Mechanical thrombectomy in peripheral interventions: A multitask and effective tool in a widening scenario. Current evidence and technical tips.

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Interventional Treatment-Options

- Aspiration
- Selective thrombolysis
- Thrombectomy
- Therapy of underlying pathologies
Aspiration of Arterial Emboli

After Aspiration
Aspiration in Arterial Occlusions

Occlusion of the right SFA after Angioseal
Arterial Occlusion after Angioseal

Thrombus-aspiration of an acute SFA-occlusion
Interventional Options in acute Arterial Occlusions

- Aspiration
- **Selective thrombolysis**
- Thrombectomy
- Therapy of underlying pathologies
Indication for local Thrombolysis

- Acute and subacute (up to 1 mo. (-6 mo.)) occlusions
- Native arteries and bypasses

- Success dependent on
  - Age of occlusion / thrombus
  - Can fail in cardiac (older) emboli
Local Lysis in acute Occlusions

Thrombo-embolic left popliteal occlusion

Intermediate result
Local Lysis in Acute Occlusions

after 16 hours of local lysis + balloon-angioplasty
Local bleeding after 12h low-dose thrombolysis
Interventional Options in Acute Peripheral Occlusions

- Aspiration
- Selective Thrombolysis
- Thrombectomy
- Therapy of PAOD

- Rotarex
- X-Sizer
- AngioJet
- Hydrolyser
- ClotBuster
- Acolysis
- Laser
Rotarex mechanical debulking: The Leipzig experience in 1,200+ patients

- Single center registry:
  - Use of Thrombectomy device in OPAD patients
  - Safety and efficacy

- Consecutive patient enrollment
  - Real world scenario
  - 1,809 patients treated (from 1/2005 – 11/2013)
  - 1,572 patients were analyzable (86.9%)
Rotarex mechanical debulking in acute/subacute thrombotic lesions: The Leipzig experience in 525 patients

Intervention Feature

- Native „virgin“ arteries
- Surgical bypasses
- Redo procedures
- In-stent procedures

525 Acute/Subacute
Rotarex mechanical debulking in acute/subacute thrombotic lesions: Onset of symptoms

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute (&lt;14 days)</td>
<td>211</td>
<td>40.2%</td>
</tr>
<tr>
<td>Subacute (&lt;3 months)</td>
<td>314</td>
<td>59.8%</td>
</tr>
</tbody>
</table>

## Rotarex mechanical debulking in acute/subacute thrombotic lesions: Clinical status – Rutherford class on admission

<table>
<thead>
<tr>
<th>Rutherford Score</th>
<th>Patient with events, n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>42 (8.0)</td>
</tr>
<tr>
<td>3</td>
<td>159 (30.3)</td>
</tr>
<tr>
<td>4</td>
<td>249 (47.6)</td>
</tr>
<tr>
<td>5</td>
<td>57 (10.9)</td>
</tr>
<tr>
<td>6</td>
<td>18 (3.4)</td>
</tr>
<tr>
<td>Total</td>
<td>525 (100)</td>
</tr>
</tbody>
</table>

Table 2. Baseline Rutherford scores among patients at enrollment Debulking Devices on acute/subacute thrombotic lesions
## Rotarex mechanical debulking in acute/subacute thrombotic lesions: Angiographic and procedural characteristics

<table>
<thead>
<tr>
<th>Total Vascular access sites</th>
<th>525</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antegrade</td>
<td>150 (28.6%)</td>
</tr>
<tr>
<td>Crossover</td>
<td>337 (64.2%)</td>
</tr>
<tr>
<td>Retrograde</td>
<td>38 (7.2%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sheath diameter device (French)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>334 (59.2)</td>
</tr>
<tr>
<td>8</td>
<td>230 (40.8)</td>
</tr>
</tbody>
</table>

| Mean lesion length (cm) | 15.9 (2-27.8) |

<table>
<thead>
<tr>
<th>Intervention area</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AIC</td>
<td>30 (5.1%)</td>
</tr>
<tr>
<td>SFA</td>
<td>346 (58.3%)</td>
</tr>
<tr>
<td>Popliteal</td>
<td>128 (21.6%)</td>
</tr>
<tr>
<td>SFA + Popliteal</td>
<td>89 (15.0%)</td>
</tr>
</tbody>
</table>

**Table 3. Overall Angiographic and procedural characteristics among 525 patients treated with Mechanical debulking devices for acute/subacute thrombotic arterial lesions.**
### Type of lesion (complain symptoms) (n=593 lesions/525 patients) vs. n (%)

<table>
<thead>
<tr>
<th>Calcification</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No/mild</td>
<td>392 (76.7)</td>
</tr>
<tr>
<td>Moderate</td>
<td>63 (12.3)</td>
</tr>
<tr>
<td>Severe</td>
<td>56 (11.0)</td>
</tr>
</tbody>
</table>

