Temperature profiles of 980 nm and 1470 nm endovenous laser ablation, endovenous radiofrequency ablation and endovenous steam ablation

Wendy Malskat
Margot Stokbroekx
Cees van der Geld
Tamar Nijsten
Renate van den Bos

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ABSTRACT

Background: Endovenous thermal ablation (EVTA) techniques are very effective for the treatment of varicose veins, but their exact working mechanism is still not well documented. The lack of knowledge of mechanistic properties has led to a variety of EVTA protocols and a commercially driven dissemination of new or modified techniques without robust scientific evidence. The aim of this study is to compare temperature profiles of 980 and 1470 nm endovenous laser ablation (EVLA), segmental radiofrequency ablation (RFA) and endovenous steam ablation (EVSA).

Methods: In an experimental setting, temperature measurements were performed using thermocouples; raw potato was used to mimic a vein wall. Two laser wavelengths (980 and 1470 nm) were used with tulip tip fibers, and 1470 nm also with a radial emitting fiber. Different powers and pullback speeds were used to achieve fluences of 30, 60 and 90 J/cm. For segmental RFA, 1 cycle of 20 seconds was analyzed. EVSA was performed with 2 and 3 pulses of steam per cm. Maximal temperature increase, time span of relevant temperature increase, and area under the curve of the time of relevant temperature increase were measured.

Results: In all EVLA settings, temperature rise peaked and decreased rapidly. High fluence is associated with significantly higher temperatures and increased time span of temperature rise. Temperature profiles of 980 and 1470 nm EVLA with tulip tip fibers did not differ significantly. Radial EVLA showed significantly higher maximal temperatures than tulip tip EVLA. EVSA resulted in mild peak temperatures for longer duration than EVLA. Maximal temperatures with 3 pulses per cm were significantly higher than with 2 pulses. RFA temperature rises were relatively mild, resulting in a plateau shaped temperature profile, similar to EVSA.

Conclusion: Rise in temperature during EVLA is fast with a high peak temperature for a short time, where EVSA and RFA have longer plateau phases and lower maximal temperatures. Temperature profiles of 980 and 1470 nm EVLA are similar. Overall, differences in temperature levels of EVTA techniques are minimal.

INTRODUCTION

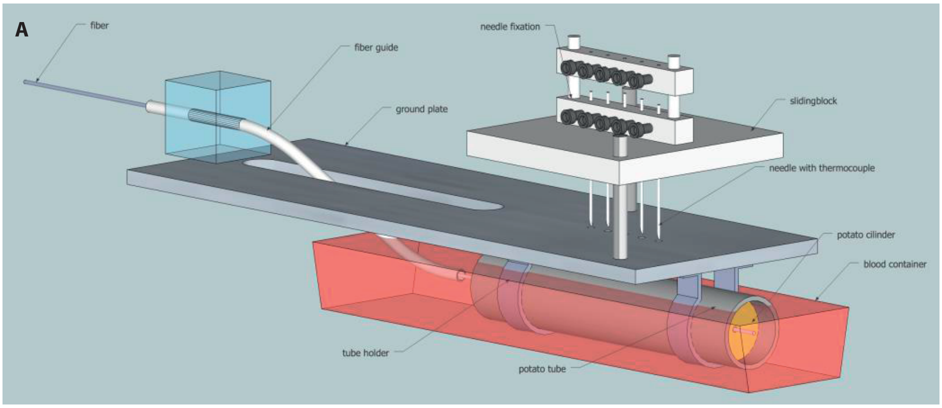
Endovenous thermal ablation (EVTA) techniques are nowadays commonly used as minimally invasive therapy for saphenous varicose veins. In comparison to surgical stripping or ultrasound guided foam sclerotherapy, endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) are proven to have a higher success rate and lower complication rate (1). The efficacy and safety of endovenous steam ablation (EVSA) for varicose veins has been shown in sheep and humans in a pilot study (2).

Although EVTA (EVLA, RFA and EVSA) treatments are very effective, the exact working mechanism is not well documented, especially of EVLA of which temperature profiles and its determinants (e.g., power, wavelength, type of fiber tip and pull back speed) are not well studied. It is generally thought that thermal injury to the venous wall is responsible for vein occlusion in EVTA treatments (3-6). Recently, we performed endovenous simulated laser experiments showing no difference in the temperature profile between 940 and 1470 nm lasers suggesting wavelength independent temperature profiles (7). Also, experimental temperature measurements in EVSA demonstrated a dose-response relationship of heat induction of 1, 2 and 3 pulses of steam per cm (8). However, comparison of temperature profiles between the different EVTA treatments (i.e., EVLA, RFA and EVSA) in the same experimental setting, has never been performed.

