



**VNUS**<sup>®</sup>  
MEDICAL TECHNOLOGIES, INC.

## RECOVERY Trial

Final Results

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## RECOVERY Trial Investigators

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## RECOVERY Trial

- Six center, single-blinded randomized trial of ClosureFAST vs. Endovenous Laser
- Purpose: Determine if patient recovery and other short term outcomes are different between RF 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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## RECOVERY Trial

- Primary Endpoints
  - 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 Endpoints
  - Vein occlusion status
  - Post-operative tenderness
  - Presence of reflux
  - Vein clinical severity score (VCSS)\*
  - Post-procedural analgesics use\*
  - Patient health-related quality of life (CIVIQ2)\*

\*These endpoint data are contained in the manuscript only

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## Trial Methods

- Investigators required to have experience with both ClosureFAST and 980 nm endovenous laser procedures
- Patients were randomized to RF or laser treatment via electronic system with randomization balancing at each study site
- Patients were blinded to the therapy delivered
- ClosureFAST treatment was at 120°C for 20 seconds per treated vein segment with a double treatment near the SFJ
- Laser fiber pullback speed was 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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## RECOVERY Trial

### Patient Demographics

| Demographics  |                 |                 |         |
|---------------|-----------------|-----------------|---------|
| Variable      | CLF             | EVL             | P-value |
| Female N (%)  | 29 (83 %)       | 31 (76 %)       | 0.57    |
| Weight (lbs.) | 158 ± 20 ( 35 ) | 165 ± 28 ( 41 ) | 0.20    |
| Age           | 52 ± 13 ( 35 )  | 52 ± 15 ( 41 )  | 0.82    |

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## RECOVERY Trial

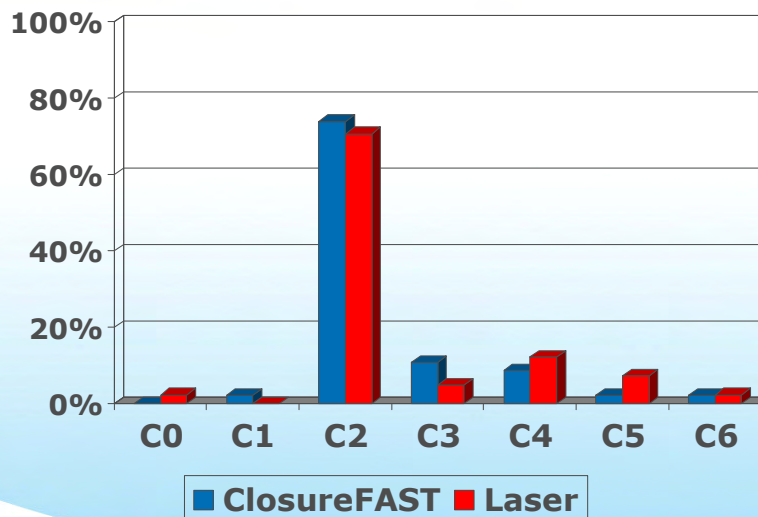
### Pre-Treatment Measurements / Tumescence Anesthesia Volume Used

|  | CLF               | EVL               |
|--|-------------------|-------------------|
| Vein Length Treated                              | 39.6 cm ± 13.4 cm | 42.2 cm ± 14.7 cm |
| Vein Diameter (3cm from Saphenofemoral Junction) | 7.1 mm ± 2.3 mm   | 7.8 mm ± 2.1 mm   |
| Tumescence Volume Used                           | 287 cc ± 167 cc   | 265 cc ± 161 cc   |

