

RECOVERY

Study Results

In a comparative multi-center study on the treatment of great saphenous reflux, the Venefit™ procedure, delivered by the Covidien ClosureFast™ Endovenous Radiofrequency Ablation (RFA) Catheter, demonstrated less pain, less bruising and fewer complications than laser ablation. Patients experienced a faster road to recovery with a better quality of life. The results are quite comforting.



Venefit™

Targeted Endovenous Therapy



COVIDIEN

RECOVERY STUDY

A comparison of the patient experience between those treated with the Venefit™ procedure, using the Covidien ClosureFast™ Endovenous Radiofrequency Ablation (RFA) Catheter, and those treated with 980 nm laser ablation.

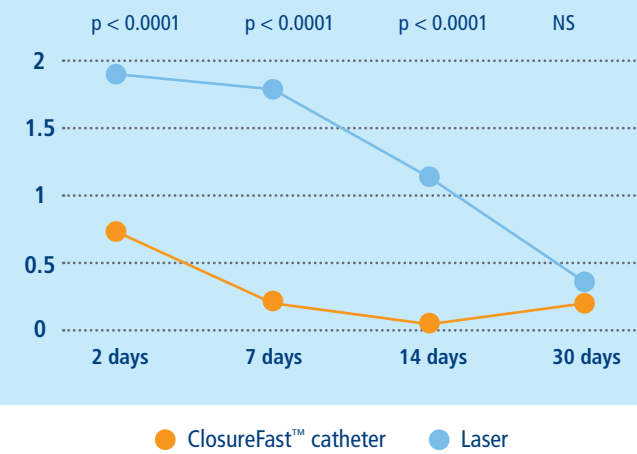
KEY FINDINGS

Less Pain

The Covidien ClosureFast™ catheter demonstrated significantly lower pain levels than the laser ablation group during periodic follow-up visits.

PAIN SCORE AT FOLLOW-UP VISITS

(Scale: 0 none to 10 max)

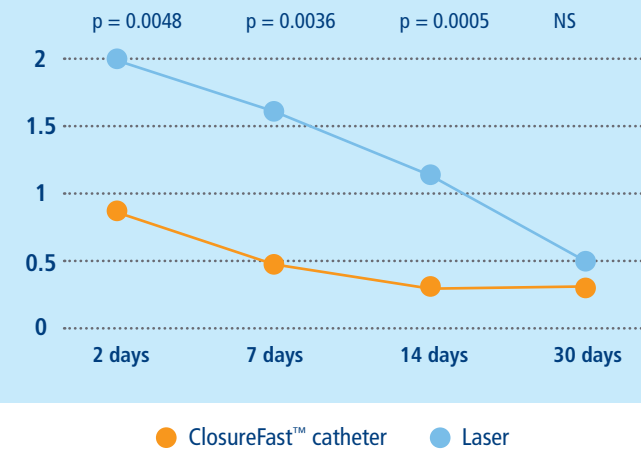


Less Tenderness

The Covidien ClosureFast™ catheter demonstrated significantly lower tenderness levels than the laser ablation group during periodic follow-up visits.

TENDERNESS SCORE AT FOLLOW-UP VISITS

(Scale: 0 none to 10 max)

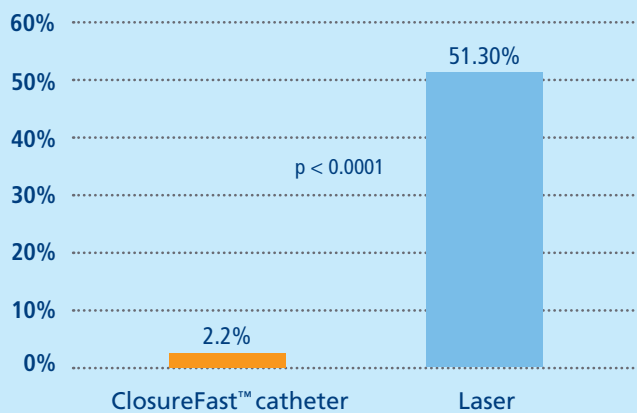


Less Ecchymosis

“One limb treated with the Covidien ClosureFast™ catheter compared with 21 of the laser ablation treated limbs showed ecchymosis covering more than 25% of the treated area across all visits.”

ECCHYMOSIS

% of Patients suffering from moderate to severe ecchymosis* (bruising) after treatment



*Defined as bruising over greater than 25% of the treated surface area

Fewer Complications

Complications were statistically more prevalent in the laser ablation group than in the Covidien ClosureFast™ catheter group.

