SOCIÉTÉ FRANÇAISE DE PHLEBOLOGIE

Study on delivered energy with the new VeinCLEAR™ endovenous radiofrequency ablation system. Concept of delivered energy control.

Étude de l'énergie délivrée avec le nouveau système d'ablation endoveineuse par radiofréquence VeinCLEAR™. Le concept du contrôle de l'énergie délivrée.

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Summary

The Radiofrequency (RF) GVS segmental ablation, introduced in 2007 by VNUS Medical Technologies, has proven its excellent tolerance and efficacy, with more than 99% immediate closure (1-Proebstle, 2- Rasmussen).

This efficacy relies on a perfect control of the delivered energy via a thermocouple. Since 2014, a new RF procedure, VeinCLEAR™, brings a significant scientific improvement, by revealing this delivered energy during each cycle.

Thanks to this input, we have been able to collect and analyse the delivered energies during 539 cycles for the treatment of 50 Great Saphenous Veins (GSV).

We have been able to show that the VeinCLEAR™ procedure is totally accurate and efficient (auto check system). Furthermore, this available permanent control of the energy delivered by the operator allowed us to propose a new RF protocol, broader and more accurate, based on 3 cycles and a new concept of "double control of the energy output".

Keywords: radiofrequency, connected object, energy, varicose veins.

Résumé

L'ablation segmentaire de la GVS par radiofréquence (RF), introduite en 2007 par VNUS Medical Technologies, a démontré son excellente tolérance et son efficacité, avec plus de 99 % de fermeture immédiate (1-Proebstle, 2-Rasmussen).

Cette efficacité repose sur un contrôle parfait de l'énergie délivrée par un thermocouple.

Depuis 2014, une nouvelle procédure VeinCLEAR™, qui apporte une amélioration scientifique significative en révélant la valeur de l'énergie délivrée à chaque cycle.

Grâce à cette contribution, nous avons pu recueillir et analyser les énergies livrées pendant 539 cycles pour le traitement de 50 grandes veines saphènes (GSV).

Nous avons pu montrer que la procédure VeinCLEAR™ est totalement précise et efficace (système de contrôle automatique).

En outre, ce contrôle permanent disponible de l'énergie fournie par l'opérateur, nous a permis de proposer un nouveau protocole RF, plus large et plus précis, basé sur 3 cycles et un nouveau concept de « double contrôle de sortie d'énergie ».

Mots-clés : *radiofréquence, objet connecté, énergie, varices.*

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Introduction

GSV Radiofrequency segmental ablation developed since 2007 by VNUS Medical Technologies showed its excellent tolerance and high efficacy with an immediate closure rate superior to 99% (Proebstle; Rasmussen). This efficacy relies on a perfect control of the energy via a thermocouple.

Since 2014, a new RF system VeinCLEAR™ has added a significant scientific step forward, clearly revealing this delivered energy during each cycle. Thanks to this input we have been able to collect and analyze the delivered energy of 539 RF treatment cycles and 50 Great Saphenous Veins (GSV).

We have been able to validate the perfect efficacy of the VeinCLEAR™ system not only on standard diameter veins but also on bigger veins with diameters superior to 10 mm.

This new opportunity to control the system, lead us to propose a new RF treatment protocol, more accurate with a broader range of 3 cycles, thus defining a new concept of “delivered energy double control”.

System Description

The VeinCLEAR™ procedure is a typical Great Saphenous Vein RF treatment, using a catheter similar to the VNUS Medical technologies’, already documented, with a 7 cm heating element at the tip, and heating the vein along 7 cm segments at 120 °C, for 20 second cycles.

RF Medical Co. Ltd. also that manufactures RF ablation systems for thyroid, liver and other tissues, had the idea of monitoring energy levels at the end of each cycle with the V1000 generators series. The double control, of Temperature via the thermocouple and of Energy by the operator (who may adjust energy) shows the global quality of the system.

