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Venous Hemodynamics After Total Hip Arthroplasty: A Comparison Between Portable vs Stationary Pneumatic Compression Devices and the Effect of Body Position



Jonathan L. Berliner, MD^a, Philippe A. Ortiz, BA^a, Yuo-yu Lee, MS^b,
Theodore T. Miller, MD^c, Geoffrey H. Westrich, MD^{a,*}

^a Department of Adult Reconstruction and Joint Replacement Service, Hospital for Special Surgery, New York, New York

^b Department of Biostatistics, Hospital for Special Surgery, New York, New York

^c Department of Radiology and Imaging, Hospital for Special Surgery, New York, New York

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ABSTRACT

Background: Improvements in device design have allowed for portable pneumatic compression devices (PPCDs). However, portability results in smaller pumps that move less blood. Additionally, although patients often stand when wearing PPCDs, few studies have evaluated the hemodynamic effects of PPCDs while standing.

Methods: A crossover study was performed to compare a PPCD (ActiveCare+S.F.T.; Medical Compression Systems, Or Akiva, Israel) to a stationary pneumatic compression device (SPCD) (VenaFlow; DJO Global, Carlsbad, CA) on hemodynamics in supine and standing positions among 2 cohorts composed of 10 controls and 10 total hip arthroplasty patients. Differences in baseline peak venous velocity (PVV), PVV with each PCD, and delta PVV with each PCD were assessed. A multivariate analysis was performed to examine differences between cohorts, devices, and position.

Results: In both positions, the SPCD demonstrated a larger change in PVV when compared to the PPCD ($P < .001$). The total hip arthroplasty group had a greater delta PVV while standing when considering both PCDs together ($P < .001$). When considering both cohorts, delta PVV was greater while standing, only when the SPCD was used ($P < .001$). There was no difference between standing and supine positions when the PPCD was used.

Conclusion: The SPCD demonstrated a greater capacity to increase PPV in the supine and standing positions. The SPCD generated greater values of PVV and delta PVV in the standing position. Although these results demonstrate a difference between devices, it is important to establish the PVV necessary to prevent VTE before one is considered more effective.

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Guidelines published by both the American Academy of Orthopaedic Surgeons (September 2011) and the American College of Chest Physicians (February 2012) support the use of mechanical compression devices alone or in combination with a pharmacologic agent after total hip arthroplasty (THA) for the prevention of

venous thromboembolic (VTE) disease [1,2]. There has been sustained interest in the use of mechanical prophylaxis given its proven efficacy and the comparatively high risk of bleeding complications associated with pharmacologic agents. In the past, compression device efficacy has been limited by both patient compliance and the inability to continue use after hospital discharge. Newer portable designs of pneumatic compression devices are lightweight and potentially allow for better compliance, patient satisfaction, and continuation of mechanical prophylaxis after discharge [3–7]. However, such portable devices are battery operated and have a much smaller pump mechanism [3,4]. Prior studies have demonstrated that when compared to nonmobile stationary pneumatic compression devices (SPCDs), portable pneumatic compression devices (PPCDs) have a potentially higher

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* Reprint requests: Geoffrey Westrich, MD, Adult Reconstruction and Joint Replacement Service, Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021.

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rate of compliance and therefore the potential for lower rates of deep venous thrombosis (DVT) [3,5]. PPCDs have also been shown to be as effective as chemoprophylaxis in the prevention of DVT and pulmonary embolism (PE) after THA and total knee arthroplasty [8,9].

PCDs decrease rates of DVT formation by both enhancing venous return and augmenting venous endothelial fibrinolysis [10,11]. Numerous designs are available with varying effect on venous flow as measured by the increase in venous velocity [6,7,11–13]. Several studies suggest that the magnitude of increase in venous velocity is a good hemodynamic measure of device efficacy as higher velocities may result in decreased rates of DVT [7,11,12,14]. Despite this, the minimum venous velocity augmented by mechanical compression necessary to prevent thromboembolic events is unknown.

Prior studies have demonstrated that THA alters venous hemodynamics within the lower extremity. Postoperative patients have been shown to exhibit decreased venous outflow, decreased venous capacitance, and a prolonged return to baseline that can persist for up to 6 weeks [15]. Despite this, most manufacturers use healthy subjects to assess the efficacy of new devices and many previous studies evaluating the effect of PCDs on changes in peak venous velocity (PVV) include only normal subjects [6,13]. Furthermore, although venous flow within the lower extremities is known to be position dependent, there is little evidence regarding the effect of both surgery and body position on venous hemodynamics.

