Aucun article ou résumé dans cette revue ne peut être reproduit sous forme d'imprimé, photocopie, microfilm ou par tout autre procédé sans l'autorisation expresse des auteurs et de l'éditeur. Editions Phlébologiques Françaises
No article or abstract in this journal may be reproduced in the form of print, photocopy, microfilm or any other means without the express permission of authors and the editor. Editions Phlébologiques Françaises

Thermal ablation of the saphenous veins by bipolar radiofrequency RFITT®. Results of a prospective study on 119 patients with 2 years of follow-up. Technical considerations.

Ablation thermique des veines saphènes par radiofréquence bipolaire RFITT®. Résultats d'une étude prospective sur 119 patients avec 2 ans de suivi. Considérations techniques.

Hamel-Desnos C.[1], Desnos P.[2]

Summary

Objectives: To investigate the effectiveness and safety of bipolar radiofrequency-induced thermotherapy (RFITT®) for thermal ablation of saphenous vein (SV) trunks performed at a medical centre.

Design: Open prospective single-centre study.

Patients and Methods: Patients with incompetent SVs (C2s-C6 CEAP classification) were eligible, in the absence of recent thromboembolic events, intraluminal thrombotic sequelae or important tortuosity of the target vein that might prevent the vein catheterisation.

No sedation was administered and all RFITT® procedures were performed under strictly tumescent local anesthesia.

No complementary phlebectomy was performed; foam sclerotherapy was administered, where necessary, for tributaries, usually in a deferred mode.

The main criterion was occlusion of the treated vein (duplex-scan-DS).

Side effects were recorded. Tolerance was assessed through a visual-analog-scale (VAS score 0-10, max. pain = 10) for pain during the procedure and for 10 days thereafter, and by return to normal activity and time off work.

Résumé

Objectifs : *Évaluer l'efficacité et la sécurité de la radiofréquence bipolaire RFITT® (radiofrequency-induced-thermotherapy) dans l'ablation thermique des veines saphènes (VS), réalisée en cabinet médical.*

Design : *Étude ouverte, monocentrique prospective.*

Patients et méthodes : *Les patients porteurs d'une insuffisance de VS, classés C2s-C6 selon la classification clinique CEAP, étaient éligibles en l'absence d'un évènement thromboembolique récent, de séquelles thrombotiques endoluminales ou de tortuosités du tronc à traiter, susceptibles de compromettre la cathétérisation.*
Aucune sédation n'était administrée, et toutes les procédures RFITT® ont été réalisées sous anesthésie locale stricte, par tumescence.
Aucune phlébectomie n'a été réalisée en complément du traitement du tronc, et lorsque cela a été nécessaire, un traitement des tributaires a été effectué uniquement par mousse sclérosante, le plus souvent de façon différée.
Le critère principal était l'occlusion de la VS traitée (écho-Doppler – ED).
Les effets secondaires ont été répertoriés. La tolérance était évaluée par le score douleur en per-procédure et sur les 10 jours suivants le traitement, selon échelle visuelle analogique (EVA score 0 à 10, avec score maximal de douleur 10), par le retour à une activité normale et par le temps d'arrêt de travail.

1. *Claudine Hamel-Desnos, médecin vasculaire, Société Française de Phlébologie, 46, rue Saint-Lambert, 75015 Paris, France. Hôpital privé Saint-Martin, 18, rue des Rocquemonts, 14050 Caen, France.*
E-mail : claudine@desnos.eu - Téléphone : + 33 231 43 34 34 - Fax : + 33 231 43 33 30
2. *Philippe Desnos, médecin vasculaire, Société Française de Phlébologie, 46, rue Saint-Lambert, 75015 Paris, France.*

Aucun article ou résumé dans cette revue ne peut être reproduit sous forme d'imprimé, photocopie, microfilm ou par tout autre procédé sans l'autorisation expresse des auteurs et de l'éditeur. Editions Phlébologiques Françaises
No article or abstract in this journal may be reproduced in the form of print, photocopy, microfilm or any other means without the express permission of authors and the editor. Editions Phlébologiques Françaises

Patients scored their satisfaction from 0-10 (max. satisfaction = 10).

Results: 168 incompetent SVs consisting of 126 great SVs (GSVs), 36 small SVs (SSVs) and 6 anterior accessory SVs (ASVs) were treated in 119 patients (71% women) whose average age was 58 and BMI 25.

The average trunk diameter was 8-mm. Mean lengths (cm) of treated veins were: GSV 48, SSV 24, and ASV 19 respectively.

The procedures and their postoperative course were uneventful and particularly well tolerated.

The mean pain score was 2 for the procedure and 1 for the 10 days thereafter, with good resumption of normal activity and no time off work. Mean satisfaction score was 9.2.

Average follow-up was 28 months (> 36 months for 41 patients).

On final DS-assessment (independent operator), 92% of SVs were completely occluded, 7.4% partially occluded; only one SV (0.6%) was totally permeable.

The power used was 19-watts (18-20W) on average, and mean duration of application was 6 seconds/cm.

Conclusion: The RFITT® technique appears to be well-tolerated, safe and effective for SV occlusion in the medium-term. For a power setting of 18-W, we recommend a minimum threshold of application time of 5-6sec/cm.

