The sapheno-femoral junction valvuloplasty in the post-thrombotic syndrome: a proposal with the use of a new device

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Abstract

Before developing deep venous thrombosis (DVT), most patients suffering from post-thrombotic syndrome (PTS) have a normal great saphenous vein (GSV). After DVT, the GSV plays a vicarious function, but many patients develop secondary varicose veins (VVs) and the previous positive contribution of the GSV vanishes. In these cases the ablative strategy is generally implemented with positive results in the short-term, but commonly with late varicose recurrences. In two cases the authors preferred a different approach to preserve and recover the GSV vicarious function by sapheno-femoral junction (SFJ) valvuloplasty. Out of 43 cases we treated with SFJ stretching valvuloplasty performed with the new OSES device (V-OSES), we proposed this operation to two patients (A and B) suffering from PTS and secondary VVs at an early stage, classified as C3 and C4 (Clinical-Etiology-Anatomy-Pathophysiology classification, CEAP). In the V-OSES operation a gentle stretching force is applied onto the apex of the opposite valve commisures so that the valve cross-section becomes oval and the cusp's length excess is retrieved. The operation was performed on the SFJ valve having incompetent, but floating cusps visible on ultrasound (US) scan. This reparative technique was undertaken under local anesthesia and was combined with disconnection of the incompetent tributaries and/or perforators. The US-duplex scanning showed that the SFJ valves were competent at month 16 (B) and 20 (A) follow-up after surgery and the GSV vicarious function was preserved. The stretching valvuloplasty operation is intended to repair the SFJ valve incompetence and preserve the GSV vicarious function. This approach may be useful in primary VVs, but especially in PTS when superficial reflux appears and secondary VVs are at early stage. The SFJ reparative operation may be combined with the conventional GSV conservative strategies, including incompetent tributaries ablation/disconnection. This approach does not seem to have been already reported in the literature and needs further confirmation.

Introduction

Since the post-thrombotic syndrome (PTS) is a consequence of a deep venous thrombosis (DVT), we cannot neglect that these patients may be suffering from thrombophilia, but, more often, they may have developed DVT as a result of trauma or surgery. In general they have not the stigmata (genetic, hormonal, etc.) of patients with primary varicose veins (VVs). Before developing a DVT, these patients usually have a normal great saphenous vein (GSV). However it is a *fact* that most patients suffering from PTS develop secondary VVs. In these cases the ablative strategy is generally implemented with positive results in the short-term, but commonly with late varicose recurrences, regardless of the type of ablative treatment performed.

The GSV system acts anatomically and functionally in parallel to the deep system and therefore plays a vicarious function in case of deep venous hypertension, which leads to the diversion of blood towards the superficial system. The vicarious function of the saphenous system plays a positive role in the early phase of PTS, however - sooner or later - the overload accumulating into the saphenous system causes a progressive dilatation of the vicarious circuit and leads to valve incompetence with a resulting backward flow. Then secondary VVs appear and decrease the previous GSV vicarious function with an overall clinical and hemodynamic deterioration.

The surgical correction of deep reflux in PTS (by valvuloplasty, transposition, bypass, neovalve) involves rather complex procedures, mostly with uncertain or poor results, and has therefore been limited to special cases and performed in highly specialized surgical centres.[1] On the contrary the correction of the superficial reflux in PTS, in secondary VVs, is commonly treated by ablative techniques (stripping, endovenous thermal or chemical ablation, etc.) to ablate or destroy the GSV and its tributaries. Others techniques [stab avulsion, phlebectomy, *ablation selective des varices sous anesthesie locale* (ASVAL), *i.e.* selective varicose vein ablation under local anesthesia] aim to reduce the VVs reservoir. Others disconnect the sapheno-femoral junction (SFJ) trying to spare the GSV trunk as a backward draining conduit [*cure conservatrice et hémodynamique de l'insuffisance veineuse en ambulatoire* (CHIVA), *i.e.* outpatient conservative hemodynamic management of varicose veins], etc. (Figure 1). All ablative conservative techniques show positive clinical results at short-term follow-up, but in the mid- or long-term the varicose veins still tend to relapse in many cases.

The authors propose a different approach to PTS, which envisages SFJ stretching valvuloplasty in combination with incompetent tributaries disconnection or ablation to preserve or recover as much- and as long as possible the GSV vicarious function.

