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Three-Year Follow-up of Patients With Iliac Occlusive Disease Treated With the Viabahn Balloon-Expandable Endoprosthesis

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Abstract

Purpose: To assess the midterm safety and effectiveness of the Gore Viabahn Balloon-Expandable Endoprosthesis (VBX Stent-Graft) in the treatment of patients with de novo or restenotic aortoiliac lesions. **Materials and Methods:** The prospective, multicenter, nonrandomized, single-arm VBX FLEX clinical study (*ClinicalTrials.gov* identifier: NCT02080871) evaluated 134 patients (mean age 66 ± 9.5 years; 79 men) up to 3 years after treatment with the VBX Stent-Graft. A total of 213 lesions were treated with 234 stent-grafts. The primary safety endpoint was a composite of major adverse events (MAEs), which were evaluated through 30 days and 9 months. Secondary outcomes collected through 3 years included freedom from target lesion revascularization (TLR), target vessel revascularization (TVR), clinically-driven TLR (CD-TLR), and CD-TVR as well as Rutherford category, resting ankle-brachial index (ABI), and functional status. A univariate analysis determined any correlation between baseline variables and TLR. **Results:** The observed composite percentage of MAEs was 2.3%, well below the 17% performance goal ($p<0.001$). Of the 134 patients in the per protocol analysis, 107 (80%) completed the study. The 1-year Kaplan-Meier estimate of primary patency was 94.5% and assisted primary patency was 99.0%. The estimate of freedom from TLR per-lesion/vessel was 97.6% at 9 months and 91.2% at 3 years. The 9-month estimate of freedom from CD-TLR was 98.6% and the 3-year estimate was 98.1%. The 3-year mean resting ABI was 0.93 ± 0.19, an improvement of 0.17 ± 0.26 from baseline ($p<0.001$). At 3 years, 82 patients (92.1%) improved ≥1 Rutherford category from baseline, and 77 patients (86.5%) maintained or improved upon their baseline functional status. **Conclusion:** The VBX Stent-Graft is a robust and durable treatment option for aortoiliac occlusive disease as evidenced by the sustained 3-year safety and effectiveness outcomes.

Keywords

aortoiliac occlusive disease, balloon-expandable stent, covered stent, peripheral artery disease, stent-graft, target lesion revascularization

Introduction

Peripheral artery disease (PAD) is a highly prevalent global health concern that adversely affects quality of life; however, the implications of the disease extend beyond the patients' overall health.[1-3] In 2010, Mahoney et al[2] emphasized the high economic burden associated with PAD treatment in the United States.[2]

Aortoiliac occlusive disease (AIOD) accounts for approximately one-third of all PAD cases in the United States.[4] Bismuth et al[5] previously detailed the discourse surrounding open surgical repair vs endovascular intervention for the treatment of AIOD.[5] While endovascular procedures are recommended for the treatment of AIOD, especially in patients with TransAtlantic Inter-Society Consensus II (TASC II) A or B lesions, advances in stent technology allow physicians to treat TASC II C and D

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lesions as well.[6] These patients also exhibited better early and late clinical success rates when undergoing primary stenting instead of balloon angioplasty followed by selective stenting.[7] The debate has now evolved to whether a bare metal or covered stent is best suited for patients with AIOD.

A clinical study first reported in 2017[5] evaluated the Gore Viabahn Balloon-Expandable Endoprosthesis (referred to as the VBX Stent-Graft; W. L. Gore & Associates, Flagstaff, AZ, USA) for treatment of AIOD patients with de novo or restenotic lesions in the common/external iliac arteries. The 9-month data from the study indicated good short-term outcomes.[5] The study investigators now report the 3-year results from the same patient population to ascertain midterm safety and efficacy of the VBX Stent-Graft.

Materials and Methods

Study Design and Patient Enrollment

The prospective, multicenter, nonrandomized, single-arm VBX FLEX clinical study (*ClinicalTrials.gov* identifier: NCT02080871) evaluated the safety and efficacy of the VBX Stent-Graft in patients with challenging AIOD. The study design, patient enrollment, ethical considerations, and study procedures are discussed in detail in the initial report from the pivotal trial[5] and are summarized here.

A total of 140 patients with tortuous iliac arteries, severe lesion calcification, total occlusions, and a need for direct or kissing stents at the aortic bifurcation were enrolled at 27 sites around the United States and New Zealand between December 2013 and August 2015. Six subjects (Table 1) from the original intention-to-treat population did not meet the eligibility criteria,[5] leaving 134 patients (mean age 66 ± 9.5 years; 79 men) in the per protocol analysis. The most common comorbidities were smoking (127, 94.8%) hypertension (113, 84.3%), hyperlipidemia (104, 77.6%), and coronary artery disease (56, 41.8%).[5] Approximately 75% of patients presented with a baseline Rutherford category of 3 or higher; almost a third of patients had TASC II C/D lesions (Table 2). Most lesions (182, 86.7%) were characterized as stenosis rather than occlusion. The mean maximum stenosis was $62.1\% \pm 15.9\%$, and the average lesion length was 26.6 ± 16.3 mm. A total of 213 lesions were treated with 234 stent-grafts.

