Femoral Vein Blood Flow Velocities

INTRODUCTION

An important mechanism for the prevention of deep vein thrombosis (DVT) is the augmentation of venous blood flow in the lower extremities. Various studies indicate that both knee-high (calf-length) and thigh-high compression garments reduce the incidence of DVT; there is no clear indication as to which type should be used on patients.

External Pneumatic Compression (EPC) devices which consist of garments, which can be called sleeves, are manufactured from a combination of foam/fabric or plastic with non-woven liners or a combination thereof. The garments are designed to be wrapped around the lower extremity and secured with Velcro®. Depending upon the style chosen, a garment can be a calf or thigh length. The garment(s) are then connected to a pump that inflates and deflates bladders contained within the garment. Cycle times vary from manufacturer to manufacturer. Typically, the inflation cycle is 10-15 seconds with a 45-50 second “rest” before inflation resumes. The pumps run continuously and some inflate the left and right extremity simultaneously, while others cycle between the left and right leg.

External Pneumatic Compression of the lower extremity decreases venous stasis by increasing venous return through the deep veins of the legs. This augmentation of the venous blood flow is regarded as an important therapy for the prevention of (DVT). The therapy enhances blood flow clearance from the soleal sinuses, valve sinuses and axial veins. Studies have reported the femoral vein blood flow velocity that calf-high devices provide significantly greater peak velocity flow augmentation than thigh-high devices. To evaluate the augmentation of a new product, VasoPress®. Several different types of EPC devices were compared to the VasoPress to determine if there were any significant differences between calf, foot and/or thigh compression blood flow velocities.

THE STUDY

A duplex ultrasound-imaging scan by Sony was used to measure femoral venous blood flow. A male volunteer with no history of DVT, hypertension, diabetes, stroke, and vascular or cardiac pathologies was recruited for the study. EPC products used for the study were VasoPress by Compression Therapy Concepts, Flowtron DVT by Huntleigh Healthcare, ALP by Currie Medical and SCD by Kendall.

SUBJECT SELECTION

A normal adult subject, fulfilling the criteria listed below, was recruited to the study.
Age: Over 40 years Old
No History of DVT, Hypertension, Diabetes, Stroke, Vascular or Cardiac Pathologies

OBJECTIVE

To determine the femoral vein velocities in normal subjects using four types of External Pneumatic Compression Systems (EPC).
CONDITIONS

The studies were conducted at ambient conditions of room temperature and humidity. This data was recorded on the case report form for the subject.

PROCEDURE

The Femoral Vein Blood Velocity (FVBV) of one of the limbs of the subject was measured, non-invasively, using a Duplex ultrasonic velocity measurement system. The measurements were made according to the procedure that follows. The results were entered into a case report form. Measurements were made on the limb with and without the EPC device. The entire set of measurements for one subject was made in one continuous session.

DETAILED PROCEDURE

- Have subject lie supine with legs horizontal.
- Measure the FVBV on the chosen limb before placing the first EPC on the subject.
- Place the first EPC on the subject following specific instructions below.

CLINICAL PROCEDURE

Step:

1. Measure the FVBV on the leg before initiating the first cycle, keep the velocity detector in place and record the next sequence of events.

2. First Cycle (continuous Measurement of FVBV):
   a. Allow the product to achieve and maintain pressure beneath the garment/sleeve of 40 mmHg during the pressure phase.
   b. Allow the product to decompress.

3. Repeat step (2) for 10 cycles with first product while continuously measuring the FVBV.

4. Remove the first product and measure the FVBV immediately following removal.

5. Allow the subject to rest for 5 minutes.

6. Measure the FVBV at this time, and proceed to the next step if the velocity has returned to the baseline level measured in step (1).

Repeat steps (1) through (6) for the second, third and fourth products, using appropriate set-up procedures.
Methods of Evaluation:

The FVBV measurements were recorded on the case report form. Following tabulation and calculations the data was subjected to appropriate analyses to assess the difference in results obtained between the products.

Equipment

Duplex ultrasonic scanner with Doppler. Manufacturer: Sony Model: Acuson 128xp Serial Number: 0271

Case Report Form

The case report form was used to record the subject information, conditions of study, date/time of study, and FVBV measurements.

Record Retention

All originals of case reports, charts, data forms, computer tabulations and statistical analyses will be maintained in the files of Compression Therapy Concepts, Inc.

Results

<table>
<thead>
<tr>
<th>Product</th>
<th>Average Augmented Velocity</th>
<th>Base Velocity</th>
<th>Augmented Base</th>
<th>% Aug</th>
<th>Compression Stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>VasoPress Calf VP 501M</td>
<td>56.8</td>
<td>16.4</td>
<td>40.4</td>
<td>246</td>
<td>14.12</td>
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<tr>
<td>VasoPress Thigh VP 530M</td>
<td>62.6</td>
<td>26.3</td>
<td>36.3</td>
<td>138</td>
<td>9.29</td>
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<tr>
<td>VasoPress Foot VP 520</td>
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<td>3.6</td>
<td>11.9</td>
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<td>4.42</td>
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<tr>
<td>Currie Calf ALP 1</td>
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<td>Currie Foot ALP 11</td>
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<td>Flowtron Calf DVT 10</td>
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<tr>
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</tbody>
</table>

Calculations:

% Aug = Average Augmented Velocity / Std Deviation of Average Augmented Velocity

Compression Stability = Augmented Base / Base Velocity
CONCLUSION

The peak velocity augmentation with VasoPress was similar or better than the other models tested. This difference was not a non-parametric statistical procedure, which allows a distribution free inference, thus not assuming that the population distribution has any specific form was used in analyzing the findings. A risk of 0.05 was selected for determining statistical significance.

In conclusion, the aforementioned analysis found that the VasoPress was more stable and steady in application than the other products evaluated when measured by pressure or variability of pressure. Some products had higher pressure but much more variability. Measuring the peak compression velocity of the products, by relating it to the variability of compression, (Average Compression/Standard Deviation), not only does VasoPress show that in all categories the products evaluated are nearly equal to the VasoPress; however the VasoPress exceeds all the other products, except in one case, where VasoPress is equal to the other product. This could be interpreted to mean that VasoPress provides more consistent flows given the compression applied.

Respectfully Submitted,

Nabeel Kouka, MD, MBA
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