

Covered Stents in Longer Lesions

Peter A. Soukas, MD, discusses the available data, his clinical experiences, and techniques for better outcomes and restenosis prevention.



In which instances of femoropopliteal disease do you select a covered stent as opposed to a bare-metal or drug-eluting option?

The data for covered stents are really quite good. We published a paper last year¹ looking at covered stents for bare-metal ISR where we had an average ISR lesion length of 24.5 cm. The mean diameter was 5.6 mm, and an average of 2.5 Viabahn stents (Gore & Associates, Flagstaff, AZ) were implanted. We demonstrated a 1-year primary patency rate of 85.1% and a 3-year primary patency rate of 81.4%. The 3-year secondary patency rate was 96% for patients being treated for ISR—arguably the most challenging subset of patients we have to deal with. Real-world practice does confirm that covered stents are an especially attractive alternative for patients with long disease.

The recently published VIASTAR data are also very compelling.² VIASTAR was a seven-center EU study of 141 patients with an independent ultrasound core lab assessing patency at 1, 6, 12 months. This was a randomized trial of bare-metal stents (BMS)—SMART (Cordis Corporation, Bridgewater, NJ), LifeStent (Bard Peripheral Vascular, Inc., Tempe, AZ), and EverFlex (Covidien, Mansfield, MA)—versus the Viabahn covered stent. The two groups were fairly well matched, although the average lesion length was 17 cm in the bare-metal group and 19 cm in the Viabahn covered stent group. Seventy-two of the patients in this trial had TASC C and D lesions. To be eligible for the trial, the lesion length had to be between 10 and 35 cm. The 1-year primary patency rate for the Viabahn group was

78%, whereas in the bare-metal group, it was 54%. If you look at the data for lesion length > 20 cm, it was 73% for Viabahn versus 33% for the bare-metal group. We now have conclusive, evidence-based, level 1 clinical trial data for long lesion lengths supporting that covered stent performance is superior to BMS.

In the United States, we currently do not have drug-eluting balloons available, although the Zilver PTX stent (Cook Medical, Bloomington, IN) recently became available. In the ZILVER PTX registry, which was a real-world registry, the investigators were allowed to implant up to four 80-mm-long Zilver PTX stents for patients outside of the randomized trial.³ When you examine the subgroup analysis of that study in patients with long lesions > 14 cm, or patients with bare-metal in-stent restenosis (ISR), the primary patency rates at 1 year were 77%. This rate is good, but certainly not a panacea for long femoropopliteal disease.

How does mechanical flexibility factor into long-term results?

The distal superficial femoral artery and above-knee popliteal artery are subject to significant mechanical forces, and it should come as no surprise that stents develop fractures in that hostile environment. We know that certain stents seem to have a lower risk of stent fracture than others: Viabahn, because it is a single nitinol wire, and Supera (Idev Technologies, Inc., Webster, TX), which is not cut from a single tube of nitinol, but rather is six pairs of woven nitinol wire. These two stents seem to have the greatest degree of flexibility and the lowest reported incidence of stent

fracture. While one can debate the importance of stent fracture with regard to its relationship to patency, there are some earlier data that show a strong correlation between stent fracture and loss of primary patency.⁵ I think it is probably more related to what type of stent fracture you are talking about—type III and IV stent fractures seem to have a negative impact on patency.

What observations have been made, both anecdotally and in studies, regarding the amount and nature of restenosis with covered stents?

Primary patency is independent of lesion length in covered stents, and the pattern of restenosis is also markedly different. Because Viabahn is a covered stent, neointimal hyperplasia does not occur within the body of the graft, due to the physical barrier of the polytetrafluoroethylene. Restenosis at either the proximal or distal edge may still develop. Would you rather deal with a 1-cm edge stenosis or a 30-cm proliferative occlusion? I would rather tackle the former than the latter.

