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Protocol adaptation of OCT in lower limb arteries revascularisation

- 2 M Dubosq¹, BO Patterson², R Azzaoui¹, T Mesnard^{1,3}, A De Préville¹, J Sobocinski^{1,3}
- 4 ¹Vascular surgery, Aortic centre, CHU Lille, France
- 5 ²St George's Vascular Institute, NHS Trust, London
- 6 ³Inserm U1008, University of Lille, France
- 8 Conflicts of interest:
- 9 J Sobocinski received speaker fees from AbbottVascular

11 Abstract

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- In lower limb arteries, assessment of stent apposition and/or the single opening of the diseased artery remains poor since this relies on 2D angiogram. Extrapolating experience gained with coronary arteries, optical coherence tomography (OCT) could provide 3D reconstructions of the arterial wall and the stent implanted. A modified protocol of OCT acquisition, which usually includes large amount of iodine contrast flush, is presented here in 3 patients with long and complex occlusion of the superficial femoral artery (SFA). Its potential benefits and wider application to improve patient outcomes are discussed.
- 21 Introduction:
- 22 2D angiogram is used to assess intraoperative results of balloon angioplasty and/or stenting.
- 23 It is probably an acceptable modality in short lesions but is not able to provide 3D
- 24 appreciation of long complex arterial lesions. This could contribute toward some early &

mid-term procedural failures¹. IVUS provides accurate intravascular evaluation of 25 inadequate stent positioning or significant recoil missed with 2D angiogram^{2,3,4}. Its use has 26 not been widespread so far mainly due to its unproven cost-effectiveness ⁴. 27 28 Optical Coherence Tomography is another endovascular imaging technique initially used in coronary arteries⁵. OCT is a recent technology for cross-sectional and 3D-imaging in 29 30 biological systems with ultra-high resolution approaching that of histology. It provides endoluminal images and controls spatial opening of the stenotic/occluded artery after 31 treatment. This lightening technology is based on echo lead-time measure and the intensity 32 of a coherent light source in the near-infrared region instead of acoustic waves in IVUS^{4,6}. 33 Study comparison (to IVUS) in popliteal and infrapopliteal vessels showed OCT provided an 34 35 excellent image quality and better visualisation of arterial wall layers of the different plaque components³. In coronary arteries, OCT seems even better in detecting stent malapposition 36 and edge dissections, but similar to IVUS in the assessment of lumen and stent dimensions⁵. 37 Two major limitations are usually described for arterial OCT in other situations: vessel 38 diameter >5mm⁴ & the need for iodine contrast injection to flush the artery for each OCT 39 acquisition^{4,7}. 40 41 Arterial lesions in lower limb may be up to 50cm long and maximum current length of OCT 42 probes available in one imaging run is 7.5cm, meaning the single final control would require 43 an unacceptable amount of iodine contrast. We proposed and validated an adaptation of the OCT protocol based on isotonic saline in 3 44 45 patients treated for critical limb ischemia with complex superficial femoral artery (SFA) 46 lesions.

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48 <u>Case</u>:

Three patients presented with TASC C (n=1) and D (n=2) lesions of the SFA were treated at Lille University Hospital on March 2018. Procedures were performed with flat-panel mobile detector (Elite, GE Healthcare). Parameters of the imaging system were configured to achieve a compromise between imaging quality and low radiation exposure. All procedures were performed under local anaesthesia with sedation. Controlateral puncture of the common femoral artery is our preferred option for SFA lesions. After placement of a 6Fr by 55mm sheath (Flexor Ansel-1, CookMedical) with US guidance, patients received 50UI/kg of heparin. Initial 2D cine fluroscopic run confirmed the lesions depicted with preoperative US and/or CTA. All lesions were successfully crossed using either .018" CTO wire in 2 or using a subintimal approach with .035" stiff hydrophilic guidewire in 1. Prolonged (>3minutes) and progressive balloon angioplasties (diameter 5mm) at 8atm were performed in all 3 patients. 2D-cine fluoroscopy and OCT acquisitions were then executed to evaluate the need of reballooning or stent implantation. OCT acquisitions require the use of OCT catheter (DragonFly Optis, AbbottVascular) and dedicated generator (Ilumien, AbbottVascular). The protocol of OCT acquisitions comprised a first step where the shaft of the catheter was flushed with 2cc of iodine contrast and then a second step where the treated segment of artery was flushed via an automatic power injection of 80cc of isotonic saline at 10cc/sec through the long sheath positioned just above the lesion to be evaluated. The OCT catheter was previously positioned at the level of the arterial segment being evaluated; it automatically detected the saline bolus arrival and launch the acquisition over a maximum length of 7.5cm segment. In both control imaging modalities further stenting was required in all patients due to significant recoil and focal occlusive dissection.

