Three-year European follow-up of endovenous radiofrequency-powered segmental thermal ablation of the great saphenous vein with or without treatment of calf varicosities

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Background: Radiofrequency segmental thermal ablation (RSTA) has become a commonly used technology for occlusion of incompetent great saphenous veins (GSVs). Midterm results and data on clinical parameters are still lacking.
Methods: A prospective multicenteral trial monitored 295 RSTA-treated GSVs for 36 months. Clinical control visits included flow and reflux analysis by duplex ultrasound imaging and assessment of clinical parameters according to the CEAP classification and Venous Clinical Severity Score (VCSS).
Results: A total of 256 of 295 treated GSVs (86.4%) were available for 36 months of follow-up. At 36 months, Kaplan-Meier survival analysis showed the probability of occlusion was 91.8% and the probability of no reflux was 95.3%, and 96.9% of legs remained free of clinically relevant axial reflux. If complete occlusion was present at the 12-month follow-up, the risk of developing new flow by 24 and 36 months of follow-up was 3.7% and 4.1%, respectively. Diameters of the GSV measured 3 cm distal to the saphenofemoral junction reduced from 5.8 ± 2.1 mm at screening to 2.2 ± 1.1 mm at 36 months. The average VCSS score improved from 3.9 ± 2.1 before treatment to 0.9 ± 1.5 at 3 months ($P <$ .0001) and stayed at an average <1.0 during the complete 36 months of follow-up. Only 41.1% of patients were free of pain before treatment; at 36 months, 251 (98.0%) reported no pain and 245 (95.7%) did not experience pain during the 24 months before. At 36 months, 189 of 255 legs (74.1%) showed an improvement in CEAP class compared with the clinical assessment before treatment ($P <$ .001). Stages C_3 and C_4 combined to 46% before treatment and dropped constantly to a combined level of 8% at 36 months. However, the proportion of C_2 legs that dropped from 52.3% before treatment to <10% at 12 months showed a constant increase thereafter, reaching 33.3% at 36 months.
Conclusion: RSTA showed a high and durable success rate in vein ablation in conjunction with sustained clinical efficacy. (J Vasc Surg 2011;■■:■■■.)

Shortly after its introduction, radiofrequency segmental thermal ablation (RSTA) became a technique used worldwide for heat-induced obliteration of incompetent great saphenous veins (GSVs). From the beginning, RSTA achieved immediate GSV ablation rates of >99% in addition to a very moderate side effect profile and a remarkably short average time interval for return to normal activity of <2 days.[1,2] These findings have been corroborated re-

cently, describing occlusion rates of 98% to 100% at 6 months of follow-up, further demonstrating that a vein diameter >12 mm is not related to a decreased ablation rate.[3] In addition, a prospective randomized trial proved that the side effect profile of RSTA compared favorably with endovenous laser ablation using a 980-nm diode laser and typical blunt-tipped bare fibers.[4]

Because of the widespread use of RSTA, midterm results of the first clinical trial of RSTA, including the durability of once achieved GSV occlusions and the postinterventional course of clinical signs and scores, are of special interest. This report presents the 3-year update of the European RSTA Study Group with follow-up data retrieval from up to 86.4% of treated patients.

PATIENTS AND METHODS

Study design. Within a prospective, nonrandomized, multicenter cohort study, results at 36 months were obtained on safety data and clinical outcomes of RSTA of the GSV in otherwise unselected consecutive patients with clinically relevant chronic venous disease and GSV incompetence. Control visits, including duplex ultrasound (DUS) examination, were scheduled at 3 days and at 3, 6,

12, 24, and 36 months after the study treatment. Previous reports have described enrollment criteria, the study device, the treatment procedure and its evaluation protocol with patient follow-up, and also some feasibility data as well as early safety and clinical outcome data of parts of this cohort.[1,2] Study treatments were performed at eight clinical sites in Germany and France after approval by local authorities and local ethical review boards according to the Declaration of Helsinki and its later extensions.

