

INITIAL CLINICAL EXPERIENCE IN AN AMBULATORY ENVIRONMENT WITH A SELF-EXPANDING BIDIRECTIONAL PERIPHERAL STENT

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INTRODUCTION

In the past 10 years, indications for endovascular treatment for the management of peripheral arterial disease have increased significantly. Endovascular treatment is associated with a reduction in perioperative morbimortality and length of hospitalisation.

The vascular surgery department of Nantes University Hospital in western France treats over 800 patients with infrainguinal lesions annually.

The strategy adopted in treating these patients depends on the status of the patient (claudication/critical/limb ischemia) of the lesion length (< or > 15cm) and the type of hospitalisation conventional/ambulatory).

Case 1 (moderate level of difficulty): Stenting of the right common femoral artery and recanalisation-stenting of the R superficial femoral artery

CLINICAL CHARACTERISTICS

Patient 44 years of age presenting severe claudication of the lower limbs, predominantly on the right (Class 3 according to the Rutherford classification). His only cardiovascular risk factor was continuing tobacco use. His principal medical-surgical antecedents aside from

his arteriopathy were a fracture of the right ankle and the removal of nine teeth, as well as a childhood fracture of the femur (unoperated). No allergies were found. The ultrasound and angiography scan were consistent and found, aside from right external iliac lesions, a right common

femoral stenosis combined with right and left femoral-popliteal thromboses. The distal networks were relatively well preserved. Indication of revascularisation of the R superficial femoral artery.

PROCEDURE

Dorsal decubitus. Local anaesthesia and sedation. Retrograde puncture of the left femoral artery, introduction of a 6F 45cm long introducer into the L common iliac artery.

Global arteriography of the aorta and the lower limbs, which established the absence of R and L external iliac lesions, a R common femoral stenosis of 80% (Figure 1), and a R femoral-popliteal thrombosis of over 20cm (TASC D) (Figure 2). The diameters of the right common femoral and superficial femoral were estimated at 7 and 5.6mm respectively.

Crossover with a 0.035, 260cm stiff guidewire and a UF5F catheter. Catherisation of R iliofemoral artery. The long introducer was placed in the first centimetres of the R common femoral artery.

Direct stenting of the deep common femoral artery with a 7-40mm PMSX stent (PEROUSE MEDICAL). Precise stent deployment using a pin-pull technique. Passage of the guidewire through the stent struts. Recanalisation of subintimal superficial femoral artery and re-entry into the mid-popliteal artery (P2). Direct stenting with two 6-100mm PMSX (PEROUSE MEDICAL) stents and a 6-80mm PMSX (PEROUSE MEDICAL) stent; using a 120cm delivery

catheter. Good pushability and trackability of the PMSX catheter. No resistance during the pin-pull deployment step. Remodelling with a 5-100mm balloon.

The arteriographic examination was satisfactory. The introducer was removed and manual compression was carried out for 10 minutes.

Procedure performed under heparin (50IU/kg) and antibiotic prophylaxis with Cefacidal.

Postoperative treatment with double anticoagulant (75mg/day aspirin and 75mg/day Clopidogrel) for 6 months, then Clopidogrel alone (75mg/day) permanently.

CLINICAL EXAMINATION AND ULTRASOUND IMAGING AT TWO MONTHS

Patient re-examined almost two months after endovascular revascularisation of the R lower limb. The patient was asymptomatic (Rutherford 0). Upon examination the patient had a small right retropliteal

hematoma with no severity criterion, probably due to the subintimal recanalisation of the right SFA. The ultrasound showed stents implanted on the right without thrombosis or restenosis.

Prescription of a double anticoagulant for a total period of 6 months, and an ultrasound examination every 3 months for the first year in order to detect the occurrence of restenosis or thrombosis.

CLINICAL EXAMINATION AND ULTRASOUND IMAGING AT 6 MONTHS

At 6 months, the patient was asymptomatic. The ultrasound showed no restenosis neither at the level of the implanted stents nor distally.

