STENT GRAFTS FOR ILIO-FEMORAL DISEASE

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

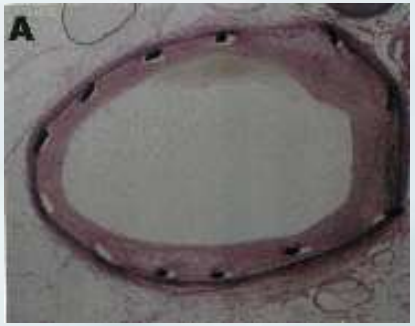
Affiliation/Financial Relationship	Company
▪ Grant/Research Support	▪ WL Gore, Medtronic
▪ Consulting Fees/Honoraria	▪ Abbott Vascular, Bard Peripheral Vascular, Boston Scientific, Cordis, Medtronic

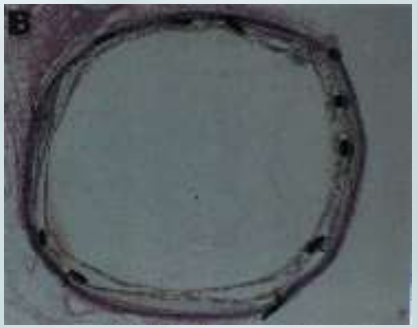
Covered Stents

Rationale: For Covering

Early animal work showed that PTFE covered stents could significantly reduce restenosis and limit neointimal thickness.

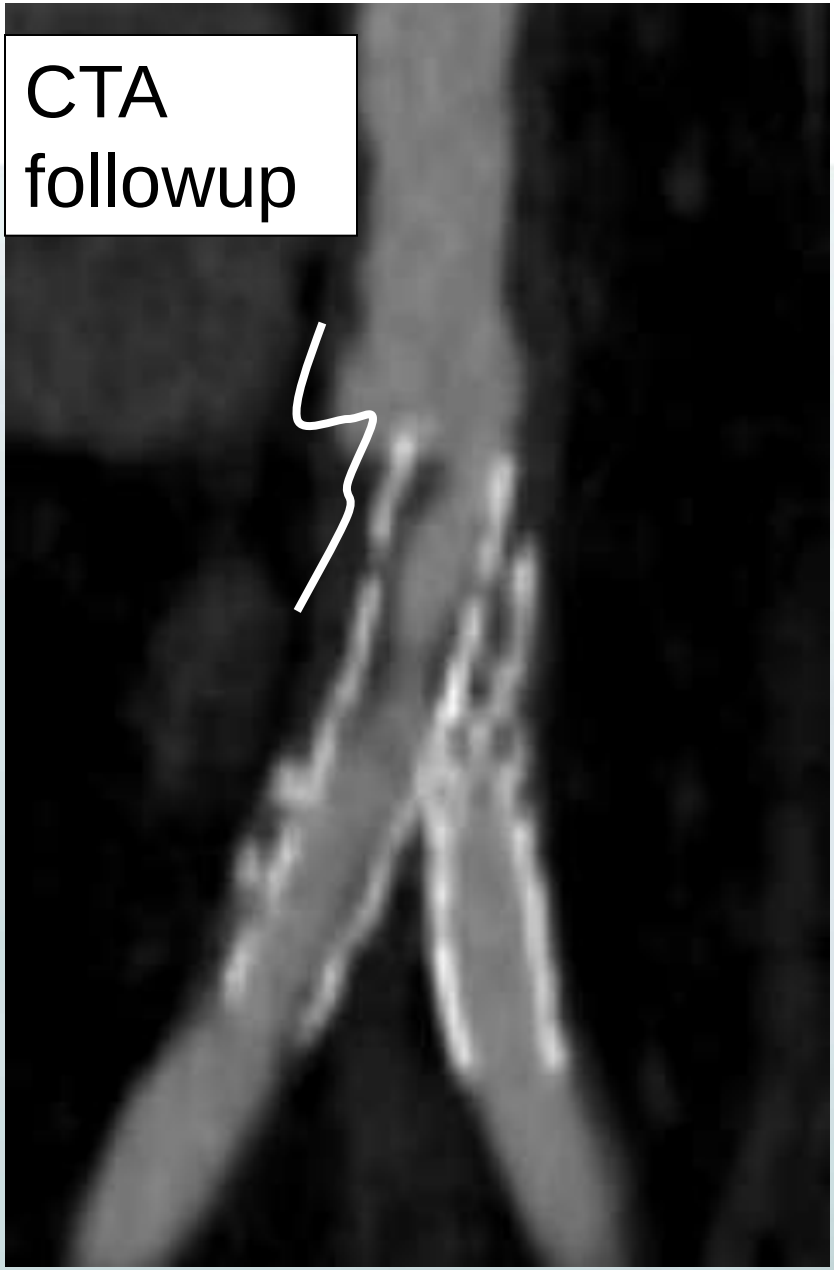
Stent type	Neointimal (µm)
Uncoated corrugated ring (28 day)	72±23
ePTFE+corrugated ring (28 day)	18±03*
Uncoated slotted tube (28 day)	93±16
ePTFE+slotted tube (28 day)	17±04***
ePTFE+slotted tube (56 day)	13±02
* P<0.007 compared to uncoated corrugated ring	
**P<0.0001 compared to uncoated slotted tube	



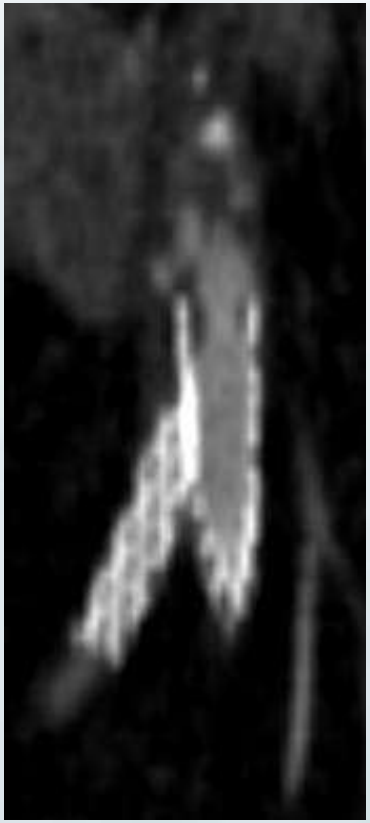


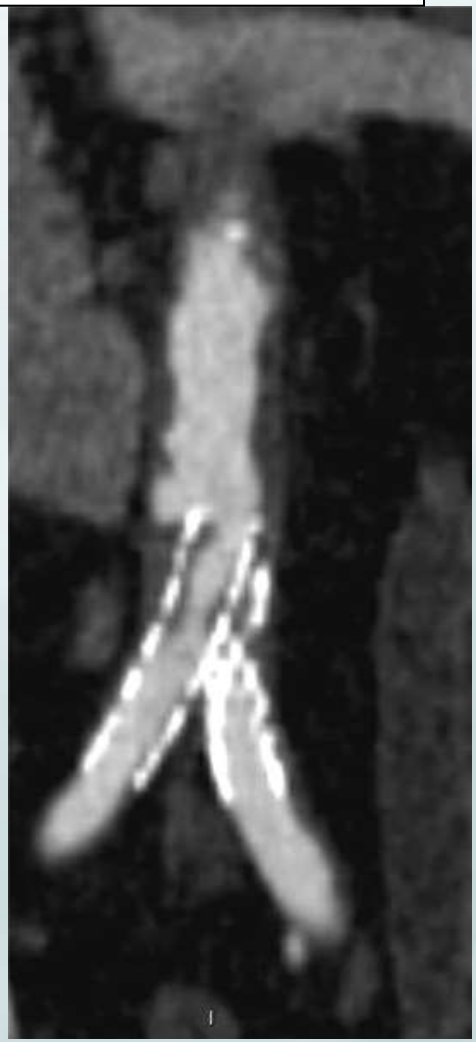
Rogers, C & E. Edelman. A Non-GLP Study of Biologic Responses to Uncoated and PTFE Coated Steel Stents in Rabbit Iliac Arteries. (1997)

