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The VIVID trial 12-month outcomes of the venous stent for the iliofemoral vein using the Duo venous stent system

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ABSTRACT

Objective: There are varying anatomical and mechanical demands of stent placement in the iliofemoral venous segment; the Duo Venous Stent System is designed to address these issues. The purpose of the VIVID (Venous stent for the Iliofemoral Vein Investigational clinical trial using the Duo Venous Stent System) study was to investigate the safety and efficacy of the Duo Venous Stent System for the treatment of patients with nonmalignant iliofemoral venous obstructive disease.

Methods: This was an international, prospective, multicenter, single-arm study that enrolled patients with symptomatic nonthrombotic (NT), post-thrombotic (PTS), or acute deep vein thrombotic (aDVT) iliofemoral venous outflow obstruction. The primary safety end point was freedom from major adverse events at 30 days after the index procedure. The primary efficacy end point was primary patency of stent-bearing segments at 12 months. Secondary and observational end points included symptom relief, primary-assisted patency, secondary patency, and device success. Patients remain in follow-up for 36 months.

Results: A total of 162 patients were enrolled at 30 sites in the United States and Poland. The primary safety end point was achieved in 98.7% of patients against a predefined performance goal of 89.0% ($P < .0001$). The primary safety end point was achieved in 100%, 95.0%, and 100% of the NT, PTS, and aDVT cohorts, respectively. The primary efficacy end point was met in 90.2% compared with the performance goal of 77.3% ($P = .0002$). Primary patency was observed in 95.2% of patients with NT disease, 79.4% of those with PTS, and 86.7% of those with aDVT. No stent fracture, migration, or embolization occurred through 12 months. Patient-reported outcomes showed improvements in Venous Clinical Severity Score, Villalta, EQ-5D-3L, and VEINES-QoL/Sym scores from baseline through 6 and 12 months.

Conclusions: Through 12 months, the Duo Venous Stent System is safe and effective for the treatment of nonmalignant iliofemoral venous obstructive disease. (J Vasc Surg Venous Lymphat Disord 2025;13:101995.)

Clinical Relevance: The VIVID (Venous stent for the Iliofemoral Vein Investigational clinical trial using the Duo Venous Stent System) investigational device exemption trial is the first study of a hybrid, venous stent specifically designed to address the anatomic challenges of the iliofemoral venous system. The Duo Venous Stent System consists of a self-expanding nitinol Duo Hybrid Stent used independently or in conjunction with the flexible extension Duo Extend Stent. This is the first report of primary outcomes from the VIVID Study, assessing the safety and efficacy of the Duo Venous Stent System to treat patients with nonmalignant, symptomatic iliofemoral venous outflow obstruction. The Duo Venous Stent System successfully met its 12-month safety and effectiveness performance goals.

Keywords: Iliofemoral venous obstructive disease; Duo Venous Stent System; Safety; Patency; Quality of life

Acute or chronic iliofemoral venous obstruction can lead to significant morbidity that may lead to quality of life (QoL) and activity limitations. The central venous pathology can cause signs and symptoms of venous hypertension including lower extremity pain, edema, skin changes (hyperpigmentation, induration, inflammation, fibrosis,

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lipodermatosclerosis), and venous stasis ulceration.[1,2] The etiologies are primarily nonthrombotic (NT) obstruction (eg, May-Thurner Syndrome), acute thrombotic (aDVT), and chronic post-thrombotic syndrome (PTS).[2-4]

Venous stent placement can be effective for patients where venous obstruction has negatively impacted QoL despite conservative treatment.[2-4] Recently, dedicated venous stents have been developed and studied in investigational device exemption (IDE) trials,[5-11] and are now recommended by international guidelines for the treatment of symptomatic iliofemoral venous outflow obstruction.[2,3] Unlike iliac arterial stents, venous stents need to balance high crush resistance in the pelvis and excellent flexibility, because they are frequently placed underneath the inguinal ligament. The iliac vein anatomy is also unique in that compliant veins are stented through a tortuous anatomy in the pelvis.

The Duo Venous Stent System is designed to address the need for crush resistance and flexibility at different segments of the iliofemoral venous tract. The VIVID (Venous stent for the Iliofemoral Vein Investigational clinical trial using the Duo Venous Stent System) study assessed the safety and efficacy of the Duo Venous Stent System to treat patients with nonmalignant, symptomatic iliofemoral venous outflow obstruction.

ARTICLE HIGHLIGHTS

- **Type of Research:** A prospective, multicenter, single-arm, nonblinded investigational device exemption trial
- **Key Findings:** The primary safety end point of freedom from major adverse events at 30 days after the index procedure was achieved in 98.7% ($P < .0001$) of the 162 patients enrolled in the study, against a predefined performance goal of 89.0% ($P < .0001$). The primary efficacy end point of primary patency of stent-bearing segments at 12 months was met in 90.2% compared with the performance goal of 77.3% ($P = .0002$). No stent fracture, migration, or embolization occurred through 12 months. Patient-reported outcomes showed improvements in Venous Clinical Severity Score, Villalta, EQ-5D-3L, and VEINES-QoL/Sym scores from baseline through 6 and 12 months.
- **Take Home Message:** Through 12 months, the Duo Venous Stent System is safe and effective for the treatment of nonmalignant iliofemoral venous obstructive disease.

METHODS

Study design. VIVID (NCT04580160) is a prospective, multicenter, single-arm, nonblinded IDE trial conducted in the United States and Poland to investigate the safety and efficacy of the Duo Venous Stent System for treatment of patients with nonmalignant iliofemoral obstructive disease. The study was designed to enroll up to 160 patients at 45 international centers. The study protocol was approved by ethics committees and/or investigational review boards at all participating centers. All patients provided written informed consent before enrollment.

A data safety monitoring board oversaw study safety, and events were adjudicated by the Clinical Events Committee (CEC). An independent core laboratory (Syntropic Core Lab, Columbus, OH) assessed all imaging, including radiography, duplex ultrasound (DUS), intravascular ultrasound (IVUS), and venography.

Stent design. The Duo Venous Stent System is comprised of the Duo Hybrid and Duo Extend Stents (Fig 1). Both stents are self-expanding and are mounted on a disposable delivery system. Both stents contain four radiopaque markers on the cranial and caudal ends.

The cranial strength of the Duo Hybrid Stent is paired with caudal flexibility, allowing treatment from the confluence of the iliac veins through the common femoral vein. The Duo Hybrid has a distinct integrated design that uniquely combines multiple mechanical properties into a single stent. These properties are precisely varied along the length of the stent to deliver radial outward force, crush resistance, and flexibility where needed. This stent is laser-cut from one continuous, high purity nitinol tube with no junction between segments. The stent is available in 12- to 18-mm diameters and 60- to 160-mm lengths and is delivered on a 9F or 10F system. The Duo Hybrid can be used independently or with the Duo Extend. The use of Extend was at the physician's discretion based on the need to extend coverage.

The Duo Extend is also a laser-cut nitinol stent; it encompasses the flexibility of the caudal segment of the Duo Hybrid stent with the intention to integrate with the Duo Hybrid Stent to extend therapy to treat longer lesions, including extension across the inguinal ligament. The stent is available in 12- to 16-mm diameters and 40- to 140-mm lengths and is delivered on a 9F or 10F system.

Patient enrollment and eligibility. Study centers enrolled patients with symptomatic, unilateral, nonmalignant venous outflow obstruction. Key inclusion and exclusion criteria are presented in Supplementary Table I (online only). Patients were enrolled prospectively into three venous disease state classifications, defined by the enrolling investigator: NT, PTS, and aDVT. The NT subgroup was defined as symptomatic patients with iliofemoral venous obstruction and no history of DVT. The PTS subgroup was defined as patients with total occlusion or stenosis of iliofemoral segments requiring stent placement with symptoms onset of >14 days or any obstruction of the iliofemoral segments with history of ipsilateral DVT within 2 years, regardless of symptom onset. The aDVT subgroup was defined as patients experiencing a first episode of acute symptomatic ipsilateral

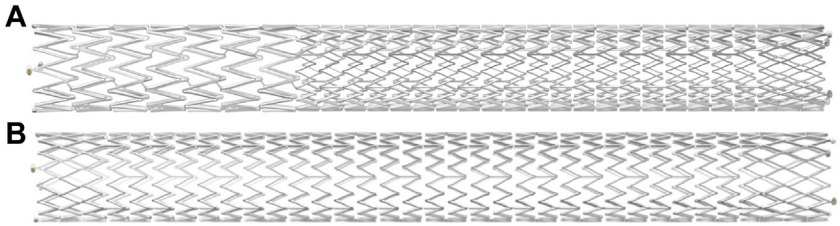

Fig 1. Duo hybrid **(A)** and extend **(B)** stent designs.

DVT ≤14 days old with acute thrombus and iliofemoral obstruction requiring stent placement and successful removal of the thrombus before stent placement. The study planned to enroll a minimum of 20% of the total patients into each of the three venous disease state classification groups; however, the subset minimum was eliminated due to enrollment challenges associated with the coronavirus disease 2019 (COVID-19) pandemic.

Procedure and follow-up. The final eligibility of all patients was confirmed using baseline IVUS measurements during the index procedure, as detailed in the Supplementary Methods (online only) Procedure and follow-up. Imaging requirements and postdilatation measurements are also detailed.

Procedural techniques for iliofemoral venoplasty and stent placement were deferred as per the institutional standard of care. All patients received either dual antiplatelet and/or antiplatelet/anticoagulation combination therapy. The minimum anticoagulation treatment durations were 3 months for NT patients and 12 months for thrombotic patients. Further detail is provided in the Supplementary Methods (online only) Antiplatelet and anticoagulation regimen section.

Follow-up visits were scheduled at 30 days, 6, 12, 24, and 36 months.

End points. The primary safety and efficacy end points were CEC- and core laboratory-adjudicated. The primary safety end point was freedom from major adverse events (MAEs) at 30 days after the index procedure (per patient). The definition of MAEs is detailed in Supplementary Table II (online only). Time zero was defined as the index procedure and for patients with at least one MAE, the date of the event is the date of the earliest MAE. Patients were still considered evaluable for the 30-day primary safety end point if they had a late 30-day follow-up visit or missed the 30-day visit, but a visit occurred beyond 30 days. Because of this, the number of evaluable patients for the primary safety end point could be higher than the number of patients presenting for a visit at 30 days.

The primary efficacy end point was primary patency of the stent-bearing segment(s) at 12 months (evaluated through day 390). Primary patency was defined as a composite of freedom from occlusion or stenosis of >50% within the stented segment and freedom from clinically driven target lesion revascularization (CD-TLR), defined as an endovascular or surgical procedure for new, recurrent, or worsening symptoms and core-laboratory adjudicated >50% stenosis or occlusion. IVUS was required if DUS suggested >50% stenosis or occlusion of the stented segment, or if the DUS was nondiagnostic or suboptimal (eg, due to obesity). The number of evaluable patients for the primary efficacy end point could be higher than the number of patients presenting for a 12-month visit if a CD-TLR occurred before or including day 390.