ARTERIOGRAPHIC ASSESSMENT

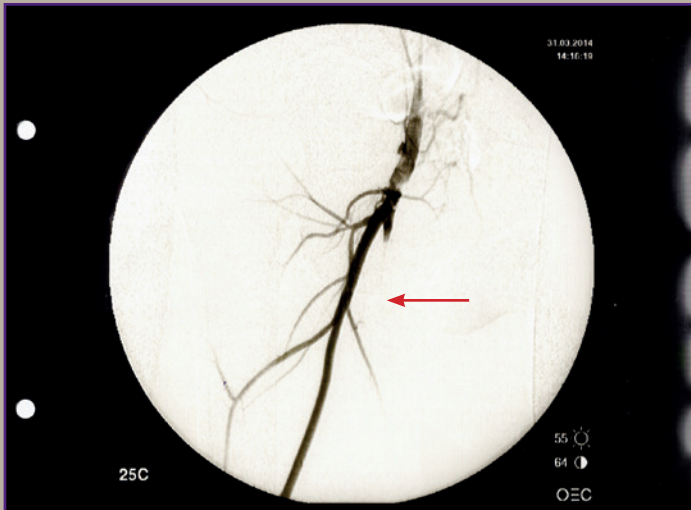


Figure 1

R common femoral artery stenosis of 80%



Figure 2

R femoral-popliteal artery thrombosis of over 20cm (TASC D)

FINAL ARTERIOGRAPHY

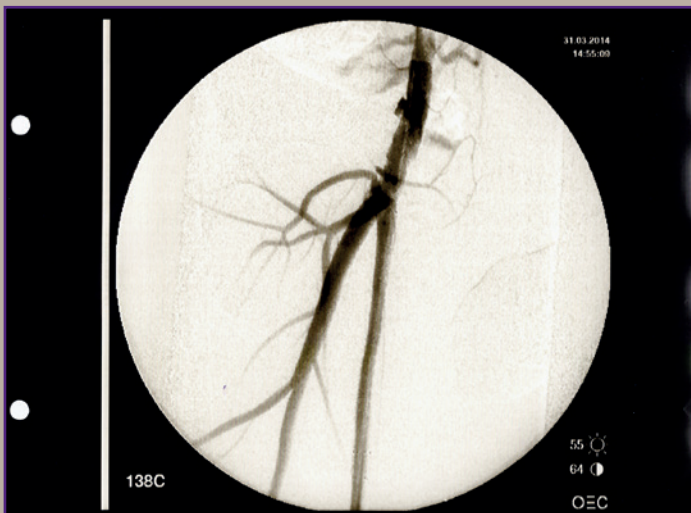


Figure 3

Permeability of the R femoral trigone

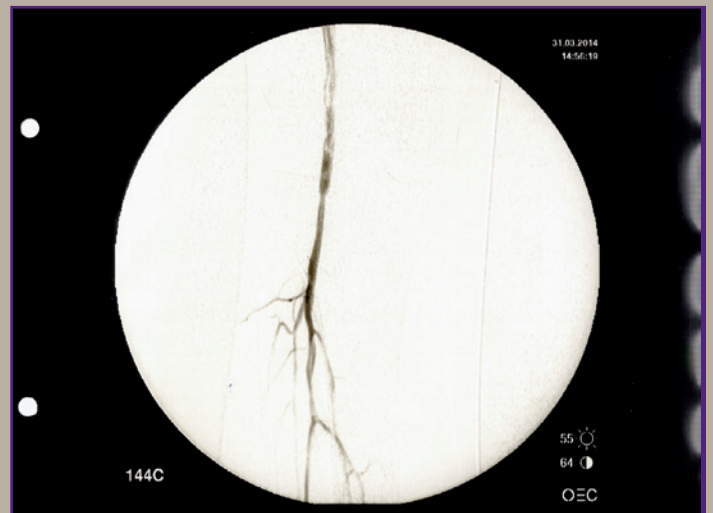


Figure 4

Permeability of the R femoral-popliteal axis

CONCLUSION

The catheter of the PMSX stent has a shaft length compatible with treatment of the superficial femoral arteries by crossover. The good pushability of the catheter justifies the absence of pre-dilatation of the lesion before stenting. The PMSX stent has remarkable stability at the time of implantation, allowing for high placement precision. Mid-term follow-up will tell us more about the risk of fracture in vivo of this latest-generation stent.

