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Jens P. Tesmann

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Jens P. TESMANN[1]
Helmut THIERBACH[2]
Andrea DIETRICH[1]
Heiko GRIMME[1]
Thomas VOGT[3]
Knuth RASS[3]

[1] Kurpark Center of Dermatology, König-Karl-Str. 28, 70372 Stuttgart, Germany
[2] Villamed, Dayclinic of Varicose Surgery, Munich, Germany
[3] Department of Dermatology, Saarland University Hospital, Homburg/Saar, Germany

Reprints: J. P. Tesmann <j.tesmann@email.de>

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Radiofrequency induced thermotherapy (RFITT) of varicose veins compared to endovenous laser treatment (EVLT): a non-randomized prospective study concentrating on occlusion rates, side-effects and clinical outcome.

Background: Radiofrequency obliteration (RFO) and endovenous laser treatment (EVLT) are established techniques in varicose therapy. A novel bipolar RFO technique – Radiofrequency Induced Thermotherapy (RFITT) – was introduced in 2007. Comparative studies of RFITT and EVLT with one year follow-up are missing. *Objective:* Comparison of RFITT with EVLT concentrating on occlusion, side-effects, and patients' satisfaction in a prospective non-randomized study. *Methods:* 133 patients with incompetent GSV or SSV were treated by RFITT (n=66) or EVLT (n=67). Follow-up at days 1, 7, and months 3, 12 included duplex, digital photoplethysmography (DPPG), assessment of VCSS and patients' satisfaction. *Results:* Both groups were balanced concerning clinical parameters. Occlusion rates were in trend in favour of EVLT (96.9%) *vs* RFITT (88.9%), p=0.093, at 12 months follow-up. Functional outcome by DPPG (refilling time: 30.8 *vs* 31.9 sec.), and side-effects were comparable apart from pain in the first postoperative week, which was more frequent in the EVLT group (0 *vs* 16.4%, p=0.001). Change in VCSS from baseline was advantageous for EVLT (89.9% *vs* 79.3%, p=0.005). Major complications did not occur. Both techniques provided excellent satisfaction results. *Conclusion:* After one year RFITT is similarly as effective and safe as EVLT treatment of varicose insufficiency, but needs improvement in treatment parameters.

Key words: EVLT, great saphenous vein, RFITT, small saphenous vein, varicose veins, VCSS

Minimal invasive procedures for treatment of varicose veins like endovenous laser therapy (EVLT) and radiofrequency obliteration (RFO) have been successfully established in the last decade [1-6]. In 2007 a new method of RFO for the treatment of varicose veins was introduced by Celon AG Medical Instruments (Teltow, Germany), called RadioFrequency Induced Thermotherapy (RFITT). This technique has been used so far in the ENT medicine area and in the treatment of solid tumors for some years, whereby a non-moving bipolar catheter-tip is inserted in the interstitial target. An impedance-controlled shut-down of energy avoids overheating the target [7, 8]. For treatment of varicose veins the bipolar catheter tip needs to be moved, which is a challenge to optimize the parameters of treatment [9, 21, 23, 27].
Alternating currency (AC) of radiofrequency generates heat (85-100°C) directly in the venous wall by causing high frequency oscillations of ions or water molecules similar to the microwave effect [10] *(figure 1)*. This results in coagulation of cells and collagen fibrils, thermoelectric tissue destruction of the intima, clot formation and subsequent fibrosis of the vessel [9-12]. Interestingly, perforation of the vessel has not been reported yet, which might be related to the impedance feedback function of the applicator: when tissue heating of the vessel induces dryness, electric resistance of the tissue rises strongly, leading to a stoppage of energy deposit. Thus, energy output is adapted to the size of the vessel wall and perforations with subsequent ecchymoses are avoided [9, 12]. Compared with conventional RFO the RFITT approach allows a considerably faster application with a catheter pullback over a few minutes [10].
Controlled studies on radiofrequency ablation methods compared with EVLT are rare and report predominantly short-term results of GSV ablation with a focus on post-procedural side effects [13, 19, 21]. The objective of the following study was therefore to evaluate the efficacy as well as side effects and patients' satisfaction of RFITT for the treatment of both great and small saphenous vein insufficiencies compared to the established 810 nm diode endovenous laser ablation with a 1-year follow-up.

