The initial report on 1-year outcomes of the feasibility study of the VENITI VICI VENOUS STENT in symptomatic iliofemoral venous obstruction

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ABSTRACT

Objective: The objective of this study was to assess the safety and efficacy of a dedicated venous stent (the VICI VENOUS STENT; VENITI, Fremont, Calif) for treatment of symptomatic iliofemoral venous outflow obstruction.

Methods: Thirty patients (24 female; median age, 43 years) were enrolled in the feasibility phase of an international, multicenter investigational device exemption trial from June 2014 to February 2015. All patients exhibited unilateral venous disease with ≥50% stenosis in the iliofemoral veins. Patients within 3 months of acute deep venous thrombosis or with prior surgical or endovascular intervention of the target vessel were excluded. Lesions were primarily of post-thrombotic causes (63%), with a left limb-right limb ratio of 5:1. Nine patients (30%) had lesions extending beneath the inguinal ligament. Median baseline stenosis was 91%; 11 patients (37%) had occlusions.

Results: Fifty-one stents were implanted successfully in 30 patients. Median residual stenosis was 0%, as estimated by venography and intravascular ultrasound. Median follow-up was 701 days. At 12 months, primary, assisted-primary, and secondary patency was 93%, 96%, and 100%, respectively. The stent occluded in two patients through the 12-month window (occurring at 19 and 385 days). Both occlusions occurred in patients presenting with post-thrombotic obstruction. No patients in this cohort exhibited stent fracture at 12 months. Symptomatic improvement of ≥2 points on the Venous Clinical Severity Score was observed in 23 patients (85%) at 12 months (median score improvement, 5 points). There was a median 12-month pain reduction of 20 mm on the visual analog scale score and 15-point improvement on the Chronic Venous Insufficiency Questionnaire score. Scores improved significantly on all three clinical and quality of life scales at 6 and 12 months.

Conclusions: The VICI VENOUS STENT is safe and feasible for treatment of symptomatic iliofemoral venous obstruction, with excellent 12-month patency rates and significant improvement seen in clinical symptoms and quality of life indices. The pivotal phase (170 patients, 22 centers) of this investigational device exemption trial is currently ongoing. (J Vasc Surg: Venous and Lym Dis 2017;■:1-9.)

Stenotic or occlusive lesions in the iliofemoral veins can arise from post-thrombotic syndrome, reported to develop in up to half of patients experiencing deep venous thrombosis (DVT).[1] Obstruction can also develop from nonthrombotic iliac vein lesions with compressive causes such as May-Thurner syndrome, which are highly prevalent and often silent in the general population. Acute iliofemoral DVT is often associated with a compression lesion, but nonthrombotic iliac vein lesions may also be a permissive condition to later venous obstruction and symptomatic chronic venous disease without previous DVT.[2]

Despite that the "method of choice" in the treatment of femoroiliocaval chronic venous obstruction is presently venoplasty and stent placement, there are several concerns. Because it is not known at what degree of obstruction the venous flow is restricted, no tests are presently available for the accurate diagnosis of hemodynamically significant venous outflow blockage to direct trreatment.[3,4] A morphologic obstruction of >50% stenosis has arbitrarily been chosen to be significant because of favorable clinical response when stented.[5] Clinicians have also been reluctant to place stents under the inguinal ligament, applying current guidance against arterial stenting across flexion points to venous stenting. However, this guidance (along with many others as they relate to arterial stenting) may not transfer to the venous system.[6] Last, a dedicated venous stent has long been

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Author conflict of interest: M.R. serves as a principal investigator and advisor for VENITI and a consultant for Abbott Vascular, Boston Scientific, Medtronic, and Zimmer/Biomet. W.M. holds a limited financial interest in VENITI and is a member of the VIRTUS steering committee, for which he receives compensation for his time. S.B. serves as a consultant for W. L. Gore & Associates and has received speaker's fees from VENITI, Cook, Bard, Volcano, BSCI, Medtronic, and OptiMed. P.N. is a stockholder and member of MAB and a proctor for VENITI. D.B. is employed by Syntactx, a company that has received research funding from VENITI (the sponsor of the work).

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missing in the armamentarium of the interventionist. Historical performance of venous stenting in the iliofemoral veins has relied on inherently suboptimal arterial stents deployed in a vascular system with different engineering demands and deployment challenges.

In the past few years, several venous stent platforms have received CE mark, with U.S. investigational device exemption (IDE) trials under way. These include the Zilver Vena stent (Cook Medical, Bloomington, Ind), the sinus-Venous stent (OptiMed, Ettlingen, Germany), the Venovo stent (Bard, Tempe, Ariz), and the VICI VENOUS STENT (VENITI, Fremont, Calif). To date, no venous stent has been approved by the U. S. Food and Drug Administration, and to our knowledge, this is the first report of 12-month outcomes in an IDE trial for a dedicated venous stent.