Case 2 (moderate level of difficulty): Recanalisation of common iliac artery and stenting of the right external iliac and superficial femoral arteries

CLINICAL CHARACTERISTICS

Patient 54 years of age presenting exertional ischemia in the lower right limb (Class 3 according to the Rutherford classification). His cardiovascular risk factors were treated hypercholesterolemia and continuing tobacco use estimated at 40 packs/year. His

principal medical-surgical antecedents were cardiac failure and ischemic cardiopathy with atrial flutter. Procedures on the right hip and the left knee were noted, without further specification. Ultrasound imaging and an angiography scan found thrombosis

of the right common iliac artery, explaining the patient's symptomatology. These lesions were amenable to ambulatory endovascular treatment.

PROCEDURE

Dorsal decubitus. Local anaesthesia and sedation. Retrograde puncture of the left femoral artery under ultrasound guidance. Introduction of a 6F-45cm long introducer into the L common iliac artery.

Global arteriography of the aorta and the lower limbs established R common iliac thrombosis, R proximal external iliac stenosis and superficial femoral stenosis in the proximal 1/3. The diameter of the right external iliac and superficial femoral were estimated at 6 and 5.4mm respectively.

Crossover with a 0.035-260cm stiff guidewire and a UF catheter. Recanalisation of R subintimal common iliac artery.

Catheterism of the right external iliac stenoses and right superficial femoral artery. The guidewire was positioned in advance in the popliteal artery. The introducer was positioned in the right common iliac artery.

We began with direct stenting of the superficial femoral artery by a PMSX (PEROUSE MEDICAL) 6-20mm stent (delivery catheter length of 120cm), which stent was remodelled by a 5-20mm balloon. Good pushability and trackability of the PMSX catheter. Precise deployment despite the short, narrow lesion. Then direct stenting of the right external iliac artery by a PMSX (PEROUSE MEDICAL) 6-40mm stent with

good expansion of the stent, which was remodelled by a 5-20mm balloon. Finally, a balloon expensible stent was chosen to perform direct stenting of the common iliac artery (7-40mm).

Arteriographic examination was satisfactory. Withdrawal of the equipment and puncture closure with a 6F closure system.

Procedure performed under heparin (50IU/kg) and antibiotic prophylaxis with Cefacidal. Postoperative double anticoagulant treatment (75mg/day aspirin and 75mg/day Clopidogrel) for 6 months, then Clopidogrel alone (75mg/day) permanently.

CLINICAL EXAMINATION AND ULTRASOUND IMAGING AT TWO MONTHS

Patient re-examined two months after right external iliac recanalisation and right femoral superficial stenting. Clinically, the patient was asymptomatic (Rutherford 0). The puncture points showed no complications.

Ultrasound showed good permeability of the iliac and femoral stents. It was noted however that there was a stenosis of over 50% on the right popliteal, but without clinical repercussions.

Prescription of a double antiaggregant for a total period of 6 months, and an ultrasound examination every 3 months for the first year in order to detect the occurrence of restenosis or thrombosis.

CLINICAL EXAMINATION AND ULTRASOUND IMAGING AT SIX MONTHS

At 6 months, the patient was asymptomatic. The ultrasound showed no restenosis at the level of implanted stents. De novo progressive stenosis of right external iliac artery was identified. Ultrasound examination will be performed at 12 months.



Preoperative angiography showing the common iliac, external iliac and superficial femoral lesions.

