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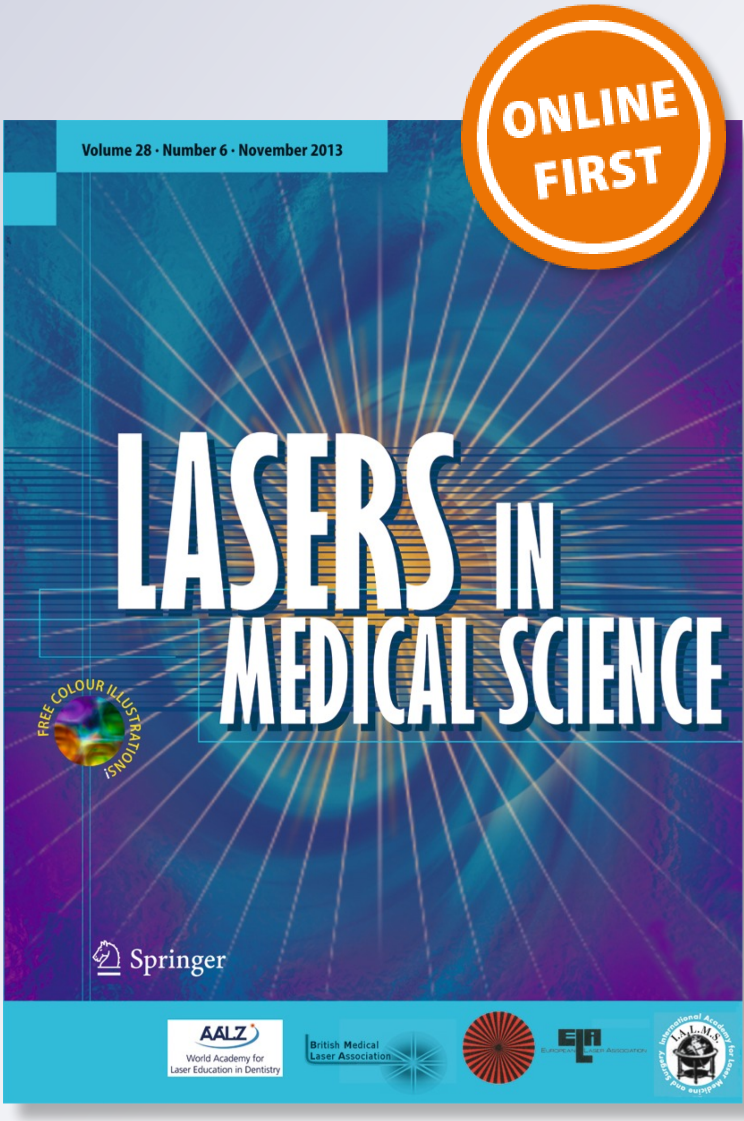

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ORIGINAL ARTICLE

Commonly used fiber tips in endovenous laser ablation (EVLA): an analysis of technical differences

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Abstract Many different types of fiber tips have been developed over the last few years to be used in endovenous laser ablation (EVLA) procedures. All these new but different tips claim a certain superiority over the other tips. Evidence for a best tip is however lacking. Four of these fiber tips have been compared in this article: (1) the bare fiber, (2) the Tulip-Tip, (3) the NeverTouch™ tip, and (4) the radially emitting tip. The aim of this paper is to provide information on the technical differences between these fiber tips and differences in their underlying heat transfer mechanisms. Although all tips are effective in the primary goal of EVLA, namely to occlude the incompetent vein, they differ in side effects, they differ in side effects, practicality, and cost. Although these new tips have improved EVLA, the perfect tip is not on the market yet.

Keywords Endovenous laser ablation (EVLA) · Fiber tips · Varicose veins · Heat transfer

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Introduction

When in 1998 the first endovenous laser ablation (EVLA) treatments were performed, it was done with materials readily available. The fibers used were standard 600-μm fibers, stripped and cleaved to have a flat-tip bare end. The treatments proved to be effective and a better alternative to surgical stripping. Navarro, Min, and Boné in the USA were the first to publish about the use of EVLA therapy [1]. To protect their interest, a method patent was filed by Diomed in 1999 and granted in 2002 under patent number US6,398,777, also known as the "777" patent [2]. In the patent text, there is an interesting paragraph: "It is a further object of present invention to provide such a method that introduces a fiber optic line into the vein lumen to deliver intraluminal laser energy with direct contact of the tip of the fiber optic line with the vein wall." This paragraph obviously suggests that direct interaction between the laser tip and vein wall was considered essential and that other ways of heat transfer from tip to the target vein wall were thought to be irrelevant for a good treatment result.