ARTICLE HIGHLIGHTS

- **Type of Research:** Feasibility phase of a multicenter, international investigational device exemption trial
- **Take Home Message:** Thirty patients were treated with the VENITI VICI VENOUS STENT System implantation with a 100% technical success, with no residual stenosis. At 12 months, there were no stent fractures, two stents occluded, and primary patency was 93%, with five patients requiring prophylactic intervention to maintain patency.
- **Recommendation:** These 12-month results suggest that the VENITI VICI VENOUS STENT is safe and effective. Studies to investigate long-term clinical utility are warranted.

METHODS

Study design. The Evaluation of the VENITI VICI Venous Stent System in Patients with Chronic Iliofemoral Venous Outflow Obstruction (VIRTUS) IDE trial is a prospective, single-arm, international multicenter trial of adults aged ≥18 years with symptomatic chronic obstruction (luminal diameter reduction ≥50%) of the iliofemoral venous system. Treated venous segments included the common iliac vein (CIV), external iliac vein (EIV), and common femoral vein (CFV). Inclusion criteria required patients to present with unilateral and clinically significant venous obstruction, defined as clinical class ≥C3 of the Clinical, Etiology, Anatomy, and Pathophysiology classification or a Venous Clinical Severity Score (VCSS) pain score ≥2. Exclusion criteria included pulmonary emboli within 6 months of enrollment, contralateral venous disease, venous obstruction extending into the inferior vena cava, active coagulopathy, and intended concurrent venous procedure within 30 days of stent implantation (eg, thrombolysis, thrombectomy, saphenous vein ablation, placement of inferior vena cava filter, endovenectomy). Patients were also excluded if they had undergone previous surgical or endovascular intervention in the target vessel, excepting thrombolysis for DVT at least 3 months before the VIRTUS index procedure. Thirty patients were implanted in the feasibility phase at 9 U.S. and European centers from June 2014 through February 2015. The pivotal phase, comprising an additional 170 patients enrolled at 22 centers worldwide, is ongoing. This study was registered on Clinicaltrials.gov in April 2014. Follow-up is scheduled for 5 years. A Clinical Events Committee adjudicated all events related to the primary safety and effectiveness end points, and a Data and Safety Monitoring Board monitored safety outcomes. The principles outlined in the Declaration of Helsinki were followed. The study was approved by the Institutional Review Board at each study center. All patients gave informed consent.

Device description. The VICI VENOUS STENT System is a self-expanding nitinol stent with a closed-cell, uniform design composed of 24 sinusoidal strut rings and proprietary alternating curved bridging elements. It is available in 12-, 14-, and 16-mm diameters and 60-, 90-, and 120-mm lengths. The coaxial design delivery system is compatible with a 9F sheath introducer, which may be delivered through the femoral or jugular veins.

Imaging and definitions. Multiplanar venography was used to assess baseline percentage diameter stenosis; both venography and intravascular ultrasound (IVUS) were used to guide stent sizing and extent of stent placement and to assess postprocedural residual stenosis. The vein area at the site of maximum narrowing was determined using the planimetry function on the IVUS console. This was compared with the vein diameter in the nearest nondiseased segment of each vein segment, or if it was not possible to define, literature-reported reference values were used. Venography was used to assess patency at 12 months; duplex ultrasound was used if patients refused venography. Biplane radiography was used to detect stent fracture at 12 months. All data are site reported, fully monitored, and 100% source verified. Final data lock awaits completion of pivotal phase follow-up; the data presented are current as of an April 2017 snapshot.

Primary end points. The primary safety end point was a composite of major adverse events (MAEs) occurring within 30 days of the index procedure. MAEs were defined as device- or procedure-related death, device- or procedure-related bleeding at the access site or target vessel requiring intervention or blood transfusion ≥2 units, device- or procedure-related injury occurring at the target vessel segment or access site requiring intervention, device-or procedure-related DVT outside of the target vein segment, clinically significant pulmonary embolism, and stent embolization. The primary effectiveness end

point was the 12-month primary patency rate at 12 months, defined as freedom from occlusion or thrombosis within the target vessel *and* freedom from surgical or endovascular intervention on target vessels (which are found to have restenosis or stent occlusion) to maintain patency *and* freedom from in-stent restenosis >50%, as assessed by venography. Primary end points will be assessed with core laboratory-reported data from the full pivotal trial population.

Quality of life (QOL) and clinical severity metrics. Treatment success was also measured by improvement in clinical assessment and QOL scales at 6 and 12 months. These consisted of the VCSS,[7] 20-item Chronic Venous Insufficiency Questionnaire (CIVIQ-20),[8] and visual analog scale (VAS).[9] A secondary end point for the VIRTUS study is whether at least 50% of patients experienced 50% VCSS improvement at 12 months after intervention.

