

# Srovnání 2 typů radiálních laserových vláken (1-ringových a 2-ringových) v nitrožilní léčbě křečových žil pomocí laseru o vlnové délce 1470 nm

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XXII. Slovenský kongres cievnej chirurgie s  
medzinárodnou účasťou 2018

# Endovenous methods

- **THERMAL TUMESCENT (TT)**

- 1) laser ablation (EVLA)
- 2) radiofrequency (RFA)
- 3) superheated steam (EVSA)

Audi TT, 2017



- **NONTHERMAL NONTUMESCENT (NN)**

- 1) mechanico-chemical ablation (MOCA)
- 2) biological glue



- **THERMAL NONTUMESCENT (TNT)**

Holmium laser

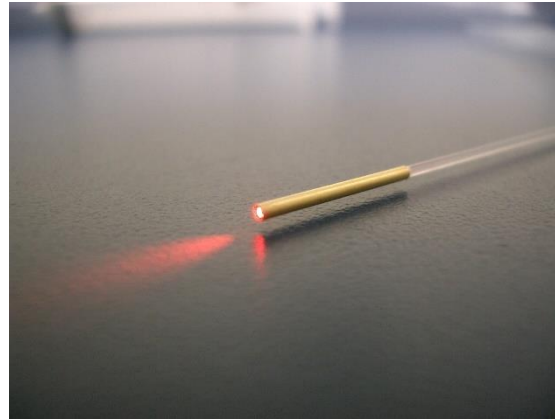
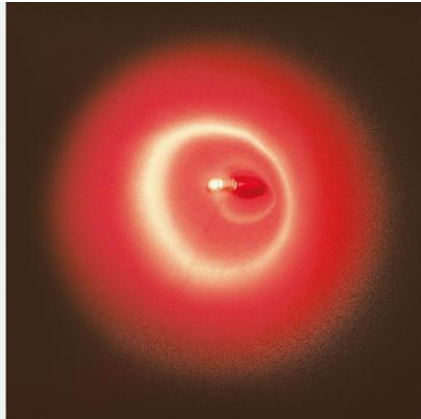
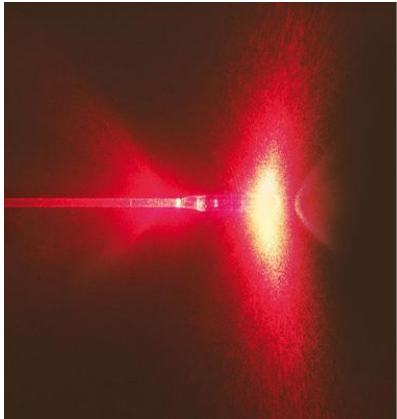
- **NONTHERMAL TUMESCENT (NTT)**

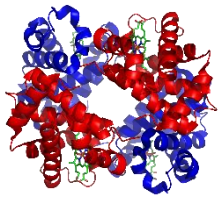
stripping/tumescent



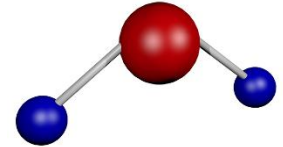
# Endovenous laser evolution.....

- wavelenghts:
  - 810 nm ...980 nm ...1320 nm ...1470 nm ...1560 nm...1920 nm
- fibre types:
  - bare fibres ..... covered fibres
  - frontal emmision.....radial emmision





