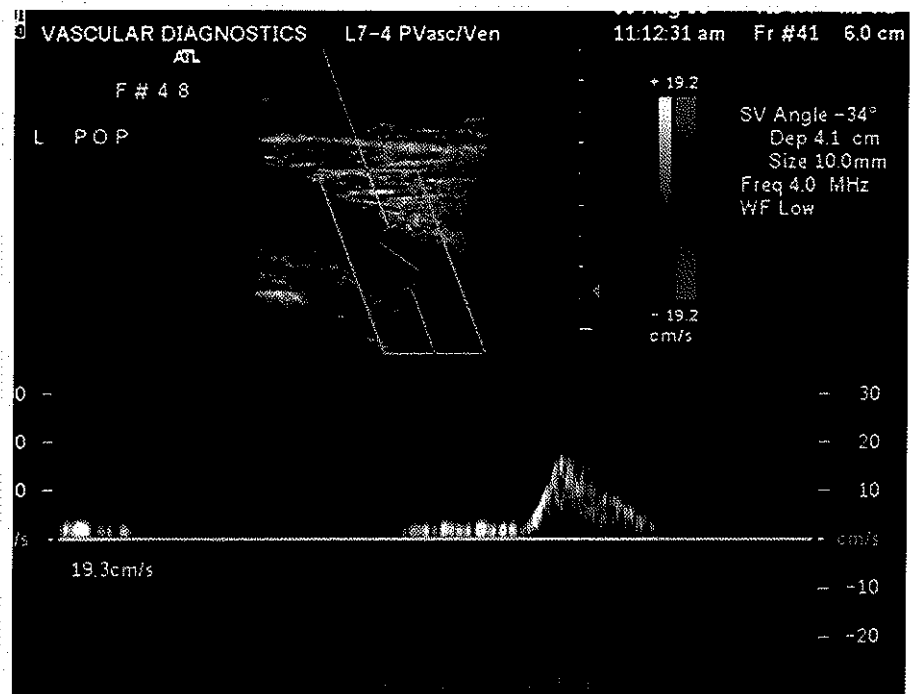

Fig. 1 The three components that comprise the FDC are the actuator, the compression pad, and the shoe. (Published with permission from Leap Frogg LLC, Grand Junction, CO, USA.)

pressures used in this study were 314 mm HG for the FDC and 130 mm HG for the AVI. We applied the compression devices to the feet and actuated them according to the instructions provided by the manufacturers. A random number table was used to determine which leg the FDC was applied (right or left leg), and applied the AVI to the other leg. We also randomly chose which device would be activated first, and did not activate them simultaneously. Once randomization determined to which leg a device would be applied, and the device activation sequence, we initiated assessments.

The common femoral vein, just caudal to the entrance of the saphenous branch, was the first site to be examined. We initially imaged the vein in a transverse plane; then rotated the transducer 90° to examine the vein in a longitudinal plane. The technician maintained the angle of the transducer at 60° or less. We initially recorded a baseline venous velocity with no device activation. We noted the time of device activation and the peak velocity reading. We recorded a baseline and three peak velocity readings (Fig. 2). For the popliteal and posterior tibial veins, we used the same sequence of examinations. We examined the popliteal in the midsegment and the posterior tibial approximately 6 cm proximal to the medial malleolus. We then performed the same sequence of examinations on the opposite leg with actuation of the comparative foot pump.

According to the manufacturer's specifications, the AVI was required to run through a series of three cycles of compression and rest for calibration before measurements were taken. Manufacturer's specifications for the FDC do

Fig. 2 The sample baseline and peak velocity readings associated with mechanical compression are shown.

not delineate a series of cycles of compression for calibration.

Following acquisition of ultrasonic data, the foot pumps were left in place on the participants' feet and the subjects were asked to complete a survey regarding each device. Subjects rated each device using a five-point Likert scale to assess shoe size, fit, and comfort (Appendix 1).

