### **Clinical Studies**

# Assisted Patency with Primary Stent Placement in Distal Anastomotic Stenoses of Lower Limb Bypass Grafts

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PURPOSE: To evaluate the feasibility and effectiveness of primary stent placement for treating distal anastomotic infragenicular bypass stenoses in terms of technical success and middle-term (2-year) patency rates.

MATERIALS AND METHODS: Twenty-one patients underwent primary stent placement for the treatment of distal anastomotic stenoses after infragenicular bypasses. Patients underwent clinical and color flow and duplex Doppler ultrasonographic (US) examinations 1, 3, 6, and 12 months after the endovascular procedure and every year thereafter if no complications occurred. Angiography was performed in patients with positive findings at the clinical and US examinations to evaluate the need for repeat endovascular and/or surgical treatment. The mean follow-up was 18.3 months (range, 2–30 months).

RESULTS: Twenty-two clinically significant (>50%) distal anastomotic stenoses were detected in 22 infragenicular grafts created in the 21 patients. The median time between endovascular treatment and surgery was 7.5 months (range, 3–18 months). The mean stenosis length was 1.4 cm (range, 0.8–2.4 cm). Twenty-four stents were implanted, two of which were used to treat restenosis immediately below the previously implanted stent. The technical success rate was 100%. No complications occurred during any of the treatments, and no periprocedural major events or complications were registered. At follow-up, the cumulative primary, primary assisted, and secondary patency rates for the treated graft stenoses were 95%, 95%, and 100%, respectively, at 6 months; 71%, 81%, and 86% at 1 year; and 71%, 76%, and 81% at 2 years. The limb salvage rate was 88%.

CONCLUSIONS: Although this study was limited to a small number of patients, stent placement seems to be a feasible and effective tool in the endovascular treatment of distal anastomotic infragenicular bypass graft stenoses.

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**Abbreviations:** ABI = ankle-brachial index, DSA = digital subtraction angiography, PTA = percutaneous transluminal angioplasty, PTFE = polytetrafluoro-ethylene

ACCORDING to recent therapeutic protocols and Transatlantic Inter-Soci-

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ety Consensus recommendations, the bypass graft is currently considered the most durable and effective therapy for limb salvage in patients with limb-threatening lower-extremity ischemia (1–3). Long-term follow-up bypass patency (3–5 years) varies from 51% to 75%, depending on the type of bypass performed (saphenous vein or prosthetic graft) (3–8).

During the 1st year after peripheral bypass, the risk of clinically significant stenosis is very high (9). Close bypass surveillance is therefore mandatory to detect graft stenosis, which, if uncorrected, can lead to graft occlusion. Although the accu-

rate and timely treatment of these lesions improves graft patency, an agreement about the selection of the optimal method of repair has not been reached.

Open surgical repair (patch angioplasty or short jump grafts) is an effective and durable treatment for infrainguinal bypass graft stenoses, with a technical success rate of 92% and patency rates ranging from 78% to 88% at 14 months (10–12). However, complex reconstructive techniques may be necessary to maintain graft patency and limb salvage.