Bare Metal Stents

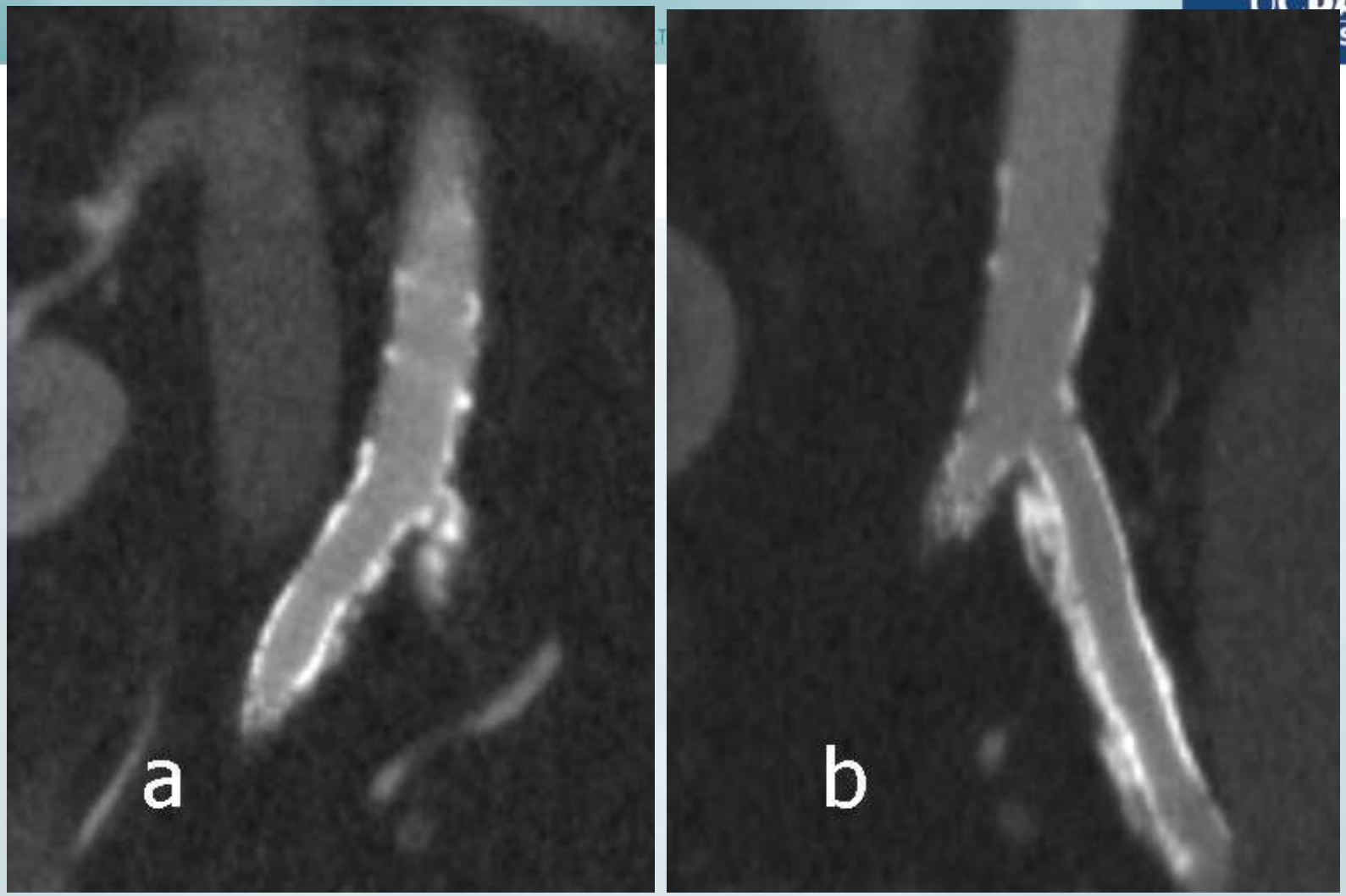


Intimal hyperplasia





Courtesy of Saher Sabri



Coronal MPR images of the right (a) and the left (b) common iliac arteriess from a CTA at 24 months post procedure showing patency of the covered iliac stents and no intimal hyperplasia

Outcomes of Covered Kissing Stent Placement Compared with Bare Metal Stent Placement in the Treatment of Atherosclerotic Occlusive Disease at the Aortic Bifurcation

Saher S. Sabri, MD, Asim Choudhri, MD, Gianluigi Orgera, MD, Bulent Arslan, MD, Ulku C. Turba, MD, Nancy L. Harthun, MD, Klaus D. Hagspiel, MD, Alan H. Matsumoto, MD, and John F. Angle, MD

PURPOSE: To review the outcomes with the use of balloon-expandable covered iliac kissing stents as compared with bare metal stents in the treatment of atherosclerotic disease at the aortic bifurcation.

MATERIALS AND METHODS: A review of consecutive patients from a single institution with atherosclerotic occlusive disease at the aortic bifurcation treated with balloon-expandable kissing stents was performed between January 1, 2002, and September 1, 2007. Fifty-four patients were identified and divided into two groups: those with bare metal stents and those with covered stents. Technical and clinical success (Fontaine classification), complications, and patency at follow-up were documented.

RESULTS: Twenty-six patients (17 men, nine women; mean age, 61 years; age range, 39–79 years) received covered stents and 28 patients (15 men, 13 women; mean age, 61 years; age range, 38–82 years) received bare metal stents. Technical success was achieved in 100% of patients in both groups. Major complications occurred in three of the 26 (11%) with covered stents ($P = .66$) and two of the 28 patients (7%) with bare metal stents. The median follow-up was 21 months (20 months for covered stents vs 25 months for bare metal stents; range, 1–62 months). Twenty-two of the 26 patients (85%) with covered stents had sustained improvement in clinical symptoms during the follow-up period compared with 15 of the 28 patients (54%) with bare metal stents ($P = .02$). Primary patency rates at 1 and 2 years were 92% and 92%, respectively, for covered stents and 78% and 62% for bare metal stents ($P = .023$).

CONCLUSIONS: The use of covered balloon-expandable kissing stents for atherosclerotic aortic bifurcation occlusive disease provides superior patency at 2 years as compared with bare metal balloon-expandable stents.

J Vasc Interv Radiol 2010; 21:995–1003

"Covered Versus Balloon Expandable Stent Trial"

- Prospective multi-center randomized trial (Australia)
- Atrium covered stent (V12) compared to BX BMS in TASC B,C, and D lesions

Mwipatayi P *J Vasc Surg* 2011; 54: 1561-1570

A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease

Bibombe P. Mwipatayi, MMed (Surg), FCS (SA), FRACS,[a,b] Shannon Thomas, MBBS (Hons),[a] Jackie Wong, MPH,[a] Suzanna E. L. Temple, PhD, MBA,[a,c] Vikram Vijayan, MRCS, FRCS,[a] Mark Jackson, MD, FRACS,[d] and Sally A. Burrows, BMath Grad Dip Med Stat,[e] on behalf of the Covered Versus Balloon Expandable Stent Trial (COBEST) Co-investigators,* *Perth, Western Australia and Gold Coast, Queensland, Australia*

Objective: This trial was conducted to determine if covered stents offer a patency advantage over bare-metal stents in the treatment of aortoiliac arterial occlusive disease.

