Shockwave lithotripsy facilitates large-bore vascular access through calcified arteries

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ABSTRACT

Background: Our objective is to explore the Peripheral Intravascular Lithotripsy (IVL) System in the treatment of calcific access vessels during thoracic endovascular aortic repair (TEVAR), endovascular aortic repair (EVAR), and transcatheter aortic valve intervention.

Methods: This retrospective, single-center study evaluated the outcomes of patients undergoing TEVAR, EVAR, or transcatheter aortic valve intervention with severe calcific arterial disease between July 2018 and August 2019. Maximum circumferential calcification, length of calcification, and inner/outer diameter measurements were collected with curved planar reformation by medical imaging software (Aquarius APS, TeraRecon, Foster City, Calif). Effective luminal gain was calculated using the minimal inner diameter and the largest bore passed within the vessel lumen. End points included technical success, mortality, adverse events, and requirement for bail out maneuvers. Technical success was defined as successful delivery and deployment of device or endograft.

Results: Nine patients were included (mean age, 79.3 ± 9.79 years; range, 59-97 years]). four transcatheter aortic valve replacement, one TEVAR, one EVAR, and three fenestrated EVAR. Six patients (66.7%) had more than one artery treated; the segments treated included common iliac artery (seven patients [77.8%]), the external iliac artery (seven patients [77.8%]), and the common femoral artery (one patient [11.1%]). The average inner iliac vessel diameter was 3.38 ± 0.99 mm (range, 1.87-4.72 mm). The average outside diameter of device introduced was 7.2 ± 0.94 (range, 6.3-8.8 mm) with 229% effective luminal gain. Technical success was achieved in 100% of cases with a 0% mortality. Adjunctive measures were needed in five cases (55.6%). One vessel perforation was controlled with covered stent (Viabahn; W. L. Gore & Associates, Flagstaff, Ariz) deployment. Dissection was identified in two cases requiring stent placement. Two cases required the use of the Terumo International Systems SOLOPATH Balloon Expandable TransFemoral System (Terumo Interventional Systems, Somerset, NJ). One case deployed a Viabahn stent applying the "crack and pave" technique.

Conclusions: As the population of the United States ages, calcified arterial disease will become an everyday clinical conundrum. Furthermore, the procedures for which the IVL system is geared toward facilitating will likely also increase in use. The IVL system is an additional tool in the vascular surgeon's armamentarium to obtain large-bore access in these calcified vessels. Further studies are needed to better assess the clinical effectiveness of the IVL system. (J Vasc Surg Cases and Innovative Techniques 2021;7:164-70.)

Keywords: Calcified arteries; Access; Difficult access; Large-bore; Lithotripsy

The application of endovascular therapies in the treatment of cardiovascular disease is gaining increasing popularity. A major limitation to large-bore access in complex interventions is the calcification of access vessels. Intimal and medial arterial calcification represent a pathologic response to noxious stimuli. Intimal calcification results from lipid accumulation and a resultant proinflammatory state.[1] Medial calcification represents the remodeling of an amorphous mineral deposit resulting in osteogenic differentiation of vascular smooth muscle cells.

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Although it may not always result in stenosis, vascular calcification can contribute to the loss of elasticity and compliance. The use of large-bore access in endovascular interventions in this setting leads to compliance mismatch and failure stress of the vessel, which can clinically translate into intimal dissection, restenosis, distal embolization, and rupture.[2-4] Furthermore, increased lesion complexity results in adjusted device use and ultimately increased procedure supply costs.[5]

The Peripheral Intravascular Lithotripsy (IVL) System (Shockwave Medical, Inc., Fremont Calif) modifies intimal and medial calcium via pulsatile sonic pressure waves.[3] Direct and circumferential opposition to the vessel lumen via a balloon allows for efficient treatment of a calcified vessel narrowing. The device consists of a generator, connector cable, and IVL catheter. The Shockwave M5 system is available in balloon diameters of 3.5 to 7.0 mm and length of 60 mm with sheath compatibility of 6F to 7F and a crossing profile of 1.4 to 1.9 mm. This 0.014-inch over-the-wire device has been approved for iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal artery applications. The catheter has dual capabilities: IVL and balloon angioplasty. Insufflation to pressures of 2 or 4 atm of pressure are used for lithotripsy. The nominal pressure of the angioplasty balloon is 6 atm and burst is 10 atm. Each catheter can deliver 30 pulses at a rate of 1 pulse per second and a maximum of 10 cycles. Should further treatment be deemed necessary an additional catheter is required. Although each catheter retails for $3450.00, the cost of the system is institution specific, making generalizable comparisons difficult.

