Data-Driven Treatment Approach to In-Stent Restenosis

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More than 81 million Americans are affected by some form of cardiovascular disease.[1,2] Peripheral artery disease (PAD) is a growing public health concern in the United States and affects 8 million Americans.[2,3] Left untreated, PAD can result in increasingly morbid outcomes.[4] Endovascular revascularization of occluded arteries is the ideal course of treatment. Placement of stents is the standard course of treatment for occluded coronary arteries; however, stent placement presents unique challenges when used in the peripheral arteries due to the dynamic stresses and motion of the arteries. Furthermore, in-stent restenosis (ISR) due to neointimal hyperplasia after stent implantation has plagued the field and has emerged as the Achilles' heel of this era of vascular interventions.

Although there have been promising developments in treating ISR, data supporting these novel therapies have lagged behind. This article details the results from three randomized trials comparing different therapies to standard percutaneous transluminal angioplasty (PTA) for ISR: the FAIR trial, which looked at drug-coated balloons (DCBs); the EXCITE ISR trial, which studied excimer laser atherectomy (ELA); and the RELINE trial, which analyzed the use of the GORE® VIABAHN® Endoprosthesis.

PATHOPHYSIOLOGY

ISR can be defined either clinically or angiographically. Clinically, it is defined as hemodynamically significant stenosis within a stent causing recurrent ischemia. Angiographically, it is defined as the presence of > 50% diameter stenosis within a stent.[5]

The artery can be divided into three distinct layers: the intima consisting of endothelial cells, the media made up of smooth muscle cells, and the adventitia made up of collagen fibers and fibroblasts. Balloon angioplasty and stenting of an artery induces a localized inflammatory response, which precipitates neointimal proliferation and tissue growth.[6,7] Peripheral arteries undulate and are subjected to the triplanar intermittent stresses of compression, flexion, and torsion. The placement of a stent inhibits the artery's natural movement. Furthermore, current nitinol stent systems are oversized for use in peripheral arteries and result in chronic outward radial force that causes long-term inflammation. Thus, the placement of the stent results in mechanical trauma to the walls of the artery, which in turn triggers an inflammatory response. The basement membrane of the media is fractured, resulting in a phenotypic switch of the smooth muscle cells from quiescent to proliferative. The mechanical trauma results in inflammation in the adventitia, which acts as positive feedback for the phenotypic switch of the smooth muscle cells of the media and also results in further proliferation of fibrotic cells. The proliferation and fibrosis in these two layers ultimately manifests in the migration of this overgrowth into the media, resulting in neointimal hyperplasia.[8,9]

Cellular proliferation can potentially result in significant ISR, thereby causing recurrence or deterioration of clinical symptoms, necessitating target lesion revascularization (TLR). Several anatomic and clinical risk factors increase the overall occurrence of restenosis, including longer lesion lengths, smaller vessel diameters, and diabetes mellitus.[10]

INCIDENCE OF IN-STENT RESTENOSIS

Stent placement in peripheral arteries is associated with a high rate of ISR; it has been reported to occur in up to 40% of femoropopliteal lesions treated with bare-metal stents within 1 year of treatment.[11-13] The most common course of treatment after ISR is PTA; however, nearly 65% of patients will return with ISR following this retreatment within 2 years. Recently, the VIASTAR trial showed a 1-year ISR rate of 45% and a 2-year rate of 58.8% in bare-metal stents and 36.9% at 2 years with the GORE VIABAHN Device.[14]

CLASSIFICATION

A classification scheme for management of ISR lesions was recently proposed by Tosaka et al.[15] The lesions are classified by visual estimate on angiography (Figure 1):

