Comparison of a nonpneumatic device to four currently available intermittent pneumatic compression devices on common femoral blood flow dynamics

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ABSTRACT

Objective: The purpose of the present study was to compare common femoral vein blood flow enhancement during external mechanical compression using the novel, nonpneumatic Recovery Force Health Movement and Compressions (MAC) System (Recovery Force USA, Fishers, Ind), and four currently available intermittent pneumatic compression devices.

Methods: The MAC device was compared with the Kendall SCD 700 (Cardinal Health, Dublin, Ohio), Arjo Huntleigh Flowtron ACS900 (Arjo, Malmö, Sweden), ActiveCare+S.F.T. (Zimmer Biomet, Warsaw, Ind), and Circul8 (Ortho8, Rocklin, Calif). Doppler ultrasound measurements for each device were directly obtained from the right common femoral vein by a registered vascular technologist. The peak flow velocity and the time taken to reach the peak were calculated. For the MAC system only, the subjects were asked to walk a minimum of 500 steps while wearing the system, which was then checked for slippage. Leg size measurements were obtained using the noncontact Sigvaris Legreader XT5 (Vialis Ortopedia, Turin, Italy). The MAC device is not yet commercially available, and the present study was a prequel to clinical studies of venous thromboembolism prevention.

Results: We recruited a broad range of 20 subjects who varied in age (mean ± standard deviation [SD], 50.5 ± 16.2 years), body mass index (mean ± SD, 26 ± 5.5 kg/m^2), gender (male, 25%; female, 75%), and right calf circumference (mean ± SD, 37.2 ± 5.5 cm). The peak flow velocity compared with the baseline measurements was significantly greater for the Recovery Force Health MAC System for three (Kendall SCD 700, $P = .02$; ActiveCare+S.F.T., $P = .003$; Circul8, $P < .001$) of the four comparisons. Although the difference was not significant, the Arjo Huntleigh Flowtron ACS900 (SD, 3.4 cm/s) had more measurement variability in the peak flow velocity compared with baseline than did the MAC System (SD, 1.9 cm/s). The MAC had a significantly ($P < .001$) faster rise time to peak flow compared with the comparison devices. It was the only device to achieve the target peak flow velocity over baseline of at least three times in every body mass index group. Finally, the MAC System met the goal of <2.5 cm of movement after ambulation in 100% of the measurements, with 75% of the measurements showing no movement.

Conclusions: The MAC System is a mobile device that remained in place during ambulation and provided more consistent external mechanical compression in the desired range compared with the other three devices included in the present study. (J Vasc Surg Venous Lymphat Disord 2021;9:1241-7.)

Keywords: Blood flow; Common femoral vein; Duplex ultrasound; Nonpneumatic compression; Pneumatic compression

The risk of venous thromboembolism (VTE) is increased in hospitalized patients for a variety of reasons, including immobility, infection, surgery, chemotherapy, and any condition that promotes a procoagulant state.[1-4] The options for deep vein thrombosis (DVT) prophylaxis include both pharmacologic and mechanical therapies, which can be used alone or in combination. An important caveat regarding the use of pharmacologic therapies is that the VTE risk considerations must be balanced against the potential bleeding risk. In a systematic review, it was found that the use of external mechanical compression reduced the risk of venous thrombosis by

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60%.[1] The efficacy of external mechanical compression as monotherapy has made it especially useful for patients for whom the use of anticoagulant therapy is contraindicated because of their bleeding risk.[2-5]

The full potential of mechanical compression therapy for DVT prophylaxis will not be realized until a device has been developed that will enhance a patient's mobility in the hospital and at home,[6] addresses compliance issues, and meets or exceeds the blood flow enhancement realized by the currently available devices. The Recovery Force Health Movement and Compressions (MAC) System (Recovery Force USA, Fishers, Ind) is a wearable, comfortable, bladder-free, quiet, wireless, and portable device with a 48-hour rechargeable battery applying intermittent (nonpneumatic) active leg compression. The present study was designed to measure and compare the common femoral vein peak blood flow velocity, rise time to peak flow, and calculated peak flow velocity compared with baseline for five currently available mechanical compression devices using duplex ultrasonography in a group of subjects with different leg sizes. The work was performed to determine the potential ability of this nonpneumatic compression device to favorably alter venous hemodynamics compared with pneumatic compression devices routinely available in clinical practice and to serve as a prequel to clinical studies evaluating its efficacy in preventing VTE.

