Safety and Efficacy of the S.M.A.R.T Control Stent for Iliaco-femoral Occlusive Disease in Contemporary Clinical Practice

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Shinshu University Hospital, Department of Cardiology
Yusuke Miyashita
Diabetes mellitus (DM) and renal Insufficiency (RI) are the predominant risk factors on the likelihood of developing PAD. This situation is not only a clinical but also an economic challenge which contributes to an increasing prevalence of vascular disease in every country. Aortoiliac (AI) arterial lesions are found in one third of patients with symptomatic peripheral artery disease (PAD).
Learn From ESC 2011 guideline -Aorto-Iliac lesions-

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>When revascularization is indicated, an endovascular-first strategy is recommended in all aortoiliac TASC A–C lesions.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>A primary endovascular approach may be considered in aortoiliac TASC D lesions in patients with severe comorbidities, if done by an experienced team.</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>Primary stent implantation rather than provisional stenting may be considered for aortoiliac lesions.</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>

\(^a\)Class of recommendation.  
\(^b\)Level of evidence.  
TASC = TransAtlantic Inter-Society Consensus.
General agreement of endovascular reconstruction for severe aortoiliac occlusive disease
-From TASC II guideline-

- The technical and initial clinical success of endovascular reconstruction of iliac stenoses exceeds 90% in all reports in the literature. (100% for focal iliac lesions, whereas 80 to 85% long segment iliac occlusions) ⇒ Recent device developments geared towards treatment of total occlusions.

- Factors negatively affecting the patency of such interventions include
  - Quality of run off vessels
  - Severity of ischemia
  - Length of diseased segments
  - Female gender decrease patency of external iliac artery stents

These fait accompli mentioned in TASC II documents was built based on traditional research published around 2000-2005. It doesn't reflect recent clinical practice.
Contemporary Outcomes After Endovascular Treatment for Aorto-Iliac Artery Disease

Yoshimitsu Soga, MD; Osamu Iida, MD; Daizo Kawasaki, MD; Yasutaka Yamauchi, MD; Kenji Suzuki, MD; Keisuke Hirano, MD; Ryoji Koshida, MD; Daisuke Kamoi, MD; Junichi Tazaki, MD; Michiaki Higashitani, MD; Yoshiaki Shintani, MD; Terutoshi Yamaoka, MD; Shinya Okazaki, MD; Nobuhiro Suematsu, MD; Taketsugu Tsuchiya, MD; Yusuke Miyashita, MD; Norihiko Shinozaki, MD; Hiroki Takahashi, MD; on behalf of REAL-AI investigators

Background: The patency and complications in aorto-iliac (AI) stenting remain poorly understood. The aim of this paper was to investigate the safety and efficacy after AI stenting.

Methods and Results: This study was performed as a large-scale multicenter, retrospective registry. A total of 2,147 consecutive patients with AI disease were enrolled. The safety endpoints were procedure success, complications and 30-day mortality. The efficacy endpoints were primary, assisted primary and secondary patency, overall survival, freedom from major adverse cardiovascular events (MACE; all-cause death, myocardial infarction and stroke), and major adverse cardiovascular and limb events (MACLE; any repeat revascularization for limb and leg amputation in addition to MACE). Procedure success, complication rate and 30-day mortality were 97.6%, 6.4% and 0.7%. Primary patency was 92.5%, 82.6% and 77.5% at 1, 3 and 5 years, assisted primary patency was 97.0%, 92.7% and 91.0% at 1, 3 and 5 years and secondary patency was 90.0%, 98.7% and 98.5% at 1, 3 and 5 years. The overall survival rate was 95.0%, 87.6%, and 79.3% at 1, 3 and 5 years. The cause of death was cardiovascular in 44.1%. Freedom from MACE (MACLE) was 93.3% (89.9%), 84.4% (76.7%), and 74.9% (66.8%) at 1, 3 and 5 years. Female gender, diabetes, renal failure, absence of aspirin, reference vessel diameter <8.0mm and outflow lesion were found to be independent predictors of primary patency.

Conclusions: The safety and efficacy after AI stenting are feasible compared to surgical reconstruction.

