

# Why Drug-Eluting Stents Are My Gold Standard

Experience with patients treated with Zilver PTX.

**WITH HIROYOSHI YOKOI, MD, AND FABRIZIO FANELLI, MD**

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Atherosclerosis is the leading cause of occlusive arterial disease, and the most frequently affected artery is the superficial femoral artery (SFA). Many authors have reported poor medium- to long-term patency in SFA angioplasty and stenting, although the immediate outcomes were generally satisfactory. Major progress has been made with endovascular therapy for the SFA, and improvements in devices and technology have resulted in an increase in the early-stage success rate, even with complex lesions. However, with bare-metal stents (BMS), there are high rates of restenosis in patients who have Transatlantic InterSociety Consensus (TASC) grade C or D lesions at least 15-cm long, suffer from microangiopathy or diabetes, are women, or are undergoing hemodialysis. In addition, if in-stent restenosis, whether occlusive or diffuse, develops, it tends to recur even if balloon dilatation is carried out, which presents major clinical problems.

Results of a randomized trial comparing the Zilver PTX drug-eluting peripheral stent (Cook Medical, Bloomington, IN) to bare-metal stents showed a patency rate of 83.4% (Zilver PTX) versus 64.1% (bare-metal stent).<sup>1</sup>

Zilver PTX, which was approved for clinical use in Japan in July 2012 and in the United States in November 2012, is the first drug-eluting stent (DES) for treatment of the SFA, and high expectations have been placed on its use for prevention of restenosis. DES present a novel treatment modality because of the inhibition of neointimal proliferation. The enthusiastic results of DES have led to widespread application of these devices.

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## SAFETY AND EFFICACY IN USING THIS DEVICE TO PREVENT RESTENOSIS

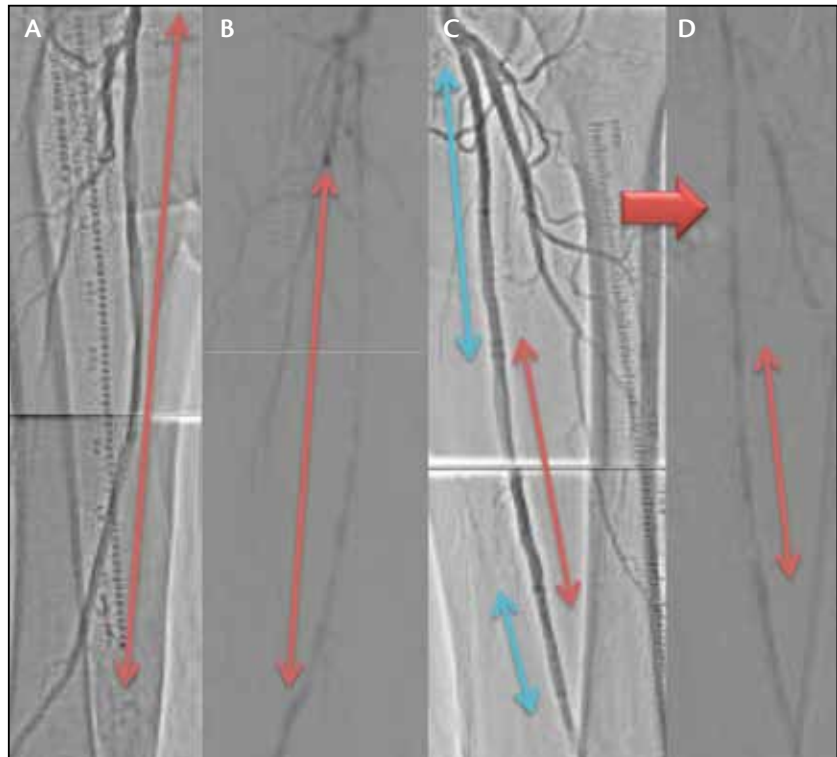
By Hiroyoshi Yokoi, MD



### CASE 1: BILATERAL SFA OCCLUSION

An 80-year-old man visited the hospital with bilateral intermittent claudication and was found to have bilateral complete SFA occlusion of TASC grade D. At that time (2011), the only types of Zilver PTX that could be used at Kokura Memorial Hospital in Japan were a pair of 6-F, 60-mm stents and a 6-F, 40-mm stent, which were not adequate for this case. Three 6-F, 100-mm SMART BMS stents (Cordis Corporation, Bridgewater, NJ) were inserted for the right complete SFA occlusion. For the left complete SFA occlusion, two 6-F, 60-mm Zilver PTX stents at a proximal position, a 6-F, 100-mm SMART stent at a central position, and a 6-F, 40-mm Zilver PTX stent at a distal position were used. The patient was then discharged.

