UTILIZING INTRAVASCULAR LITHOTRIPSY FOR LARGE BORE ACCESS

in EVAR and TEVAR Procedures

Faculty

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Clinical Director of Research
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Faculty Disclosures

- **Dr. Dua:** Educational consultant—Boston Scientific, Penumbra
- **Dr. Lombardi:** Consultant—Cook Medical, Shockwave Medical, Medtronic
- **Dr. Muck:** Speakers' Bureau—Shockwave Medical

Program Information

- Provided by HMP Education, LLC, an HMP Global company
- Supported by an educational grant from Shockwave Medical

Learning Objectives

- Identify current best practices for large-bore access in EVAR and TEVAR procedures
- Understand the data surrounding lithotripsy for large-bore access
- Safely obtain large-bore access during endovascular aortic repairs

EVAR = endovascular aortic aneurysm repair; TEVAR = thoracic EVAR.

Size Matters! Mechanisms of Action in Large-Bore Access

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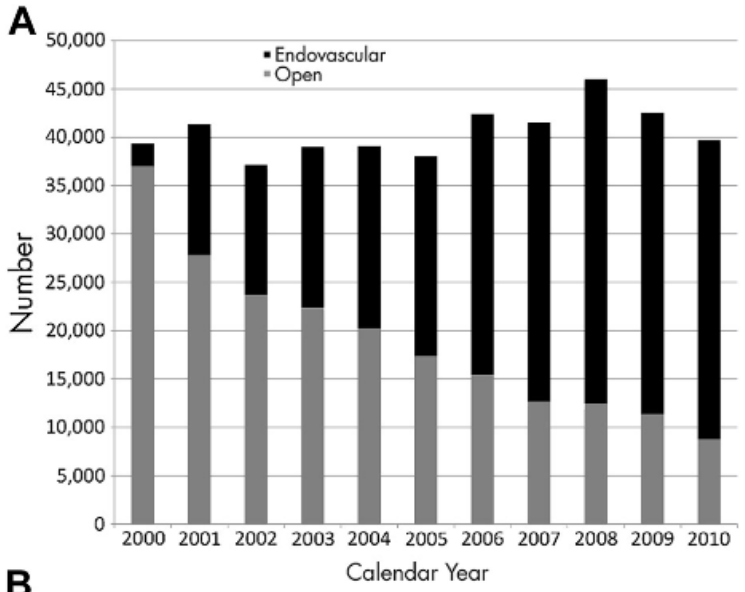
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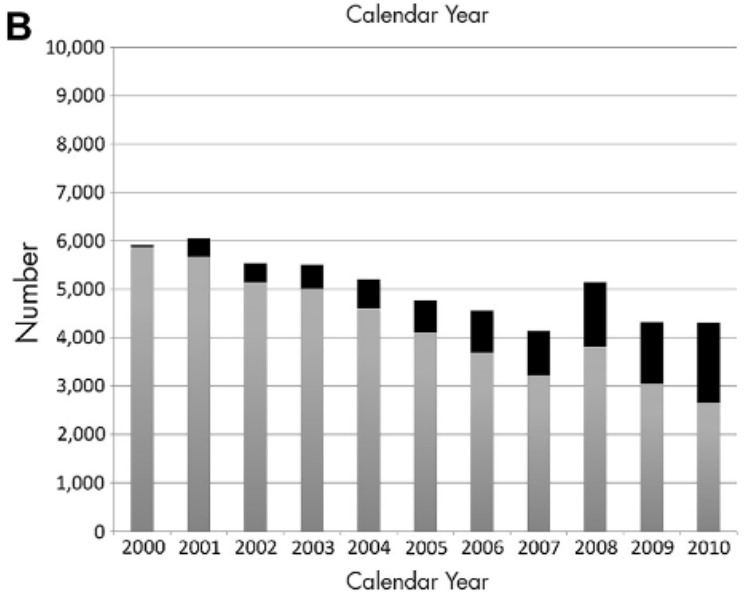
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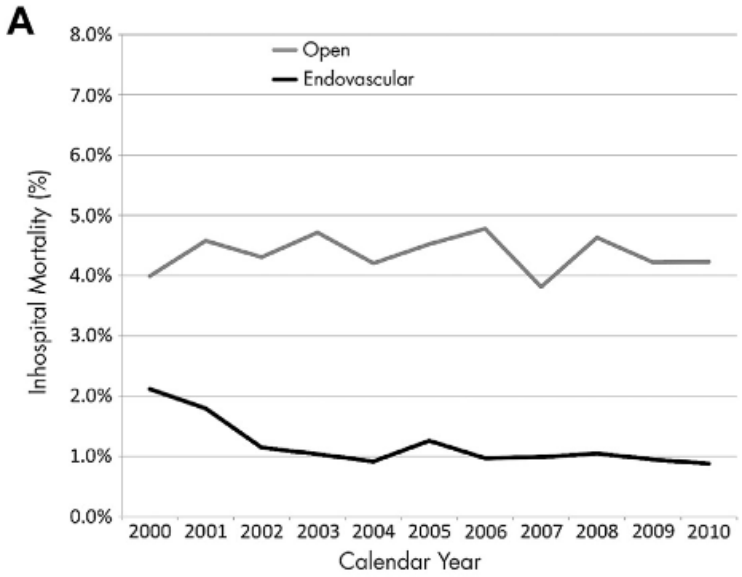
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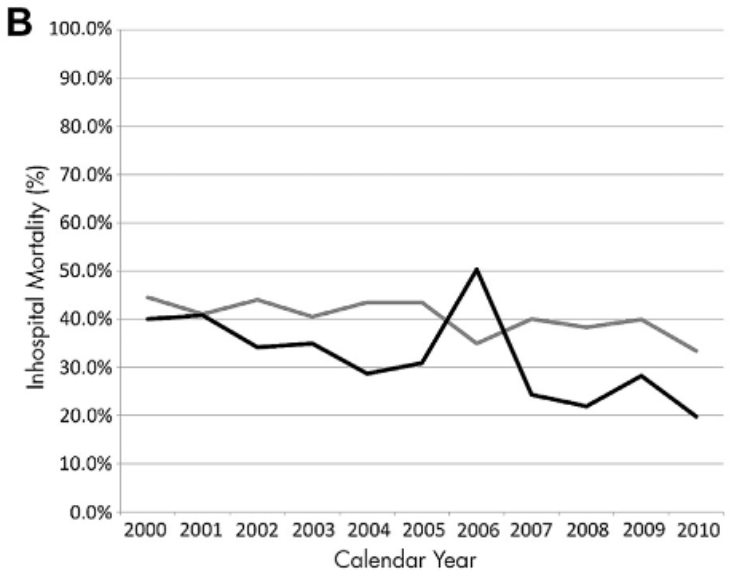
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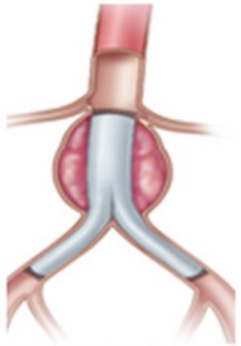
Calendar Year

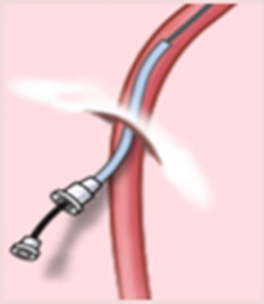
Percutaneous vs Open Surgical Access for EVAR

VQI



13,087 EVARs Access:
Percutaneous: 64%
Open Surgical: 36%

PERCUTANEOUS ACCESS



✓Technical success: 96%
✓Less cardiac complications
✓Less blood loss
✓Shorter hospital stay

CONCLUSION

Use
PERCUTANEOUS ACCESS
over
OPEN SURGICAL ACCESS
for EVAR.

Percutaneous access is associated with decreased operative time, EBL, and LOS and should be considered when possible.

VQI = Vascular Quality Initiative®; EBL = estimated blood loss; LOS = length of stay.

Siracuse JJ, et al. *J Vasc Surg.* 2018;68(1):91-99.

The Problem

- Major contraindications to perc access
  - Iliac artery torsion
  - Calcification
- Nearly 50% of pts fall outside IFU for access vessel size
  - Adjuncts described include iliac conduit, crack and pave, balloon-expandable sheaths, direct aortic puncture, transcaval delivery, alternative access point (ie, axillary, carotid)
  - Each of these adjuncts comes with additional complication potential

IFU = instructions for use.

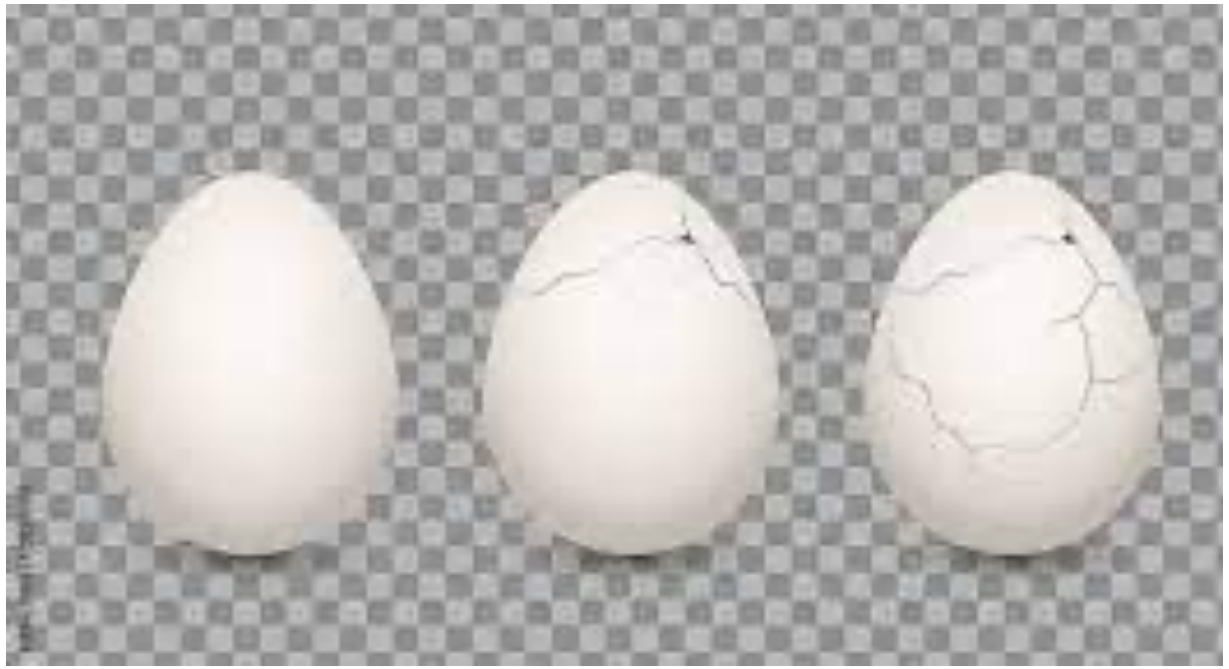
A Calcified Conundrum…

- Iliac is calcified with small lumen
- Not possible to pass device
- Complications include torrential hemorrhage if tear at bifurcation

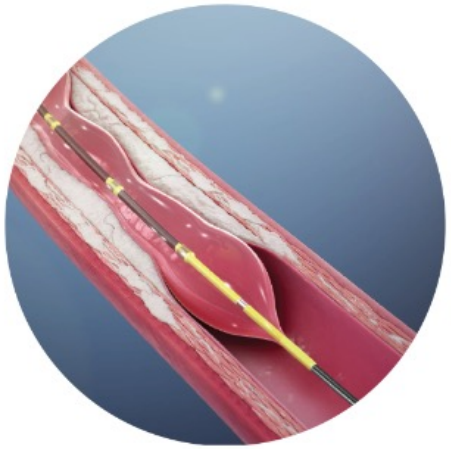
How am I going to get this device through this tight iliac!!!???

Enter Intravascular Lithotripsy (IVL)

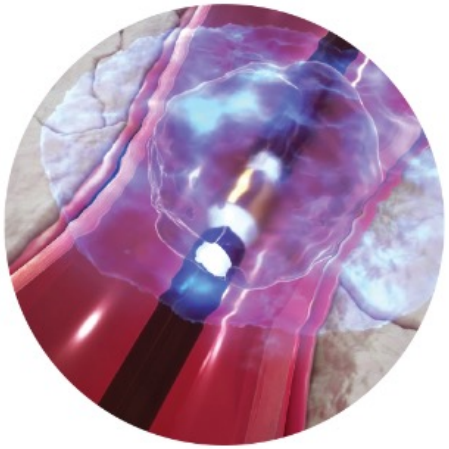
How Does It Work?