Statistical methodology. Because of the small sample size (N = 30), nonparametric reporting methods were used. Continuous variables were expressed as median and range, and continuous variables were expressed as number and percentage. *P* values were calculated with the Wilcoxon signed rank test. Patency was assessed using the standard definitions of primary patency, assisted-primary patency, and secondary patency through 12 months.[10] Kaplan-Meier curves were calculated and displayed through the time point at which the standard error of the estimate remained <10%.[10] Kaplan-Meier survival curves of primary, assisted primary, and secondary patency were generated with SPSS version 22 (IBM Corp, Armonk, NY).

RESULTS

Baseline characteristics. Baseline demographic and anatomic characteristics for 30 feasibility phase patients are presented in Table I. This population of patients was composed primarily of younger women (median age, 43 years; 80% female) presenting with severe edema (50% C3). Twenty-six of 30 patients (87%) had a VCSS pain score ≥2 (moderate or severe pain). Seventeen of 30 patients (57%) had moderate or severe pain on the VAS. On the CIVIQ-20 questionnaire, 23 of 30 (77%) patients rated their pain as moderate, severe, or intense. A majority of patients (63%) had post-thrombotic obstruction, with a left limb-right limb ratio of 5:1. Fifteen patients (50%) had lesions that spanned the CIV and EIV; of these, nine patients (30%) had lesions extending beneath the inguinal ligament into the CFV. The median baseline stenosis was 91% (range, 50%-100%). Eleven patients had occlusions of the target vessel, and an additional three patients had preocclusive (95%-99% stenosis) lesions.

Study procedure and follow-up. Fifty-one stents were placed in 30 patients, with a median of two stents per patient. Fourteen patients had stents placed in the CFV.

Table I. Baseline demographics and lesion characteristics

Variable	(N = 30)
Age, years	43 (20-76)
Female	24 (80)
History of DVT	19 (63)
History of smoking	11 (37)
PVD	1 (3)
HTN	7 (23)
PE	2 (11)[a]
History of VTE	19 (63)
Coagulation disorder	5 (17)
CEAP class	
0	1 (3)
3	15 (50)
4	11 (37)
5	2 (7)
6	1 (3)
No. with VCSS pain score ≥2	26 (87)
No. with VAS score ≥45 mm (moderate-severe pain)	17 (57)
No. rating pain intensity ≥3 (moderate, severe, or intense) on CIVIQ-20 questionnaire	23 (77)
Lesion etiology	
Post-thrombotic	19 (63)
Nonthrombotic	11 (37)
Lesion characteristics	
Left leg	25 (83)
Right leg	5 (17)
Isolated CIV lesions	11 (37)
Isolated EIV lesions	4 (13)
CIV and EIV lesions	6 (20)
CIV, EIV, and CFV lesions	9 (30)
Target lesion length, mm	128.5 (30-247)

CEAP, Clinical, Etiology, Anatomy, and Pathophysiology classification; *CFV,* common femoral vein; *CIV,* common iliac vein; *CIVIQ-20,* 20-item Chronic Venous Insufficiency Questionnaire; *DVT,* deep venous thrombosis; *EIV,* external iliac vein; *HTN,* hypertension; *PE,* pulmonary embolism; *PVD,* peripheral vascular disease; *VAS,* visual analog scale; *VCSS,* Venous Clinical Severity Score; *VTE,* venous thromboembolic disorder.
Continuous variables are reported as median (range), and categorical variables are reported as number (percentage).
[a]Only 19 patients are reported with data for this variable.

Access was attained through the femoral vein in 93% of patients, most commonly under local anesthesia (63%). Predilation was used in 83% of cases; all patients underwent postdilation. Both IVUS and venography detected residual stenoses in six patients after stent deployment, with a maximum residual stenosis of 50% in one patient as assessed by IVUS (venography estimated 12% stenosis in this patient). Procedural characteristics are summarized in Table II. A representative subject's preprocedural and postprocedural venography is displayed in Fig 1. All patients were prescribed long-term anticoagulant

Table II. Procedural characteristics, site reported

Variable	(N = 30)
Baseline stenosis, venography	
Diameter of stenosis, %	91 (50-100)
No. of occlusions	11
No. of preocclusive lesions	3
Postprocedural stenosis	
Stenosis on venography, %	0 (0-12)
Stenosis on IVUS, %	0 (0-50)
No. of patients with residual stenosis	6 (20)[a]
Access site	
Femoral	28 (93)
Jugular	1 (3)
Both	1 (3)
Anesthesia type	
Local	19 (63)
General	11 (37)
No. of stents implanted	2 (1-2)
Oversizing on IVUS, %	11 (0-78)
Oversizing on venography, %	14 (−41 to 60)[b]
Predilation	25 (83)
Postdilation	30 (100)
Length of stay, days	1 (0-9)

IVUS, Intravascular ultrasound.
Continuous variables are reported as median (range), and categorical variables are reported as number (percentage).
[a]Residual stenoses were observed in six patients by both IVUS and venography.
[b]Negative percentages represent undersized devices.

therapy (or antiplatelet therapy for five patients) per protocol guidelines (Fig 2) with 93% compliance at 12 months. As of data cutoff of April 2017, median follow-up was 701 days (range, 23-840 days). All 30 patients have available 30-day follow-up; 27 patients (90.0%) have 6-month follow-up. Twenty-eight patients (93%) have available 12-month follow-up data; the 12-month assessment was conducted within the visit window (365 days ± 60 days) in 27 patients. Seventeen patients (61%) have 24-month follow-up data available. Two patients exited the study (at days 425 and 715, respectively).

