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CASE SERIES
Structural intervention

Orbital atherectomy to facilitate transfemoral transcatheter aortic valve implantation in patients with calcified iliofemoral arteries: a case series

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Background The transfemoral (TF) approach drives most of the advantages of transcatheter aortic valve implantation (TAVI) over surgical aortic valve replacement. Alternative accesses for TAVI are associated with higher complication rates, but are still considered in ∼5% of cases due to peripheral arterial disease (PAD). Percutaneous transluminal angioplasty can still allow TF-TAVI in selected cases with severe calcific PAD; however, ancillary techniques for calcium management are often needed.

Case Summary Orbital atherectomy was selected to facilitate TF-TAVI in two patients with different degrees and aspects of calcific PAD. Pre-procedural computed tomography analysis was key to choose the most appropriate technique for calcium management. We describe our experience with a step-by-step procedural approach to orbital atherectomy-assisted TF-TAVI.

Discussion PAD is not uncommon in patients affected by severe symptomatic aortic valve stenosis. Orbital atherectomy can still allow TF-TAVI in selected cases with severe calcific PAD. A meticulous patient selection and a standardized, step-wise procedural execution are mandatory to optimize outcomes.

Keywords Transcatheter aortic valve implantation • Transfemoral • Peripheral arterial disease • Calcium modification • Orbital atherectomy • Case report

ESC curriculum 4.2 Aortic stenosis • 9.3 Peripheral artery disease

Learning points

- Use of the transfemoral route to perform transcatheter aortic valve implantation (TAVI) should be the preferred approach and is the main driver for lower morbidity and mortality in trials comparing transcatheter with surgical aortic valve replacement (SAVR).
- Calcific iliofemoral disease can be treated to make the iliofemoral route suitable for TAVI—hereby, choosing the most appropriate calcium modification technique is paramount.
- Orbital atherectomy can be applied for treatment of both concentric and eccentric calcified lesions that require calcium debulking and can as such expand indications for transfemoral TAVI.

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Introduction

Transfemoral (TF) access for transcatheter aortic valve implantation (TAVI) is the preferred approach for the treatment of severe aortic stenosis (AS) and is the main driver for lower morbidity and mortality in randomized clinical trials comparing transcatheter with surgical aortic valve replacement (SAVR).[1] TAVI by alternative access is associated with increased peri-procedural complications and worse clinical outcomes, which negate the benefits of TAVI over SAVR, and is also discouraged in current guidelines.[2–4]

However, not infrequently patients with AS may have extensive peripheral arterial disease (PAD), with 5% to 8% considered ineligible for safe TF-TAVI due to severe arterial calcification and a narrowed luminal diameter.[5] To render these patients suitable for TF approach, treating the diseased iliofemoral segments with percutaneous transluminal balloon angioplasty (PTA) alone is often inadequate and not safe (risk of vessel rupture, spiral dissection), particularly in the presence of severe arterial calcification. Hence, ancillary techniques for calcium management are required.

Intravascular lithotripsy (IVL) has been reported to be a safe and effective method to treat concentric calcifications in this context.[6] The