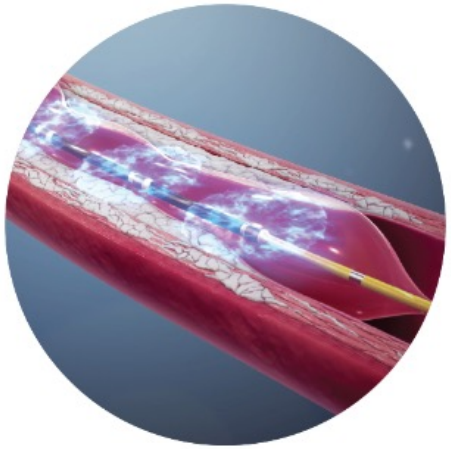
Procedural Steps to Perform IVL



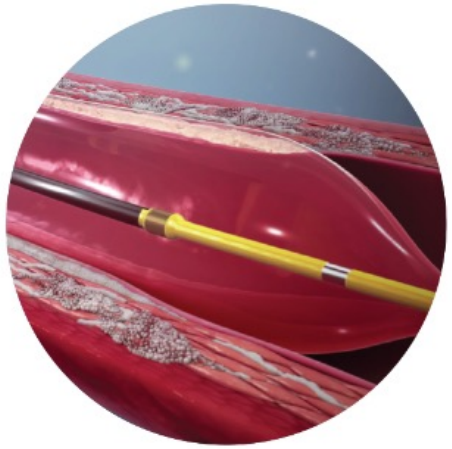
1 The IVL Catheter is delivered across a calcified lesion over an 0.014" wire and the integrated balloon is expanded to 4atm to facilitate efficient energy transfer



2 An electrical discharge from the emitters vaporizes the fluid within the balloon, creating a rapidly expanding & collapsing bubble that generates sonic pressure waves



3 The waves create a localized field effect that travels through soft vascular tissue, selectively cracking intimal and medial calcium within the vessel wall



4 After calcium modification, the integrated balloon may subsequently be used to dilate the lesion at low pressure in order to maximize luminal gain

Conclusion

- Calcified iliac vessels significantly increase risk of serious complications during EVAR/TEVAR and limit options
- Endoconduits are expensive, time-consuming, and associated with increased risks compared to perc
- IVL safely fractures/cracks calcium making it more pliable and allowing safe delivery of large devices via percutaneous access

Data on Transfemoral Access of Calcified Iliofemoral Arteries

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Why Use IVL to Assist EVAR/ TEVAR?

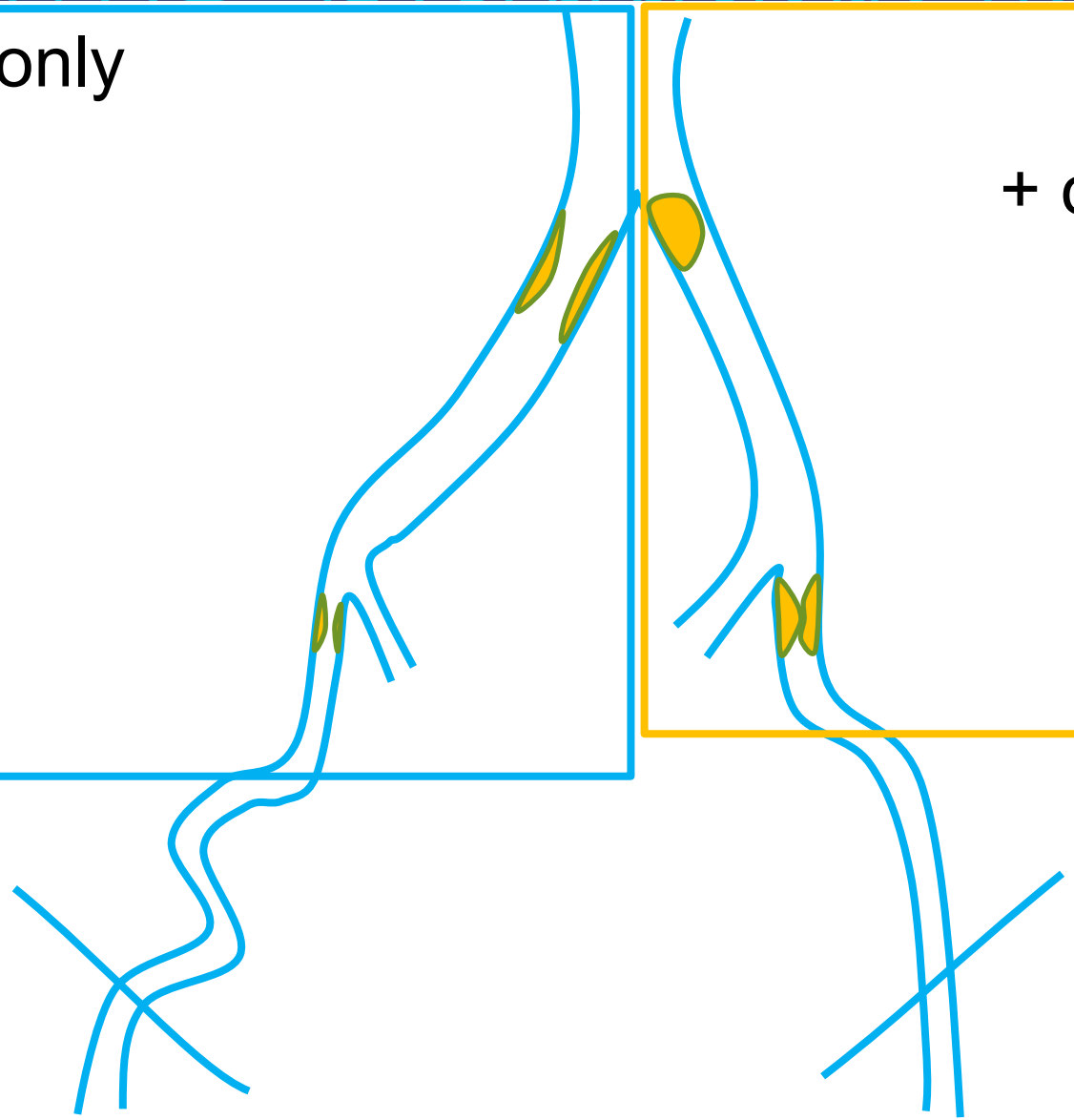
Endograft access only

To facilitate

- Endograft delivery

To avoid

- Trauma
- Rupture
- Dissection
- Stenting



Endograft access

+ occlusive iliac disease

To facilitate

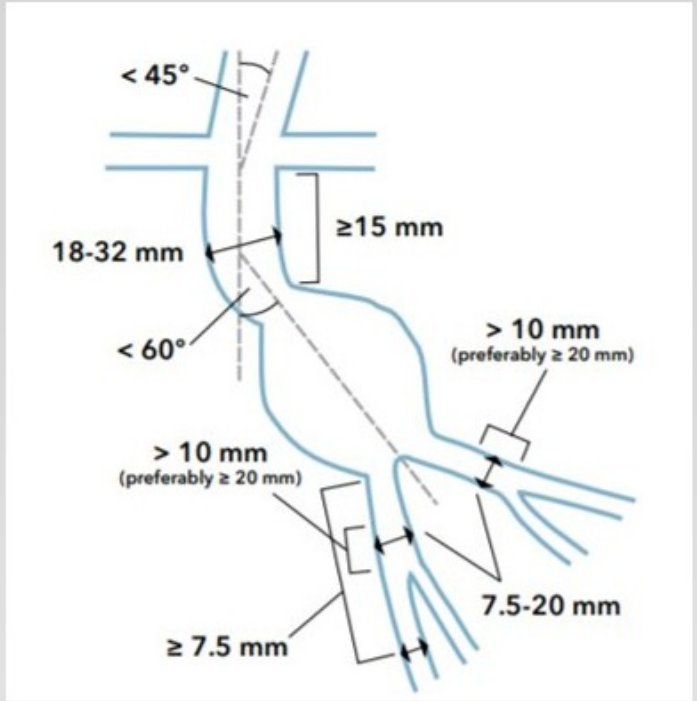
- Endograft delivery

+

- To improve iliac circulation
  - And peripheral flow
- Improve limb expansion

EVAR—Anatomic Criteria

- **Neck diameter** (10-20% oversize)
  - Device-dependent (largest is 36mm)
- **Proximal neck length**
  - 7-15 mm
- **Angulation** <60° (above and below)
  - More severe angles require longer neck
- Iliac seal zone length/diameter
  - Require 2 cm distal seal
- Access vessels
  - 14-20 Fr delivery systems
  - Generally, need 6-7 mm, minimal tortuosity, no circumferential calcium

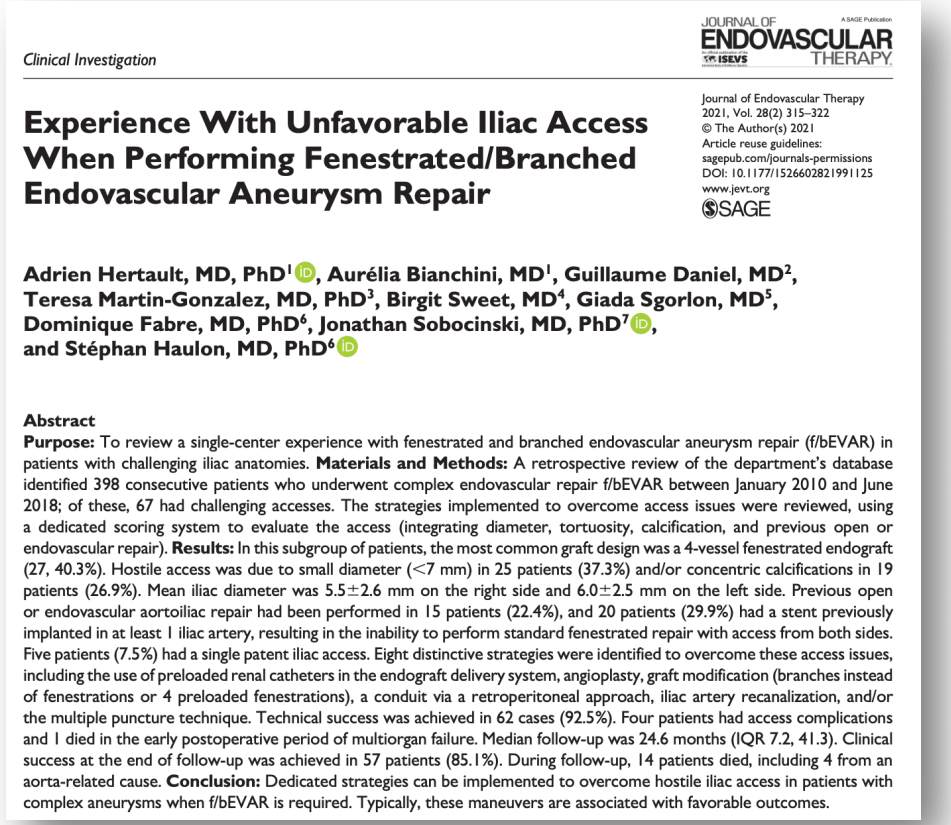


Hostile Access, Risk of Failure and SCI

Hostile:

< 7 mm

conc lesion



Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

Experience With Unfavorable Iliac Access When Performing Fenestrated/Branched Endovascular Aneurysm Repair

Journal of Endovascular Therapy
2021, Vol. 28(2) 315–322

DOI: 10.1177/15266028219911125
www.jevt.org
SAGE

Adrien Hertault, MD, PhD[1], Aurélia Bianchini, MD[1], Guillaume Daniel, MD[2], Teresa Martin-Gonzalez, MD, PhD[3], Birgit Sweet, MD[4], Giada Sgorlon, MD[5], Dominique Fabre, MD, PhD[6], Jonathan Sobocinski, MD, PhD[7], and Stéphan Haulon, MD, PhD[6]

Abstract

Purpose: To review a single-center experience with fenestrated and branched endovascular aneurysm repair (f/bEVAR) in patients with challenging iliac anatomies. **Materials and Methods:** A retrospective review of the department's database identified 398 consecutive patients who underwent complex endovascular repair f/bEVAR between January 2010 and June 2018; of these, 67 had challenging accesses. The strategies implemented to overcome access issues were reviewed, using a dedicated scoring system to evaluate the access (integrating diameter, tortuosity, calcification, and previous open or endovascular repair). **Results:** In this subgroup of patients, the most common graft design was a 4-vessel fenestrated endograft (27, 40.3%). Hostile access was due to small diameter (<7 mm) in 25 patients (37.3%) and/or concentric calcifications in 19 patients (26.9%). Mean iliac diameter was 5.5±2.6 mm on the right side and 6.0±2.5 mm on the left side. Previous open or endovascular aortoiliac repair had been performed in 15 patients (22.4%), and 20 patients (29.9%) had a stent previously implanted in at least 1 iliac artery, resulting in the inability to perform standard fenestrated repair with access from both sides. Five patients (7.5%) had a single patent iliac access. Eight distinctive strategies were identified to overcome these access issues, including the use of preloaded renal catheters in the endograft delivery system, angioplasty, graft modification (branches instead of fenestrations or 4 preloaded fenestrations), a conduit via a retroperitoneal approach, iliac artery recanalization, and/or the multiple puncture technique. Technical success was achieved in 62 cases (92.5%). Four patients had access complications and 1 died in the early postoperative period of multiorgan failure. Median follow-up was 24.6 months (IQR 7.2, 41.3). Clinical success at the end of follow-up was achieved in 57 patients (85.1%). During follow-up, 14 patients died, including 4 from an aorta-related cause. **Conclusion:** Dedicated strategies can be implemented to overcome hostile iliac access in patients with complex aneurysms when f/bEVAR is required. Typically, these maneuvers are associated with favorable outcomes.