Many lawsuits have been fought over this patent, and ways to market endovenous laser techniques which are not infringing the patent have been investigated. One result was the use of covered fiber tips like the Bright-Tip (Vascular Solution, Minneapolis, MN, USA).

In the research following the first EVLA studies, it became clear that the results, defined as total occlusion of the varicose vein, were so good that other systems, like using different fiber tip constructions and laser wavelengths, could not anymore surpass the efficacy of the existing system. Nevertheless, many studies were published with different laser sources and/or tips. The only progress made was to obtain better patient-related outcome parameters like postoperative pain and lost days for working. In this respect, the bare fiber tip was shown to introduce perforations to the vein wall [3–5], as well as minor postoperative complications as pain and bruising [6].

Many claims have been made about the required effects of fiber tips. First, a fiber tip has to transfer the laser power to its surroundings, aimed to heat up the vein wall by various methods discussed further in this paper. Second, despite the lack of publications showing a *direct* relation between vein wall perforation and postoperative complications because perforations only show after harvesting the vein or from in vitro experiments, the current assumption nevertheless is that perforations are the main cause of postoperative pain and bruising. A modern fiber tip therefore has to prevent these perforations and has to evenly heat up the vein wall to minimize the risk of recanalization. Unfortunately, virtually all trials comparing fibers tips have also varied other parameters like wavelength, laser power, and pullback velocity. It is therefore not clear whether the conclusions of these trials are a result of the fiber tip, wavelength, power setting, or all combined.

In two articles [7, 8], a bare fiber tip and the Tulip-Tip, a fiber tip that prevents vein wall perforations, were compared in an animal study and in a human randomized controlled trial, showing that a well-designed fiber tip can prevent vein wall perforations and also that this fiber significantly improves secondary postoperative outcomes as pain and bruising [7]. These findings therefore strongly support the contention that vein wall perforations are the cause of adverse postoperative effects. In one of these studies, the two tips were compared with all other parameters equal, i.e., equal wavelength, laser power, and pullback velocity [8]. The aim of this article is to compare four commonly used fiber tips, technically as well as on the basis of heat transfer mechanisms.

Heat transfer mechanisms

Although not yet fully understood, some theories have been developed about the different heat transfer phenomena taking place within a vein during EVLA [9–12]. In general, the goal is to heat up the vein wall in an even way to cause irreversible injury of the whole vein wall. In Fig. 1 the main concepts have been illustrated, namely direct irradiation of light and consequent absorption by the vein wall; the formation, propagation, and distal condensation of steam bubbles and the resulting heat pipe effect [13]; heat convection and conduction; and the heat radiated and conducted to the vein wall by a hot tip [14]. Depending on which mechanism predominates, one or the other fiber tip design might be prevalent.

The light from the laser is guided through a fiber and emitted from the tip where it radiates almost all of its energy into the blood-filled vein lumen. Blood surrounding the tip absorbs some of the laser power and heats up, causing convective and conductive heat transfer interactions with the vein wall. Also, some of this blood will coagulate, and a small part at the tip will subsequently carbonize due to the high amount of concentrated laser power. Depending on the used power, wavelength, the used tip and carbonization on the surface of the tip, it can also cause steam bubbles to form, adding boiling as a heat transfer phenomenon.

Some of the laser power will not be absorbed by the target chromophore in the blood but reaches the vein wall directly due to scattering by the blood. This laser power will be absorbed by the vein wall in which water is the main chromophore and, if power and vein wall absorption are sufficient, causes irreversible injury to the vein wall. The amount of light reaching the vein wall directly depends on the absorption and scattering coefficients of blood and the distance between the tip and the vein wall, therefore also depending on the type of tip.

In practice, mainly three different laser wavelengths are being used: 810, 980, and 1470 nm. The absorption coefficient of blood depends on the wavelength used [15–17]. Using different wavelengths, different chromophores can be targeted, by which it is possible to optimize EVLA efficacy using "selective photothermolysis", the same principle used, for example, for the treatment of portwine stains [18]. An 810-nm laser mainly targets hemoglobin whereas a 1,470-nm laser targets water molecules. If carbonization on the laser fiber tip takes place the effect of selective photothermolysis diminishes.

