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Confined by the complexity of calcium?

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The evolution of peripheral Intravascular Lithotripsy

Marianne Brodmann (Medical University of Graz, Graz, Austria) gives an overview of recent data on Intravascular Lithotripsy (IVL), outlines early experience with the technology, and highlights key features of the new Shockwave M^{5+} IVL catheter.

CALCIFICATION HAS represented a big challenge in achieving optimal outcomes for patients with peripheral arterial disease (PAD). It has been noted in the literature that "peripheral artery calcification restricts vessel expansion, resulting in a higher residual stenosis that reduces procedural effectiveness."[1]

In terms of treatment options, researchers have found that percutaneous transluminal angioplasty (PTA) of calcified peripheral artery lesions can result in suboptimal vessel expansion, and that angioplasty of calcified lesions is associated with acute loss of patency. While plaque modifying devices such as atherectomy have been shown to improve lumen diameter and reduce bailout stenting, vascular complications and higher rates of procedural distal embolisation still persist, along with suboptimal patency.[2]

In 2017, I was introduced to a new technology that represented promise in addressing the shortcomings of existing technologies used for plaque modification and for treating calcified PAD: IVL. "IVL is based on the established therapeutic strategy of using acoustic pressure waves to treat renal calculi, with specific modifications in delivery to address vascular calcium," Dean J Kereiakes (The Christ Hospital and Lindner Research Center, Cincinnati, USA) *et al* detail. They note that these adaptations include the incorporation of lithotripsy emitters (a source of acoustic pressure waves) on the shaft of a balloon angioplasty catheter that deliver localised pulsatile acoustic pressure waves circumferentially to modify vascular calcium at low pressures of 4atm.[1] Acoustic pressure waves impact on both the superficial and deep calcium, changing vessel compliance and allowing for a safe and controlled luminal expansion.

Marianne Brodmann

Most recently, the PAD III randomised control trial sought to compare outcomes in patients with femoropopliteal artery calcification receiving vessel preparation with IVL or PTA prior to drug-coated balloon (DCB) for symptomatic PAD. Gunnar Tepe (RoMed Klinikum, Rosenheim, Germany) *et al* note that the trial enrolled patients with moderate or severe calcification in the femoropopliteal artery who underwent vessel preparation with IVL or PTA prior to DCB or stenting. The primary endpoint was core lab-adjudicated procedural success (residual stenosis $\leq$30% without flow-limiting dissection) prior to DCB or stenting. Procedural success was greater in the IVL group (65.8% vs. 50.4%; p=0.01) and the percentage of lesions with residual stenosis $\leq$30% (66.4% vs. 51.9%; p=0.02) was greater in the IVL group, while flow-limiting dissections occurred more frequently in the PTA group (1.4% vs. 6.8%; p=0.03). Post-dilatation (5.2% vs. 17.0%; p=0.001) and stent placement (4.6% vs. 18.3%; p<0.001) were also greater in the PTA group.[3] The one-year data from PAD III will be published during 2022.

In our early experience with IVL at the Medical University of Graz, we focused our application of the first generation M^5 IVL catheter (Shockwave Medical) to femoropopliteal lesions. It became evident that the technology had the capabilities of providing a solution for calcified PAD treatment in additional vessel beds such as below-the-knee disease, which led to the introduction of a dedicated product to treat infrapopliteal disease in the form of the S^4 catheter (Shockwave Medical). We also saw the application of M^5 expand into larger vessels, with utilisation in the common femoral and iliac arteries and successful outcomes achieved. In order to optimise outcomes in larger vessels, additional features were required to improve efficiency.

Shockwave Medical recently introduced the M^{5+} catheter. This incorporates new features to optimise outcomes and further the application of IVL within the peripheral vasculature, inlcuding:

- An expanded size matrix—The introduction of a larger 8mm balloon optimises treatment in larger vessels, giving physicians the ability to modify such vessels and reducing the need for adjunctive PTA to further luminal gain post-IVL. It may also reduce the need for adjunctive stenting.
- Faster pulsing—Increased pulse frequency (two pulses per second) reduces treatment cycle duration by 50% and thus improves procedural efficiency.
- An extended working length—The M^{5+} utilises a longer 135cm catheter shaft to broaden access options and cater for diversifying patient needs if upper extremity access is required.