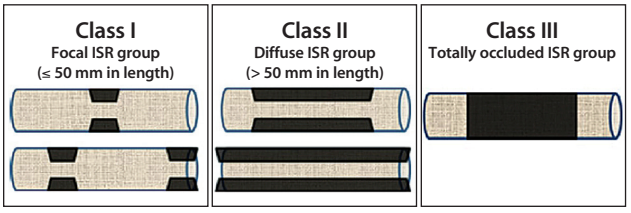


Figure 1. Visual estimate of lesion classification on angiography. Reprinted from J Am Coll Cardiol, Vol 59, Tosaka A, Soga Y, Iida O, et al, Classification and clinical impact of restenosis after femoropopliteal stenting, pg 16-23, Copyright 2012, with permission from Elsevier.[15]

- Class I: the focal (≤ 50 mm in length) ISR group; includes lesions within the stent body, edge, or a combination.
- Class II: the diffuse (> 50 mm in length) ISR group; includes stent body and edge lesions.
- Class III: the totally occluded ISR group; includes chronic occlusion within the entire length of the stent.

A classification system, such as the Tosaka classification, allows for targeted optimal therapy based on the disease state. Similar to the TASC classification system[16] for de novo PAD, the Tosaka classification could dictate the best evidence-based treatment strategies for each tier of the classification system.

DATA LANDSCAPE

Treatment options for ISR include PTA, cutting or scoring balloons, atherectomy devices, covered stent systems, DCBs, drug-eluting stents, and/or direct drug delivery. In an initial study conducted by Dick et al comparing the rates of binary ISR after using either conventional PTA or cutting-balloon angioplasty, it was found that both treatments were ineffective and were associated with a 6-month restenosis rate of 73%.[17] Most reports of ISR treatment have been single-center, observational studies with limited follow-up. However, there have been three recent multicenter, prospective, randomized trials comparing therapeutic options for the treatment of ISR: the EXCITE ISR trial, the FAIR trial, and the RELINE trial.

EXCITE ISR Trial

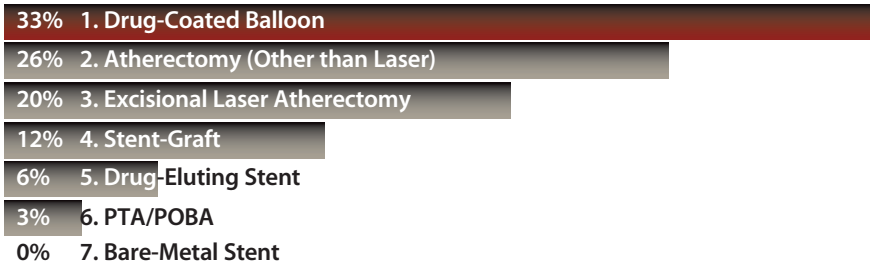
The EXCITE ISR trial was a multicenter, randomized study that aimed to compare the efficacy of ELA and PTA versus conventional PTA alone in treating femoropopliteal ISR. The study was the

ASK THE EXPERTS

Expert panel indicated that the GORE VIABAHN Device is the therapy they are most likely to use in long, Tosaka Class II lesions and Tosaka Class III ISR occlusions.

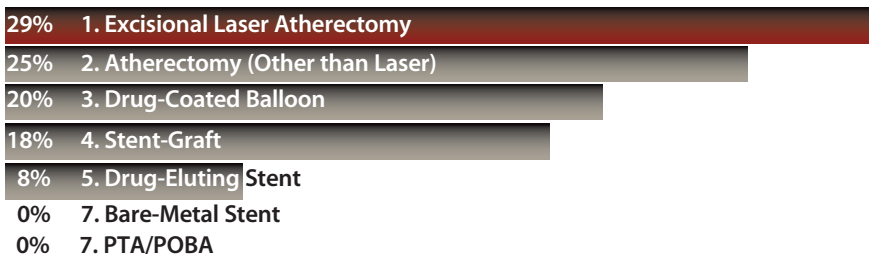
4-cm Tosaka Class I Lesion

In order of primacy, which three therapies are you most likely to use as your primary treatment for a 4-cm stenosed ISR lesion (Tosaka Class I) presenting for the first time as an ISR lesion?