# Endovenous laser



## Haemoglobin-specific lasers (HSLWs)

- 808, 810, 940 nm
- dominant chromophor: Hb, myoglobin → erythrocytes

## Water-specific lasers (WSLWs)

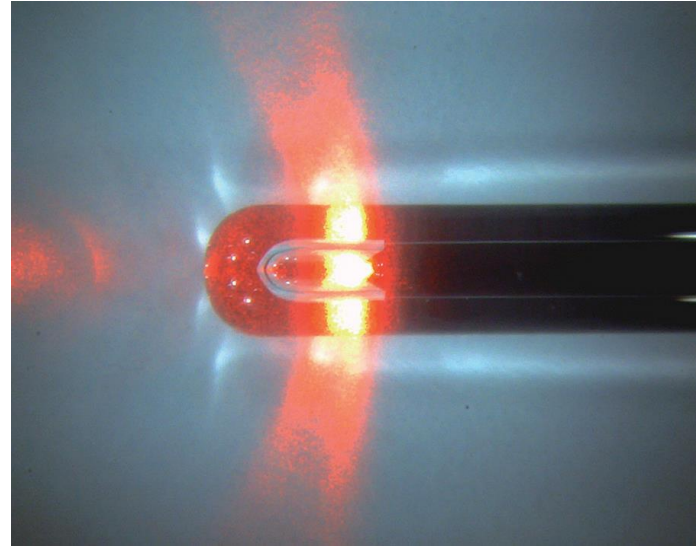
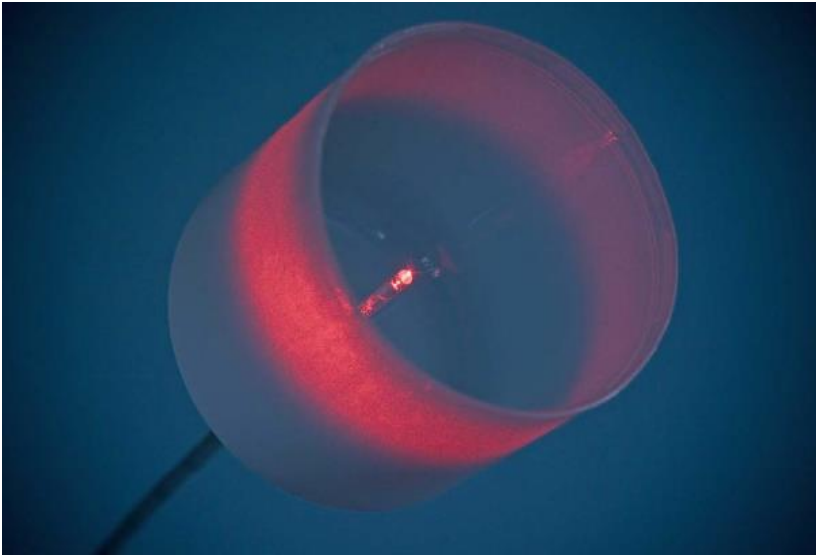
- 1320, 1470, 1560, 1920 nm
- dominant chromophor: H<sub>2</sub>O → vein wall
- less side effects ?

Pannier F, Rabe E, Maurins U. First results with a new 1470-nm diode laser for endovenous ablation of incompetent saphenous veins. *Phlebology* 2009; 24: 26-30.

Maurins U, Rabe E, Pannier F. Does laser power influence the results of endovenous laser ablation (EVLA) of incompetent saphenous veins with the 1 470-nm diode laser? A prospective randomized study comparing 15 and 25 W. *Int Angiol* 2009; 28: 32-7.

Almeida J, Mackay E, Javier J, et al. Saphenous laserablation at 1470 nm targets the vein wall, not blood. *Vasc Endovascular Surg* 2009; 43: 467-72.

