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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