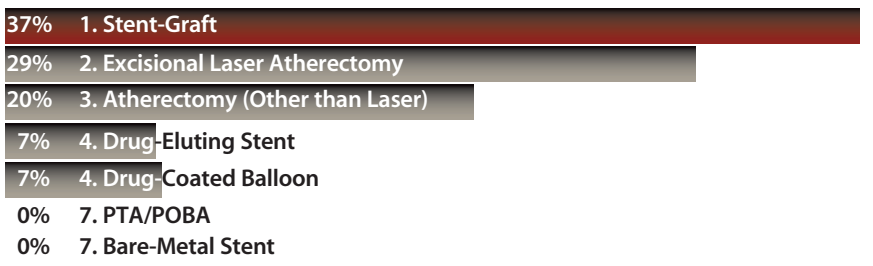
10-cm Tosaka Class II Lesion

In order of primacy, which three therapies are you most likely to use as your primary treatment for a diffusely stenosed 10-cm ISR lesion (Tosaka Class II) that required one intervention 14 months ago?



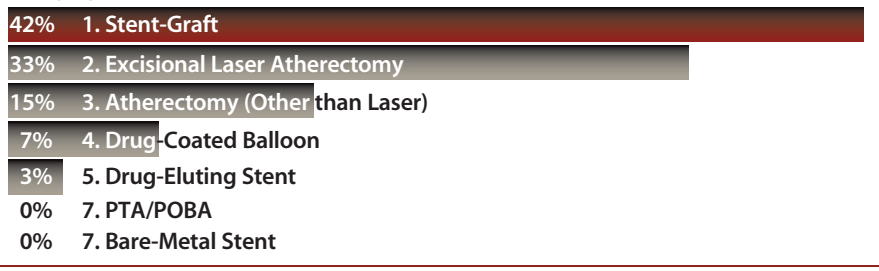
17-cm Tosaka Class II Lesion

In order of primacy, which three therapies are you most likely to use as your primary treatment for a diffusely stenosed 17-cm ISR lesion (Tosaka Class II) that required three interventions in the past 18 months?



20-cm+ Tosaka Class III Lesion

In order of primacy, which three therapies are you most likely to use as your primary treatment for a chronically occluded stent with a stenosed length of 20+ cm (Tosaka Class III) that required multiple prior reinterventions?



first randomized trial to demonstrate the benefits of utilizing atherectomy in combination with PTA in the lower extremities.[18] There were 250 patients randomized 2:1 between 2011 and 2014 at 40 sites. The primary efficacy endpoint of the study was determined by freedom from clinically driven TLR at 6 months. This included binary restenosis (unspecified peak systolic velocity ratio), return of clinical symptoms, and deteriorated ankle-brachial index or Rutherford classification.

The study included real-world, long ISR lesions averaging 19.6 cm in the ELA+PTA arm and 19.3 cm in the PTA-alone arm. The use of ELA resulted in a significantly higher procedural success rate of 93.5% compared with 82.7% for PTA alone ($P = 0.03$). The use of ELA was also associated with a significantly higher rate of freedom from major adverse events compared with PTA alone (94.2% vs 79.2%, respectively; intent-to-treat, $P < 0.001$). Lastly, the ELA+PTA arm demonstrated both a significantly higher patency rate (approximately 40% for ELA+PTA vs 20% for PTA) at 12 months and a higher rate of freedom from TLR after 12 months (approximately 47% for ELA+PTA vs 28% for PTA).

FAIR Trial

The FAIR trial was a randomized, controlled trial aimed at assessing the efficacy of DCB angioplasty to standard PTA in treating ISR of the superficial femoral artery. There were 119 patients randomized 1:1 at five sites. The primary endpoint of the trial was the 6-month binary restenosis rate (> 50%) as evidenced by duplex ultrasound with a peak systolic velocity ratio > 2.4. The secondary endpoints included technical success of access and treatment resulting in < 50% residual stenosis. Additionally, the study aimed to measure 12-month recurrent ISR of > 50% and freedom from TLR at 6 months and 12 months. Overall, the FAIR trial looked at shorter lesions, averaging approximately 8.2 cm in length in both study arms. At 12 months, there was a significant improvement in primary patency in the DCB group (DCB, 70.5% vs standard PTA, 38.5%; $P = 0.004$). Freedom from clinically driven TLR also increased in the DCB group (DCB, 90.8% vs standard PTA, 52.6%; $P < 0.0001$).[19,20]

