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Radiofrequency-Powered Segmental Thermal Obliteration Carried out with the ClosureFast Procedure: Results at 1 Year

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This prospective and multicenter study shows the results at 1 year of radiofrequency-powered segmental thermal obliteration (RSTO) carried out with the ClosureFast® procedure. The RSTO clinical and duplex ultrasound imaging results were evaluated at 3 days, 3 months, 6 months, and 1 year. All procedures were carried out on outpatients under tumescent local anesthesia. Among the 295 members who were treated, 289 were reexamined at 3 days, 290 at 3 months, 289 at 6 months, and 220 at 1 year. Occlusion scores were 99.7%, 99.3%, 98.6%, and 96.9% at, respectively, 3 days, 3 months, 6 months, and 1 year. At 3 cm below the saphenofemoral junction, before the procedure, the greater saphenous vein (GSV) diameter was 5.4 ± 2 mm (range 2-18). It decreased to 4.5 ± 1.7 mm at 3 days, 2.4 ± 1.5 mm at 6 months, and 1.3 ± 0.9 mm at 1 year. In members reexamined at 1 year, the decrease in diameter of the treated vein compared with the preprocedural measurement was 79% ($p < 0.001$, *t*-test). At 1 year, in 58% of the cases, duplex ultrasound imaging at mid-thigh level could not show the GSV trunk. Preprocedural pain that was present in 57.5% of the cases decreased to 10.8% of the cases at 3 days and 2% of the cases at 1 year ($p < 0.001$, χ^2 test). Among the treated limbs, 70.1% did not present with any postprocedural pain at any time of the follow-up. On the third day, the patients evaluated the mean pain intensity at 0.7 ± 1.6 on a visual analog scale of 0−10. During the follow-up, no painful indurations were noticed in 67.7% of the legs. No thromboembolic complications were reported. Paresthesias were observed in 3.4% of the cases. Invalidity clinical score, evaluated at 3.9 ± 2 before the procedure, decreased to 3.5 ± 1.2 on the third day, 0.9 ± 1.5 at 3 months, 0.7 ± 1.2 at 6 months, and 0.5 ± 1.1 at 1 year. This study confirms the efficacy of RSTO when using ClosureFast, which allows obliteration of the GSV trunk in 97% of cases at 1 year with few side effects and almost no postprocedural pain.

INTRODUCTION

Truncular thermal obliterations of the short and great saphenous vein (GSV) using radiofrequency or laser procedures have become alternatives that are less invasive than traditional surgery, which removes the cross and saphenous trunk (stripping and high ligation). Equivalent to stripping without high ligation, these alternatives are all the more proposed since in 50% of GSV truncular insufficiency cases the ostial valve remains patent and no physiopathological justification can be established.[1-4] At present, after endovenous thermal treatment, the radiofrequency (RF) and laser obliteration scores are almost the same: respectively, 87% and 98% at 5 and 3 years.[5] With experience, the morbidity rate of these two techniques is now

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very low and the previously reported paresthesias have become very rare since indications are well-known.

Endovenous laser morbidity is mainly due to the pain occurring along the treated vein length and the hematomas appearing several days after the procedure and probably caused by traumatic laser perforations.[6,7] Conversely, RF treatment morbidity is almost nil.[5] The drawbacks of ClosurePlus®, initially the only available technique, are mainly its complexity and its duration since the catheter withdrawal speed should not exceed 3 cm/min. Another drawback is the necessary complete exsanguination of the treated vein since, to obtain very efficient results, perfect contact between the electrodes and the venous wall is necessary. Without a complete exsanguination a coagulum may appear on the electrodes, requiring catheter removal to clean the electrodes, thus increasing the procedure time.

The ClosurePlus system uses a new catheter that compensates for these difficulties. An initial feasibility study has demonstrated the efficiency of this technique.[8] This study reports the results at 1 year of RF-powered segmental thermal obliteration (RSTO) performed with this new device.

PATIENTS AND METHODS

A nonrandomized and prospective multicenter study evaluated the clinical results and duplex ultrasound imaging of RSTO performed with the ClosureFast® system in patients presenting with chronic venous disease related to GSV insufficiency. This study was carried out in eight different centers in Germany and France after approval by the local ethical review boards according to the Declaration of Helsinki. Every center had been using the ClosurePlus catheter for several years, and all of the centers were in training for ClosureFast catheter use. Written informed consent was obtained from all patients enrolled in this study, and clinical data were collected on standardized case report forms in each center.

