Endovenous laser ablation of the incompetent great saphenous vein (GSV), small saphenous vein (SSV), and GSV recurrences with stump (SR) using a new 1470 nm laser and fiber, 3-month results from a prospective single-centre study

Endovenöse Laserablation bei Stammvarikosis der Vena saphena magna (VSM) und Vena saphena parva (VSP) sowie bei VSM-Krossenrezidiven (KR) mit neuer radiär abstrahlender Laserfaser – 3 Monatsergebnisse einer prospektiven single-centre-Studie

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ABSTRACT

Introduction The thermal ablation of varicose saphenous veins of the lower extremities is a well-accepted treatment option in Germany due to its high efficacy, application safety, and high patient satisfaction. The objective of the prospective observational study (POS) was to investigate surgical success, patient satisfaction, and the occurrence of side effects in the treatment of the great saphenous vein (GSV), small saphenous vein (SSV), great saphenous vein recurrences (SR) using the ENDOTEQ 360 ° FUSED Fiber ™.

Material and Methods The ENDOTEQ 360 ° FUSED Fiber ™, operates at a wavelength of 1470 nm with a beam angle of 60°. A total number of 162 varicose veins (GSV n = 76, SSV n = 65, SR n = 25) in 144 patients were included in the POS and followed up over a period of 3 months. For the treatment of GSV and SR, a fibre with a core diameter of 600 µm, tip diameter of 1.8 mm and 8 W of energy was used. For the treatment of the SSV, a fibre with a core diameter of 400 µm, a tip diameter of 1.3 mm and 6 W of energy was selected.

Results At the follow-up visit 10–14 days post surgery (visit 2) and 3 months post surgery (visit 3), all thermally treated GSVs (n = 76) and SSVs (n = 65) were occluded. In the SR group (n = 25), at visit 2 follow-up, 96 % of SRs remained occluded, and 4 % were partially occluded. Visit 3 showed a closure rate of 80 %, a partial closure rate of 16 % and complete recanalisation in 4 % of treated veins. Deep vein thrombosis (DVT) or pulmonary embolism (PE) did not occur in any group. Sensitivity disorders were reported in 1.4 % of the GSV group at visit 3, 6.15 % in the SSV group and none in the SR group. Patient satisfaction was very high in all groups, VSCC improved significantly in all three groups.

Summary Treatment of GSV, SSV, and SR with the ENDOTEQ 360° FUSED Fiber ™ laser system is efficient, has low complication rates and high patient satisfaction.

ZUSAMMENFASSUNG

Einleitung Die thermische Venenablation varikös veränderter Stammvenen der unteren Extremität ist in Deutschland aufgrund der guten Wirksamkeit, Anwendungssicherheit und hoher Patientenzufriedenheit eine anerkannte und häufig durchgeführte Behandlungsmöglichkeit. Zielsetzung der prospektiven Anwendungsbeobachtung (AWB) war die Untersuchung des Operationserfolges, der Patientenzufriedenheit und des Auftretens von Nebenwirkungen bei endovenöser Behandlung der varikös veränderten

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Vena saphena magna (VSM), Vena saphena parva (VSP) sowie bei Krossenrezidiven (KR) unter Verwendung der ETQ 360° FUSED Fiber™.

Material und Methoden Insgesamt wurden 162 varikös veränderte Venen (VSM n = 76, VSP n = 65, KR n = 25) bei 144 Patienten behandelt und in die AWB eingeschlossen. Ein duplexsonographisches Follow-up erfolgte nach 10–14 Tagen sowie 3 Monaten. Die ETQ 360° FUSED Fiber™ hat eine Wellenlänge von 1470 nm bei einem beam angle von 60°. Für die endovenöse Therapie der VSM und von KR wurde eine Faser mit einem Faserkerndurchmesser von 600 µm bei einem Spitzendurchmesser von 1,8 mm und 8 Watt Behandlungsenergie eingesetzt. Zur Behandlung der VSP wurde ein Faserkerndurchmesser von 400 µm bei einem Spitzendurchmesser von 1,3 mm und 6 Watt Behandlungsenergie gewählt.