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, prospective, comparative study
- **Key Findings:** A new nonpneumatic mobile device that remains in place during ambulation provided more consistent external mechanical compression in the desired range compared with four other commercially available pneumatic compression devices.
- **Take Home Message:** A nonpneumatic compression device can be as effective as pneumatic compression devices, with the potential for better compliance, for the prevention of venous thromboembolism.

METHODS

Sample and setting. The IntegReview institutional review board approved the present study on May 23, 2019.

Participants. Volunteer participants were recruited by word of mouth and posted flyers. All the participants provided written informed consent. The study was conducted using an independent laboratory space, a space for entrepreneurs, creators, and innovators to work and collaborate. The participants were English-speaking adults, aged ≥18 years, who had been recruited from the Indianapolis geographic area using a combination of flyers, a list of participants from a previous study, and referral. The following vulnerable patients were excluded from the study: pregnant women, prisoners, the homeless, and the cognitively impaired. Guidance from the Food and Drug Administration has recommended 15 as the practical minimum number of participants.[7] Therefore, we enrolled 20 participants, which would allow ≥15 subjects to be tested in case a few of them could not participate or an issue had occurred with the testing.

Instruments. The RF Health Movement and Compressions (MAC) System (Recovery Force USA, Fishers, Ind) is a novel device not yet commercially available. It is applied to the legs of patients to provide intermittent active compression, which results in increased venous blood flow to reduce the risk of DVT. The RF Health MAC System is a wireless, portable, and wearable nonpneumatic device (Fig). During use, it also tracks the patient's position and activity for healthcare providers to monitor adherence to the DVT prophylaxis and mobility protocols. The data displayed on the device allow caregivers to monitor the patient's movement, orientation, and activity. Such data could be used to identify the risk factors for hospital-acquired events related to the patient's activity.

Application and mechanism of action. A disposable fabric, moisture-wicking strap (MAC strap) is wrapped around the patient's calf. A controller is then attached to the strap in two places: the strap mounts and securement ring. Inside the controller is a small DC (direct current) motor that moves the securement ring in and out of the controller, contracting and retracting the strap. When the strap is contracted, compression is applied to the patient's calf muscle. When the strap is retracted, the compression force on the patient's calf muscle is released. This provides the blood flow "pumping" action once per minute. Using this mode of action, the MAC System (Recovery Force USA) uses mechanical force to provide intermittent compression, not pneumatic force. The system does not require a powered air supply; thus, the risk of aerosolization of potential contaminants or germs is mitigated because no blowing air is used. Also, the device components are either disposable (the MAC strap) or the surfaces are easily disinfected (MAC controller and charging hub), allowing for ease of cleaning and mitigation of cross-contamination. In addition, the device has no air connections or pneumatic pumps to clean between patients.

The Cardinal Health Kendall SCD 700 (Cardinal Health, Dublin, Ohio) is often used for DVT prevention in the acute care setting. This pneumatic device consists of a pump that plugs into a wall outlet and is mounted on the end of the bed with tubes that plug into a disposable sleeve that is used on the leg. This device provides each patient with an automated, customized compression cycle.