Study Objectives

The first goal of the study is to collect the delivered energy during each cycle. The second goal is to analyze the coherence between the delivered energies, the veins diameters and the Number of cycles.

Depending on this coherence, the operator may decide to validate a cycle or to add another one, thus applying an incremental energy to reinforce occlusion and final clinical efficacy.

This study also verifies the clinical efficacy and safety of 3 successive cycles on the same segment that have been applied in case of SFJ wider than 11 mm.

As the system proved to be reliable, we are proposing a new treatment protocol with 3 cycles in bigger SFJ.

Material and Methods

From February to November 2015, 50 limbs with GSV incontinence have been treated with VeinCLEAR™ catheter and generator.

All treated limbs were C2 or C3. 25 patients with a SFJ with a diameter superior to 10 mm had 3 cycles on their SFJ. 25 patients with a SFJ with a diameter inferior to 10 mm received 2 or 2, 5 cycles on their SFJ. The saphenous trunks have been treated with 1, 1.5 or 2 cycles.

The VeinCLEAR™ system behaves like a smart connected device, controlling and permanently maintaining the Temperature at 120 °C.

The VeinCLEAR™ system revealed us the delivered energy during each cycle and we have wanted to investigate the relationship between a cycle’s energy and the vein diameter.

In order to calculate the theoretical energy required depending on the vein heated segment diameter, we followed the standard formula of energy calculation (LEED) commonly used for thermal treatments: LEED (J/cm) = D (mm) x 10.

Three steps protocol

1st step: thermal treatment of the vein

We used as basic principle that all the SFJ should be treated by at least 2 cycles, and the junctions wider than 10 mm received an additional cycle (Total of 3 cycles). On the trunks, this protocol included 1 or 2 cycles on the same segment depending on its diameter.

2nd step: emission checking

After each cycle, the energy delivered by the machine is checked by the operator who verifies if it has been sufficient.

3rd step: Delivered energy potential adjustment

Lastly, the operator has been able to compensate a potential lack of energy comparatively to the LEED, by adding a 1/2 cycle of 10 s or an entire 20 s cycle (principle of delivered energy double control).

All the delivered energies and their adjustments on each segment, have been collected for statistical analysis.

In case a second cycle was needed on a segment, it was started when the temperature reached 60°C without waiting for the temperature to decrease to 37°C.

The absence of any clinical side effect (inflammation, paresthesia, skin burn, and ecchymosis) has been verified during the first week post treatment.

Closure of the GSV has been controlled with color duplex ultrasound at day 7 and 1-month post treatment for all patients.

Results

Clinical Results

The average length of treated vein was 42.6 cm **(Figure 1)**.

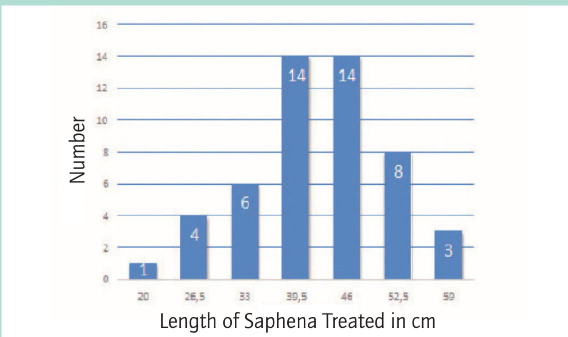

FIGURE 1 : Treated saphenous length.

The average diameter of treated vein was 8.4 cm **(Figure 2)**.

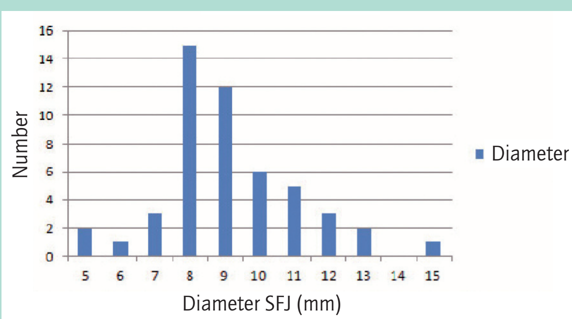

FIGURE 2 : Treated saphenous diameter.

