Improved hemodynamic effectiveness and associated clinical correlations of a new intermittent pneumatic compression system in patients with chronic venous insufficiency

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Purpose: **A new intermittent pneumatic compression device (SCD Response System) has recently been shown in healthy volunteers to have the ability to detect the postcompression refilling of the calf veins and to respond by initiating the subsequent cycle when these veins are full. This has proven to be more effective in expelling blood proximally than the conventional intermittent pneumatic compression device (SCD Sequel System). The aim of this study was to test the influence of venous disease on the postcompression refill time detected by means of the SCD Response and the effectiveness of the new system in expelling blood in patients who have venous reflux caused by post-thrombotic syndrome or varicose veins.**

Methods: **This open, controlled trial was conducted in an academic vascular unit with 10 patients who had post-thrombotic syndrome and 10 patients who had varicose veins. The new SCD Response System was tested against the existing SCD Sequel System in both legs in the supine, semirecumbent, and sitting positions. The refilling time sensed by means of the device was correlated with the venous filling index by using air plethysmography. The total volume of blood expelled per hour during compression was compared with that expelled by the SCD Sequel System in the same volunteers and in the same positions.**

Results: **An inverse association was found between the mean postcompression refilling time in the sitting position and the venous filling index of the apparently healthy or less severely affected leg (r = –0.52, *P* = .019), the refill time being significantly shorter in patients with advanced venous disease. The SCD Response System increased the volume expelled per hour in the post-thrombotic leg, when compared with the SCD Sequel System, by 109.9% (*P* = .005) in the supine position, by 85.1% (*P* = .009) in the semirecumbent position, and by 40.2% (*P* = .005) in the sitting position. The corresponding results in the more severely affected leg in patients with varicose veins were 71.9% (*P* = .005) in the supine position, 77.9% (*P* = .005) in the semirecumbent position, and 55.7% (*P* = .013) in the sitting position. Similar improved results were also found in the contralateral leg in both groups.**

Conclusions: **The deflation settings of the new SCD Response System are able to be adjusted selectively, correlating with the physiological severity of chronic venous insufficiency. By achieving more frequent compression cycles, the new system is more effective than the current one in expelling blood proximally, confirming our earlier findings in healthy volunteers. Further studies testing a possible improved efficacy in preventing deep venous thrombosis in this high-risk group are justified. (J Vasc Surg 2001;33:915-22.)**

Venous thromboembolism is common among patients who are hospitalized and carries a significant morbidity rate in both the short term (pulmonary embolism, fatal or not) and the long term (post-thrombotic syndrome). Although most cases are now preventable by using mechanical, pharmacological, or combined prophylactic modalities, the incidence of venous thromboembolism is still unacceptable in high- or very high-risk groups, as defined by means of clinical risk factors, necessitating an individual protective strategy.[1,2]

A history of deep venous thrombosis (DVT) constitutes a well-known risk factor for its postoperative recurrence,[3] and venous stasis has been considered to be a major pathophysiological risk factor.[4,5] DVT sequelae of venous occlusion, valve destruction, or both lead to a short refill time, impaired calf muscle pump function, incomplete venous emptying, and increased ambulatory venous pressure.[6,7] These hemodynamic alterations tend to aggravate in the long term, resulting in the development of the post-thrombotic syndrome. This progressively deteriorating venous stasis constitutes a major predisposing factor for DVT, in addition to any coexisting hematological cause.[8,9] Similarly, patients with varicose veins have also been reported to have an increased incidence of postoperative DVT,[9-12] probably for the same hemodynamic reasons.