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## RECOVERY Trial

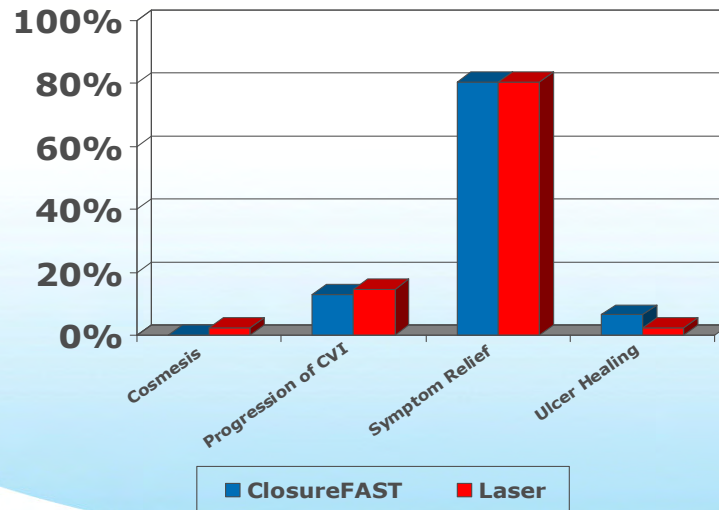
### CEAP Clinical Class at initial screening



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## RECOVERY Trial

### Primary Clinical Intent



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## RECOVERY Trial

- Results

- 100% vein occlusion and reflux free in both RF and laser groups

- Procedure Time

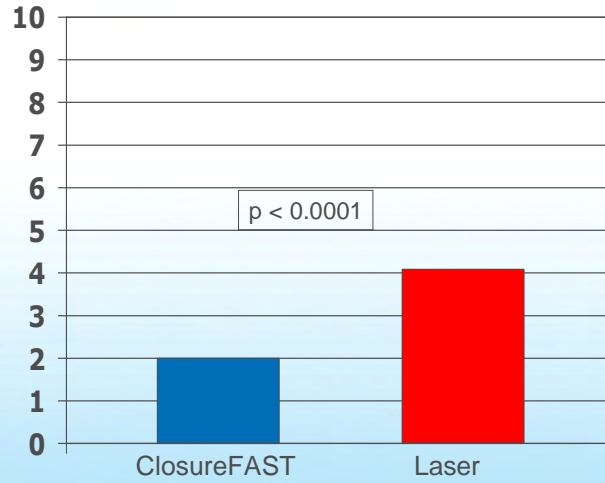
|                           | ClosureFAST (N=46) | Laser (N=41) |            |
|---------------------------|--------------------|--------------|------------|
| Energy on time (min)      | 2.5* ± 0.8         | 4.8 ± 1.8    | p < 0.0001 |
| Cath in to cath out (min) | 12.6 ± 10.2        | 16.0 ± 7.9   | p = 0.09   |

\*Data available for 45 limbs

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## RECOVERY Trial

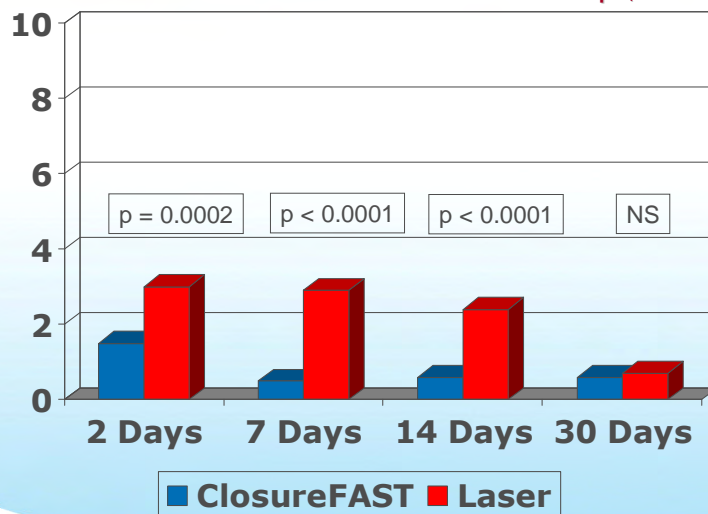
Overall Maximum Pain Score (0 none to 10 max)



