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Three-year follow-up and quality of life of endovenous radiofrequency ablation of the great saphenous vein with the ClosureFast™ procedure: Influence of BMI and CEAP class

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Abstract

Purpose: Endovascular ablation of the great saphenous vein has been proposed as a less invasive alternative to conventional ligation and stripping of varicose veins. Outcomes of patients treated with the radiofrequency ablation ClosureFast™ system over an eight-year period from a single-center were evaluated.

Methods: Three-year follow-up data included duplex ultrasound scan, complication rate, and questionnaires to assess patients' QOL, level of pain, and days off work.

Results: A total of 1080 consecutive patients (49.5 ± 18.6 years, 72% female, mean body mass index: 25.44 ± 4.1 kg m^{-2}) underwent radiofrequency ablation for incompetent saphenous veins in a single institution. Occlusion of the great saphenous vein was obtained in 98.6% and 93.8% cases at the end of the procedures and within 36 months, respectively. Only three deep venous thromboses and minor complications occurred in this series throughout the first week from the procedure. A decrease of the external vein diameter, equal to 72.7% and 31.1% of the pretreatment diameter, was observed at 1 week and 36 months, respectively. The average Aberdeen Varicose Vein Questionnaire score improved from 18.06 ± 9.47 before treatment to 11.56 ± 10.23 at 12 months, with no significant differences in the subsequent follow-up. SF-36 QOL scores significantly improved after the procedure in all domains, while there were no changes over time. Patients reported a prompt return to normal daily activities (1.5 ± 0.7 days) and work (3.1 ± 1.9 days). Body mass index influenced QOL scores, while it did not affect great saphenous vein diameter reduction during the follow-up. On the contrary, Clinical Etiologic Anatomic Pathophysiologic class significantly influenced both great saphenous vein diameter reduction after the treatment and QOL scores within 36 months.

Conclusion: Results of this retrospective monocentric, large patients study suggest that radiofrequency ablation of the great saphenous vein may be a safe and efficient alternative to conventional surgery.

Keywords

Chronic venous insufficiency, varicose veins, endovenous technique, radiofrequency ablation, QOL

Introduction

Venous insufficiency is a high-frequency condition that affects approximately 25% of the Western population and often impairs the QOL.[1] In addition to causing symptoms such as swelling and leg pain, superficial venous insufficiency could lead to severe limitations in normal daily activities and a poor quality of life. Moreover, it can progress to cause complications of venous hypertension including skin ulceration, even

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in the absence of deep venous insufficiency. Most of the patients who seek surgery for cosmetic purposes or pain not controlled by compression hose are relatively young and desire rapid return to normal daily activities and work.

Until recently, the gold standard treatment of such condition has been high ligation of the saphenofemoral junction (SFJ) and stripping of the great saphenous vein (GSV) and/or of the small saphenous vein (SSV) from the groin to the ankle, with removal of branch varicosities.[2,3]

In recent years, for several reasons including patients' preference and health costs, there is certainly a shift towards shorter hospitalization stay and outpatient treatments. Minimally invasive treatments, such as radiofrequency ablation (RFA), or endovenous laser ablation (EVLA) of the saphenous vein (thermoablation), have replaced surgical stripping for the treatment of venous diseases in many areas of the world because of their lower rate of complications, decreased invasiveness,[4,5] reduced pain, and quicker recovery and return to work.[6,7] The efficacy and safety of endovascular techniques of saphenous vein ablation, compared to high ligation and open surgical stripping, have been well demonstrated in a number of studies.[8,9]

Endovenous RFA was approved for use by the National Institute for Health and Clinical Excellence (NICE) in the UK in 2001, and the guidance was published in September 2003.[10]

The ClosureFast™ technique (Covidien/Medtronic, Minneapolis, MI, USA) had been introduced in 2007, and it consists of a catheter with a 7-cm heat-generating tip which delivers radiofrequency (RF) energy to the saphenous vein wall under ultrasound guidance resulting in segmental venous spasm and collagen shrinkage with minimal thrombus formation.[11] Non-randomized case-series of ClosureFast™ procedures showed a high success rate in vein ablation in conjunction with endured maintenance of the initially achieved ablation and low recurrence rate.[5,12]

This retrospective report presents eight-year experience with RFA after ClosureFast™ treatment, with three-year follow-up data, and evaluation of periprocedural and post-intervention patient satisfaction, level of pain, and QOL.

Methods

Study design and patient selection

Between 2009 and 2016, 1080 consecutive patients with incompetence of the SFJ and/or GSV documented by preoperative DUS were treated by RFA at the Department of Surgery of Istituto Auxologico Italiano with ClosureFast™ RFA. RFA of varicose veins was performed if the following inclusion criteria were fulfilled: proper vein size (from 4 to 14 mm), no history of deep vein thrombosis, no uncorrectable coagulopathy, and no pregnancy. Exclusion criteria were duplication of the saphenous trunk or an incompetent accessory GSV (AAGSV), deep venous incompetence, arterial insufficiency, or a tortuous GSV rendering the vein unsuitable for endovenous treatment. Patients' symptoms and signs were recorded using the Clinical Etiologic Anatomic Pathophysiologic (CEAP) classification $C_{2-4}E_pA_sP0_r$.[13] All treatments and assessments were performed by the same vascular team with experience in the management of venous disease.