The study participants were scheduled for evaluation through hospital discharge and had follow-up visits at 30 days, 9 months, and annually through 3 years. Clinical evaluations conducted during follow-up included assessment of antiplatelet/anticoagulation therapy, Rutherford category, resting ankle-brachial index (ABI)/toe-brachial index (TBI), the EQ-5D health status measurement tool in 5 dimensions (EuroQol, Rotterdam, the Netherlands; available at *http://www.euroqol.org/eq-5d-products/eq-5d-3l.html*), the walking impairment questionnaire (WIQ), and adverse events. Iliac artery duplex ultrasound was performed at visits up to 12 months and as clinically indicated thereafter. Similarly, angiography was scheduled only as indicated.

Ultrasound and angiography imaging analyses were performed by 2 independent core laboratories: VasCore (Boston, MA, USA) and Yale University Angiographic Laboratory (New Haven, CT, USA), respectively. An independent Data Safety Monitoring Board reviewed safety trends and a Clinical Events Committee adjudicated adverse

Table 1. Subject Enrollment and Compliance.[a]

ITT cohort	140
Excluded from per protocol analysis	6 (4.3)
Previous bypass in target limb at enrollment	3 (2.1)
Gangrene at time of enrollment	1 (0.7)
Inadequate ipsilateral blood flow	1 (0.7)
Aneurysm blood flow interfered with device placement	1 (0.7)
Per protocol cohort	134
Completed the study	107 (79.9)
Discontinued the study	27 (20.1)
Withdrew consent	6 (4.5)
Investigator decision	2 (1.5)
Lost to follow-up	8 (6.0)
Death	8 (6.0)
Other	3 (2.2)

Abbreviation: ITT, intention to treat.
[a]Data are given as the number (percentage).

Table 2. Baseline Characteristics of the 134 Subjects in the Study and Procedure Outcomes.[a]

Age, y	66 ± 9.5
Men	79 (59.0)
Resting ABI (199 limbs)	0.77 ± 0.22
Rutherford category	
2	26 (19.4)
3	101 (75.4)
4	7 (5.2)
TASC II classification	
A	50 (37.3)
B	41 (30.6)
C	32 (23.9)
D	11 (8.2)
Kissing stent procedure	57 (42.5)
Technical success[b]	134 (100)
Procedural success[c]	130 (97.0)

Abbreviations: ABI, ankle-brachial index; TASC, TransAtlantic Inter-Society Consensus.
[a]Continuous data are presented as the mean $\pm$ standard deviation; categorical data are given as the number (percentage).
[b]Technical success is defined as successful device delivery.
[c]Procedural success is defined as residual stenosis $\leq$30% at completion and freedom from device-/procedure-related serious adverse events.

events to discern any relationship with the device, procedure, and disease.

Study Outcomes

The primary study endpoint was major adverse events (MAEs) at 30 days, including myocardial infarction, device-/procedure-related death, and target lesion revascularization (TLR) or vascular event–related amputation above the metatarsals in the treated leg through 9 months.

The secondary outcomes evaluated in the study were acute procedural and 30-day clinical success; primary, primary assisted, and secondary patency rates through 12 months; freedom from TLR and clinically-driven TLR (CD-TLR) and target vessel revascularization (TVR) and CD-TVR; and changes in Rutherford category, resting ABI or TBI, and functional status from baseline to follow-up.

Definitions

An adverse event was any investigator-reported medical occurrence experienced by a study participant, whereas a serious adverse event (SAE) was an occurrence that led to deterioration, impairment, hospitalization, reintervention, or death. An unanticipated adverse device effect (UADE) was any serious adverse effect on health or safety as well as any life-threatening problem or death that was associated with the device.

TLR was a revascularization procedure occurring within the treatment segments using a percutaneous intervention, surgical bypass, thrombolysis, or other invasive means. Similarly, TVR was defined as the revascularization of the treated vessel with the same interventions as listed above. CD-TLR referred to treated segment revascularization when there was evidence of new ischemic signs, namely, target lesion diameter stenosis >50% or worsening of the Rutherford category stemming from the lesion. CD-TVR was similarly defined for revascularization of the treated vessel. In TVR cases free of clinical or functional ischemia, the lesion diameter stenosis had to be $\geq$70%.

Procedural success was defined as $\leq$30% residual stenosis at completion and freedom from device-/procedure-related SAEs until discharge. Thirty-day clinical success was an improvement of one or more Rutherford categories between baseline and 30 days and freedom from device-/procedure-related SAEs within 30 days.

Statistical Analysis

The study was designed around a null hypothesis that maintains at least 17% of subjects would experience the composite MAE endpoint when using the VBX Stent-Graft. This null hypothesis was tested using a binomial exact test with a 5% type I error rate. The Wilcoxon signed-rank test was used to test significance.