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Materials and Methods

In the case of SFJ incompetence with free-floating valve cusps visible on ultrasound (US) scan, the valve may be eligible for repair. The oval-shaped external support (OSES - a medical device manufactured by Assut Europe SpA, Rome, Italy) is a new and innovative medical device, especially intended for venous valve repair by a stretching movement (Figure 2). Being purposely oversized (large diameter about 30 percent greater than the native valve diameter), it is placed outside the vein and sutured at the apex of the opposite valve commissures (Figure 3). Consequently, the OSES device applies an external and gentle stretching force onto the valve's walls, thus extending the inter-commissural diameter and reducing the cusps excessive length (stretching valvuloplasty), consequently restoring the valve competence in most cases.[2,3] Out of 43 cases we treated personally with SFJ external stretching valvuloplasty with the placement of the OSES device (V-OSES) to repair the junctional reflux, two patients had PTS and secondary VVs. A 36-year-old woman (A) had acute DVT of

the right limb, two years before, with femoral-popliteal involvement. The treatment with low-molecular-weight heparin, oral anticoagulants and elastic stockings offered an initial clinical improvement, but then she started to develop secondary VVs, heaviness and foot edema, and was classified as CEAP-C3 (Clinical-Etiology-Anatomy-Pathophysiology classification). The ultrasound investigation revealed a femoral-popliteal recanalization with deep reflux, SFJ and saphenous trunk incompetence, medial accessory saphenous competence, and incompetence of a perforator in the lower part of the thigh. The other patient was a 45-year-old man (B), who had a femoral-iliac DVT on the right side following a trauma in a car accident and limb immobilization. Medical therapy and elastic stockings did not prevent the PTS. After 3.5 years, he had skin discoloration, foot edema and secondary infra-genicular VVs classified as CEAP-C4. The ultrasound revealed a satisfactory recanalization of the iliac tract, an almost complete obstruction of the femoral vein, SFJ and saphenous trunk incompetence in the upper third of the leg. In these two cases, the laboratory tests detected no thrombophilia or hormonal abnormalities; no venous hemodynamic tests [*e.g.*, venous refilling time, ambulatory venous pressure (AVP), air plethysmography (APG)] were performed.

The two patients agreed with the proposal of intervening on the SFJ with the V-OSES technique, along with a disconnection of incompetent tributaries and perforators in the same session. They also agreed to undergo US-guided foam sclerosis or stab avulsion of residual incompetent tributaries in a later session, if need be. The surgery was performed under local anesthesia and general sedation in an outpatient setting. The patients were discharged with an elastic stockings prescription with no additional therapy. The postoperative course was simple and uneventful.

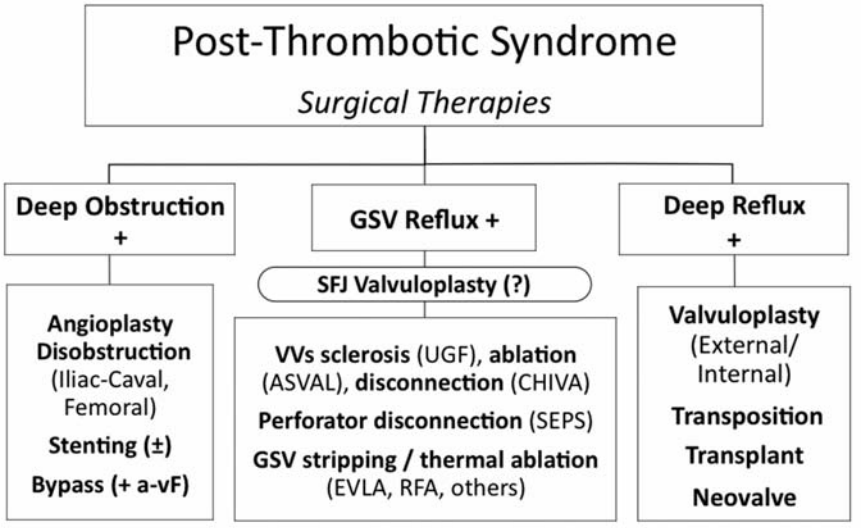

Figure 1. Algorhythm of surgical therapies that can be applied in post-thrombotic syndrome (PTS). In advanced-stage PTS, a combination of superficial and deep reflux can be detected along with deep obstruction/recanalization. In this case, the superficial one is commonly treated first. The conventional ablative techniques are useful, but they also eliminate the positive vicarious function previously played by the greater saphenous vein (GSV). A strategy for preserving this vicarious function should consider the saphenofemoral junction (SFJ) valvuloplasty and the GSV conservative technique at an early stage of superficial reflux. This strategy may be combined with other conservative techniques, such as the *cure conservatrice et hémodynamique de l'insuffisance veineuse en ambulatoire* (CHIVA) and *ablation selective des varices sous anesthesie locale* (ASVAL). Indeed, it is a proposal … to be confirmed.