Ergebnisse Alle thermisch behandelten VSM (n = 6) und VSP (n = 65) waren bei Visite 2 und Visite 3 vollständig verschlossen. In der KR Gruppe (n = 25) zeigten sich bei Visite 2 Verschlussraten von 96 % und Teilverschlussraten von 4 %. Bei Visite 3 konnten noch Verschlussraten von 80 % und Teilverschlussraten von 16 % nachgewiesen werden. In 4 % der Fälle kam es zu einer vollständigen Rekanalisierung. Tiefe Beinvenenthrombosen (TVT) oder Lungenembolien (LE) wurde in keiner der Kohorten diagnostiziert. 1,4 % der an der VSM behandelten Patienten gaben bei Visite 3 Sensibilitätsstörungen im Behandlungsareal an, in der VSP Gruppe waren es 6,15 %. Patienten der KR Kohorte gaben keinerlei Einschränkungen bezüglich der Sensibilität an. Die Patientenzufriedenheit war in allen Gruppen sehr hoch, in allen 3 Gruppen verbesserte sich der Venous Clinical Severity Score (VSCC) signifikant.

Zusammenfassung Die Behandlung der VSM, VSP und von KR mit der ETQ 360° FUSED Fiber™ ist effizient, komplikationsarm und mit einer hohen Patientenzufriedenheit assoziiert.

Introduction

Thermal ablation of trunk varicose veins of the lower extremities is carried out frequently in Germany, as it is very effective and safe, and results in high patient satisfaction. The most commonly used procedures are radiofrequency ablation (RFA) and endovenous laser ablation (EVLA). Laser ablation was first carried out in 1998 and has been developed further since then. At first a bare fibre laser (wavelength 810–980 nm) was used. The introduction of radial lasers with wavelengths of 1320–1550 nm both improved the efficacy and reduced the side effects. The advantage of longer wavelengths is the absorption maximum in water-containing structures such as the endothelium. The effectiveness of the laser energy in the vessel wall is thus increased, which leads to a higher rate of occlusion [2, 4].

Materials and methods

Most of the commercially available radial fibres have a beam angle of about 80 ° with targeted energy release on the vessel wall. Studies on the efficacy and safety of the method have been carried out [1, 4, 5, 8]. The ETQ 360° FUSED Fiber™ is a radial fibre with a wavelength of 1470 nm and a beam angle of 60°. The interaction between the tissues and the probe occurs at the anterior tip due to the small beam angle. Any carbonisation of the probe or adhesion to the tissues is thereby minimised. In addition, the small beam angle should also reduce side effects such as sensory disorders and at the same time achieve better occlusion rates. To date, there are no study data on the efficacy and safety of this laser.

At the Vein Centre in Freiburg, from September 2016 to April 2017, we carried out a prospective observational study (POS) on patients undergoing laser ablation of the great saphenous vein (GSV) and the small saphenous vein (SSV), or for recurrent saphenofemoral incompetence (SR) with a long residual GSV stump using the new radial laser fibre ETQ 360° FUSED Fiber™ from Endoteq.

In addition to determining the success of the procedure and the rate of side effects, the POS also aimed to assess patient satisfaction on the basis of a six-point scale as is used for school grades in Germany (1 = excellent, 6 = very poor) and the venous clinical severity score (VCSS).

One hundred and forty-four patients were enrolled in the study and a total of 162 saphenous varicose veins were treated by laser ablation (GSV n = 76, SSV n = 65, SR n = 25). Inclusion criteria were trunk varicose veins of the GSV or SSV requiring treatment or recurrent saphenofemoral incompetence with a residual saphenous vein stump measuring at least 0.7 cm in length. The procedures were performed by two experienced vein surgeons.

Preoperatively the severity of the varicose veins was determined on the basis of the clinical findings in accordance with the CEAP classification and the Venous Clinical Severity Score (VCSS) (▶ **Table 1**). The diameter of the GSV was also ascertained preoperatively, taking measurements with duplex ultrasonography at 3 cm and 10 cm (▶ **Table 2**). For the SSV, the diameter was measured at 3 cm (▶ **Table 2**). In the group with recurrent saphenofemoral incompetence, the maximum diameter of the GSV stump was measured (▶ **Table 2**).

A fibre with a core diameter of 600 µm, a tip diameter of 1.8 mm, and 8 watts of energy was used to treat the GSV and SR. A probe with a fibre core diameter of 400 µm, a tip diameter of 1.3 mm and

▶ **Table 1** Preoperative CVI classification (%).