Device description

The VNUS ClosureFast™ Endovenous Radiofrequency Ablation system is the latest version of a minimally invasive system for endovascular coagulation of blood vessels in patients with superficial venous reflux.

It consists of two elements: the ClosureFast™ RFA catheter and the VNUS ClosureRFG3™ generator. The catheter and the associated procedure are termed Venefit™. The patent for ClosureFast was filed in 2005 and granted in 2009 (US patent 7517349 B2).[14]

The generator is a high-frequency (460 kHz) bipolar microprocessor. It adjusts the delivered output power by measuring the thermal impedance of the vein and maintains the 120°C temperature for 15 s. The first 5 s are necessary to reach the temperature of 120°C. The control unit displays power, temperature, and elapsed time throughout the procedure.

The generator delivers RF energy to the catheter, which consists of a coil of wire with a positive temperature coefficient of resistance surface and an electrode with a pressure sensitive variable resistance. This smart surface provides a real-time temperature feedback system that controls RF current flow at the interface between the catheter and the tissue and ensures that the wire heats tissue to a constant temperature of 120°C.[11,14] This temperature has been shown to be sufficient to cause agitation of the collagen molecules in the vein wall, heating, and then denaturation of the protein.[15] As the tissue heats up, it warms the tip of the catheter, which in turn reduces the RF flow and avoids overheating of the tissue.[16] In this way, the catheter eliminate the need for continuous pull-back of the energy source as in the case of laser ablation allowing for more controlled and repeatable RFA and consistent, reproducible delivery of energy.

Procedure

Venous DUS were obtained in all patients preoperatively to assess for reflux in the deep and superficial

veins and to determine the course and tortuosity of the GSV.

The ClosureFast™ system was used according to described methods.[12,17] Briefly, the leg was prepped and draped, and the ClosureFast™ catheter was inserted into the GSV percutaneously through a 7F vascular sheath, using Seldinger technique. Intraoperative ultrasound vein (Esaote MyLab™25) evaluation permitted selection of the correct site for puncture. Tumescence fluid (consisting in 1 L of normal saline, 50 mL lidocaine 1%, and 10 mL sodium bicarbonate 8.4%) was injected using an infusion pump (Dispenser DP 20, Nouvag AG, Goldach, CH) with the catheter in situ into the saphenous sheath containing the GSV under ultrasound guidance. The visible varicosities are treated by phlebectomy in the same session. The catheter was heated to 120°C for repeated 20 s cycles.

Post-procedural follow-up

Duplex ultrasound. Postoperative DUS of the operated limb were obtained upon completion of the procedure and at 1 week, 1, 6, 12, 24, and 36 months. All examinations were conducted by a member of the surgical team, and comments by the patients were recorded and audited. DUS was performed to assess occlusion of the GSV defined as the absence of any blood flow along the entire length of the treated vein beginning from 3 cm distal to the SFJ and continued from there, and non-compressibility. External (adventitia-to-adventitia) vein diameter was also measured in supine position 3 cm below the SFJ. Furthermore, flow and compressibility of the femoral and popliteal vein as well as calf veins were tested in order to detect deep venous thrombosis.

Quality-of-life questionnaire. Patients were asked to fill in the Medical Outcomes Study Short Form 36 Health Survey (IQOLA SF-36 Italian Version 1.6)[18] and the Aberdeen Varicose Vein Questionnaire (AVVQ)[19] in order to assess their general and disease-specific QOL score, respectively, at the 1-week and 12-, 24-, and 36-month follow-ups. The SF-36 is a generic QOL instrument, containing 36 items. It consists of eight multi-item domains: physical functioning (PF), role–physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role–emotional (RE), and mental health (MH). Each domain is scored from 0 (worst) to 100 (best). The AVVQ is a validated and reliable instrument for measurement of disease-specific QOL in patient with varicose veins. It produces scores from 0 (no venous symptoms) to 100 (worst venous symptoms).

Additionally, patients had been specifically asked to indicate in the questionnaire the days off work and the level of pain experienced during and after the procedure using a Numeric Rating Scale (NRS, 0–10).

Data presentation. Patient data were captured using a paper case report form. Categorical variables were reported as number and percentages. For numeric variables, minimum, maximum, mean, and standard deviation (sd) were calculated and are presented as mean $\pm$ sd.

Statistics. Descriptive summary statistics were used for safety analysis. DUS results with respect to demographic characteristics of patients and risk factors were analyzed using Friedman's test. External GSV diameters, SF-36, and AVVQ scores were tested using analysis of variance (ANOVA) with repeated measures. Statistical analysis was performed using STATA (STATA Corp., version 14.0, College Station, TX, USA). Values of $p < 0.05$ were considered statistically significant.

Ethics. All subjects gave approved written consent before participating. The study was approved by the local Ethic committee of this Institution (statement CE 30.05.2006).