The DISRUPT PAD I, II, and III studies investigated the use of the IVL system on moderate to severely calcified femoropopliteal lesions.[3] The safety and usefulness of the IVL system on calcified infra-popliteal arterial stenosis was evaluated in the DISRUPT Below-The-Knee study.[6] In a recent publication, Brodmann et al[7] evaluated the safety and feasibility of the IVL System on stenotic common femoral arteries. With 21 patients the target access and delivery of treatment was successful in all patients. Non-flow-limiting dissections were noted in five patients (23.8%). No perforation, distal embolization, or thrombus complications were appreciated. This study is the first to evaluate the feasibility of the IVL system to facilitate large-bore access in a diverse assortment of endovascular cases.

METHODS

Between July 2018 and August 2019, the IVL system was used in nine cases to assist with luminal gain for large-bore vascular access. This study is a single-institution retrospective review. Preintervention computed tomography angiography was analyzed with the assistance of medical imaging software, Aquarius APS (TeraRecon, Foster City, Calif).[7] Regions treated with IVL technology were identified. The luminal measurements of maximally calcified vessel segments were obtained using a curved planar reformation or centerline before the intervention. The minimal inner diameter was noted. The outer diameter was measured demonstrating the imposed constraint of calcified arterial disease. The maximal circumference of calcified artery was determined using the clock face application of Aquarius APS (Table). Intraoperative imaging, operative reports, and material logs were reviewed determining the items handled during the case, allowing the reviewers to identify the largest outer diameter applied to the vessel lumen (Fig 1). This value was used in calculating the effective luminal gain. Given the degree of calcification and small luminal size, the decision to have Peripheral IVL System available was made preoperatively. If the patient had an anatomy with significant calcification and a luminal diameter of less than that required by the sheath needed for device delivery, the patient was considered for lithotripsy use. The device was used in all patients in this descriptive study. The duration and degree of balloon inflation was deferred to operating surgeon, typically two to three cycles are used per area. End points included immediate technical success, mortality, adverse events, and the need for bail out maneuvers and adjunctive procedures. Technical success was defined as successful delivery and deployment of device or endograft. Patient informed consent was not required because there was no identifiable information outlined in the study.

RESULTS

Patient cohort. Nine patients were included in this study in a relatively even distribution between male (55%, 5 patients) and female (45%, 4 patients). The mean age of patients was 79.3 ± 9.79 years (range, 59-97 years). The patients underwent the following procedure: four transcatheter aortic valve replacements, one thoracic endovascular aortic repair (TEVAR), one endovascular aortic repair (EVAR), and three fenestrated EVAR (Table). Technical success reported in all cases with no perioperative morbidity or mortality. Six patients (66.7%) had more than one artery treated; the segments treated included common iliac artery (seven patients [77.8%]), the external iliac artery (seven patients [77.8%]), and the common femoral artery (one patient [11.1%]). The mean length of arterial calcification was 42.1 ± 31.1 mm (range, 5.69-109.00 mm). There were varying degrees of arterial calcification ranging from one-half to the full circumference of the artery (Fig 1). One patient had full circumferential calcification resulting in an inner diameter of 1.87 mm. The mean inner diameter of these patients at maximal calcification was 3.38 ± 0.99 mm (range, 1.87-4.72 mm). In this study, no patient underwent predilation. No embolic filters were used. No evidence of distal embolization was appreciated. Post treatment of the affected segments allowed for an average effective luminal gain of 3.67 mm or 229 ± 64.39% (range, 171%-337%).