The lack of knowledge of mechanistic properties in EVTA treatments has led to a variety of EVTA protocols and a commercially driven dissemination of new or modified techniques without robust scientific evidence. Therefore, we compared the temperature profiles (maximum temperature, seconds of heating > 50°C and area under the curve of the maximum temperature set against the time) of 980 and 1470 nm EVLA, segmental RFA and EVSA in an experimental setting simulating clinical conditions to asses differences in their main working mechanisms (i.e. heating of veins).

METHODS

The experimental set-up (Figure 1) consisted of a transparent plastic box, in which a poly vinyl chloride (PVC) tube was fixed. The tube was filled with 30 mm diameter cylinders of raw potato, to mimic a vein. Raw potato was chosen because it has a solid structure, consists of 80% water (which is similar to a vein wall), is relatively stable under high temperatures and can be cut. These cylinders had a 2.4 mm diameter hole in the centre, in which the laser fiber, radiofrequency or steam catheter was inserted. The box was filled with heparinized pig blood. The temperature measurements were performed with 5 0.5 mm K-type thermocouples (TC; Omega KMQSS-IM050G-150) connected to a data sampler (Omega, Pico TC08). Five TCs were positioned within the PVC tube (TC 1, 2, 3,



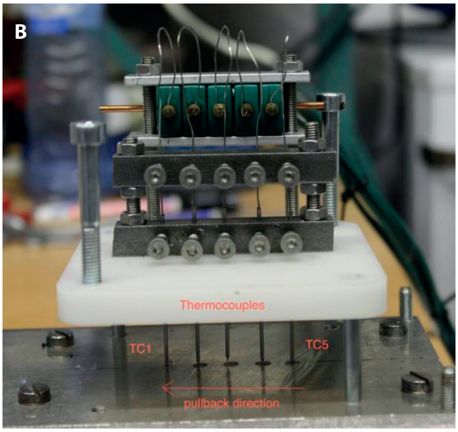
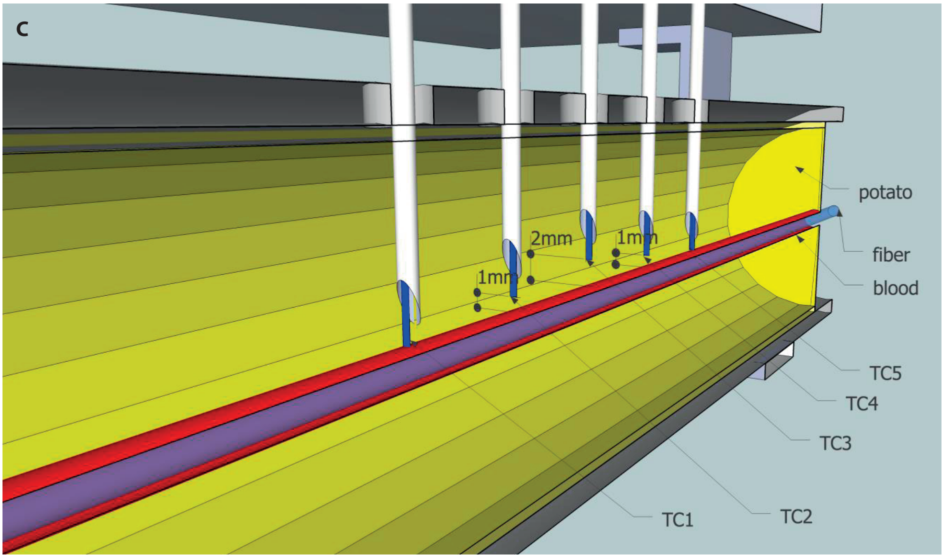


Figure 1. a. Schematic reproduction of the experimental setting. b. Detail of sliding block with thermocouples (TC1, thermocouple 1; TC5, thermocouple 5). c. Cross-section of potato with position of thermocouples (TC2, thermocouple 2; TC3, thermocouple 3; TC4, thermocouple 4) in relation to the fiber/catheter. TC 2, 3 and 4 are positioned inside the potato 'wall'.



