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Short-Term Clinical Experience with a Dedicated Venous Nitinol Stent: Initial Results with the Sinus-Venous Stent

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WHAT THIS PAPER ADDS

Endovascular treatment in patients with deep venous occlusive or obstructive disease, by PTA and stent placement, is an emerging field; however, dedicated venous stents have only recently become available. This study describes a first experience with one such device, the sinus Venous stent. This device distinguishes itself from previously used stent designs aimed at the arterial system by increased radial force and flexibility, and greater diameter and length. It is postulated that dedicated venous stents will become the new standard for treatment of venous compression and post-thrombotic syndromes in the future.

Objective: Deep venous stenting has become the primary treatment option for chronic venous obstructive disease, both for iliac vein compression and post-thrombotic venous lesions. Until recently, only stents aimed at arterial pathology were used, because no dedicated venous stents were available. However, three such stents have now become available. These venous stents are characterized by increased length, diameter, flexibility, and radial force. This study reports an early experience with one of these devices; the sinus Venous stent (OptiMed GmbH, Ettlingen, Germany).

Methods: Between March 2012 and July 2014, 75 patients were treated with the sinus Venous stent: 35 cases of iliac vein compression syndrome and 40 cases of unilateral chronic obstruction in post-thrombotic syndrome (PTS). Diagnosis of relevant obstruction was made using clinical evaluation, duplex ultrasound, and magnetic resonance venography. Patency during follow up was assessed with duplex ultrasound. Clinical improvement was assessed by VCSS, Villalta score, rate of ulcer healing, and improvement of venous claudication.

Results: The cumulative patency rates at 3, 6, and 12 months were 99%, 96%, and 92%, respectively. The cumulative assisted primary patency rates were 99% at 3, 6, and 12 months. The cumulative secondary patency rate at 12 months was 100%. Differences exist in patency rate between the subgroups of non-thrombotic and post-thrombotic, with the first showing no re-occlusions. All re-thromboses in the PTS group were treated by ancillary treatment modalities. VCSS and Villalta score decreased significantly after stenting, as did venous claudication. Morbidity was low without clinically relevant pulmonary embolism, and mortality was nil. Although two out of seven ulcers healed temporarily, no ulcer remained healed at 12 months follow up.

Conclusion: Short-term clinical results using the sinus Venous stent are excellent, with significant symptom reduction, low morbidity rates, and no mortality. Loss of stent patency is seen less often compared with arterial stents described in the literature.

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INTRODUCTION

Therapy for chronic deep venous disease has long been characterized by the sole use of conservative treatment modalities, both in cases of valvular insufficiency and venous obstructive disease. Open surgical or endovascular approaches were reserved for the most severe cases, which still holds true for deep venous valvular insufficiency. In recent years, however, the treatment options in chronic

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deep venous obstructive disease have changed dramatically. Endovascular treatment, by use of percutaneous transluminal angioplasty (PTA) and stenting of post-thrombotic obstructions and venous compression syndromes, such as May-Thurner syndrome (MTS), has become standard care in a large number of specialized centers worldwide. The low morbidity, absence of mortality, and excellent short and long-term results mean that worldwide interest in this type of treatment is rapidly increasing and more and more centers are starting to offer this treatment. It is, therefore, remarkable that until very recently no stents dedicated to deep venous pathology were available.

Neglén et al. showed good results with the Wallstent, a metal stent frequently used in arterial pathology, with high radial force, although limited flexibility and poor positioning qualities.[1] Also, nitinol stents have been used and show comparable results between study groups.[2] Recent study of arterial designed self-expanding nitinol stents in a mostly post-thrombotic population, showed patency rates of 74%, 81%, and 96% at 1 year for primary, assisted primary, and secondary patency, respectively.[3] The arterial design, however, incorporates properties that might hamper applicability in the venous system.[4] Arterial and venous anatomy and hemodynamics differ greatly in physiological and pathophysiological conditions; especially in terms of shear stress, vessel diameter, and flexibility. Moreover, PTA and stenting in arterial disease is generally reserved for pathology of athero-thrombotic origin, without scarring of the vessel wall and or external compression.

Recently a number of dedicated venous stents have been announced or became available; namely the Veniti Vici (VENITI inc., St. Louis, MO, USA), Zilver Vena (Cook, Bloomington, IN, USA), and sinus Venous (OptiMed, Ettlingen, Germany). All three devices are designed to accommodate the need for greater length, diameter, flexibility, and radial force in the venous system. To the authors' knowledge, only clinical data regarding the Zilver Vena have been published. O'Sullivan et al. showed excellent results for the Zilver Vena stent in a challenging population with many acute DVT patients and malignant venous obstructions; they reported a short-term patency rate of 85%.[5]

This study evaluates safety and short-term clinical outcome when using the sinus Venous stent in routine patient care at a tertiary venous center. As iliac vein compression syndromes differ greatly in their etiology from post-thrombotic disease, use of the device will be evaluated separately for both types of pathology.