Table. Description of large-bore devices, confirmation of luminal gain, complications, and adjunct procedures

Patient identifier	Age, years	Type of Surgery	Large-bore device Used	Confirmation of compliance	Complications and adjunct procedures
1	97	TAVR	26-mm Medtronic CoreValve Evolut R	6 × 60 Shockwave; Cook 10 Fr/Cook 14F/19F Terumo International Systems SOLOPATH Balloon Expandable TransFemoral System	Perforation requiring Viabahn (8 × 50), POBA 7 × 40
2	71	TAVR	29-mm Medtronic CoreValve Evolut PRO	7 × 60 mm Shockwave	Crack and pave with 10 × 100 Viabahn and Armada 10 × 40
3	82	TAVR	29-mm Medtronic CoreValve Evolut PRO	6 × 60 Shockwave, 7 × 60 Shockwave	None
4	75	TAVR	29-mm Medtronic CoreValve Evolut	6 × 60 mm Shockwave; 18F Terumo International Systems SOLOPATH Balloon Expandable TransFemoral System; 8 × 49, 9 × 20 mm POBA 18F Gore DrySeal Flex Introducer Sheath	Dissection requiring Viabahn VBX 8 × 100, Viabahn VBX 8 × 40
5	83	TEVAR	Cook Zenith Alpha Thoracic Endovascular Graft 36 × 32 × 209	7-mm Shockwave; 7 × 80 POBA	Dissection requiring Viabahn 10 × 50
6	83	AAA	Endologix AFX 28 × 80 Endologix Vela Proximal Endograft 34 × 80	6 × 60 mm Shockwave on R; 7 × 60 mm Shockwave on L; L dilated to 10 × 40 DORADO PTA Balloon	None
7	59	fEVAR	Cook Zenith p-Branch device 30 × 22 B Cook Zenith Endovascular Graft 24 × 81	7 × 60 Shockwave; 16 and 18 mm dilators; 7 mm POBA	None
8	81	fEVAR	Gore TAG Thoracic Endoprosthesis 37 × 200 Gore TAG Thoracic Endoprosthesis 40 × 100 Gore EXCLUDER AAA Endoprosthesis 35 × 145 Cook Zenith Flex AAA Endovascular Graft Main Body Extension 36 × 73 Gore TAG Thoracic Endoprosthesis 45 × 100	6 + 7 mm POBA; 18, 20, and 22 mm dilators; 7 × 60 mm Shockwave; 8 mm POBA; 24F Gore DrySeal Flex Introducer Sheath	None
9	83	fEVAR	Endologix Vela Proximal Endograft 34 × 34 × 80 Endologix AFX 28 × 100 Cook Zenith Alpha Thoracic Endovascular Graft 34 × 34 × 80	7 × 60 mm Shockwave; 8-mm POBA; 18, 20, 22 mm dilators	None

AAA, Abdominal aortic aneurysm; fEVAR, fenestrated endovascular aortic repair; POBA, plain old balloon angioplasty; TAVR, transcatheter aortic valve replacement; TEVAR, thoracic endovascular aortic repair.

Transcatheter aortic valve intervention. Case 1 is a 97-year-old man with hypertension, coronary artery disease requiring coronary artery bypass, and symptomatic severe aortic stenosis underwent placement of a 26-mm Medtronic CoreValve Evolut R (Medtronic, Dublin, Ireland). Preoperative imaging demonstrated a severely diseased aortoiliac system; a total length of 99.4 mm of calcified plaque was appreciated. Minimal arterial lumen was noted to be 3.59 mm with a maximum of 83.3% arterial wall replaced by calcium. The left common iliac artery and the left external iliac artery were treated with IVL (6 × 60 mm) allowing for the placement of a 19F Terumo International Systems SOLOPATH Balloon Expandable TransFemoral System. Minor extravasation

Patient Identifier	Target Vessel	Length of Lesion(s) (mm)	Maximal Degree of Circumferential Calcification	Pre-Treatment Inner/Outer Diameter (mm)	Maximum OD Passed (mm)
1	L CIA and EIA	56.2, 15.1, 15, 13.1		3.59/8.15	6.33
2	L CIA and EIA	104, 15.8		3.56/10.3	7.5
3	R CIA and EIA	109, 29.6		2.44/10.4	6.33
4	R EIA and CFA	85.9, 43.8		1.95/7.53	6.7
5	R CIA	66.6		4.14/10.9	7.1
6	L CIA	52		1.87/13.5	6.3
7	R CIA and EIA	82.4, 53.6		3.96/8.64	8.5
8	R EIA	48.1, 36.2, 22.5, 15		4.72/7.83	8.8
9	R CIA and EIA	7.88, 68.7, 12.8, 8.99, 5.69		4.25/8.51	7.3