Inclusion Criteria

All patients presented with venous insufficiency demonstrated by duplex ultrasound imaging and reflux in the GSV revealed by compressing maneuvers—manual relaxation of the calf and/or Valsalva maneuver with reflux duration of >500 msec. Presence or lack of reflux on the terminal valve was not an exclusion criterion for enrollment. Exclusion criteria did not consider diameter or location since the concerned trunk was the GSV trunk, which, by definition, is subfascial, almost always straight, and easy to catheterize. The only exclusion criterion was saphenous thrombus. Patients had to be 18-80 years old. Pregnant women or patients presenting with old or fresh deep venous thrombus were excluded from study enrollment.

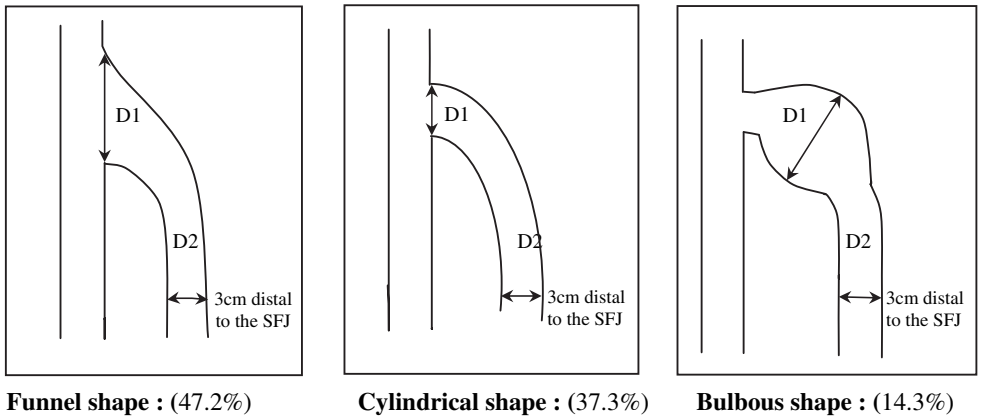
Treatment Procedure with the ClosureFast Technique

The ClosureFast catheter (VNUS Medical Technologies, San José, CA) is composed of a 7 cm heating antiadhesive-coated part situated at the catheter extremity as well as a handle with a cable releasing system connected to the RF generator. The heating element consists of a spiral wire that is heated by a 460 kHz alternating current and produces 120 °C for a 20 sec cycle. A thermocouple situated at the distal part of the heating element enables performance of a retro control on the generator action that regulates the energy in order to obtain and maintain a 120 °C temperature.

RF treatment was done with a previously described technique.[8] The procedure was totally performed under ultrasound guidance using a probe cover and sterile gels. Vein access was achieved either by phlebotomy or by percutaneous puncture using a 7F, 11-cm-long sheath to introduce the catheter previously flushed with heparinized serum. Once the GSV had been catheterized, the catheter tip was positioned just below the ostium of the superficial epigastric vein, about 1-2 cm below the saphenofemoral junction (SFJ).

Patients were in reverse Trendelenburg position to allow better GSV exsanguination. Tumescent liquid infiltration was performed under ultrasound guidance. Different Klein solutions were used. The infiltration was progressively carried out downward into the saphenous compartment by infiltration around the saphenous trunk. While the tumescent liquid was injected, a temperature decrease was commonly observed at the thermocouple level, about 6 cm from the catheter tip, which ensured the correct working of the thermocouple and an accurate position of the catheter in the GSV.

After duplex ultrasound imaging to check the tumescence quality and to ensure that the catheter position was at least 1 cm below the skin surface, the procedure consisted of two 20 sec therapeutic cycles delivered at the GSV termination in order to increase the energy dose delivered on the first treated part; then, each segment of the vein was treated for only one cycle. Before starting a new therapeutic cycle, the catheter was repositioned to the adjacent segment guided by shaft markers in



Funnel shape : (47.2%) **Cylindrical shape :** (37.3%) **Bulbous shape :** (14.3%)

Fig. 1. Preprocedural morphological characterization of the SFJ. D1, largest SFJ diameter between femoral vein and 3 cm below: 8.42 ± 2.3 mm (range 2.3-18); D2, diameter of the GSV trunk 3 cm below its termination in the femoral vein: 5.4 ± 2 mm (range 2-18).

Table I. Patients' comorbidities

Comorbidities	%
Cardiovascular diseases	1.5
Peripheral arterial lesions	1.0
Diabetes	3.6
Hypertension	18.0
Obesity	0.5
Thyroid pathologies	9.3

6.5 cm steps to allow a 5 mm overlap of the treated vein segments.