Results

After one month, the two patients had relieved symptoms, a better quality of life and were satisfied with the procedure. The SFJ was competent at duplex evaluation. Some residual varicose veins were reduced in size and some were treated with foam sclerotherapy as planned. During the follow-up, at month 20 (A) and 16 (B), the clinical improvement was evident, both subjectively and objectively. The SFJ valves proved to be competent at duplex scanning, while the GSV trunks were incompetent and draining backward as expected. Instrumental evaluation tests were not performed. The patients continued to wear elastic stockings, when needed, and tolerated them better than before.

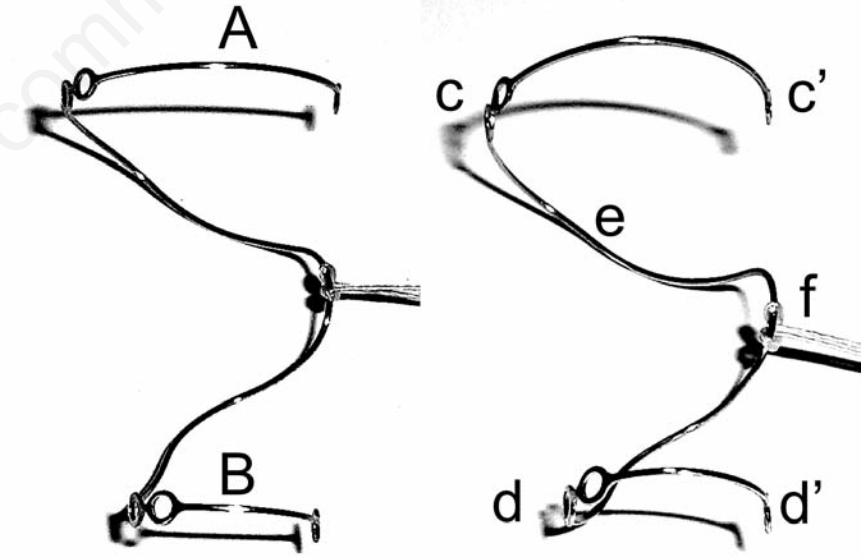

Figure 2. A picture of the oval-shaped external support (OSES) device. It looks like a vascular stent in Nitinol alloy submitted to a treatment for biocompatible and super-elastic performance. It comprises two oval arches (A-B), which are active elements, to treat 2 near valves with different diameters. They are provided with multiple eyelets (c,c' and d,d') intended for stitching and securing the device to the vein wall. The multiple eyelets, as well as the different device sizes, are intended to achieve a correct stretching action and compliance. The two oval arches (A-B) are connected by a long element (e) giving stability and also elastic flexibility in any direction. For easy positioning of the device, it is equipped with handles (f) to be removed after placement.

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Discussion

On the basis of the introductory remarks, the authors proposed and then performed the stretching V-OSES operation on the incompetent SFJ in two cases of young adults suffering from PTS and recent secondary VVs with SFJ and truncal reflux. The aim was to preserve the GSV vicarious function by SFJ repair and refluxive tributaries disconnection or ablation, to restore the GSV positive hemodynamic contribution. Although we found a limited number of previous reports concerning primary VVs [4,5] in the medical literature, we couldn't find any about secondary VVs in PTS.

In general, the only pre-requisite to perform the V-OSES operation is the presence of free-floating valve cusps that are visible at ultrasound investigation. The correct eligibility criteria for valve repair are important, because a positive outcome can be more easily achieved in the case of young adult patients with valve incompetence at an early stage (Table 1). For this reason a thorough pre-operative US investigation is mandatory for an accurate evaluation of mobility, consistency, and also symmetry of the valve cusps.

