

# Quick Compendium: The S.M.A.R.T. Stent

## A Concise Compilation of Contemporary, Relevant Studies

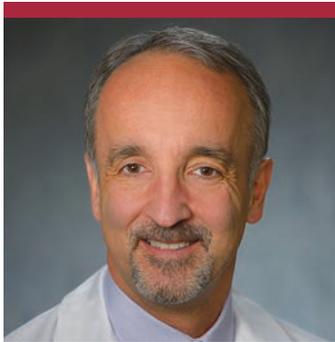
Presented by  Cath Lab Digest

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# SMART Self-Expanding Nitinol Stent for the Treatment of Atherosclerotic Lesions in the Superficial Femoral Artery (STROLL): 1-Year Outcomes

*Journal of Vascular and Interventional Radiology* 2015



WILLIAM A. GRAY, MD

Dr. William A. Gray and colleagues (Columbia Presbyterian Medical Center, New York, New York) report in the *Journal of Vascular and Interventional Radiology* the results of the single-arm, multicenter, prospective, open-label STROLL study (SMART Nitinol Self-Expanding Stent in the Treatment of Obstructive Superficial Femoral Artery Disease).<sup>1</sup>

The STROLL study was designed as a pivotal trial to provide clinical data to support expanding the indication of the SMART stent to include treatment of lesions in the superficial femoral artery (SFA). The trial design and inception were based on input from the FDA and with the guidance of the VIVA Physician group. The STROLL study enrolled 250 patients with a wide range of inclusion and exclusion criteria to reflect real-world patient selection. Inclusion criteria included patients with symptomatic limb ischemia (Rutherford/Beck category 2–4) with an ankle-brachial index (ABI)  $\leq 0.8$ , with lesions  $\geq 4$  cm and  $\leq 15$  cm in length, with lesions located at least 3 cm proximal to the superior edge of the patella, and with a patent popliteal artery with single-vessel runoff or

**“The SMART Vascular Stent System proved to be safe and effective for endovascular treatment of obstructive SFA and proximal popliteal artery disease, based on 1-year vessel patency and associated hemodynamic and clinical improvements.”**

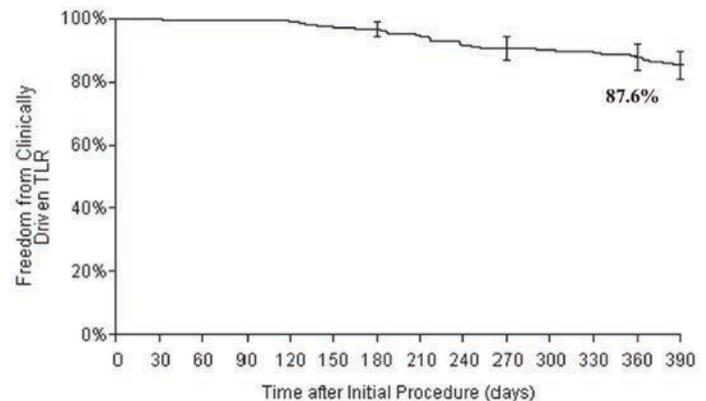
better. The study took place at 39 U.S. centers from August 2008 to March 2010.

The primary safety endpoint was freedom from major adverse events (MAEs: death, amputation, target lesion revascularization [TLR]) at 30 days. The primary efficacy endpoint was primary patency, defined as no significant flow reduction detected by duplex ultrasound at 12 months. Secondary endpoints included the following acute procedural success measures: 1) Technical success, defined as achieving  $<50\%$  residual stenosis by any percutaneous method; 2) Procedural success, defined as  $<50\%$  final diameter stenosis by any percutaneous method without MAEs; and 3) Device success, defined as achieving 50% final residual diameter stenosis by assigned treatment only. Secondary endpoints also included stent fracture rates, Rutherford/Beck class change, ABI, and all safety endpoints. All primary and secondary endpoints were independently validated.

All patients (100%) met the primary safety endpoint with no MAEs at 30 days. The overall 1-year MAE rate was 14.4% (driven by TLR, 12.3%) plus 2.1% all-cause mortality, an 0.4% amputation rate, and an absence of significant embolic events.

