

RECOVERY Trial

Final Results
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Study Design

- Six center, single-blinded randomized trial of the ClosureFAST™ Catheter vs. Endovenous Laser
- Purpose: Determine if patient recovery and other short term outcomes are different between ClosureFAST and laser treatment
- 69 patients; 87 limbs treated (46 CLF; 41 EVL)
- Patient follow up at 2, 7, 14, and 30 days after treatment

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Endpoints

- Primary
 - Presence and intensity of post-operative pain (using a visual analog scale)
 - Presence and severity of bruising
 - Incidence of sequelae (post-procedure adverse events)
- Secondary
 - Vein occlusion status
 - Post-operative tenderness
 - Presence of reflux
 - Vein clinical severity score (VCSS)
 - Patient health-related quality of life (CIVIQ2)

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Trial Methods

- Investigators required to have experience with both ClosureFAST and 980 nm endovenous laser procedures
- Patients electronically randomized to ClosureFAST or laser treatment with randomization balancing at each study site
- Patients blinded to therapy delivered
- ClosureFAST treatment at 120 °C for 20 seconds per treated vein segment with double treatment near SFJ
- Laser fiber pullback speed 1.5 mm/sec to deliver 80 J/cm at 12 Watts
- Post-procedure
 - Compression bandages for 24 to 72 hours
 - Thigh high or higher class II compression stockings for 2 weeks
 - 30 minutes of daily ambulation

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Patient Demographics

Variable	CLF	EVL	P-value
Female N (%)	29 (83 %)	31 (76 %)	0.57
Weight	158 ± 20 (35)	165 ± 28 (41)	0.20
Age	52 ± 13 (35)	52 ± 15 (41)	0.82
Length of treated segment (cm)	35.6 ± 13.4 (45)	42.2 ± 14.0 (41)	0.38
Diameter 3cm from SFJ	5.1 ± 2.3 (46)	6.0 ± 2.8 (41)	0.12
CEAP (class 2)	43 (93.5%)	36 (87.8%)	0.47

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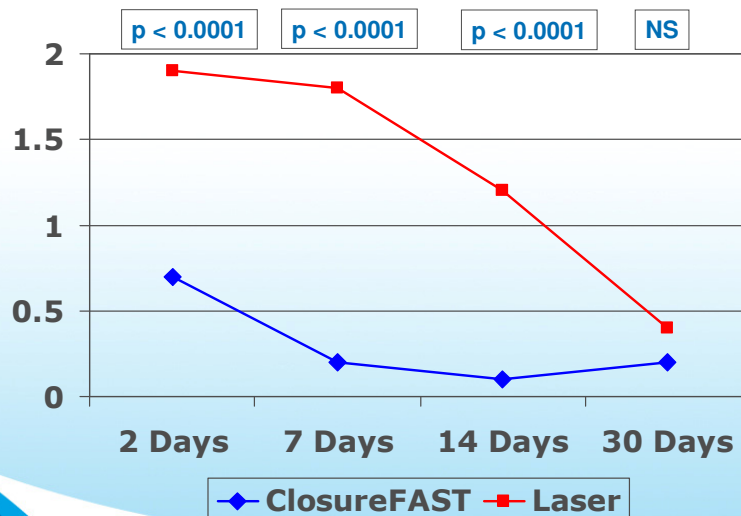
Primary Endpoint Findings

Pain
Tenderness
Ecchymosis
Adverse Events/Complications

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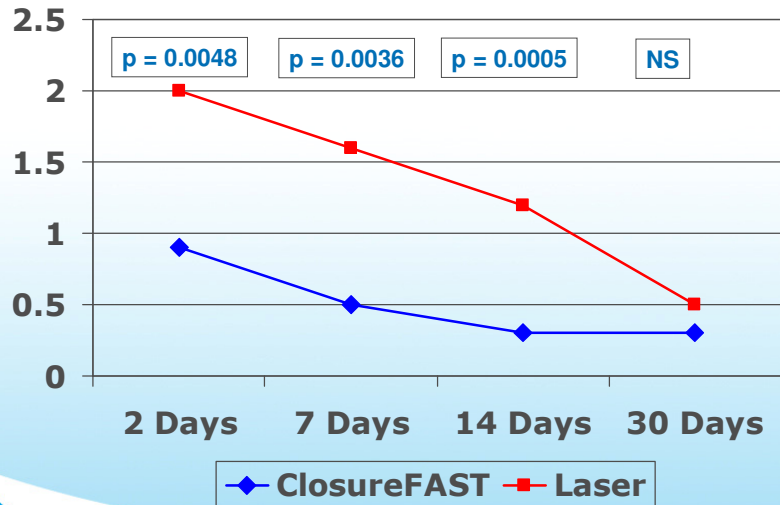
Pain Score at Follow Up Visits