Kaplan-Meier estimates were calculated for freedom from TLR, TVR, CD- TLR, and CD-TVR, as well as primary, primary assisted, and secondary patency rates. Univariate analyses were conducted to reveal statistically significant relationships between TLR and sex, diabetes, hypertension, hyperlipidemia, coronary artery disease, prior treatment for PAD on study limb, Rutherford category, TASC II classification, proximal vessel diameter to device ratio, distal vessel diameter to device ratio, total number of segments, and total number of devices. The Fisher exact test and Mantel-Haenszel chi-square test were used to compare categorical variables; continuous variables were compared using the *t* test. Univariable analyses were also conducted to find any correlation between TLR and patient and lesions characteristics; multivariate modeling techniques could not be utilized due to the low number of TLR events observed in this study. The threshold of statistical significance was $p<0.05$. Statistical analyses were conducted using SAS software (version 9.3; SAS Institute, Inc, Cary, NC, USA).

Results

The initial report from the VBX FLEX study details the immediate procedure outcomes.[5] Of the 134 patients in the per protocol analysis, 107 (80%) completed the study (Table 1). The remaining patients were largely lost to follow-up (8, 6.0%), died (8, 6.0%), or withdrew consent (6, 4.5%). At the time of the index procedure 95% of patients were on antiplatelet therapy, more than half (60.4%) of those were on dual antiplatelet therapy. At 3-year follow-up, 95.9% remained on antiplatelet therapy (66.2% dual).

Primary Outcome

The observed composite percentage of MAEs was 2.3%, well below the 17% performance goal ($p<0.001$). There was no device-/procedure-related death or myocardial infarction reported within 30 days of the index procedure. While death after 30 days was not a primary endpoint, there were no device-/procedure-related deaths recorded through 3 years. Additionally, there were no amputations above the metatarsals reported over the course of the study. Three patients (2.3%) underwent TLR within 9 months of the index procedure.

Secondary Outcomes

Procedural success was 97.0% and 30-day clinical success was 90.8% (Table 2). The Kaplan-Meier estimates of primary, primary assisted, and secondary patency by lesion at 12 months were 94.5%, 99.0%, and 99.5%, respectively

Table 3. Kaplan-Meier Estimates of Secondary Outcomes Through 36 Months.

	Per Patient			Per Lesion/Vessel		
Outcomes	9 mo	24 mo	36 mo	9 mo	24 mo	36 mo
Freedom from TLR, %	97.7 (n=133)	93.1 (n=124)	91.4 (n=113)	97.6 (n=212)	92.3 (n=198)	91.2 (n=180)
Freedom from CD-TLR, %	98.5 (n=133)	97.7 (n=127)	97.7 (n=119)	98.6 (n=212)	98.1 (n=204)	98.1 (n=192)
Freedom from TVR, %	97.7 (n=133)	92.3 (n=124)	90.6 (n=112)	97.7 (n=216)	92.4 (n-202)	91.4 (n=184)
Freedom from CD-TVR, %	97.7 (n=133)	96.9 (n=127)	96.1 (n=118)	98.1 (n=216)	97.7 (n=208)	97.1 (n=195)

Abbreviations: CD, clinically driven; TLR, target lesion revascularization; TVR, target vessel revascularization.

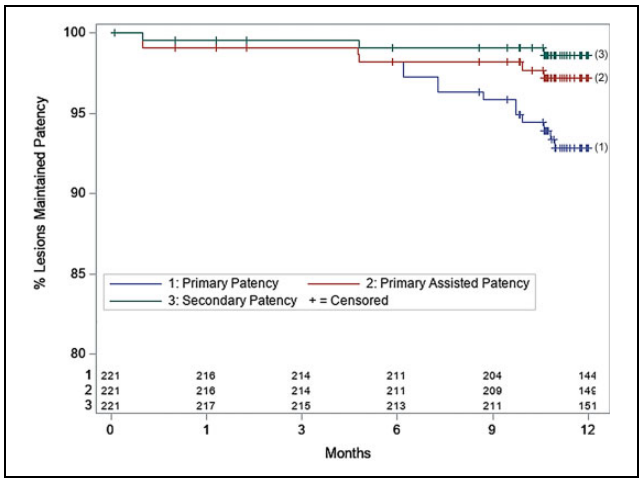

Figure 1. Patency (primary, assisted primary, and secondary) by lesion from baseline through 12-month follow-up.

(Figure 1). As shown in Table 3, the 9-month estimate of freedom from TLR per lesion was 97.6% (5 TLRs), which reduced to 91.2% (18 TLRs; Figure 2) in 3 years. CD-TLR estimates were 98.6% (3 CD-TLRs) and 98.1% (4 CD-TLRs) at 9 months and 3 years, respectively (Figure 2). Of the 217 vessels treated, 97.7% vessels (5 TVRs) were free from TVRs at 9 months and 91.4% of vessels (18 TVRs) at 3 years. The 9-month and 3-year rates of freedom from CD-TVR were 98.1% (4 CD-TVRs) and 97.1% (6 CD-TVRs), respectively. Through all time points, there was a minimal difference on a per-lesion vs per-patient basis (Table 3).