In conclusion, I firmly believe the incorporation of these new features on the M^{5+} catheter will help expand the boundaries of how we tackle calcified PAD in our daily practice.

> **"The incorporation of these new features on the M^{5+} catheter will help expand the boundaries of how we tackle calcified PAD in our daily practice.**

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Removing the access barriers of calcium in EVAR with the Shockwave M5+

Emiliano Chisci (Ospedale San Giovanni di Dio, Florence, Italy) tells *Vascular News* that the Shockwave M5+ Intravascular Lithotripsy (IVL) catheter "should be the first-choice treatment" for a narrowed and calcified iliac axis in endovascular aneurysm repair (EVAR) and thoracic endovascular aortic repair (TEVAR) cases, exemplifying in particular the benefits of its extended size matrix in this case report.

OUR VASCULAR UNIT IS REGULARLY performing both open and endovascular procedures for abdominal aortic aneurysm (AAA) repair so we can tailor the procedure to each patient according to age, anatomical features and comorbidities.

Our rate of open versus EVAR is nearly 50/50. EVAR is preferred for high-risk patients when they are not suitable for open repair. We do not stress indications for one or the other technique and this is important to highlight in relation to our choice for the following challenging case treated by endovascular means. In our practice, nearly 10% of endovascular cases are made more complex by the presence of iliac calcification.

Herein we report the case of a patient considered at high risk for open (>6% risk for death and cardiovascular complications) with multiple comorbidities. The computed tomography (CT) scan showed a rapidly growing juxtarenal AAA of 56mm in diameter, occlusion of the right external iliac artery and a very tight stenotic left iliac axis. The referring symptom for this patient was the presence of severe claudication of the left leg. Due to the very high-risk profile, the therapeutic decision was for EVAR. The challenges for this case were the short, hostile neck and the very poor iliac axes: one occluded and the other one with multiple circumferential iliac stenoses greater than 80%. In some places, the patent lumen was less than 3mm, with severe calcification of the wall extending to the entire length of the left iliac axis (Figure 1).

> **"[The M5+] offers an extended size matrix with the introduction of an 8mm catheter to optimise the treatment of large vessels.**

Emiliano Chisci

For the short, hostile neck, a low-profile Alto graft (Endologix) was chosen. It was decided that the right occluded external iliac artery was not to be re-opened since it was clinically asymptomatic. The real concern was how to advance the graft (15Fr) through the left iliac axis if the lumen was in some places less than 3mm.

We needed to crack the calcium, change the vessel compliance and attain enough lumen expansion to make the delivery of the graft feasible without using a conduit, stent, stent graft or even the Dotter's manoeuvre, which significantly increases the risk of rupture in such a case due to the severity of the circumferential calcium. The solution we agreed upon was to use the Shockwave M5+ IVL catheter. Despite the graft being low profile (15Fr), we felt without the use of IVL we would not be able to attain enough lumen expansion to avoid adjunctive stenting. We believed the choice of IVL would allow us to safely fracture the calcium and then assess if percutaneous transluminal angioplasty (PTA) or stenting was required after the delivery of the graft, minimising the risk of complications such as the rupture of the iliac axis itself.

We decided to treat the iliac axis using primarily the 8x60mm M5+ IVL catheter, which is the newest catheter to be released by Shockwave Medical and offers an extended size matrix with the introduction of an 8mm catheter to optimise the treatment of large vessels. The catheter also features faster

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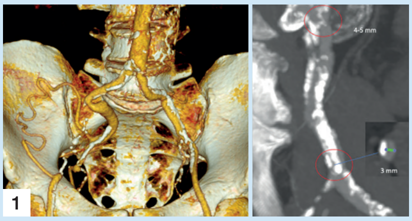

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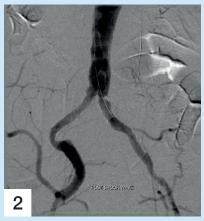

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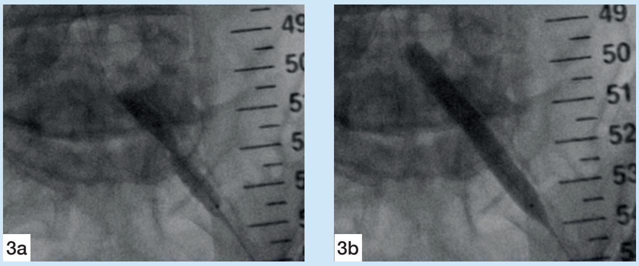