The primary patency was 81.7% at 1 year by Kaplan-Meier estimate. Primary patency compared by lesion length (mean, 39.4 mm, 74.0 mm, and 118 mm) was 79.4%, 78.1%, and 56.8%, respectively.

Absence from clinically driven



**FIGURE.** Freedom from clinically driven target lesion revascularization [TLR].

Reprinted with permission from Gray WA, et al. *J Vasc Interv Radiol.* 2015 Jan; 26(1): 21-28.

TLR at 1 year was 87.4%.

The proportion of patients with Rutherford/Beck class 3–4 was 54.2% at baseline and was reduced to 8% at 1 year. Similar improvement was seen in ABI: 81.0% of patients had an ABI  $>0.8$ , compared to 84.5% of patients suffering from an ABI  $\leq 0.8$  before the procedure.

Stent fractures were seen in 2% of patients (4/197), all type 1 (single tine). Three (3 of 4) of the stent fractures were observed within the first 6 months and none of the fractures progressed in severity at 1 year. There was no association between stent fracture and restenosis.

The authors recognize that lack of randomization was a limitation of this study; however, the study design was based on objective performance goals rather than randomly assigning stents against percutaneous transluminal angioplasty. The study was limited to patients with lesion lengths

less than 15 cm. In addition, the rate of stent fractures and fracture complexity in this study as compared to other studies is difficult to interpret due to variations among study designs and analysis.

The authors concluded, the SMART vascular stent is both safe and effective for treatment of short to intermediate length lesions in the SFA and proximal popliteal arteries, with durable clinical symptomatic and hemodynamic improvement at 1 year, as evidenced by increases in the ABI and reduction in Rutherford/Beck class.

Authors' disclosure: The STROLL study was funded by Cordis. Study authors included non-compensated or paid consultants, and employees of Cordis.

## REFERENCE

1. Gray WA, Feiring A, Cioppi M, et al. S.M.A.R.T. self-expanding nitinol stent for the treatment of atherosclerotic lesions in the superficial femoral artery (STROLL): 1-year outcomes. *J Vasc Interv Radiol.* 2015 Jan; 26(1): 21-28. doi:10.1016/j.jvir.2014.09.018.

# Twelve-Month Results of Percutaneous Endovascular Reconstruction for Chronically Occluded Superficial Femoral Arteries: A Quality-of-Life Assessment

*Journal of Invasive Cardiology* 2006

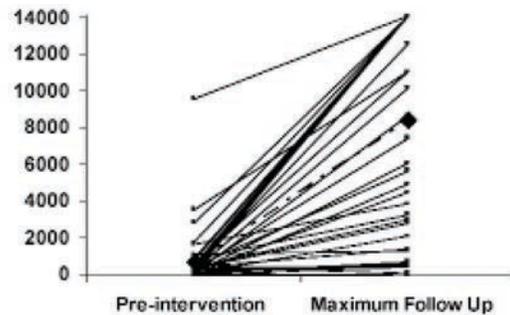


ERIC DIPPEL, MD

Dr. Eric Dippel and colleagues (Davenport, Iowa), in the *Journal of Invasive Cardiology*, report their experience with the SMART stent. The study investigated technical feasibility and quality of life (QOL) after primary stenting of a chronic total occlusion (CTO) of the superficial femoral artery (SFA).

This is a single-center, retrospective analysis of 44 patients (51 limbs), who underwent successful revascularization with angioplasty and primary stenting techniques for CTO TASC D lesions of the SFA (occlusion length 15.5 cm, treated with an average of 2.7 stents/lesion). The stent diameter was oversized by 1–2 mm greater than target reference vessel lumen, and post dilatation was performed with a balloon diameter equal to the reference vessel lumen by visual estimate. High pressure inflations were avoided. The stent length maximized coverage of the disease segment. Post procedure, patients were counseled on risk factor modification, and encouraged to participate in regular walking programs and refrain from tobacco use.

**“The low TLR is consistent with other data on the SMART stent and confirms the durability of the procedure.”**



**FIGURE 1.** Pre- and post-intervention WIQ scores. Reprinted with permission from Dippel E, et al. *J Invasive Cardiol.* 2006 Jul; 18(7): 316-321.