# 1470 nm radial fibre



## radial emitting fibre (2008)

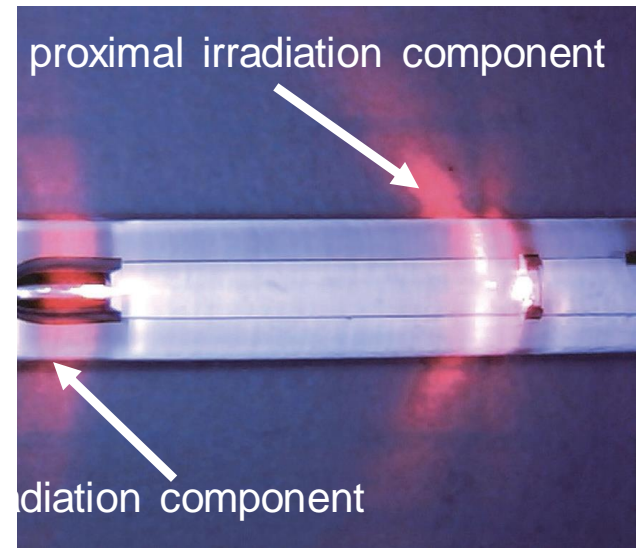
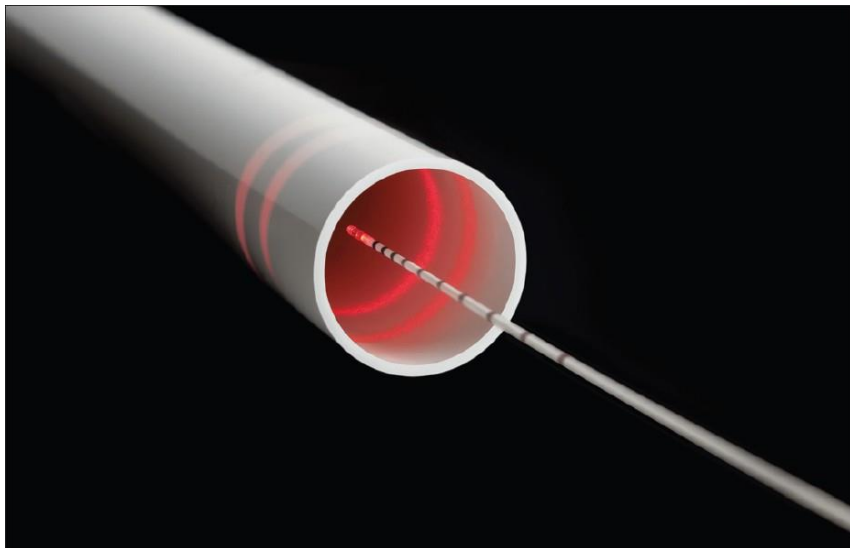
- homogeneous effect
- less perforation – less pain and bruising
- sticking to the vein

F Pannier, E Rabe, et al. Endovenous laser ablation of great saphenous veins using a 1470 nm diode laser and the radial fibre - follow-up after six months. *Phlebology* 2011;26:35-9.

Schwarz T, von Hodenberg E, et al. Endovenous laser ablation of varicose veins with the 1470-nm diode laser. *J Vasc Surg.* 2010 Jun;51(6):1474-8.

# 1470 nm radial 2ring™ fibre

- more homogeneous distribution of energy in to the vein wall
- less pronounced sticking effect



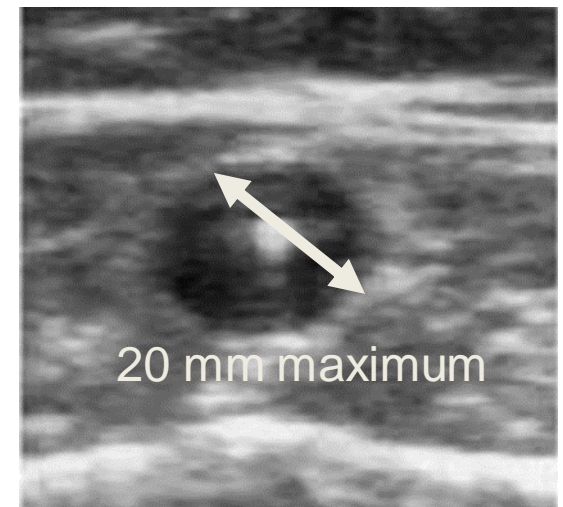
# AIM

- to compare the clinical efficacy and safety of two laser fiber types (radial 1 ring and 2 ring) in endovenous laser ablation (EVLA) of saphenous varicose veins of the lower limb.