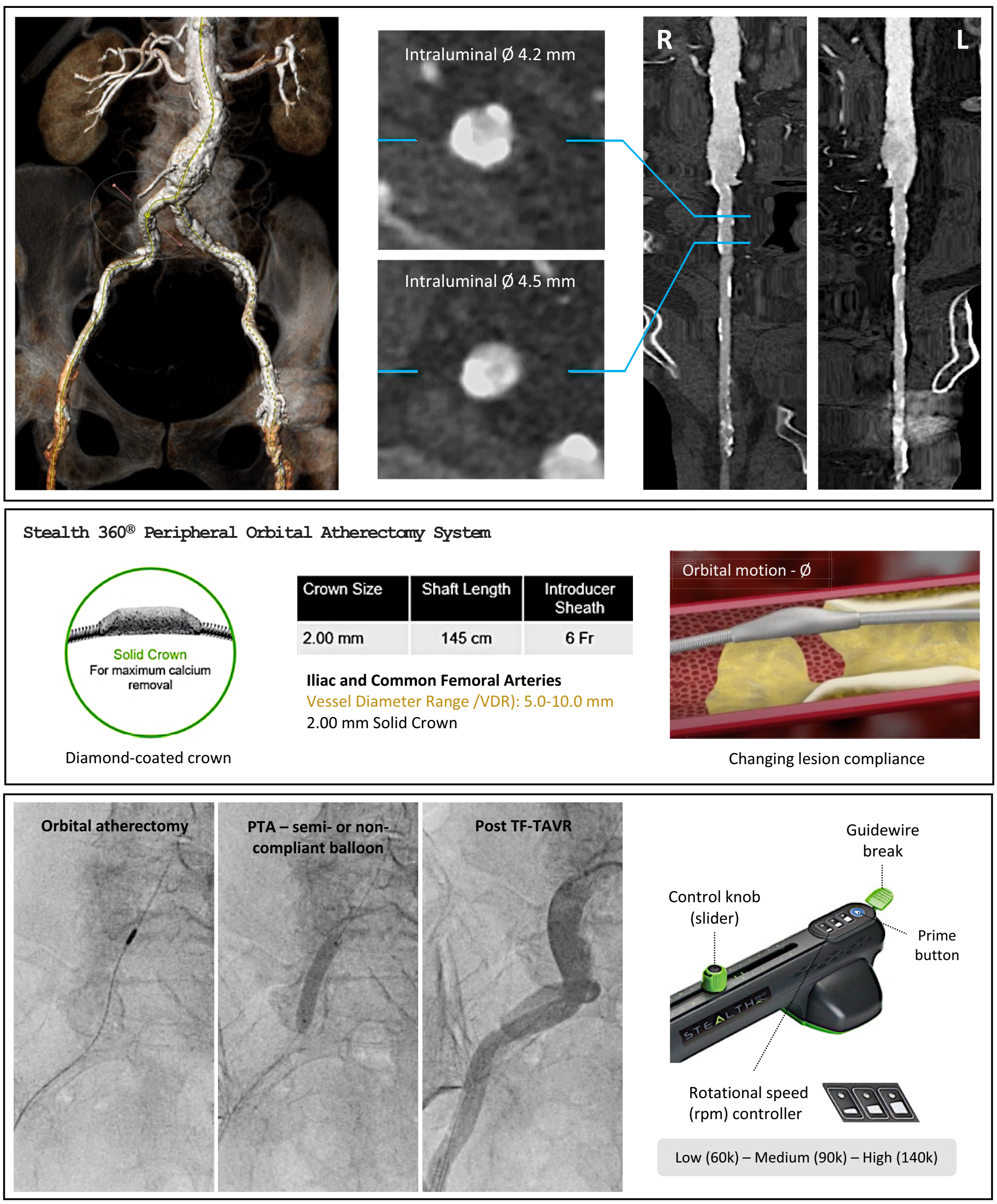

Figure 1 Timeline. Patient selection and execution of orbital atherectomy-assisted TF-TAVI. Upper panel: Preliminary computed tomography imaging showing severe bilateral iliofemoral calcific disease. Middle panel: Stealth 360® peripheral Orbital Atherectomy System (OAS; Cardiovascular Systems CSI, USA). Lower panel: Intraprocedural sequence of an OAS-assisted TF-TAVI case. Left to right: orbital atherectomy, balloon angioplasty, final result after TF-TAVI. PTA, percutaneous transluminal angioplasty; TF-TAVI, transfemoral transcatheter aortic valve implantation.

