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# Aspiration thrombectomy for acute limb ischemia

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**Rabih Chaer, MD, MSc**  
**Professor and Chief**  
**Division of Vascular Surgery**



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# Acute Limb Ischemia Disease State Overview

The reported incidence of ALI is 1–1.5 individuals per 10,000 individuals per year

Reported  
**Mortality Rate**  
**15% - 20%**

Reported  
**Amputation Rate**  
**10-15%**  
at 30-days



# Contemporary outcomes of endovascular interventions for acute limb ischemia

R. Byrne, A. Taha, E. Avgerinos, L. Marone, M. Makaroun, R. Chaer  
JVS 2013

- Technical success is higher with OR for patients presenting with failed bypass grafts
- Amputation rates are comparable
- Overall mortality rates are significantly higher at 30 days and 1 year in the OR group



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JVS September 2025



## Comparison of open and endovascular therapy for infrainguinal acute limb ischemia in the era of percutaneous thrombectomy

Marissa C. Jarosinski, MD MSc<sup>1</sup>, Kevin Li, BS<sup>2</sup>, Elizabeth A. Andraska, MD MSc<sup>1,2</sup>, Katherine M. Reitz, MD MSc<sup>1,3</sup>, Nathan L. Liang, MD MSc<sup>1,2</sup>, Rabih Chaer, MD MSc<sup>1,2</sup>, Edith Tzeng, MD<sup>1,3</sup>, Natalie D. Sridharan, MD MSc<sup>1</sup>

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### Abstract

**Introduction:** Endovascular treatment of acute limb ischemia (ALI), primarily consisting of catheter-directed thrombolysis (CDT), has been shown to reduce mortality without affecting limb salvage. Percutaneous thrombectomy (PT) devices have expanded endovascular approaches while decreasing thrombolytic use. While many advocate for an endovascular-first approach, it's unclear which patients would benefit most from each strategy.

**Methods:** We included adults (18+) who underwent revascularization for infrainguinal ALI (01/2016–12/2023) at a multihospital healthcare system. We compared amputation and mortality after endovascular vs. open approaches using logistic regression, Kaplan-Meier curves, and cox regression.

**Results:** We included 315 patients: 145 undergoing an endovascular-first strategy (89 CDT, 51 PT, 5 angioplasty/stent) and 170 undergoing open therapy (132 open thrombectomy, 38





# Contemporary Cohort

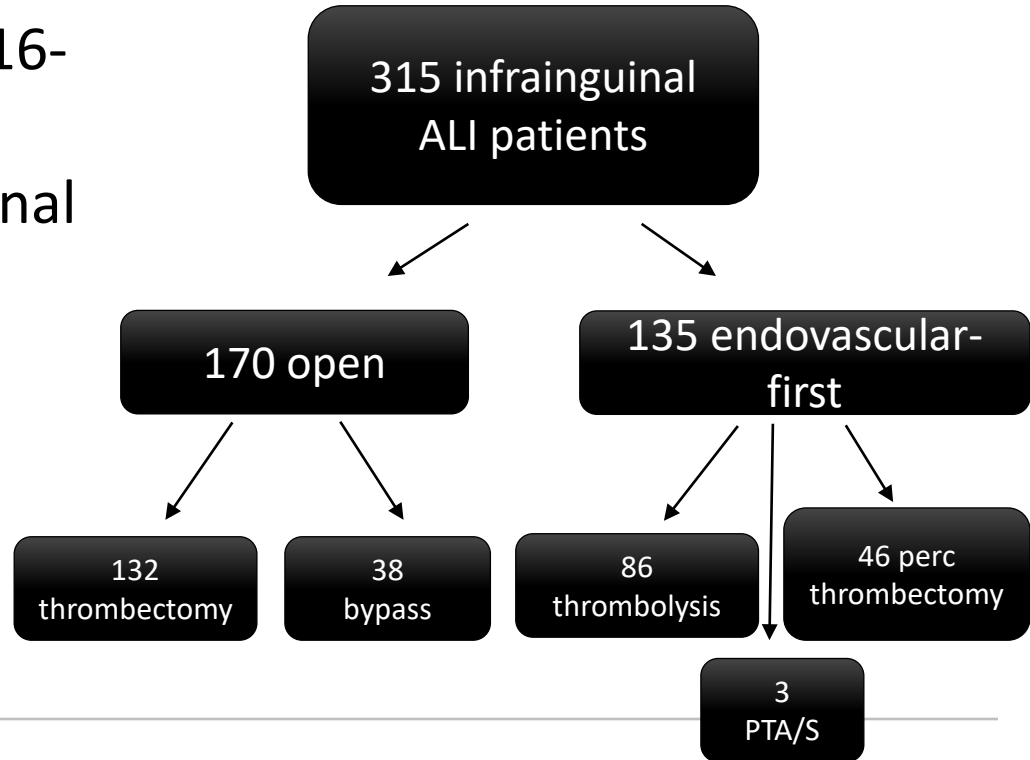
Retrospective chart review multi-hospital healthcare system (1/2016-12/2023)

**Inclusion:**  $\geq 18$  y/o with infrainguinal ALI undergoing endovascular or open treatment

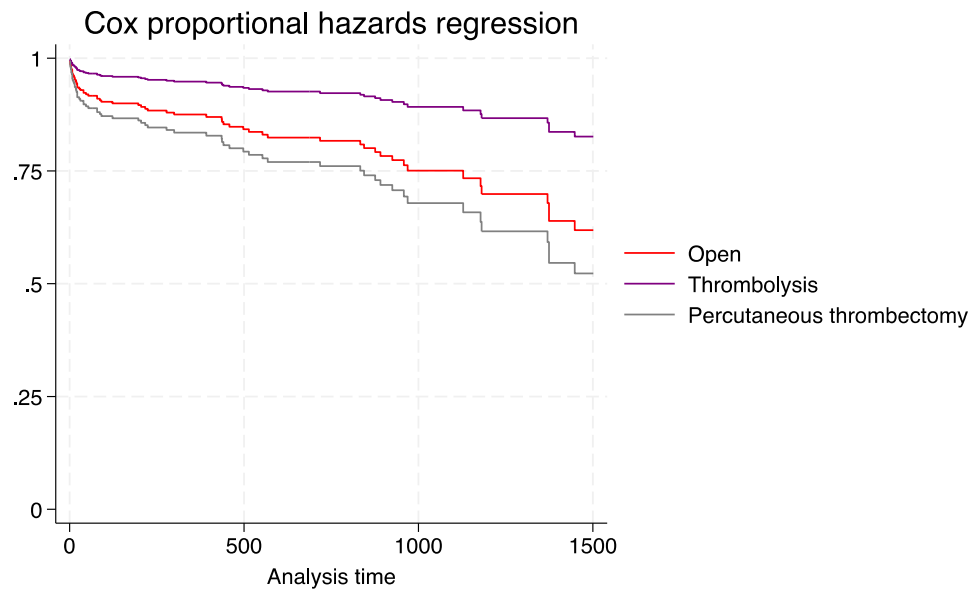
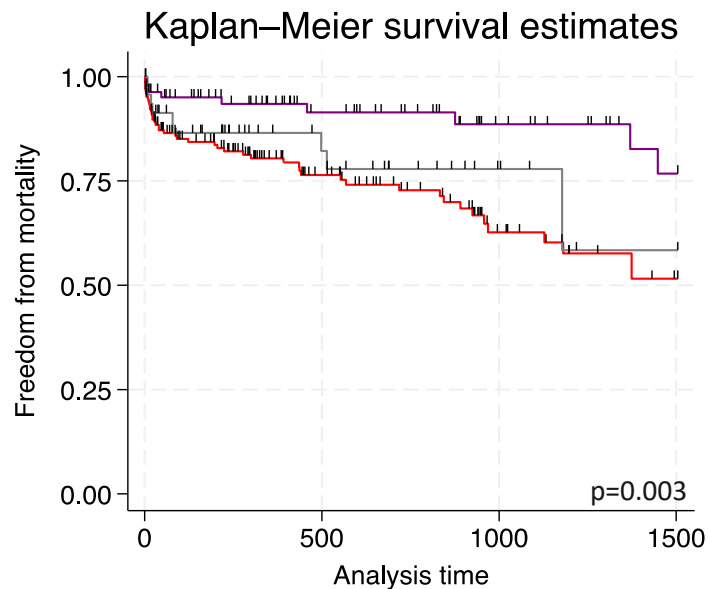
**Exclusion:**

ALI secondary to trauma, dissection, iatrogenic injury, popliteal aneurysm, COVID