Optical and geometric properties of different fiber tips

Four different fiber tips will be considered, shown in Fig. 2, namely (1) a hard clad 600-μm bare fiber, (2) a Tulip-Tip

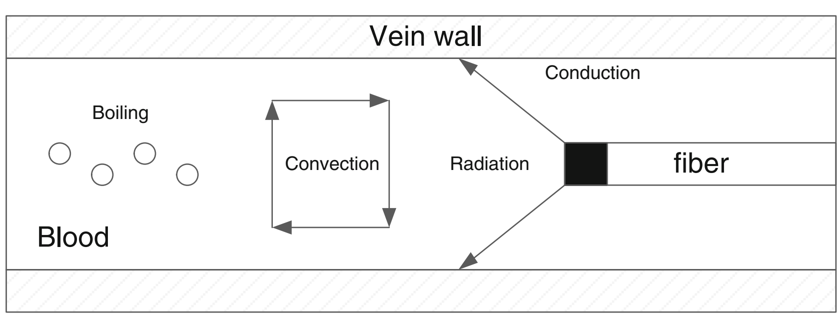

Fig. 1 Heat transfer mechanisms in a vein

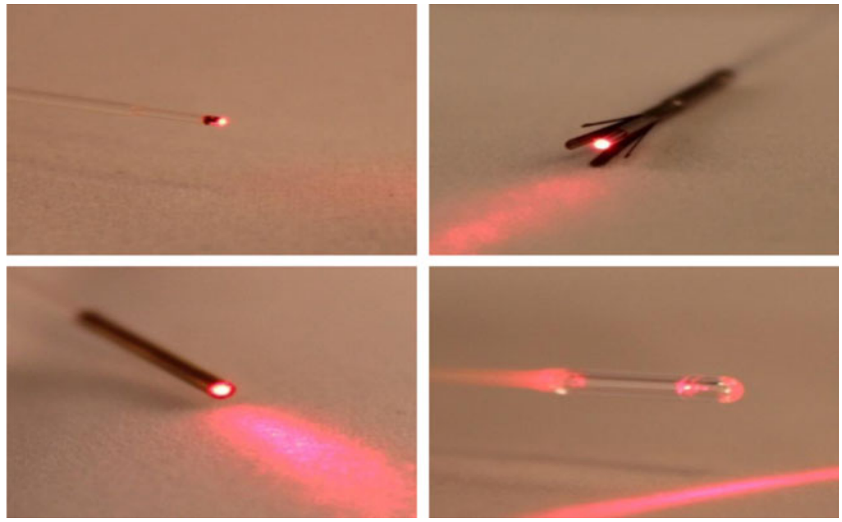

Fig. 2 Different fiber tips considered: bare fiber tip (*upper left*), Tulip-Tip (*upper right*), NeverTouch™ (*lower left*), and radial (*lower right*)

(Tobrix), (3) a covered tip (NeverTouch™, Angio Dynamics), and (4) a radially emitting tip (Tobrix and Biolitec).

1. The bare fiber tip is the most commonly used fiber. A bare fiber consists of three layers: a core (600 μm), the cladding (30 μm), and the jacket (150–200 μm). At the distal part of the fiber, the jacket is removed over a length of 5–6 mm to expose the bare cladding and core.
2. The Tulip-Tip has a bare fiber tip too but eliminates contact of the tip with the vein wall by means of geometric constraints. The "Tulip"-like petals act as an elastic resistance against the vein wall, keeping the tip away from it.
3. The NeverTouch™ tip is similar to the 600-μm core bare fiber except a tube with a lens has been placed over the distal tip. This causes the emitted light to be more divergent. The manufacturer's claim is that it focuses the power over a 2.2-times larger tip area, causing a 56 % lower irradiance. We actually doubt this claim, based on ray tracing analysis of the ball tips (Fig. 11 of Verdaasdonk et al. [19]). Besides, the fluence rate at the tip is similar to that of a bare fiber, and it will still perforate the vein wall when it touches the wall. In addition, the scattering properties of the blood will strongly diminish this divergent light propagation behavior.
4. The radially emitting tip is a quartz tip with a cone shape inside in order to reflect and broaden the laser light in a radial direction. The tip diameter varies between 1.3 and 2 mm. Again, the blood scattering behavior will diminish the emitted broadening.