Keywords: *bipolar radiofrequency ablation, saphenous veins, varicose veins, varices, thermal ablation.*

Les patients scoraient leur satisfaction de 0 à 10, la satisfaction maximale étant 10.

Résultats : *168 VS incontinentes, soit 126 grandes VS (GVS), 36 petites VS (PVS) et 6 VS accessoires antérieures (VSA) ont été traitées, chez 119 patients (71 % de femmes), avec un âge moyen de 58 ans et un IMC (indice de masse corporelle) de 25.*

Le diamètre tronculaire moyen était de 8 mm. La longueur moyenne (cm) des veines traitées était : GVS 48, PVS 24, et VSA 19 respectivement.

Les procédures et leurs suites se sont déroulées sans incident particulier, et ont été particulièrement bien tolérées.

Le score moyen de la douleur a été de 2 pour la procédure et de 1 pour les 10 jours suivants, avec un retour très rapide à l'activité courante et aucun arrêt de travail. Le score moyen de satisfaction était de 9,2.

Le suivi moyen a été de 28 mois (> 36 mois pour 41 patients).

Lors du dernier contrôle ED (opérateur indépendant), 92 % des VS étaient complètement occluses, 7,4 % l'étaient partiellement ; seulement une VS (0,6 %) était totalement perméable.

La puissance utilisée était de 19 watts (18-20 W) en moyenne, et le temps moyen d'application de 6 secondes/cm.

Conclusion : *À moyen terme, le traitement des VS par technique RFITT® apparaît bien toléré, sûr et efficace en termes d'occlusion de la veine. Pour une puissance utilisée à 18 W, nous recommandons un seuil minimal de temps d'application de 5-6 s/cm.*

Mots-clés : radiofréquence bipolaire, veines saphènes, varices, ablation thermique.

Introduction

Thermal ablation (TA) using radiofrequency (RFA) or endovenous laser ablation (EVLA), has become the first line of treatment for saphenous vein (SV) insufficiency, taking precedence over conventional surgery [1, 2, 3, 4].

The RFITT® technology (Radiofrequency-induced thermotherapy; Olympus Surgical Technologies Europe, Hamburg, Germany), also called the ***Celon method***, is a bipolar RFA device, dedicated to this indication.

It was perfected in 2007 and marketed in France from 2008.

The bipolar-Celon-RFITT® technology is based on thermal destruction of the venous wall, using a radiofrequency current that ***induces localized heat***.

This heat reaches a temperature of 60°C to 100°C on the interior of the venous wall, with this being sufficient to destroy the collagen (minimum heat necessary = 60°C), while avoiding lesions to neighboring tissue [5].

The bipolar applicator is introduced directly into the SV lumen using a 5 or 6-French introducer; it has a 13-mm active tip, consisting of two cylindrical electrodes separated by an insulator **(Figure 1)**.

The applicator is slowly withdrawn from proximal to distal direction whilst delivering the radio frequency energy; so heat is applied in a continuous mode, with an acoustic signal that enables the control of the withdrawal speed.

The vein is thermally destroyed by means of the locally concentrated current flow and this contracts the vein diameter until it closes.

Aucun article ou résumé dans cette revue ne peut être reproduit sous forme d'imprimé, photocopie, microfilm ou par tout autre procédé sans l'autorisation expresse des auteurs et de l'éditeur. Editions Phlébologiques Françaises
No article or abstract in this journal may be reproduced in the form of print, photocopy, microfilm or any other means without the express permission of authors and the editor. Editions Phlébologiques Françaises

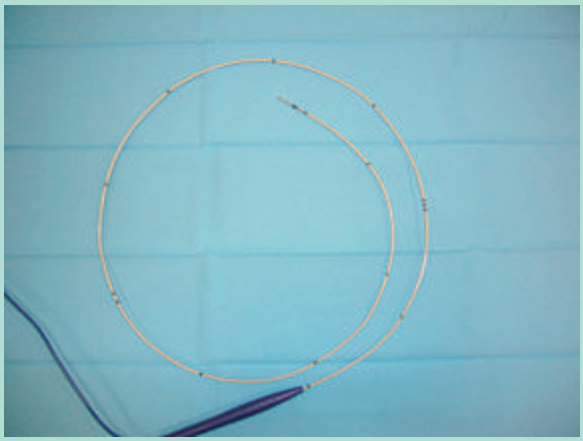

FIGURE 1 : RFITT® applicator, with bipolar active tip (length of bipolar tip = 13 mm); marks on the applicator every 10 cm.



FIGURE 2 : RFITT® unit. Visible settings: power (watts) and duration of application (minutes and seconds in total).

During the procedure, the tissue impedance of the vein, is checked constantly by the unit, and where appropriate, the power (P) output is automatically reduced, with a resulting change to the acoustic signal **(Figure 2)**.

In 2007, the settings recommended by the manufacturer were a P of 25-W and a withdrawal speed (or application time) of 1 sec/cm, using a single pass.

On the basis of several studies, the manufacturer reviewed this recommendation: it is now recommended to use a P of 18-W and an application time of 3.5 to 6-sec/cm, depending on the diameter of the vein to be treated, using several passes where necessary.

In fact, in 2009, in a multicenter study, the P used was 25-W at the start of the study, then subsequently 22-W (with slower withdrawal) [6].

