

# VNUS Closure® FAST Radiofrequency of the Great Saphenous Vein for Superficial Venous Insufficiency: Experience of the CH of Cholet in France

Birama Togola<sup>1\*</sup>, Laurent Muller<sup>2</sup>, Bréhima Bengaly<sup>1</sup>, Drissa Traoré<sup>1</sup>, Drissa Ouattara<sup>1</sup>, Cheick Sekou Ahmed Touré<sup>1</sup>, Mahamadou Coulibaly<sup>1</sup>, Abdoulaye Kanté<sup>1</sup>, Hamadoun Dicko<sup>3</sup>, Boubacar Diallo<sup>3</sup>, Michel Peret<sup>2</sup>, Nouhoum Ongoiba<sup>1</sup>, Jean Louis Debrux<sup>4</sup>

<sup>1</sup>Department of Surgery “B” of the CHU Point “G”, Bamako, Mali

<sup>2</sup>Department of Vascular and Thoracic Surgery of the CH de Cholet, France

<sup>3</sup>Department of Anesthesia and Intensive Care of the “CHU Point G”, Bamako, Mali

<sup>4</sup>Department of Thoracic and Cardiovascular Surgery CHU, Angers, France

Email: \*togolib@yahoo.fr

**How to cite this paper:** Togola, B., Muller, L., Bengaly, B., Traoré, D., Ouattara, D., Touré, C.S.A., Coulibaly, M., Kanté, A., Dicko, H., Diallo, B., Peret, M., Ongoiba, N. and Debrux, J.L. (2021) VNUS Closure® FAST Radiofrequency of the Great Saphenous Vein for Superficial Venous Insufficiency: Experience of the CH of Cholet in France. *World Journal of Cardiovascular Surgery*, 11, 43-50.

<https://doi.org/10.4236/wjcs.2021.115007>

**Received:** April 30, 2021

**Accepted:** May 28, 2021

**Published:** May 31, 2021

Copyright © 2021 by author(s) and

Scientific Research Publishing Inc.

This work is licensed under the Creative

Commons Attribution International

License (CC BY 4.0).

<http://creativecommons.org/licenses/by/4.0/>



Open Access

## Abstract

**Background:** The objective of this work was to evaluate the first results of the radio ablation of the great saphenous vein in the processing of chronic venous insufficiency. **Method:** This is a monocentric retrospective study of radio ablation of the great saphenous vein using VNUS Closure® FAST for superficial venous insufficiency of the great saphenous vein, between January 2012 and December 2014. **Results:** 42 patients (57 limbs) were operated on with this technology. There were 33 women and 9 men (mean age: 46.5 years). Thirty-nine patients (92.8%) were symptomatic. Thirty-two patients (76.1%) were classified CEAP 2. The average diameter of the saphenous vein was  $8.5 \pm 1.5$  mm. Three patients (7.1%) had a percutaneous approach. A perfect occlusion of the saphenous vein was observed in all patients. No incident or undesirable event was observed during the procedure. One case of delayed deep-vein thrombosis was observed. At one month of follow-up, six patients (14.2%) had induration opposite to the occluded vein. Forty-three percent of the patients stated they were very satisfied with the procedure. **Conclusion:** The effectiveness, security and simplicity of the closure method are real. More studies are necessary to assess the long-term results of this procedure.

## Keywords

Varicose, Great Saphenous Vein, Endovenous Therapy, Radiofrequency Ablation

## 1. Introduction

Crossectomy with ligation of the collaterals and stripping of the saphenous trunks is considering the gold standard in the treatment of varicose veins in superficial venous insufficiency of the lower limbs. However, this surgery is associated with complications and above all with a non-negligible recurrence rate [1] [2]. Over the past decade, endovenous methods considered being less invasive, in particular radiofrequency and laser, have appeared in the therapeutic arsenal of varicose veins of the lower limbs. According to some studies [3] [4] [5] radiofrequency of the great saphenous vein is safe, effective or even superior to the classic crossectomy. This less invasive technology has fewer complications and allows a quick return to activities. In the USA, these endovenous techniques dominate the therapeutic arsenal of varicose veins. In France, venous radio ablation is gaining ground due to the simplicity of the procedure and the equipment used but carried out by a limited number of practitioners.