*L: Left; R: Right; CIA: Common Iliac Artery; EIA: External Iliac Artery; CFA: Common Femoral Artery

Fig 1. Description of calcified arterial disease.

was noted at the conclusion of the case at the left external iliac artery. This was controlled using a Gore VIABAHN Endoprosthesis (6 × 80 mm; W. L. Gore & Associates, Flagstaff, Ariz). The area subsequently treated with balloon angioplasty (7 × 40 mm). The patient tolerated the procedure well and his hospital course was uncomplicated.

Case 2 is a 71-year-old man with hypertension, carotid artery stenosis treated with left carotid endarterectomy, bilateral renal artery stenosis with bilateral renal artery stents, coronary artery disease requiring coronary artery bypass, and symptomatic severe aortic stenosis underwent placement of a 29-mm Medtronic CoreValve Evolut PRO. Similar to case 1, the patient had severe aortoiliac occlusive disease of 119.8 mm in length and a maximum calcified arterial circumference of 91.7%. Minimal arterial lumen was noted to be 3.56 mm. The left common iliac and external iliac arteries were treated with IVL (7 × 60 mm). The sheath would not pass. The surgeons used a "crack and pave" method. A Gore VIABAHN Endoprosthesis (10 × 100 mm) was deployed, covering the common and external iliac arteries. The left internal iliac artery was occluded before the intervention. The stent was further expanded with a 10 × 40 Armada angioplasty balloon. A 20F Gore DrySeal Flex Introducer Sheath was passed without resistance. The remainder of the procedure proceeded uneventfully.

Case 3 is an 82-year-old man with hypertension, congestive heart failure, cerebrovascular accident, and symptomatic severe aortic stenosis treated with implantation of a 29-mm Medtronic CoreValve Evolut PRO with right common femoral access. Given the patient's significant occlusive disease, the IVL device (6 × 60 and 7 × 60 mm) was applied to the right common iliac and external iliac arteries with 138.6 mm of calcified plaque with a maximal circumference of 83.3% (Figs 2 and 3). The smallest calcified diameter was 2.4 mm. Treatment of this segment allowed for the placement of a 19F Terumo International Systems SOLOPATH Balloon Expandable TransFemoral System with an outer diameter of 6.33 mm, 263% luminal gain. No intraoperative or postoperative complications were noted.

Case 4 is a 75-year-old woman with hypertension, congestive heart failure, coronary artery disease complicated by myocardial infarction requiring percutaneous coronary intervention, chronic kidney disease, and symptomatic severe aortic stenosis who underwent placement of a 29-mm Medtronic CoreValve Evolut R via a right common femoral approach. Treated segments of the right external iliac and common femoral arteries were noted to be of 129.7 mm total length with a maximal circumference of 83.3% on preoperative imaging. Severe occlusive disease resulted in a minimal inner diameter of 1.95 mm. A variety of interventions were applied, ultimately leading to a successful implantation of the aforementioned device. The segment was treated with IVL (6 × 60 mm) allowing for placement of an 18F Terumo International Systems SOLOPATH Balloon Expandable TransFemoral System. Angioplasty (8 × 49 and 9 × 20 mm) was applied to the area of disease allowing for placement of an 18F Gore DrySeal Flex Introducer Sheath. On completion angiography, a dissection of the right external iliac artery was appreciated. This dissection was successfully addressed with Gore VIABAHN Endoprostheses (8 × 100, 8 × 40 mm).

TEVAR/fenestrated EVAR/EVAR. Case 5 is an 83-year-old woman with chronic obstructive pulmonary disease, peripheral arterial disease, and a 6-cm descending thoracic aortic aneurysm. The right common iliac artery had a 66.6-mm area of calcification with a maximal circumference of 91.7%. The right common iliac artery with a minimal diameter of 4.14 mm was treated with a 7 × 80 IVL system. This facilitated placement of an 18F Gore Dry Seal Sheath. After successful deployment of a Cook Zenith Alpha Thoracic Endovascular Graft 36 × 32 × 209 (Cook Medical, Bloomington, Ind), a dissection of the previously treated segment of iliac artery was noted. This was successfully treated with a Gore VIABAHN Endoprosthesis (6 × 40 mm).