4, 5) at three different distances from the fiber (TC 1 and 5 at 0 mm, TC 2 and 4 at 1 mm, TC 3 at 2 mm), because it was hypothesized that the temperature profiles would differ for various positions due to heat development by the moving fiber. The thermocouples were fixed on a sliding block, inserting and positioning the TCs for each experiment.

The EVTA, RFA and EVSA devices used and their settings were similar to clinical practice (2, 9). Two laser wavelengths were used: 980 nm Diode (Quanta System, Solbiate Olona, VA, Italy) and 1470 nm BioLitec, ElVeS (Quanta System ,Solbiate Olona, VA, Italy) with tulip tip fibers (10) (Tobrix, Waalre, The Netherlands) and 1470 nm also with a radial emitting fiber (11) (Tobrix, Waalre, TheNetherlands). A tulip tip is an umbrella-like cover that centers the laser fiber in the vein (diameter 600μm). A radial emitting fiber emits the laser light perpendicular to the fiber (diameter 2 mm). For steam ablation, the Steam Vein Sclerosis system (CERMA SA, Archamps, France) was used (fiber diameter 1.2 mm). For RFA, a segmental heating catheter of 7F (2.3 mm) diameter (ClosureFast catheter, VNUS Medical Technologies Inc, San Jose, Calif) with a 7-cm heating element was used.

For EVLA, 6 pullback speeds (0.5, 1, 1.5, 2, 3 and 4 mm/s), were combined with different laser settings (varying from 3 to 12 Watt (W) for both wavelengths), achieving linear endovenous energy densities (LEED) of 30 J/cm, 60 J/cm and 90 J/cm. In order to reach accurate and constant pullback speeds, a linear motor with frequency regulator was used. For segmental RFA, temperature experiments were done with 1 cycle of 20 seconds. EVSA was performed with 2 and 3 pulses of steam per cm separately. Every measurement was repeated 5 times, which resulted in 10 measuring points at 0 and 1 mm and 5 at 2 mm distance from the fiber.

To study the temperature profiles, dTmax, dt and dtdT were calculated from the graphical representation. Here, dTmax was defined as the maximum temperature increase above room temperature (20°C). Maximum temperatures above 50°C (thus an increase of 30°C above room temperature) were considered relevant, since it is the assumed threshold for collagen denaturation needed to irreversibly damage the vein wall (12-14). Parameter dt was defined as the time span that the temperature increase was relevant (duration of dTmax > 30°C). Parameter dtdT represents the area under the curve of the time that the temperature increase was more than 30°C.

STATISTICAL ANALYSES

The three continuous temperature measures (dTmax, dt and dtdT) are presented as means with a standard deviation (SD). We used SPSS 15.0 software (SPSS Inc, Chicago, Il) for the analyses. The comparison of these measures between the different settings of each EVLA device was done by ANOVA testing. Independent T-tests were performed to compare different EVLA wavelengths (980 nm and 1470 nm), different EVLA fiber tips (tulip and radial), and 2 and 3 pulses of EVSA. Two-sided p-values were considered to be significant if <0.05.

RESULTS

EVLA

Table 1 shows the results of dTmax at 0 mm, dt and dtdT for 980 nm tulip, 1470 nm tulip and 1470 nm radial EVLA. Temperature profiles of EVLA tulip 980 and 1470 nm are depicted in Figure 2 and Figure 3.

Temperature profiles of 980 and 1470 nm EVLA were measured with tulip tip and radial fibers, with levels of energy varying from 30 to 90 J/cm. In all EVLA settings, the temperature rise peaked and decreased rapidly. In all settings, dTmax was at least 30°C (Tmax ≥ 50°C) at 0 mm distance from the fiber tip. At 1 mm distance, most values of dTmax were below 30°C. At 2 mm distance, none of the settings exceeded a dTmax of 30°C. In most settings, dt is more than 5 s. The results will be listed in detail below.