Key Words: Aorto-iliac disease; Endovascular therapy; Patency; Stents
The overall primary patencies were 92.5%, 82.6% and 77.5% at 1, 3 and 5 years, assisted-primary patencies were 97.0%, 92.7% and 91.9% at 1, 3 and 5 years and the secondary patencies were 99.0%, 98.7% and 98.5% at 1, 3 and 5 years.
Efficacy (durability) of EVT with stenting for AIOD

Left (A): primary patency between stenosis and occlusion (77.8% vs. 76.5% at 5-year, Logrank p=0.10),
Right (D): primary patency among TASCII category (TASCII A, B, C, D; 77.8%, 78.0%, 73.3%, 80.5% at 5-year, Logrank p=0.55)
There are no direct comparisons of long-term outcomes among stents.

A half of lesions were treated with S.M.A.R.T stent in REAL-AI registry.

Iida O, Soga Y, et al. JEVT 2013

<table>
<thead>
<tr>
<th>Table 2. Lesion Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use of stent</strong></td>
</tr>
<tr>
<td>Self-expandable stent</td>
</tr>
<tr>
<td>Luminexx</td>
</tr>
<tr>
<td>SMART</td>
</tr>
<tr>
<td>Self X</td>
</tr>
<tr>
<td>Wall RP</td>
</tr>
<tr>
<td>Balloon-expandable stent</td>
</tr>
<tr>
<td>Palmaz</td>
</tr>
<tr>
<td>Express LD</td>
</tr>
</tbody>
</table>
Safety and Efficacy of the S.M.A.R.T Control Stent for Aorto-Iliac Occlusive Disease in Contemporary Clinical Practice

S.M.A.R.T.

VS.

Luminexx
Selfex
Zilver
Wall
Express LD

Iida O, Soga Y, et al. JEV'T 2013
Safety and Efficacy of the S.M.A.R.T Control Stent for Aorto-Iliac Occlusive Disease in Contemporary Clinical Practice

- **Study design:** Retrospective analysis for prospectively maintained database
- **Hypothesis:** Durability of S.M.A.R.T is superior to that of non-S.M.A.R.T in AI disease
- **Study material:** S.M.A.R.T (n=1196) vs. non-S.M.A.R.T (n=1345), (after matching 996 vs. 996)
- **Outcome measures:** Primary patency, event free survival
- **Statistical analysis:** Propensity matching analysis

Iida O, Soga Y, et al. JEVT 2013 inpress
Safety and Efficacy of the S.M.A.R.T Control Stent for Aorto-Iliac Occlusive Disease in Contemporary Clinical Practice

<table>
<thead>
<tr>
<th>Variables</th>
<th>Before propensity score matching</th>
<th>After propensity score matching</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variables</td>
<td>S.M.A.R.T stent group</td>
<td>Non-S.M.A.R.T stent group</td>
<td></td>
</tr>
<tr>
<td>Patients characteristics</td>
<td>S.M.A.R.T stent group</td>
<td>Non-S.M.A.R.T stent group</td>
<td>P value</td>
</tr>
<tr>
<td>Diabetes mellitus (DM)</td>
<td>47% (576)</td>
<td>49% (652)</td>
<td>0.87</td>
</tr>
<tr>
<td>Renal insufficiency (Cre&gt;1.5mh/dL)</td>
<td>26% (308)</td>
<td>27% (365)</td>
<td>0.42</td>
</tr>
<tr>
<td>History of heart failure</td>
<td>11% (132)</td>
<td>13% (178)</td>
<td>0.10</td>
</tr>
<tr>
<td>Lower limb characteristics</td>
<td>12% (115)</td>
<td>11% (110)</td>
<td>0.77</td>
</tr>
<tr>
<td>Critical limb ischemia/Claudication</td>
<td>22% (260)/14% (186)</td>
<td>86% (1159)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>ABI before procedure</td>
<td>0.59±0.25</td>
<td>0.64±0.24</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>ABI before procedure</td>
<td>18% (182)</td>
<td>16% (155)</td>
<td>0.22</td>
</tr>
<tr>
<td>ABI before procedure</td>
<td>0.62±0.23</td>
<td>0.62±0.23</td>
<td>0.60</td>
</tr>
<tr>
<td>ABI before procedure</td>
<td>0.62±0.23</td>
<td>0.62±0.23</td>
<td>0.60</td>
</tr>
<tr>
<td>Lesion Characteristics</td>
<td>0.62±0.23</td>
<td>0.62±0.23</td>
<td>0.60</td>
</tr>
<tr>
<td>TASC A and B/C and D</td>
<td>71% (853)/29% (343)</td>
<td>76% (1017)/24% (328)</td>
<td>0.01</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>58±40</td>
<td>46±38</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>52±35</td>
<td>51±39</td>
<td>0.30</td>
</tr>
<tr>
<td>Lesion calcification</td>
<td>49% (587)</td>
<td>54% (722)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Lesion calcification</td>
<td>51% (506)</td>
<td>51% (508)</td>
<td>0.92</td>
</tr>
<tr>
<td>Outflow lesions</td>
<td>42% (497)</td>
<td>34% (457)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Outflow lesions</td>
<td>38% (380)</td>
<td>37% (364)</td>
<td>0.49</td>
</tr>
</tbody>
</table>