During the whole energy delivery, the treated part was compressed either manually or with the help of the ultrasound probe, thus enabling visualization, at the heating tip, of echo occurrences, which are vibrating images that give evidence of the treatment efficiency. Once the procedure was performed, according to the selected puncture point, the introducer shaft could be removed, to allow treatment of the distal part of the saphenous trunk. Phlebectomies were performed to remove completely the varicose network. Postprocedural compression stockings for several weeks were systematically proposed. All procedures were ambulatory, and patients did not have any physical activity restrictions. Nonsteroidal anti-inflammatory drugs and analgesics were provided to the patients as needed.

Follow-Up

The patients were followed up at 3 days, 3 months, 6 months, and 1 year. Each follow-up visit consisted of clinical and duplex ultrasound imaging examination.

Duplex Ultrasound Imaging

The anatomy of the SFJ was studied before the procedure: It appeared as a funnel, cylindrical, or bulbous shape (Fig. 1). The largest diameter of these three shapes was labeled ''D1.'' Before and after the procedure as well as at each follow-up examination, the GSV was measured at three different levels: at the SFJ level (D1), at 3 cm distal to the SFJ, and at 15 cm distal to the SFJ. These diameters are reported in Table I. Each follow-up visit included determination of saphenous vein compressibility and the existence of a reflux and/or an exclusively anterograde flux along the whole length of the treated vein. The length of the still patent SFJ stump was measured, and the presence of a protrusive thrombus in the common femoral vein was systematically searched for. The presence or absence of a reflux on the terminal saphenous valve was not searched for. Venous occlusion of the treated vein was defined as well as the absence of any flux on its whole length more than 3 cm below the SFJ.

Clinical Examination

Each follow-up visit included a clinical examination, the completion by the patient of a questionnaire, and a duplex ultrasound imaging examination of the treated member. Patients' symptoms and signs were recorded using the CEAP (clinical, etiological, anatomical, and pathophysiological) clinical classification and the Venous Clinical Severity Score (VCSS).[9,10] Morbidity and side effects were recorded at each follow-up visit. Pain was evaluated using a visual analog scale (0-10).

Table II. Repartition of the limbs treated according to their preprocedural CEAP clinical classification

CEAP class	$n = 295$	%
C1	3	0.8%
C2	154	52.4%
C3	93	29.0%
C4	43	16.3%
C5	1	0.4%
C6	1	0.4%

Statistics

At each follow-up visit, the different measurable parameters were expressed as mean ± standard deviation, and proportions were expressed as percentages (95% confidence interval). For patients with bilateral treatment, general symptoms were treated as one for the two procedures on each member and all member characteristics were separately studied.

RESULTS

Between April 2006 and March 2007, 225 patients (295 limbs) were treated. Fifty-eight patients (29.9%) presented with bilateral varicose veins, and 48 underwent bilateral treatment in the same session.

Patients

The patients were 50.55 ± 13.6 years old (range 18-80) and 73.8% of them were women. The associated pathologies are reported in Table I. CEAP clinical class distribution is reported in Table II. The preprocedural VCSS score was between 1 and 11 with a 3.9 ± 2 mean score. The SFJ was defined as funnel-shaped (47.2%), cylindrical (37.3%), or bulbous (14.3%) (Fig. 1). The GSV diameter at 3 cm distal to the SFJ was 5.4 ± 2 mm (range 2-18).

In 56.6% of the cases, phlebectomies were performed during the procedure, and sclerotherapy was performed at leg level in 12.9% of the cases. Among the 295 treated limbs, 290 were examined at 3 months, 289 at 6 months, and 220 at 1 year, i.e., 75% of the treated limbs.

Delivery of Thermal Energy

The total procedure time, measured from catheter insertion to catheter removal and including the injection of tumescent liquid, was 16.4 ± 8.2 min. The total energy delivery time was 2.2 ± 0.6 min (range 1-4). Veins were treated with an average 6.7 ± 1.7 therapeutic cycles. The average vein length treated was 36.7 ± 10.8 cm.

Duplex Ultrasound Analysis

Occlusion rates were 99.7%, 99.3%, 98.6%, and 96.9% at 3 days, 3 months, 6 months, and 1 year, respectively. Lack of reflux percentage was 99.6%, 100%, 100%, and 100% at 3 days, 3 months, 6 months, and 1 year, respectively. The patent stump length was 1.5 ± 0.7 cm at 6 months. Table III reports the evolution of the GSV measured at 3 cm distal to the SFJ (4.5mm ± 1.7 at 3 days, 2.4mm ± 1.5 at 6 months and 1.2mm ± 0.9 at 1 year FU).