After 8 months, the patient visited the hospital again due to recurrence of bilateral intermittent claudication, and angiographic assessment was repeated. The patient's estimated glomerular filtration rate was depressed (26 mL/minute), and angiography was carried out using carbon dioxide. There was diffuse in-stent restenosis with the BMS in the right and left SFA; with the DES, no restenosis was found at the distal position in the left SFA, and only localized restenosis was found at the proximal position (Figure 1). The pattern of in-stent restenosis in the SFA is closely connected to the prognosis,<sup>2</sup> and these findings showed not only lower rates of restenosis with DES than with BMS, but more favorable patterns of restenosis. ■



**Figure 1.** BMS (red arrows) after placement in the right SFA (A), showing diffuse in-stent restenosis after 8 months (B). Zilver PTX stents (blue arrows) and BMS after placement in the left SFA (C); at 8 months, findings show no restenosis in the Zilver PTX at the distal position and only focal restenosis (thick red arrow) at the proximal position, while diffuse restenosis (thin red arrow) was found in the BMS, which was placed centrally (D).

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## RESTORING PATENCY IN THE SFA

By Fabrizio Fanelli, MD



### CASE 1: SHORT SFA OCCLUSION

A 54-year-old man with life-limiting right claudication (< 50 m) presented with several risk factors: diabetes, heavy smoking (> 30 cigarettes/day), and hypertension.

In the previous 6 months, a progressive worsening of symptoms was observed. The patient was under medical therapy with statins, aspirin, and an oral hypoglycemic drug.

Clinical examination confirmed the pathological condition with an ankle-brachial index (ABI) of 0.4 on

the right side and 0.9 on the left. An ultrasound color Doppler (USCD) showed an occlusion of the middle portion of the right SFA. This was confirmed with selective digital subtraction angiography (DSA), which was performed via a contralateral retrograde common femoral approach (Figure 1A).

The occlusion was managed endoluminally with a standard 0.035-inch hydrophilic Glidewire (Terumo Interventional Systems, Somerset, NJ) in combination with a straight 4-F Beacon catheter (Cook Medical).

Due to the characteristics of the lesion (short occlu-

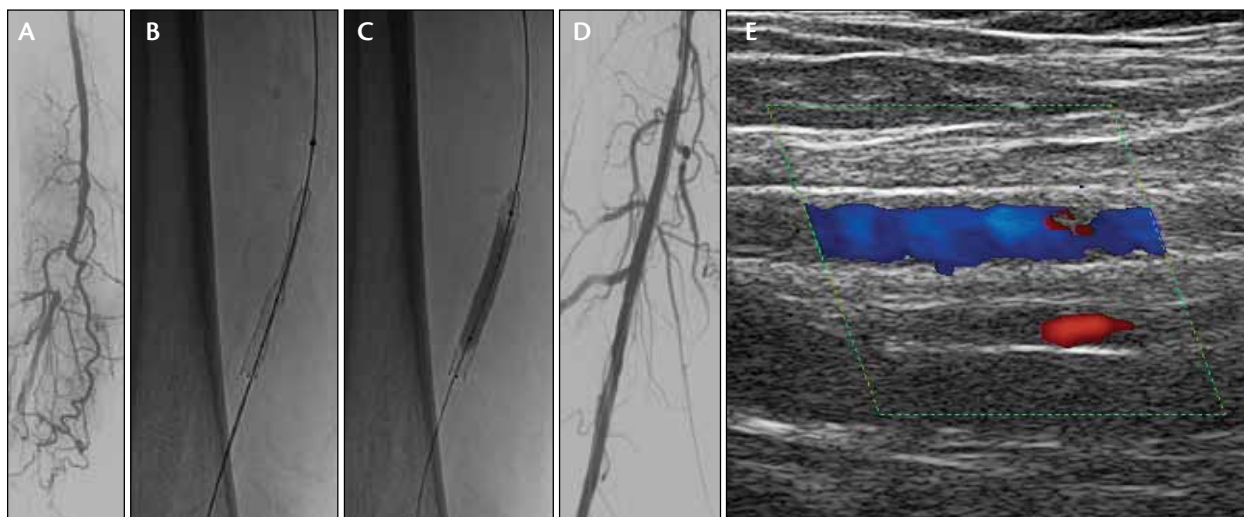


Figure 1. Occlusion of the middle portion of the right SFA (A). Insertion of 6-F, 60-mm Zilver PTX using a 7-F, 45-cm Flexor introducer (B). Postdilatation of Zilver PTX using a 5-F, 60-mm low-profile balloon (C). Final angiogram, showing good flow within the stent (D). USCD showing complete patency of the stent with no restenosis (E).