Methods: The Covered Versus Balloon Expandable Stent Trial (COBEST), a prospective, multicenter, randomized controlled trial, was performed involving 168 iliac arteries in 125 patients with severe aortoiliac occlusive disease who were randomly assigned to receive a covered balloon-expandable stent or bare-metal stent. Patient demographic data, clinical signs and symptoms, TransAtlantic Inter-Society Consensus (TASC) classification, and preprocedure and postprocedure ankle-brachial index measurements were recorded. The primary end points included freedom from binary restenosis and stent occlusion of the treated area, as determined by ultrasound imaging or quantitative visual angiography, or both. Postprocedural follow-up was at 1, 6, 12, and 18 months.

Results: Aortoiliac lesions treated with a covered stent were significantly more likely to remain free from binary restenosis than those that were treated with a bare-metal stent (hazard ratio [HR], 0.35; 95% confidence interval (CI), 0.15-0.82; $P = .02$). Freedom from occlusion was also higher in lesions treated with covered stents than in those treated with a bare-metal stent (HR, 0.28; 95% CI, 0.07-1.09); however, this did not reach statistical significance ($P = .07$). Subgroup analyses demonstrated a significant difference in freedom from binary restenosis for covered stents in TASC C and D lesions compared with a bare stent (HR, 0.136; 95% CI, 0.042-0.442). This difference was not demonstrated for TASC B lesions (HR, 0.748; 95% CI, 0.235-2.386).

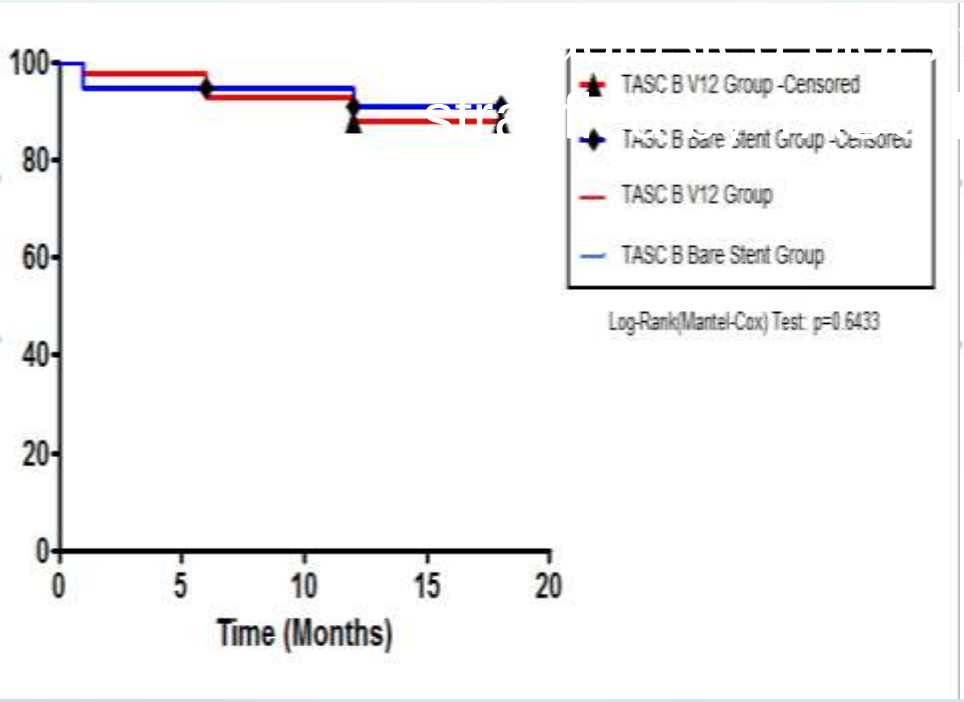
Conclusions: COBEST demonstrates covered and bare-metal stents produce similar and acceptable results for TASC B lesions. However, covered stents perform better for TASC C and D lesions than bare stents in longer-term patency and clinical outcome. (J Vasc Surg 2011;54:1561-70.)

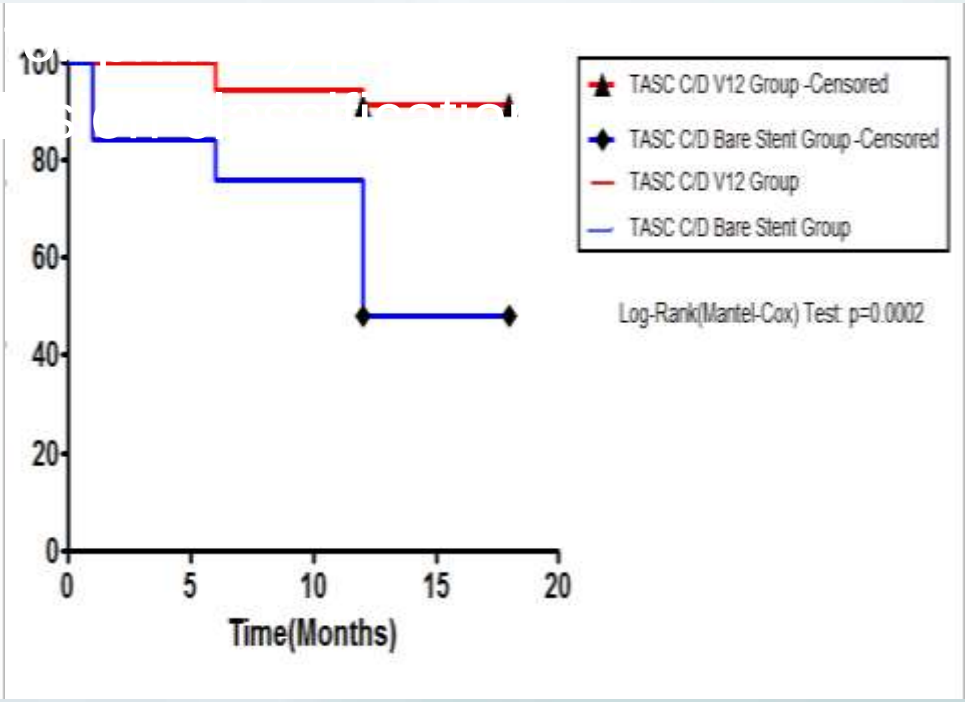
COBEST

- Aortoiliac lesions treated with a covered stent were significantly more likely to remain free from binary restenosis at 18 months than those that were treated with a BMS (HR, 0.35; 95% CI, 0.15-0.82; *P* .02).
  - 18 months: 88% vs 68%
- TVR during the study period demonstrated that there was less reintervention in the covered-stent group compared with the BMS group (OR, 21; 95% CI, 0.07-0.64;*P .006).*
  - 18 months: 2.5% vs 16%