Patient follow-up. Each follow-up visit consisted of a clinical examination, the completion of a questionnaire, and DUS examination of the treated leg in horizontal and reverse Trendelenburg position. Supine position for DUS examinations was preferred rather than standing to allow comparison with diameters obtained intraoperatively.

The primary study end points were occlusion of and lack of reflux in the treated vein. Vein occlusion was defined as absence of any blood flow along the entire length of the treated vein length determined by DUS imaging beginning from 3 cm distal to the saphenofemoral junction (SFJ) and continued from there. The 3-cm limit was selected because the occlusion status of the GSV proximal to this limit frequently had to be regarded nonspecific due to the variable entry-site of several tributaries. On the other hand, a precise measurement with a typical 4-cm length linear ultrasound probe is still possible. Secondary end points included the evaluation of side effects, adverse events, clinical outcomes, and patient recovery after the treatment.

Patient symptoms and signs were recorded using the CEAP clinical classification[5] and the Venous Clinical Severity Score (VCSS).[6] The side effects and complications associated with the procedure were recorded and analyzed. Postprocedural pain and tenderness, the latter represented the discomfort level in response to touch or palpation, were evaluated using an analog scale, with the minimum of 0 representing no pain and a maximum of 10 representing worst possible pain. The analog scale was used in a nonvisual fashion after explaining it to the patient.

Statistical methods. Baseline characteristics, including demographics, medical history, or venous symptoms were summarized using descriptive statistics. End point analysis was performed at the 2-year follow-up or longitudinally along distinct follow-up intervals if required. Measurable parameters were expressed as mean ± standard deviation and proportions were expressed as percentage with a 95% confidence interval. Data were analyzed on a per-patient or a per-leg basis as appropriate for presentation of clinical data. Patients with bilateral treatment were treated as one for data analyzed on a per-subject basis. For data analyzed on a per-leg basis, the two legs were treated separately. If appropriate, for matched-pairs analysis only, those patients and legs were evaluated who completed the 3-year follow-up.

Kaplan-Meier analysis was used to describe recurrences of flow and reflux within treated veins. To protect across inferences and to preserve size of α, the type 1 error rate, the Tukey-Kramer honestly significant difference test was used to make multiple comparisons of means over time.

Contingency table analysis using likelihood ratio χ^2 statistics were used to test the hypothesis that the response rates were the same in each sample category. Continuity correction was applied, and exact *P* values were computed when cell sparseness rendered the analysis suspect. All analysis was performed using SAS 9.2 software (SAS Institute Inc, Cary, NC).

RESULTS

A total of 225 patients and 295 legs were treated from April 2006 to March 2007 at eight study centers in Germany and France. Patients with incompetent GSVs who met inclusion and exclusion criteria were offered treatment within this study. At the 3-year follow-up, 194 patients with 256 treated legs from seven centers were available, representing a proportion of 86.2% and 86.8% of the original study treatments, respectively. Thirty-one patients were not able to attend the 3-year follow-up, mainly because they moved to remote locations or because they declined further follow-up visits for personal reasons. Of 194 patients with follow-up at 3 years, 35.1% were treated at the center with the highest recruitment. Only two centers contributed <5% of the treated patients.

Patient characteristics. Patients were an average age of 47.1 ± 12.1 years (range, 18-74 years). Women comprised 74.5% of treated individuals. The proportion of women was not <69% in any study center. The mean body mass index of the 225 patients was 25.3 ± 4.6 kg/m² (range, 16.2-43.6 kg/m). Patient comorbidities were moderate: 72 significant medical conditions among 49 of the 214 patients (22.9%) were reported. Medical conditions with a frequency of >5% were arterial hypertension in 35 (17.8%) and thyroid disease in 19 (8.4%). Bilateral treatments were performed in 66 of 214 patients (30.8%). Among the 256 legs monitored for 36 months, distribution was 127 right legs and 129 left legs, which was almost equal. The average treated length of the GSV from the SFJ to the site of vein access at the distal point of reflux was 36.8 ± 10.5 cm. All RSTA interventions were performed under tumescent local anesthesia (TLA) with an average of 331 ± 107 mL of TLA administered per treated GSV, corresponding to an average of 9.4 ± 3.5 mL of TLA per cm of treated vein length.