Procedural tips & tricks to enhance the safety and efficacy of Stealth 360-assisted PTA and facilitate large-bore access in calcified iliofemoral arteries

Access

- Arterial puncture of the common femoral artery (TAVR access)
- Pre-closure with Perclose ProGlide/ProStyle™ system
- Insertion of 8F introducer sheath

Target vessel wiring

- Either primary wire the iliofemoral artery with the ViperWire OR exchange for the ViperWire with a microcatheter (ViperWire 0.014'' body/0.018'' spring tip)

Orbital Atherectomy with Stealth 360

- Insertion of the Stealth 360 Peripheral Orbital Atherectomy System (OAS) with slow advancement and retraction of the crown (~3 cm forward and ~1 cm backward with continuous movement)
- Maximum of 30 seconds treatment per spin cycle
- Strong recommendation to start with low speed (60k rpm). Incrementally increase to medium speed (90k rpm) and high speed (120k rpm) only when there is no longer significant pitch/tone changes or tactile resistance
- The average is ~4-6 cycles at incremental speeds

Pauses/Rest – in-between spin cycles

- Rest times must equal or exceed spin times
- During the pause/rest cycles, push the blue Prime button on the device handle to increase flow of Viper-slide fluid. This helps to clear away particles/debris.
- Always pause in a patent area of the vessel. Do not start and stop within a tight lesion unless it has been treated and blood flow is not compromised

End of Orbital Atherectomy

- Stop orbital atherectomy when audible sound and tactile feedback suggest smooth system advancement
- Complete treatment of the target vessel with inflation of a non-compliant PTA balloon (7 mm) to maximize luminal gain

Insertion of large-bore introducer sheath

- Exchange the ViperWire with a 0.035'' stiff guidewire
- Introduce the large bore introducer sheath (14F-18F) on the stiff guide wire

Figure 2 OAS-assisted TF-TAVI. Procedural tips and tricks to enhance the safety and efficacy of Stealth 360-assisted PTA and facilitate large-bore access in calcified iliofemoral arteries. OAS, orbital atherectomy system; PTA, percutaneous transluminal angioplasty; TF-TAVI, transfemoral transcatheter aortic valve implantation.

generation of micro-fractures within the calcified segment increases vessel compliance and facilitates luminal expansion by PTA and subsequent safe TAVI delivery system advancement. In the case of presence of eccentric and/or intraluminal calcific disease, the fracturing effect of acoustic waves can be reduced and a debulking procedure by means of atherectomy may be required.[7,8]

We report on the first European experience with the Stealth 360® peripheral Orbital Atherectomy System (OAS; Cardiovascular Systems CSI, USA) utilized to facilitate TF-TAVI in two patients with severely calcified iliofemoral arteries, sharing a detailed procedural plan including tips and tricks to enhance the safety and efficacy of this procedure. The Stealth 360® peripheral OAS with a diamond-coated solid crown uses an off-axis centrifugal force to achieve 360°contact with the vessel wall and enables the differential sanding of calcium to facilitate debulking (*Figure 1*). The crown of OA presents diamond chips on front and back, allowing calcium ablation during both antegrade and retrograde motion and making crown entrapment or lodging unlikely. This risk may be considered higher in case of rotablation.[9]

Case 1

A 75-year-old patient with severe, symptomatic AS was referred for TAVI. A contrast-enhanced multi-slice computed tomography (MSCT) of the aorta and iliofemoral arteries showed severe bilateral iliofemoral calcific disease. The right iliofemoral artery was the least diseased, but showed eccentric calcifications at the level of the right common iliac artery and a residual lumen of 4.2–4.5 mm (*Figure 1*). The puncture site at the level of the common femoral artery (CFA) was relatively calcium-free. Orbital atherectomy with a Stealth 360® OAS 2.0 mm solid crown was performed. A detailed description of all procedural steps can be found in *Figure 2*. Several passages were required to cross the narrowest calcific arterial stenoses, with speeds of

Technologies to modify calcification and improve vessel compliance in preparation of TF-TAVR in cases with calcified iliofemoral access		
	Orbital Atherectomy 	Intravascular lithotripsy 
Mode of calcification modification	Calcium sanding + fracturing	Calcium fracturing
Type of calcification – Efficacy		
- Concentric calcifications	++	++
- Eccentric calcifications	++	+/-
Type of calcification – Efficacy		
- Intimal calcification/Intraluminal	++	++
- Medial calcification	-	++
Target vessel diameter	5 mm - 10 mm	up to 8 mm
Sheath compatibility	6F	7F
Wire	0.014''-0.018'' ViperWire™	0.014" coronary wire
Post-dilatation	Recommended (NC balloon)	Recommended (NC balloon)
Ease-of-use/time consumption	Ok/moderate	High/minimal

Figure 3 Technologies to modify calcification and improve vessel compliance in preparation of TF-TAVI in cases with calcified iliofemoral access. Comparison of orbital atherectomy and intravascular lithotripsy. NC, non-compliant; TF-TAVI, transfemoral transcatheter aortic valve implantation.

