

Covered Stents

Presented by:

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Peripheral Covered Stents

- Have been in use since 1996.
- There are over 500,000 worldwide implants.
- Numerous clinical studies are conducted and written each year.
- The clinical differences are substantial from a bare metal stent.

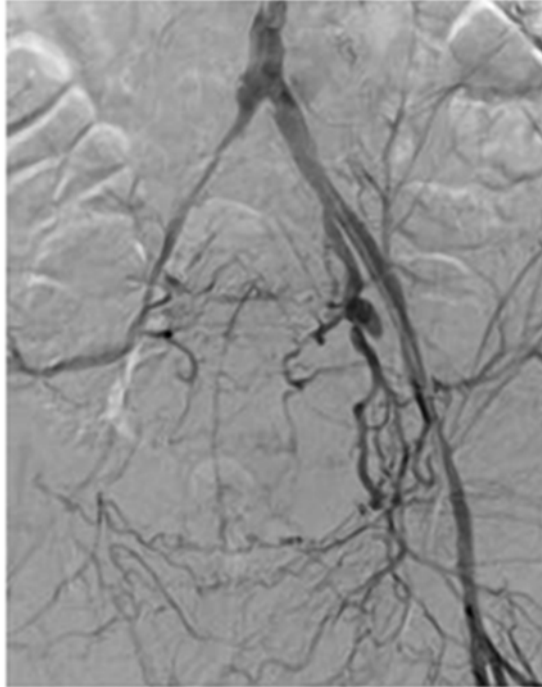
Benefits of Covered Stents

- Covers and seals off the diseased and irregular tissue of the arterial wall.
- ePTFE Lining
 - Limits in-stent restenosis
- Nitinol Stent
 - Conformable yet durable
- Contoured proximal edge
 - May improve flow dynamics as blood enters endoprosthesis

Revascularization of the Iliac Artery



CT angiogram demonstrating the right iliac occlusion



Initial angiogram demonstrating occlusion of the right external iliac artery



Completion angiogram after placement of 7 mm x 10 cm graft in external iliac and balloon expandable stent in common iliac

The Covered Versus Balloon Expandable Stent Trial (COBEST)

- A prospective, multicenter, randomized controlled trial
- 168 iliac arteries in 1125 patients randomized to covered balloon-expandable stent or bare-metal stent



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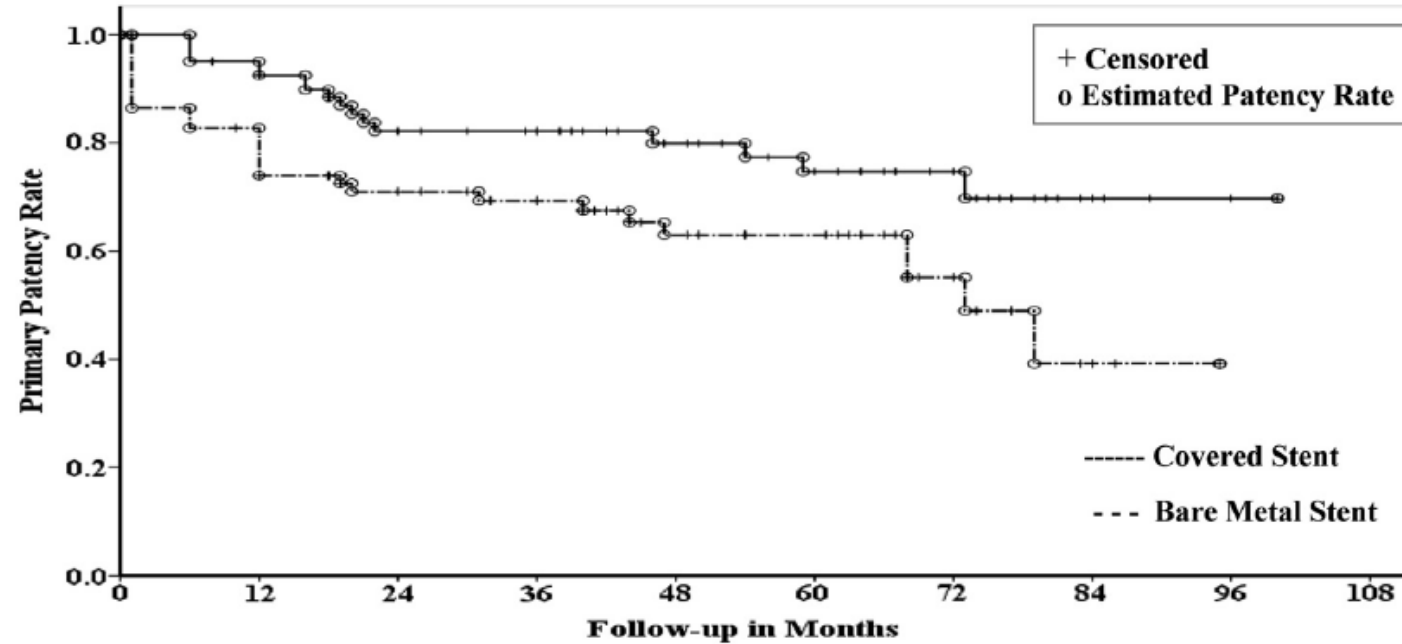
Clinical research study

