Stenting of the common femoral artery for atherosclerotic lesions: is it feasible and how and when we do it

P. Goverde MD,
K. Lauwers MD, L. Helsloot MD, K. Taeymans MD, P. Verbruggen MD,
Vascular Clinic ZNA, Antwerp, Belgium
Speaker’s name: Peter Goverde

- I have the following potential conflicts of interest to report:
  - Consulting:
    - Abbott Vascular; Angioslide; Atrium Maquet Getinge group; Bard Peripheral Vascular; Cardionovum; Cordis Cardinal Health; IMDS; Ivascular; Stille; Veyran; Ziehm Imaging
Which factors can determine the boundaries of current common femoral artery treatment?

- Complexity of the lesion
- Anatomy & characteristics of the vessel
- Access to the lesion
- Used material
- Effects of the intervention to the treated vessel
- etc
Forces acting in the FA

Lansky, A; Angiographic Analysis of Strut Fractures in the SIROCCO Trial. TCT 2004
Forces acting in the FA

Creation of straight leg 3D FPA model

Creation of leg in flexion 3D FA model

Forces acting in the FA

CFA boundaries and therapeutical consequences

- **CFA** poses unique anatomic challenges

- **Arterial motion** is dynamic and varies with age/disease/lesion and personal habit

- **Arterial motion** causes local biomechanical forces

- **These biomechanical forces** pose a significant challenge for stent choice
Stent design should respond to natural anatomic forces

- **Goal:** Allow arteries to maintain as much natural behavior and function as possible while addressing atherosclerotic issues.
- **Dynamic forces of the CFA** require a compliant stent to minimize chronic vessel injury and stresses on stent that can lead to fracture.
  - Mismatch can lead to stresses and fracture on stent or injury to the vessel.
  - Energy should transfer to either stent or vessel.
  - Stent should mimic rather than resist the vessel.

Evidence for CFA stenting

**Endovascular Treatment of Common Femoral Artery Disease**

Medium-Term Outcomes of 360 Consecutive Procedures

Robert F. Bonvini, MD,*† Aljoscha Rastan, MD,* Sebastian Sixt, MD,* Elias Noory, MD,* Thomas Schwarz, MD,* Ulrich Frank, MD,‡ Marco Roffi, MD,‡ Pierre André Dorsaz, PhD,† Uwe Schwarzwälder, MD,* Karlheinz Bürgelin, MD,* Roland Macharzina, MD,* Thomas Zeller, MD* Bad Krozingen, Germany, and Geneva and Chur, Switzerland

**Objectives**

The purpose of this study was to evaluate the technical feasibility, safety, and 1-year efficacy of the endovascular treatment of atherosclerotic common femoral artery (CFA) obstructions.

**Background**

Atherosclerotic CFA obstruction is a known cause of symptomatic peripheral arterial disease. Although surgical endarterectomy is considered the therapy of choice for this condition, little is known about the percutaneous options.

**Methods**

Using a prospectively maintained single-center database, we retrospectively analyzed the outcomes of 360 consecutive percutaneous interventions of the CFA for atherosclerotic disease and assessed procedural success, in-hospital complications, and 1-year patency and target lesion revascularization rates.

**Results**

Ninety-seven procedures (26.9%) were isolated CFA interventions, whereas 157 (43.6%) and 152 (42.2%) also involved inflow and outflow vessels, respectively. Bifurcation lesions were present in 140 cases (38.9%), and concomitant treatment of the profunda femoral artery was performed on 93 occasions (25.8%). Chronic total CFA occlusions were recanalized in 60 cases (16.7%). Balloon angioplasty was performed as the primary intervention in virtually all cases (98.6%), whereas stenting was needed for suboptimal angioplasty results in 133 procedures (36.9%). Failures—defined as a final angiographic result with a >30% residual stenosis—were observed on 26 occasions (7.2%). In-hospital major (i.e., requiring surgery) and minor (i.e., treated percutaneously or conservatively) complications occurred in 5 (1.4%) and 18 (5.0%) procedures, respectively. One-year follow-up data were available for 281 patients (87.5%). Restenosis >50% by duplex scanning and target lesion revascularization were observed in 74 of 268 (27.6%) and 64 of 322 (19.9%) procedures, respectively.

**Conclusions**

This large series suggests that the percutaneous approach may be a valid alternative to surgery for CFA atherosclerotic obstructions.  