U.T. Zierau, however, recommends a P of 18-W and an average application duration of at least 3.5 sec/cm, involving several segmented applications (several passes) if necessary, for example, in venous ectasia [7].

We hereby offer our personal experience of RFITT®, reporting the results of an **open prospective single center study** started in 2009, and discussing the possible technical options to improve the technique.

The main objective of this study was to assess the rate of occlusion, in the medium term, of SVs treated by TA with the RFITT® technique. The judgment criterion was a duplex-scan assessment (DS).

The secondary objectives were to examine the feasibility of the technique, assessment of the tolerance, and the side effects, as well as the return to normal activity, the time off work, and patient satisfaction.

Ethics

In accordance with the legal obligations in force in France, prior to patients' decision concerning treatment, all of them received detailed written and verbal information about the proposed technique, the benefits and risks, as well as the alternative treatment options.

Before we performed the procedure, all patients had to sign a written consent form and gave their consent for us to use their data for scientific purposes.

Statistics

Descriptive statistics were used to capture the patients and procedure parameters for the patients sample and per vein analysis.

Time-to-event was calculated using Kaplan-Maier analysis, and occlusion survival curves were generated both per patient and per vein.

IBM SPSS Version 20 was used for the statistical analysis.

Patients and Methods

Criteria of inclusion

For eligibility, the patients had to be suffering from symptomatic varices with SV trunk insufficiency whether or not this included an incompetence of the terminal and/or pre-terminal valves.

SV could be a great SV (GSV), a small SV (SSV) or an anterior accessory SV (ASV).

Trunk reflux at thigh level had to be at least 0.5 second on a DS-assessment, with the patient in a standing position.

Aucun article ou résumé dans cette revue ne peut être reproduit sous forme d'imprimé, photocopie, microfilm ou par tout autre procédé sans l'autorisation expresse des auteurs et de l'éditeur. Editions Phlébologiques Françaises
No article or abstract in this journal may be reproduced in the form of print, photocopy, microfilm or any other means without the express permission of authors and the editor. Editions Phlébologiques Françaises

The clinical stage from the CEAP (clinical, etiological, anatomic, pathophysiological) classification had to be C2s to C6.

Patients had to sign an informed consent form before inclusion.

Non-inclusion criteria

Patients presenting with pregnancy, an episode of deep or superficial vein thrombosis occurring less than three months previously, endoluminal sequelae of thrombus in the SV to be treated, or important tortuosities of the target vein that might interfere with catheterisation, could not be included in this study.

Methods

The investigator had had good experience of TA, having already performed numerous EVLA procedures before the study began.

Since the RFITT®-procedure is performed in a manner very similar to that of EVLA, a learning curve of 10 RFITT®-procedures was judged sufficient.

Our experience soon matched that of **Zierau** [7], making it possible to establish that the application settings recommended by the manufacturer in 2007 were not optimal.

In fact, during this learning curve, we noted two failures out of the first four RFITT®-procedures.

These TA had been performed at a P of 22-W, and a single pass with a withdrawal speed of 1 sec/cm. The procedures were therefore subsequently performed using a P of 20-W, followed by 18-W, with a longer application time than that recommended.

All procedures were performed in the doctor's office at a clinic, in a treatment room set aside for the purpose.

The treatment consisted of a thermal ablation of the saphenous trunk only; no treatment of the sapheno-femoral or sapheno-popliteal junctions was performed.

The patient received no sedation, and purely local anesthetic was administered, through tumescence, as is regularly done for any TA in our medical center.

Before starting the procedure, with the patient in the standing position, a pre-therapeutic systematic Duplex-scan examination was again performed (duplex-scan Siemens-Antares®-13.5-MHz probe, Germany) and if necessary, the skin was marked, especially at the site selected as the most relevant for percutaneous puncture.

The mark was checked with the patient standing and then supine.

With the patient lying down (patient lying face down for SSV TA), the procedure consisted first of inserting a 10-cm 5-French Terumo® sheath, using percutaneous venous puncture under ultrasound-guidance (generally in the leg for the GSV) and a guide wire.

The inserted sheath allows introduction of the RF catheter into the SV.

Then, with the patient in the Trendelenburg position, the tip of the thermal catheter was positioned, under ultrasound-guidance, between 1 and 2-cm under the sapheno-femoral junction for the GSV (respecting the epigastric vein), or the sapheno-popliteal junction when existing, for the SSV.

Tumescent anesthesia was then performed under ultrasound-guidance.

The fluid for the tumescent anesthesia consisted of lidocaine 200-mg diluted in 500-mL of saline solution.

On average 250 to 350-mL of fluid were injected for a GSV and 200 to 250-mL for a SSV, using a 22-Gauge Terumo® needle of 40-mm in length and a pump (dispenser DP 20 Nouvag®, Switzerland).

Thermal application was then performed.

When the tip of the thermal catheter became carbonized, thermal catheter was completely removed from the vein, cleaned with normal saline solution, and reintroduced into the vein up to the height required (preliminary safety tracking with Steristrip® on the catheter to avoid going beyond the desired treatment area).

No phlebectomy was performed on tributaries but complementary treatments were administered, where necessary, using foam sclerotherapy, usually after a three-month interval.

Thromboprophylaxis

At the beginning of the study, the patients received systematic thromboprophylaxis with fondaparinux (2.5 mg/day) for six days from the date of the procedure, representing 75 patients (45%).

