Patient-centered outcomes of a dual action pneumatic compression device in comparison to compression stockings for patients with chronic venous disease

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ABSTRACT

Objective: The ACTitouch (AT) device (Tactile Medical, Minneapolis, Minn) represents a new generation of pneumatic compression devices by combining sustained compression with intermittent pneumatic compression. The sustained compression mode provides automatic pressure adjustment every 30 minutes, ensuring pressure consistency regardless of leg volume changes and environmental influences. Designed for mobile patients, this device has not been studied in comparison to standard compression stockings (CS).

Methods: A two-arm, randomized, multicenter pilot study was conducted. Patients with primary chronic venous disease (C3-C6) and a documented history of low adherence to compression therapy were randomized at 10 centers to use the AT device or 30 to 40 mm Hg graduated CS. Primary end points were patient-reported comfort and ease of use. Secondary end points included compliance (measured by a device meter and patient diaries), limb volume change (by water displacement and circumferences), and change in disease severity (using Venous Clinical Severity Score, Venous Insufficiency Epidemiological and Economic Study on Quality of Life/Symptoms, and EuroQol-5 Dimension 3-Level). Patients were assessed at 15 and 30 days after randomization. Eighty-nine patients (136 limbs) received either AT (66 limbs) or CS (70 limbs).

Results: Patients in the AT group found the device easy to apply (71% compared with 37.5% in the CS group; $P = .0001$), easy to remove (89% compared with 59% in the CS group; $P = .0001$), and comfortable to wear (71% compared with 58% in the CS group; $P = .125$). Compliance with compression was not significantly different between the groups (100% vs 88%, AT and CS groups, respectively, at 15 days; 87% vs 85% at the end of the study; $P = .97$). Daily use was not different either (10.7 hours in the AT group, 11.7 ± 2.7 hours in the CS group). In the AT group, in addition to self-reporting, the patient's compliance was objectively measured by a usage meter built into the device. The average time of compression use reported by patients was 2.5 hours higher than measured by the device, and the limits of agreement were −6 hours to +11 hours. These findings indicate that self-reported time of use is highly unreliable and tends to overestimate the actual use.

Conclusions: This is the first trial comparing an adaptive pneumatic compression device with CS in previously noncompliant patients with C3 to C6 chronic venous disease. The study demonstrated that even within limitations of a pilot project, use of the AT device is comparable to CS in the patient's acceptance and compliance and likely to have equal or better clinical outcomes. (J Vasc Surg: Venous and Lym Dis 2017;5:699-706.)

Chronic venous disease (CVD) represents one of the most prevalent diseases in the United States[1] and globally. It affects between 80% and 85% of the population and impairs quality of life in 40% to 60% of adults.[2] Effective management of patients with CVD[3] includes compression therapy. Current therapeutic choices are compression stockings (CS), multilayer bandage systems, paste bandage systems, and pneumatic compressive devices.[4-6]

Compression reduces the venous systolic pressure peaks associated with venous hypertension[7] and decreases transcapillary leakage into the interstitial space.[8] Wearing compression devices during ambulation produces the best physiologic and clinical outcomes, and efforts have been focused on designing compression garments that allow the patient to remain fully ambulatory.

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Tactile Medical was the study sponsor and provided funding for the subject-related study costs to each participating institution. The sponsor provided funding to MedNet Solutions, Inc (Minnetonka, Minn) to conduct the statistical analysis, which was completed at independent direction of the authors. The authors received no specific funding for this work. Tactile Medical provided funding for the statistical analysis but played no role in the data collection, analysis, decision to publish, or preparation of the manuscript.

Clinical Trial registration: NCT02015221.

Author conflict of interest: none.

Additional material for this article may be found online at www.jvsvenous.org.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2213-333X

http://dx.doi.org/10.1016/j.jvsv.2017.06.003

The effects of compression therapies are achieved only after consistent use.[9] Poor compliance with compression therapy is perceived as the major disadvantage of this modality compared with invasive treatment options.[8,10-12]

The pressure delivered by a compression device should be consistent during the time of use. However, edema substantially varies during the day with changes in body position and physical activity.[13,14] Such changes result in substantial variability in the dose of compression and the patient's comfort. An ideal compression delivery system should easily adapt to the variation in limb volume and deliver uniform pressure regardless of these changes.