Eur J Vasc Endovasc Surg (2015) 49, 248–254

Editor's Choice — The Impact of Early Pelvic and Lower Limb Reperfusion and Attentive Peri-operative Management on the Incidence of Spinal Cord Ischemia During Thoracoabdominal Aortic Aneurysm Endovascular Repair

B. Maurel [a], N. Delclaux [a], J. Sobocinski [a], A. Hertault [a], T. Martin-Gonzalez [a], M. Moussa [a], R. Spear [a], M. Le Roux [a], R. Azzaoui [a], M. Tyrrell [b], S. Haulon [a,*]

[a] Aortic Centre, Hôpital Cardiologique, CHRU de Lille, INSERM U1008, Université Lille Nord de France, 59037 Lille Cedex, France
[b] King's Health Partners, London, UK

WHAT THIS PAPER ADDS
This paper reports the impact of an optimized spinal cord protection strategy on spinal cord ischemia rates after endovascular thoracoabdominal aneurysm repair performed in a high volume center.

Objective/background: Spinal cord ischemia (SCI) is a devastating complication following endovascular thoracoabdominal aortic aneurysm (TAAA) repair. In an attempt to reduce its incidence two peri-procedural changes were implemented by the authors in January 2010: (i) all large sheaths are withdrawn from the iliac arteries immediately after deploying the central device and before cannulation and branch extension to the visceral vessels; (ii) the peri-operative protocol has been modified in an attempt to optimize oxygen delivery to the sensitive cells of the cord (aggressive blood and platelet transfusion, median arterial pressure monitoring >85 mmHg, and systematic cerebrospinal fluid drainage).
Methods: Between October 2004 and December 2013, 204 endovascular TAAA repairs were performed using custom made devices manufactured with branches and fenestrations to maintain visceral vessel perfusion. Data from all of these procedures were prospectively collected in an electronic database. Early post-operative results in patients treated before (group 1, $n = 43$) and after (group 2, $n = 161$ patients) implementation of the modified implantation and peri-operative protocols were compared.
Results: Patients in groups 1 and 2 had similar comorbidities (median age at repair 70.9 years [range 65.2–77.0 years]), aneurysm characteristics (median diameter 58.5 mm [range 53–65 mm]), and length of procedure (median 190 minutes [range 150–240 minutes]). The 30 day mortality rate was 11.6% in group 1 versus 5.6% in group 2 ($p = .09$). The SCI rate was 14.0% versus 1.2% ($p < .01$). If type IV TAAAs were excluded from this analysis, the SCI rate was 25.0% (6/24 patients) in group 1 versus 2.1% (2/95 patients) in group 2 ($p < .01$).
Conclusion: The early restoration of arterial flow to the pelvis and lower limbs, and aggressive peri-operative management significantly reduces SCI following type I–III TAAA endovascular repair. With the use of these modified protocols, extensive TAAA endovascular repairs are associated with low rates of SCI.

Article history: Received 24 August 2014, Accepted 25 November 2014, Available online 6 January 2015
Keywords: Endovascular repair, Peri-operative management, Spinal cord ischemia, Thoracoabdominal aortic aneurysm

SCI: 14% vs 1.2% with early restoration

Risk of failure

Risk of spinal cord ischemia

SCI = spinal cord ischemia.

Hertault A, et al. *J Endovasc Ther.* 2021;28(2):315-322. Maurel B, et al. *Eur J Vasc Endovasc Surg*. 2015;49(3):248-254.

Limb Occlusion

Aorta and Major Branches

Eur J Vasc Endovasc Surg (2021) 62, 532–539

Limb Graft Occlusion Following Endovascular Aneurysm Repair for Infrarenal Abdominal Aortic Aneurysm with the Zenith Alpha, Excluder, and Endurant Devices: a Multicentre Cohort Study

Table 2. Factors associated with risk of limb graft occlusion after standard endovascular aneurysm repair (EVAR) of nested case control cohort

	Controls (n = 165)	Limb occlusions (n = 55)	Odds ratio (95% CI) of limb graft occlusion	
			Univariable	Multivariable Model 1*
Limb compression	36 (21.8)	10 (18.2)	0.77 (0.33–1.77)	1.56 (0.43–5.57)
Kinking of graft in common iliac artery	18 (10.9)	15 (27.3)	3.18 (1.43–7.08)	2.05 (0.71–5.92)
Distal landing zone outside IFU‖	7 (4.2)	3 (5.5)	1.29 (0.33–4.97)	1.04 (0.19–5.84)
External iliac artery diameter < 10 mm	113 (68.5)	45 (81.8)	3.27 (1.31–8.13)	4.99 (1.46–16.99)
Distal landing zone in external iliac artery	16 (9.7)	12 (21.8)	2.72 (1.15–6.45)	5.91 (1.30–26.75)
Adjunctive procedure¶	20 (12.1)	9 (16.4)	1.41 (0.60–3.29)	0.58 (0.14–2.37)

"In conclusion, the present analysis confirmed landing in the external iliac artery and narrow external iliac diameter as risk factors for limb graft occlusion."

Bogdanovic M, et al. *Eur J Vasc Endovasc Surg.* 2021;62(4):532-539.

Intraprocedure Adverse Events during Fenestrated-Branched Endovascular Aortic Repair (FB-EVAR) of Complex Abdominal and Thoracoabdominal Aortic Aneurysms (TAAA)

Retrospective, single-center study

600 patients undergoing FB-EVAR

122 IAEs in 105/600 patients (18%)

Aneurysm Related:	9%
Access Related:	8%
Graft-Related:	1%

RISK FACTORS FOR IAE

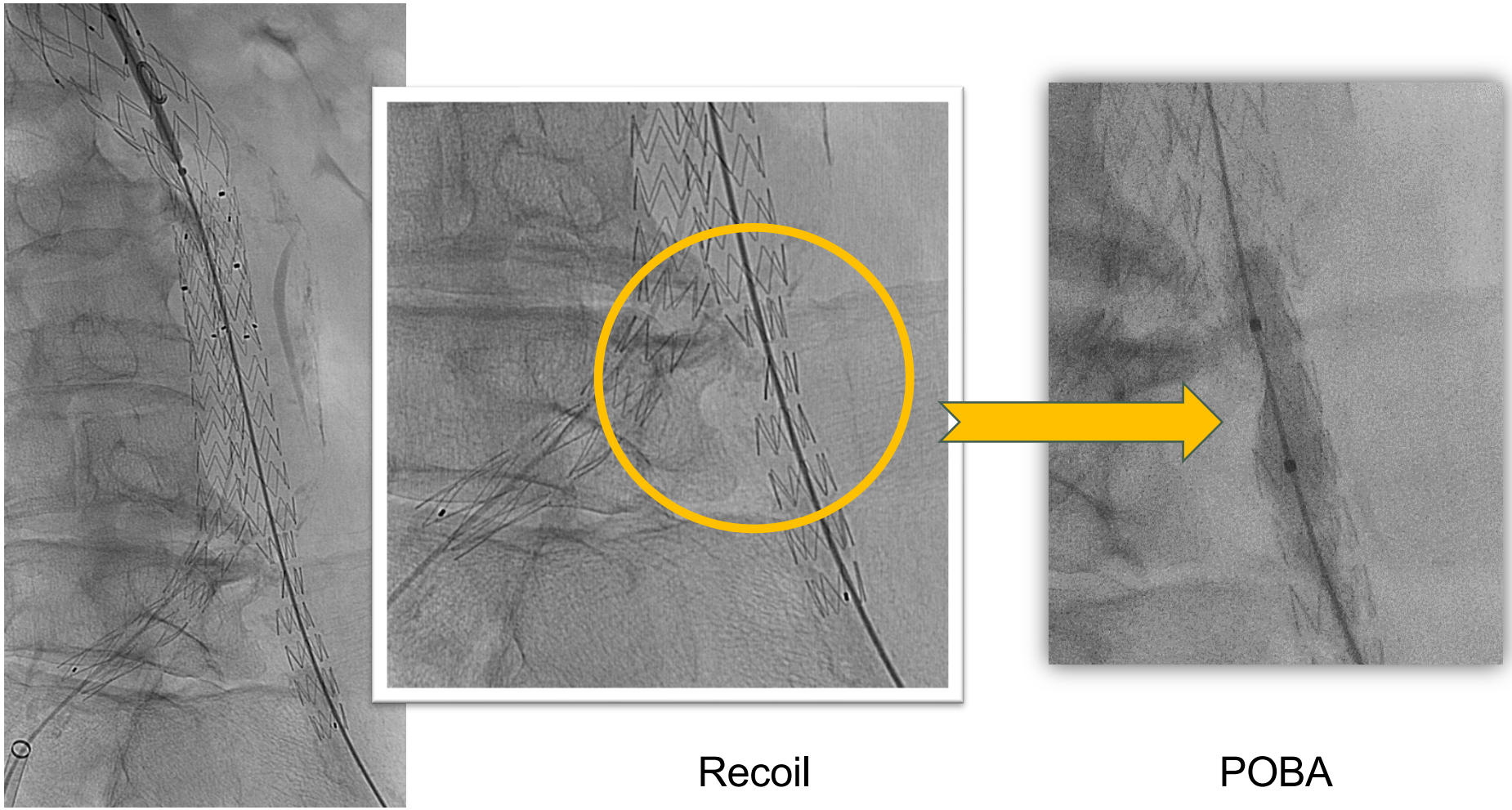
Female Sex	44% vs. 22%	*P<.001*
Smaller Renal Artery Diameter	5.4 mm vs. 5.8 mm	*P<.001*
TAAAs (More extensive disease)	72% vs. 54%	*P<.03*

IAEs resulted in more secondary interventions and in target artery instability

IAE = intraprocedure adverse event.

Tenorio ER, et al. *J Vasc Surg*. 2022;75(3):783-793.

Graft Limb Occlusion Is a Recognized Complication of Endovascular Aneurysm Repair



Recoil

POBA

Limb occlusion rate of 3.7%

External iliac artery
≤10 mm is strong independent predictor

POBA = plain old balloon angioplasty.

Carroccio A, et al. *J Vasc Surg.* 2002;36(4):679-84. Faure EM, et al. *J Vasc* Surg. 2015;61(5):1138-45.e2.