Of the 256 legs available at the 3-year follow-up, 30 (11.7%) had undergone venous interventions previous to study treatment, however, not affecting the GSV. These included 3 vein strippings, 1 patient each with ligation, endovenous laser and phlebectomy, radiofrequency ablation, and radiofrequency ablation with concomitant sclerotherapy; 7 phlebectomies, 15 sclerotherapies, and 1 unspecified. Concomitantly with the study treatment, phlebectomy was performed in 147 of 256 legs (57.4%) and foam sclerotherapy of tributaries in 31 legs (12.1%). An incompetent accessory anterior saphenous vein in one leg was treated with segmental thermal ablation immediately after study treatment. During the study follow-up of 36 months, 11 of 256 legs (4.3%) received additional treat-
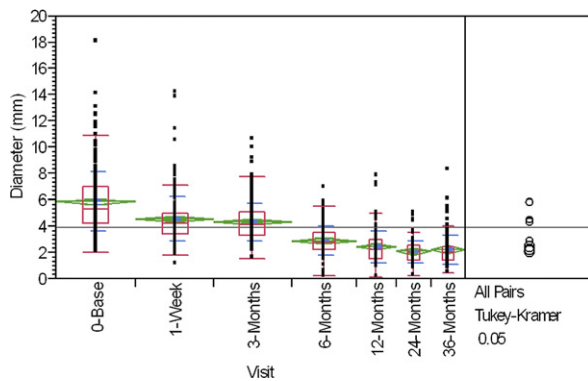
Fig 1. Diameters of 254 great saphenous veins (GSV) before study treatment and its later fibrotic stages during follow-up as measured 3 cm below the saphenofemoral junction. Numbers of evaluable GSVs decreased to 112 at 36 months. Data are given as average ± standard error (*green*) and standard deviation (*light blue*) as well as median (*horizontal line*) with 25% and 75% quantiles (*red box*).

ments for persisting varicose tributaries, comprising phlebectomy in 1 and sclerotherapy in 10.

DUS examination of proximal vein diameter. Immediately after segmental thermal ablation, vein occlusion with absence of spontaneous and augmented flow was demonstrated by US examination in all but one leg, which showed delayed occlusion. Furthermore, vein wall thickening was evident immediately after treatment in 100% of the GSVs. Pretreatment vein diameters measured in supine position at 3 cm distal to the SFJ showed an average diameter of 5.8 ± 2.1 mm (range, 2.0-14.0 mm). Fig 1 displays the average vein diameters 3 cm inferior to the SFJ and the time course of corresponding US measurements during follow-up.

A pronounced shrinkage of the average diameter was visible already at 1 week after the procedure to 4.5 ± 1.7 mm with a further reduction to 2.9 ± 1.1 mm at 6 months, resembling 78% and 49% of the pretreatment diameter, respectively. Tukey-Kramer pair-wise analysis revealed statistically significant reductions ($P < .05$) in vein diameter when comparing baseline values with all follow-up values and when comparing diameters at 1 week and 3 months with diameters at 6, 12, 24, and 36 months.

DUS examination of nonoccluded stump lengths of the GSV. At the week 1 postprocedural follow-up, the mean nonoccluded stump lengths at the SFJ of 250 GSVs was 1.0 ± 0.7 cm. No extension of the thrombus into the common femoral vein was observed

Interestingly, the average nonoccluded stump lengths of the treated GSV did not change much during the 36-month follow-up. Corresponding values at 3, 6, 12, 24, and 36 months were 1.2 ± 0.7, 1.2 ± 0.7, 1.1 ± 0.7, 1.1 ± 0.7, and 1.2 ± 0.7, respectively. Tukey-Kramer pair-wise analysis revealed a relevant difference only between the 1-week and 3-month follow-up ($P < .05$), indicating that increase of the nonoccluded stump lengths is not a natural process more than 3 months after the procedure.