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## RECOVERY Trial

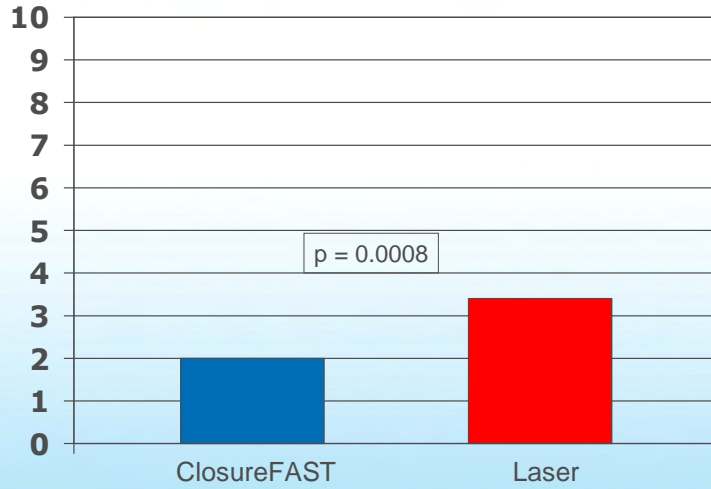
Maximum Pain Score Since Previous Follow Up (0 none to 10 max)



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## RECOVERY Trial

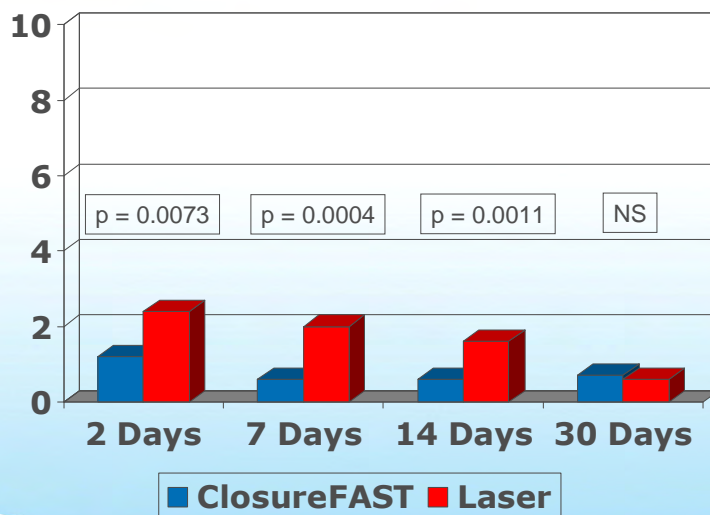
Overall Maximum Tenderness Score (0 none to 10 max)



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## RECOVERY Trial

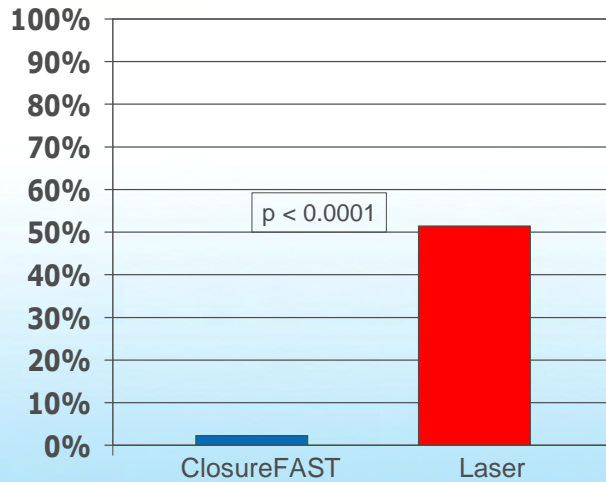
Maximum Tenderness Since Previous Follow Up (0 none to 10 max)