Early and late safety outcomes. One patient (3.3%) experienced an MAE within 30 days of the index procedure. The day after the index procedure, this patient developed a hematoma at the puncture site, with a false aneurysm of the superficial femoral artery observed on imaging. This was resolved with implantation of a covered stent. Three patients experienced early serious adverse events (arteriovenous fistula formation, in-stent restenosis, and exacerbation of asthma symptoms). Overall, 10 patients (all post-thrombotic) experienced at least one serious adverse event at least possibly related to the device or procedure during all follow-up, with 9 of 10 patients requiring reintervention. Details of all secondary interventions through 12-month follow-up are listed in Table III.

One patient was classified as C6 (active ulceration) at baseline assessment, with two ulcers of moderate severity and duration (per VCSS). At 6 months (latest available follow-up assessment before the patient's withdrawal from study), one ulcer had healed and the other had diminished in size.

Patency and stent integrity. Primary, assisted-primary, and secondary patency was estimated as 93%, 96%, and 100% at 12 months (Fig 3). Two post-thrombotic patients experienced stent occlusion through the end of the 12-month follow-up visit window, with one early occlusion at 19 days and one occlusion detected at 385 days. Both required reintervention to restore patency. Five post-thrombotic patients underwent prophylactic intervention to maintain patency through 12-month follow-up. Three of these five patients had disease extending to the CFV. In the 11 nonthrombotic patients, all stents remained patent through all follow-up. At 12 months, 25 patients (89.3%) had available biplane radiographs; none showed any evidence of stent fracture, as reported by the sites.

Of the two patients (both female) experiencing stent occlusion, both had a history of DVT, with occlusive lesions or 99% stenosis in the left limb. Both patients had lesions in the CIV and EIV; in one patient, the lesion extended into the CFV. In this patient, residual stenosis was observed after the index procedure, with postprocedural venography estimating 12% residual stenosis and IVUS estimating 50% residual stenosis.

QOL and VCSS. The 6-month and 12-month scores on the VCSS, VAS, and CIVIQ-20 metrics are presented in Table IV. Scores on all three clinical and QOL scales improved significantly at 6 and 12 months. At 12 months, VCSS had decreased a median of 5 points from baseline. Seventeen patients (63%) had ≥50% score reduction; 23 of 27 patients (85%) experienced symptomatic improvement (≥2-point score improvement). Only two patients (7%) exhibited worsened VCSS scores at 12 months.

At 12 months, median VAS score change was a pain reduction of 20 mm. Five patients (19%) experienced pain worsening compared with 22 patients (81%) with pain amelioration. VAS score decreased from a median baseline classification of moderate pain (60 mm) to mild pain at 12 months (21 mm).

On the CIVIQ-20 questionnaire, a median baseline score of 48 points improved to 33 points at 12 months (median score change, 15 points improvement). Twenty-one of 27 patients (78%) considered themselves as having improved QOL at 12 months. Of the six patients (22%) who considered themselves worsened at 12 months, three patients scored themselves within 2 points of their baseline score.

