Midterm Results of Endovascular Treatment of Superficial Femoral Artery Disease with Biodegradable Stents: Single-Center Experience

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ABSTRACT

Purpose: To assess the midterm efficacy of a biodegradable poly-L-lactic acid (PLLA) stent in the treatment of superficial femoral artery (SFA) occlusive disease.

Materials and Methods: Between June 2009 and April 2011, 35 de novo SFA lesions were treated with 43 biodegradable stents. This nonrandomized, retrospective, single-center study included patients with moderate or severe claudication, lower-limb rest pain, or ischemic ulceration restricted to the toes; symptoms were classified as Rutherford category 2 (48.6%), 3 (37.1%), 4 (8.6%), or 5 (5.7%). The population included 28 men and had a mean age of 71 years (range, 51–81 y). Follow-up included clinical examination and color-flow duplex imaging. Mean follow-up was 38.3 months (range, 30–58 mo).

Results: Technical success was reported in all patients (100%). There were no intraoperative or immediate (< 30 d) complications.. During follow-up, one in-stent occlusion and seven in-stent restenoses occurred, all of which were successfully treated with percutaneous transluminal angioplasty. Primary and secondary patency rates were 77.1% and 97.1% at 24 and 36 months, respectively. No stent recoil or stent fracture was encountered. Late follow-up (> 12 mo) by ultrasound confirmed total reabsorption of the stent structures. Clinical improvement (ie, an upward shift of at least two Rutherford categories) was achieved in all 35 patients.

Conclusions: Midterm results for biodegradable PLLA stents for atherosclerotic SFA lesions were associated with high technical success and secondary patency rates, without stent recoil and vessel remodeling.

ABBREVIATIONS

ABI = ankle brachial index, CFD = color flow duplex, DES = drug eluting stent, PLLA = poly-L-lactic acid, PSVR = peak systolic velocity ratio, PTA = percutaneous transluminal angioplasty, SFA = superficial femoral artery, TASC = TransAtlantic Inter-Society Consensus

Despite encouraging early patency rates in the superficial femoral artery (SFA) with the use of nitinol stents (1,2) and more recently with drug-eluting stents (DESs) (3,4), the permanent metallic structure interacts with surrounding tissue and can cause physical irritation, long-term endothelial dysfunction, or chronic inflammatory reactions (5), resulting in inferior results compared with bypass surgery in the medium and long term (6,7,10,11).

The rationale for the implantation of fully biodegradable stents is to initially prevent immediate vascular recoil. Throughout follow-up, the mechanical stiffness reduces, enabling positive vessel wall remodeling. The biodegradable stent is designed to minimize pathophysiologic mechanisms of restenosis through its material properties (8–10). In the long term, the stent should be completely reabsorbed, thereby reducing the likelihood of late restenosis (11).

Most biodegradable stent research has been dedicated to coronary arterial treatment (12,13), with limited experience in the treatment of the SFA available in the

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Table E1 is available online at *www.jvir.org*.

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literature. In 2005, Biamino et al (14) reported the feasibility and safety of the Igaki–Tamai stent for SFA atherosclerotic disease at a mean follow-up of 6 months (14,15). The present study was designed to retrospectively assess the feasibility of biodegradable stent implantation in the treatment of SFA atherosclerotic disease on immediate and midterm follow-up at a single center.

MATERIALS AND METHODS

The treatment center's institutional review board approved the present observational, retrospective study. Between June 2009 and April 2011, 35 patients (28 men; mean age, 71 y; age range, 51–81 y) with moderate or severe claudication (Leriche–Fontaine classification IIB), lower-limb rest pain, or ischemic ulceration restricted to the extremity of the foot only (Rutherford categories 2–5) (16) were assessed for peripheral endovascular procedures. Patients with moderate or severe claudication underwent endovascular revascularization at their request for improved ambulation and/or quality of life. Patients with rest pain or ischemic ulceration to the extremity of the foot were advised to undergo revascularization.