Flow and reflux analysis. Blood flow and reflux were assessed by DUS examination along the treated vein from the SFJ toward the distal point of study treatment. Recurrence of any blood flow more distal than 3 cm from the SFJ, recurrence of any reflux, and recurrence of any axial reflux in the treated leg originating from the SFJ were described and plotted according to the Kaplan-Meier method.

At 3 days after study treatment, one vein exhibited flow with augmentation and showed reflux along the entire treated segment despite a narrowed lumen. This vein was occluded at the 3-month follow-up and at all later follow-up dates. Therefore, this GSV was judged to have delayed occlusion rather than reopening and was not included in the Kaplan-Meier analysis.

Recurrence of blood flow, reflux, and axial reflux. By DUS examination, blood flow in any part of the treated vein from 3 cm below the SFJ or more distally was observed during the 3-year follow-up in 21 GSVs. In reverse, no blood flow within the treated GSV was observed in 99.7%, 98.6%, 96.3%, 94.5%, and 92.6% at 3, 6, 12, 24, and 36 months. Standard error of the confounding Kaplan-Meier analysis (Fig 2, *A*) was <5% at all times. If a leg reached the 12-month follow-up visit without detection of flow, the chance to develop new flow during the consecutive 12 months was 3.7%. If a leg reached the 24-month follow-up visit without detection of flow, the chance to develop new flow during the consecutive 12 months was 4.1%.

Reflux of >500-ms duration in any part of the treated GSV was observed by DUS examination during the 3-year follow-up in 12 GSVs. No reflux within the treated GSV was observed in 99.7%, 99.3%, 99.0%, 97.2%, and 95.7% at 3, 6, 12, 24, and 36 months, respectively (Fig 2, *B*). Standard error was <1% at all times. If occlusion of the treated GSV was observed at the 12-month follow-up, the risk that new reflux would develop during 24 months of follow-up was 2.9%. If occlusion of the treated GSV was observed at 24 months, the risk of developing new reflux during 24 months of follow-up was 3.3%.

Axial reflux as defined recently,[7] originating at the SFJ and conducted within the initially occluded GSV or by different parallel pathways down to the calf region, was observed during the 3-year follow-up in only five GSVs. As reported in more detail in Table I,[7] only two cases resulted from full recanalization of the RSTA-treated GSV, one at 6 months and another after 36 months. In two legs the accessory anterior saphenous vein was involved as the route of axial reflux, and in one instance carrying the reflux to the distal thigh and entering the GSV at a point where no study treatment was applied before due to a lack of incompetency at the time of study treatment. In the second leg with involvement of the accessory anterior saphenous vein, the axial reflux was conducted through the GSV stump for <3 cm, then transferred to the proximal competent accessory anterior saphenous vein. In the last leg, after a 6-cm recanalization, reflux was conducted down to the calf through a ventral thigh tributary.

Clinical response to study treatment: CEAP. We are well aware that the CEAP classification originally was
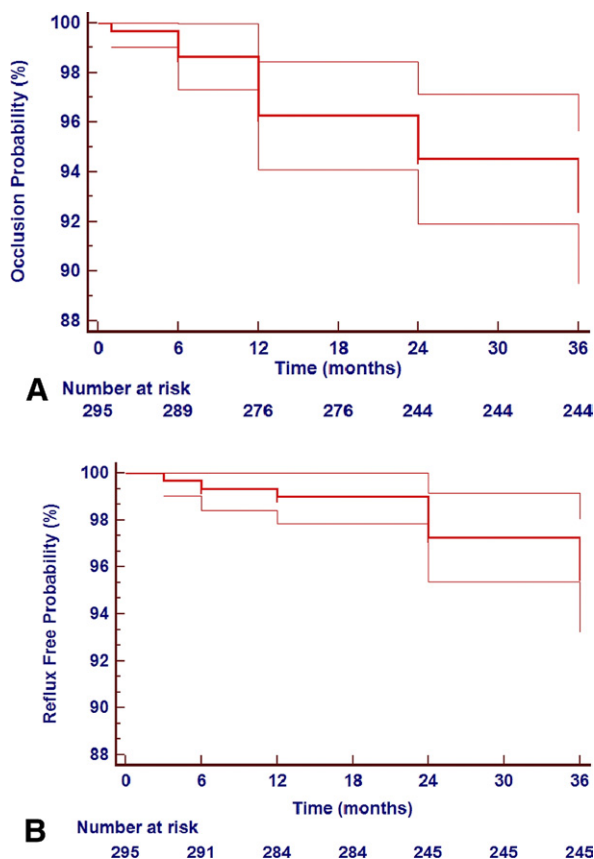
Fig 2. A, Time-to-flow analysis shows any flow within the treated vein, according to Kaplan-Meier methods. Numbers in the lower line indicate legs at risk at a given follow-up time. **B,** Time-to-reflux analysis, indicating any reflux within the treated vein, regardless if clinically relevant or not, is shown according to the method of Kaplan and Meier. Numbers in the lower line indicate legs at risk at a given follow-up time. Standard errors were <0.1 at all times.