Mwipatayi P *J Vasc Surg* 2011; 54: 1561-1570

COBEST: 18-Month Results





TASC B

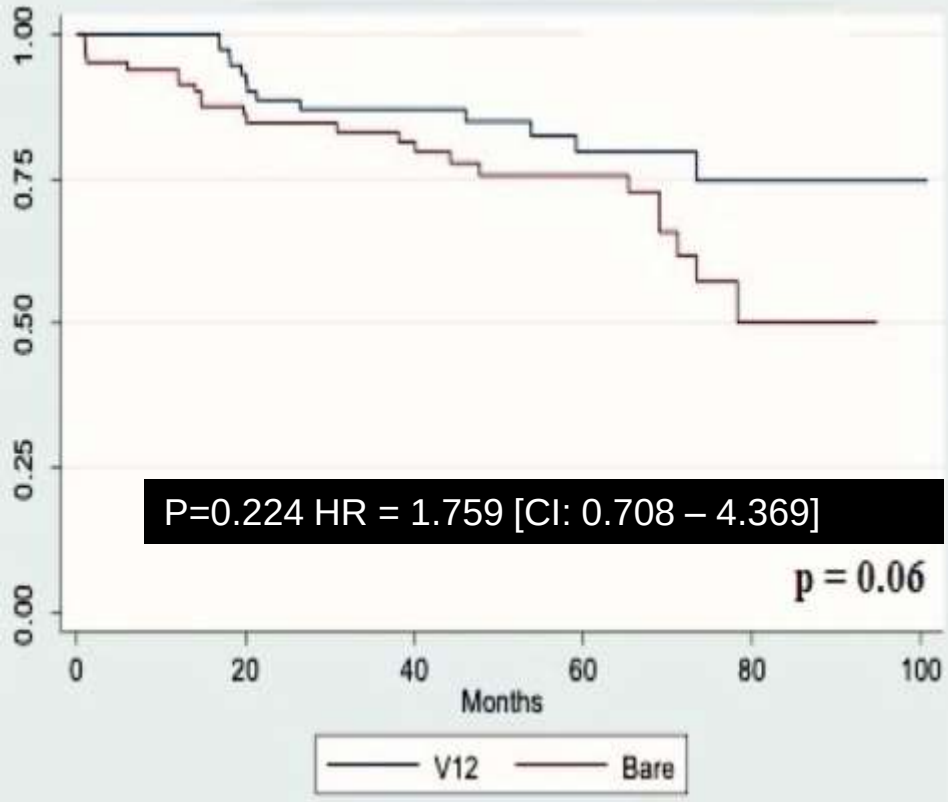
TASC C/D

Freedom from restenosis at 18-months 88% vs 46%

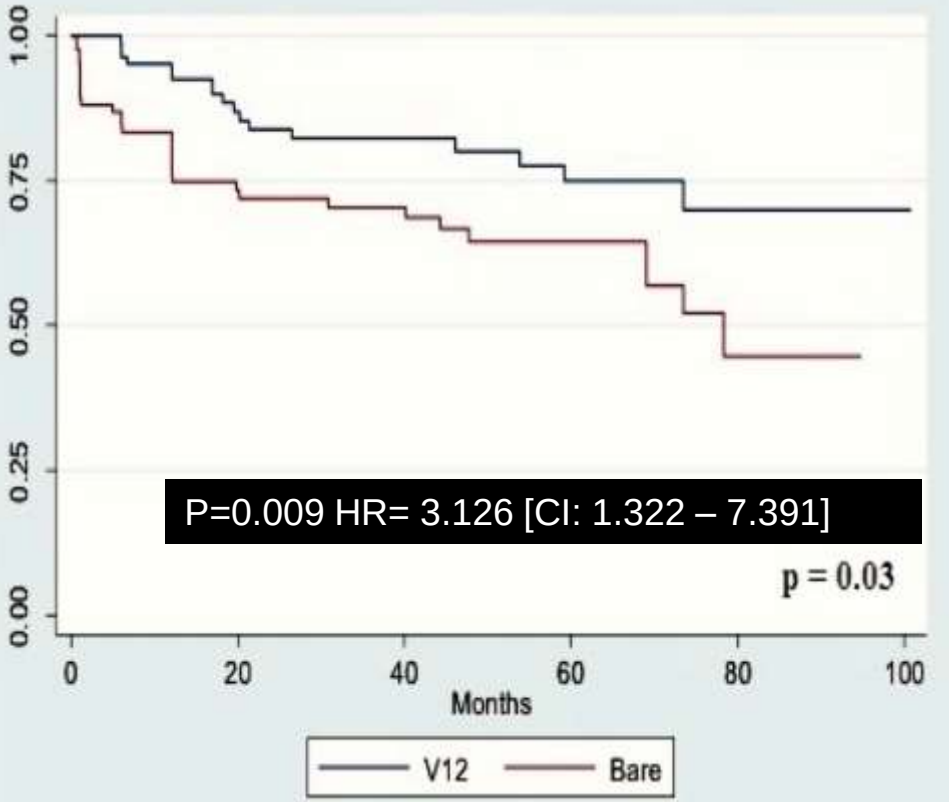
Mwipatayi P *J Vasc Surg* 2011; 54: 1561-1570

COBEST: 5-Year Results

Cox adjusted plots for primary patency stratified by TASC lesion classification



TASC B

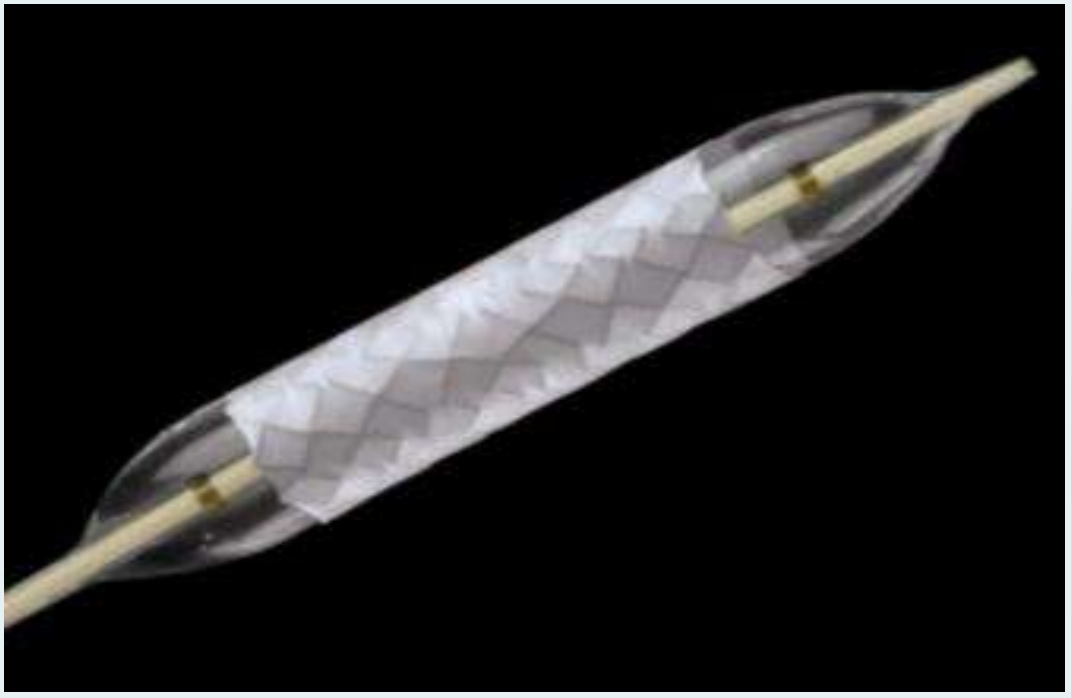


TASC C/D

Mwipatayi P LINC 2015

ICARUS

iCAST Atrium Registry Ultrasound Study



ICARUS: Clinical Study Design

- Prospective, multicenter, non-randomized, single arm
  - 26 US sites, 1 site in Germany
  - 165 subjects
  - Follow-up at 30 days, 6 months and 9 months post-procedure for primary endpoint
  - Yearly follow-up through 3 years post-procedure
  - Comparison to Objective Performance Criteria from meta-analysis of stents approved at the time of study planning (2005 timeframe)

Primary Endpoint Results

ITT Population N=152

Endpoint	Rate	95% CI	<16.57
Combined Rate	**8.1% (10/123)**	**13.4%**	**P=0.005**
30 day death	0		
TLR within 9 months	2.9% (4/138)		
Restenosis within 9 months	4.9% (6/123)		