The ACTitouch (AT) system (Tactile Medical, Minneapolis, Minn) is uniquely designed to provide two modes of compression delivery: static pneumatic compression during ambulation and intermittent pneumatic compression while at rest. The device self-adjusts the pressure at 30-minute intervals to maintain consistent compression levels, thereby compensating for limb volume changes.[15] Similar to graduated CS, AT delivers a pressure profile in the sustained mode of 40 mm Hg to the foot and ankle area, 30 mm Hg to the midcalf, and 20 mm Hg to the upper calf.

The use of the AT device, however, may have associated disadvantages. The AT is bulkier and heavier than CS. The option of modifying the compressive mode (from sustained to intermittent pneumatic compression and back) could be perceived as adding a burden to use, which may affect the patient's compliance. A patient's initial willingness to use compression and long-term adherence to it are significantly influenced by the ease of its use (donning and doffing) as well as by device comfort. These subjective aspects of use have been incompletely studied for some compression devices but not for the AT. Unlike any other compressive device, the AT measures the duration for which the device is used, providing a unique opportunity to objectively measure compliance of the patient.

Prior research has demonstrated that the AT is well tolerated and better accepted by patients (enhanced quality of life) compared with multilayer bandages.[16] The purpose of this prospective study was (1) to compare the ease of use and compliance characteristics of the AT with below-knee CS (30-40 mm Hg), as a common compressive clinical standard, and (2) to assess the efficacy of both compressive interventions in reducing limb volume.

METHODS

Study design. The current investigation was designed as a large, two-arm, prospective, randomized, multicenter pilot study that would evaluate the ease of use, comfort, and treatment compliance of the AT compared with a standard compression garment in patients with chronic venous insufficiency (CVI). Blinding was not possible in a study that was designed to evaluate differences between two overtly visible strategies of compressive interventions.

Study population. The study subjects were recruited from patients who presented with unilateral or bilateral CVI (defined as clinical class C3-C6 CVD)[3,17] and had received treatment within established clinical practices. All sites in this study received approval by their local or a central Human Investigation Review Board. The study procedures conformed to the ethical guidelines of the Declaration of Helsinki, and all patients offered written informed consent. The specified inclusion and exclusion criteria are listed in the Appendix, online only. Two important inclusion criteria should be noted: (1) the study sought to enroll patients with a history of *low adherence to compression garment therapy*, as documented by their physician; and (2) patients were required to have leg circumferences within the following ranges: ankle, 12 to 44 cm; calf, 22 to 60 cm; and below the knee, 22 to 68 cm. The rationale for this approach was to evaluate interstrategy subjective ease of use in individuals for whom this would logically be a real-world clinical goal.

Randomization. After provision of informed consent, eligible subjects were stratified into two treatment groups by their Clinical, Etiology, Anatomy, and Pathophysiology classification score (a less severe clinical class C3 to C5 cohort and a more severe C6 cohort). Subjects were then randomly assigned into groups designated to receive either a standard compression garment or the AT within the clinical class strata. Randomization was carried out by a computer-generated scheme developed by MedNet Solutions, Inc (Minnetonka, Minn).

For subjects with bilateral CVI, the right leg was designated the "study" leg, and the randomized device was applied as instructed on that leg for the duration of the study period. The other leg received the comparator strategy of care.

Garment or device use. Subjects with limbs assigned to standard compression were instructed to wear the assigned compression garment during all wakeful hours for 30 days. The standard compression garments consisted of individually fitted 30 to 40 mm Hg graduated CS. Subjects with limbs assigned to AT use were instructed to use the device in the sustained pressure mode during all hours when they were awake (at least 10 hours each day) and in the intermittent pneumatic compression mode for 2 hours each day for 30 days.

Instruction protocol. All subjects were provided instruction in the donning and doffing of their assigned compression treatment (AT or CS). After subjects demonstrated appropriate donning and doffing of the treatment device, they were required to twice don and doff the device themselves; this process was timed and

documented. The subjects were instructed to continue use of the assigned treatment on leaving the clinic for the remainder of the day until bedtime. The subjects were given a Subject Diary with instructions to record compression use. The AT subjects were also provided with the AT device User's Manual and the AT Quick User Guide.