Rutherford 3 ischemia

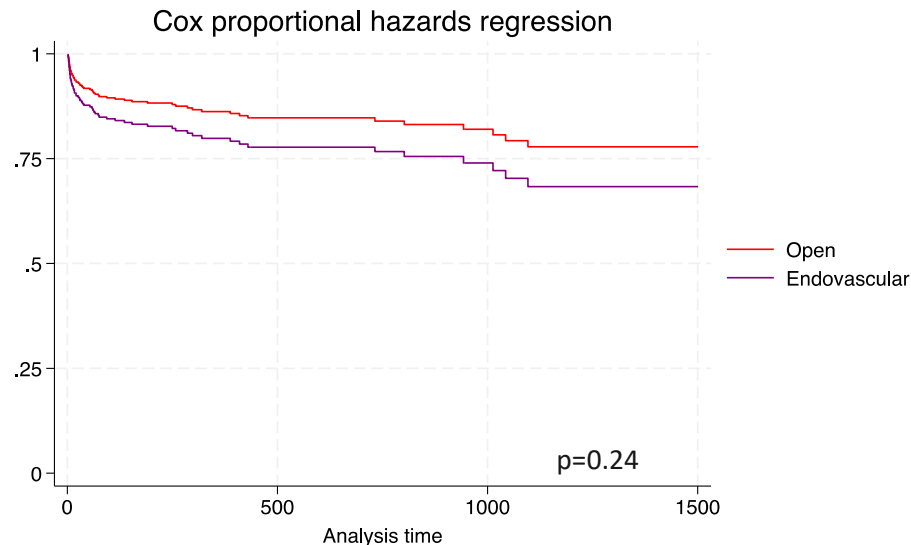
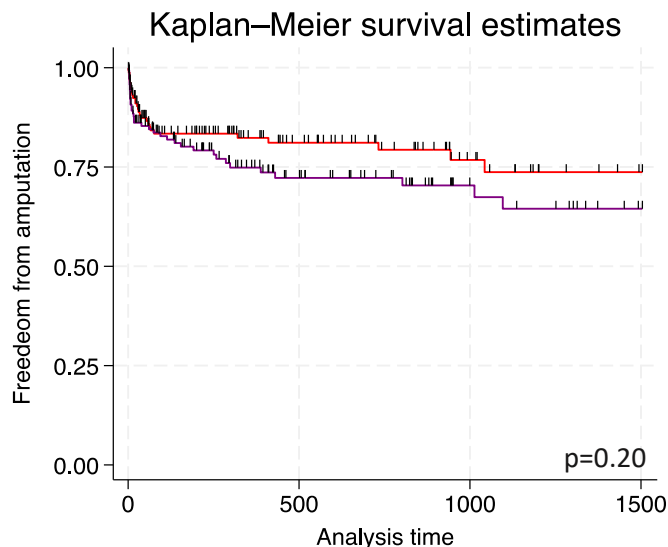


# Patients undergoing thrombolysis had lower mortality than open



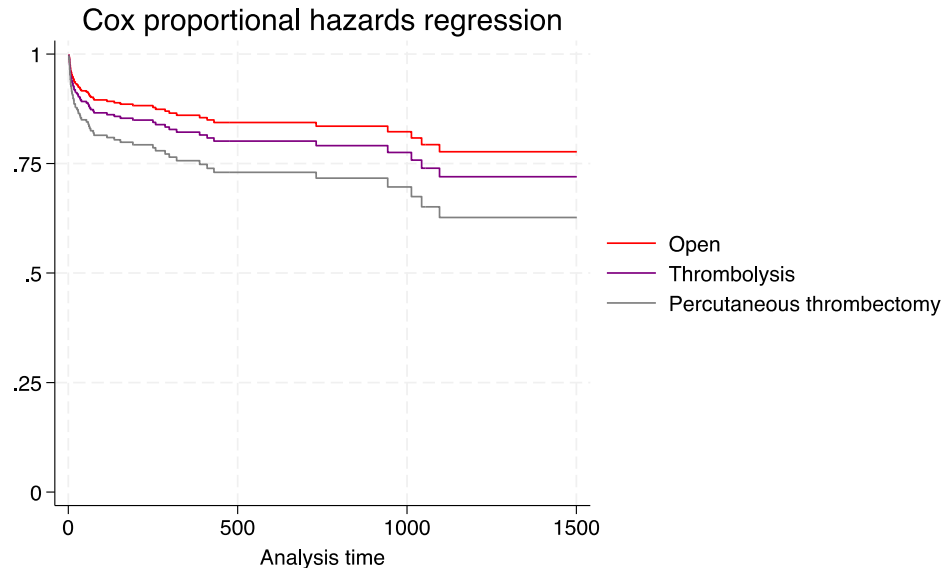
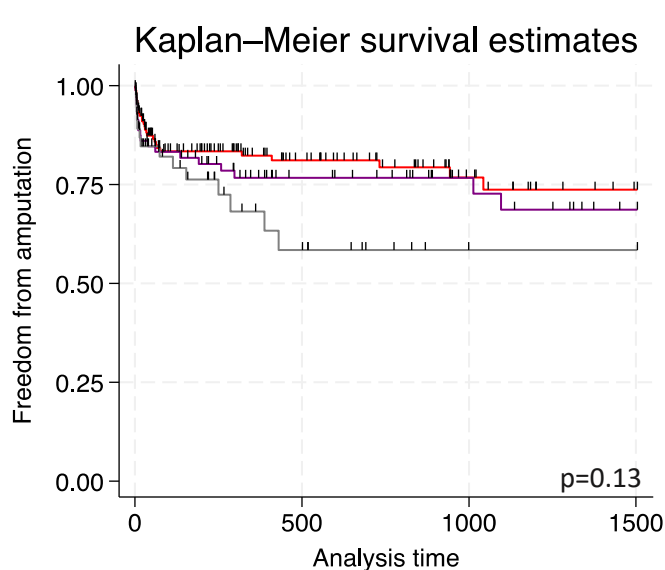
	Total	Mortality	Adjusted Hazard Ratio
Open	170	48 (28%)	ref
Thrombolysis	86	9 (10%)	0.38 (0.17-0.83), p=0.02
Percutaneous thrombectomy	46	9 (20%)	1.38 (0.61-3.10), p=0.43

# Endovascular therapy had equivalent limb salvage overall



	Total	Amputation	Adjusted Hazard Ratio
Open	170	30 (18%)	ref
Endovascular	145	36 (25%)	1.41 (0.80-2.48), p=0.24

# Endovascular therapy had equivalent limb salvage overall

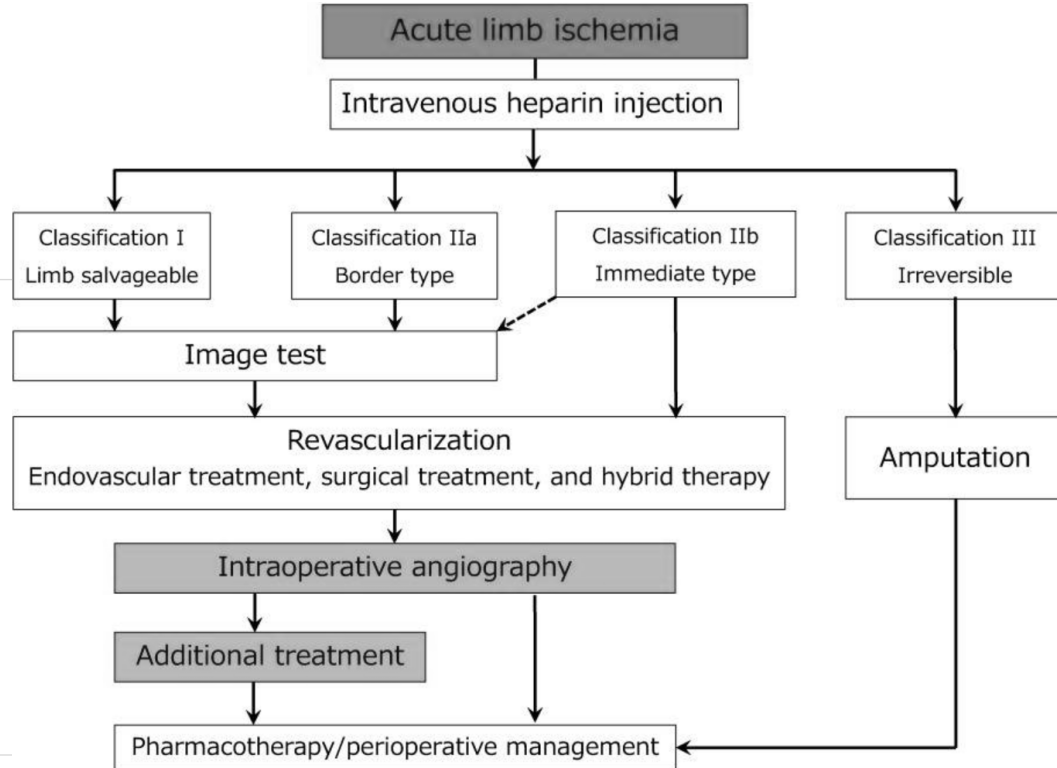


	Total	Amputation	Adjusted Hazard ratio
Open	170	30 (18%)	ref
Thrombolysis	86	19 (22%)	1.20 (0.62-2.34), p=0.59
Percutaneous thrombectomy	46	14 (30%)	1.73 (0.85-3.54), p=0.13

# ALI Treatment Algorithm

## Treatment options:

- Open Surgical Revascularization
- Catheter Directed Thrombolysis
- Endovascular Thrombectomy
- Hybrid approach



# 2020 ESVS Guidelines for ALI: Fogarty



## ESVS Guidelines

### CLINICAL PRACTICE GUIDELINE DOCUMENT

#### European Society for Vascular Surgery (ESVS) 2020 Clinical Practice Guidelines on the Management of Acute Limb Ischaemia

##### Recommendation 14

It is recommended that patients with acute limb ischaemia should have access to treatment in a hybrid theatre, or operating theatre with C arm equipment, and by a clinical team able to offer a full range of open or endovascular interventions during a single procedure.

