FlowOx - A Novel Device for Improving Blood Flow to Ischemic Feet?

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Abstract

Mild negative oscillating pressure pulses (NPP) applied to a limb of a patient improves blood flow to the limb and to the skin. Patients suffering from peripheral arterial occlusive disease (PAOD) may benefit from a transient increase in blood flow to reduce pain and facilitate wound healing. A novel device (FlowOx™) has been developed, and tested on patients with reduced peripheral circulation. The NPP technology improved blood flow to the skin of the toes of patients with PAOD grade 2 or 3 (Fontaine classification) with about 60% (n=8, P<0.05).

Introduction

A new FlowOx™ boot and negative pressure pulse generator has been developed. The system is able to apply negative pressure pulses to the limbs of patients without the creation of pressure points. The experimental cycle consisted of 5 minutes of measurements without pulsing, followed by 5 minutes with pulsing before the final 5 minutes without pulsing.

Materials & Methods

Blood flow was measured using PeriFlux System 5000 laser Doppler probes. The system allows a non-invasive, continuous, real-time measurement of the microcirculation (small arteries, capillaries and small veins).

A clinical trial was performed on 8 patients selected according to the criteria in the table (right). 1

Results

Blood flow measurements from one patient using 3 probes placed at the calf (a), the foot (b) and on the toe (c, d) is the measurement of the pressure inside the device. The negative pressure pulses (-40 mmHg) lasted for 10 seconds with 7 seconds normal (atmospheric) pressure. Higher levels of negative pressure (-60 & -80 mmHg) was also tested but did not show a statistically significant increase in blood flow compared to baseline (data not shown). Changes in blood flow values in individual patients (measured on the toes). The median increase was 60% and statistically different from baseline measurements (p<0.05).

Further work must be done to evaluate if a transient increase in blood flow can induce long lasting benefits to the patients. It may be that transient increase in blood flow and oxygenation will improve wound healing, reduction in rest pain and potentially allow revascularization to occur. Further studies are warranted.

Discussion

The options for treatment of PAOD include medical treatment and intervention /revascualrization (endovascular angioplasty (PTA) or open reconstruction). Treatment also involve ambulatory exercise, modification of risk-factors such as smoking cessation, change in diet, medication etc. Endovascular treatment consists of angioplasty of obstructions, with or without concomitant stent-implantation. There are many patients, however, who are too fragile to undergo intervention/surgery or to do physical exercise. These patients could benefit from a device to be used at home to transiently improve blood flow and oxygenation of the skin.

Conclusion

NPP applied by a FlowOx™ boot may be used to enhance skin blood flow of the toes in patients with reduced peripheral circulation. There is also a trend (not statistically significant) towards increased circulation in other skin areas. Further studies need to be carried out to evaluate the effect of NPP in patients with reduced peripheral circulation. It will be important to look at long term effects to understand implication for wound healing.

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