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Table I. Hemodynamic characteristics and anatomical pattern of reflux of both legs in patients who have post-thrombotic syndrome and patients who have varicose veins with air-plethysmography and duplex ultrasound scanning

Patient group	*OF (%)*	*OFSO (%)*	*VV (mL)*	*VFI (mL/s)*	*EF (%)*	*RVF (%)*	*Superficial venous reflex (n [%])*	*Deep venous reflex (n [%])*
Post-thrombotic								
Post-thrombotic leg	39.3 (11.4)	28.2 (8.0)	86.3 (63.6)	3.3 (3.7)	27.4 (29.8)	51.7 (40.0)	8 (80)	10 (100)
Contralateral leg	46.2 (17.5)	–	79.7 (55.4)	1.8 (1.4)	40.3 (20.7)	39.9 (32.1)	5 (50)	5 (50)
Varicose veins								
Most severely affected leg	56.8 (14.0)	–	132.9 (50.4)	3.8 (6.8)	28.3 (17.1)	56.7 (21.4)	10 (100)	1 (10)
Less severely affected leg	52.8 (16.8)	–	127.8 (40.4)	2.5 (4.2)	26.2 (11.0)	49.9 (32.1)	10 (100)	1 (10)

Results are shown as the median and (interquartile range).
The VFI of the post-thrombotic leg was significantly higher when compared with the contralateral leg ($P < .001$), the remaining intragroup associations being all statistically nonsignificant. *OF,* Outflow fraction; *OFSO,* outflow fraction with superficial occlusion; *VV,* venous volume; *VFI,* venous filling index; *EF,* ejection fraction; *RVF,* residual volume fraction.

It has been reported that post-thrombotic limbs have a compromised hemodynamic response to intermittent pneumatic compression devices used as a means of preventing DVT.[13] A possible explanation is that the existing compression systems are not yet fully optimized, which is supported by the recent observation that after manual calf compression the postcompression refill time of the leg veins is significantly shorter in the presence of chronic venous insufficiency (CVI).[14] Many investigators have already optimized the settings of the intermittent pneumatic compression (IPC) devices, including pressure, slope of pressure, and compression type (sequential vs uniform).[15,16] We have recently improved these settings, demonstrating that adjustment of the deflation period according to the individual postcompression refill time of the veins allows more compression cycles with time, which results in a significant increase in the volume expelled during compression in healthy subjects.[17]

The aim of this study was to test the influence of venous disease on the device-detected postcompression refill time (SCD Response Compression System, Tyco Healthcare, Mansfield, Mass) and also the effectiveness of this new compression system in making adjustments as a result of positioning on the basis of its ability to assess the individual postcompression refill time in patients with CVI (post-thrombotic or varicose veins). The final end-point was to compare the effect of the new compression system on venous return with that of the current sequential compression system (SCD Sequel System, Tyco Healthcare) in the same groups of patients. Improved effectiveness of the SCD Response System in decreasing venous stasis in patients with CVI would, subsequently, justify further studies to investigate the possibility of an improved efficacy in preventing DVT in this high-risk group.

PATIENTS AND METHODS

Patient selection and evaluation. Potential subjects for the study were identified from the outpatient clinic and the records of our clinical vascular laboratory. Patients who were examined or tested for bilateral varicose veins or unilateral post-thrombotic syndrome, respectively, were included. The inclusion criteria were: (1) bilateral varicose veins caused by saphenofemoral or saphenopopliteal junction incompetence and (2) a history of DVT with significant recanalization and reflux in the deep venous system, as diagnosed with color-coded duplex ultrasound scanning (CCDU). The exclusion criteria included the presence of any local leg condition interfering with sleeve placement (such as dermatitis, ischemic vascular disease, extreme leg deformity, or edema), a history of congestive heart failure, and duplication of the proximal superficial femoral vein, which would preclude an accurate estimation of global deep venous return. We selected the patients who had varicose veins to be matched for age and sex with the patients who had post-thrombotic syndrome to counteract the influence of age on venous physiologic parameters,[18] which could influence the augmented venous outflow and preclude comparison between the two groups. A detailed history was obtained, a physical examination and lower-limb venous CCDU were performed as a means of assessing each leg, and a CEAP class and clinical score were assigned.[19,20] CCDU was performed with the ATL HDI 3000 scanner by using a linear broadband 7-4 MHZ transducer (Advanced Technology Laboratories, Bothell, Wash). We used CCDU to examine the patients in the standing, sitting, and reverse Trendelenburg positions to assess the superficial and deep venous system of the legs for patency and presence of reflux, as described earlier.[21] Reflux, induced in the standing position by means of distal compression of the limb followed by sudden release, was considered to be significant when the duration of the retrograde flow was more than 0.5 seconds. All patients with post-thrombotic syndrome (3 men and 7 women), had a history of unilateral proximal DVT (3 recurrent cases), which affected the left leg in seven cases; the last episodes were 3 to 53 years ago (median, 7 years). The median age (interquartile range) in patients with post-thrombotic syndrome and patients with varicose veins was 53.5 years (24 years) and 56 years (18.3 years), respectively ($P = .91$). The corresponding figures for CEAP class and clinical score were 4 (2) and 3 (2; $P = .035$) and 4.8 (2.5) and 2 (0.5; $P < .001$), respectively. Air-plethysmography (APG-1000; ACI Medical, Sun Valley, Calif) was subsequently performed in both legs as a means of calculating the outflow fraction, with and without superficial occlusion (the former in post-thrombotic legs only), venous volume, venous filling index (VFI), ejection fraction, and residual volume fraction[7]; all parameters were measured three times and averaged.

All subjects gave written informed consent; the study protocol and the informed consent were approved by the Institutional Review Board.

Description of the SCD Response Compression System. A detailed description of the new compression system has been published.[17] The SCD Response Compression System uses a method similar to segmental air-plethysmography[7] to estimate the postcompression refilling of the leg veins and, thus, the individual refill time. The longer refill time between both legs is being used to prevent compressing a leg before the actual refill is complete, and compression commences when both legs are refilled.

Flow and velocity measurements. Flow and velocity measurements (peak velocity, total volume flow, and peak volume flow during compression) were performed at the level of the proximal superficial femoral vein with the same ATL HDI 3000 scanner, as described earlier.[17] The normal venous return in the lower limbs when flow velocity is recorded by means of duplex scanning has a respiratory, cardiac, or combined phasic pattern.[22] During the 11 seconds of leg compression, there is augmentation of the normal venous velocity, but after the end of compression, venous return is practically undetectable. Some time is necessary for the veins to refill and flow to be re-established; progressively, the velocity of venous return is increasing, and when the veins are fully refilled, both the normal phasic pattern and baseline velocity of venous return have recovered. The time necessary for the complete return of the normal phasic pattern of the femoral venous flow as determined by means of Doppler waveforms was considered to be the duplex scan-derived postcompression refill time, as we described earlier,[17] and it was measured in both legs. All measurements were repeated in both legs and in the supine, semirecumbent, and sitting positions with the two SCD system types. The total volume of blood expelled during compression periods in 1 hour and the corresponding peak volume expelled in 1 hour were calculated by multiplying these basic single-cycle measurements and the number of cycles per hour as determined by means of the individual deflation time. The reproducibility of our method has been published[17]; to increase the accuracy of flow and velocity measurements, which depend on vein diameter that changes with respiration,[23] we averaged four to six (median, 5) consecutive measurements. To decrease the systemic error in flow measurements, we compared the two types of SCD systems in a paired fashion.

Statistical analysis. The Kolmogorov-Smirnov test was used as a means of testing normal distribution of the data. If this was not the case or when the sample size was less than 15, non-parametric tests were used. Statistical significance between different groups was assessed by using the Wilcoxon signed-rank test. The Pearson correlation or Spearman correlation coefficient method, when appropriate, was used in bivariate correlation. SPSS software for Windows, version 9 (SPSS, Chicago, Ill), was the statistical package used for statistical analysis. P values of .05 or less were considered to be statistically significant.