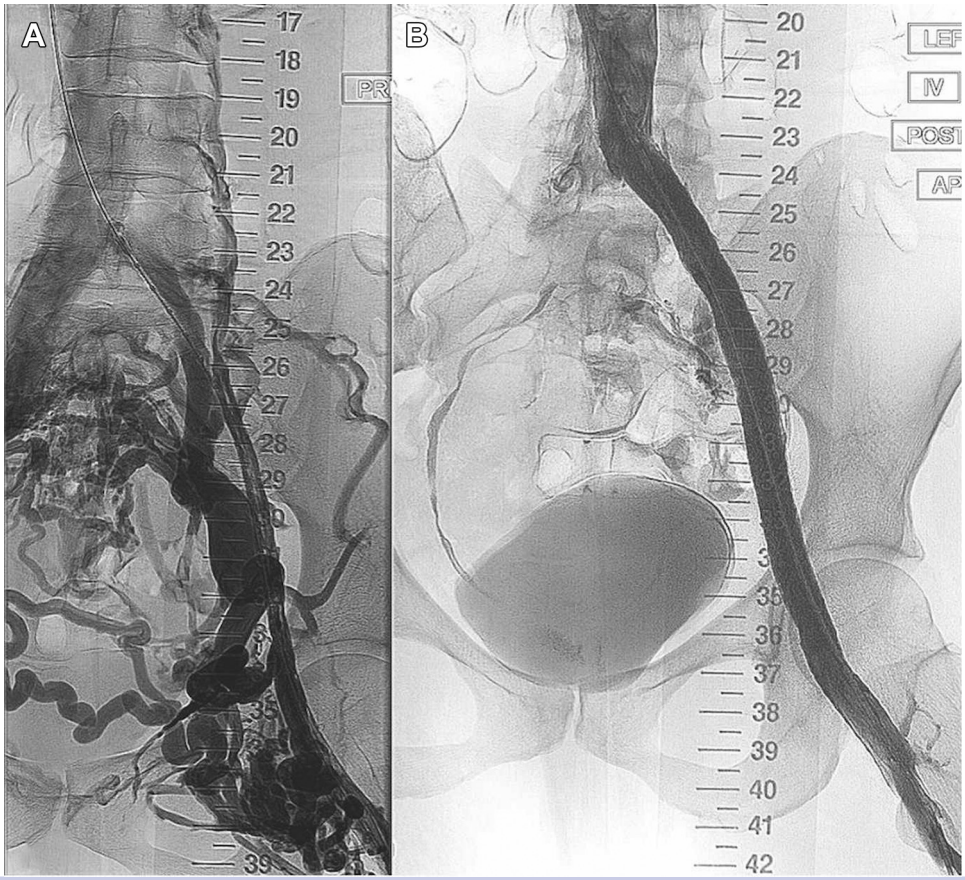

Fig 1. Preprocedural and postprocedural venography for a 44-year-old post-thrombotic woman with a 160-mm lesion extending into the common femoral vein (CFV). **A,** Preprocedural venography demonstrated significant collateralization, with occlusion of the external iliac vein (EIV) as the most severe lesion. The patient was implanted with three stents, with total stented length of 240 mm. **B,** Postprocedural venography visualized no residual stenosis (confirmed with intravascular ultrasound [IVUS]). The patient experienced no serious adverse events or interventions during follow-up, with Venous Clinical Severity Score (VCSS) decreasing from 8 (at baseline) to 0 at 12 months.

DISCUSSION

In this first of its kind report on a prospective, multicenter feasibility study of a dedicated venous stent, a high 12-month patency rate was observed with no major safety concerns. The procedure was also associated with significant clinical improvement as assessed by VAS, VCSS, and CIVIQ. Despite satisfactory outcome, stent placement for treatment of iliofemoral venous obstructions presents a substantial challenge for clinicians. Determination of treatment strategy is complicated by the lack of a threshold for hemodynamically significant stenosis meriting endovascular intervention. The clinician is also faced with limited, suboptimal choices of nonvenous stents and custom configurations with variable outcomes.[5] In general, consistently good outcomes have been observed in the stenting of nonthrombotic lesions, but the level of evidence has remained low, with a lack of controlled prospective trials evaluating performance and safety outcomes until now.

The engineering challenges presented by the deep venous system are significant and manifold: the stent must have sufficient crush resistance and outward radial force to withstand constant compression in venous compressive disorders and maintain flow lumen in fibrotic venous occlusions. In addition, sufficient stent flexibility is desirable in anatomic locations susceptible to flexion stress, such as the junction of EIV and CFV segments deep to the inguinal ligament. There is currently no dedicated venous stent commercially available in the United States; however, reports of early single-center experiences in Europe have now been published with the Cook Zilver Vena and the OptiMed sinus-Venous stents—both nitinol stents with an open-cell design.[11,12] In 2013, O'Sullivan et al[11] reported the 30-day outcome of the Zilver Vena stent in 20 patients with a high rate of active malignant disease (50%). A majority of treated patients also underwent adjunctive thrombolysis and thrombectomy before stenting. With early thrombosis in three patients, the authors reported a 30-day duplex ultrasound patency rate of 85%. Preliminary outcomes from the prospective Evaluation of the Zilver Vena Venous Stent (VIVO-EU) trial of 35 patients