Patients with covered stents who develop restenosis are often not symptomatic with recurrent claudication, which is why it is critically important that these patients return for duplex surveillance ultrasound, especially in the first year after implantation. Most patients who develop an edge restenosis with a covered stent will have a normal resting ankle-brachial index. In my practice, I obtain a duplex at 1 month, then every 4 months for the first year, and every 6 months for 2 years. I still obtain a duplex at least once a year thereafter. Restenosis usually occurs within the first year.

What about the possibility of covered stents “going down hard” if they do go down?

This is such an integral part of this discussion. If you review clinical trial data of covered versus BMS (eg, VIBRANT and VIASTAR), there was no statistically significant difference in the incidence of acute limb ischemia—both groups had a very low incidence of < 4%. In the VIPER trial, only one patient in the entire 119-patient cohort had acute limb ischemia that required therapy. This patient was treated with thrombolytic therapy with a successful outcome.

Dr. Lensvelt's three-center study from Europe of stent-grafts for long SFA disease found that the incidence of acute limb ischemia was < 3% when the Viabahn graft did go down.¹⁰ In the majority of cases, this was successfully treated with thrombolytic therapy.

Review of the single-center studies and randomized trials reveals consistency of the data. They all show a < 4% incidence of acute limb ischemia in the event of stent graft thrombosis.

There is no question that for long lesion lengths, particularly chronic total occlusions, covered stents offer a distinct advantage. I hope operators will be encouraged and supported by these recent data to feel confident in adding stent grafts to their therapeutic toolbox.

Which factors might influence restenotic occurrence in covered stents, for better or worse?

One of the strengths of the VIPER study⁶ was the independent angiographic and ultrasound core labs. The angiographic core lab documented that in 30% of cases, the stent grafts were oversized (defined as > 20% larger than the vessel lumen at the proximal landing zone). If you look at the primary patency rates based on whether the stent was oversized, if the stent was not oversized by more than 20%, the primary patency rate at 12 months was 88% on the proximal end of the stent and 87% on the distal end, which is really remarkable. If you, as the operator, were meticulous in your vessel sizing, you could achieve a nearly 90% patency rate at 1 year. This is better than anything else out there right now. Clearly, proper sizing is of critical importance. In the VIBRANT trial completed several years ago, the 5-mm device was not available, resulting in stent grafts that were grossly oversized.⁷ It should come as no surprise that if you place a 6-mm stent in a 3-mm artery, you are probably going to have a problem with restenosis at the edges. Unquestionably, proper sizing has a dramatic affect on the likelihood of edge restenosis.

There is a common myth that you need at least three-vessel runoff or there is a higher risk of thrombosis or restenosis. The VIPER and VIASTAR trials demonstrated there was no difference in terms of patency between single-, double-, or three-vessel runoff. If I'm unsure about which size I should put in, IVUS is the best way to assess the true luminal diameter.

What are some things you routinely do in order to gain better outcomes, both in restenosis prevention and other areas?

With covered stents, we live and die by how meticulous we are with our technique. In the coronary arteries, we learned the concept of geographic miss long ago. If you balloon something and you don't cover it with a stent, you are going to have restenosis due to vessel injury. It is very important to keep track of your predilatation sites; if you ballooned it, it must be covered. After placing the Viabahn, it's critical to ensure the balloon isn't inflated outside the margins to avoid a higher likelihood of restenosis.

If the patient has significant inflow disease or outflow disease, it's important to treat it at the time of the

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stent graft implantation to provide brisk laminar flow coming into and exiting the stent graft. In our article about using the Viabahn for ISR, we performed inflow intervention in approximately 25% of cases, and outflow intervention in nearly 40%.¹ I suspect that's why our results were a little better than expected.

Lastly, operators can be too cute. It is much more important to cover all the disease and to stent from a healthy segment to a healthy segment than try to preserve a little collateral. Amir Motarjeme, MD, published a very interesting analysis where he looked at his early experience with Viabahn when trying to avoid covering collaterals.⁸ Concerned that this strategy could potentially cause competitive flow, he changed his practice pattern. Dr. Motarjeme found his patency rates and thrombosis rates were actually better when he covered all the disease, instead of stopping short to preserve individual collaterals. It is more important to cover all of the disease, just don't cover the profunda!

