

# Endovenous radiofrequency powered segmental thermal ablation (Closure FAST) of great saphenous veins

## Treatment-related side effects and postinterventional quality of life

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### Keywords

Endovenous, saphenous vein, varicose vein, radiofrequency, laser, reflux, venous insufficiency, chronic venous disease, duplex ultrasound

### Summary

**Background:** Radiofrequency powered segmental thermal ablation Closure FAST has become a globally engaged technology for ablation of incompetent great saphenous veins (GSVs). Mid-term results of slowly resolving side effects are still not described. **Methods:** RSTA-treated GSVs (n = 295) were followed for 24 months in a prospective multicenter trial. Clinical control visits included flow and reflux analysis by duplex-ultrasound and assessment of treatment related side effects at all times. **Results:** 280 of 295 treated GSVs (94.9%) were available for 24 months follow-up. According to the method of Kaplan and Meier at 24 months after the intervention 98.6% of treated legs remained free of clinically relevant axial reflux. The average VCSS score improved from  $3.9 \pm 2.1$  at screening to  $0.7 \pm 1.2$  at 24 months follow-up ( $p < 0.0001$ ). While only 41.1% of patients were free of pain before treatment, at 24 months 99.3% reported no pain and 96.4% did not experience pain during the 12 months before.

At 24 months n=3 legs showed pigmentation along the inner thigh and one leg showed study-treatment related paresthesia. **Conclusion:** Radiofrequency powered segmental thermal ablation Closure FAST showed a very moderate side-effect profile in conjunction with a high and durable clinical success rate.

### Schlüsselwörter

Endovenös, Vena saphena, Varikose, Radiofrequenz, Laser, Reflux, venöse Insuffizienz, chronisch-venöse Insuffizienz, Duplex-Ultraschall

### Zusammenfassung

**Hintergrund:** Die radiofrequenzbetriebene segmentale thermische Ablation Closure FAST wurde zwischenzeitlich zu einer weltweit eingesetzten Technik zur Ausschaltung insuffizienter Stammvenen. **Methodik:** In einer europäischen Multicenter-Studie wurden insgesamt 295 insuffiziente Venae saphena magna an 225 Patienten behandelt. In der bislang über 24 Monate durchgeführten Nachkontrolle wurden neben duplexsonographischen und klinischen Untersuchungen auch Patientenbefragungen unter Einsatz von Analogskalen zur Erhebung von subjektiven patientenbezogenen qualitativen Daten eingesetzt, um zusätzlich zu hämodynamischen und klinischen Kriterien auch be-

stimmte Aspekte von therapieassoziierten Nebenwirkungen und Einschränkungen der peri- und postinterventionellen Lebensqualität zu erfassen. Dabei konnten nach zwei Jahren rund 95% der Patienten und behandelten Beine nachuntersucht werden. **Ergebnisse:** Hämodynamisch bemerkenswert zeigten nur 4 von 280 nachuntersuchten Beinen nach 24 Monaten einen axialen Reflux, d. h., 98,6% der Beine waren frei von klinisch relevanten Refluxen. Dabei verbesserte sich der durchschnittliche VCSS (venous clinical severity score) von  $3,9 \pm 2,1$  vor der Studienbehandlung auf  $0,7 \pm 1,2$  nach 24 Monaten ( $p < 0,0001$ ). Während vor der Studienbehandlung nur 41,1% der Patienten keine Schmerzen in dem behandelten Bein beklagten, waren bei der 24 Monatskontrolle 99,3% der Patienten schmerzfrei und 96,4% waren auch in den 12 Monaten zuvor ohne Schmerzen geblieben. Nach 24 Monaten waren an Nebenwirkungen, die mit der Studientherapie assoziiert waren, Pigmentierungen an drei Beinen, eine Parästhesie an einem Bein verblieben. **Schlussfolgerung:** Die radiofrequenzbetriebene segmentale thermische Ablation Closure FAST ist eine effektive Behandlungsmethode zur Stammvenenablation, verbunden mit einem sehr moderaten Nebenwirkungsprofil.