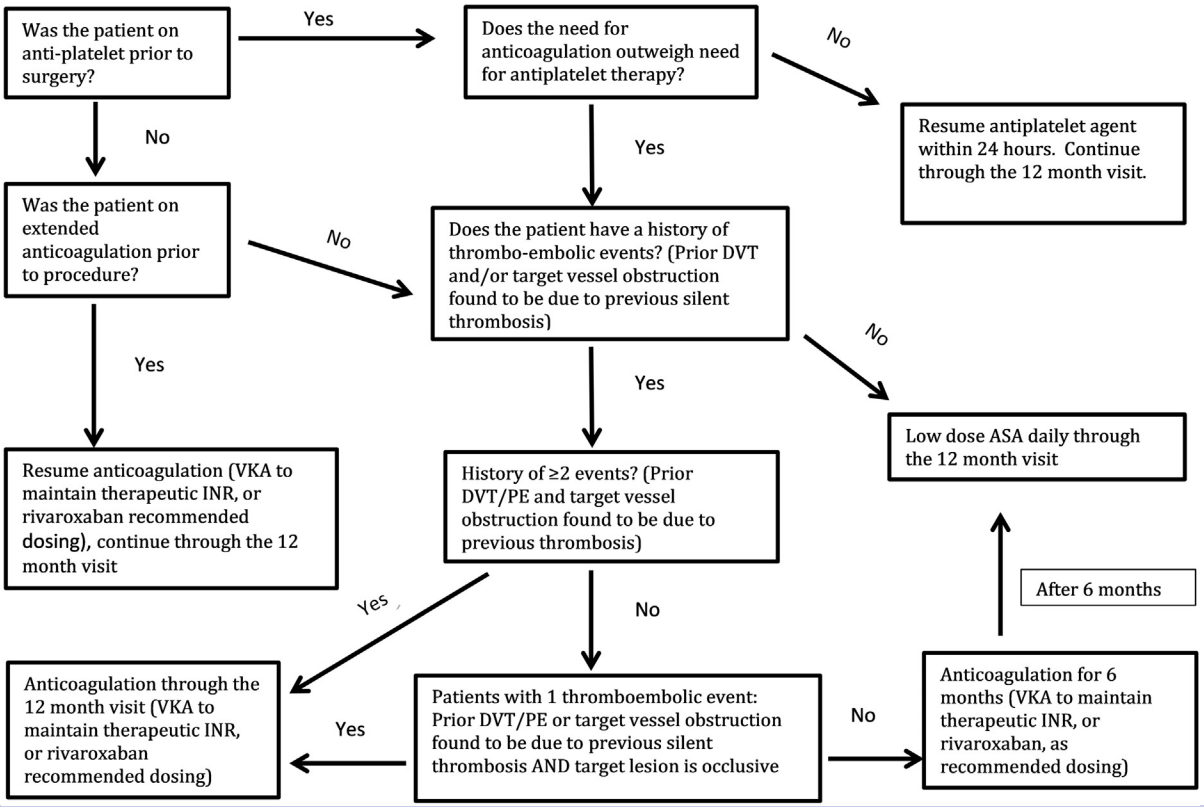

Fig 2. Protocol algorithm for extended anticoagulation. *ASA,* Acetylsalicylic acid; *DVT,* deep venous thrombosis; *INR,* international normalized ratio; *PE,* pulmonary embolism; *VKA,* vitamin K antagonist.

reported 87% patency at 12 months (defined as freedom from occlusion).[13] In 2015, de Wolf et al[12] published short-term outcomes after initial European experience with the sinus-Venous stent in 75 patients (53% post-thrombotic, 47% nonthrombotic).[12] Stent placement was not performed if post-thrombotic lesions extended

Table III. Secondary interventions

Days since procedure	Secondary intervention	Reason for intervention
7	Thrombin injection	AVF formation
20/77/308/378	Thrombolysis and venoplasty Venoplasty and stent Venoplasty and stent Venoplasty and stent removal and stent insertion	Stenosis of CIV stent and occlusion of EIV stent Progressive thrombus of CIV and EIV stents Focal stent collapse at inguinal ligament causing 80% stenosis Focal stenosis at inguinal ligament
1/367	Viabahn stent Venoplasty	Puncture site hematoma and false aneurysm of SFA Restenosis of the EIV and CIV stents (46% diameter reduction in both stents)
287	Thrombectomy and stent relining	Thrombus formation in CIV and EIV stents
367	Venoplasty and stent extension into distal IVC	Stent compression at the level of the inguinal ligament (44% diameter reduction with IVUS, >50% with venography at EIV-CFV junction), with 5-mm migration of stent
378	Venoplasty	Thrombus formation in stent (35% diameter reduction in CIV stent, 40% in EIV stent)
385	Venoplasty and stent	High-grade EIV in-stent restenosis
420	Venoplasty	Left CIV, EIV, and CFV in-stent stenosis (46% diameter reduction)

AVF, Arteriovenous fistula; *CFV,* common femoral vein; *CIV,* common iliac vein; *EIV,* external iliac vein; *IVC,* inferior vena cava; *IVUS,* intravascular ultrasound; *SFA,* superficial femoral artery.
Days since procedure lists the date of reintervention. All data and classifications for target vessel reinterventions are site reported.