- The primary composite endpoint rate is 8.1%
- Since the 95% confidence interval is below the protocol specified criteria of 16.57%, the study stent met its primary effectiveness endpoint

BOLSTER

Clinical Study

INNOVATION

UCDAVIS HEALTH SYSTEM

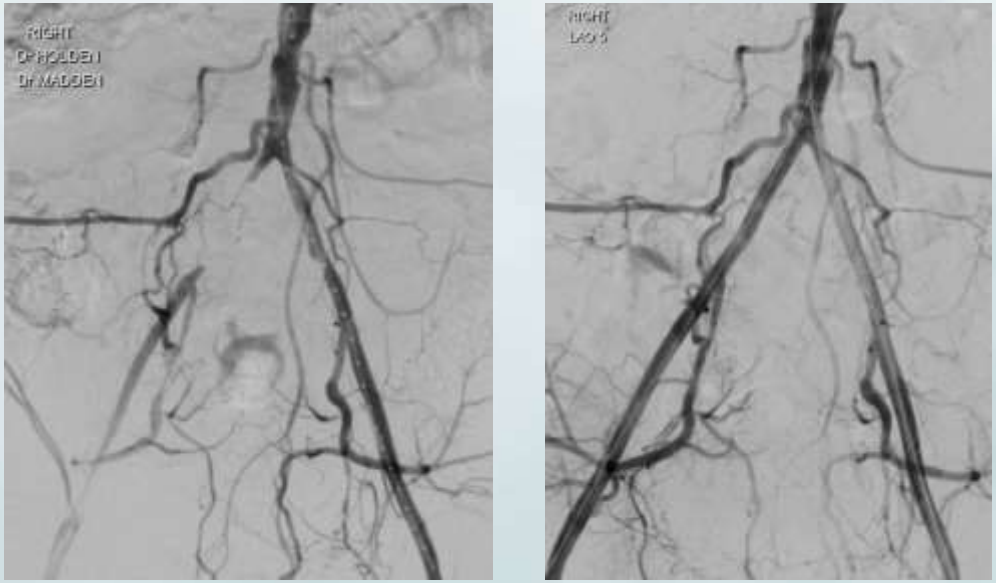
Lifestream balloon expandable, stainless steel PTFE endograft

Trial Enrollment Complete!

Number of Subjects	154
Primary Endpoint Follow Up	9 Months Post-Procedure – Performance Goal
Length of Subject Follow-Up	36 Months Post-Procedure

Viabahn BX Endoprosthesis

Balloon expandable, heparin bonded, PTFE endograft

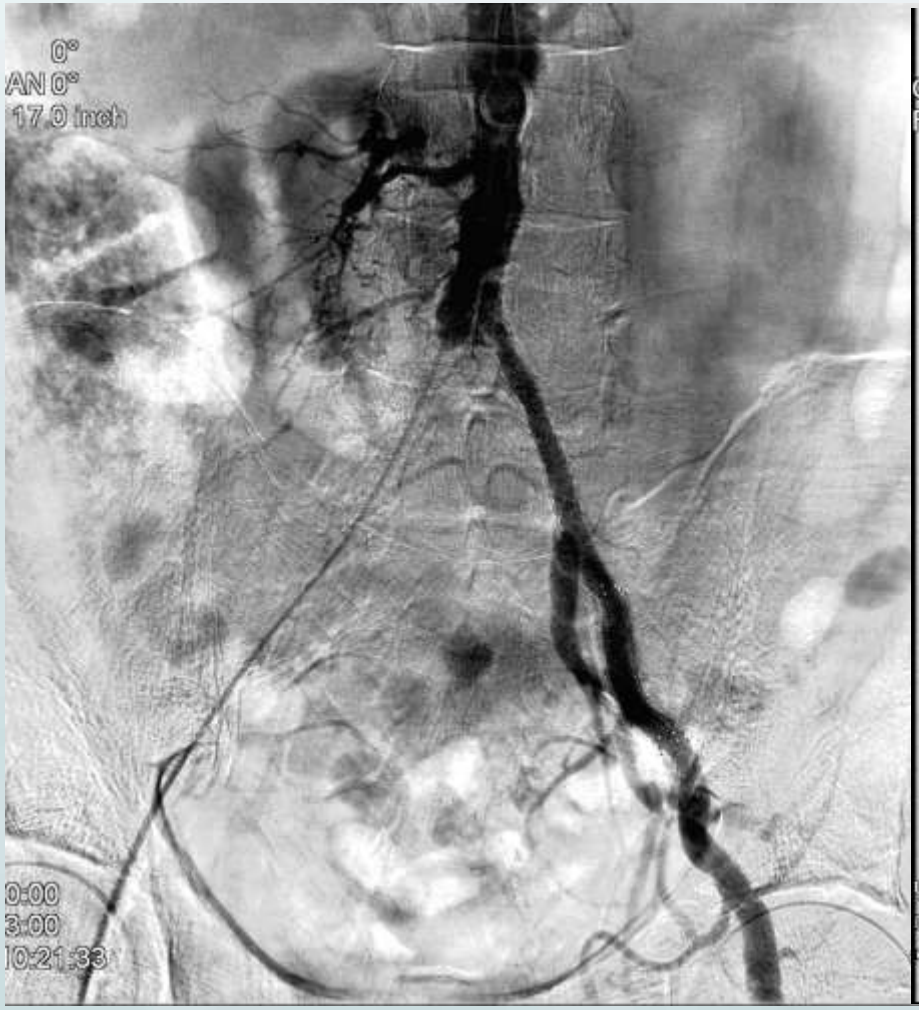


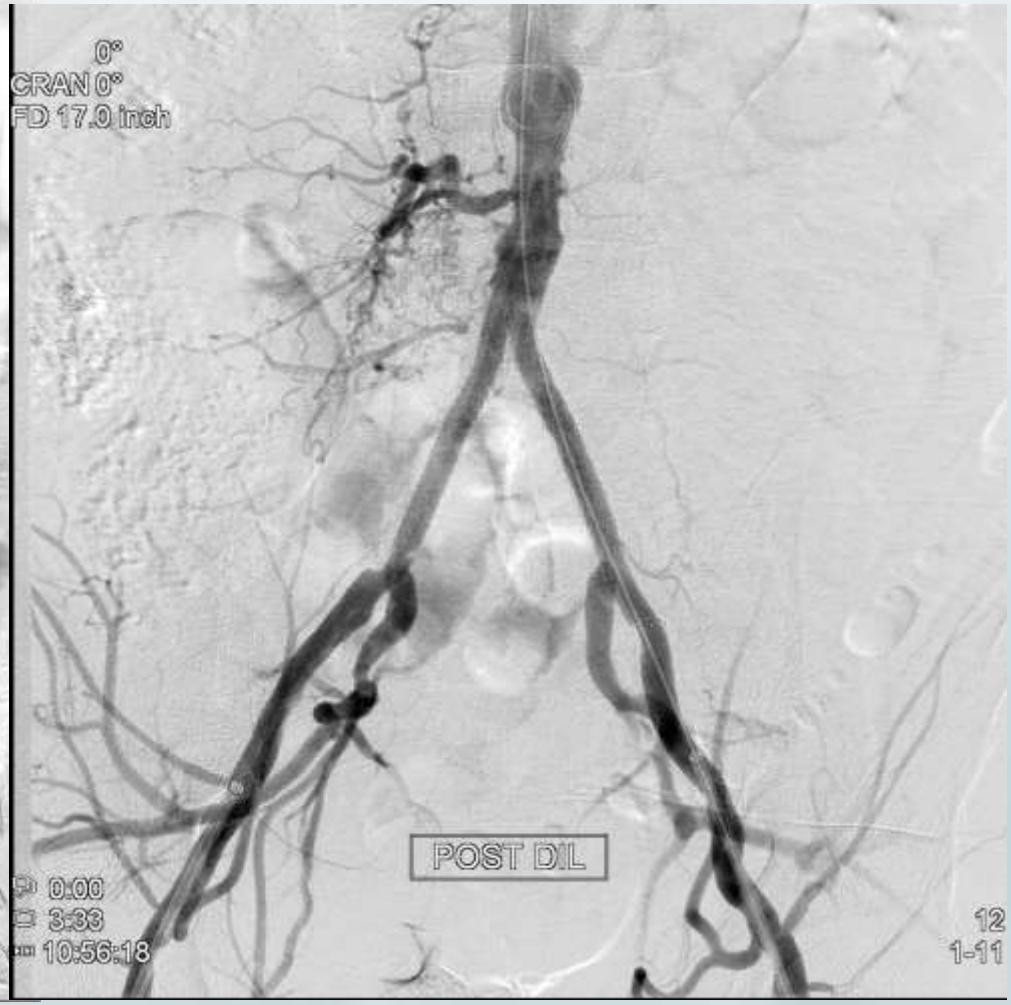
FIH completed, Viabahn BX FLEX IDE Trial in process