(J Am Coll Cardiol 2011;58:792-8) © 2011 by the American College of Cardiology Foundation
Evidence for CFA stenting

Endovascular treatment of common femoral artery obstructions

Frederic Baumann, MD, Mirka Ruch, MD, Torsten Willenberg, MD, Florian Dick, MD, Dai-Do Do, MD, Hak-Hong Keo, MD, Iris Baumgartner, MD, and Nicolas Diehm, MD, Berne, Switzerland

Objective: To evaluate the clinical efficacy of endovascular therapy of symptomatic obstructions of the common femoral artery (CFA).

Methods: Consecutive series of patients undergoing endovascular therapy of chronic CFA obstructions between 1995 and 2009 and who were followed systematically within a prospectively maintained database. Clinical assessment was based on current guidelines including ankle-brachial index (ABI) and was performed at baseline and the day of discharge and then repeated at 3, 6, and 12 months and annually thereafter. Technical success of intervention was defined as a final residual diameter stenosis of <30%. Sustained clinical improvement was defined as a sustained upward shift of at least one category on the Rutherford classification compared with baseline without the need for repeated target lesion revascularization (TLR) or amputation in surviving patients. Limb salvage was defined as absence of a major (ie, above the ankle) amputation. Survival analysis was performed using the Kaplan-Meier method.

Results: Ninety-eight patients (38 women, mean age 72 ± 11 years) presented with 104 ischemic limbs, 20 of which (19%) were classified as having critical limb ischemia (CLI). Technical success rate was 98%. Stents were placed in eight CLI patients (40%) and in 20 claudicants (24%). Mean ABI improved from 0.28 to 0.54 (P < .001) in CLI patients and from 0.61 to 0.85 (P < .001) in claudicants. Mean follow-up was 16 months. Primary sustained clinical improvement rates at 3, 6, 12, and 24 months were 55%, 55%, 40%, and 0% in CLI patients and 81%, 75%, 68%, and 52% in claudicants, respectively. Limb salvage rates at 24 months were 94% in CLI patients and 100% in claudicants. After adjustment for confounding factors, presence of ischemic ulcers (hazard ratio [HR], 4.7; 95% confidence interval [CI], 1.49-14.85; P = .009), obstruction of the femoropopliteal arterial tract (HR, 3.9; 95% CI, 1.66-9.16; P = .002) and diabetes mellitus (HR, 2.3; 95% CI, 1.02-5.28; P = .045) were independently associated with lower rates of sustained clinical improvement.

Conclusions: Endovascular therapy of CFA obstruction is associated with high rates of sustained clinical success in claudicants with patent femoropopliteal outflow. Presence of ischemic skin ulcers and diabetes mellitus, however, are associated with impaired efficacy of endovascular CFA treatment. (J Vasc Surg 2011;53:1000-6.)
Endovascular Treatment of Profunda Femoris Artery Obstructive Disease: Nonsense or Useful Tool in Selected Cases?

K.P. Donas a,e, G.A. Pitoulias b,c,*e, A. Schwindt a, S. Schulte d, M. Camci d, R. Schlabach a, G. Torsello a

a Department of Vascular Surgery, St. Franziskus Hospital Münster, Germany and Center for Vascular and Endovascular Surgery of Münster University Hospital, Münster, Germany
b Division of Vascular Surgery, G. Gennimatas Hospital, Aristotle University of Thessaloniki, Thessaloniki, Greece
c Research Fellow of Center for Vascular and Endovascular Surgery of Münster University Hospital, Münster, Germany
d Center of Vascular Surgery, Media Park Clinic Cologne, Cologne, Germany

Submitted 19 June 2009; accepted 6 October 2009
Available online 10 November 2009

KEYWORDS
Profunda femoris artery occlusive disease;
Endovascular treatment;
PTA;
Critical limb ischaemia;
Profundoplasty

Abstract. Background: To evaluate the therapeutic value of endovascular techniques for the treatment of profunda femoris artery obstructive disease (PFAOD) in critical limb ischaemia (CLI) patients, with technically demanding open profunda repair.

Design: Retrospective study of prospectively collected data of 15 consecutive CLI patients with technically demanding surgical treatment of PFAOD, that were treated by endovascular means in two European Centers of Vascular Surgery.

