Treating in-stent occlusions with the Rotarex catheter: The ROBINSON study

final 6-month results in 30 patients

Dr. Michel Bosiers
Conflict of interest

☐ have the following potential conflicts of interest to report:
  ☐ Consulting
  ☐ 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 and subacute ischemia of the limb...

**Thromboembolectomy**
- Suboptimal results
- Increased morbidity and mortality

**Addition surgical treatment**

**Thrombus aspiration**
- Time-consuming
- Questionable efficiency
- Insufficient collateral clearing

**Chemical thrombolysis**
- Risk of complex hemorrhagic complications
- Complex and expensive [Intensive Care Unit]

**Mechanical thrombectomy**
- Minimally invasive option for rapidly recanalizing
- Lower complication rate
- Lower costs [No Intensive Care Unit]
The risk of complications increases with the duration of the infusion from 4% at 8 hours to 34% at 40 hours.
Mechanical thrombectomy

Technical success rate was 97.7%
Mechanical thrombectomy

Rotarex mechanical debulking: The Leipzig experience in 1,200+ patients

**Intervention Feature**
- In-stent procedures: 338 Procedures
- Native 'virgin' arteries
- Surgical bypasses
- Redo procedures

**Rotarex mechanical debulking in In-stent procedures: Acute results**
- Procedural success rate: 326 (96.4%)
- Mean time follow-up: 12 ± 2.4 months

**Rotarex mechanical debulking in In-stent procedures: Clinical Follow-up: 30-day results**

<table>
<thead>
<tr>
<th>Major Adverse Events (MAE) to 30 postoperative day</th>
<th>Events</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>4</td>
<td>1.2</td>
</tr>
<tr>
<td>MI *</td>
<td>6</td>
<td>1.8</td>
</tr>
<tr>
<td>TLR **</td>
<td>9</td>
<td>2.7</td>
</tr>
<tr>
<td>TVR ***</td>
<td>3</td>
<td>0.9</td>
</tr>
<tr>
<td>Major Amputation</td>
<td>7</td>
<td>2.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>29</strong></td>
<td><strong>6.7</strong></td>
</tr>
</tbody>
</table>

**Rotarex mechanical debulking in In-stent procedures: Clinical Follow-up: 12 months results**

<table>
<thead>
<tr>
<th>Major Adverse Events (MAE) to 12-months</th>
<th>Events</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>31</td>
<td>9.2</td>
</tr>
<tr>
<td>MI *</td>
<td>7</td>
<td>2.1</td>
</tr>
<tr>
<td>TLR **</td>
<td>43</td>
<td>12.7</td>
</tr>
<tr>
<td>TVR ***</td>
<td>41</td>
<td>7.9</td>
</tr>
<tr>
<td>Major Amputation</td>
<td>47</td>
<td>3.9</td>
</tr>
</tbody>
</table>

FMRP - 2017
Product information

- Removal of the thrombotic occlusion material
- Aspiration into the side cutting windows
- Shredding of the occlusion material into miniscule particles
- Transport of debris out of the blood vessel
Robinson study

A Prospective, non-randomized, multi center, controlled physician-initiated trial: 

ROtarex Belgium IN-Stent Occlusion
Study design

• **Study Objective:**
  To evaluate the **safety** and **efficacy** of recanalization of acute and subacute femoropopliteal stent occlusions with the **Rotarex® S catheter (Straub Medical)**

• **Primary Endpoint:**
  - **Efficacy endpoint**: technical success of the Rotarex device, defined as removal of all thrombotic material, documented by angiography pre- and post-procedure: **residual stenosis of the lesion <30%**
  - **Safety endpoint**: Absence of procedure related complications: embolization, amputation, perforation or hemorrhage.
Participating centers

• **BELGIUM**
  • M. Bosiers, K. Deloose, J. Callaert - AZ Sint-Blasius, Dendermonde
  • P. Peeters, J. Verbist - Imelda Hospital, Bonheiden
  • L. Maene, R. Beelen - OLV, Aalst
  • K. Keirse - RZ Heilig Hart - Tienen
  • J. Hendriks, P. Lauwers – University Hospital Antwerp - Edegem
Inclusion criteria

30 out of 30 patients enrolled (100%)

Main inclusion criteria

• Symptomatic acute or subacute stent occlusion in the femoropopliteal artery
• Target Vessel Diameter ≥3.0 mm and ≤ 8.0 mm
Study overview

Timeline

<table>
<thead>
<tr>
<th></th>
<th>proc</th>
<th>disch</th>
<th>1 M</th>
<th>6 M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical exam</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rutherford</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duplex Ultrasound</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Patient Demographics