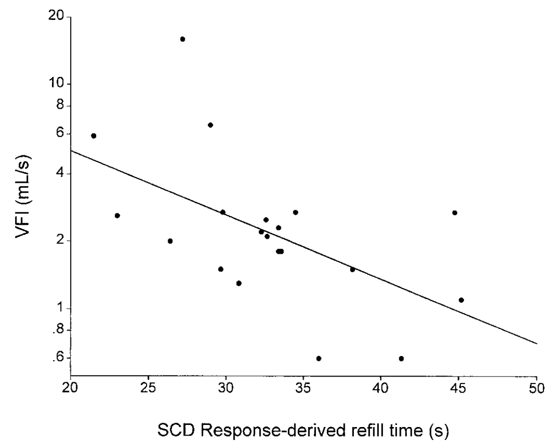

Fig 1. Scatter plot showing a linear relationship between the SCD Response-derived refill time and VFI in the combined group of the less severely affected leg in patients with post-thrombotic syndrome and patients with varicose veins (n = 20, r = –0.52, P = .019).

RESULTS

The hemodynamic characteristics and anatomical pattern of reflux of all legs are shown in Table I. A linear relationship was found between the duplex scan-derived refill time of the apparently healthy or less severely affected leg and the SCD Response device-derived refill time in the sitting position (mean of 5-7 readings per leg) in both the patients with post-thrombotic syndrome(r = 0.75, P = .012) and patients with varicose veins (r = 0.92, P <.001), confirming our earlier findings in healthy subjects.[17]

In the combined group of 20 legs, an association (r = –0.52, P = .019, Fig 1) was found between the SCD Response-derived refill time in the sitting position and VFI of the apparently healthy or less severely affected leg (this is the leg used by the compression system to estimate refill time). A similar association and correlation coefficient (r) between refill time and VFI was found in patients with post-thrombotic syndrome (r = –0.6, P = .07) and patients with varicose veins (r = –0.52, P = .13). The results of the hemodynamic comparison of the two SCD devices are shown in Figs 2, *A* and *B*, 3, *A* and *B*, and Table II. The SCD Response Compression System increased the total volume of blood expelled per hour in the post-thrombotic leg by 109.9% (P = .005) in the supine position, 85.1% (P = .009) in the semirecumbent position, and 40.2% (P = .005) in the sitting position (Fig 2, *A*). The corresponding figures for the contralateral leg were 68.6% (P = .005) in the supine position, 82.5% (P = .017) in the semirecumbent position, and 66.3% (P = .005) in the sitting position. The SCD Response Compression System also increased the total volume of blood expelled per hour in both legs with varicose veins (Fig 2, *B*). In the more severely affected leg with varicose veins,

