Is the Indigo system a surgeon’s best friend?
My experience

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University of Siena - Italy
Disclosure

Speaker name:

...Gianmarco de Donato..................................

I have the following potential conflicts of interest to report:

☐ Consulting (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
BACKGROUND
Current treatment of acute limb ischemia
- possibility and limitations of Fogarty embolectomy
- from Fogarty to hybrid tx, to Indigo system

NEW SOLUTION
- Indigo system in case of
  - acute limb ischemia
  - acute on chronic ischemia
  - graft & endograft thrombosis
  - intraprocedural embolism
Acute Lower Limb Ischemia

Background

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
Acute Lower Limb Ischemia

Background

The technical success rate of surgical thromboembolectomy (TE) 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.
### Findings at intraoperative angiography

(HP group – n=210)

<table>
<thead>
<tr>
<th>I. Native arterial lesions (stenosis underlying thrombosis)</th>
<th>n = 90</th>
</tr>
</thead>
<tbody>
<tr>
<td>II. Residual thrombus in SFA &amp; popliteal firmly adherent to the arterial wall</td>
<td>n = 54</td>
</tr>
<tr>
<td>III. Residual thrombus in BTK vessels (not appropriately reached by the balloon catheter thromboembolectomy)</td>
<td>n = 58</td>
</tr>
<tr>
<td>IV. Vessel injury after intraluminal Fogarty’s balloon catheter manipulation</td>
<td>n = 8</td>
</tr>
</tbody>
</table>

(† Vasc Surg 2014;59:729-36.)
HYBRID TREATMENT

2 Steps

1. FOGARTY

PTA ± Stenting

2. ENDO

Covered stenting

Fibrinolysis through multiple side hole infusion catheter

thrombus fragmentation and aspiration by large guiding-catheter
Vessel injury after Fogarty Hybrid treatment of ALI
Hybrid treatment of ALI
Limitations

1. Fogarty → Poor visual estimated outflow from distal vessels

2. completion angiography

3. Primary covered stenting

4. distal embolization
The ideal thrombectomy catheter

- Safe
- Effective
- Atraumatic profile
- Simple setting
- Flexible
- No lytic agent
- No risk of hemolysis (hydrodynamic forces)
The ideal thrombectomy catheter

- Safe
- Effective
- Atraumatic profile
- Simple setting
- Flexible
- No risk on hemorrhage
- No risk of hemolysis (hydrodynamic forces)

Syringe-based thrombosuction
The ideal thrombectomy catheter

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- Simple setting
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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 aspiration thrombectomy system designed for peripheral intervention

The Indigo catheters:
- dedicated, last generation system
- designed specifically to address the limitations of conventional technology:
  - trackability,
  - risk of vessel injury,
  - incomplete revascularization
INDIGO CAT8 XTORQ with SEP
MECHANICAL CLOT ENGAGEMENT
Proprietary Separator Technology

MAXIMISED ASPIRATION POWER
Large Lumen Aspiration

TIP DIRECTIONALITY
For Circumferential Aspiration

ADVANCED TRACKING TECHNOLOGY
Multiple Materials Transitions
Indigo System

Simple and Effective

• Pure continuous vacuum
• Single operator design
• No warm up or time limit
• Hands free aspiration
• Simple setup

Data on file at Penumbra, Inc. based on testing with CAT5.

All brands and product names are registered trademarks of their respective owners.
Aspiration Efficiency

More Aspiration

Aspiration Volume (mL in 20 sec)\textsuperscript{a}

<table>
<thead>
<tr>
<th>Product</th>
<th>Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competitor A</td>
<td>3</td>
</tr>
<tr>
<td>Competitor A 8F</td>
<td>12\textsuperscript{b}</td>
</tr>
<tr>
<td>CAT3</td>
<td>14</td>
</tr>
<tr>
<td>CAT5</td>
<td>56</td>
</tr>
<tr>
<td>CAT6</td>
<td>90</td>
</tr>
<tr>
<td>CAT8</td>
<td>160</td>
</tr>
</tbody>
</table>

\textsuperscript{a} Data on file at Penumbra, Inc.

\textsuperscript{b} Data on file at Penumbra, Inc.
Circumferential Aspiration

STR

TORQ

XTORQ

2.24 mm$^2$

15 mm$^2$

25.4 mm$^2$

a. Data on file at Penumbra, Inc.
Competitor vs. Indigo

8 Transition Zones for Advanced Tracking

Penumbra Indigo System
Aspiration Catheter

Competitor
Aspiration Catheter

Up to 21× the Aspiration Power

195 cc/min

Penumbra Indigo System
Aspiration Catheter

9 cc/min

Competitor
Aspiration Catheter

a. Data on file at Penumbra, Inc.
MY FIRST CASE
BACKGROUND OF MY FIRST CASE WITH INDIGO

1. Some conflicting results with other mechanical thrombectomy system

2. Very positive feedback from neuroradiologists (Stroke Unit @ University of Siena)

3. Possibility to borrow ACE 64 (neuro catheter from Penumbra)

Incomplete reperfusion and need of thrombolysis
SFA DES Occlusion

ACE 64

- CLI (ABI 0.36), CABG, previous intracranial hemorrhage
- SFA recanalization and 3 DES implantation
- ABI 0.95