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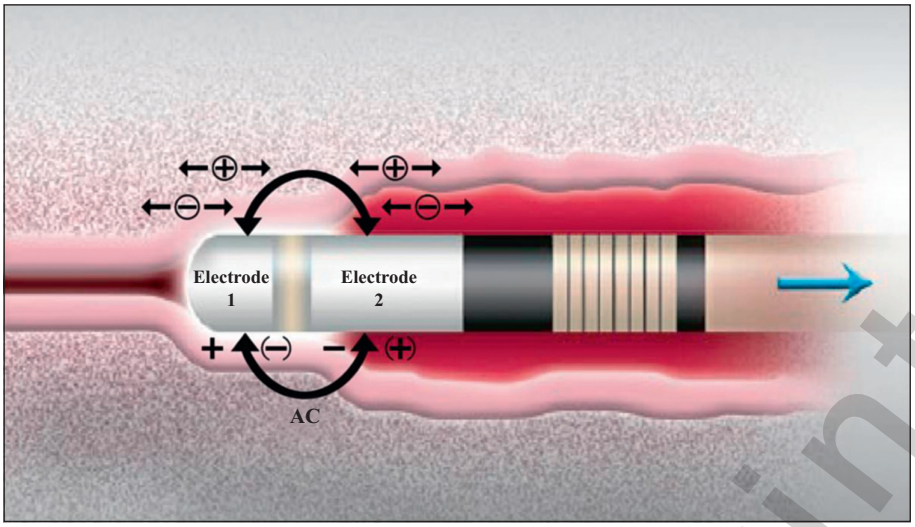

Figure 1. RFITT round tip catheter with bipolar electrodes heating up the venous wall through oscillation of ions and water molecules.

Patients and methods

Patients

Ethics committee approval (Ärztekammer des Saarlandes, Saarbrücken, Germany) was obtained (Identification-No. 39/08), the study was non-randomized. The choice of which treatment should be applied – RFITT or EVLT – was left to the patients, based on equal written information and oral communication about both procedures. All patients gave written informed consent to each treatment procedure. Both methods were approved for the interventional treatment of varicose veins by the regulatory authorities and the treatment protocols were followed exactly according to the manufacturers' guidelines. The surgeon (JPT) was familiar with both procedures warranting more than 30 RFITT and 120 EVLT treatments before starting this study.

For sample size calculation, we assumed 1-year re-canalisation rates of 2.5% for EVLT as shown by Min and colleagues, who presented the largest case series on 810nm EVLT at the time of study conception [22] and 17% for RFITT extrapolated according to an oral presentation by Camci in September 2007 at the annual German Society of Phlebology Meeting, who presented the first RFITT data with a recurrence rate of 15% at 3 months follow-up [23]. Given the difference of 14.5%, a sample size of 65 participants per group was required to detect this difference on a 5% significance level with 80% statistical power [24].

133 patients with incompetent saphenofemoral or saphenopopliteal junction (reflux >1 sec on the Doppler trace of Duplex ultrasound) accompanied by GSV or SSV insufficiency were treated between December 2007 and August 2008. Patients represented all clinical stages of venous insufficiency. Patients with recurrent varicosis after high ligation and stripping, insufficiency grade I according to Hach, SSV with incompetent Giacomini-vein, deep vein thrombosis, clotting disease, peripheral arterial disorder, severe systematic diseases, heart pacer or pregnant/nursing women were excluded. Before treatment, the diameter of the proximal and distal insufficiency point of vein was recorded in standing position. As an established functional test, quantitative DPPG (ELCAT D-PPG Vasoquant VQ 4000, Wolfratshausen, Germany), was used to measure the venous refilling time (RT) in a sitting position [14].

66 patients were treated with RFITT (Celon AG Medical Instruments, Teltow, Germany) and 67 patients received EVLT by 810 nm Diode Laser (MedArt Diode Laser 435, MedArt A/S, Hvidovre, Denmark) using 200-250 mL perivenous tumescent local anaesthesia (TLA; 1L of physiologic saline contained prilocaine 700 mg, epinephrine 1 mg and 10 mL of bicarbonate 8.4%) in both groups as described elsewhere [15]. Mini-phlebectomies were performed simultaneously in both groups with a comparable extent of incisions. Following treatment, a non-stretched compression bandage was applied to the limb for 24 hours followed by a class two compression stocking for 3 further weeks. Low molecular weight heparins were given for 10 days starting directly after treatment and patients were only prescribed non-steroidal antiphlogistics (Naproxen 500 mg twice a day) in case of pain caused by inflammation of the GSV or SSV regions being assessed by the physician.