Secondary end points assessed at 12 months included patient symptom improvement measured by the Venous Clinical Severity Score (VCSS) pain score, primary-assisted patency, and secondary patency (Supplementary Table II, online only).

Observational end points included device, lesion, and procedural success (Supplementary Table II, online only). Additional observational end points included stent fracture, migration, and embolization. MAEs, CD-TLR, clinically driven target vessel revascularization (Supplementary Table I, online only), and ulcer healing were also collected over 12 months. Changes in the European Quality of Life-5 Dimensions-3 Level (EQ-5D-3L), VEINES QoL/Sym, and Villalta scores were also measured.

Statistical analyses. All statistical analyses were based on the intent-to-treat (ITT) population, which included all patients who had the Duo Venous Stent System. The planned sample size of 160 patients provided an overall power of ≥90% to evaluate the primary safety and efficacy end point hypotheses against the performance goals. A one-sample exact binomial test was used with a one-sided type I error controlled at 2.5% for the primary safety point. Disease state-specific (ie, NT, PTS, and aDVT) performance goals were calculated from the point estimates for major bleeding, pulmonary embolism, and periprocedural mortality from a previously published meta-analysis[4] and converted to freedom from estimates and application of a 10% noninferiority margin. In VIVID, the safety performance goal for the NT group was 89.0%, PTS was 88.0%, and aDVT was 87.0%. However, given the similarity of the disease state-specific performance goals,

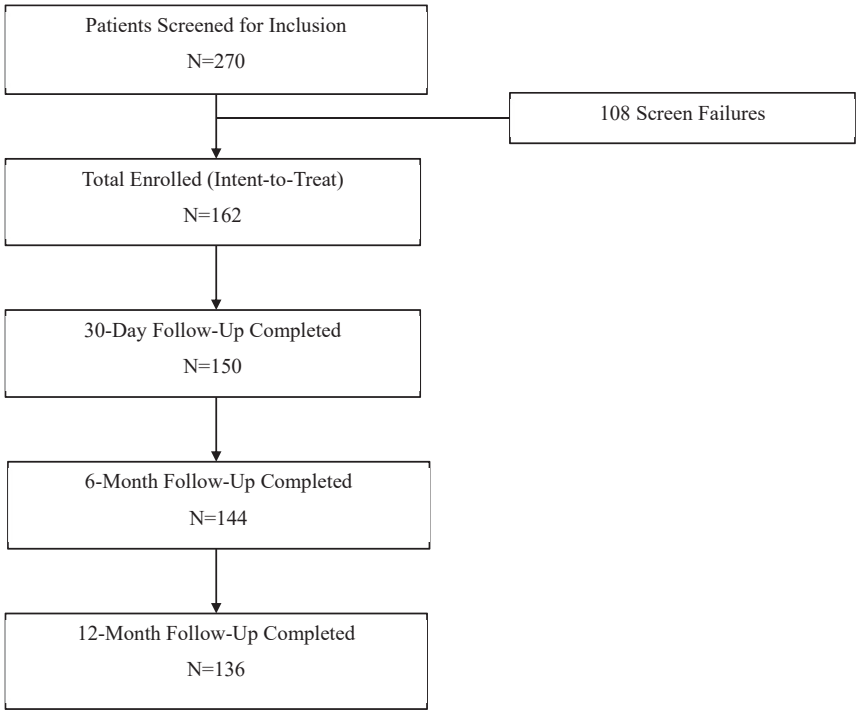

Fig 2. Patient flow chart.

it was determined that a disease state-specific goal was not needed and the performance goal for the primary safety end point (freedom from MAEs at 30 days) was 89.0%. The performance goal for the primary efficacy end point (primary patency of the stented segment at 12 months) was also based on the same meta-analysis,[4] that is, the lower 95% confidence interval (CI) with a margin of 10%. The performance goal for the primary efficacy end point in the VIVID study was based on the proportions of ITT patients prospectively enrolled in each of the disease states (ie, NT, PTS, and aDVT). The performance goal was established at 83.0% for NT, 66.0% for PTS, and 70.0% for aDVT. The overall target performance number was set when all enrolled patients completed the index procedure and was established at 77.3%. The overall primary efficacy and safety end points were hypothesis tested; however, the primary efficacy and safety end points for each individual disease state were not powered to detect statistical differences.

Continuous data are reported as mean ± standard deviation. Categorical variables are reported as frequencies and percentages. Kaplan-Meier methodology was used to assess time-to-event end points.

All analyses were prespecified in the statistical analysis plan. Data were analyzed with STATA version 17.0 or higher. A *P* value of less than .025 was used to determine statistical significance for the primary end points.

RESULTS

Enrollment and patient follow-up. Between November 2021 and December 2022, 270 patients were screened for eligibility in the VIVID study (Fig 2). Of these, a total of 162 patients were enrolled across 30 centers throughout the United States and Poland. One hundred fifty patients (92.6%) completed the 30-day follow-up, 144 (88.9%) completed the 6-month follow-up, and 136 (84.0%) completed the 12-month follow-up.

Baseline demographic, clinical, and procedural characteristics. Demographics and baseline characteristics are presented in Table I. The mean age was 59.4 ± 15.8 years and 63.0% of patients were male. Of the 162 enrolled, patients were classified as NT (64.2%), PTS (25.9%), and aDVT (9.9%). Thirteen patients (8.0%) had a history of severe acute respiratory syndrome coronavirus 2 infection before study enrollment and outside of the 60-day exclusion window. Most patients (86.4%) had an onset of symptoms >14 days that led to venous stent placement. The majority (66.0%) of patients presented with edema (Clinical, Etiological, Anatomical, Pathophysiological [CEAP] C3) followed by hyperpigmentation (13.0%; CEAP C4a). Most patients (52.5%) reported moderate pain (VCSS pain score 2), followed by severe (25.6%), mild (15.0%), and no pain (6.9%).

