How The ArtAssist Pneumatic Compression Device Can Heal Ulcers From Critical Limb Ischemia And Relieve Rest Pain Noninvasively

Andrew Nicolaides, MS, FRCS

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Hemodynamics of Intermittent Pneumatic Compression

In patients with occlusive arterial disease, ischemic rest pain and ulceration occur when tissue perfusion is reduced because of a low arteriovenous pressure gradient despite maximum arteriolar vasodilatation.

In a normal person, the arteriovenous pressure gradient (dP) in the horizontal position is the difference between the arterial pressure (e.g. 120 mmHg) and the venous pressure (e.g. 5 mmHg). In this case dP=120-5=115 mmHg. On sitting up, both the arterial and venous pressures at the ankle increase by an equal amount: the hydrostatic pressure, which depends on the height of the heart from the ankle (e.g. 60 mmHg). Thus, in the sitting position, arterial pressure will be 120+60=180 and venous pressure 5+60=65 mmHg. dP will remain the same: 180-65=115 mmHg.

The ArtAssist device takes advantage of the high venous pressure in the veins in the sitting position. It provides rapid compression of the foot and then the calf to 120 mmHg for three seconds. The rapid compression ensures that maximum pressure is reached within 300 ms. This is repeated three times every minute. This intermittent pneumatic compression empties the veins and in the presence of competent venous valves the venous pressure at the ankle is reduced to 15 mmHg. There is no effect on the arterial pressure which remains 180 mmHg. As a result dP becomes 180-15=165 mmHg. This increased dP results in increased arterial flow by 114%.¹

In an ischemic leg with an ankle pressure of 30 mmHg when measured in the horizontal position and with a venous pressure of 5 mmHg, dP will be 30-5=25 mmHg. In the sitting position both arterial and venous pressures will increase by the same amount: 60 mmHg. Arterial pressure will become 90 mmHg and venous pressure 65 mmHg. dP will remain the same: 90-65=25 mmHg. Application of intermittent pneumatic compression and reduction of the venous pressure to 15 mmHg will result in a dP of 90-15=75 mmHg and an increased tissue perfusion. In the study of Labropoulos² the application of the device in 20 limbs with critical limb ischemia demonstrated increased flow by 100% in the popliteal, 70% in the medial gastrocnemial and 55% in the genicular collateral arteries.

At this point another physiological mechanism comes into action. Increased flow in the arterioles and small peripheral arteries including collateral arteries stimulates the production of nitric oxide, MMPs, MCP-1 and other substances, and provided the stimulation is continued for several hours per day these vessels, particularly the collaterals due to remodeling enlarge and increase in number (angiogenesis).^{3,4}

Clinical Studies

Three randomized controlled trials have demonstrated that the use of the ArtAssist device for at least 3 hours per day in patients with intermittent claudication, doubled or trebled the claudication distance.⁵⁻⁷

Louridas performed a pilot study on 30 legs with critical ischemia (25 patients).⁸ Ten legs presented with rest pain and 23 with tissue loss. At a mean follow-up of 3 months 14 (42%) legs were amputated and 19 (58%) were saved. Eleven of the amputated legs were in patients with chronic renal failure. The amputation rate excluding this group was 13.6% (3/22). Toe pressures measured initially and after 3 months on the pump showed a significant improvement (P = 0.03). Forty percent of the patients presenting with rest pain improved while 26% of the foot ulcers healed. Mortality was 12%.

In a second study performed at the Mayo Clinic, Rochester, 107 patients with critical limb ischemia and active ulcers were treated at home with intermittent pneumatic compression.⁹ Ulcers were present in 101, previous amputation had been performed in 23 and diabetes was present in 60. Complete wound healing with limb preservation occurred in 40% of patients with transcutaneous PcO2 tension less than 20 mmHg, in 46% of those with diabetes on insulin and in 28% of those with previous amputation. The authors concluded that patients with critical limb ischemia and nonhealing wounds at high risk



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of amputation can achieve complete wound healing and limb preservation by using an intermittent pneumatic compression device.

A larger study by Sultan showed a higher limb salvage rate in 171 nonreconstructable limbs with more device usage of 6+ hours per day until ulcer healing, amputation or death.¹⁰ All patients were Rutherford category \geq 4. Mean toe pressure increased from 40 to 55 mmHg (P=0.0001) and mean popliteal flow increased from 35 to 56 cm/s (P < 0.001). Limb salvage at 3.5 years was 94%. Mortality at 30 days was 0.6%. The median cost of treating a patient with the ArtAssist device was 3,988 Euro.

Conclusion

Intermittent pneumatic compression with the ArtAssist device in limbs with critical ischemia increases tissue perfusion and produces relief of rest pain and healing of ulcers. The increased collateral circulation is maintained even when intermittent pneumatic compression is switched off. Within 3 months, the systolic ankle pressure becomes significantly increased. This method of treatment appears to be cost effective.

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