There were 12 lesions with edge stenosis among the overall 18 TLRs. Ad hoc angiographic analysis of patients with TLR revealed improper device selection and technical error were the two most common explanations for lesion revascularization. Undersizing <10% was present in 5 lesions, oversizing <10% was noted in 5 lesions, and oversizing >10% in only 2 instances (Figure 3).

At 9 months, 106 of 112 patients (94.6%) exhibited an improvement from their baseline Rutherford category; no patient experienced a decline (Figure 4) through 3 years. The majority of patients (82/89, 92.1%) saw an improvement in the Rutherford category from baseline ($p<0.001$). The mean ABI was 0.93 ± 0.19 at 3 years, which was

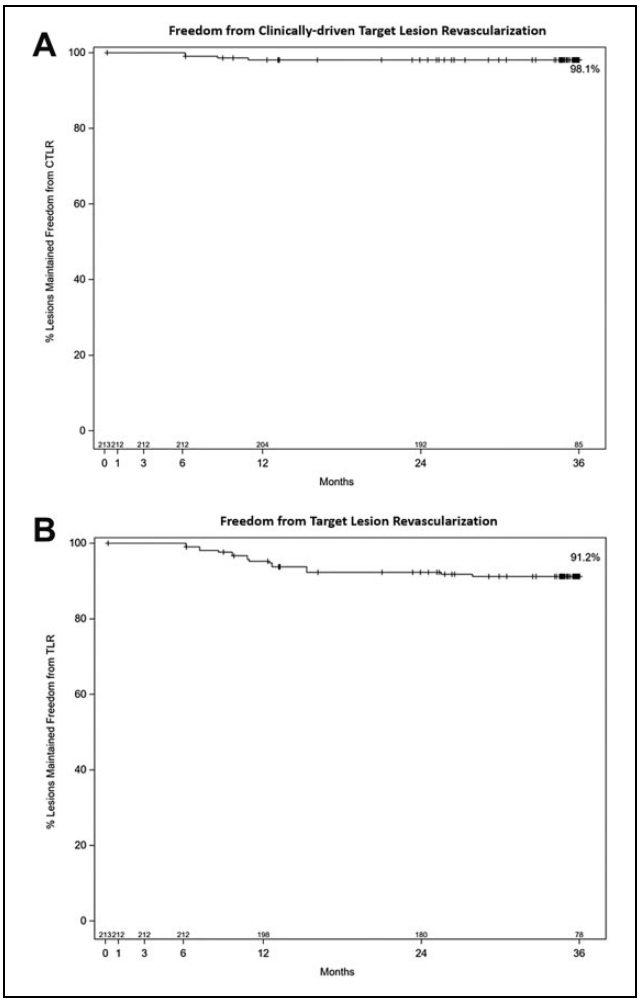

Figure 2. Freedom from (A) clinically driven target lesion revascularization (CD-TLR) and (B) TLR through 3-year follow-up.

0.17 ± 0.26 higher than the mean baseline ABI ($p<0.001$; Figure 5). The mean TBI was 0.46 at baseline and 0.61 at 3 years.

Over 85% of evaluable patients noted maintained or improved overall health status at each follow-up interval through 36 months. Median WIQ scores found improvement in walking status compared to baseline at all follow-up intervals (Figure 6).

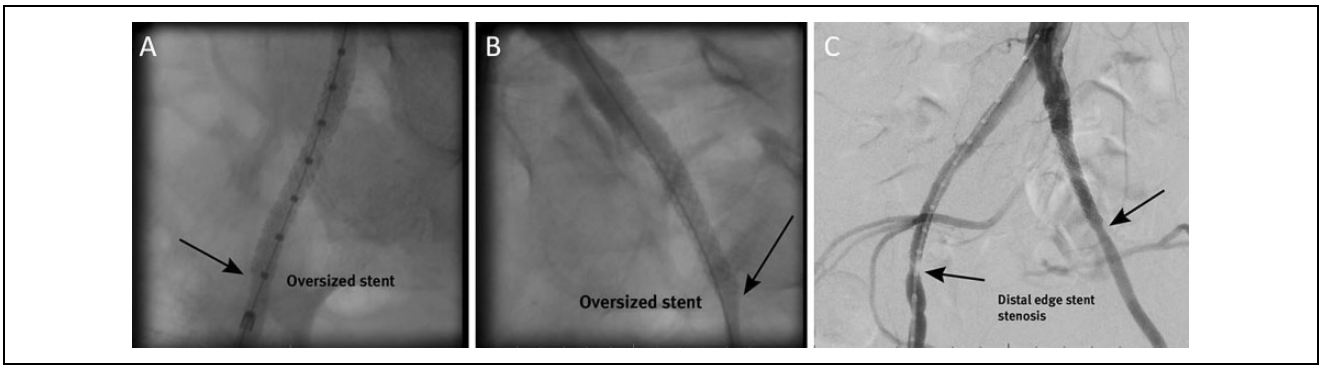

Figure 3. (A, B) Angiograms at the time of implantation in bilateral external iliac arteries showing stent oversizing. (C) Angiogram at 11 months after the index procedure showing restenosis at the distal edge of the stents bilaterally.