The methods of emitting the laser light are the same for the bare fiber, the Tulip-Tip, and the NeverTouch™ tip. In air, the emitted beam out of a flat fiber surface can be well described as a three-dimensional cone; its divergence is determined by the laser wavelength used and limited by the numerical aperture (the sine of half the angle of divergence of the light emission out of the fiber, see Fig. 1). In the blood, the numerical aperture of the fiber is reduced by the refractive index of the blood, thus by a factor of about 1.34. In addition, the scattering behavior of the blood changes the straight lines of the emitted light into a diffuse light distribution, roughly within a 1-mm distance from the fiber tip.

Carbonization

When enough laser power is being absorbed by the blood, it heats up to temperatures high enough to cause coagulation. A relatively small part of the coagulum also carbonizes. This carbonization covers part of the tip as a thin layer, absorbing about 45 % of the laser power [20] and converting it into a broader spectrum of IR light, becoming in essence a black-body radiator. However, this black-body radiation causes a negligible estimated temperature increase of the vein wall [21]. Nevertheless, it is this carbonization that causes the tip of the fiber to reach very high temperatures [19, 22, 23], also assumed to cause vein wall perforations following tip–wall contact. In addition, the hot layer is the main source of the production of steam bubbles [13].

The impact of the carbonization depends on the tip itself; the geometry of the tip plays an important role in the accumulation of carbon particles, as well as the adhesion properties of the material itself. All fiber tips accumulate a lot of coagulum when held still in a container-filled with blood. A result can be seen in Fig. 3. The amount of carbonization is not likely to differ for different laser wavelengths [20]. However, we observed that an 810-nm laser causes more coagulation than the other wavelengths used, at identical power levels.

Fig. 3 Coagulum on a fiber tip held stationary in blood; the laser at 1,470 nm wavelength emitted 1,000 J of energy at a rate of 6 W

Analysis of differences in heat transfer effects

The goal during EVLA, from a technical perspective, is to heat up the vein wall in an even way. During an EVLA procedure, however, the fibers will touch the vein in many different ways, from different angles and distances to the vein wall. A common situation for the position of the four fiber tips is illustrated in Fig. 4. Unfortunately, a quantitative comparison between the effects of the four fiber tips is currently impossible as relevant data like tip and wall temperatures are not available for all tips.

Bare fiber

The bare fiber has a diameter of 0.6 mm. In air, it radiates its energy at a maximum angle of 22° off the center axis, i.e., a full divergence angle of 44°. Due to the refractive index of the laser light of about 1.34 in the blood, this angle reduces in blood by a factor of 1.34 to 16.4°.

The penetration depth δ in blood of a light beam emitted out of a 0.6-mm diameter bare fiber is about

$$\delta = \frac{1}{\mu_a + \mu'_s}$$

where μ_a, μ'_s are the absorption and reduced scattering coefficients of blood. Using values for blood for an 810- and 1,470-nm laser [10, 17], this yields about δ_{810}=0.6 mm and $\delta_{1,470}$=0.27 mm, implying that the light starts to scatter and become diffuse at these distances. So, it is basically only the scattered light that reaches the vein wall. Furthermore, the light intensity inside the vein is reduced by the coagulum and the carbonization layer, where the carbonized part actually absorbs almost 50 % of the emitted laser light power [20]. Therefore, it is likely that convection and boiling take an important place, as well as conduction, as the probability that the bare fiber touches the wall frequently during EVLA procedures seems high.

When touching the vein wall, the tip most likely transfers its heat by conduction as charring of the vein wall has frequently been reported in literature. Charring generally occurs when tissue is heated to temperatures of over 300 °C, and tip temperatures in the range of 800–1,200 °C are feasible if carbonization is present [22–24]. Therefore, it is likely that most heat transfer occurs due to conduction and convection by steam bubbles. However, the coagulum around the tip might act as a buffer. During retraction of the tip, the coagulum coating detaches and there will be direct contact between the tip and the wall resulting in an increased probability of perforation due to the high temperature of the tip.

Tulip-tip

The Tulip-Tip shares some properties with the bare fiber, such as the surface area of light emission (irradiance). However, it is considered to be always centered within the vein; therefore, no heat transfer due to touching the vein wall can take place. A small amount of laser power may be absorbed and conducted through the petals of the tip though. The tulip construction also influences the spatial pattern of irradiation because the tip tends to be centered in the middle of the vein (the tulip petals are of low stiffness). Also, the tulip petals have a fixed length which is relatively long compared to the diameter of a regular vein, delimiting a minimal distance between the tip and vein