Table 1. EVLA measurements

	980 nm# Tulip fiber			**1470 nm# $ Tulip fiber**			**1470 nm#$ Radial fiber**		
	30 J/cm*	**60 J/cm***	**90 J/cm***	**30 J/cm***	**60 J/cm***	**90 J/cm***	**30 J/cm***	**60 J/cm***	**90 J/cm***
dTmax 0 mm (mean ± SD)	49 ± 4	51 ± 7	65 ± 10	48 ± 8	59 ± 19	60 ± 12	68 ± 14	87 ± 16	94 ± 7
dt (mean ± SD)	4 ± 1	13 ± 3	22 ± 8	5 ± 2	15 ± 6	30 ± 5	5 ± 1	18 ± 4	26 ± 0
dtdT (mean ± SD)	193 ± 30	563 ± 136	1291 ± 281	220 ± 66	843 ± 316	1431 ± 306	236 ± 74	912 ± 203	1465 ± 37

dTmax, maximal temperature increase in degrees Celsius (°C) above room temperature (20°C); SD, standard deviation; dt, duration of dTmax >30°C in seconds (s); dtdT, area under the curve (°C x s) of the time that the temperature increase is >30°C;. *Statistical comparisons of dTmax, dt and dtdT between the three fluence rates (30, 60 and 90 J/cm) of each device (980 nm tulip fiber, 1470 nm tulip fiber and 1470 nm radial fiber) were highly significant (ANOVA; p<0.001, except for dTmax of 1470 nm tulip fiber p=0.03); **#**Differences in the distribution of dTmax, dt and dtdT between 980 nm and 1470 nm tulip fiber lasers were not significant (Independent T-test; p=0.82. 0.10 and 0.18 respectively); **$**dTmax was significantly higher for 1470 nm radial fiber compared to 1470 nm tulip fiber (Independent T-test; p<0.001) whereas dt and dtdT were comparable (Independent T-test; p=0.11 and p=0.20 respectively).

LEED

A higher total level of delivered energy per cm vein length, resulting from a relatively high power and/or a lower pullback speed, generated a higher dTmax at 0 mm in all EVLA devices. A dt <5 s seemed to be associated with a relatively low total level of energy per cm vein length (30 J/cm).

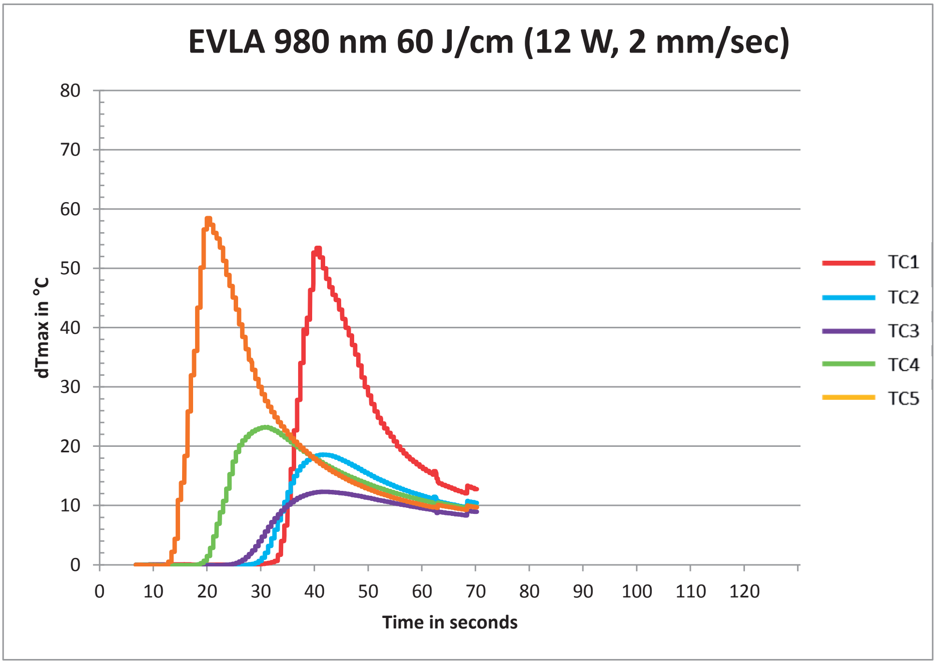


Figure 2. Temperature profile of 980 nm tulip EVLA. dTmax, maximal temperature increase above room temperature (20°C); TC1, thermocouple 1; TC2, thermocouple 2; TC3, thermocouple 3; TC4, thermocouple 4; TC5, thermocouple 5.