# Our study

- non-randomized prospective study of 94 patients/limbs with primary varicose veins from January 2014 to September 2016
- CEAP C2-C4, length of treated GSV segment > 30 cm
- patient follow-up were performed 1 and 7 days, 3, 6 and 12 months after the procedure.
- no adjunctive treatments (ie, sclero, phlebectomy...) were performed for 12 months after procedure
- great saphenous vein (GSV) diameter 20 mm or smaller in a standing position





# Exclusion criteria

- varicose veins primarily associated with incomplete perforating veins measuring 2 to 3 mm or larger
- incompetent ipsilateral SSV or AAGSV
- severe obesity
- unfavorable general condition related to disorders of organs, such as the heart, lungs, liver, and kidney
- infections of the lower limbs complicated by cellulitis
- acute deep vein thrombosis or a history of deep vein thrombosis, a history of superficial thrombophlebitis
- thrombophilia
- lymphedema of the lower limbs
- peripheral arterial occlusive disease (ABI < 0,8)
- history of venous surgery
- pregnant women or those who may be pregnant
- those receiving steroids

# Procedures

- Laser Biolitec Ceralas E 1470 nm (CeramOptec GmbH, Bonn, Germany)
- ultrasound-guided percutaneous approach
- tumescent local anesthesia (TLA) in the track of GSV
- fibre insertion and positioning (0.5 cm distal to SFJ)
- power of 10W, continuous fiber pullback, LEED 80-100 J/cm
- no concomitant phlebectomy
- thigh compression stockings for 3 weeks



