Accepted: 16 November 2021

DOI: 10.1002/lsm.23500

CLINICAL REPORT

Safety and efficacy of endovenous laser ablation (EVLA) using 1940 nm and radial emitting fiber: 3-year results of a prospective, non-randomized study and comparison with 1470 nm

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Abstract

Objectives: To evaluate the safety, efficacy and ≥36 months outcomes of endovenous laser ablation (EVLA) by means of 1940 nm laser with radial fiber for the treatment of truncal vein insufficiency and compare the results to a historical cohort, obtained via reviewing the literature.

Methods: This prospective, non-randomized, single-center clinical study included 139 consecutive patients with 177 incompetent great saphenous (GSV, $n = 135$) and short saphenous veins (SSV, $n = 42$). The maximum laser power (Pmax. 10 W) and pullback velocity were adjusted individually ($V_{max} = 1$ mm/s). The laser fiber was placed at the junction to the deep vein under duplex monitoring. Simultaneous phlebectomies were performed on all the patients. Regular follow up with clinical and duplex ultrasound examination (DUS) were carried out postoperatively at 1 month (1 M), 6 months (6 M), 12 months (12 M), 24 months (24 M), 36 months, and after that (≥36 M). The results were compared with three cohorts (total 616 EVLA procedures with 1470 nm laser and radial fiber) from literature (criteria: >100 procedures, follow-up of ≥2 years).

Results: The follow-up rate was 100%, 91%, 73%, 48%, and 23% of the truncal veins at 1, 6, 12, 24, and ≥36 M, respectively. In comparison to the literature using 1470, a lower average linear endovenous energy density (LEED) (53 vs. 77–82 J/cm) resulted in 100% (6 M) and 96.5% (24 M) occlusion rates, reduced local ecchymosis (2.2% vs. 3.2%–18.7%) and reduced average postoperative pain levels (1.3 vs. 2.18). Regarding adverse events, induration (1.1% vs. 1.8%), skin burns (0% vs. 0.45%), endovenous heat-induced thrombus propagation (EHIT) in the deep veins (2.3% vs. 1.8%) and laser-induced persistent paresthesia (2.2% vs. 0.5%–2.9%) were comparable. Recanalizations observed in this study (GSV 0, SSV 3) were asymptomatic and required no treatment. At ≥36 M reflux in the accessory veins was observed in 5% versus 10.5% of patients. Reintervention was required in none (0% vs. 21%). At >36 M, short average stump lengths of 1 cm (GSV) and 0.3 cm (SSV) were observed.

Conclusion: EVLA with 1940 nm laser with radial emitting fiber is as safe and effective as 1470 nm laser for the treatment of truncal vein insufficiency. Lower postoperative pain, low analgesic requirements, short convalescence add to patients' comfort. EVLA with 1940 nm laser-guided by intraoperative DUS permits reproducible placement of the radial fiber at the saphenofemoral and saphenopopliteal junction, enabling further studies to assess the effect of shorter stump length on patterns and frequency of recurrence without increased risk of EHIT.

KEYWORDS

1940 nm laser, EVLA, truncal vein insufficiency, Thulium laser, varicose veins

INTRODUCTION

The current spectrum of therapeutic options for incompetent truncal veins varies from open surgical crossectomy and stripping to the minimally invasive endovenous thermal and non-thermal occlusion techniques. The past years witnessed lots of studies comparing the different modalities.[1–3] As a result, the endovenous thermal ablation with radiofrequency (RFA) or laser (EVLA) have been proved to be safe and effective.[1–3] Currently, the American Venous Forum (AVF), the National Institute for Health and Care Excellence (NICE), and the European Society of Vascular Surgery (ESVS) guidelines recommend endovenous thermal ablation as the first choice of treatment of incompetent truncal veins.[4–6] Experimental models and clinical studies showed that EVLA with a laser emitting at wavelengths of 800–980 nm and bare fiber application can cause perforation of the treated vein, leading to pain, ecchymosis, and/or nerve damage.[7,8] Analysis of the absorption spectrum of water reveals that wavelengths longer than 1300 nm showed a higher absorption coefficient in water and reduced hemoglobin absorption.[9] That is why the contemporary choice of practice for EVLA is using a longer wavelength laser (predominantly 1470 nm laser) with radial emitting fiber technology.[10,11] Further analysis of the absorption coefficient in water beyond 1470 nm reveals a second local absorption maximum at around 1940 nm with the absorption coefficient in water for 1940 nm being greater than 980 and 1470 nm (Figure 1).[9,10,12] This implies that that EVLA with 1940 nm would require lesser energy to achieve the desired occlusion of the vein with even lower complication rates.

After experimental evaluation of 1940 nm wavelength for EVLA in the bovine foot model,[13] this wavelength is systematically used in a clinical setting for the treatment of varicose veins. The clinical application of this wavelength showed promising immediate outcomes, with 100% early occlusion rates and few complications.[14] This study aims to evaluate and establish the short- and mid-term (0–36 months) safety, efficacy, and effects on patients' comfort of this innovative EVLA 1940 nm wavelength with regular follow-ups planned for up to 10 years and compare the results to the currently available literature for EVLA using 1470 nm Laser and radial fiber as a benchmark.

MATERIALS AND METHODS

This prospective, single-arm, single-center, non-randomized, observational study (approved by the ethics committee of Diakonie-Klinikum Schwaebisch Hall and University Heidelberg) involved 177 consecutive EVLA procedures in 139 patients, between June 2013 and December 2014. Written consent was obtained from all patients before enrollment into the study. The inclusion criteria were set as age >18 years, incompetency of great saphenous veins (GSV) or small saphenous veins (SSV), and diameter of truncal vein ≤15 mm. Patients suffering from or with a history of thrombophlebitis of the GSV or SSV, deep vein thrombosis, history of previous varicose vein surgery, and not willing to take part in the study were excluded. Patient demographics, CEAP Classification,[15] Venous Clinical Severity Score (VCSS),[16] preoperative and postoperative duplex ultrasound examination (DUS) findings, perioperative details, and all adverse events and complications were recorded and compiled in a homemade standardized tabular form (Microsoft Excel). The generic or disease-specific quality of life was not measured. Board-certified vascular surgeons performed the standardized preoperative and postoperative ultrasound examinations in a standing position (LogiQ S8; GE Healthcare). Reflux was defined as a retrograde flow for more than 500 milliseconds on provocation. Additionally, the transverse outer diameters of the truncal veins at 7 (designated G1–G7 in