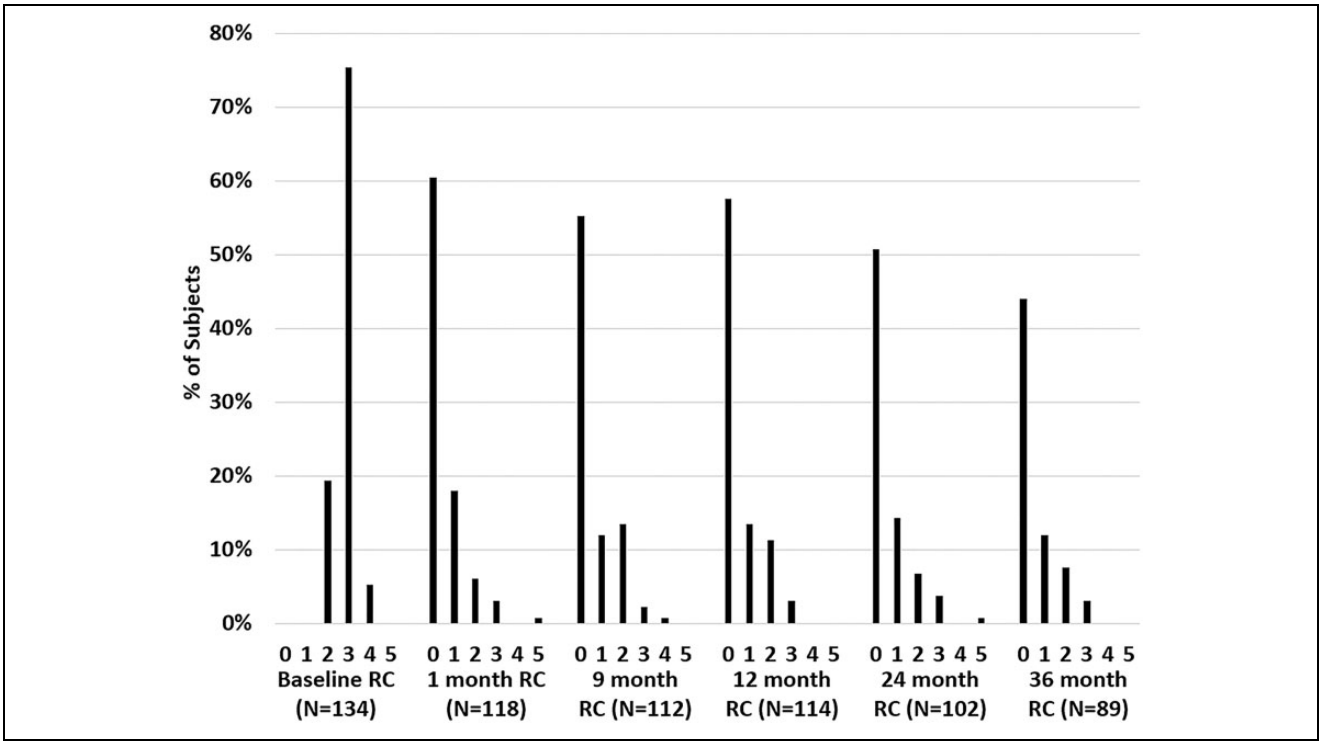

Figure 4. Distribution of Rutherford categories (RCs) from baseline to 3-year follow-up.

Adverse Events

Overall, there were 35 device-/procedure-related adverse events experienced by 24 patients (17.9%). There were also 11 device-/procedure-related SAEs arising in 8 patients (6.0%). Four SAEs occurred after the 9-month analysis and included 2 stent occlusions, 1 stent thrombosis, and 1 iliac artery occlusion. The 3 occlusion events were adjudicated to be related to the disease, whereas the stent thrombosis event occurring at 12 months was device related. All SAEs were resolved with treatment, and 2 SAEs warranted TLR (the stent occlusion at 2 years and the iliac artery occlusion). There were no UADEs or device deficiencies recorded over the course of the study.