Limb and Lesions background in S.M.A.R.T stent group is statistically worse than those in non-S.M.A.R.T stent group.
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Primary patency and event-free survival

After matching

![Graphs showing primary patency and event-free survival](image-url)
Use of the S.M.A.R.T. stent was associated with greater primary patency in patients with renal insufficiency (Cr>1.5) and critical limb ischemia.

However, in CLI patients, the use of S.M.A.R.T stent was not significantly associated with primary patency after adjustment for TASC classification and the presence of outflow lesions; the adjusted HR was 0.605 [0.358, 1.025] (p = 0.062).

On the other hand, in patients with elevated creatinine levels (>= 1.5 mg/dl), the use of SMART stent was still significantly associated with the outcome after the same adjustment; the adjusted HR was 0.575 [0.386, 0.857] (p = 0.007).

Iida O, Soga Y, et al. JEVT 2013
After propensity matching analysis, the durability of S.M.A.R.T. stent was superior to that of the other stents. The particular design characteristics of the S.M.A.R.T. stent may have accounted for the better results in AI lesions.
TASC II classification of Femoro-Popliteal lesions (TASC 2006 documents)

**TASC II S 58**
There is general agreement that for acute failure of PTA of an SFA lesion, stent placement is indicated. A recent randomized trial has demonstrated significantly higher primary patency rates of stenting vs. PTA of femoropopliteal artery lesions TASC A and B at 1-year follow up.
ABSOLUTE trial (Absolute/Dynalink stent, Abott)

A

Primary endpoint

Absolute stent (Abott)

RESILIENT 1- and 2-Year Clinical Outcome

**Stent Fracture Rate**
- 12 month: 3.1%
- 18 month: 3.8%

**Graphs**
- PTA & LifeStent vs PTA Alone
  - 1-Year Freedom from TLR: 87% vs 45%
  - 2-Year Freedom from TLR: 78% vs 42%
  - 1-Year Clinical Success: 72% vs 32%
  - 2-Year Clinical Success: 68% vs 24%

Learn From ESC 2011 guideline

- **TASC II A-C lesions**
  ⇒ *Endovascular-first* strategy
  *Primary stent* should be considered in TASC B

- **TASC II D**
  ⇒ *Primary endovascular approach may* be considered in
  1) Pts with severe comorbidities
  2) availabilities of experienced interventionist

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**Recommendations for revascularization in patients with femoropopliteal lesions**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>When revascularization is indicated, an endovascular-first strategy is recommended in all femoropopliteal TASC A–C lesions.</td>
<td>I</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Primary stent implantation should be considered in femoropopliteal TASC B lesions.</td>
<td>IIa</td>
<td>A</td>
<td>285, 286, 291</td>
</tr>
<tr>
<td>A primary endovascular approach may also be considered in TASC D lesions in patients with severe comorbidities and the availability of an experienced interventionist.</td>
<td>IIb</td>
<td>C</td>
<td></td>
</tr>
</tbody>
</table>

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Eur Heart J. 2011;32:2851-906
Clinical Issues after SFA Revascularization