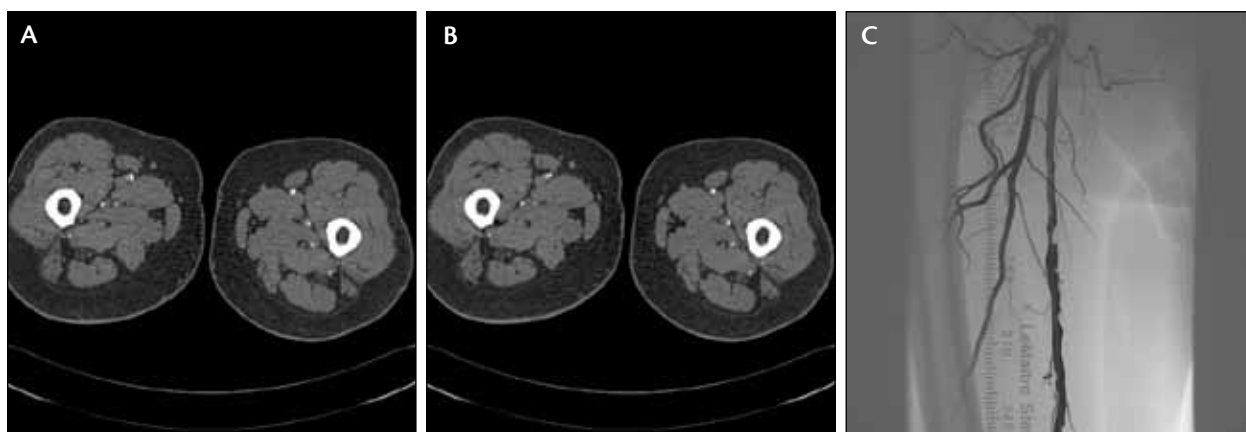


Figure 2. A preocclusive stenosis of the SFA was demonstrated on CT angiography on the axial plane (A, B) and DSA (C).

sion) and of the patient (young, with several risk factors), we decided to perform primary stent treatment. A 6-F, 60-mm Zilver PTX device was inserted through a 7-F, 45-cm Flexor introducer (Cook Medical) (Figure 1B). The stent was postdilated with a 5-F, 60-mm low-profile Admiral balloon (Medtronic, Inc.) (Figure 1C).

The final angiogram showed a good flow within the stent and in the distal portion of the leg (Figure 1D). Clinical conditions improved immediately, with an ABI of 0.9.

After 6 years of follow-up, the patient is still asymptomatic. USCD confirmed complete patency of the stent without any sign of restenosis (Figure 1E).

## CASE 2: MULTIPLE STENOSES IN THE SFA

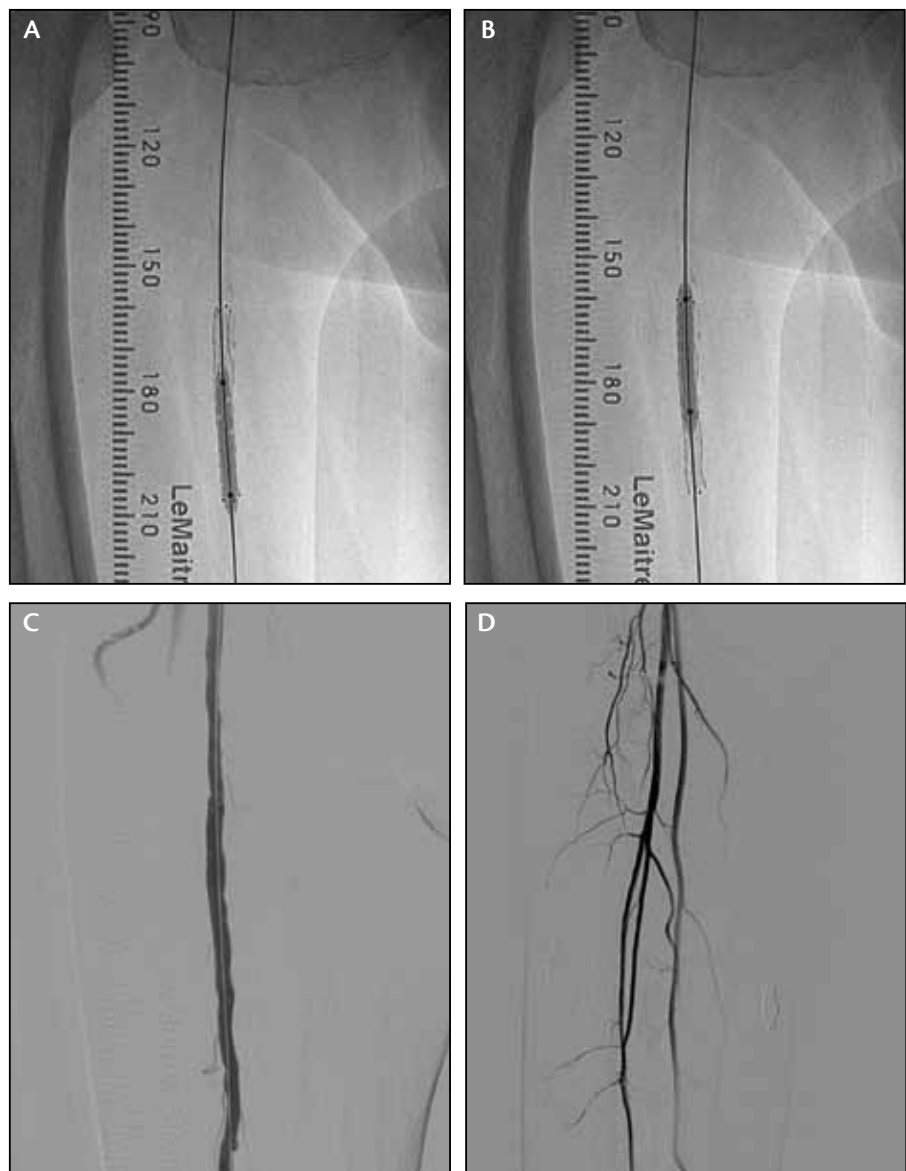
A 57-year-old male smoker with diabetes on medical therapy with aspirin, statins, and an oral hypoglycemic drug presented with severe right claudication (< 50 m) and multiple stenoses of the SFA.