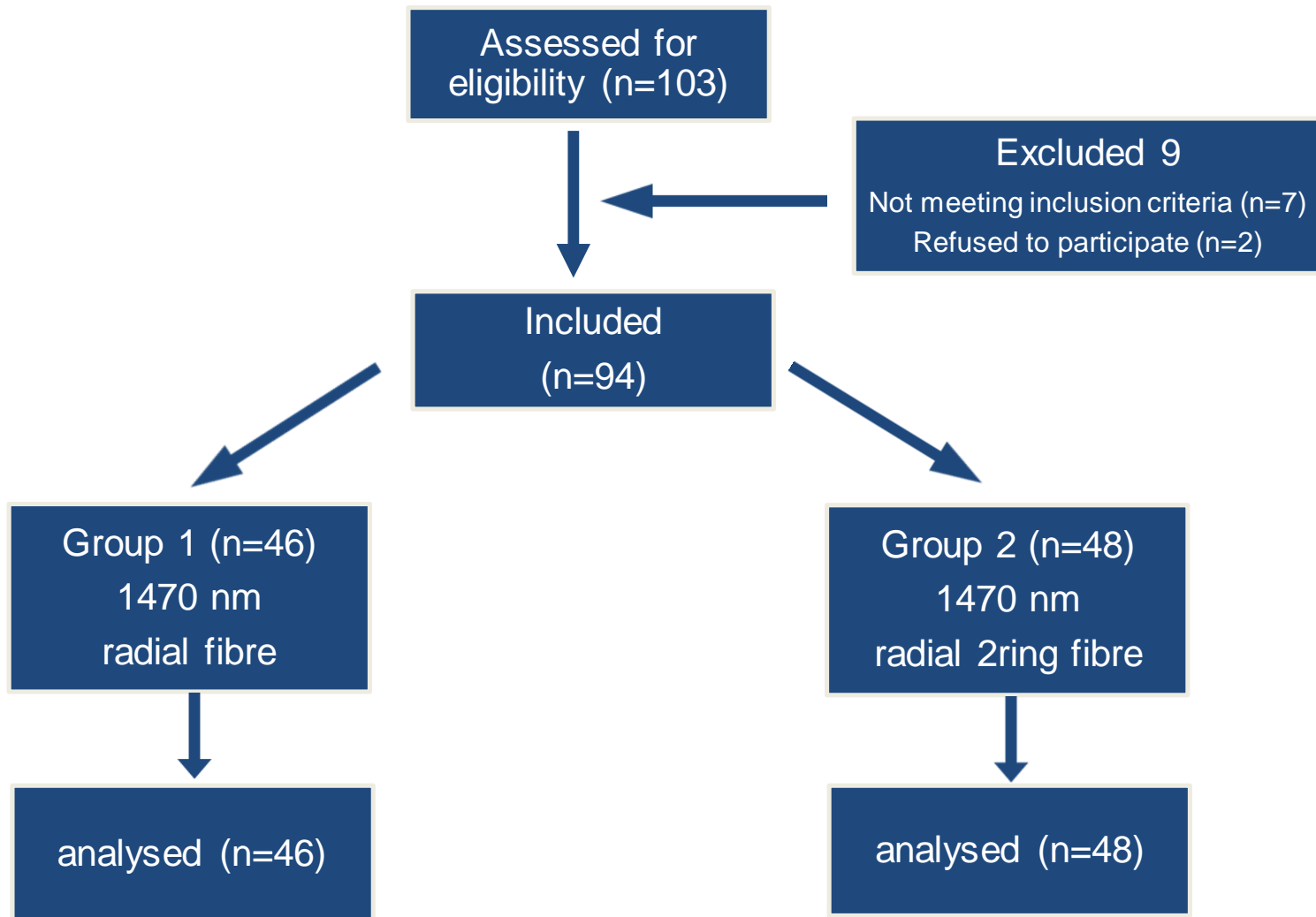
# Study primary endpoints

- primary efficacy endpoint
  - occlusion rate
  - DUS 1 and 6 days, as well as 3 and 6 months after surgery
- primary safety endpoint
  - incidence of pain
  - same observation period

# Study secondary endpoints

- secondary safety endpoint
  - postoperative pain (visual analog scale, VAS)
  - postoperative bruising
  - adverse events
  - study equipment failure
- 1 and 6 days, as well as 3, 6, (and 12) months after surgery

# Diagram of the study



# Demographic data for patients

	Group 1 (n=46) 1470 nm, radial 2 ring	Group 2 (n=48) 1470 nm radial ring	P ( $\chi^2$ )
mean age (years)	49.1 +/- 8.4	51.3 +/- 9.6	NS
women (%)	75 %	73 %	NS
treated veins - GSV	46 (100 %)	48 (100 %)	-
BMI (kg/m <sup>2</sup> )	26,2	26,6	NS
GSV diameter (mm)			
junction	8,2 +/- 1.5	8,7 +/- 1.6	NS
knee level	6.7 +/- 0.6	6,6 +/- 0.5	NS
CEAP			
C2	32 (70 %)	35 (72 %)	NS
C3	8 (19 %)	10 (20 %)	
C4	6 (11 %)	3 (8 %)	

# Efficacy assessment

## Occlusion rates

- 1 and 6 days, 6 and 12 months (DUS)

	Group 1 radial fibre	Group 2 2ring fibre	P value
1 day	100 %	100 %	-
6 days	97.9 %	100 %	NS
3 months	97.9 %	100 %	NS
6 months	97.9 %	100 %	NS
12 months	97.9 %	100 %	NS