We entered data from each subject into a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, WA, USA) and transferred it to the data table of SPSS version 16 (Chicago, IL, USA). The primary outcome was to determine if the FDC and AVI were statistically equivalent.

To calculate the mean we used the equation:

$$\mu = \frac{P1 + P2 + P3}{3} - B$$

where P = peak reading and B = baseline.

When we reference differences throughout this article, we are referring to the paired difference of the mean peak velocities.

To calculate the mean difference we used the equation:

$$\mu diff = \mu FDC - \mu AVI$$

where FDC = Frogg Dynamic Compression and AVI = A-V Impulse.

A test of the mean differences that failed to yield a significant difference would not translate to device equivalence: that is, if the mean differences in augmentation of the two devices were statistically similar, we could not necessarily conclude the devices were equivalent because a difference was not detected [17].

We tested statistical equivalence of the FDC and the AVI by constructing a zone of indifference. We calculated 95% CI and the upper and lower limits of the zone of indifference using 0.50 SD from the mean of the difference of the two devices. This zone was calculated for each of the veins investigated. We obtained this zone of indifference with data from a random selection of 20 subjects from the cohort using a random number table that was concealed until the interventions were assigned. We then calculated 95% CI on the mean of the difference for the remaining 40 subjects. If the 95% CI fell within the zone of indifference we could accept our hypothesis that the mean difference between the two devices is less than a 0.50 SD. An advantage of the zone of indifference analytic strategy is the ability to show device equivalence [17].

To assess the degree of velocity augmentation, we calculated the ratio of peak velocity to resting velocity for both devices from all 60 subjects. We used a one-sided t-test to test this ratio. To assess the effects of gender on the mean differences in the degree of velocity augmentation, we used a t-test. We obtained Pearson correlation coefficients to investigate the association of body habitus and age with the differences. To assess subject comfort and acceptability, we performed paired t-tests with SPSS version 16 statistical software.

Results

We could not conclude that the devices were equivalent or different as the experiments for equivalence tests based on the zone of indifference were inconclusive. For the direct comparison analysis in the common femoral vein, the confidence intervals for the observed effects overlapped the upper and lower limits of the zone of indifference (Fig. 3). For the direct comparison analysis in the popliteal vein, the confidence intervals for the observed effects overlapped the lower limit of the zone of indifference (Fig. 4). The same results occurred in the posterior tibial vein (Fig. 5).

The FDC augmented the venous velocity 11.65 times greater (p = < 0.001) than the resting velocity in the posterior tibial vein and 3.22 times greater (p = < 0.001) than the resting velocity in the popliteal vein (Table 2). The AVI foot pump augmented the venous velocity 15.03 times greater (p = < 0.001) than the resting velocity in the posterior tibial vein and 4.24 times greater (p = < 0.001) than the resting velocity in the popliteal vein (Table 2). We could not use the ratio of peak velocity to resting velocity for the common femoral vein because of the large variations likely attributable to the effects of respiration [20]. The SD of the mean peak velocities for the FDC was smaller than that of the AVI in the popliteal and the posterior tibial veins. In the posterior tibial vein the SD of the AVI was 40% larger than the FDC (Table 3). The narrower distribution of the mean peak velocity with the FDC suggests it is more consistent in augmenting venous velocity (Fig. 6).

We found no association between BMI and the differences in the mean peak velocity in the common femoral vein (r = 0.03; p = 0.822), the popliteal vein (r = 0.024; p = 0.858), or the posterior tibial vein (r = −0.470; p = 0.722) with mechanical compression. There was an association with age and the differences in the mean peak velocity in the common femoral vein (r = −0.399; p = 0.002), but none in the popliteal vein (r = 0.136; p = 0.305) or in the posterior tibial vein (r = 0.118; p = 0.373) with mechanical compression. There were no differences between the means of the differences in men and women in the common femoral vein (p = 0.909), the popliteal vein (p = 0.608), and the posterior tibial vein (p = 1.00).