100% of occlusion have been observed without any local complication nor significant side effect.

The low post treatment pain was identical to what has been described in literature [1, 2]: 2 on a scale of 10. The sick leave has been less than 3 days in all cases. There has been no thromboembolic complications, nor post-treatment paresthesia.

Study of cycles:

539 cycles have been applied and studied. The target temperature of 120°C has been reached and permanently maintained in all cases. The energy curves plots are displayed with an appropriate software after downloading the parameters on a USB key. All curves showed a consistent pattern **(Figure 3)**.

Study of LEED on SFJ:

The catheter placed 2 cm before the SFJ, heats the vein on both sides of the resistance, and on a length greater than 7cm due to diffusion.

FIGURE 5 : Intraoperative recording of energy and temperature.

With the various energy levels collected we have been able to calculate the approximate length of energy diffusion, 1 cm on each side, meaning that the energy in one segment is applied on 9 cm (at least for the first cycle) and not 7 cm.

Furthermore, diffusion plus overlap during adjacent cycles lead to addition of 2.5/7 of the total energy. So the result of calculated delivered energy on 7 cm is very close from LEED effectively delivered on 2 adjacent cycles.

Thus, from a scientific point of view it's better to use the energy figure directly displayed on the generator's screen and expressed per 7 cm segments and per cycle.

The delivered energy on SFJ during first cycle is on average 425 Joules. It's 337 Joules (– 17%) for the second cycle at the same place.

This corresponds to a 60J LEED for the first cycle plus 50J for the second, and 110 J/cm for 2 consecutive cycles on a same segment.

The delivered energy on an isolated truncular segment treated with a first cycle has been of 420 Joules with an average LEED of 60 J/cm. The average LEED on 2 adjacent truncular segments is only 382 J/7 cm (52 J/cm), because of overlapping and energy diffusion between 2 adjacent segments, as explained in a preceding chapter.

A second cycle applied on a same truncular segment always leads to a lower energy 43 J/cm (– 17%) due to the thermocouple thermal control.

An additional half cycle has occasionally been added to a standard cycle. It gives 190 J/ cm so 28 Joules/ cm.

Role of tumescence:

With tumescence, the delivered energy in a cycle is significantly superior, + 20% (60 + 50 J/cm) compared to the delivered energy without any tumescence (40 + 34 J/cm).

VeinCLEAR™ ™ delivers a very accurate energy:

The delivered energy on 3 successive adjacent segments of 7 cm plus 6,5 cm and 6,5 cm thus 20 cm giving 420 J + 373 J + 383 J = 1176 J on 20 cm, with a LEED of 58,3 Joules per cm.

Successive energies on a same segment:

The delivered energy during 2 cycles on the same segment is very accurate: 750 Joules (LEED de 110 J/ cm). It's very consistent with very little variations (4%) **(Figure 4)**.

Energy delivered during 3 cycles:

3 successive cycles are not proposed in the Vnus™ / Covidien™ protocol. However it is very realistic to propose more energy (with a 3rd cycle) for the biggest sapheno-femoral junctions wider than 10 mm.

Thus 25 SFJ superior to 10 mm have been successfully treated with 3 successive cycles.

All the saphenous veins have been occluded and no adverse events were observed.

The successive energies during 3 cycles on a same segment are regressive because of local thermal control via thermocouple.

In this case the delivered energies are as follows 424 J, then 337 J and 310 J, with corresponding LEED of 60J + 50 J + 40 J/cm, with a total of 150 J/cm for 60 seconds.

In 25 JSF with such treatment, the controlled delivered energy leads to less than 4% variation, confirming system consistency and accuracy in every case **(Figure 5)**.