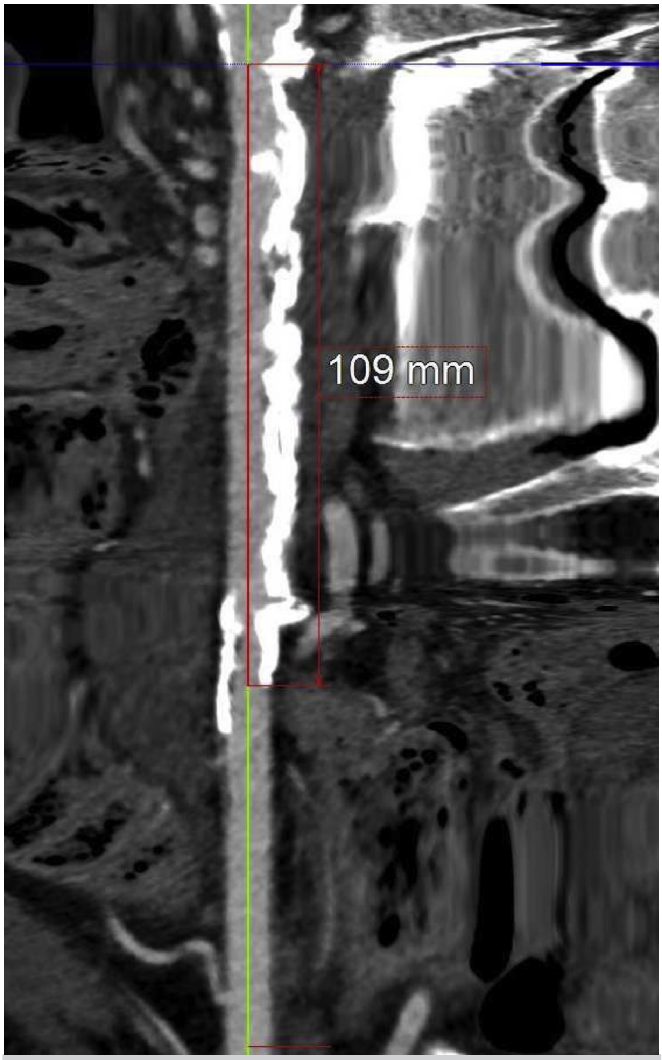

Fig 2. Measuring length of lesion using centerline.

Case 6 is an 83-year-old woman with hypertension, chronic obstructive pulmonary disease, peripheral arterial disease, and an infrarenal abdominal aortic aneurysm with severe calcifications of the aorta and iliofemoral system with circumferential calcification associated with an inner diameter of 1.87 mm. A 52-mm segment of left common iliac artery was treated with a 7 × 60 IVL system then dilated with a 10 × 40 DORADO PTA Balloon, facilitating the placement of a 17F Endologix sheath (Endologix, Inc., Irvine, Calif). A 6 × 60 IVL system was applied to the right iliac artery. The remainder of the procedure proceeded uneventfully.

Case 7 is a 59-year-old man with hypertension and a 5.2-cm juxtarenal abdominal aortic aneurysm. The patient underwent an endovascular aneurysm repair using a Cook P branch graft and unibody. In doing so, his right common and external iliac arteries were noted to be calcified to a maximal circumference of 66.7% with a minimal diameter of 3.96 mm. This region was treated with a 7 × 60 mm IVL system. To confirm adequate luminal gain 16- and 18-mm dilators and a 7-mm balloon angioplasty were used. Ultimately, a 22F Cook sheath was advanced without difficulty. No intraoperative or postoperative complications were appreciated.

