Advanced Endovascular Techniques for Treating Calcified Lower Extremity CTO Lesions

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Drug-Coated Balloons for Calcified Lesions

ILLUMINATE Global: Real world patients with >40% severely calcified lesions

Key baseline characteristics

- N = 371
- Lesion (N) 417
- Avg Lesion length 7.5 cm
- CTO 31.3%
- Ca++ 40.8%

Primary Patency @ 12 months

High degree of severe calcification: Calcific radio-opacities noted on both sides of the arterial wall extending > 1cm

What is severe calcification?

According to Stellarex US: severely calcified lesions

Then how should this calcification be classified?

The Impact of Residual Stenosis of Calcified Lesions

- 118 SFA-CTOs treated with nitinol stents
- 43% residual stenosis > 30%

DEFINITIVE Ca++ Trial

123 Pts. 168 fem-pop lesions (81% mod / sev calcified)
Mean LL = 39.06 ± 27.0 mm (9.5 % CTOs)

Definition of severe Ca++: calcification noted on both sides of the arterial wall > 1cm in length.

Primary Efectiveness: residual stenosis after atherectomy

< 50 % residual stenosis after atherectomy

92.0 %

(did not achieve success-criteria of primary endpoint)

Residual stenosis after atherectomy

33.3 %

Silverhawk, Turbo-Hawk, Hawk One

Laser

Phoenix Atherectomy System (Atheromed)

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Roberts et al., Catheterization and Cardiovascular Interventions 84:236–244 (2014)
When and why we consider Atherectomy in calcified lesions

- Atherectomy allows for plaque modification.
- Ballooning becomes easier, lumen gain in shorter lesions
- Atherectomy decreases stenting rate and potentially improves DCB-effectiveness
- Filter protection in calcified lesions is mandatory
- Not practical / effective in long and severely calcified lesions

Lithoplasty® for Calcified Lesions

Lithotripsy delivery 4 atm
Nominal pressure 6 atm
Rated Burst Pressure 10 atm
Sizes: ∅ 3.5 - 7 / 60 mm

Pulsatile mechanical energy to disrupt superficial and deep calcium

DISRUPT PAD Studies

DISRUPT PAD I - II:
- Safety and efficacy study
- Two-phase, prospective, non-randomized, multi-center study

DISRUPT PAD III:
- Multicentre, prospective, randomized: TASC A-C fem - pop
- DCB vs. DCB plus Lithoplasty

Inclusion of lesions which are usually excluded from studies

DISRUPT PAD I
35 subjects, 3 sites
Jan 2014 – Sep 2014

DISRUPT PAD II
60 subjects, 8 sites
Jun 2015 – Dec 2015

DISRUPT PAD III
2016 – currently enrolling

The PQ Bypass Concept

A fully percutaneous bypass approach to treat SFA-disease, regardless of its complexity.

PQ Bypass System

5.5, 6, 6.7mm OD
100, 150 and 200 mm length

Snare Device
Stent Graft
15.11.2017

Initial Angiography

Initial Phlebography

Ultrasound-guided puncture of a posterior tibial vein

Nitinol-Basket for GW-snaring

Vein Passage

Vein Passage to distal reentry-point

Reentry back into the Artery
Reentry back into the Artery

Stent graft Implantation

Proof of Concept

Dr. J. Joyce - El Camino Hospital
Off-the-shelf devices
35 limbs in 21 subjects treated for CTO
Primary patency @ 1 year: 82%
Secondary patency @ 4 years: 91%
No objective venous morbidity

K/M Curve – Primary Patency
New Generation Stents with increased Radial Force / High Flexibility

The Supera implant has 20 lb. compression resistance

Greater than 4x compression resistance

Supera® 6.0 x 100 mm
Supera® 5.0 x 100 mm

Standard Nitinol Stents 6.0 x 100 mm

Supera Clinical Outcomes (Freedom from TLR) in Ca++ at 3 Years

Supera Clinical Outcomes (Freedom from TLR) in Ca++ at 3 Years

<table>
<thead>
<tr>
<th>Freedom from TLR % Over Time in Severe Calcium</th>
<th>12 months</th>
<th>24 months</th>
<th>36 months</th>
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<tbody>
<tr>
<td>55%</td>
<td>92%</td>
<td>83%</td>
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SuperB Data - Severe Calcification

% of Lesions with Severe Calcification (SUPERB Trial)

Patency (VIVA 12 months) 88%

Failure of a Standard Nitinol Stent
After implantation of a Nitinol covered stent 7/150mm and post-dilatation with 7/20mm high-pressure balloon

Supera 6.5/200mm into 7mm Viabahn

6-months FU after relining with Supera stents

PAVE & CRACK – Technique
Leipzig Registry

• N = 66, 54 men, (71.4±8.5 years)
• Mean lesion length: 26.9 ±11.2 cm
• TASC D: 77.6% & TASC C: 32.4 %
• 92.4% CTO

PAVE & CRACK – Technique
Leipzig Registry – 1° & 2° Patency

Procedural success: 100 %
Technical success:  98.5 %
(1 case with residual stenosis > 30%)

Neto M et al, submitted
Summary

Highly calcified lesions require a combination of endovascular tools and techniques to achieve satisfactory results.