### Intervention Feature

| De-novo lesions     | 466/593 (78.6) |
| Previous Balloon Angioplasty | 127/593 (21.4) |

* Loss of 82 lesions analysis, due to inadequate images

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Rotarex mechanical debulking in acute/subacute thrombotic lesions: Early results

- Procedural success rate: 513 (97.7%)

- Main performed procedure
  - Rotational Thrombectomy alone: 143 (27.2%)
  - Rotational Thrombectomy + PTA: 206 (39.2%)
  - Additional Stenting: 150 (28.6%)
  - Additional Thrombolysis: 73 (13.9%)

- Mean time follow-up: 12 ± 2.4 months
Rotarex mechanical debulking in acute/subacute thrombotic lesions: Early results

- Stenting-rate: 28.6%
- Full lesion stenting: 6.9%
- Focal stenting: 21.7%

Rotarex mechanical debulking in acute/subacute thrombotic lesions

Clinical Follow-up: 12 months results

74.1% of claudicants with improvement of Rutherford class

Case 1: Subacute SFA In-Stent Occlusion

Subacute in-stent occlusion right SFA
Case 1: Subacute SFA In-Stent Occlusion

Result after Rotarex-thrombectomy
Case 1: Subacute SFA In-Stent Occlusion

Result after additional balloon angioplasty
Case 1: Subacute SFA In-Stent Occlusion
Case 2: Subacute SFA In-Stent Occlusion
Rotarex mechanical debulking:
The Leipzig experience in 1,200+ patients

Intervention Feature

- In-stent procedures
- Native "virgin" arteries
- Surgical bypasses
- Redo procedures

338 Procedures
<table>
<thead>
<tr>
<th>Duration</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute (&lt;14 days)</td>
<td>73 (21.6)</td>
</tr>
<tr>
<td>Subacute (&lt; 3 months)</td>
<td>114 (33.8)</td>
</tr>
<tr>
<td>Chronic (&gt; 3 months)</td>
<td>151 (44.6)</td>
</tr>
</tbody>
</table>

Rotarex mechanical debulking in In-stent procedures: Onset of symptoms (n=338)
### Table 2. Baseline Rutherford scores among patients at enrollment Debulking Devices for in-stent procedures (n=338)

<table>
<thead>
<tr>
<th>Rutherford Score</th>
<th>Patient with events, n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>2 (0.6)</td>
</tr>
<tr>
<td>2</td>
<td>58 (17.2)</td>
</tr>
<tr>
<td>3</td>
<td>212 (62.7)</td>
</tr>
<tr>
<td>4</td>
<td>28 (8.3)</td>
</tr>
<tr>
<td>5</td>
<td>38 (11.2)</td>
</tr>
<tr>
<td>6</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>338 (100)</strong></td>
</tr>
</tbody>
</table>
### Rotarex mechanical debulking in In-stent procedures: Angiographic and procedural characteristics

<table>
<thead>
<tr>
<th>Total Vascular access sites</th>
<th>338</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antegradeg</td>
<td>118 (34.9%)</td>
</tr>
<tr>
<td>Crossover</td>
<td>176 (52.1 %)</td>
</tr>
<tr>
<td>Retrograde</td>
<td>44 (13%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sheath diameter device (French)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
</tr>
<tr>
<td>8</td>
</tr>
</tbody>
</table>

| Mean lesion length (cm) | 16.3 (4.7-24.8) |

<table>
<thead>
<tr>
<th>Intervention area</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIC</td>
</tr>
<tr>
<td>SFA</td>
</tr>
<tr>
<td>Popliteal</td>
</tr>
<tr>
<td>SFA + Popliteal</td>
</tr>
<tr>
<td>Proximal BTK</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

*Table 3. Overall Angiographic and procedural characteristics among 338 patients treated with Mechanical debulking devices for in-stent procedures.*
Rotarex mechanical debulking in In-stent procedures:
Early results

• Procedural success rate: 326 (96.4%)

• Main performed procedure
  • Rotational Thrombectomy alone: 68 (20.9%)
  • Rotational Thrombectomy + PTA: 195 (59.6%)
  • Additional Stenting(re-stenting): 41 (12.6%)
  • Additional Thrombolysis: 45 (13.9%)
  • Associated BTK treatment: 75 (23.1%)

• 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>

Table 4. Major Adverse Events (MAE) to 30 postoperative day. Values are rate numbers (%) of observations

- *Myocardial infarction
- **Target-lesion revascularization
- ***Target-vessel revascularization
Rotarex mechanical debulking in In-stent procedures: Clinical Follow-up: 12 months results

69.7% of claudicants with improvement of Rutherford class

Follow up

Number of patients

Rutherford classes (RF)

Baseline
Follow up
Case 3: Rotarex-Thrombectomy of left Femoral Bifurcation
Case 4: Rotarex-Thrombectomy
Pelvic Occlusion