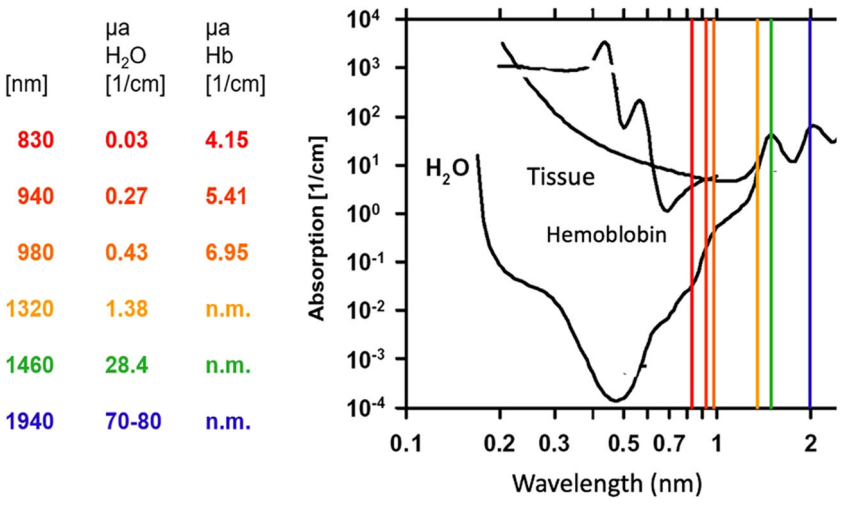

FIGURE 1 Absorption of laser energy from various laser wavelengths by water.[9,10] μa H_2O, coefficient of absorption in water; μa Hb, coefficient of absorption in hemoglobin

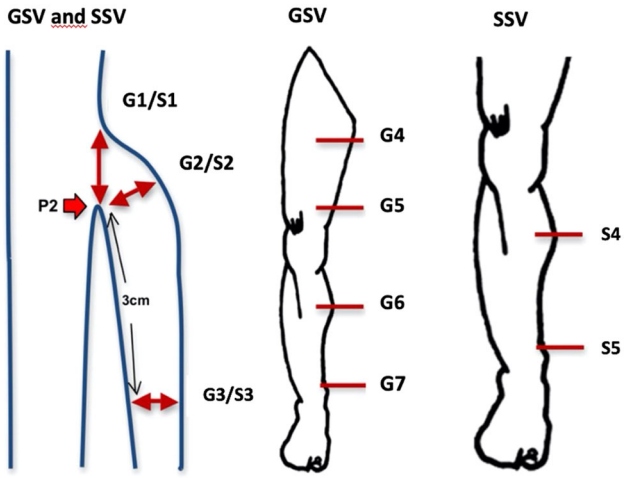

FIGURE 2 Measured outer diameters of the great and the small saphenous vein (GSV, SSV). G1, Outer diameter of GSV at the junction with the deep vein. G2, Outer diameter of GSV measured from distal ostial point (P2) at saphenofemoral junction (SFJ), perpendicular to the vessel lumen. G3, Outer diameter of GSV 3 cm peripheral to the junction to the deep vein. G4, Outer vein-diameter at the level of the perineum for GSV. G5, Outer vein-diameter at the upper border of Patella for GSV. G6, Outer vein-diameter at the level of the tibial tuberosity for GSV. G7, Outer vein-diameter proximal to the medial malleolus for GSV. S1, Outer diameter of SSV at the junction with the deep vein. S2, Outer diameter of SSV measured from distal ostial point (P2) at saphenopopliteal junction (SPJ). S3, Outer diameter of SSV 3 cm peripheral to the junction to the deep vein. S4, Outer vein-diameter at the level of the tibial tuberosity for SSV. S5, Outer vein-diameter proximal to the medial malleolus for SSV

case of GSV) and 5 (designated S1–S5 in case of SSV) predefined points were recorded (Figure 2).

EVLA procedure

EVLA was carried out by means of Thulium-Fiber-Laser (Vela XL; Starmedtec GmbH) emitting at 1940 nm in continuous mode and a radial fiber (Saturn Side Fiber, 600 µm Radial fiber, Light Guide Optics, LGO). The entire EVLA procedure was performed in spinal ($n = 82$) or general anesthesia ($n = 90$) with tumescence or only tumescence anesthesia ($n = 5$) under DUS guidance (LogiQ e; GE Healthcare). The introducer sheath (6 F) was positioned in the vein in Seldinger's technique in the anti-Trendelenburg position. The usual puncture site was distal to the incompetent vein segment. Based on our comprehensive clinical and experimental experience with EVLA using radial fiber and the assumption that shorter Stump length could mean low reoccurrence, we carefully placed the catheter exactly at the distal ostial point (P2) (Figure 3a) at the saphenofemoral (SFJ) or saphenopopliteal junction (SPJ). Finally, perivenous tumescence was injected with a tumescence pump along the whole length of the vein. EVLA was performed in Trendelenburg position after final verification of correct fiber position. Intraoperative monitoring with DUS showed signs of thermal activity and ablation of the vein, where thickening of the vein wall, luminal echogenicity, and incompressibility can be realized. Adjunct procedures (phlebectomies, ligature of perforator veins, high ligation, stripping) were performed if deemed necessary. Postoperative class III compression stockings for 24 hours and class II for a minimum duration of 2 weeks were mandatory in all patients. All patients received low molecular weight heparin for postoperative thromboprophylaxis for 5 days. Analgesic (Ibuprofen 600 mg/dose) were administered orally on patients' request.

EVLA dosimetry

The maximum pullback velocity was 1 mm/s (continuous) and was realized manually, with the help of markings on the laser fiber and paying attention to a metronome set to 1 beat/s. A reduced pullback velocity resulted in an increased thermal effect, visible in the simultaneously performed ultrasound. The minimum power of the laser system was set to 3-W and this was increased proportionally to the vein diameter (1 W for every mm of vein diameter, max. 10 W), to achieve the required linear endovenous energy density (LEED).[8]

EVLA documentation

The operative procedural details like type of anesthesia, adjunct procedures, length of the treated vein, volume of the tumescence, laser power (W), pullback velocity (mm/s), and LEED (J/cm) were documented on a homemade standardized protocol.