Subgroup Analysis

The univariate analyses revealed 3 categorical variables correlated significantly with TLR (Table 4). The analysis found female patients required TLR more frequently compared to male patients (16.4% vs 2.5%, p=0.008). Additionally, TLR was required in 1.7% of patients with 1 treated segment as compared with 13.3% of patients with 2 or 3 treated segments (p=0.023). Lastly, there were 2.0%,

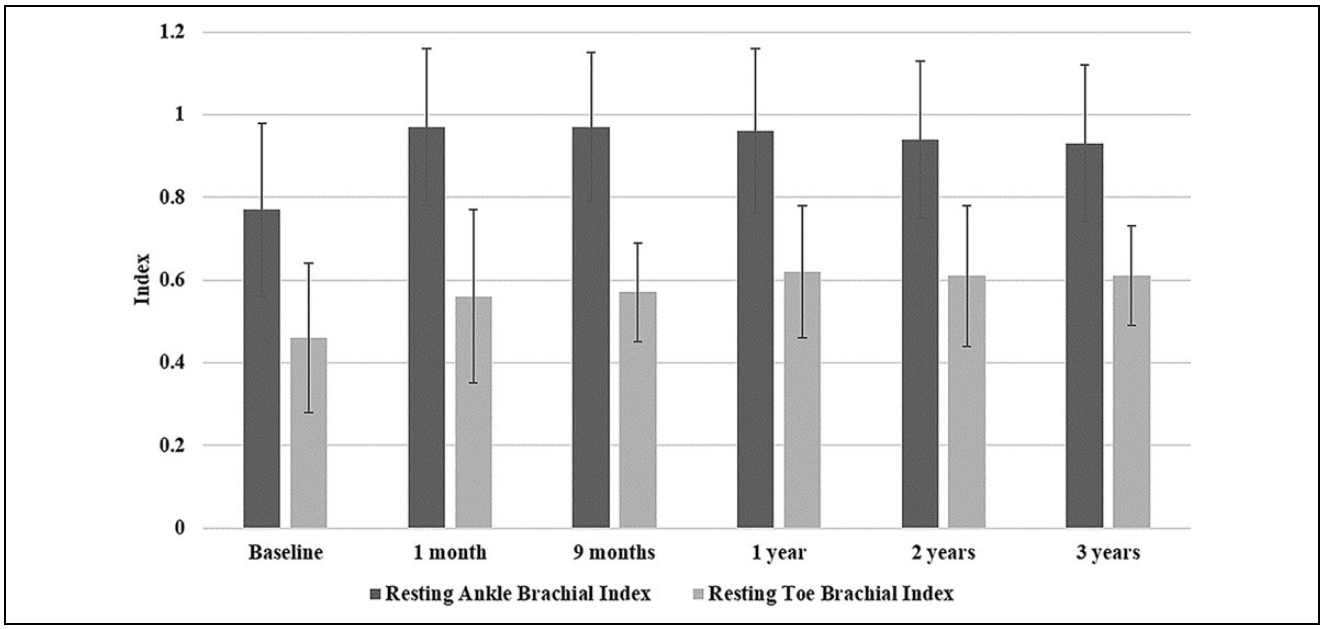

Figure 5. Ankle- and toe-brachial indices from baseline to 3-year follow-up.

