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Randomized study Endovenous Laser Ablation versus RF VNUS ClosureFAST of Incompetent Great Saphenous Vein Using Tumescent Anesthesia Saphenous Vein: One year results.

noven, 31 May 2013



# Pilot RF VNUS CF vs. EVLA Radial 1470 nm

| Procedure   | no | Occlusion rate after<br>1 year | Time to<br>normal<br>function<br>( days) | Back to work<br>( days) |
|-------------|----|--------------------------------|--|-------------------------|
| VNUS        | 83 | 100 %                          | 1,4                                      | 2,6                     |
| EVLT 980    | 62 | 98,0 %                         | 3,2                                      | 4,4                     |
| Radial 1470 | 51 | 93,0 %                         | 1,4                                      | 2,9                     |
| Stripping   | 66 | 95,6 %                         | 3,2                                      | 4,2                     |



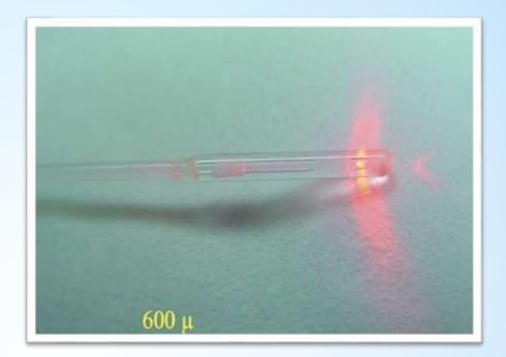
## Treatment of incompetent GSV: VARICO II

Endovenous techniques, using tumescent:
 Endovenous laser ablation (radial tip, 1470nm)
 RF VNUS ClosureFAST

Literature: Almeida JI et al, J Vasc Interv Radiol 2009 Jun;20(6): 752-9. Perrin M et al, Int Angiol 2010 Aug;29(4):303-7. Nordon IM et al, Ann Surg 2011 Dec;254(6):876-81.

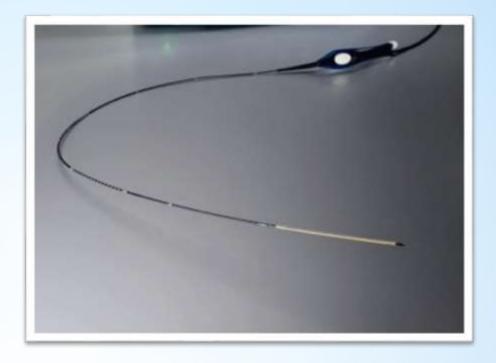


# EVLT 1470nm radial tip



Radial emitting laser fiber with blunt tip
 Homogenous circumferential (360°) energy emission.
 Energy delivery during Pull Back (1470nm,10 watt 70-80J/cm)





## **RF VNUS Closure** fast

Radiofrequency current induced heating coil
 RF segmental ablation / Short energy cycle
 No energy delivery during pull back
 Conducting heating (temperature controlled)



# Study design: VARICO II trial



Long term endpoints (5 year follow-up):
 Duplex and clinically detected recurrences at the saphenofemoral junction
 Clinical results, CEAP, VCSS, Aberdeen, QoL (EuroQuol5, VAS)



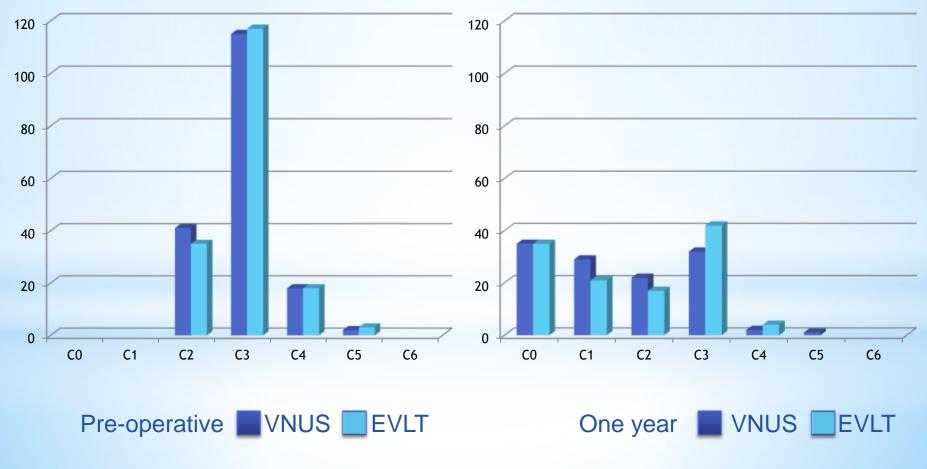
## VARICO II trial : one year results

Patients lost to follow up
11 VNUS and 9 EVLA
One year FU
122 VNUS and 120 EVLA
44 VNUS and 43 EVLA not evaluated yet