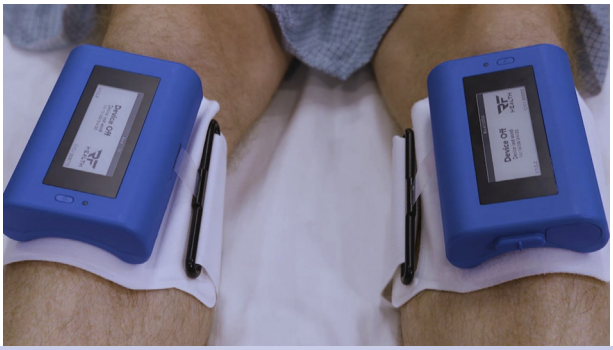

Fig. The RF Health MAC System (Recovery Force USA) is a lightweight (300-g) portable device. The dimensions of the device are 13.3 cm long, 8.9 cm wide, and 3.2 cm high. It is a wireless, portable, and wearable nonpneumatic device that allows for monitoring of the patient's movement, orientation, and activity. The device consists of a controller, which is mounted to the strap through a securement ring. A small DC (direct current) motor in the controller moves the securement ring in and out to contract and retract the strap.

The Arjo Huntleigh Flowtron ACS900 (Arjo, Malmö, Sweden) is a DVT prophylaxis system used in the acute care setting that plugs into a wall outlet and has a pneumatic pump that mounts at the foot of the bed. It has the capability of providing uniform and sequential modalities from one pump.

The Zimmer Biomet ActiveCare+S.F.T. (Zimmer Biomet, Warsaw, Ind) is a portable pneumatic compression system that uses a smaller pump than the other pneumatic devices, which allows it to hang around the patient's neck or shoulder. However, it still requires tubing to connect from the sleeves on the calf to the pump. Primarily considered an at-home product, the ActiveCare was one of the first of its type to allow for DVT prevention therapy to be used as a portable system in the at-home environment. This device delivers continuous enhanced circulation therapy via compression to the legs and works by synchronizing the compressions to the respiration cycle.

The Ortho8 Circul8 (Ortho8, Rocklin, Calif) is a portable and rechargeable pneumatic DVT prevention device that is targeted for postoperative patients at home. The device is equipped with a pump on the side of the sleeve that slowly inflates and deflates to apply pressure to the patient's calf.

Procedures. The study subjects who had agreed to participate were scheduled for data collection and asked to bring or wear shorts to expose their lower leg for testing. On arrival at their assigned time, the informed consent document was reviewed and completed for each study participant. Before the initiation of data collection, all the participants were given the opportunity to ask additional questions, reminded of the voluntary nature of the study, and received a copy of the informed consent form for their personal records. Next, each participant was assigned a subject identification number, and the key was stored in a password-protected file.

The calf and leg size measurements were performed using the noncontact Sigvaris Legreader XT5 (Vialis Ortopedia, Turin, Italy) measurement device. This device was used to standardize the measurement process. The measurements included the total leg volume, calf circumference at the widest part of the mid-calf, ankle circumference at the smallest part of the ankle, and height from the kneecap to the floor. Photographs of the leg from the front and side views were also taken and saved. The purpose of taking the photographs was to provide a visual record of the leg size and shape that produced the measured blood flow results.

Each participant was asked to lie on the examination table, and the angle of the thigh and leg through knee flexion was confirmed at 60° using a goniometer. This was performed to ensure a similar position for all participants and eliminate any hemodynamic changes that could create heterogeneity in the comparisons. The diameter of the common femoral vein was measured, and the peak flow velocity (cm/s) baseline measurement was taken using duplex ultrasonography by a registered vascular technologist.

After completion of the baseline measurements, three additional measurements of the peak flow velocity and rise time to the peak (seconds) were obtained from the right leg during active compression. These measurements were used to calculate the overall mean peak flow velocity and rise time to peak flow for each participant to reduce the potential for error from a single measurement. The peak flow velocity was recorded to compare the velocity change from baseline with that resulting from the compression offered by the devices. An increase in the peak flow velocity of three or more times that of baseline was set as a target to ensure that a significant change had been observed. The rise time to peak was measured to demonstrate the acceleration time, with the understanding that a shorter time will increase the shear stress. This process was used for all duplex ultrasound measurements for all five devices included in the present study. The analysis of the measurements was performed in a blinded fashion, and the compression devices were not revealed until all the results had been processed. In addition, the investigators did not perform the testing.

