Latest experience with Dual Layer Stents in the lower limbs

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Disclosure

Speaker name:
Torsten Fuss

I have the following potential conflicts of interest to report:

☒ Consulting (Terumo, Biotronik, Abbott, Optimed, Straub)
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Renzan Concept

- Dual Layer Stent for superior femoral (SFA) and popliteal arteries
- leverage micromesh protection Dual Layer Stent and delivery system design from Roadsaver
- design for high radial strength, low chronic outward force, improved fracture resistance and durability
- braided design for superior flexibility and adaptation to femoropopliteal arteries
Stent Features & Benefits

Dual Layer Braided Stent with Micro-mesh Technology

**Inner layer**
- **Micro-mesh**: very small cell size, designed to limit plaque prolapse and reduce distal embolization

**Outer layer**
- **Conformability**: braided Nitinol design to allow for in-vivo stent tapering and conformability
- **Flexibility**: closed cell stent designed to have similar flexibility to an open cell stent, resulting in excellent vessel wall apposition and adaptation to tortuous anatomy
- **Visibility**: 3 markers on each stent end designed for improved visibility
Renzan Delivery Catheter Design

- fully repositionable with up to 50% deployment
- push/pull handle: designed for a simple and controlled deployment process without stent jumping
- guidewire compatibility: 0.018”
- sheath compatibility: 6.0 Fr (min. ID: 0.087”/2.2 mm)
- construction: rapid exchange
- diameter 5 up to 8 mm and length 40 up to 100 mm (120 and 150 are coming soon)
Delivery Catheter Angiography View

- Retractor (at proximal stent)
- Predictor marker
- Distal outer cath marker
- Radiopaque sliding soft tip
Multi Axis Fatigue Testing

- MAPS Testing
  - competitors: Renzan, Supera, Everflex, Smart Flex, Zilverflex
  - 10 year=10 million cycles for multi-axis loading

- Results
  - competitor bare metal stents: 3-16 fractures
  - Renzan: **0 Fractures**

Data on file at MicroVention. TR16-232, Renzan =11, TR16-172, other brand stents n=1
Renzan Ovine Study

- **Implant Summary:**
  - 2 ovine models
  - 3 stents implanted in SFA/iliac arteries
  - 6,7,8 mm OD stents, 150mm length

- **Follow-up Highlights: 60 Days**
  - good stent radiopacity
  - no flow issues, side branches patent
  - stents well apposed to vessel wall
  - no migration

- **Histology:**
  - minimal vessel injury
  - minimal inflammation
  - minimal uncovered struts
  - stent almost completely incorporated into vessel wall
  - organized neointima composed of smooth muscle cells

Data on file at MicroVention
Renzan Porcine Study

GLP Study Design
- porcine model: Yucatan 50-70kg, Qty 8
- 4 animals/timepoint: 30, 180 Days
- stenting in iliac and SFA
- SFA stents covering side branch
- 5-8 mm OD, 40 mm lengths, 4 stents per animal

Follow-up Highlights: 30 & 180 Days
- good stent radiopacity
- no flow issues, side branches patent
- stents well apposed to vessel wall
- all stents patent

Histology:
- minimal vessel injury
- good neo-intimal coverage
- minimal inflammation

Data on file at MicroVention. TR16-098
Own Experience

- 7 real world patients
- High cardiovascular risk (3 or more risk factors)
- 2 or multi level PAOD
- 4 patients with occlusion from 4 up to 8 cm
- 4 weeks follow up in 7 patients and 3 in 12 weeks completed
## Patient characteristics - comorbidities

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### 4 weeks follow up

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Case examples

1. Case – stenosis popliteal artery (P2)
Case examples

2. Case: Occlusion of distal SFA and popliteal artery
Case examples

3. Case: short occlusion in the hunter channel
Case examples

4. Case: occlusion of the EIA
Conclusion

• very good performance under the release: good visibility, easy, safe and correct placement
• very good performance in complex lesions, lesions with severe calcification/recoil and in challenging regions with tortuous anatomy
• no peripheral embolization in lesions with soft plaques/occlusions
• no occlusion of important side branches
• very good early results after 4 weeks and 3 month without re-stenosis/early thrombosis/re-occlusion under dual antiplatelet therapy for 4 weeks
• aggressive vessel preparation is mandatory
Thanks for your attention