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Case report: **Recanalisation of chronic iliofemoral venous occlusion in a patient with PAD and saphenous reflux**

In this case report for *Vascular News*, experts outline the importance of recognising chronic venous obstruction as a crucial contributor to non-healing wounds in patients firstly diagnosed with peripheral arterial disease (PAD). Mohammad E Barbati, consultant vascular and endovascular surgeon, and Houman Jalaie, consultant vascular and endovascular surgeon, and head of the European Venous Center Aachen-Maastricht at the University Hospital RWTH Aachen (Aachen, Germany), describe a case involving the recanalisation of a chronic iliofemoral venous occlusion in a patient already known to have PAD and saphenous reflux. Recanalisation and stenting were performed to restore patency of the iliofemoral tract. The patient's severe lymphorrhoea resolved, the wound healed after three months, and the two Venovo™ Venous Stents (BD) remained patent at 18 months' follow-up.

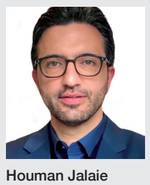
A 68-year-old male patient with two years' history of a non-healing wound in his lower right leg was referred to our venous outpatient clinic. The patient had undergone a right-sided below-the-knee bypass due to PAD two years ago using the contralateral great saphenous vein.

The patient presented with a wound healing disorder since bypass surgery on the proximal medial side of his lower right leg with a severe lymphorrhoea *(Figures 1 and 2)*. Additionally, he suffered from pain, tension, swelling, hyperpigmentation, and disabling venous claudication, which severely impaired him in his daily life.

The patient reported this wound had a two-year history of non-healing despite multiple surgical treatments. Past medical history was significant for a provoked deep vein thrombosis (DVT) after a trauma leading to immobilisation 10 years ago. He added that "the thrombosis was healed long ago and is not a problem anymore".

The colour duplex ultrasound examination revealed a chronic occlusion of the proximal part of the right common femoral vein (CFV) and the entire external iliac vein (EIV). The common iliac vein (CIV) was detected as not affected. There was a reflux of great saphenous vein and retrograde flow of internal iliac vein. The femoral vein (FV) and the deep femoral vein (DFV) were patent *(Figure 3)*. The arterial flow of the right leg was detected as normal with a patent below-the-knee bypass. A magnetic resonance venography confirmed the duplex ultrasound findings.

Mohammad E Barbati



Houman Jalaie

After signing a consent form, the patient was planned for recanalisation and stenting. The right FV access was obtained under ultrasound guidance. A venogram showed complete occlusion of the proximal part of the CFV and the full length of the EIV *(Figure 4)*. A hydrophilic 0.35" angled Terumo wire and a 5 French 65cm-long vertebral shape diagnostic catheter were used to recanalise the occluded vein segments. Antegrade recanalisation by conventional technique remained unsuccessful at crossing the occluded segment below the inguinal ligament. Therefore, a sharp recanalisation was carried out using the back of a hydrophilic 0.18" Terumo to achieve a small channel. After traversing the pathology, the predilatation was performed using high-pressure balloons (16x40mm and 14x40mm, Atlas® Gold, BD). Intravascular ultrasound (IVUS) visualised post-thrombotic trabeculation also in the CIV. After determination of proximal and distal landing zones, two overlapping dedicated venous stents (16x120mm and 14x100mm, Venovo™ Venous Stent System) were deployed. The proximal and distal landing zones were iliocaval confluence and CFV just above the ostium of the DFV, respectively. The length of overlapping zone was approximately 2cm. Postdilatation of stents was performed with the same balloons. The final venogram and IVUS demonstrated an excellent outcome with fully-restored patency of the iliofemoral tract *(Figure 5)*.

We started a therapeutic anticoagulation one day before the procedure using rivaroxaban and the therapy was continued until now. Knee-high compression stocking (Class II) was prescribed and the patient was discharged after two days. The lymphorrhoea ceased and the wound healed after three months. The venous stents remained patent at 18 months postprocedure *(Figure 6)*.