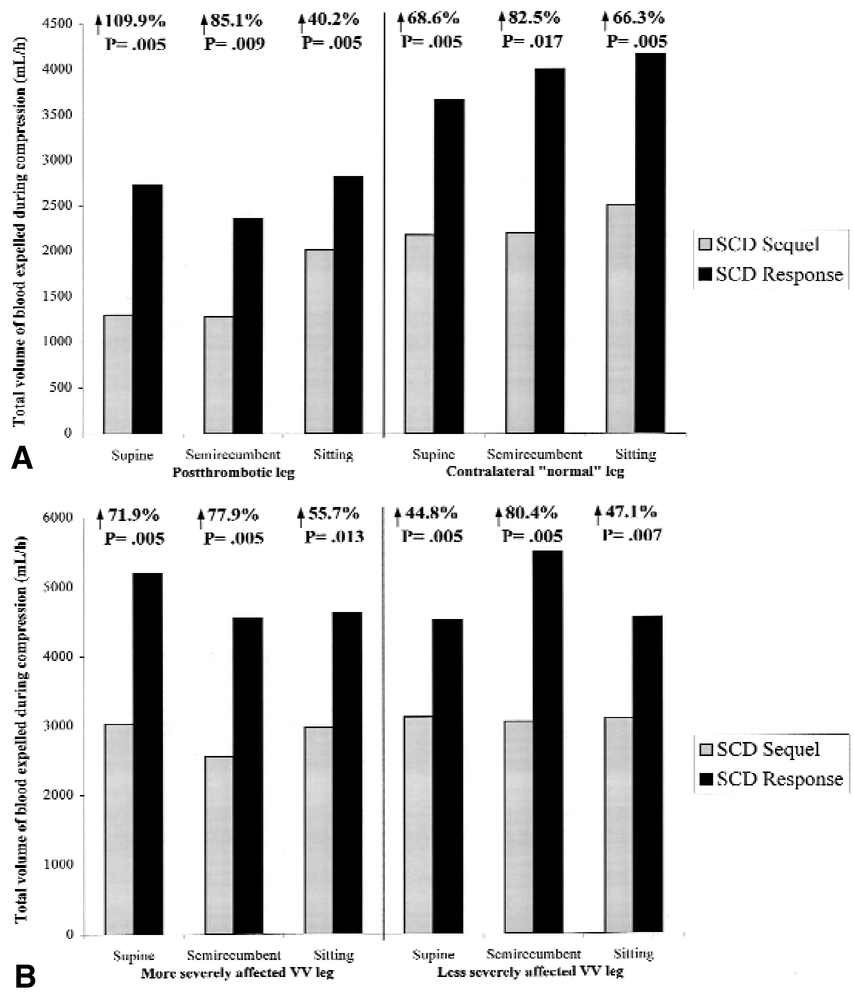

Fig 2. Comparison of total volume expelled per hour during compression by the SCD Response Compression System with that expelled by the SCD Sequel Compression System, in the supine, semirecumbent, and sitting positions in post-thrombotic legs and the contralateral "normal" ones (**A**) and in patients with varicose veins, bilaterally (**B**). *Arrows* indicate the percentage increase with the SCD Response.

the SCD Response device increased the total volume of blood expelled per hour by 71.9% (P = .005), 77.9% (P = .005), and 55.7% (P = .013) in the supine, semirecumbent, and sitting positions, respectively. The corresponding figures for the contralateral, less severely affected leg were 44.8% (P = .005), 80.4% (P = .005), and 47.1% (P = .007). A similar increase in the peak volume of blood expelled per hour was found in most positions and legs (Fig 3, *A* and *B*).

The new device achieved comparable flow increases when the post-thrombotic or the more severely affected leg with varicose veins was compared with the contralateral leg in the supine (P = .46), semirecumbent (P = .21), and sitting positions (P = .89). Similar results were found in the subgroups of patients with post-thrombotic syndrome in the supine (P = .39), semirecumbent (P = .06), and sitting positions (P = .80) and in patients with varicose veins in the supine (P = .72), semirecumbent (P = .72), and sitting positions (P = .80).

In almost all comparisons, we did not observe a statistically significant difference between the single-cycle parameters, total volume flow, peak volume flow, or peak velocity generated by the two types of SCD compression devices, despite the significant increase of the inflation cycling rate. When the SCD Response system was used in the sitting position, the compression rate was even higher (Table II).

DISCUSSION

In this current study, we investigated the venous hemodynamics of a new compression system for sequential IPC in patients with CVI, confirming our earlier findings that favored the new system in healthy volunteers. The ability of the new system to apply compression according to individual refilling time and the severity of venous stasis makes it ideal for patients with CVI and especially patients with post-thrombotic syndrome (high or very high-risk groups), in whom a combination of pro-

