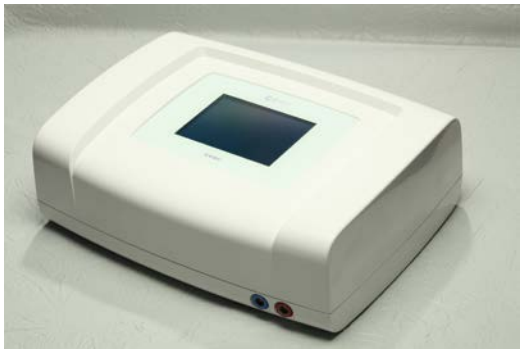
GSV treatment with Radio Frequency EVRF device and CR45i catheter

CLINICAL STUDY



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INTRODUCTION

Fcare Systems USA LLC is the Miami based headquarters for the Americas Fcare Systems NV. These products have been designed, produced and sold as the most advanced thermocoagulation systems to dramatically improve the appearance of leg veins and telangiectasia.

Fcare Systems Europe, established in Antwerp, Belgium, is a leading manufacturer of medical and beauty equipment. Fcare Systems designs products for the medical and esthetical medical industries.

Fcare Systems works together with highly recognized researchers and opinion leaders to improve the quality of its products.

To meet your needs and the needs of those receiving treatments, our dedicated research and development team continues to rise to the challenge of designing the most advanced solutions. It is our priority to develop cosmetic technology that allows you to confidently treat with superior comfort and results.

Fcare Systems sells its products through an international network of distributors. Products are available in more than 19 countries. Every month they are adding distributors in other parts of the world so that patients can benefit from their technologies.

Fcare Systems, manufacturer of the TC 3000/THERMOCOAGULATOR, first device to be FDA approved is now launching the EVRF®, an upgraded version of this successful line of thermocoagulators. EVRF® will work as a platform for future technologies.

Fcare Systems decided to do a clinical study on the treatment of the Great Saphenous Vein (GSV) and associated perforators with Dr Thomas Niesen, who has a great experience with the VNUS closure system and did many cases.

The monopolar high frequency thermocoagulation has been used for 13 years for variscose veins treatments and since last year in Europe for saphena magna. It

generates a 4 to 12 MHz radio frequency (high frequency), which allows an effective treatment of the vein Wall, with minimal damage to the surrounding tissues. It causes less pain and improves the post-surgery results.

The goal of this Clinical Study is to estimate the effectiveness of the treatment and the permanent results using the Belgium device EVRF with the CR45i (for GSV) and CR12i or 30i (for perforators) catheters to remove the internal saphena and perforators of patients with femoral saphenous flow problem.

For more than 30 years, St. Louis Surgical Consultants has been one of the leaders in advanced surgical care, providing evaluation and treatment of a full range of complex problems. Trained at the Washington University Medical Center in St. Louis and certified by the American Board of Surgery, our physicians are among the most well-regarded in the greater St. Louis metropolitan area. Their surgical skills include traditional and state-of-the-art general and vascular techniques.
The surgeons at St. Louis Surgical Consultants have received advanced training beyond general surgery and are able to do laparoscopic procedures, including minimally invasive colo-rectal surgery.
Located on the St. Luke's Medical Center campus, our physicians have access to consulting physicians and rehabilitative care. We are dedicated to offering seamless, quality patient care.

I. HOW DOES THERMOCOAGULATION WORK ?

The EVRF is a radio frequency device that invokes, together with the special insulated needle, a temperature increase in the small varicose veins. For the bigger varicose veins and the Saphena magna a special designed catheter will be used.

A special flexible miniature catheter has been created whereby the tip of the catheter is not insulated. One channel will guide the RF signal to the tip of the catheter. The catheter will thus be only heated up at the tip and the RF will not have the possibility to disperse into the body of the patient.

This technology allows a temperature increase on a small spot without burning the tissue around the treated area. The temperature of the vein only will increase and not the surrounding skin nor tissue. As such, the EVRF finds an answer to the problem all lasers expose, namely an unpleasant and sometimes even painful

increase of temperature in the area in between the vein and the surface of the skin.