Clinical examination showed an ABI of 0.4 on the right leg and 0.9 on the contralateral side. USCD showed multiple stenosis along the right SFA. CT angiography confirmed the presence of a severe preocclusive stenosis in the right SFA. On the axial images, the lesion appeared very calcified (Figure 2A and 2B).

DSA was performed with a retrograde contralateral femoral approach using a braided 6-F Ansel Introducer (Cook Medical). Selective angiography confirmed the preocclusive stenosis of the SFA (Figure 2C). The lesion was crossed with a hydrophilic angled 0.035-inch Glidewire (Terumo Interventional Systems) in combination with a 4-F straight Beacon catheter (Cook Medical).

Due to the high quantity of calcium at the level of the lesion, we decided to avoid angioplasty to reduce the risk of dissection. Primary stenting using a Zilver PTX (6 mm X 6 cm) was performed. The selection of Zilver PTX was based on the excellent long-term results reported in the literature, especially in cases of such young patients.

Predilatation was not necessary because the stent presents a very low profile in combination with good pushability. However, a balloon postdilatation (Cook Medical) was subsequently performed (Figure 3A and 3B). Final DSA confirmed complete patency of the stent, with an improve-



**Figure 3.** Postdilation of Zilver PTX performed with a low-profile balloon (A, B). The final angiogram showed a good flow within the stent (C) and an improved runoff (D).

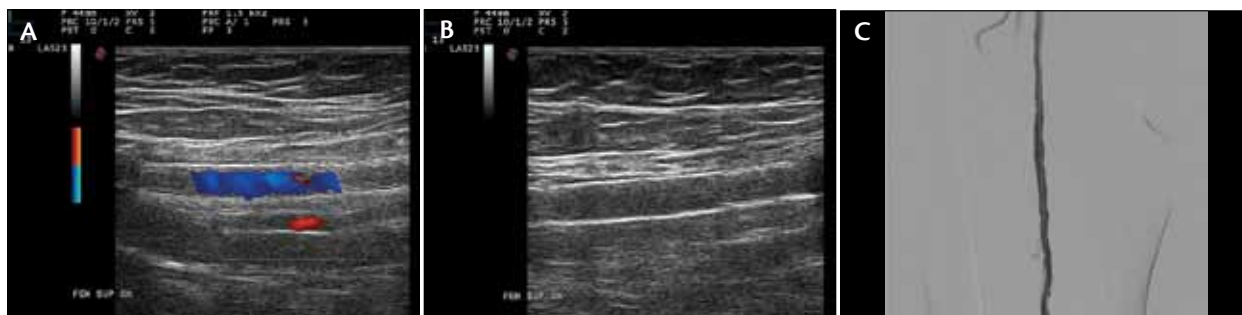


Figure 4. USCD at 3-year follow-up (A, B) and DSA at 5-year follow-up (C) showed complete patency of the Zilver PTX stent.

ment of the distal runoff (Figure 3C and 3D); ABI index improved up to 0.9. After the procedure, the patient was managed with clopidogrel for 2 months, followed by aspirin. USCD at 3-year follow-up showed complete patency of the stent. (Figure 4A and 4B).

Angiography performed at 5-year follow-up showed complete patency of the stent without any sign of intimal hyperplasia (Figure 4C). The patient's clinical conditions were good with an ABI index of 0.85 on the right side. ■

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#### Suggested reading:

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