Results

From 2009 to 2016, a total of 1080 GSV were treated using the ClosureFast™ technique. Among the enrolled patients, 778 patients (72%) were females. A total of 223 patients were smokers or ex-smokers, 40 had diabetes mellitus, and 193 had hypertension. All treated cases were unilateral. The mean GSV diameter was 6.1 ± 1.8 mm. All patients presented with gross varicosities in the saphenous territory (CEAP II–VI). Details of the enrolled patients are summarized in Table 1.

The successful passage of the catheter into the saphenous vein was achieved in 98.8% cases. The mean treatment length of the GSV from the SFJ to the site of vein access at the distal point of reflux was 44.2 ± 12.2 cm.

A total of 1064 patients (98.5%) attended their one-week follow-up appointments. At the 1-, 6-, 12-, 24-, and 36-month follow-ups, 95.0%, 92.0%, 78%, 75%, and 72% of patients were available. Patients were not able to attend follow-up mainly because they moved to remote locations or because they declined further visits for personal reasons. DUS showed complete occlusion in all but 12 GSV (1.1%) at the end of the procedure. One week post-procedure, 49 patients (4.6%) showed open GSV defined as flow in the treated GSV 3 cm below the SFJ. Follow-up DUS showed vein occlusion rates of 98.6%, 96.3%, 95.7%, 94.4%, and 93.8% at 1, 6, 12, 24, and 36 months, respectively. External vein

Table 1. Preoperative clinical characteristics of patients with varicose veins treated by radiofrequency ablation.

Age (years) mean ± standard deviation (range)	49.5 ± 18.6 (18–79)
Sex	
Female	778 (72.0)
Male	302 (28.0)
GSV diameter (mm) mean ± standard deviation (range)	6.1 ± 1.8 (4.0–14.0)
Body mass index (kg m^{-2}) mean ± standard deviation (range)	25.44 ± 4.1 (21.7–30.7)
Smoking history	
Current smoker	67 (6.2)
Ex-smoker	156 (14.4)
Diabetes mellitus	40 (3.7)
Hypertension	193 (17.9)
Ischemic heart disease	26 (2.4)
CEAP clinical class	
II	734 (68.0)
III	248 (23.0)
IV	65 (6.0)
V	33 (3.0)
VI	0 (0.0)

Note: Values are expressed as *n* (%).
CEAP: Clinical Etiologic Anatomic Pathophysiologic.

Table 2. Reported side effects one week after treatment of varicose veins with ClosureFast™ (1064 patients).

	One-week follow-up, *n* (%)
Major complications	
Deep vein thrombosis	3 (0.3)
Pulmonary embolism	0 (0.0)
Minor complications	
Paresthesia	17 (1.6)
Thrombophlebitis	7 (0.8)
Pigmentation	36 (3.3)
Ecchymosis	46 (4.3)
Edema	15 (1.4)
Skin burn	0 (0.0)

Note: Values are expressed as *n* (%).

diameters were measured in supine position at 3 cm distal to the SFJ. Mean vein diameter decreased from 6.1 ± 1.8 mm before the treatment to 4.4 ± 1.6 mm one week after the procedure, with a further reduction to 1.9 ± 1.4 mm at 36 months, equal to 72.1%, and 31.1% of the pretreatment diameter, respectively (Figure 1). Age, sex, and risks factors did not influence DUS results, as for Friedman's test.

Complications were regarded as minor if they required no therapy and major if they required treatment, admission to hospital, or led to permanent adverse sequelae. Deep venous thrombosis was observed in three patients throughout the one-week follow-up period. Only minor complications occurred in the other patients in this series. Ecchymosis along the course of the GSV not associated with any pain or discomfort was observed in 46 patients. Seventeen of the earliest patients had paresthesia and 36 had skin pigmentation. Seven patients had transient superficial thrombophlebitis around the knee in a treated segment of a superficial collateral of the GSV (Table 2).

A total of 1064 (98.5%), 842 (78%), 810 (75%), and 778 patients (72%) filled in the questionnaires at 1 week, 12, 24, and 36 months from the procedure, respectively. In the SF-36 scores, for all domains, there was a significant improvement from pretreatment to one week. Major improvements were seen in the domains of bodily pain, general health, mental health, vitality, and physical functioning. For domains of general health and role–emotional, there were no significant differences from 1 week to 12 months and over time. For all other domains, significant improvements were observed also from 1 week to 12 months, while there were no changes over time (Figure 2 and Table 3).

In the AVVQ, a slight score deterioration was observed at one week with respect to the pretreatment level. However, the mean score improved significantly at 12 months, with no significant differences in the subsequent follow-up (Figure 3).

Patients who complained of pain that lasted longer than three days were administered with oral analgesia (Ketorolac 30 mg), which was followed by paracetamol (1 g/tablet), four times a day on demand. The mean NRS score was 3.2 ± 0.5 during the procedure and 1.9 ± 0.6 after one week (range 0–10) ($p < 0.05$). Patients reported a return to normal daily activities within 1.5 ± 0.7 days (range 0–8). Patients went back to work after a mean time of 3.1 ± 1.9 days (range 1–8).