Follow-up clinical examinations and DUS were carried out postoperatively at 1 month (1 M), 6 months (6 M), 12 months (12 M), 24 months (24 M), 36 months (36 M), and yearly after that till January 2021. The patients followed up after 3 years were grouped together as >36 M. The postoperative DUS included two additional measurements; non-occlusion distance (NOD) and the deep vein thrombus distance (DVTD). NOD which represents the longest stump length was defined as the maximum distance between the SFJ/SPJ (P1) and the most peripheral part of the non-occluded vein stump (Figure 3). DVTD was defined as the shortest distance between the SFJ/SPJ (P2) and thermal-induced occlusion or endovenous heat-induced thrombus (EHIT[17]) (Figure 3). Non-occlusion was defined as compressibility of an EVLA treated vein segment with reflux after provocation within 1 week postoperatively. Vein-recanalization was defined when a segment of an initially occluded vein was compressible with reflux. This was classified as central when the recanalized vein segment was connected to SFJ or SPJ or peripheral or complete.

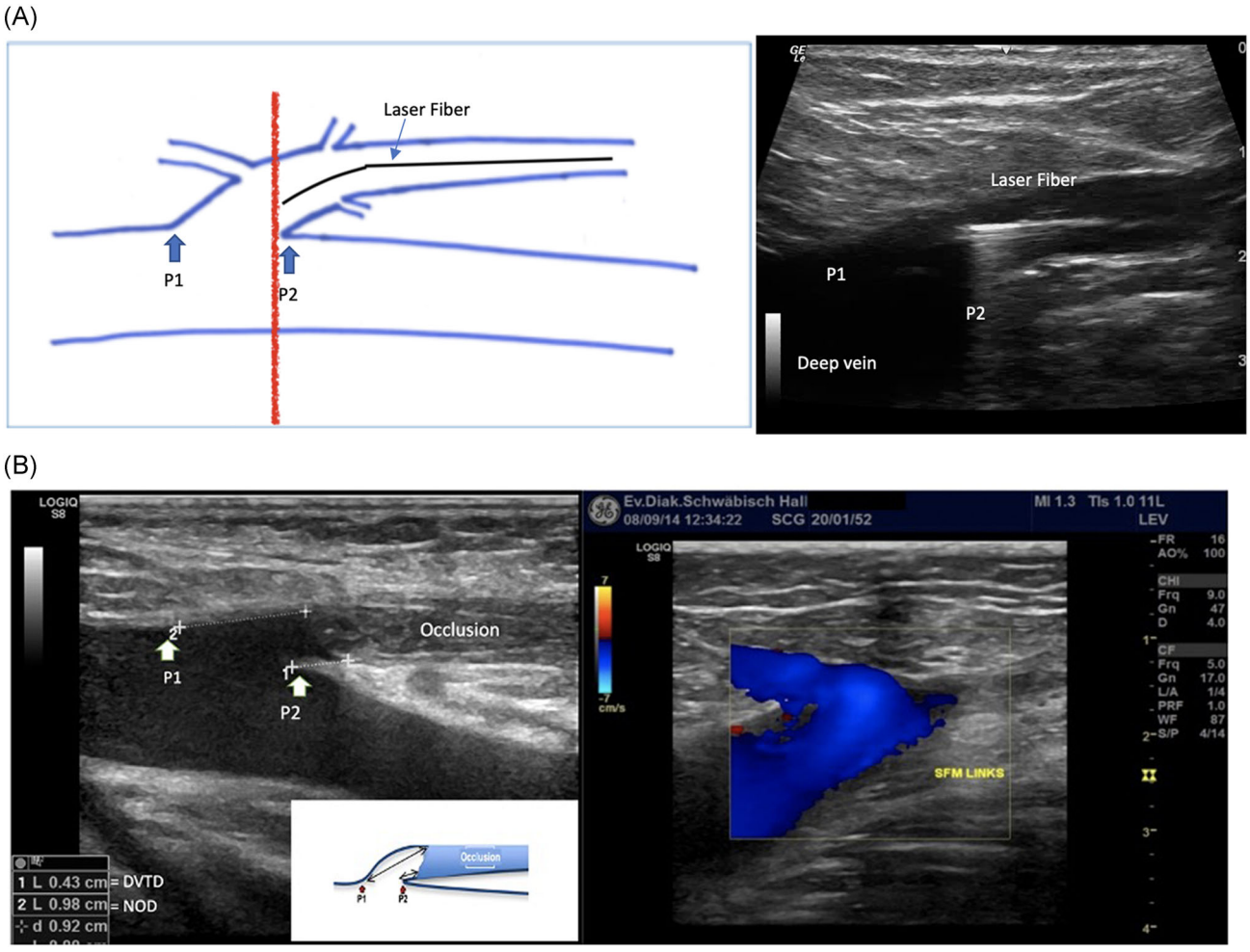

FIGURE 3 (A) Placement of the laser fiber at the distal ostial point (P2) at the saphenofemoral (SFJ) or saphenopopliteal junction (SPJ). After placement, tumescence anesthesia was infiltrated. (B) Left, Postoperative ultrasound demonstrating stump length or non-occlusion distance (NOD: measurement 2) and the deep vein thrombus distance (DVTD). (B) Right, Postoperative ultrasound demonstrating an ideal NOD of <3 cm and thrombosed GSV with a decreased diameter as compared to the non-occluded vein segment with blood flow. P1, the proximal ostial point at saphenofemoral junction (SFJ) or saphenopopliteal junction (SPJ). P2, the distal ostial point at SFJ/SPJ

Evaluation

The procedure was evaluated for its efficacy, safety, and patients' comfort. The parameters to evaluate the efficacy of the procedures were: elimination of reflux, reduction in the vein diameter, stump length (NOD), and absence of vein-recanalization and neo-reflux in accessory veins as seen during follow-up DUS. The results of EVLA were divided into three color-coded categories. Green (Cat1); included asymptomatic patients with appropriate occlusion of the treated vein, without recanalization and without any neo-reflux in the accessory veins. Yellow (Cat2); included symptomatic (Cat2s) or asymptomatic (Cat2a) with neo-reflux in accessory veins, in connection to the treated truncal vein. Red (Cat3); included EVLA failures, symptomatic (Cat3s) or asymptomatic (Cat3a) patients with recanalization of the previously occluded truncal vein. Patients with disease progression were not included in this categorization and were documented separately.

The safety profile was assessed by the absence of thrombus propagation in the deep veins (EHIT[17]), length of DVTD, and absence of postoperative complications. The grades of EHIT were documented according to the Kabnick Classification. Paresthesia was defined as laser-induced paresthesia (LIP), occurring along the course of the vein or in the region innervated by the saphenous or the sural nerve, and mechanical induced paresthesia (MIP), occurring in areas of phlebectomies.

For assessment of patients' comfort and quality of life VCSS, analgesia requirement, and time required to return to normal daily activities were documented. Postoperative pain was scored 0-10 on the numerical analog scale (NAS).