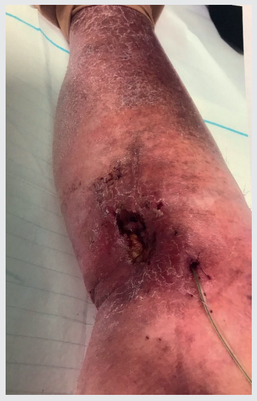


Figure 1. Preoperative image of non-healing wound

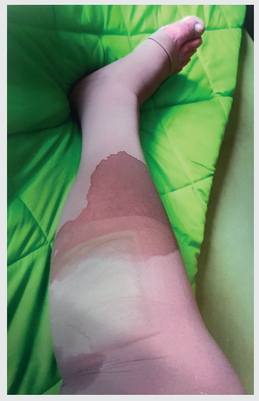


Figure 2. Severe lymphorrhoea

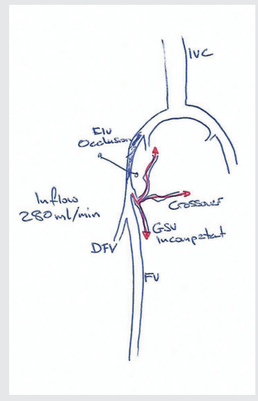


Figure 3. Preoperative venous mapping based on duplex ultrasound

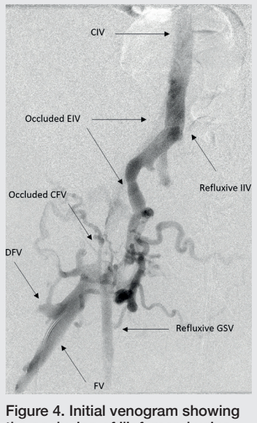


Figure 4. Initial venogram showing the occlusion of iliofemoral veins, reflexive internal iliac vein (IIV), and great saphenous vein (GSV), as well as collaterals

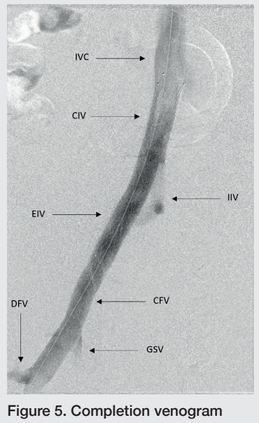


Figure 5. Completion venogram

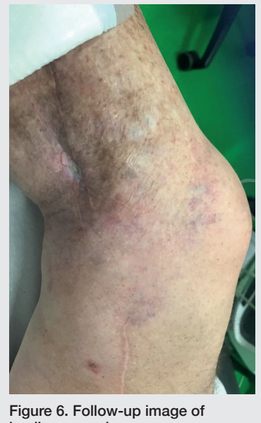
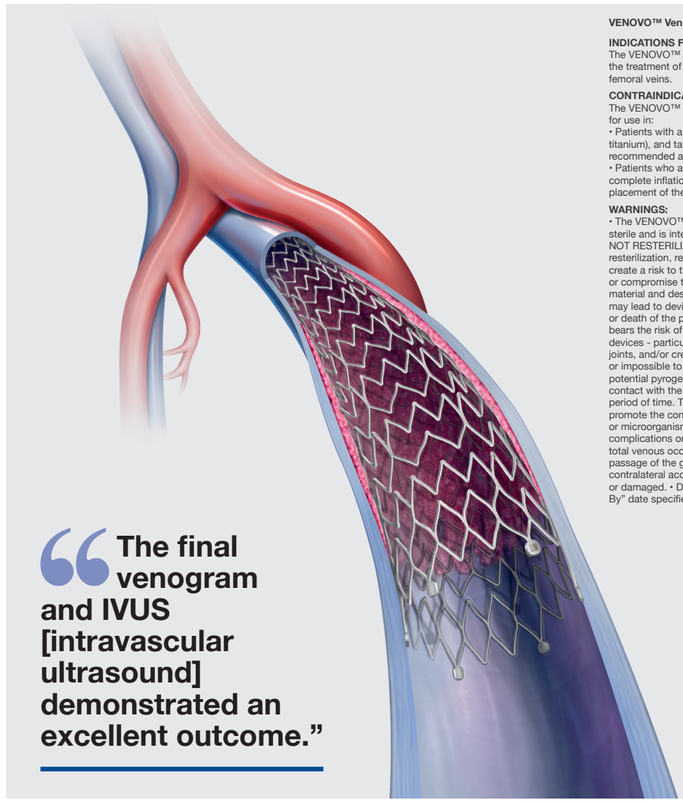