Clinical outcomes were assessed by a Walking Impairment Questionnaire (WIQ) and ankle-brachial index (ABI) at pre- and post-intervention, every 3 months for the first year and then every 6 months thereafter, for a mean follow-up of 374 days.

Successful revascularization was achieved in 90.2% of the cases (in 9.8%, operators were unable to cross and maintain intraluminal position). One patient developed acute thrombosis within 24 hours of the index procedure, and was successfully treated with intra-arterial thrombolysis, rheolytic embolectomy, and angioplasty.

Following treatment with angioplasty and the SMART stent, there was a significant improvement in clinical outcomes: mean WIQ score and ABI both improved, from 722 (pre intervention) to 8,421 (post intervention) and from 0.61 to 0.91, respectively ( $P < 0.0005$ ).

At 12 months, clinically driven target lesion revascularization (TLR) was 11.8%. During the same follow-up period, 3 patients (6.8%) died (cancer, myocardial infarction), and 2 patients underwent amputation (both had severe infra-trifurcation vessel disease).

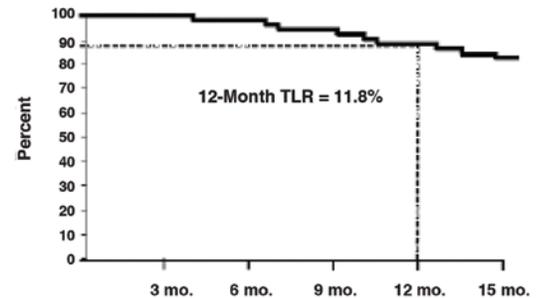
Study limitations included a small, non-comparative, non-randomized population at a single center; in addition to the inherent limitation of the lack of consistent standardized endpoints (among trials) to enable data comparability.

As a balancing factor against possible treatment bias, the authors saw parallel improvement in objective measure (ABI) and clinical outcomes (WIQ score).

The study concluded:

1) Long, complex SFA CTO lesions can be revascularized with a very high technical success rate utilizing a percutaneous approach;

2) Patients with claudication experience a dramatic improvement



**FIGURE 2.** Kaplan-Meier curve showing clinically driven freedom from revascularization [TLR = target lesion revascularization]. Reprinted with permission from Dippel E, et al. *J Invasive Cardiol.* 2006 Jul; 18(7): 316-321.

in their QOL and sense of well being following percutaneous endovascular reconstruction of SFA CTOs. The qualitative improvements are reinforced by the objective improvement of the ABI;

3) The low TLR is consistent with other data on the SMART stent and confirms the durability of the procedure.

Study disclosure: This study was supported by a research grant from the manufacturer of the SMART stent, Cordis.

## REFERENCE

- Dippel E, Shammas N, Takes V, et al. Twelve-month results of percutaneous endovascular reconstruction for chronically occluded superficial femoral arteries: a quality-of-life assessment. *J Invasive Cardiol.* 2006 Jul; 18(7): 316-321.

# Long-Term Outcomes of SMART Stent Implantation in Patients with Femoro-Popliteal Disease

*Catheterization and Cardiovascular Interventions* 2016

**D**r. Junya Matsumi and colleagues (Department of Cardiology, Shonan Kamakura General Hospital, Kanagawa, Japan) report in *Catheterization and Cardiovascular Interventions* the 10-year outcomes of SMART stent implantation in patients with femoro-popliteal disease (FPD).<sup>1</sup>

This is a single-center retrospective analysis that evaluated 319 limbs in 269 patients who underwent endovascular therapy (EVT) for treatment of de novo or restenotic FPD. Throughout the follow-up periods, patients were assessed for symptoms of lower limb ischemia, including ankle brachial pressure index (ABI) examination and duplex ultrasonography.

The primary endpoint was primary patency rate, defined as patency without restenosis or major amputation. Secondary endpoints included the following:

- 1) Secondary patency, defined as patency after target lesion revascularization (TLR);
- 2) Major adverse events (MAEs), including death, major amputation, and TLR;
- 3) Primary persistence of clinical benefit (PPCB), defined as an upward shift in the Rutherford classification of <2 points compared to Rutherford classification after the procedure;
- 4) Secondary persistence of clinical benefit (SPCB), defined as an upward shift in the Rutherford

**“Our study has elucidated the long-term outcomes of SMART stent implantation for femoro-popliteal lesions during a follow-up period of 10 years.”**

classification of <2 points after TLR.

