More About The Value And Limitations Of The Tigris Dual Component Stent For SFA-Pop Lesion Treatment: What Makes It Different

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Disclosure
Speaker name:
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I have the following potential conflicts of interest to report:
- Receipt of grants/research support
- Receipt of honoraria and travel support
- Participation in a company sponsored speakers’ bureau
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
X I do not have any potential conflict of interest

TIGRIS STENT
- CE marked November 2011
- Indications for use under CE mark
  The Gore® TIGRIS® Vascular Stent is intended for endovascular stenting of symptomatic de-novo or restenotic lesions of the native superficial femoral artery (SFA) and proximal popliteal artery (PPA) with reference vessel diameters ranging from 4.0–6.5 mm and lesion lengths up to 240 mm.
- FDA approval February 2017
- FDA approval July 2016
- Indications for use in the United States
  The Gore® TIGRIS® Vascular Stent is intended to improve luminal diameter in patients with symptomatic de-novo or restenotic lesions of the native superficial femoral artery (SFA) and proximal popliteal artery (PPA) with reference vessel diameters ranging from 4.0–6.5 mm and lesion lengths up to 240 mm.
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WHAT MAKES IT DIFFERENT – DUAL COMPONENT DESIGN
Designed to:
- Maximize flexibility while minimizing risk of stent fracture
- Allow axial compression while resisting stent elongation
- Naturally conforms and allows vessel movement

WHAT MAKES IT DIFFERENT – ELONGATION TESTING
Less elongation provides deployment accuracy and decreased potential for stent fracture

WHAT MAKES IT DIFFERENT – STRAIGHTENING FORCE TESTING
Less straightening force allows the stent to naturally conform to vessel movement

- MINIMAL ELONGATION RATE
- LESS STRAIGHTENING FORCE – HIGH CONFORMABILITY
WHAT MAKES IT DIFFERENT – LONGITUDINAL COMPRESSION TEST

Less resistance to compression allows the stent to naturally conform to vessel shortening and decreases potential for stent fracture.

WHAT MAKES IT DIFFERENT – DUAL COMPONENT DESIGN

Proven CBAS Heparin Surface technology

TIGRIS Italian Multicentre Registry for the Treatment of Femoro-Popliteal Artery Disease
A Physician-Initiated Registry

STUDY DESIGN

Physician-initiated, prospective, multicentre, single arm registry
- 4 Interventional Radiology Units
- 4 Vascular Surgery Department

OBJECTIVE

To evaluate the feasibility and safety of the Gore® Tigris® Vascular Stent for the treatment of distal SFA with or without involvement of popliteal artery when used inside the IFU

Ethics Committee approved (first centre late February 2017)

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PATIENT POPULATION: 121 patients, mean age 72 +/- 10 years, male 79
- DM: 55 %
- Hypertension: 81 %
- Current smokers: 30 %
- Former smokers: 48 %
- Dislipidemia: 49 %
- Cardiac disease: 32 %
- Renal disease: 10 %
- Previous TIA: 7.5 %

LESION LENGTH: mean 12.8 cm ± 8.8 cm

RUTHERFORD CLASSIFICATION:
- Rutherford III: 48 pts. 39.7%
- Rutherford IV: 35 pts. 30%
- Rutherford V: 38 pts. 31.3%

Mean ABI pre procedure: 0.41, DS 0.1

DISTAL RUN-OFF:
- 3 vessels 22 (18.2 %)
- 2 vessels 44 (36.4 %)
- 1 vessel 55 (45.4 %)

LESION CHARACTERISTICS:
- LOCATION:
  - right limb: 61 pts.
  - left limb: 60 pts.
  - SFA: 70 pts. 57.8 %
  - proximal SFA: 3 pts. 4.3 %
  - mid SFA: 11 pts. 15.7 %
  - distal SFA: 56 pts. 80 %
  - distal SFA + popliteal a.: 29 pts. 24 %
  - distal SFA + P1: 20 pts. 69 %
  - distal SFA + P1 + P2: 7 pts. 24 %
  - distal SFA + P1-P3: 2 pts. 7 %
  - popliteal a.: 22 pts. 18.2 %
  - P1: 4 pts. 18.3 %
  - P2: 5 pts. 22.7 %
  - P1 + P2: 1 pt. 4.5 %
  - P2 + P3: 1 pt. 4.5 %
  - P1 + P2 + P3: 11 pts. 50 %

PRELIMINARY RESULTS

POST-PTA LONG DISSECTION:
Gore Tigris 5x60 mm + 6x 80 mm

TOTAL MORTALITY:
- 2 women 22 (18.7 %)
- 2 women 14 (11.6 %)
- 1 woman 50 (41.8 %)
CONCLUSIONS

Single and multicentre, retrospective registries reported in Literature show the dual component Gore Tigris Vascular Stent could represent a reliable device for the treatment of obstructive disease of SFA and popliteal artery with good results at 12 and 24 months follow up.

The preliminary results of our Registry show promising results of this device not only in case of de novo lesions but also in case of bail out stenting.

Long term follow up and larger cohort of patients are needed to confirm the preliminary results of our Registry also in longer and very complex lesions.