Class	Level	References
I	C	Consensus

##### Recommendation 18

For patients undergoing open and endovascular surgery for acute limb ischaemia, completion angiography is recommended.

Class	Level	References
I	C	Lipsitz and Veith (2001), <sup>73</sup> Zaraca <i>et al.</i> (2010) <sup>79</sup>



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# 2020 ESVS Guidelines for ALI: Lysis

EJVES 2020; 59; 173-218

## Recommendation 23

For patients with acute onset claudication (Rutherford grade I) that does not threaten the limb, (percutaneous) catheter-directed thrombolysis is not recommended.

Class	Level	References
III	B	Braithwaite <i>et al.</i> (1999), <sup>107</sup> Korn <i>et al.</i> (2001) <sup>108</sup>

Ruth I → NO

## Recommendation 24

For patients with Rutherford grade IIa acute limb ischaemia, it is recommended that (percutaneous) catheter-directed thrombolysis is considered as an alternative to surgery.

Class	Level	References
I	A	The STILE trial (1994), <sup>91</sup> Comerota <i>et al.</i> (1996), <sup>100</sup> Enezate <i>et al.</i> (2017), <sup>13</sup> Ouriel and Veith (1998), <sup>101</sup> Bath <i>et al.</i> (2019) <sup>27</sup>

Ruth IIa → Yes as alternative to surgery

## Recommendation 25

For patients with Rutherford grade IIb acute limb ischaemia, (percutaneous) catheter-directed thrombolysis may be considered if initiated promptly, and may be combined with percutaneous aspiration or thrombectomy.

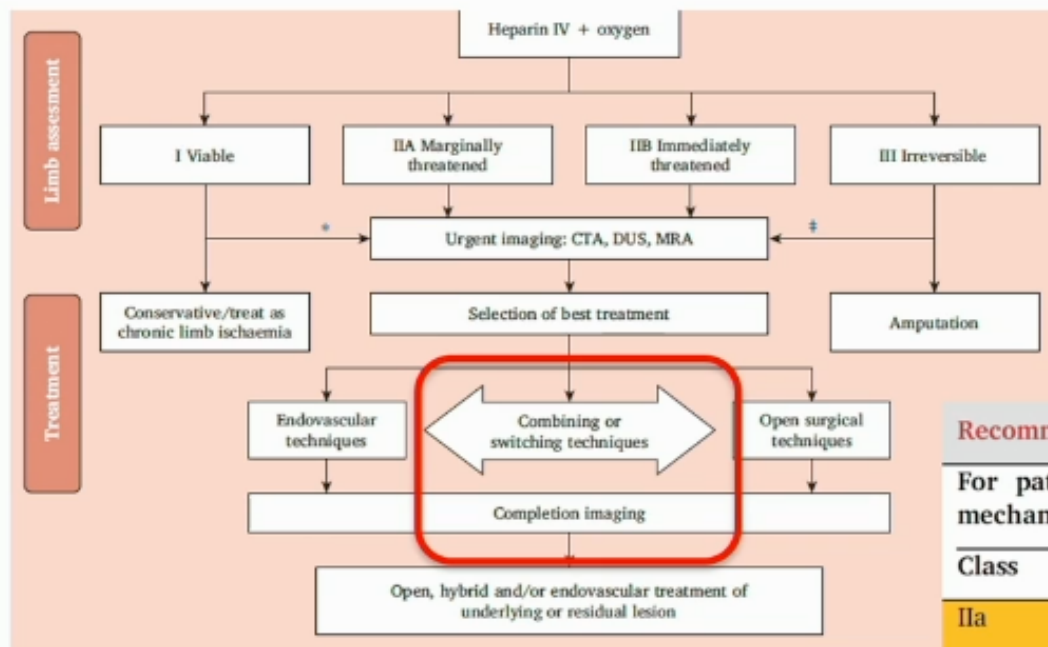
Class	Level	References
IIb	B	Ebben <i>et al.</i> (2019), <sup>14</sup> Acosta and Kuoppala (2015), <sup>17</sup> Braithwaite <i>et al.</i> (1997), <sup>109</sup> Grip <i>et al.</i> (2014), <sup>23</sup> (2018) <sup>25</sup>

Ruth IIb → Yes but “promptly” & with aspiration / thrombectomy



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# ESVS Guidelines Support Endovascular Approach



*- Paradigm shift from open to endo is going on*

## Recommendation 33

For patients with acute limb ischaemia, aspiration and mechanical thrombectomy should be considered.

Class	Level	References
Ila	C	Kwok et al. (2018), <sup>141</sup> Zehnder et al. (2000), <sup>147</sup> Byrne et al. (2014), <sup>148</sup> Kronlage et al. (2017) <sup>152</sup>



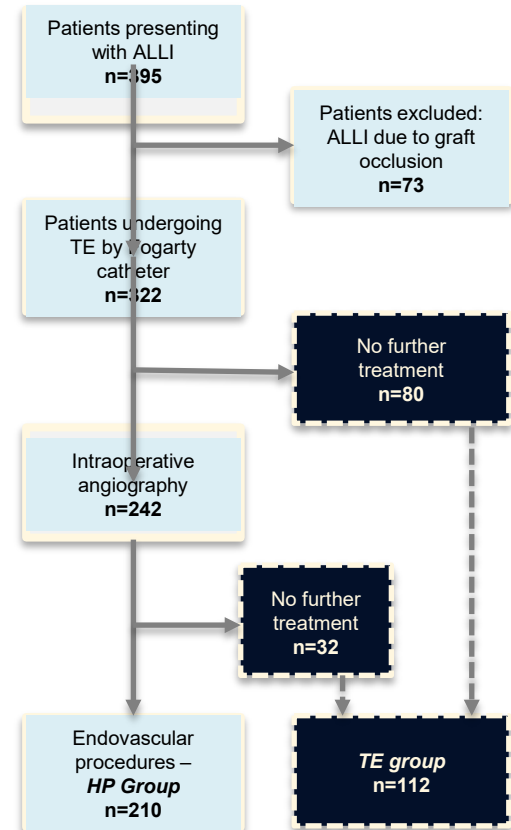
# Fogarty® Embolectomy vs. Hybrid

(surgical + endovascular)

From the Society for Vascular Surgery

The combination of surgical embolectomy and endovascular techniques may improve outcomes of patients with acute lower limb ischemia

Gianmarco de Donato, MD, Francesco Setacci, MD, Pasqualino Sirignano, MD, Giuseppe Galzerano, MD, Rosaria Massaroni, MD, and Carlo Setacci, MD, *Siena, Italy*



de Donato G, Setacci F, Sirignano P, et al. The combination of surgical embolectomy and endovascular techniques may improve outcomes of patients with acute lower limb ischemia. *J Vasc Surg.* 2014;59:729–736. doi:10.1016/j.jvs.2013.09.016.

The clinical results presented herein are for informational purposes only, and may not be predictive for all patients. Individual results may vary depending on patient-specific attributes and other factors.

# Fogarty<sup>®</sup> Embolectomy vs. Hybrid

Primary patency and estimated freedom from reintervention **favor**ed an endovascular hybrid approach at 2 and 5 years

## Finding Post-Surgery

Native arterial lesions (stenosis underlying thrombosis)

N=90

Residual thrombus in superficial femoral artery (SFA) & popliteal firmly adherent to the arterial wall

N=54

Residual thrombus in below-the-knee (BTK) vessel (not appropriately reached by the balloon catheter thromboembolectomy)

N=58

Vessel injury after intraluminal passage of Fogarty balloon catheter

N=8

86%

of patients required  
additional endovascular  
intervention post surgical  
embolectomy



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de Donato G, Setacci F, Sirignano P, et al. The combination of surgical embolectomy and endovascular techniques may improve outcomes of patients with acute lower limb ischemia. *J Vasc Surg.* 2014;59:729–736. doi:10.1016/j.jvs.2013.09.016.