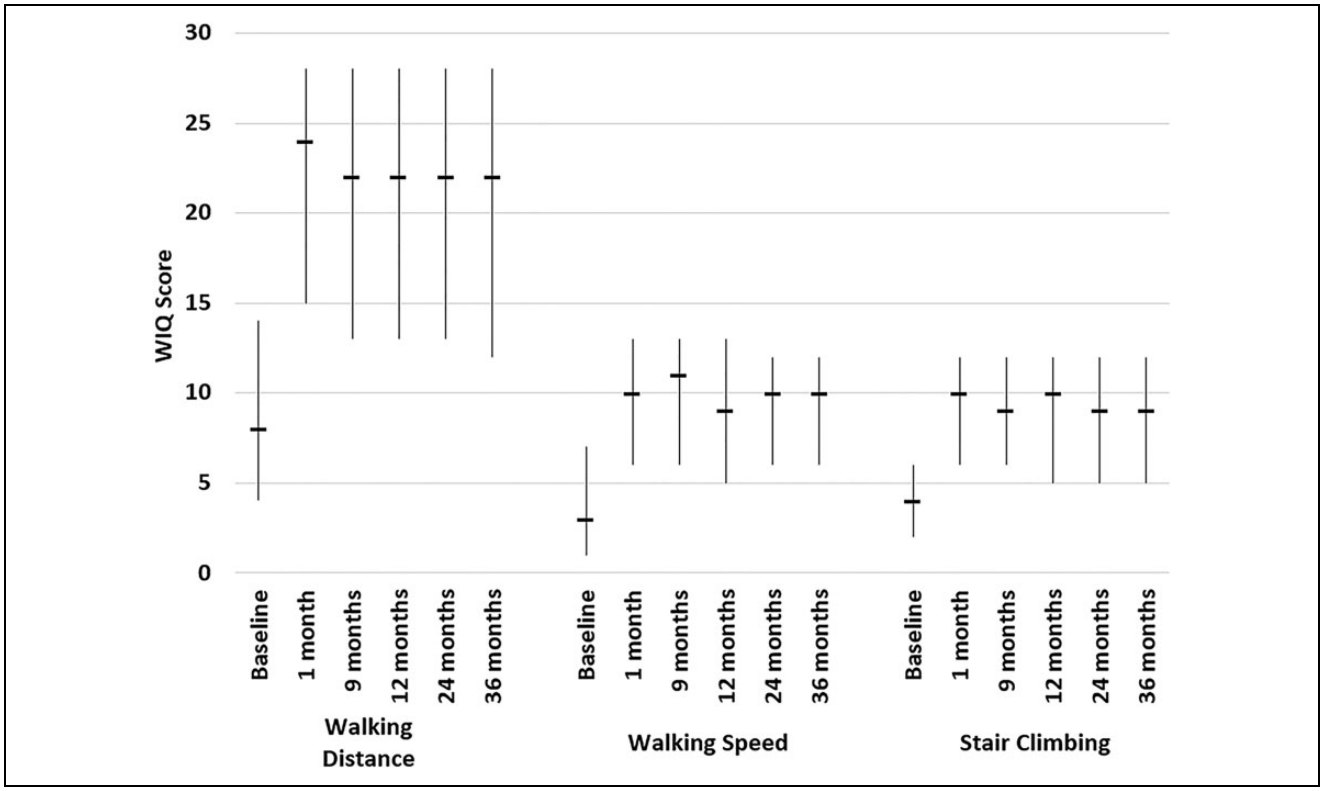

Figure 6. Walking impairment questionnaire (WIQ) changes from baseline to 36-month follow-up.

Table 4. Results of Univariate Analysis in Patients With vs Without Target Lesion Revascularization.[a]

Variable	TLR	No TLR	p
Age, y	60.45 ± 10.61	66.11 ± 9.33	0.059
Sex			
Male	2/79 (2.5)	77/79 (97.5)	0.008
Female	9/55 (16.4)	46/55 (83.6)	
Diabetes			
Yes	2/38 (5.3)	36/38 (94.7)	0.728
No	9/96 (9.4)	87/96 (90.6)	
Hypertension			
Yes	8/113 (7.1)	105/113 (92.9)	0.378
No	3/21 (14.3)	18/21 (85.7)	
Hyperlipidemia			
Yes	9/104 (8.7)	95/104 (91.4)	>0.99
No	2/30 (6.7)	28/30 (93.3)	
Coronary artery disease			
Yes	5/56 (9.0)	51/56 (91.1)	>0.99
No	6/78 (7.7)	72/78 (92.3)	
Prior treatment in study limb for PAD			
Yes	18/179 (10.0)	161/179 (89.9)	0.084
No	0/34 (0)	34/34 (100)	
Rutherford category			
2	2/26 (7.7)	24/26 (92.3)	0.772
3	9/101 (8.9)	92/101 (91.1)	
4	0/7 (0)	7/7 (100)	
TASC II class			
A/B	8/91 (8.8)	83/91 (91.2)	0.721
C/D	3/43 (7.0)	40/43 (93.0)	
Proximal vessel diameter to device ratio			
Undersized device	10/145 (6.9)	135/145 (93.1)	0.224
Same size device	0/1 (0)	1/1 (100)	
Oversized device	8/67 (11.9)	59/67 (88.1)	
Distal vessel diameter to device ratio			
Undersized device	10/101 (9.9)	91/101 (90.1)	0.483
Same size device	0/1 (0)	1/1 (100)	
Oversized device	8/111 (7.2)	103/111 (92.8)	
Number of segments			
1	1/59 (1.7)	58/59 (98.3)	0.023
2 or 3	10/75 (13.3)	65/75 (86.7)	
Number of devices			
1	1/51 (2.0)	50/51 (98.0)	0.013
2	7/69 (10.1)	62/69 (89.9)	
3+	3/14 (21.4)	11/14 (78.6)	
Lesion length, mm	29.18 ± 18.53	27.76 ± 18.27	0.759
Stented length, mm	47.17 ± 13.67	46.27 ± 16.40	0.822

Abbreviations: PAD, peripheral artery disease; TLR, target lesion revascularization; TASC, TransAtlantic Inter-Society Consensus.

[a]Continuous data are presented as the mean ± standard deviation; categorical data are given as the number (percentage).

10.1%, and 21.4% of patients with 1, 2, or 3+ devices that experienced TLRs, respectively (p=0.013). Lesion length, stented length, and age did not significantly correlate with TLR.

Discussion

Current treatment of AIOD includes balloon angioplasty with primary stenting. Numerous studies have compared covered and bare metal stents to determine if one is superior for the treatment of AIOD, but the results have been mixed. Short-term results from COBEST (Covered Versus Balloon Expandable Stent Trial) revealed similar outcomes for the 2 stent designs in TASC II A and B lesions, but the covered stent was found to exhibit greater freedom from binary restenosis in TASC II C and D lesions.[8] The 5-year results of COBEST reiterated the short-term advantages of a covered stent, documenting long-term durability and greater freedom from TLR in patients treated with the stent-graft.[9] Other advantages of the covered stent included sustained improvement in ABI, freedom from reintervention, and freedom from occlusion.[8,10] Therefore, various experts have recommended covered stents as the primary or first-line treatment of AIOD, especially in patients with TASC II C or D lesions.[4,11]

Covered stents can be self-expanding or balloon-expandable, but there is a lack of data comparing the 2 types of devices in this application. Therefore, the chosen stent design largely depends on physician preference. Many of our investigators are of the opinion that balloon-expandable stents deploy more accurately and offer greater radial strength. Additionally, balloon-expandable stents are more likely to maintain their expanded configuration, are stronger, and perform better in areas of calcification, whereas self-expanding stents have greater conformability and are more suited to areas with tortuosity.