In 2008 in addition to the classic crossectomy, we introduced venous radio ablation by the VNUS Closure<sup>®</sup> (Closure<sup>®</sup>) process (VNUS Medical Technologies, San Jose, California) at Cholet hospital center. This technology was less offered to patients because of its cost because the catheter was not reimbursed by social security.

The objective of this was to assess the accessibility and the first results of the method, but above all to describe the difficulties associated with its practice by the vascular surgeon in the Cholet HOSPITAL center.

## 2. Patients and Methods

From January 2012 to December 2014, 42 patients for 57 limbs underwent radio ablation of the great saphenous vein by the Closure<sup>®</sup> process. There were 33 women and 9 men (mean age: 46.5 years, range 28 and 71). All of these patients presented with symptomatic superficial venous insufficiency in the form of varicose veins. A preoperative Doppler ultrasound was performed to confirm ostial insufficiency and/or truncal insufficiency by the existence of a reflux greater than 0.5 s but also to measure the diameter of the vein at the level of the saphenofemoral juncture (JSF) and at the level of the saphenous trunk. The main eligibility criterion for the Closure<sup>®</sup> method was the diameter of the saphenous trunk between 3 and 12 mm. Any patient whose measured diameter of the saphenous trunk was less than 3 mm or greater than 12 mm was not eligible.

Pregnant women, patients unable to walk as well as those with deep vein thrombosis were not included.

The patient received complete information about the procedure and signed an informed consent during the preoperative consultation. Venous marking was performed by the angiologist (echo marking) the day before the operation, or by the surgeon before entering the operating room. All patients were operated on as outpatient surgery under general anesthesia.

### Statistical analysis:

Data were collected and entered into Excel and analyzed with SPSS 12 for Windows software (SPSS Inc., Chicago, Illinois). Data are presented as mean  $\pm$  standard deviation or as proportions. Chi<sup>2</sup> or Fischer tests were used to compare the proportions, the Student test to compare the means. A p value < 0.05 was considered significant.

## 3. Results

During the study period, 42 patients with 57 limbs were eligible for the Closure<sup>®</sup> method.

The sex ratio was 3.6. Thirteen patients (30.9%) had no risk factors. Three patients (7.1%) were hypertensive. In five patients (12.0%), the pregnancy favored varicose veins. One patient had undergone varicose vein surgery using CHIVA technique (Hemodynamic treatment of Venous Insufficiency on Ambulatory).

Thirty-nine patients (92.8%) were symptomatic. Thirty-two patients (76.1%) were classified as CEAP 2. In six patients (14.2%), the indication was given because of a complication of varicose veins such as superficial phlebitis (**Table 1**).

In three patients (7.1%), the consultation was motivated for an aesthetic reason. Truncal insufficiency alone was observed in two patients (4.7%). The mean diameter of the saphenous vein was 8.5 mm  $\pm$  1.5 (range 5 and 10 mm). Sixteen patients (32%) were classified ASA II (**Table 2**).

Three (7.1%) patients had a percutaneous approach. In four patients (9.5%), the saphenous vein was approached both at the ankle and at knee.

No incidents or adverse events were observed during the procedure except a difficulty for visualizing the saphenous femoral juncture (JSF) in an obese patient.

**Table 1.** Demographic characteristics and risk factors of patients who benefited from the Closure<sup>®</sup> radio frequency process.

Characteristics	Effective	Percentage
Mean age	46.5	
Men	9	21.4
Women	33	78.6
Overweight	5	12.0
Smoking	16	38.0
High blood pressure (HTA)	3	7.1
Family risk for varicose	17	40.4
Pregnancy	5	12.0
Superficial venous thrombosis	6	14.2
Deep venous thrombosis	3	7.1
CHIVA technique	1	2.3

CHIVA: Hemodynamic Treatment for Insufficiency Venous on Ambulatory.

Perfect saphenous vein occlusion was observed at the end of all procedures.

No immediate postoperative pain was observed in 78.5% while 16.7% had moderate pain.

Venous thromboprophylaxis was performed in 85.7% after an evaluation of the risk of venous thromboembolism according to the SCV score.

Only one patient (2.7%) presented with deep vein thrombosis for ultrasound control on day 3. It was an extension of a thrombus to the femoral vein. This thrombus had disappeared at 1 month after effective curative anticoagulation. No case of hematoma was observed.