Patient characteristics, comorbidities, and lesion classifications are outlined in **Table 1**. All patients were preoperatively assessed with color-flow duplex (CFD) imaging. Inclusion criteria for endovascular treatment with biodegradable stents was a de novo SFA symptomatic lesion ($\geq$ 60% stenosis or occlusion detected with CFD systolic velocity ratio measurement) with a patent popliteal artery free from significant stenosis ($>$ 50%) and at least one patent tibial artery extending to the foot, as confirmed by angiography. Patients were excluded if the lesions were 1 cm or less from the femoral bifurcation or 3 cm or less from the proximal margin of the intercondylar fossa, or if the presence of significant stenotic ($>$ 50%) or occlusive disease was noted in the inflow arteries.

Table 1. Patient Characteristics (N = 35)

Characteristic	Value
Age (y)	
Mean	71
Range	51–81
Male sex	28 (80)
Comorbidities	
Hypertension	30 (85.7)
Hyperlipidemia	21 (60)
Diabetes	8 (22.8)
Current smoker	12 (34.3)
CAD	16 (45.7)
Lesion classification	
Rutherford II	17 (48.6)
Rutherford III	13 (37.1)
Rutherford IV	3 (8.6)
Rutherford V	2 (5.7)

Values in parentheses are percentages.
CAD = coronary artery disease.

All vascular lesions were classified according to the recommended standards from the modified TransAtlantic Inter-Society Consensus (TASC) II (7) as type A (single stenosis $\leq$ 10 cm in length, single occlusion $\leq$ 5 cm) or type B (multiple stenotic or occlusive lesions each $\leq$ 5 cm or single stenosis or occlusion $\leq$ 15 cm not involving the infrageniculate popliteal artery). Lesion characteristics and classifications, arterial measurements, pre- and postoperative ankle brachial index (ABI) measurements, and distal runoff were recorded (**Table E1**, available online at *www.jvir.org*).

The biodegradable Remedy stent (Kyoto Medical Planning, Kyoto, Japan; **Fig 1**) is made of a poly-L-lactic acid (PLLA) monofilament and decomposes in the presence of oxygen through a series of spontaneous chemical reactions; the PLLA is transformed into carbon dioxide and water, in what is known as the citric acid cycle, over a period of 12–18 months. Radial strength is reduced within 6 months. Radiopaque gold markers, located at the proximal and distal ends of the stent and designed to facilitate identification of the stent extremities during placement, remain within the vessel and are incorporated into the arterial wall. The stent has a standard thickness of 0.24 mm (0.009 inches) and ranges from 36 to 78 mm in length and from 5 to 8 mm in width. The stent is mounted on a standard percutaneous transluminal angioplasty (PTA) balloon catheter fixed with a polytetrafluoroethylene clip positioned at the proximal end of the balloon. Stent

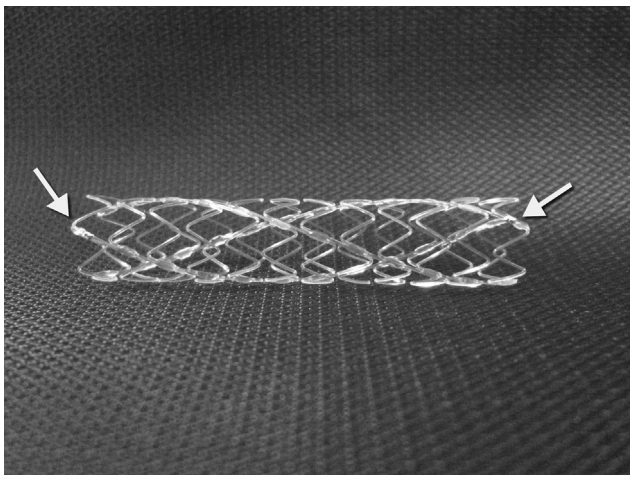

Figure 1. Macroscopic view of the Igaki–Tamai stent, a premounted, balloon-expandable PLLA stent that is also self-expandable with straight bridges and gold markers at both ends (arrows). The PLLA monofilament (molecular mass, 183 kDa) coil stent is designed in a zigzag helical structure. The PLLA decomposes in the presence of oxygen following implantation, over a period of 12–18 months. (Reproduced with permission from Kyoto Medical Planning).