Comparison with a historical cohort

Inclusion criteria were set to; studies (randomized and non-randomized) reporting >100 EVLA procedures on truncal veins with 1470 nm laser with radial fiber and a follow-up of ≥2 years. A literature search in Medline on February 3, 2021, with keywords; "varicose veins" and "1470 nm" revealed 56 articles (since 2009). Other keywords "radial," "EVLA" were used separately and in combination with "1470 nm" to search for further relevant articles. A critical analysis of the abstracts revealed 3 publications matching the inclusion criteria[18–20] and a total of 616 EVLA procedures in 576 patients. The described results of these historical cohorts were compared in the discussion section to the here presented 1940 nm-EVLA-group in terms of procedural details, complications, reoccurrence, and occlusion rates.

Statistical analysis

Mean values were calculated using Microsoft Excel. Analysis of variance for repeated measures, *t* test, and Fischer exact test were used to determine the statistical significance, and a $p < 0.05$ was considered to be statistically significant.

RESULTS AND FOLLOW-UP

The patients' demographics, CEAP Classification are listed in Table 1. The follow-up results are summarized in Tables 2a and 2b and compared to 1470 nm literature data in Tables 3a–3c. The average length of treated GSV ($n = 135$) was 50.4 cm (17–89 cm) and SSV ($n = 42$) was 23.9 cm (10–44 cm) with an employed average LEED of 59.2 J/cm for GSV and 47.9 J/cm for SSV. Mini-Incision Phlebectomies were performed in all the patients. The average incisions above the knee were 2 (range 1–10) and below the knee were 7 (0–30).

Early postop results

Mild ecchymosis was seen at the puncture points for the tumescence anesthesia. In four patients (2.2%) moderate ecchymosis was observed. Two patients developed circumscribed lower leg lymphocele, because of the phlebectomies. No other local complications like skin burns (0%), varicophlebitis (0%) were observed. Thrombus propagation (EHIT) was diagnosed within the first postoperative week in four extremities (2.3%; all Grade 2) and was treated with parenteral/oral therapeutic anticoagulation for 4 weeks. Deep vein thrombosis (0%) or pulmonary embolism (0%) was not observed in any of the patients. Complete resolution of thrombus propagation occurred by no later than 4 weeks, without any consequence or damage to the deep veins. This was confirmed by DUS and the anticoagulation was discontinued subsequently. Patients reported low postoperative pain levels (average postop pain levels 1.3). Most of the patients could resume normal daily bodily activities the next day after the procedure. The average days to return to work was 4 days (range 0–21 days).

TABLE 1 Patients' characteristics (mean; range) and CEAP classification

	Females	Males	Total
Number (Percentage)	85 (61%)	54 (39%)	139 (100%)
BMI (kg/m^2)	25.9 (18.9–43.9)	27.2 (23.7–33)	26.4 (18.9–43.9)
Mean age in years (range)	55 (25–90)	56 (23–85)	56 (23–90)
Preoperative VCSS Score	6 (2–21)	6 (4–18)	6 (2–21)
CEAP Classification of number (percentage) of veins of females, males, total respectively.			
C1	0	0	0
C2	14 (13.1)	9 (12.9)	23 (13)
C3	65 (60.7)	21 (30.0)	86 (48.6)
C4	14 (13.1)	28 (40.0)	42 (23.7)
C5	1 (0.9)	7 (10.0)	8 (4.5)
C6	13 (12.2)	5 (7.1)	18 (10.2)
Total veins treated	107 (100)	70 (100)	177 (100)

Abbreviations: BMI, body mass index; VCSS, Venous Clinical Severity Score.

Midterm postoperative results

A significant postoperative improvement in the VCSS ($p < 0.05$) was observed throughout the follow-up period (Tables 1, 2a, and 2b). All patients with LIP and MIP were followed up yearly. Patients that could not attend the follow-up visits were interviewed telephonically and didn't account for the actual follow-up rate (Tables 2a and 2b). LIP and MIP regressed with time in 63.6% (7/11) and 66.7% (12/18) extremities respectively. Persistent LIP was present in 2.2% and persistent MIP in 3.4% of extremities. EVLA failures (Cat3a) observed in 2 (1.5%) and 3 (3.5%) patients at 12 and 24 M, respectively, were asymptomatic and occurred in the SSV with partial peripheral recanalization and segmental reflux. No recanalizations were observed in the GSV. Symptomatic neo-reflux (Cat2a: 5%) was observed only in the anterior accessory saphenous vein (AASV).

TABLE 2a Follow-up results (Clinical and duplex ultrasound findings)

	1 M	6 M	12 M	24 M	>36 M
Follow-up rate[a]	100% (177/177)	91% (161/177)	72.8% (129/177)	48% (85/177)	23% (40/177)
Follow-up rate[a] (Patients)	100% (139/139)	89,9% (125/139)	76.3% (106/139)	46% (64/139)	22.3% (31/139)
Occlusion rates	100% (177/177)	100% (161/161)	98.5% (127/129)	96.5% (82/85)	100%[b] (40/40)
Green (Cat 1)	177/177 (100%)	161/161 (100%)	127/129 (98.5%)	78/85 (92%)	38/40 (95%)
Yellow (Cat 2)	0	0	0	4/85 (4.7%)	2/40 (5%)
Red (Cat 3)	0	0	2/129 (1.5%)	3/85 (3.5%)	0
NOD/Stump length GSV (cm)	0.6 (0–3.8)	0.7 (0–2)	0.7 (0–3.2)	0.8 (0–4)	1 (0-3.5)
NOD/Stump length SSV (cm)	0.3 (0–1.9)	0.4 (0–2.8)	0.2 (0–1.0)	0.3 (0–2)	0.3 (0-1.5)
DVTD GSV (cm)	0.4 (0–3.3)	0.4 (0–2)	0.5 (0–2.5)	0.5 (0–3.5)	0.7 (0-2.5)
DVTD SSV (cm)	0.2 (0–1.4)	0.3 (0–3.1)	0.1 (0–0.7)	0.3 (0–1.8)	0.3 (0-1.7)
VCSS	4 (0–13)	2 (0–21)	2 (0–10)	1 (0–4)	2 (0-6)

Abbreviations: DVTD, deep vein thrombus distance; GSV, great saphenous vein; NOD, non-occlusion distance; SSV, small saphenous vein; VCSS, Venous Clinical Severity Score.

[a]Clinical and DUS follow-up rate.

[b]Increase in the occlusion rates was caused by patients lost to follow-up.