Materials: All patients had critical limb ischaemia with a history of at least two previous vascular reconstructions in the ipsilateral groin and severe co-morbid conditions. All patients had good common femoral artery flow, long occlusion of the superficial femoral and popliteal arteries and impairment of crural arteries.

Methods: Twelve patients underwent balloon angioplasty alone and, in the other three cases, an additional stent placement was necessary, due to flow-limiting dissection. The follow-up (mean 29.2 ± 10 months) included a surveillance protocol with the best medical treatment and duplex scanning at 1, 3, 6, 12 months and yearly thereafter.

Results: The endovascular approach was technically successful in all cases and the procedure-related morbidity and mortality rates were 0% for the entire follow-up period. The 3-year primary and secondary patency rates of the treated segment were 80% and 86.7%, respectively. The limb salvage rate was 93.3%.
Different Nitinol Stent Classes are available: BUT WHAT CAN WE USE?

<table>
<thead>
<tr>
<th>Standard Nitinol Stents (SNS)</th>
<th>Vascular Mimetic Stent</th>
<th>Covered/Stent Grafts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smart (Cordis)</td>
<td>Supera (Abbott)</td>
<td>Viabahn (Gore)</td>
</tr>
<tr>
<td>Protégé Everflex (eV3)</td>
<td></td>
<td>Hemobahn (Gore)</td>
</tr>
<tr>
<td>LifeStent (Bard)</td>
<td></td>
<td>Fluency (Bard)</td>
</tr>
<tr>
<td>Luminexx (Bard)</td>
<td></td>
<td>Flair (Bard)</td>
</tr>
<tr>
<td>Absolute (Abbott)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Xpert (Abbott)</td>
<td></td>
<td>Tigris (Gore)</td>
</tr>
<tr>
<td>Zilver (Cook)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete SE (Medtronic)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misago (Terumo)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smart Flex (Cordis)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Supera’s design results in
- improved strength
- flexibility
- durability

*Independent testing conducted by Medical Device Testing Services, Minnetonka, MN. Data on file, IDEV Technologies.
Radial Strength

- Independent testing* showed
  - The Supera stent has a minimum of 4 times the radial strength of standard nitinol stents
  - The Supera stent has 360% stronger crush resistance than standard nitinol stents

*Independent testing conducted by Medical Device Testing Services, Minnetonka, MN.
Data on file, IDEV Technologies.
Our approach

• **Surgical endarterectomy:**
  - Young patients
  - De novo lesions
  - Very calcified
  - CFA/SFA/PFA involvement

• **Endovascular:**
  - Patients un-fit for surgery
  - Possible wound problems /scar tissue
  - Very obese patients
Type of CFA lesion

- Severe calcification
  - Surgical endarterectomy
- No/mild/moderate calcification
  - Endovascular

Lesion not to pass
- Risk of PFA damage
- Risk of inadequate PTA result

Lesion can be passed

Our approach
Our approach

Lesion not to pass
Risk of PFA damage

Intimal hyperplasia
Recurrent disease

Balloon angioplasty
If available debulking/DCB

Risk of atherosclerotic
Balloon angioplasty
1:1 or 1:+1

Succesfull wire passage

Bifurcation
2 wire technique
Kissing balloon

Residual stenosis (>50 %)
Recoil/Dissection/Calcium
Stenting SUPERA VMI

Unsuccesfull: double stenting or consider surgery

Technical succes: Stop
Case example
Vascular Clinic ZNA
CFA Supera follow-up survey

- Single centre, physician initiated, prospective, non-randomised follow-up study
  - Started 2010 – 2016
  - Real life patient population
  - 36 patients
# Baseline Patient Demographics: n = 36

<table>
<thead>
<tr>
<th></th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male Gender (%)</td>
<td>58.3</td>
</tr>
<tr>
<td>Mean Age (years ± SD)</td>
<td>76.5±5.98</td>
</tr>
<tr>
<td>Mean BMI (± SD)</td>
<td>31.4±5.7</td>
</tr>
<tr>
<td>Nicotine abuse (%)</td>
<td>72.2</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>75</td>
</tr>
<tr>
<td>Hypercholesterolemia (%)</td>
<td>63.9</td>
</tr>
<tr>
<td>Diabetes (type 1=2) (%)</td>
<td>58.3</td>
</tr>
<tr>
<td>Vascular History (%)</td>
<td>66.7</td>
</tr>
<tr>
<td>Recurrent disease (%)</td>
<td>36.1</td>
</tr>
<tr>
<td>Coronary History (%)</td>
<td>52.8</td>
</tr>
<tr>
<td>Cerebrovascular History (%)</td>
<td>13.9</td>
</tr>
<tr>
<td>Renal insufficiency (%)</td>
<td>30.6</td>
</tr>
</tbody>
</table>
### TASC DISTRIBUTION