THE GORE VIABAHN DEVICE FOR IN-STENT RESTENOSIS

The GORE VIABAHN Device has been applied in the treatment of ISR lesions for many years, and in theory, this ePTFE-lined endoprosthesis may be a more attractive alternative by virtue of the fact that recurrence risk is independent of lesion length.[14] The SALVAGE trial, a prospective, single-arm trial of ELA followed by implantation of a GORE VIABAHN Device in ISR lesions, supported the safety of this approach with a decreased need for repeat revascularization (17.4% at 12 months).[21] Kazemi et al reported a 65% 12-month primary patency rate for 17 patients with ISR and an average lesion length of 15 cm.[22] Ansel et al noted a 65% 12-month primary patency rate for 27 patients with an average lesion length of 26 cm.[23] Monahan et al reported a 62% 12-month primary patency rate in 24 patients,[24] and Gorgani et al reported a 63% primary patency rate at 24 months for 22 patients with an average lesion length of 21.4 cm.[25] Al-Shammeri et al noted 83% 12-month and 81% 36-month primary patency rates for 27 patients with an average lesion length of 24.4 cm.[26] Of note, 35.7% of patients in this series were treated with adjunctive ELA before stent graft implantation, 25% of patients received concomitant inflow interventions, and 39% were treated with outflow interventions.

Prompted in part by these very encouraging findings of the application of the GORE VIABAHN Device in ISR lesions, a prospective, multicenter, randomized trial of PTA versus the GORE VIABAHN Device for the treatment of femoropopliteal ISR lesions (RELINE trial) was conducted.

RELINE Trial Design

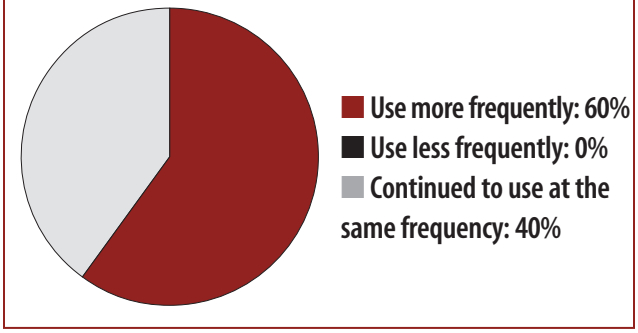
The RELINE clinical study was a prospective, randomized trial conducted at seven centers in Europe comparing the GORE VIABAHN Device versus PTA for the treatment of ISR of the superficial femoral artery.[27] This study was designed as a real-world trial that sought to enroll a wide range of patients (Rutherford category 2–5) with ISR of the superficial femoral artery with a wide range of lesion lengths (4–27 cm) and with a minimum of one vessel runoff that did not require intervention. Key exclusion criteria were untreated, flow-limiting inflow stenoses; aneurysms of the superficial femoral artery; no intact runoff vessel; and a documented history of type 2 heparin-induced thrombocytopenia.[27]

RELINE Trial Enrollment

This trial prospectively randomized 100 patients to PTA treatment or GORE VIABAHN Device implantation 1:1. Fifty-three patients were randomized to PTA, and 47 patients were randomized to the GORE VIABAHN Device. Nine patients in the PTA arm and eight patients in the GORE VIABAHN Device arm were excluded due to inclusion/exclusion and/or procedural violations. This left 44 patients in the PTA arm

ASK THE EXPERTS

How will the data from the RELINE trial impact your use of the GORE VIABAHN Device for ISR?



