Recanalization and stenting of chronic iliac venous outflow obstruction

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Stents used: 14mm x 100mm and 16mm x 150mm

sinus-Venous

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CASE REPORT

1. Introduction

Venous outflow obstruction as a cause of chronic venous disease has been neglected for a long time. Partly because other factors like valve incompetence and reflux were the main focus of attention, partly because long-term outcome of revascularization was poor. Treatment options have long been limited to invasive surgical techniques like cross-over femorofemoral bypass grafting with limited patency rates. Over the last 2 decades however, minimal invasive treatment options gained popularity, mainly through improvement in endovascular materials, i.e. innovative stent design. With increasing experience, recanalization and stenting of venous obstructions have evolved and the endovascular approach is now generally accepted as a superior treatment in most patients. Although patency rates after stenting of chronic venous obstruction are relatively high, early failure remains a serious problem. Mainly, this is a result of significant stent compression or kinking at the location of the treated lesions. Over the last years we have found several stents on the market to comprise unfavourable characteristics like limited radial force and / or flexibility. In the case of a common and external iliac vein obstruction, both of these features are of the highest importance. The external compression of the common iliac artery must be overcome and the strong curvature at the level of the internal / external confluence asks for optimal flexibility. This report deals with the recanalization and stenting of a chronic postthrombotic iliac vein obstruction, using the sinus-Venous stent.

2. Clinical problem

A 41 year old female was referred to our institution with chronic venous claudication, peripheral leg edema and ulcerations on the left leg. In 2007 she had a deep venous thrombosis which was treated with oral anticoagulation. Further evaluation in our center showed flow obstruction and common iliac vein compression on duplex examination and postthrombotic changes in the external iliac vein on MR venography. The patient was scheduled for recanalization and stenting of the common and external iliac vein.

3. Intervention

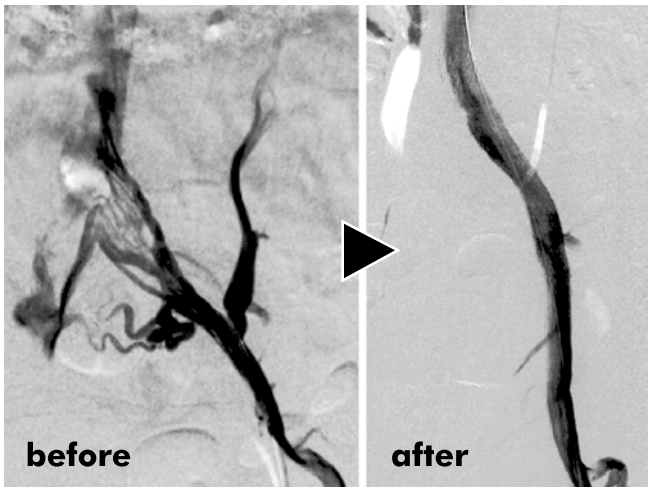
Due to the possibility of extreme pain sensation associated with venous recanalization and stenting all of our procedures are performed under general anesthesia.

Access to the vein was as always done through an antegrade puncture of the femoral vein under ultrasound guidance. Then the external and common iliac vein was passed with a curved 5F catheter and stiff hydrophilic guidewire. After predilation, stenting was performed with a 16 x 150 mm sinus-Venous stent, extended down to the level of the saphenous vein inflow with a 14 x 100 mm sinus-Venous stent.

