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Long-Term Evaluation of Percutaneous Directional Atherectomy

An interview with James F. McKinsey, MD, about the use of percutaneous directional atherectomy in 579 lesions in the treatment of lower extremity ischemia.

In the US population, more than 20% of individuals older than age 75 are affected by symptomatic peripheral arterial disease (PAD). Traditional treatment options for the two major PAD classifications, critical limb ischemia (CLI) and claudication, have included surgical bypass, endovascular therapy, or primary amputation. Based on his 15 years of clinical experience as a conventional open and endovascular vascular surgeon, Dr. McKinsey is well aware of the advantages and disadvantages of endovascular intervention versus that of open surgical bypass for symptomatic PAD. Due to the possibility of prolonged recovery times and the potential complications (eg, graft infection or thrombosis, distal embolization, and wound breakdown or infection) associated with surgical bypass grafting, Dr. McKinsey has adopted a philosophy of, when possible, using endovascular therapy first for the treatment of PAD. Evolving endovascular options, such as the SilverHawk directional atherectomy device (ev3, Inc., Plymouth, MN) introduced in 2003, offer a minimally invasive alternative that needed to be evaluated for long-term patency and limb salvage, the key measures for treatment success.

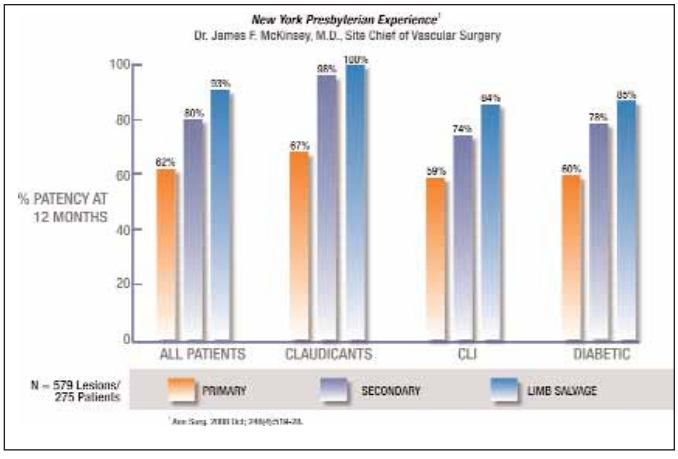

Figure 1. Primary and secondary patency and limb salvage data at 12 months.

From 2004 to 2007, Dr. McKinsey has maintained a prospective database of SilverHawk procedures, documenting the treatment of 579 lesions in 275 patients (a total of 364 interventions)—101 claudication patients (36.7%) and 174 CLI patients (63.3%). He recently detailed the long-term outcomes of these interventions with the SilverHawk peripheral atherectomy device in the October 2008 edition of *Annals of Surgery*, and he summarizes his experiences in this interview.

What were your objectives in evaluating the use of percutaneous atherectomy in 579 lesions with lower extremity ischemia?

Dr. McKinsey: Two key objectives at the center of any debate about optimal endovascular treatment of lower extremity PAD are long-term patency and limb salvage, especially in patients with CLI. In 2004, the SilverHawk atherectomy device presented us with a novel, minimally invasive endovascular alternative to the endovascular standard of angioplasty and adjunctive stenting. This directional debulking device has a small-caliber design with a high-speed carbide cutting disc capable of cutting long ribbons of obstructing atheroma and then storing them in the nose cone of the device for later removal. When we first started collecting the prospective dataset that ultimately included 579 consecutive percutaneous infrainguinal occlusive arterial lesions, the existing reports of short-term results of atherectomy involved only small numbers of patients with minimal follow-up. Evaluating these excisional atherectomy interventions over a period of 3 years as lead investigator collaborating with my colleagues helped us gain extensive experience with the device and support our findings with comprehensive data.

TABLE 1. PATIENT DEMOGRAPHICS

Characteristics		N (%)
Age		70+11.8 (range, 37–102 y)
Gender	Male	172 (62.5)
	Female	103 (37.5)
Risk Factors	DM	186 (67.6)
	CRI†	75 (27.3)
	HTN	231 (84)
	Chol	148 (53.8)
	CABG	70 (25.5)
	CAD	134 (48.7)
	CHF	70 (25.5)
	Hx MI	77 (28)
	Angina	30 (10.9)
	COPD	26 (9.5)
	Smoking	127 (46.2)
Indications	Claudication	101 (36.7)
	Rest pain	30 (10.9)
	Tissue loss	144 (52.4)
Number of lesions per patient		2.1+1.4

DM, diabetes mellitus; CRI, chronic renal insufficiency; HTN, hypertension; Chol, high cholesterol; CABG, coronary artery bypass graft surgery; CAD, coronary artery disease; CHF, congestive heart failure; Hx MI, history of myocardial infarction; COPD, chronic obstructive pulmonary disease.
†Serum creatinine >1.2 mg/dL.

What was the overall design for this 4-year prospective study?

Dr. McKinsey: From March 1, 2004 to the present, we have maintained a prospective database of patients treated with lower extremity percutaneous interventions including atherectomy with institutional IRB approval. Our institutional bias was to perform endovascular therapy first and then perform surgical bypass in those patients who repeatedly fail endovascular therapy. We included patients with claudication (101 patients or 37.7%) and limb-threatening ischemia (174 patients or 63.3%); cases of acute ischemia requiring immediate revascularizations and iliac lesions were excluded.

Lesions were considered successfully treated with peripheral directional atherectomy when there was less than a 30% residual restenosis. Patients requiring adjunct therapy, including balloon angioplasty or stenting, were classified as atherectomy requiring adjunctive angioplasty or stenting therapy.