The FDC tended to be more acceptable to subjects when compared with the AVI. The acceptance survey indicated

Fig. 3 The graph shows that the results from the test sample are not in the equivalence zone in the common femoral vein.
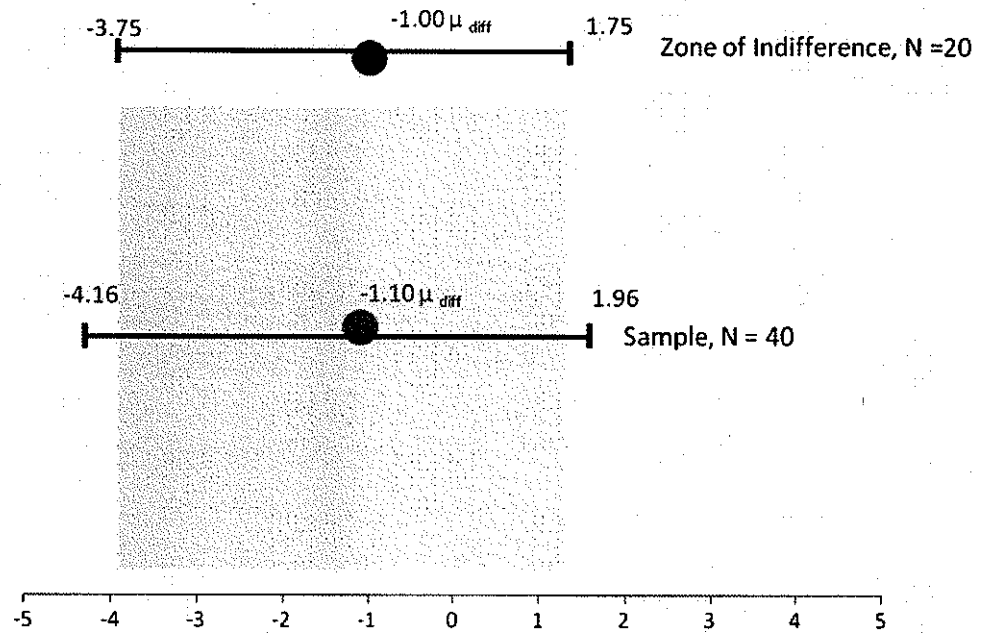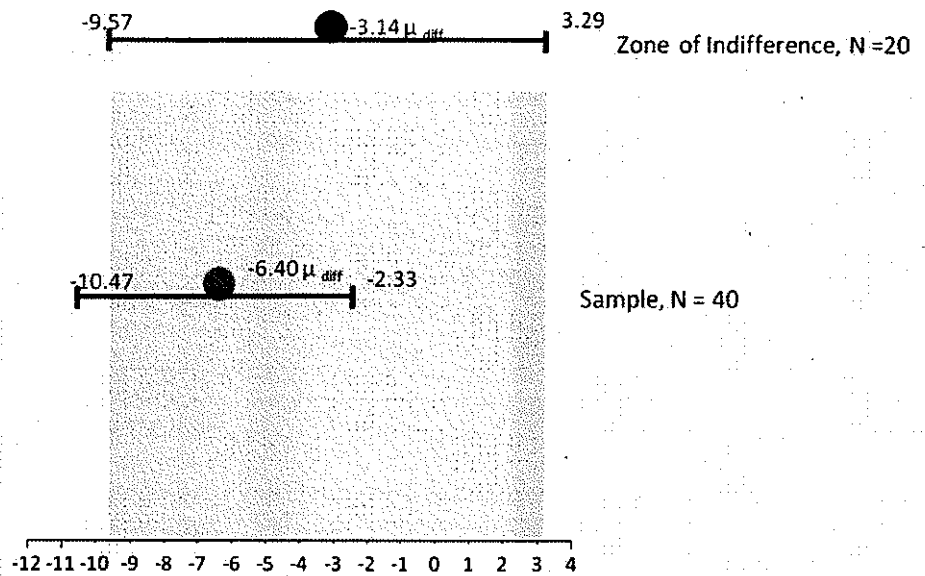