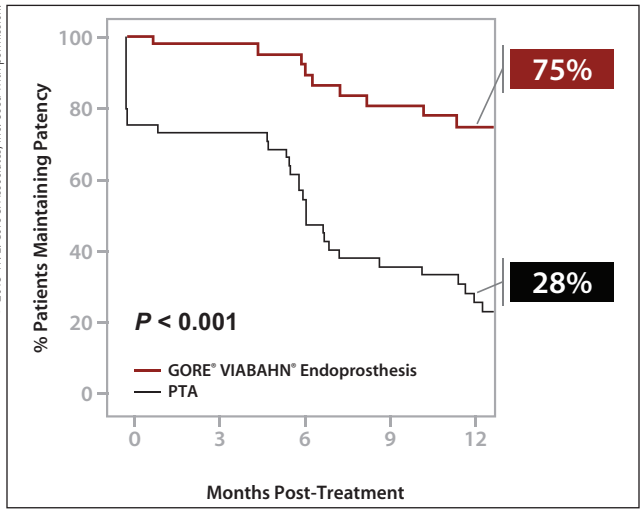


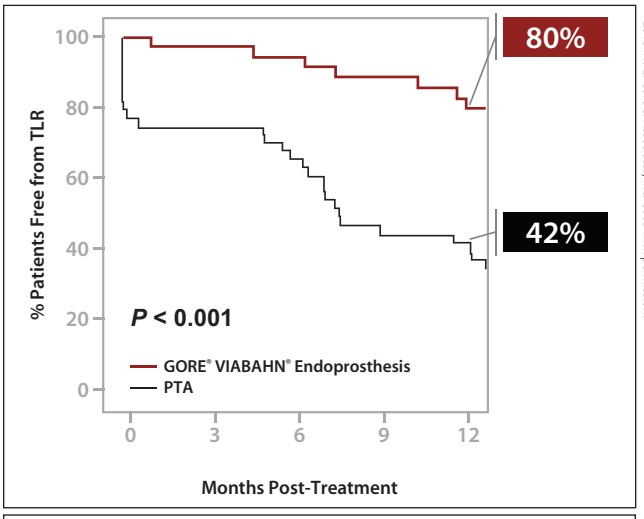
Figure 2. Twelve-month primary patency rates for the GORE VIABAHN Device compared to PTA in the per-protocol analysis.

TABLE 1. 12-MONTH PRIMARY PATENCY

	GORE VIABAHN Device	PTA	*P* Value
Intent-to-treat	72.5%	24.2%	< 0.001
Per-protocol	75%	28%	< 0.001
Optimal PTA (as treated)	75%	37%	< 0.001

TABLE 2. FREEDOM FROM TLR AT 12-MONTH FOLLOW-UP

	GORE VIABAHN Device	PTA	*P* Value
Intent-to-treat	81%	41%	< 0.001
Per-protocol	80%	42%	< 0.001
Optimal PTA (as treated)	80%	54%	< 0.001



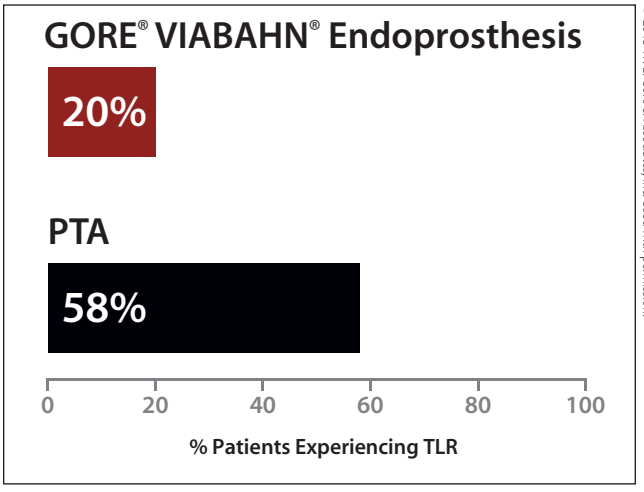


Figure 3. At 12 months, TLR rates were almost three times higher for patients who received PTA versus those who were treated with the GORE VIABAHN Device (Kaplan-Meier estimates of freedom from TLR in the per-protocol analysis).

and 39 patients in the GORE VIABAHN Device arm available for per-protocol analysis. The vast majority of patients enrolled were Rutherford category 2 or 3 (only 21% in the PTA arm and 13% in the GORE VIABAHN Device arm were Rutherford category 4 or 5). Approximately one-third of the patients in both treatment groups were diabetic, and approximately 40% were current smokers in both groups.