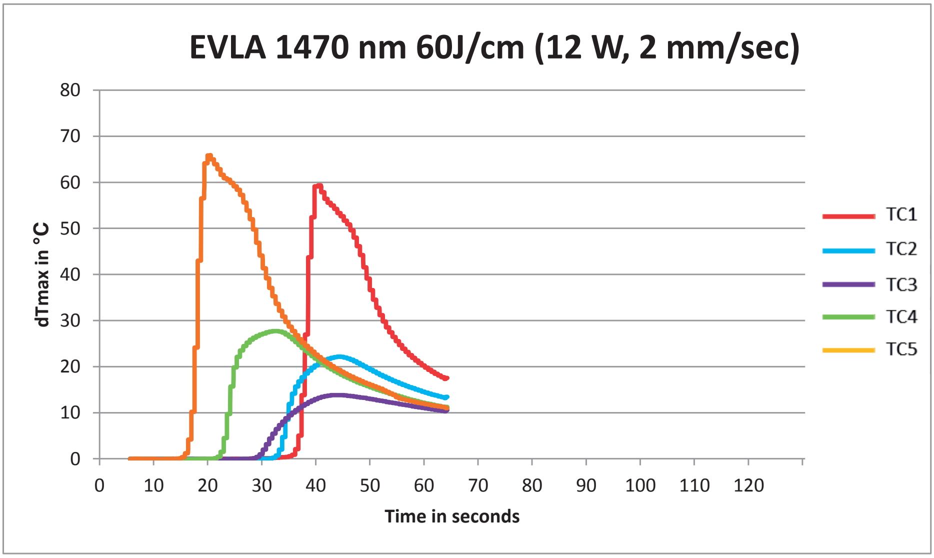


Figure 3. Temperature profile of 1470 nm tulip EVLA. dTmax, maximal temperature increase above room temperature (20°C); TC1, thermocouple 1; TC2, thermocouple 2; TC3, thermocouple 3; TC4, thermocouple 4; TC5, thermocouple 5.

Statistical comparison of dTmax, dt and dtdT between 30, 60 and 90 J/cm of each device (980 nm tulip fiber, 1470 nm tulip fiber and 1470 nm radial fiber), were highly significant (ANOVA; $p < 0.001$, except for dTmax of 1470 nm tulip fiber $p = 0.03$), indicating an increasing dTmax at 0 mm, dt and dtdT at higher LEED.

Wavelengths

The p-values of dTmax 0 mm, dt and dtdT were not significantly different between 980 and 1470 wavelengths (Independent T-test; $p = 0.82$, 0.10 and 0.18 respectively). Temperature profiles of 980 and 1470 nm EVLA were comparable.

Fiber tips

For 1470 nm EVLA, dTmax at 0 mm was significantly higher for the radial fiber than for the tulip tip fiber (Independent T-test; $p < 0.001$). However, dt and dtdT were comparable (independent T-test; $p = 0.11$ and 0.20 respectively).

EVSA

In Table 2, results are presented of dTmax at 0 mm, dt and dtdT for 2 and 3 pulses of steam. Temperature profile of EVSA is shown in Figure 4.

Temperature curves of EVSA showed a plateau phase, with a relatively constant temperature for a longer period of time. With 2 and 3 pulses of steam per cm, dTmax was over 30°C at 0 mm distance of the EVSA catheter. At 1 and 2 mm distance, dTmax was below this cut-off point. dTmax at 0 mm was significantly higher with 3 pulses of steam, than with 2 pulses (Independent T-test; $p = 0.024$). A significant difference was also found in dt; with 2 pulses/cm, dt was significantly lower than with 3 pulses (Independent T-test; $p < 0.001$), but both had a mean dt > 5 s.

Table 2. RFA and EVSA measurements

	RFA	**EVSA**	
	1 cycle	**2 pulses***	**3 pulses***
dTmax 0 mm (mean ± SD)	39 ± 11	43 ± 3	52 ± 7
dt (mean ± SD)	14 ± 9	17 ± 1	32 ± 2
dtdT (mean ± SD)	524 ± 318	583 ± 40	1308 ± 152

dTmax, maximal temperature increase in degrees Celsius (°C) above room temperature(20°C); SD, standard deviation; dt, duration of dTmax >30°C in seconds (s); dtdT, area under the curve (°C x s) of the time that the temperature increase is >30°C. *Statistical comparisons of dTmax 0 mm, dt and dtdT between 2 and 3 pulses of steam were significant (Independent T-test, p=0.02. <0.001 and <0.001 respectively).

RFA

Table 2 shows results of dTmax at 0 mm, dt and dtdT for RFA. Temperature profile of RFA is depicted in Figure 5.