Shockwave IVL to Optimize Iliac Access

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

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2020, Vol. 27(3) 473–480

DOI: 10.1177/1526602820914598
www.jevt.org

SAGE

Intravascular Lithotripsy for Treatment of Calcified Lower Extremity Arterial Stenosis: Initial Analysis of the Disrupt PAD III Study

George Adams, MD, MHS, MBA[1], Nicolas Shammas, MD, MS[2], Sarang Mangalmurti, MD[3], Nelson L. Bernardo, MD[4], William E. Miller, MD[5], Peter A. Soukas, MD[6], Sahil A. Parikh, MD[7], Ehrin J. Armstrong, MD, MSc, MAS[8], Gunnar Tepe, MD[9], Alexandra Lansky, MD[10], and William A. Gray, MD[11]

Contents lists available at ScienceDirect

Cardiovascular Revascularization

17/118 Pts for large-bore access

Stenting: 41%

Methods: The Disrupt PAD III Observational Study is a prospective, non-randomized, multi-center single-arm study to assess the 'real-world' safety and effectiveness of the Shockwave Peripheral IVL System for the treatment of de novo calcified lesions in the peripheral arteries, with a goal of treating 1500 patients. This is an analysis of consecutive patients enrolled for treatment of an iliac artery, a specified sub-group, with at least moderate calcification and a minimum length of 20 mm.

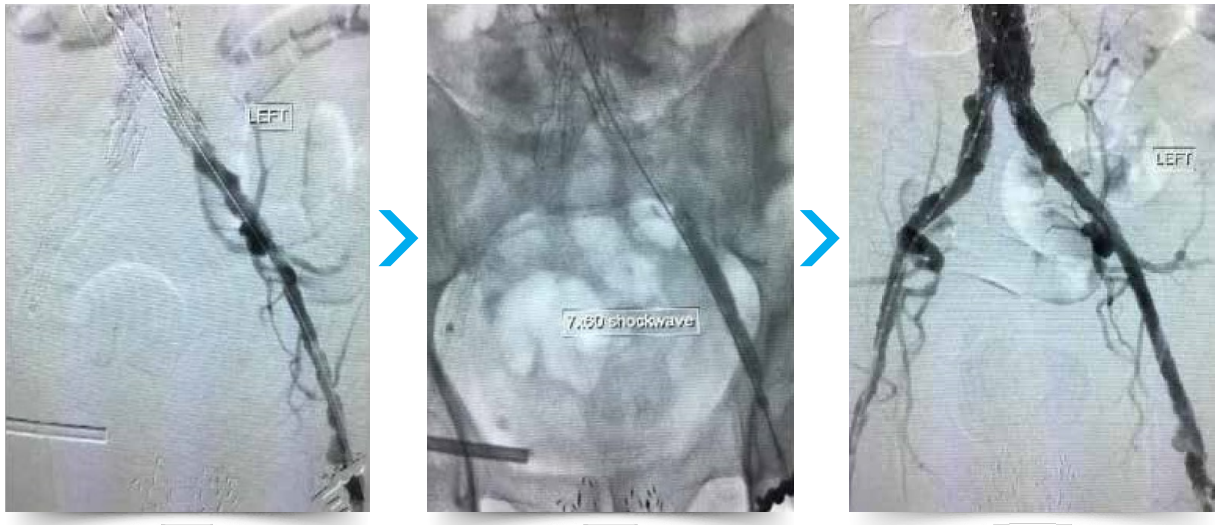
Results: Between December 2017 and July 2019, 118 patients with a total of 200 lesions were enrolled across 20 sites. 101 patients were treated primarily for claudication or critical limb ischemia, while 17 patients were treated to optimize the iliac vasculature for large-bore access. All 118 patients had successful IVL catheter delivery. The average reference vessel diameter was 7.3 mm ± 1.9 mm, with an average diameter stenosis of 83.1% ± 13.4% and an average lesion length of 58.3 mm ± 57.6 mm. Severe calcification was present in 82.0% of overall cases. Stent placement was performed in 72.9% of the overall cases. As expected, the access group received less adjunctive therapies including stents (41.2%, $p < 0.001$). Angiographic complications were minimal with no flow-limiting dissections and a final mean residual stenosis of 12.0% ± 12.1% with no differences between the groups.

Conclusions: Acute results with IVL in calcified iliac lesions suggest that it is a safe and effective option for calcified, stenotic iliac disease. IVL can be used successfully both for treatment of PAD symptoms and to optimize access for large-bore procedures.

Adams G, et al. *J Endovasc Ther*. 2020;27(3):473-480. Armstrong EJ, et al. *Cardiovasc Revasc Med*. 2020;21(10):1262-1268.

IVL Facilitates Safe Transfemoral Access Pre-EVAR and TEVAR

Case example



- Highly calcified left iliac limiting safe delivery of thoracic endograft
- 7.0 mm IVL
- 180 pulses delivered to left iliac
- Angiogram following successful deployment of 24 Fr TEVAR

Intravascular lithotripsy

- Enables percutaneous endovascular treatment without stent or additional surgical intervention
- May enable full and unrestricted stent expansion and replace pave and crack techniques

Clinical experience pre-EVAR/TEVAR

Patients included	n	10
	AAA	40% (4)
	TAA	50% (5)
	Type B dissection	10% (1)
	Moderate/severe calcium	100% (10)
Sheath size	Percutaneous access	100% (10)
	16 Fr	10% (1)
	18 Fr	30% (3)
	20 Fr	20% (2)
	22 Fr	30% (3)
	24 Fr	30% (1)
Safety and effectiveness	Dissections	0 grade D or greater
	Perforations	0 perforations
	Residual stenosis	8%

Single-Center Experiences

Safety and Efficacy of Lithoplasty in Treating Severely Calcified Iliac Arterial Disease: A Single Center Experience

Qais Radaideh, MD; Nicolas W Shammas, MD, MS; Gail A Shammas, BSN, RN; John Shammas BS

The Midwest Cardiovascular Research Foundation, Davenport, Iowa

Abstract: Calcified iliac arteries may pose a challenge to treat using endovascular techniques. Shockwave lithoplasty was recently approved to treat severe calcified peripheral arterial disease. We present 7 patients with iliac artery disease treated with Shockwave lithoplasty prior to definitive treatment with stenting. High acute procedural success was noted with no complications. Mean stent diameter post lithoplasty after Shockwave was similar to expected stent diameter per manufacturer's label. We conclude that Shockwave lithoplasty before stenting of calcified iliac arteries can lead to excellent stent expansion and high acute procedural success.

VASCULAR DISEASE MANAGEMENT 2019;16(6):E76-E78.
Key words: iliac, severe calcium, Shockwave, chronic total occlusion

Kissing Intravascular Lithotripsy Facilitated Endovascular Repair of a Complex Saccular Abdominal Aortic Aneurysm With Narrowed Distal Aorta

A First-in-Human Report

Nauman Khalid, MD, Micaela Iantorno, MD, MHS, Evan Shlofmitz, DO, Hayder Hashim, MD, Ron Waksman, MD, Nelson Bernardo, MD

Radaideh Q, et al. [www.hmpgloballearningnetwork.com]. Last updated June 2019. https://www.hmpgloballearningnetwork.com/site/vdm/content/safety-and-efficacy-lithoplasty-treating-severely-calcified-iliac-arterial-disease-single. Khalid N, et al. *JACC Cardiovasc Interv.* 2019;12(12):e97-e99.

Key Takeaways for IVL

PREDICTABLY SAFE	Lower risk of rupture/dissection >> no need for endoconduits
DISTINCTLY INTUITIVE	Unique MOA cracks calcium safely >> lower use of stents
CONSISTENTLY EFFECTIVE	Optimizes lumen gain >> low residual stenosis

***Safe** and **minimally invasive** approach*

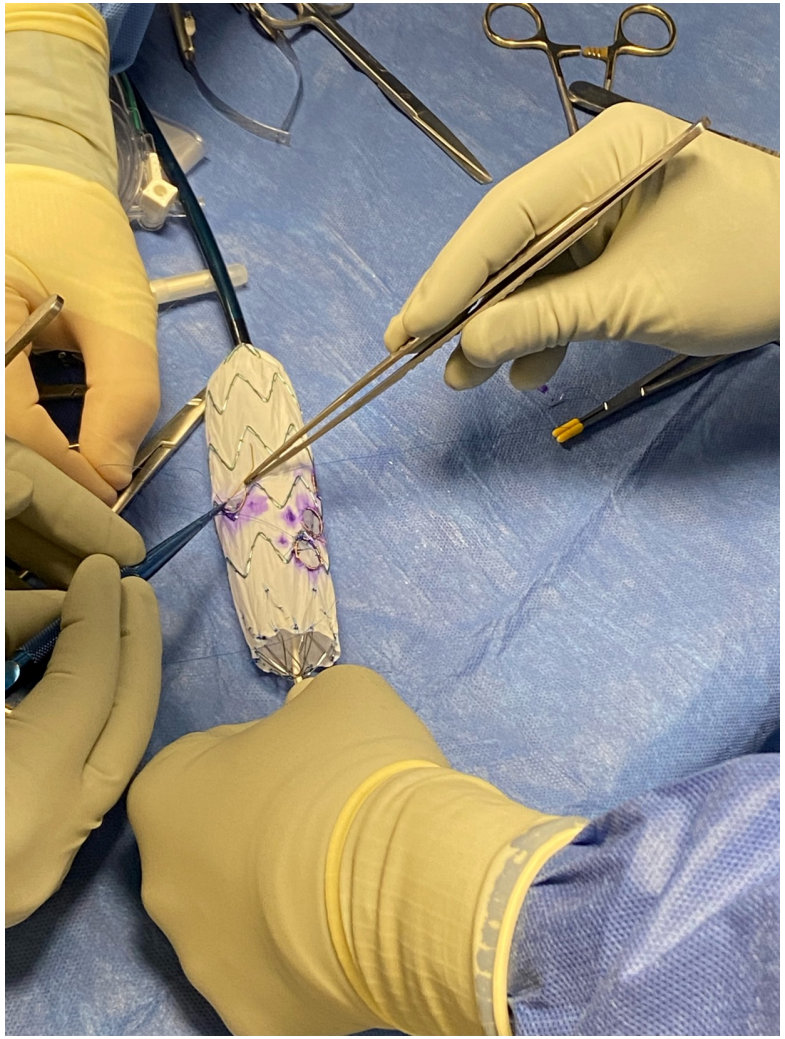
MOA = mechanism of action.