Although percutaneous transluminal angioplasty (PTA) has been advo-

Table 1 Summary of Den	nographic and	Clinical Data		
Patient	Rutherford		Stent Size	
No/Sex/Age (y)	Classification	Details of Grafts	(mm)	Outcome after Primary Stent Placement
1/M/64	5	Left CFA to bPA (vein graft)	4 × 30	PTA performed at 9 mo for anastomotic intrastent restenosis. Patent at 24-mo follow-up.
2/M/71	4	Right CFA to ATA (PTFE graft)	$3 \times 18$	Patent at 24-mo follow-up.
3/F/68	4	Right SFA to bPA (vein graft)	$4 \times 24$	Died due to myocardial infarction at 2 mo.
4/M/65	4	Left CFA to TPT (PTFE graft)	$2.5 \times 18$	Patent at 24-mo follow-up.
5/M/81	4	Left CFA to TPT (vein graft)	$2.5 \times 18$	Graft occlusion at 4 mo treated with placement of a new stent. Patent at 24-mo follow-up.
6/F/74	5	Left CFA to ATA (vein graft)	$3 \times 24$	Graft occlusion at 8 mo treated with surgery.
7/M/73	4	Left CFA to bPA (vein graft)	$4 \times 18$	Patent at 24-mo follow-up.
8/M/78	4	Right CFA to PTA (vein graft)	$4 \times 30$	Patent at 24-mo follow-up.
9/M/63	4	Right CFA to PeA (vein graft)	$2.5 \times 18$	Patent at 24-mo follow-up.
10/F/62	4	Left CFA to PTA (vein graft)	$3 \times 18$	Patent at 24-mo follow-up.
11/M/65	5	Right CFA to ATA (vein graft)	$3 \times 24$	Patent at 24-mo follow-up.
12/M/68	4	Left SFA to bPA (PTFE graft)	$4 \times 18$	9 months: graft occlusion: below-knee amputation.
13/F/86	4	Right CFA to ATA (vein graft)	3 × 18	7 months: anastomotic restenosis: new stenting proced.
				15 months: graft occlusion: below-knee amputation.
14/M/69	5	Right CFA to PeA (vein graft)	$2.5 \times 18$	Patent at 24-mo follow-up.
15/M/65	4	Right CFA to TPT (vein graft)	$2.5 \times 18$	Patent at 24-mo follow-up.
16/F/55	4	Left CFA to bPA (PTFE graft)	$4 \times 30$	Patent at 24-mo follow-up.
17/F/89	5	Right CFA to PTA (vein graft)	$3 \times 24$	15 months: died (myocardial infarction).
18/M/76	4	Right CFA to PeA (vein graft)	$2.5 \times 18$	Patent at 24-mo follow-up.
19/M/74	4	Left CFA to bPA (vein graft)	$4 \times 18$	Patent at 24-mo follow-up.
		Left CFA to bPA (vein graft)	$4 \times 30$	Patent at 24-mo follow-up.
20/M/73	4	Right CFA to PTA (vein graft)	$4 \times 24$	10 months: intrastent restenosis: PTA: no relief of symptoms: surgery.
21/F/69	5	Right CFA to PTA (vein graft)	$3 \times 18$	Patent at 24-mo follow-up.

Note.—ATA = anterior tibial artery, bPA = below-knee popliteal artery, CFA = common femoral artery, PeA = peroneal artery, PTA = posterior tibial artery, SFA = superficial femoral artery, TPT = tibioperoneal trunk.

cated as an alternative to surgery, with an initial technical success rate of up to 87%, 1- and 2-year patency rates are only 29%–53% (9,13–15).

The aim of our study was to evaluate the feasibility and effectiveness of primary stent placement for the treatment of severe distal anastomotic infragenicular bypass stenoses in terms of technical success and middle-term (2-year) patency rates.

#### MATERIALS AND METHODS

From January 2000 to March 2003, 141 infragenicular bypasses (113 in situ saphenous vein grafts, 16 reversed saphenous vein grafts, and 12 composite grafts) were performed at our institution in 138 patients with ischemic limb disease. Our routine grafts surveillance program included clinical evaluation and color flow and duplex Doppler ultrasonographic (US) examinations 1, 6, and 12 months after sur-

	No. of Grafts*	No. of Vein Grafts	No. of PTFE Grafts
Bypass Configuration			
Femoropopliteal, below knee			
Femoroanterior tibial	4 (18)	3	1
Femorotibioperoneal trunk	3 (14)	3	0
Femoroposterior tibial	5 (23)	4	1
Femoroperoneal	3 (14)	3	0

gery and for every year thereafter if there are no complications.

The entire graft was scanned with US, and Doppler samples were obtained at 1–2-cm intervals. A stenosis was classified as clinically significant (stenosis >50%) at US if it had a peak systolic flow velocity gradient of at least 2.5. If clinically significant stenoses were suspected at clinical and US

examination, patients were scheduled to undergo arteriography to confirm the diagnosis of focal distal anastomotic stenoses.

All patients with a clinically significant distal anastomotic infragenicular bypass stenosis were enrolled in our study. Each patient provided informed consent before undergoing endovascular treatment. This study was

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