Novel helical stent design elicits swirling blood flow pattern and inhibits neointima formation in porcine carotid arteries

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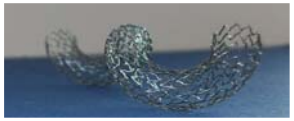
Background

- Swirling blood flow patterns in the vasculature augments vessel wall shear stress, which in turn may have a profound effect to suppress neointima formation post stent implant.
- Veryan Medical, Ltd has developed a novel peripheral stent with 3D centreline curvature

Objective

- The objectives of this study were to determine, using a porcine model of carotid stenting:
  - Evaluation of BioMimics 3D stent deliverability to assess any issues at time of implant
  - Evaluation of angiographic and duplex ultrasound data to assess a trend towards an increase in swirling flow in BioMimics 3D stents relative to controls at implant and pretermination
  - Evaluation of histological endpoints to assess if there is a trend toward lower neointimal thickness and % stenosis in the BioMimics 3D stents



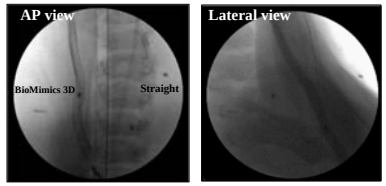
Example of a stent with BioMimics 3D technology

Methods

- Test system: Juvenile domestic Yorkshire hybrid pigs (N=10, body weight 42.7±3.5 Kg)
- Stent implant procedure:
  - Animals were implanted with one BioMimics 3D stent in a carotid artery and one straight stent in contra-lateral carotid artery according to standard technique
  - Mean lumen diameter (mLD) within the stent were measured
- Angiographic restudy, termination, & specimen harvest:
  - Angiographic restudy at one-month post-implant
  - After termination, the carotid arteries were excised and processed for histological analysis
- Color Doppler and Duplex ultrasound examination
  - Assess a trend towards an increase in swirling flow in the BioMimics 3D stents relative to control segment
- Stented carotid segments were embedded in methyl methacrylate; histologic sections were prepared using the precision saw-and-grinding method
- Histologic sections were evaluated by computer-assisted planimetric histomorphometry to measure:
  - area of arterial lumen
  - internal elastic lamina (IEL) area
  - thickness of neointima
  - area of neointima (IEL area – lumen area)
  - % area stenosis ([1-(luminal area/IEL area)] X 100)
- Histomorphologic assessment of vessel wall response

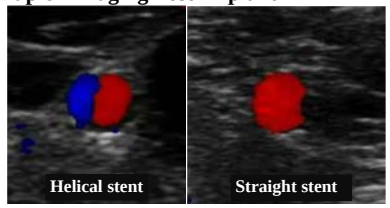
Results

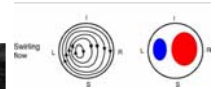
Angiography Immediately Post-Implant



Swirling blood flow pattern was observed in a BioMimics 3D stent immediately after implantation, using small-volume contrast injection. In straight stents, swirling flow pattern was not detected.

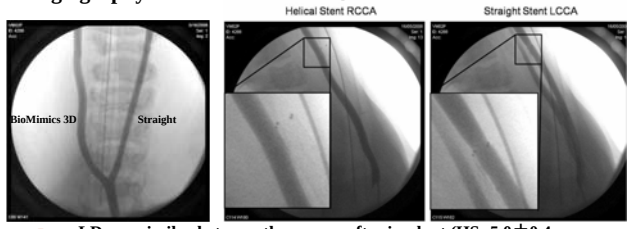
Duplex Imaging Post-Implant





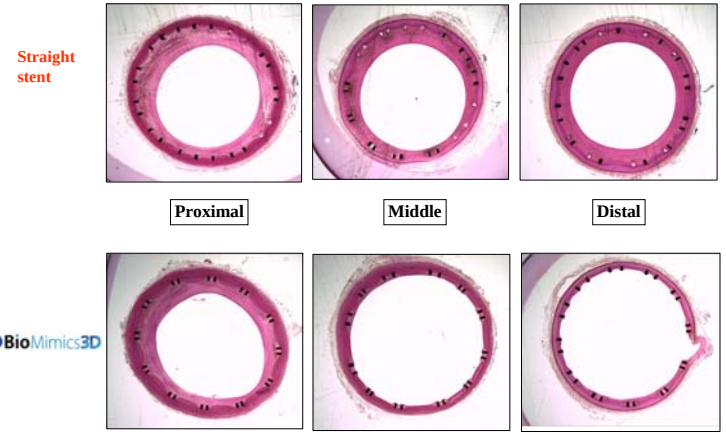
Swirling blood flow pattern was evident by the presence of bi-directional flow in a BioMimics 3D stent immediately after implantation. Orientation of flow is uni-directional i.e. no swirl is present in straight stents.

Angiography One Month Post-Implant

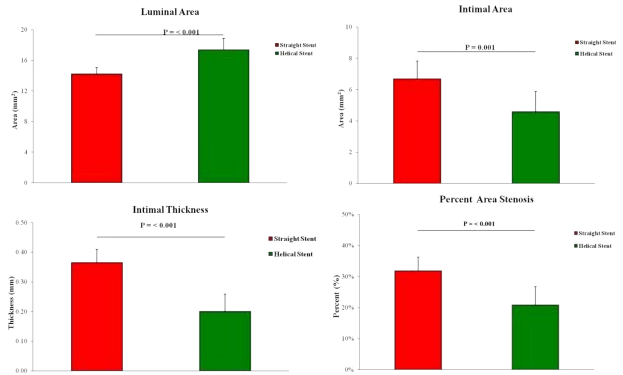


- mLD was similar between the groups after implant (HS: 5.0±0.4mm, SS: 5.0±0.4mm; P=0.903), while all animals showed higher mLD in HS at one-month (HS: 5.2±0.6mm, SS: 4.7±0.6mm; P=0.053).

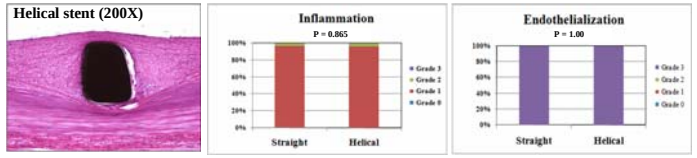
Histology of Carotid Stents at One Month Post-Implant



Histomorphometry



Histopathologic scoring



- Neointima within stented segments consisted of smooth muscles in an organised extra-cellular matrix, with uniform endothelial cell coverage both in BioMimics and Straight stent.
- Inflammation score was equivalent between BioMimics 3D and Straight stent

Summary

- BioMimics 3D stents were readily deployed in straightforward manner using standard equipment and supplies, into pig carotid arteries
- BioMimics 3D stents were capable of imposing a helical profile on a porcine disease free common carotid artery
- The subsequent reshaping of the vessel induces swirling flow as verified using duplex Doppler ultrasound and digital subtraction angiography
- Histopathology studies indicate that the helical stents reduces levels of neo-intimal thickness by 45% (P<0.001) and stenosis by 34% (P<0.001) when compared to straight stents in a porcine carotid model.
- Extensive endothelialisation of the stented vessel segment has taken place at one-month

Conclusions

- BioMimic 3D stent provides a novel potential therapeutic strategy for vascular intervention
- BioMimics 3D design promotes swirling blood flow and inhibits neointima formation in stented porcine carotid arteries, possibly due to the enhancement of vessel wall shear stress
- Neointimal morphology was mostly similar to standard stent