The study endpoints are presented for follow-up over the following periods: 1, 3, 5, 7, and 10 years.

The overall survival rates after the procedure were 93.8%, 84.3%, 75.5%, 65.3%, and 57.7% at years 1, 3, 5, 7, and 10, respectively. Overall primary patency rates were 87%, 79%, 68%, and 53%, respectively, during the above follow-up periods. Further survival analyses are shown in Table 1.

Multivariate analysis (aimed at estimating the hazard ratios for covariates deemed responsible for loss of primary patency in a univariate analysis) revealed lesion length and hemodialysis as factors with statistically significant effects for the loss of primary patency. Specifically, the analysis revealed that lesion length (with >200 mm vs <100 mm) significantly promoted primary patency loss ( $P=0.002$ ), as well as hemodialysis ( $P=0.005$ ).

Limitations identified by the authors include those of a retrospective, single-center study. Data regarding stent fracture rates were not available. Although the study was long-term (10 years), there were patients lost to follow-up and possible selection bias based on the compliance of patients that did return for follow-up.

**Table 1. Further Survival Analyses.**

	Years After SMART Implantation				
	1	3	5	7	10
<b>Primary Patency</b>					
<b>Overall</b>	87.9	79.4	68.1	53.7	50.3
<b>TASC IIA/B</b>	92.3	84.9	76.5	64.7	62.0
<b>TASC IIC/D</b>	80.0	70.4	58.9	34.4	NA
<b>Run-off ≥2</b>	91.2	83.7	69.8	59.6	59.6
<b>Run-off ≤2</b>	85.0	76.2	67.0	48.9	42.5
<b>Secondary Patency</b>	96.5	91.7	85.0	73.8	67.7
<b>Clinical Benefits</b>					
<b>MAE-Free</b>	84.7	71.8	57.6	39.8	37.3
<b>TLR-free</b>	89.7	84.0	76.0	64.0	64.0
<b>PPCB</b>	87.7	79.4	66.4	51.6	45.7
<b>SPCB</b>	97.2	94.1	87.3	79.5	74.9
<b>Survival</b>					
<b>Overall</b>	93.8	84.3	75.5	65.3	57.7
<b>IC patients</b>	95.0	89.0	79.5	70.0	63.8
<b>CLI patients</b>	86.8	54.7	50.1	33.4	NA

[CLI=Critical Limb Ischemia; IC=Intermittent Claudication; MAE=Major Adverse Events; PPCB=Primary Persistence of Clinical Benefit after SMART implantation; Run-off=Number of patent below the knee vessels; SPCB=Secondary Persistence of Clinical Benefit after SMART TLR; TLR=Target Lesion Revascularization; TASC=TransAtlantic Inter-Society Consensus]

The authors concluded that SMART stent implantation produced favorable long-term results, whereby the setting of TASC IIA/B lesion(s) produced better outcomes compared to the setting of TASC IIC/D lesion(s).

Conflict of interest: None disclosed.

## REFERENCE

1. Matsumi J, Tobita K, Shishido K, et al. Long-term outcomes of SMART stent implantation in patients with femoro-popliteal disease. *Catheter Cardiovasc Interv.* 2016 Nov; 88(5): 832-841. doi: 10.1002/ccd.26718.

# Three-Year Outcome of Two Different Nitinol Stents for the Treatment of De Novo Aortoiliac Lesions

Angiology 2015

**D**r. Yoshiaki Shintani and colleagues (Department of Cardiology, Cardiovascular Center, Shin-Koga Hospital, Kurume, Japan) report in *Angiology* the results of a multicenter, retrospective analysis of a prospectively maintained database (Aorto-Iliac stenting [REAL-AI] registry) that compared the SMART nitinol stent (Cordis) to the Luminexx nitinol stent (Bard) for treatment of de novo aortoiliac (AI) lesions.<sup>1</sup> The study took place between January 2005 and December 2009. In

order to minimize differences and adjust variables between the SMART and the Luminexx groups, a propensity score matching analysis was performed that utilized a logistic regression model. After matching, there were 284 lesions per group, with no significant differences between the two groups.