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

Presented at the VIVA meeting, Las Vegas, Nev, October 19-23, 2009; the LINC meeting, Leipzig, Germany, January 25-28, 2010; C3 meeting, Baltimore, Md, June 20-24, 2010; ANZSVS Vascular Meeting, Gold Coast, State, Country, August 2-5, 2010; 10th China National Annual Congress of Vascular Surgery, Nanjing, China, September 24-26, 2010; Veith meeting, New York, NY, November 17-21, 2010; and CACVS 2011 Congress, Paris, France, January 27-29, 2011.

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5 year COBEST Data



Time (Months)	0	12	24	36	48	60	72	84	96
Advanta V12 Stent (n. at risk)	83	74	52	47	35	28	17	5	2
Standard Error (%)	-	2.95	4.54	4.54	4.93	5.84	5.84	7.27	7.27
BMS (n. at risk)	85	66	46	40	28	23	10	3	1
Standard Error (%)	-	4.89	5.13	5.27	5.94	5.94	7.36	11.2	11.2

Fig 1. Kaplan-Meier curve of overall primary patency rates of both stent groups. The overall patency rate was 74.7% in the covered stent (CS) group vs 62.9% in the bare-metal stent (BMS) group at 60 months of follow-up (log-rank test, $P = .01$). *n at risk*, Number of stents at risk of severe restenosis.

Durability of Balloon Expandable

Durability of the balloon-expandable covered versus bare-metal stents in the Covered versus Balloon Expandable Stent Trial (COBEST) for the treatment of aortoiliac occlusive disease

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Nishath Altaf, PhD, FRCS,^a Marek Garbowski, MB BS, FRACS,^f and Mark Jackson, MD, FRACS,^g on
behalf of the COBEST co-investigators,* *Perth, Sydney, and Queensland, Australia; and Singapore*