Subject surveys. Several standardized surveys, both physician and patient reported, were carried out to assess symptoms. The Venous Clinical Severity Score (VCSS) was completed by the physician. The patient reported both a generic quality of life instrument (EuroQol-5 Dimension) and the disease-specific Venous Insufficiency Epidemiological and Economic Study on Quality of Life/Symptoms questionnaire. Finally, all patients completed custom ease of use and comfort surveys as these were administered.

Ease of donning and ease of doffing were quantified by asking subjects to respond to two questions at their initial study visit and again at their final study visit:

1. How easy is the device to put on?
2. How easy is the device to take off?

Possible responses were presented as a 5-point Likert scale with options ranging from very easy to very difficult.

Similarly, comfort was quantified by asking subjects to respond to three questions:

1. How comfortable was the device when first applied?
2. How comfortable was the device when you wore it during the day?
3. [AT only] How comfortable was the device when you wore it while plugged in (intermittent mode)?

Possible responses were again presented as a 5-point Likert scale. However, for this measure, options ranged from very comfortable to very uncomfortable.

Leg volume measurements. Two methods were used to quantify leg edema: water displacement and circumferential measurements. Water displacement volumetry was completed only for subjects who could safely participate in the procedure and fit into the volumeter. Volume measurements were carried out as previously reported.[18] Circumferential measurements by tape measure of both legs were taken at 4-cm intervals starting at 10 cm above the bottom of the subject's heel, while the subject was standing, and continued to the knee (tibial tuberosity).

Compliance measurements. CS use was recorded in a specific Subject Diary. The time the subject applied and removed the CS each day was recorded. The diary was also designed to record additional information, such as adverse events. Compliance with AT use in both sustained and intermittent modes was recorded by the Compliance Tracker function of the AT device controller. These data were reviewed and recorded by site staff at both the 15-day and the final visits. Wear time for each mode was analyzed to calculate average wear time. The Subject Diary also was used to self-report and to record the time the subjects put on and took off the AT in both sustained and intermittent modes, and this diary was again used to record adverse events.

Safety. Adverse events were reported and included any event with a clinical significance that was greater than anticipated or occurred with a frequency greater than that usually observed during use of venous compression techniques.

Statistical analysis. This study was considered to be a pilot investigation based on the lack of data from which to calculate intergroup ease of use treatment effects. The investigators chose to enroll approximately 80 completed subjects and to include 40 in each study group. Whereas the analyses conducted are thus descriptive, formal tests of intergroup differences were conducted using t-test, χ^2 test, and one-way analysis of variance. Change from baseline analyses were performed using analysis of covariance. All tests were two sided, with a P value $\leq .05$ used to reject the null hypothesis. Agreement between the two limb volume measurement techniques was assessed using the Bland-Altman limits of agreement methodology.

As a pilot study, it was not pre hoc feasible to perform a power calculation to guide statistical analysis for any single outcome measurement. As such, point estimates of differential effects for each strategy of care on the proposed end points were designed to permit more robust future evaluation in a subsequent definitive outcomes trial. Subjects with missing outcome data were included in an intention-to-treat analysis. Data from the subjects who failed to complete the study were used to determine the adherence to therapy in each randomized group.

RESULTS

Subject characteristics. Eighty-nine subjects were randomized and included in the final analysis. The majority of these subjects were male (56%) with a median age of nearly 63 years. A majority of these subjects also had bilateral CVI (52.8%). Additional characteristics of the subjects are presented in Table I.