At 1 month, six patients (14.2%) had induration along the path of the occluded saphenous vein. Skin dysesthesia was reported by 23.9% and 19% of patients had residual pain. No case of recanalization or reflux has been documented.

Forty-three percent of patients were very satisfied with the procedure (**Table 3** and **Table 4**).

**Table 2.** Primary presentation according to clinic of patients having benefited from the Closure<sup>®</sup> radio frequency process.

Clinical	Effective	Percentage
Symptomatic	39	92.8
Aesthetic	3	7.1
Bilateral	15	35.7
Right	12	28.5
Left	15	35.7
Ostia insufficiency and trunk	40	95.2
Trunk insufficiency	2	4.7
ASA I	26	61.9
ASA II	16	38.0
CEAP2	32	76.1
CEAP3	9	21.5
CEAP4	1	2.4

CEAP: Clinic-Etiology-Anatomy and Pathology classification.

**Table 3.** Post-operative effects on the 3rd day of patients having benefited from the Closure<sup>®</sup> radio frequency process of the great saphenous vein.

Post operatives effects	Effective	Percentage
Simple	33	78.5
Weak pain	7	16.7
DTV	1	2.4
STV	1	2.4
Total	42	100.0

DTV: Deep Venous Thrombosis; STV: Superficial Venous Thrombosis.

**Table 4.** Postoperative follow-up at 1 month for patients having benefited from the Closure<sup>®</sup> radio frequency procedure of the great saphenous vein.

Post operatives affects	Effective	Percentage
Very satisfied	18	42.9
Dysesthesia	10	23.9
Weak pain	8	19.0
Induration	6	14.2
Total	42	100.0

#### 4. Comments

Long saphenous vein obliteration by the Closure<sup>®</sup> radio frequency method is the equivalent of excisional surgical technology, which aim to remove incontinent saphenous trunks. The originality of this truncal removal technique is that it fully respects the saphenofemoral junction and does not require an inguinal incision.

At the start of the system in 1998, the difficulties mainly related to the descent of the catheter lengthened the duration of the procedure and could be the cause of some failures [3] [5]. In 2007, the introduction of a new catheter (VNUS Closure<sup>®</sup> Fast) facilitated this procedure. Descent is easy and the energy delivered to the catheter is regular, improving the quality of the result [5] [6]. The phase of learning of the ultrasound by the surgeon seems to be essential in the procedure. Doppler ultrasound is important preoperatively for the eligibility diagnosis (the diameter of the vein must not be greater than 10 mm), intraoperatively for percutaneous approach to the vein, visualize the position of the catheter at 2- about 3 cm of the JSF, and immediately postoperatively for the control of the perfect occlusion without reflux of the treated vein, but also for the absence and the follow-up of a deep vein thrombosis [4]. In the USA, since 2005 under the influence of social security, carrying out the procedure in an “office setting” or “out-patient” has galvanized the method. Currently, many surgeons prefer to perform endovenous techniques under local anesthesia called tumescent. This tumescent solution is made from a mixture of 1% lidocaine with sodium bicarbonate at a ratio of 1/5. Tumescent anesthesia reduces postoperative pain, protects tissues near the vein such as the saphenous nerve from damage, but also prevents skin burns by reducing the size of the vein. While tumescent infiltration could initially be done by hand, nowadays the development of an automatic pump or syringe has facilitated this procedure. However, the volume of the tumescent anesthesia solution used can reach 250 - 450 cc. In the study by Proebstle *et al.* [7], local anesthesia is associated in 41% of cases with intravenous sedation. Wall *et al.* [8] did not find any significant difference in terms of complications, postoperative pain and aesthetic appearance between conventional surgery performed under local anesthesia or under general anesthesia.

The success rate of radiofrequency varies between 87% and 100% depending on the study [1] [9]. The new Closure<sup>®</sup> Fast catheter has resulted in an anatomi-

cal success rate of around 100% [4] [5]. In our series we had 100% immediate occlusion and at 1 month of the treated saphenous vein. In the meta-analysis by Van Den Boss *et al.* [1] published in 2009 comparing the results of different therapeutic methods, the success rate after 3 years of radiofrequency follow-up was evaluated at 84% with the original catheter. With the new Closure<sup>®</sup> fast catheter, Enzler [10] found a success rate of 94% at 1 year. Some studies [1] [5] [9] [10] [11] [12] showed a better return to activities, less postoperative pain, a significant improvement in clinical symptoms, low morbidity and better quality of life after radiofrequency compared to classical surgery and other therapeutic methods. The time to return to normal activity varies from 2 to 7 days. At the start of our experience, the duration of sick leave was identical to that of conventional surgery. However, over time, return to work was done on D5 after Doppler ultrasound.