In limbs with follow-up at 1 year, the treated vein decreased in diameter by 19.9% at 3 days, 26.6% at 3 months, 43.5% at 6 months, and 78.8% at 1 year ($p < 0.001$, t-test). At 1 year, in 58% of the cases, duplex ultrasound imaging could not detect the GSV trunk at mid-thigh level. Duplex ultrasound imaging could detect a flux on the length of the treated vein in two cases out of 289 at 3 months (0.7%), in two cases out of 290 at 3 months (0.7%), in three cases out of 289 at 6 months (1%), and in six cases out of 220 (2.7%) at 1 year. Most of the time, detected fluxes were segmental repermeabilization zones with no systematic reflux.

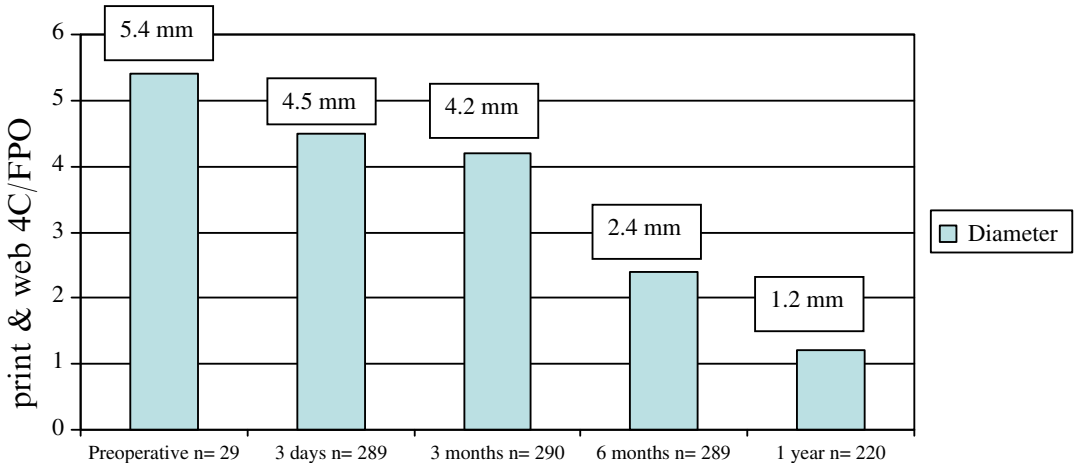
Clinical Results

For patients, return to normal daily activities took an average of 1.22 days (range 0-3.2). Symptoms and clinical signs of improvement could be observed from the third day onward.

Preprocedural pain was detected in 57.5% of the treated patients and decreased to 10.8% 3 days after the procedure and 2% at 1 year ($p < 0.001$, χ^2 test). During the follow-up, 70.1% of the treated limbs were no longer painful after the procedure. On the third day, using an analog scale of 0-10, the patients evaluated the mean pain intensity at 0.7 ± 1.6. The maximum postprocedural pain was 2.8 ± 1.6. The percentage of limbs presenting with edema before the procedure decreased from 52.8% to 6.4% at 3 days, 8.3% at 6 months, and 1.8% at 1 year ($p < 0.001$, χ^2 test).

Hematomas could be detected in 1.4% of cases along the course of the saphenous trunk and the phlebectomies. Similarly, ecchymoses were observed in 5.8% of the limbs, without distinction between those due to the treatment itself or to tumescent anesthesia. Painful indurations due to the treatment were evaluated at 1.9 ± 1.2 on an analog scale from 1 to 10. During the follow-up, no painful indurations were reported on 67.7% of the limbs. The incidence of superficial venous

Table III. Diameter reduction of the GSV 3 cm below its termination.



thrombosis was 1%. No thromboembolic complications were reported. Paresthesia was reported in 3.4% of the cases (three observed during follow-up). Pigmentations were observed in 3.1% of the cases. Invalidity clinical score was 3.9 ± 2 before the procedure and decreased to 3.5 ± 1.2 at 3 days, 0.9 ± 1.5 at 3 months, 0.7 ± 1.2 at 6 months, and 0.5 ± 1.1 at 1 year. Ninety-nine percent of the patients said they would recommend this procedure to friends or relatives.