TABLE 2b Follow-up results (postoperative complications)

	1 M	6 M	12 M	24 M	>36 M
Wound infection	0	0	0	0	0
Ecchymosis	4/177	0	0	0	0
Skin discoloration	1.1% (2/177)	1.2% (2/161)	0	0	0
Postoperative pain intensity (NAS)	1.3 (range 1–3)	0	0	0	0
Avg. doses of oral analgesics	1.8 (1–10)	0	0	0	0
EHIT	4 (2.3%)	0	0	0	0
Persistent LIP (*n*)[a]	6.2% (11)	3.9% (7)	2.8% (5)	2.2% (4)	2.2% (4)
MIP[a]	10.2% (18)	6.2% (11)	4.5% (8)	4.5% (8)	3.4% (6)

Abbreviations: EHIT, endovenous heat-induced thrombus; LIP, laser-induced paresthesia; MIP, mechanical-induced paresthesia; NAS, Numerical Analogue Scale.

[a]All patients with LIPs and MIPs were followed-up yearly (at least telephonically) and the rate of persistent paresthesia was calculated from total EVLA procedures.

Fate of the truncal vein

A progressive, statistically significant ($p < 0.05$) gradual reduction in the diameters of both GSV and SSV throughout the follow-up period could be observed (Figure 4 and Table 4). This reduction was drastic within the first 4 weeks with significant changes occurring throughout the follow-up period. Ultrasound examination revealed complete disappearance (resorption) of segments of the treated veins. For example, at 12 M the GSV 3 cm peripheral to the SFJ (G3) could not be identified in 75% of cases. The average diameters G1 and G2 showed a slight increase from 12 to 24 M. This was statistically not significant. A slight, statistically insignificant increase in the average stump length (NOD) was observed over the follow-up period (Tables 2a and 2b).

DISCUSSION

EVLA using radial fiber aims at causing homogenous thermal damage, denaturation of proteins, vacuolization, and shrinkage of the vein.[21,22] This causes occlusion of the vein and elimination of reflux, resulting in resorption of the damaged vein, as seen in DUS in many patients. Ever since EVLA was introduced, research has been carried out to improve its efficacy, safety, and patients'

TABLE 3a Summary of literature review and comparison of studies' and patients' characteristics[18–20]

	Lawson et al.[18]	Pavei et al.[19]	Jibiki et al.[20]	Setia et al. (Current Study)
Wavelength and Fiber type	1470 nm	1470 nm	1470 nm	1940 nm
	Radial	Radial	Radial	Radial
Study type	Prospective, non-randomized	Cross-sectional study	Retrospective, non-randomized	Prospective, non-randomized, observational.
Comparison group	EVLA vs. RFA	None	EVLA vs. Stripping	Historical Cohort
Follow-up (in Months)	60 M	114 M	24 M	>36 M
EVLA procedures (patients)	171 (153)	225 (203)	220 (220)	177 (139)
GSV:SSV	171:0	183:42	197:23	135:42
Procedures in Females	76% (GSV + SSV)	73% (GSV)	NS	61% GSV + SSV)
		74% (SSV)		

Abbreviations: EVLA, endovenous laser ablation; GSV, great saphenous vein; NS, not specified; RFA, radiofrequency ablation; SSV, small saphenous vein.

TABLE 3b Summary of literature review and comparison of the intraoperative details of the studies[18–20]

	Lawson et al.[18]	Pavei et al.[19]	Jibiki et al.[20]	Setia et al.
Adjunct procedures	0	0	Selective	Phlebectomies ($n = 177$)
Preoperative VCSS	4.04 (GSV + SSV)	6.3 (GSV)	NS	6 (GSV + SSV)
		5.4 (SSV)		
Average preoperative D1 (in mm)	NS	12 (SFJ)	7.3 (SFJ + SPJ)	8.3 (SFJ)
		10 (SPJ)		6.4 (SPJ)
Anesthesia type	TA	NS	GA + TA	TA ± GA
Average tumescence	NS	NS	300–500 ml	6.4 ml/cm (GSV)
				8.9 ml/cm (SSV)
Intraoperative duplex monitoring	NS	NS	NS	Yes
Catheter Position from SFJ/SPJ	1.5–2 cm	NS	2 cm	At SFJ/SPJ
Pullback	Continuous	NS	Continuous	Continuous (max. 1 mm/s)
Laser power	10 W	Variable (1 W/mm vein D)	10 W	Variable (1 W/mm vein D)
Average LEED (cumulative)	80 J/cm	NS	77 J/cm	53 J/cm
Average LEED (GSV)	NS	82 J/cm	NS	59.2 J/cm
Average LEED (SSV)	NS	93 J/cm	NS	47.9 J/cm

Abbreviations: D1, diameter of the SPJ/SFJ; GA, general anesthesia/spinal anesthesia; GSV, great saphenous vein; LEED, linear endovenous energy density; NS, not specified; SFJ, saphenofemoral junction; SPJ, saphenopopliteal junction; SSV, small saphenous vein; TA, tumescence; VCSS, Venous Clinical Severity Score.

comfort. The current laser systems employ wavelengths in the near-infrared spectrum and depending on their absorption characteristics in tissue chromophores, these can be divided into more hemoglobin absorbing or shorter wavelengths (810, 940, 980, 1064 nm) and more water-absorbing or longer wavelengths (1320 and 1470 nm).[12] The recent trend towards using longer wavelength with radial fiber is supported by numerous experimental and clinical studies and randomized controlled trials, comparing the hemoglobin-targeting to the water-targeting laser systems[3,11,14,23–26] (Table 5). This strategy exhibits lower postoperative complications and similar occlusion rates as compared to the shorter wavelength with bare fiber.[23–25] Based on the results of these exhaustive studies, the German S2K guidelines recommend that longer wavelengths with radial fiber should be used for EVLA.[11]

Ex vivo investigations using the wavelength of 1940 nm in the ox-foot model,[13] a power of up to 6 W resulted in microscopic changes limited predominantly to the intima and media (Figure 5). Bearing these results in mind and the fact that light at 1940 nm wavelength is

TABLE 3c Summary of literature review and comparison of postoperative results and complications of the studies[18–20]