Initial evaluation. At initial evaluation, 71% of patients in the AT group found the device easy to apply compared with 37.5% in the CS group ($P = .0001$). A high proportion (89%) of patients reported the AT device as easy to doff in contrast to 59% in the CS group ($P = .0001$). Comfort was reported to be good in both cohorts, with 70% of the AT users recording the device comfortable to wear compared with 58% of the CS group. This trend favored

Table I. Study population demographics and venous disease characteristics

	AT (n = 66)	Standard compression (n = 70)
Age[a]		
Mean (SD)	63.3 (10.5)	61.1 (11.7)
Median (minimum-maximum)	62.8 (30.0-88.9)	61.2 (24.0-85.4)
Gender[a]		
Male	37/66 (56.1%)	38/70 (54.3%)
Female	29/66 (43.9%)	32/70 (45.7%)
BMI,[a] kg/m^2		
No.	66	69
Mean (SD)	35.1 (8.1)	35.6 (8.7)
Median (minimum-maximum)	34.9 (19.6-57.1)	35.1 (17.7-57.1)
Affected limbs[a]		
Bilateral	47/66 (71.2%)	47/70 (67.1%)
Unilateral	19/66 (28.8%)	23/70 (32.9%)
CEAP score		
C3	22/66 (33.3%)	23/69 (33.3%)
C4	26/66 (39.4%)	26/69 (37.7%)
C5	10/66 (15.2%)	13/69 (18.8%)
C6	8/66 (12.1%)	7/69 (10.1%)
Calculated limb volumes, mL		
No.	65	70
Mean (SD)	2974.2 (821.1)	2982.6 (925.1)
Median (minimum-maximum)	2991.3 (1420.0-4856.4)	2979.8 (1062.7-5076.3)

AT, ACTitouch; *BMI,* body mass index; *CEAP,* Clinical, Etiology, Anatomy, and Pathophysiology; *SD,* standard deviation.
[a]Data point is reported on a per subject basis and subjects with bilateral disease appear twice, once in each arm.

AT users, although this was not statistically significant ($P = .125$).

Thirty-day evaluation. After 30 days of use of the two compressive strategies, the patient-focused ease of use responses changed. AT device users reported a small decrease in the reported ease of use from 71% to 65%. In contrast, at the 30-day visit, 55% of the CS group rated these garments as easy to put on, representing a 20% increase from the initial 37.5% rate. The difference between the two groups at this 30-day time point was not statistically significant ($P = .26$). The advantage of AT in doffing persisted. Nearly all (90%) patients responded that the AT was easy to doff, whereas only 66% of CS patients reported their garment to be easy to doff ($P = .0024$).

Compliance. The initial adherence to the compressive strategy was higher in the AT group. All AT patients used the device during the first 15 days compared with only 88% of patients in the standard compression group. However, by the end of the study period of observation, the fraction of patients in the AT group who continued using the device was comparable to garment adherence in the CS group (87% vs 85%, respectively; $P = .97$). AT subjects used the device on average 9.4 ± 3.1 hours a day in the sustained mode and 1.3 ± 1.1 hours a day in the intermittent mode for a total time of 10.7 hours a day. This use was not different from the duration of use of the CS patients (average, 11.7 ± 2.7 hours a day).

In the AT group, in addition to self-reporting, the patient's compliance was objectively measured by a usage meter built in the device. The average time of compression use reported by patients was 2.5 hours higher than measured by the device, and the limits of agreement were −6 hours to +11 hours. These findings indicate that self-reported time of use is highly unreliable and tends to overestimate the actual use.

Limb volume measurements. Table II displays the changes in limb volume from baseline to days 15 and 30. At the 30-day visit, nearly one-third (29%) of all limbs enjoyed a volume decrease ≥10% compared with baseline volume. It is noteworthy that the AT group demonstrated a significant volume reduction advantage compared with the standard compression garment use in obese patients (body mass index >30; Table III).

This study employed both water displacement and circumference-based methods of limb volume measurements. In this study, agreement between the two methods was poor. The limb volume values obtained by water displacement technique averaged 805 mL higher than the calculated values derived from circumference measurements, and the limits of agreement

Table II. Limb volume change by treatment group at 15 and 30 days

	AT		Standard compression	
	Mean	SD	Mean	SD
First 15 days				
Water displacement	−95.3	574.5	−23.2	491.1
Calculated	−79.6	264.0	12.4	305.1
30 days				
Water displacement	−106.3	444.5	9.2	446.8
Calculated	−58.4	308.9	4.9	366.0

AT, ACTitouch; *SD*, standard deviation.
Negative values (mL) indicate decrease of volume and represent circumferential measurements.

were from +2450 mL to −839 mL. The values of the limb volume change from the baseline to the end of treatment were on average 183 mL lower when obtained from the water displacement technique compared with values calculated from limb circumference measurements (Figs 1 and 2). The difference in leg volume between morning (6 AM to 10 AM) and midday (11 AM to 2 PM) was insignificant. The values (mean ± standard deviation) of the leg volume in the morning and afternoon were 3474 ± 1017 mL and 3542 ± 1315 mL by water displacement technique and 3257 ± 840 mL and 3030 ± 912 mL by circumference measurements.