Fig. 4 The graph shows that the results from the test sample are not in the lower limit of the equivalence zone in the popliteal vein.

for the variable 'size', 82% of the subjects rated the FDC very good or great whereas 56% rated the AVI very good or great. For the variable 'fit', 83% rated the FDC very good or great and 63% rated the AVI very good or great. For the variable 'comfort', 82% rated the FDC very good or great and 73% rated the AVI very good or great.

Discussion

The relatively common and potentially serious complications of thromboembolic disease in lower extremity arthroplasty warrant routine prophylactic measures. Various professional associations disagree on the best intervention for reduction of postoperative thromboembolic disease, and protocols for prevention are not applied universally [14]. However, there is a general consensus for the use of mechanical devices in high-risk patients for prevention of venous thromboembolism [16]. Foot pumps are recognized as an effective mechanical device [15]. The need for an efficacious, accepted, and easily administered mechanical foot pump for prevention of thromboembolic disease is of interest to clinicians. To provide the greatest degree of prophylaxis against thromboembolic events

Fig. 5 The graph shows that the results from the test sample are not in the lower limit of the equivalence zone in the posterior tibial vein.
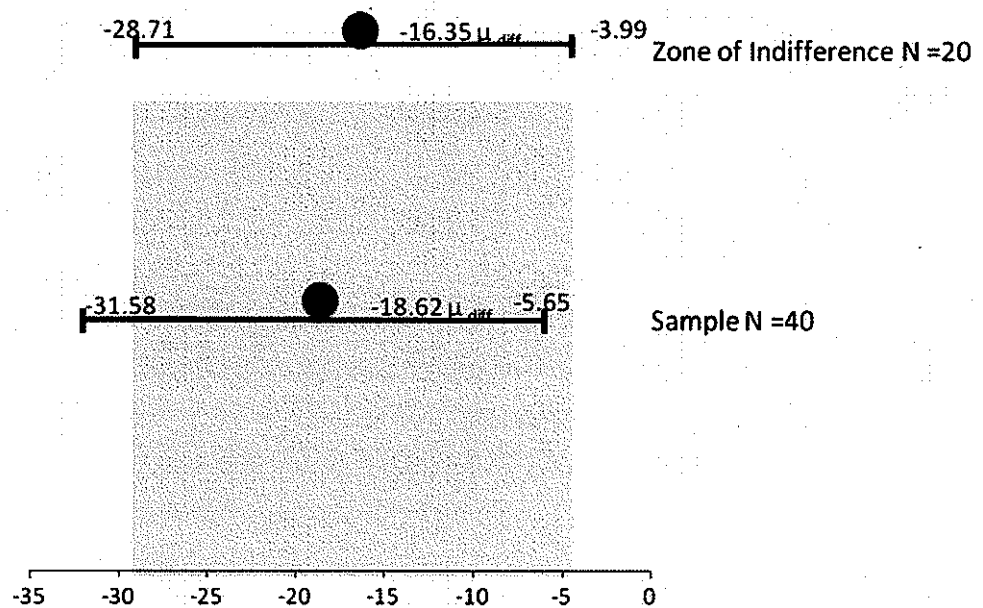

Table 2. Results of the degree of augmentation for the FDC and the AVI

Investigated vein	μ Greater than resting velocity	Standard deviation	95% Confidence level (lower–upper limit)
Posterior tibial FDC (n = 60)	11.65	4.74	10.38–12.92
Posterior tibial AVI (n = 60)	15.03	7.58	12.85–17.20
Popliteal FDC (n = 60)	3.22	1.09	2.94–3.51
Popliteal FDC (n = 60)	4.24	2.04	3.71–4.77

Table 3. Results of the mean peak venous velocity and standard deviation in the posterior tibial vein