Standard bRFO (RFITT) technique

The rounded tip bipolar RFITT applicator (Celon ProCurve 1200-S15) was inserted into the vein through a 5F vessel introducer kit ("Radiofocus", Fa. Terumo, Germany) and advanced directly 1-2 cm close to the SFJ or SPJ according to Camci *et al*. [10]. Power was supplied by the Celon "Power" generator set to an output of 20 W as recommended by the manufacturer treatment protocol, monitoring the procedure through a connected laptop using "Celon Power Monitor" software giving treatment time, function of both electrodes and administered energy in Joules. Pullback speed was controlled through acoustic impedance feedback as described above and was 0.7-1 cm/sec.

Standard laser technique

The procedure was performed as described previously [1]. In brief, after duplex mapping the GSV or SSV was

cannulated at the distal insufficiency point (DIP) and a 5F catheter (scaled 1 cm) was introduced using Seldinger's technique. The guide wire was replaced by a laser bare fiber which was positioned 1-2 cm before the SFJ or SPJ and connected to the 810nm Diode laser generator. After TLA, the bare fiber, which was tightly locked to the scaled catheter, was withdrawn delivering 15 W laser power in a continuous pull-back fashion. The applied energy dose was registered as endovenous energy fluence equivalent, EFE, a more precise dosage parameter than LEED, taking into account the diameter of the treated vein. The EFE was intended to be at least 20 J/cm^2 vein surface as recommended in the literature [15, 20]. Resulting pullback speed was 0.1-0.2 cm/sec.

Follow-up

Patients' outcome was evaluated on days 1 and 7, and after 3 and 12 months. All 133 patients presented at the 3 month follow-up and 128 patients at the 12 month follow-up (recall rate: 96.2%; RFITT: n=63; EVLT: n=65). Treated limbs were assessed clinically, by duplex ultrasound and DPPG. The primary objective of the study was recurrence at the SFJ or SPJ assessed by colour coded duplex imaging. Criteria for a successful GSV/SSV ablation on duplex ultrasound were non-compressibility or disappearance of the treated segment together with absence of flow on duplex ultrasound >1 sec in the SFJ/SPJ. Treatment failures were defined as veins demonstrating flow and/or reflux in the treated segments irrespective of the patient's clinical improvement. For this purpose, three different recanalization types were defined:

– Type A (proximal recanalization): flow or reflux on colour duplex image > 3 cm from the SFJ or SPJ without complete recanalization.

– Type B (complete recanalization): recanalization of the entire treated vein segment.

– Type C (distal recanalization): recanalization at the distal point of treatment without complete recanalization.

As secondary objectives the Venous Clinical Severity Score [25] and the functional outcome (venous RT by DPPG), assessed both before and one year after treatment, were recorded. Additionally, patients were asked to assess their clinical symptoms before treatment and on follow-up, including side effects, cosmetic and overall satisfaction using questionnaires based on visual analogue scales. The patients were finally asked if they would choose the applied treatment again.

Statistics

Categorical variables of the two groups were compared using the chi-square test; random variables were analyzed as median by Mann-Whitney-U test. The distributions of venous RT are presented as box-plots, the pre- and postoperative RT changes, as well as the relative VCSS changes [$(VCSS_{preoperative} - VCSS_{12months\ postoperative}) / VCSS_{preoperative}$] were compared by Wilcoxon ranked-sum test. A p-value of < 0.05 was considered statistically significant. All statistical analyses were performed with statistical software PASW Statistics 18 (SPSS, Inc., Chicago, IL).

Results

Patients' demographic and clinical characteristics were balanced *(table 1)*. In the RFITT group 42 patients received treatment of the GSV, and 24 patients were treated at the SSV. EVLT was carried out on GSV in 46 and SSV in 21 patients, showing no significant differences in median

Table 1. Patients' demographic and clinical characteristics.