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N = 30</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (%)</td>
<td>23 (76.67%)</td>
<td></td>
</tr>
<tr>
<td>Age (min – max; ±SD)</td>
<td>71.24 (51.75 – 87.33 ; ±9.39)</td>
<td></td>
</tr>
<tr>
<td>Nicotine abuse (%)</td>
<td>22 (73.33%)</td>
<td></td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>22 (73.33%)</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>10 (33.33%)</td>
<td></td>
</tr>
<tr>
<td>Renal insufficiency (%)</td>
<td>4 (13.33%)</td>
<td></td>
</tr>
<tr>
<td>Hypercholesterolemia (%)</td>
<td>21 (70.00%)</td>
<td></td>
</tr>
<tr>
<td>Obesity (%)</td>
<td>9 (30.00%)</td>
<td></td>
</tr>
</tbody>
</table>
# Procedural & Lesion characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N = 30</strong></td>
<td></td>
</tr>
<tr>
<td>Procedure time ((min - max; \pm SD))</td>
<td>62.03 min ((30.0 – 120.0; \pm 24.47))</td>
</tr>
<tr>
<td>Scopy time ((min – max; \pm SD))</td>
<td>19.21 min ((8.00 – 36.70; \pm 8.31))</td>
</tr>
<tr>
<td>Contrast ((min – max; \pm SD))</td>
<td>79.23 mL ((20.00 – 150.00; \pm 33.46))</td>
</tr>
<tr>
<td>Cross-over performed (%)</td>
<td>30 ((100.00%))</td>
</tr>
<tr>
<td>Inflow Lesion (%)</td>
<td>1 ((3.33%))</td>
</tr>
<tr>
<td>Outflow lesion (%)</td>
<td>13 ((43.33%))</td>
</tr>
<tr>
<td><strong>Lesion length ((min – max; \pm SD))</strong></td>
<td>170.50 mm ((15.0 – 500.0; \pm 146.29))</td>
</tr>
<tr>
<td>Ref Vessel Diameter ((min – max; \pm SD))</td>
<td>5.43 mm ((4.00 – 7.00; \pm 0.63))</td>
</tr>
<tr>
<td>Calcified lesion (%)</td>
<td>6 ((20.00%))</td>
</tr>
</tbody>
</table>
### Efficacy endpoint

Technical success: residual stenosis of the lesion <30% after Rotarex treatment?

<table>
<thead>
<tr>
<th>Additional treatment</th>
<th>Covered stent</th>
<th>Covered stent</th>
<th>Covered stent</th>
<th>Covered stent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BMS</td>
<td>BMS</td>
<td>BMS</td>
<td>BMS</td>
</tr>
<tr>
<td></td>
<td>DCB</td>
<td>DCB</td>
<td>DCB</td>
<td>DCB</td>
</tr>
<tr>
<td></td>
<td>DES</td>
<td>DES</td>
<td>DES</td>
<td>DES</td>
</tr>
<tr>
<td></td>
<td>Thrombolysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>DCB + BMS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>VMI</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Yes: 16  
No: 14
Safety endpoint

Safety endpoint: Absence of procedure related complications?

Perforations?

- No: 29
- Yes: 1

Distal Embolization

- No: 26
- Yes: 4

Number of days between procedure and discharge:

- Mean = 2.93 days
- Median = 1 day
6-month Freedom from amputation

Freedom from Amputation

Cumulative Limb Salvage Rate (%)

Number at risk

Time (days)

0 30 60 90 120 150 180 210

0 20 40 60 80 100

92.3%
6-month Primary Patency

Primary Patency Rate

Cumulative Primary Patency Rate (%)

Time (days)

Number at risk

63.9%

59.7%
6-month Freedom from TLR

Freedom from Target Lesion Revascularization

Cumulative f-TLR rate (%)

Time (days)

Number at risk

30  28  26  26  25  20  16  4

67.9%
6-month PP – *stand alone therapy vs additional treatment*

**Primary Patency - stand alone vs additional treatment**

![Graph showing primary patency rates over time for two groups: stand alone therapy and additional treatment. The graph includes cumulative primary patency rate (%) on the y-axis and time in days on the x-axis. The graph compares the performance of the two groups, showing the number at risk at different time points.](image)

**Number at risk**

- **Group: 0**
  - 14
  - 13
  - 11
  - 11
  - 10
  - 7
  - 5
  - 0

- **Group: 1**
  - 16
  - 15
  - 14
  - 14
  - 14
  - 11
  - 10
  - 3

**P = 0.4993**

64.9%

52.4%
6-month Rutherford evolution

<table>
<thead>
<tr>
<th></th>
<th>baseline</th>
<th>discharge</th>
<th>1MFU</th>
<th>6MFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF5</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>RF4</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>RF3</td>
<td>14</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>RF2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>RF1</td>
<td>0</td>
<td>4</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>RF0</td>
<td>0</td>
<td>22</td>
<td>16</td>
<td>13</td>
</tr>
</tbody>
</table>
& what about the price...? Case example!

- **Thrombolysis**: € 8,406
- **ROBINSON additional treatment**: € 4,800
- **ROBINSON stand alone**: € 4,012

**Total Costs**:
- **Hospital Room**: € 3,743
- **Pharmaceutical costs**: € 1,689
- **Material costs**: € 1,700
- **Treatment cost (physicians)**: € 3,374
Conclusion

Rotarex Mechanical Debulking seems to be a safe and effective option to treat (sub)acute in-stent restenosis occlusions in the SFA.

With less complication rates compared to thrombolysis

& less financial costs for the patient/institution