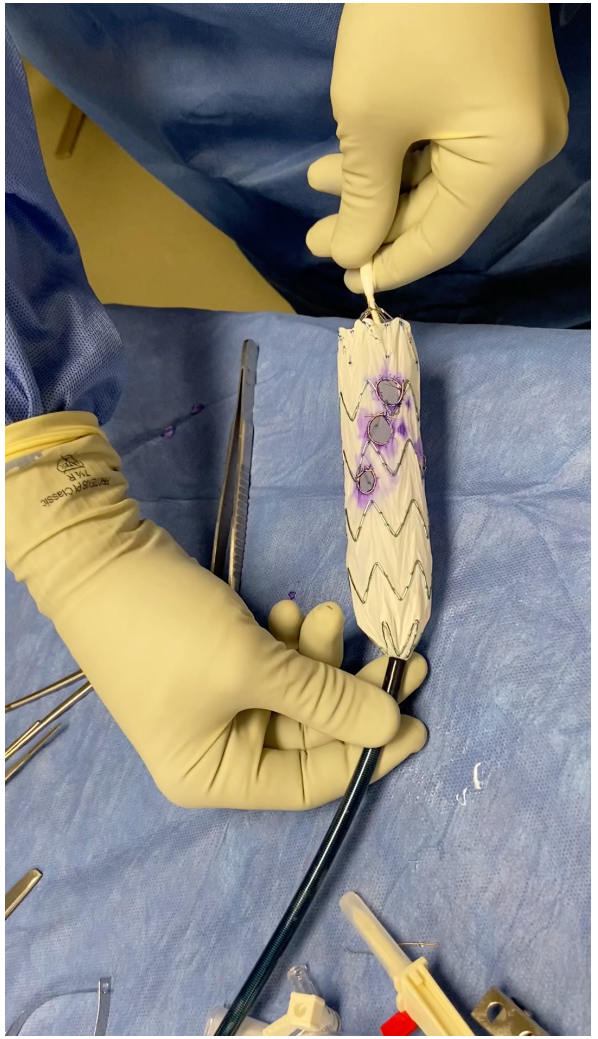
Large Bore Access for Our EVAR Patients

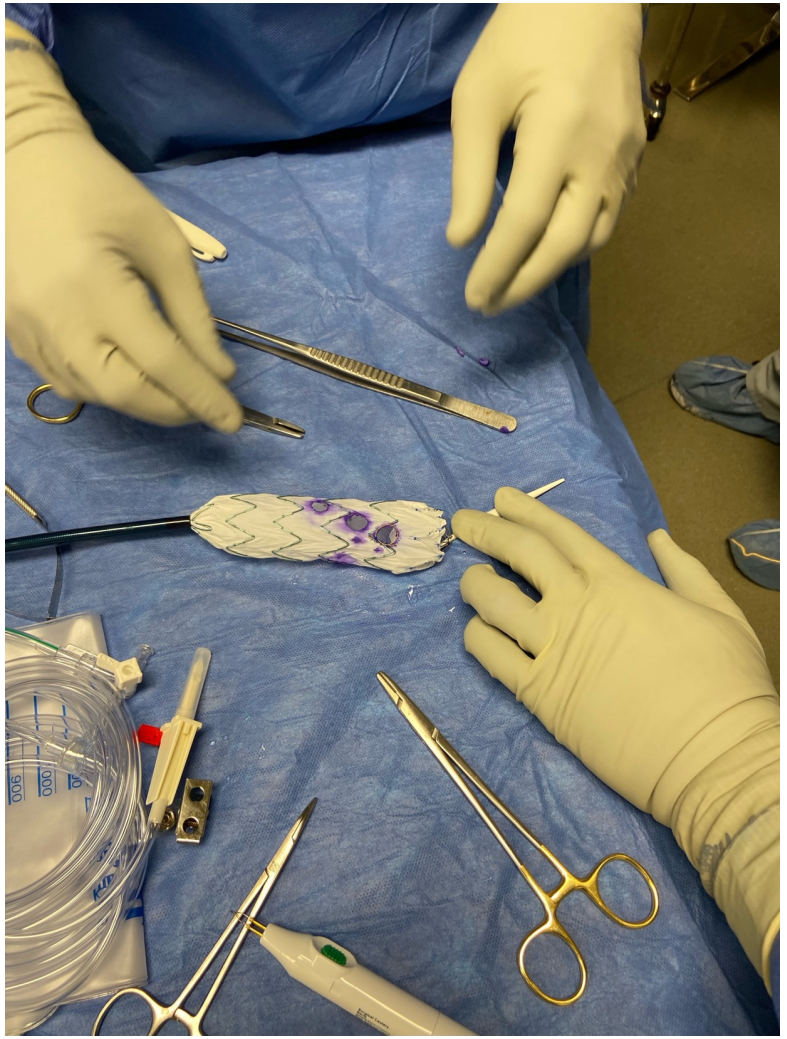
Patrick Muck, MD, FACS
Chief—Division of Vascular Surgery
Trihealth—Good Samaritan Hospital
Cincinnati, Ohio

