NEW NITINOL STENTS IN THE SFA: ARE THEY BETTER THAN THE OLD ONES FOR PATENCY AND EFFECTIVENESS – ESPECIALLY FOR MORE COMPLEX LESIONS

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Disclosures

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DSMB member Covidien Medical, Boston Scientific

NEW NITINOL STENTS

Everflex
Smart Flex
Innova
BioMimics
Supera

EVERFLEX STENT

DURABILITY II

LESION LENGTH 8.9CM
Occlusion 48.1 (138/287)
Calcification, % (No.)
None/mild 30.0 (86/287)
Moderate 26.8 (77/287)
Severe 43.2 (124/287)
Ulcerated 10.5 (30/287)

OUTCOME OF DURABILITY II
SMART FLEX STENT

FEATURES OF SMART FLEX

MINIMAL PERSISTENT OUTWARD FORCE

S.M.A.R.T.® Flex OUS clinical Trial results
Two clinical trials in New Zealand and Germany with a total enrollment of 35 patients were completed in the 2nd quarter of 2010

<table>
<thead>
<tr>
<th></th>
<th>12 Months (n=27)</th>
<th>14 Months / NZ only (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from MACE</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Primary Patency*</td>
<td>85.2%</td>
<td>84.6%</td>
</tr>
<tr>
<td>Average Lesion Length</td>
<td>84 mm</td>
<td>76 mm</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>92.6%</td>
<td>84.6%</td>
</tr>
<tr>
<td>Reported Fracture Rate (Type 1, 2, 3 and 4)</td>
<td>0%</td>
<td>0%</td>
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</tbody>
</table>

Reported Fracture Rate
(Pooled results for ≤120 mm stent)
Primary Patency for ≤ 150mm stent  80.7% in Germany only at 12months

Innova Stent Design
- Evenly spaced connectors balance stress distribution to help increase durability and reduce risk of fracture
- Connectors are offset on adjacent rows to maintain flexibility
- Optimized strut dimensions
  - Strut width, length, thickness and angles designed for strength
- Premium materials & finishing
  - High-grade Nitinol and meticulous surface polishing/finishing/improve fracture resistance

SuperNOVA Clinical Data

Study design:
- Prospective, multicenter, controlled, single-arm, non-inferiority trial to evaluate the Innova™ Self-Expanding Stent System in superficial femoral and proximal popliteal lesions
- 55 sites, 299 patients in the U.S., Japan, Europe and Canada
- Included lesions 30 mm – 190 mm with reference vessel diameters from 4 mm to 7 mm
- Study reported longest average lesion length of any SFA stent approval study: 9.32 cm

Study Endpoints Results at 12-months
- Mild-free rate 87.5%
- Primary patency 77% for core matrix (stents 20-150 mm) 74% for full matrix (stents 20-200 mm)
- Freedom from TLR 89%
- Fracture rate 1.9%
BIOMIMICS 3D STENT

Proof of concept: histology
Porcine carotid model with 30-day histology showed 45% reduction in neointimal thickness (P < .001)

Proof of concept: cadaver
Helical curvature of biomimetic stent accommodates femoropopliteal shortening in leg flexion

Mimics Randomized Control Trial

Mimics RCT: Primary Patency
Kaplan Meier Estimate of Survival from Loss of Patency

Mimics Study: Lesion Characteristics

Comparison with Other Studies

<table>
<thead>
<tr>
<th>Lesion Location</th>
<th>SFA</th>
<th>SFA/Popliteal</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>92%</td>
<td>6%</td>
<td>2%</td>
<td>36%</td>
<td>6%</td>
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<tr>
<td></td>
<td>77%</td>
<td>12%</td>
<td>12%</td>
<td>54%</td>
<td>10%</td>
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<tr>
<td></td>
<td>0.08</td>
<td>0.99</td>
<td>0.99</td>
<td>0.50</td>
<td>1.00</td>
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</tbody>
</table>

Lesion Length

Calcification

Moderate to Severe

Cumulative Survival

BioMimics 3D

Control stent

Stents were CR Bard LifeStent

Follow-up: 12 Months

N=41/41

Lost to follow-up (1); withdrawn consent (2)

Follow-up: 24 Months

N=22/22

Lost to follow-up (1); withdrawn consent (1); Death (1)

*N=24/26 LifeStent (CR Bard)

24/26 Control Stents were CR Bard LifeStent

Lead-in Phase

N=10

Randomized Phase I

N=76

Randomised Phase II

N=76

BioMimics 3D

N=50

Death (1); withdrawn consent (3); lost to follow-up (2)

Follow-up: 12 Months

N=44/44

Follow-up: 24 Months

N=41/41

Withdrawn consent (1); no re-consent to 24 month protocol (2)

Control stent

N=26

Lost to follow-up (1); missed 12-m visit (1)

Follow-up: 12 Months

N=24/25

Follow-up: 24 Months

N=22/22

Lost to follow-up (1); withdrawn consent (1); Death (1)

Comparison with Other Studies

Superb | Zilver | Pyxis | Durability | Risk | In FACT | LeVeen |

Total Occlusion

25% | 30% | 48% | 44% | 25.8% | 20.8%

Calcium (severe)

44% | 37% | 43% | 42% | 5% | 17.6%
Log rank test $P = 0.135$

91%  91%

92%

76%

Months

24  6  12

0  20  40  60  80  100

Cumulative Survival

What is the value of the longer term benefit?

- Improved patency improves clinical outcomes in claudics.
- Incremental health economic benefits.

PATENCY AND STENT LENGTH

CONCLUSION

New stents have engineering advantages which appear to incrementally enhance performance.

Vessel preparation for stent implantation may be much more important than previously appreciated.

The hope would be that with decreased “Fall-off” of patency with these newer stents, drug delivery would further improve for DES.