A Randomized, Placebo-Controlled Limb Salvage Trial Using the ArtAssist Pneumatic Compression Device

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Background: High pressure, rapid pneumatic compression of the foot, ankle and calf (the ArtAssist® device, ACI Medical, San Marcos, CA) has been shown to significantly increase popliteal artery blood flow and cutaneous blood flow to the foot in ischemic limbs. Recent randomized trials have shown that pain free walking distances and ankle/brachial pressures in patients with intermittent claudication have been improved significantly. Pilot studies have shown improvements in limb salvage with critically ischemic limbs but no randomized placebo-controlled trial has yet been performed to certify and quantify the effects on patients with rest pain and tissue loss. This study was designed to determine if the limb salvage rate is significantly improved in patients with critical limb ischemia over a two year period and to identify those patients that were better candidates for this therapeutic modality.

Materials and Methods: We performed a randomized, placebo-controlled, single blind study using patients with critical limb ischemia and nonreconstructable vessels. The experimental group received the ArtAssist pneumatic compression device that delivers high pressure (120 mmHg), rapid (0.33 second rise time) compressions to the foot, ankle and calf for 3 seconds with 17 seconds of virtually no pressure (three cycles per minute). There is a one second delay between pressures applied to the foot/ankle areas and the calf. The placebo device delivered a low pressure (20 mmHg) that was slowly reached over the three seconds of inflation. Otherwise, the timing of the placebo device was identical to the experimental device. Patients applied the device at home for one hour, three times a day. There were 84 patients with 99 critically ischemic limbs. Patients were assessed using toe pressures, ankle/brachial indices, transcutaneous oxygen pressures ($TcPO_2$) in both supine and sitting (dependant) positions. There were 28 patients with renal failure with 34 ischemic limbs and 56 patients without renal failure with 65 ischemic limbs. Patients were followed for 24 months.

Results: Nonrenal failure patients in the experimental group had a limb salvage rate of 86% compared with 32% in the control group ($p=0.014$). For those patients with renal failure, the limb salvage rates were 67% in the experimental group and 30% in the control group ($p=0.54$).

Conclusion: This form of external pneumatic compression significantly improves the limb salvage rate in nonrenal failure patients with nonreconstructable, chronic, critical limb ischemia. Limbs with TcPO2's that increase at least 15 mmHg from supine to sitting had the best prognosis for limb salvage.

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