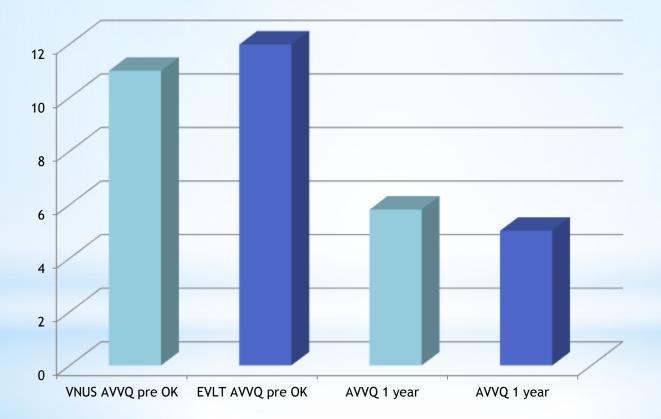


## CEAP classification pre-op and after one year



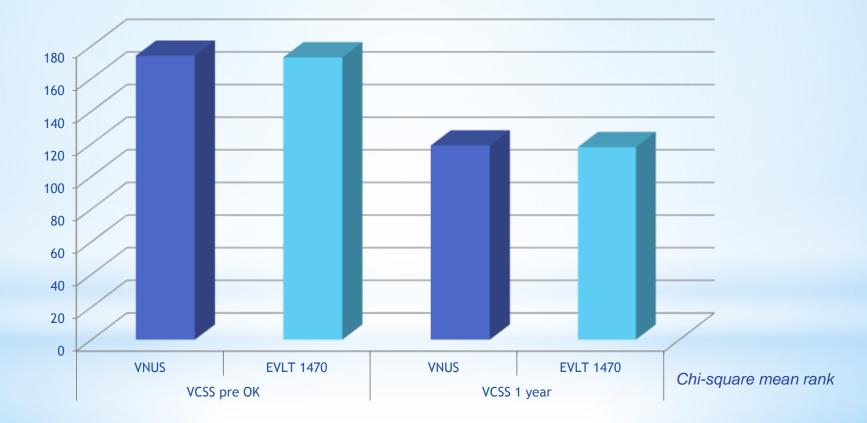


#### AberdeenVVQ pre and 1 year





## VCSS pre-operative and after one year





### VAS pain scores VNUS vs Radial EVLA



#### 77 % of VNUS and 74% of radial patients does not use painkillers



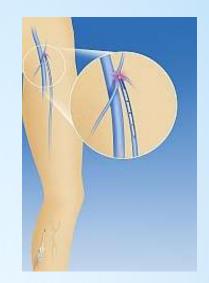
# Daily activities and back to work (EuroQuol5)

|                  |        | N   | Mean ( days) | SD   |
|------------------|--------|-----|--------------|------|
| Daily Activities | VNUS   | 122 | 1,45         | 1,40 |
|                  | Radial | 120 | 1,13         | 0,82 |
| Back to Work     | VNUS   | 122 | 2,10         | 1,93 |
|                  | Radial | 120 | 2,17         | 2,26 |

Does not want to undergo this surgery again : VNUS 3,9 % Radial 1,5%



## VARICO II Occlusion



Partial occlusion was observed after 1 ClosureFast procedure and 1 failure occurred after radial EVLA.

Total primary occlusion rate after 12 months was 99,0 % after both treatments.



## Conclusion

RF VNUS Closurefast and EVLA (1470nm, radial tip) show no statistical difference in recurrences from the GSV or sapheno-femoral junction

Successful recovery (daily activities and back to work)

Both procedures are well tolerated, save and effective