(Scale: 0 none to 10 max)



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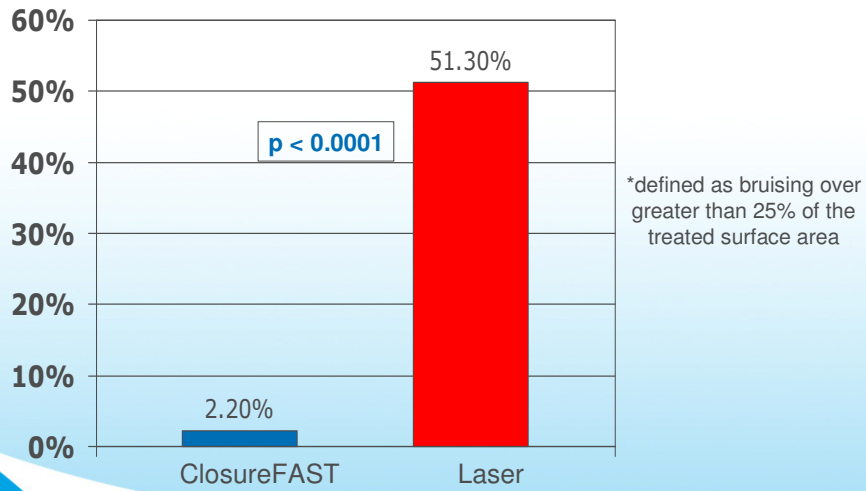
Tenderness Score at Follow Up Visits (Scale: 0 none to 10 max)



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Ecchymosis

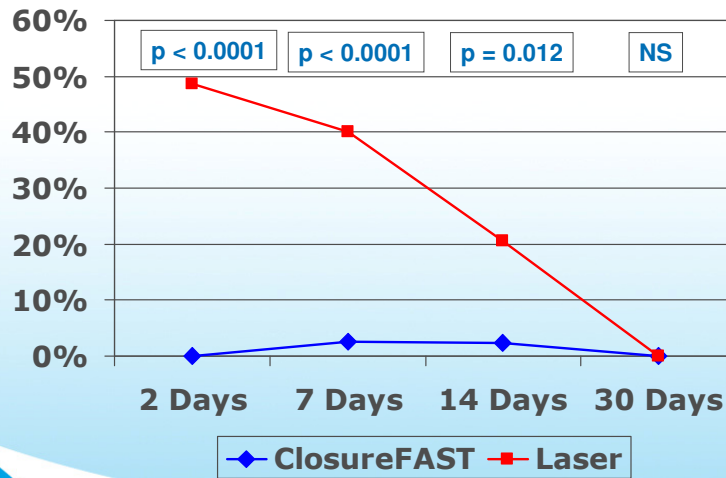
% of Patients Suffering from Moderate to Severe Ecchymosis* (Bruising) After Treatment



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Ecchymosis

Ecchymosis (Bruising) of More Than 25% of Treatment Area



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Ecchymosis

Presence of Any Ecchymosis (Bruising)



ClosureFAST treated limbs had significantly less bruising for four weeks after treatment

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Sequelae

Post-procedure adverse events

	Laser (n=41)	ClosureFAST (n=46)
Phlebitis	6 (14.6%)	0
Erythema	4 (9.8%)	0
Paresthesia	2 (4.9%)	1 (2.2%)
Thrombus extension	1 (2.4%)	0
Induration	1 (2.4%)	0
Hyperpigmentation	0	1 (2.2%)
Infection	0	0
New Telangiectasia	0	0
Skin burn	0	0
Limbs w/ Sequelae	9* (22.0%)	2 (4.4%)