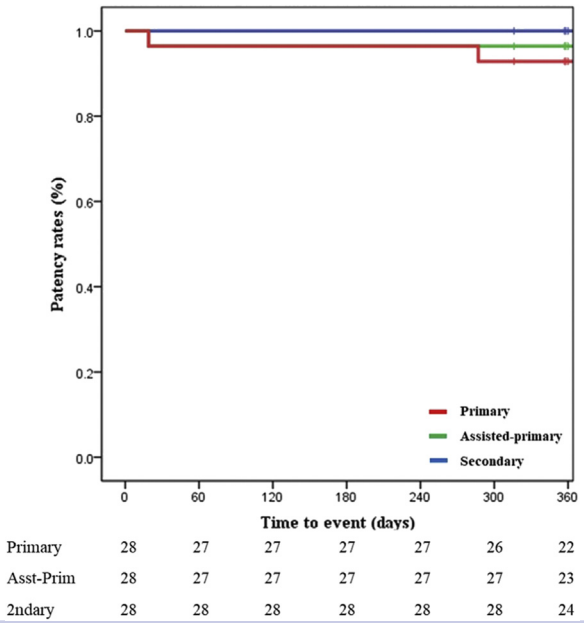

Fig 3. Cumulative patency rates, Evaluation of the VENITI VICI Venous Stent System in Patients with Chronic Iliofemoral Venous Outflow Obstruction (VIRTUS) investigational device exemption (IDE) trial, feasibility phase.

below the saphenofemoral junction or if inflow was compromised. The authors reported excellent patency rates through 1 year (92% primary patency). Similar to our findings, the authors reported overall low morbidity and 100% patency in nonthrombotic patients.

Numerous reports have confirmed significantly higher patency rates with nonthrombotic lesions compared with post-thrombotic lesions.[5] We observed 100% patency in the 11 patients treated with nonthrombotic lesions. In a 2007 report of an 8-year single-center experience with iliofemoral stenting using braided Elgiloy stents, Neglén et al[14] reported a 3.2% rate of stent occlusion through 2 years; all occlusions occurred in post-thrombotic patients, despite a majority of patients presenting with nonthrombotic indications. In an analysis of factors associated with early and late stent occlusions, the authors found that stents were nine times more likely to occlude if patients presented with chronic occlusions. Stents extending to the CFV were 3.8 times more likely to occlude. An additional analysis identifying factors associated with severe in-stent area reduction (ISAR, defined as >50% area reduction) found that ISAR was 26.7 times more likely to occur in patients with thrombotic causes; ISAR was also 8.3 times more likely in occlusions vs nonocclusive lesions and 5.5 times more likely with stents extending to the CFV.[15]

A 2008 subset analysis of treated limbs with braided stents placed across the inguinal ligament found that etiology and degree of obstruction were far more significant associated factors than whether the stent crossed the inguinal ligament into the CFV.[6] In a single-center experience of 110 patients treated for post-thrombotic occlusions, Ye et al[15] reported a 3-year primary patency rate of 70%. Interestingly, the authors found that patients with persisting collaterals after stenting had a significantly higher rate of early thrombosis, theorizing that parallel flow through collateral vessels compromised establishment of sufficient flow through the stents. A multivariate analysis of factors leading to in-stent obstruction during all follow-up found that stent length was the only significant predictor of late ISAR.[15] In our study, of the nine patients with CFV involvement, three required prophylactic intervention and one required reintervention to restore patency.

An important observation from the feasibility phase of this trial was the critical importance of proper use of IVUS, both during stent placement and in postprocedural assessment of treatment success, as demonstrated in the patient with early occlusion. Postprocedural venography demonstrated a good result, with sufficient coverage of the lesion and adequate inflow; however, careful consideration of the postprocedural IVUS scan illustrates the persistence of multiple collateral channels and significant residual disease at the level of the CFV, indicating that the stent did not extend far enough (Fig 4). It is critical for the stent to cover the entire obstruction *as assessed by IVUS*, as opposed to venography, which may underestimate the lesion.[16]

The major limitation of this analysis was the relatively small number of patients in the feasibility cohort of the trial. Data collection and analysis continue in the pivotal cohort with 170 additional subjects. We are further limited by a lack of data collection on the existence or severity of venous reflux in this population of patients.

Table IV. Quality of life (QOL) and clinical severity scores, before and after the procedure

	Baseline (N = 30)	6 months[a] (n = 26)	*P* value	12 months (n = 27)	*P* value
CIVIQ-20	48 (24-97)	28 (20-91)	.001	33 (20-89)	<.001
VAS	60 (6-98)	23 (0-84)	.002	21 (0-94)	.001
VCSS	10 (2-25)	5 (0-30)	<.001	4 (0-23)	<.001

CIVIQ-20, 20-Item Chronic Venous Insufficiency Questionnaire; *VAS*, visual analog scale; *VCSS*, Venous Clinical Severity Score.
Scores are represented as median (range).
P values comparing baseline scores with scores at 6 and 12 months were calculated with the Wilcoxon signed rank test.
[a]At 6 months, 27 patients had VCSS scores. The one patient with 6-month VCSS data (and no VAS or CIVIQ-20 data) at 6 months had completed form responses for only 3 of 10 VCSS domains (all 0).

