

Methods: An Earlybird probe was attached over the posterior tibial artery at the medial malleolus of the treated limb. Several successive intermittent recordings were done of different duration, ranging from 7 seconds to 15 minutes. Per-operative flow velocities were continuously recorded. Real time processing and post processing were performed by in house software, developed in MATLAB (MathWorks® R2018a). The study was approved by the regional ethical committee.

Results: An 86 year old female presented with rest pain (Fontaine III, Rutherford 4, Wifl 2) in her right leg over the last month. CT angiography revealed an occlusion of her right external iliac artery. A digital subtraction angiogram confirmed the findings. The lesion was passed by cross over with a catheter and predilated. A stent (S.M.A.R.T Control, Cordis) was placed, followed by balloon dilation.

Mean velocity (v_{mean}) before the intervention was found to be 4.58 cm/s. After revascularisation measurements showed an in-

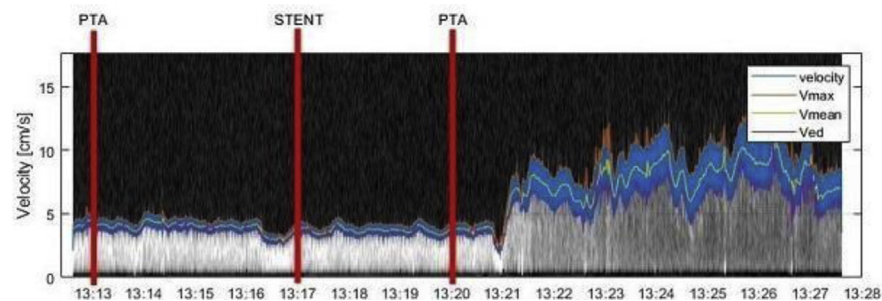


Figure: Velocities during endovascular treatment]

crease to $v_{\text{mean}} = 7.81$ cm/s, which is an increase of v_{mean} of 3.23 cm/s (171 % of baseline).

Conclusion: Earlybird detects changes in flow velocities during an endovascular revascularisation procedure. Further investigations are needed to assess threshold values and evaluate Earlybird's monitoring capabilities in predicting patient outcome. Earlybird could be a future tool for clinical decision making during endovascular treatment.

Disclosure: Nothing to disclose

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<https://doi.org/10.1016/j.ejvsf.2020.07.006>

The Use Of Selective Filtration Of Monocytes From Peripheral Blood In Patients With Vascular Ulcers Promotes Healing. A Pilot Study In A High Volume Vascular Surgery Centre

Chronic Wound Management

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Introduction: Monocytes have a documented action to promote the healing of trophic lesions through the regenerative action of the transformation of M1 macrophages into M2 macrophages, with multilineage potential comparable to that of mesenchymal stem cells (MSC). Patients affected by peripheral artery disease in

Rutherford 5 and 6 stage may be considered suitable. The monocytes can be harvested from peripheral venous blood and injected both in peri-arterial leg areas and in ulcerative lesions.

Methods: From 2015 to 2018, 200 procedures were performed in our centre for obstructive arterial disease of the lower limbs, causing PAD. Twelve (12) patients were considered non-revascularisable (5.5%). This was a first therapeutic approach in 7/12 (58.3%), while it was proposed as a therapeutic alternative in patients already subjected to previous operations and / or revascularisation attempts in 5 (41.6%). Demographic and clinical features are collected. An informed consent was obtained in all patients. In 72.5% three or four cycles were performed. All patients followed post-operative medical therapies and adjuvant medications during the months following treatment.

Results: Comorbidities included hypertension in 91%, CRC in 63%, dyslipidaemia in 90%, cardiopathy in 72%, COPD in 63%, diabetes in 20%, smoking in 55% (of which 50% ex-smokers) at median follow up of 18 months DS (+/- 7 months) the survival rate was 81.8% (ES 0,11) the limbs salvage was 51.1% (ES 0,15). Amputation rate was respectively: minor 45.5% and major 9%. Considering minor amputation as a limb salvage, this percentage increased to 83.4%. Four deaths unrelated to therapy were observed. The pain with VAS score measurement varied from reduction in 36.3% to disappearance in 27.2%. Data regarding TCpO2 has increased : a post-operative median level in the examined patients was 24.8 mmHg T2.