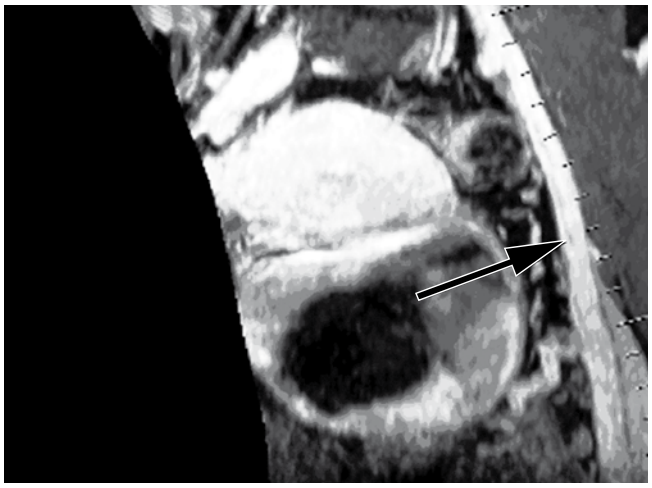
The segmental design of the stent enables stable and accurate positioning during its release using the pull-back system. After post-dilation a rotational cone-beam CT showed optimal deployment and apposition of the two stents. After intervention the patient was placed under vitamin K antagonist anticoagulation treatment for at least 6 months. 3 month follow-up showed healed ulcerations on the left leg and significant improvement of complaints. The stented segments were patent without signs of luminal narrowing on duplex.

4. Summary and critical evaluation

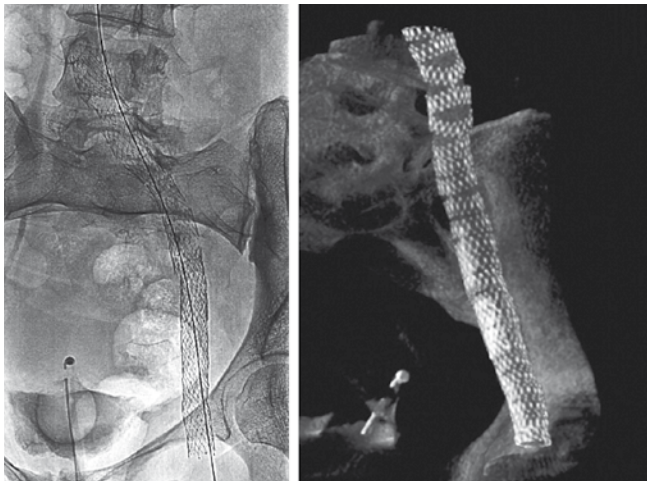
A female patient with chronic venous outflow obstruction was successfully treated by the implantation of two sinus-Venous stents. The sinus-Venous stent comes in diameters up to 18 mm and lengths up to 15 cm. The pull-back release and segmental design accommodate precise positioning of the proximal stent at the iliac confluence and the distal stent at the level of saphenous vein inflow. Finally, the high radial force and optimal flexibility of the sinus-Venous stent resulted in outstanding dilatation and configuration of the stented segments.

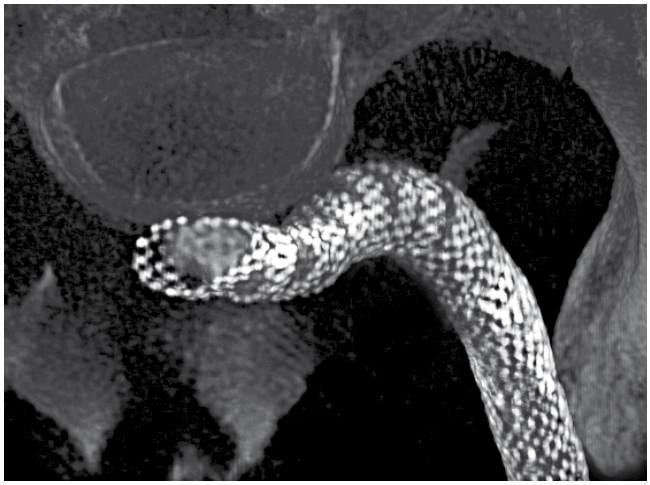


Phlebology from the recanalized external iliac vein (A) shows extensive trabeculation in the common iliac vein, associated with a May-Thurner syndrome.



The collaterals coming from the common iliac vein were also visible on the pre-operative MR venography. Furthermore, postthrombotic strands causing significant obstruction of flow were seen in the external iliac vein (arrow).





Reconstruction of a post-operative cone-beam CT showing optimal flexibility of the sinus-Venous stent at the level of the internal / external confluence. Note the segmental design which enables this favorable configuration.