Many Good People with Bad Problems

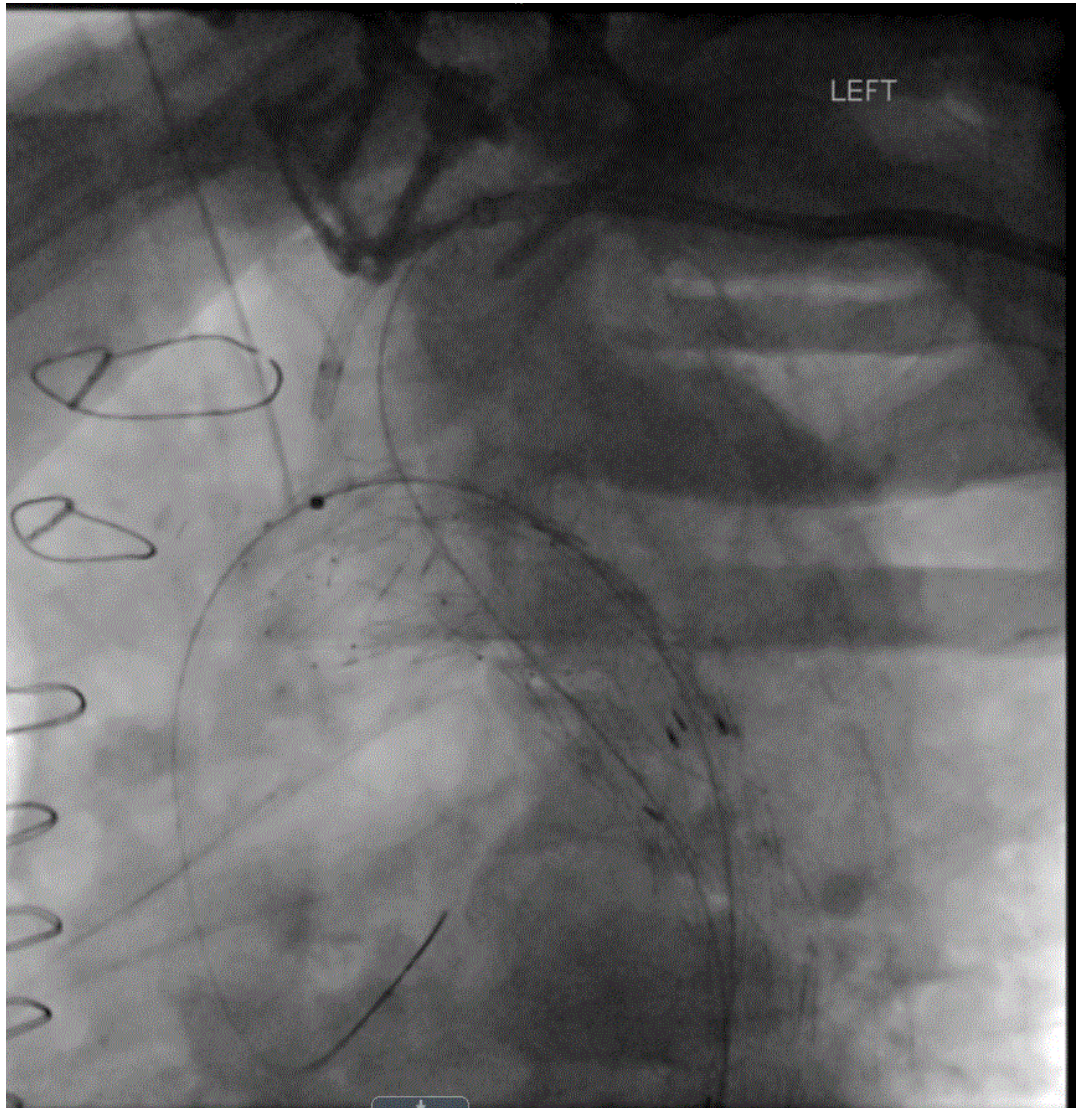
More and More PMEGs…

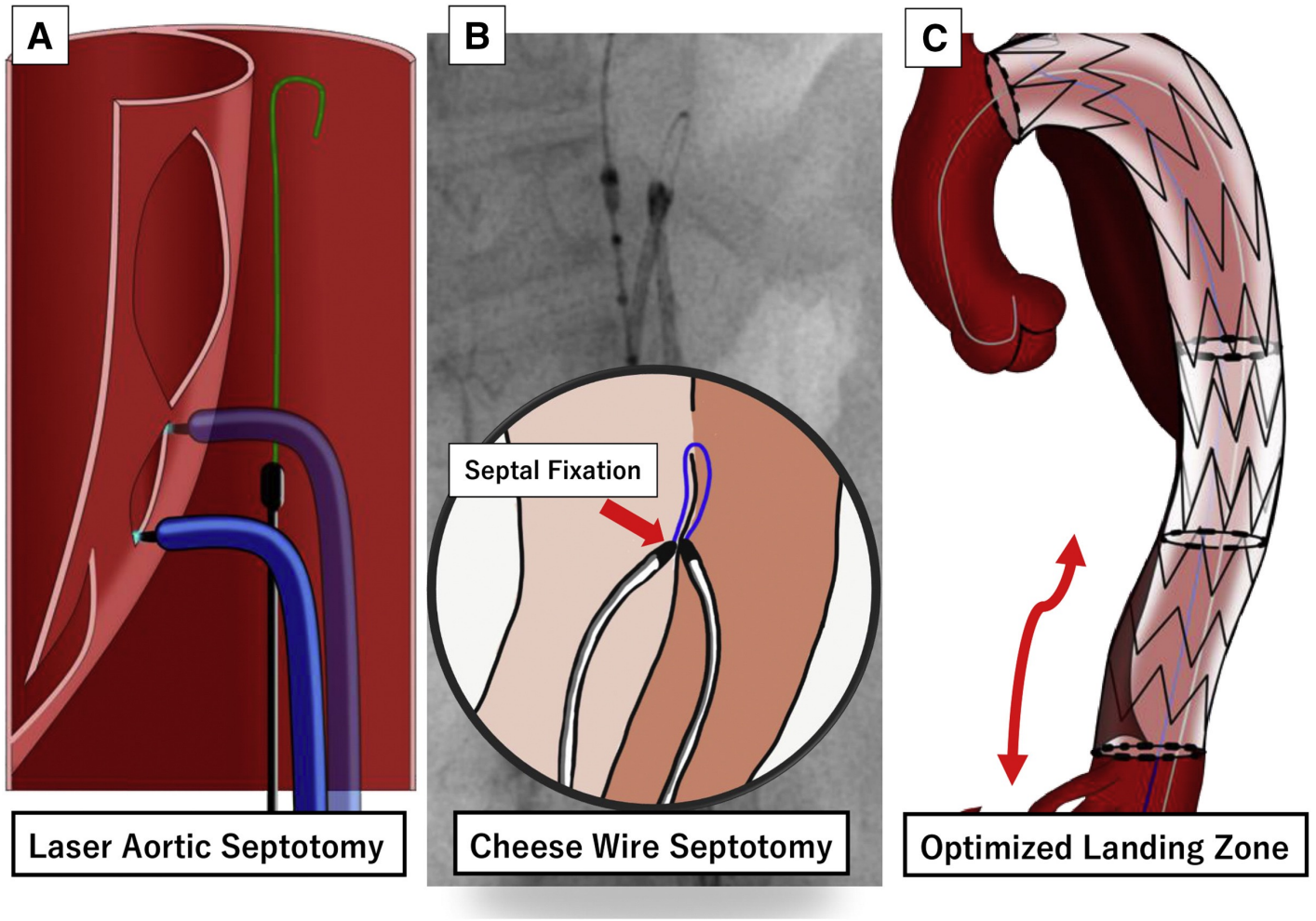






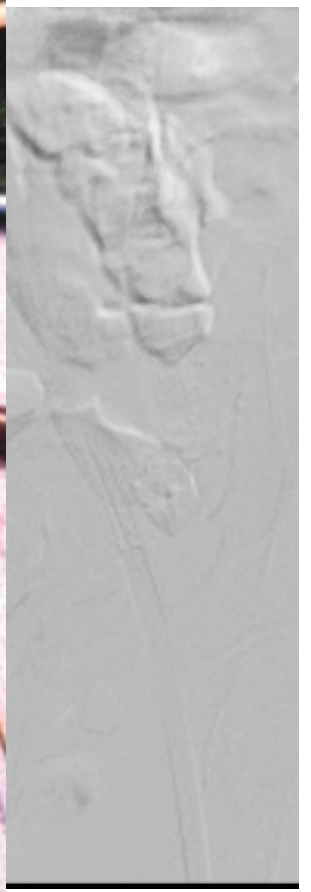
More and More Laser Fens



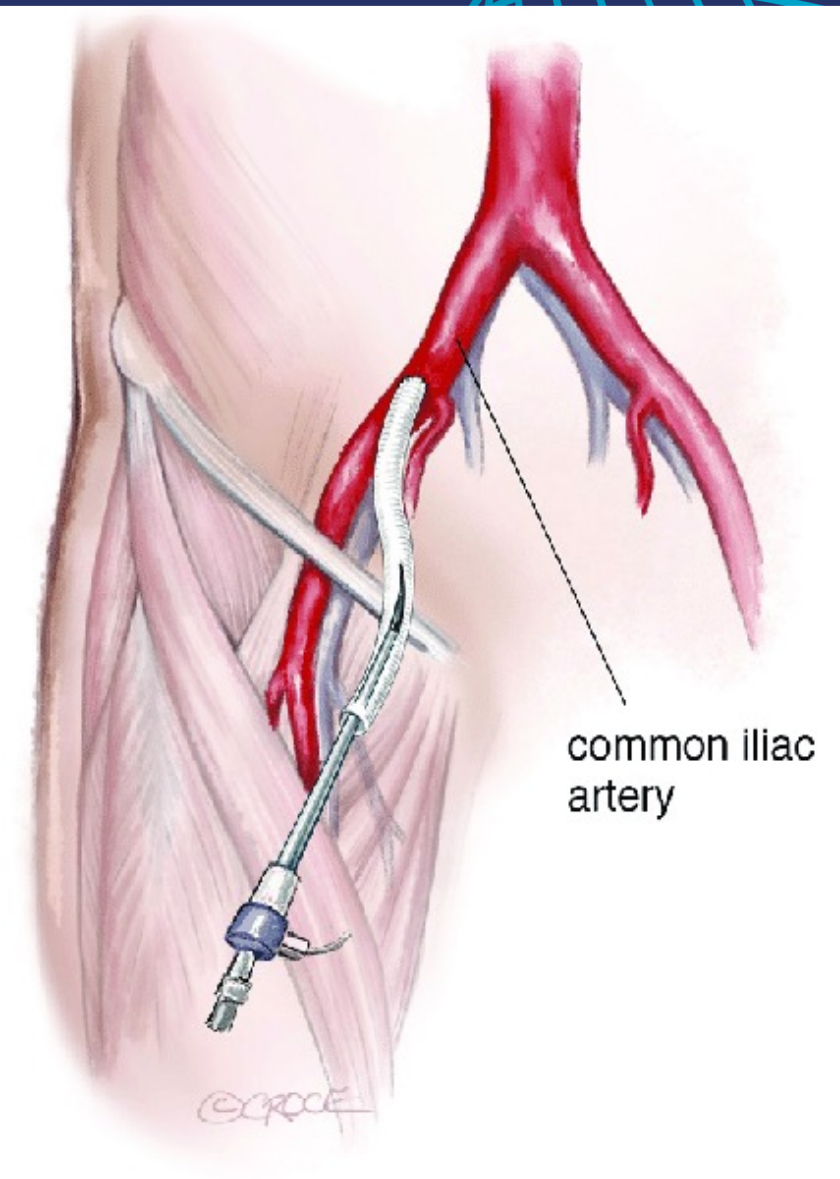


EVAR Access Issues Are Real—12%

Access Site Complications are Real



For Years the Only Answer = Open Conduits



Access Complications

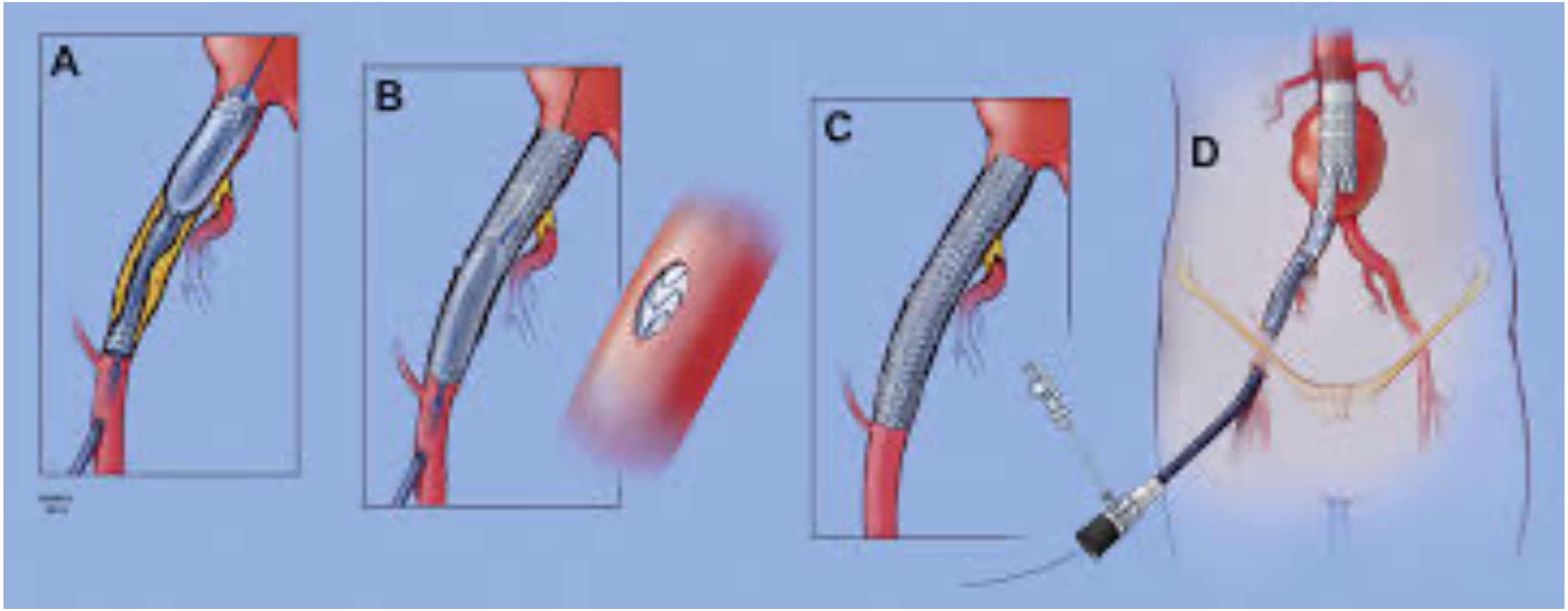
The long-term implications of access complications during endovascular aneurysm repair

Thomas F. X. O'Donnell, MD, Sarah E. Deery, MD, MPH, Laura T. Boitano, MD, Marc L. Schermerhorn, MD, Jeffrey J. Siracuse, MD, W. Darrin Clouse, MD, Mahmoud B. Malas, MD, Hiroo Takayama, MD, PhD, *and* Virendra I. Patel, MD, MPH, *Boston, Mass; New York, NY; Baltimore, Md; Charlottesville, Va; and San Diego, Calif*

addition to death, patients with access site complications had higher rates of other major complications, including reoperation during the index hospitalization (19% vs 1.2%; $P < .001$), myocardial infarction (3.5% vs 0.7%; $P < .001$), stroke (0.8% vs 0.2%; $P < .001$), acute kidney injury (12% vs 3%; $P < .001$), and reintubation (5.7% vs 0.8%).

O'Donnell TFX, et al. *J Vasc Surg*. 2021;73(4):1253-1260

Then Endovascular, Controlled Rupture with Covered Graft

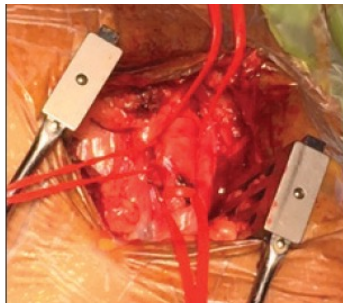


Alternative Access Approaches Have Tradeoffs

Nonfemoral alternative access procedures are available, but each has tradeoffs.

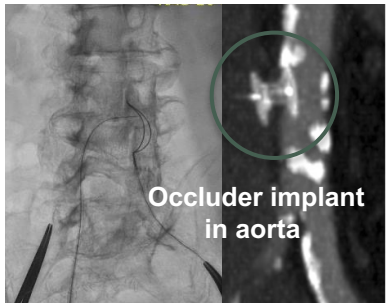
- Unlikely to implement "minimalist" TAVR, which reduces length of stay and hospital resource utilization
- Atypical room setup, which may impact procedural flow and scheduling efficiency
- Longer learning curve to achieve proficiency, which may impact complication rates and patient outcomes
- Have access route-specific complications, including major bleeding and stroke, which can drive morbidity

	Moderate sedation	Percutaneous	"Typical" room setup	Procedure time	Device cost	Length of stay
Transfemoral	+++	+++	+++	+++	+++	+++
IVL-transfemoral	+++	+++	+++	+++	++	+++
Axillary/ subclavian			---	++	+++	
Transcarotid	---	---	---	+++	+++	
Transcaval	++	+++	+++	--	---	



Subclavian/axillary

Transcarotid



Transcaval

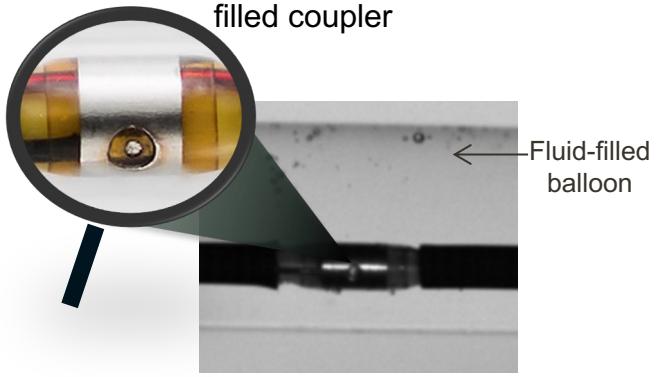
TAVR = transcatheter aortic valve replacemen.

McCarthy FH, et al. *J Thorac Cardiovasc Surg.* 2017;154(4):1224-1232. Doshi R, et al. *Clin Cardiol.* 2018;41(3):326-332. Greenbaum AB, et al. *J Am Coll Cardiol.* 2017;69(5):511-521. Paone G, et al. *Ann Thorac Surg.* 2018;106(4):1105-1112.

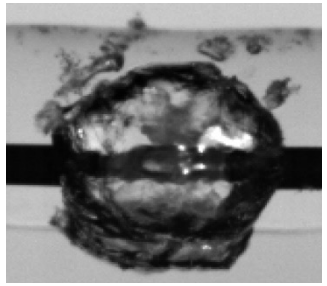
IVL's Unique Mechanism of Action

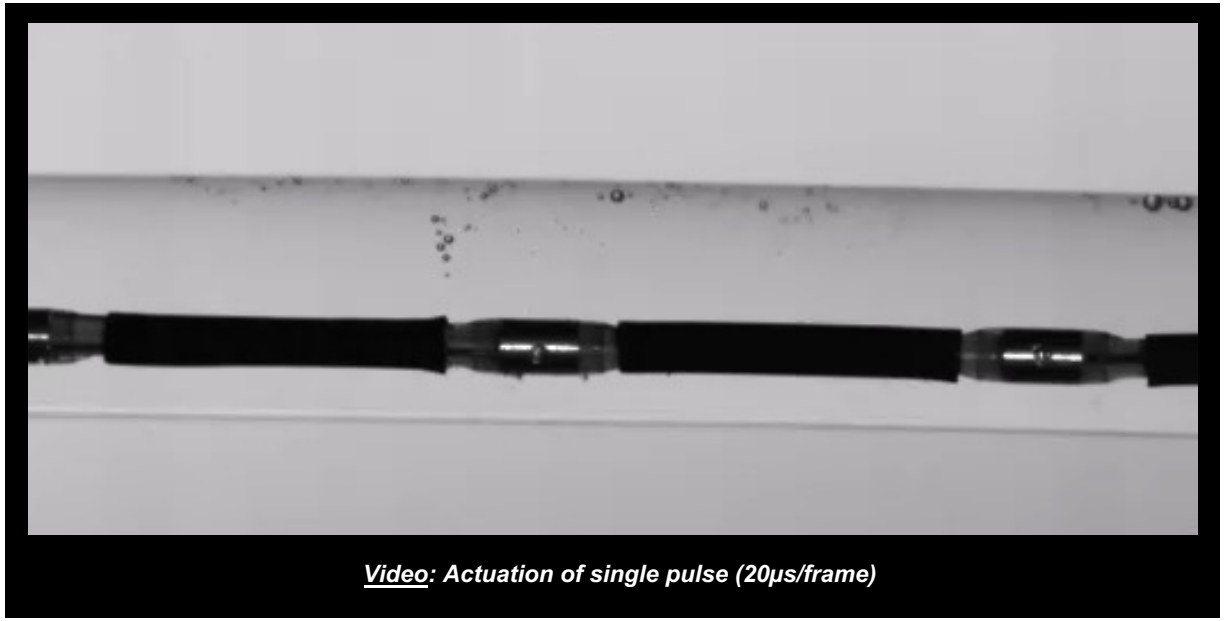
High-speed sonic pressure wave created safely inside integrated balloon

1 **Unfocused lithotripsy energy** is created at the emitters which are contained in a fluid-filled coupler