RELINE Trial Results

The mean lesion length was 19 cm (range, 3–27 cm) in the PTA arm and 17.3 cm (range, 3–33 cm) in the GORE VIABAHN Device arm. There were nine bailout stent procedures after failed PTA in the PTA arm and none in the GORE VIABAHN Device arm. The as-treated ("optimal PTA") analysis excluded the nine patients who underwent bailout stenting.

At 12 months, the primary patency rate was 28% in the PTA arm and 75% in the GORE VIABAHN Device arm (Figure 2 and Table 1).

The 12-month primary patency according to intent-to-treat, per-protocol, and optimal PTA analyses all demonstrated a highly statistically significant difference between the two arms of the study (Table 1). The percentage of patients requiring TLR up to 12 months was three times lower for the GORE VIABAHN Device arm (Figure 3 and Table 2).

Device-related adverse events were infrequent in both treatment arms at 5.8% in the PTA arm and 2.2% in the GORE VIABAHN Device arm ($P = 0.62$). Zero GORE VIABAHN Device fractures were identified by the core angiographic laboratory. At 12 months, clinical success was maintained (at least one Rutherford category improvement in claudication symptoms) in 85% of patients in the PTA arm and 94% of patients in the GORE VIABAHN Device arm ($P = 0.139$).

RELINE Trial Conclusions

This prospective, randomized trial demonstrated superiority of the GORE VIABAHN Device as compared with PTA in

the treatment of restenotic nitinol stents in the superficial femoral artery, with superior primary patency at 12 months, and an approximately threefold reduction in the number of patients requiring a TLR rate at 12 months. This trial also demonstrated a low incidence of serious device-related adverse events in both arms of the study and an absence of fracture of the GORE VIABAHN Device in this application.

TABLE 3. RECENT RANDOMIZED, PROSPECTIVE, MULTICENTER ISR TRIALS

	FAIR Trial		EXCITE ISR Trial		RELINE Trial	
	IN.PACT Drug-Coated Balloon (Medtronic)	PTA	ELA + PTA (Spectranetics Corporation)	PTA	GORE VIABAHN Device	PTA
Mean lesion length (cm)	8.2	8.2	19.6	19.3	17.3	19
% CTOs	24%	33%	31%	37%	23%	25%
Moderate to severe calcification	10%*	9%*	27%	9%	33%	25%
Primary patency at 12 months	70.5%	37.5%	40%**	20%**	75%	28%
Freedom from TLR at 12 months	91%	53%	47%**	28%**	80%	42%

*RELINE trial and EXCITE ISR trial report "moderate to severe calcification," while the FAIR trial reports only "heavy calcium."
**1-year estimates based on Kaplan-Meier curves.[17]

RANDOMIZED TRIALS IN PERSPECTIVE

The RELINE clinical study demonstrated superiority of the GORE VIABAHN Device as compared with PTA in the treatment of femoropopliteal ISR lesions. The only other prospective, multicenter, randomized trials evaluating other treatments compared with PTA were the EXCITE-ISR trial of ELA and the FAIR trial of paclitaxel DCBs.[18,20] Although comparisons of these trials are complicated by the fact that the patient populations and average lesion lengths varied, it appears the application of the GORE VIABAHN Device is associated with a very favorable 12-month primary patency rate and freedom from need of repeat intervention (Table 3).