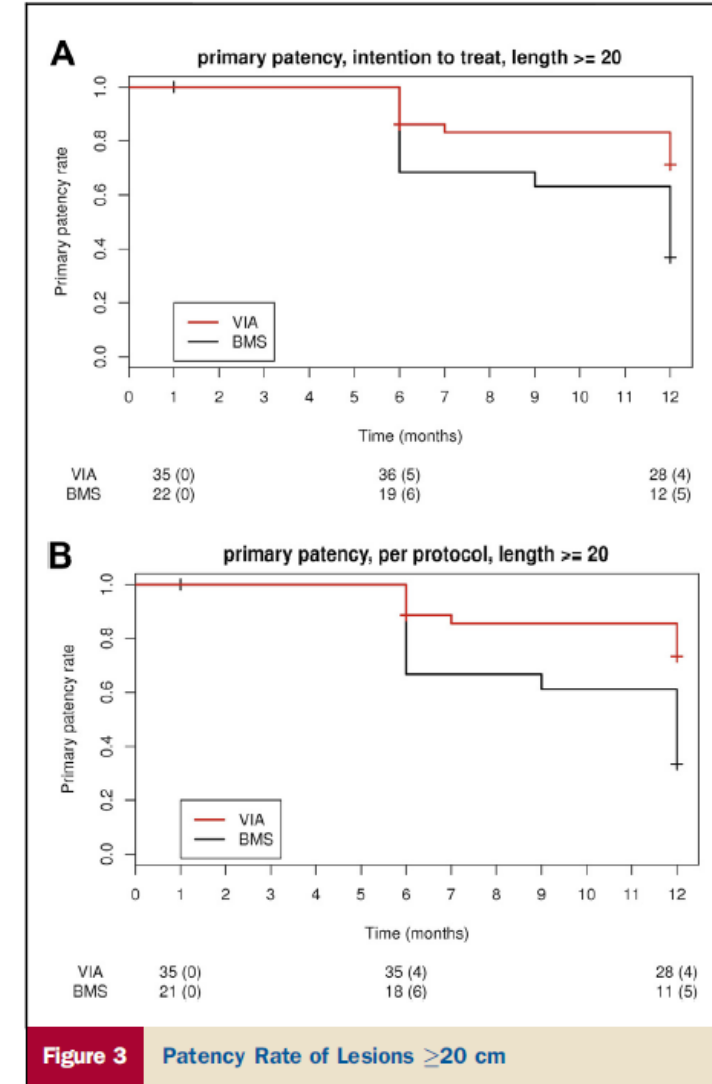
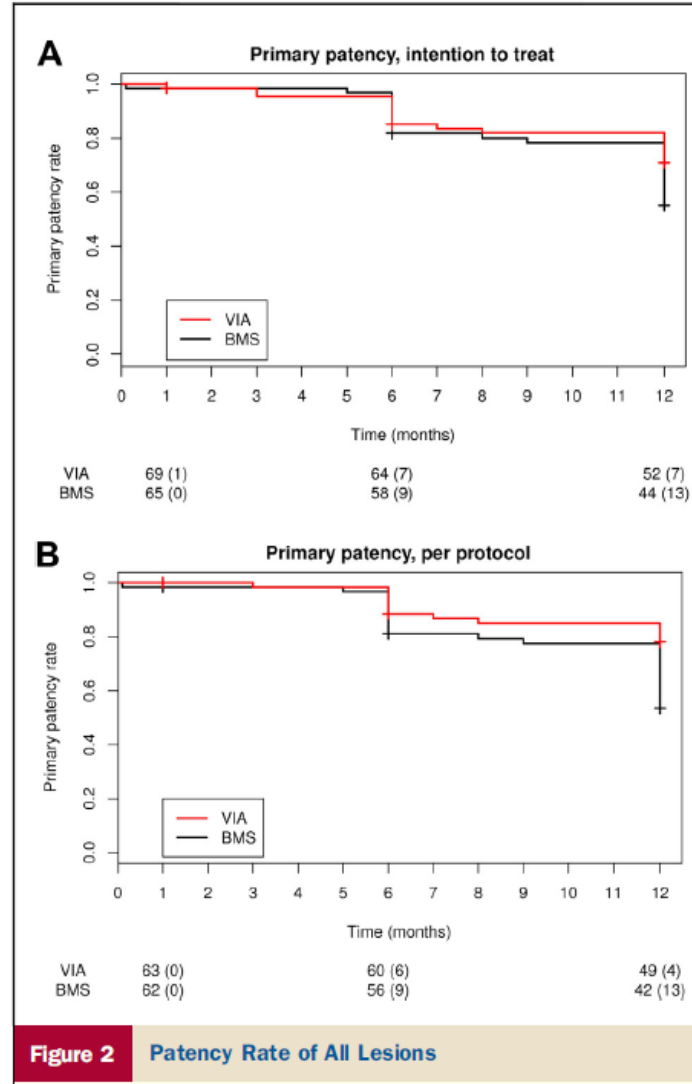
VIASTAR TRIAL

