Endovascular Revascularization is the Best Option in CLI: When and How?

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**Definition:**
- Critical reduction of the arterial perfusion
- Arterial pressure
  - < 50 mmHg (ankle)
  - < 30 mmHg (toe)

**Rutherford Category**

4  Ischaemic rest pain
5  Ulcera and gangrene
Distribution of Lesions in CLI
The SFA-CTO
Highly calcified occlusion right SFA

Unsuccessful wire-passage

2.5mm Turbo-Laser
Subintimal Recanalization
Subintimal Angioplasty

10-15% failures due to inability to re-enter the true lumen.

Major potential problem:
Distal extension of the dissection with involvement of the first popliteal segment or below.
Re-Entry-Devices

Pioneer Catheter

Outback Catheter

Crossing Success
> 95%
After Crossing ... What`s next?

Just stent it.
Summary
12 months restenosis vs. lesion length

Data from randomised trials

Modified from Schillinger et al, EURO-PCR 2008
Risk Factors for Stent-Fractures

- Multivariante Analysis

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>RR</th>
<th>p</th>
<th>95% KI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent length &gt;160mm</td>
<td>5.559</td>
<td>&lt;0.0013166</td>
<td>3.166</td>
</tr>
<tr>
<td>Severe Calcification</td>
<td>3.941</td>
<td>&lt;0.0012261</td>
<td>2.261</td>
</tr>
</tbody>
</table>

Location of the stent was no predictor!

Scheinert D, Sax J et al. TCT 2007
Insufficient Radial Resistive Force Results in Suboptimal Deployments

Angio AP projection

% MLD 15%

Angio LAO projection

% MLD 42%
SUPERA Stent
Interwoven Nitinol Design

• Diameter:
  – 4.0 – 10.0 mm
• Length:
  – 40 – 150 mm
• Introducer:
  – 7F
• Working length:
  – 90 cm
  – 120 cm
Leipzig SUPERA-Registry

SFA-Registry (n=107)

88 patients had an x-ray screening after 14.1 +/- 4 months: No stent fractures detected!
Characteristics of Patients with Infrapopliteal Obstructions

- Severe symptoms
  - Often critical ischemia
- Diabetes mellitus in up to 80%
- Older patients
- Significantly more concomitant diseases
  (Cardiac, cerebrovascular, renal, pulmonar)
OP vs. Interventional Therapy

- Surgery
- Interventional therapy

Decision depending on
- Comorbidity
- Availability of veins
- Morphology of the obstruction
Bypass vs. Angioplasty in Severe Ischemia of the Leg (BASIL)

Amputation-free Survival

Recommendation 35: Choosing between techniques with equivalent short- and long-term clinical outcomes

- In a situation where endovascular revascularization and open repair/bypass of a specific lesion causing symptoms of peripheral arterial disease give equivalent short-term and long-term symptomatic improvement, endovascular techniques should be used first [B]

The less invasive Technique should be preferred
Techniques for Recanalization of Infrapopliteal Lesions

- Cutting/Scoring balloon
- Atherectomy
- Laser-recanalization
- Stent-implantation
- DES / DEB
Angiosculpt Scoring Balloon

Semi-compliant balloon with an external nitinol shape memory helical scoring edge
Short Infrapopliteal Lesions

TPT-occlusion
Silverhawk Atherectomy Device

Tissue Storage Tip

Cutter

Tissue excised from the lesion
ZilverHawk Experience BTK

• 36 patients, 53% CLI
• 49 infrapopliteal lesions
• 98% technical success using the SilverHawk

• 2-years follow-up
  – No major amputation, no bypass-surgery
  – Primary patency (duplex) 60 %

Zeller et al., J Endovasc Ther 2007
CSI Orbital Atherectomy System (OAS)

• Rotational atherectomy system using an excentric diamond crown

• Crown sizes
  – 1.2 mm
  – 1.7 mm
  – 1.9 mm

• Three different speeds:
  – 80,000 rpm
  – 140,000 rpm
  – 200,000 rpm
OAS Atherectomy System

TPT-occlusion

OAS 1.7 mm

Stand-alone result
TYPE AND DISTRIBUTION OF 2,893 LESIONS in 417 Consecutive Diabetic with Ischaemic Foot Ulcer:

(Graziani et al. unpublished data)
Equipment for PTA of Extensive Infrapopliteal Lesions

- **Hydrophilic 0.018” or 0.014” guidewire**
  - V18 Control-wire (Boston Scientific)
  - PT2, PT Choice, PT Graphix (Boston Scientific)

- **Low-profile balloons**
  - Diameter 2.0 – 3.5 mm
  - Length 80 – 210 mm
  - OTW 0.018” eg. Pacific Extreme (Invatec)
  - OTW 0.014” eg. Amphirion (Invatec)
Diabetes Patient with Foot Ulcers
PTA of diffuse infrapopliteal lesions