Subsequently, this prevention protocol was only applied to those study participants who were at risk, the other patients only receiving one fondaparinux injection just before the procedure was started.

Therefore, in this second part of the study, four patients (2%) received six days of fondaparinux, 80 (48%) only received one fondaparinux injection, and seven (4%) patients were already taking oral anticoagulants.

For the vast majority of patients (92.4%), a 15-20 mmHg compression stocking was put in place on the operating table at the end of the procedure.

Unless otherwise indicated with this compression, patients were invited, for their own comfort, to wear this stocking in daytime for 8 through 10 days.

Pain assessment for the procedure

By the end of the procedure, just before leaving the treatment room, patients were asked for their perception of the pain for the entire treatment, using a visual analog scale (VAS from 0 to 10, whereby 10 = maximal pain).

Aucun article ou résumé dans cette revue ne peut être reproduit sous forme d'imprimé, photocopie, microfilm ou par tout autre procédé sans l'autorisation expresse des auteurs et de l'éditeur. Editions Phlébologiques Françaises
No article or abstract in this journal may be reproduced in the form of print, photocopy, microfilm or any other means without the express permission of authors and the editor. Editions Phlébologiques Françaises

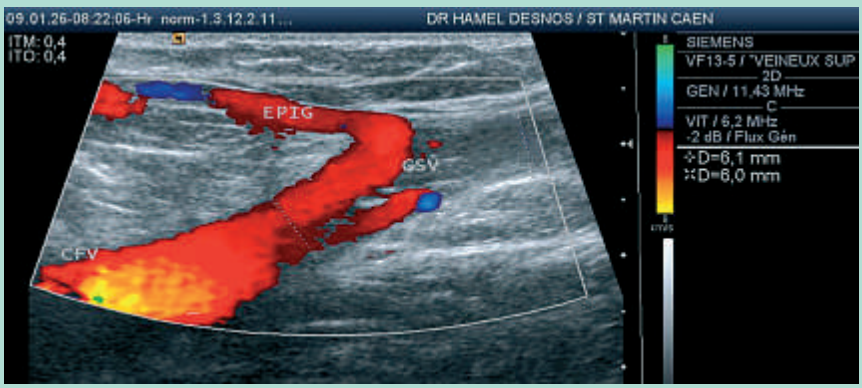

FIGURE 3 : Duplex-scan image of a great saphenous vein (GSV) at sapheno-femoral junction (SFJ), at 10-day follow-up; the GSV is occluded except at the SFJ, so that the physiological drainage of the afferent veins of the SFJ is possible.

Follow-up visits

A post-operative visit took place at 10 days, and then, depending on residual varices, a visit was planned for about three months hence, if necessary. Thereafter the patient was seen every year **(Figure 3)**.

All visits included a clinical examination and a systematic duplex-scan assessment.

On Day-10, the patient was again asked to complete an assessment of the pain for the 10 days following the procedure, using the VAS.

The duplex-scan assessment permitted the effectiveness of the treatment to be checked as well as the absence of deep or superficial vein thrombosis.

According to the UIP consensus [8]**, to assess the treatment success, duplex-ultrasound findings were defined by:**

- **"Total occlusion"** of the vein: total incompressibility and absence of color flow;
- **"Partial occlusion"** of the vein: partial compressibility and presence of color flow in part of the lumen;
- **"Total permeability"** of the vein: complete compressibility and presence of color flow in the entirety of the lumen.

By the end of the study, to minimize the loss to FU of patients, a dedicated team (PD and two secretaries) was in charge to contact all the patients for a final DS-assessment; this final assessment was performed by a different operator from the person who performed the RF-procedure.

Results

All of the general data are summarized in **Table 1**.

Between 2009 and 2012, **168 lower limbs** with SV insufficiency were treated using RF-Celon-RFITT®, representing 119 patients (71% female) included consecutively, whose average age was 58. The SVs were divided into 126 GSVs, 36 SSVs and 6 ASVs.

Group	All patients	
Patients*		
Total	117	(100%)
Man	33	(28.2%)
Woman	84	(71.8%)
Age (years)	58.4 ± 14.3	(17-87)
BMI	25.4 ± 4.8	(17-43)
Number of veins treated	168	(1.4/Pt.)
Vein Treated*		
GSV	126	(75%)
SSV	36	(21.4%)
ASV	6	(3.6%)
Clinical CEAP status*		
CEAP 1	0	
CEAP 2	128	(76.2%)
CEAP 3	19	(11.3%)
CEAP 4	16	(9.5%)
CEAP 5	3	(1.8%)
CEAP 6	2	(1.2%)

TABLE 1 : General data for all patients.
BMI: body mass index. Pt.: patient. GSV: great saphenous vein. SSV: small saphenous vein. ASV: anterior accessory saphenous vein. CEAP: clinical, etiological, anatomic, pathophysiologic classification.
* Number (percentage)

The characteristics of the treated veins and data for the modalities of the treatment are stated in **Table 2**.

The trunk diameters were measured, with the patient in the standing position, at mid-thigh (GSV) or mid-calf (SSV), excluding focal dilatation.

On average, the P used was 19-W and the application time was 6 sec/cm. To achieve this application time, several segmental passes of the bipolar applicator were performed along the SV. In particular, several passes were systematically performed on the proximal portion of the SV.