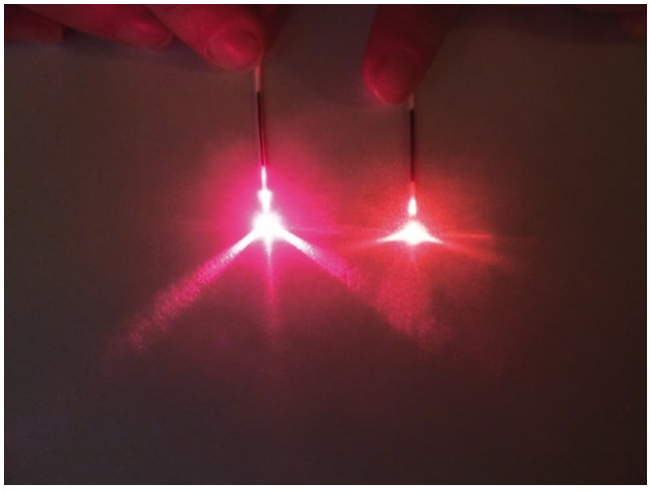
	GSV (n = 76)	SSV (n = 65)	Recurrence (n = 25)
C2	20 (26.3)	15 (23)	7 (28)
C3	45 (59.2)	37 (56.9)	15 (60)
C4	6 (7.9)	10 (15.4)	2 (8)
C5	1 (1.3)	2 (3)	1 (4)
C6	2 (2.6)	1 (1.5)	0

▶ **Table 2** Baseline data given as the mean and (standard deviation). DM = diameter, BMI = body mass index, GSV = great saphenous vein, SSV = small saphenous vein.

	DM 1 (mm)	DM 2 (mm)	BMI	Age	Vein length (cm)
GSV	7.23 (2.28)	6.34 (1.89)	27.54 (15.59)	55 (13)	44.01 (9.62)
SSV	5.93 (1.1)		27.73 (5.36)	60 (12)	17.31 (4.97)
GSV stump	7.82 (2.77)		27.95 (5.15)	57 (10)	17.3 (6.63)

▶ **Table 3** Operation data given as the mean and (standard deviation) .TLA = tumescent local anaesthesia, LMWH = low molecular weight heparin.

	TLA (ml)	Laser energy (J)	LMWH (days)	Specific energy (J/cm)	Specific TLA (mL/cm)
GSV	257.22 (11.46)	2481.47 (791.79)	7.33 (3.61)	56.41 (12.75)	5.98 (2.25)
SSV	123.12 (50.01)	787.88 (305.58)	6.78 (4.17)	45.29 (11.97)	7.67 (4.15)
GSV stump		301.38 (166.92)	6.36 (3.6)	168 (53.15)	



▶ **Fig. 1** The figure shows the different beam angles of the laser probes. Right: the ETQ 360° FUSED Fiber with a beam angle of 60°. Left: conventional laser probe with a beam angle of 80°. The interaction between the tissues and the probe occurs at the anterior tip due to the smaller beam angle. Any carbonisation of the probe or adhesion to the tissues is thereby minimised.

6 watts of energy was selected for the SSV. In each case, the glass tip is welded to the fibre and has the same diameter as the fibre itself.

Access to the vein was achieved via a 16G intravenous cannula for the 400 µm probe and a 14G intravenous cannula for the 600 µm probe. It was not necessary to use a sheath.

All laser treatments of the GSV and SSV were carried out under tumescent local anaesthesia (TLA). SR was treated under general anaesthetic without TLA in 88 % of the cases, and under TLA in 12 %.

The procedure consisted of endovenous ablation of the saphenofemoral junction (SFJ) or saphenopopliteal junction (SPJ) by placing the laser fibre close to the opening, and also treating the anterior or posterior accessory saphenous veins (if the diameter of the vessel allowed the appropriate puncture). In addition to the thermal treatment, foam sclerotherapy of the tributary varicose veins was also performed in 89.8 % of cases, and 25.3 % of the patients had a mini-phlebectomy.

All cohorts were given postoperative thromboprophylaxis with low molecular weight heparin (LMWH) for six days. Six patients were already on anticoagulants beforehand, and this treatment was continued. The thromboprophylaxis was prolonged for 10–30 days if there were any risk factors for deep vein thrombosis (DVT), e. g. if there was a past history of DVT, if the patient was taking oestrogens or was known to have thrombophilia. This applied to 17 patients.

Clinical and duplex ultrasound follow-up examinations were carried out after 10–14 days (visit 2) and after 3 months (visit 3). All patients attended after 10–14 days (visit 2) but only 95.2 % came for visit 3. On the basis of the history, patient satisfaction was assessed using a six-point scale (1 = excellent, 6 = very poor). In addition, the duration of analgesic use and the number of days of sick leave were documented. The clinical examination recorded the VCSS and the presence of bruising, hyperpigmentation or neurological deficits (e. g. paraesthesia/dysaesthesia). Statistical analysis of the VCSS was carried out with the Kruskal Wallis chi-squared test.