Baseline lesion and procedural details are shown in Table II. The target limb was the left leg in 79.6% of patients (129/162). The most cranial lesion location was the common iliac vein in 91.3% (137/150), and the most caudal lesion location was the external iliac vein in 46.0% (69/150) with 18.7% (28/150) extending into the common femoral vein. The mean lesion length was 55.2 ± 44.6 mm. The Duo Hybrid Stent was placed alone in 112 patients (69.1%), whereas 50 patients (30.9%) were treated with both the

Table I. Demographics and baseline characteristics

Demographics and baseline characteristics	Total (n = 162)	NT (n = 104 [64.2%])	PTS (n = 42 [25.9%])	Acute thrombotic (n = 16 [9.9%])
Age, years	59.4 ± 15.8	61.5 ± 15.0	55.3 ± 16.4	56.4 ± 17.5
Male	102 (63.0)	71 (68.3)	22 (52.4)	9 (56.2)
White/Caucasian	134 (82.7)	84 (80.8)	38 (90.5)	12 (75.0)
BMI, kg/m^2	30.1 ± 5.7	30.9 ± 5.8	29.2 ± 5.5	26.9 ± 4.3
Prior superficial venous ablation to the target limb	23 (14.2)	21 (20.2)	2 (4.8)	0 (0)
Previously diagnosed and resolved DVT in target limb	24 (14.8)	3 (2.9)	17 (40.5)	4 (25.0)
Previously diagnosed and resolved DVT in the nontarget limb	9 (5.6)	2 (1.9)	7 (16.7)	0 (0)
Contralateral venous obstructive disease	9 (5.6)	8 (7.7)	1 (2.4)	0 (0)
Onset of symptoms that led to venous stenting intervention				
≤14 days	25 (15.4)	4 (3.8)	7 (16.7)	14 (87.5)
>14 days	137 (86.4)	100 (96.2)	35 (83.3)	2 (12.5)
CEAP classification[a]				
C0	2 (1.2)	0 (0)	2 (4.8)	0 (0)
C1	1 (0.6)	1 (1.0)	0 (0)	0 (0)
C2	1 (0.6)	1 (1.0)	0 (0)	0 (0)
C2r	0 (0)	0 (0)	0 (0)	0 (0)
C3	107 (66.0)	65 (62.5)	27 (64.3)	15 (93.8)
C4	9 (5.6)	8 (7.7)	1 (2.4)	0 (0)
C4a	21 (13.0)	15 (14.4)	5 (11.9)	1 (6.2)
C4b	3 (1.9)	2 (1.9)	1 (2.4)	0 (0)
C4c	0 (0)	0 (0)	0 (0)	0 (0)
C5	8 (4.9)	4 (4.8)	3 (7.1)	0 (0)
C6	9 (5.9)	6 (5.8)	3 (7.1)	0 (0)
C6r	1 (0.6)	1 (1.0)	0 (0)	0 (0)
VCSS pain				
0 — None	11 (6.9)	5 (4.9)	3 (7.3)	3 (18.8)
1 — Mild	24 (15.0)	16 (15.5)	6 (14.6)	2 (12.5)
2 — Moderate	84 (52.5)	56 (54.4)	24 (58.5)	4 (25.0)
3 — Severe	41 (25.6)	26 (25.2)	8 (19.5)	7 (43.8)

BMI, Body mass index; *CEAP,* Clinical, Etiological, Anatomical, Pathophysiological; *DVT,* deep vein thrombosis; *NT,* nonthrombotic; *PTS,* post-thrombotic syndrome; *VCSS,* Venous Clinical Severity Score.
Values are mean ± standard deviation or number (%).
[a]Site-reported classification based on patient symptoms. Sites reported as either category or subcategory.

Duo Hybrid and Duo Extend Stents. The mean stented length was 126.4 ± 46.9 mm and most patients (67.3%) received one stent. The preintervention mean stenosis was 71.2 ± 15.0%, which was reduced to a postintervention mean stenosis of 6.7 ± 9.6%.

Primary end points. The primary safety end point (freedom from MAEs at 30 days) was achieved in 98.7% (157/159; 95% CI. 95.5%-99.8%), meeting the predefined performance goal of 89.0% ($P < .0001$) (Table III). There were two patients who experienced a CEC-adjudicated MAE (both patients were in the PTS cohort and had developed a new thrombus in the stented segment requiring reintervention). There were no reports of device- or procedure-related deaths, major bleeding, venous injuries, amputations, or embolizations.

The primary efficacy end point (primary patency of the stent-bearing segment at 12 months) was met in 90.2% of patients (119/132; 95% CI, 83.1%-95.0%), thus meeting the target performance goal of 77.3% ($P = .0002$) (Table III). Of the 13 patients who did not meet the primary efficacy end point, 7 (5.3%) experienced a CD-TLR and 6 (4.5%) were not patent in the absence of a CD-TLR. Of those patients experiencing CD-TLR, two reinterventions