p = 0.021

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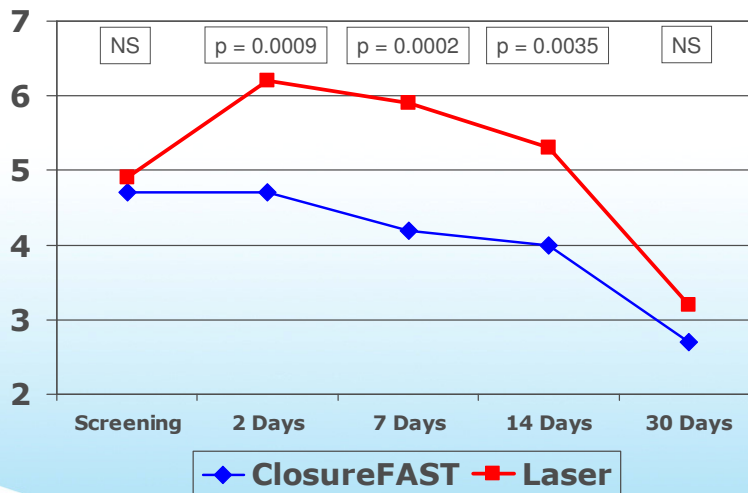
* 9 laser treated limbs experienced a sequelae with 14 total events

Secondary Endpoint Findings

Venous Clinical Severity Scores (VCSS)
Patient Quality of Life (QOL) Parameters

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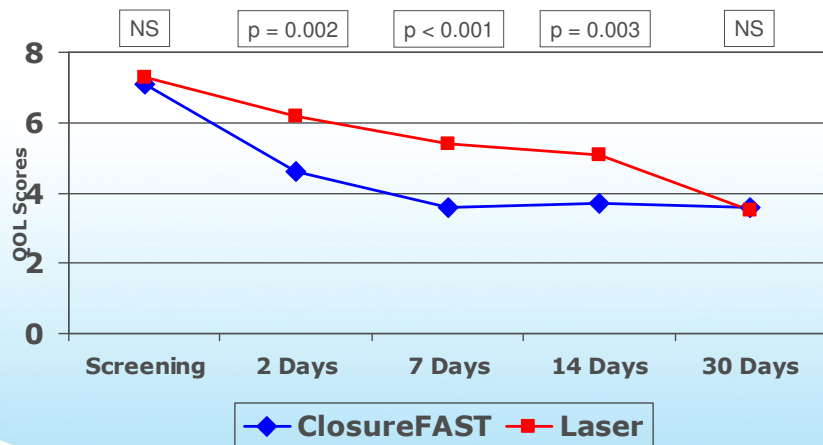
Venous Clinical Severity Score (VCSS)



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Quality of Life Score: Pain

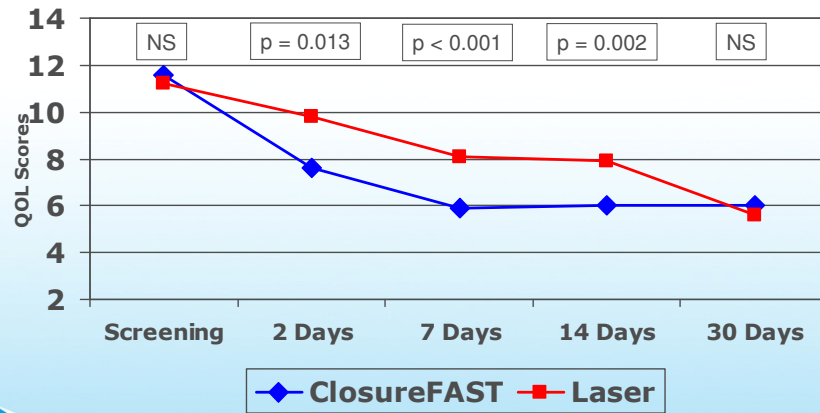
Note: Lower score reflects a better QOL



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Quality of Life Score: Physical