The clinical results presented herein are for informational purposes only, and may not be predictive for all patients. Individual results may vary depending on patient-specific attributes and other factors. **Lightning 7 and Penumbra ENGINE were not used in this study.**

## Mechanical thrombectomy in acute limb ischemia: ad Interim results of the INDIAN UP Trial

Gianmarco de DONATO <sup>1</sup>, Edoardo PASQUI <sup>1</sup>\*,  
Maria A. RUFFINO <sup>2</sup>, Massimo SPONZA <sup>3</sup>, Angelo SPINAZZOLA <sup>4</sup>, Giuseppe GUZZARDI <sup>5</sup>,  
Francesco INTRIERI <sup>6</sup>, Daniele SAVIO <sup>7</sup>, Giancarlo PALASCIANO <sup>1</sup>, INDIAN UP Trial group ‡

<sup>1</sup>Unit of Vascular Surgery, Department of Medicine, Surgery and Neuroscience, University of Siena, Siena, Italy; <sup>2</sup>EOC - Ente Ospedaliero Cantonale, Lugano, Switzerland; <sup>3</sup>S. Maria della Misericordia Hospital, Udine, Italy; <sup>4</sup>ASST Crema, Crema, Italy; <sup>5</sup>Maggiore della Carità Hospital, Novara, Italy; <sup>6</sup>Santa Annunziata Hospital, Cosenza, Italy; <sup>7</sup>San Giovanni Bosco Hospital, Turin, Italy

‡Members are listed at the end of the paper.

\*Corresponding author: Edoardo Pasqui, Unit of Vascular Surgery, Department of Medicine, Surgery and Neuroscience, University of Siena, Siena, Italy.  
E-mail: pasqui11@student.unisi.it

### ABSTRACT

**BACKGROUND:** Penumbra/Indigo aspiration thrombectomy Systems (Penumbra Inc.) in patients with acute lower limb ischemia (ALLI) is becoming a fundamental alternative to surgical and intra-arterial thrombolysis. The INDIAN UP trial represents the second phase of the Italian national multicenter trial evaluating the safety and effectiveness of the device in the treatment of ALLI.

**METHODS:** To assess vessel patency, the TIPI (Thrombo-aspiration In Peripheral Ischemia), is used. The TIPI flow in three different moments: at presentation, immediately after thromboaspiration, and after all adjuvant procedures. The primary outcome is the technical success of the thrombo-aspiration with the investigative system, defined as near complete or complete revascularization TIPI 2 - 3. Safety and clinical success rate were collected at one month follow-up.

**RESULTS:** A total of 250 patients were enrolled. The mean age was 72.2±13.1 years and 72.1% were male. Rutherford grade on enrolment was I in 10.8%, IIa in 34.9%, and IIb in 54.4%. Primary technical success (TIPI 2-3 flow) was achieved in 90.8% of patients. Adjunctive procedures were needed in 158 cases. After all interventions, assisted primary technical success was 96.4%. No systemic bleeding complications or device related serious adverse events were reported. At one month follow up, survival rate was 97.2%, limb salvage was 97.6%. Primary patency was 89.6% and 13 (5.4%) reinterventions were registered.

**CONCLUSIONS:** The updated results of the INDIAN UP trial have confirmed the high value of the mechanical thromboaspiration device Indigo Penumbra in the treatment of ALLI in a large variety of clinical and anatomical settings.

(Cite this article as: de Donato G, Pasqui E, Ruffino MA, Sponza M, Spinazzola A, Guzzardi G, et al.; INDIAN UP Trial group. Mechanical thrombectomy in acute limb ischemia: ad Interim results of the INDIAN UP Trial. J Cardiovasc Surg 2023;64:247-54. DOI: 10.23736/S0021-9509.23.12668-1)

**KEY WORDS:** Lower extremity; Ischemia; Endovascular procedures; Peripheral arterial disease.



- 250 patients were enrolled
- Primary technical success (TIMI 2-3 flow) was achieved in 90.8% of patients
- At one month follow up, survival rate 97.2%, limb salvage 97.6%



# STRIDE Study Objective & Design

**Objective:** Collect safety and performance data on the Indigo<sup>®</sup> Aspiration System in a patient population with lower extremity acute limb ischemia (LE-ALI)

16 sites (13 USA, 3 EU)

119 patients (55 female, 64 male)

Safety and performance endpoints

Long-term follow-up to 1 year

30-day safety and efficacy results published in Journal of Vascular Surgery November 2023<sup>1</sup>



# Key Eligibility Criteria

## Key inclusion criteria

Acute ( $\leq 14$  days) occlusion of lower limb artery(ies) (below inguinal ligament)

Rutherford Category I, IIa, or IIb score

Firstline treatment with Indigo Aspiration System

$\geq 18$  years old

## Key exclusion criteria

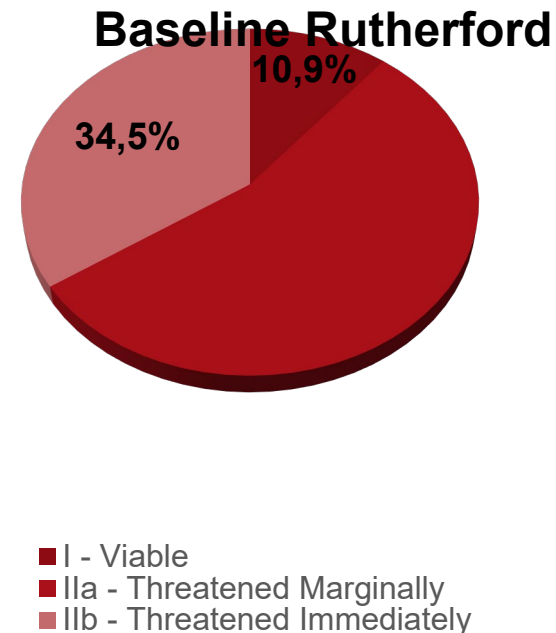
- Target vessel size  $< 2$  mm
- Amputation in the ipsilateral limb
- Target thrombus in a saphenous vein bypass graft
- Absolute contraindication to contrast administration
- Life expectancy of  $< 1$  year



# Baseline

## Thrombus, Lesion, & Clinical Severity

Thrombus & Lesion Evaluation	(N=119)
Median Target Thrombus Length (mm, IQR) (n=113)	80.0 [40.0, 197.0]
Tandem Lesion <sup>a</sup> (n=119)	18.5% (22/119)



# Results

## Efficacy

Primary Endpoint	All Patients	Secondary Safety Endpoint	All Patients
Target Limb Salvage at 30 days	98.2% (109/111)	Mortality at 30 days	3.4% (4/119)
Secondary Efficacy Endpoints		Device-related SAEs <sup>a</sup>	0.8% (1/119)
Technical Success	96.3% (105/109)	Major bleeding, peri-procedural <sup>b</sup>	4.2% (5/119)
Patency at 30 days	89.4% (101/113)		
Improvement in Modified SVS runoff score (pre- vs. post-procedure), median [IQR] n=106 (51 female, 55 male)	6.0 [0.0, 11.0]		

### No peri-procedural major bleeds were device-related

- Four patients met the criteria for major bleeding due to a transfusion of 2 or more units of PRBC and 1 met criteria due to a drop in hemoglobin of > 5 g/dL
- Four had a pre-procedure hemoglobin value below 10 g/dL and hematocrit 31% or less, and two had a reported history of chronic anemia

# Historical control surgical outcomes vs. STRIDE

Outcome	Open Surgery	STRIDE
Target Limb Salvage at 30 days	83.1% <sup>1</sup>	98.2% (109/111)
Patency at 30 days	78.6% <sup>2</sup>	89.4% (101/113)
Mortality at 30 days	13.2% <sup>3</sup>	3.4% (4/119)
Major bleeding	21.0% <sup>4</sup>	4.2% (5/119)

1. Veenstra EB, van der Laan MJ, Zeebregts CJ, et al. A systematic review and meta-analysis of endovascular and surgical revascularization techniques in acute limb ischemia. *J Vasc Surg.* 2020 Feb;71(2):654-668.e3. doi: 10.1016/j.jvs.2019.05.031.

2. Grip O, Wanhainen A, Michaëlsson K, et al. Open or endovascular revascularization in the treatment of acute lower limb ischaemia. *Br J Surg.* 2018 Nov;105(12):1598-1606. doi: 10.1002/bjs.10954.

3. Taha AG, Byrne RM, Avgerinos ED, et al. Comparative effectiveness of endovascular versus surgical revascularization for acute lower extremity ischemia. *J Vasc Surg.* 2015 Jan;61(1):147-54. doi: 10.1016/j.jvs.2014.06.109.