Device	μ Peak venous velocity (n)	Standard deviation	Standard error of the mean
FDC	67.70 (60)	24.57	3.17
AVI	84.27 (60)	34.32	4.43

associated with arthroplasties, a well-designed mechanical foot pump should consistently augment venous velocity and be acceptable to patients and caregivers. We compared the novel foot pump with a FDA-approved foot pump and evaluated: (1) the ability to increase venous return flow velocity with each cycle of foot compression, (2) the degree of velocity augmentation, (3) the effects of body habitus, age, and gender on the difference in mean peak velocity, and (4) the ratings for comfort and acceptability.

Our study has limitations. First, the ranges or the treatment effect of peak venous velocity needed to reduce the risk of thromboembolic disease with mechanical compression are unknown [9, 18, 24, 25]. The 0.50 SD difference of clinical importance may not have been an appropriate standard effect size, given the high variability of readings and the threshold of augmentation to circumvent DVT are unknown. The suggestion in clinical drug

trials is that researchers choose 0.25 or 0.50 if no prior knowledge regarding clinical performance of the test drug is available [7]. Second, the researchers and subjects were not blinded to the two devices. This may have caused subjects to subjectively rate the FDC higher for acceptability because it is the novel device. Third, investigator or procedural bias may have occurred between the two ultrasound technicians. The researchers sought to minimize this effect by multiple trainings and standardizations of ultrasound assessments. Finally, use of the Likert scale to assess subject's acceptability is not substantiated by the use of a validated measure.

The inconclusive results of the zone of indifference, the primary outcome, do not allow us to conclude the two devices are equivalent or different. The nuances or peculiarities of this study do not allow for comparison of our primary outcomes with the literature on foot pumps.

The degree of velocity augmentation from baseline to peak velocity showed that the FDC and AVI consistently augment blood. A study tested the AVI at two different user settings and reported no difference in the mean velocities between the two settings, and concluded the hemodynamic role of foot pumps for prevention of

Fig. 6 The graph shows the results of the mean peak venous velocity elicited by the FDC and AVI in the posterior tibial vein.
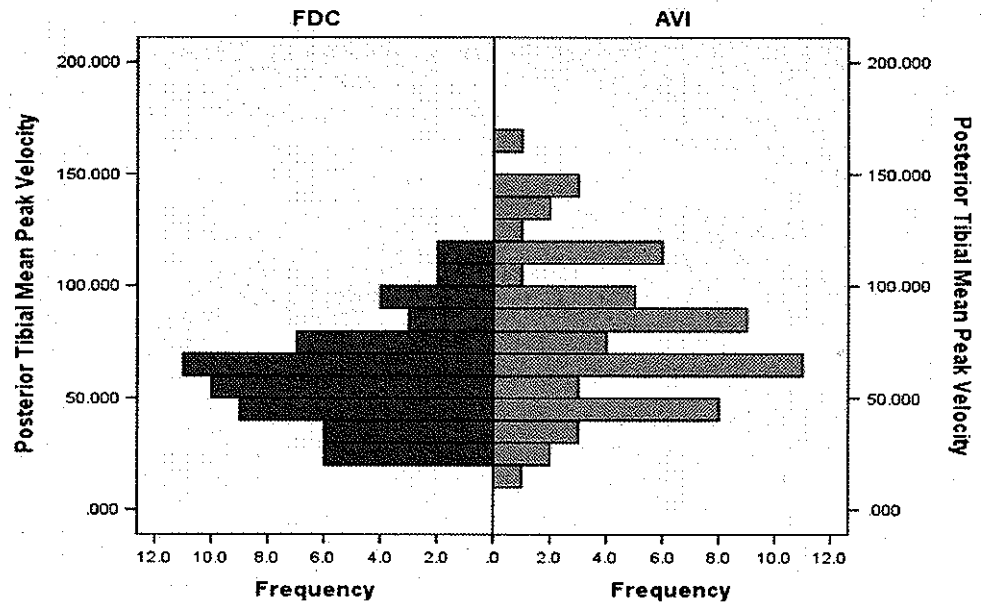
thromboembolic disease is unidentified [9]. We observed that the initial peak velocity with the FDC was greater than the subsequent peak augmentations. Analysis confirmed that the first compression yielded greater venous augmentation than the subsequent compressions. The FDC allows for two user settings of compression, 20 seconds and 30 seconds. For this study, the compression cycles were set at 20 seconds. We recommend that the device be set at 30-second intervals to allow for maximum pooling of venous blood in the plantar plexus. The more volume of blood in the chamber may allow for the foot pump to facilitate greater augmentation of blood with primary compression [10].