Table II. Baseline lesion and procedural characteristics

Baseline lesion and procedural details	Total (n = 162)	NT (n = 104)	PTS (n = 42)	Acute thrombotic (n = 16)
Target limb				
Left	129 (79.6)	83 (79.8)	30 (71.4)	16 (100)
Right	33 (20.4)	21 (20.2)	12 (28.6)	0 (0)
Lesion location (most cranial)				
IVC	2.0 (3/150)	0 (0/0)	4.8 (2/42)	6.2 (1/16)
Common iliac vein	91.3 (137/150)	90.2 (83/92)	92.9 (39/42)	93.8 (15/16)
External iliac vein	6.0 (9/150)	9.9 (9/92)	0 (0/0)	0 (0/0)
Common femoral vein	0.7 (1/150)	0 (0/0)	2.4 (1/42)	0 (0/0)
Lesion location (most caudal)				
IVC	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
Common iliac vein	35.3 (53/150)	44.6 (41/92)	16.7 (7/42)	31.3 (5/16)
External iliac vein	46.0 (69/150)	52.2 (48/92)	28.6 (12/42)	56.3 (9/16)
Common femoral vein	18.7 (28/150)	3.3 ((3/92)	54.8 (23/42)	12.5 (2/16)
Preintervention stenosis, %	71.2 ± 15.0	69.5 ± 14.9	75.5 ± 15.9	71.5 ± 11.6
Postintervention stenosis, %	6.7 ± 9.6	5.4 ± 8.4	8.6 ± 10.4	10.1 ± 13.2
Mean lesion length, mm (No. patients)	55.2 ± 44.6 (145)	45.1 ± 25.3 (90)	74.9 ± 67.4 (40)	63.4 ± 43.3 (15)
Mean stented length, mm (No. patients)	126.4 ± 46.9 (147)	114.6 ± 35.6 (89)	154.2 ± 60.2 (42)	118.3 ± 31.4 (16)
Stents extended below inguinal ligament, %	18.7	3.3	54.8	12.5
Duo hybrid stent alone	112 (69.1)	84 (80.8)	17 (40.5)	11 (68.8)
Duo hybrid stent placed with duo extend	50 (30.9)	20 (19.2)	25 (59.5)	5 (31.2)
Stents used				
1	109 (67.3)	82 (78.8)	16 (38.1)	11 (68.8)
2	49 (30.2)	21 (20.2)	23 (54.8)	5 (21.3)
3	4 (2.5)	1 (1.0)	3 (7.1)	0 (0)
Procedure time, minutes	56.9 ± 32.2	45.7 ± 21.7	81.7 ± 42.5	64.8 ± 16.4
Fluoroscopy time, minutes (No. patients)	13.4 ± 13.9 (159)	10.4 ± 14.0 (103)	20.4 ± 13.4 (40)	15.0 ± 7.1 (16)
Site location				
Hospital	96 (59.3)	46 (44.2)	34 (81.0)	16 (100)
Office-based laboratory	62 (38.3)	57 (54.8)	5 (11.9)	0 (0)
Ambulatory surgical center	4 (2.5)	46 (44.2)	3 (7.1)	0 (0)

IVC, Inferior vena cava; *NT*, nonthrombotic; *PTS*, post-thrombotic syndrome.
Values are number (%) or mean ± standard deviation.

occurred within 30 days of the index procedure owing to stent occlusion. The remaining cases of CD-TLR occurred on average 150.4 days from index procedure (range, 41-249 days) and were prompted by leg swelling (n = 1) or thrombosis (n = 2)/deep vein thrombosis (n = 2). The 12-month Kaplan-Meier estimates of primary, primary assisted, and secondary patency are shown in Fig 3, *A*.

In subgroup analyses, the primary safety end point was achieved in 100% (103/103), 95.0% (38/40), and 100% (16/16) of the NT, PTS, and aDVT cohorts, respectively (Table III). Primary patency of the stented segment at 12 months was observed in 95.2% of patients (79/83) with NT disease, 79.4% (27/34) of those with PTS, and 86.7% (13/15) of those with aDVT (Table III). The 12-month Kaplan-Meier estimate of primary patency by disease state is shown in Fig 3, *B*.

Secondary end points. Primary-assisted patency and secondary patency at 12 months were 94.7% (124/131) and 95.4% (125/131), respectively (Table IV). Primary-assisted patency at 12 months in the NT, PTS, and aDVT cohorts was 98.8% (81/82), 88.2% (30/34), and 86.7% (13/15), respectively. Secondary patency at 12 months in the NT, PTS, and aDVT cohorts was 98.8% (81/82), 91.2% (31/34), and 86.7% (13/15), respectively.

There was a sustained improvement in the VCSS from baseline to 12 months in all cohorts (ie, ITT, NT, PTS, and aDVT) (Fig 4, *A*). The score improved from a median of 2 (moderate pain) at baseline to 0 (no pain) at 12 months.

Table III. Primary safety and effectiveness end points

Primary safety and efficacy end points	Total (n = 162)	NT (n = 104)	PTS (n = 42)	Acute thrombotic (n = 16)
Primary safety at 30 days	98.7 (157/159) PG: 89.0% $P < .0001$	100 (103/103)	95.0 (38/40)	100 (16/16)
Device- or procedure-related death	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
Device- or procedure-related bleed at target vessel and/or lesion	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
Device- or procedure-related venous injury	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
Target limb major amputation	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
Clinically significant pulmonary embolism	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
Stent embolization outside of target vessel	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
New thrombus within stented segment requiring intervention	1.3 (2/159)	0 (0/0)	5 (2/40)	0 (0/0)
Primary Patency at 12 months	90.2 (119/132) PG: 77.3% $P = .0002$	95.2 (79/83)	79.4 (27/34)	86.7 (13/15)
Occlusion or stenosis >50%	4.5 (6/132)	1.2 (1/83)	8.8 (3/34)	13.3 (2/15)
Total occlusion	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
CD-TLR	5.3 (7/132)	3.6 (3/83)	11.8 (4/34)	0 (0/15)

CD-TLR, Clinically driven target lesion revascularization; *NT,* nonthrombotic; *PG,* performance goal; *PTS,* post-thrombotic syndrome.
Values are percent (n/N).