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## RECOVERY Trial

### Moderate to Severe Ecchymosis (Bruising) After Treatment

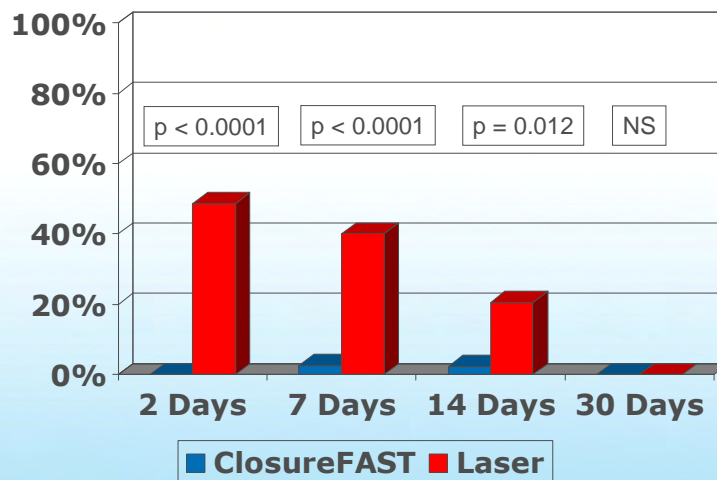


Moderate to severe ecchymosis is defined as bruising over greater than 25% of the treated surface area

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## RECOVERY Trial

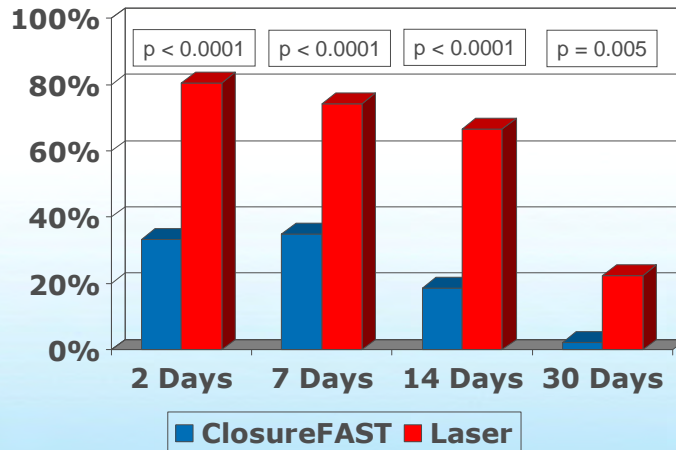
### Ecchymosis (Bruising) Over More Than 25% of Treatment Area



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## RECOVERY Trial

### Presence of Any Ecchymosis (Bruising)



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

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## RECOVERY Trial

### Sequelae (post-procedure adverse events)

|                          | ClosureFAST<br>(n=46) | Laser<br>(n=41)   | p-value                       |
|--------------------------|-----------------------|-------------------|-------------------------------|
| Thrombus extension       | 0                     | 1 (2.4%)          |                               |
| Hyperpigmentation        | 1 (2.2%)              | 0                 |                               |
| Phlebitis                | 0                     | 6 (14.6%)         |                               |
| Paresthesia              | 1 (2.2%)              | 2 (4.9%)          |                               |
| Erythema                 | 0                     | 4 (9.8%)          |                               |
| Infection                | 0                     | 0                 |                               |
| Induration               | 0                     | 1 (2.4%)          |                               |
| Skin burn                | 0                     | 0                 |                               |
| New Telangiectasia       | 0                     | 0                 |                               |
| <b>Limbs w/ Sequelae</b> | <b>2 (4.4%)</b>       | <b>9* (22.0%)</b> | <b><math>p = 0.021</math></b> |

\* 9 Laser treated limbs experienced a sequelae with 14 total events

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## RECOVERY Trial – Conclusions

- 100% Vein occlusion in both RF and laser groups
- Procedure times were similar between RF and laser
- Compared to laser, RF treatment with ClosureFAST produced significantly
  - Less pain  $p < 0.0001$
  - Less tenderness  $p = 0.0008$
  - Less bruising  $p < 0.0001$
  - Fewer adverse events  $p = 0.021$

- From the dates March 23, 2007 to December 14, 2007 a six-center single-blinded randomized trial was conducted evaluating the patient recovery experience of patients treated with the VNUS ClosureFAST RF Catheter and the 980nm endovenous laser
- The study was sponsored by VNUS Medical Technologies
- The data presented here has been independently reviewed for completeness and accuracy
- Data is on file