The high variability in limb volume values resulted in the intercohort treatment differences not being measurably statistically different. In a data set characterized by high measurement variability, we observed a trend for limb volume reductions in favor of AT use, which will require future confirmation (Table II). This limb volume measurement variability also contributed to the study's inability to clarify a physiologic relationship between the duration of compression use (whether by days of use and hours per day) and associated limb volume reduction. However, those patients who used AT >5 hours per day had a mean limb volume reduction of 129 mL (by water displacement) or 80 mL (circumference calculation) between the baseline and day 30 measurements compared with an increase in volume by 49 mL (by water displacement) or 149 mL (circumference calculation) in patients who used standard garment compression.

Table III. Limb volume reduction >10% by device and body mass index

	Limbs with volume decrease at 30 days >10% from the baseline, % (No.)		
Body mass index	AT	Standard compression	*P*
<30	17 (3)	18 (3)	NS
>30	44 (12)	17 (6)	.019
All patients	33 (15)	18 (9)	NS

AT, ACTitouch; *NS*, not significant.

VCSS and quality of life assessment. Table IV displays the comparative data for these subjective efficacy measures for AT and CS patients at the baseline and 30-day visits. There were no differences between the two groups at any time point. The mean and median VCSS score of ~9 assigns these patients to a mild CVI symptom category.

There was no difference in the generic quality of life EuroQol-5 Dimension values between the two treatment cohorts from the baseline to the 30 day visit. The mean score of 0.7 was consistent with a mild impact on CVI. The Venous Insufficiency Epidemiological and Economic Study on Quality of Life/Symptoms survey measurement, like the generic quality of life values, demonstrated similar findings, with comparable scores reported from both groups at baseline and at the 30-day visit.

DISCUSSION

The effective treatment of CVD includes long-term use of compression therapy, which requires patients to adhere to this treatment. Whereas existing data define the clinical effectiveness of these approaches, studies rarely evaluate the patient-focused comfort and ease of use for limb compression. To our knowledge, this is the first study that has objectively measured the compliance of patients with two forms of CVI compression therapy. As well, this study represents the first attempt to compare the limb edema reduction benefit with the patient-reported duration of use of the compression intervention.

All AT patients used the device during the first 15 days of this study compared with 88% of patients in the CS group. The percentage of patients in the AT group who continued using the device until the end of the study (87%) was similar to that in the sustained compression group (85%; $P = .97$). These data demonstrate a surprisingly high compliance rate in both treatment groups. This high compliance rate is discordant with the commonly shared clinical impression that relatively few (≤40%) patients with CVD are compliant with prescribed

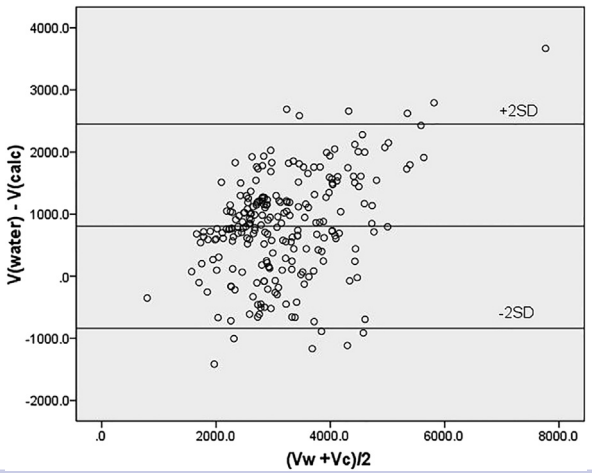

Fig 1. Comparison of limb volume measurement. Bland-Altman plot comparing limb volume measurement using water displacement technique vs calculated from limb circumferences. *SD,* Standard deviation.

compression therapy. Whereas this high compliance could easily be attributed to the selection of patients willing to enroll in a prospective clinical trial, we note that investigators enrolled subjects who were considered to be "compression noncompliant." Yet, within their identical clinical and investigational practice site of care, a high rate of compliance was achieved throughout the study. Patients in the AT group self-reported higher daily device use compared with the Compliance Tracker values (mean, 2.6 hours; 95% confidence interval, 2.1-3.2 hours).