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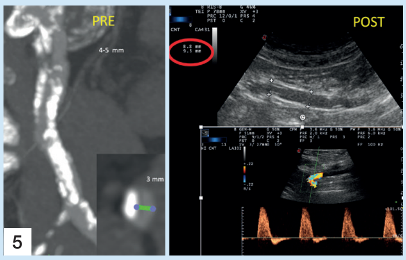

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1: Preoperative CT scan

2: Post-Shockwave CO2 angiography

3: (a) Configuration of the balloon at the first IVL inflation highlighting significant wasting caused by the extensive calcification; (b) Post-dilation with a 12mm PTA following graft implantation

4: Final CO2 angiography—Alto AB3480 main body, left limb Ovation iX (Endologix) 10x140mm from femoral access, right limb VBX (Gore) 11x79mm (x2) from brachial access

5: Preoperative CT scan compared to ultrasound imaging of the same left iliac axis; polyphasic velocimetry at the level of the left common artery

continued from page 3

pulsing to increase procedural efficiency, reducing treatment time by 50% when compared to the legacy M^5 catheter, and the longer shaft length extends access options. In fact, in this case we had the opportunity to use the brachial access from above if the femoral access was not feasible. We did not use pre-dilatation with a standard PTA balloon since we thought that, in such a calcified vessel, the risk of dissection was too high. We learned from our experience that some dissections can make the graft more difficult to advance without adjunctive manoeuvres such as stenting or stent grafting. The stenotic lesion was difficult to pass, even with a 0.014" wire. In our opinion, the 8mm M^{5+} IVL catheter used in this case has the best vessel apposition and the highest possibility to modify the compliance of the vessel in such anatomical features. A total number of 10 cycles of 30 pulses were administered at 4atm, covering the entire left iliac axis. The post-Shockwave CO2 angiography (Figure 2) showed patency of the iliac artery with a residual stenosis at the ostium of the common iliac artery. However, due to the modification and the change in compliance of the artery, the 15Fr graft was easily advanced through the iliac vessel without any issue.

The graft was then post-dilated with a 12mm standard PTA balloon in order to increase the graft wall adaptation (Figure 3). The final angiography done with CO2

Cracking the calcium conundrum: How the Shockwave M^{5+} can provide increased efficiency in challenging CLTI patients

In this case report, **Enrique Alejandre-Lafont** (Kantonsspital St Gallen, St Gallen, Switzerland) demonstrates how the faster pulsing of the new Shockwave M^{5+} Intravascular Lithotripsy (IVL) catheter has increased efficacy in challenging chronic limb-threatening ischaemia (CLTI) patients.

OUR MULTIDISCIPLINARY TEAM IS specialised in the treatment of peripheral arterial disease and in particular CLTI. As the complexity of endovascular procedures increases, so too does the need for functional solutions for the growing challenges of these procedures. One of the most challenging obstacles is the amount, distribution and consistency of the calcifications of the vessel walls, especially in total occlusions and high-grade stenoses.[1] Calcium plays a crucial role in the success and outcome of below-the-knee (BTK) interventions and is one of the biggest challenges in endovascular recanalisation. With increasing calcium burden, the outcome of an endovascular procedure is increasingly jeopardised, leading to higher rates of dissection, recoil and failed response to drug-eluting technologies.[2]
This is evident in the literature, but also our daily experience shows us that calcium has a significant influence on the outcome of an intervention, not only in terms of crossing and dilatation, but also in terms of patency and amputation-free survival. Therefore, effective techniques for the treatment of vascular calcifications are of essential interest and are subjects of current investigations, still failing to prove undisputed superiority over plain old balloon angioplasty.[3]

Enrique Alejandre-Lafont

A novel technique follows a different path in dealing with calcium. Intravascular lithotripsy (IVL) does not perform a substantial debulking and thus has not the inherent risk of substantial vessel trauma. Instead it focuses on a plaque remodelling to gain lumen and vessel compliance. Promising results have been recently published for the treatment of BTK atherosclerosis.[4] The technique and practical advice has been described in recent publications.[5]

"With the new M^{5+} catheter, the speed of pulse frequency has doubled, halving IVL therapy delivery time by 50%."