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Early experience with the dedicated sinus-Venous stent

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Retrospective analysis of 57 patients treated for chronic venous disease

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RETROSPECTIVE ANALYSIS

1. Introduction

Recently, the treatment of central venous obstruction entered a very exciting era. For long, open surgery was the only answer, but the invasive nature of the procedure and discussable long-term patency rates limited popularity of venous reconstructions. Endovascular treatment, by use of percutaneous transluminal angioplasty (PTA) and stenting, both of venous compression syndromes like the May-Thurner syndrome (MTS), and post-thrombotic obstructions has now become standard care in a great number of specialized centers worldwide. Nevertheless, stent related issues encountered during the procedure and follow-up hampered outcome, since only arterial designed stents were available for a long time.

The sinus-Venous stent, a true dedicated venous stent, was recently introduced to offer optimal stent configuration within the venous vasculature and limit stent related complications, thus increasing short- and long-term patency and potentially expand indications.

2. Indications

The main issue to overcome when treating obstructive venous lesions is to withstand the compression by adjacent structures or intraluminal fibrosis, which in most cases is extensive. However, increasing strength of a stent limits flexibility, which hampers usefulness in veins. The sinus-Venous stent however, found the optimal balance between the highest radial force and flexibility. The following indications illustrate the efficacy of the sinus-Venous stent to treat a variety of venous diseases.

May-Thurner syndrome. MTS is a common cause of venous claudication complaints. In its most traditional appearance, the obstruction of the left common iliac vein is caused by the overlying right common iliac artery.

A high radial force of the venous stent is essential to endure the continuous compression by the artery. The sinus-Venous stent shows excellent strength, still maintaining flexibility **(Figure 1)**.