Conclusion: The filtration procedure with mononuclear cells is safe and must be applied selectively. In high volume centres it is possible to evaluate candidate patients for this type of intervention. Additional procedures must be associated to complete the

therapeutic procedure. Due to the increasing complexity and comorbidity of patients, careful selection is required; a multidisciplinary approach and accurate patient follow up is needed. Multicentre studies with multiple cases are needed to validate the Results.

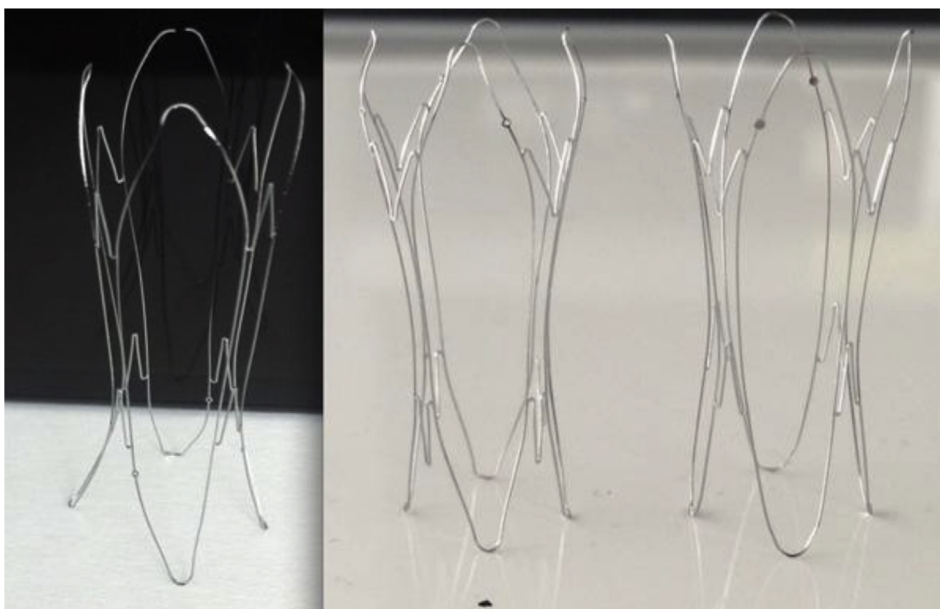
Disclosure: Nothing to disclose

<https://doi.org/10.1016/j.ejvsvf.2020.07.007>

Petalo, A Novel Compliant Venous Stent for the Treatment of Patients with IJVS Non-Thrombotic Stenosis and Resistant Headache

Venous Diseases (including Malformations)

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[Figure 1]

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Introduction: Headache is the third most prevalent illness in the world with an estimated 1 billion sufferers worldwide with a vast proportion of patients reported to be poor responders to available therapies. Headache is related to idiopathic intracranial hypertension caused by insufficient venous drainage of the brain which is the potential result of a stenosis of the venous sinus and Internal jugular veins (IJVs).

Current venous stent concepts available on the markets are related to arterial stent design with a high degree of radial strength.

This preclinical study aimed to investigate the safety and efficacy profile of a novel compliant venous scaffold (CVS) denominated Petalo CVS (Figure 1), specifically designed for non-thrombotic obstructive IJV diseases.

Methods: Twelve healthy pigs weighing 90 kg were used to test Petalo CVS. The devices were implanted into the IJVs using a common femoral vein percutaneous approach. The safety profile including the success rate of device releasing, anchoring, and positioning was evaluated immediately. Fracture, migration,

primary patency, and endothelial response were assessed at 1, 2, 3, and 6 months after the study procedure.

Results: A total of 32 devices were successfully released in both IJVs. The positioning was precise, and no immediate migration occurred. In all cases, the devices were able to control the leaflets of the valve. No procedure or device related complications were reported, and all pigs successfully completed the different scheduled follow up periods. The primary patency rate was 100% and no fracture or migration of the device into the brachiocephalic trunk was reported. Histological examination revealed only minimal lesions with minimal or absent inflammatory reaction surrounding the incorporated metallic rods.

Conclusion: The results of this preclinical porcine model study in terms of primary patency even in the absence of anticoagulant drugs, absence of migration or rupture of the stent and the minimal inflammatory response, support the extensive use in humans. Petalo won in 2019 the Grant of the Italian Minister of Health for the First in Human Project in patients with chronic headache, poor

responders to Best Medical Therapy with non-thrombotic obstructive IJV diseases.

Disclosure: Nothing to disclose

<https://doi.org/10.1016/j.ejvsvf.2020.07.008>

Design of 3D Printed PCL Scaffolds Toward Vascular Tissue Engineering

Vascular Biology

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