We here describe the case of an 82-year-old woman with CLTI in the left leg. Initial angiography depicts a severely calcified occlusion distal of the P3 segment of the popliteal artery with complete occlusion of the anterior tibial artery, the tibioperoneal trunk, fibular tibial artery and posterior tibial artery (Figure 1).

The intervention was performed under local anaesthesia and via antegrade access in the left groin. After sonographic-guided infiltration with 10cc of lidocain 1% the common femoral artery was punctured and, via sonographic guidance, a 6Fr Terumo (10cm) was inserted using the Seldinger technique. Angiography revealed generalised severe calcific arteriosclerosis without relevant stenoses in the common femoral artery, APF, superficial femoral artery and P1 and P2 segments of the popliteal artery. The culprit lesion was localised in the proximal part of the distal lower limb. The foot showed a three-vessel runoff, so that all three vessels were classified as target lesions. After application of 5000IE of heparin the occlusions were crossed with an 0.018 Advantage guidewire (Terumo) and a pre-dilatation with a 2x40mm Sterling balloon (Boston Scientific) was performed to facilitate the delivery of the Shockwave catheter. After switching to a 0.014" V14 wire (Boston Scientific) a 4x60mm Shockwave M^{5+} IVL catheter was inserted. With the new M^{5+} catheter, the speed of pulse frequency has doubled, halving IVL therapy delivery time by 50%, which markedly reduces intervention time and raises acceptance in patients who struggle to tolerate longer procedure times.

The integrated balloon of the M^{5+} catheter was placed in the proximal anterior tibial artery and inflated up to a maximum of four atmospheres of pressure. After application of 30 pulses, the pressure was raised to six atmospheres and then completely deflated. This was repeated three times in the anterior tibial artery and four times in the tibioperoneal trunk (Figure 3) with the ending of the balloon in the peroneal artery. After that, angiography showed the complete exclusion of the AAA, absence of any endoleak and patency of both iliac limbs without residual stenosis or flow-limiting dissections (Figure 4). The IVL treatment was really effective in changing the compliance and allowing for safe and controlled luminal expansion. During the one-month postoperative follow-up, colour Doppler ultrasound showed that the iliac axis expanded from 4–5mm to 9.3mm (Figure 5).

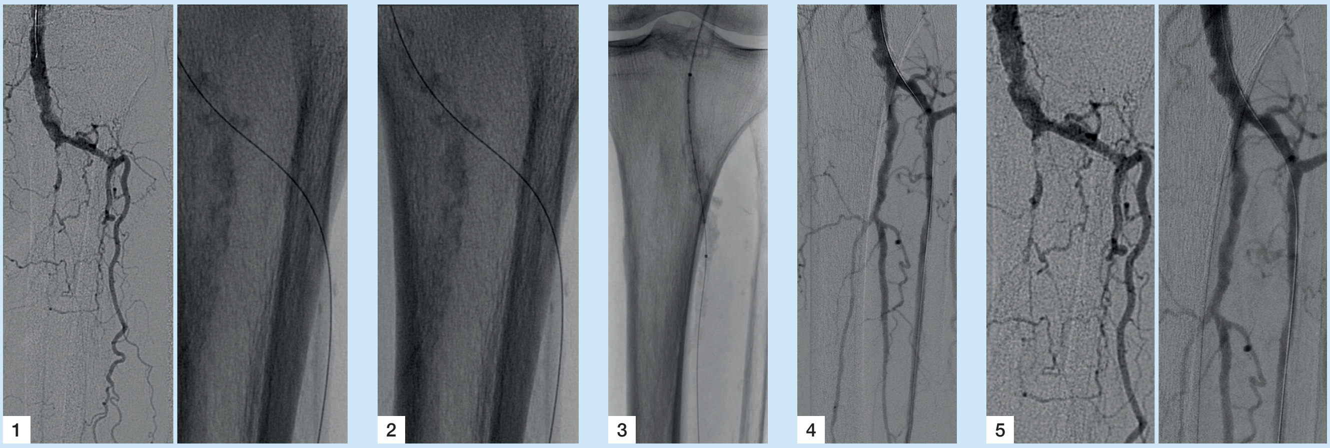
The patient was discharged on postoperative day two, no 30-day complications occurred and claudication disappeared on the left side. Sac shrinkage was >1cm at one month follow-up.

In conclusion, the utilisation of IVL simplified the procedure and made the delivery of the graft easy and safe while shortening the procedural time.