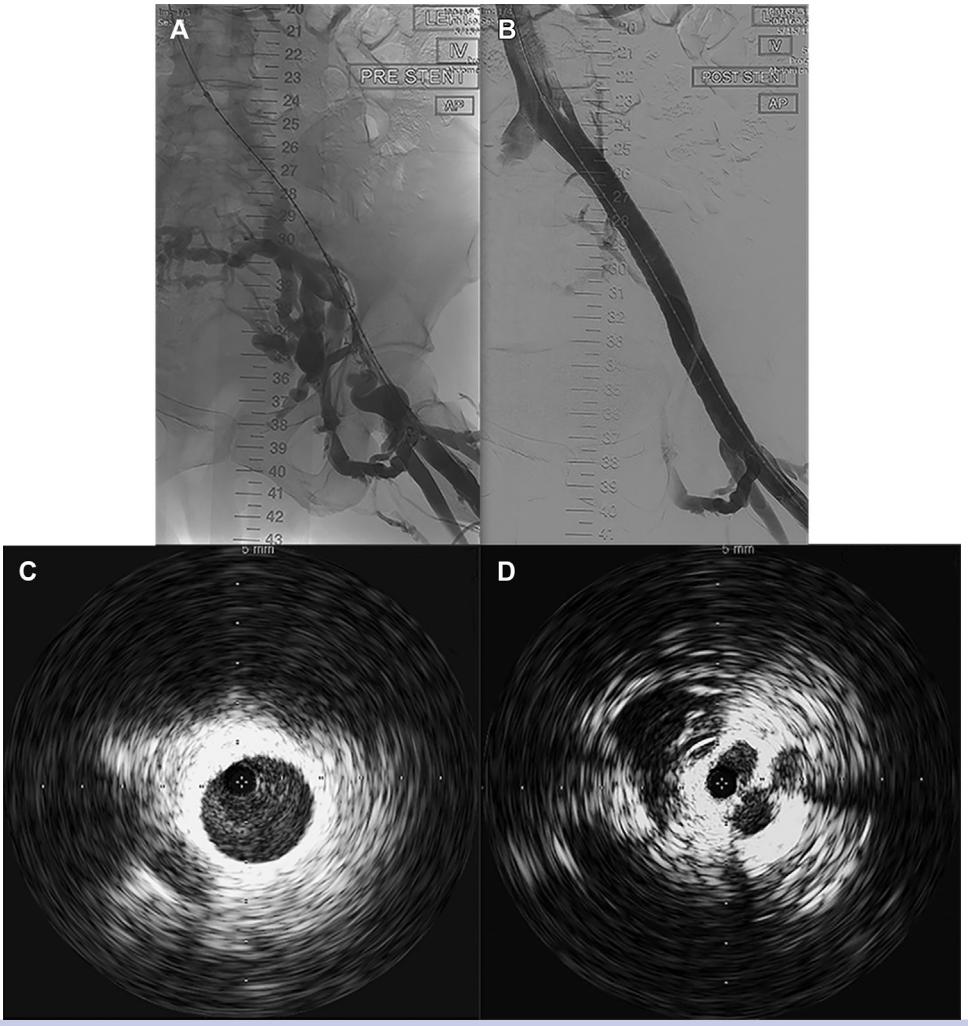

Fig 4. Preprocedural and postprocedural imaging for the sole patient experiencing early loss of patency. This patient was a 45-year-old post-thrombotic woman with 160-mm common iliac vein (CIV) and external iliac vein (EIV) lesion and clinical class C3. **A,** Preprocedural venography demonstrated occlusion and a significant collateral network. Two stents were placed with a total stented length of 200 mm. **B,** Postprocedural venography appeared to demonstrate a good result, with no residual stenosis and satisfactory inflow and outflow. **C,** Postprocedural intravascular ultrasound (IVUS) showed a well-expanded stent with adequate lumen throughout the stent system (image taken at the EIV level). **D,** A postprocedural IVUS image immediately peripheral to the stent at the level of the common femoral vein (CFV) showed trabeculation and multiple lumens, suggesting inadequate stent coverage of the lesion and subsequently poor inflow to the stent system. The patient presented with stent occlusion at 19 days after the index procedure.

CONCLUSIONS

This study reports that use of the VICI VENOUS STENT is safe and feasible through 12 months, with the patients' QOL and clinical scores improving significantly by all metrics. Outcomes from the larger pivotal trial are forthcoming and will provide a sample size suitable for more detailed analyses.

AUTHOR CONTRIBUTIONS

Conception and design: MR, WM, PN
Analysis and interpretation: MR, WM, DB, PN
Data collection: MR, WM, SB
Writing the article: MR, DB, PN
Critical revision of the article: MR, WM, SB, DB, PN
Final approval of the article: MR, WM, SB, DB, PN
Statistical analysis: DB
Obtained funding: Not applicable
Overall responsibility: MR

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