Restenosis
(intimal hyperplasia)
Drug eluting stent for SFA
Zilver® PTX® Drug-Eluting Stent

- Designed for the SFA
- PMDA approved
- Paclitaxel only
  - No polymer or binder
  - 3 mg/mm² dose density
- Stent Platform: Zilver® Flex™
4-Year Primary Patency (PSVR < 2.0)
Zilver PTX vs. Standard Care – Drug Effect

Zilver PTX
(n = 239)
Optimal PTA + BMS
(n = 129)

67.6%  
LL: 66 ± 39mm

45.5%  
LL: 63 ± 41mm

Ansel GM, et al. VIVA 2013

\( p < 0.01 \) log-rank
ST (stent thrombosis) after Zilver-PTX implantation

3 days later, acute thrombotic occlusion was occurred at Rt SFA treated with Zilver-PTX stent (6.0*120mm*3).
Coronary and Peripheral DES

Stent Thrombosis Rate

Stent Thrombosis rate (Overall)

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Thrombosis Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOBORI</td>
<td>0.0% (at 12 months)</td>
</tr>
<tr>
<td>Cypher</td>
<td>0.4% (at 270 days)</td>
</tr>
<tr>
<td>TAXUS Element</td>
<td>0.4% (at 12 months)</td>
</tr>
<tr>
<td>Xience Prime</td>
<td>0.5% (at 12 months)</td>
</tr>
<tr>
<td>Endeavor</td>
<td>0.8% (at 9 months)</td>
</tr>
</tbody>
</table>

Zilver-PTX 1.2% (within 30 days)

References:
1. Dr. Sigmund Silber Munich, presented at: AHA 2008; No Late and no Very Late Stent Thrombosis with a Drug-Eluting Stent of the Second Generation: 2 Years Results from the Randomized NOBORI-I trial
3. Dr. Kereiakes, at al. Journal of the American College of Cardiology 2010;56:264-71. Primary Results of the PERSEUS Trial
4. FDA Summary of Safety and Effectiveness Data
5. FDA Summary of Safety and Effectiveness Data
A univariable logistic generalized estimating equations model of occurrence of thrombus in a stent section vs ratio of uncovered to total stent struts per section demonstrated a marked increase in risk for LST as the number of uncovered struts increased. The odds ratio for thrombus in a stent with a ratio of uncovered to total stent struts per section >30% is 9.0 (95% CI, 3.5 to 22).

Angioscopic assessment for arterial repair
BMS (S.M.A.R.T) vs. DES (Zilver-PTX)@2months

S.M.A.R.T, BMS (7.0*100mm)
*Stent strut fully embedded and invisible (grade 3)

Zilver-PTX, DES (7.0*120mm)
*Stent strut exposed (grade 0)

Angioscopic assessment for arterial repair
BMS vs. DES @2months

Angioscopic assessment for arterial repair
BMS vs. DES @12months

Ishihara T, Iida O, et al. ACC 2014

Grade 0: stent struts exposed
Grade 1: struts bulged into the lumen, although covered
Grade 2: struts embedded by the neointima, but translucent
Grade 3: struts fully embedded and invisible

P=0.46

Ishihara T, Iida O, et al. ACC 2014
Heterogeneity of neointimal coverage
DES vs. BMS @ 1 year

DES
- Homogeneity: 9%
- Heterogeneity of 1 grade: 27%
- Heterogeneity of 2 grades: 46%
- Heterogeneity of 3 grades: 18%

BMS
- Homogeneity: 58%
- Heterogeneity of 1 grade: 17%
- Heterogeneity of 2 grades: 25%

DES versus BMS: P = 0.004

Ishihara T, Iida O, et al. ACC 2014
SMART Nitinol Self-Expanding Stent in the Treatment of Obstructive Superficial Femoral Artery Disease:

Three-year Clinical Outcomes from the STROLL Trial

Michael R. Jaff, DO
Professor of Medicine, Harvard Medical School
Medical Director, VasCore, Vascular Ultrasound Core Laboratory
Boston, Massachusetts
Primary Patency: composite endpoint of absence of clinically driven TLR and DUS assessed binary restenosis defined as diameter stenosis >50% (non-patent).