Observational end points. Observational end points are shown in Table IV. Device success (per stent introduced) was achieved in 98.6% (216/219), lesion success in 100% (162/162), and procedural success in 100% (162/162). There were no reports of stent fracture, migration, or embolization through 12 months.

At 12 months, Kaplan-Meier estimates of freedom from CD-TLR and clinically driven target vessel revascularization were 96.2% (95% CI, 91.7%-98.3%) and 95.6% (95% CI, 90.9%-97.9%), respectively. The Kaplan-Meier estimate of freedom from MAEs was 95.5% (95% CI, 90.9%-97.8%). At 12 months, eight patients had experienced an MAE; seven were reported as a new thrombus within the stented segment requiring reintervention and one was a clinically significant pulmonary embolism confirmed by computed tomography angiography.

Clinically meaningful improvements in QoL and functional outcomes were observed at 12 months compared with baseline (Fig 4). There were improvements in both the baseline VEINES-Sym (52.6 ± 24.9 vs 76.9 ± 21.9) (Fig 4, *B*) and VEINES-QoL scores (51.4 ± 23.8 vs 75.9 ± 23.6) (Fig 4, *C*) at 12 months. Sustained improvements in the EQ-VAS health state score (Fig 4, *D*) and all five dimensions of the EQ-5D-3L score were also noted over 12 months. The Villalta Score improved from 10.4 ± 4.8 at baseline to 3.3 ± 3.9 at 12 months (Fig 4, *E*). Of the 13 venous wounds that were present at baseline, only one wound remained ongoing at 12 months, and it was noted to be "improved." Only two patients had new wounds during the 12-month follow-up period (both patients were classified as NT and were CEAP C4b and C6 at baseline).

DISCUSSION

In the prospective, multicenter, single-arm VIVID IDE study, the Duo Venous Stent System met its primary safety and efficacy end points. The primary safety end point was achieved in 98.7% of patients, and there were no instances of stent fracture, migration, or embolization through 12 months. The primary efficacy end point was met in 90.2%. Positive patient outcomes were noted as reflected by improvements in the VCSS, Villalta, EQ-5D-3L, and VEINES-QoL/Sym scores from baseline through 12 months.

The primary safety and efficacy outcomes reported in the VIVID study are comparable with other IDE trials, which report 30-day MAE rates of 1.0% to 6.5% and 12-month primary patency rates ranging from 84.0% to 89.9%.[5-11] Occurrence of stent migration ranged from none in the Abre (Medtronic, Minneapolis, MN) and VERNACULAR (BD, Franklin Lakes, NJ) studies to one migration reported within 12 months in the VIVO Study (Cook Medical, Bloomington, IN) and two periprocedural migrations reported in the VIRTUS Pivotal IDE (Boston Scientific, Marlborough, MA). No cases of stent migration occurred in VIVID. Except for the VIRTUS Pivotal IDE (10/281 [3.6%]), stent fractures through 12 months were not reported in any of the other IDE trials. Although the VIVID study of the Duo Venous Stent System shows consistent results with other venous stent trials, the results cannot be compared directly owing to differences in study design, baseline patient and lesion characteristics, and end point definitions. European studies have also evaluated the safety and efficacy of various venous stents for the treatment of iliofemoral obstructive disease in cohort