Acute left pelvic occlusion
Crossover Rotarex-thrombectomy
Case 4: Rotarex-Thrombectomy
Pelvic Occlusion

After Rotarex

Kissing-Stents

Result
Case 5: Subacute Iliac In-Stent Occlusion
Case 5: Subacute Iliac In-Stent Occlusion
Case 5: Subacute Iliac In-Stent Occlusion
Case 5: Subacute Iliac In-Stent Occlusion
Case 5: Subacute Iliac In-Stent Occlusion
Case 6: Occlusion of a Prosthetic Bypass

- Bypass right iliac to SFA
- „Jump“-graft to pop. Artery
- Femoral bypass-occlusion for 6 months
- Severe claudication
Case 6: Occlusion of a Prosthetic Bypass
Case 6: Occlusion of a Prosthetic Bypass
Case 6: Occlusion of a Prosthetic Bypass
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Case 6: Occlusion of a Prosthetic Bypass
Rotarex in AMI

- 2011 – 2015:
- 31 Patients with Acute SMA Occlusion
  (Main Occluded Arterial Trunk)

Etiology:
- Atrial Fibrillation/arrhythmia  26
- Acute Myocardial Infarction  4
- Aortic Thrombus Embolie  1
CASE 7: Acute SMA Thrombosis

Left Brachial Access
6 F (90 cm)

Guiding-Catheter
110 cm MP or JR
CASE 7: Acute SMA Thrombosis

V 0.018“ Guidewire Passage

Support-catheter:
Microcatheter, z.B.
Quickcross (Spectranetics)
CASE 7: Rotarex in Acute SMA Occlusions
CASE 7: Rotarex in Acute SMA Occlusions
Rotarex in SMA Occlusions

Acute Results

- Technical Success 100%
  (Visible SMA Distal Arcade Flow)
- Mean average Duration 27.4 min
- Hospitalar Mortality (16/31) 51.6%
  - 2 deaths due to short gut syndrome

- Overall mortality due to AMI 61%
Acute Mesenteric Ischemia
Prognostic Factors

TIME!

LATE DIAGNOSIS
PATIENTS WITH HIGHER PROBABILITY

Autopsies: 213 AMI Subjects
in 2/3 of patients, diagnosis was not established before
Surgery/Death.

Real-World Registry DEB for Extensive Femoropopliteal Lesions

-- Single center registry of femoropopliteal lesions
-- All--comers, Rutherford class 2 -- 6
-- 288 limbs treated

-- In.Pact PTX--Balloon (mainly In.Pact Pacific) (Medtronic)

-- Follow--up:
-- Clinical, ABI
-- Duplex at 3 months and every 6 months thereafter
-- (PSV $\geq$ 2.5 m/sec)
-- Data--collection ongoing
Real-World-Registry DEB for Femoropopliteal Lesions

Atherectomy before DEB

-- Limbs treated: 83
-- Laser: 10
-- Silver/TurboHawk 16
-- Rotarex 57
  -- 6F Rotarex 26
  -- 8F Rotarex 31
Realworld Fempop DEB-Registry
Rotarex + DEB

Fraction of Rotarex cases: (57 / 288) 19.8 %

Combination Rotarex + DEB was to the discretion of the interventionalist

No exclusion-criteria (eg subintimal passage)
Rotarex + DEB for Femoropopliteal Lesions (n=57)

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stenosis</td>
<td>17 (29.8%)</td>
</tr>
<tr>
<td>Occlusion</td>
<td>40 (70.2%)</td>
</tr>
<tr>
<td>Lesion-length</td>
<td>238 ± 98 mm</td>
</tr>
<tr>
<td>De-novo / restenosis</td>
<td>35 (61.4%)</td>
</tr>
<tr>
<td>ISR</td>
<td>22 (38.6%)</td>
</tr>
</tbody>
</table>
Rotarex + DEB for Fem-pop Lesions: Safe and Effective?

- Thrombolysis: 3 (5.3 %)
- Perforation: 3 (5.3 %)
- Viabahn: 1

- Stents implanted: 16 / 57 (28 %)
- Full-lesion: 1
- Focal: 15
Rotarex + DEB Registry

Freedom from restenosis

Mean lesion length: 238 ± 98 mm

De-novo/Restenosis: 61.4 %

In-Stent Reocclusion: 38.6 %
Conclusion

-- The removal of arterial thrombus and embolic material is fast and effective with the Rotarex catheter.

-- The extension of use in the Native arteries, Venous Synthetic Bypasses, as well as for ISR lesions is feasible and safe

-- Especially, the combination of Rotarex with drug eluting technology is promising and deserves further investigation.
Rotarex mechanical debulking

- The use of the Rotarex-catheter in In-stent procedures proved to feasible and safe
- If suspicious of thrombus within the In-stent lesion, pretreatment with Rotarex before adjunctive therapy (DEB, for example) appears to be a reasonable approach
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