In our opinion, the Shockwave M5+ catheter should be the first-choice treatment for a narrowed and calcified iliac axis in EVAR/TEVAR cases. We have a protocol for cases like this one described:

1. IVL preferably with 8mm of the entire iliac axis at 4atm
2. Angiography (to exclude threatening complications)
3. Deliver the graft (EVAR or TEVAR)
4. Only after the delivery of the graft, if further expansion is required, adjunctive manoeuvres should be performed (i.e. PTA, stent, stent grafting).

***Emiliano Chisci** is a consultant vascular and endovascular surgeon at the Ospedale San Giovanni di Dio in Florence, Italy.*



1. Initial angiography showing a severely calcified occlusion of the proximal BTK vessels

2. Unsubstracted image depicts the underlying calcifications being severe and mixed type (intimal and medical); in the anterior tibial artery an 0.018” guidewire is shown after successful crossing of the occlusion

3. Intravascular lithotripsy with a Shockwave M5 4x60mm balloon; here the treatment of the distal P3 and tibioperoneal trunk is shown

4. After IVL and DCB a three-vessel runoff could be achieved without further need for stenting

5. Direct comparison of the angiography prior and after IVL

showed a complete recanalisation of the distal P3, anterior tibial, tibioperoneal trunk, peroneal and posterior tibial.

An additional drug-coated balloon (DCB) percutaneous transluminal angioplasty with two Ranger balloons (Boston Scientific) 4mm was performed. The final result is shown in Figure 4 and Figure 5.

The puncture site was closed with AngioSeal (Terumo), which is done in our department without exception under sonographic guidance. Standard time for bed rest after AngioSeal is two hours in our department. No compression is applied.

Postprocedural medication includes dual antiplatelet therapy with ASS 100mg/d and clopidogrel 75mg/d for three months after DCB.

The rest pain subsided after the intervention. Oscillography and duplex control on the following day showed no more critical perfusion and no relevant residual stenosis.

In our daily practice, IVL has become standard in heavily calcified lesions. We observe a low rate of relevant dissections and a remarkable lumen gain without the typical early recoil after plain old balloon angioplasty. Thus, we seldom use stenting or atherectomy devices any more. IVL is a promising technology, however we still need to further understand the therapy and where it can provide most effective application. From our experience and the current acute data published, we believe it does not jeopardise any escalation of therapy if it fails, leaving the option to perform any kind of atherectomy, dilatation or stenting available.

Our decision to utilise IVL is determined from the result of the predilatation. If the smaller balloon does not inflate fully at nominal pressure, we regard it as a lesion suitable for IVL. Otherwise, we treat the lesion with larger balloons and if the balloon size reaches nominal vessel diameter we conclude with DCB.

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Expanding access boundaries in complex calcium: Shockwave M^{5+} from a brachial approach to facilitate EVAR and stenting

Outlining an "extremely challenging" case, **Stefano Fazzini** (Tor Vergata University, Rome, Italy) details how the Shockwave M^{5+} Intravascular Lithotripsy (IVL) catheter has made it possible to treat iliac arteries with an antegrade approach from a brachial access.

AT THE LEVEL OF THE AORTOILIAC district, many patients are affected by associated vascular disease—either occlusive (AIOD) or aneurysmatic (abdominal aortic aneurysm; AAA). These two pathologies are the same expression of atherosclerotic disease and are often associated with extensive and severe calcification.

This clinical status creates challenges for the treatment approach, which could be difficult by endovascular means. For these reasons, in high-risk patients, we need the right tool to assist an EVAR and/or stenting to allow for endograft delivery, avoiding trauma and other complications, and to guarantee an ideal vessel patency at the same time.

We describe a case recently treated at our institution: a 65-year-old man considered at high risk for open repair (previous stroke, type II diabetes, dyslipidaemia, chronic obstructive pulmonary disease [COPD], former smoker) with symptomatic AIOD (rest pain of the right leg, Rutherford IV) associated with a small AAA.

The anatomical status was described as: 40mm AAA of distal aorta, extremely calcified tight stenosis at the origin of common iliac arteries bilaterally, diffuse iliofemoral calcification with complete total occlusion of the right external iliac artery associated to common femoral artery stenosis and long complete total occlusion of the superficial femoral artery. The ankle-brachial index (ABI) was 0.3 on the right and 0.7 on the left.