A patent has been awarded for the flexible catheter. A copy of the patent application and the patentability study can be provided upon request.

The catheter is placed in an especially designed hand piece, which allows the doctor to easily introduce the catheter in the vein, with minimal pain or discomfort for the patient.

The catheter today comes in three sizes, a GSV catheter, a 0,7mm catheter and a 0,3mm hand piece design catheter for different sizes of veins.

The GSV catheter is called Cr45i.

II. PATIENT SELECTION

II.1 Inclusion criteria

Insufficiency of the great saphenous vein with functional and/or esthetical inconvenience and/or insufficient tributaries.

II.2 Exclusion criteria

1. Deep venous insufficiency
2. For Great Saphenous Vein (GSV): Cross dilation with more than 2 incompetent side-branches and maximal diameter of the saphenous vein > 15 mm
3. Therapeutically anticoagulation or hypocoagulopathy

4. Hypercoagulopathy

5. Peripheral arterial occlusive disease

6. Pregnancy

7. Patients younger than 18 years

III. AIM OF THE STUDY

In this trial, we would like to evaluate the use of thermocoagulation of the great saphenous vein (GSV) as well as the tributaries. An assessment will be made on the efficacy and the tolerability of the thermocoagulation. We will include 50 patients.
We want to measure the effectiveness of the treatment method and the permanent results after the treatment.

We want to see whether thermocoagulation is a viable treatment method compared to other treatment methods and elaborate on the advantages and disadvantages.

We will control for postoperative data and measure the vein preoperative, after 7 days, 1 month and after 6 months.

We will also look for occlusion after 1 month and after 6 months. We will note the possible side-effects of this treatment: looking for the postoperative incapacity to work, the amount of painkillers used, the appearance of postoperative ecchymosis, periphlebitis and a postoperative quality of life-score.

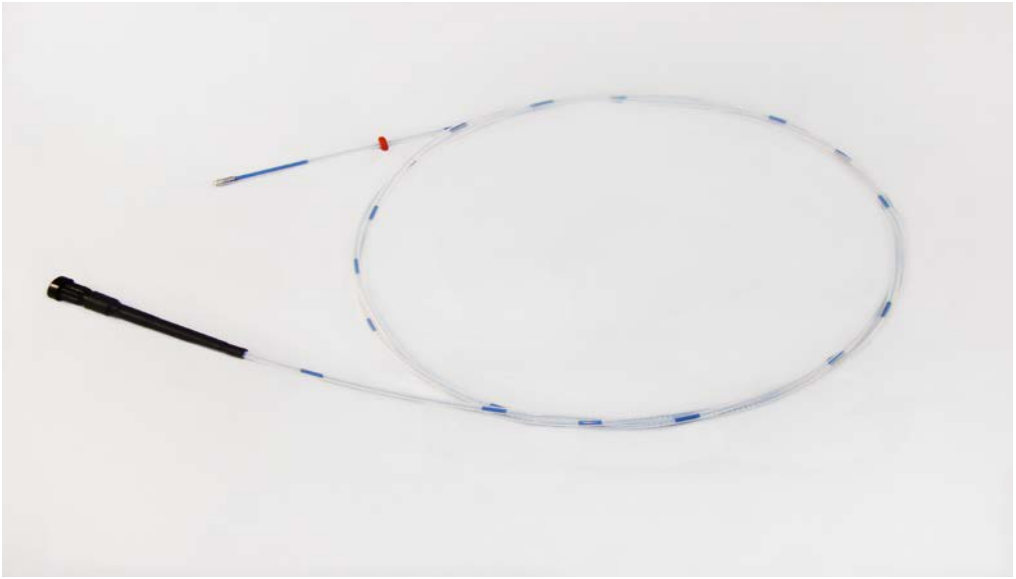
IV. MATERIALS AND METHODS

Material used:

- EVRF system is the radio frequency generator
- CR45i is the catheter used to treat the great saphenous vein (GSV)

EVRF DEVICE

CR45i CATHETER



CR45i CATHETER

V. TRIAL DESIGN

1. Primary end point is the measurement of the closure of the vein. This measurement will be done after 1 month and after 6 months.