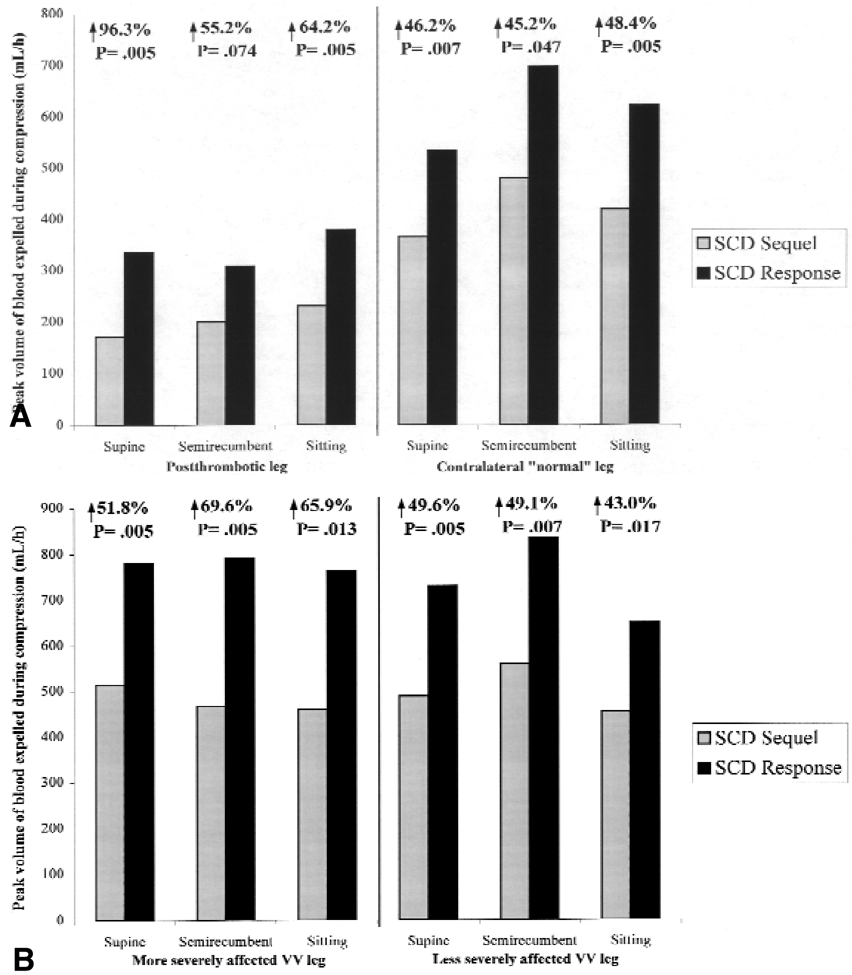

Fig 3. Comparison of peak volume expelled per hour during compression by the SCD Response Compression System with that expelled by the SCD Sequel Compression System, in the supine, semirecumbent, and sitting positions in post-thrombotic legs and the contralateral "normal" ones (**A**) and in patients with varicose veins, bilaterally (**B**). *Arrows* indicate the percentage increase with the SCD Response.

Table II. Compression rate (cycles per hour) and augmented single-cycle venous outflow data in patients with post-thrombotic syndrome (group I) and patients with varicose veins (group II), generated by means of the SCD Response Compression System versus SCD Sequel System, in the supine, semirecumbent and sitting positions.

				Post-thrombotic or more severely affected leg			*"Normal" or less severely affected leg*		
Group	*Position*	*SCD Type*	*Compression rate*	*Peak velocity (cm/s)*	*Total volume flow (mL/min)*	*Peak volume flow (mL/min)*	*Peak velocity (cm/s)*	*Total volume flow (mL/min)*	*Peak volume flow (mL/min)*
I	Supine	Sequel	50.7 (0)	24.7 (7.5)	139.8 (136.7)	202.4 (206.7)	29.8 (8.1)	234.2 (187.4)	433.0 (357.4)
		Response	81.8 (8.3)*	24.4 (5.8)	186.2 (227.3)*	240.6 (275.8)*	28.6 (9.0)	277.4 (169.2)	433.9 (339.4)
	Semirecumbent	Sequel	50.7 (0)	23.80 (13.25)	136.8 (197.4)	236.0 (395.3)	27.1 (7.38)	236.6 (57.6)	568.8 (276.2)
		Response	79.1 (8.1)*	19.9 (3.7)	156.20 (80.15)	223.5 (154.3)	27.8 (1.9)	280.5 (98.3)	509.2 (205.3)
	Sitting	Sequel	50.7 (0)	18.50 (20.04)	216.4 (267.0)	273.5 (393.0)	26.5 (11.9)	270.3 (144.8)	496.0 (253)
		Response	84.7 (8.2)*	19.80 (14.96)	176.70 (307.15)	272.2 (432.9)	21.10 (8.66)	272.6 (128.1)	473.7 (189.2)
II	Supine	Sequel	50.7 (0)	35.5 (20.4)	325.9 (213.6)	608.3 (371.5)	35.3 (13.1)	335.8 (153.8)	577.9 (309.5)*
		Response	78.3 (8.0)*	36.2 (18.0)	349.2 (177.0)	559.1 (327.8)	33.9 (16.2)	326.5 (161.7)	562.9 (206.5)
	Semirecumbent	Sequel	50.7 (0)	31.3 (11.5)	275.2 (136.7)	553.4 (367.4)	31.5 (13.3)	328.5 (216.3)	662.2 (370.0)
		Response	75.0 (5.7)*	30.0 (9.5)	322.9 (145.6)	634.3 (295.2)	29.3(14.5)	403.0 (208.5)	695.0 (488)
	Sitting	Sequel	50.7 (0)	28.2 (11.8)	319.7 (231.8)	545.3 (524.3)	25.6 (8.6)	333.8 (273.8)	537.7 (390.8)
		Response	81.8 (22.3)*	24.6 (9.0)	314.2 (161.7)	567.2 (149.0)	23.7 (12.3)	333.0 (189.5)	545.4 (296.0)