DUS patency: stent non-patency defined as a diameter stenosis >50% with a specific a peak systolic velocity ratio as measured by Duplex Ultrasonography.

Clinically driven TLR: any intervention in the stented target lesion following documented recurrent symptomatic leg ischemia by Rutherford/Becker Classification (2,3,4) with a resting or exercise ABI < 0.8 and >50% diameter in-lesion stenosis by angiography. Or >70% in-lesion diameter stenosis by angiography in the absence of ischemic signs and symptoms.
Freedom from Clinically-Driven TLR: 1080 days

![Graph showing survival rates over time. The graph indicates a trend towards decreasing survival rates from 100% at time 0 to 78.5% at 1080 days. The table below the graph provides additional data points for survival rates and events.]

<table>
<thead>
<tr>
<th>Clinically Driven TLR</th>
<th>0</th>
<th>30</th>
<th>90</th>
<th>180</th>
<th>270</th>
<th>360</th>
<th>540</th>
<th>720</th>
<th>900</th>
<th>1080</th>
</tr>
</thead>
<tbody>
<tr>
<td># Entered</td>
<td>250</td>
<td>250</td>
<td>247</td>
<td>244</td>
<td>235</td>
<td>213</td>
<td>206</td>
<td>184</td>
<td>175</td>
<td>161</td>
</tr>
<tr>
<td># Censored</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>5</td>
<td>4</td>
<td>8</td>
<td>53</td>
</tr>
<tr>
<td># Incomplete</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td># At Risk</td>
<td>250</td>
<td>249</td>
<td>246</td>
<td>243</td>
<td>232</td>
<td>213</td>
<td>202</td>
<td>181</td>
<td>170</td>
<td>131</td>
</tr>
<tr>
<td># Events</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>15</td>
<td>6</td>
<td>14</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td># Events/Month</td>
<td>--</td>
<td>0.0</td>
<td>0.5</td>
<td>2.3</td>
<td>5.0</td>
<td>2.0</td>
<td>2.3</td>
<td>0.5</td>
<td>0.5</td>
<td>0.2</td>
</tr>
<tr>
<td>% Survived</td>
<td>100.00%</td>
<td>100.00%</td>
<td>99.60%</td>
<td>96.73%</td>
<td>90.47%</td>
<td>87.91%</td>
<td>81.87%</td>
<td>80.50%</td>
<td>79.07%</td>
<td>78.50%</td>
</tr>
<tr>
<td>SE</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.41%</td>
<td>1.15%</td>
<td>1.92%</td>
<td>2.14%</td>
<td>2.57%</td>
<td>2.69%</td>
<td>2.85%</td>
<td>3.64%</td>
</tr>
</tbody>
</table>
## Cumulative stent fracture rate

<table>
<thead>
<tr>
<th>Stent Fracture</th>
<th>6-month</th>
<th>12-month</th>
<th>24-Month</th>
<th>36-Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I</td>
<td>1.49% (3/202)</td>
<td>2.03% (4/197)</td>
<td>2.3% (4/177)</td>
<td>3.6% (6/169)</td>
</tr>
<tr>
<td>Type II</td>
<td>0.0% (0/202)</td>
<td>0.0% (0/197)</td>
<td>0.0% (0/177)</td>
<td>0.0% (0/169)</td>
</tr>
<tr>
<td>Type III</td>
<td>0.0% (0/202)</td>
<td>0.0% (0/197)</td>
<td>0.0% (0/177)</td>
<td>0.0% (0/169)</td>
</tr>
<tr>
<td>Type IV</td>
<td>0.0% (0/202)</td>
<td>0.0% (0/197)</td>
<td>0.0% (0/177)</td>
<td>0.0% (0/169)</td>
</tr>
<tr>
<td>Type V</td>
<td>0.0% (0/202)</td>
<td>0.0% (0/197)</td>
<td>0.0% (0/177)</td>
<td>0.0% (0/169)</td>
</tr>
<tr>
<td>Any Stent Fracture</td>
<td>1.49% (3/202)</td>
<td>2.03% (4/197)</td>
<td>2.3% (4/177)</td>
<td>3.6% (6/169)</td>
</tr>
</tbody>
</table>

*Type I: Single Strut fracture*
*Type II: Multiple single Strut fracture*
*Type III: Complete transverse linear separation without stent displacement*
*Type IV: Complete transverse linear fracture with stent displacement*
*Type V: Spiral dissection of stent*
Position of S.M.A.R.T stent in recent endovascular era

Aorto-iliac lesions
・The durability of S.M.A.R.T. stent was superior to that of the other stents. The particular design characteristics of the S.M.A.R.T. stent may have accounted for the better results in AI lesions.