Role of Covered Stents in Aortoiliac Interventions

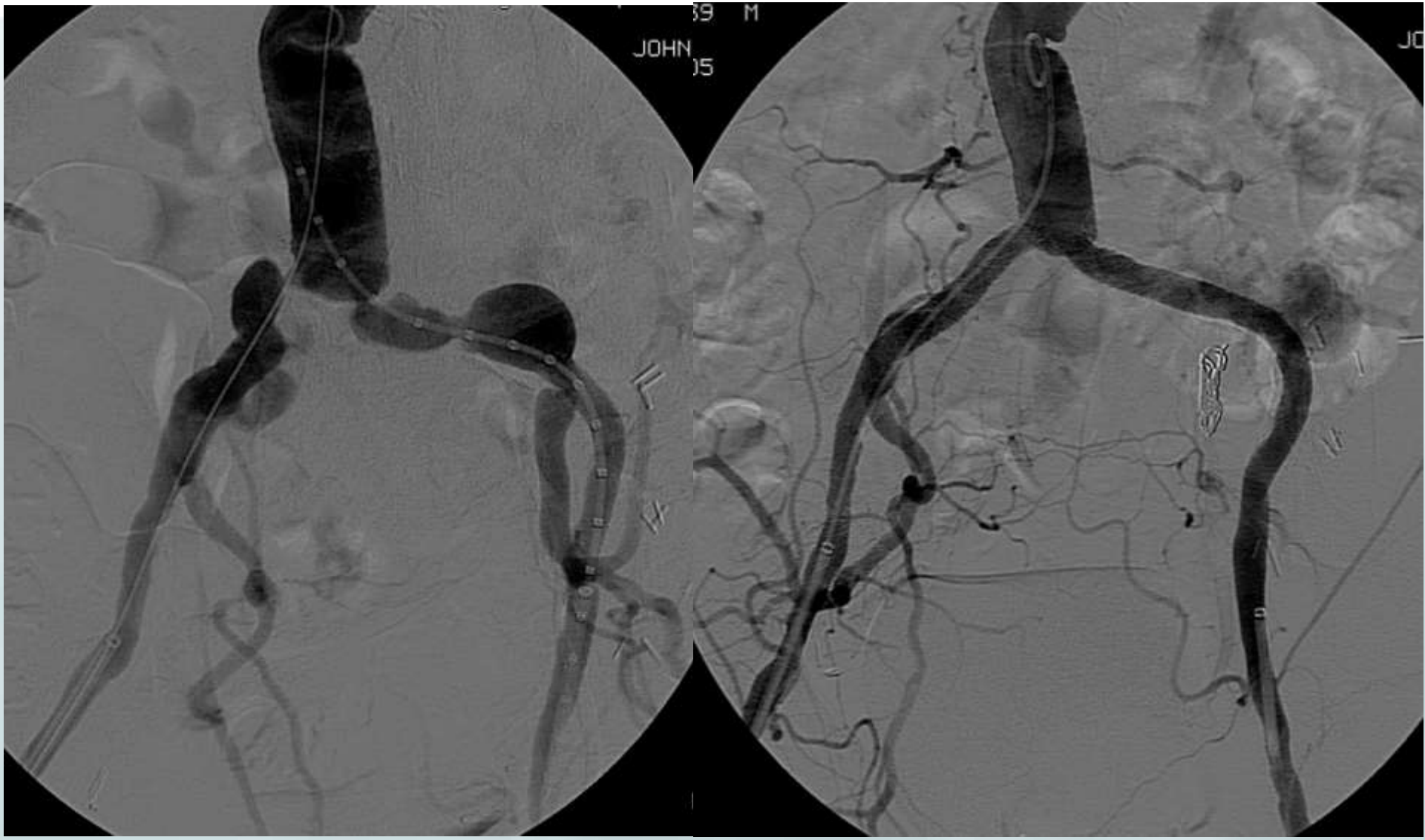
- Complex Disease: TASC C and D
- Aortoiliac bifurcation disease
- Instent restenosis?
- Rupture/perforation
- Pseudoaneurysm/aneurysm

Iliac Instent Restenosis





Aneurysmal and Occlusive Disease



What About for the SFA?

GORE VIABAHN® Endoprosthesis

- Incremental improvements:
  - Lower profile
  - Proximal contoured edge to reduce the risk of proximal edge restenosis
  - Heparin Bioactive Surface

Key Advantages

- Patency rate independent of lesion length
- Good results for long occlusions/stenoses
- When restenosis occurs, it is usually focal, edge restenosis
- Effective for instent restenosis

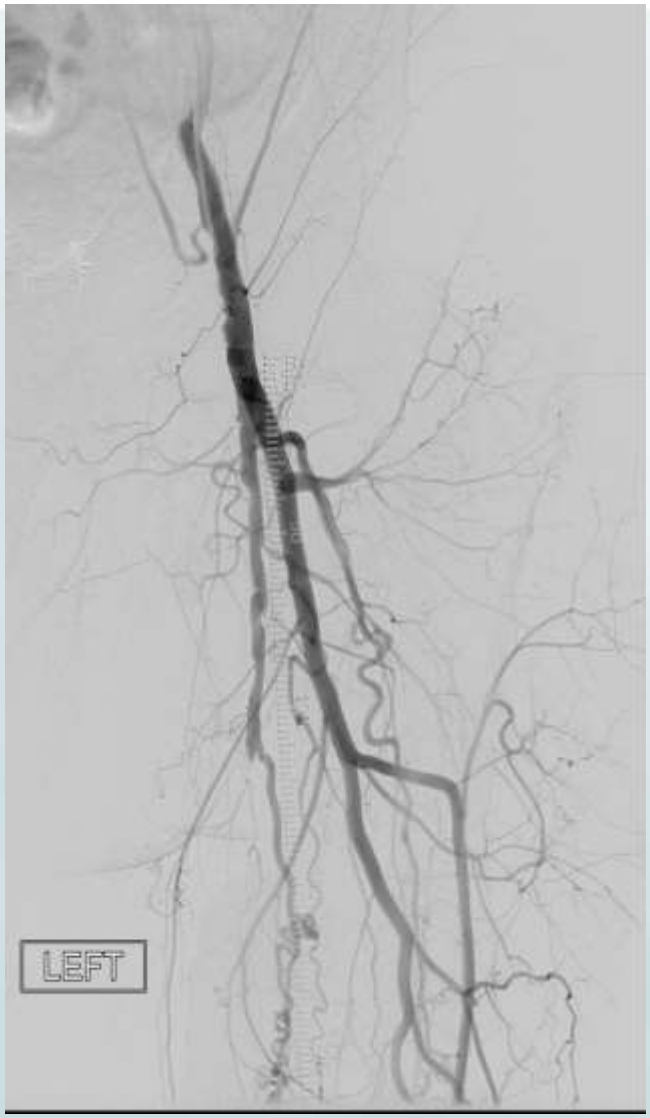
Better than BMS for Long Lesions? VIASTAR Trial