2 Electrical energy is delivered to the emitter, initiating the steam bubble, which expands and collapses, creating **sonic pressure waves**

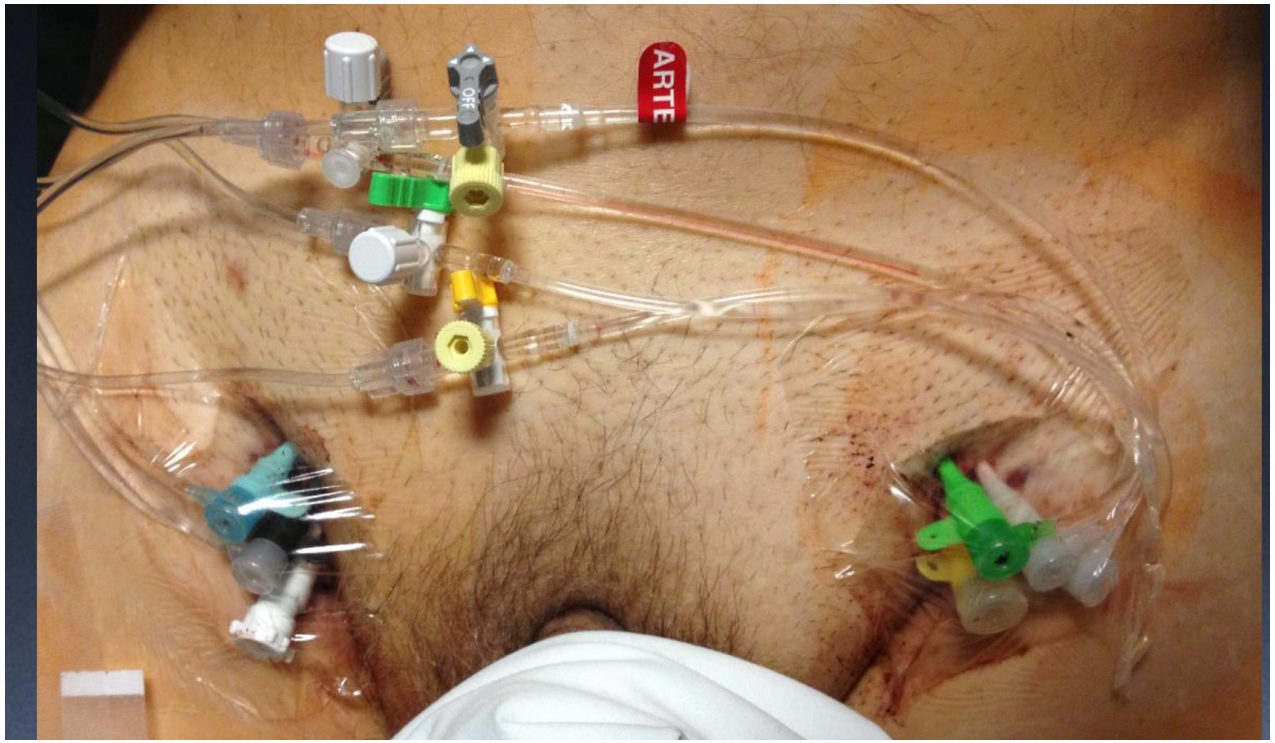




***Video*: Actuation of single pulse (20µs/frame)**

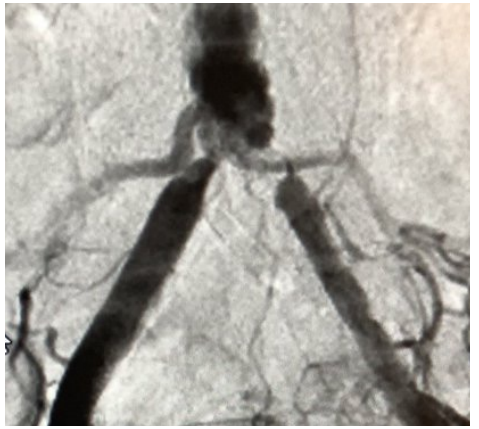
Intravascular Lithotripsy????

- I’m not a urologist
- Is that really our mentality?



Complicated Vascular Access Precludes Early Discharge Protocols

- Percutaneous transfemoral (TF) TAVR often permits early-discharge (“minimalist”) protocols, which reduce resource utilization and cost and improve patient satisfaction
- Complicated vascular access is a barrier to early discharge protocols
  - Transfemoral TAVR is precluded or complicated by severe iliac calcification and stenosis
  - Periprocedural vascular complications drive increased cost and increased length of stay
  - Nonfemoral access generally requires increased cost and/or length of stay
- While alternative access is necessary in 5-10% of TAVR patients, complicated vascular access is estimated in 12-21% of patients
- Intravascular lithotripsy (IVL) safely modifies iliac artery calcium, preserving the benefits of transfemoral TAVR access



Babaliaros V, et al. *JACC Cardiovasc Interv.* 2014;7(8):898-904. Di Mario C, et al. *Catheter Cardiovasc Interv*. 2018;91(2):354-355. Ali N, et al. *Eur J Heart Fail.* 2018;20(4):642-650. Okoh AK, et al. *Cardiovasc Revasc Med.* 2019. Rogers T, et al. *Catheter Cardiovasc Interv.* 2018;92(5):964-971.

Shockwave IVL Is a Simple and Safe Procedure to Facilitate TF-TAVR

IVL facilitates transfemoral TAVR in complicated patients and supports a minimalist approach, which has been shown to

- Maximize procedure throughput and predictability
- Minimize time-to-ambulation and hospital length-of-stay
- Minimize or eliminate some hospital resource utilization, including ICU and OR time

IVL is a simple and safe system that maintains typical transfemoral procedure workflow.

- Short learning curve and minimal technical support requirement
- Typical transfemoral room setup, fits in standard workflow
- Enables procedural consistency and efficiency
- Minimizes vascular complications—stenting not required
- Effective in enabling transfemoral TAVR in calcified patients

ICU = intensive care unit; OR = operating room.

Madhavan MV, et al. *Catheter Cardiovasc Interv*. 2020;95(5):959-968. DiMario C, et al. *JACC Cardiovasc Interv.* 2019:12(5);502-504.

IVL Preserves Transfemoral Access Pre-TAVR

Case example

• 7.0 mm IVL delivered to bilateral iliac arteries

• Post-IVL iliac arteries allowing safe passage of a 26 mm TAVR device (minimum vessel diameter required > 5.5 mm)
• Endovascular femoral repair
• Patient discharged following day

• Post-IVL10% residual DS in both iliac and CFA arteries
• No dissections, perforations or stent placement

Intravascular lithotripsy

- Preserves transfemoral TAVR delivery in the presence of calcified iliac disease
- Safety and acute effectiveness allow the safe passage of large-bore devices

Clinical experience pre-TAVR

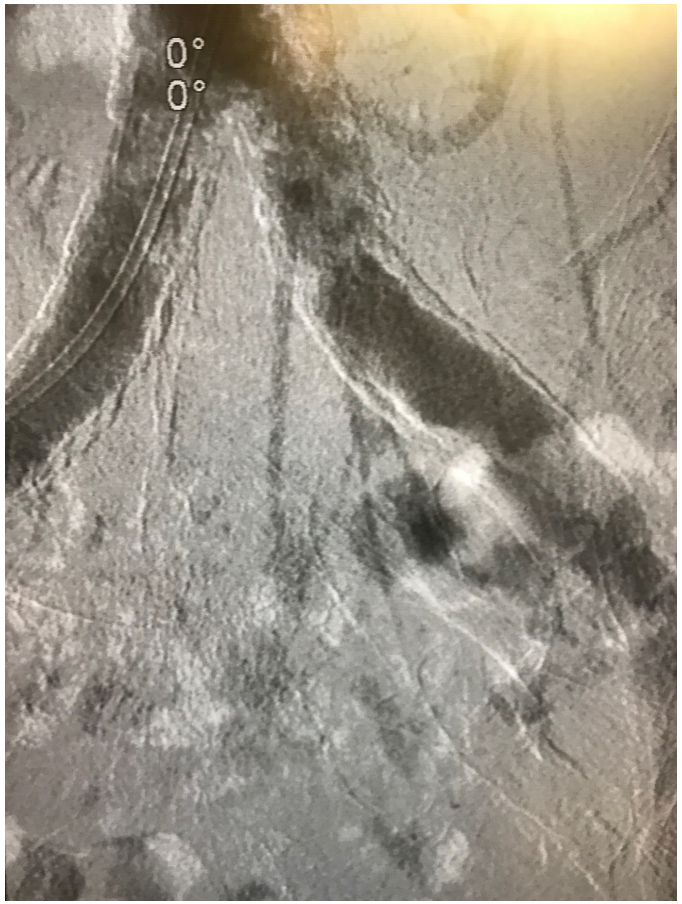
Patients included	n	42
	Diameter stenosis	58.6 ± 17.5%
	Calcification (max arc)	265.5 ± 88.3°
Sheaths	14Fr ID	78.5%
	16Fr ID	21.4%
Safety	Dissections	0 grade D or greater
	Perforations	0
	Provisional stents	0
	Pseudoaneurysm	2.3% (1)
	Endarterectomy	2.3% (1)
Effectiveness	TF valve delivery	100% (42)
	Same-procedure	100% (42)
	Transcatheter closure	92.8% (39)

TF = transfemoral; DS = diameter stenosis.

DiMario C, et al. *JACC Cardiovasc Interv.* 2019:12(5);502-504.

Challenging Iliofemoral Access for Percutaneous Heart Pump Insertion

- Mechanical circulatory assist devices are frequently used to assist cardiac output in cardiogenic shock or during high-risk PCI
- Transfemoral percutaneous heart pump access can be precluded or complicated by severe iliac calcification, stenosis, and tortuosity
- Alternative access via subclavian/axillary approach is possible, but may require a significant learning curve or confer additional case complexity
- IVL safely modifies iliac artery calcium and achieves luminal gain, which may enable transfemoral percutaneous heart pump placement



PCI = percutaneous coronary intervention.

Al Kindi AH, et al. *J Thor Cardiovasc Surg.* 2014;147(2):644-651. Ali N, et al. *Eur J Heart Fail.* 2018;20(4):642-650.

IVL Facilitates Safe Transfemoral Impella Insertion

Case example

Calcified iliac access

Percutaneous heart pump won't advance

IVL cracks calcium

Percutaneous heart pump advances easily

Intravascular lithotripsy

- Maximizes luminal gain and improves compliance
- Preserves transfemoral percutaneous heart pump delivery in the presence of calcified iliac disease
- Safety and acute effectiveness allow the safe passage of large-bore devices

Clinical experience pre-percutaneous heart pump

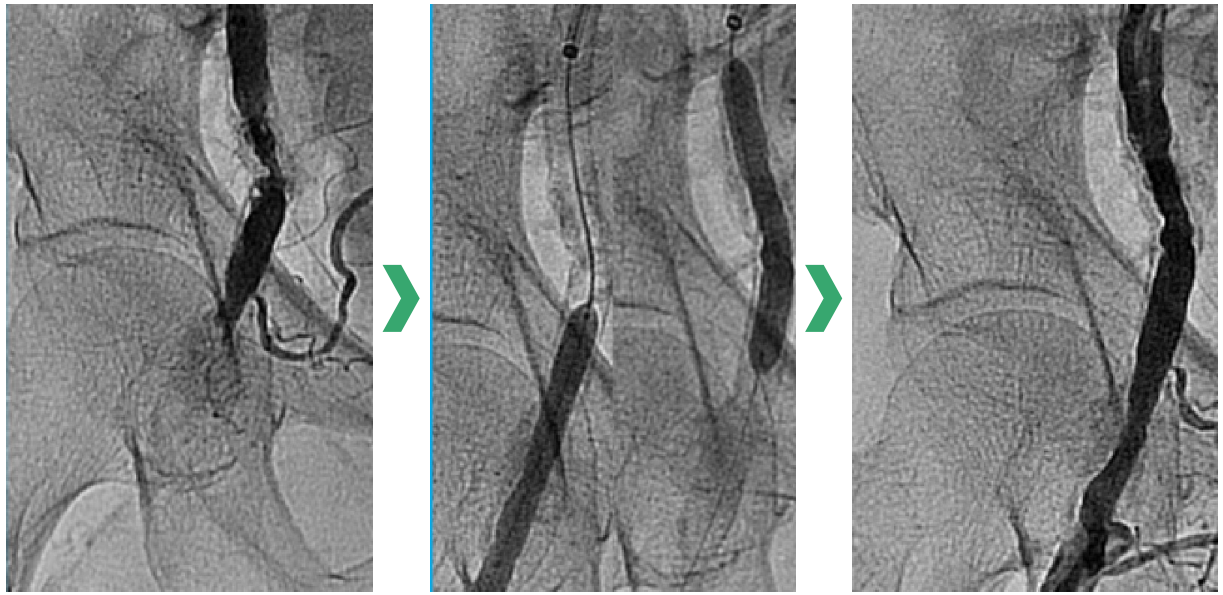
Patients included	N	12
	HRPCI/CS	9/3
	Planned percutaneous heart pump	10
	Planned IVL	5
Procedural	Percutaneous heart pump	11
	IVL cath/pulses	7.0/180
Safety	Dissections/ perforations	0
	Provisional stents	0
	Surgical repair	0
	Psuedoaneurysm	0
	Hematoma > 10cm	0
Effectiveness	TF percutaneous heart pump delivery	(100%)
	Transcatheter closure	(75%)

HRPCI/CS = high-risk PCI and cardiogenic shock.