4. Kolte D, Kennedy KF, Shishehbor MH, et al. Endovascular versus surgical revascularization for acute limb ischemia: a propensity-score matched analysis. *Circ Cardiovasc Interv.* 2020 Jan;13(1):e008150. doi: 10.1161/CIRCINTERVENTIONS.119.008150.





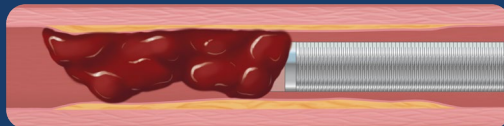
# CAVT. Penumbra



## **Bolt Mode**

Modulated Aspiration  
Designed to Rapidly  
Remove Thrombus  
and Restore Flow

Friction builds between large  
thrombi and the catheter when  
under continuous aspiration



**Bolt Mode** modulates between full  
aspiration and ambient pressure to  
break the friction and ingest the clot



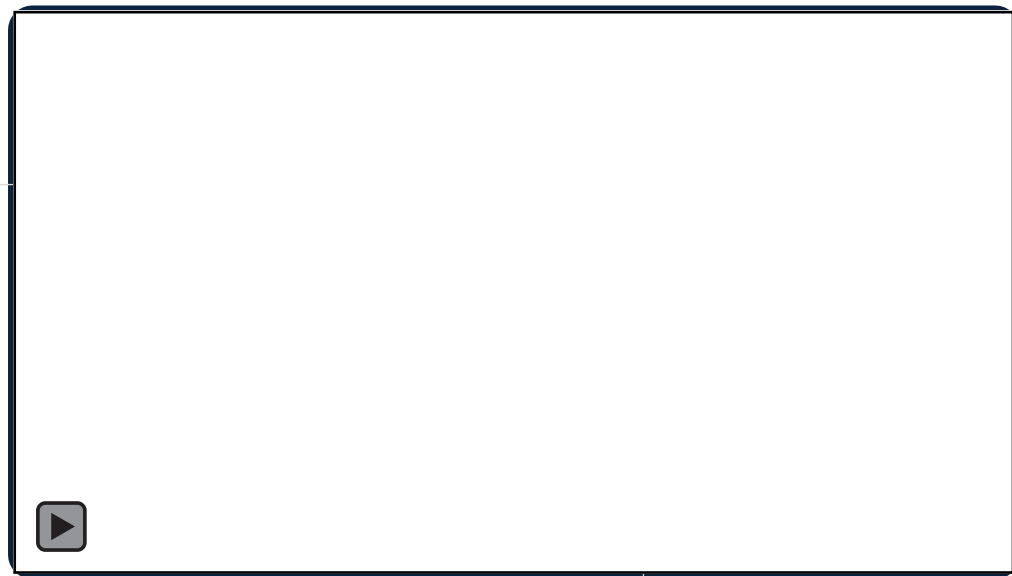
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# CAVT



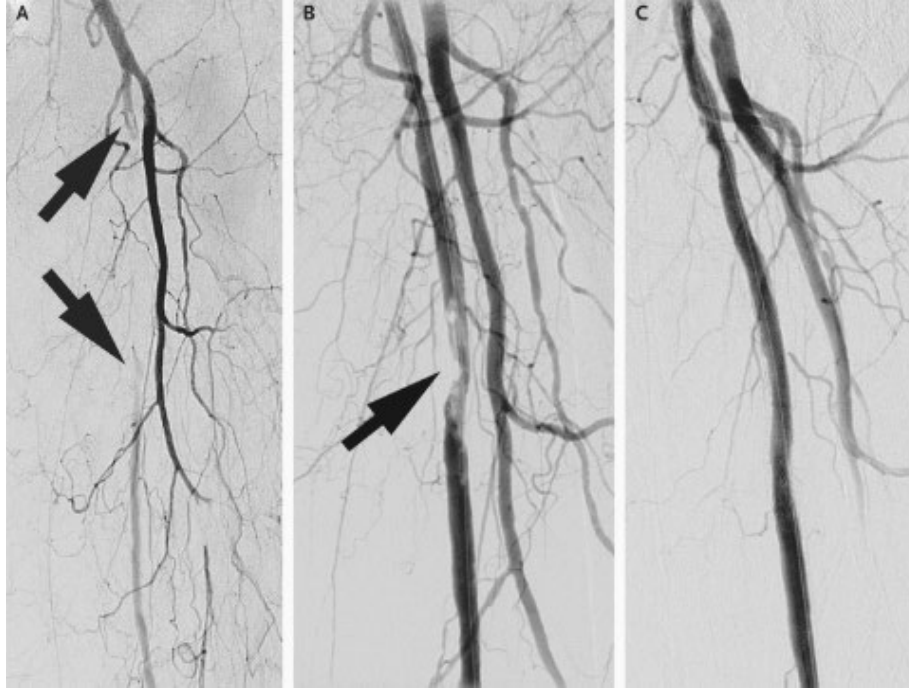
## ***Bolt Mode***

Modulates between full aspiration and ambient pressure to break the friction and ingest clot



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# 77 yo female with ALI Embolization related to Afib



# Lightning Bolt 6X with TraX Dilator



**6 F Profile for Flexibility & Strength**

## **Advanced Coil-Winding**

designed for superior trackability through complex anatomy

## **Enhanced Hydrophilic Coating**

designed for smoother passage in challenging vessels

## **TraX Dilator for Seamless Tracking**

- **Penumbra's First Arterial-Designed Dilator**  
enables precise vessel selection
- **99% Ledge Reduction**  
ensures continuous navigation without disruptions

Photographs taken by and on file at Penumbra, Inc.

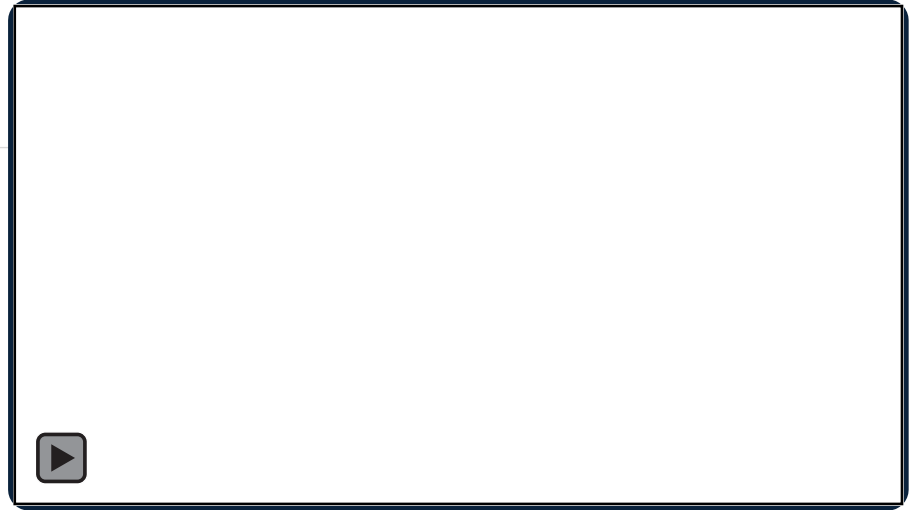
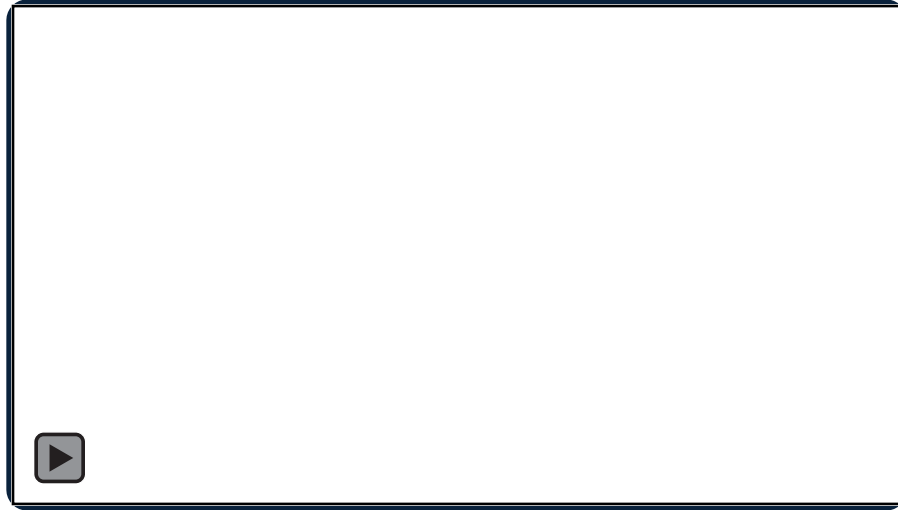


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# The Next Generation of CAVT