Because the MAC System was designed as a mobile device, before completing the Doppler ultrasound measurements, once the device had been applied to the thickest part of the right calf, the position of the device was marked on the participants' leg using a washable marker. The participants were then asked to walk 500 steps. After the walk was completed, the position of the MAC System was measured to assess for slippage. All data were collected using a case report form and

Table I. Demographic data (n = 20)

Variable	Value
BMI group, no. (%)	
<18.5 kg/m^2	2 (10)
18.5-24.9 kg/m^2	5 (25)
25-29.9 kg/m^2	7 (35)
≥30 kg/m^2	6 (30)
Gender, no. (%)	
Female	15 (75)
Male	5 (25)
Age, years	
Mean	50.5
Median	53.5
Minimum	18
Maximum	71
SD	16.2
BMI, kg/m^2	
Mean	26.0
Median	26.2
Minimum	18
Maximum	35
SD	5.5

BMI, Body mass index; *SD,* standard deviation.

stored electronically in a password-protected file. Slippage was measured only for the MAC System because it applicable to that device only. The device covers a smaller area of the calf, and the patient is allowed to walk without removing the device. Therefore, slippage of the device can make it ineffective because the calf below the application area has a smaller perimeter and compression will not be properly applied.

The total duration for each subject was ~1 hour. All the participants received a $25.00 Amazon gift card for remuneration and signed a compensation confirmation form.

Statistical analysis. Descriptive statistics were used to summarize the participant demographics. The RF Health MAC System was compared with the other four devices using the Kruskal-Wallis test and post hoc Mann-Whitney *U* test. The level of significance was set at $P < .05$.

RESULTS

Participant demographics. To meet the recruitment goal of 15 participants, 21 participants were enrolled. Participant 1 was used as a pilot subject to test our study protocol. Thus, the data from participant 1 were not included in the participant demographics or analyses. After completion of the pilot subject run, the study team was able to successfully recruit 20 participants and obtained complete data for the final analyses. The group of participants successfully recruited varied in gender, age, body mass index (BMI), BMI group (Table I), and leg size (Table II).

Blood flow measurements. The measurements of the rise time to peak flow and peak flow velocity were obtained directly from the duplex ultrasound scans. The mean rise time to peak of 0.5 second and measurement variability (standard deviation [SD], 0.2) was lowest with the RF Health MAC System. Furthermore, testing of the mean values found a significantly faster rise time to peak flow compared with the four comparison devices (Table III).

For the peak velocity, although both the mean and the maximum were highest with the Arjo Flowtron device (41.4 cm/s), the Flowtron also had the highest SD (Table IV). The Circul8 had the lowest SD but also the lowest mean maximum and peak flow velocity (Table IV).

The peak flow velocity over baseline was calculated using the baseline and peak flow velocity values obtained using Doppler ultrasonography. The RF Health MAC System had a significantly higher peak flow velocity vs the baseline compared with the Kendall SCD 700 (Cardinal Health), ActiveCare+S.F.T. (Zimmer Biomet), and Circul8 (Ortho8; Table V). No significant differences were found between the RF Health MAC System and the Arjo Huntleigh Flowtron ACS900 (Arjo). The RF Health MAC System had more measurements and spent more time (85%) in the target range of three or more times compared with any of the other devices. In addition, the RF Health MAC was the only device to achieve a peak flow velocity of three or more times compared with baseline for every BMI group (Table VI).