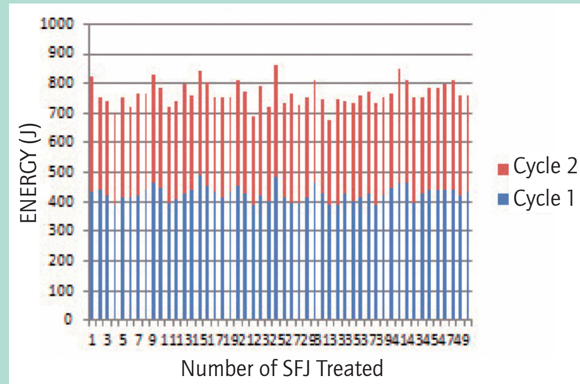

FIGURE 3 : 50 SFJ Energy developed by 2 Cycles

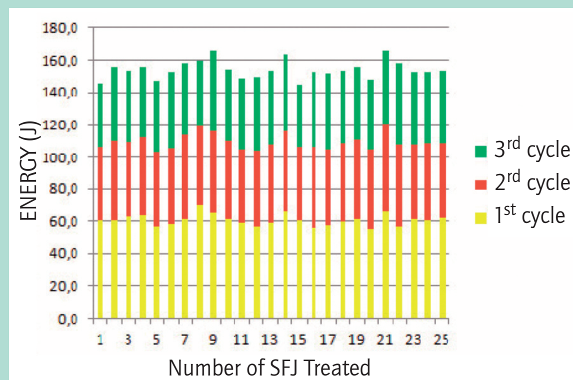

FIGURE 4 : 50 SFJ Energy developed by 2 Cycles

Discussion

The main interest of our study is to show that 539 saphenous segments have been occluded using a broader protocol, with a 3 cycles range without any complications (no pain nor other deleterious clinical sign).

22 SFJ of 11 to 15 mm (105 J/7cm) have been treated with 3 cycles and perfectly occluded.

The 539 cycles have their energies extremely well controlled, with a virtually faultless automatic process.

There is virtually no failure in the electronic curve plots downloaded from the generator.

- Thus, the energy in 2 or 3 successive cycles is extremely accurate as if the second and third cycles were balancing the preceding one.
- The energy delivery in 2 cycles (100 J/cm) or 3 cycles (150 J/cm) on the same segment is operated with a very small standard deviation (4%) as shown in **figure 4 and 5**.

Vnus™ Medical technologies and COVIDIEN™ released in 2007 their simpler protocol with ClosureFAST™ based on a limited number of cycles (1 or 2 cycles) to be completed on a 7 cm vein segment: 2 cycles at the SFJ and 1 cycle on the trunk.

This protocol has been efficient to treat small diameter veins, 6 to 9 mm SFJ and saphenous trunks less than 6 mm, as in the series of 495 veins by **PROEBSTLE** in 2008, which we participated in [1].

But this protocol certainly is insufficient for the treatment of veins with a diameter greater than 10 mm that in principle require more energy.

This COVIDIEN™ protocol has 2 major disadvantages:

- On one hand, it barely considers the diameter of the vein to be treated.
- On the other hand, it does not consider the delivered energies, which leads to the loss of many scientific data.

Indeed, another way to evaluate RF efficiency is to study the energy levels, that we may name, dually controlled delivered energy, as it is regulated first by the thermocouple, then by the surgeon.

Since the advent of thermal treatments in 2000, the research community has been trying to accurately calculate the effective delivered energy of endovenous treatments [3, 4].

This appropriate energy level is somewhere between a too low level leading to a closure failure [5], and an overload of energy causing deleterious effects.

For 980 nm laser, a classical simple equation is used for energy: E = D (mm) x 10 [6, 7].

With this 980 nm, the energy applied on a 6 mm vein should be 60 J/ cm in order to be efficient.