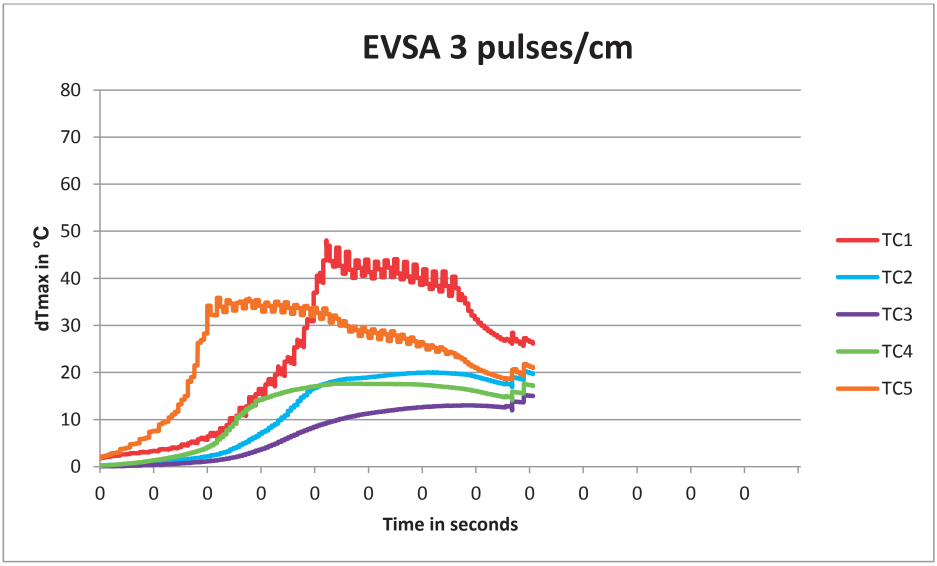


Figure 4. Temperature profile of EVSA. dTmax, maximal temperature increase above room temperature (20°C); TC1, thermocouple 1; TC2, thermocouple 2; TC3, thermocouple 3; TC4, thermocouple 4; TC5, thermocouple 5.

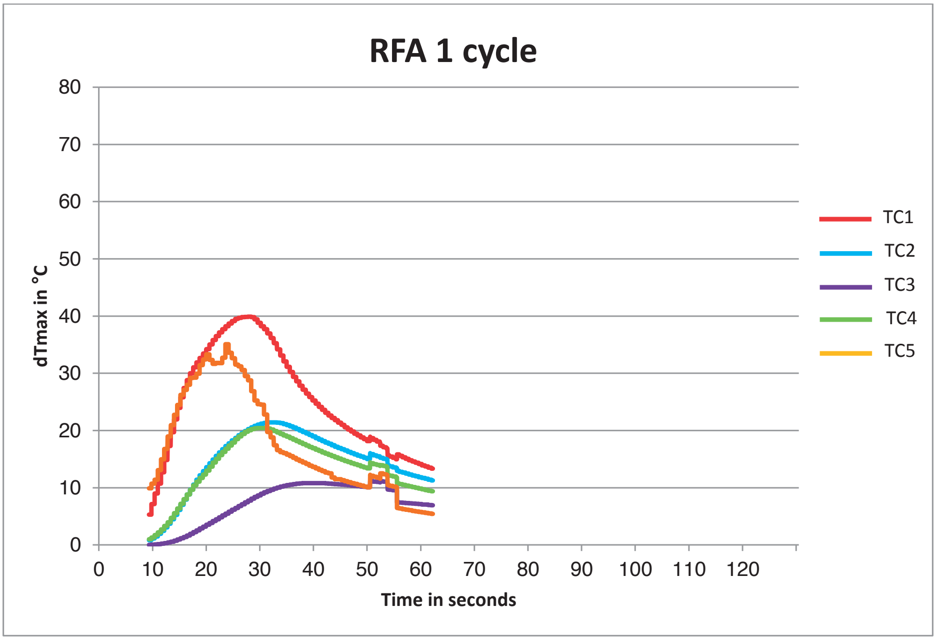


Figure 5. Temperature profile of segmental RFA. dTmax, maximal temperature increase above room temperature (20°C); TC1, thermocouple 1; TC2, thermocouple 2; TC3, thermocouple 3; TC4, thermocouple 4; TC5, thermocouple 5.

Temperature curves of segmental RFA showed a plateau phase, with a relatively constant temperature for a longer period of time. dTmax was over 30°C at 0 mm distance of the RFA catheter. At 1 and 2 mm distance, dTmax was below this cut-off point for both measurements. Also, dt was > 5 s.

