Spot Stenting with VascuFlex Multi-Loc

P. Goverde MD, K. Taeymans MD, K. Lauwers MD
Vascular Clinic ZNA
Antwerp, Belgium
Disclosure

Speaker’s name: Peter Goverde

- I have the following potential conflicts of interest to report:

Grant/Research Support/Consulting Fees/Honoraria:

Abbott Vascular; Angioslide; Bard Peripheral Vascular; Bentley; B Braun endovascular; Cardionovum; Cordis Cardinal Health; CTI; IMDS; Ivascular; Getinge group; Stille; Ziehm Imaging
Anatomical background

Implants reduce vessel compliance and the ability to absorb deformation

1. Smouse HB Changes in major peripheral arteries during joint movement before and after stent placement in the cadaver model. TCT 2004
Limitations of stenting strategies

Patency rates decrease with stent length

Because of long lesions and/or because of long stents?

Limitations of stenting strategies

Stents may fracture depending on design, stent length, site, movements of vessels and overlap

Patency rates decrease over time even with DES, due to permanent trauma from chronic outward force of common oversized Nitinol stents.

Limitations of stenting strategies

Treatment of **in-stent restenosis (ISR)** is limited (costly, time consuming, high recurrency rate).

ISR 2-year recurrence

- 49.9 % in class I (focal)
- 53.3 % in class II (diffuse)
- 84.8 % in class III (occlusive)

Limitations of stenting strategies

Stents may limit surgical option by blocking reconnection site for surgical bypass.
DCB therapy is limited as scaffolding is needed in up to 50% of cases with long lesions.
Shorter is better?!

Short stents may have several advantages:

• Less acute and chronic trauma on vessel wall because of less material

• Less impact on biomechanical properties of vessel because of gaps between stents

• Individual stenting strategy depending on lesion morphology
B. Braun VascuFlex® Multi-LOC

- Six stents on one delivery system
- Each stent is freely positionable
- Each stent has high radial force (closed cell design)
- It is made to cover long lesions with less material
- It maintains the natural vessel movement
B. Braun VascuFlex® Multi-LOC

Stent-Diameter: 5 – 8 mm
Stent-Length: 6x 13 mm
Guide Wire Compatibility: 0.035”
Sheath Compatibility: 6F
Shaft-Length: 80 cm / 130 cm
Objective: VascuFlex® Multi-LOC in de-novo and restenotic lesions in SFA and P1, P2, P3

Number of Patients: up to 500 patients worldwide

Inclusion Criteria: Lesions with unsatisfying angiographic results due to dissection or recoil after POBA/DCB
Reference Vessel Diameter: 4.0 mm – 7.0 mm
Lesion length: 2 cm – 27 cm
Rutherford classes 2 – 5
At least 2 stents (distance min. 0,5 mm)
Diameter stenosis pre-procedure must be ≥ 70%
Primary Endpoint: TLR at 6 months

Sec. Endpoints: TLR at 12 months
Walking distance (pre & post, 6 & 12 months)
ABI (post, 6 & 12 months)
Patency (Duplex ultrasound at 6 and 12 months)
Rutherford classifications at 6 and 12 months
Rutherford classification distribution change at 6 and 12 months
Amputation rate at 6 and 12 months
Quality of Life assessment (questionnaire post & 6 months)
### 12 month results (N=75)

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLR:</td>
<td>9.3 %</td>
</tr>
<tr>
<td>at 12 months (n=75)</td>
<td></td>
</tr>
<tr>
<td>TASC C/D lesions:</td>
<td>51.1 %</td>
</tr>
<tr>
<td>Procedural success:</td>
<td>100 %</td>
</tr>
<tr>
<td>Primary Patency:</td>
<td>85.7 %</td>
</tr>
<tr>
<td>Mean lesion length:</td>
<td>14.5 cm</td>
</tr>
<tr>
<td>Lesion length saved from stenting:</td>
<td>47.0 %</td>
</tr>
</tbody>
</table>
• 79 year old man
• Diabetes type 1
• Smoker >50 y
• Hypercholesterolaemia
• AHT
• PTCA/CABG
• Chronic renal insufficiency
• Rutherford Becker 5: ulcers Toe 1,2,4 > 3months
• Rest pain
Case
Case
Case
Case
Case
Case
Case
Case 26
Does it work? ???
Case
CT angio 3 months
Case
CT angio 3 months
Rationale for spot stenting concept

• spot stenting overcomes the limitations of full metal jacket stenting by avoiding fracture, high TLR rates, and difficulties in fu ISR treatment. It also preserves surgical options.

• spot stenting maintains the natural motion of the fempop artery by leaving unstiffened artery segments to absorb the forces caused by limb movement. It reduces metal burden by 50%.

• spot stenting addresses fempop atherosclerosis challenges such as elastic recoil, calcium spots, and dissections.

• spot stenting has demonstrated favourable clinical results in conceptual research (Hong et. al) and dedicated registries (LOCOMOTIVE).
Conclusions

We need still to go a long way
But we know that “less (stent) can be more”
: the “Multi-Loc pathway” especially when combined with DCB
Spot Stenting with VascuFlex Multi-Loc

P. Goverde MD, K. Taeymans MD, K. Lauwers MD
Vascular Clinic ZNA
Antwerp, Belgium