Because the RF Health MAC System is a mobile device, after placement of the system and before any Doppler ultrasound testing, the study team asked the

Table II. Right leg measurements

Value	Volume, cm^3	Ankle circumference, cm	Calf circumference, cm	Calf length, cm	CFV diameter, cm
Mean	2170.3	22.9	37.2	38.1	1.1
Median	2300.4	22.6	38.0	38.5	1.1
SD	641.7	2.6	5.5	2.3	0.2
Minimum	933.0	18.6	25.1	34.3	0.7
Maximum	3272.0	27.9	46.2	41.6	1.6

CFV, Common femoral vein; *SD,* standard deviation.

Table III. Rise time to peak flow

Measure	RF Health MAC System	Kendall SCD 700	Arjo Huntleigh Flowtron ACS900	ActiveCare+S.F.T.	Circul8
Mean	0.5	1.7	1.7	1.6	1.9
Median	0.5	1.7	1.4	1.5	1.9
SD	0.2	0.8	0.8	0.8	0.6
Minimum	0.3	0.5	0.5	0.5	1.2
Maximum	1.3	3.5	3.0	3.2	3.7
P value	Reference	<.001	<.001	<.001	<.001

SD, Standard deviation.
Data presented as seconds.

participants to ambulate 500 steps and then checked the position. This test verified that the RF Health MAC System achieved its goal of <2.54 cm of movement for all the measurements. For 15 of the volunteers, the device remained in the exact location and for 5, it had moved 0.25 to 2 cm.

DISCUSSION

The RF Health MAC System compared favorably in most aspects with the other four devices. For a broad range of body types, it consistently achieved the clinical goals for blood flow enhancement across a range of variables, including leg circumference and BMI, providing a good representation of the hospital patient population. Therefore, it could have a wide application more easily without compromising its performance. The common femoral vein was chosen as the segment for evaluation because it is far from the device and is the main outflow vein for the entire lower limb. The RF Health MAC System had a significantly faster rise time to peak flow than any of the other devices. This could be important because the device induces a greater shear stress and thus would be more efficient in preventing stasis and more likely to increase fibrinolytic activity.[8-11] The hemodynamic changes observed have not been optimized and translated into enhanced VTE prevention in clinical studies. Thus, more work is needed in this area. More specifically, the optimal compression force, time, and cycle have previously been discussed but never been tested to maximize the effects of intermittent compression in preventing VTE.[8,12] A threefold increase in the peak flow velocity was chosen to demonstrate an adequate and consistent change and that the device provided results at least as good as previously reported data for existing devices.[8,12] This new system stays in place during ambulation, allowing for better compliance because it is not necessary to remove and reapply it.

In the absence of clinical data, the use of the RF Health MAC System, given its hemodynamic performance, should be at least comparable for preventing VTE as the other devices. However, the device also has considerable benefits that make its use more attractive. Despite the effectiveness of intermittent pneumatic compression when used as intended, numerous compliance issues are associated with the currently available external mechanical compression devices.[13-17] Recent direct observational studies of inpatients found noncompliance rates ranging from 50% to 74%.[15,16] Although a recent meta-analysis found that the mean rate of external mechanical compression device noncompliance among postoperative patients was 25%, it was not possible to confirm that the devices had been used correctly. Data have supported that even with implementation of strategies to improve compliance, most patients will not receive adequate mechanical prophylaxis and that healthcare providers appropriately order prophylactic measures but do not follow-up to ensure application.[16] The most often reasons reported for patient noncompliance include discomfort, excessive noise during operation, sleep disturbances, device not reapplied after patients

Table IV. Peak flow velocity

Measure	RF Health MAC System	Kendall SCD 700	Arjo Huntleigh Flowtron ACS900	ActiveCare +S.F.T.	Circul8
Mean	36.0	30.0	41.4	30.3	16.0
Median	30.8	25.5	32.0	25.1	14.8
SD	14.5	18.1	26.7	15.9	5.2
Minimum	21.1	10.0	17.0	12.9	10.8
Maximum	74.4	85.6	123.7	68.8	32.7

SD, Standard deviation.
Data presented as centimeters per seconds.