METHODS

The study included 75 patients treated for symptoms and complaints related to unilateral chronic iliofemoral venous obstructive disease with the sinus Venous stent at a tertiary referral hospital, between March 2012 and July 2014. Patients who were suspected of having iliofemoral deep venous obstruction received both duplex ultrasonography (DUS) imaging and magnetic resonance venography (MRV) to confirm the diagnosis.[6] Patients were included when: (A) signs of unilateral iliofemoral deep venous obstruction were present on DUS and MRV (>50% diameter stenosis and the presence of a collateral network), (B) clinically significant signs and symptoms of chronic obstructive venous disease were present, and (C) the femoral and deep femoral veins were patent. Patients with inferior vena cava involvement or bilateral iliofemoral occlusive disease were excluded. Furthermore, patients were excluded in whom post-thrombotic aberrations extended below the level of the saphenofemoral junction in the common femoral vein, as these patients are treated in a hybrid fashion, stent placement combined with endophlebectomy and AV fistula creation.[7] Moreover, patients with a history of DVT less than 1 year ago were excluded as sufficient natural recanalization might still occur.[8] Upon intake baseline data were collected, consisting of CEAP, Venous Clinical Severity Score (VCSS), Villalta score, and assessment of venous claudication.[9–11] Venous claudication was defined as the onset or worsening of pain and/or heaviness during (mild) exercise, which subsides during rest, especially when sitting or lying down. Venous claudication was only considered in patients with a proven venous obstruction. The location and extent of obstruction or external compression, the presence of collateral veins, the inflow at the common femoral vein from all three major branches (great saphenous vein, femoral vein and deep femoral vein), the outflow through the inferior vena cava and valve competence (< 0.5 seconds of reflux) all were evaluated. Left iliac vein compression (LIVC) or right iliac vein compression syndrome was considered when external compression of the common iliac vein (CIV) created >50% diameter reduction at this point as shown by DUS and/or MRV and collaterals were present.[12,13]

Duplex ultrasonography

DUS examination was done using a Hitachi Aloka ProSound ALPHA 7 Premier machine (Aloka, Tokyo, Japan) and consisted of scanning the venous system from the supra-renal vena cava down to the common femoral vein in the supine position with a convex array transducer, UST-9130 (frequency range, 3–6 MHz). Using a high-frequency UST-5411 (frequency range, 5–16 MHz) compound linear array transducer with pulsed wave Doppler (5 MHz), scanning from the upper groin to below the knee to test for distal obstructive lesions (>50% diameter reduction) and valvular incompetence (>0.5s reflux), in the standing position, was performed.

Magnetic resonance venography

All MRV examinations were performed on a 1.5-T MRI system (Achieva, Philips Medical Systems, Best, the Netherlands). The technique has been described in detail before.[6] In short, a dedicated 12 element phased array peripheral vascular coil with a cranio-caudal coverage of 128 cm (Philips Medical Systems) was used for signal reception. A fixed dose of 20 mL gadobutrol (Gadovist 1.0, Bayer Schering Pharma, Berlin, Germany) was administered

intravenously as a single dose at a rate of 1.0 mL/s in the median cubital vein, using a remote controlled injection system (Medrad Spectris, Indianola, PA, USA). A five station three dimensional ultrafast gradient echo (TFE) sequence with fat suppression (SPIR) was used for high resolution imaging of the venous vasculature from the popliteal veins up to the right atrium.

PTA and stenting

Procedures were performed in a dedicated angiosuite (AlluraClarity, Philips Medical Systems, Eindhoven, the Netherlands). All interventions in post-thrombotic syndrome (PTS) patients were performed under general anesthesia, while iliac vein compressions were treated under local anesthesia. Heparin (5.000 IU) was administered to all patients currently not using oral anticoagulants, and coumadin was continued in all other cases (a maximum INR of 4 was accepted at the time of intervention). Venous access was obtained through the ipsilateral femoral vein, at least 15 cm distal to the femoral confluence under ultrasound guidance. A 10F sheath was needed to facilitate stent introduction. The technique for traversing stenotic and occluded venous segments has been described before.[14] Pre-dilatation to the size of the anticipated stent is essential for sinus Venous stents. Pre-dilatation was done increasing in size from 12 to 16 mm from the common femoral vein to the common iliac vein (12 mm powerflex and 16 mm maxi LD, Cordis, Johnson & Johnson, Diegem, Belgium; 14 mm Armada, Abbott, North Chicago, IL, USA). Maximum pressure needed for full balloon expansion was 12 atm. All venous segments were stented with the sinus Venous. Post-dilatation was always performed. Post-stenting assessment of in and outflow was done by single plane antero-posterior angiography. Conebeam CT imaging was performed to evaluate stent configuration and apposition. Post intervention, patients were generally discharged the next day. The anticoagulation regimen consisted of 6 months of treatment with coumadin, with a target INR of 3—4, according to Dutch guidelines for thrombosis service.[15] This regimen was started the evening after the intervention. Full dose tinzaparine was started directly post-intervention and continued until the INR was >3 on two separate days. Antiplatelets were not used. In patients already using coumadin prior to the intervention, these drugs were continued during hospitalization.