Results are shown as the mean and (interquartile range). The compression rate when using the SCD Response was significantly higher in the sitting position in comparison with the semirecumbent and supine positions ($P \leq .05$).
*Significant differences between SCD Sequel and SCD Response ($P < .05$).

phylactic modalities, including IPC, has been recommended.[1,2] Sequential compression systems are helpful in DVT prophylaxis through several mechanisms.[4,7,15,24-28]

The SCD Response System was developed as a means of detecting the individual postcompression time, which is known to be impaired in patients with CVI.[14] The classic settings of the SCD Sequel System used as a control were fixed: an 11-second inflation period followed by 60 seconds of cuff deflation to allow the veins to refill (50.7 cycles per hour). In contrast, the new SCD Response device uses a technique similar to segmental air-plethysmography as a means of detecting the individual's refill time and minimizes venous stasis by applying pneumatic compression in an individual inflation-deflation pattern, as described earlier,[17] according to the severity of venous stasis. This is supported by the statistically significant correlation we found between refill time and the hemodynamic severity of CVI, as expressed by VFI. VFI expresses the gravitational refilling rate of the veins caused by positioning and depends on refill time. The pathophysiological similarity between postcompression refill in the sitting position and the refilling of the veins when in the standing position[29] explains the correlation of postcompression refill time and VFI. VFI correlated significantly with SCD Response-derived refill time in the whole group; however, similar correlation coefficients were found in both subgroups, which were only marginally significant, and this was probably because of the small number of patients in each group. The complex phenomenon of venous refilling in the sitting position with the involvement of the so called "venoarteriolar reflex,"[30] which decreases the arterial inflow to maintain constant flow,[30,31] explains clearly why a perfect association between VFI and postcompression refill time cannot be expected. The venoarteriolar reflex is impaired in CVI, but tends to normalize with the SCD system, complicating further venous hemodynamics.[32] However, the SCD Response System is able to adjust the deflation period according to any refill time changes. To avoid compressing a leg before its veins have been fully refilled, the new device always commences compression when both legs are refilled, using the longest postcompression refill time of both legs; this is being determined by the "normal" or less severely affected leg. We have previously shown in healthy volunteers that refill time varies significantly in different patients and positions. Therefore, even in the case of purely unilateral disease, the use of the new device is also justified. Theoretically, a better hemodynamic benefit in the post-thrombotic leg could be achieved if a separate refill time was estimated for each leg and individual compression was applied, according to a shorter refill time. However, aside from compliance issues and technical complexity, venous disease tends to occur bilaterally.[33,34] This was confirmed in this study, in which more than 50% of the patients with post-thrombotic syndrome had contralateral superficial or deep venous reflux or both, often hemodynamically significant. These findings support further the clinical applicability of the SCD Response System in these patients.