The primary endpoint was primary patency, defined as treated lesions that remained patent at follow-up without restenosis or repeat revascularization. Secondary endpoints included the following:

- 1) Primary assisted patency, defined as patent lesions that underwent repeat revascularization to maintain the patency;
- 2) Secondary patency, defined as occluded lesions that were reopened by repeat revascularization;
- 3) Major adverse limb events (MALEs), which included major amputation and major reintervention (i.e., new bypass grafts, jumping, interposition graft revision, or the use of thrombectomy or thrombolysis in the stents).

There were no statistically significant differences in the perioperative complications between the SMART and Luminexx groups (both 6.3%). Follow-up was performed one month after the procedure and every 6 months thereafter. The primary patency rates at 1, 2, and 3 years after SMART and Luminexx placement showed no significant difference (92.0%, 86.1%, and 83.5% vs 94.9%, 88.6%, and 82.2%, respectively).

The assisted primary patency and secondary patency rates at 3 years were not significantly different between the SMART and Luminexx groups (91.7% vs 93.2%, and 99.2% vs 98.8%).

At 3-year follow-up, major adverse limb events (MALE) occurred in 9 cases. Five limbs underwent major amputations (2 in the SMART group, 3 in the Luminexx group), and 4 limbs required bypass surgery. Freedom from MALE

was not statistically significant between the SMART and Luminexx groups (98.3% vs 97.3%, respectively).

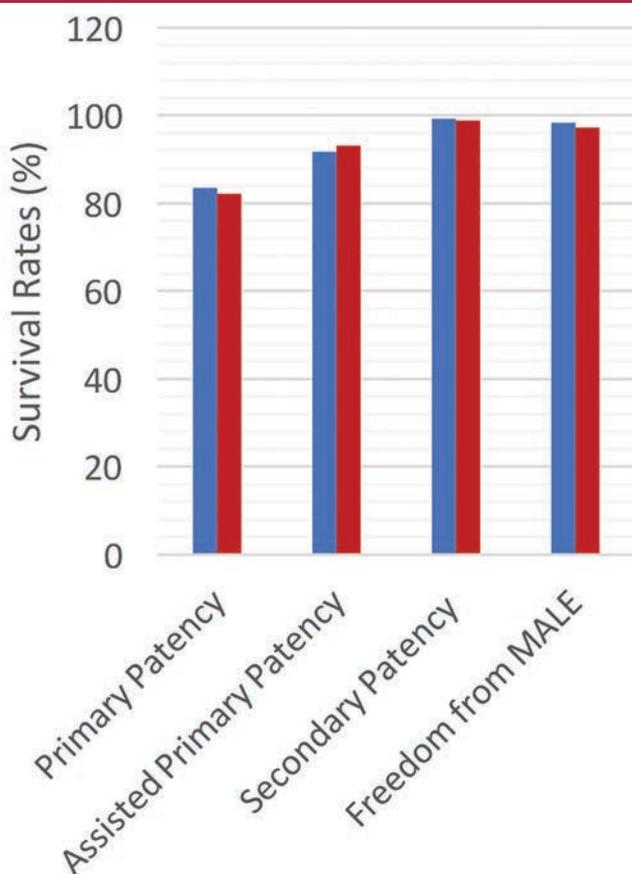
Limitations identified by the authors included those of retrospective non-randomized analysis. Additionally, the study included first-generation bare metal stents (SMART and Luminexx only) and did not evaluate other available nitinol stents. The authors suggest investigating alternative stents as well.

The authors concluded that the use of either SMART or Luminexx nitinol stents for AI lesions provides good long-term (3-year) patency and freedom from MALE.

Conflict of interest: None disclosed.