A key and clinically relevant study outcome was defined by the comparison of patient-friendliness (defined as a combination of ease of donning, ease of doffing, and comfort of use) between AT and CS groups.

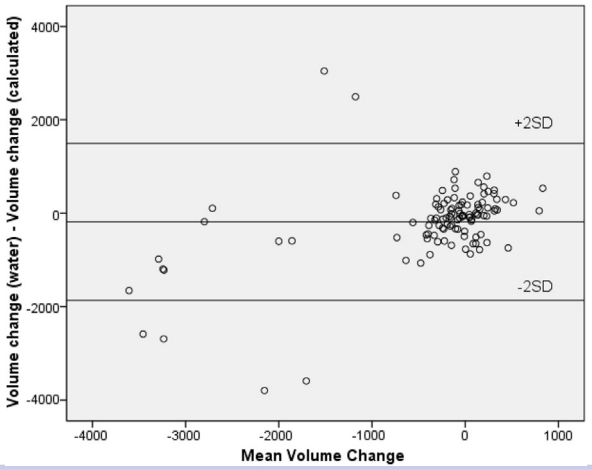

Fig 2. Comparison of limb volume change. Bland-Altman plot comparing change in limb volume from the baseline to 30 days measured using water displacement technique vs calculated from limb circumferences. *SD,* Standard deviation.

Table IV. Venous Clinical Severity Score (VCSS) at baseline and day 30 and change

	Total (N = 117)	AT (n = 56)	Standard compression (n = 61)
Baseline	9.6 ± 3.4	9.9 ± 3.4	9.4 ± 3.4
Day 30	8.9 ± 3.5	9.1 ± 3.4	8.7 ± 3.6
Change	−0.7 ± 2.5	−0.7 ± 2.5	−0.7 ± 2.4

AT, ACTitouch.
Values are reported as mean ± standard deviation.

These data demonstrate that although comfort was comparable during use of either compression intervention, the ease of donning and ease of doffing were definitively superior for those individuals who used the AT device. These findings are concordant with the similar rates of compliance observed at the end of the study. Finally, this study validates the previously reported data that compared AT with multilayer bandaging use and that evaluated positive AT patient acceptance, tolerance, and comfort in association with beneficial clinical outcomes.

Delivery of effective compression is a core principle that underlies all therapies used across the full spectrum of patients with CVI. To benefit from a compressive device or garment, the patient has to use the therapy. Poor compliance with compression therapy is a recognized challenge in this population of patients. This study examined factors influencing the patient's adoption and longer term use of compression by comparing compression garments with AT device use. The comparator treatment in this investigation was chosen to be a custom-fitted 30 to 40 mm Hg elastic stocking (CS), which had a static pressure profile similar to that of the AT device. The ease associated with CS sliding over the skin can be measured by the "friction factor." This force has been measured in vitro for 30 to 40 mm Hg and can require 150 to 180 N (same as lifting a 30- to 40-pound weight).[19] By contrast, a major advantage of AT is that it requires less flexibility and less effort to don this device. Whereas an AT patient still needs to bend over, the extent of the reach and flexibility required to don the AT is significantly less. This factor likely accounts for the higher proportion of patients in the AT group who found it easier to don compared with garment donning in the CS group (71% vs 37.5%, respectively; $P = .0001$). Similarly, a higher proportion of patients found AT easier to doff than garment removal in the CS group (89% vs 59%, respectively; $P = .0001$).