Follow up

Standardized follow up was performed at 2 and 6 weeks and 3, 6, and 12 months post intervention. Follow up data collection consisted of VCSS and Villalta score assessment, rate of relief of venous claudication and ulcer healing (defined as full re-epithelialization). DUS was performed to assess patency at every visit. Patency was defined as flow in a lumen with $<50\%$ diameter compared with the stent diameter. All data were collected prospectively using a preset protocol.

Statistical analysis

Frequencies and percentages were used to present categorical data. Median values with the range were used for continuous data. Categorical data were analyzed by the χ^2 test. Kaplan—Meier survival analysis was used to calculate patency rates. An α of $\leq .05$ was used to indicate statistical significance.

Ethical approval for research

Under Dutch law, patients treated at a university hospital give automatic consent for their anonymized data to be used in research, unless explicit objections are made.

RESULTS

Demographics

Seventy-five patients with unilateral chronic ilio-femoral venous obstruction (CVO) were treated by placement of the sinus Venous stent during the study period. The median age was 45 years (range 18—77), and 49 (65%) patients were female. Complaints and symptoms were caused by post-thrombotic disease in 40 (53%) patients. In the other 35 (47%) patients, CVO was caused by primary iliac vein compression syndrome (left sided in 33 patients). In the post-thrombotic patient group, 35 (88%) had suffered a DVT in their medical history. In the other five patients no DVT was ever diagnosed clinically; however, there were signs on MRV and DUS of vein wall scarification and trabeculation in the common and/or external iliac vein, consistent with prior DVT (Table 1). All post-thrombotic ilio-femoral obstructive lesions were occlusive on the intra-procedural venogram. Post-thrombotic occlusion was restricted to the CIV in two (5%) patients, present in CIV and external iliac vein (EIV) in five (13%), present in the EIV and common femoral vein (CFV) above the sapheno-femoral confluence in four (10%) and extending from the CIV to the CFV above the sapheno-femoral confluence in 29 (73%) patients. C class of CEAP was C4—6 (i.e. skin changes) in 21 (28%) patients. Forty (53%) patients presented with venous claudication. Based on the Villalta scale, 13 (33%) legs were scored as having mild, 11 (28%) moderate, and 13 (33%) severe PTS. In three (8%) patients the Villalta scale was <5 points, that is venous claudication was the indication for treatment in those patients (which highlights the inability of the Villalta scale to adequately assess PTS in some cases). Venous claudication was present in 25 (63%) patients in the PTS and 16 (46%) in the iliac vein compression groups. Seven (9%) patients had an active venous ulcer, four in the PTS, and three in the iliac vein compression syndrome group. Other demographics and subdivision into subgroups can be found in Table 1.

Procedure

All post-thrombotic occlusions required recanalization. Technical success was achieved in all cases. In 43 patients (57%) one stent was used, in 27 patients (36%) two stents, and in five patients (7%) three stents were used. When applicable, the stent was placed as accurately as possible at

Table 1. Demographics of the total, PTS, and iliac vein compression subgroups.

Baseline	Total	PTS	Iliac vein compression
N	75	40	35
Number of females	49 (65%)	24 (53%)	25 (71%)
Average age (years)	45 (17—77)	45 (17—68)	44 (18—77)
Single DVT	38 (51%)	28 (70%)	5 (14%)
Recurrent DVT	9 (12%)	7 (18%)	2 (6%)
Silent DVT[a]	5 (7%)	5 (13%)	0 (0%)
Time between DVT and Treatment (years)	6 (1—37)	6 (1—37)	
Left sided DVT		29 (83%)	
Right sided DVT		5 (14%)	
Bilateral DVT		1 (3%)	
Left sided stenting	72 (96%)	39 (98%)	33 (94%)
Right sided stenting	8 (11%)	6 (15%)	2 (6%)
C-class 0	8 (11%)	4 (10%)	4 (11%)
C-class 1	9 (12%)	7 (18%)	2 (6%)
C-class 2	13 (17%)	6 (15%)	7 (20%)
C-class 3	24 (32%)	11 (28%)	13 (37%)
C-class 4	11 (15%)	6 (15%)	5 (14%)
C-class 5	3 (4%)	2 (5%)	1 (3%)
C-class 6	7 (9%)	4 (10%)	3 (9%)
Median Villalta		11.5 (2—24)	
Venous claudication	40 (53%)	25 (63%)	16 (46%)
Superficial venous reflux	61 (81%)	33 (83%)	28 (80%)
Deep venous reflux	19 (25%)	12 (30%)	7 (20%)
Perforator vein reflux	17 (23%)	5 (13%)	12 (34%)