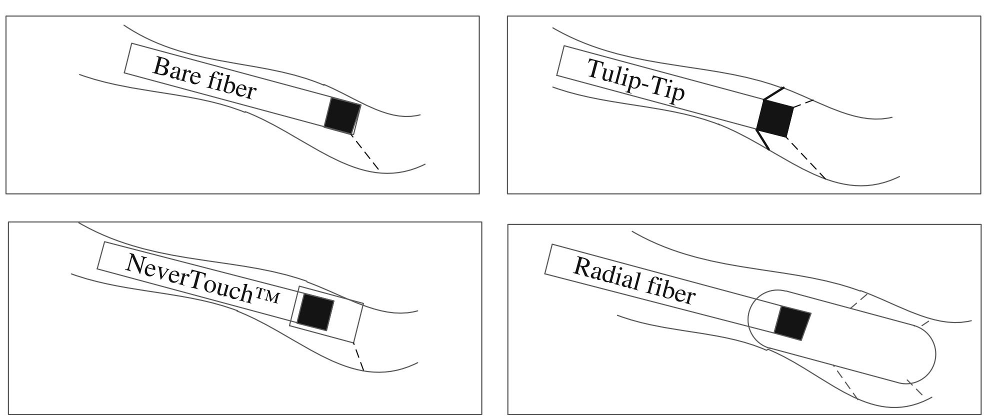

Fig. 4 Illustration of different fiber tips in a real-life situation

wall. Compared to a bare fiber, the length the (scattered) laser light has to travel to reach the vein wall is longer. When considering the trapping of coagulum inside the tulip construction, blocking direct radiation, more heat transfer in the form of convection and boiling is to be expected.

The tulip petals cause the fiber tip to accumulate more debris compared to a bare fiber tip. Steam formation of the Tulip-Tip will be similar to the bare fiber, i.e., both fiber tips have a comparable heat pipe effect.

NeverTouch™

The NeverTouch™ fiber tip has a lower irradiance than the bare fiber and Tulip-Tip due to the welded glass fitting around the distal part of the fiber, having an increased diameter of 905 μm, thus a 2.28-times larger emitting surface area. A small experiment where both tips were held in air perpendicular to a sheet of paper showed that the light was more divergent, about 1.6 times, implying that it also has a larger divergence in blood, although the exact factor may differ from 1.6 because of internal reflection losses [19]. As the irradiance is lower and emitted at a larger divergence, less power may reach the vein wall in a direct way, leaving other forms of heat transfer to deliver the laser energy. Again, however, the scattering nature of blood will diminish the extent of this conclusion.

The tip temperature is dependent on the carbonization layer thickness at the tip and the absorbed laser power. Therefore, it is hard to estimate a quantitative difference between the NeverTouch™ tip, the bare fiber, and the Tulip-Tip. If the laser is operated at a minimum power level, it is expected that the extent of carbonization could be lower. However, once carbonization is formed, a significant part of the laser power will be absorbed independent of the lower irradiance, and the effects will be similar to those of the bare fiber, i.e., a high carbonized tip temperature and the production of steam bubbles.

Radial

The radial tip radiates its energy in a radial direction, implying a shorter distance between the surface of emission and the vein wall than that of the other fiber tips (assuming the tip is centered in the middle of the vein). Because the surface area is at least larger by one order of magnitude than that of the bare fiber tip, the irradiance of the radial fiber is lowered by the same factor; therefore, less carbonization is to be expected. When an 810-nm laser is used in combination with the radial tip, the light penetration depth is larger than the distance between the tip and vein wall. Therefore, the radial tip will transfer most of its energy as direct laser irradiation to the blood near its surface and to the vein wall. However, when a 1,470-nm laser is being used, the penetration depth is more than a factor of four lower than at 810 nm; therefore, less direct irradiation of the wall is to be expected. Nevertheless, during 1,470-nm EVLA with the radial tip, steam bubbles are being observed, implying that the blood is heated up to temperatures exceeding 100 °C by direct absorption of the laser light. Concluding, the amount of direct irradiation of the vein wall depends strongly on the amount of blood available between the tip and the vein wall, the vein diameter, and the wavelength used.

Discussion

Several different types of fiber tips have been developed over the last few years. All of the tips have proven to be successful in EVLA procedures. However, some are able to reduce postoperative trauma. Compared to the bare fiber, Tulip-Tip has been successful in reducing vein wall perforations by means of a geometric restraint. The NeverTouch™ tip increases the irradiation area and makes the emitted laser power more divergent, i.e., it reduces the irradiance. The radial tip distributes the emitted laser power over a greater area but is likely closer to the vein wall, thus causing more direct wall irradiation. Nevertheless, up to now, there is no strong evidence that one system produces superior EVLA efficacy than another. In part, this is because trials comparing different EVLA systems almost invariably differ in more aspects than tip design alone. In many cases, the wavelength of the laser, the output power, and the pullback velocity also vary. More trials in which only the different tips are varied are needed to obtain a scientifically significant clinical comparison of the different tip designs.