# Safety assessment

## Primary endpoint

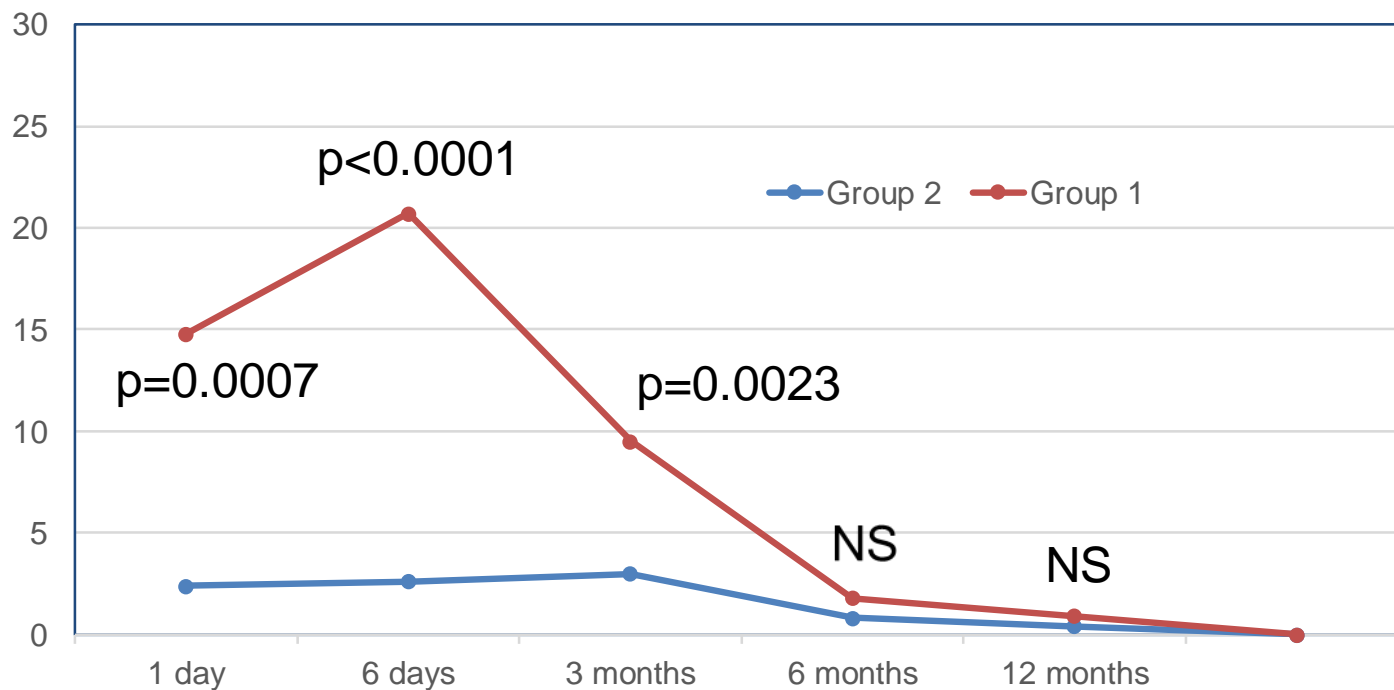
- **pain in treated area**
- rates of pain (3% vs. 14.8 %) were lower in Group 2, but not significantly