Case 8 is an 81-year-old man with hypertension, chronic obstructive pulmonary disease, melanoma of the ear, and a thoracoabdominal aortic aneurysm. Preoperative computed tomography angiography demonstrated significant calcified stenoses at the right external iliac artery resulting in an affected length of 121.8 mm and minimal true diameter of 4.73 mm. The segment was treated with 6- and 7-mm balloon angioplasties, sequential dilation (18F, 20F, 22F), 7 × 60 mm IVL system, and an 8-mm balloon angioplasty ultimately allowing for the passage of a 24F Gore DrySeal Flex Introducer Sheath. The patient underwent a complex thoracic aortic aneurysm repair with TEVAR, aorto-aortic graft of the thoracic to the perivisceral aorta, visceral vessel stenting, and endovascular aortic stent graft for infrarenal aorta.

Case 9 is an 83-year-old woman with hypertension, left breast cancer, bilateral carotid artery stenoses, and an enlarging 6-cm juxtarenal abdominal aortic aneurysm associated with a high-grade superior mesenteric artery stenosis and a celiac artery occlusion with symptoms of chronic mesenteric ischemia. Treatment with 7 × 60 mm IVL system, 8-mm balloon angioplasty, and 18-, 20-, and 22-mm dilators of the right common and external iliac arteries allowed for a complex thoracoabdominal endovascular repair with superior mesenteric artery, celiac artery, and bilateral renal artery stenting. The patient's postprandial abdominal pain improved significantly. No intraoperative or postoperative complications were noted.

DISCUSSION

Endovascular therapy allows for the treatment of numerous conditions across multiple specialties. This study is a reflection of the collaborative effort between cardiology, cardiothoracic surgery, interventional radiology, and vascular surgery. The number of commercially available endovascular devices is growing exponentially. Despite decreasing device profiles, vascular access continues to be a frequent concern. Interventionists must take into consideration excessive iliac tortuosity, small caliber vessels, occlusive arterial disease, and vessel wall calcification. Fortunately, many of these trepidations can be identified on baseline imaging, highlighting the importance of high-quality preoperative imaging and planning. The IVL system can be applied based on the preoperative identification of a heavily calcified access vessel, the intraoperative imaging, or the degree of resistance encountered during the introduction of an endovascular device. Verification of luminal gain can be

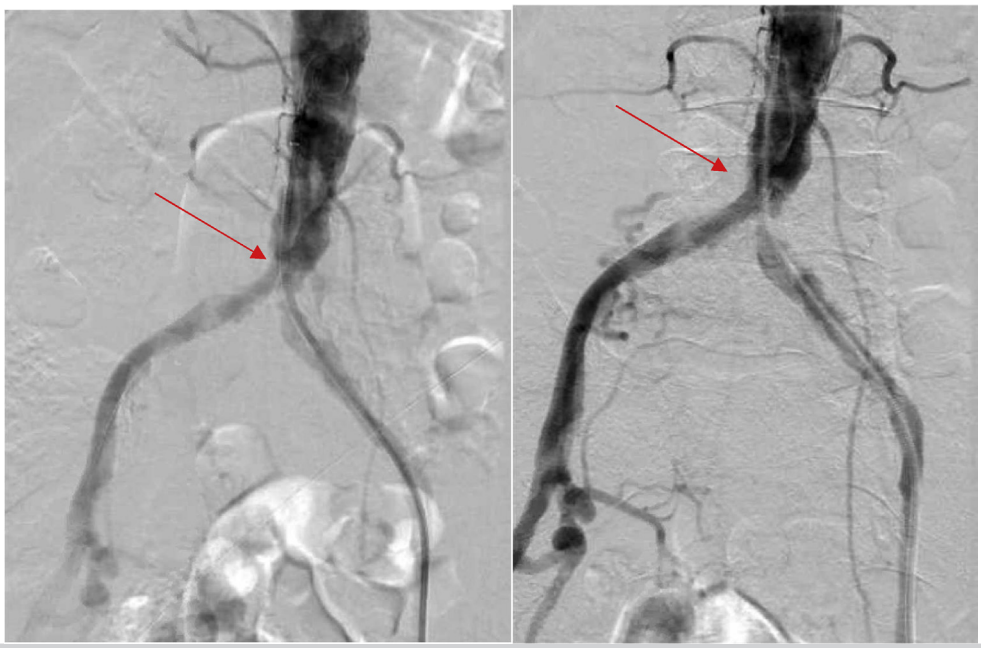

Fig 3. Before and after the application of the peripheral intravascular lithotripsy (IVL) system.

accomplished in a variety of ways, including but not limited to passage of dilators, angioplasty balloon insufflation, and gentle advancement of the large-bore system.