DISCUSSION

In terms of technical realization, RSTO with the ClosureFast system suppresses all the previously described drawbacks of RF with the ClosurePlus catheter treatment, especially procedure time. With the ClosurePlus catheter, the mean time from insertion to catheter removal is 41 ± 5 min for a 37 ± 2 cm[11] vein length. With the ClosureFast catheter, treatment time is 16.4 ± 8.2 min for the same average vein length treated and with no coagulum formations. The ClosurePlus system delivers thermal energy to the part of the vein in contact with the electrodes. Continuous catheter withdrawal allows treatment of the vein in a homogenous way provided an effective withdrawal speed of 2-3 cm/min is respected on the whole length of the treated vein during the whole procedure.

Most of the time, the catheter is manually removed, which may sometimes be difficult to perform. With the ClosurePlus system, the RSTO procedure is different since thermal energy is delivered to 7 cm segments of the vein in contact with the 7 cm heating part of the catheter. Therefore, the energy delivery is the same for each venous segment. A 5 mm overlap between two treated adjacent segments ensures complete treatment of the vein. Laser procedures with discontinuous shooting (one shot every 3 mm) offer the same advantages. These procedures are considered more efficient, more reliable, and more reproducible than procedures using continuous shooting and for which the delivered energy depends on the removal speed of the laser fiber.[12]

Another technical evolution depends on the choice of temperature applied to the vein: 85 °C for the ClosurePlus system vs. 120 °C for the ClosureFast system. This difference has to be balanced since the two systems use different methods of thermal energy delivery. The difference between the obliteration scores at 1 year with the ClosurePlus system and with RSTO (87.1%[13] and 96% in this study) tends to confirm that the new way of using RF increases the treatment efficiency.

The decrease in saphenous vein diameter becomes significant at 3 months, which probably shows the importance of the initial parietal inflammatory reaction. Beyond this period of time, vein retraction (shrinkage) is progressive up to 1 year (Table III). RSTO efficiency does not interfere with treatment tolerance since, in this study, complication rates are very low.

No thrombotic complications, such as deep venous thrombosis and, more specifically, common femoral thrombosis from the SFJ, were observed; such complications could have occurred since this catheter delivers greater energy than the ClosurePlus catheter with a potentially more important thermal diffusion. However, the manufacturer does advise positioning the catheter tip 2 cm at least from the terminal vein. Thanks to its unfolding electrodes, the ClosurePlus catheter tip can easily be controlled by ultrasound monitoring; but the lack

of electrodes on the ClosureFast catheter requires more careful ultrasound monitoring: Transverse sections and external compressions with the ultrasound probe have to be performed. Moreover, once the catheter tip has been positioned, the flexion angle of the knee should not be modified. The introducer sheath is generally positioned below the knee and represents a fixed point for the catheter. Should the knee be flexed or extended, the catheter tip would be moved, respectively, closer to or farther from the SFJ.

Postprocedural pain and paresthesia are quite rare with the ClosureFast system despite the 120 °C temperature of the heating part of the catheter. Tumescent anesthesia used for this technique also helps to protect the surrounding tissues. An extensive perivenous infiltration should also be performed along the whole length of the treated vein and, to ensure its efficiency, under ultrasound monitoring.

The Endovenous Radiofrequency Obliteration versus Ligation and Vein Stripping (EVOLVeS) study[11] is the only prospective study comparing conventional stripping and the RSTO procedure. It demonstrates that the ClosurePlus technique induces fewer ecchymoses and results in better life quality up to 2 years. RF treatment gives little postprocedural pain, which is why it outdoes endovenous treatment. Usually, after laser treatment, about 70% of patients present with pain extending along the treated vein length and >50% require analgesics.[14] After laser treatment, Kabnick[15] reported an average pain score of 2.2-2.6 on a scale of 0-5.

After endovenous laser treatment, ecchymoses are also more frequent than with RF procedures. They are likely due to vein perforation by laser, which does not occur with RF.[14,16] In this study, superficial venous thrombosis, reported in 1% of the cases, may correspond to insufficient varicose vein exereses during endovascular obliteration. They are more frequently observed after laser treatment and amount to 5-10% of the cases.[17,18]

Since very few failures were observed (six recanalizations on 295 included limbs), it has not been possible to bring forward risk factors such as the diameter or the morphological characteristics of the SFJ. The only patient presenting with a complete GSV recanalization was obese, which could be a risk factor as it has already been mentioned in a previous study about the ClosurePlus catheter.[19]

CONCLUSION

This study confirms RSTO efficiency; it allows GSV obliteration close to 100% at 1 year. Side effects are rare and postprocedural pain almost nil; this simple and rapid technique should therefore be favored and become the predominant procedure for truncular GSV obliteration. Long-term results and recurrence scores would nevertheless be necessary to evaluate the hemodynamic impact of GSV trunk removal with SFJ preservation.

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