Aucun article ou résumé dans cette revue ne peut être reproduit sous forme d'imprimé, photocopie, microfilm ou par tout autre procédé sans l'autorisation expresse des auteurs et de l'éditeur. Editions Phlébologiques Françaises
No article or abstract in this journal may be reproduced in the form of print, photocopy, microfilm or any other means without the express permission of authors and the editor. Editions Phlébologiques Françaises

Group	All patients	
Patients*		
Total	117	(100%)
Anesthesia*		
Local tumescent anesthesia alone	117	(100%)
Other	0	(0%)
Maximum power output (Watts)**	20	(6-20)
Mean power output (Watts)	19	
Diameter of vein treated (mm)**		
GSV	7.8 ± 2.2	(3.5-14.0)
SSV	7.7 ± 2.2	(4.5-15.5)
ASV	8.4 ± 4.5	(4.0-14.0)
Overall Length of vein treated (cm)**	41.6 ± 14.1	(8-66)
GSV	47.9 ± 9.4	(13-66)
SSV	23.6 ± 7.2	(8-42)
ASV	19 ± 8.5	(10-32)
Treatment time**		
Total (second)	259.0 ± 171.2	(26-921)
Second/cm	6.4 ± 3.6	(1.35-23.68)
Follow-up period (days)**	848.2 ± 395.2	(12-1434)
Occlusion status at last FU*		
Totally occluded	155	(92%)
Partial	12	(7.4%)
Totally permeable	1	(0.6%)

TABLE 2 : Characteristics of treated veins and treatment methods data.
GSV: great saphenous vein. SSV: small saphenous vein.
ASV: anterior accessory saphenous vein. FU: follow-up.
* Number (percentage)
** Mean ± standard deviation (minimum-maximum)

No patient had a phlebectomy associated with thermal ablation, either concomitantly or deferred. Nine patients (7.6%) received additional sclerotherapy during the thermal procedure and 17 patients (14.4%) received deferred treatment.

On average, patients wore the compression stocking for 3.8 ± 1.6 days after the procedure.

Feasibility - Efficacy

Two procedures (2 patients) could not be completed due to "technical failures". In one case, this was due to the impossibility of moving the thermal catheter forward into the vein, after cleaning, due to carbonization. In the other case, there was a technical failure of the thermal catheter.

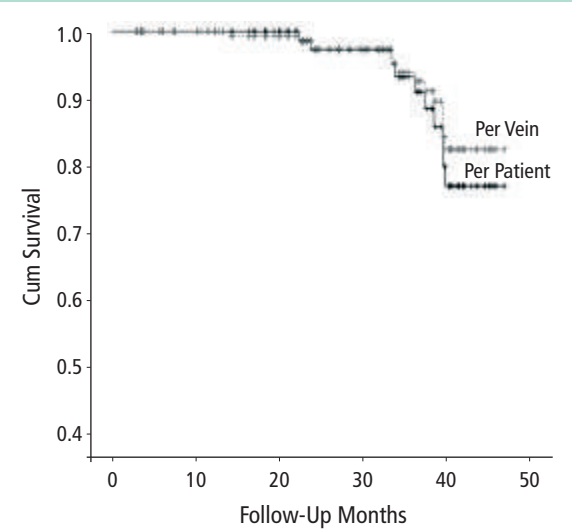

FIGURE 4 : Kaplan-Meier graph showing numbers at risk, cumulative complete occlusion, and combined complete and partial occlusion rates over time for the whole cohort of veins treated with RFITT® (n = 168). Complete or partial occlusion rates were 95% and 5% at 360 days (respectively).

Of the remaining 117 patients, 35 had at least two saphenous veins treated.

At the short term-follow-up, 96% (n = 159) of the SVs were totally occluded along the treated segment, 4% (n = 7) were partially occluded.

Overall, the average length of vein occlusion was 48-cm (extreme 8-66), respectively: GSV 48, SSV 24 and ASV 19.

Average follow-up (FU) was **28 ± 13 months** (3-47) and 41 patients had a FU longer than **36 months (Table 2)**.

Eleven patients (9.3%) experienced a FU-time of less than 6 months and nine (7.6%) 6-12 months of FU, while 30 patients (25%) had a FU up to 24 months and 27 (22.9%) up to 36 months.

Apart from one patient who died from hepatic neoplasia one year after undergoing the procedure, all of the patients were seen again for a final DS-assessment.

By the end of the follow-up (mean FU 28 months), 92% of SVs were completely occluded, 7.4% partially occluded; only one SV (0.6%) was totally permeable, without reflux.

Survival analysis

In our patient sequence, the mean time to occlusion was 44.5 months (95%, range 43-46); Kaplan-Maier survival curves are provided per patient and per vein in **Figure 4**. The figure shows that the cumulative survival of occlusion was higher than 0.95, even after 36 months, with no difference with regard to the SSV and GSV **(Figure 4)**.