## REFERENCE

1. Shintani Y, Soga Y, Takahara M, et al. Clinical outcomes of SMART versus Luminexx nitinol stent implantation for aortoiliac artery disease: a propensity score-matched multicenter study. *Angiology*. 2015; 66[9]: 875-881. doi: 10.1177/0003319714564207



**FIGURE.** Long term (3-yr) primary and secondary endpoints.

# Efficacy of the SMART Control vs Other Stents for Aortoiliac Occlusive Disease in Contemporary Clinical Practice

*Journal of Endovascular Therapy* 2013



OSAMU IIDA, MD

**D**r. Osamu Iida and colleagues (Cardiovascular Center at the Kansai Rosai Hospital, Hyogo, Japan) compared in the *Journal of Endovascular Therapy* the safety and efficacy of the SMART Control stent [Cordis] vs other stents in patients with symptomatic aortoiliac occlusive disease (AIOD) over a period of 4 years.<sup>1</sup>

The paper reports the results of subgroup analysis of data from the REtrospective Multicenter AnaLysis of AortoIliac Stenting (REAL-AI) registry, which enrolled consecutive patients who underwent stent placement for de novo and restenotic lesions in 18 centers in Japan between 2005–2009.

This analysis evaluated a total of 2036 symptomatic patients that underwent endovascular therapy to treat 2541 AIOD lesions (Rutherford category 2–6) with stenting between 2005 and 2009 at 18 centers in Japan. These patients were divided into 2 subgroups: the SMART stent group (955 patients, 1196 lesions) and the “other” stent group (1081 patients, 1345 lesions). The “other” stent group included self-expanding (Luminexx [Bard], Wallstent [Boston Scientific], and SelfX [Abbott Vascular]), and balloon-expandable (Express LD [Boston Scientific],

**“The particular design characteristics of the SMART stent may have accounted for the better results in aortoiliac lesions.”**

Palmaz [Cordis]) stents.

To adjust for baseline differences between the 2 stent groups, and to better assess the effect of the stent itself, propensity-matched analysis was also performed. Based on a multivariate logistic regression model, each patient was assigned a propensity score. Lesions treated with the SMART stent or with other stents were matched 1:1 on the basis of their estimated propensity score.

Primary patency (freedom from restenosis/re-occlusion or repeat revascularization) and event-free survival (freedom from death, major amputation, or any reintervention) were both evaluated at 4 years before and after propensity-matching analysis. Other outcomes measured before and after propensity matching included freedom from major amputation, surgical conversion, target lesion revascularization (TLR), and major adverse limb events (MALE). Propensity-matching analysis was performed based on a multivariate logistic regression to adjust for baseline differences between the 2 subgroups.

Before propensity matching, the SMART subgroup was associated with greater age, critical limb ischemia, lower ankle-brachial index (ABI), and had longer lesions, compared to other stents ( $P=0.0001$ ). Additionally, lesions treated with the SMART stent had more frequent TASC C/D ( $P=0.01$ ), with a trend toward more chronic total occlusions ( $P=NS$ ). More than half (64%, 865/1345) of the lesions in the

other stent group were treated with balloon-expandable stents.

After propensity-matching analysis, 4-year primary patency was greater for the SMART stent group (86% vs 76%,  $P=0.001$ ).

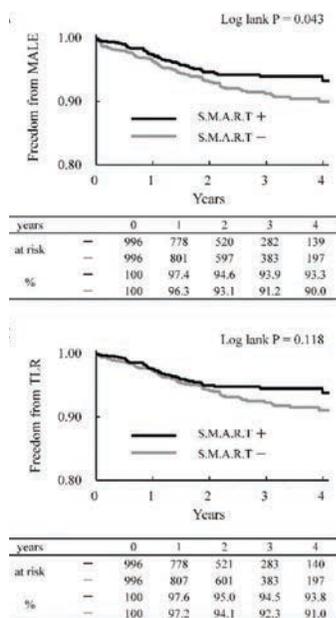
The SMART stent was associated with greater primary patency in patients with renal insufficiency and critical limb ischemia in the univariate subgroup analysis.

Event-free survival was similar between groups (75% vs 77%).

Unadjusted clinical outcomes, including freedom from MALE, amputation, TLR, and surgical conversion did not differ significantly between groups before propensity matching. After propensity matching, however, freedom from MALE, mainly driven by freedom from TLR, was higher in the SMART group (93% vs 90%,  $P=0.043$ ).

Limitations identified by the authors are that of a retrospective, non-blinded study. Evaluation for restenosis was not performed by angiography, but by duplex and ABI instead. Also, evaluation of outflow procedures and status were not captured. Finally, severity grading of the lesions was performed using mainly TASC classifications; however, lesion length and caliber were assessed visually.