2. The trial is not double-blind but is a validation of the treatment technique. Closure of the treated vein is a primary indication of the effectiveness of the treatment.

3. The trial is non randomized and not blind.

4. The treatment dosage and treatment protocols are explained in the attachment.

5. The expected duration of the trial is 18 months, with follow up intervals of 6 months.

V.1 Preoperative patient assessment

AGE	GENDER	OCCUPATION	CEAP-score	BMI-index	QUALITY OF LIFE score

V.2 Preoperative duplex-mapping

Measuring the diameter of the great saphenous vein (GSV), at standard referential points, with the patient in standing position and/or measuring the tributaries at two different points (most distal and most proximal part). Also the length of the refluxing part of the vein should be measured. With the tributaries, we will use a drawing.

V.3 GSV Procedure

1. Access is made to the saphenous vein at its most distal part of reflux by puncture and introducing a sheath and a catheter.

2. Localization of the fiber tip at 2 cm distal to the sapheno-femoral junction by controlling the position with preoperative ultrasound.

3. Injection of tumescent anesthesia abundantly in the saphenous eye (minimally 250ml/vein), the saphenous vein should complete surrounded with liquid.

4. Tumescent anesthesia : solution of 1, 4% bicarbonate (500ml) + 1 amp Xylocaine 2%.

5. Trendelenburg position.

6. Energy deliverance protocol.

7. Measuring the used energy : total used energy/cm.

8. Measuring the length of the treated vein.

V.5 Postoperative treatment

1. Compressive bandage or stockings for 10 days after GSV treatment, 5 days after treatment of the tributaries.

2. DVT prophylaxis for 10 days: Clexane 40 1/day if risk factors are present.

3. Mobilization as soon as possible.

4. Clinical evaluation after 1 week measuring ecchymosis and noting pain and number of painkillers.

5. Quality of life (QOL) score preoperative, after 7 days and after 1 month.

6. Duplex control after 1 month and 6 months postoperatively.

7. Postoperative pain score : visual analogue score (1-10) at day 2, 5, 7 and day 10.

8. Postoperative patient satisfaction rate: rating 1-10 at clinical control after 1 month and 6 months.

V.6. Analysis and reporting

For this pilot study we will report the available data.

VI. RISKS AND BENEFITS

VI.1 Risks

There are very limited risks for the patients, included in the study. The treatment protocol attached will not cause any permanent risks for the patient.

There are two potential risks:

1. When we observe after the operation that the veins have not been closed or that the occlusion is not complete. (a new operation or treatment has to be done).

2. Burning of the skin when the treatment is done outside the treatment protocol. (Burning is minimal and if it occurs, discomfort is temporary, as the skin will regenerate after a period of 12 to 18 weeks).

VI.2 Benefits

The benefits for the patients:

- This is a day clinic operation compared to stripping which allows the patient to walk the next day.
- Less pain than with traditional stripping.
- For the attributes there is a permanent occlusion, less recurrence.

VII. METHOD

52 patients, with femoral saphenous flow problems were treated from August 15, 2014, until June 5, 2015, with the EVRF, the CR45i catheter and a power of 25 watts. The speed removal of the catheter was first after 15 shots and then after 3 or 4 shots for each half centimeter.

The total power used, as well as the size of the treated vein, was recorded. The protocol we followed goes along with the thermocagulation techniques, beginning with the removal at 2cm of the femoral saphena junction and injecting a tumescent solution.

An evaluation was carried out during the same week of the surgery and during the month, using a post-surgery pain scale, post-surgery satisfaction of the patient and ultrasonic results of the treatment.