The purpose of this study is to compare the effect of a PPCD (ActiveCare+S.F.T.; Medical Compression Systems, Or Akiva, Israel) to that of a stationary compression device (VenaFlow; DJO Global, Carlsbad, CA) on venous hemodynamics among both healthy control subjects and postoperative THA patients. The study also aims to determine the effect of patient position on venous hemodynamics by measuring hemodynamic changes in both supine and standing positions.

Methods

A crossover study was performed to evaluate the hemodynamic effects of 2 PCDs in both supine and standing positions. Ethical approval from the hospital's institutional review board was obtained prior to conducting the study. Written consent was obtained from each study subject prior to obtaining measurements. The 2 devices under investigation were the ActiveCare+S.F.T. (Medical Compression Systems), a PPCD, and the VenaFlow (DJO Global), an SPCD. The ActiveCare+S.F.T. delivers sequential compression at a pressure of 50 mm Hg and uses 8 seconds of compression followed by 36–56 seconds of decompression in synchronization with the respiratory-related venous phasic flow. The VenaFlow is a rapid inflation asymmetrical compression device. It is inflated rapidly once every minute with a duration of compression of 6 seconds, at a preset pressure of 45–52 mm Hg.

All study subjects were analyzed with both devices. Computer randomization was used to determine which device was applied and tested first.

Two cohorts were evaluated in the study, one composed of 10 healthy control subjects and the other composed of 10 postoperative THA patients. All patients were >18 years of age and those within the THA cohort had undergone primary unilateral THA for an indication of primary osteoarthritis. All surgeries were performed by a single surgeon (senior author G.W.) via a posterolateral approach during a 6-month period between the dates of September 2015 and February 2016. Within the THA cohort, the study was performed on postoperative day 2 for all study subjects. The healthy cohort was composed of employees at the authors'

institution who volunteered to be part of the study. No patient with a history of DVT, PE, congestive heart failure, peripheral vascular disease, prior arterial reconstruction, saphenous vein stripping, vasculitis, varicose veins, venous insufficiency, or morbid obesity (body mass index >40) was included in the study.

For each study subject, the PCD selected to be tested first was applied to both lower extremities, with readings obtained from only the operative extremity in the THA cohort and the right lower extremity in the control cohort. The application of each PCD was performed by the testing ultrasound technician and conformed to the manufacturer's specifications. Both devices are calf pump design PCDs and were therefore placed directly onto the leg and wrapped circumferentially around the calf region. Baseline readings of PVV were obtained while in the supine position after the PCD had been applied, but not turned on. Before measurement of the PVV, the common femoral vein was checked for the absence of acute thrombosis; none was seen within any of the test subjects. Using the LOGIQ e9 (GE Healthcare) ultrasound unit with a 9-MHz linear probe, the common femoral vein above and below the junction with the greater saphenous vein was identified, and the skin was marked with an indelible marker by the ultrasound technician performing the readings. Baseline venous velocity was determined at the 2 marked locations. At each position, 3 separate measurements of PVV were obtained using either power Doppler or color Doppler sonography.

Next, the device was powered on and the device pressure, cycle time, inflation time, and hold time were set to the respective manufacturer's recommended settings. After several pump cycles of compression (minimum 5 minutes), a wave tracing of venous blood flow, consistent with inflation of the pump, was recorded. Using the proprietary software within the ultrasound scanner, the PVV was calculated. The change in venous velocity from baseline to peak was also calculated and defined as delta PVV. Next, the device was turned off and the patient was placed in a standing position. Again, baseline readings were obtained 3 times, the device was turned on, allowed to cycle, and 3 readings, timed with inflation of the pump, were then obtained. The study subject was then asked to lie back down in the supine position, and the same series of events was performed for the alternate PCD.

Statistical Analysis

Univariate Analysis

Differences between the control cohort and the THA cohort in baseline PVV, PVV with VenaFlow, PVV with ActiveCare+S.F.T., delta PVV with VenaFlow, and delta PVV with ActiveCare+S.F.T. were assessed using Wilcoxon rank-sum test in either the supine or standing position. To determine the effect of position on hemodynamics, Wilcoxon signed-rank test was used to compare, within each cohort, supine to standing baseline PVV, supine to standing PVV with VenaFlow, supine to standing PVV with ActiveCare+S.F.T., supine to standing delta PVV with VenaFlow, and supine to standing delta PVV with ActiveCare+S.F.T.

