

The ArtAssist[®] Device in Chronic Lower Limb Ischemia. A Pilot Study.

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Abstract

Patients with chronic critical limb ischemia following a failed bypass graft or with non-reconstructable distal disease diagnosed angiographically, have a very poor prognosis. This is a prospective pilot study to assess the influence of the ArtAssist[®] Device on pedal blood flow and amputation rate.

Thirty-three legs in 25 patients were evaluated. Ten legs presented with rest pain, and 23 legs with tissue loss. Nine legs had previously undergone bypass surgery. 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, a known risk factor. 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 patients presenting with rest pain improved, while 26% of foot ulcers healed on the pump. Mortality rate was 12%. The results from this prospective study are encouraging but need to be validated in a larger prospective randomized study.