“A Paradigm Shift in Arterial Clot Removal: Surgery to Endovascular”

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Conflict of interest

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* I have the following potential conflicts of interest to report:

- Research contracts
  - Consulting (Endologix, Penumbra)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

* I do not have any potential conflict of interest
Acute limb ischemia

1. How my vascular surgery practice was before – and why I changed?

2. Why Indigo System?

3. INDIAN Registry

4. What is the best case to start with Indigo System

5. Advanced cases with Indigo, tips & tricks
Acute limb ischemia

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Thrombo-embolectomy by Fogarty balloon catheter is an efficient treatment for acute arterial ischemia of lower limb, especially when ischemia occurs in healthy artery.
Fogarty embolectomy for acute on chronic ischemia
The technical success rate of surgical thromboembolectomy may be limited by:
- residual thrombus,
- chronic atherosclerotic disease underlying the thrombosis
- vessel injuries secondary to balloon catheter passage

Intraoperative angiography after Fogarty:
- endovascular adjuvant procedures (*hybrid technique*)
The combination of surgical embolectomy and endovascular techniques may improve outcomes of patients with acute lower limb ischemia.

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(J Vasc Surg 2014;59:729-36.)
From Fogarty to hybrid treatment

2 Steps
1. FOGARTY
2. ENDO

PTA ± Stenting

Covered stenting

thrombus fragmentation and aspiration by large guiding-catheter

Fibrinolysis through multiple side hole infusion catheter

Vascular and Endovascular Surgery
As a Vascular Surgeon, I have realized for years that Fogarty embolectomy or hybrid surgery was not the perfect option for all cases.
The ideal thrombectomy catheter

- Safe
- Effective
- Atraumatic profile
- Simple setting
- Flexible
- No lytic agent
- No risk of hemolysis (hydrodynamic forces)
Acute limb ischemia

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Endovascular solutions for Thrombectomy

**Sringe-based thrombosuction**

**Catheter direct thrombolysis**

**Rheolytic pharmaco-mechanical thrombectomy**

**Rotational mechanical thrombectomy**
The ideal thrombectomy catheter

- Safe
- Effective
- Atraumatic profile
- Simple setting
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Rheolytic pharmaco-mechanical thrombectomy
The ideal thrombectomy catheter

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Rotational mechanical thrombectomy

- Rotational system & risk of small vessel injury
From Fogarty to total endovascular solution – The aspiration thrombectomy system

Background from cerebral stroke
Penumbra system has began the market leader in stroke

- dedicated design for intracranial navigation
- atraumatic tip
- trackability
- aspiration power
The Indigo catheters:
- dedicated, last generation system
- designed specifically to address the limitations of conventional technology:
  - trackability,
  - risk of vessel injury,
  - incomplete revascularization
MAXIMISED ASPIRATION POWER
Large Lumen Aspiration

TIP DIRECTIONALITY
For Circumferential Aspiration

ADVANCED TRACKING TECHNOLOGY
Multiple Materials Transitions
Penumbra ENGINE

One Touch for Maximum Aspiration
Powerful, Deep Vacuum

-29 inHg\(^a\)
(- 0.96 Atm)

Easy Setup
Sleek, Simple Design

Live Feedback During Procedure
Integrated Clot Catcher

Vascular and Endovascular Surgery

\(^a\) Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. Images used with permission. Consents on file at Penumbra, Inc. Individual results may vary depending on a variety of patient-specific attributes.
INDIGO CAT8 XTORQ with SEP
XTRACT technique

The contralateral sheath with RHV/Tuohy is positioned as close to the lesion as possible and the Indigo CAT8 is advanced through sheath over a wire.

The Indigo CAT8 is placed just proximal to the face of the clot and wire is retracted.

Aspiration is applied to Indigo CAT8 via Penumbra ENGINE until CAT8 becomes occluded (recommend waiting at least 90 seconds).

The Indigo CAT8 is removed under aspiration to ensure clot remains engaged in catheter tip and clot is extracted out of the body.