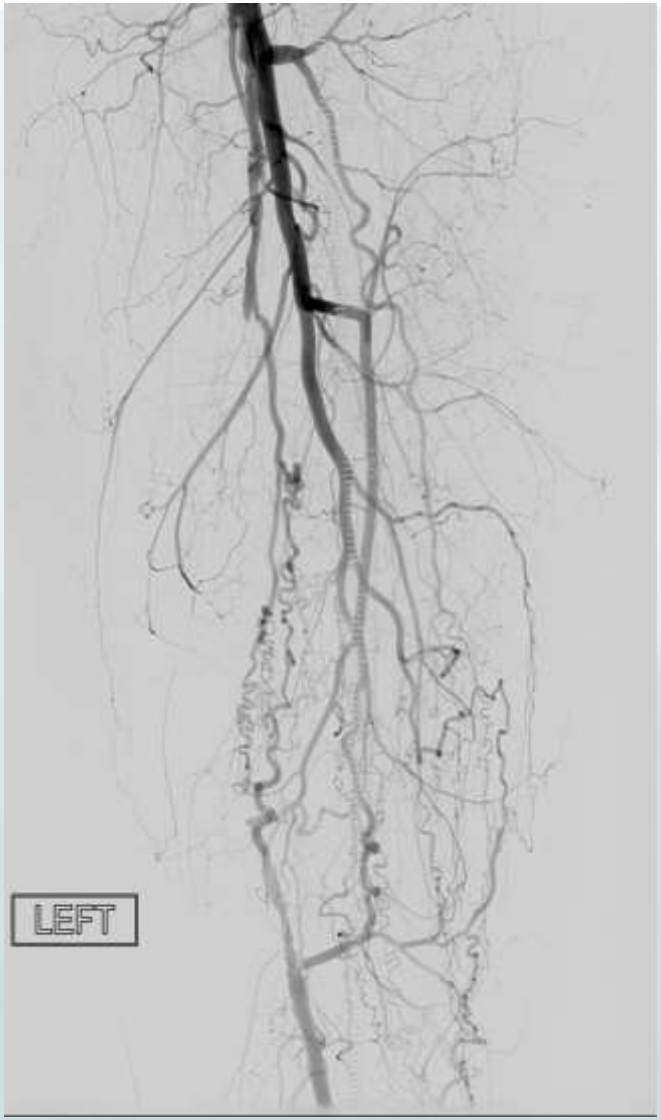
- European randomized trial of Viabahn vs. bare nitinol stent for long SFA lesions
- Newest generation Viabahn endoprosthesis:
  - Low profile
  - Heparin bioactive surface
  - Proximal contoured edge
- 142 patients enrolled at 7 European Centers
- Rutherford category 2 - 5

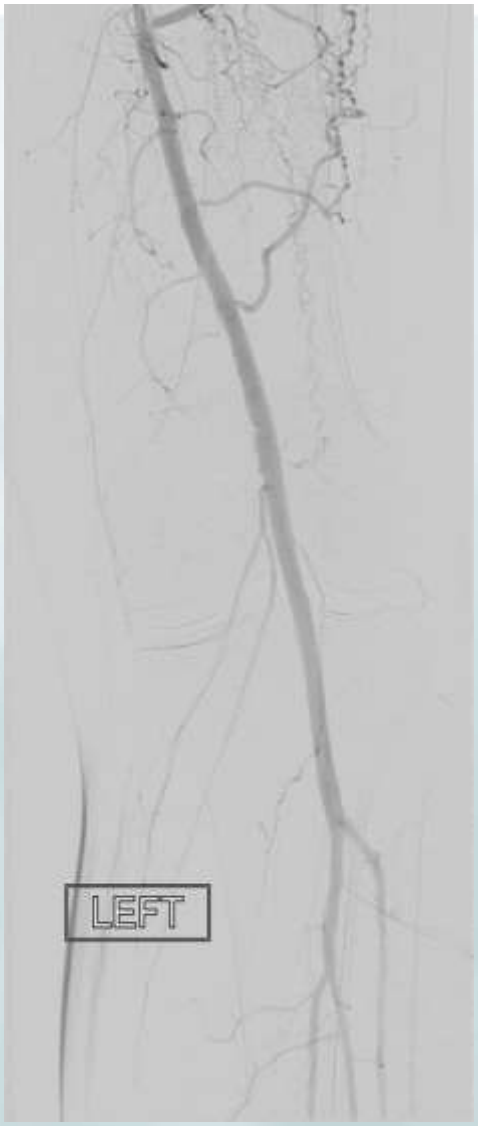
VIASTAR Outcomes

	VIABAHN™	BMS	P Value
Lesion length (cm)	19.0 ± 6.3	17.3 ± 6.6	P = 0.13
Occlusion	79%	70%	P = 0.21
12-month Primary Patency (all)	78.1%	53.5%	P = 0.009
12- month Primary Patency (> 20 cm)	73.3%	33.3%	P = 0.004
12-month Freedom from TLR	84.6%	77.0%	P = 0.37
Ankle-Brachial Index	0.94 ± 0.23	0.85 ± 0.23	P < 0.05