Inguinal neovascularization has been strongly implicated in varicose recurrence after crosssectomy with ligation of the collaterals and stripping. It has been established that in long saphenous truncal incontinence, the saphenofemoral junction is often continent. As a result, the interest of the classic crosssectomy arises [13]. According to Creton and the Closure group [3] who had observed less recurrence after radiofrequency, endovenous methods, by the absence of an inguinal incision and the preservation of the saphenofemoral junction, constitute a barrier to recurrence. However, some authors [1] [14] believe that venous ablation by laser is more effective than radiofrequency and surgery. However, for others [3] [4], radio ablation is better tolerated because of the duration and consistency of the energy transmitted to the walls of the vein, unlike the laser which causes perforations which cause pain. Classic crosssectomy can have a high morbidity in particular a long convalescence, an inguinal infection, a deep vein thrombosis, hematomas and postoperative pain or even nerve damage. However, endovenous methods such as radiofrequency are not without side effects or complications (ecchymosis, hematoma, pain, indurations, deep vein thrombosis, and dysesthesia). In the meta-analysis by Luebke *et al.* [12] comparing radiofrequency and conventional surgery, there was less hematoma and bruising after radiofrequency during the first 3 weeks postoperatively. These authors did not find a significant difference in terms of serious complications such as deep vein thrombosis.

According to NIJSTEN T *et al.* [2], the frequency of deep vein thrombosis rarely seems to be greater than 1% after radiofrequency. A number of preventive measures are recommended to reduce the risk of deep vein thrombosis: good anticoagulation in patients at high risk of thrombosis, administration of LMWH postoperatively for 1 week, good location of the catheter below of JSF under the epigastric collateral, good administration of tumescent local anesthesia, Doppler echo control at 1 week.

Neurological lesions like cutaneous dysesthesia along the pathway of the saphenous vein have been reported during endovascular therapy such as radiofre-

quency with a lower prevalence than that of conventional surgery. They are linked to an extravasation of the sclerosing product or to the intensity of the energy delivered to the walls of the vein.

A good tumescent infiltration or tumescent local anesthesia helps prevent this nerve damage. The dysesthesia presented by almost a quarter of our patients could possibly be due to our lack of experience or insufficient tumescent infiltration. By its mechanism of action, radiofrequency induces an inflammatory reaction, which may be responsible for indurations and residual pain.

According to some studies, the satisfaction rate after a radio-ablation of the great saphenous vein reaches 95%. The cost of the procedure appears to be high compared to a conventional crosssectomy [15]. However, this difference is quickly made up by a quick return to normal activities and an early return to work.

## 5. Conclusion

Minimally invasive or endovenous techniques seem to give good results while allowing an earlier return to work. The vascular surgeon is obliged to appropriate these new technologies for satisfaction of his increasingly demanding patients.

## Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

## References

- [1] Van den Bos, R., Arends, L., Kockaert, M., Neumann, M. and Nijsten, T. (2009) Endovenous Therapies of Lower Extremity Varicosities: A Meta-Analysis. *Journal of Vascular Surgery*, **49**, 230-239. <https://doi.org/10.1016/j.jvs.2008.06.030>
- [2] Nijsten, T., Van den Bos, R.R., Goldman, M.P., Kockaert, M.A., Proebstle, T.M., Rabe, E., Sadick, N.S., Weiss, R.A. and Neumann, M.H.A. (2009) Minimally Invasive Techniques in the Treatment of Saphenous Varicose Veins. *Journal of American Academy of Dermatology*, **60**, 110-119. <https://doi.org/10.1016/j.jaad.2008.07.046>
- [3] Creton, D. and Closure Group. (2006) Saphenous Venous Obliteration by the VNUS CLOSURE® Radiofrequency Method: 5-Year Results of the Prospective Multicenter Study. *Phlebology*, **59**, 67-72.
- [4] Roland, L. and Dietzek, A.M. (2007) Radiofrequency Ablation of the Great Saphenous Vein Performed in the Office: Tips for Better Patient Convenience and Comfort and How to Perform It in Less Than an Hour. *Perspectives in Vascular Surgery and Endovascular Therapy*, **19**, 309-314.
- [5] Proebstle, T.M., Vago, B., Alm, J., Göckeritz, O., Lebard, C. and Pichot, O. (2008) Treatment of the Incompetent Great Saphenous Vein by Endovenous radiofrequency Powered Segmental Thermal Ablation: First Clinical Experience. *Journal of Vascular Surgery*, **47**, 151-156. <https://doi.org/10.1016/j.jvs.2007.08.056>
- [6] Kabnick, L.S. (2007) Commentary on "Radiofrequency Ablation of the Great Sa-