	EVLT	RFITT	P
Number of treatments	67	66	
- GSV, n (%) - SSV, n (%)	46 (68.7) 21 (31.3)	42 (63.6) 24 (36.4)	0.585
Median age (range)	57 (23-81)	53.5 (26-78)	0.196
Gender			
- male, n (%) - female, n (%)	24 (35.8) 43 (64.2)	19 (28.8) 47 (71.2)	0.459
Mean body mass index, kg/m^2 (SD)	24.8 (3.8)	24.5 (4.0)	0.599
Side			
- right, n (%) - left, n (%)	32 (47.8) 35 (52.2)	32 (48.5) 34 (51.5)	0.933
C classification (CEAP)			
- C2, n (%) - C3, n (%) - C4, n (%) - C5, n (%)	24 (35.8) 33 (49.3) 8 (11.9) 2 (3.0)	21 (31.8) 35 (53.0) 10 (15.2) 0	0.548
Mean preoperative venous refilling time, sec. (SD)	13.75 (7.5)	13.47 (5.0)	0.680
Median GSV diameter, mm (range)	5.85 (3.0-12.7)	5.75 (3.8-10.4)	0.919
Median SSV diameter, mm (range)	3.40 (2.3-7.7)	4.15 (2.3-9.2)	0.100

GSV and SSV diameters in either group *(table 1)*. RFITT was administered with significantly less energy doses (EFE/LEED) compared with EVLT in both GSV ($p<0.001$) and SSV ($p<0.001$), as shown in detail in *table 2*.

After 12 months the overall occlusion rate was in trend superior in the EVLT group with 96.9% compared with 88.9% in the RFITT group (p=0.093). Proximal recanalizations (type A) occurred in 3.2% (RFITT) and 1.5% (EVLT), complete recanalizations of the treated vein segment (type B) were found in 4.8% and 1.5% respectively, and distal type C recanalizations were only observed in the RFITT group (3.2%). None of these differences were significant. The functional outcome as measured by DPPG 3 and 12 months after treatment improved significantly to baseline ($p<0.001$), but showed no differences between the two procedures *(figure 2)*.

No major side effects such as thrombo embolic events or skin burns were seen in any group, but minor discomfort occurred. During the first week EVLT patients suffered significantly more pain through inflammation in the treated segments of GSV and SSV (assessed by a physician), while RFITT patients had no pain at all (0 *vs* 16.4%, p=0.001). In contrast, dysaesthesia was seen more frequent after RFITT, especially after treating the SSV (12.5% *vs* 4.8%), but without significant difference (p=0.611). Dyspigmentation was only rarely found in both groups three months after treatment of the GSV (RFITT 2.4% *vs* EVLT 4.3%) *(table 3)*.

A complete physical recovery achieving full activity within the first 3 postoperative days was achieved in trend more often by patients who received RFITT (92.4% *vs* 80.6 %, p=0.095) *(figure 3)*.

Side effects as assessed by a patient's questionnaire after 1 week stated by VAS 1-5 ("1" being less, "5" being most) showed overall mild reactions with no significant differences between the groups. But there were significantly more patients who would undergo the same procedure after one week in the RFITT group (100% *vs* 89.6%, p=0.013), an advantage, which however was lost one year after treatment *(table 4)*.

Cosmetic and overall satisfaction of patients stated by VAS 1-6 ("1" meaning "excellent", "6" meaning "failed") showed very good results for both groups, with no significant differences *(table 5)*.

VCSS improved significantly in both groups from baseline to 12 months postoperative ($p<0.001$). EVLT achieved a relative VCSS reduction of 89.9% whereas treatment with RFITT reduced the clinical score by 79.3% *(figure 4)*. The difference between the groups was significant (p=0.005).

Discussion

Endovenous ablation of varicose veins has become a frequent and popular, minimally-invasive treatment that is performed mostly with tumescent anaesthesia on an outpatient basis. EVLT and RFO have been developed simultaneously during recent years, but the disadvantages of RFO (*e.g.* slow pullback time, frequent need for a second catheter pass, high rate of additional treatment and relative difficulty in treating larger veins) outweighed its potential advantages of inducing fewer side effects like ecchymosis, haematoma, pain, induration and "phlebitis" as compared with EVLT [17, 18]. In 2007, new techniques of RFO were introduced, the VNUS ClosureFAST radiofrequency ablation and the Celon radiofrequency-induced thermotherapy (RFITT). To the best of our knowledge our article is the first publication comparing 810 nm EVLT with RFITT in a non-randomized prospective study providing one year follow-up. Although the study was not randomized, patients' clinical and demographic characteristics were balanced in both groups, especially as demonstrated for CEAP classification and vein diameters. A limitation of our study could be seen in the number of participants after one year, which was underpowered to detect the observed differences (*e.g.* recanalization and recovery), probably being significant.