Duplex ultrasonography was used to evaluate treatment success, i. e. the distance of the proximal part of the occluded veins from the SFJ. In addition, the occurrence of post-ablation thrombus extension (PATE) and DVT were ruled out. The PATE class is based on the post-ablation superficial thrombus extension (PASTE) and endovenous heat induced thrombosis EHIT classifications [7]:

- PATE 0: thrombus extends to the deep vein (= planar occlusion = desired therapeutic success)
- PATE I: thrombus extends a few millimetres into the deep vein, with partial obstruction of the lumen up to 25 %
- PATE II: thrombus extends into the deep vein, with partial obstruction of the lumen up to a maximum of 50 %
- PATE III: partial obstruction of the lumen > 50 %
- PATE IV: complete obstruction of the deep vein

All patients enrolled in the study gave their written consent to the use of their data.

Results

GSV group

All GSVs treated by thermal ablation (n = 76) were occluded at visit 2 and visit 3. Hyperpigmentation was seen in 9.6 % up to visit 3. Bruising in the treated area was diagnosed in 11.8 % at visit 2: this had regressed by visit 3 in all cases. Sensory disorders occurred in 6.6 %, falling to 1.4 % by visit 3. PATE II was determined in one case (1.4 %) at visit 2; the findings were normal again after treatment with LMWH for 20 days. There were no cases of DVT. The mean duration of sick leave was 1.59 days and postoperative analgesia was taken for 0.37 days. The mean VCSS improved significantly from 6.22 preoperatively to 2.07 after 3 months ($p < 0.05$).

SSV group

All treated SSVs (n = 65) were occluded at visit 2 and visit 3. Bruising was seen in two cases (3.1 %) at visit 2: this had regressed in both cases by visit 3. Hyperpigmentation was seen in two cases at visit 3 (3.1 %). Sensory disorders were present in five cases (7.69 %) at visit 2, falling to four patients (6.15 %) at visit 3. There were no cases of PATE or DVT. The mean duration of sick leave was 0.97 days and postoperative analgesia was taken for 0.45 days. The mean VCSS improved significantly from 6.54 preoperatively to 1.41 after 3 months ($p < 0.05$).

Recurrent saphenofemoral incompetence (SR) group

Occlusion of the GSV stump was found in 96 % at visit 2. In one case (4 %) there was only partial occlusion with reflux. After 3 months, 80 % of the GSV stumps were closed: one case (4 %) showed only partial occlusion without reflux, three cases (12 %) were partially occluded with reflux, and one case (4 %) had a fully recanalised GSV stump with reflux. There was no correlation between the diameter or length of the stump and treatment failure. Nor was there any relationship between the anticoagulation and the occlusion rate. There were no cases of DVT and one patient (4 %) had PATE II. The apposition thrombus regressed completely after treatment with rivaroxaban 20 mg daily for 28 days. The mean duration of sick leave was 3.16 days, postoperative analgesia was taken for 0.64 days. The mean VCSS improved significantly from 6.48 preoperatively to 1.75 after 3 months ($p < 0.05$).

Discussion

Treatment of the GSV with the ETQ 360° FUSED Fiber from Endoteq™ showed 100 % occlusion after three months with a good safety profile. Pannier et al. 2011 had already reported similarly good outcomes with the 1470 nm radial laser from Biolitec™. Using a considerably higher energy density of 90.8 J/cm to treat 50 GSVs, they showed an occlusion rate of 100 % after 6 months. Serious complications such as DVT did not occur in this study either, although it showed a slightly higher rate of sensory disturbances (6 %). In our study, sensory disorders occurred in only 1.4 % after three months. This suggests that the lower energy when the ETQ 360° FUSED Fiber is used may reduce the occurrence of adverse effects such as sensory disorders. The occlusion rates are comparable to those after using fibres with higher energy densities.

A meta-analysis by Boersma et al. 2016 [1] on the endovenous treatment of the SSV with EVLA found an occlusion rate of 98.5 % in 2950 cases from a total of 28 studies. Sensory disorders were reported by 4.8 % of patients. Samuel et al. 2013 [6] reported an occlusion rate of 96.2 % after one year in 53 SSVs treated with EVLA. With the ETQ 360° FUSED Fiber™, we achieved an occlusion rate of 100 % after three months. Sensory disorders occurred in 6.15 % of cases. Taking the short follow-up period into account, our results are similar to those of Borsma et al. and Samuel et al. Overall, we achieved high patient satisfaction, and the time off work lasted only a few days.

