First experience: investigating the Supera stent in the CFA. Is Supera a valuable alternative for common femoral endarterectomy?

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Disclosure slide

Speaker name: Koen Deloose, MD

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

  - Consulting: Medtronic, Spectranetics, Biotronik, Abbott, Bard, iVascular, Bentley, Cook, GE Healthcare

  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s)

- I do not have any potential conflict of interest
CFE = Golden standard....

**Ballotta et al. (Surgery 2010;147:268-274)**
- 8 yr single center, prospective study, 117 pts
- PPR @ 1, 3, 5 & 7 yrs: 100%, 99%, 96%, 96%
- APP: 100% - LSR: 100%

**Kang et al. (J Vasc Surg 2008;48:872-7)**
- 5 yr single center, prospective study, 58 pts
- PPR @ 1 & 5 yrs: 93%, 91%
- APP: 100%

**Kechagias et al. (World J Surg 2008;32:51-54)**
- 15 yr single center, prospective study, 111 pts
- PPR: na-LSR @ 5, 10, 15 yrs: 93,7%, 93,7%, 85,2%
- f-TLR @ 5, 10, 15 yrs: 68%, 50,6%, 42,5%
CFE = Dark side

Ballotta et al. (Surgery 2010;147:268-274)
6.6% minor complication rate
Mainly lymph leaks

Kang et al. (J Vasc Surg 2008;48:872-7)
13.8% complication rate
5% required reintervention

Kechagias et al. (World J Surg 2008;32:51-54)
17.1% wound infection rate
9% hematomas
CFE = Dark side

Derksen et al. (Vasc End Surg 2009;43:69-75)
140 pts, retrospective
- 14% wound infection rate
- 9% superficial infections
- 5% deep infections
- 2 cases involvement of patch

Cardon et al. (Ann Chir 2001;126(8):777-82)
- 18% minor complication rate
- 3.6% major complication rate
Is endovascular an alternative?

- Bulky, eccentric, heavily calcified plaques
- Frequently femoral bifurcation involvement
- Location prone to crush
- (surgical/endovascular) access area
- Relatively fixed segment
CFEVT = alternative...

LIMITED DATA

A LOT OF QUESTIONS

- Long term follow-up?
- No standardized imaging FU
- No Kaplan-Meier curve outcome analysis

MODERN ENDOVASCULAR DEVICES
Is endovascular an alternative?

Bulky, eccentric, heavily calcified plaques

Crush risk (Surgical/endovascular) access area
Is endovascular an alternative?

Bulky, eccentric, heavily calcified plaques

Crush risk

Diagram showing force vs. deflection for different stent types, with a note that Supera stents have greater than 4x compression resistance compared to standard Nitinol stents.
Is endovascular an alternative?

(Surgical/endovascular) access area
Let’s prove...

Physician initiated, prospective, multicenter, single arm trial to evaluate the Supera Peripheral Vascular Mimetic Implant Device (Abbott Vascular°) for symptomatic (RB 2-4) CFA disease treatment
Participating centers

**Belgium**

- AZ. Sint Blasius Hospital Dendermonde
  - K. Deloose (PI), J. Callaert, M. Bosiers
- OLV Hospital Aalst
  - L. Maene, R. Beelen
- ZNA Stuivenberg Hospital Antwerp
  - P. Goverde, K. Lauwers
- Imelda Hospital Bonheiden
  - J. Verbist, W. Van Den Eynde

**France**

- Hôpital Nord Laennec, CHU, Nantes
  - Y. Gouëffic
- Clinique Rhône Durance, Avignon
  - C. Brunet
Main in/exclusion criteria

- **Rutherford classification from 2 to 4**
- Guidewire has crossed the lesion
- **De novo lesions (stenosis > 50%/occlusions) within the CFA**, between the origin of the circumflex Iliac Artery and the proximal (1cm) SFA
- Angiographic evidence of a patent deep femoral artery
- At least one runoff to the foot
- Presence of **another stent in the target vessel**
- **Previous open surgery** in the target limb
- Patients contraindicated for antiplatelet therapy, anticoagulants or thrombolytics
- Persistent acute intraluminal thrombus at the target lesion site
- Perforation at the angioplasty site
- Deep femoral artery occlusion
Primary endpoint

Efficacy endpoint

Primary patency @ 12 months, defined as:

Freedom from >50% restenosis as indicated by an independent core-lab verified duplex ultrasound peak systolic velocity ratio (PSVR) <2.5 in the target vessel with no re-intervention (TLR) within 12 months

Safety endpoint

Peri-procedural adverse events up to 30 days post-procedure, as defined per ISO 14155:2011
Secondary endpoint

**Technical success;** defined as ability to cross/stent lesion to achieve residual angiographic stenosis <30%

**Primary patency rate @ 1 & 6 months;** defined as freedom from >50% restenosis on duplex ultrasound (peak systolic velocity ratio (PSVR) <2,5) in the target vessel with no reintervention within 1 & 6 months

**Freedom from TLR @ 1, 6 & 12 month;** defined as repeat intervention to maintain/re-establish patency within region of treated arterial vessel

**Clinical success @ follow-up;** defined as an improvement of Rutherford Classification at 1, 6 & 12 month follow-up
# Timetable

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*Euro imaging research Rome, Italy
Enrollment

66 out of 100 patients are enrolled

OLV Hospital, Aalst 37
AZ Sint-Blasius, Dendermonde 18
ZNA, Antwerp 4
Imelda, Bonheiden 1
CHU, Nantes 4
Clinique Rhône-Durance, Avignon 2
First enrollment

Male patient, RB 3 left leg, 75 yr

Preoperative imaging
First enrollment

Male patient, RB 3 left leg, 75 yr

Preoperative imaging
First enrollment

Male patient, RB 3 left leg, 75 yr

Preoperative imaging
## Conclusion

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VMI-CFA study

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