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- 72 A 6mm by 100mm ABSOLUTE stent (AbbottVascular) was implanted in patient with TASC C
- 73 lesion; 1 patient with TASC D lesions received a 5mm by 200mm SUPERA stents
- 74 (AbbottVascular) + 2 ABSOLUTE stents 6mm by 150mm proximally while the last patient
- 75 received 2 ABSOLUTE stents: 5mm-150mm and 6mm-100mm for long F1-F2 lesion. Post-
- 76 implantation balloon inflation of the ABSOLUTE stent (AbbottVascular) was systematically
- 77 performed but not for the SUPERA stent.
- 78 Final 2D cine fluoroscopy showed a good result with appropriate stent expansions (images)
- in all cases.
- New OCT acquisitions showed discrepancies in stenting results in 2 patients:
- 81 In the TASC C patient, appearance of stent malapposition of the ABSOLUTE stent at some
- 82 points and significant stenosis of the native proximal SFA that was thought to be free of
- 83 lesions were depicted. Additional stent implantation after balloon angioplasty of the native
- 84 proximal SFA and re-ballooning of the ABSOLUTE stent with a 6mm balloon were performed
- 85 [Figure 1].
- The one TASC D patient required re-ballooning of the ABSOLUTE stents [Figure 2].
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- 88 Median amount of isotonic saline volume injected per patient for OCT acquisitions was
- 400cc [400 to 480cc]. Median Iodine contrast (Xenetix 300mg/mL, Guerbet, France) volume
- 90 injected was 27cc [20cc to 40cc]; median Dose Area Product was 14mGycm² [8-21].
- 91 Procedural time was 115min [85 to 140min].
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- 93 The postoperative course was uneventful for all patients. Postoperative US duplex showed
- 94 excellent flow restoration within the femoro-popliteal artery in all 3 patients. Patients were
- 95 discharged under dual antiplatelet therapy for at least 2 months.

The 3-month follow-up visit exhibited good patency of the revascularised femoropopliteal segment.

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Discussion:

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The "gold standard" imaging control modality after endovascular revascularisation is 2Dangiography. Despite poor image resolution, 2D-angiography remains easy to use at low cost. The benefit of OCT technique in this setting would be to improve the accuracy and the quality of the initial revascularisation, since it visualises and characterizes the wall of the artery, visualising not only atherosclerotic plaque characteristics after stent implantation but also late restenosis phenomena⁶. Applications in the coronary arteries are well established but few authors reported its use in the lower limb^{5,8}. (Frequency-Domain)-OCT, used in the 3 patients described, is able to detect intimal tears and dissections after infra-inguinal angioplasty, which appears crucial for high-quality imaging in long segments of larger arteries, such as femoral arteries. Moreover, super-fast image acquisition helps to reduce the lead-time and flushing bolus required for blood replacement. Most of OCT acquisitions in the artery are frequency-domain based; reducing the noise and thus the definition of images provided. OCT requires intra-arterial injection of contrast agent to flush and clean the arterial lumen during data acquisition. This represents a huge limitation when the arterial segment treated is long. The use of Dextran and isotonic saline has already been proposed as an alternative to contrast agent to reduce nephrotoxicity⁸, but no practical details or results on their applicability and feasibility in clinical practice have been published so far.

Two main elements in the method here presented enable it to be achieved:

First, the use of automatic power injection able to standardise the rate and volume injected, then the placement of the long sheath close to the lesion and OCT probe avoiding flow dilution and reducing the remaining blood streaks. From our experience, the OCT acquisitions with hand-injected saline are not workable – the flow-rate and volume injected are too low and not good enough to clean the arterial lumen compatible with good OCT images quality. By extension, the amount of saline volume injected for the whole procedure due to OCT acquisitions could reach up to 1.5L for long SFA lesions and should be taken into account in patients with cardiac insufficiency – after discussion with the anaesthesiologist's team. Moreover, in our practice, we only flush catheters and sheaths with isotonic heparinised saline during procedure. In this specific setting, unprepared isotonic saline without additional heparin was used for OCT acquisitions to avoid massive anticoagulation of the

patient that would expose them to an excessive bleeding risk.

seen with the initial 2D angiogram or the preoperative duplex scan. This tool potentially helped to improve the outcomes of these patients by reducing the risk of postoperative early thrombosis; this also represent a valuable tool in determining the need for additional stenting and/or balloon angioplasty.

Although OCT is an expensive technique there is potential for preventing early postoperative failure and subsequent re-intervention. The protocol proposed in this work based on the injection of isotonic saline would extend its applicability to lower limb revascularisation. This could be worthwhile assessing as part of a prospective randomized study on clinical perspectives but also health economical aspects.

In these first 3 patients, OCT depicted defects in stent expansion and de novo lesions not

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Figures legend

Figure 1: patient with TASC C lesion; control OCT after initial stenting showed malapposition

of the laser-cut stent and stenosis of the proximal native artery (centre) missed with the 2D

cine fluoroscopic run (left). The final angiogram was satisfying (right).

Figure 2: patient with TASC D lesion; the distal part of the SFA received a woven self
expansible stent (left). The final OCT control before (left) and after (centre and right) a

second prolonged balloon angioplasty.