In our study, the 12 month occlusion rate of EVLT (96.9%) was well in the range of recently published data [17, 18, 22]. The RFITT occlusion rate (88.9%) did not differ significantly and was in line with data published by Camci *et al.* (90%; follow-up of 103 days) [10], Goode *et al.* (74%; follow-up of 237 days) [21] and Boon *et al.* (88.7%; follow-up 1 year) [27].

Taking into account that all types of recanalization occurred mostly after treatment of GSV, we assume that under-dosing is the main reason for these data. Since vein diameters did not differ between groups, applied energy – regulated through impedance feedback – was probably not sufficient in treating GSV by RFITT as the endovenous fluence equivalent (EFE) was 17.91 J/cm^2 and therefore below the threshold of 20 J/cm^2 as defined by Proebstle *et al.* for EVLT [15, 20]. In contrast, only a few recanalizations occurred in SSV applying an EFE of 25.6 J/cm^2 by RFITT.

Interestingly, Boon *et al.* worked with 20 Watts powersetting, too, but needed a LEED of 42.17 $\pm$ 15.0 J/cm to reach 88.7% occlusion after one year [27]. This important difference might be explained through the different generator

Table 2. Applied energy dosage.

	EVLT	RFITT	P
Median endovenous fluence equivalent, (EFE) in J/cm^2 (range)	34.1 (13.3-86.8)	19.9 (9.7-49.7)	< 0.001
- GSV	*27.4 (13.3-47.1)*	*17.9 (9.7-29.0)*	< 0.001
- SSV	*55.1 (26.4-86.8)*	*25.6 (11.5-49.7)*	< 0.001
Median linear endovenous energy dose, (LEED) in J/cm (range)	40.5 (24.0-67.3)	25.1 (20.0-62.8)	< 0.001
- GSV	*40.4 (24.0-58.0)*	*25.6(20.3-38.7)*	< 0.001
- SSV	*45.9 (32.0-67.3)*	*24.6 (20.0-62.8)*	< 0.001

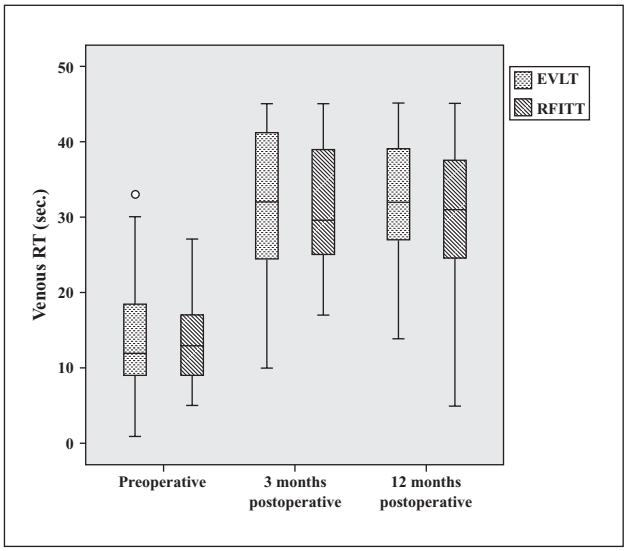

Figure 2. Functional outcome [improvement of venous refilling time (RT)] assessed by DPPG before, 3, and 12 months after endovenous ablation by RFITT (diagonal stripes) and EVLT (points) demonstrated by boxplots. The pre- and 3 month postoperative changes were highly significant for both groups ($p<0.001$), whereas the intergroup comparison showed no differences (preoperative: p=0.682, 3 months postoperative: p=0.700, 12 months postoperative: p=0.368).