At 30 days, the percentage of patients in the AT group who found it easy to don decreased to 65%; however, CS group patients enjoyed an increase in ease of doffing to 55%, but this difference was not statistically significant ($P = .26$). This most likely reflects a training effect in the CS group and is consistent with the common clinical observation that patients who consistently use stockings

experience less difficulty over time. Because the ease did not change significantly in the AT group, it is likely that the influence of the initial bias was insignificant. By contrast, at 30 days, patients in the AT group rated doffing even more favorably (90%), whereas only 66% of the CS patients found stockings easy to doff ($P = .0024$).

Study limitations. Some findings of this study may be helpful for designing future studies of compression therapy. One example is the lack of agreement between the water displacement method and the circumference measurements used to assess changes in limb volume. Although some past studies have demonstrated agreement between these techniques,[20] most of these have been performed in highly selected populations of healthy volunteers or nonobese patients. Factors that contributed to discrepancies between the two techniques in this study were qualitatively reported as the inability of patients to properly and consistently position the limb in the measuring vessel. Because of either obesity or swelling, some limbs were simply too large to fit, whereas others were squeezed into the vessel, leading to inaccuracies in measurement. In addition to patient-related variability, the water displacement technique is also operator dependent, which makes it less reliable and impractical compared with circumference measurements.

Although one of the inclusion criteria was a diagnosis of CVI, and a history of VTE and lymphedema were among the exclusion criteria, there were no formal requirements for a duplex ultrasound examination. It is therefore possible that some of the patients were misclassified as having primary disease. This bias was minimized by selecting site investigators who are experts in venous and lymphatic diseases and by holding monthly telephone conferences with all site investigators discussing enrollment criteria and related issues.

This study was designed as a pilot investigation that included a relatively small sample size. This study therefore lacked the statistical power to detect potentially important differences in each measured outcome. However, the multicenter, randomized design contributes to the strength of the study. Whereas the results of selected formal statistical tests are presented, emphasis should be placed on observed effect size estimates and trends. The findings of this study should be instrumental in designing future studies of compression therapy.

CONCLUSIONS

The AT device was easy to don and doff and was comfortable. These are characteristics that are usually associated with a good potential for long-term acceptance by patients. The observed trend that suggested an associated benefit in achieving limb volume reduction (magnified in obese patients) was greater with the AT device than with CS. The significant discrepancy between patient-reported compliance and device-recorded compliance highlights the importance of inclusion of objective measurements of compliance in future studies, especially in definitive randomized controlled trials of compressive efficacy.

AUTHOR CONTRIBUTIONS

Conception and design: FL, MS
Analysis and interpretation: FL, MS
Data collection: Not applicable
Writing the article: FL, MS
Critical revision of the article: FL, MS
Final approval of the article: FL, MS
Statistical analysis: Not applicable
Obtained funding: Not applicable
Overall responsibility: FL

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Submitted Feb 27, 2017; accepted Jun 11, 2017.

Additional material for this article may be found online at www.jvsvenous.org.

APPENDIX (online only).

Eligibility

Ages eligible for study	18 years and older (adult, senior)
Sexes eligible for study	All
Accepts healthy volunteers	No

Criteria

Inclusion criteria.

- Diagnosis of unilateral or bilateral chronic venous insufficiency with or without leg ulcers
- Documented history of low adherence to compression garment therapy
- Clinical, Etiology, Anatomy, and Pathophysiology classification of C3 to C6
- Leg circumferences within the following ranges: ankle, 12-44 cm; calf, 22-60 cm; below the knee, 22-68 cm

Exclusion criteria.

- History of skin sensitivity to any of the components of ACTitouch or compression garments
- History of acute deep venous thrombosis or pulmonary embolism within the last 3 months
- Ankle-brachial index < 0.8
- Acute thrombophlebitis
- History of pulmonary edema or decompensated congestive heart failure
- Currently has an active infection of the skin, such as cellulitis requiring antibiotics
- Poorly controlled diabetes with a hemoglobin A_{1c} value of $>10\%$
- Exhibits any condition that, according to the principal investigator, justifies the subject's exclusion from the study, such as a medical condition whereby an increase in venous or lymphatic return is undesirable
- Subjects with open ulcers must be able to follow their care regimen for ulcer healing concurrently with the assigned study regimen.
- Participating in another clinical trial
- Changes to medications that affect edema within the last 30 days
- Currently pregnant or trying to become pregnant