Figure 6. Follow-up image of healing wound



"The final venogram and IVUS [intravascular ultrasound] demonstrated an excellent outcome."

VENOVO™ Venous Stent System

INDICATIONS FOR USE:
The VENOVO™ Venous Stent System is indicated for the treatment of stenoses and occlusions in the iliac and femoral veins.

CONTRAINDICATIONS:
The VENOVO™ Venous Stent System is contraindicated for use in:
• Patients with a known hypersensitivity to nitinol (nickel-titanium), and tantalum • Patients who cannot receive recommended antiplatelet and/or anti-coagulation therapy • Patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter proper placement of the stent or the stent delivery system.

WARNINGS:
• The VENOVO™ Venous Stent System is supplied sterile and is intended for SINGLE USE ONLY. DO NOT RESTERILIZE and/or REUSE the device. Reuse, restenlization, reprocessing and/or repackaging may create a risk to the patient or user, may lead to infection or compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness, or death of the patient. Reusing this medical device bears the risk of cross-patient contamination as medical devices - particularly those with long and small lumina, joints, and/or crevices between components- are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications or death. • DO NOT use in patients with total venous occlusion that cannot be dilated to allow passage of the guidewire. • DO NOT use the device with contralateral access. • DO NOT use the pouch is opened or damaged. • DO NOT use the device after the "Use By" date specified on the label. • Persons with allergic reactions to nitinol (nickel-titanium) alloy and/or tantalum may suffer an allergic response to this implant. • DO NOT expose the delivery system to organic solvents, e.g., alcohol. • The stent is not designed for repositioning or recapturing. • Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures. • If a long lesion needs to be stented consider using the longest available stent rattier than overlapping stents. If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol) • The long-term outcomes following repeat dilatation of endothelialized stents are unknown. • The safety and effectiveness of this device for use in the arterial system have not been established.

PRECAUTIONS:
The device is intended for use by physicians who have received appropriate training. • During system flushing, observe that saline exits at the catheter tip. • The delivery system is not designed for use with power injection systems. • Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution. • Prior to stent deployment, remove slack from the delivery system catheter outside the patient. • If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit. • Store in a cool, dark, dry place. • Do not attempt to break, damage, or disrupt the stent after placement.

Potential Complications and Adverse Events
Complications and Adverse Events which may occur include, but are not limited to the following: • Allergic/anaphylactoid reaction • Amputation • Aneurysm • Arteriovenous fistula • Death related to procedure • Death unrelated to procedure • Dissection • Embolization, venous • Embolization, stent • Extravasation • Fever• Hemorrhage/bleeding requiring a blood transfusion • Hematoma, remote site • Hematoma, puncture site • Hypotension/hypertension • Incorrect positioning of the stent requiring further stenting or surgery • Intimal injury/dissection • ischemia/infarction of tissue/organ • Local infection • Mal position (failure to deliver the stent to the intended site) • Open surgical repair• Pain • Pulmonary embolism

Pseudoaneurysm • Renal failure • Respiratory arrest • Restenosis • Rupture • Septicemia/bacteremia • Stent Fracture • Stent Migration • Vasospasm • Venous occlusion/thrombosis, remote from puncture site • Venous occlusion/thrombosis, near the puncture site • Venous occlusion/restenosis of the treated vessel.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.

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