<table>
<thead>
<tr>
<th>TASC</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tasc A</td>
<td>0</td>
</tr>
<tr>
<td>Tasc B</td>
<td>11</td>
</tr>
<tr>
<td>Tasc C</td>
<td>19</td>
</tr>
<tr>
<td>Tasc D</td>
<td>6</td>
</tr>
</tbody>
</table>

### LESION LOCATION

<table>
<thead>
<tr>
<th>Location</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFA</td>
<td>8</td>
</tr>
<tr>
<td>CFA + EIA</td>
<td>15</td>
</tr>
<tr>
<td>CFA + bifurcation</td>
<td>9</td>
</tr>
<tr>
<td>CFA + EIA + bifurcation</td>
<td>4</td>
</tr>
<tr>
<td>Procedure (1/3)</td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td></td>
</tr>
<tr>
<td>Vessel preparation: predilatation is mandatory</td>
<td></td>
</tr>
<tr>
<td>Sizing</td>
<td>1/1 or 1/+1</td>
</tr>
<tr>
<td>Slow inflation</td>
<td>2 min</td>
</tr>
<tr>
<td>Mean lesion length</td>
<td>58.6 mm</td>
</tr>
<tr>
<td>Reference vessel diameter</td>
<td>5.87 mm</td>
</tr>
<tr>
<td>Mean stenosis before treatment</td>
<td>86.2%</td>
</tr>
<tr>
<td>Number of occlusions</td>
<td>2</td>
</tr>
<tr>
<td>Presence Moderate to heavy calcifications</td>
<td>18</td>
</tr>
<tr>
<td>Use of Drug Coated Balloon (mainly for)</td>
<td>3</td>
</tr>
</tbody>
</table>
## Procedure (2/3)

<table>
<thead>
<tr>
<th>Stents used</th>
<th>40</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5 mm</strong></td>
<td>5</td>
</tr>
<tr>
<td><strong>6 mm</strong></td>
<td>27</td>
</tr>
<tr>
<td><strong>7 mm</strong></td>
<td>8</td>
</tr>
<tr>
<td>Mean stent diameter</td>
<td>5.58 mm</td>
</tr>
<tr>
<td>Mean stent length</td>
<td>68.7 mm (Mean lesion length : 163.20 mm)</td>
</tr>
<tr>
<td>Number stents / patient</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>32 pt^n</td>
</tr>
<tr>
<td>2</td>
<td>4 pt^n</td>
</tr>
<tr>
<td>Procedure 3/3</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>Mean residual stenosis at end of procedure (%)</td>
<td>21 , 34</td>
</tr>
<tr>
<td>Mean Heparine (IU)</td>
<td>5600 IU</td>
</tr>
<tr>
<td>Mean contrast</td>
<td>79,20 ml</td>
</tr>
<tr>
<td>Access hemostasis closure device</td>
<td>96</td>
</tr>
<tr>
<td>Technical success (&lt;30% diameter residual Stenosis)</td>
<td>98</td>
</tr>
</tbody>
</table>
Results:
- ASA & clopidogrel
- Follow-up with US
- RX in +/- 50 

NO FRACTURES
Primary PATENCY 1 year: 34/36 : 94 %

Concern: puncture + sheat introduction through Supera for reintervention: still possible as access
puncture + sheath introduction through Supera
Conclusions

Supera VMI system in CFA:

- Treat / stent the whole diseased segment
- Extraordinary characteristics: radial strength, flexibility, durability
- Flexion / extension angiogram can be done
- Shows excellent fracture & kink resistance solution where "classical" nitinol stents are not indicated
- Patency rates in our institution: very promising
- Can be answer for progressive / extensive disease in CFA for selective patients
Thank you for your attention
Stenting of the common femoral artery for atherosclerotic lesions: is it feasible and how and when we do it

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