This surgical procedure is generally feasible in all eligible cases, is technically simple, is not time consuming (15-30 min in most cases), can be performed under local anesthesia and, if need be, general sedation. A great deal of attention must be paid to the placement of sutures that secure the stretching device to the apex of the opposite commissures, because this is a crucial step that affects the anatomical, hemodynamic and clinical results. These apices are not always easily identifiable, as a reversed V shaped line on the vein wall, and also due to venous spasm induced by usual and even gentle surgical manipulation or to the thickness of the wall. In these cases the surgeon can rely on the images and the measures from the pre-operative duplex scanning that need to be accurately transferred on a paper sketch of the SFJ. The learning curve is short for experienced surgeons. The most important requirement is to have a forward-looking mentality and culture and be willing to achieve new goals and use innovative methods.

In comparison with the conventional external valvuloplasty techniques, the V-OSES operation entails a new and unique approach. We gained extensive experience with the conventional external *banding/wrapping* techniques,[6,7] as well as the SFJ *plication*,[8] which are narrowing techniques, thus involving the opposite of the *stretching* technique. However all of these techniques aim to reduce the vessel area with cusp bundling and implicitly unpredictable erratic or uncertain cusp apposition. This drawback can be overcome by performing the correct stretching operation, which does not involve a cross-sectional area reduction and applies a calibrated, elastic and

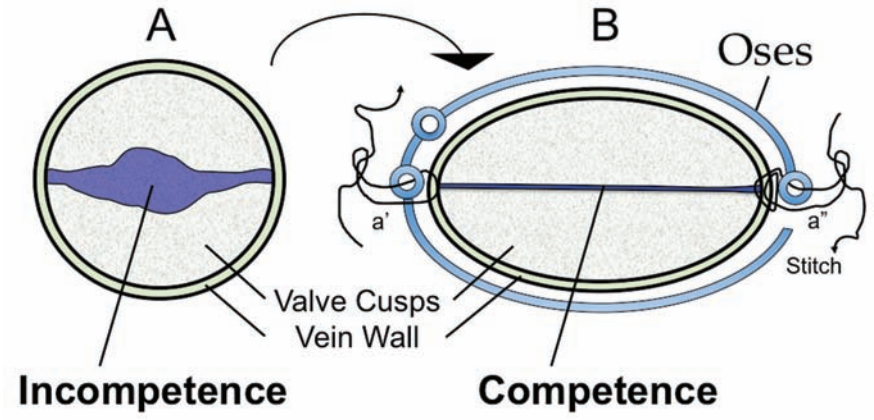

Figure 3. The *working concept* of the stretching valvuloplasty technique with the oval shaped external support (V-OSES) device. The cross-section of the incompetent valve bulb (A) shows circular shape and slackened cusps/leaflets, causing valve incompetence and reflux. A proper OSES device should be over-sized by about 30% compared with to the native valve diameter. A correct positioning of the device and its fixation by sutures onto the vein walls (a', a") acts like a spring performing a gentle action and modifies the valve bulb that acquires an oval shaped cross-section (B). The stretching action onto the inter-commissural diameter retrieves the slackened cusps and restores the valve competence.

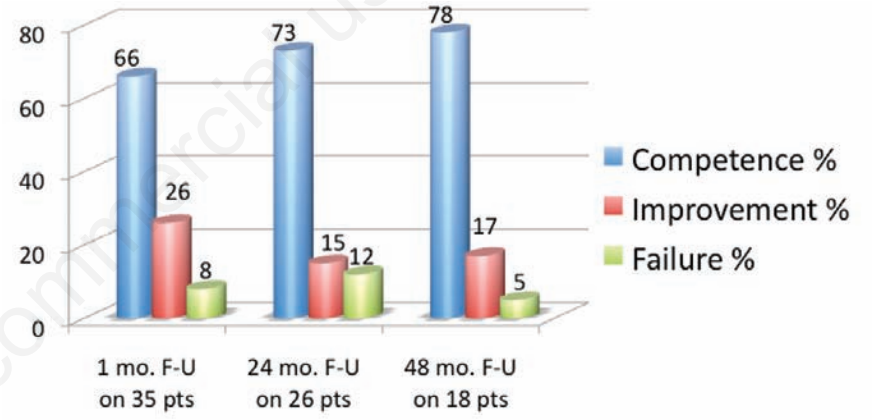

Figure 4. Chart showing a duplex scanning pattern at 1-24-48-month follow-up, after sapheno-femoral junction stretching valvuloplasty by using the oval shaped external support device. Among a cohort of 38 consecutive cases of primary varicose veins, 18 were checked at 48 months by ultrasound duplex scanning: 14 (78%) showed a repaired incompetence, 3 (17%) had a reduced incompetence and 1 (5%) was a failure.