- Prospective, Randomized, Single-blind, multicenter study
- Covered stent 72 vs BMS 69 patients.
- Clinical outcomes and patency rates were assessed at 1, 6, and 12 months

CLINICAL RESEARCH

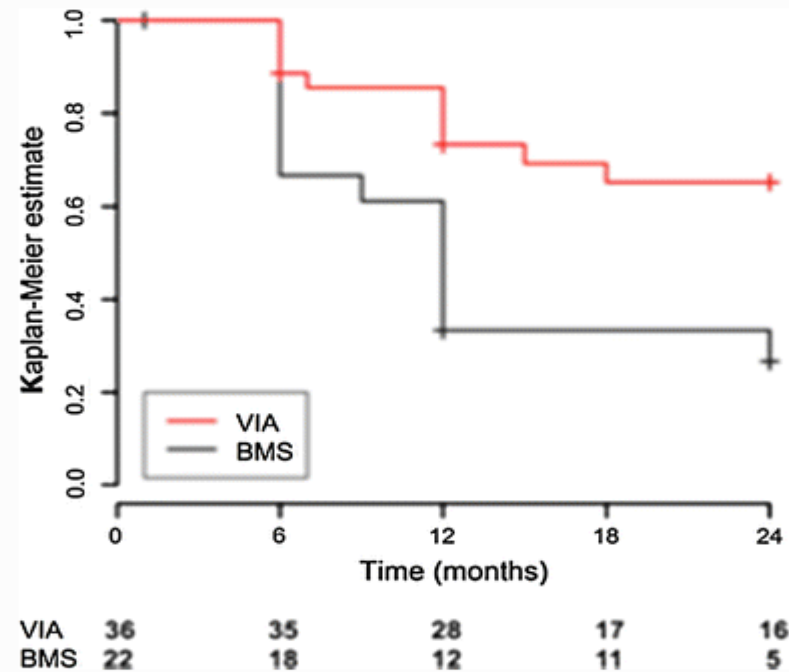
Heparin-Bonded Covered Stents Versus Bare-Metal Stents for Complex Femoropopliteal Artery Lesions

The Randomized VIASTAR Trial (Viabahn Endoprosthesis With PROPATEN Bioactive Surface [VIA] Versus Bare Nitinol Stent in the Treatment of Long Lesions in Superficial Femoral Artery Occlusive Disease)



Sustained Benefit at 2 years: VIASTAR Trial

From: [Sustained Benefit at 2 Years for Covered Stents Versus Bare-Metal Stents in Long SFA Lesions: The VIASTAR Trial](#)