90 000 rpm ultimately achieving satisfactory calcium debulking. Following orbital atherectomy, the TAVI access vessel was protected by means of a contralateral 0.018 in safety wire. The diseased segment was further dilated using a 7 mm Z-MED® balloon (NuMED, USA). The ViperWire was finally exchanged with a 0.035 in stiff guidewire, on which a 14F expandable TAVI introducer sheath was advanced without difficulty. TF-TAVI was successfully performed with a Navitor 25 mm transcatheter aortic valve (Abbott, IL, USA). The large-bore access site was closed utilizing the ProStyle™ (Abbott, USA) closure system (*Supplementary material, Video 1*).

Case 2

A 79-year-old patient with severe AS was referred for TAVI. An MSCT scan demonstrated bilateral iliofemoral PAD with concentric vessel calcifications and a minimal residual luminal diameter of 4.5 mm, considered suitable for OAS-assisted TF-TAVI. The CFA puncture site was free from calcium. Stealth 360® OAS was performed and calcium debulking was achieved following multiple passages of a 2.0 mm solid crown at a maximal speed of 90 000 rpm. Subsequent to this, a safety wire was positioned through the contralateral access and further intraluminal expansion was obtained with a 7 mm Z-MED® balloon. This allowed the introduction of a 14F expandable sheath and permitted successful TF-TAVI with a Navitor 27 mm without vascular complications.

Both patients were mobilized and discharged homewards the following day. No vascular complications were reported after discharge.

Discussion

TAVI is best performed via the TF route for a multitude of reasons. First of all, clinical outcomes including mortality and major morbidities such as stroke, vascular complications and major bleeding are demonstrably lower in case of TF-TAVI as compared to non-TF-TAVI approaches.[1,2] Secondly, most TAVI are performed in conventional catheterization laboratories rather than hybrid rooms, where surgical assistance to support alternative access routes can be difficult. Thirdly, transaxillary or transcarotid access increases radiation exposure for the structural interventionalist and its team. Finally, the ability to perform TF-TAVI using a minimalist approach with local anesthesia or mild conscious sedation also mitigates the risk of post-procedural delirium. Efforts should therefore be made to pursue a TF-TAVI option whenever possible, and this without jeopardizing procedural safety.

Converting a hostile iliofemoral arterial access to one that allows the safe delivery of a transcatheter heart valve is an integral part of this strategy. To achieve this, adjunctive therapies to PTA are required in case of the presence of severe arterial calcification. While IVL has been used successfully to facilitate TF-TAVI in predominantly concentric calcified lesions, orbital atherectomy can be applied for treatment of both concentric and eccentric calcifications that require calcium debulking[10] (*Figure 3*).

When engaging in these more challenging TF-TAVI cases, it is strongly recommended to use a 0.018 in safety wire—either introduced from a contralateral or a lower ipsilateral arterial access. A safety wire can be useful to treat complications at the level of the IVL- or orbital atherectomy-treated segments and to bail-out vascular closure failures.

Finally, a control contrast angiography at the end of the procedure should also be encouraged in order to exclude important vascular injury at the iliac and/or femoral artery.

Importantly, a limitation of both IVL- and orbital atherectomy-assisted TF-TAVI is that the puncture site cannot be treated with either technique. Proceeding with TF-TAVI in case the puncture site is calcified or significantly diseased still carries a higher risk of vascular closure device failure.

Conclusions

Orbital atherectomy is a new tool in the arsenal to facilitate TF-TAVI in selected cases with calcific iliofemoral disease. A meticulous stepwise approach to this technique is paramount to its success.

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Supplementary material

Supplementary material is available at *European Heart Journal – Case Reports*.

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Data availability

The data underlying this article are available in the article and in its online *supplementary material*.

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