The calcification extended more than 50% of each iliac axis, but the three main lesions to treat were 3cm right common iliac artery stenosis, 4cm left common iliac artery stenosis and 8cm right external iliac artery complete total occlusion. Both common iliac arteries had extremely calcified and eccentric stenosis with a narrowed minimum lumen diameter of 1.5mm and a reference vessel diameter of

Stefano Fazzini

10mm. The right occluded external iliac artery had a reference vessel diameter of 7mm.

We believed that the patient was best suited for endovascular treatment; a triple treatment of bilateral common iliac artery stenting and right external iliac artery recanalisation was mandatory to improve the blood inflow to the peripheral district and solve the symptoms.

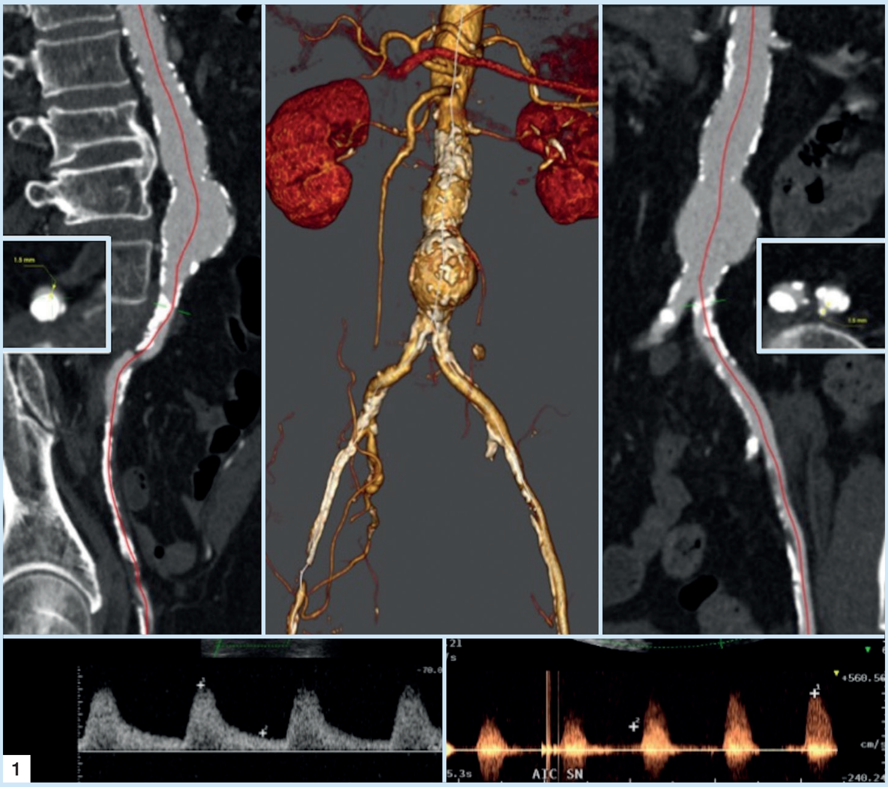
A standard iliac kissing stent could be not indicated in case of associated distal AAA.

Our decision was to perform an EVAR with iliac stenting of the very narrow and calcified access vessels, with an 8cm calcified complete total occlusion of the right external iliac artery.

Our aim for the case was to facilitate the endograft delivery, avoid access complications, and attain the best possible stent expansion. We decided to perform vessel preparation using IVL in order to improve vessel compliance, facilitate the required stent expansion and reduce the rate of recoil in the bilateral eccentric lesions.

In this challenging case, a low-profile aortic endograft (Cordis Incraft AAA stent graft system, Cardinal Health) used in conjunction with kissing covered stents (Viabahn VBX, Gore) in place of iliac limbs (off-label) and a complete total occlusion recanalisation/stenting was our strategy.

When planning to treat the hostile femoral access, which consisted of right concentric stenosis with a long external iliac artery complete total occlusion, it was decided a brachial approach to deliver IVL could be extremely useful. Thanks to the recent introduction of the Shockwave M^{5+} IVL catheter, the increased length of 135cm allowed us to perform vessel preparation on the iliac vessels, the recanalisation and calcium modification with IVL and stenting from above. This approach would facilitate treatment of the right side, and enable left



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> **This extremely challenging case shows how the M^{5+} has changed how we deal with hostile access and iliac occlusive disease at the same time.**

femoral access for the endograft delivery and stenting.