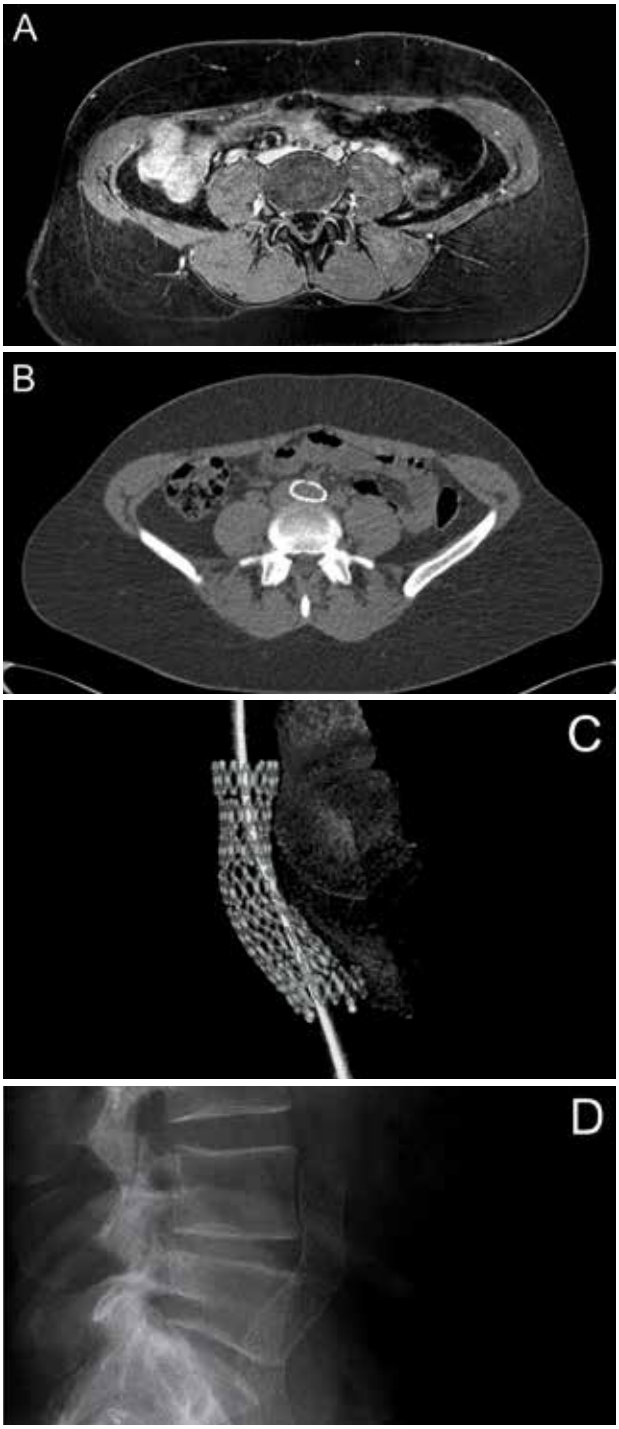
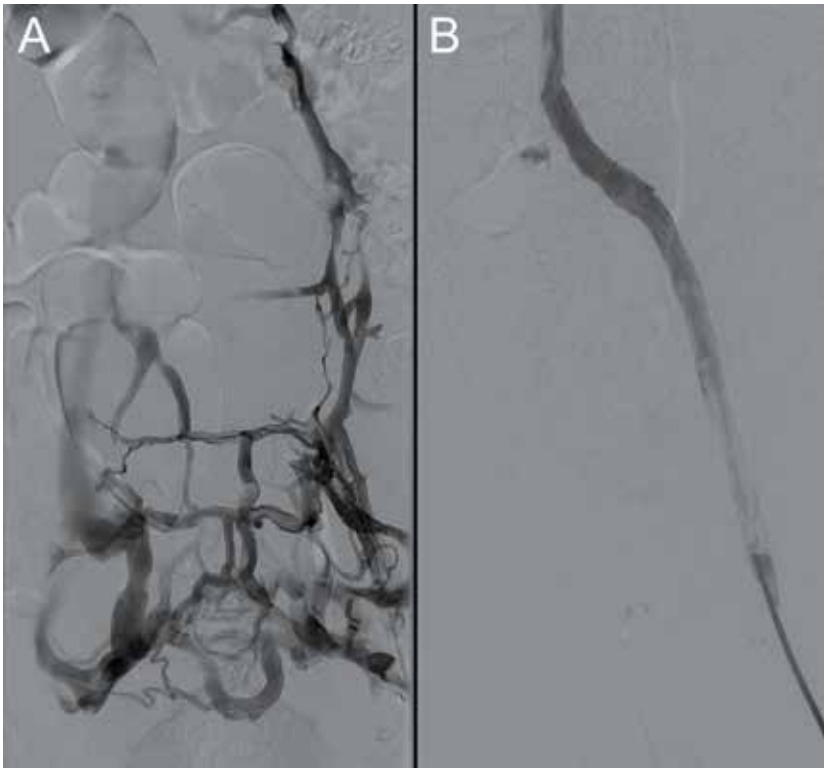


