Review of a Novel DVT Prevention and Mobility Device: Doppler Ultrasound Blood Flow Analysis on Subjects with Varied Leg Sizes

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Introduction

In the US, DVTs are a leading cause of preventable hospital death, affecting 350,000-900,000 patients and 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

Demonstrate that the use of the novel **non-pneumatic** Movement and Compressions System (MAC System™) by RF Health can result in clinically meaningful increases in peak flow velocity and rise time to peak flow as measured at the common femoral vein by Doppler ultrasound in subjects with varied leg sizes.

Aims

Aim 1. Is the use of the MAC System associated with (**1a**) at least **three times increase** in peak flow velocity and (**1b**) rapid rise time to peak flow (≤1 sec) at the common femoral vein as measured by Doppler ultrasound?

Aim 2. Do peak flow velocity and rise time to peak differ among subjects based on body mass index (BMI)?

Figure 1: Sigvaris XT5 LEGREADER

Materials & Methods

- Volunteer participants were recruited from the Indianapolis, IN geographical area.
- 20 participants were successfully consented for data analysis.
- Leg size measurements were taken using a non-contact leg measurement device, the LEGREADER XT5 by Sigvaris (Figure 1).
- The MAC System was applied to the thickest part of the right calf.
- Doppler ultrasound was used to measure (1a) peak blood flow velocity and (1b) rise time to peak flow. All Doppler ultrasound measurements were obtained by a vascular certified ultrasound technician.

Participant Demographics (N=20)

Table 1: Frequency Demographics		
BMI Group	**n**	**%**
1. under 18.5	0	0
2. 18.5-24.9	5	25
3. 25-29.9	7	35
4. 30+	8	40
Gender		
Female	12	60
Male	8	40

Table 2: Descriptive Demographics			
	Mean	**Median (min., max)**	**SD**
Age	42.7	43.5 (18, 70)	15.1
BMI	29.8	29 (19.2, 53)	9.2

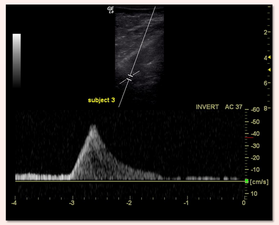

Figure 2: RF Health MAC System Doppler ultrasound blood flow curve

Table 3: Right Leg Measurements					
	Leg volume (mL)	**Ankle circumference (cm)**	**Calf circumference (cm)**	**Calf length (cm)**	**Common femoral vein diameter (cm)**
Mean	2573.1	24.0	40.1	39.1	1.1
Median	2644.2	23.9	40.2	39.1	1.1
Std.	763.7	2.8	5.6	2.0	0.2
Minimum	1473.3	19.9	30.8	36.3	0.8
Maximum	4469.2	31.7	54.1	43.0	1.6

- The increase in peak flow velocity over baseline for the smallest calf (30.8) was 3.7 and the largest calf (54.1) was 4.6.

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Results (N=20)

Table 4: Peak Flow Velocity & Increase over Baseline-5 Run Average		
	Peak flow velocity (cm/sec)	**Increase in peak flow velocity over baseline**
Mean	44.86	4.26
Median	43.19	3.86
Std. Deviation	13.80	1.34
Range	58.36	5.45
Minimum	23.18	2.67
Maximum	81.54	8.12

The overall mean peak flow velocity was 44.9 cm/sec, with a range of 23.2-81.5.

The overall mean increase in peak flow velocity over baseline was 4.3 with a range of 2.7-8.1.

The mean rise time to peak was 0.54 seconds and SD .09 seconds.

The rise time to peak was 0.5 seconds for the majority (82%) of the participants, with a range of .25-1 seconds.

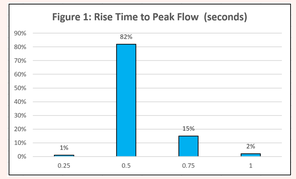

Table 5: Peak flow velocity, peak flow velocity over baseline, and rise time to peak flow by BMI group				
	BMI group	**N=20**	**Mean**	**Std. Deviation**
Peak flow velocity	18.5-24.9	5	38.3	7.2
	25-29.9	7	40.5	12.9
	30+	8	52.8	14.9
Peak flow velocity over baseline	18.5-24.9	5	3.6	0.8
	25-29.9	7	3.5	0.7
	30+	8	5.3	1.4
Rise time to peak	18.5-24.9	5	0.6	0.1
	25-29.9	7	0.5	0.1
	30+	8	0.5	0.1

The MAC System achieved **three times increase** or greater in peak flow velocity over baseline in all BMI groups.

A significant difference was found in peak flow velocity over baseline by BMI group.

Table 6: ANOVA Group Comparisons						
		Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
Peak flow velocity	Between	846.30	2.00	423.15	2.60	0.10
	Within	2770.58	17.00	162.98		
	Total	3616.88	19.00			
Peak flow velocity over baseline	Between	14.95	2.00	7.47	6.64	0.01
	Within	19.13	17.00	1.13		
	Total	34.08	19.00			
Rise time to peak flow	Between	0.00	2.00	0.00	0.01	0.99
	Within	0.15	17.00	0.01		
	Total	0.15	19.00			

Table 7: Post hoc Bonferroni							
	BMI Group		**Mean Difference (I-J)**	**Std. Error**	**Sig.**	**95% Confidence**	
						Lower Bound	**Upper Bound**
Peak flow velocity over baseline	18.5-24.9	25-29.9	0.09	0.62	1.00	-1.56	1.74
		30+	-1.71	0.60	0.03	-3.32	-0.10
	25-29.9	18.5-24.9	-0.09	0.62	1.00	-1.74	1.56
		30+	-1.80	0.55	0.01	-3.26	-0.34
	30+	18.5-24.9	1.71	0.60	0.03	0.10	3.32
		25-29.9	1.80	0.55	0.01	0.34	3.26

- Peak flow velocity over baseline was significantly higher in the 30+ BMI group as compared to BMI groups 18.5-24.9 and 25-29.9.
- There was no difference in peak flow velocity over baseline between BMI groups 18.5-24.9 and 25-29.9.

Conclusions

Participants were successfully recruited (N=20) among varied ages, genders, BMIs, and leg sizes.

Aim 1a. The use of the MAC System was associated with a mean peak flow velocity over baseline of 4.3, which achieved the goal of at least a **three times increase**.

Aim 1b. In 100% of the measurements, the MAC System had a rise time to peak flow of ≤1.0 seconds, with a mean of 0.54 seconds and low variability (SD=0.09 seconds), thus achieving the overall goal.

Aim 2. No differences were found in either peak flow velocity or rise time to peak between BMI groups.

- The MAC System achieved at least a **three times increase** in peak flow velocity over baseline across all BMI groups in a range of calf sizes from 30.8-54.1 cm.
- Although not significant, peak flow velocity trended up as BMI increased (38.3cm/sec-40.5cm/sec-52.7cm/sec).
- A significantly higher peak flow velocity over baseline in the 30+ BMI group was identified as compared to the other 2 BMI groups.

Areas for Future Study

- Although not significant, peak flow velocity trended up as BMI increased (38.3cm/sec-40.5cm/sec-52.7cm/sec). Thus, studies to better understand the reasons for higher peak flow velocity and peak flow velocity over baseline in the 30+ BMI group may be worth pursuing.
- Future studies should purposefully sample for subjects with a BMI of 18.5 or less to validate blood flow performance over baseline.
- Given the importance of mobility in DVT prophylaxis, especially in acute care, comparative effectiveness[5] studies on blood flow performance among the currently used intermittent pneumatic compression devices are needed.

References

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