Femoral Blood Flow for DVT Prophylaxis: A Comparison of a Novel Non-Pneumatic Device to Four Currently Available Intermittent Pneumatic Compression Devices

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Introduction

In the US, DVTs are a leading cause of preventable hospital death, affecting 350,000-900,000 patients with an estimated 60,000-100,000 annual deaths.[1,2] DVTs are the fifth most common reason for hospital readmission, the third most frequent complication of total joint replacement (TJR), and are associated with an estimated annual cost of $10 billion.[3]

DVT prophylaxis in patients with limited mobility includes the use of anticoagulant medications and mechanical compression of the lower limbs. For effective DVT prophylaxis using mechanical compression, enhanced blood flow in the common femoral vein of ***at least three times over baseline and a short rise time to peak flow*** are particularly important.[4]

Purpose

Compare femoral vein blood flow enhancement during external mechanical compression between the novel, ***non-pneumatic*** RF Health Movement and Compressions (MAC System™) and four currently available ***intermittent pneumatic compression devices***: Cardinal Health Kendall SCD™ 700, Arjo Huntleigh Flowtron® ACS900, Zimmer Biomet ActiveCare+S.F.T.®, and Ortho8 Circul8.

Aim

Using Doppler ultrasound, measure and compare common femoral vein peak blood flow velocity, rise time to peak flow and calculated peak flow velocity over baseline for five mechanical compression devices in a group of subjects with varied leg sizes.

Materials & Methods

- Volunteer participants were recruited from the Indianapolis, IN geographical area.
- 21 participants were successfully recruited: participant 1 served as the pilot test subject, and the other 20 provided data for analysis.
- Leg size measurements were taken using a non-contact leg measurement device, the LEGREADER XT5 by Sigvaris.
- Due to the mobile and tubeless design, the MAC System was measured when applied and re-measured following 500 walked steps while wearing the system to determine slippage.
- Doppler ultrasound on the right leg by a vascular certified ultrasound technician was used to measure (1) peak blood flow velocity and (2) rise time to peak flow on device.
- Each participant received remuneration for their participation in the study.

Participant Demographics (N=20)

Table 1: Descriptive Demographics

	Age	BMI
Mean	50.5	26.0
Median	53.5	26.2
Std Dev	16.2	5.5
Minimum	18.0	18.0
Maximum	71.0	35.4

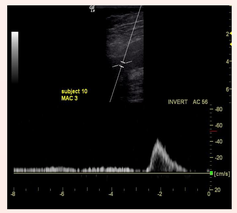
Table 2: Frequency Demographics

Female	15	75%
Male	5	25%
BMI		
Group 1: under 18.5	2	10%
Group 2: 18.5-24.9	5	25%
Group 3: 25-29.9	7	35%
Group 4: 30+	6	30%

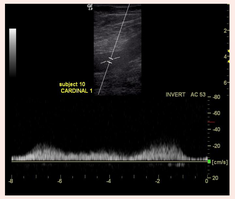
Table 3: Right Leg Measurements

	Right leg volume (mL)	Right ankle circumference (cm)	Right calf circumference (cm)	Right calf length (cm)	Common femoral vein diameter (cm)
Mean	2170.3	22.9	37.2	38.1	1.1
Median	2300.4	22.6	38.0	38.5	1.1
Std. Deviation	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

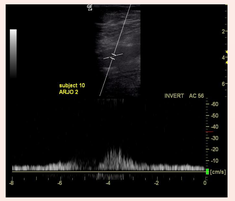
Subject 10: Blood flow Curve Sample for each Device



RF Health MAC System



Cardinal Health Kendall SCD700



Arjo Huntleigh Flowtron ACS900

Zimmer Biomet ActiveCare+S.F.T.

Ortho8 Circul8

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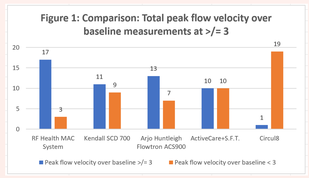
Results (N=20)

Table 4: Peak Flow Velocity over Baseline: Descriptive Data Comparison*

	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
Std. Deviation	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	0.022	NS	0.003	<0.001

*Goal is at least 3X over baseline

Significance testing using Kruskal-Wallis with post-hoc Mann - Whitney U found the MAC System had a significantly higher peak flow velocity over baseline as compared to Kendall SCD 700, ActiveCare+S.F.T., and Circul8. No significant difference was found between the MAC System and Arjo Huntleigh Flowtron ACS900.



The MAC System had more measurements (Figure 1) in the target range of ≥ 3 than any of the other comparison devices.

Significance testing using Kruskal-Wallis/post-hoc Mann -Whitney U found that the MAC System had a significantly faster rise time to peak flow as compared to all other devices.

Table 5: Rise Time (seconds) to Peak Flow*

	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
Std. Deviation	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	<0.001	<0.001	<0.001	<0.001

*Goal is rise time to peak flow as fast as possible

Table 6: Mean Peak Flow Velocity over Baseline by BMI Group

BMI Group	N	RF Health MAC System	Kendall SCD 700	Arjo Huntleigh Flowtron ACS900	ActiveCare +S.F.T.	Circul8
Under 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

Table 6 shows the mean peak flow velocity over baseline for each device by BMI group. Target values are highlighted in green and values below target are highlighted in red.

The MAC System met the goal of less than 1 inch of movement after ambulation in 100% of measurements; 75% of measurements found no movement.

Conclusions

- A broad range of subjects (N=20) were successfully recruited representing a variety of age, BMI, gender, and leg sizes.
- Peak flow velocity over baseline measurements were significantly higher for the MAC System in 3 out of 4 comparisons.
- While not significantly different, the Arjo Huntleigh Flowtron ACS900 (SD= 3.4) had more measurement variability in peak flow velocity over baseline than the MAC System (SD=1.9).
- The MAC System had a significantly faster rise time to peak flow than all other comparison devices.
- The differences in both peak flow velocity over baseline and rise time to peak between the MAC System and the other devices is easily seen in the shape of sample blood flow curves.
- The MAC System was the only device to achieve the target peak flow velocity over baseline in every BMI group.

Clinical Implications

- Consistency in achieving enhanced blood flow in excess of 3x over baseline is important for the prevention of deep vein thrombosis.[4]
- Commonly used intermittent pneumatic compression (IPC) devices require bladders and tubes that hinder mobility and have a negative impact on adherence with recommended use.[5]
- The MAC System is a mobile system that remained in place during ambulation and provided more consistent external mechanical compression in the desired range as compared to all comparison devices.
- The MAC System's non-pneumatic technology consistently achieved clinical goals for blood flow enhancement in a varied sample of subjects.

References

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