Aucun article ou résumé dans cette revue ne peut être reproduit sous forme d'imprimé, photocopie, microfilm ou par tout autre procédé sans l'autorisation expresse des auteurs et de l'éditeur. Editions Phlébologiques Françaises
No article or abstract in this journal may be reproduced in the form of print, photocopy, microfilm or any other means without the express permission of authors and the editor. Editions Phlébologiques Françaises

	Per Patient	Per Vein
None	106 (89.9%)	154 (91.6%)
Paresthesia*	11 (9.3%)	13 (7.8%)
Lymphatic tumefaction (lymphocele)	1 (0.8%)	1 (0.6%)
Hematoma	0	0
SVT	0	0
DVT	0	0
Pulmonary Embolism	0	0

TABLE 3 : Complications after the RFITT® procedure.
* Sensory impairment

Safety and tolerability

All of the procedures were well tolerated. The average pain score was assessed by the patients at 2.1 ± 1.5 (on a VAS of between 0 and 10; maximum = 10) for the procedure itself while, for the 10 days following the procedure, the average score was 1.0 ± 1.5.

A satisfaction and quality-of-life survey showed very good and immediate resumption of normal life; the satisfaction score was on average **9.2** ± 0.84 on a scale of 0 to 10 (maximum satisfaction = 10).

There was no sick leave.

Most patients = 106 (89.9%), experienced no complications at all, corresponding to 152 veins (91.6%).

When present, side effects were minimal. A localized tumefaction in the knee area, of lymphatic origin (lymphocele), was recorded and was swiftly resolved.

Sensory neurological disturbances (paresthesia) were described in 13 cases (7.8%), which involved 7 GVSs and 6 SSVs.

All disappeared spontaneously in less than 6 months, with the exception of one case of persistence of episodic symptoms for one year.

None of these cases required specific treatment.

The application time for these patients was 9.14-sec/cm on average (median 8.07; extr. 4.28-23.68).

No neurological motor complications and or thromboembolic events occurred during the series of treatments.

Due to injections for tumescent anesthesia, ecchymosis was common and regular, while no hematoma (with liquid collection seen in B-mode echography) occurred **(Table 3)**.

Discussion

At two-year FU, our study shows a high rate of SV occlusion, using the Celon-RFITT®-technique.

Our medium-term results confirm the efficacy already described in the literature for short-term studies of TA of the SV with the RFITT® device [6, 7, 9, 10, 11, 12]; this efficacy appears to be equivalent to that obtained with the EVLA and ClosureFast® (now called Venefit®) procedures [11, 12].

Our series only investigated the efficacy, tolerance, and safety of the RFITT®-technique based on the criteria we use in real life [13]. Consequently, one of the limitations of this study was the absence of a quality-of-life questionnaire (QOL).

In fact, clinical studies on the various methods of treating varicose veins always show an improvement of QOL, irrespective of the treatment method used. Several comparative studies have also demonstrated than QOL questionnaires are not relevant nor do they discriminate in demonstrating any statistical difference between various types of ablative or surgical treatments for saphenous veins [14, 15, 16].

In our study, the mean application time (T) was of 6 sec/cm (for a P of 19-W on average), *i.e.* longer than those used in the other studies with RFITT®-technique.

Under these conditions, pain scores demonstrate that the tolerance was good for all procedures (mean pain score 2.1; max. pain score 3.6). However, the risk of paresthesia may increase in the post-operative period for a T ≥9 sec/cm (P 18-W).

In fact, when using the Celon RFITT®-device at P 18-W, an application time of 5 sec/cm corresponds to an energy output of 63 joules/cm, and 6 sec/cm to 76 joules/cm.

This can be compared with other TA techniques:
- EVLA: energy (linear-endovenous-energy-density) of at least 60 J/cm is recommended;
- ClosureFast®: a processing cycle (20 seconds) is provided at an energy of 60 J/cm;
- Steam: a pulse corresponding to 60 joules.

Therefore, the new settings of T of 3.5 to 6 sec/cm for P 18-W, that have been recommended for Celon RFITT® by the manufacturer since 2012, seem to be more realistic than the initial recommendations made in 2007, T of 1 sec/cm for a P of 22-W.

In our opinion, however, if the P used is 18-W, a basis of T of 5-6sec/cm would be logical in common practice.

On the other hand, it should be noted that certain practitioners prefer to use very low P (5-6W), to prevent carbonization of the thermal catheter, but this means that the application time has to be very greatly extended. In fact, regardless of the method used, for any TA the determining factor for obtaining venous occlusion is the amount of energy delivered. This energy being equal to P × T (power × time), the more P is reduced, the more T should be extended in order to obtain **sufficient energy**.

In fact, the improvement of the coating of the RFITT® catheter tip would be desirable to avoid carbonization.

Aucun article ou résumé dans cette revue ne peut être reproduit sous forme d'imprimé, photocopie, microfilm ou par tout autre procédé sans l'autorisation expresse des auteurs et de l'éditeur. Editions Phlébologiques Françaises
No article or abstract in this journal may be reproduced in the form of print, photocopy, microfilm or any other means without the express permission of authors and the editor. Editions Phlébologiques Françaises

The type of anesthetic used and the treatment environment, as well as the absence of concomitant phlebectomies, participate to the good tolerability observed in our study.

The pain assessment during the procedure was made possible by using strictly local anesthesia; the very low score observed confirms that recourse to general anesthesia would not have been justified.

Moreover, the strict use of local anesthesia allows for continuous monitoring of the risks of neurological damage since the patient is able to alert the practitioner to the slightest signs of pain during the thermal application. Currently, neurological complications seem to be significantly higher when the procedures are performed under general anesthesia [17].