Comparison of EVTA's

For both EVSA and segmental RFA, temperature curves showed a plateau phase, with a relatively constant temperature for a longer period of time, whereas for EVLA the temperature rise peaked and decreased more rapidly with less of a plateau phase. Also, the settings of EVLA in high LEED (90) J/cm, generated a higher dTmax, than RFA and EVSA. However, all devices were comparable in achieving a sufficient dTmax over 30°C at fiber or catheter level, and a dt >5 s. All EVTA devices could induce an adequate temperature rise at the fiber or catheter level and they all led to a long enough time span at the temperature needed for collagen denaturation.

DISCUSSION

This is the first experimental study that showed temperature profiles of EVLA for different wavelengths with tulip and radial fiber tips, in EVSA and segmental RFA. This study allowed us to compare temperature profiles of most of the available different endovenous thermal therapies, used in patients with varicose veins.
The results of these temperature measurements showed several interesting characteristics. We will discuss the results per device.

EVLA

The temperature rise of EVLA increased with higher LEED. Temperature behavior of EVLA was different compared to EVSA or segmental RFA; the peak temperature was higher for a shorter time. Possibly, high peak temperatures may result in vein wall perforation and/or more perivenous damage, causing (minor) side effects such as pain and ecchymoses, which seemed to occur more often in EVLA than in segmental RFA (15).

Temperature profiles of 980 and 1470 nm with tulip tip fibers did not differ significantly, which was in agreement with our previous findings (7). High LEED on the other hand, was again proven to be associated with significantly higher temperatures and increased time span of temperature rise, compared to lower LEED. It is likely that the alleged differences in side effect profiles between different wavelengths, as described in previous studies were the result of differences in administered J/cm (16), power (17) or laser tip design (18), rather than difference in wavelength.

Radial 1470 nm EVLA resulted in a significantly higher dTmax at 0 mm than tulip 1470 nm EVLA, but a comparable temperature profile with a peak shaped curve. The most likely explanation for the significant difference in dTmax is that radial fibers have a larger diameter than bare fibers and are therefore closer to the thermocouples. Also direct absorption of the laser light by the thermocouples could be an explanation for higher temperature measurements. In an additional experiment, we tested that direct irradiation of the thermocouple by the radial fiber resulted in barely any temperature rise, so direct emittance can be excluded as possible explanation for the difference.

EVSA

The dTmax of EVSA with 3 pulses per cm was significantly higher than with 2 pulses. Also, dt and dtdT were larger for EVSA with 3 pulses per cm. This outcome is in line with previously reported temperature measurements which led to the recommendation of administering 2 or more pulses per cm in human veins (8). EVSA resulted in mild peak temperatures for longer duration than EVLA, which was graphically shown as a long plateau phase. This implicated a longer homogeneous temperature rise of the vein wall, compared to EVLA, and could possibly result in a milder side effect profile, similar to segmental RFA. A clinical randomized trial should assess this possible difference.

Segmental RFA

Segmental RFA temperatures were measured for the standard setting (1 cycle). The catheter of segmental RFA was 2.2 mm in diameter and was therefore closer to the thermocouples than the other devices. However, this did not lead to significantly higher temperature measurements at catheter level. The temperature rise was relatively mild; comparable to EVSA and lower than EVLA. Parameter dt was > 5 s. This also resulted in a plateau shaped temperature profile, similar to EVSA. Segmental RFA values of dt and dtdT in our experiment were comparable to EVLA tulip tip 980 nm and 1470 nm at 60 J/cm. This is in line with the reported 68.2 J/cm as described by Proebstle et al. (19). The energy level of 1 cycle segmental RFA seemed to correlate with 60 J/cm EVLA, but the temperature profile was different because of the lack of peak temperature in segmental RFA. The absence of a peak temperature could be the explanation of the milder side effect profile of RFA, compared to EVLA (15).

In conclusion, temperature rise during EVLA is fast with a high peak temperature for a short time, whereas EVSA and RFA temperature increases have longer plateau phases and lower maximum temperatures. Temperature profiles of 940 / 980 nm and 1470 nm EVLA are again proven to be similar (7). Overall, differences in temperature levels of endovenous thermal ablation techniques are proven to be minimal. The studied temperature profiles suggest that in clinical practice all 3 EVTA methods will result in sufficient heating to obliterate the targeted vein, with more minor side effects (pain, ecchymoses) in EVLA, due to higher maximum temperatures.

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