SEQUELAE

Post-procedure adverse events

Sequelae	Laser (N=41)	ClosureFast™ catheter (N=46)
Phlebitis	6 (14.6%)	0
Erythema	4 (9.8%)	0
Paresthesia	2 (4.9%)	1 (2.2%)
Thrombus extension/DVT	1 (2.4%)	0
Hyperpigmentation	0	1 (2.2%)
Infection	0	0
Limbs w/ Sequelae	9 (22.0%)	2 (4.4%)

Statistical significance: p = 0.021.

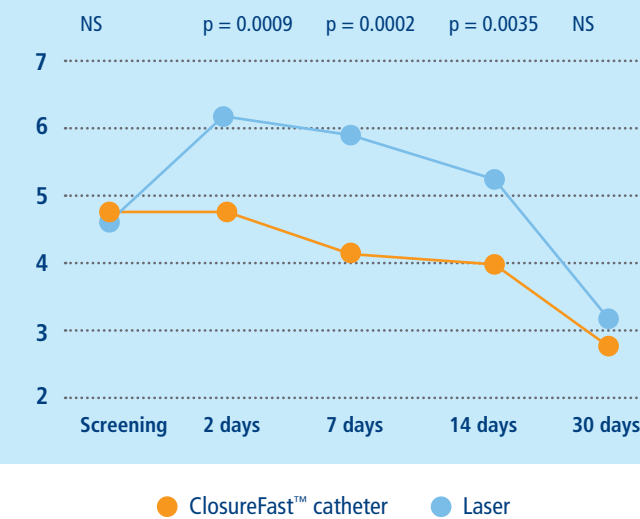
*9 laser treated limbs experienced sequelae with 14 total events

Venous Clinical Severity Scores (VCSS)

• “There were no significant differences between treatment groups at screening. However, at 48-hour, 1-week and 2-week visits, subjects in the Covidien ClosureFast™ catheter group had significantly reduced scores compared with the laser ablation group.”

• “The advantage of the Covidien ClosureFast™ catheter (in VCSS) was due to less post-operative pain and edema.”

VENOUS CLINICAL SEVERITY SCORE (VCSS)

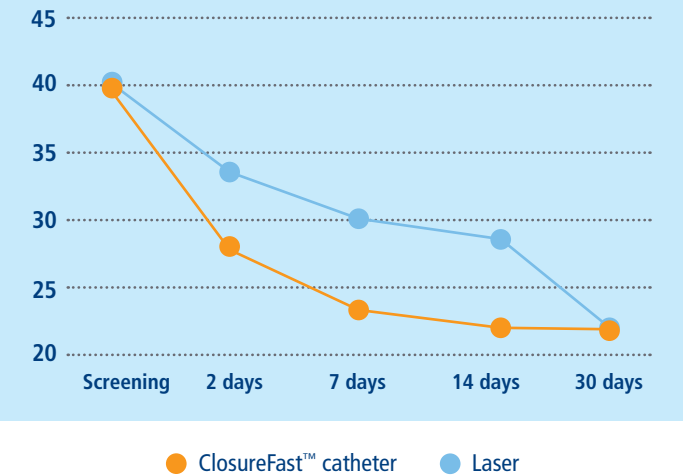


Better Quality of Life

Surveys confirmed that patients experienced significantly less pain, fewer physical limitations and faster improvement to their quality of life when treated with the Covidien ClosureFast™ catheter. Global quality of life dimensions included: Pain, Social, Psychological and Physical.

QUALITY OF LIFE SCORE: GLOBAL

Note: Lower score reflects a better QOL



INDICATION: The ClosureFast™ catheter is intended for endovascular coagulation of blood vessels in patients with superficial venous reflux.

CONTRAINDICATIONS: Patients with thrombus in the vein segment to be treated.

CAUTION: The vein wall may be thinner in an aneurysmal segment. To effectively occlude a vein with an aneurysmal segment, additional tumescent infiltration may be needed over the aneurysmal segment, and the treatment of the vein should include segments proximal and distal to the aneurysmal segment.

CAUTION: No data exists regarding the use of this catheter in patients with documented peripheral arterial disease. The same care should be taken in the treatment of patients with significant peripheral arterial disease as would be taken with a traditional vein ligation and stripping procedure.

POTENTIAL RISKS & COMPLICATIONS: Potential complications include, but are not limited to, the following: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, adjacent nerve injury, skin burns, deep vein thrombosis.

¹ Almeida JJ, Kaufman J, Gökçeriz O, et al. Radiofrequency Endovenous ClosureFast Versus Laser Ablation for the Treatment of Great Saphenous Reflux: A Multicenter, Single-Blinded, Randomized Study (RECOVERY Study). J Vasc Interv Radiol. 2009;20:752-759.

² Dietzek A, Two-Year Follow-Up Data From a Perspective, Multicenter Study of the Efficacy Of The ClosureFast Catheter, 35th Annual Veith Symposium. November 19, 2008. New York.



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VTH0381 11/11

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