Figure 1 Stenting for May-Thurner syndrome

Retrospective Analysis



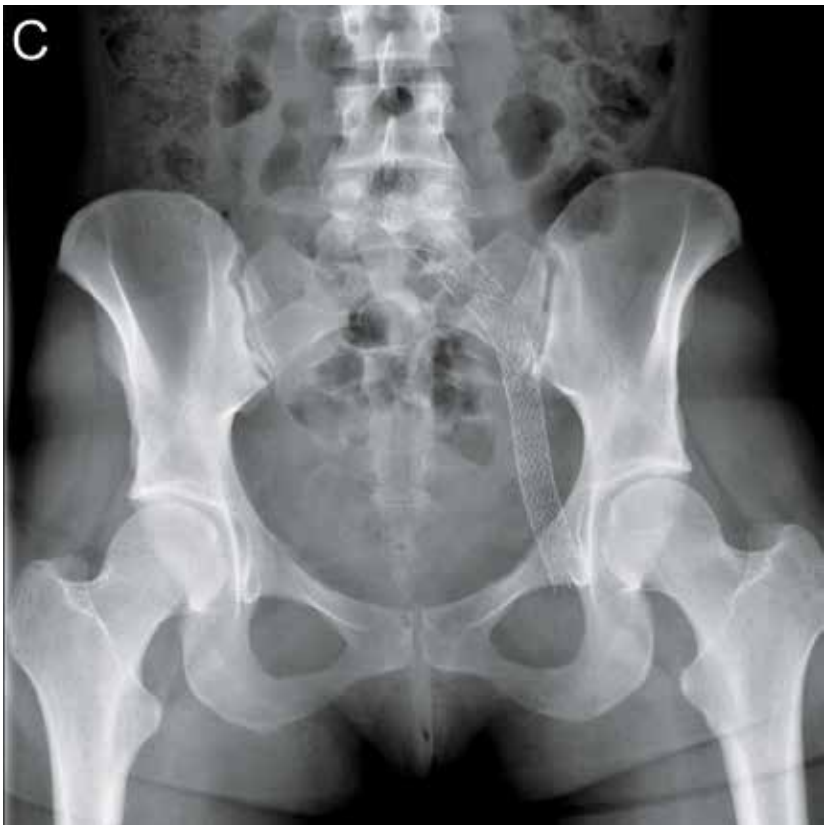


Figure 2 Stenting for chronic iliac venous obstruction

Post-thrombotic obstruction. PTO is characterized by moderate to extensive intraluminal fibrotic stranding which obstructs venous blood flow. After recanalization, prior to stent placement, thorough balloon dilatation is necessary to break these fibrotic fibers.

This facilitates controlled stent deployment and optimizes the configuration of the sinus-Venous stent **(Figure 2)**.

In more extensive cases where post-thrombotic changes extent into the common femoral vein, stent extension over the inguinal ligament is required. Due to optimal flexibility and radial strength of the sinus-Venous however, this does not cause any kinking or residual stenosis.

Deep venous thrombosis. In many cases of acute deep venous thrombosis, an underlying compression (e.g.May-Thurner) can be identified. Treating this cause of outflow obstruction by stent placement is essential to limit the risk of early re-thrombosis. Furthermore, residual thrombosis after thrombolysis might also be an indication for stenting to optimize blood flow and enhance further thrombolysis. It should be noted however, that early patency rates might be lower due to a hypercoagulability state.

3. Overall results

From November 2012 till August 2013, 57 patients were treated for chronic venous obstructive complaints at our tertiary referral center. In total 121 sinus-Venous stents were implanted. Most complaints were caused by PTS (36 patients) or MTS (15 patients). Six patients were stented for residual thrombosis or an identified underlying lesion after thrombolysis. Short term patency was calculated for 35 selected patients who underwent stenting for chronic iliocaval obstructive disease with adequate in- and outflow on completion

angiography, but without surgical desobstruction and arteriovenous fistula (AVF). Cumulative primary patency in this selected group was 97% at 3 months, and 89% at 6 months. Cumulative secondary patency rate was 100% at 3 and 6 months **(Figure 3)**.

We experienced no stent-related complications as kinking or stent fracture. Furthermore, no major bleeding complications or pulmonary emboli were seen.

