Reviewer's report

Title: Acute oxygenation changes on ischemic foot of a novel intermittent pneumatic compression device and of an existing sequential device in severe peripheral arterial disease.

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Reviewer: Ryan D. Sheldon

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In their manuscript titled “Acute oxygenation changes on ischemic foot of a novel intermittent pneumatic compression device and of an existing sequential device in severe peripheral arterial disease”, Manfredini et al. examined the acute effects of two IPC devices on limb hemodynamics and distal tissue oxygenation in patients with peripheral arterial insufficiency. This manuscript addresses a potentially important topic in that few studies have sought to examine effects of other combinations of compression characteristics (i.e. location, frequency, pressure, etc.) of IPC devices beyond the traditional 3s inflation/17s deflation at 120mmHg foot + calf devices. Additionally, the reviewer applauds the authors for examining a considerably heterogeneous clinical population, albeit the sample size is relatively small, and for examining phasic differences (i.e. inflated versus deflated phases) in their outcome measures for each treatment. However, while there is merit for studies in this area, a major limitation in the experimental approach, as is detailed below, cannot be rectified without repeating the experiments. Additionally, I have outlined other issues that the authors may choose to address going forward.

Major Compulsory Revisions

1. The major thrust of this manuscript is to compare the novel “GP” device with the traditional “SFC” device. However, as the authors state in the limitations section, treatment was performed in the supine position. The authors correctly recognize in the introduction that a major factor in the effectiveness of IPC devices in improving limb hemodynamics is the augmentation of the A-V pressure gradient. IPC accomplishes this by overcoming hydrostatic pressure to assist in venous outflow, subsequently increasing arterial inflow. In the supine position, hydrostatic pressure is virtually non-existent and there is this little impedance of venous outflow for the SFC device to overcome. That SFC devices do not augment arterial inflow in the absence of a hydrostatic column was shown to be the case by Dr. Van Bemmelen 20 years ago (J Vasc Surg 1994;19:1052–8), and virtually all studies on IPC devices as well as clinical practice employs treatment with the patient in the seated position for this reason. Additionally, in contrast to the statement in the introduction that current devices “are less effective in improving foot perfusion of ischemic limbs”, two recent trials with large sample sizes reported rather remarkable clinical improvements in patients with critical limb ischemia using traditional IPC devices in the seated
Thus, the conflicting findings between the current manuscript and other studies in the literature with regards to the effects of SFC are likely due to the supine position of the subjects in the current manuscript. In order to accurately compare the effects of GP vs. SFC IPC treatments it is essential that studies be repeated with subjects in the seated position to give a true comparison of the clinical utility between these two devices.

2. Blood pressure data was not reported. It is essential for interpretation of the current results that blood pressure data from before, during, and after the treatment, especially since the compression pressure of the GP device was apparently varied based on subject blood pressure. Additionally, it is conceivable that the greater amount of tissue compressed and the proximal application of the GC device relative to the SFC device could evoke central responses by affecting total peripheral resistance. It would be useful to include calculations of leg vascular conductance before, during, and after treatment.

Minor Essential Revisions.

1. There is considerable baseline variability, particularly in figure 3 and table 3. Because during treatment values are expressed relative to baseline it makes interpretation difficult. This might be expected in a clinical population such as this, however, what was inter-day variability in baseline measurements repeated on the same limbs? It may be of use to express the during treatment data as percent of baseline within each subject to control for inter-subject variability.

2. More information regarding the specifics of the GP device are needed. What is the size of the cuff? How proximal to the knee is it placed? The actual pressure used should be reported.

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests