Original article

VNUS Closure radiofrequency ablation of varicose veins
From Closure PLUS to Closure FAST

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Keywords
Radiofrequency segmental thermal ablation, varicose veins, endovenous procedure, VNUS Closure FAST

Summary
Endovenous procedures are increasingly being used to eliminate epifascial variose veins. The radiofrequency therapies VNUS Closure and VNUS Closure FAST Catheter have established themselves and boast very good results compared to other endovenous procedures with regard to closure rates and postoperative quality of life. Equipment and method: Between February 2005 and December 2009, a total of 2413 patients comprising 3366 great and small saphenous veins were operated upon at the Vascular and Venous Diseases Department of DERMATOLOGIKUM HAMBURG. 2241 great and small saphenous veins were treated with the VNUS Closure FAST catheter, 1125 great and small saphenous veins were treated with the Closure PLUS catheter system. Additionally, 264 recurrent varicose veins were treated with the Closure FAST system. Ultrasound examinations were conducted 7 days after the treatment, again 6 weeks after the treatment, and at the follow-up examination one year after treatment. Any recanalisations were treated immediately. Between January 2007 and January 2009, 57 patients were also treated for perforant veins between stages C-4 and C-6. Gender and age distributions, as well as CEAP classifications corresponded to standard distributions. Compression stockings were only administered in the case of advanced chronic venous insufficiency (C-4 to C-6). The patients were anticoagulated before treatment by means of a low molecular weight heparin as a single shot prophylactic. Anticoagulation through thrombocyte aggregation inhibitors or dicumarin was continued. Results: 1089 great and small saphenous veins were examined after removal with Closure PLUS radiofrequency therapy. The primary closure rate after 6 weeks was 98.9%; after one year, 91.2%; after two years 99.0%; after three years, 98.2%; and after four years, 100%. 2241 great and small saphenous veins were treated with the VNUS Closure FAST Radiofrequency System. 2096 great and small saphenous veins were examined after treatment. The primary closure rate after 7 days was 99.7%; after 6 weeks, 99.6%; after one year, 98.8%; and after two years, 100%. The rate of minor complications after Closure FAST Radiofrequency catheter treatment of the great saphenous vein was 5.3%; after treatment of the small saphenous vein, 5.9% in total. No major complications – such as deep vein thromboses or pulmonary embolisms – were caused, and neither was burning of the skin. The closure rate one week after RFS treatment was 84.6%; after 6 weeks, 86.2%; and after one year, 78.3%. In all of the recurring varicose veins, the recirculation was successfully eliminated. Conclusion: The VNUS Closure FAST Radiofrequency catheter represents a standardised, established procedure for treating epifascial varicose veins to ensure the certain elimination of recirculation. The development of Closure PLUS 6-French and 8-French catheter into Closure FAST Radiofrequency catheter has led not only to a reduced operation duration but also a safe and high closure rate after follow-up. With the new concept of segmental ablation the Closure FAST system eliminates the catheter pullback variability and standardises and simplifies the procedure. The success of the treatment is shown by the complete decomposition of the vein underneath the inflow of the superficial epigastric vein or the inflow of the gastrocnemic veins. However, the long term results for the Closure FAST system are awaited eagerly. The current high closure rates and high patient satisfaction rates give us cause to look ahead with hope.

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Development of the VNUS radiofrequency catheter therapy for treatment of varicose veins
Phlebologie 2010; 39: 61–68
Received: February 22, 2010
accepted: February 22, 2010

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The first radiofrequency catheter VNUS closure treatment for elimination of epifascial varicose veins was performed successfully by Noppeney in 1998 in Germany (23). The first catheter treatment in the USA took place in 1999 (17).

Methods

During VNUS Closure radiofrequency catheter treatment, energy in the high frequency range is delivered to the vein wall via a bipolar current. Closure of the treated vein results by formation of a fibrosis which is broken down by the body over time.

Our own patients have been treated with radiofrequency catheters for saphenous varicose veins since 2005. Two catheters are available for this procedure that differ in the number of electrodes in the treatment umbrella array (▸ Fig. 1a):

- VNUS Closure 6-French Catheter,
- VNUS Closure 8-French Catheter.

The vein is entered by puncture in the area of the lower insufficiency point. After a guide wire is inserted into the vein, the 8-French sheath is positioned over it. Placement of the catheter is performed under ultrasound visualization below the inflow of the superficial epigastric vein with a distance of 2 cm from the deep vein.

After catheter placement, the patient is brought into anti-Trendelenburg position with the operating table and the vein is infiltrated with tumescent solution from the lower insufficiency point up to the thermoelement under ultrasound visualization. In treatment under general anesthesia, the injection of physiological saline solution takes place. The working temperature is 80°C.

Closure is performed by manual withdrawal of the catheter. For the first 4 cm, the withdrawal speed is 1 cm/min, then 3 cm/min. The duration of treatment varies between 20 and 30 minutes, depending on the location of the lower insufficiency point.

Since January 2006, our patients have been exclusively treated with the 8-French catheter. The treatment protocol has been changed to the effect that the first 4 cm are treated twice over 8 minutes, similar to the currently used Closure FAST catheter protocol. In addition, after this time, treatment of the accessory veins also is performed with the catheter.

The Closure FAST catheter has been in use since March 2007 for the great saphenous vein and since May 2007 for the small saphenous vein (▸ Fig. 1b). Energy transfer takes place through delivery of energy to a 7 cm long heating element (37, 38). The optimal working temperature of 120°C is reached after 5 seconds and is transferred to the vein wall over 20 seconds per obliteration cycle. The treatment parameters are standardized and the energy delivery is reproducible. Maintenance of the parameters is monitored by the generator.

Treatment of the sections of the vein takes place segmentally, up to the lower point of insufficiency (▸ Fig. 1d). The first segment of the great saphenous vein and small saphenous vein is treated each twice, three times when diameter is larger than 1.2 cm. The duration of treatment is shortened to 2-3 minutes with the procedure (30).

Post-operatively, closure of the saphenous vein should be performed directly below the superficial epigastic vein which is always remains intact in order to ensure physiological flow from the cranial vein sections to the deep vein system. By placing the tip of the catheter distal to the inflow of the superficial epigastric vein, the anterior accessory saphenous vein, that almost as a rule discharges into the superficial epigastric vein, is not closed with it. It must — in order to prevent recurrence — undergo additional puncture. Improper crossectomies form new distal recirculations through the accessory veins.

The procedure technique recommends initially placing the catheter below the junction of the superficial epigastric vein in the saphenous vein (▸ Fig. 1d) Subsequently, the anterior accessory saphenous vein is punctured on the ventral thigh and a guide wire is placed in the vessel.

Should the posterior accessory sapheneous vein also be treated, puncture of this vessel takes

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place afterwards on the proximal inner side of the thigh and a second guide wire is inserted. If the accessory veins show a diameter of less than 2 mm in the ultrasound, puncture is possible, but not the advancing of the sheath or catheter. After placement of the guide wire, the great saphenous vein is infiltrated with tumescent or saline solution from the sheath up to the inguinal region and segmental thermal ablation of the saphenous vein is performed (▸ Fig. 1e). Afterwards, the 7-French sheath is advanced over the guide wire in the anterior accessory saphenous vein. The catheter tip is placed at the inflow to the superficial epigastric vein and the vessel is infiltrated with tumescent or saline solution under ultrasound visualization here as well (▸ Fig. 2a).

- In intact vessels, a single treatment of the proximal segment takes place over 20 seconds.
- With reflux, the entire reflux segment is treated with the catheter.

Treatment of the posterior accessory saphenous vein takes place accordingly. For treatment of the small saphenous vein, the catheter tip is placed distal to the inflow of the gastrocnemius vein or better in the femoropopliteal or Giacomini vein, in order to close this section and prevent recurrence (▸ Fig. 2b).

For treatment of incompetent perforant veins, that discharge into the recirculation and contribute to a worsening of the chronic venous insufficiency, a special RFS catheter is available (▸ Fig. 1c). Entry takes place via transcutaneous puncture of the perforant vein guided by ultrasound and placement of the catheter tip in the point of transverse fascia. Subsequently, tumescent anesthesia or infiltration of the vein with saline solution takes place and the duration of radiofrequency catheter obliteration is for 4 minutes. The working temperature is 85° and is controlled by impedance of the generator. After each minute, the catheter is rotated by 90°. Energy is delivered to the vein wall by two electrodes at the tip of the catheter. Varicose side branches should be treated at the same time by mini-phlebectomy or foam sclerotherapy.

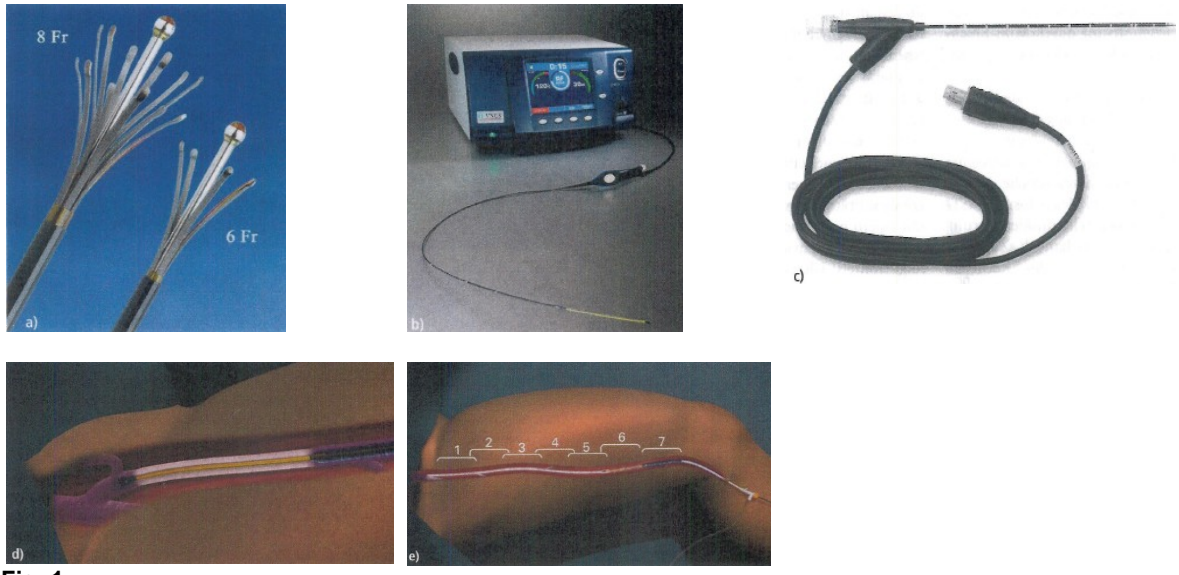

Fig. 1
Radiofrequency obliteration (Reprinted courtesy of VNUS Medical GmbH Deutschland)
a) Closure PLUS 6-French and 8-French catheters;
b) FAST catheter with generator;
c) RFS catheter;
d) Positioning of catheter tip;
e) Segmental thermal obliteration

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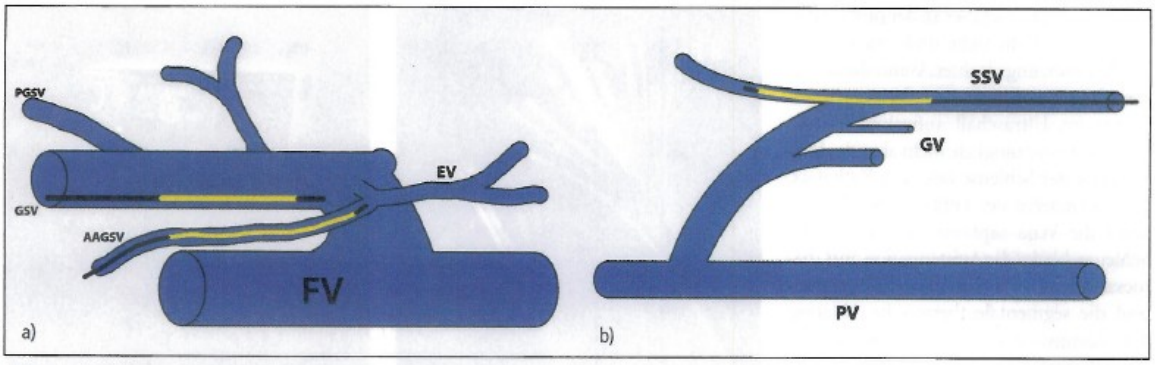

Fig. 2 Positioning of the catheter tip for treatment of
a) VSM and VSAA; **b)** VSP

Recurrent varicose veins with reflux from the sapheno-femoral junction or saphenopopliteal junction in the venous plexus and distal revulsion via incompetent saphenous veins or accessory veins are treated with a combination of Closure FAST catheter and foam sclerotherapy (Äthoxysklerol® 3%). Initially the catheter is placed near the junction or the opening. The foam is infiltrated over the positioned catheter under ultrasound visualization. Afterwards, the accessory or other saphenous vein is treated accordingly.

Since August 2009 patients in our departments that showed a great saphenous vein diameter of over 1.5 cm primarily near the opening were routinely crossectomized or underwent a ligature of the opening in the region of the small saphenous vein in addition to Closure FAST treatment.

Table 1 Numbers of patients in the study period 2/1/2005-12/31/2009

		Patients	**Saphenous vein**
Total		2,413	3,366
RFO	PLUS	761	1,125
Closure	FAST	1,652	2,241

Table 2 Stump length of the great saphenous vein

n=2,241	**Stump length (mm)**
1 year	8.1
2 years	7.8
3 years	5.9

Compression stockings were only administered in the case of advanced chronic venous insufficiency (C-4 to C-6). Patients received preoperative anticoagulation as a single shot prophylactic of low molecular weight heparin. Follow-up was conducted with post-operative ultrasound examinations after 7 days, 6 weeks and at yearly follow-up.

Results

From March 2005 until December 2009, 3,366 procedures were performed with the VNUS Closure radiofrequency catheter system in the Vascular and Venous Diseases Department at Dermatologikum Hamburg, in which 2,241 saphenous veins were treated with the Closure FAST catheter (▸ Table 1). In half of the cases, accessory veins could be treated as well at the same time. The treatment time of all vein sections from puncture until the sheath removal was on average 17 minutes for the great saphenous vein and 12 minutes for the small saphenous vein.

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The stump lengths of the great saphenous vein near the junction were reduced from 8 mm seven days post-treatment to 5.9 mm on average after three years (▸ Table 2).

In 2005, the VNUS Closure Plus System was used for treatment of 300 great saphenous veins. The primary closure rate for the 6-French catheter was 84% at the end of the year in 2005. These earlier unsatisfactory results were traced back to energy of the 6-French catheter delivered to the vein wall being too low (38, 42). After revision of the treatment protocol so that only the 8-French catheter was used and simultaneous treatment of the accessory veins, the primary closure rate improved to over 98% at the 1 year follow-up.

The results, when taken together with those of the Closure Plus 6-French and 8-French radiofrequency catheters, achieved a high primary closure rate of 98.9% after six weeks (▸ Table 3). At the one year follow-up, recanalizations were found in 68 saphenous veins corresponding to a closure rate of 91.2% and are largely attributable to use of the 6-French catheter (▸ Table 3).

Since using the VNUS Closure FAST catheter, the closure rates consistently fall between 98.8% to 100% at the two year follow-up (▸ Table 3).

In the follow up, three types of recurrent varicose veins could be verified after VNUS Closure radiofrequency ablation (▸ Table 4):

Table 3 Closure rate after radiofrequency ablation

Radiofrequency obliteration	n	Follow-up		Open	Closure rate (%)
Closure PLUS (6-Fr/8-Fr)	1,125	6 weeks	1,098 (97.6%)	12	98.9
		1 year	773 (68.7%)	68	91.2
		2 years	493 (43.8%)	5	98.9
		3 years	271 (24.1%)	5	98.2
		4 years	40 (3.6%)	0	100
Closure FAST	2,241	7 days	2,096 (93.5%)	5	99.8%
		6 weeks	1,509 (67.3%)	6	99.6%
		1 year	807 (36.0%)	10	98.8%
		2 years	224 (10.0%)	0	100%

- Group I: complete or segmental re-opening of saphenous vein
- Group II: recurrent recirculation through the accessory vein during closure or disintegration of saphenous vein,
- Group III: Recanalization via the saphenous veins, in which the interior of the saphenous vein was permeated with obliterative connective tissue elements and fibrotic septa.

Neovascularization or reflux through isolated subcutaneous veins have not occurred to date. The closure rate with the 6-French catheter amounts to only 68.2%. This was caused by a complete recanalization of the saphenous vein and accessory veins being untreated. Although significantly lower, primarily complete recanalization of the saphenous vein also occurred with the 8-French catheter treatment.

Only 21 recurrences occurred in saphenous veins treated with the Closure FAST radiofrequency catheter, of which 14 were classified in Group III (▸ Table 5). 2,096 saphenous veins were examined in follow up. No new recirculations had formed in the accessory veins. The subgroup analysis of the recurrence after Closure FAST catheter treatment showed that in the seven Group I recurrences, there were four saphenous veins with a diameter of over 1.5 cm near the junction. The reflux segments were between 4 and 20 cm. Of the 14 open vessels of Group III, nine veins showed a near junction diameter over 1.5 cm (▸ Table 5).

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Patients, that showed a Group I and II recurrence after radiofrequency treatment, were initially immediately retreated with the Closure PLUS 8-French catheter, then with the Closure FAST catheter starting in 2007. All vessel sections closed secondarily. The recurrent varicose veins in Group II were treated with 3% Äthoxysklerol® foam sclerotherapy under ultrasound visualization. Patients with a saphenous vein diameter of over 1 cm near the junction were crossectomized in addition or underwent opening ligation. This resulted in a secondary 100% closure rate as well.

264 recurrent varicose veins after Babcok surgery, CHIVA or isolated crossectomy were treated by a combination of Closure FAST catheter and foam sclerotherapy. All vein sections treated with the Closure FAST catheter were closed. The foam sclerotherapy primarily lead to complete occlusion of the venous plexus only in 30% of the cases. 52 patients underwent sclerotherapy again with the assistance of Doppler sonography in the region of the sapheno-femoral junction.

Patients with insufficient perforant veins with chronic venous insufficiency in stages C4 to C6 were treated concomitantly with the RFS catheter. The RFS catheter was not used in cases of blow-out phenomenon through insufficiency of the perforant vein. Instead the transfascial perforant vein was transected with a short cut and ligated. From January 2007 until January 2009, 78 perforant veins were examined in 57 patients (▸ Table 6). The closure rates were

- 84.6% after one week,
- 78.3% after one year,

Table 4 Recurrent varicose veins after Closure radiofrequency ablation

n=3,221		6 French	8 French	FAST
n		192	933	2,096
Group	1	47	21	7
	2	12	7	-
	3	2	1	14
Total		61 (31.8%)	29 (3.1%)	21 (1.0%)
Closure rate		68.2%	96.9%	99.0%

Table 5 Recurrent varicose veins after Closure FAST radiofrequency ablation

(n=21)	Group 1	Group 3
open	7	14
of them Ø > 1.5-2.2 cm	4	9
Reflux segments	4-20 cm	4 cm complete

Table 6 RFS catheter (Examination period 01/07-01/09)

57 Patients 78 perforant veins	Follow-up	Open	Closure rate
7 days	78 (100%)	12	84.6%
6 weeks	58 (74%)	8	86.2%
1 year	46 (59%)	10	78.3%

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Table 7 Complications according to Closure FAST

Complications	VSM (n=1,354)		VSP (n=742)	
	n	%	n	%
none	1,282	94.7	698	94.1
Paresthesia	24	1.8	15	3.4
Hematoma	8	0.6	2	0.3
Hyperpigmentation	27	2.0	0	0
Phlebitis	25	1.9	3	0.4
Pain	23	1.7	3	0.4
Ecchymosis	28	2.1	3	0.4
Edema	0	0	14	1.9

Complications

Perioperative complications after Closure FAST treatments are rare. Mostly these occur between the first and sixth weeks in the context of an inflammatory reaction. These symptoms are reversible already after six weeks with the exception of paresthesias and hyperpigmentations. The complication rate with treatment of the great saphenous vein amounts to a total 5.3% and 5.9% of the small saphenous vein (▸ Table 7). Parethesias occur in treatment of the great saphenous vein largely in the thigh layer, while they occur often after small saphenous vein treatment after distal treatment.

> To reduce the paresthesia rate, it is imperative that the tumescent solution be accurately infiltrated perivascularly (17).

Paresthesias were declining overall at 2 or 3 year follow-up. It is especially important to take into account hyperpigmentation if the vein to be treated lies directly under the skin pre-operatively. A good prognosis for the reduction of pigments exists if the vein is still detectable by ultrasound and did not completely break down. To avoid hyperpigmentation and phlebitis, it is better to perform mini-phlebectomy on the large subcutaneous varicose side branches in the thigh region.

Phlebitis of the saphenous veins was largely a problem for great saphenous vein treatment and principally on the inner side of the thigh. Hematomas were defined as free perivascular fluid detectable by sonography. Hematomas occurred near the junction as a rule. To what extent these resulted from a thermal injury due to the catheter or an injury due to the needle during the tumescent treatment could not be differentiated retrospectively.

Ecchymoses are the result of needlestick injury of subcutaneous veins during tumescent anesthesia. These normally completely disintegrate after three weeks. Skin burns such as those described in the literature (34, 40) have never occurred. These are caused by incorrect positioning of the thermoelement at the skin level or due to insufficient insulation of the veins from the skin by the user. Deep vein thromboses or pulmonary embolisms, as described in the literature, were not induced (3, 10, 16, 18).

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Table 8 Energy delivery to vein wall

Methods		Joule/cm
Laser		15-180
Closure	FAST	68-117
	PLUS	30
RFITT®		8-21

A total of 25 patients were treated with the NVUS Closure FAST radiofrequency catheter system carried out with an intraoperative lateral branch avulsion as mini-phlebectomy as well in 2009 under complete anticoagulation with vitamin K antagonists with an INR at 3.5. No consequential hematomas - those that were a burden for the patients - occurred.

Discussion

Treatment of epifascial varicose veins with the VNUS Closure FAST radiofrequency catheter system has been established and absolutely standardized in its applicability in comparison to other endovenous procedures (4, 5, 9, 11, 13, 18, 22, 23, 25, 32, 33, 36, 39). Recirculation has been successfully eliminated to a great extent (5, 9). The use of the method corresponds to the applicable guidelines for treatment of varicose veins (22). The poor results of the Closure PLUS generation of catheters was caused by too little energy being delivered to the vein wall during treatment (▸ Table 8). This applies fundamentally to the 6-French catheter at 30 J/cm. High rates of recurrence after low energy output laser treatment have been described (28-30).

The topic of closure of the saphenouse veins and success of the operation has been dealt with inconsistently (20). The superficial epigastric vein should remain intact in all cases, because it fulfills a flushing function and prevents the smallest lateral branches that discharge between the inflow of the superficial epigastric vein and the femoral vein in the sapheno-femoral junction from becoming refluxive. On the other hand, the physiological outflow of subcutaneous veins from the cranial inguinal region to the deep vein system takes place through this vessel. Closure of the great saphenous vein should be performed directly below the inflow of the superficial epigastric vein. Reflux-free, open segments harbor the risk of recurrence formation in follow-up. Mumme, et al. followed up on 458 patients after crossectomy of the great saphenous vein. They determined that in 251 patients, the saphenous stump was too long, was the cause of recurrence formation and therefore represented an error in surgical technique.

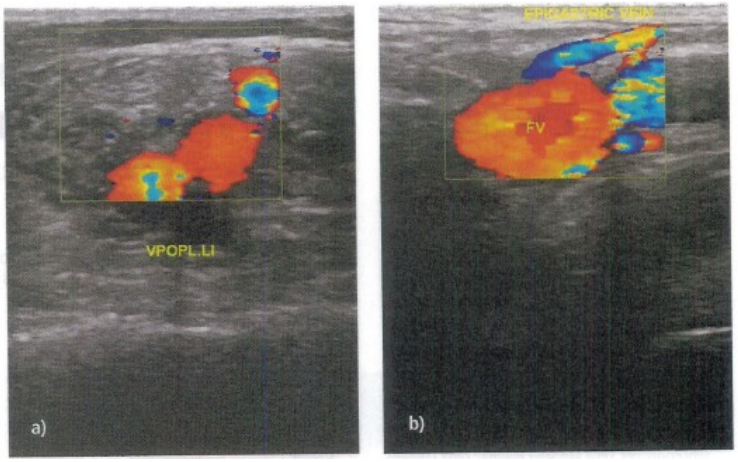

Fig. 3 1 year follow-up
a) V. saphena parva; **b)** V. saphena magna

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From high ligature, we are also aware of high recurrence rates with formation of recirculation particularly distal through the accessory veins (2, 6-8,19, 24, 31). In treatment of the small saphenous vein, the closure should be performed directly distal to the inflow of the gastrocnemius vein. The final outcome is not in the documentation of the vein closure, but in the evidence that the body has completely absorbed the treated vein sections (▸ Fig. 3). Experience has shown that Closure FAST catheter treatment achieves this after one year (14, 15, 26, 27). Previously treated vein segments that were still detectable by ultrasound could be recanalized in follow-up.

With the VNUS Closure FAST catheter, a primary closure was successful even with vein sections with large lumens (>2 cm). Based on our own experience, treated veins with a large diameter of over 1.5 cm bear a risk of recanalization. Our patients showed 21 open saphenous veins, 13 with a diameter of over 1.5 cm. Since August 2009 patients in our departments that showed a great saphenous vein diameter of over 1.5 cm primarily near the opening were routinely crossectomized or underwent a ligature of the opening in the region of the small saphenous vein in addition to Closure FAST treatment.

> Recirculation in the treatment of recurrent varicose veins can reliably be stopped with the Closure FAST catheter.

However, foam sclerotherapy is not successful in reliably closing the venous plexus. As a consequence, a revision of the sapheno-femoral junction should also be performed here.

The perforant vein catheter (RFS) was used in our department between 2007 and 2009. Advanced chronic venous insufficiency with pronounced skin lesions is a very good indication for this treatment. In the mid 2010, the second generation of RFS catheters should become available. Energy will be delivered then via a short heating element, similar to the Closure FAST system. It is hoped that better primary closure rates will result from this catheter system.

Perioperative complication rates after radiofrequency catheter obliteration are very low (1, 32, 35, 36, 39, 40, 41). In comparison to conventional open procedures and to laser catheter applications, the patient benefits significantly in regards to postoperative quality of life (1, 15, 40).

Epifascial varicose vein treatment is possible under anticoagulation. Platelet aggregation inhibitors or Dicumarol do not need be discontinued as a rule. Catheter treatment does not normally lead to hematomas. These are largely the result of lateral branch avulsion. Appropriate atraumatic surgical techniques reduce this risk.

Limitations

A shortcoming in the treatment of the great saphenous vein with the catheter system exists in the uncertainty of leaving accessory veins untreated, which are not primarily detectable by ultrasound examination. This affects at least 50% of our patients. Experience shows that over the years these vessels are wider in diameter up to 4 mm through compensation, without a reflux having been detected to date.

Conclusion and Outlook

This uncertainty and the knowledge that significant recurrence only appeared after 7-10 post-operative years with conventional open procedures (40) means long-term results are eagerly awaited. The closure rates currently achieved with the VNUS Closure FAST radiofrequency catheter system and high acceptance on the side of patients gives us cause to look into the future with hope.

Conflict of Interest

The corresponding author states that no conflict of interest exists.

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