VII.1 Pre-operative Data

CEAP					
C1	C2	C3	C4	C5	C6
0	0	5	9	9	7

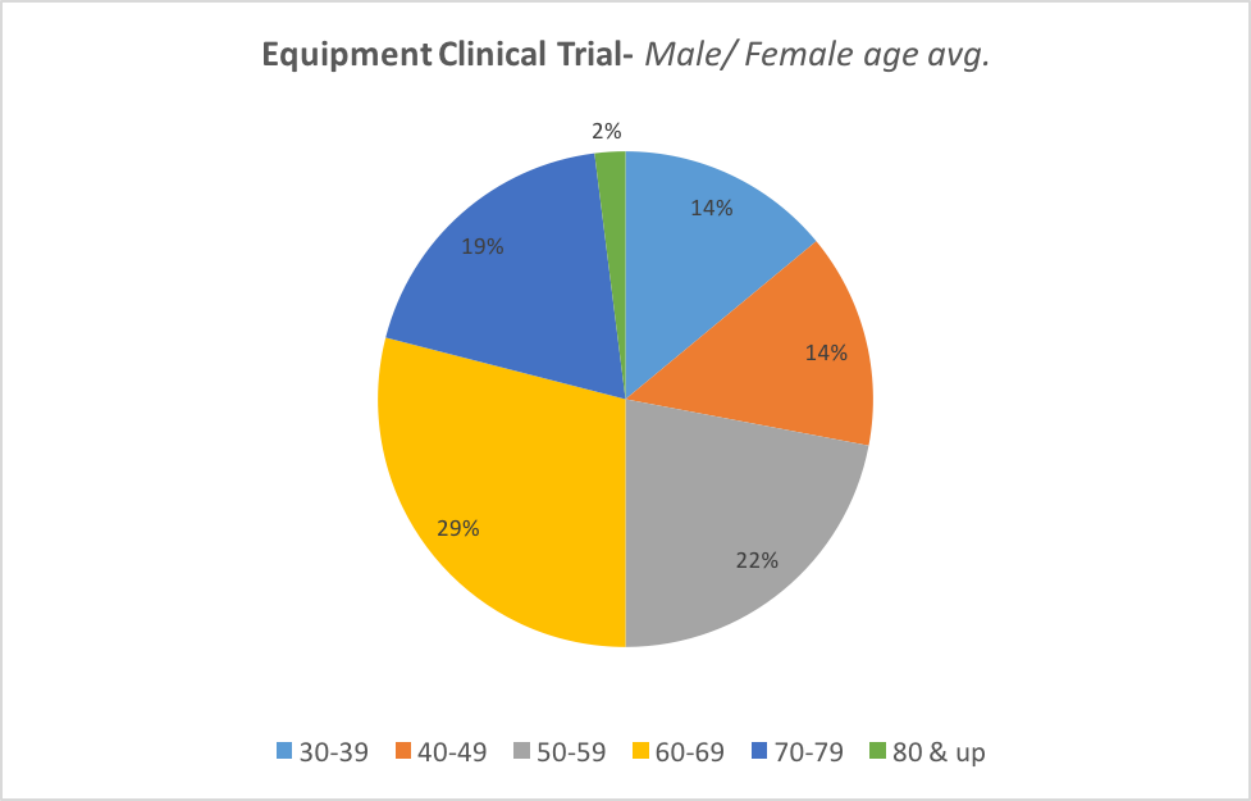
- All the patients had a local anesthesia and tumescence injection.
- Number of GVS.
- 52 patients and 52 GSV were treated.
- No reticular no callateral

VIII. RESULTS

52 cases based on 52 patients were treated with this procedure, with a saphena diameter of 1.8cm, transmitting 16,880 Joules average total energy.