Table I. Limbs with axial reflux[7] from the saphenofemoral junction of the calf region developing after successful ablation of the great saphenous vein (*GSV*) by study treatment

Limb	First observation	Pattern of axial reflux during follow-up
1	6 months	Full recanalization of RSTA-treated GSV with reflux to midthigh, reflux to calf region via anterolateral thigh tributary down to calf level
2	24 months	GSV recanalization with reflux along the proximal 6 cm, then reflux via tributary down to knee level, there re-entering the GSV with continued reflux
3	24 months	Axial reflux carried via incompetent accessory anterior vein entering the GSV slightly proximal knee level, GSV incompetent distal from there. Originally RSTA-treated part of the GSV remained closed without flow
4	36 months	Full recanalization of GSV with reflux down to calf level
5	36 months	Axial reflux through 2.7 cm stump of GSV via neovascularization to accessory anterior saphenous vein and down to calf area

Table II. Pretreatment CEAP class distribution of 280 limbs before study treatment

CEAP Class	No. (%)
C_0	0 (0.0)
C_1	3 (1.1)
C_2	143 (51.1)
C_3	91 (32.5)
C_4	41 (14.6)
C_5	1 (0.4)
C_6	1 (0.4)

not designed to monitor treatment results. In this study, however, the clinical part of CEAP was used for the restaging of patients in yearly intervals and showed quite interesting results.

The pretreatment maximum CEAP clinical class distribution is summarized in Table II, showing 85.5% of legs had a pretreatment CEAP class of ≤C_3, with C_2 alone in 52.3%. In general, all 256 legs that were available at the 36-month follow-up were in CEAP classes C_1 to C_4 before study treatment, except one leg in stage C_6. However, because clinical stage C_6 is not fully reversible, contingency analysis, as displayed in Fig 3, *A,* was limited to clinical stages C_0 to C_4. Of these 255 legs assessed at 36 months, 189 (74.1%) showed an improvement in CEAP class if compared with the clinical assessment before the study treatment ($P < .001$). No change of CEAP class was observed in 64 legs (25.1%), whereas CEAP class worsened in only 2 legs (<1%).

Remarkably, the proportion of legs in clinical stages of C_2, C_3, or C_4 dropped from 99% to <20% during the first

year of follow-up and increased slightly to 30% at 2 years and to 41% at 3 years. However, the more severe clinical stages C_3 and C_4 with 46% of legs before treatment showed an ongoing improvement during follow-up reaching a proportion of finally 7% at 2 years and 8% at 3 years. Fig 3, *B* displays the most relevant CEAP stages C_2 to C_4 more clearly. It seems noticeable that the proportion of legs in clinical stage C_2, after a drop from 52.3% before treatment to <10% immediately thereafter was increasing again slowly toward the 2-year follow-up to a value of >20% and to 33.3% at 3 years. The proportion of legs in clinical stage C_4, however, showed an ongoing constant drop from 14.1% before study treatment to almost 3% at the 2-year follow-up and 4% at the 3-year follow-up.