Femoropopliteal lesions
・Primary patency rate with S.M.A.R.T stent is 81.7% at 12 months, 74.9% at 24 months and 72.7% at 36 months, respectively.
・Balance of safety and efficacy (DES versus BMS) is clinically important decision making of stent use.

S.M.A.R.T could be still first line therapy and well work in recent endovascular era because of its truth and result.
Real-World Registry DEB for Extensive Femoropopliteal Lesions

Single center registry of femoropopliteal lesions
288 limbs treated, All-comers, Rutherford 2-6

Lesion-length: \( 24.0 \pm 10.1 \text{ cm} \)
Stenosis / occlusion: 34.7\% / 65.3\%
De-novo: 51.7\%
Restenosis: 11.1\%
In-stent restenosis (ISR): 37.2\%

Primary Patency

Days follow-up

<table>
<thead>
<tr>
<th>Days</th>
<th>0</th>
<th>90</th>
<th>180</th>
<th>270</th>
<th>360</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number at risk</td>
<td>249</td>
<td>236</td>
<td>195</td>
<td>163</td>
<td>137</td>
</tr>
</tbody>
</table>

77.6\% @ 1 year

Schmidt A @ LINC 2013
DEB vs. DES in Long SFA lesions

- Single Center
- Retrospective with propensity score analysis
- IN.PACT DEB vs. Zilver PTX
- 228 patients
- Mean lesion length = 19 cm

<table>
<thead>
<tr>
<th>Major Adverse Events</th>
<th>IN.PACT (DEB)</th>
<th>Zilver PTX (DES)</th>
<th>p</th>
<th>adjusted p</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>131</td>
<td>97</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any TLR</td>
<td>19.3% (21/109)</td>
<td>21.5% (17/79)</td>
<td>0.705</td>
<td>0.55</td>
</tr>
<tr>
<td>Clinical-driven TLR</td>
<td>15.6% (17/109)</td>
<td>19.0% (15/79)</td>
<td>0.543</td>
<td>0.572</td>
</tr>
<tr>
<td>Loss of Patency</td>
<td>23.9% (26/109)</td>
<td>30.4% (24/79)</td>
<td>0.319</td>
<td>0.372</td>
</tr>
</tbody>
</table>

DEB provisional Stent rate = 18.3%
ESPRIT I Trial
Evaluation of Esprit BVS in the Treatment of Patients With Occlusive Vascular Disease of the SFA, CIA and EIA

Lesion Characteristics

- External Iliac (%) 11.4
- SFA (%) 88.6
- Target lesion length (mm) 35.5
- Occlusion length (mm) 22.9
- Total occlusions (%) 30.6

Duplex Ultrasound Results to 12 Months

<table>
<thead>
<tr>
<th></th>
<th>1-Month</th>
<th>6-Month</th>
<th>12-Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLR rate</td>
<td>1.26</td>
<td>1.26</td>
<td>8.8%</td>
</tr>
<tr>
<td>Restenosis</td>
<td>0%</td>
<td>0%</td>
<td>12.9%</td>
</tr>
</tbody>
</table>

Lammer J@LINC 2014
**MAJESTIC Trial** To Study Self-Expanding DES System Designed To Treat Superficial Femoral Artery (SFA) Lesions

Platform: Innova™, Drug: Paclitaxel, Polymer: Fluorocopolymer

*Boston Scientific Begins Clinical Trial Of Innova™ Peripheral Vascular Drug-Eluting Stent System. The trial is projected to enroll **55** patients across **15** centers in Europe, Australia, and New Zealand. The first implantation in the MAJESTIC trial was performed by **Andrew Holden, MD**, who is Director of Interventional Radiology at Auckland City Hospital in Auckland, New Zealand.*