The influence of BMI and CEAP class on follow-up and QOL was evaluated. Subjects were classified into two groups according to their BMI, as underweight and normal weight if BMI < 25.0 ($n = 488$, 45.2%), or overweight and obese if BMI > 25.0 ($n = 592$, 54.8%), and in other two groups according to their CEAP clinical class, as CEAP class II ($n = 734$, 68.0%), and CEAP classes III, IV, and V ($n = 346$, 32.0%). Figure 4 shows the external GSV diameter before the treatment and the time course during the follow-up as a function of BMI and CEAP class. No statistically significant differences were observed in mean vein diameter between the two BMI groups in any time point within 36 months (Figure 4(a)). Subjects with CEAP classes III, IV, or V had a lower diameter reduction with respect to those belonging to the class II (61.6% vs. 83.7% at 36 months, $p < 0.05$) (Figure 4(b)).

Table 3. SF-36 health related quality-of-life outcomes after treatment of varicose veins with ClosureFast™.

	Pretreatment	1 Week	12 Months	24 Months	36 Months
Physical functioning, PF	82.0 (17.7)[a]	86.1 (12.1)[a,b]	88.8 (18.5)[b]	90.3 (16.6)	89.8 (16.1)
Role–physical, RP	81.1 (21.9)[a]	84.8 (12.7)[a,b]	90.5 (19.1)[b]	92.0 (17.7)	89.7 (20.2)
Bodily pain, BP	70.0 (21.7)[a]	79.7 (18.2)[a,b]	86.6 (19.7)[b]	86.2 (20.0)	85.0 (21.5)
General health, GH	63.7 (13.5)[a]	65.3 (11.9)[a]	63.9 (13.8)	64.5 (13.8)	63.6 (15.3)
Vitality, VT	66.0 (19.0)[a]	70.5 (15.8)[a,b]	77.5 (17.6)[b]	75.7 (16.3)	75.2 (19.0)
Social functioning, SF	90.3 (15.1)[a]	92.3 (11.2)[a,b]	95.8 (13.7)[b]	95.9 (13.0)	94.8 (13.5)
Role–emotional, RE	92.1 (18.2)[a]	93.7 (10.6)[a]	94.3 (15.1)	95.8 (14.6)	97.3 (18.0)
Mental health, MH	78.1 (14.9)[a]	83.5 (11.2)[a,b]	86.8 (13.7)[b]	86.0 (13.1)	84.9 (14.8)

Note: Questionnaire scale (0 = worst, 100 = best). Number of evaluable questionnaires decreased from 1064 at 1 week to 778 at 1 year. Values are expressed as mean (sd). The apex symbols mark the significant contrasts after ANOVA analysis.
[a]Pretreatment vs. one-week post-procedure.
[b]One-week post-procedure vs. one-year post-procedure.

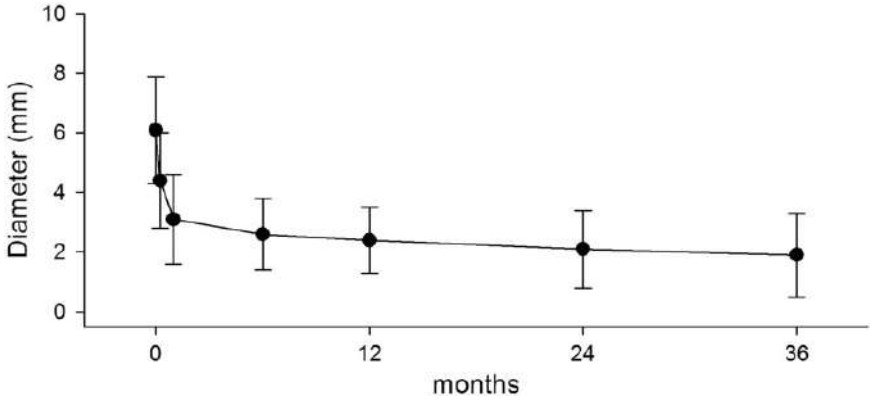

Figure 1. External (adventitia-to-adventitia) diameters of the GSV before treatment and during follow-up as measured 3 cm below the SFJ, assessed by DUS examination. Number of evaluable GSV decreased from 1064 at 1 week to 778 at 36 months. Data are presented as mean ± sd.

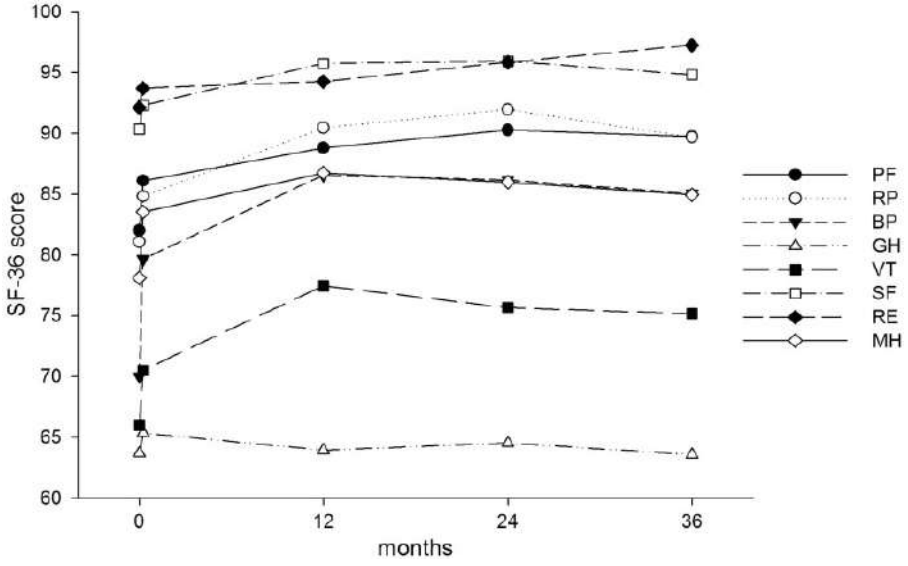

Figure 2. Medical Outcome Study Short Form-36 domains scores up to 36 months after treatment of varicose veins with ClosureFast™. Number of evaluable questionnaires decreased from 1064 at 1 week to 778 at 36 months.

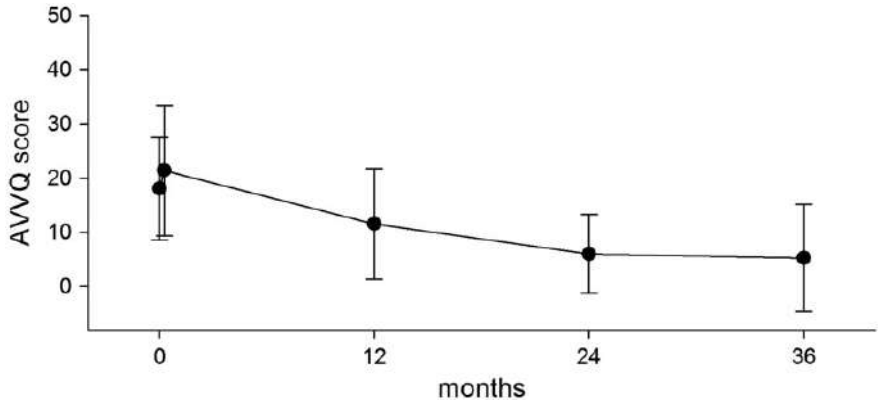

Figure 3. Disease-specific QOL score (AVVQ) up to 36 months after the treatment of varicose veins with ClosureFast™. Number of evaluable questionnaires decreased from 1064 at 1 week to 778 at 36 months. Data are presented as mean ± sd.

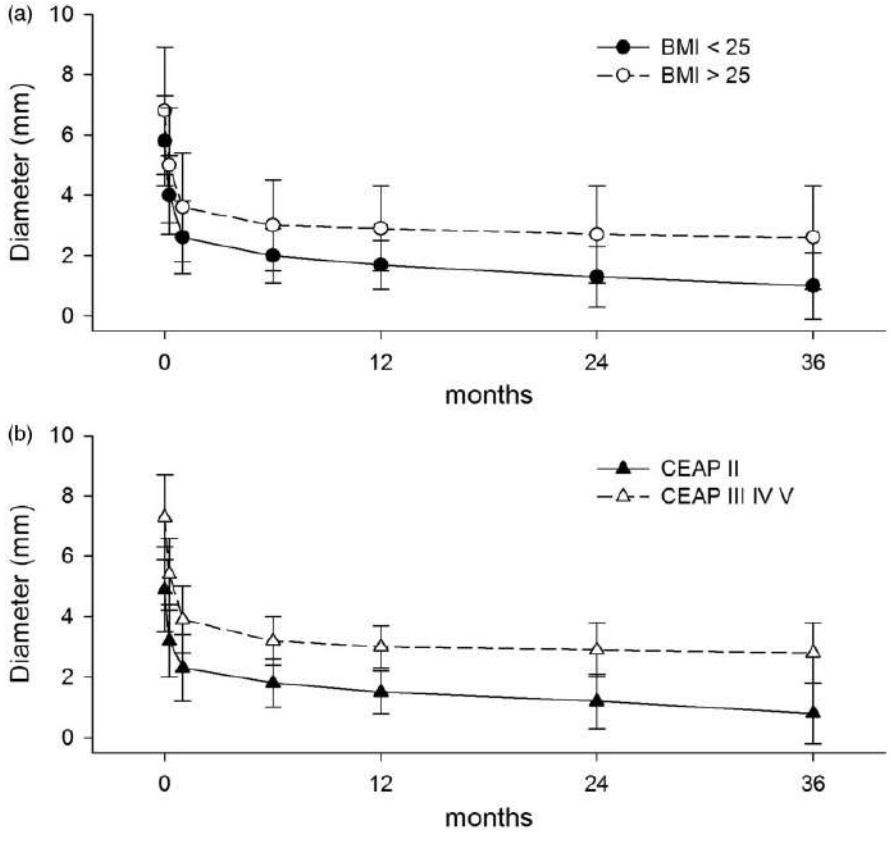

Figure 4. External (adventitia-to-adventitia) diameters of the GSV before treatment and during follow-up as measured 3 cm below the SFJ, assessed by DUS examination, in (a) underweight and normal weight subjects (BMI < 25.0, $n = 488$, 45.2%), and in overweight and obese subjects (BMI > 25.0, $n = 592$, 54.8%), and in (b) subjects belonging to CEAP clinical class II ($n = 734$, 68.0%), and to CEAP clinical classes III, IV, and V ($n = 346$, 32.0%). Number of evaluable GSV decreased from 1064 at 1 week to 778 at 36 months. Data are presented as mean ± sd. Differences in GSV diameters between groups were analyzed using analysis of variance with repeated measures.