The authors concluded that the durability of the SMART stent was superior to that of other stents, which might reflect differing design characteristics. The authors suggested that the hexadic structure with 6-bridge design of the SMART stent



**FIGURE.** Comparison of freedom from [top] major adverse limb events (MALE) and target lesion revascularization (TLR) [bottom] after propensity matching analysis. Freedom from major adverse limb events in the S.M.A.R.T. group was higher ( $P=0.04$ ). Reprinted with permission from Iida O, et al. *J Endovasc Ther.* 2013 Jun; 20(3): 431-439.

might account for the better results in aortoiliac lesions.

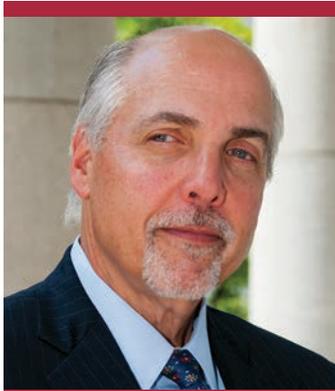
Conflict of interest: None disclosed.

## REFERENCE

- Iida O, Soga Y, Takahara M, et al. Efficacy of the S.M.A.R.T. Control vs. other stents for aortoiliac occlusive disease in contemporary clinical practice. *J Endovasc Ther.* 2013 Jun; 20(3): 431-439. doi: 10.1583/12-4156MR.1.

# Qualifying and Interpreting Data: Contemporary Peripheral Artery Trial Definitions

Endovascular Today 2013



MICHAEL R. JAFF, DO

Although trial data may appear black and white, with similar values falling under shared headings, meaningful comparisons of these elements are rarely simple, 1:1 evaluations. For example, no two trials evaluating superficial femoral artery (SFA) therapies are completely alike. Additionally, it would be virtually impossible to conduct a variety of trials with matching patient populations, physicians with the same skill levels, and hospitals with identical equipment.

Following is a list<sup>1</sup> of some factors that should be considered in order to gain a complete understanding of a given trial's results.

## Calcification:

Arterial calcification in peripheral arterial disease (PAD) trials is common. The greater the extent of calcification, in general, the lower the patency rate and the greater the risk to the success of the intervention. Unfortunately, there is no uniform grading scale to define the extent of arterial calcification.

## Chronic Total Occlusions:

Most infrainguinal peripheral artery disease (PAD) device trials include a component of chronic total occlusions. The term highlights certain important factors: First, "chronic" suggests that the lesion is not largely thrombus-based, but more likely atherosclerotic, fibrotic, and calcific. Second, a total occlusion means that the artery is 100% blocked. Trials with patient cohorts that include larger percentages of lesions that are chronically occluded will undoubtedly have lower patency rates, and may also have a higher periprocedural complication rates.

## Duplex Ultrasonography:

A commonly used method of measuring patency following a vascular intervention. Classically, a ratio of the fastest speed of blood flow, peak systolic velocity ratio (PSVR) within a stenosis compared to a proximal reference segment is used. Recent data suggests that a PSVR > 2.4 is a more accurate representation of > 50% stenosis. However, a conservative version of PSVR > 2.0 is also used for clinical trials.

## Lesion Location:

The general rule is that more distal lesions have lower patency rates.

## Major Adverse Cardiovascular Events (MACE):

A commonly used endpoint; it includes myocardial infarction, stroke, or death from any cause.

## Major Adverse Events (MAE):

Defined by individual trials and may include MALE [major adverse limb events], POD [post-operative death], MACE [major adverse cardiac events], RAS [reintervention, amputation, or restenosis], or a combination.

## Major Adverse Limb Events (MALE)

A recent definition by Conte et al<sup>2</sup>, defined as above-ankle amputation or the need for major reintervention.

## Primary Patency:

Maintained patency without any repeat intervention.

## Primary Patency (Kaplan-Meier analysis):

Calculated using a statistical tool that predicts population survival in a study even when the population changes for reasons other than death; frequently used to compensate for patients lost to follow-up.

## Primary Patency (Per Protocol Analysis):

Every patient is counted, difficult when patients are lost to follow-up.

## Primary-Assisted Patency:

Defines the durability of an intervention that failed initially, but not to the level of thrombosis, and was re-treated.