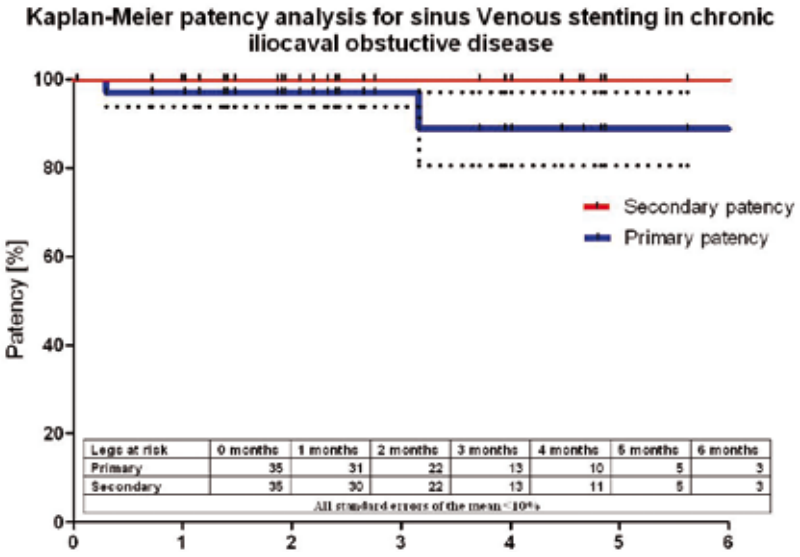


Figure 3 Kaplan-Meier patency sinus-Venous

4. Discussion

In contrast to arteries, veins have lesser inert strength and are continuously compressed, flexed and stressed by adjacent structures. Therefore, stents implanted within venous structures should be able to move effortless with the movement of the vein. Stents that are too rigid have a tendency to straighten the vein forcefully. This might lead to injury of the vein at the edges of the stent and cause recurrent obstruction. The sinus-Venous stent is characterized by a segmental stent design which enables maximal radial force still maintaining excellent flexibility.

Deployment of a segmental stent. Deployment of the sinus-Venous stent should be performed slowly to allow the stent segments to fully open. When the device is pulled back too fast, the individual segments might be positioned slightly separated. Although it is recommended to prevent this configuration, our experience indicates that the sinus-Venous stent re-shapes itself and shows significantly improved alignment and apposition at 2 weeks follow-up **(Figure 4)**.

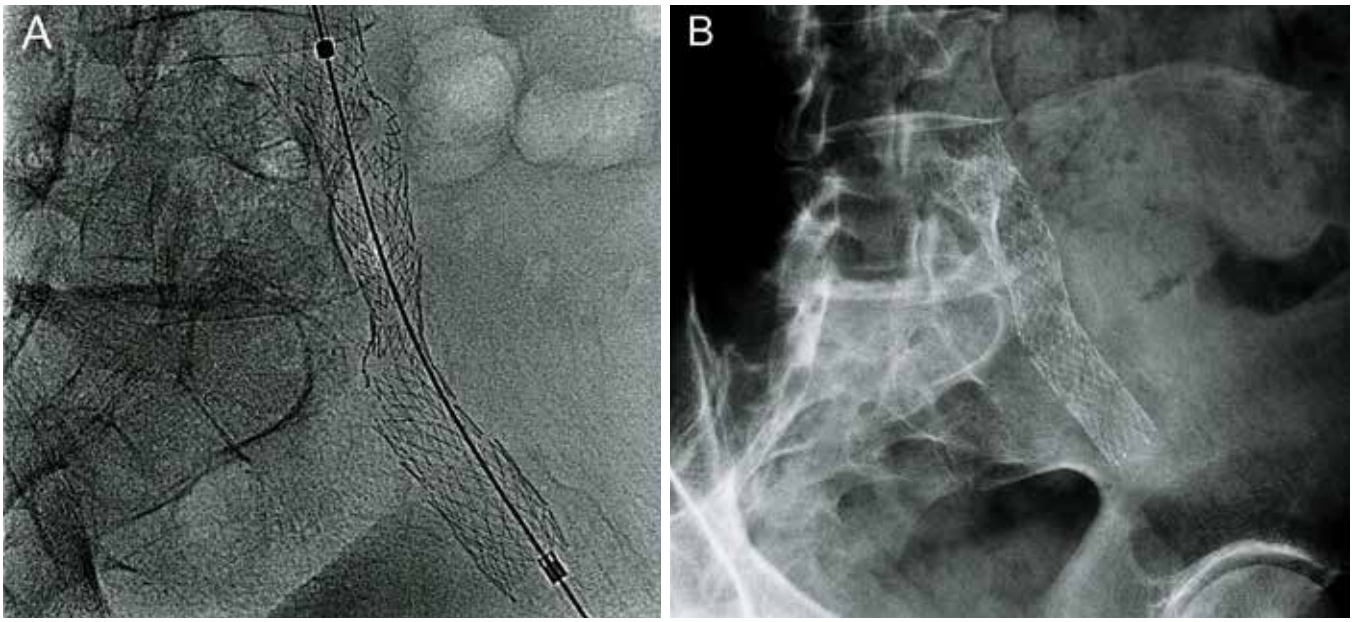


Figure 4 sinus-Venous configuration directly after placement (A) and at 2 weeks follow-up (B)