Coincidentally, it exactly is the same average energy developed by the ClosureFast™ and VeinCLEAR™ catheter in a saphenous vein during a first cycle (420 J and 7 cm long).

Energy yield of ClosureFast™ and laser being approximately the same, it is clear that the COVIDEN™ protocol based on one or 2 cycles is not broad enough to meet the large scale of vein diameters, and a 3rd cycle is missing for larger veins.

Increase of efficient energy levels is necessary and based on several facts:

- We are now certain that two consecutive cycles on SFJ do not bring more than 110 J/ cm, which is the theoretical dose for 10 or 11 mm veins.
- The biggest saphenous veins need important energy quantities to obtain a SFJ retraction.
- They need the incremental energy of a 3rd cycle that leads to always 150 J/cm, theoretical energy for a 15 mm vein.

It seems to us that the **Calcagno** [8] publication showing the COVIDIEN™ protocol that allows all diameters to be treated, is not convincing enough due to numerous loss to follow up patients.

Our first study on energy delivery presented at **2008 Copenhagen EVF**, already showed that energy levels of ClosureFast™ radiofrequency are low [9].

Lutsenko publication and Moscow school demonstrated at the 2014 EVF in Paris that 3 and even 4 RF cycles had no deleterious effects, but the authors have not been able to release information on energy quantities delivered during these cycles [10].

The daily practice of ClosureFast™ showed us that 3 cycles on the same segment is efficient and clinically well tolerated, in case of an important tumescence. But this tumescence disturbs a lot the ultrasound checking of the vein immediate occlusion, so to the extent that there is no clinical or echo graphic criteria for immediate closure, and thus no way to compensate a potential failure.

So, the best way to guarantee a complete occlusion is to program an energy delivery bigger than the theoretical, and increase the number of cycles peroperatively.

Energy delivered during 3 cycles:

1-Even if today RF is very efficient (99.5% occlusion), yields of laser and RF Joules do not necessarily correspond.

2-Tumescence contributes to more energy delivered. However, it's impossible to know if this incremental energy is captured by the vein wall or transmitted to the tumescent liquid (currently unquantifiable).

New suggested protocol:

VeinCLEAR™ reliability being proven, we are suggesting this new RF protocol, more accurate allowing to broaden the energy levels (1 to 3 cycles) in order to adjust to increasing vein diameters (5 to 16 mm).

On the SFJ, closure must be ensured with at least two cycles:

- Two cycles are treating a vein less than 10 mm.
- Three cycles are necessary to treat veins wider than 10 mm.

On the saphenous trunk:

- One cycle treats a vein less than 6 mm.
- Two cycles treat a vein of 7 to 10 mm.
- Three cycles are necessary to treat an ectasia more than 10 mm wide.

During the procedure, the operator has a direct view on the energy delivered during the cycle, and can immediately check the cycle validity and eventually adjust it with more energy, before moving on to the subjacent segment.

Most often, the readjustment is of 1/2 cycle (190J/7 cm) eventually 1 cycle (283 J/7 cm) to stick to the exact protocol correlation between diameter and energy.

Thanks to this protocol, the VeinCLEAR™ system is perfectly reliable with its dual control, thermal via the thermocouple and generator, energetic with the operator at the end of each cycle. The operator always has the choice.

The new cases treated with this protocol, not included in this study are fully satisfying.

New studies are necessary and we are attentive to any practitioner who may experience failures with this method.

Key point is that we may rely on the machine, giving one cycle for a vein less than 6 mm, 2 cycles from 7 to 10 mm, and 3 cycles over 10 mm. This standardized protocol already is very effective.

Conclusion

The new VeinCLEAR™ system is efficient, safe, flexible and adaptable to different vein diameters, with a protocol now based on 3 cycles.

Furthermore, a preoperative checking of energy is possible, bringing a self-assessment to the system and an even more accurate energy adjustment.

This study of RF delivered energy in Joules, with a dual control, allows accurate scientific data collection that confirm system reliability and enables a better energy control.

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