Clinical response to study treatment: VCSS. At baseline, the average VCSS of 256 legs monitored for 36 months was 3.9 ± 2.1. The minimum VCSS observed at study entry was 1, representing the sole presence of varicose veins or venous edema with ankle swelling in the evening.
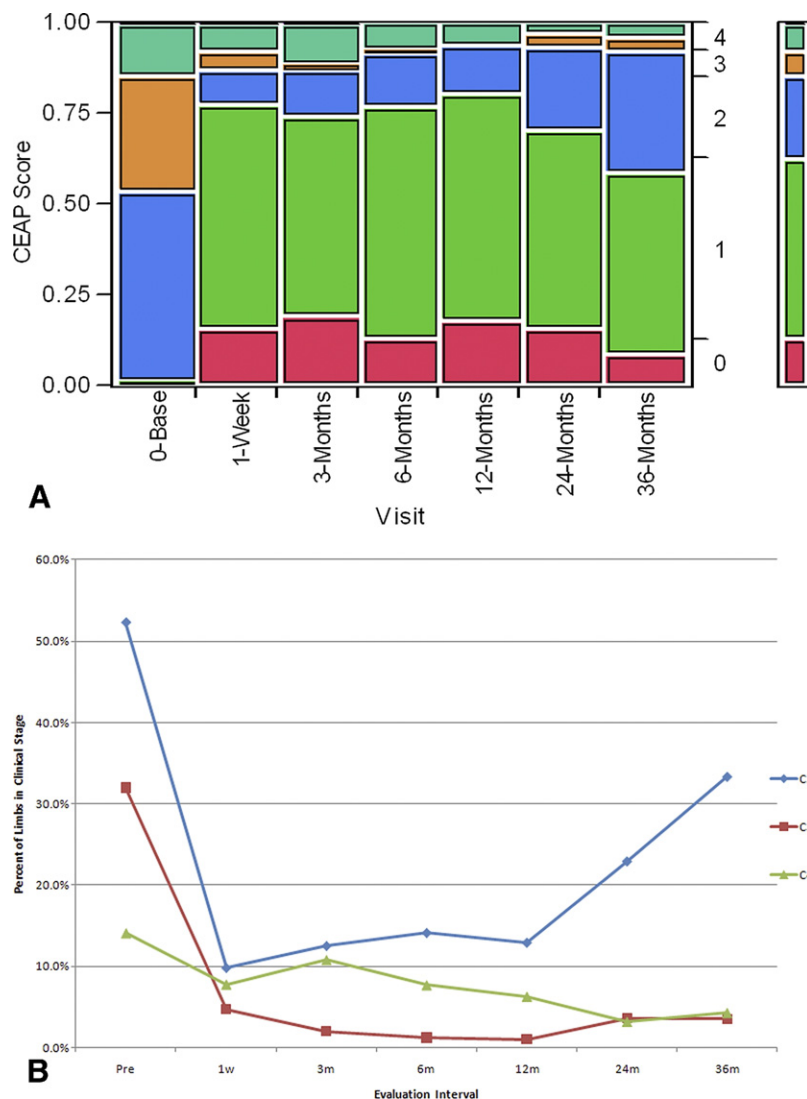
Fig 3. A, Mosaic plot of CEAP stages C_0 to C_4 during follow-up from baseline until 36 months after study treatment. **B,** Time course of the distribution of CEAP stages C_2, C_3, and C_4 after study treatment.

The maximum baseline VCSS was 11 in three patients, one of whom was a man classified C_6 according to CEAP. This patient presented with an medial ankle ulceration of <2-cm diameter until the 3-month follow-up but showed no more ulceration from 6 months of follow-up on.

The time course of VCSS along follow-up is displayed in Fig 4. Interestingly, the drop of VCSS after study treatment, but even more between 1 week and 3 months, was maintained throughout the entire follow-up period. The average VCSS score improved to 3.5 ± 1.1 at 1 week and to 0.9 ± 1.5 at the 3-month follow-up. Average VCSS stayed <0.7 up to 24 months but increased slightly to 0.9 at 36 months. However, the average reduction in VCSS scores from screening and at 1 week to 3, 6, 12, 24, and 36 months were statistically significant at the .05 level, as revealed by Tukey-Kramer analysis.