[a] Silent DVT: no anamnestic history of DVT, but clear signs of previous DVT on imaging.

the iliac confluence to cover the obstruction, with special care not to cover the contralateral inflow. In three patients, however, one in the PTS group and two in the iliac vein compression group, positioning was deemed too central into the inferior vena cava (IVC), touching the IVC wall and thereby covering the contralateral inflow. No further action was taken. In a fourth patient acute thrombosis of the stented tract was observed during the procedure and was directly and successfully treated by percutaneous thrombectomy. Throughout follow up this patient's stents remained patent. Intra-procedural kinking and/or fracture of stents were not seen.

Follow up

The ultrasound examination at 2 weeks showed suboptimal positioning of the CIV stent in two patients with iliac vein compression lesions. In both cases, the stents were placed too peripherally, resulting in persistent compression of the left CIV by the overlying right common iliac artery (which did not require re-stenting as the recurrent stenosis was <50%). Optimal stent distention was seen in all cases distal to the CIV. Mild compression, that is oval rather than round configuration of the stent was noticed at the level of the left common iliac vein because of the overriding right iliac artery in most cases (Fig. 1); however, no significant diameter stenosis (>50%) was seen, compared with the diameter of a fully expanded stent.

Patient follow up had a median duration of 5.4 (range 1.0—18.0) months. The overall cumulative primary patency was 99% at 3 months, 96% at 6 months, and 92% at 12 months. Assisted primary patency rates were 99% at 3, 6 and 12 months, and the secondary patency rate was 100% during the total follow up period (Fig. 2A). Cumulative primary patency rates for the iliac vein compression group were 100% during follow up (Fig. 2B). The cumulative primary patency rates of the post-thrombotic group at 3, 6, and 12 months were 97%, 93%, and 85%, respectively (Fig. 2C). For all reported patency rates the standard error of the mean was <10.0. Loss of primary patency was seen in three post-thrombotic patients, in all cases re-thrombosis occurred (Fig. 3). Residual compression in one patient with a history of a spondylodesis by metal rods and screws led to

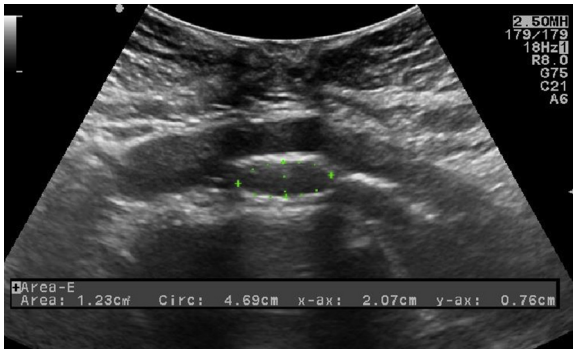
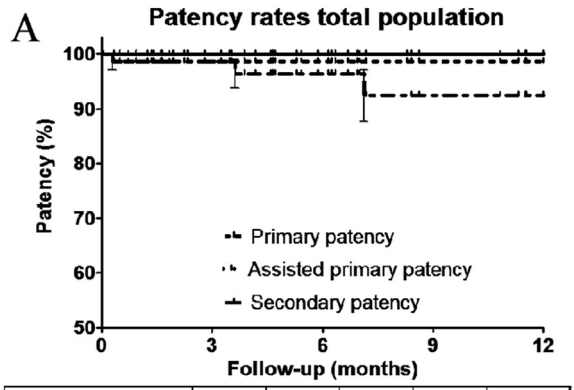
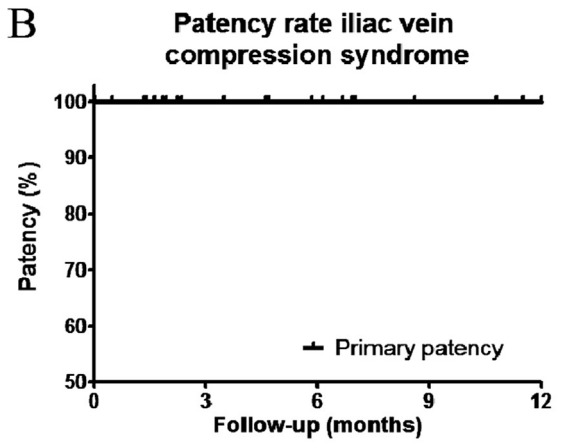