Under local anaesthesia, a percutaneous left brachial access was performed. A long 7Fr sheath was positioned at the level of the distal aorta, and a 7mm Shockwave M^{5+} catheter was used in the left common iliac artery delivering three cycles (30 pulses) at 4atm. The 7mm M^{5+} requires a 6Fr sheath but a 7Fr was chosen to allow delivery of the covered stents in this case. A percutaneous left common femoral access was performed. The vessel preparation with IVL allowed the crossing of a Prostyle (Abbott) preclosure positioning and sequentially the delivery of a low-profile aortic endograft (Cordis Incraft) without any complication and/or dissections.

After the endograft deployment, the contralateral gate was cannulated from above, and four cycles of the M^{5+} catheter were delivered at 4atm) in the right common iliac artery.

An angiogram following IVL confirmed better lumen gain and no subsequent trauma or rupture. Kissing stents were then performed (Viabahn VBX 8x79mm). These stents were post-dilatated up to 12 mm at the level of the aortic gate by using a kissing balloon 12x40 mm and up to 9mm distally.

The crossing profiles were 14Fr and 7Fr on the left and right common iliac artery, respectively, with a bilateral reference vessel diameter of 10mm. The stent graft outer profile was larger than minimum lumen diameter by 200% and 50% on the right and left common iliac artery, respectively.

We proceeded and performed an intraluminal recanalisation of the external iliac artery from above. A pre-dilatation with a 4x100mm percutaneous transluminal angioplasty (PTA) was done, prior to delivering the three remaining cycles of our 7mm Shockwave M^{5+}. The use of IVL facilitated good lumen gain and we decided to implant a self-expandable bare stent (Protégé 7x 80, Medtronic) followed by ballooning (7x80 PTA).

The remaining treatment included a PTA/drug-coated balloon of the right common femoral artery and PTA of left hypogastric artery (tight stenosis).

The completion angiogram showed an optimal positioning of the aortic endograft, kissing stents and right iliac stent, in the absence of residual stenosis and complications.

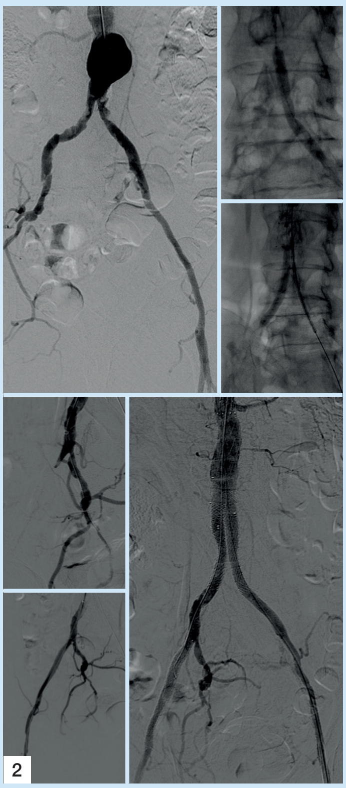
No complications at the level of access occurred, and the patient was discharged after the computed tomography (CT)-scan control on the second postoperative day in good condition, having improved the ABI up to 0.7 (+133%) and 0.9 (+28%) on the right and left leg, respectively. The luminal gain at the origin of the common iliac arteries increased up to 7mm (+360%).

The one-month duplex scan control confirmed a successful outcome, by showing a sealed AAA and a direct flow (three phases) at the level of the common femoral arteries. Moreover, the patient revealed he could walk a distance longer than 1 km and had achieved a better quality of life.

This extremely challenging case shows how the M^{5+} has changed how we deal with hostile access and iliac occlusive disease at the same time.

This advancement in the peripheral IVL portfolio allows us to treat iliac arteries with an antegrade approach from a brachial access. This new option can expand the boundaries in cases of hostile femoral arteries or unavailable contralateral access.

Stefano Fazzini *is consultant of vascular surgery and researcher at Tor Vergata University in Rome, Italy.*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1: Preoperative CT angiography and duplex scan

2: Procedure. In clockwise order: preoperative angiogram, vessel preparation from above by IVL treatment, EVAR, iliac kissing covered stenting, right external iliac artery recanalisation IVL stenting, completion angiogram

3: Postoperative computed tomography angiography and duplex scan

3

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