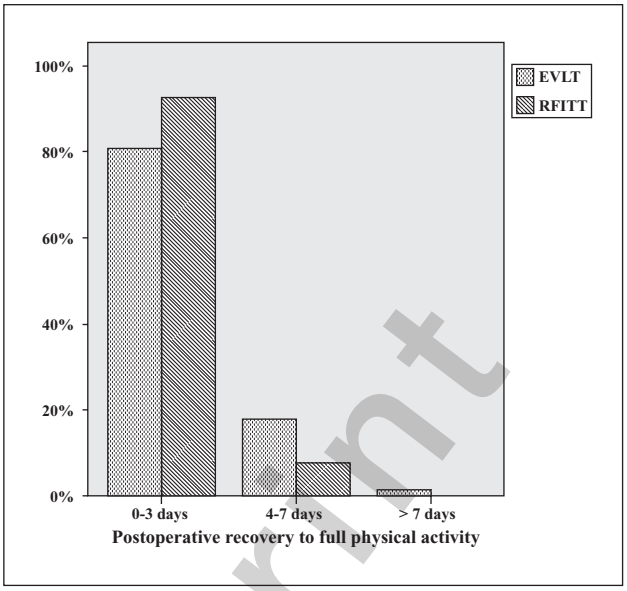

Figure 3. Recovery of patients to full physical activity after endovenous ablation by RFITT (diagonal stripes) or EVLT (points) as assessed by a patient's questionnaire.

type (Precision) they used, which only delivers an acoustical impedance feedback to control pullback. LEED was then calculated based on the length of the treated vein segment and 20 Watts powersetting. In our study, applied energy in joules was directly measured by the Celon Power generator. We observed that there is not a linear delivery of Jouls per cm. Therefore the calculated LEED of Boon *et al.* might be too high.

However, the efficacy of energy delivered by RFITT seems to be very high, since EFE and LEED of RFITT were significantly lower than EFE and LEED of EVLT (19.9 J/cm^2 *vs* 34.1 J/cm^2 and 25.1J/cm *vs* 40.5 J/cm). One might assume that RFITT, which generates heat directly in the vein wall, needs less energy than heating up the vein through the generation of steam bubbles and convective heat transfer to the intima [3]. On the other hand, the primary target for occlusion of a vessel might be the direct damage of the intima without need for perforation and/or destruction of the media and adventitia. This was shown for RFITT [12] and could explain why there is significantly less pain after RFITT (0%) compared to EVLT (16.4%) in the first postoperative days. Postoperative pain might additionally influence the time to resuming full daily activity, which was in trend superior for RFITT with 92.4% of the patients recovering in the first 3 postoperative days *(figure 3).* Similar positive effects for radiofrequency ablation compared with EVLT in the early postoperative period were also recently shown for the VNUS ClosureFAST approach, providing occlusion rates of 97% after one year [13, 19]. Additionally, the lower frequency of side effects after RFITT when compared with EVLT might explain the significant difference of patients, who would undergo each treatment again in favour of RFITT in the first postoperative week. Nevertheless, it is of importance that, in this study, EVLT was performed using a bare fiber and 810nm wavelength. Novel laser devices (*e.g.* radial fiber, 1,320 nm, 1,470 nm wavelength)

Table 3. Physician's assessment of postoperative side-effects.

	EVLT	RFITT	P
Postoperative pain, n (%), one week	11 (16.4)	0	0.001
- GSV	*4 (8.7)*		0.118
- SSV	*7 (33.3)*		0.003
Dysaesthesia, n (%), one week	1 (1.5)	4 (6.1)	0.208
- GSV	*0*	*1 (2.4)*	0.477
- SSV	*1 (4.8)*	*3 (12.5)*	0.611
Dyspigmentation, n (%), three month	2 (3.0)	1 (1.5)	1.000
- GSV	*2 (4.3)*	*1 (2.4)*	1.000
- SSV	*0*	*0*	

Table 4. Patients' assessment of postoperative side effects (one week) and re-treatment.

Postoperative side effects	EVLT	RFITT	P
Pain	82.1%	78.8%	0.667
- VAS (1-5), mean±SD	1.58±0.88	1.25±0.44	0.081
Bruising	77.6%	72.7%	0.552
- VAS (1-5), mean±SD	1.21±0.46	1.33±0.52	0.194
Inflammation/Phlebitis	1.5%	0%	n.s.
- VAS (1-5), mean±SD	2.0 (n=1)		
Dysaesthesia	1.5%	6.1%	0.208
- VAS (1-5), mean±SD	2.0 (n=1)	2.25±0.50	1.000
Percentage of patients who would undergo same procedure again			
- after 1 week	89.6%	100%	0.013
- after 12 months	93.8%	93.7%	1.000

Table 5. Patients' assessment of cosmetic and overall satisfaction at 12 month follow-up.