- Patients 56
- Diabetes mellitus 82%
- Clinical vascular status
  - Rutherford Class IV 15 (27%)
  - Rutherford Class V 43 (73%)
- Average lesion length 18.5 cm (5 – 30 mm)
- Occlusion 45 (80%)
- Successfully recanalized limbs 50 / 56 (89%)
- Successfully recanalized arteries 54 / 71 (76%)
Clinical and angiographical follow-up after PTA of diffuse BTK-lesions

Follow-up in \( n \) 29
- Mean follow-up (months) 3.4 ± 1.6

Clinical follow-up:

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Improvement</td>
<td>21</td>
<td>72.4%</td>
</tr>
<tr>
<td>Unchanged</td>
<td>7</td>
<td>24.1%</td>
</tr>
<tr>
<td>Worsened</td>
<td>1</td>
<td>3.4%</td>
</tr>
</tbody>
</table>

- Bypass-surgery 0
- Minor amputation 5 (17%)
- Major amputation 0

Schmidt et al. LINC 2006
How can we improve the results of BTK angioplasty?

• Revascularization of multiple vessels?
Angioplasty in Diabetes - Patients
Angioplasty in Diabetes - Patients
Angioplasty in Diabetes-Patients
Angioplasty in Diabetes - Patients
How can we improve the results of BTK angioplasty?

- Alternative approaches for CTO`s in case of failure to cross:
  - Transpedal
  - Transcollateral
Transpedal Recanalization - Sheathless technique -
Transpedal Recanalization
Transpedal Recanalization
Transpedal Recanalization
Transpedal Recanalization
Transpedal Recanalization
Transpedal Approach for infrapopliteal Angioplasty

- Success-rate in long BTK-occlusions ~ 80%
- 29 patients with infrapopliteal occlusions and failed antegrade intervention
- Retrograde access in all patients possible
- Interventional success in 21 / 29 (72.4 %)

Baker et al. J Endovasc Ther 2008
How can we improve the results of BTK angioplasty?

• Stents and DES?
Stents for Revascularisation of Infrapopliteal Arteries

Re-occlusion PTA 2 weeks after PTA

BX-Stent 2.5/33mm
**Stents dedicated for Infrapopliteal Arteries**

- **Selfexpanding stents**
  - Astron Pulsar (Biotronik)
  - Xpert-Stent (Abbott)
  - Maris Deep (Invatec)

- **Balloon-expandable stents**
  - Chromis Deep (Invatec)

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<tr>
<th>Ø</th>
<th>Max. length</th>
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<tr>
<td>3, 4 mm</td>
<td>80 mm</td>
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<tr>
<td>2-4 mm</td>
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</table>
# PTA vs. Stenting for infrapopliteal Obstructions

<table>
<thead>
<tr>
<th></th>
<th>Angioplasty n=74</th>
<th>Stenting n=58</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural Success</td>
<td>79%</td>
<td>95%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Clinical Improvement</td>
<td>74%</td>
<td>90%</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Clinical Patency 12 Months</td>
<td>53%</td>
<td>84%</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Angiographic Restenosis Rate 53%

Scheinert D et al. EuroPCR 2003
## DES vs. Bare-metal Stent in Infrapopliteal Arteries

- Non-randomized comparison BMS vs. Cypher
- 6-months angiographic binary restenosis

<table>
<thead>
<tr>
<th>Study</th>
<th>BMS (%)</th>
<th>DES (%)</th>
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<tbody>
<tr>
<td>Scheinert 2006</td>
<td>56</td>
<td>0</td>
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<tr>
<td>Siablis 2006</td>
<td>55</td>
<td>4</td>
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<tr>
<td>Bosiers 2006</td>
<td>-</td>
<td>0</td>
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</table>
Cypher – BTK Registry
Angiographic Stent Patency

Primary and Secondary Patency

- Primary Patency
- Secondary Patency

FU-Time | Patency
--- | ---
6 months | 98.2% | 98.2%
12 months | 94.1% | 95.9%
24 months | 89.2% | 95.9%

Log Rank = 0.4551

Scheinert D et al. TCT 2006
Cypher for BTK
Cypher for BTK  6-months FU
Novel Treatment Concept

**IN.PACT AMPHIRION**

Paclitaxel-eluting PTA Balloon Catheter

built on the proven, first BTK dedicated, Amphirion DEEP™ balloon platform

Worldwide first case performed LIVE @ LINC 2009
Leipzig Experience with DEB BTK

After 2.5/120mm In.PACT Deep

3 months – follow-up
Unless you try to do something beyond what you have already mastered, you will never grow.