The common femoral artery is the preferred site for large-bore vascular access. Access of this vessel can be performed percutaneously in a minimally invasive manner, is easily available if a cut-down is required, and can be completed under procedural sedation without the need for intubation. In many patients, lower extremity peripheral arterial disease (PAD) precludes the common femoral artery as a site of access. In up to 15% to 20% of transcatheter aortic valve intervention candidates, this route might be precluded by the previously described concerns and, as a result, more invasive methods may be necessary, such as transaxillary, transaortic, transapical, transcarotid, trans-septal, and transcaval routes.[8]

Chronic atherosclerotic occlusive disease of the lower extremities is the third leading cause of atherosclerotic vascular morbidity after ischemic heart disease and stroke.[2] PAD will become an increasing clinical concern as the cohort of people aged 65 and older in the United States is expected to double by 2050.[9] Therefore, the technology needed to address PAD is clinically important. The IVL system transforms electric energy into pulsatile sonic pressure waves; disruption of intimal and medial calcium resulted in significant and effective luminal gain in this study. Angioplasty can be performed with lower pressures minimizing arterial dissection and enhancing vessel compliance. Contraindications to this device include an inability to pass a 0.014-inch wire past the lesion and in-stent restenosis. Severity of arterial calcification does not represent a barrier to use. Although it can be applied in isolation with success, the IVL system does not preclude the use of additional tools to obtain further luminal expansion. Intervention with the IVL system is quick, lasting 1 to a few minutes with a minimal addition of intermittent fluoroscopy. The device itself does not require contrast. Although it may not adequately reflect an increase in arterial compliance, postintervention imaging is recommended to assess for the presence of immediate complications.

A dissection was diagnosed and treated with a covered self-expandable stent in two patients. Additionally, a perforation of the left external iliac artery was identified after the removal of a large-bore sheath. Wire access was maintained and this too was treated with a covered self-expanding stent. Further luminal gain was required in one case; a self-expandable stent was sequentially enlarged to facilitate the placement of a large-bore sheath. It is unclear whether the covered stent with an outer diameter of 5 to 8 mm would have passed the area of stenosis before the application of the IVL system. As a result, this outcome cannot be considered a failure of the IVL system. Although largely successful, the advancement of a large-bore sheath through areas of significant disease is associated with complications. It is important to note that these difficulties are not necessarily the direct result of the IVL system. Owing to confirmed reports of device

malfunction, Terumo Medical Corporation/Terumo Medical Canada Inc. initiated a voluntary recall of the SOLOPATH Balloon Expandable TransFemoral System and the SOLOPATH Re-collapsible Balloon Access System in April 2019.[10] Tip dislodgement from the outer diameter of the sheath may have contributed to the dissections seen in our study. Nonetheless, one perforation and two dissections were appreciated. These intraoperative findings highlight the importance of maintained wire access and the immediate availability of bail-out maneuvers. An array of covered stents should be available at the time of sheath removal. Direct and clear communication with the operative team, including anesthesia, nurses, and technicians throughout the procedure is of central importance.

The purpose of this article was to explore the Peripheral IVL System in the treatment of calcific access vessels during TEVAR, EVAR, and transcatheter aortic valve intervention. The study is limited by its small size and retrospective nature. There is no official calcification system to describe and compare calcified arterial disease. In this study, we used a variety of descriptors, including length of the lesion, maximal degree of circumferential calcification, and pretreatment inner to outer diameter measurements. In future studies, a volumetric analysis of luminal size may be of benefit. It is difficult to assess the anatomic and physiologic effect of our intervention. Comparisons of studies before and after noninvasive flow accompanied with imaging studies of the treated segments before and after treatment may help to elucidate this question.

During endovascular therapy, calcified arterial disease is commonly encountered. With an aging population, this disease process will become more common. The IVL system can assist in addressing this concern. It can be used in isolation or in adjunct with other tools. While preliminary data is promising, a larger prospective study with a matched control of similar complexity would be necessary better assess the clinical effectiveness and long-term effects of the IVL system in the assistance of large-bore endovascular access.

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