

# Does Laser Treatment Have a Role in Lower Extremity Ischemia After All?

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## Purpose

Published trials on laser angioplasty for critical limb ischemia (LACI 21 and LACI Belgium2) point out the clinical efficacy of excimer lasering in lower extremity ischemia.

## Methods

The LACI 2 study enrolled, at 15 sites in the United States and Germany, 145 patients with 155 critically ischemic limbs (rest pain in 29%, ischemic lesions in 71%). Patients presented with severe and diffuse vascular disease typical of critical limb ischemia. In the 423 lesions, 41% were in the SFA, 15% were in the popliteal artery, and 41% were in infrapopliteal arteries. Further, 70% of the patients had a combination of stenoses and occlusions, making treatment very complex.

## Results

In-hospital serious adverse events (SAEs) were infrequent in this very fragile patient group. There were no deaths, perforations with surgical repair, or bypasses as a result of the procedure, and no patient had acute limb ischemia postintervention. SAEs during the 6-month enrolment period included 10% mortality which was almost exclusively owing to cardiac causes. Major amputation was required in 11 cases, whereas four limbs received surgical intervention. Endovascular reinterventions were performed in 24 cases, as could be expected given the complexity of the disease. However, of surviving legs, 69% improved in Rutherford Category, 27% maintained the same Rutherford Category, and only 4% declined. At 6 months, limb salvage was achieved in 93% of the surviving legs.

Based on the LACI 2 protocol, a prospective multicenter registry was set-up in Belgium to support the national device registration file. The LACI Belgium study enrolled 48 patients, which presented with 51 chronic critically ischemic limbs (Rutherford category 4, 5, or 6) and were poor candidates for bypass surgery. Risk-factor distribution was similar as the LACI 2 population.

After 6 months, a limb salvage rate of 90.5% was obtained (38 of 42 remaining patients). Six patients died, five because of cardiac disease and one from general systemic deterioration. Minor amputation, defined as an amputation of the distal or the mid-foot, leaving the patient with an ambulatory foot, was required in 6 patients throughout the follow-up period. Four patients needed a major amputation, defined as amputation at or above the ankle. Surgical intervention was given to two patients, and two patients received endovascular reintervention. Freedom from any of the above-mentioned adverse events was observed in 76% of surviving patients at the end of the 6-month follow-up period.

Allie and colleagues compared the cost-effectiveness of the current treatments in the US for CLI (infringuinal bypass surgery, PTA and primary amputation) with the use of the excimer laser for lower extremity ischemia treatment (based on LACI 2 results), and concluded that the utilization of a LACI pathway as first revascularization treatment strategy may provide clinical and economic cost savings in treating CLI patients.<sup>3</sup>

## References

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