Furthermore, there was a significant improvement in the Physical Component Summary (PCS) domain of SF-36, which had been worked out by the mean average of all of the physically relevant questions (PF, RP, BP, and GH), and in the Mental Component Summary (MCS) domain of SF-36, which had been worked out by the mean average of all of the emotional relevant questions (VT, SF, RE, and MH) from pretreatment to

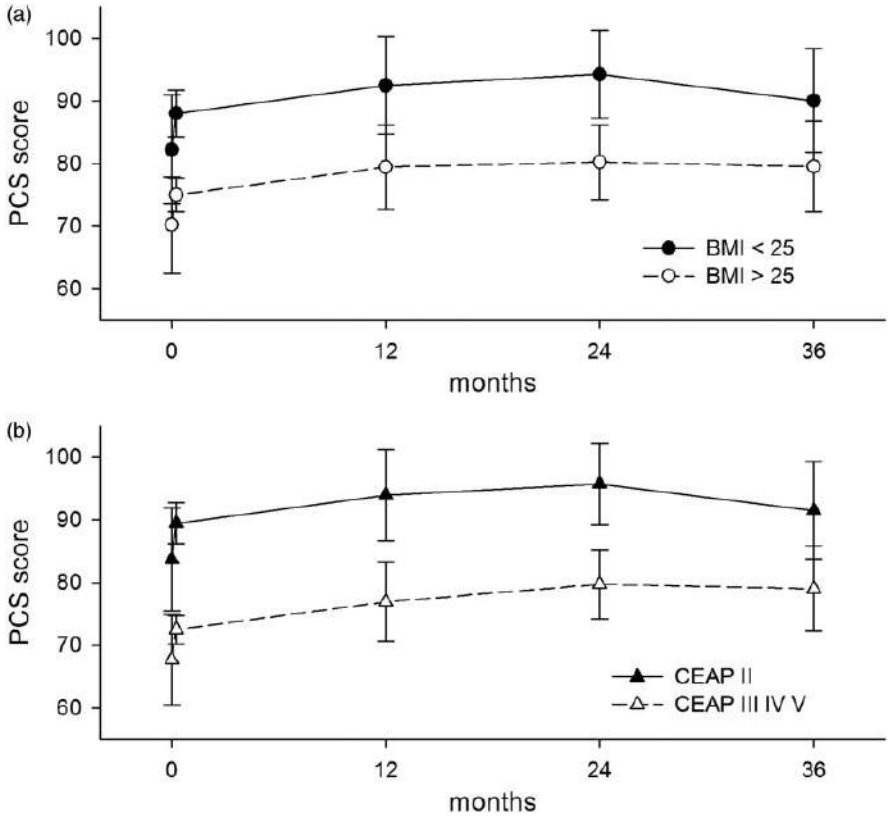

Figure 5. Physical Component Summary (PCS) domain scores, which comprises physical functioning, role–physical, bodily pain, and general health domains, of the Medical Outcome Study Short Form-36 up to 36 months after treatment of varicose veins with ClosureFast™, in (a) underweight and normal weight subjects (BMI < 25.0, $n = 488$, 45.2%), and in overweight and obese subjects (BMI > 25.0, $n = 592$, 54.8%), and in (b) subjects belonging to CEAP clinical class II ($n = 734$, 68.0%), and to CEAP clinical classes III, IV, and V ($n = 346$, 32.0%). Number of evaluable questionnaires decreased from 1064 at 1 week to 778 at 36 months. Data are presented as mean $\pm$ sd. Differences in PCS domain scores between groups were analyzed using analysis of variance with repeated measures.

24 months in both BMI groups, with a statistically significant difference between the two groups ($p < 0.05$) (Figures 5(a) and 6(a)). Underweight and normal weight subjects (BMI < 25.0) had major improvements in AVVQ scores with respect to overweight and obese subjects (Figure 7(a)). Significant differences were also observed in PCS and MCS domains of SF-36 and AVVQ scores between subjects belonging to CEAP class II and those belonging to CEAP classes III, IV, and V (Figures 5(b), 6(b), and 7(b), $p < 0.05$).