Multivariate Analysis

Multiple linear regression based on generalized estimating equation was performed with delta PVV as the primary outcome. The multivariate analysis was designed to examine differences in delta PVV between cohorts, the devices tested, and patient positions to account for the repeated measure design of the study when controlling for age, gender, and baseline PVV. In addition, an interaction term was introduced between position and device tested. This allowed for the examination of the relationship between devices and delta PVV to be different between positions or the relationship between positions and delta PVV to be different

between devices if the interaction effect was significant. Subsequent multiple linear regression analyses were performed by evaluating outcome separately for the standing and supine positions, adjusting for age, gender, and baseline PVV.

For the statistical analyses, all alpha significance levels were set to 0.05. A power analysis was not performed prior to undertaking the study as the number of study subjects included in each group was determined by both funding and access to available participants. Furthermore, the clinically significant value of PVV necessary to prevent VTE is unknown. Using the pooled standard deviation for PVV of 32 mL/min as a proxy for clinically significant change, group sample sizes of 10 would allow for detection of a difference of 32 in a design with 4 repeated measures with 80% power and a 0.05 alpha level.

Results

Ten healthy control subjects and 10 patients after THA completed the study protocol without complications. There were no observed malfunctions with either of the PCDs during the course of the study. Demographics were compared between the 2 cohorts revealing a significantly lower age among the control group (28.7 vs 64.6, $P = .0002$) (Table 1). No difference in sex was found between the 2 groups (control group 60% female, THA group 70% female, $P = .99$).

Univariate Analysis

Venous hemodynamic measurement values (mL/min) for both cohorts in supine and standing positions are displayed in Table 1.

Control vs THA Groups

In the supine position, the THA cohort had significantly lower venous velocity at baseline when compared to the control group (26.9 vs 34.6, $P = .04$). There was no significant difference between the 2 groups at baseline when in the standing position (17.7 vs 16.0, $P = .12$). There were no other significant differences between the control group and the THA group in either the supine or standing position, including PVV and delta PVV with either device tested (Table 1).

Supine vs Standing

Within the control group, baseline PVV was higher in the supine position (34.6 vs 16.0, $P = .004$; Table 2). Also within the control group, no significant differences in delta PVV were found between supine and standing positions when testing either device (SPCD 87.1 vs 127.9, $P = .06$; PPCD 40.5 vs 32.6, $P = .345$) (Table 2). Within the THA group, delta PVV with the SPCD was greater when in the standing position (155.7 vs 86.8, $P = .004$). When testing the PPCD in the THA cohort, no significant differences were found between supine and standing positions (37.8 vs 41.9, $P = .85$) (Table 2).

Table 1
Cohort Comparison in Both Standing and Supine Positions.

	Standing		P-Value	Supine		P-Value
	Control	THA		Control	THA	
Baseline PVV	16.0 (5.0)	17.7 (3.7)	.12	34.6 (7.9)	26.9 (11.7)	.04
PVV with SPCD	143.9 (41.5)	173.4 (48.4)	.24	121.7 (44.4)	113.6 (39.5)	.85
PVV with PPCD	48.5 (6.1)	59.6 (20.9)	.16	75.0 (14.1)	64.7 (10.1)	.14
Delta PVV SPCD	127.9 (39.7)	155.7 (48.2)	.31	87.1 (47.7)	86.8 (42.4)	.79
Delta PVV PPCD	32.6 (8.0)	41.9 (22.1)	.27	40.5 (18.0)	37.8 (7.5)	.91

All measurements of peak venous velocity in ml/min. PVV taken before application, PVV taken after application of VenaFlow, and PVV taken after application of ActiveCare are compared between control and total hip replacement groups at standing and supine positions. A P value of $<.05$ shows a significant result and the null hypothesis is rejected.

Multivariate Analysis

Multiple linear regression analysis demonstrated that when adjusting for age, gender, and baseline PVV, the THA cohort was found to have a significantly greater change in PVV as compared to the control cohort when considering both standing and supine positions together ($P < .01$). A significant interaction term between position and device was found ($P < .01$). The delta PVV was found to be significantly greater in the standing position, only when the SPCD was used ($P < .01$). There was no difference between standing and supine positions when the PPCD was used ($P = .14$) (Table 3). A significant difference was found between the stationary and portable compression devices in both the standing and supine positions, with the SPCD resulting in a larger change in PVV ($P < .01$) (Table 3).

