

# The effects of intermittent negative pressure on macro-and microcirculation and functional exercise capacity: a single case report

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## Introduction

An 83-year-old Caucasian male, smoker, non-diabetic (Height: 170 cm; Weight: 75 kg; Waist-to-hip ratio: 1.02; BMI: 26). Previously he was an eager tennis player, but that last two years he had kept clear of the game due to intermittent calf pain bilaterally when ambulating. The right leg had been constantly worse with blue colour on his foot that did not disappear. The patient had no wounds or skin disease. We hypothesized that INP-therapy would increase macro-and microvascular capacity in the lower extremity exposed to INP therapy, and that this would constitute an improved functional capacity measured as walking performance.

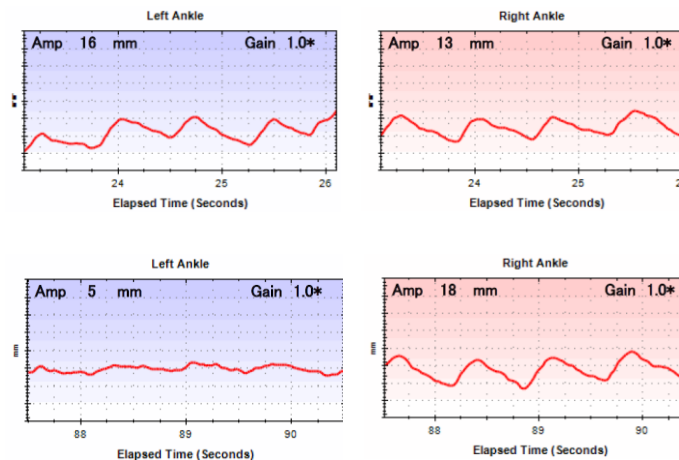
## Method

It was decided to offer the patient a 9-week course of intermittent negative pressure (INP) therapy, with a novel device indicated to improve macro-and microcirculation (FlowOx™, Otivio AS, Oslo, Norway). The patient was expected to adhere to a routine using the device at home for a 2-hour treatment broken into timed sections. He agreed to use the INP-device on his right leg only through the first nine weeks, using his contralateral leg as a control. Time was recorded on a USB provided with the device and monitored by the clinician. To test our hypothesis that if INP-therapy would enhance skin perfusion and walking performance we performed vascular and performance tests before (baseline) and after 9-weeks of INP-treatment. Skin perfusion pressure (SPP) and segmental pulse volume recording (SPVR) were measured using SensiLase PAD-IQ (Vasamed Inc., Eden Prairie, MN, USA). Additionally, ankle brachial index (ABI) was obtained using a small, lightweight, high sensitivity pocket 2 MHz Doppler probe (Ultra Tec PD1, United Kingdom). Lastly, functional exercise capacity was assessed outdoors using a 6-min walking distance test (6MWD)

on relatively level surface. The patients was asked to walk at his own maximal pace, covering as much ground as he could during the allotted 6-minute time. The same route was repeated after 9-weeks of intervention. To verify test results on the 6MWD, distance was monitored using a GPS device (Suunto, Ambit 3 Sport GPS watch, Vantaa, Finland) and Mobile GPS App (MapMyWalk, Under Armour, Inc., Baltimore, US), respectively, throughout the study period.

## Results

The patient used the INP-device for two-hours per day except two days he had to travel with his family. He continuous to smoke throughout the study time, and was pessimistic about his ability to improve his calf pain.



**Figure 1:** Pulse-volume recording in distal ankle. Upper figures denotes baseline recordings in left (control leg) and right leg (testleg). Lower two figures denotes SPVR measures after 9-weeks of INP-therapy.

**Table 1.**

Recorded scores	Week 0	week 9
SPVR <sup>a</sup> testleg (mm)	13.0	18.0
SPVR <sup>a</sup> control (mm)	16.0	5.0
ABI testleg (%)	56	59
ABI control (%)	67	60
6MWD (m)	460	490
Claudication time (min.sec)	1.35	1.57
SPP digit – Hallux testleg (mmHg)	45	118
SPP digit - Hallux control (mmHg)	75	132
SPP ankle – lateral testleg (mmHg)	74	109
SPP ankle – lateral control (mmHg)	78	25

a: SPVR: Segmental Pulse Volume Recording

b: SPP: Skin Perfusion Pressure

## Discussion

The patient adhered to a full 2-hour treatment with INP using it for 2-hours per day for 63 days in total. The test results demonstrated increased macrovascular (ABI, SPVR) and microvascular circulation (SPP) in testleg. However, the control leg also improved SPP in the hallux (posterior tibial artery's angiosome, while SPP decreased in the distal leg (peroneal artery's angiosome). The SPP values indicates that his arteries are not equally diseased. The lower SPP values is consistent with his left leg's reduced PVR measures. However, 25 mmHg is a low value, and indicates critical ischemia, which is not consistent with the patient's symptoms. The SPP data, therefore, suggest that the SPP data should be interpreted with caution. More importantly his functional exercise capacity improved, consistent with the aforementioned vascular tests. These overall results were consistent, and it is therefore likely that the improvements seen is due to the treatments itself. Interestingly the SPVR on his left leg (control) got worse through the study period (Figure 1).

## Conclusion

The results of 9-week INP therapy indicate that this may provide a valuable strategy for patients with peripheral arterial disease as prophylactic treatment of ischemic limbs and an alternative to vascular surgery.