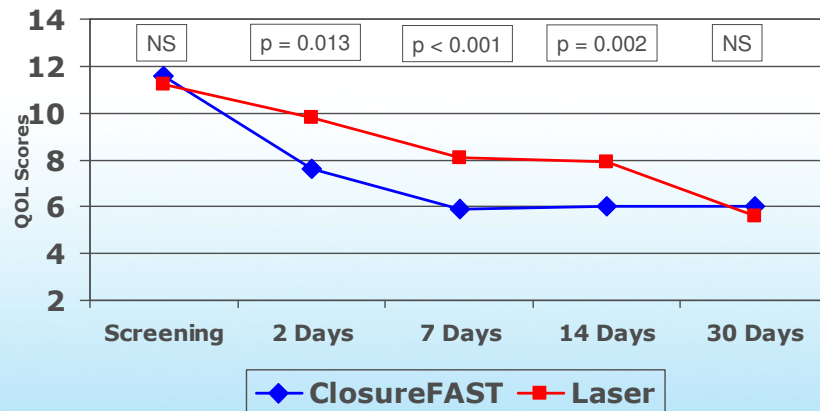
Note: Lower score reflects a better QOL



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Quality of Life Score: Social

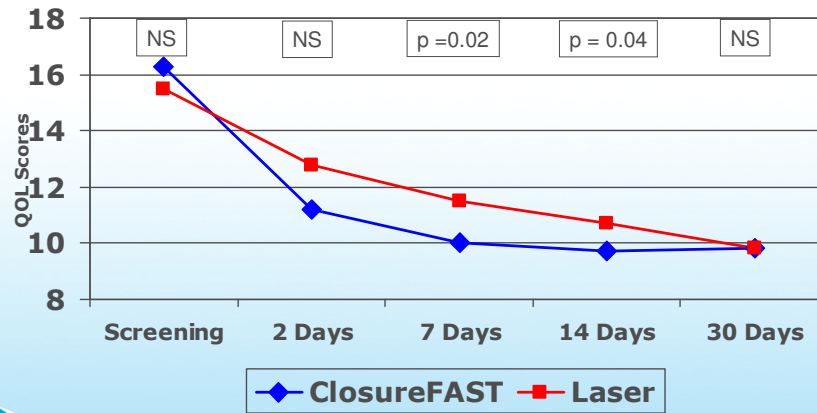
Note: Lower score reflects a better QOL



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Quality of Life Score: Psychologic

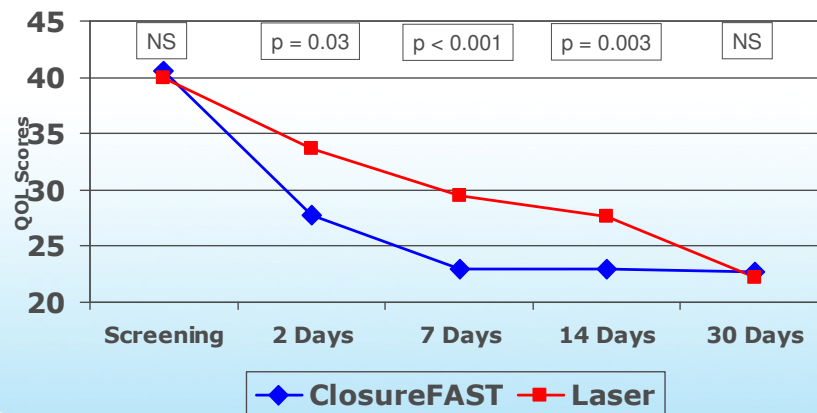
Note: Lower score reflects a better QOL



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Quality of Life Score: Global

Note: Lower score reflects a better QOL



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Quality of Life: Summary

- Overall QOL was significantly better for patients treated with ClosureFAST
 - Out to two weeks after treatment
- Patients treated with ClosureFAST realized improved QOL more than twice as fast as those treated with endovenous laser
- Specific QOL dimensions were significantly better for patients treated with ClosureFAST ablation
 - Pain
 - Physical activity
 - Psychological
- CIVIQ2 QOL surveys confirmed patients experienced significantly less pain, fewer physical limitations, and faster improvement to QOL when treated with ClosureFAST

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RECOVERY Trial: Conclusions

- ClosureFAST proved to be significantly superior to endovenous laser ablation when evaluating post-procedural recovery and patient QOL parameters
- Compared to laser ablation, treatment with ClosureFAST produced significantly
 - Less pain **p < 0.0001**
 - Less bruising **p < 0.0001**
 - Less tenderness **p = 0.0008**
 - Fewer adverse events **p = 0.021**
 - Greater improvement in VCSS scores* **p = 0.0035**
 - Better quality of life* **p = 0.045**

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* Out to 14 days