All clinical data, operative reports, and procedural angiograms were reviewed independently by a dedicated research team that reviewed degree of stenosis, location of lesion, length, TransAtlantic Symptomatic Stenosis Classification (TASC), and procedural success.

Patient follow-up consisted of a standard protocol of 2 weeks after the procedure, followed by 3-, 6-, 12-, 18-month and then yearly follow-ups, which included physical examination, noninvasive vascular flow studies, pulse volume recordings (PVR), and arterial duplex evaluation. Arterial duplex ratios between 2.4 to 5.0 of the velocity of the proximal adjacent artery to the arterial lesion were considered to have a moderate degree of restenosis, with reintervention based on clinical symptoms. Patients with a ratio >5 were classified as having a severe restenosis and thus as primary failures. Patients with hemodynamically significant restenosis who underwent reinterventions with further atherectomy or other endovascular therapies were classified as secondarily patent. Patients requiring surgical bypass were considered endovascular failures.

Patency and limb salvage analysis was performed using SPSS V 16 for Kaplan-Meier survival analysis as well as Chi-square analysis.

Can you highlight the key findings derived from your prospective patient database?

Dr. McKinsey: We performed 375 primary, standalone atherectomies; 187 assisted atherectomies, of which 44 were stents and 143 were angioplasty; and 17 adjunctive atherectomies.

As shown in Table 1, our patient population included a

high incidence of diabetes, hypertension, chronic renal insufficiency, and smoking. The mean number of lesions treated per patient was 2.1±1.4 lesions. Mean follow-up was 12.5 months, with a range of 0.5 to 48.2 months. Classified by anatomic location as well as degree of stenosis, lesions included 199 superficial femoral artery, 110 popliteal, 218 tibial vessels, and 52 multilevel (femorotibial, femoropopliteal, or popliteal-tibial) vessels. Although there was no statistically significant difference between the primary and secondary patency of lesions based on location (femoral, popliteal, or tibial) and treatment, there was a significant difference in patients with extensive, multilevel disease.

Key patency results indicate that 18-month primary and secondary patency rates for all lesions were 52.7% and 75%, respectively. The 18-month primary and secondary patency rates for claudicants of 58% and 82.5% compares to 49.4% and 69.9% for CLI patients. The reintervention rates in claudicants were 25.3% and 30.1% for the CLI group.

Limb salvage was 100% in claudicants, with overall limb salvage of 92.4% per patient at 18 months. The 18-month 7.6% amputation rate using atherectomy compares favorably to the 16% overall amputation rate at 6 months observed for angioplasty and stenting versus bypass observed in the BASIL trial (Bypass versus Angioplasty in Severe Ischaemia of the Leg, a multicenter, randomized controlled study). Multivariate Cox modeling of risk factors revealed that location of disease and the presence of diabetes and chronic renal insufficiency were the only statistically significant predictor of decreased limb salvage.

Additional noteworthy findings are that of the 275 total patients treated with atherectomy, only 12 (or 4.4%) required surgical bypass, and no patients required an emergency bypass. Although 40 patients developed moderate stenosis by duplex evaluation, they did not undergo reintervention due to a lack of clinical symptoms. None of the patients who underwent surgical bypass had a change in the surgical bypass target vessel location because of the atherectomy.

Patients with claudication did very well with primary intervention with approximately a 60% patency at 30 months and 100% limb salvage, but the patency rate was increased to more than 80% with secondary endovascular intervention. These numbers are not dissimilar to those of surgical bypass with vein graft. For patients with CLI, overall patency was decreased relative to claudicants; however, secondary patency was 70%, and limb salvage exceeded 80%. This confirms that with continued follow-up and occasional minimally invasive reintervention, excellent long-term patency and limb salvage can be obtained.

The incidence of complications was very low, with the most common complication being local groin hematoma in 4.1%. The perioperative mortality rate was 1.1%, and the incidences of pseudoaneurysm, embolization, and thrombosis were each <1%.

What are your conclusions for using SilverHawk atherectomy to treat 579 lower extremity lesions?

Dr. McKinsey: In this largest reported series of percutaneous infrainguinal excisional atherectomies to date, as well as the longest follow-up, we demonstrated that these interventions are associated with a low periprocedural complication rate. Of the 29% of patients undergoing a reintervention, most were treated with endovascular techniques. An 18-month secondary patency rate of nearly 80% was observed in claudicants and 70% in CLI patients. The demonstrated limb salvage rate of >80% of patients with limb threat compares favorably to most surgical series with a lower instance of complications.

Our study demonstrated that percutaneous excisional atherectomy is beneficial in patients with multiple comorbitities and that, with this option, we can treat regions that may be hostile for other percutaneous interventions. It proved to be effective in the infrapopliteal regions, even in the diabetic patient population.

Based on the results of this prospective 4-year study, we believe that excisional atherectomy is an essential tool in the vascular surgeon's armamentarium. We demonstrated that this novel, minimally invasive, endovascular treatment option offers distinct advantages, such as the patient's ability to more rapidly return to normal activities, minimal morbidity, shorter hospital stays, and decreased hospital costs, as well as decreased wound and lower extremity complications.

We are continuing to follow these patients in this prospective registry to determine the longer-term 5-year results as well as performing subset analyses of the dataset to attempt to further define which patients will benefit the most from this novel endovascular therapy. Future studies in a prospective randomized fashion are being considered to further compare endovascular modalities.

The SilverHawk device was shown to be an effective endovascular therapy for patients with claudication and CLI with a low mortality rate, low complication rate, low amputation rate, and rare need for conversion to surgical bypass. ■

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Additional Reading: McKinsey JF. Novel treatment of patients with lower extremity ischemia: use of percutaneous atherectomy in 579 lesions. Annals of Surgery. *2008;248:519-528.*