Lightning Bolt 6X with TraX

Click to play videos



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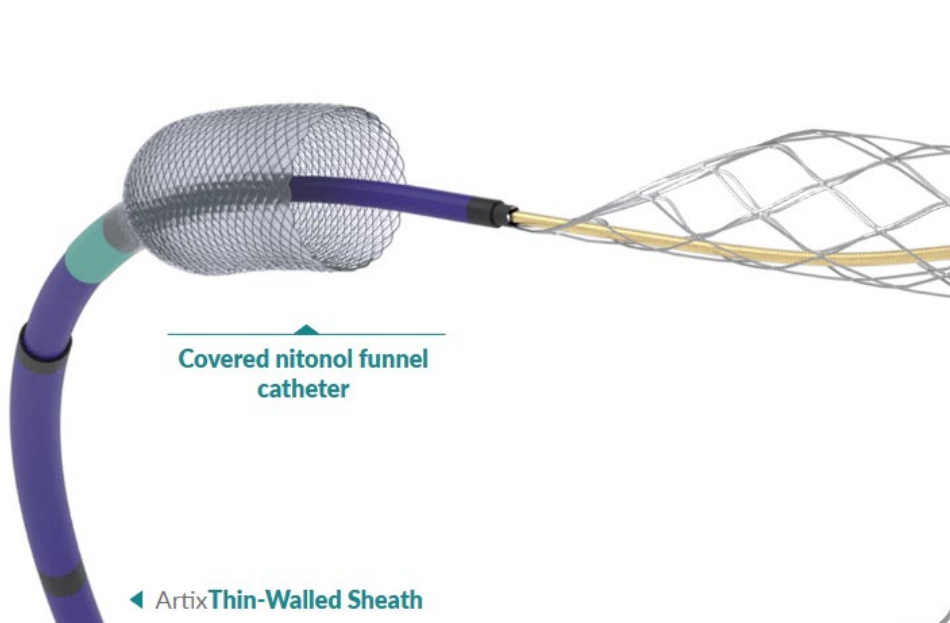
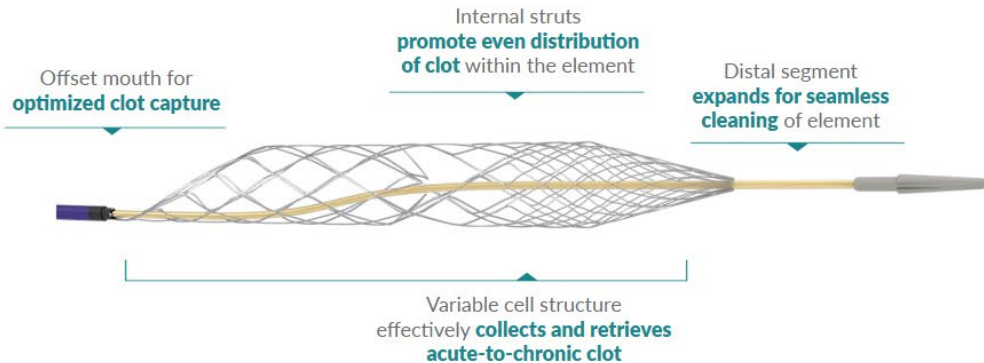
# Artix MT Mechanical Thromboectomy Device

## Broad Treatment Range

2 sizes increase options for above and below the knee thrombus

3-6 mm vessels

4-8 mm vessels



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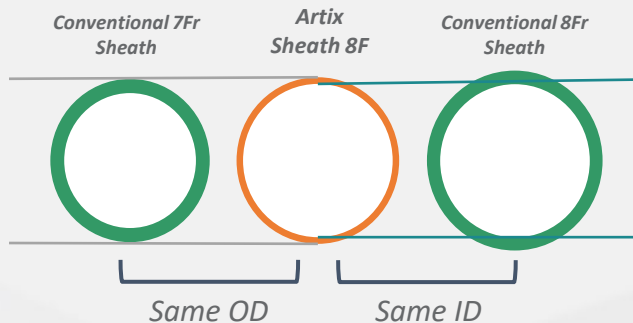
◀ Artix Thin-Walled Sheath

# Artix Thin-Walled Sheath & Funnel Catheter

Up-and-Over Sheath with Telescoping Funnel Catheter to Maintain Sheath and Wire Access

## Artix Thin-Walled Sheath

*Ultra low-profile sheath optimized for peripheral access and clot extraction*



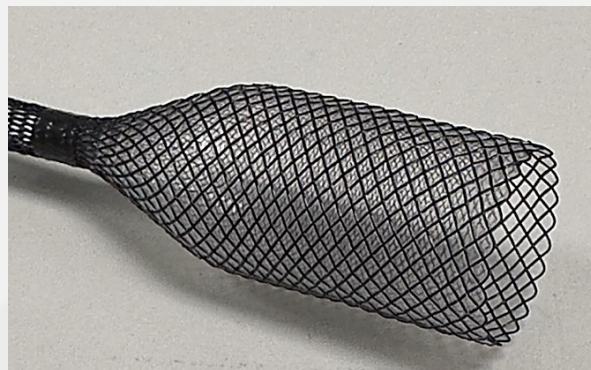
- 8F sheath with a 7Fr access profile
- 65cm & 90cm lengths
- Enhanced trackability and kink resistance for up-and-over approach
- Hydrophilic coating for smooth insertion



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## Artix Funnel Catheter

*Covered funnel catheter enables efficient thrombectomy*



- Restricts proximal flow to reduce risk of clot migration\*
- Improves clot retrieval by compressing clot into catheter



*Porcine model flow restriction test*

\*According to benchtop testing compared to control. Internal data on file.

NOTE: To attempt to minimize risk of arterial embolization of blood clots, use of a device that entraps clots may potentially be helpful, but this has not yet been demonstrated to be effective in the arterial system.

# ALI Artix case. History

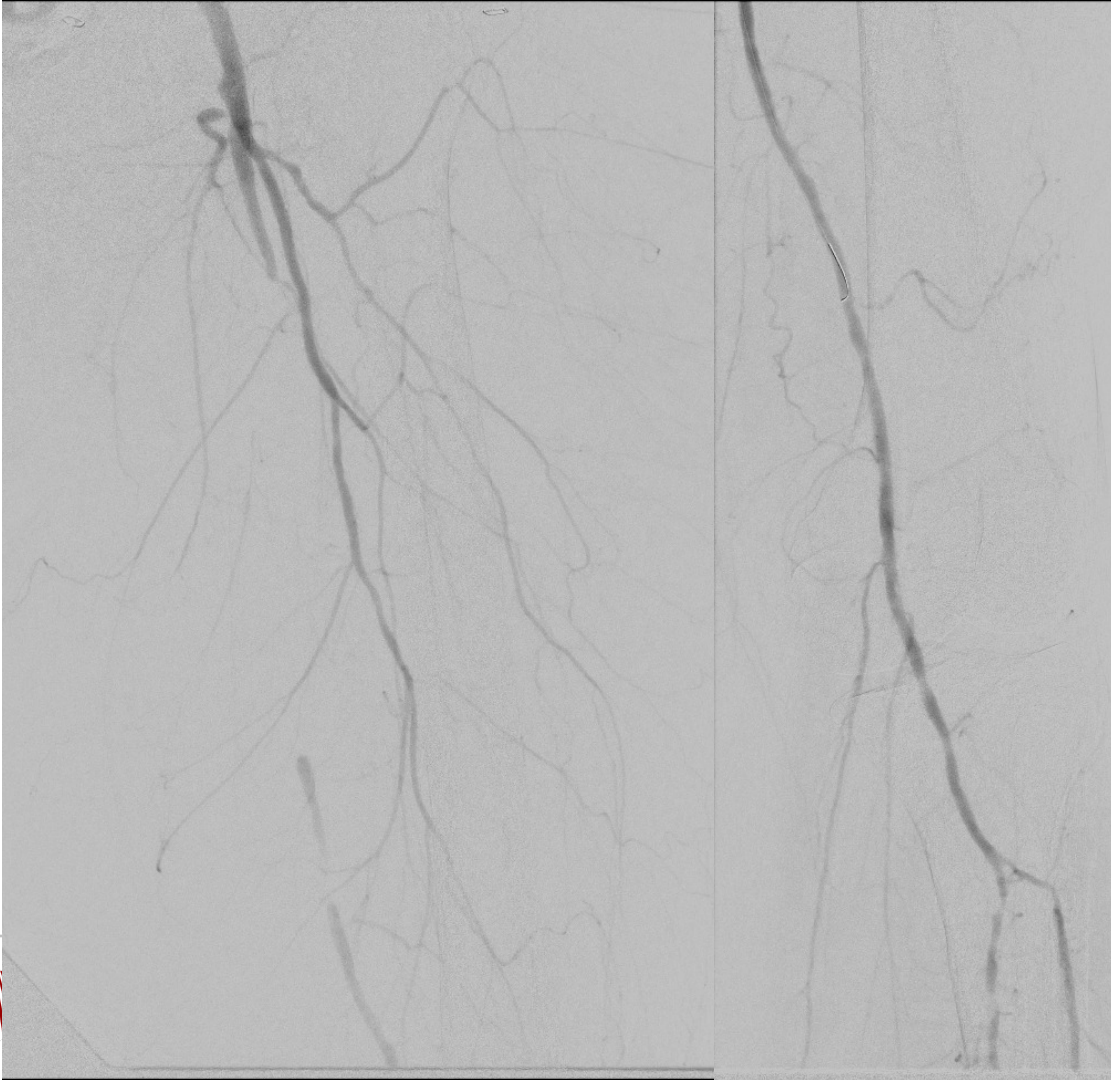
60 yo with progressive left calf pain x 2 months