Discussion

Among the available endovascular techniques, RFA was designed to ablate the GSV through a catheter-directed heat application to minimize discomfort and complications associated with conventional stripping.[20] Several advantages emerged after RFA, including decreased pain, shorter hospital stay, and faster return to work.[21] ClosureFast™ has exhibited significant improvement in the easiness of use and the procedure speed over the previous generation catheters while maintaining the favorable patient recovery profile seen with the RFA technology.[7]

In the present retrospective study, the results of 1080 ClosureFast™ procedures performed in the same institution by the same vascular team were evaluated, focusing on results from follow-up DUS and patients' satisfaction. In the current series, there was complete occlusion of the GSV in the treated segments in all but 98.9% procedures at the end of the treatment, and in 95.7%, 94.4%, and 93.8% at 12, 24, and 36 months, respectively. Deep venous thrombosis was observed in three patients throughout the follow-up period. Two patients were found to have an extension of an asymptomatic, non-occlusive thrombus into the common femoral vein on a routine scan one week after the procedure. One patient developed atrial fibrillation and was treated with oral anticoagulant therapy with Apixaban (2.5 mg twice a day). Minor complications

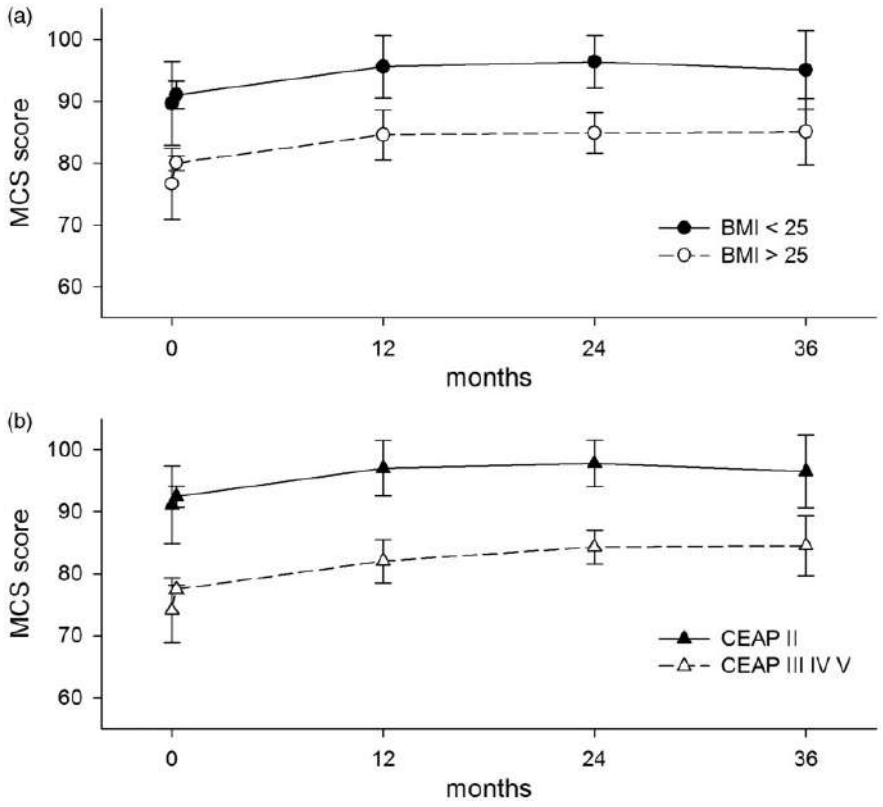

Figure 6. Mental Component Summary (MCS) domain scores, which comprises vitality, social functioning, role–emotional, and mental health domains, of the Medical Outcome Study Short Form-36 up to 36 months after treatment of varicose veins with ClosureFast™, in (a) underweight and normal weight subjects (BMI < 25.0, $n = 488$, 45.2%), and in overweight and obese subjects (BMI > 25.0, $n = 592$, 54.8%), and in (b) subjects belonging to CEAP clinical class II ($n = 734$, 68.0%), and to CEAP clinical classes III, IV, and V ($n = 346$, 32.0%). Number of evaluable questionnaires decreased from 1064 at 1 week to 778 at 36 months. Data are presented as mean $\pm$ sd. Differences in MCS domain scores between groups were analyzed using analysis of variance with repeated measures.

occurred in the other patients in this series, which resolved either spontaneously or with ointment and local nonsteroidal anti-inflammatory cream. These results are comparable very favorably with recently published data, which on the other hand report results from a noticeably smaller population. In a series of 155 patients treated with ClosureFast™ in an outpatient setting, an occlusion rate of 94.1% after a mean follow-up of 12.2 months was reported.[22] Another study provided results from 183 consecutive RFA procedures with a technical success rates equal to 92.0% and 88.8% at six months and one year, respectively, with significant symptomatic improvements.[4]

Varicose veins often influence daily activities and patients' social life. In the present study, QOL was analyzed using two questionnaires. Data clearly showed that pain and any limitations due to leg problems improved after the treatment, and it had a positive effect on important aspects of life. The QOL improved significantly following treatment. As assessed by the SF-36 results, the health status of patients improved one week after RFA with further improvements at 12 months, mostly in bodily pain, and general health. The QOL instrument showed positive effects of ClosureFast™ with regard to the amount of discomfort, daily activities, and social aspects after the procedures. In addition, the disease-specific AVVQ improved from 12 months and onward. This suggests that these patients may perceive fewer problems with their daily activities. Such improvement in generic and disease-specific QOL after treatment of varicose veins is well known[18] and in line with that reported in other existing studies.[8,23] The improvements persisted throughout the 36-month follow-up period and show that RFA is an efficient treatment with long-term beneficial effects in patients with varicose veins.