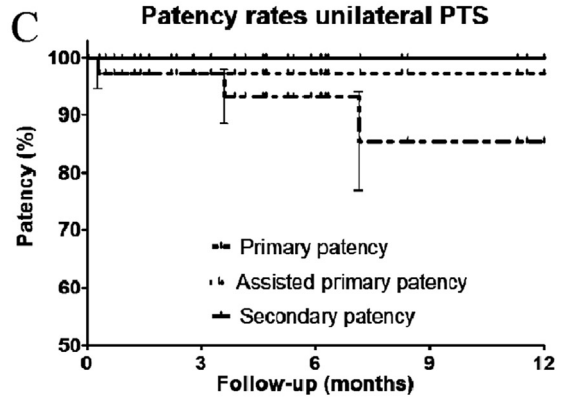
Figure 1. Ultrasound control after stenting the common iliac vein on the left side to treat May-Thurner syndrome, showing the typical oval shape of the stent with sufficient radial force to lift the overlying right common iliac artery. Smallest intraluminal diameter is 7.6 mm, compared with 12 mm more distally, but with a very adequate surface area of 1.23 cm^2.



Subjects at risk	Baseline	3 months	6 months	9 months	12 months
Primary Patency	75	50	34	21	14
Assisted primary patency	75	49	34	21	14
Secondary patency	75	50	35	22	15



Subjects at risk	Baseline	3 months	6 months	9 months	12 months
Primary Patency	35	25	18	12	7



Subjects at risk	Baseline	3 months	6 months	9 months	12 months
Primary Patency	40	26	17	10	7
Assisted primary patency	40	25	17	10	7
Secondary patency	40	26	18	11	8

Figure 2. Kaplan—Meier analysis of patency rates of (A) the total population, (B) the iliac vein compression syndrome population, and (C) the PTS population.

quick stenosis and thrombosis of the stented common iliac vein. This was treated by catheter directed thrombolysis followed by re-stenting of the CIV with a high radial strength balloon expendable stent (Andrastent XL 43 mm, Andramed, Reutlingen, Germany). In a second patient the stent placed in the CIV was mistakenly stretched during placement, leading to a significant gap between the struts of the stent; at this point the right common iliac artery slipped into the gap causing a persistent stenosis during follow up. This was treated by re-stenting with a second well placed sinus Venous stent. In the third patient, with a history of IV drug abuse into the common femoral vein, the fibrotic vein was not pre-dilated with enough pressure. During follow up, significant stenosis was seen at this level, which was treated solely using high pressure re-PTA. Other complications during follow up are noted in Table 2.

Clinical improvement

Median Villalta score in the PTS group decreased from 11.5 (2—24) before treatment to 5.0 (0—16) at last follow up, which constituted a decrease of 6.5 ($p \leq .001$). VCSS decreased 3 points, from 8 (3—21) pre-intervention to 5 (0—16) at last follow up in the PTS group and decreased 2 points from 6 (2—19) to 4 (1—16) in the iliac vein compression group, both decreases were statistically significant ($p \leq .001$ and $p = .019$). Venous claudication subsided in 18 out of 25 patients in the PTS group ($p \leq .0001$) and in 14 out of 16 patients in the iliac vein compression group ($p = .0002$). Two of four ulcers healed in the PTS group, and none healed in the iliac vein compression group. Both healed ulcers recurred during follow up.

DISCUSSION

In this study, short-term results for use of the segmental sinus Venous stent in chronic venous obstructive disease are very favorable, both in the post-thrombotic syndrome and iliac vein compression syndrome. In a previous study, initial data on PTA and stenting in a similar population from the same center were presented.[3] In both studies, PTA and stenting were shown to be safe and feasible when using self-expandable nitinol stents with good patency rates, mild complication rates, and no mortality. Other authors have shown similar favorable results of deep venous stenting during recent decades, including those series in which patients were stented with other stent types, especially the Wallstent (Boston Scientific).[1,16,17] As the Wallstent suffers from significant foreshortening, precise positioning is sometimes difficult in inexperienced hands and occurrence of skip lesions may occur. Therefore, earlier reports mentioned the need for considerable overlapping of multiple stents to prevent incomplete treatment of obstructive lesions. Multiple centimeter overlaps make the stented segment even more rigid. Furthermore, to prevent retrograde migration the Wallstent has to be placed well into the inferior vena cava, potentially impairing contralateral outflow and increasing the risk of contralateral iliac vein thrombosis. Arterial designed nitinol stents have their own shortcomings and differ from venous designed stents in several ways.