Currently, there are 3 balloon-expandable covered stents that can potentially be used in the treatment of AIOD in the United States: the Gore VBX, the LifeStream (BD/Bard Peripheral Vascular, Tempe, AZ, USA), and the iCAST/Advanta V12 (Getinge, Hudson, NH, USA). The BOLSTER trial (Balloon Expandable Vascular Covered Stent in the Treatment of Iliac Artery Occlusive Disease) evaluated the safety and effectiveness of the LifeStream stent. The short-term findings of the trial were promising, and the 24-month data revealed low reintervention rates and improvements in clinical outcomes and quality of life.[12] The US-based iCARUS trial evaluated the 3-year safety and effectiveness outcomes associated with the iCAST covered stent. At 3 years, AIOD patients treated with iCAST had a late clinical success rate of 72.4% and a freedom from TLR rate of 86.6%.[13] While these values are similar to those from the VBX FLEX trial, the two trials are not entirely comparable as they studied different patient populations. Only 5.8% of lesions treated in the iCARUS trial were TASC II C and there were no TASC II D lesions. In contrast, ~30% of the lesions treated in the VBX FLEX trial were TASC II C or D. Therefore, the VBX FLEX trial provides insight on a novel device in a relatively more

complex and challenging patient population. COBEST also evaluated the Advanta V12 stent-graft, and the 5-year data revealed high rates of patency and freedom from TLR[9]; however, key differences in study design and patient population hinder a direct comparison of results from COBEST and the VBX FLEX trial.

The previously published 9-month data from the VBX FLEX trial showed encouraging short-term safety and effectiveness outcomes in patients with straight-forward and challenging lesions.[5] Since the primary endpoints evaluated short-term changes, it is more beneficial to focus on data gleaned from the secondary endpoints to determine intermediate- and midterm outcomes. The freedom from CD-TLR estimates at 9 months and 3 years were >98%, which demonstrates sustained device effectiveness. The estimates of freedom from CD-TVR were similar at each time point. The TLR and TVR results are clinically encouraging and help emphasize midterm device effectiveness in a large majority of the patient population. At 9 months, TASC II A/B results were similar to those of C/D, and this observation persisted through 36 months.

Univariate analyses were conducted to discern the factors that would predict increased likelihood of lesion revascularization following stent-graft placement. The numbers of treated lesions and implanted devices were 2 factors that correlated significantly with TLR. It is likely that patients with numerous lesions, who often require more devices, have a greater atherosclerotic burden, which subsequently predisposes them to require more interventions. This data should not imply that these patients are worse candidates for the device; rather, it reflects the patient's extensive disease and greater atherosclerotic burden.

Sex was another factor that correlated with TLR as female patients were significantly more likely to require revascularization. Historically, female patients have worse outcomes following angioplasty. Various research publications and registry data previously reported higher rates of mortality in women following angioplasty.[14-17] The women in the study by Timaran et al[18] had significantly poorer rates of primary patency and were at increased risk for intervention than the men in the study. Additionally, Rosenman et al[15] reported higher rates of minor complications and lengths of hospitalization in female patients. These collective findings have been attributed to the smaller body habitus typically seen in female patients.[15,17] Therefore, for a given amount of atherosclerotic disease, this may be associated with a greater cross-sectional area reduction in females, which subsequently manifests as worse clinical outcomes.

More than 92% of patients experienced an improvement in Rutherford category that was sustained for the duration of the 3-year study period. This improvement was also corroborated by sustained ABI improvement at 3 years. This seemingly instantaneous improvement in Rutherford category can be attributed to an increase in perfusion secondary to intervention at the index procedure. Enhanced peripheral blood flow relieves claudication symptoms, which subsequently betters quality of life and functional state, findings that are further confirmed by the EQ-5D quality of life questionnaire and WIQ, respectively.

Limitations

As previously described in Bismuth et al,[5] the limitations were the nonrandomized design, the specific eligibility criteria, and the diverse outcome definitions.

Conclusion

The 3-year follow-up from the VBX FLEX study demonstrates the midterm safety and effectiveness of the VBX in the treatment of AIOD. The quantitative and qualitative results of the study prove the device and procedure are both robust and durable.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Jean M. Panneton and Jean Bismuth are consultants and speakers for W. L. Gore & Associates. Bruce H. Gray is a consultant for W. L. Gore & Associates, with compensation paid to his hospital. Andrew Holden is a member of the medical advisory boards for W. L. Gore & Associates, Medtronic, and Boston Scientific, and he is a clinical investigator for W. L. Gore & Associates, Boston Scientific, Cook, Endologix, Bard, Shockwave, Trireme, Surmodics, ReFlow, and Intact Vascular.

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