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### Radiofrequenzbetriebene segmentale thermische Ablation Closure FAST bei Stammvenen – Nebenwirkungen und Lebensqualität nach dem Eingriff

Phlebologie 2010; 39: 69–71  
Received: March 15, 2010  
accepted: March 15, 2010

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Radiofrequency powered segmental thermal ablation ClosureFast (RSTA) quickly after its introduction in 2006 has become a globally used technique for thermal ablation of incompetent great saphenous veins (GSVs). Already in the first study, RSTA achieved immediate GSV ablation rates of more than 99% in addition to a very moderate short term side effect profile and a remarkably quick return to normal activity of less than two days (1, 2). Another study corroborated these findings recently describing occlusion rates of 98 to 100% at six months follow-up after RSTA additionally showing that a diameter of more than 12 mm is not related to a decreased ablation rate (3).

Because of the widespread use of segmental thermal ablation ClosureFast, the results of the European study regarding the mid-term results with respect of more durable side effects like paraesthesia may be of interest. A remarkably high data retrieval rate of as much as 95.1% of treated patients available at 2-year follow-up makes the collected information even more valuable.

## Patients and methods

Within a prospective, non-randomized, multi-center cohort study 24-months results were obtained on safety data and clinical outcomes of RSTA of the GSV in patients suffering from chronic venous disease and GSV incompetence. Clinical control visits including duplex-ultrasound examination were scheduled at 3 days, 3, 6, 12 and 24 months after study treatment. Inclusion criteria, technical details of the study procedure, feasibility data as well as early safety and clinical outcome data of parts of this cohort has been described already (1, 2). Study treatments were per-

formed at eight different 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.

The primary endpoints of the study were occlusion of and lack of reflux in the treated vein. Secondary endpoints included the evaluation of side effects, adverse events, clinical outcomes and patient recovery following the treatment. Results apart from side effects were to be reported in a different place

## Results

A total of 225 patients and 285 limbs were treated from April 2006 on at 8 study centers in Germany and France. At 2-year follow-up 214 patients with 280 treated limbs from 7 Centers were available, representing a proportion of 95.1% and 94.9% of the original study treatments, respectively. Patients' age ranged from 17 to 74 years with an average of  $47.1 \pm 12.1$  years.

According to the method of Kaplan and Meier at 24 months after the intervention 94.1% of GSVs were free of flow and 96.5% were free of reflux, and much more important, 98.6% of treated legs remained free of clinically relevant axial reflux at 24 months. The average VCSS score improved from  $3.9 \pm 2.1$  at screening to  $0.7 \pm 1.2$  at 24 months follow-up ( $p < 0.0001$ ). While only 41.1% of patients were free of pain before treatment, at 24 months 99.3% reported no pain and 96.4% did not experience pain during the 12 months before.

For patients, after vein ablation, return to normal daily activities took an average of 1.2 days (range 0–3.2). On the third day after the study procedure, using an analog

scale of 0–10, the patients evaluated the mean pain intensity at  $0.7 \pm 1.6$ . The average maximum postprocedural pain was reported to be  $2.8 \pm 1.6$ . Haematomas could be detected in 1.4% of cases along the course of the saphenous trunk (► Tab. 1). Similarly, ecchymoses were observed in 5.8% of the limbs, the incidence of superficial venous thrombosis was 1%. No thromboembolic complications were reported. Paresthesia was reported in 3.4% of the cases, pigmentations were observed in 3.1%. Ninety-nine percent of the patients said they would recommend this procedure to friends or relatives. The whole set of observed side effects is displayed in table 1. Remarkably at 24 months of follow-up only 3 legs of 280 showed hyperpigmentation along the course of the GSV on the study treated leg. Only one patient complained of persisting paresthesia in an area attributable to the saphenous nerve. Other side effects were not detected any more at 3 months follow-up or thereafter and generally occurred with a low frequency.

## Discussion

Outcome measurement in treatment of venous disorders must not only rely on haemodynamic examination like the duplex ultrasound follow-up of thermally ablated saphenous veins – despite it is a totally necessary condition for the success of any treatment modality and the subsequent improvement of the patient's clinical condition. Unfortunately, a validated quality-of-life score was not incorporated in the present study. However, four randomized controlled trials (4–7) have compared traditional RF ablation (ClosurePlus) versus surgical vein stripping, all of them describing less side effects and superior outcome of quality-of-life issues with RF ablation. Findings included faster recovery, less postoperative pain, fewer adverse events, and superior quality-of-life (QOL) scores.