Do you use covered stents in treating in-stent restenosis with other devices? What are the pros and cons to this option?

One of the limitations of our study is that it was a single-center, nonrandomized cohort of patients. They were very well matched to those in other published trials, but it wasn't randomized data. However, we do have preliminary randomized data with regard to the RELINE trial recently completed in Europe. Thomas Zeller, MD, is the primary investigator for the RELINE trial, which examined covered stents versus angioplasty for bare-metal ISR. Marc Bosiers, MD, presented the 6-month outcomes of RELINE at LINC this year, demonstrating that at 6 months, there was already a significant difference showing a 95% primary patency rate in the covered stent group, versus only 55% in the percutaneous transluminal angioplasty group.⁹

What changes have you seen since the Viabahn platform began to incorporate a heparin coating?

Early patency data with the old 5-mm device were less compared to the 5- and 6-mm diameters. However,

in VIPER, there was no patency difference among the 5-, 6-, and 7-mm devices, suggesting that the improved performance of the 5-mm device may be related to less oversizing and thromboresistance from the heparin coating.

What other technological changes might further improve restenosis rates in covered stents?

There are several investigators examining ways to decrease the incidence of edge restenosis with covered stents, which is the Achilles' heel of this particular device. Operators have been using the TAPAS catheter (TherapeuticX, Inc., San Diego, CA, distributed by Spectranetics Corporation, Colorado Springs, CO), or the Clearway RX (Atrium Medical Corporation, Hudson, NH) to deliver paclitaxel to the edges with the hope of preventing restenosis. Drug delivery by means of an infusion balloon or some type of infusion catheter is an intriguing concept to try to prevent edge restenosis, as is the placement of drug to the ends of the stent graft. The burdensome and expensive regulatory process in the United States would certainly be a major challenge as well. In light of recent studies, covered stents should be considered as first-line therapy for patients with long occlusive femoropopliteal disease and ISR, provided vessels are > 4.5 mm with at least one patent runoff vessel. Patients must be able to comply with close duplex surveillance follow-up. ■

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1. Shamerri OA, Bitar F, Ghitelman J, Soukas PA. Viabahn for femoropopliteal in-stent restenosis. *Ann Saudi Med*. 2012;32:575-582.
2. Lammer J, Zeller T, Hausseger KA, et al. Heparin-bonded covered stents versus bare metal stents for complex femoro-popliteal artery lesions: the randomized VIABAHN trial. *J Am Coll Cardiol*. 2013; doi:10.1016/j.jacc.2013.05.079.
3. Zeller T, Dake MD, Tepe G, et al. Treatment of femoropopliteal in-stent restenosis with paclitaxel-eluting stents. *J Am Coll Cardiol Interv*. 2013;6:274-281.
4. Scheinert D, Scheinert S, Sax J, et al. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. *J Am Coll Cardiol*. 2005;45:312-315.
5. Saxon RR, Chevre A, Jones PA, et al. Heparin-bonded, expanded polytetrafluoroethylene-lined stent graft in the treatment of femoropopliteal artery disease: 1-year results of the VIPER (Viabahn endoprosthesis with heparin bioactive surface in the treatment of superficial femoral artery obstructive disease) trial. *J Vasc Interv Radiol*. 2013;24:165-173.
6. Geraghty PJ, Mewissen MW, Jaff MR, Ansel GM; VIBRANT Investigators. *J Vasc Surg*. 2013;58:386-395.
7. Lensvelt MM, Golchroo B, Kruse RR, et al. The outcome of failed endografts inserted for superficial femoral artery occlusive disease. *J Vasc Surg*. 2013;57:415-420.
8. Motarjeme A. Collateral arteries: to cover or not to cover? *Endovasc Today*. 2012;8:27-33.
9. Bosiers M. RELINE study: Randomized comparison of endoluminal grafting with Viabahn vs. PTA for femoral artery in-stent restenosis—6 months results. Presented at: LINC 2013; January 24, 2013; Leipzig, Germany.