Moreover, the results of the present study support the findings of other studies that have shown less post-procedural pain after RFA.[23–25] One possible explanation for the reduced pain scores following RFA may be that the controlled heating and segmental ablation technique of ClosureFast™ reduces the number of

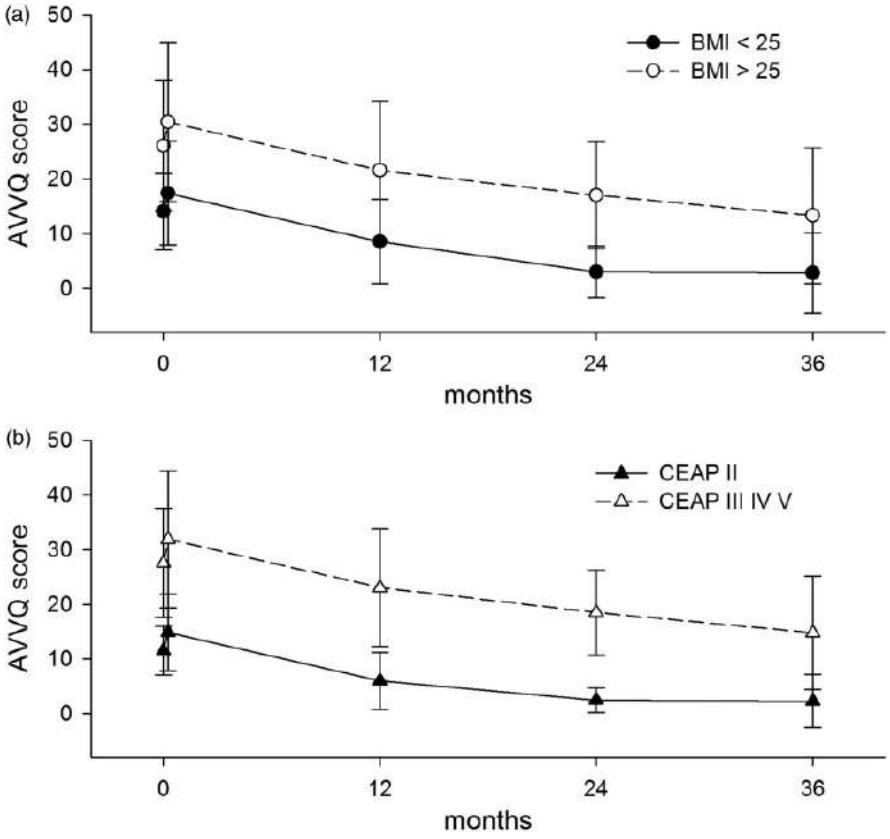

Figure 7. Disease-specific QOL score (AVVQ) up to 36 months after treatment of varicose veins with ClosureFast™, in (a) underweight and normal weight subjects (BMI < 25.0, $n = 488$, 45.2%), and in overweight and obese subjects (BMI > 25.0, $n = 592$, 54.8%), and in (b) subjects belonging to CEAP clinical class II ($n = 734$, 68.0%), and to CEAP clinical classes III, IV, and V ($n = 346$, 32.0%). Number of evaluable questionnaires decreased from 1064 at 1 week to 778 at 36 months. Data are presented as mean ± sd. Differences in AVVQ scores between groups were analyzed using analysis of variance with repeated measures.

vein wall perforations and the extravasation of blood into the tissues[26]; this has been shown to occur after the use of the 980 nm laser in animal models and in humans.[27] The early resume to normal activities (1.5 ± 0.7 days) followed by a much more rapid return to work (3.1 ± 1.9 days) is consistent with previously published data.[23,28] Previous research reported mean values for return to work of 4.7 days (range 1.2–8.2) compared with 12.4 days (range 8.7–16.2) in patients undergoing conventional surgery.[28] In a study comparing RFA with EVLA, similar data were found: the majority of patients returned to normal activities and to work within 3–7 days,[23] after RFA. These attributes are not only pleasing to the patient, but they also bear important considerations for overall cost of the procedure that may offset the higher specific costs for the ClosureFast™ catheter and for duplex scanning in the operating room.[8,22]

Finally, to the best of authors' knowledge, this study presented for the first time data regarding the influence of BMI and CEAP class on outcome and QOL of RFA. BMI influenced disease-specific and physical and mental domains of QOL questionnaires, while it did not affect GSV diameter reduction during the follow-up. On the contrary, CEAP clinical class significantly influenced both GSV diameter reduction after the treatment and QOL scores within 36 months.

This study is limited by the relative short follow-up. Moreover, follow-up data and questionnaire responses were available from fewer patients, as the time from the procedure increases.

In conclusion, based on the presented data, patients treated with the ClosureFast™ system experienced high rates of complete post-procedural saphenous vein occlusion. RFA of the GSV is extremely easy to apply and very reliable both in terms of clinical results and patient's satisfaction. Reduced post-surgical pain, low complication rate, and a faster social and job recovery highlight this technique as a safe and effective treatment for superficial vein insufficiency. The RFA procedure should be compared to other endovascular modalities (i.e., laser thermal ablation,

mechanochemical ablation) for treatment of incompetent GSV and to conventional surgical stripping in prospective randomized clinical trials with long-term follow-up to establish its overall superiority.

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