Interestingly, before treatment, only 41.1% of patients were free of pain in the treated leg, at 36 months, 251 legs (98.0%) were reported free of pain, and 245 (95.7%) did not experience pain in the treated leg during the 24 months before.

Side effects. Side effects in generally were mild and occurred with a low frequency, as listed in Table III. Remarkably at 36 months, only 1 of 256 legs showed hyperpigmentation over the course of the treated GSV, and only 1 patient complained of persisting paresthesia in an area attributable to the saphenous nerve. No more side effects were detected at 3 months of follow-up or afterward and generally occurred with a low frequency.

DISCUSSION

Segmental thermal ablation has already been proven to be a highly efficient and fast procedure for GSV ablation.[1] Now, 3-year follow-up showed that the high ablation rates
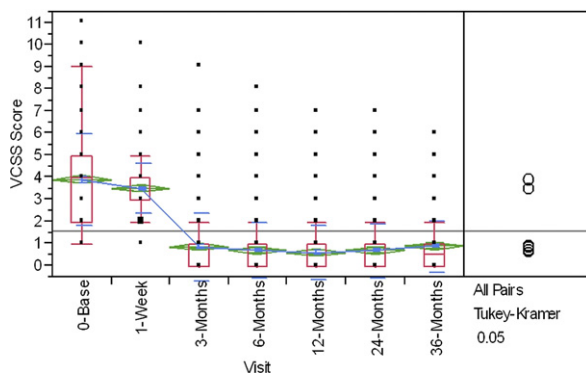
Fig 4. Time course of the Venous Clinical Severity Score (*VCSS*) during follow-up in 256 legs monitored for 36 months. Data are given as average ± standard error (*green*) and standard deviation (*light blue*) as well as median (*horizontal line*) with 25% and 75% quantiles (*red box*).

Table III. Frequency of side effects during follow-up after segmental thermal ablation of initially 280 legs and 256 legs after 36 months

Follow-up interval	1 week	3 months	12 months	24 months	36 months
Ecchymosis, %	5.8	...	...	...	...
Paresthesia, %	3.4	2.0	0.4	0.4	0.4
Pigmentation, %	2.4	1.4	1.0	1.1	0.4
Erythema, %	2.0	...	...	...	...
Hematoma, %	1.4	...	...	...	...
Phlebitis, %	1.0	...	...	...	...
DVT/PE, %	0.0	...	...	...	...

DVT, Deep vein thrombosis; *PE,* pulmonary embolism.

obtained initially could not only be maintained but could also transfer into durable clinical benefits in VCSS and clinical CEAP stage. In only 4.3% of treated GSVs was new reflux detected by DUS imaging, and only 2.0% of treated legs revealed new axial reflux with 86.4% of treated legs examined at the 3-year follow-up.

The occlusion rate seems to be much better than the one described for the preceding method with Closure PLUS (VNUS Technologies).[8] However, RSTA seemed to preserve the favorable side effect profile despite delivering linear energy densities[9] of >120 J/cm during the first treatment cycle and >70 J/cm thereafter. These energy doses compare with current recommendations for endovenous laser treatment of the GSV but elicited fewer side effects in a prospective randomized multicenter trial against 980-nm laser treatment using bare fibers.[4] In particular, pain, tenderness, and ecchymosis were less frequent in the segmental thermal ablation group during the first 2 weeks after the procedure. These findings were corroborated by a recent observational study comparing segmental thermal ablation with 980-nm laser ablation.[10] A paresthesia frequency of 0.4% in our study compares favorably with 1470-nm endovenous laser ablation showing a paresthesia rate of 7.6% at 12 months after treatment.[11]

Heat-induced shrinkage of the GSV diameter, a surrogate marker for the delivery of a sufficient dose of thermal energy during endovenous ablation, 3 cm below the SFJ showed a value of 78% at 1 week after segmental thermal ablation. A representative report on typical endovenous laser ablation described shrinkage of 66% after 6 weeks.[12] Apart from shrinkage, we focused on the nonoccluded stump length of the GSV after segmental thermal ablation serving as a natural sinus to collect venous blood from the area and also preventing thrombus extension during the initial phase after endothermal GSV ablation. In our study, the nonoccluded stump length was at an average that was constant during the complete follow-up time of 36 months, varying only slightly from 10 to 12 mm, suggesting that an increasing stump length during follow-up is not a normal phenomenon, but instead may indicate proximal recanalization.