Severe constant pain x 1week, treated for neuropathy at outside hospital ED

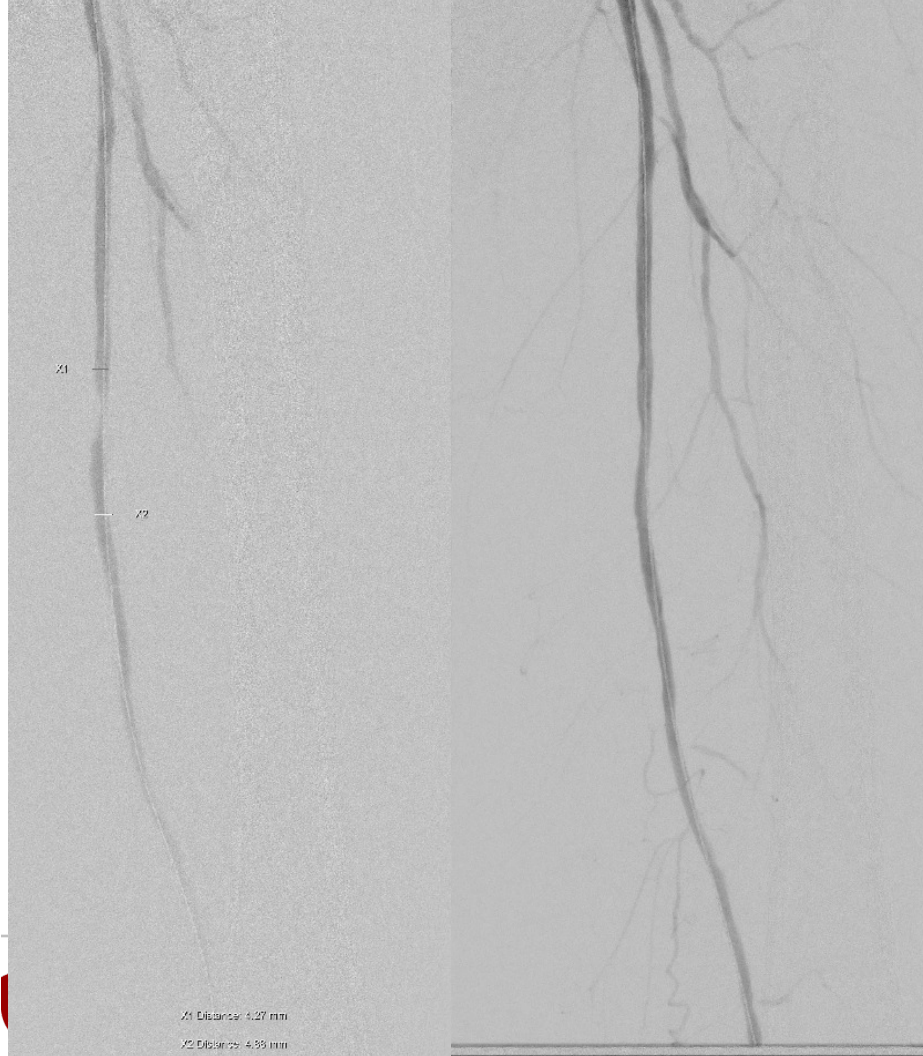
Foot numbness, decreased sensation





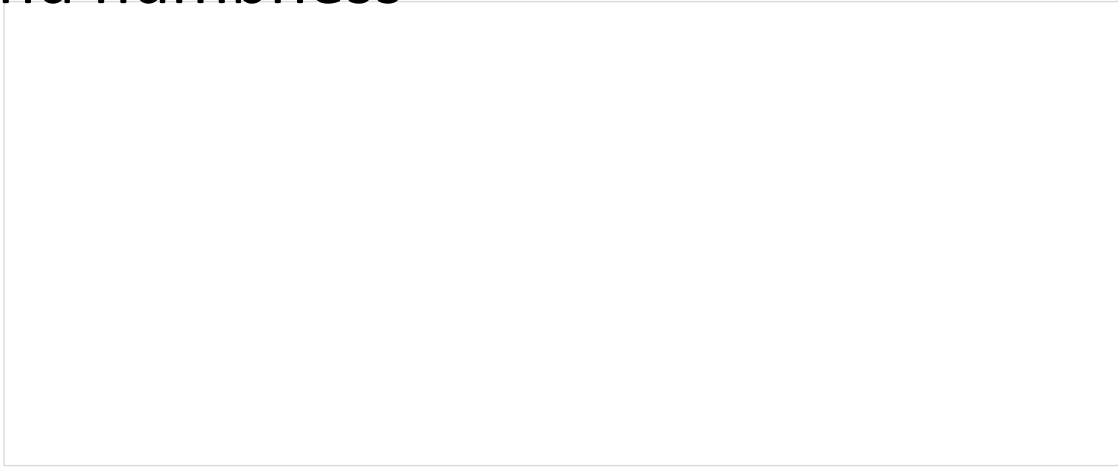


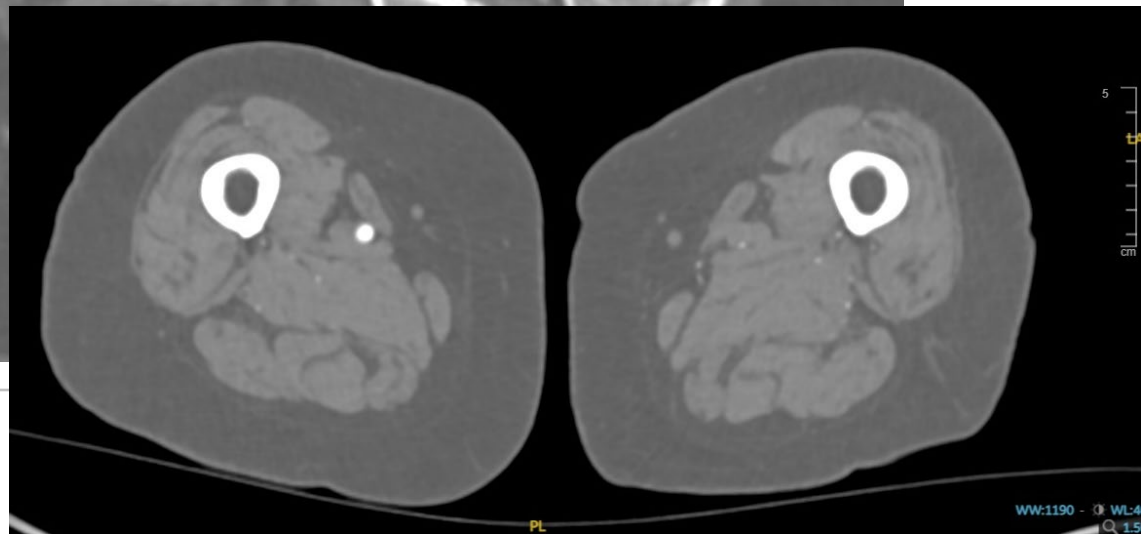
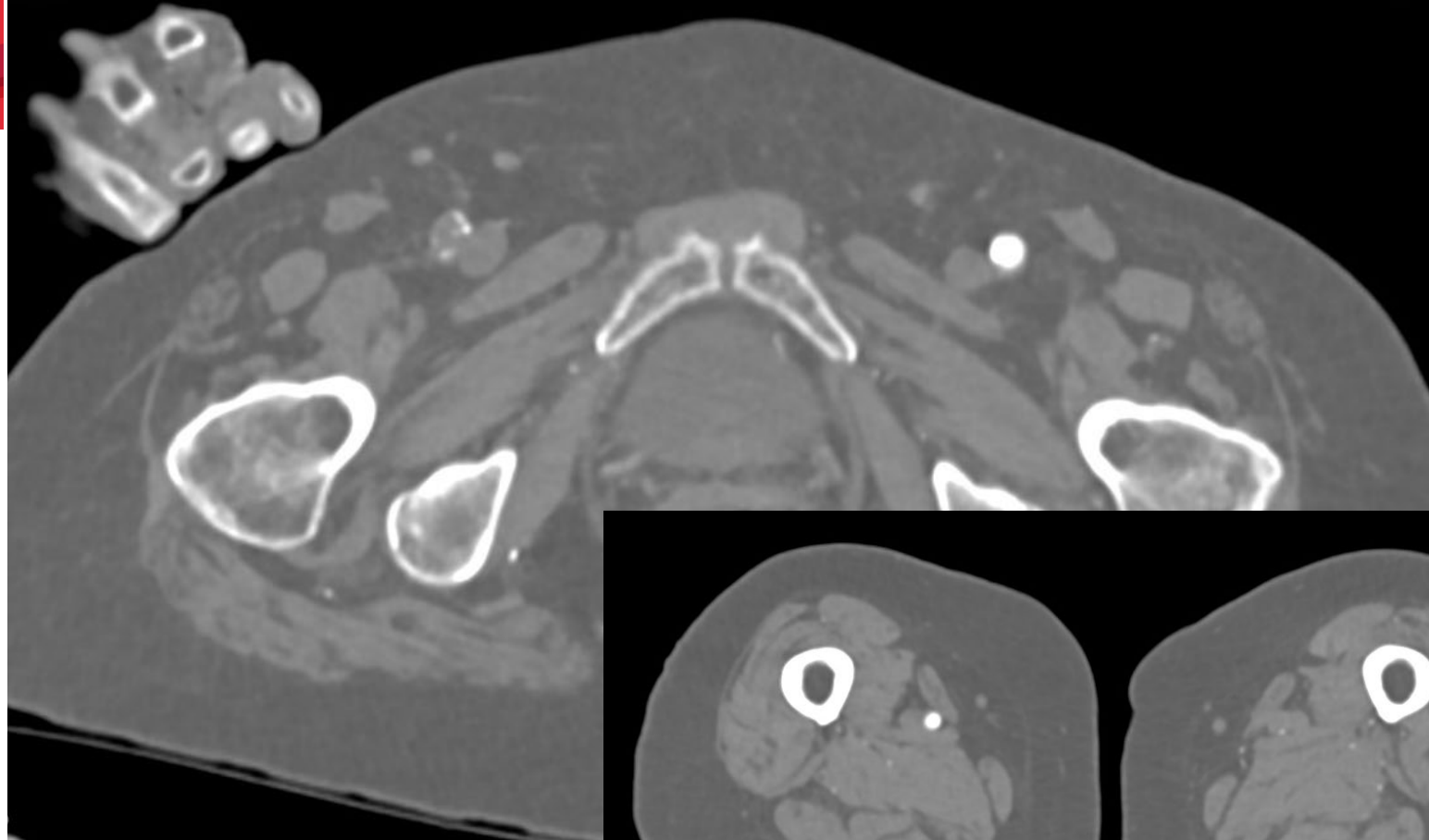
PTA, DCB  
4 comp fasciotomy