Clot corked in catheter.
Post-EVAR limb occlusion – case

Embolus at risk of migration in the only patent hypogastric artery

- Clot engaged

- Clot removal

XTRACT techn
INDIGO SYSTEM: CAT + SEP

PROCEDURAL STEPS

1. Deliver Indigo Catheter to location of clot

For complete instructions and Important Safety Information please refer to the current Instructions for Use.
INDIGO SYSTEM: CAT + SEP

PROCEDURAL STEPS

2

NO FLOW in the catheter means that the catheter is working!
INDIGO SYSTEM: CAT + SEP
PROCEDURAL STEPS

For complete instructions and Important Safety Information please refer to the current Instructions for Use.
INDIGO SYSTEM: CAT + SEP

PROCEDURAL STEPS

4

Indigo Catheter marker
Separator bulb marker

Flow
1. How my vascular surgery practice was before – and why I changed?

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5. Advanced cases with Indigo, tips & tricks
The Indian registry
(The \textit{Indigo} system in acute lower limb malperfusion)

To evaluate, in a controlled setting, the early safety and effectiveness of the Penumbra/Indigo aspiration thrombectomy Systems in patients with acute limb ischemia

- Prospective
- Multicenter (Italy)
- 150 patients
- Estimated primary completion date: \textit{March} 2019

ClinicalTrials.gov Identifier: NCT03386370
Efficacy data

In case of chronic lesion or residual thrombus after Indigo:
- additional PTA or stents
- additional lysis

EJVES 2021 in press
Acute limb ischemia

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Poptideal embolism (be sure the clot is fresh <14 days)

P1-P2 embolism

INDIGO SYSTEM:
CAT 8 XTORQ + SEP 8

Final result
ALI at 4 am, Jan 1st 2019

Procedural time 15 min, fluoroscopy 6’30”
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Mechanical thrombectomy for ALI at different levels
Iliac leg thrombosis (AFX stent graft)
Thrombus lasting >14 days
Advanced case #1
Thrombo-aspiration of distal embolism from popliteal aneurysm
Advanced case #1
Thrombo-aspiration of distal embolism from popliteal aneurysm

CAT 3 over a 0.014” gw

Plantar loop by Indigo CAT 3
Advanced case #1
Thrombo-aspiration of distal embolism from popliteal aneurysm
**Advanced case #1**

**Thrombo-aspiration of distal embolism from popliteal aneurysm**

a) Clinical presentation of acute forefoot occlusion (good pulsation of anterior and posterior tibial artery at the ankle)
b) Angiography shows acute below-the-ankle (BTA) vessel occlusion
c) Indigo CAT 3 advancing through the BTA vessels with the plantar loop technique
d) Macroscopic aspect of thrombi aspirated
e) Angiography after Indigo thromboaspiration revealing nice patency of plantar arch
f) Clinical appearance on day 1 post-op

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**Endovascular TODAY**

ET 2019 September
Renal thrombosis
Mechanical thrombectomy for acute clots at different levels
Advanced case #2
Thrombo-aspiration of BTK & BTA thrombosis in autoimmune disease

Complete BTK & BTA vessels occlusion
Advanced case #2
Thrombo-aspiration of BTK & BTA thrombosis in autoimmune disease

CAT 6 in ATA & dorsal artery
Advanced case #2

Thrombo-aspiration of BTK & BTA thrombosis in autoimmune disease
Advanced case #2
Thrombo-aspiration of BTK & BTA thrombosis in autoimmune disease

Final angio
Embolism from popliteal aneurysm
Advanced case #4
Thrombo-aspiration of proximal & distal embolism from popliteal aneurysm.
Advanced case #4
Thrombo-aspiration of proximal & distal embolism from popliteal aneurysm
Advanced case #4
Thrombo-aspiration of proximal & distal embolism from popliteal aneurysm.

CAT 6 in dorsalis pedis
Advanced case #4
Thrombo-aspiration of proximal & distal embolism from popl aneur

CAT 6 in dorsalis pedis
- Safe (no trauma)
- Effective
Conclusions
Paradigm shift from open to endo

Mechanical Percutaneous Aspiration Thrombectomy With The Indigo System

When Indigo first option
- All acute on chronic limb ischemia
- Embolism is popliteal and tibial arteries
- Distal Embolism after open or endo procedures
**Recommendation 33**

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

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The catheter-tracking technology allows the device to reach the foot even from a contralateral approach.

- Flexible, atraumatic tip, large-bore catheter
- The system is not provided of any rotational components

- No rapid stream of fluid / no hydrodynamic forces

- The catheter-tracking technology allows the device to reach the foot even from a contralateral approach

1. the risk of vessel injury is truly minimized
2. no risk of intravascular haemolysis and acute renal insufficiency
3. Access to any located peripheral arterial or venous thrombosis