Even if the focus of today is on reduction of treatment-related side effects and reduction of periprocedural impairment of patients' quality of life, one still has to remember that the primary treatment goal is ablation of pathologic refluxes in incompetent saphenous veins. Side effect reduction by delivery of lower energy doses seems easy; however, concomitant reduction of ablation rates may be a logic consequence, as in a recent report on 1500-nm laser ablation with a delivered endovenous energy of only 53.4 J/cm and an occlusion rate that dropped to 93.3% by 6 months of follow-up.[13] Segmental thermal ablation actually provides high ablation rates (Fig 2) in conjunction with a very moderate side effect profile. Such high ablation rates can even be achieved by RSTA with vein diameters >12 mm.[3] In our study, only 5 of 256 legs (2.0%) presented with recurrent axial reflux.

Outcome measurement in treatment of venous disorders cannot only rely on DUS evaluation of ablated saphenous veins, even though it is a necessary condition for the improvement of the patient's clinical condition. At the time when this study was designed, scores on instruments for measurement of quality of life, such as the Medical Outcomes Study Short Form 36 Health Survey[14] and the Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ),[15] appeared not as mandatory as they are today and were not included in the protocol of this study.

Instead, clinical classification according to CEAP[5] and the VCSS[6] were used to re-evaluate patients at any given follow-up interval, even though neither instrument was designed for measurement of treatment-related outcomes in early clinical stages of venous disease. Before treatment, VCSS averaged about 5 (range 2-12), indicating moderate venous disease in our patients. However, statistics were able to show improvement of the VCSS to baseline ≤3 months after study treatment and, furthermore, that our patients maintained this level throughout the 36-month follow-up (Fig 4).

CEAP is a detailed descriptive tool for classification of venous disease but originally was not designed for measurement of treatment success during follow-up. Interestingly, the prevalence of skin changes (C_4) in our study dropped

from about 15% at screening to 4% at 36 months. Edema (C_3) disappeared almost instantly after study treatment and did not recur during 36 months of follow-up in a relevant proportion of patients. Varicose veins (C_2) were not completely eliminated, because treatment of thigh-level tributaries was not allowed by the study protocol. However, after achieving a reduction of C_2 to 10% to 15% during the first year of follow-up, an increase to >30% was noticeable at the 3-year follow-up, suggesting a risk of around 10% per year to develop new C_2-varicosities in a treated leg. This may reflect the natural course of the disease; however, the numbers reported in a case-control study over 5 years were only 17% during the entire study period.[16] In our study, however, it remains unclear if this higher number of new C_2 varicosities could be related to untreated thigh varicosities, as requested by the study protocol, to avoid overlap in treatment-related symptoms to the study procedure.

CONCLUSIONS

The 3-year follow-up after segmental thermal ablation proves endured maintenance of an initially achieved ablation rate of 100%, with only 2.0% of axial reflux during the study follow-up of 36 months. This successful ablation is achieved with a very moderate side effect profile and is further connected to an improvement in CEAP class grading and VCSS. This highly effective treatment should be compared with other modalities for treatment of incompetent GSVs in prospective randomized trials.

AUTHOR CONTRIBUTIONS

Conception and design: TP
Analysis and interpretation: TP
Data collection: TP, JA, OG, CW, TN, CL, OP, CS, DC
Writing the article: TP
Critical revision of the article: TP, JA, OG, CW, TN, CL, OP, CS, DC
Final approval of the article: TP, JA, OG, CW, TN, CL, OP, CS, DC
Statistical analysis: TP
Obtained funding: TP, JA, OG, CW, TN, CL, OP, CS, DC
Overall responsibility: TP

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