The strict use of local anesthesia also makes it possible to work outside an operating theatre, in a less stressful environment for the patient, and to be able to mobilize the patient immediately after the procedure [18].

Moreover, in our practice, we do not perform phlebectomies associated with TA [19]. The medical procedure is therefore minimally invasive, and once the procedure is complete, the patient resumes normal activities without stopping work, and with a minimum amount of pain, as shown in this study by the average pain score for the week following the procedure.

Patients had the choice of whether they wanted to wear elastic compression stockings after the procedure; on average they only wore them for 3.8 days, which confirms the good tolerability after the procedure.

The health-authorities in France advise only prescribing thromboprophylaxis after TA in the case of patients at risk [20]. We applied these recommendations in the second part of the study; the other patients received a single injection of fondaparinux immediately before the procedure.

No thromboembolic event occurred during the entire study.

In our study, no patient had phlebectomies, and only 7.6% of the patients received concomitant foam sclerotherapy on tributaries, while 14.4% received foam sclerotherapy in a deferred mode.

To save the requirement for additional treatment, we made sure to carefully select the most relevant site for introducing the RF-catheter, to disconnect the maximum of the largest tributaries, while also taking the neurological risk into account.

Sutton showed that the risk of thrombosis developing after TA was higher if accompanied by phlebectomies and general anesthesia [21].

Phlebectomies increase the trauma of the intervention, lengthen the operating time, and encourage the surgeon to resort more frequently to general anesthesia.

To date, there has been no evidence that additional treatment of tributaries should be performed in a deferred mode rather than concomitantly [19, 22, 23, 24], but a minimally traumatic intervention, short intervention time, and immediate mobilization are probably the determining factors for reducing the risks of thrombosis [21, 25].

Finally, few studies have been conducted using bipolar radiofrequency-induced thermotherapy (RFITT®) for saphenous veins, and some authors still question the parameters initially given by the manufacturer [26, 27]**.**

This paper adds some clinical data and provides a little more evidence as to the optimal regulation for power and application time.

It also indicates a very high tolerance of the procedure when performed under strictly local tumescent anesthesia, and challenges the use of general anesthesia for thermal ablation.

The relevance of systematic extensive concomitant phlebectomies is also questionable.

Conclusion

In our series, the RF-Celon-RFITT® procedure appears to be well tolerated, safe, and effective for SV occlusion, at mid-term follow-up.

Consequently, RFITT® can be an alternative to EVLA using radial fibers and to RF Venefit®; however, the improvement of the coating of the RFITT® catheter tip would be desirable to avoid carbonization.

For a power setting of 18-W, we recommend a minimum threshold of application time of 5-6 sec/cm.

Thanks are due to:

Diklah Geva (www.Integristat.com) for statistics and advice on statistical analysis.

M-P. Fiorantino MD, **V. Tripey** MD, **V. Wodey** MD, **G. Boitelle** MD, **F. Chantrel** MD, **P. Desnos** MD, **L. Moraglia** MD, **J.B. Viguier** MD, vascular physicians, for their involvement and help in the clinical and DS-assessments performed during follow-up.

Funding: Olympus Surgical Technologies Europe provided funding for the statistical analysis.

Conflict of interest: **P. Desnos** was paid expenses for advising Olympus Surgical Technologies Europe.

References

1. Gloviczki P., Comerota A.J., Dalsing M.C., Eklof B.G., Gillepsie D.L., Gloviczki M.L., et al. The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J. Vasc. Surg. 2011 ; 53 : 2S-48S.

Aucun article ou résumé dans cette revue ne peut être reproduit sous forme d'imprimé, photocopie, microfilm ou par tout autre procédé sans l'autorisation expresse des auteurs et de l'éditeur. Editions Phlébologiques Françaises
No article or abstract in this journal may be reproduced in the form of print, photocopy, microfilm or any other means without the express permission of authors and the editor. Editions Phlébologiques Françaises