# ALI Artix case.

93yo woman, NH resident, with acute onset of left foot pain and numbness

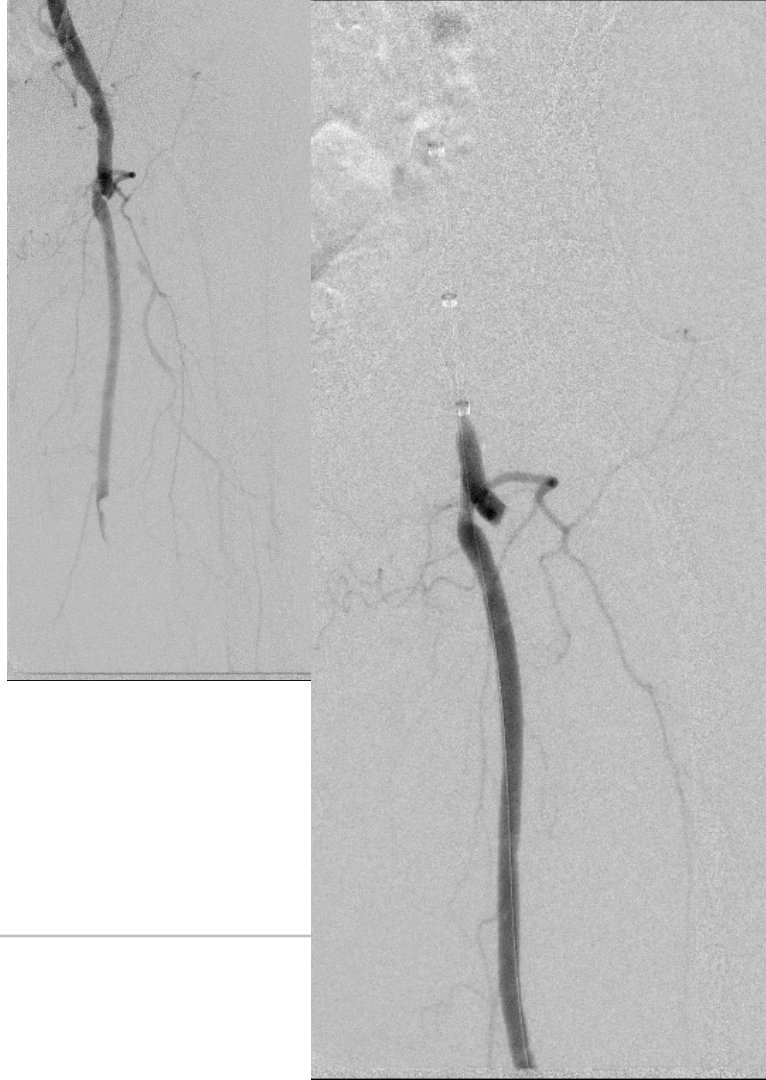


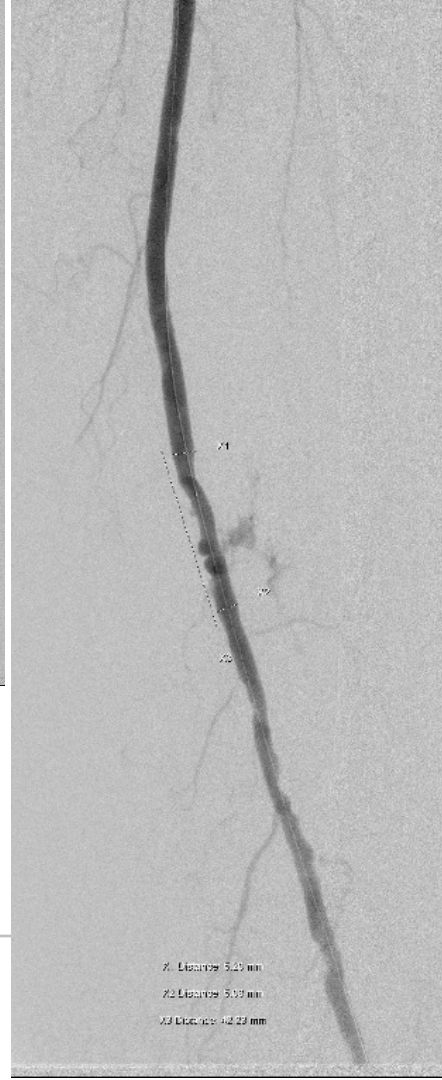


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Hybrid approach:  
Right femoral cutdown, embolectomy  
LLE MT



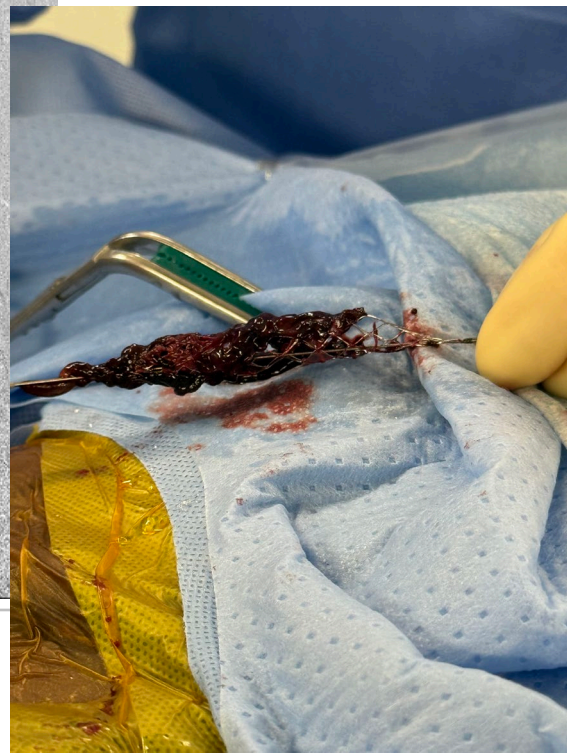




s/p 3-6mm Artix MT

6mm Viabahn

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# Conclusion

- Sufficient data supporting percutaneous thrombectomy as first line treatment, even in Rutherford 2B
- Call for a multi center trial
- Modify guidelines
- Devices continue to improve and allow for successful revascularization





# Vascular and Endovascular Surgery Division



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