

# One- to Two-Year Results with SilverHawk Plaque Excision in the Superficial Femoral Artery: Why This May Work Whereas the Old Atherocath and Other Techniques Have Failed

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## Background

Current nonsurgical interventions in peripheral arterial disease yield suboptimal long-term results. The superficial femoral artery (SFA), in particular, presents substantial treatment challenges owing to the myriad forces exerted upon it during normal leg movement. Regardless of treatment modality, high SFA restenosis rates are common. With the development of the SilverHawk Plaque Excision System, peripheral lesions can now be treated by precise removal of atherosclerotic plaque (Figure 1).

## Methods

From June 2003 to January 2005, 386 peripheral lesions in 220 patients were treated via plaque excision. Duplex ultrasonography, ankle-brachial index (ABI) measurement, and clinical evaluation were or will be performed at 1, 3, 6, and 12 months. One-year follow-up has been completed in 102 patients with 154 treated lesions. Here we present the 1-year follow-up data for the 104 (67.5%) SFA lesions.

## Results

Patient demographics included 50% with coronary arterial disease (CAD), 45% with insulin-dependent diabetes mellitus (IDDM), and 41% smokers. Thirty-eight percent of patients presented with rest pain and/or tissue loss (Rutherford Becker score 4, 5, or 6). Lesions included TASC ratings of A (23%), B (39%), C (28%), and D (10%). Forty percent of lesions contained moderate-to-severe calcification.

Technical success was achieved in 92.2% of SFA lesions as judged by < 20% residual stenosis. There were no major complications. Seventy-eight percent (81 of 104) of patients received stand-alone atherectomy. Adjunctive treatments included balloon angioplasty (22%) and stent placement (8.6%). Each procedure collected an average of 140 mg of tissue, with a range from 30 to 410 mg.

Primary patency determined via duplex ultrasound at 1 year was 86%. Mean ABI increased from  $0.52 \pm 1.4$  to  $0.68 \pm 2.0$ . Fifteen patients experienced restenosis/occlusion and were treated with repeat atherectomy plus PTA (2 patients), stent-supported angioplasty (9), or bypass surgery (4).

## Conclusions

Plaque excision achieved a high degree of patency in the SFA at 1 year. Further long-term follow-up and randomized trials that directly compare plaque excision with other treatment modalities are warranted. A detailed comparison of the old and new devices will be presented.