2. National Institute for Health and Clinical Excellence (NICE). Varicose veins in the legs. The diagnosis and management of varicose veins. July 2013; NICE clinical guideline 168;guidance.nice.org.uk/cg168.
3. Practice guidelines. Superficial Venous Disease. American College of Phlebology 2014 http://phlebology.org/resources/PDFs/SuperficialVenousDiseaseGuidelines.pdf.
4. Document developed under the auspices of The European Venous Forum, The International Union of Angiology, The Cardiovascular Disease Educational and Research Trust (UK) Union Internationale de Phlébologie. International Angiology 2014 April ; 33(2) : 87-208. Management of chronic venous disorders of the lower limbs Guidelines according to scientific evidence.
5. Reich-Schupke S., Mumme A., Stucker M. Histological findings in varicose veins following bipolar radiofrequency-induced thermotherapy – Results of an *ex vivo* experiment. Phlebology 2011 ; 26 : 69-74.
6. Camci M., Harnoss B., Akkersdijk G. Effectiveness and tolerability of bipolar radiofrequency-induced thermotherapy for the treatment of incompetent saphenous veins. Phlebologie 2009 ; 38 : 5-11.
7. Zierau U.T., Lahl W. The endovenous RFITT-treatment of varicose veins, a new method of interventional phlebology. Phlebologie 2009 ; 38 : 12-6.
8. De Maeseneer M., Pichot O., Cavezzi A., Earnshaw J., van Rij A., Lurie F., et al. Duplex Ultrasound Investigation of the Veins of the Lower Limbs after Treatment for Varicose Veins - UIP Consensus Document. Eur. J. Vasc. Endovasc. Surg. 2011 ; 42 : 89-102.
9. Zierau U.T., Lahl W. Neue Ergebnisse zur RFITT von Stammvenen. Vasomed. 2011 ; 23 : 216-21.
10. Braithwaite B., Hnatek L., Zierau U., Camci M., Akkersdijk G.J.M., Nio D., et al. Radiofrequency-induced thermal therapy: results of a European multicentre study of resistive ablation of incompetent truncal varicose veins. Phlebology 2013 Feb ; 28(1) : 38-46. doi: 10.1258/phleb.2012.012013. Epub 2012 Aug 3.
11. Goode S.D., Chowdhury A., Crockett M., Beech A., Simpson R., Richards T., et al. Laser and radiofrequency ablation study (LARA study): a randomised study comparing radiofrequency ablation and endovenous laser ablation (810 nm). Eur. J. Vasc. Endovasc. Surg. 2010 ; 40(2) : 246-53.
12. Tesmann J.P., Bartz V., Thierbach H., Dietrich A., Grimme H., Vogt T., et al. Radiofrequenz obliteration der Stammvarikosis: Celon RFITT *versus* VNUS ClosureFast™. Vasomed. 2010 ; 22 : 220.
13. Hamel-Desnos C. Routine evaluation of the results of the treatments for varicose veins. How should this be done in practice? Phlébologie 2013 ; 66, 3 : 19-21.
14. Kalodiki E., Lattimer C.R., Azzam M., Shawish E., Bountouroglou D., Geroulakos G. Long-term results of a randomized controlled trial on ultrasound-guided foam sclerotherapy combined with saphenofemoral ligation *vs* standard surgery for varicose veins. J. Vasc. Surg. 2012 ; 55 : 451-7.
15. Rasmussen L., Lawaetz M., Bjoern L., Blemings A., Eklof B. Randomized clinical trial comparing endovenous laser ablation and stripping of the great saphenous vein with clinical and duplex outcome after 5 years. J. Vasc. Surg. 2013 ; 58 : 421-6.
16. Rasmussen L., Lawaetz M., Serup J., MS, Bjoern L., Vennits B., Blemings A., Eklof B. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy, and surgical stripping for great saphenous varicose veins with 3-year follow-up. J. Vasc. Surg. Venous and Lym. Dis. 2013 : 1-8.
17. Hamel-Desnos C., Desnos P., Allaert F.-A., Kern P. Thermal ablation of saphenous veins is feasible and safe in patients older than 75 years: a prospective study (EVTA study). Phlebology 2014 ; DOI : 10.1177/0268355514540882
18. Hamel-Desnos C., Gérard J.-L., Desnos P. Endovenous laser procedure in a clinic room: feasibility and side effects study of 1700 cases. Phlebology 2009 ; 24 : 125-30.
19. Hamel-Desnos C. Thermal ablation and additional treatments. Ablation thermique et traitements complémentaires. Phlébologie 2013 ; 66, 2 : 70-8.
20. Occlusion de grande veine saphène par radiofréquence par voie veineuse transcutanée. Service évaluation des actes professionnels. Rapport de la Haute Autorité de Santé (HAS), avril 2008 ; http://www.has-sante.fr
21. Sutton P.A., El-Duhwaib Y., Dyer J., Guy A.J. The incidence of post-operative venous thromboembolism in patients undergoing varicose vein surgery recorded in Hospital Episode Statistics. Ann. R. Coll. Surg. Eng. 2012 ; 94 : 481-3.
22. Onida S., Lane T.R.A., Davies A.H. Phlebectomies: to delay or not to delay? Phlebology 2012 ; 27 : 103-4.
23. Carradice D., Mekako A.I., Hatfield J., Chetter I.C. Randomized clinical trial of concomitant or sequential phlebectomy after endovenous laser therapy for varicose veins. Br. J. Surg. 2009 Apr ; 96(4) : 369-75.
24. Brittenden J., Cotton S., Elders A., et al. A randomized trial comparing treatments for varicose veins. N. Engl. J. Med. 2014 ; 371 : 1218-27.
25. San Norberto Garcia E.M., Merino B., Taylor J.H., Vizcaino I., Carlos Vaquero C. Low-Molecular-Weight Heparin for prevention of venous thromboembolism after varicose vein surgery in moderate-risk patients: a randomized, controlled trial. Ann. Vasc. Surg. 2013 ; 27 : 940-6.
26. Newman J.E., Meecham L., Walker R.J., Nyamekye I.K. Optimising treatment parameters for Radiofrequency Induced Thermal Therapy (RFiTT): A comparison of the manufacturer's treatment guidance with a locally developed treatment protocol. Eur. J. Vasc. Endovasc. Surg. 2014 Jun ; 47(6) : 664-9.
27. Badham G.E., Strong S.M., Whiteley M. An *in vitro* study to optimise treatment of varicose veins with radiofrequency-induced thermo therapy. Phlebology 2015 ; 30 (1) : 17-23.