STENTING OF RIGHT SUPERFICIAL FEMORAL ARTERY

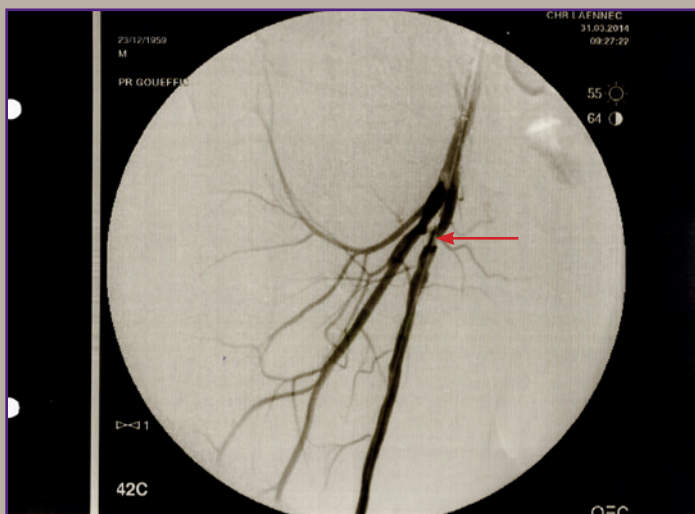


Figure 1
Before

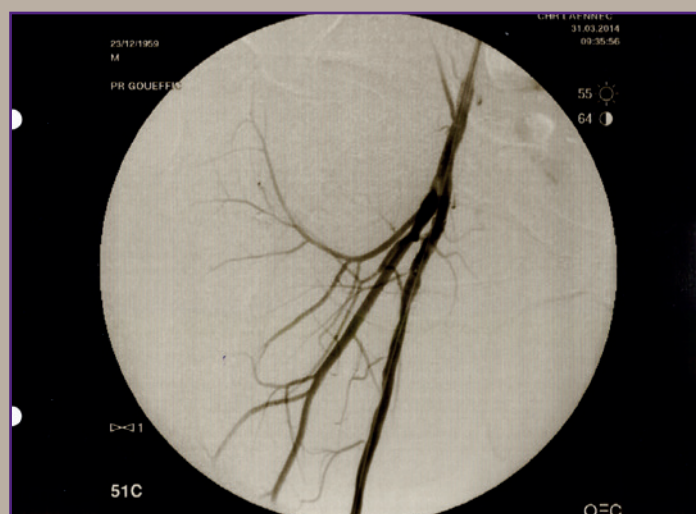


Figure 2
After

STENTING OF THE RIGHT EXTERNAL ILIAC ARTERY

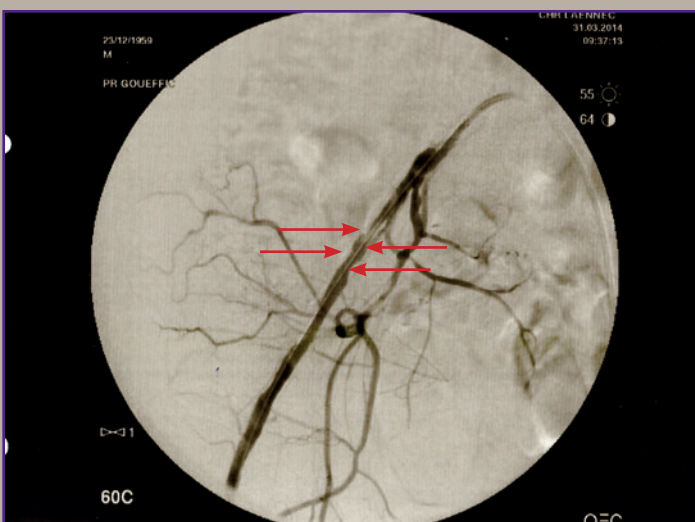


Figure 3
Before

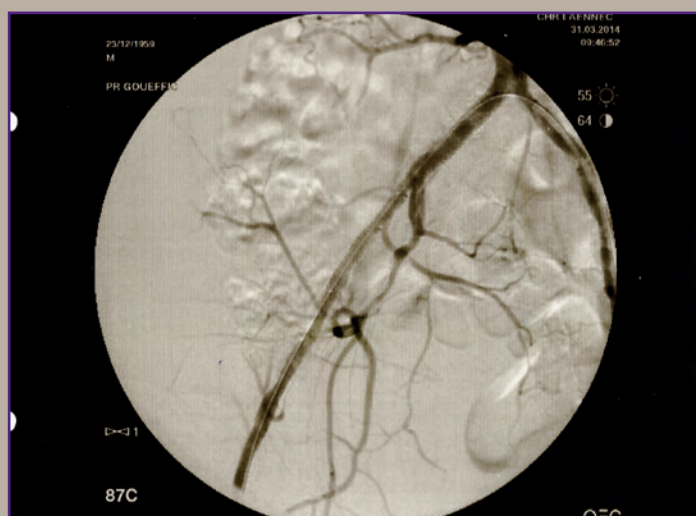


Figure 4
After

CONCLUSION

The PMSX (PEROUSE MEDICAL) stent has shown itself to be precise, with an effective radial force allowing treatment of superficial femoral and external iliac lesions, stenosing and occlusive lesions. The use of self-expanding stents is recommended in the external iliac artery because of the tortuosity of this artery.

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