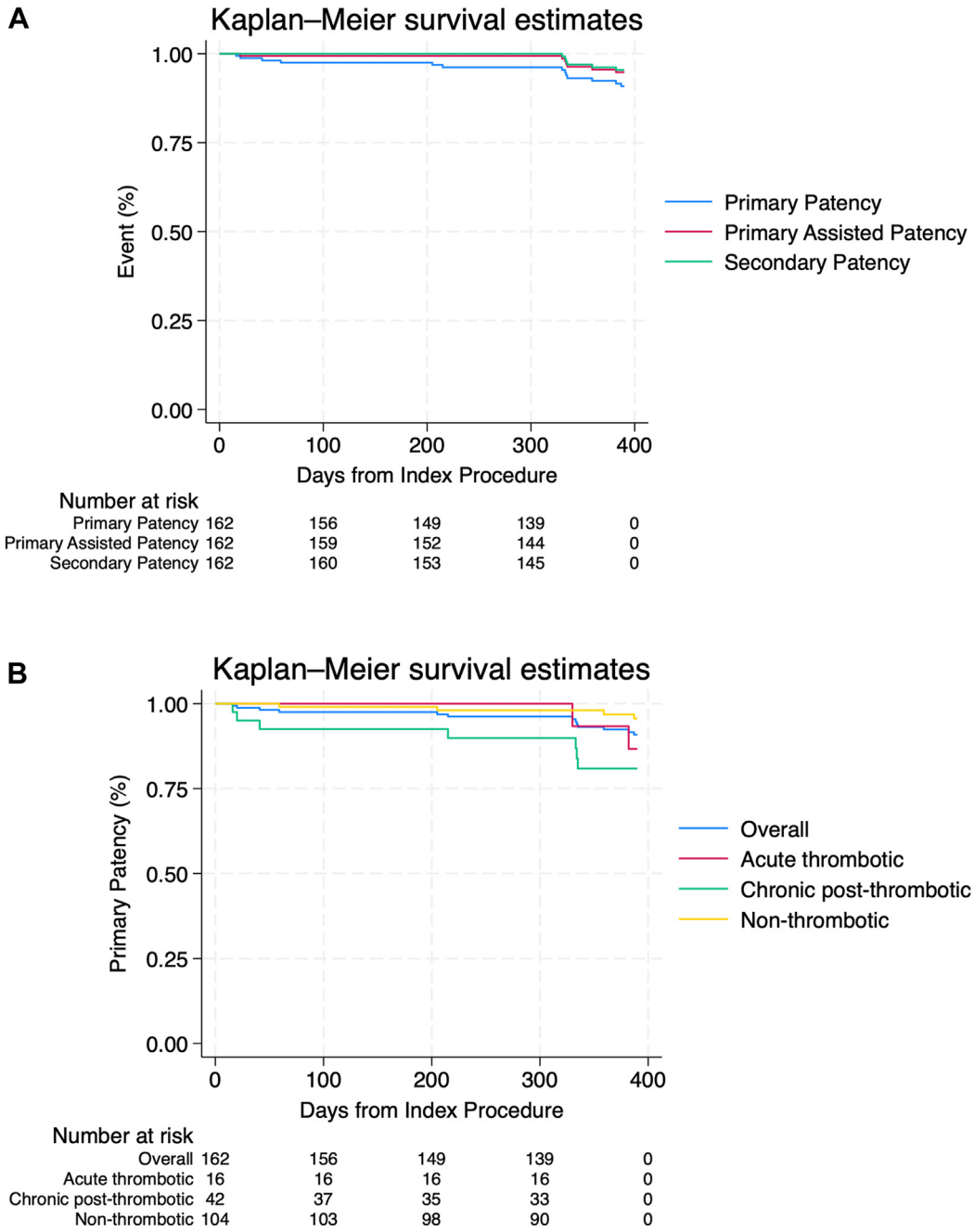

Fig 3. **(A)** Primary patency. **(B)** Primary patency by venous disease state classification.

studies, but the studies were of a smaller size and differing methodology relative to the aforementioned IDE studies.[12,13]

VIVID enrolled patients during the COVID-19 pandemic (November 2021 to December 2022). COVID-19 has been associated with excessive hypercoagulability and had the potential to negatively affect MAE occurrence and decrease patency outcomes. The performance goals for both the primary safety and primary effectiveness end points were established based on research before the COVID-19 pandemic. As such, the protocol was modified in January 2021 to evaluate the primary safety and effectiveness hypotheses in populations that remained negative for severe acute respiratory syndrome coronavirus 2 through 12 months (n = 135) and all ITT patients (n = 162). Importantly, there were no differences in the primary safety and effectiveness outcomes between the two cohorts.

The VIVID trial included the first use of a combination-type stenting system (Duo Hybrid and Duo Extend) that

Table IV. Secondary and observational end points

Secondary and observational end points	Total (n = 162)	Nonthombotic (n = 104)	PTS (n = 42)	Acute thrombotic (n = 16)
Secondary end points at 12 months				
Primary-assisted patency	94.7 (124/131)	98.8 (81/82)	88.2 (30/34)	86.7 (13/15)
Secondary patency	95.4 (125/131)	98.8 (81/82)	91.2 (31/34)	86.7 (13/15)
Observational end points at 12 Months				
Device success (per stent)	98.6 (216/219)	97.6 (124/127)	100 (71/71)	100 (21/21)
Device success (per patient)	98.1 (159/162)	97.1 (101/104)	100 (42/42)	100 (16/16)
Lesion success	100 (162/162)	100 (104/104)	100 (42/42)	100 (16/16)
Procedural success	100 (162/162)	100 (104/104)	100 (42/42)	100 (16/16)
Stent fracture	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
Stent migration	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
Stent embolization	0 (0/0)	0 (0/0)	0 (0/0)	0 (0/0)
KM freedom from MAEs	95.5	97.0	89.9	100
KM freedom from CD-TLR	96.2	98.0	89.9	100
KM freedom from CD-TVR	95.6	97.1	89.9	100

CD-TLR, Clinically driven target lesion revascularization; *CD-TVR*, clinically driven target vessel revascularization; *KM*, Kaplan-Meier; *MAEs*, major adverse events; *PTS*, post-thrombotic syndrome.
Values are percent (n/N) or percent.

was developed specifically to address the anatomical challenges and mechanical demands of the iliofemoral venous segment. Current dedicated venous stent systems and their relevant IDE clinical trials included a single stent design that could be overlapped if necessary to cover a lesion, thus replicating mechanical properties throughout the length of the stented segment. The most cranial aspect of the Duo Hybrid Stent was placed most frequently in the common iliac vein, ensuring the high crush resistance segment was placed in instances of compression. The Duo Extend was used in 30.9% of cases where it was placed more caudally, with the goal of providing flexibility in diseased areas subject to motion. Investigators were provided instructions to overlap the two stents by 1 to 2 cm. Overlap location was at the discretion of the operating physician. The VIVID trial was also distinct as it was the first venous stent IDE study to have a floating performance goal based on the proportion of patients that enrolled into three venous disease states (ie, NT, PTS, and aDVT). Previous IDE studies determined the performance goal from projected distribution of patients derived from the literature as opposed to actual enrollment. These disease state classifications were predefined in the protocol and assigned by the investigator at the time of the procedure. The etiologies of these diseases are distinct from one another, and the prospective enrollment allows the opportunity to learn more about the outcomes in a core laboratory-adjudicated study as well determine a more specific performance goal. Furthermore, VIVID was the only venous stent study to require the use of IVUS to determine the size of the implanted stent(s). The rationale for this requirement was based on data demonstrating that venography underestimates the reference vein size relative to IVUS.[14] Importantly, an undersized stent can lead to stent embolization or migration or impact patency; stent oversizing can result in significant low back pain and, in some cases, lead to stent explantation.[15]

Limitations. The VIVID study is limited by its single-arm, nonrandomized design. The design of this study was focused on the safety and efficacy of stent placement in nonmalignant iliofemoral venous disease, and it was not powered to assess the primary end points in each of the venous disease states. The sample size for the aDVT group was lower than anticipated and most patients presented with NT lesions, which are characteristically more focal in nature. To address this limitation, the protocol was designed prospectively with an overall performance goal calculated from disease-state specific performance goals that were weighted based on the proportion of actual enrollment. Finally, the outcomes reported herein are limited to 12 months. Follow-up is planned through 36 months.