The total volume and peak volume of blood expelled per hour by the SCD Response System were both significantly increased. The faster cycles caused by a shorter deflation period did not lead to a reduction in the ability of the SCD system to eject the pooled venous blood from the leg (Table II). The new system, by achieving more compression cycles in time (50.7 per hour for the Sequel and as many as 100 cycles per hour for the Response) achieved a mean percentage increase in total volume expelled per hour in one group that was as high as 110% (much higher in some patients). This is the critical evidence for the better hemodynamic abilities of the new device, and for that reason, it can be hypothesized that, when using the SCD Response System, venous blood pulsatility increases also in the venous valve pockets or soleal veins. Venous stasis is more prominent at these specific sites of the venous system.[35,36]

In this study, we found a compromised hemodynamic response in post-thrombotic legs for the single-cycle parameters when using both systems. However, the use of the SCD Response System increased significantly the total volume of blood expelled during all compression periods throughout 1 hour to levels that were higher than those found when using the SCD Sequel System in the apparently healthy contralateral leg (Fig 2*A*). This can be explained by the improved settings of the new device, which consist of compression-adjustment according to the individual's refill time, providing better hemodynamic coupling of pneumatic compression on a refilled venous system and minimizing the effects of venous stasis on IPC hemodynamics. For reasons yet unknown, patients with varicose veins, especially younger patients,[37] have some increased risk for the development of DVT.[9] It has been hypothesized that varicose veins may be the result of previously unrecognized DVT, precipitating its recurrence; however, it seems more logical that the incompetent superficial venous system acts as a low-resistance pathway, depriving the deep venous system from the normal protective pulsatile flow under the influence of the cardiac system, respiratory system, or both.[22] This would explain the protective role of elastic stockings in DVT prevention studies[9] and advocate the adjunctive use of pneumatic leg compression. In these cases, we would recommend the use of the SCD Response Compression System, based on its hemodynamic superiority.

Most of the hemodynamic studies testing compression devices have been carried out in healthy, young subjects who have normal venous physiology. In this study, we tested patients who had CVI whose mean age was 56.5 years, and we verified our earlier observation that favored the use of the SCD Response System in this high-risk population. The new system displayed similar or even better hemodynamic performance in patients with CVI than in healthy subjects.[17]

No change in the single-cycle parameters, total volume flow, peak volume flow, and peak velocity was found, despite the shortened deflation period. This is further evidence that the new system is sufficiently effective in increasing the venous return in comparison with the conventional one and implies that, despite the significantly shorter cycles when using the SCD Response Compression System, the leg veins were refilled by the commencement of the next cycle. If the leg compression had been carried out before the appropriate venous refilling, a decrease in flow parameters would have been found. We found lower peak velocity in the sitting position. This is to be expected, because the height of the hydrostatic column of the blood, which the expelled blood has to overcome, is significant in the sitting position. For this reason, baseline velocity in this position is also low,[38] and, thus, the percent increase in venous flow velocity is much higher.

DVT and pulmonary embolism are the main endpoints when testing different types of prophylaxis against venous thromboembolism. Therefore, DVT prevention studies[39,40] that test the efficacy of the new system are probably justified. Such studies could compare different SCD types, the SCD Response System against low–molecular-weight heparin or the efficacy of the SCD Response System in preventing DVT or pulmonary embolism in high-risk patients in addition to heparin injections.[1,2,41]

In conclusion, by achieving more frequent individually timed compression cycles with time, the SCD Response Compression System was found to be a more effective means of preventing venous stasis than the current SCD Sequel compression system in patients with CVI. The new system-assisted sensing of the impaired venous refill time led to individual adjustment of the deflation pattern, correlating well with the physiological severity of reflux. The resulting increased venous outflow was produced by the appropriate timing of the compression period to a filled venous system. Further studies investigating the possibility of improved efficacy in preventing DVT are justified.

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