The introduction of 1,470 nm in EVLA has been heralded as the solution to limit postoperative adverse effects. The initial marketing suggested that 1,470 nm is more effective than other wavelengths because the laser light is absorbed by (water in) the vein wall, not by the blood. As that assumption is not correct because blood contains a considerable amount of water, the lower pain levels most likely are a result of the lower power levels used. The preference for water absorption by 1,470 nm, and hence the preference for absorption by blood, allows the system to generate steam bubbles without a hot tip but that will not contribute to heating of the vein wall by direct irradiation. Actually, model simulations suggested that the direct absorption of the 1,470-nm light by the vein wall contributed very little to the resulting temperature increase of the vein wall [23]. The positive effects of 1,470 nm compared to 810 or 980 nm have not been quantified in a comparative study.

The ideal tip should heat up the vein wall sufficiently and homogeneously, optimizing the first aim of EVLA, namely to interrupt the reflux in the varicose vein. However, the ideal tip should not cause collateral damage like vein wall perforation.

In this respect, we propose that the combination of bare fiber and carbonization may be undesirable because the consequential high tip temperature increases the probability of causing vein wall perforations. When using the Tulip-Tip, contact between the vein wall and tip has been made impossible, but the potential importance of the carbonized hot tip layer, producing the majority of steam bubbles, remains.

Besides temperature-related aspects of tip design, there are several other aspects to take into consideration when designing a new fiber. Safety, both in material integrity and in minimizing the probability of wrong usage, is important. This includes the need for selecting a short or a long sheath and guidewire, the trade-off between more flexibility and higher success rate with a long system versus possibly a faster procedure with a short system. Visibility on ultrasound is also an important feature of a safe fiber. The aspect of cost should be taken into consideration as well. The price increase for a better tip should be balanced against the clinical advantages.

Initially, some tips have been developed to evade patent infringement. As the patent stated that direct contact of the fiber tip with the vein wall is mandatory, tips preventing that contact were developed. In a later stage, it became clear that better-designed tips that prevented vein wall perforations could substantially lower postoperative adverse effects. The Tulip-Tip is based on this insight. The NeverTouch tip has based its claim to lower adverse effects of EVLA on the larger emitting surface compared to a bare fiber tip. Radially emitting fibers have been in use for photodynamic therapy cancer treatment since the 1990s. An effect of this design is that the tip irradiance is much lower, resulting in a lower tip temperature and possibly lack of carbonization. The geometry of a radial tips suggests a more effective direct irradiation of the vein wall.

Future research on EVLA tips is seriously hampered by the lack of knowledge as to the importance of the various EVLA mechanisms. Although the risks of vein wall perforation seem agreed upon, the possible contribution of steam bubbles to EVLA efficacy is still not fully quantified compared to the other mechanisms. It is obvious that a proven importance of steam bubbles will create a different tip design compared to the case wherein steam bubbles turn out to be unimportant for EVLA efficacy. Interestingly, however, Mazaïshvili et al. [24], confirming that vein wall perforations indeed are the cause of unwanted secondary postoperative outcomes, claimed that these perforations are a result of rupturing of the vein wall by boiling gas that originates from the blood, which cannot escape due to the closure of veins by the tumescent pressure! We strongly oppose this claim, first because the vein wall is made of a very strong biological material. Secondly, the additional pressure exerted by tumescent anesthesia can only be a few millimeters of Hg. Only extremely fast *imploding* bubbles can damage strong structures, even plates of steel; however, the (slow) time scale of bubble formation and condensation during EVLA makes it impossible that steam bubbles can exceed the bursting pressure of veins. Ultrasound observation of steam bubbles during treatment invariably shows a stream of bubbles originating from the fiber tip and diminishing distally from the tip due to condensation. The stream of bubbles is clearly contained within the vein.

In conclusion, with the currently available fibers, there is evidence that fiber tips play an important role in producing the (side)effects of EVLA-therapy for varicose veins. Nevertheless, the perfect fiber tip has not been invented yet as it needs to await better knowledge of the EVLA mechanisms.

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