Firstly, the diameter of a vein is greater than that of an artery. This is particularly important in the common iliac tract as generally stent diameters of 16—20 mm are

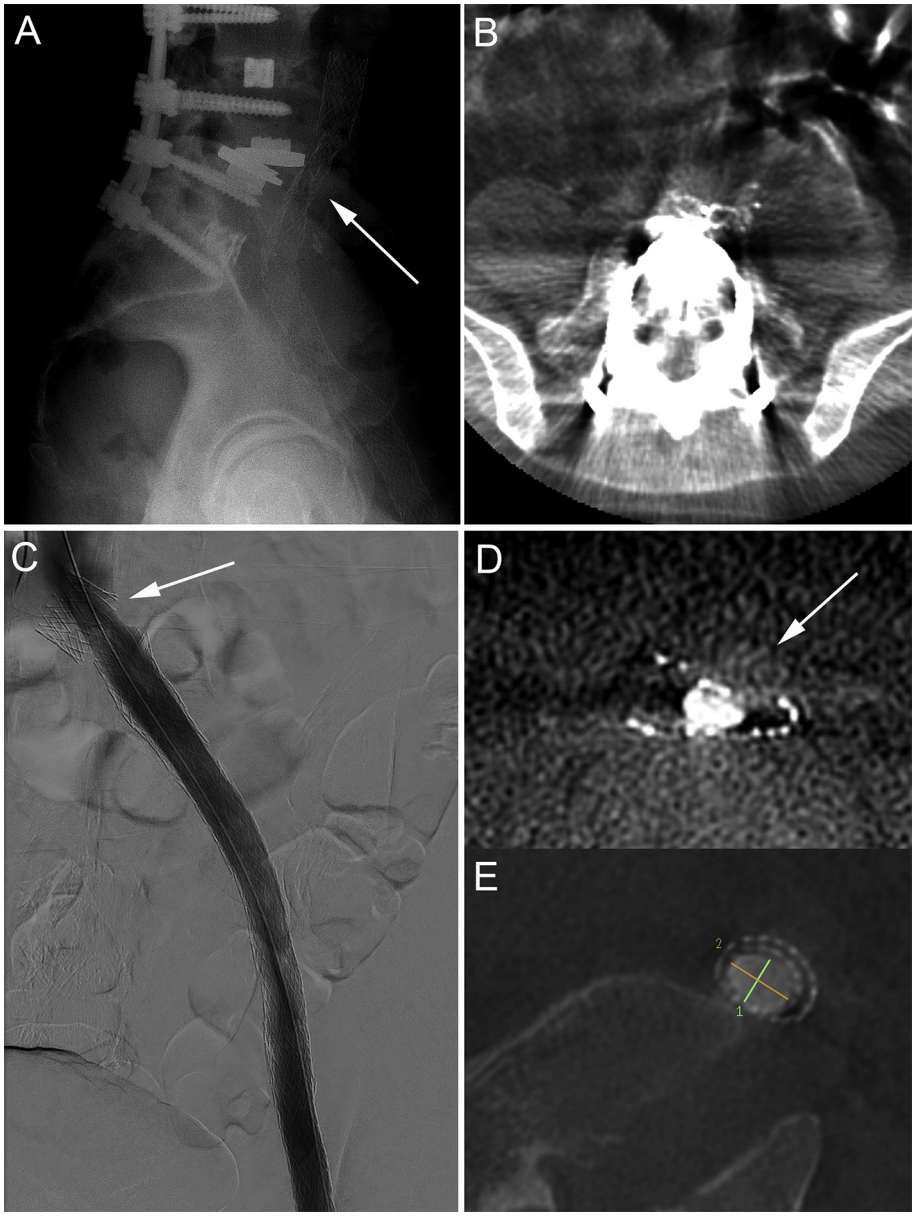


Figure 3. Loss of patency cases. (A) X-ray in lateral projection showing sub-optimal stent configuration because of extensive spondylodesis material leaving a remaining compression (white arrow). (B) Cone beam CT imaging showing significant stent compression, non-responding to repeated balloon angioplasty. (C) Completion angiography after stenting for post-thrombotic iliac vein obstruction showing a gap between stent segments at the level of the overlying common iliac artery resulting from sub-optimal deployment technique. (D) Cone beam CT imaging showing persistent compression caused by lack of stent material and therefore crush resistance at the level of the common iliac artery (white arrow). (E) Adequate surface area after re-stenting.

Table 2. Complications after stent placement.