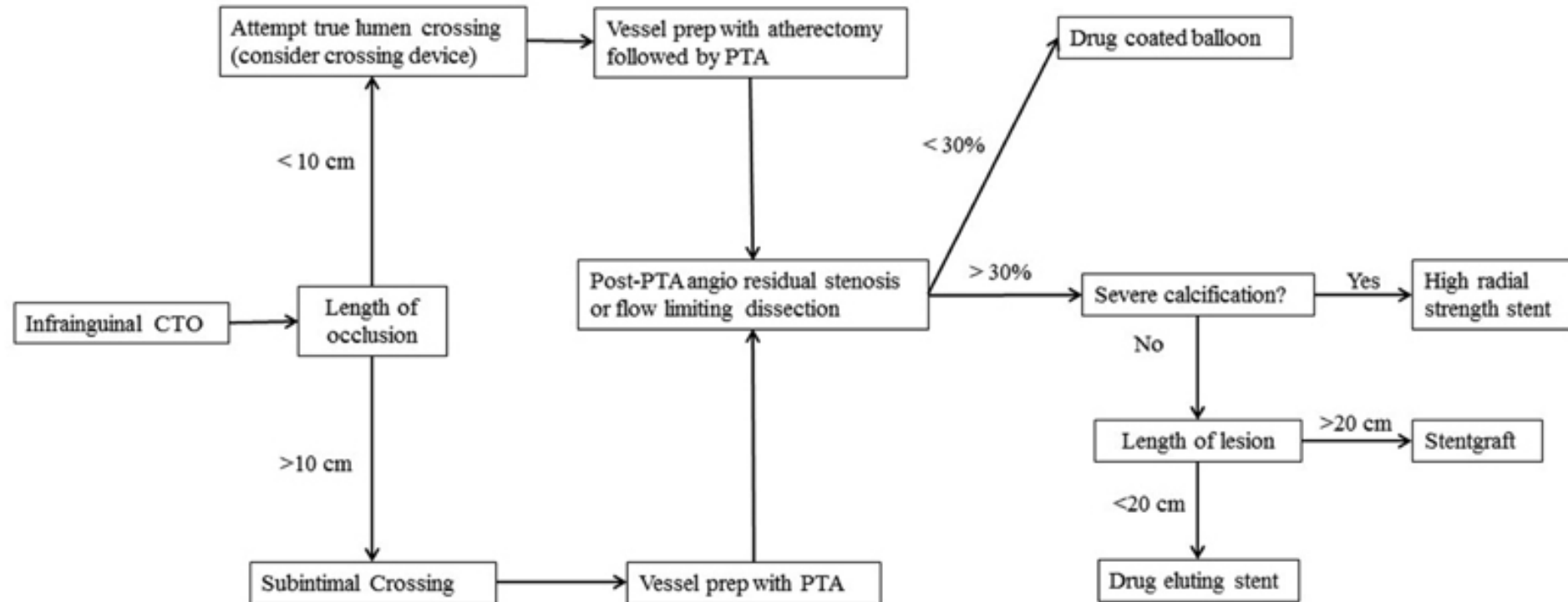


65.2%

26.7%

Primary patency of VIA (*red*) versus BMS (*black*) in SFA lesions of patients with symptomatic PAD and lesions ≥ 20 cm at 24 months (TPP): VIA 65.2 (95 % CI 0.50–0.85) versus BMS 26.7 % (95 % CI 0.12–0.59) (log rank $p = 0.004$). Abbreviations as in Fig. 1. The numbers below are patients at risk at 0, 6, 12, 18, and 24 months

Treatment Algorithm



Algorithm for endovascular CTO strategies. CTO, chronic total occlusion; PTA, percutaneous transluminal angioplasty.

Benefit of Covered Stents in HD Access

Clinical research study

Stent graft treatment for hemodialysis access aneurysms

Some of the results in this series were presented at the 6th Vascular Access Society Congress, Rome, Italy, Apr 20-22, 2009.

David Shemesh MD ^a, Ilya Goldin MD ^a, Ibrahim Zaghal MD ^b, Daniel Berelowitz MB, BChir ^b, Anthony G. Verstandig MB, BS ^b, Oded Olsha MB, BS ^a  

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Efficacy of Primary Stent-Graft Placement in the Treatment of Vascular Access Graft Outflow Tract Stenosis

Edoardo Macchi, MD , Federico Fontana, MD, Alessandro Beneventi, MD , more...

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Clinical Study

A Prospective, Randomized Study of an Expanded Polytetrafluoroethylene Stent Graft versus Balloon Angioplasty for In-Stent Restenosis in Arteriovenous Grafts and Fistulae: Two-Year Results of the RESCUE Study

Abigail Falk MD ^a , Ivan D. Maya MD ^b, Alexander S. Yevzlin MD ^c, RESCUE Investigators



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Journal of Vascular Surgery

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Clinical research study

Vascular access

Balloon angioplasty versus Viabahn stent graft for treatment of failing or thrombosed prosthetic hemodialysis grafts

Thomas Vesely MD ^a , William DaVanzo MD ^b, Terry Behrend MD ^c, Amy Dwyer MD ^d, John Aruny MD ^a

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Conclusion

- Covered stent grafts have an enduring patency advantage over the bare metal stents in long atherosclerotic lesions.
- Covered stent grafts provide superior target lesion primary patency for treatment of venous anastomotic stenoses of dysfunctional and thrombosed prosthetic hemodialysis grafts.