Patient characteristics that might effect venous velocity augmentation with mechanical devices have been unexplored. We did not directly compare the AVI with the FDC regarding age, gender, and BMI because we used paired data; however, we did analyze the effects of the aforementioned variables on the difference in peak velocities. With mechanical compression, BMI, age, and gender caused no increase or decrease in the hemodynamic parameters.

The subjects were asked to assess the devices on size, fit, and comfort to determine acceptability. Respondents subjectively rated FDC greater than the AVI in all three domains of acceptability. The literature provides data on comfort levels associated with foot pumps but there are limited data that evaluate perceptions of size and fit. A study of 43 patients undergoing joint arthroplasties measured acceptance of the AVI using a five-point Likert scale [2]. In this study, 51% of the patients found foot pumps comfortable, whereas 25.5% were neutral about them [2]. Another study on compliance and satisfaction with foot

pumps used a visual analog scale of 0 to 10 to demark the average level of patient comfort with use of the AVI. The average level of patient-reported comfort was 7.1 [6]. In a study that evaluated compliance with the PlexiPulse (KCI, San Antonio, TX, USA) in 100 patients who underwent TKAs, the authors surveyed the patients regarding their perceived comfort with the device using a nine-point Likert scale [23]. The patients rated the PlexiPulse 7.37 of 9 maximum points [23]. Furthermore, the researchers surveyed nurses for their assessment of the foot pump with respect to size and weight, however we are unable to compare or interpret these results because the authors surveyed the healthcare providers, not the patients, and we do not know if the results pertain to the variable 'size' or the variable 'weight' [23].

Noncompliance with foot pumps is a barrier to thromboembolism prevention [3–6, 16, 18, 22]. We assessed variables that might contribute to increased user compliance. The nontethered function of the FDC, the subjective rating that the FDC is more acceptable, and the simplified FDC's two-step actuation process might facilitate overall compliance in clinical settings.

Current literature supports mechanical methods of thromboprophylaxis as an adjunct to chemoprophylaxis [1, 8, 14, 15, 19]. The American Academy of Orthopaedic Surgeons' pulmonary embolism prevention guidelines delineate mechanical prophylaxis and rapid mobilization as critical constructs for prevention of pulmonary embolism events [13]. The AVI trends toward greater venous augmentation; however, the nontethered FDC consistently augments venous blood, might be more acceptable to patients in clinical settings, and allows patients to freely ambulate—core constructs for an

effective mechanical device. Future studies are necessary to assess the incidence of symptomatic venous thromboembolism using the FDC in patients with a lower extremity arthroplasty.

Appendix 1: Subject Satisfaction Survey

Id#_____
Device_____

Please take a few minutes and tell us about the device. We appreciate your valuable time and comments. All of your responses will be held confidential! Thank you in advance for your feedback.

For each of the following questions, please mark an X in the one box that best describes your answer.

1. How would you rate the device on:

	Great	Very Good	Good	Fair	Poor
A. Ease of application	☐	☐	☐	☐	☐
B. Size	☐	☐	☐	☐	☐
C. Fit	☐	☐	☐	☐	☐
D. Comfort	☐	☐	☐	☐	☐
E. Noise level	☐	☐	☐	☐	☐

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