- Acute pain at 1 month
- **Stent thrombosis**
- Conservative treatment for 10 days
- Increasing pain
- Aspiration thrombectomy by ACE 64

Clinical case at University of Siena - Italy
• Zilver PTX thrombosis
• Tibial embolization
• ALI Rutherford IIb
• Crossover approach
• ACE 64 + 4 MAX (coaxially)
CLOT ENGAGED

Temporary stent collapse

LONG SFA DES OCCLUSION
Post-op duplex US
Indigo – Siena experience

Acute on chronic ischemia

Level of application:

- iliac occlusion
- post-EVAR iliac limb occlusion
- in-stent SFA thrombosis
- cardiac embolization in diseased SFA
- femoro-popliteal bypass graft (PTFE)
- popliteal & BTK acute on-chronic occlusion
- tibial & plantar thrombosis in dialysis-dep patient
iliac occlusion
Indigo – Siena experience

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In-stent thrombosis
Indigo – Siena experience

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Indigo – Siena experience

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Popliteal & BTK acute on-chronic occlusion
Indigo – Siena experience

Acute on chronic ischemia

Level of application:
- iliac occlusion
- post-EVAR iliac limb occlusion
- in-stent SFA thrombosis
- cardiac embolization in diseased SFA
- popliteal & BTK acute on-plaque occlusion
- tibial & plantar thrombosis in dialysis-dep patient
Tibial & plantar thrombosis in dialysis dependent patient
Tibial & plantar thrombosis in dialysis dependent patient
Tibial & plantar thrombosis in dialysis dependent patient
EVIDENCE
PRISM trial

- Retrospective case review study (NCT02085551)
- N=85 patients
- Indications:
  - Failed thrombolysis
  - Acute limb ischemia
  - Distal emboli secondary to preceding intervention
  - Vessel patency, evaluated by TIMI score

<table>
<thead>
<tr>
<th>Target vessel location</th>
<th>%, n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Popliteal</td>
<td>32.9% (28/85)</td>
</tr>
<tr>
<td>Peroneal</td>
<td>7.1% (6/85)</td>
</tr>
<tr>
<td>Posterior tibial</td>
<td>4.7% (4/85)</td>
</tr>
<tr>
<td>Anterior tibial</td>
<td>5.9% (5/85)</td>
</tr>
<tr>
<td>Tibial-peroneal trunk</td>
<td>3.6% (3/85)</td>
</tr>
<tr>
<td>Superficial femoral</td>
<td>27.1% (23/85)</td>
</tr>
<tr>
<td>Profunda femoris</td>
<td>5.9% (5/85)</td>
</tr>
<tr>
<td>Common femoral</td>
<td>1.2% (1/85)</td>
</tr>
<tr>
<td>Superior mesenteric</td>
<td>3.5% (3/85)</td>
</tr>
<tr>
<td>Renal</td>
<td>2.4% (2/85)</td>
</tr>
<tr>
<td>Other</td>
<td>5.9% (5/85)</td>
</tr>
</tbody>
</table>

Benenati et al, SIR 2016, Vancouver
Results - PRISM

Benenati et al, SIR 2016, Vancouver
The Indian registry
(The Indigo system in acute lower limb malperfusion)

First investigator meeting on Sept 25, 2017
The Indian registry
(The 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: March 2019

ClinicalTrials.gov Identifier: NCT03386370

Recruiting
Acute Limb Ischaemia (ALI) Management With 'Indigo' Mechanical Aspiration System

ClinicalTrials.gov Identifier: NCT03295539
Recruitment Status: Not yet recruiting
First Posted: September 28, 2017
Last Update Posted: October 20, 2017
See Contacts and Locations

Sponsor:
Lancashire Care NHS Foundation Trust

Collaborator:
St. Franziskus Hospital

Information provided by (Responsible Party):
Bella Huasen, Lancashire Care NHS Foundation Trust

Contacts
Contact: Bella Huasen, MD 00447871800565 doctorbella.h@gmail.com
Contact: Theo Biswas, Phd, MD 00492519355829 th.biswas@gmail.com

Study Design
Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 400 participants
Intervention Model: Single Group Assignment
Masking: None (Open Label)
Primary Purpose: Treatment
Official Title: MulticentRe pOst-market exPeriencE With the INdigo Thrombectomy System for the Treatment of Acute Lower Limb Ischaemia: (Re-Open Registry)
Anticipated Study Start Date: November 1, 2017
Estimated Primary Completion Date: October 1, 2018
Estimated Study Completion Date: March 1, 2019
INDIGO SYSTEM FOR THE PERIPHERY

1. Flexible, atraumatic tip, large-bore catheter
   - The system is not provided of any rotational components
   - the risk of vessel injury is truly minimized

2. No rapid stream of fluid / no hydrodynamic forces
   - no risk of intravascular haemolysis and acute renal insufficiency

3. The catheter-tracking technology allows the device to reach the foot even from a contralateral approach
   - Access to any located peripheral arterial or venous thrombosis
A GOOD FRIEND
KNOWS ALL YOUR BEST STORIES,

A BEST FRIEND
HAS LIVED THEM WITH YOU.