In addition, a prospective randomized trial proved, that the side effect profile of ClosureFast compared favorably to endovenous laser ablation using a 980 nm diode laser and typical blunt tipped bare fibers during the first two weeks after the inter-

follow-up interval	1 week	3 months	12 months	24 months
ecchymosis (%)	5.8	-	-	-
paraesthesia (%)	3.4	2.0	0.4	0.4
pigmentation (%)	2.4	1.4	1.0	1.1
erythema (%)	2.0	-	-	-
haematoma (%)	1.4	-	-	-
phlebitis (%)	1.0	-	-	-
DVT/PE (%)	0.0	-	-	-

**Tab. 1**  
Frequency of side effects during follow-up after segmental thermal ablation (n = 280 limbs)

vention (8). Furthermore, the validated CIVIQ instrument (9), which was used to assess periprocedural quality of life, demonstrated substantially better quality of life scores at one week and two weeks after GSV ablation in the categories global, pain and physical for ClosureFast (8).

These findings were corroborated by another recent observational study comparing segmental thermal ablation with 980 nm laser ablation. Again patients who received endovenous laser treatment reported significantly more pain at ten days after the procedure and returned to work four days later than those who received segmental thermal ablation ClosureFast (10).

However, even if the combination of 980 nm diode laser and usage of bare fibers may be the most frequently used combination around the globe for laser vein ablation, in the meantime, different, predominantly water-absorbed laser wavelengths and different fiber tips have been introduced. E. g. reduced side effect profiles associated with less postinterventional pain – one of the most important quality of life categories – and reduced need for analgesics have been described in a comparative study using a 1320 nm and a 940 nm laser system with simple bare fibers (11). However, not every new laser wavelengths necessarily translates into clinical benefits. Looking at one of the more relevant side effects, paresthesia was observed with an unexpectedly high frequency of 7.6% at 12 months after treatment when using bare fibers with a 1470 nm Laser system (12). Additionally, new types of laser fiber tips, like the metal tube covered NeverTouch™, are entering the market. These new fiber tips may have the potential to increase post-interventional quality of life even when used with inexpensive, traditional 810 or 980 nm diode laser systems. Their spacer-like action obviously reduces the power density delivered to the inner vein wall, most likely resulting in less vein wall perforations and damage of the perivenous tissue.

### Durability of GSV occlusion

Even if everybody's focus today is on increase in postinterventional quality of life

and in reduction of treatment-related side effects, one still has to take into account that the primary treatment goal is ablation of pathological refluxes in incompetent saphenous veins. Under this point of view, methods presenting with three months ablation rates of great saphenous veins of not more than only around 90%, like RFITT (13), have to improve their primary ablation rates substantially before being considered a serious alternative to established endothermal ablation modalities. In endovenous laser ablation, a way to achieve an improvement of treatment related side effects seems to be the reduction of delivered energy doses. However, in sight of a proven correlation between the vein ablation rate and the delivered endovenous energy dose (14), reduced energy doses most likely will result in suboptimal mid- and longterm ablation results. Remarkably, despite its favourable side effect profile and very limited impairment of postinterventional quality of life, segmental thermal ablation ClosureFast proved to deliver linear energy densities (1) of more than 120 Joule/cm during a double treatment cycle and more than 70 Joule/cm during a single cycle. These energy doses compare well with current recommendations for endovenous laser treatment of the GSV.

Nevertheless, prospective randomized clinical trials, testing segmental thermal ablation ClosureFast against the new alternative thermal ablation techniques, are necessary now, to compare clinical efficacy, side effect profile and treatment related quality of life simultaneously under the same conditions

### Conclusion

Next to a high clinical success rate, segmental thermal ablation ClosureFast offers a remarkably

- moderate side effect profile and
- a postinterventional quality of life superior to traditional endovenous laser ablation.

However, prospective randomized trials are needed no to get more valid comparative data.

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