

Long SFA occlusion treated with Luminor DCB and iVolution self-expandable stent (T.I.N.T.I.N. trial)

J. Verbist and **W. Van den Eynde**

Dept. Vascular and Thoracic Surgery

(Imelda Hospital, Bonheiden, Belgium)



K. Deloose - L. Mæene

iVascular[®]
therapies for living

Vascular Research Center Bonheiden

J. Verbist - W. Van den Eynde

Introduction

The effectiveness of drug coated balloons (DCB) to inhibit restenosis in symptomatic superficial femoral artery (SFA) lesions, has been proven in many studies. However, the longer and the more complex these lesions are, the more bailout stenting or spot stenting is necessary.

To evaluate the 12-month outcome of a combination therapy of long TASC C and D femoropopliteal lesions with Luminor DCB and iVolution stents of iVascular, a physician initiated, prospective, non-randomized Belgian multi-center trial (T.I.N.T.I.N trial) was started.

We present you a case to illustrate the combined use of Luminor DCB and iVolution self-expandable stent in a TASC D SFA lesion.

Patient profile

The patient presented in this case, was a 79-year-old male with severe bilateral claudication (Rutherford class 3). Cardiovascular risk factors were hereditary predisposition and with history of smoking.

Magnetic Resonance Angiography (MRA) revealed multiple stenosis in the proximal SFA of the right limb followed by a 10 cm occlusion of the distal SFA (TASC D). Also, the left SFA was occluded for almost 20 cm of length (TASC D). On both sides the popliteal artery and below the knee arteries were patent.

Patient consented to have endovascular treatment and, after successful treatment of the left leg, to be included in the T.I.N.T.I.N trial for treatment of his right leg.

Intervention and methodology

We used a retrograde access from the contralateral groin, introducing a 6 French 45 cm sheath over the aortic bifurcation. Angiography confirmed the findings on MRA.

The occluded segment of the SFA was successfully passed, using an 0.018" guidewire and a low-profile support catheter.

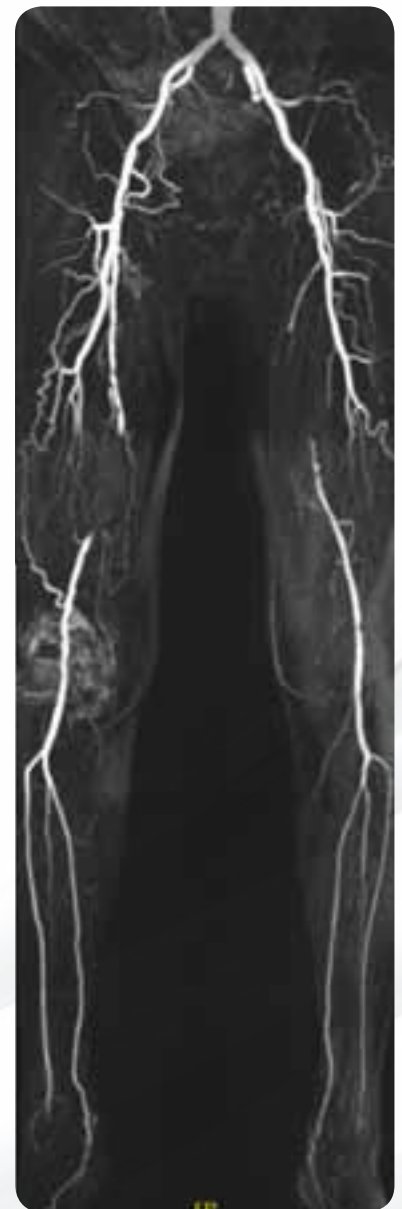


Image 1. Preoperative MRA

Pre-dilatation was performed with an Oceanus 18 PTA balloon dilatation catheter (Diameter: 4 mm/ Length:200 mm).



Image 2. Pre-dilatation with Oceanus 18

Subsequently, two Luminor 18 DCB (Diameter: 5mm/ Length: 200 mm and Diameter: 5 mm/ Length: 150 mm) were used to cover the entire affected SFA (inflation time: 180 sec/pressure: 7 atm).



Image 3. Luminor 18 DCB proximal

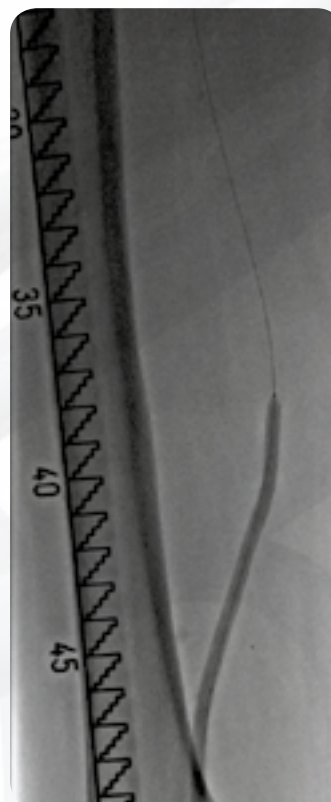


Image 4. Luminor 18 DCB distal

Angiography at this point already showed good run off, however with a long spiral dissection

Two iVolution self-expandable stents (Diameter: 6 mm/Length: 200 mm and Diameter: 6 mm/Length: 80 mm) were implanted, staying well within the boundaries of the arterial segment, treated with the drug eluting balloons.

After, a post-dilation was done with a balloon (Diameter: 5 mm/Length: 200 mm)

Angiography confirmed fully restored patency without distal embolization.

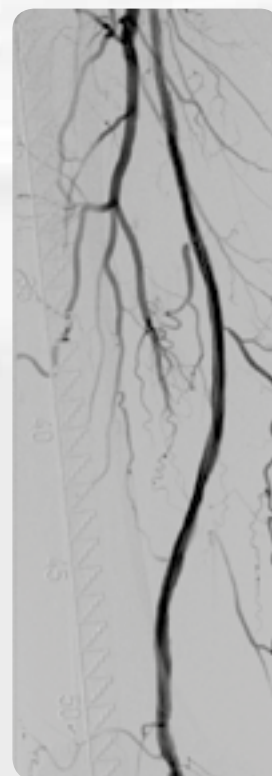


Image 5. Final result after iVolution self-expandable stent implantation

Result

Clinically, as well as on duplex scan, a perfect result was achieved immediately after the procedure and at 1 month. Further follow up, consistent with the trial requirements, has been planned.

conclusions

- This case illustrates the feasibility and safety of the combined use of Oceanus and Luminor balloons and iVolution stents in the treatment of TASC C and D SFA lesions.
- The long-term outcome will be evaluated in the T.I.N.T.I.N trial. Short term results however are very promising.