	Lawson et al.[18]	Pavei et al.[19]	Jibiki et al.[20]	Setia et al.
NOD	7.5 mm	NS	NS	7 mm (GSV) 2 mm (SSV)
Thrombus propagation	NS	NS	4/220 (1.8%)	4/177 (2.3%)
Postop pain levels (NAS)	2.18 (1.84–2.53)	NS	NS	1.3 (1–3)
Bruising/Ecchymosis	32 (18.7%)	NS	7 (3.2%)	4 (2.2%)
Induration/Skin Discoloration	NS	NS	4 (1.8%)	2 (1.1%)
Skin burns	NS	NS	1 (0.45%)	None
Varicophlebitis	NS	NS	3 (1.3%)	None
Thrombus propagation	NS	NS	4 (2%)	2 (2.3%)
Temporary LIP	2.3% (4)	NS	NS	3.9% (7)
Permanent LIP	2.9% (5)	0.5% (1)	1% (2)	2.2% (4)
Recanalization (Cat3)	2.9% (5)	0.5% (1)	0.5% (1)	3.5% (3)[a]
Asymptomatic reflux in accessory veins (Cat2a)	9.5% (16)	12.5% (23)	NS	0
Symptomatic reflux in accessory veins (Cat2s)	1.2% (2)	4.9% (9)	NS	5% (2)
Re-Do operations	NS	21%	NS	0%

Abbreviations: D, diameter; GSV, great saphenous vein; LIP, laser-induced paresthesia; NAS, Numerical Analogue Scale; NOD, non-occlusion distance; NS, not specified; SFJ, saphenofemoral junction; SPJ, saphenopopliteal junction; SSV, small saphenous vein.

[a]At 24 M follow-up 3/85 (3.5%). At ≥36 all these patients were lost to follow-up.

being more absorbed in water, EVLA with 1940 nm with a radial fiber would require lesser LEED and lesser energy per cm^2 of surface area as compared to 1470 nm to achieve the desired thermal damage to the vein. The resulting lower optical penetration depth into the tissue, may further diminish the thermal alteration of the perivenous structures and thereby reduce nerve alteration, periprocedural pain, and complication rates. Based on these physical backgrounds, it was logical that EVLA with 1940 nm with radial fiber should be clinically evaluated for its efficacy and safety. A few studies have reported their experiences with laser systems of wavelength >1900 nm in clinical[26] and experimental[21,27] studies. De Araujo et al. compared 1940 and 1470 nm laser in an ex vivo model.[21] They demonstrated that, with similar LEED values, 1940 nm laser caused higher thermal damage to the vein intima, as compared to the 1470 nm laser. Artemov et al. used a 1910 nm-laser system with bare fiber irradiation with increasing power in an animal model.[27] Laser power of 1.5 W (LEED 7,5 J/cm) led to asymmetric, incomplete destruction of the vein and hence recanalization. Using 3 W (LEED 15 J/cm) and 4 W (LEED 20 J/cm) caused more pronounced venous wall damage. Laser power of 3 W lead to minimal changes in the perivenous tissue whereas, 4 W caused vein perforation and pronounced changes in the perivenous tissue. These observations further support the use of radial fiber.

The results of the present single-center, non-randomized, clinical study, were compared to a historical cohort treated with a 1470 nm laser (Table 3a–3c). The patients' characteristics and demographics were similar but the present study comprised more SSV and female patients as compared to the other studies.[18–20] The documentation of the procedural details and the pre-and postoperative results was heterogenous and inconsistent in these studies. The missing parameters were labeled as NS (not specified).

The average length of treated GSV (50.4 cm vs. 39.1 cm[18] vs. 37 cm[19] vs. 33 cm[20]) and SSV (23.9 cm vs. 19 cm[19]) was longer as compared to the literature. Similar to the literature, the present clinical study protocol employed a pullback velocity of a maximum of 1 mm/s, guided by a metronome set at 1 beat/s and the markings on the laser fiber. Although a few research groups have suggested the use of an automatic pullback device to standardize the procedure,[28] manual pullback offers the advantage of varying the pullback speed if necessary and of reacting to the tactile feedback obtained during the procedure. Variation in pullback velocity offers the possibility to react to factors like sticking or segmental increase in vein diameter.

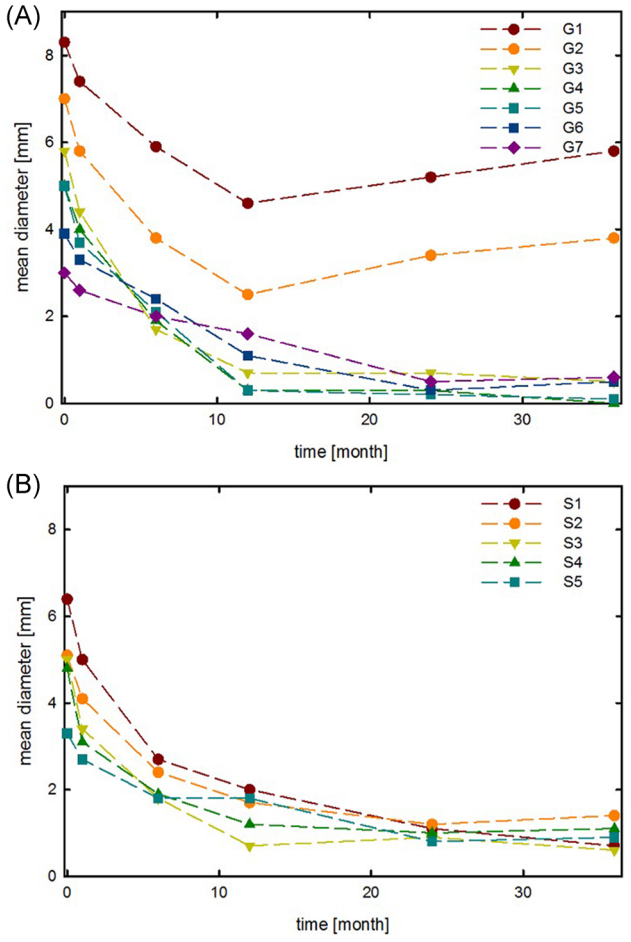

FIGURE 4 (A) Plot of the mean outer diameter (in mm) of the GSV at predefined locations along its course measured preoperatively and during follow-up. (B) Plot of the mean outer diameter (in mm) of the SSV at predefined locations along its course measured preoperatively and during follow-up. GSV, great saphenous vein; SSV, small saphenous vein

The fiber tip was placed 1.5–2 cm away from the junction to the deep vein in the compared studies and only Lawson et al.[18] reported NOD (7.5 mm at 12 M), which was not documented at and after 24 M. In the present study, the use of radial fiber and DUS guidance allowed for improved safety and placement of the catheter tip at the SFJ/SPJ in all the patients. This resulted in a short stump length (NOD) of 7 mm (GSV) and 2 mm (SSV) at 12 M, with a slight insignificant increase to 10 mm (GSV) and 3 mm (SSV) at >36 M. At 24 M 85% of the SSV and 65.6% of the GSV had a NOD < 1 cm. The importance of NOD lies in the fact that the anatomy of the SFJ can influence the development of recurrent varicose veins (RVV) and neo-reflux in the accessory saphenous veins (ASV).[29] The confluence of the accessory saphenous veins and GSV usually lies within 2 cm from the SFJ and a direct confluence of the ASV with the femoral vein is a predictor of RVV.[29] It can be inferred that; a shorter NOD will occlude the confluence of the ASV and GSV resulting in durable EVLA results. One may contemplate that fiber placement at the SPJ/SFJ may increase the rates of thrombus propagation or damage to the deep vein. In contrast, in the above-mentioned study, thrombus propagation was comparable (2.3% vs. NS[18] vs. NS[19] vs. 2%[20]).