Open redo surgery for recurrent saphenofemoral incompetence with a long residual GSV stump is demanding because of the presence of scar tissue and is associated with an increased surgical risk. In a search of PubMed, we did not find any comparative studies on the treatment of pure recurrent SFJ incompetence with EVLA. Publications on EVLA to treat recurrent varicose veins are related to residual trunk segments of the GSV or SSV [3].

The results of this study with an SR occlusion rate of 80 % after 3 months without any serious complications are very promising. The length of the treated GSV stumps was between 0.8 cm and 3.5 cm (mean 1.66 cm). A mean specific energy of 168 J/cm was used. 80 % of the patients said that they had no pain from the EVLA treatment. Our experience indicates the safety and effectiveness of EVLA in the treatment of recurrent saphenofemoral incompetence in GSV stumps.

A surgeon experienced in duplex-guided puncture and positioning of the laser fibre in the GSV stump at the SFJ is prerequisite for treating cases of recurrent saphenofemoral incompetence.

Comparisons in the current literature show similar occlusion rates for EVLA and RFA. The use of RFA is, however, associated with less periprocedural pain and less need for analgesics than conventional surgery or EVLA [9, 10].

In summary, the ETQ 360° FUSED Fiber from Endoteq™ achieves reliable occlusion of the SSV and GSV. This is associated with a low incidence of serious complications such as DVT. By using 6 Watts and a specific energy of 45.3 J/cm we did, however, expect a significant reduction in sensory disorders, especially when treating the SSV. The clinical follow-up one year after the procedure will clarify the reversibility of the sensory disorders in the treated segments. However, we did not demonstrate a distinct advantage of the ETQ 360° FUSED Fiber over frequently used probes with a beam angle of 80°.

We will also have to wait for the 12-month follow-up to see how many cases in each group have developed a long GSV or SSV stump with a possibly increased risk of recurrence.

Conflict of interest

The study was part-financed by Endoteq.

References

[1] Boersma D, Kornmann VN, van Eekeren RR, et al. Treatment Modalities for Small Saphenous Vein Insufficiency: Systematic Review and Meta-analysis. J Endovasc Ther 2016; 23 (1): 199–211

[2] Goldman MP, Mauricio M, Rao J. Intravascular 1320-nm laser closure of the great saphenous vein: a 6– to 12-month follow-up study. Dermatol Surg 2004; 30 (11):1380–1385

[3] Nwaejike N, Srodon PD, Kyriakides C. Endovenous laser ablation for the treatment of recurrent varicose vein disease--a single centre experience. Int J Surg 2010; 8 (4):299–301

[4] Pannier F, Rabe E, Maurins U. First results with a new 1470-nm diode laser for endovenous ablation of incompetent saphenous veins. Phlebology 2009; 24 (1): 26–30

[5] Pannier F, Rabe E, Rits J et al. Endovenous laser ablation of great saphenous veins using a 1470 nm diode laser and the radial fibre – follow-up after six months. Phlebology 201; 26 (1): 35–9

[6] Samuel N, Carradice D, Wallace T et al. Randomized clinical trial of endovenous laser ablation versus conventional surgery for small saphenous varicose veins. Ann Surg 2013; 257 (3): 419–26

[7] Schäffer N, Weingard I, Schuler L et al. Appositionsthrombus als Komplikation endovenöser Katheterverfahren (Post ablation thrombus extension (PATE)). Phlebologie 2018; 47 (02): 93–101

[8] von Hodenberg E, Zerweck C, Knittel M et al. Endovenous laser ablation of varicose veins with the 1470 nm diode laser using a radial fiber – 1-year follow-up. Phlebology 2015; 30 (2): 86–90

[9] Nordon IM, Hinchliffe RJ, Brar Ret al. A prospective double-blind randomized controlled trial of radiofrequency versus laser treatment of the great saphenous vein in patients with varicose veins. Ann Surg 2011; 254 (6): 876–8

[10] Hinchliffe RJ, Ubhi J, Beech A et al. A prospective randomised controlled trial of VNUS closure versus surgery for the treatment of recurrent long saphenous varicose veins. Eur J Vasc Endovasc Surg 2006; 31 (2): 212–8