CONCLUSIONS

The Duo Venous Stent System is safe and effective for the treatment of nonmalignant iliofemoral venous disease. Patients experienced meaningful clinical and QoL improvements across all disease states. Continued follow-up will be important in assessing long-term outcomes.

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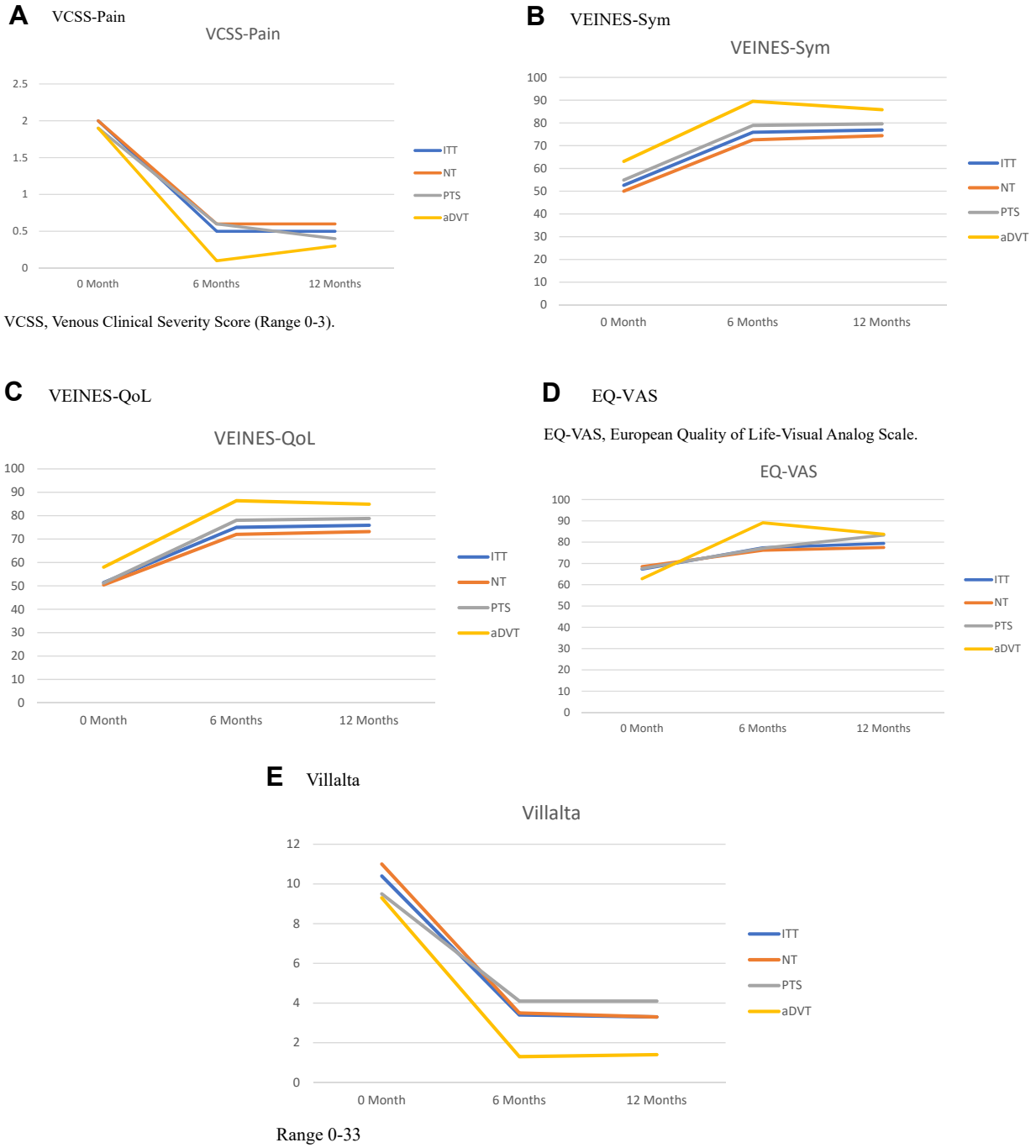

Fig 4. Quality of life (QoL) and functional assessments. **(A)** Venous Clinical Severity Score (*VCSS*). **(B)** VEINES-Sym. **(C)** VEINES-QoL. **(D)** EQ-VAS. **(E)** Villalta. *aDVT*, acute deep vein thrombotic; *ITT*, intention to treat; *NT*, non-thrombotic; *PTS*, post-thrombotic syndrome.

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Data collection: MR, KD, DD, PS, NS, AL, PG
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Final approval of the article: MR, ML, KD, DD, PS, NS, AL, PG, AN, RK, MG
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M.R. is a consultant to Abbott, Boston Scientific, Medtronic, Philips, and Terumo. K.D. is a speaker/consultant for Boston Scientific, Cook Medical, Philips, Becton Dickinson, Penumbra, and Medtronic and a consultant for W. L. Gore & Associates, Cordis, Abbott, Asahi Intecc, Veryan, and Shockwave Medical. P.G. is a consultant for Cook, Philips, Medtronic, BD, and Boston Scientific. A.N. is an employee of Technomics Research. R.K. is an employee of Syntropic. M.G. is a consultant for Vesper Medical.

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