When examining the standing and supine results separately, the THA group was found to have a significantly greater delta PVV only when in the standing position ($P < .01$). The SPCD resulted in a larger change in PVV compared to the PPCD in both the standing and supine positions ($P < .01$) (Table 4).

Discussion

The use of mechanical compression devices as prophylaxis for VTE disease after THA has become widespread due to their proven efficacy and minimal associated risk [16–18]. As such, there is a general consensus among various professional associations that mechanical devices should be used in patients after THA [1]. Although the minimum PVV or volume generated by mechanical compression necessary to prevent thromboembolic events is unknown, several studies suggest that the degree of increase in velocity is a good hemodynamic measure of device efficacy [7,11,12].

A significant difference in the devices' ability to increase PVV was found with the stationary compression device demonstrating a greater capacity to increase PVV in both the supine and standing positions. Few studies have compared the hemodynamic effects of portable versus stationary PCDs. In a study by Dohm et al [6], a mobile foot PCD was compared to a stationary foot PCD. The authors found no significant difference in augmentation of venous flow as measured by ratios of PVV to baseline venous flow. The hemodynamic effect of a PCD has been shown to vary based on the specific device design (ie, foot pumps, foot-calf pumps, calf pump) [11]. It is therefore difficult to compare the results of this study to prior studies evaluating PCDs of a different design.

It has been proposed that patient compliance may be a more important deterrent of symptomatic thromboembolic disease than a device's effect on hemodynamics [5,11,12]. The major disadvantage of many currently available PCDs is their size, weight, and requirement for continuous attachment to an external power source. Additionally, nursing and hospital staff education has not

Table 2
Body Position Comparison for Both Control and THA Cohorts.

	Control		P-Value	THA		P-Value
	Standing	Supine		Standing	Supine	
Baseline PVV	16.0 (5.0)	34.6 (7.9)	<.01	17.7 (3.7)	26.9 (11.7)	.07
PVV with SPCD	143.9 (41.5)	121.7 (44.4)	.19	173.4 (48.4)	113.6 (39.5)	<.01
PVV with PPCD	48.6 (6.1)	75.0 (14.1)	<.01	59.6 (20.9)	64.7 (10.1)	.32
Delta PVV SPCD	127.9 (39.7)	87.1 (47.7)	.06	155.7 (48.2)	86.8 (42.4)	<.01
Delta PVV PPCD	32.6 (8.0)	40.5 (18.0)	.38	41.9 (22.1)	37.8 (7.5)	.85

All measurements of peak venous velocity in ml/min. PVV taken before application, PVV taken after application of VenaFlow, and PVV taken after application of ActiveCare are compared between supine and standing positions within control and total hip replacement cohorts. A P value of <.05 shows a significant result and the null hypothesis is rejected.

been shown to improve patient compliance, suggesting that poor compliance is secondary to inherent problems related to device design rather than a lack of patient understanding [19]. Prior studies comparing the effect of device design on compliance have shown that PPCDs have a significantly higher rate of usage ranging from 50% to 75% [3,5]. A retrospective review of 1577 patients comparing rates of thromboembolic disease among those treated with enoxaparin and either a SPCD or PPCD demonstrated that the PPCD had better compliance (83% of the time vs 49%), lower rates of DVT (1.3% compared with 3.6%), and a reduced rate of clinically important PE (0% compared to 0.66%) [5]. Ultimately, the efficacy of a mechanical compression device is likely secondary to numerous factors including compliance, appropriateness of the site of compression, and effectiveness of the hemodynamic profile.

The physiologic effect of THA is known to alter venous hemodynamics within the lower extremity. Using impedance plethysmography in patients after THA, McNally and Mollan [15] reported decreased venous outflow, decreased venous capacitance, and a prolonged return to baseline that persisted for up to 6 weeks. Consistent with this known effect, patients within the THA cohort demonstrated lower baseline venous velocity compared to the healthy cohort when in the supine position. Results of the univariate analysis, which does not control for age, sex, and baseline PVV, found no other significant differences between the 2 groups when either device was used. However, results of the multivariate analysis confirmed that when considering measurements of venous velocity in both standing and supine positions, the THA cohort demonstrated a greater delta PVV than the healthy cohort. Given the likely reduction in venous flow, postoperative patients may have a greater volume of venous blood pooling within the lower extremity resulting in an increased change in PVV after inflation of the PCD. This effect may be most pronounced in the standing position and accordingly, when considering standing and supine positions separately, only in the standing position was the THA cohort found to have a greater change in PVV.