Riley R, et al. *Catheter Cardiovasc Interv.* Feb 2020.

IVL in Calcified Iliac Arteries

Case example



- Baseline angiogram showing severe calcified stenosis of R Iliac and CFA arteries
- 80% iliac DS and 100% CFA
- 6.5 mm IVL delivered to iliac and CFA arteries
- Post-IVL 10% residual DS in both iliac and CFA arteries
- No dissections, perforations, or stent placement

Intravascular lithotripsy

- Is safe and effective for both calcified symptomatic, occlusive disease and to facilitate delivery of large-bore sheaths

Disrupt PAD III observational study

		Overall (N=118)	Claud/CLI (N=101)	Access (N=17)
Patients included	RVD, mm	7.3	7.1	8.4
	% DS	83	84	80
	RC 2-3	82	72	10
	RC 4-6	35	28	7
	Severe calcification	82%	81%	89%
	RVD, mm	7.3	7.1	8.4
Safety	Flow-limiting dissections	0	0	0
	Perforations	0	0	0
	Slow flow/no reflow	0	0	0
Effectiveness	Stent utilization	73%	78%	41%
	Final % DS	12	12	13

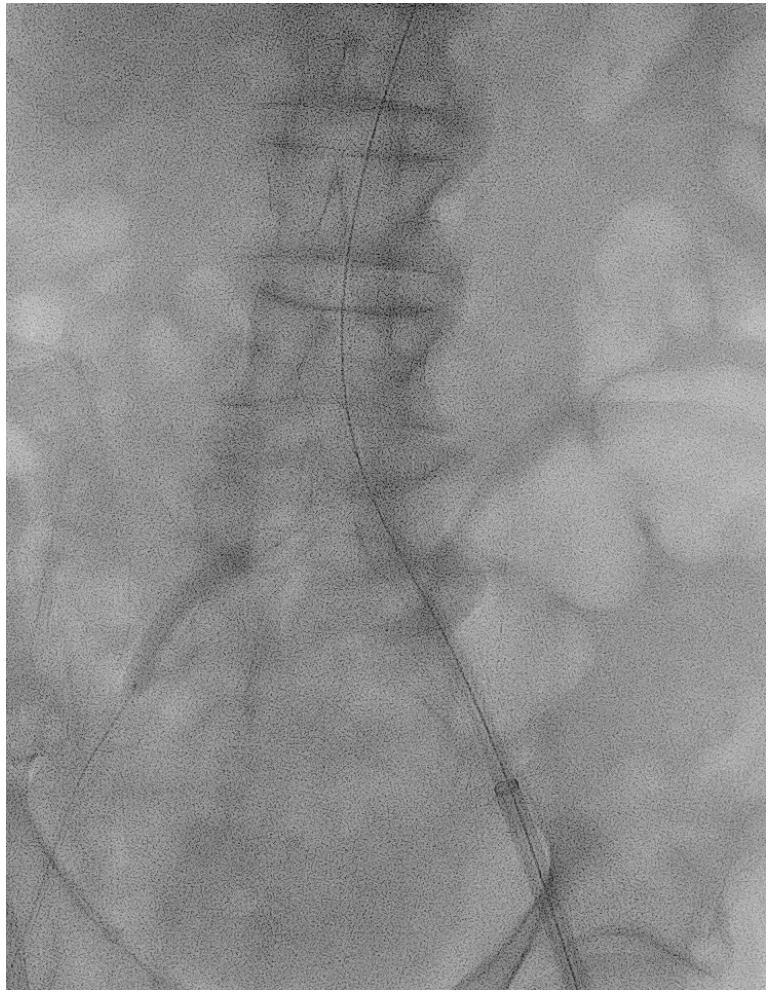
CFA = common femoral artery; claud = claudication; CLI = critical limb ischemia; RVD = right ventricular dysfunction; RC = Rutherford classification.

Armstrong EJ, et al. *Cardiovasc Revasc Med.* 2020;21(10):1262-1268.

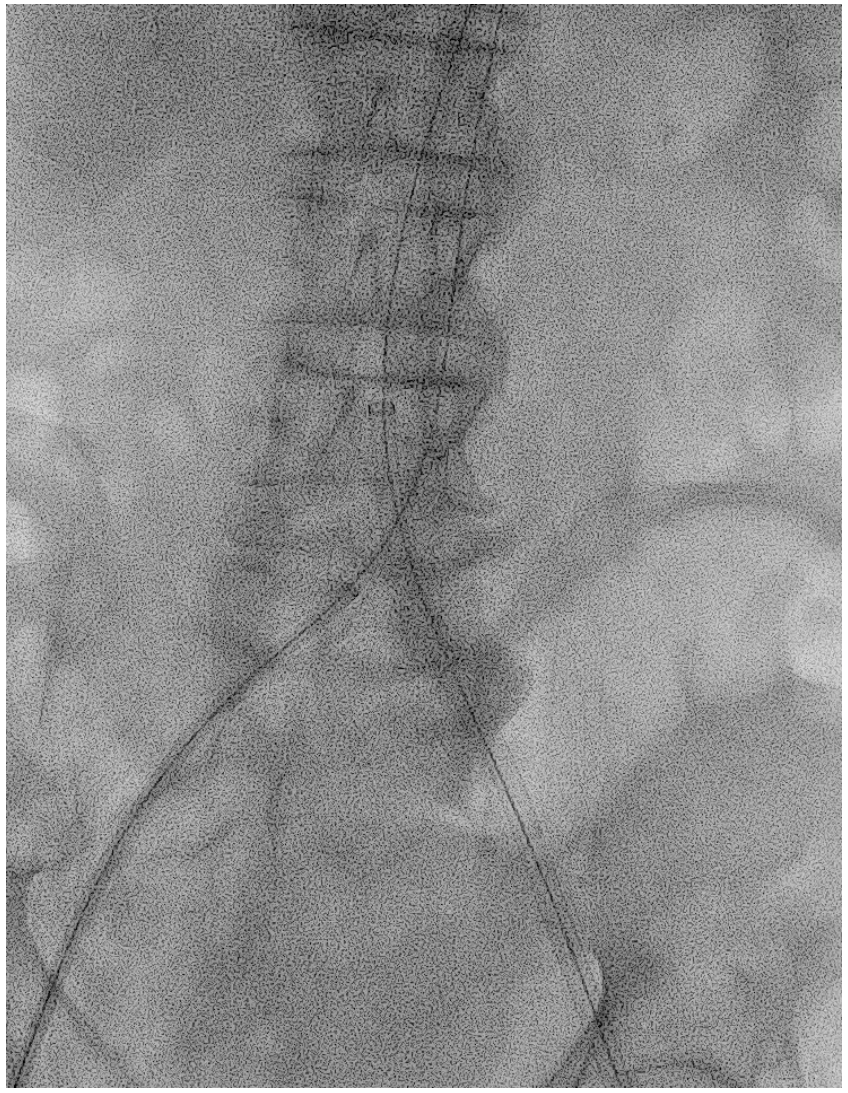
Dense, Thick, Non-Eggshell Calcifications

Dense Calcifications w/ Stenoses

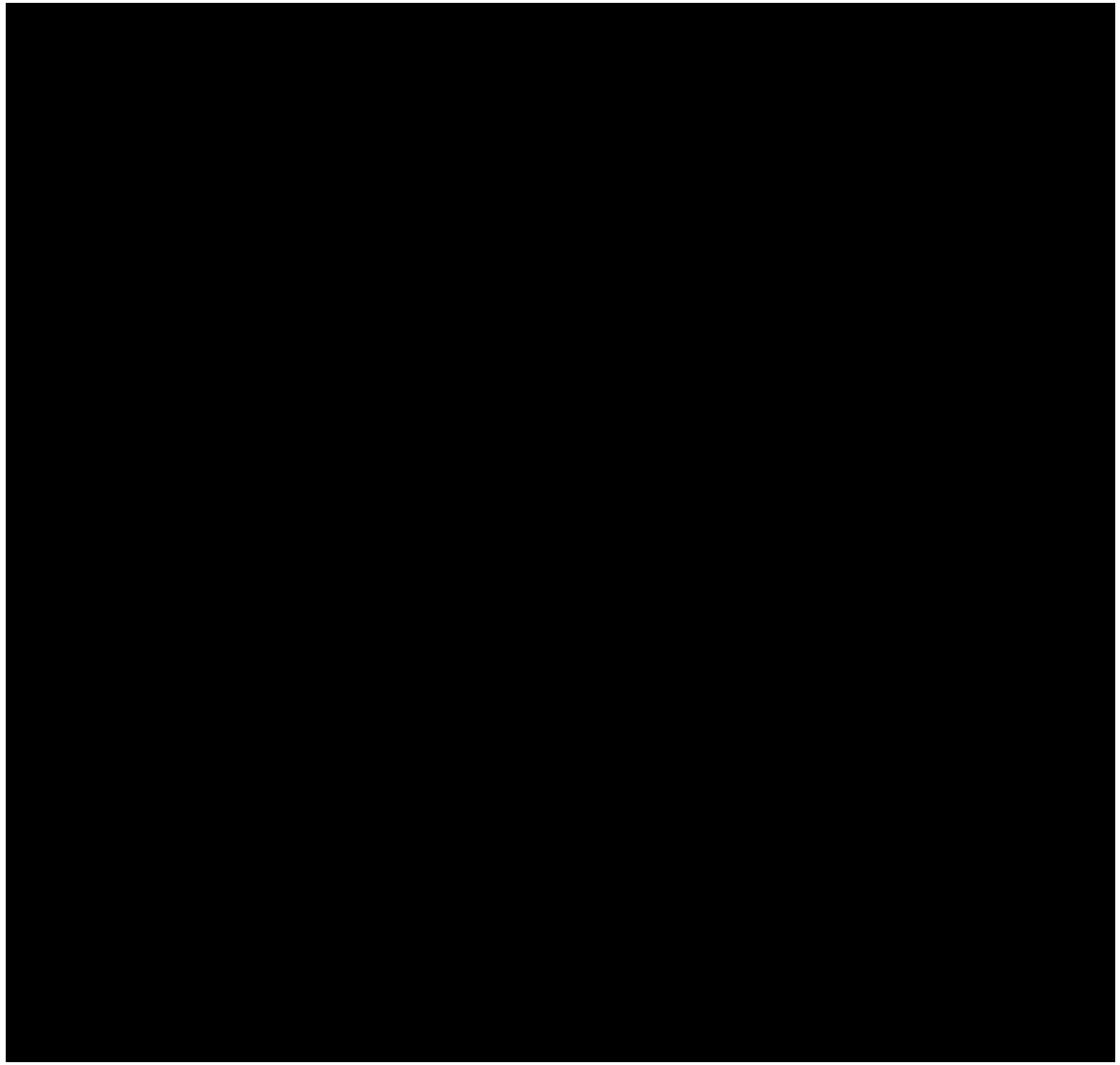
Bilateral Iliac IVLs—7 mm x 60 mm



Sheath Passage >>>>> Successful EVAR



Successful EVAR!



Conclusion

- IVL is here to stay
- Iliacs, TEVAR, EVAR, fem/pop/tib
- TCAR assistance with calcified lesions?

TCAR = transcarotid artery revascularization.