Patient #	GSV side	ocedure time (min)	Treatment time	ength (cm)	Joules (J)	Watts (W)	Results
1	left	13	3 min 09 sec	31	4725	25	closed
2	left	20	4 min 49 sec	44	7225	25	closed
3	left	20	2 min 36 sec	20	3744	24	closed
4	right	20	5 min 06 sec	44	7650	25	rtially closed
5	left	26	6 min 9 sec	48	6992	25	closed
6	right	28	10 min 24 sec	48	118565	25	closed
7	left	25	6 min 12 sec	40	9300	25	closed
8	right	17	6 min 38 sec	35	9950	25	closed
9	right	27	8 min 37 sec	48	12432	24	closed
10	left	25	8 min 06 sec	40	12150	25	closed
11	right	22	6 min 44 sec	40	10100	25	closed
12	right	27	8 min 23 sec	45	12575	25	closed
13	right	20	6 min 13 sec	40	9325	25	closed
14	left	23	8 min 47 sec	45	13175	25	closed
15	left	15	5 min 07 sec	25	7675	25	closed
16	left	17	10 min 10 sec	47	15250	25	closed
17	left	28	9 min 13 sec	40	13805	25	closed
18	right	15	4 min 05 sec	14	6105	25	closed
19	right	26	11 min 07 sec	46	16675	25	closed
21	left	26	11 min 54 sec	50	17725	25	closed
22	right	27	10 min 31 sec	45	15775	25	closed
23	right	25	4 min 49 sec	32	10255	25	closed
24	left	28	9 min 47 sec	46	14675	25	closed
25	right	22	8 min 24 sec	45	12400	25	closed
26	right	18	8 min 01 sec	38	12025	25	closed
27	right	21	9 min 12 sec	45	13800	25	closed
28	right	25	11 min 49 sec	50	17725	25	closed
29	right	15	4 min 01 sec	16	6025	25	closed
30	left	23	7 min 41 sec	45	11525	25	closed
31	right	32	8 min 32 sec	45	12875	25	closed
32	left	23	9 min 11 sec	40	13775	25	closed
33	left	22	8 min 09 sec	40	12225	25	closed
34	left	17	3 min 43 sec	17	42180	25	closed
34	left	23	10 min 37 sec	45	15925	25	closed
35	right	18	7 min 19 sec	35	10975	25	closed
37	left	15	3 min 46 sec	18	5660	25	closed
38	left	30	10 min 20 sec	42	15300	25	closed
39	left	25	8 min 36 sec	32	12875	25	closed
40	left	25	10 min 21 sec	40	15325	25	closed
41	left	25	8 min 49 sec	40	13225	25	closed
41	right	20	7 min 30 sec	36	11250	25	closed
42	right	25	10 min 34 sec	40	15850	25	closed
43	left	15	5 min 48 sec	25	8700	25	closed
44	left	22	8 min 32 sec	40	12900	25	closed
45	right	30	8 min 13 sec	36	12325	25	closed
46	right	14	2 min 12 sec	10	3300	25	closed
47	right	22	7 min 20 sec	32	11000	25	closed
48	left	20	7 min 24 sec	32	11100	25	closed
49	right	22	10 min 12 sec	32	15300	25	closed
50	left	36	8 min 1 sec	32	12475	25	closed
51	left	23	10 min 19 sec	46	152175	25	closed
52	right	21	7 min 48 sec	48	11700	25	closed

- 98% : Total occlusion of the saphena vein (51/52);
- 2% : Partial occlusion of the saphena vein (1/52);



CONCLUSION

Further to this trial, we can say that the EVRF is the most reliable device and that along with the CR45i catheter they are highly effective to remove femoral saphenous. They cause minimum pain and post-surgical side effects.

98% of total occlusion of the saphena vein is the best obtained and most of the patients were satisfied.

Dr Nielsen presented these results and technique.

Patrick Danciu is the Clinical Research Director of F Care Systems.

For more information, see www.fcaresystems.us.

Clinical study conducted in 2014-2015.

Dr Nielsen
Thomas E. Niesen, M.D. was born and raised in St. Louis, MO. He attended Tulane University, New Orleans, LA, for undergraduate and Medical School. He returned to St. Louis and did his internship and residency in surgery at Barnes Hospital, Washington University School of Medicine. He is board certified in Surgery by the American Board of Surgery.
He has been in surgical practice since 1986 at St. Luke's Hospital in Chesterfield, MO.

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