Table 1. Inclusion/exclusion criteria for venous valvuloplasty eligibility, in particular for stretching valvuloplasty by using the oval shaped external support device. More extensive experience is needed on the topic to refine criteria and match the best valvuloplasty results.

	Inclusion criteria	Exclusion criteria
Valve pattern (US)	Visibility Free floating cusps Symmetrical (substantially)	Undetectable Frozen cusps Asymmetrical (markedly)
Varicose disease	Early stage	Late stage
Patient age	Young-adult	Short life expectancy

US, ultrasound.

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gentle stretching action onto the ideal site, *i.e.* the opposite commissural apices. The Gore-external valve support[9] is also an oval-shaped device, but it has a *compressive* action as well, acting along the anterior-posterior plane. Moreover, depending on its configuration, it could not be used onto the GSV terminal valve and even requires the ligation of the first tributary (the superficial inferior epigastric vein) that is generally competent, while the OSES device is adaptive and can spare it. The OSES device consists of a slender thread-like material and has a compliant and adaptive behavior and is therefore better than previous devices that might kink in the sitting or crouching position. As to the *banding* techniques, they have been used by a few groups, mainly in deep venous system, commonly in small groups of patients.[8-12] Among them, one of the Authors obtained deep valve competence in 78 percent of cases at long-term follow-up,[10] but inferior results for SFJ valves. Others compared air- or photo-plethysmography (APG/PPG) instrumental findings after SFJ valvuloplasty *vs* stripping or VNUS ablation (VNUS Medical Techn., Inc., San Jose, CA, USA), showing an hemodynamic improvement in all cases at a 1 month follow-up.[11] The same results after SFJ valvuloplasty were found also at a 10 year follow-up.[12] The Authors have a cumulative personal experience on 43 patients treated with stretching V-OSES operation for primary VVs and on one with bilateral primary deep venous insufficiency. Among the patients treated for primary VVs, 18 out of 38 have a 4-year follow-up: 14 (78%) show an excellent valve competence, 3 (17%) have a reduced incompetence and 1 was a failure (Figure 4).[3] The two patients treated for secondary VVs in PTS, described in this report, showed SFJ competence at US-duplex evaluation after 20 and 16 months and a SFJ forward drainage as well as a preserved GSV vicarious function. Indeed, in similar cases we commonly adopt a combination of a reparative operation (SFJ valvuloplasty) together with disconnection (like in the CHIVA strategy) or ablation (like in the ASVAL technique) of the incompetent tributaries. In our opinion this is a reasonable approach, because in some randomized controlled trials (RCT) and Cochrane reviews, the CHIVA strategy showed to have better long-term results than stripping.[13-18] Moreover, the stripping or endovascular techniques give comparable long-term results.[19] Although these reports may be criticized for some aspects, more RCTs should be carried out and give an opposite result, before they can be declared inconsistent.

In conclusion, we can reasonably expect that the combination of SFJ repair and GSV conservative strategy will have a better mid-term outcome than the individual strategies applied separately. However, in order to assess the actual benefits and the overall strategy to be adopted in these cases, we need to rely on a larger clinical experience, deeper instrumental monitoring (*e.g.*, AVP, PPG, APG, etc.) and a longer clinical follow-up.

Conclusions

In case of venous valve incompetence with free-floating US-visible valve cusps, the SFJ stretching valvuloplasty by OSES device (V-OSES) is technically feasible, simple and safe. It aims to repair the SFJ incompetence and preserve the GSV forward flow. In a personal short series of eligible cases in primary VVs, the V-OSES operation has shown clinical and functional effectiveness and good long-term results in most cases.[3] If applied in PTS, at a relatively early stage or when secondary VVs appear, it may restore the vicarious function of the saphenous system. It may be combined with the conventional conservative strategies for the GSV (*e.g.* CHIVA and ASVAL, and also sclerotherapy) with a reasonable expectation that the combination may have a better mid-term outcome than the use of the ablative or conservative strategy applied separately.

This proposal does not seem to have been described in previous reports in the medical literature. Moreover two clinical positive cases have no statistical significance. Therefore it still needs to be validated by a larger clinical experience and instrumental investigation. However, since it is a reconstructive rather than an ablative surgery, it does not preclude the patient from any other therapeutic *chance*, especially in case of PTS. Even in case of failure, any other ablative option can still be implemented. Furthermore if the effectiveness of SFJ valvuloplasty is confirmed, this intervention can be considered the first-choice option in PTS, when secondary VVs appear.

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