



CELON RFITT® RADIOFREQUENCY: Results and evolution of the procedure from the beginning

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Faculty Disclosure

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OR I have **no financial relationships** to disclose.

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TECHNIQUE

CELON RFITT[®] RADIOFREQUENCY Radiofrequency Induced Thermal Therapy (2007) Olympus Company, Hamburg, Germany

CELON RFITT® RADIOFREQUENCY The BI-POLAR APPLICATOR



Diameter: I.8 mm

(Fits a 6F Sheath or a 5F with dilator)

Electrode length: 15 mm

Total length: 1200 mm



Vein wall used as a conductor between both poles; temperature reaches 65° to 95°C within the vein wall, but applicator remains <u>cold</u>

CELON RFITT® RADIOFREQUENCY The Bi-polar POWER CONTROL UNIT



- AUTOMATIC CONSTANT CONTROL of the IMPEDANCE
- With AUTOMATIC POWER CONTROL
- And AUDIO FEEDBACK

CELON RFITT® RADIOFREQUENCY THE PROCEDURE

Similar to EVLA and Closure Fast®

Percutaneous puncture (US guidance) \succ Guide wire and sheath introduction \succ Guide wire withdrawal > Applicator introduction ➢ Trendelenburg > Applicator tip positioning (US guidance) Tumescent anaesthesia (US guidance) Thermal application



EVOLUTION FROM THE BEGINNING

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CELON RFITT® RADIOFREQUENCY Settings recommended by the Manufacturer

- 2007 : Power (P) of 25W and an application time (T) of I sec/cm, using a single pass
- ▶ 2012 : P 18-20W and $T \ge 1.5$ sec/cm

T can be increased by making several passes, depending on the diameter of the vein to be treated

LITERATURE DATA

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Radiofrequency-induced thermal therapy: results of a European multicentre study of resistive ablation of incompetent truncal varicose veins

Phlebology 2012; 1-9

B Braithwaite*, L Hnatek[†], U Zierau[‡], M Camci[§], GJM Akkersdijk**, D Nio**, M Sarlija^{††}, M Ajduk^{††}, P Santoro^{‡†} and E Roche^{§§}

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- 462 patients (569 GSV and 103 SSV)
- FU between 180 and 360 days (mean 290 +/- 84)
- Complete occlusion 92% ; partial occlusion 4%; failure 3%
- Sensory disturbance 6%
- Better results (98.4%) if
 - P 18-20 W (vs 25 W)
 - T > 1.5 s/cm; no failures if T > 2.5 s/cm
 - Learning curve > 20 procedures

Settings

Zierau U.T., Lahl W. Phlebology 2009

97.6% success rate

- **I8W**
- **T** ≥ **3.4sec/cm**

S Reich-Schupke⁻ Phlebology 2011 (ex vivo experiment) "A homogeneous necrosis of the circumferential vein wall needs sufficient application time"

- Zierau U.T., Lahl W.The endogenous RFITT-treatment of varicose veins, a new method of interventional phlebology. Phlebology 2009; 38:12-16

- Reich-Schupke S., Mumme A, Sutcker M. Histological findings in varicose veins following bipolar radiofrequencyinduced thermotherapy – results of an ex vivo experiment. Phlebology 2011; 26: 69-74

OUR EXPERIENCE

CELON RFITT® RADIOFREQUENCY

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Hamel-Desnos C., Desnos P. Prospective monocentric study (Caen-France)

- Between 2009 and 2012
- I68 SV (126 GSV, 36 SSV, 6 ASV);

average truncular Ø 8.2 mm (extr. 3.5-15)

- II7 patients (71% female); mean age 58 (extr. 17-87)
 mean CEAP 2 (extr. 2-6); mean BMI 25 (extr 17-43)
- Clinic room
- No sedation; tumescent anaesthesia only
- No phlebectomy
- Complementary treatments administered, where necessary, using foam sclerotherapy, usually in a deferred mode

RESULTS

> At I Month-FU control :

- 95% (n=159) of complete occlusion; mean length of occlusion 48 cm (extr. 8-66)
- 4% (n=7) of partial occlusion
- 2 technical failures : one impossibility of moving forward the applicator into the vein after cleaning it (carbonization) and one technical failure of the applicator

RESULTS

- Apart from one patient who died from hepatic neoplasia one year after undergoing the procedure, all of the patients were seen again for a final DS assessment, performed in the great majority of cases by a different operator from the one who performed the RF procedure
- Max. FU = 4 Years; mean FU 2Y and half
 - 92% of complete occlusion
 - 7.2% of partial occlusion
 - 0.6% of total permeability

All failures, partial or total, were GSV except 1 case of SSV

TOLERANCE AND SIDE EFFECTS

- Pain score for the procedure = 2.1 (VAS 0-10; 10= max. of pain)
- Pain score for the 10 days following the procedure = 0.9
- Patients satisfaction = 9.2 (scale 0-10; 10= max. of satisfaction)
- Immediate resumption of normal activity and no work stoppage
- I localised infection
- Paraesthesia in 13 cases (8%) which involved 7 GVS and 6 SSV; disappeared in less than 6 months, except for 1 case (1 year)

Settings

Mean P 19W (extr 18-20); mean T 6 s/cm (extr.1.4-23)

Mean initial $\emptyset = 8.2 \text{ mm}$

Mean T for failures (total or partial) T 4 s/cm (extr. 2-7.4)

Mean initial $\emptyset = 8.2 \text{ mm}$

Paresthesia : **T 9 s/cm** on average

DISCUSSION

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CELON RFITT[®] RADIOFREQUENCY Best settings ?

Manufacturer and Braithwaite:

P I8-20W and $T \ge I.5 \text{ s/cm}$

- ► **Zierau P 18-20 W** and **T** ≥ **3.4 s/cm**
- Hamel-Desnos and Desnos

P I 8 W and **T 5 s/cm (5 s/cm = about 70 J/cm)**

• Others P 5-6 W and T ?

The determining element is **ENERGY (E) •** $\mathbf{E} = \mathbf{P} \times \mathbf{T}$ if $\mathbf{P} \downarrow$ **T** \uparrow

CONCLUSION



- The RF Celon RFITT[®] procedure is welltolerated and safe
- Efficacy results (venous occlusion) of RF
 Celon, in the short and medium term, similar
 to those of EVLA or other RFA
- To optimise spread of the technique, the manufacturer needs to clarify the usage protocol



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Thank you for your attention

Merci de votre attention

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