Venous flow within the lower extremities is known to be position dependent. As body position changes from standing to supine, venous velocity progressively increases with an associated decrease

in vein caliber [20,21]. Multiple studies have demonstrated that the force generated by inflation of a PCD results in the greatest increase to venous velocity and volume when the lower extremity is in a dependent position [13,22]. Increased vein diameter provides a greater volume of blood available to be compressed by the device and lower baseline flow velocity results in a larger absolute change in flow velocity. The results of this study are consistent with this physiologic phenomenon. The SPCD demonstrated the ability to generate a greater PVV in the standing position, as compared to the supine position, for patients within the THA cohort. This finding was not observed within the healthy cohort, possibly due to the fact that greater venous flow within the healthy subjects reduced the amount of venous pooling within the lower extremity in the standing position. A comparable result was found when evaluating delta PVV, with greater values occurring in the standing position among patients within the THA cohort. Similarly, when considering both THA and healthy subjects together, the SPCD demonstrated the ability to generate a greater delta PVV in the standing position as compared to the supine position.

This study has several limitations. With 10 subjects in both the THA and healthy cohorts, the study may not be sufficiently powered to detect small differences in hemodynamics between the 2 groups. However, it was capable of detecting hemodynamic differences between devices, the primary outcome of interest. The study is also subject to sampling error due to the relatively low number of participants and therefore may not be applicable to larger patient populations.

We found a significant age difference between the cohorts, with average age of the healthy cohort being approximately 36 years less than the THA cohort. This may have affected comparisons between the 2 groups, but does not affect multivariate comparisons between the devices or body positions. The researchers and subjects were not blinded to the 2 devices. This may have caused investigator or procedural bias when performing the ultrasound examination and recording data. The researchers sought to minimize this effect by multiple trainings and standardizations of ultrasound assessments. Interpretation of the results of this study is limited by the fact that the ranges or the treatment effect of PVV needed to reduce the risk of thromboembolic disease with mechanical compression is

Table 3
Multivariate Analysis Between Position and Device Tested.

Position	Device Tested	Estimate	Standard Error	P-Value
Standing	SPCD PPCD	104.6	8.4	<.01
Supine	SPCD PPCD	47.8	10.0	<.01
Standing	Supine PPCD	-11.2	7.5	.14
Standing	Supine SPCD	45.6	15.8	<.01

A significant difference exists between the stationary and portable compression devices in both the standing and supine positions, with the SPCD resulting in a larger change in PVV. No difference between standing and supine positions was identified when the PPCD was used.

A P value of <.05 shows a significant result and the null hypothesis is rejected.

Table 4
Multivariate Analysis in Standing and Supine Positions.

	Standing			Supine		
	Estimate	Standard Error	P-Value	Estimate	Standard Error	P-Value
THA vs control	89.3	22.4	<.01	10.3	21.2	.63
SPCD vs PPCD	104.6	8.4	<.01	47.8	10.0	<.01

The THA group demonstrates a significantly greater delta PVV only when in the standing position. The SPCD resulted in a larger change in PVV compared to the PPCD in both the standing and supine positions.

A P value of <.05 shows a significant result and the null hypothesis is rejected.

unknown. However, measurements of PVV are likely the best method to evaluate the hemodynamic effect of mechanical compression. Measurements of PVV are more accurate and reproducible than are determinations of volume, especially in the venous system [23,24]. Veins are elastic and distensible, which makes volume calculations less accurate. Furthermore, there are many PPCDs and SPCDs and our data cannot be extrapolated to other devices. Prior studies have documented that significant variation exists between commercially available PCDs in terms of their ability to augment venous hemodynamics after THA [11]. As a consequence, this study is unable to make conclusions regarding the hemodynamic effects of portable compression devices as a class.

The results of this study demonstrate that a difference exists between a traditional SPCD and a more contemporary PPCD when considering their ability to augment venous flow. More specifically, the SPCD had a greater capacity to increase PVV in both the supine and standing positions. When considering hemodynamic measurements obtained in the supine and standing positions together, patients after THA demonstrated larger changes in PVV than those within the healthy cohort. Finally, when considering both THA and healthy subjects together, only the SPCD was able to generate greater values of both PVV and delta PVV in the standing position as compared to the supine position. Although these results demonstrate a significant difference in the hemodynamic effects of 2 mechanical compression devices, it is important to establish the PVV necessary to prevent VTE before one device is considered a more effective form of prophylaxis.

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