	EVLT	RFITT	P
Cosmetic satisfaction			
- VAS (1-6), mean±SD	1.77±0.63	1.92±0.81	0.375
Overall satisfaction			
- VAS (1-6), mean±SD	1.69±0.73	1.76±0.73	0.575

probably warrant fewer side effects [26] and comparison of them with RFITT should be a subject of further investigations.

The RFITT system might also generate a slight disadvantage regarding dysaesthesia after treatment. We found, in trend, more dysaesthesia after RFITT than EVLT, especially treating SSV. Since high oscillation of ions or water molecules is caused in the tissue, to create heat, adjacent nerve structures could be irritated more directly than by EVLT induced convective heat transfer [3], a side effect of RFO also reported by others [17, 18].

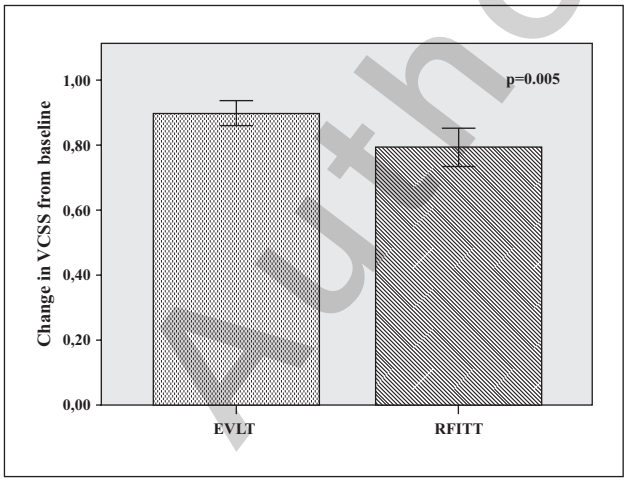

Figure 4. Significant clinical improvement of Venous Clinical Severity Score (VCSS) 12 months after treatment by RFITT (diagonal stripes) and EVLT (points) shown as changes from baseline in percent (79.3% *vs* 89.9%). Intergroup comparison was significant (p= 0.005).

Interestingly, bruising was rated low on VAS in both groups, although it is often named as side effect after EVLT [16-18]. Relatively low LEED of EVLT (mean 40.4-45.9 J/cm) could be the reason for this finding, as our power setting for EVLT was orientated on the EFE, which is based on the surface of the treated vein segment in cm^2. Functional outcome of treatment as measured by improvement of venous refilling time (RT) increased similarly and significantly to baseline for both groups after 3 months and was stable until 12 months after treatment. Nevertheless, reduction of VCSS from baseline after 12 months was significantly in favour of the EVLT group. This might correlate with the reduced occlusion rate of RFITT compared to EVLT after one year. This could also explain the lost preference of RFITT for re-treatment after one year. Although RFITT reached 88.9% occlusion and VCSS improvement of 79.3%, it could not reach the efficacy of the established EVLT. On the other hand, the RFITT-system works with significantly less energy and side-effects, resulting in earlier recovery from treatment. Cosmetic and overall satisfaction at 12 month follow-up was rated "very good" on VAS in both groups, which demonstrates that minimal invasive methods such as EVLT and RFITT are highly appreciated by the patients.

We conclude that the new procedure RFITT is as safe as the well-established 810nm EVLT and nearly as effective. Furthermore, we demonstrated that RFITT is a gentle treatment protecting the vein surrounding tissue, which results in a favourable side effect profile. A further evaluation of treated patients of this study is planned after four years.

The occlusion rates of GSV and SSV after RFITT were high but must be improved in our opinion. This is in line with recently published data by Goode *et al*. who compared RFITT and EVLT (810 nm) with a follow-up of 6 months and found occlusion rates of 74% after RFITT using a generator power setting of 23 Watts. The authors finally recommend an administration of 10-18 W, resulting in occlusion rates of 98% [21]. We would agree with this recommendation as preliminary data from an own pilot study comparing generator output of 10, 15 and 18 Watts suggest 18 Watts to be most effective (unpublished data).

However, further studies have to be undertaken to evaluate the novel radiofrequency approaches compared with themselves, EVLT and conventional surgery, especially concerning long-term efficacy in eliminating saphenous vein reflux. ■

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