Table V. Peak flow velocity change compared with baseline

Measure	RF Health MAC System	Kendall SCD 700	Arjo Huntleigh Flowtron ACS900	ActiveCare +S.F.T.	Circul8
Mean	4.4	3.4	5.1	2.9	1.9
Median	4.0	3.1	3.9	3.0	1.9
SD	1.9	1.7	3.4	1.2	0.6
Minimum	2.4	1.0	1.9	0.7	1.2
Maximum	9.1	7.7	14.5	5.6	3.7
P value	Reference	.022	NS	.003	<.001

SD, Standard deviation.
Data presented as an increase in the peak flow velocity of *X* times that of baseline.

return to bed, lack of patient education, and poor usability design.[15-18] Venous thrombosis prevention using devices that inhibit mobility are an additional factor in the noncompliance associated with the most current devices. Among the many usability issues, the requirement for a power cord and outlet, in particular, have limited the usefulness of most current intermittent pneumatic compression devices. As a result, professional guidelines "recommend the use of only portable, battery-powered devices which are capable of recording and reporting proper wear time on a daily basis for inpatients and outpatients"[2] and a goal of 18 hours of daily wear time. Even with the implementation of strategies to improve compliance, the reported data have shown that most patients do not receive adequate mechanical prophylaxis.[6] In addition, healthcare providers appropriately order prophylactic measures but often do not follow-up to ensure application.[16] The lightweight, easy application, and portability of the new device might also allow for better compliance but requires testing. Furthermore, because the VTE risk persists for ≥1 month after various procedures, this device might be best suited for the many patients discharged to home after procedures who are temporally not mobile or have limited mobility.

In our study, during use, the RF Health MAC System stayed in place without any slippage. For most subjects, the device was found in the same location and for a few patients had moved <1 in., which was our set cutoff point for strict accuracy. The device also tracks the patient's position and activity, allowing healthcare providers to monitor the patient's compliance with DVT prophylaxis and mobility protocols. The data displayed on the system also allows caregivers to monitor the patient's movement, orientation, and activity (steps taken), which can be used to prevent hospital-acquired events. It also allows the provider to set realistic and individualized goals by leveraging the data accumulated over time as a benchmark for improvement.

The present study was a robust pilot study. However, as such, our study had a limited sample size, which confined the generalization of the data. However, the testing and comparisons were performed very objectively by performing a blind analysis of the data and not taking part in the testing, mitigating the possibility of bias and providing sound and reproducible results. Further testing is needed in a hospital setting with a larger sample of patients with different demographics and characteristics. This should include compliance with intended use and the degree of interference with sleep.

CONCLUSIONS

The RF Health MAC System is a mobile device that remains in place during ambulation and provides improved external mechanical compression overall compared with the four comparison devices included in the present study. Given its promising performance and the ability for the patient to remain mobile likely will allow for better compliance. Therefore, further studies are warranted.

Table VI. Mean peak flow velocity change compared with baseline stratified by BMI group

BMI group, kg/m^2	Participants, no.	RF Health MAC System	Kendall SCD 700	Arjo Huntleigh Flowtron ACS900	ActiveCare +S.F.T.	Circul8
<18.5	2	3.8	2.7	2.3	2.3	1.9
18.5-24.9	5	4.1	2.8	5.0	3.3	1.8
25-29.9	7	4.2	3.8	5.6	2.8	2.1
≥30	6	5.3	3.7	5.5	2.8	1.8

BMI, Body mass index.
Data presented as an increase in the peak flow velocity of *X* times that of baseline.

AUTHOR CONTRIBUTIONS

Conception and design: NL, AT, JC
Analysis and interpretation: NL
Data collection: NL, KG
Writing the article: NL, KG
Critical revision of the article: NL, KG, AT, JC
Final approval of the article: NL, KG, AT, JC
Statistical analysis: NL
Obtained funding: NL, AT, JC
Overall responsibility: NL

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