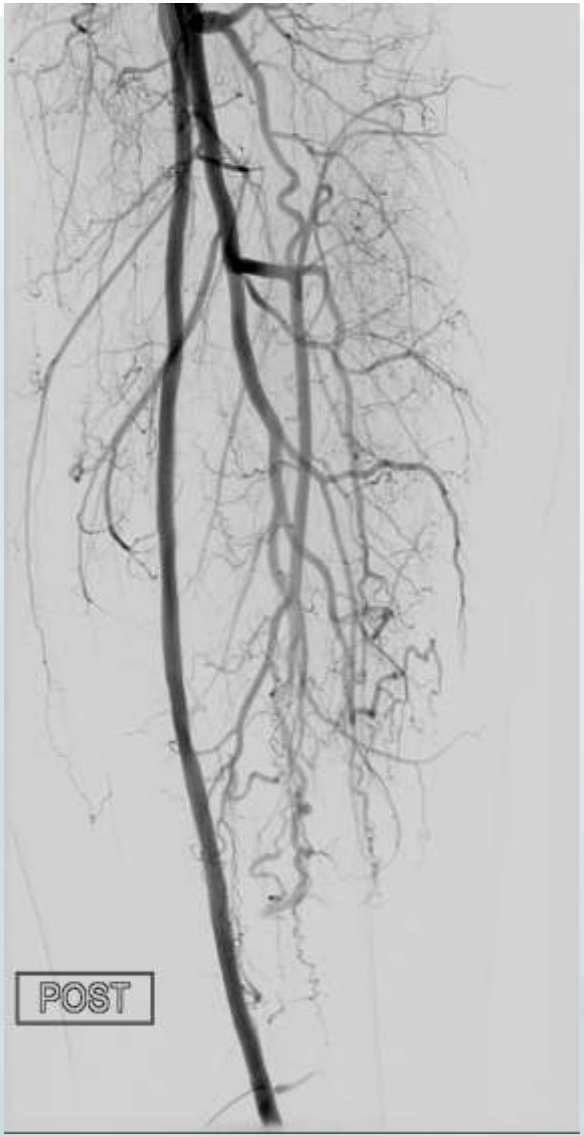
Long SFA Occlusion

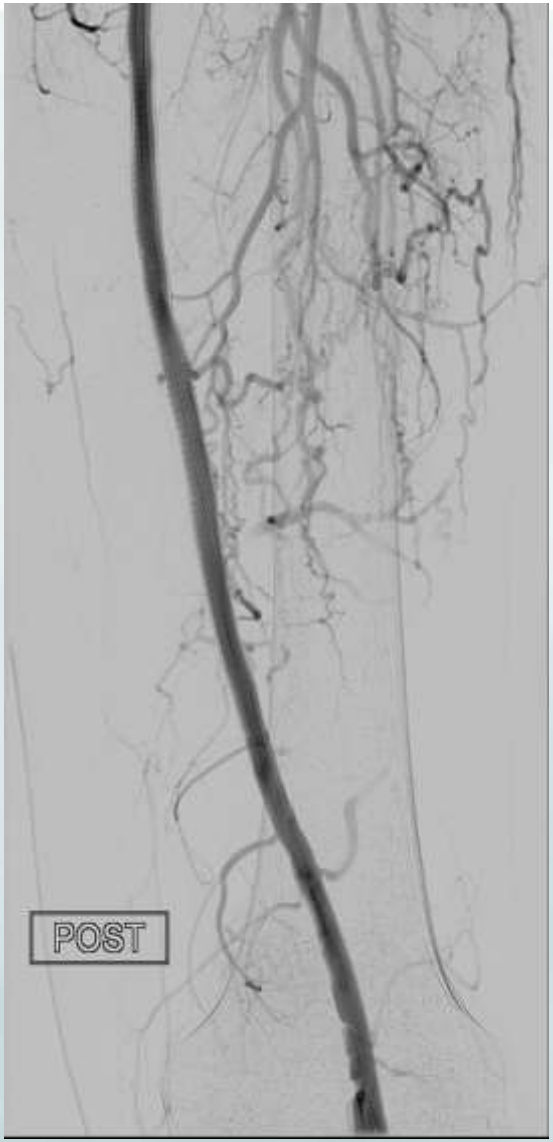


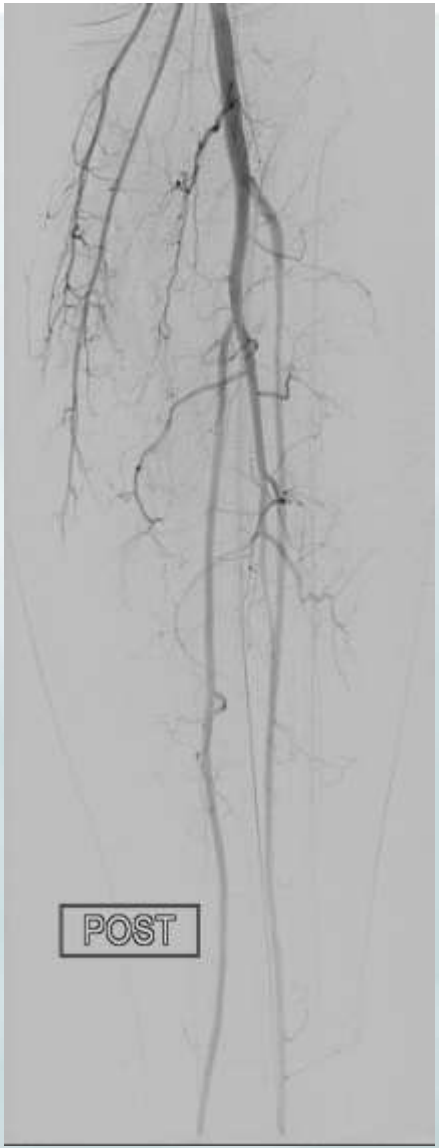




Long SFA Occlusion







RELINE Study
Viabahn for Fem-Pop ISR

100 patients randomly allocated to treatment (1:1 randomization)

47 patients randomized to GORE® VIABAHN® Endoprosthesis (intent-to-treat)

8 patients excluded from analysis by primary investigator due to inclusion / exclusion and procedural violations

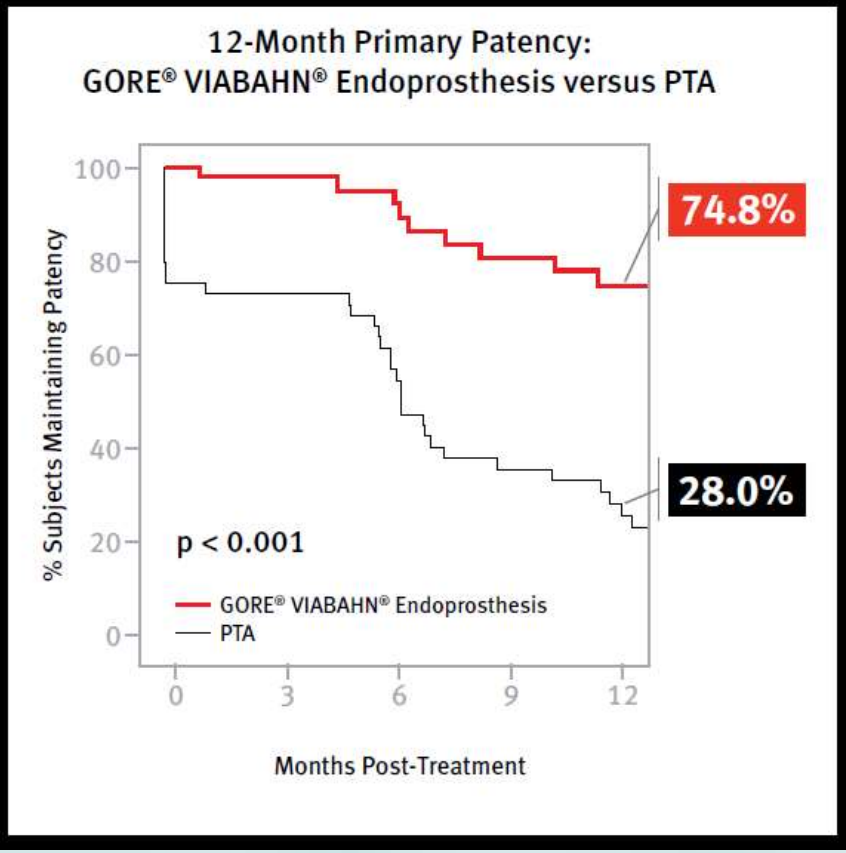
39 patients analyzed (per-protocol)

53 patients randomized to PTA (intent-to-treat)

9 patients excluded from analysis by primary investigator due to inclusion / exclusion and procedural violations

44 patients analyzed (PP)

Primary Patency



12-Month Primary Patency

	GORE® VIABAHN® Endoprosthesis	PTA	P-value
Intent-to-Treat	72.5%	24.2%	< 0.001
Per-Protocol	74.8%	28.0%	< 0.001
Optimal PTA (As Treated)	74.8%	37.0%	< 0.001

Summary

- There is robust data supporting the role of covered stents in the iliac and femoral arteries
- Most of the data, including randomized data from the COBEST Trial suggests that covered stents are superior to BMS for complex iliac disease
- Viabahn stent graft is a good option for long segment SFA disease and FP ISR