Lawson et al.[18] and Jibiki et al.[20] implemented a constant power of 10 W at 1470 nm with continuous pullback throughout the whole length of the vein. The average LEED in these historical cohorts ranged from 77 to 93 J/cm. In the presented study the laser power was adjusted based on the diameter of the treated vein and employed a lower average LEED (GSV 59.2 and SSV 47.9 J/cm).

Based on the fact that the results of EVLA are directly related to the applied thermal energy (LEED),[30] individual adjustment of the dosimetry based on

TABLE 4 Mean outer transverse diameters (range) (in mm) at predefined points along the course of great and small saphenous vein measured preoperatively and during follow-up (Figure 2 and 4)

	Preoperative	1 M	6 M	12 M	24 M	>36 M
G1	8.3 (3.9–14.5)	7.4 (3.0–15.3)	5.9 (0–16.0)	4.6 (0–10.0)	5.2 (0–13.1)	5.8 (0–13.2)
G2	7.0 (3.3–11.3)	5.8 (2.8–9.7)	3.8 (0–16.0)	2.5 (0–10.3)	3.4 (0–11)	3.8 (0–10)
G3	5.8 (3.0–9.9)	4.4 (2.4–8.2)	1.7 (0–7.4)	0.7 (0–5.1)	0.7 (0–5)	0.5 (0–4.1)
G4	5.0 (2.5–10.0)	4.0 (2.4–9.0)	1.9 (0–5.6)	0.3 (0–4.1)	0.3 (0–4)	0 (0–0)
G5	5.0 (2.1–10.1)	3.7 (1.8–7.7)	2.1 (0–6.6)	0.3 (0–3.9)	0.2 (0–4.4)	0.1 (0–3.3)
G6	3.9 (1.7–9.8)	3.3 (1.7–7.4)	2.4 (0–6.9)	1.1 (0–4.5)	0.3 (0–5.1)	0.5 (0–3.1)
G7	3.0 (1.4–5.3)	2.6 (0.2–4.6)	2.0 (0–4.8)	1.6 (0–4.9)	0.5 (0–5.1)	0.6 (0–5.1)
S1	6.4 (3.0–11.0)	5.0 (0.9–10.6)	2.7 (0–7.7)	2.0 (0–6.2)	1.1 (0–5)	0.7 (0–4)
S2	5.1 (2.6–10.0)	4.1 (0.8–7.7)	2.4 (0–5.1)	1.7 (0–5.9)	1.2 (0–5.3)	1.4 (0–5)
S3	5.0 (2.0–9.0)	3.4 (0.8–6.8)	1.8 (0–4.2)	0.7 (0–3.5)	0.9 (0–3.8)	0.6 (0–3.4)
S4	4.8 (2.0–9.5)	3.1 (0–4.7)	1.9 (0–4.4)	1.2 (0–2.6)	1 (0–3.9)	1.1 (0–3.4)
S5	3.3 (1.2–8.3)	2.7 (0–4.9)	1.8 (0–6.3)	1.8 (0–3.3)	0.8 (0–3.9)	0.9 (0–3.9)

TABLE 5 Changing trends in EVLA procedure[3,11,14,23–26]

Protocol	Prior 2006	2009	2013
Wavelength (nm)	800–1320	1470	1940
Pull-velocity (mm/s)	Diverse	1	1
Fiber	Bare fiber	Radial	Radial
Carbonization energy (J)	50	600	1000
Power (W)	15–30	8–12	3–10
Irradiance (W/cm^2)	<10,000	<400	<150
EFE (J/cm^2)	40–100	25–50	<15
LEED (J/cm)	40–80	60–100	40-80
Tissue effect	Carbonized	Cylindrical homogenous coagulation	
Occlusion rate (%)	>90	>95%	−100%
Side effects	Diverse	Pain	Minor

Abbreviations: EFE, endovenous fluence equivalent; EVLA, endovenous laser ablation; LEED, linear endovenous energy density.

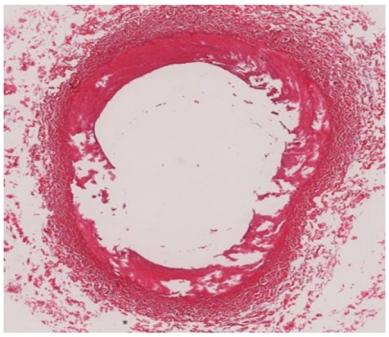

FIGURE 5 Histological changes in the vein wall limited to intima after EVLA with 1940 nm laser and radial emitting fiber application (Ox-Foot).[13] EVLA, endovenous laser ablation

vein-diameters and lower average LEED could explain the lower average postoperative pain levels (1.3 vs. 2.18[18]), ecchymosis (2.2% vs. 18.7%[18] vs. 3.2%[20]) and local complication rates—skin burns (0% vs. 0.45%[20]), varicophlebitis (0% vs. 1.3%[20]) in this study. The German S2k guideline for the treatment of varicose veins recommends a LEED of 60–100 J/cm, when using a 1470 nm wavelength laser.[11] Even though many of the patients in this study received GA and all underwent concomitant phlebectomies, most of the patients could start bodily activities on the next day of the procedure.

Being a frequent complication after phlebectomies, paresthesia was differentiated as LIP or MIP. All the patients with LIP and MIP were followed up yearly, at least telephonically. All the patients developing LIP were treated with LEED > 50 J/cm but a statistically significant relationship between LIP and LEED > 50 J/cm could not be established. This could have been because of the lower number of patients with LIP and could be reduced by further reducing the LEED. LIP was reversible in approximately 2/3 of the patients, caused no morbidity or limitations, and required no specific treatment. Rates of LIP were comparable to the available comparison studies (2.2% vs. 2.9%[18] vs. 0.5%[19] vs. 1%[20]). The differentiation between MIP and LIP mandates a meticulous clinical examination and exact localization which can be time-consuming.