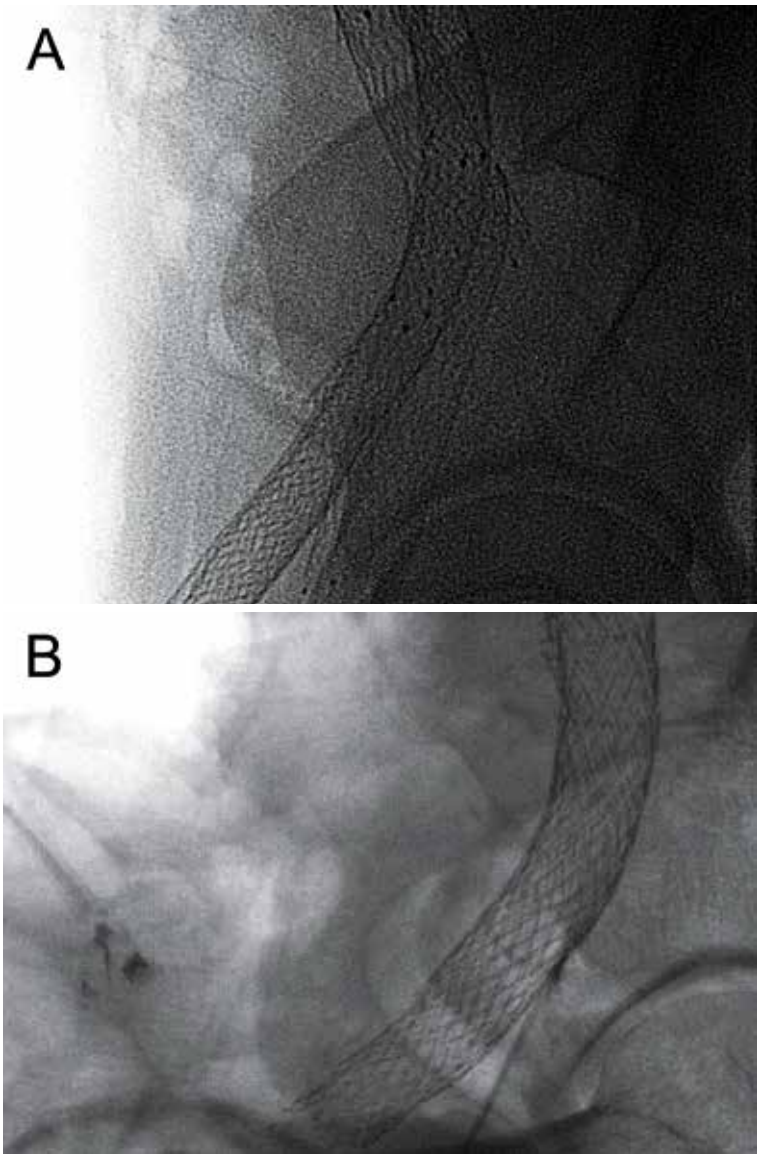


Figure 5 Overlapping stents over inguinal ligament of competitor (A) and sinus-Venous stents (B)

Overlapping and oversizing. When treating longer lesions, sometimes multiple stents are necessary to cover the entire diseased segments. In contrast to other stents, the sinus-Venous stent does not foreshorten which reliefs it from the need to overlap. However, when the length of the inserted stent oblige overlapping, this can easily be accepted and rigidity will not significantly increase **(Figure 5)**.

Figure 5A shows a more straightened configuration of two overlapped competitor stents. Although it has been mentioned before that stents within the venous vasculature should be oversized, this is mainly based upon experience with bare metal stents. The sinus-Venous stent does not migrate and oversizing is not necessary.

5. Conclusion

The sinus-Venous stent proved safe and efficient to treat chronic venous obstructions, May-Thurner lesions and residual stenosis after thrombolysis, with excellent patency results at one year follow-up. With its unique segmental design, the sinus-Venous stent brings the symbiosis between radial force and flexibility to the highest level, and makes it the optimal stent to treat venous obstructive disease.

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