- phenous Vein Performed in the Office: Tips for Better Patient Convenience and Comfort and How to Perform It in Less than an Hour". *Perspectives in Vascular Surgery and Endovascular Therapy*, **19**, 315-316.
- [7] Proebstle, T.M., Paepcke, U., Weisel, G., Gass, S. and Weber, L. (1998) High Ligation and Stripping of the Long Saphenous Vein Using the Tumescence Technique for Local Anesthesia. *Dermatologic Surgery*, **24**, 149-153. <https://doi.org/10.1111/j.1524-4725.1998.tb04068.x>
- [8] Wall, M.L., Dealey, C., Davies, R.S.M. and Simms, M.H. (2009) Local versus General Anesthesia for Varicose Veins Surgery: A Prospective Non-Randomized Controlled Trial. *Phlebology*, **24**, 61-66. <https://doi.org/10.1258/phleb.2008.008029>
- [9] Almeida, J.I., Gockeritz, O., Kaufman, J., Richard, T., Makhoul, R., Chopra, P., et al. (2009) Radiofrequency Endovenous Closure FAST versus Laser Ablation for the Treatment of Great Saphenous Reflux: A Multicenter, Single-Blinded, Randomized Study (Recovery Study). *Journal of Vascular and Interventional Radiology*, **20**, 752-759. <https://doi.org/10.1016/j.jvir.2009.03.008>
- [10] Enzler, M.A. and Van Den Bos, R.R. (2010) A New Gold Standard for Varicose Vein Treatment? *European Journal of Vascular and Endovascular Surgery*, **39**, 97-98. <https://doi.org/10.1016/j.ejvs.2009.09.008>
- [11] Stötter, L., Schaaf, I. and Bockelbrink, A. (2006) Comparative Outcomes of Radiofrequency Endoluminal Ablation, Invagination Stripping, and Cryostripping in the Treatment of Great Saphenous Vein Insufficiency. *Phlebology*, **21**, 60-64. <https://doi.org/10.1258/026835506777304692>
- [12] Luebke, T., Gawenda, M., Heckenkamp, J. and Brunkwall, J. (2008) Meta-Analysis of Endovenous Radiofrequency Obliteration of the Great Saphenous Vein in Primary Varicosis. *Journal of Endovascular Therapy*, **15**, 213-223. <https://doi.org/10.1583/07-2287.1>
- [13] Pittaluga, P., Chastanet, S. and Guex, J.J. (2008) Great Saphenous Vein Stripping with Preservation of Sapheno-Femoral Confluence: Hemodynamic and Clinical Results. *Journal of Vascular Surgery*, **47**, 1300-1304. <https://doi.org/10.1016/j.jvs.2008.01.042>
- [14] Ravi, R., Trayler, E.A., Barrett, D.A and Diethrich, E.B. (2009) Endovenous Thermal Ablation of Superficial Venous Insufficiency of the Lower Extremity: Single-Center Experience with 3000 Limbs Treated in a 7-Year Period. *Journal of Endovascular Therapy*, **16**, 500-505. <https://doi.org/10.1583/09-2750.1>
- [15] Subramonia, S. and Lees, T. (2010) Radiofrequency Ablation vs Conventional Surgery for Varicose Veins a Comparison of Treatment Costs in a Randomized Trial. *European Journal of Vascular and Endovascular Surgery*, **39**, 104-111. <https://doi.org/10.1016/j.ejvs.2009.09.012>