	Group 1	Group 2	P value
pain, number of limbs (%)	6 (14.8 %)	2 (3.0 %)	NS



# Safety assessment - VAS

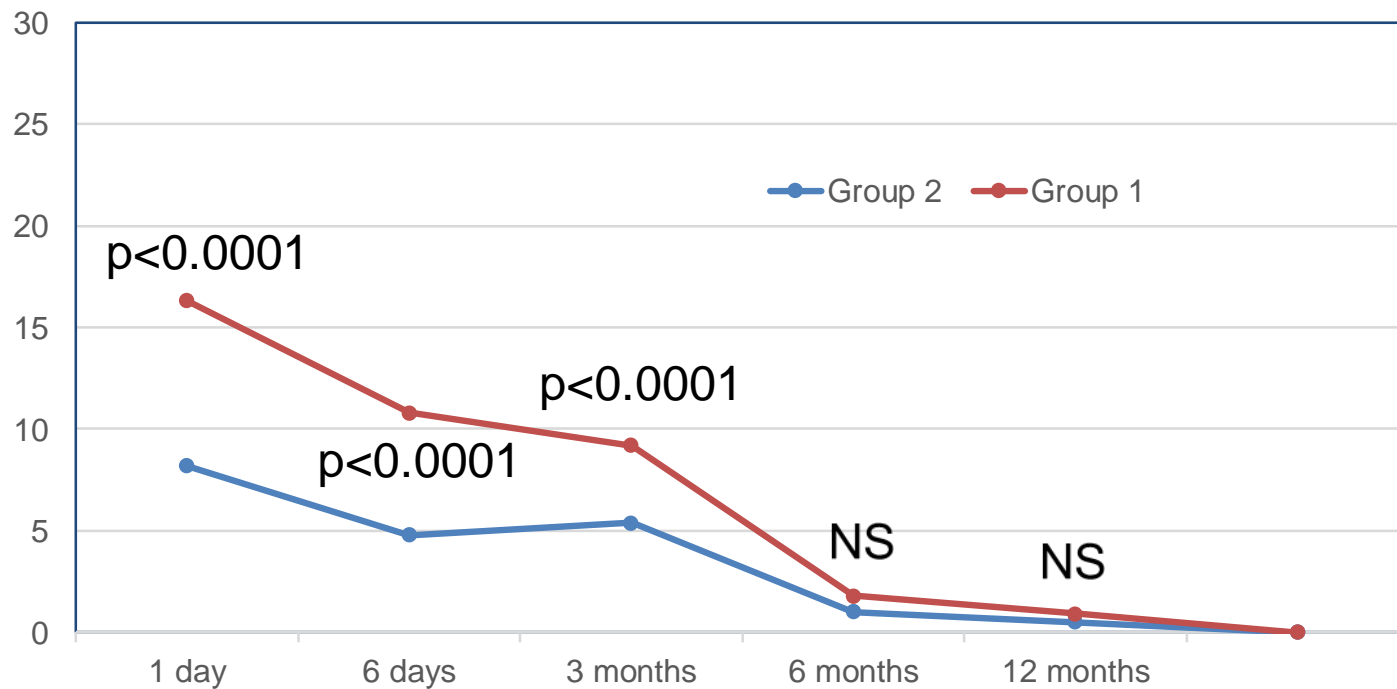
## Changes in visual analogue scale of pain



	Group 1	Group 2	P value
Maximum VAS (mean +/- SD)	20.5 +/- 17.6	6.4 +/- 4.4	p < 0.0001

# Safety assessment – VCSS

VCSS throughout the study



# Safety assessment – bruising

	Group 1	Group 2	P value
bruising	17 (37.0 %)	3 (6.5 %)	$p < 0.0001$



# Postoperative complications

	Group 1 (n = 46)	Group 2 (n = 48)	P value
<b>induration</b>	4 (8.3 %)	2 (4.3 %)	0.118
<b>tenderness</b>	2 (4,3 %)	0 (0 %)	0.528
<b>skin burns</b>	0 (0 %)	0 (0 %)	-
<b>erythema</b>	3 (6.5 %)	1 (2.0 %)	0,118
<b>paresthesia</b>	1 (2.2 %)	2 (4.2%)	0.433
<b>thrombembolisms (DVT)</b>	0 (0 %)	0 (0 %)	-

## Study equipment failure

0 %

# Summary - results

- primary efficacy and safety endpoints
  - occlusion rate and incidence of pain – NS
- secondary safety endpoints
  - maximum and mean VAS -  $p < 0.0001$  ((day 1,6, 3 months)
  - VCSS -  $p < 0.0001$  (day 1,6, 3 months)
  - bruising -  $p < 0.0001$
  - incidence of complications – NS
  - equipment failure - 0

# Conclusion

Endovenous laser treatment of saphenous vein reflux with 1470 nm and both fiber types results in clinical improvement of symptoms and comparable occlusion rates.

In the early postoperative period, 2-ring laser radial fiber seems to remove quality-of-life limitations associated with traditional („1ring“) radial fiber.

# Děkuji za pozornost!



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