Tosaka et al established that lesion length and/or the presence of a stent occlusion are predictors of patency and the need for subsequent reintervention in ISR lesions undergoing PTA.[14]

ELA enhances the outcomes after treatment of ISR lesions with DCBs.[28] Whether ELA (or other forms of atherectomy) also enhances the performance of the GORE VIABAHN Device in ISR lesions is not established, as the SALVAGE trial was a single-arm trial.

RANDOMIZED TRIAL SUMMARY

ISR continues to be a prevalent problem in the field of peripheral endovascular interventions. As the impact of PAD on health care resources increases in the United States, the need for devices that can answer the problem of restenosis is critical. The

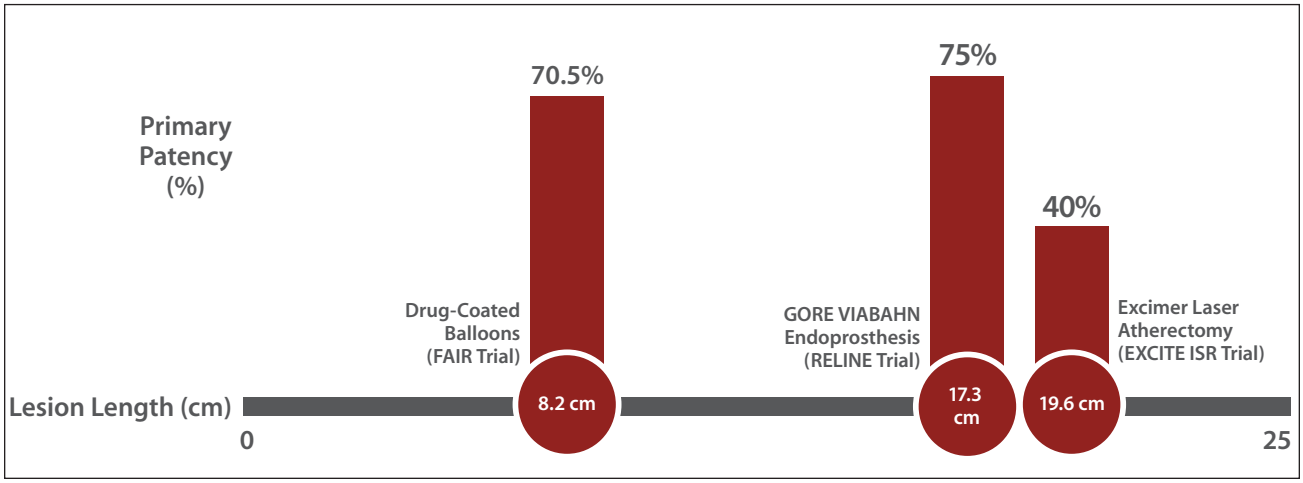


Figure 4. Twelve-month primary patency for ISR by lesion length.[18,20,27] The EXCITE-ISR trial and RELINE trial evaluated longer lesion lengths (over 17 cm) compared with the short mean lesion length of 8.2 cm in the FAIR trial.

"In summary, the limited number of multicenter, prospective, randomized ISR trials highlight the remarkable performance of the GORE VIABAHN Device in a patient population where other therapies either are not studied or underperform.

data landscape of randomized, controlled trials is scant. The FAIR trial, EXCITE ISR trial, and RELINE trial have demonstrated the benefit of new and innovative strategies to tackle this clinical challenge.

Both the EXCITE-ISR trial and the RELINE trial studied similar "real-world" long lesion lengths of over 17 cm as compared with the short mean lesion length of 8.2 cm in the FAIR trial (Figure 4). Despite being studied in lesions over twice as long as in the FAIR trial, the primary patency at 12 months was numerically greater for the GORE VIABAHN Device in the RELINE trial. In contrast to the relatively poor performance of ELA in long ISR lesions, the GORE VIABAHN Device demonstrated exceptional patency in these lesions.

In summary, the limited number of multicenter, prospective, randomized ISR trials highlight the remarkable performance of the GORE VIABAHN Device in a patient population where other therapies either are not studied or underperform. ■

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