Complications	Total population	PTS	Iliac vein compression
N	75	40	35
Proximal stent extension into vena cava	3 (4%)	1 (3%)	2 (6%)
Minor bleeding during admission	1 (1%)	1 (3%)	0 (0%)
Stent related pain needing re-admission	1 (1%)	1 (3%)	0 (0%)
Residual stent compression	2 (3%)	2 (5%)	0 (0%)
Stent tapering	2 (3%)	2 (5%)	0 (0%)
Stent stenosis	2 (3%)	2 (5%)	0 (0%)
Anticoagulation related minor bleeding during follow-up	4 (5%)	4 (10%)	0 (0%)
Stent placed proximally of common iliac vein compression location	3 (4%)	2 (5%)	1 (3%)

needed. Arterial stents are generally not offered in these diameters.

Secondly, post-thrombotic obstructions generally cover a greater length of the vein compared with arterial obstructive lesions. Therefore, more than one stent is often required in post-thrombotic patients when using arterial nitinol stents. The increased overlapping areas of the stents further reduce flexibility. Thirdly, post-thrombotic veins are often heavily scarred and have firm intraluminal fibrotic strands, which may extend over relatively long segments. Pre-dilatation, sometimes with high pressure balloons, is needed to break these fibrotic strands and dilate the fibrotic vein wall. A stent with sufficient resistive radial force is needed to maintain this diameter. This force in arterial designed stents is most often insufficient. In iliac vein compression syndromes the local pressure on a vein caught between the overlying artery and bony structures is high, and therefore calls for stents with sufficiently high resistive radial force.

Fourthly, in contrast to arteries, normal veins have a less supported wall and are more susceptible to external forces. Post-thrombotic veins might be influenced less because of the fibrotic changes. Nevertheless, it is generally recommended to land a stent in a healthy vein segment. It is therefore conceivable that particular stent properties have an effect on the integrity of the vein at this location. Optimally, stents implanted within venous structures should be able to move effortlessly with every movement of the vein. Stents with excessive rigidity might dictate the shape of the vein, thereby perhaps creating sub-optimal hemodynamics or damage to the vein wall causing stenosis, occlusion, or insufficient flow. This is especially the case when stents cross the internal iliac vein and inguinal ligament where sufficient flexibility is most important.[18] Finally, when a highly rigid stent is forced to maintain its position at two locations, there is an increased risk of kinking which might lead to stenosis (Fig. 4). In the authors' opinion, an optimal venous stent should be able to flex at two different points without narrowing at these flex points (Fig. 4), thereby preventing kink related stenosis. In general, the venous anatomy should therefore dictate the shape of the stent and not vice versa. The sinus Venous stent should prevent kinking by its segmental design. Connecting rings with close-cell design creates a high radial force. Connecting the rings with two tiny connections keeps the system sufficiently flexible (Fig. 5). However, a number of concerns