## RAS:

Reintervention, amputation, or restenosis

## Secondary Patency:

Durability of a secondary intervention, which was required

due to the complete failure of an initial intervention.

## Stent Fracture Rates:

Usually driven by method of identification (investigator, core lab, and their experience), as well as the denominator used to calculate rates (per stent or per patient basis). Each method provides a different value and stent fracture may not be comparable.

## Target Lesion

### Revascularization (TLR):

Indicates a clinical need to reintervene on the initially treated vascular lesion.

### Target Vessel Revascularization (TVR):

Failure of the entire artery, but not necessarily due to the target lesion intervention (eg. there may have been progression of native vessel atherosclerosis).

## REFERENCES

- Jaff MR. Comparing SFA device trials. *Endovascular Today*. 2013 August; 73-75. Available online at <http://evtoday.com/2013/08/comparing-sfa-device-trials/>. Accessed August 16, 2017.
- Conte MS, Geraghty PJ, Bradbury AW, et al. Suggested objective performance goals and clinical trial design for evaluating catheter-based treatment of critical limb ischemia. *J Vasc Surg*. 2009; 50: 1462-1473.

These summaries are written and provided by HMP Communications and Cardinal Health. Both HMP Communications and Cardinal Health have attempted to summarize the published studies as accurately as possible. We refer the reader to the actual study and product label (including Instructions for Use) for additional information. Cardinal Health will provide the full article upon request from healthcare professionals.

#### **INDICATIONS FOR USE:**

The **S.M.A.R.T.® Nitinol Peripheral Stent System** is indicated for use in patients with atherosclerotic disease of peripheral arteries, including iliac and superficial femoral, for TIPSS procedures and for palliation of malignant neoplasms in the biliary tree.

The **S.M.A.R.T.® CONTROL® / S.M.A.R.T.® Vascular Stent System** is indicated for use to improve luminal diameter in the treatment of patients with de novo or restenotic native lesion(s) of the superficial femoral artery and/or proximal popliteal artery with total length up to 150 mm and with a reference vessel diameter ranging from 4 mm to 7 mm.

The **S.M.A.R.T.® CONTROL™ Nitinol Stent System** is indicated for improving luminal diameter in patients with symptomatic atherosclerotic disease of the common and/or external iliac arteries up to 126 mm in length, with a reference vessel diameter of 4 to 9 mm, and angiographic evidence of a patent profunda or superficial femoral artery.

#### **RELEVANT PRECAUTIONS:**

This S.M.A.R.T. Nitinol product should only be used by physicians trained and experienced in diagnostic and interventional techniques • The delivery system is not designed for use with power injection systems • When catheters are in the body, they should be manipulated only under fluoroscopy • When treating multiple lesions, the most distal lesion should be stented first followed by the stenting of proximal lesions • Stenting in this order eliminates the need to cross and reduces the chance of dislodging stents, which have already been placed • Overlap of sequential stents is necessary but the amount of overlap should be kept to a minimum.

#### **RELEVANT CONTRAINDICATIONS:**

Patients with a known hypersensitivity to nickel titanium • Patients who cannot receive antiplatelet or anticoagulation therapy • Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

#### **RELEVANT WARNINGS:**

Once the stent is partially deployed, it cannot be recaptured using the stent delivery system. Avoid stent placement that may obstruct access to a vital side branch • As with any type of vascular implant, infection, secondary to contamination of the stent, may lead to thrombosis, pseudoaneurysm or rupture into a neighboring organ or the retroperitoneum • The stent may cause a thrombus, distal embolization or may migrate from the site of the implant down the arterial lumen • Overstretching of the artery may result in rupture and life-threatening bleeding • Persons with allergic reactions to nickel titanium (nitinol) may suffer an allergic response to this implant • Insufficient clinical data exists to support use of the Cordis S.M.A.R.T. Nitinol Peripheral Stent System in renal arteries • It is not recommended that the stent be used in patients with following characteristics: patients with poor renal function, who, in the physician's opinion, may be at risk for a reaction to contrast medium, pregnant patients, patients with bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy, patients with perforated vessels evidenced by extravasation of contrast media and patients who have aneurysmal dilation immediately proximal or distal to the lesion.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

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