Similar to the literature, true EVLA failures (Cat3) were identified with DUS at and after 12 M and were asymptomatic (Cat3a) requiring no treatment. At ≥36 all these patients were lost to follow-up. EVLA failures or recanalizations observed at 24 M in the present study (Cat3a: 3.5% vs. 2.9%[18] vs. 0.5%[19] vs. 0.5%[20]) occurred only in the course of the SSV. The LEED used in these patients was lower than the average LEED for SSV but a significant relationship between LEED and recanalization could not be established. Neo-reflux (Cat2) was observed in previously competent AASV in 4/85 (4.7%) at 24 M and 2/40 (5%) patients at ≥36 M. Both these patients were symptomatic (Cat2s) and a re-do EVLA for AASV was planned for one of them. No patients required a re-do surgery during the follow-up period (0% vs. 21%[19]). We observed a significant improvement in VCSS and a statistically significant progressive reduction in the diameter of the treated and untreated segments of the vein, caused by effective elimination of reflux. DUS in many patients exhibited complete resorption and disappearance of the vein segments. Such observations in the diameter change have not been made in any of the abovementioned studies.

Meanwhile, a few other research groups have published their experience with EVLA using laser systems with wavelength >1900 nm (Table 4).[14,21,26,30,31] Mendes-Pinto, in their prospective randomized study, reported significantly lesser rates of ecchymosis, induration, paresthesia, lesser pain duration, and reduced analgesic in the 1920 nm-group as compared to the 1470 nm-group.[26] Viarengo et al. reported long-term outcomes of EVLA with 1940 nm laser (average follow-up 803 days).[30] They reported recanalizations in 4.9% and reversible paresthesia in 7.3% of patients. All these observations are in agreement with the present study (Table 6).

LIMITATIONS OF THE STUDY

This is a non-randomized clinical study without an immediate control group. Therefore, a historical cohort has been used as a benchmark to evaluate the results. There is currently little data available for a follow-up period of 36 months or longer. A few patients with LIP and MIP were contacted telephonically, because of the limitations during the COVID-19 pandemic.

TABLE 6 EVLA with 1940: current literature

Author	Year	Wavelength [nm]	Fiber	Procedures (*n*)	Evidence grade
Schmedt et al.[14]	2014	1940 nm	Radial	72	III
De Araujo et al.[21]	2019	1940 nm vs. 1470 nm	Radial	40	IV
Mendes-Pinto et al.[26]	2016	1920 nm vs. 1470 nm	Radial	48	IIa
Artemov et al.[27]	2019	1910 nm	Bare	12	V
Viarengo[30]	2017	1940 nm	Radial	41	III
Park et al.[31]	2019	1940 nm	Bare	160	III

Abbreviations: EVLA, endovenous laser ablation.

SUMMARY

The current study shows that EVLA using a 1940 nm laser system with radial fiber and power levels up to 10 W is effective and safe to treat truncal vein incompetence. Individually adjusted dosimetry (laser power and pull-back velocity) and LEED of 40–60 J/cm, offer equivalent occlusion rates, lower local complication rates, and comparable persistent LIP as compared to EVLA with 1470 nm with radial fiber. Low postoperative pain, low analgesic requirements, short convalescence add to patients' comfort. Intraoperative DUS and radial fiber with 1940 nm Laser enables reproducible placement of the fiber exactly at the SFJ/SPJ, resulting in a short stump length. This enables future studies to evaluate the effects of stump length on incidence and patterns of recurrent varicose veins and neo-reflux in accessory veins. Concomitant phlebectomies offer the advantage of freedom from re-do surgeries, at the cost of slightly increased risk of developing paresthesia, without any increase in morbidity. Thorough expertise in DUS and elaborate documentation of vein parameters for e.g. length and multiple diameters of the treated vein and NOD, DVTD, and the status of ASV are obligate to plan, perform and evaluate the EVLA procedure. The current review of literature sheds light on the lack of standardization in documentation regarding the pre and postoperative DUS and the EVLA procedure. The long-term follow-up of c and 120 M of patients involved in this study is in progress. Randomized studies are required to evaluate the EVLA 1940 nm procedure further.

ACKNOWLEDGMENTS

The authors would like to thank the team of vascular assistants Miss Sabine Wenzel and Mrs. Sonja Herrmann and the study nurse Mrs. Natalie Schmied. Without their support, this study wouldn't have come to realization. Starmedtec GmbH, Starnberg, Germany provided the radial emitting fibers at a reduced price for the purpose of the study without any other involvement or influence on the study.

CONFLICT OF INTERESTS

CGS holds shares of iMS GmbH, Tutzing Germany, a company that produces laser systems for endovenous laser ablations. This study is based on a part of the doctoral dissertation of Anna Beisswenger at LMU Munich. Other authors have nothing to disclose.

AUTHOR CONTRIBUTIONS

Conceiving and designing the study: Claus-Georg Schmedt, Anna Beisswenger, Ronald Sroka. *Collecting the data*: Claus-Georg Schmedt, Abhay Setia, Anna Beisswenger, Slobodan Dikic, Sahit Demhasaj. *Analyzing and interpretation the data*: Claus-Georg Schmedt, Abhay Setia, Anna Beisswenger, Thomas Schmitz-Rixen, Ocean Setia, Ronald Sroka. *Writing the manuscript*: Claus-Georg Schmedt, Abhay Setia, Anna Beisswenger, Ocean Setia. *Statistical analysis*: Abhay Setia, Anna Beisswenger, Ocean Setia. *Critical revisions of the article*: Claus-Georg Schmedt, Slobodan Dikic, Sahit Demhasaj, Thomas Schmitz-Rixen, Ocean Setia, Ronald Sroka. *Final approval of the article*: Claus-Georg Schmedt, Abhay Setia, Anna Beisswenger, Slobodan Dikic, Sahit Demhasaj, Thomas Schmitz-Rixen, Ocean Setia, Ronald Sroka. *Overall responsibility*: Claus-Georg Schmedt, Abhay Setia, Anna Beisswenger, Slobodan Dikic, Sahit Demhasaj, Thomas Schmitz-Rixen, Ocean Setia, Ronald Sroka.

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How to cite this article: Setia A, Schmedt C-G, Beisswenger A, Dikic S, Demhasaj S, Setia O, et al. Safety and efficacy of endovenous laser ablation (EVLA) using 1940 nm and radial emitting fiber: 3-year results of a prospective, non-randomized study and comparison with 1470 nm. Lasers Surg Med. 2022;54:511–522.
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