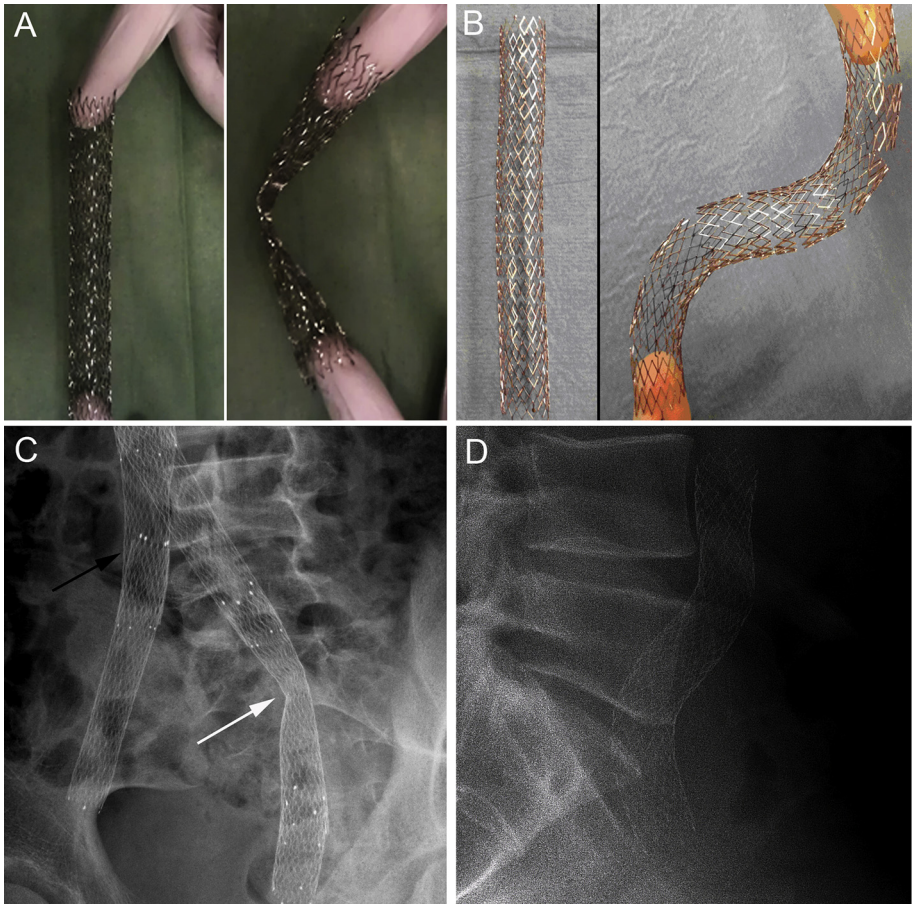


Figure 4. Arterial stent design (sinus XL stent, OptiMed GmbH, Ettlingen, Germany), versus dedicated venous stent design (sinus Venous stent, OptiMed GmbH, Ettlingen, Germany). (A) Forcing an arterial designed stent into a curve increases the risk of kinking. (B) Dedicated venous stents can be shaped easily into an "S" curve. (C) Oblique projection X-ray post stenting with arterial designed stents showing kinking on the left (white arrow) and straightening of a stent-in-stent on the right (black arrow). (D) "S" shape of a venous stent to treat a May-Thurner compression, adapting perfectly to the venous anatomy.

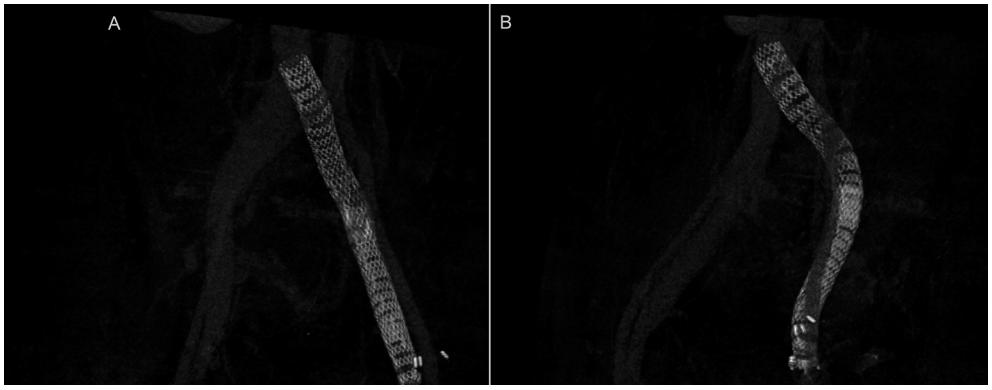


Figure 5. 3D CT reconstruction, antero-posterior (A) and oblique (B) after stenting of the left common and external iliac vein clearly showing the segmented stent design and curved configuration at the level of the internal-external iliac vein confluence and at the level of the common femoral vein, locations known to be prone to kinking or residual compression.

exist. Most importantly, at the level of the highest external force the stent segments should be placed in close proximity, to avoid a high pressure point exactly between segments, which makes delivery technically challenging, with the most important being the pressure point at the level of the overriding common iliac artery. A more or less oval shape can be seen at these levels of high compression, but a residual stenosis of more than 50% would be unacceptable. Other stented segments do not seem to suffer from focal pressure points. Also, the "bare areas" left between separate rings do not appear to predispose to restenosis, at least during the first year, as shown in this study.

As shown by Neglén et al., significant differences in outcome can be observed when comparing stenting for thrombotic and non-thrombotic disease.[1] In this series similar differences were observed; no stents occluded in the iliac vein compression sub-population, and all three loss of primary patency instances were seen in the PTS group. The higher number of re-occlusions in this group might be caused by the etiology and severity of PTS and compromised venous inflow from femoral veins resulting from extensive post-thrombotic trabeculations. Limitations of this study include the small population with short median follow up. Moreover, an in depth comparison with the use of other stents, especially the Wallstent, has not been performed.

CONCLUSION

Short-term clinical results using the sinus Venous stent are excellent, with significant symptom reduction, low morbidity rates, and no mortality. Stent related loss of patency is seen infrequently. Post-thrombotic lesions showed a lower patency compared with non-thrombotic lesions, a known reported finding.

CONFLICT OF INTEREST

Rick de Graaf has consultancy agreements with BARD GmbH/Angiomed and Optimed GmbH. Cees Wittens has consultancy agreements with Angiocare, BoMedical, Medi, Optimed GmbH, and Vascular Insights, and has received research funds from BTG, EKOS, and Sapheon. Houman Jalaie has a consultancy agreement with Optimed GmbH, and has received research funds from EKOS and ABmedica.

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