Treatment of Chronic Venous Insufficiency Including the Modern Treatment of Varicose Veins

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Chronic Venous Insufficiency

7 million Americans have Chronic Venous Insufficiency

1 million Americans will develop Ulcerations

0.15% of the Population

20,000 new Venous Ulcers yearly

2% of Nation Healthcare Budget

Treatment costs $1.9-2.5 Billion per year
Varicose Veins

24 million Americans have Varicose Veins

32% if women, 40% of men in cohort of 1566

(Edinburgh Vein Study)

Others, 20-25% women, 10-15% men

Pruirits associated with Varicose Veins (men)

Heaviness/Tension, aching, and itching (women)

Minority develop Thrombophlebitis, Eczema, Lipodermatosclerosis, and Ulceration

Beale and Gough, Eur J Vasc Endovasc Surg 30:83-95, 2005
Evans et al, J Epidemiol Community Health 53:149-153, 1999

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>VV</th>
<th>CVI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Older age</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Family history</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Female gender</td>
<td>+</td>
<td>−/+/0</td>
</tr>
<tr>
<td>Standing occupation</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Constipation/Low fiber intake</td>
<td>+/0</td>
<td>0</td>
</tr>
<tr>
<td>Obesity</td>
<td>+</td>
<td>+/0</td>
</tr>
<tr>
<td>Smoking</td>
<td>+/0</td>
<td>+/0</td>
</tr>
<tr>
<td>Oral contraceptives/HRT</td>
<td>−/0</td>
<td>−/0</td>
</tr>
<tr>
<td>Hypertension</td>
<td>+/0</td>
<td>+/0</td>
</tr>
<tr>
<td>Physical activity</td>
<td>−/0</td>
<td>−</td>
</tr>
<tr>
<td>Injury</td>
<td>−/0</td>
<td>+</td>
</tr>
<tr>
<td>History of phlebitis/clot</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

−: Negative association.
+: Positive association.
0: No association.
Chronic Venous Insufficiency

Previous DVT

Congenital/Hereditary Venous Valvular Incompetence
Chronic Venous Insufficiency

Deep Veins
Saphenous Veins
Perforating Veins
Normal

Abnormal

Joseph A. Caprini, M.D., M.S., FACS, RVT
Venous Reflux

Valvular Incompetence

Superficial, Deep, and Perforator Reflux

Elevated Venous Pressures
Venous Obstruction

Persistent Venous Obstruction

Venous Thrombosis

Iliac Vein Compression (May-Thurner Syndrome)
Venous Hypertension - Ankle Little Soft Tissue Support

Clinical Signs, Etiology, Anatomy, Pathophysiology

Clinical

No Visible or Palpable Signs of Venous Disease 0
Telangiectases or Reticular Veins 1
Varicose Veins 2
Edema 3
Pigmentation or Eczema 4a
Lipodermatosclerosis or Atrophie Blanche 4b
Healed Venous Ulceration 5
Open Venous Ulceration 6

S: symptomatic, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other complaints attributable to venous dysfunction

A: asymptomatic

Etiology

Congenital Ec, Primary Ep, or Secondary Es, No Venous Cause En
CEAP Classification

**Anatomical**

Superficial, Deep, or Perforator

- Telangiectases 1
- GSV AK 2
- GSV BK 3
- LSV 4
- Non-Saphenous 5
- IVC 6
- Common Iliac 7
- Internal Iliac 8
- External Iliac 9

(As1-5) (Ad6-16) (Ap17-18)

**Pathophysiology**

- Pelvic 10
- CFV 11
- DFV 12
- FV 13
- Popliteal 14
- Calf 15
- Muscular 16
- Thigh Perf 17
- Calf Perf 18

- Reflux,
- Obstruction,
- Both Reflux and Obstruction
Venous Severity Scoring System (VCSS)

Pain
Varicose Veins
Venous Edema
Skin Pigmentation
Inflammation
Induration
No. of Active Ulcers
Active Ulceration, Duration
Active Ulceration, Size
Compressive Therapy Use

1 = mild; 2 = moderate; 3 = severe
Diagnosis of Venous Reflux/Chronic Venous Insufficiency

Phlebography

Ambulatory Venous Pressure Measurements

PPG (S100%/Sp60%)

Agreement with Duplex Scanning 0.47

Duplex Exam – RT, PRV


APG (S100%/Sp90-100%)

Agreement with Duplex Scanning 0.83
The Duplex Exam

• No prep for a venous Duplex

• The lower extremity from the groin to the ankle needs to be accessible

• Assessing for venous obstruction = patient supine in a reversed Trendelenberg position

• Assessing for valvular incompetence = patient should be deep reversed Trendelenberg or standing.
The Duplex Exam

- The deep venous system to the ankle is assessed for acute or chronic venous disease.
- If acute DVT is found a reflux study is not performed.
- Assessment for valvular incompetence follows.
The Duplex Exam

- The standing position is ideal:
  - Allows for complete filling of the LE venous system
  - The effects of hydrostatic pressure are more evident

- Patient should stand with weight distributed to contralateral leg
The Duplex Exam

- The vein segments are interrogated in a longitudinal scan plane

- Color image is helpful in identifying venous reflux

- Pulse wave Doppler signal is taken during Valsalva maneuver or preferably during distal compression

- Time of reflux is measured in ms
The Duplex Exam

- Valsalva only reliable for proximal veins

- Distal compression is ideal for remaining segments

- Standard is becoming utilizing rapid inflation cuffs that deliver approx. 80 mmHg
The Duplex Exam
Interpretation

• Reflux is present:
  – Deep and superficial veins retrograde flow is present for > 1 sec (Deep) or 500 ms (Superficial)
  – Perforators outward flow evident for > 500 ms
The Duplex Exam - Case Examples
The Duplex Exam - Case Examples
Varicose Veins
Prevalence estimates of varicose veins:

- 10 to 15% in men
- 20% to 30% in women

Associated with pruritis, leg heaviness, and aching, and occasionally thrombophlebitis, eczema, lipodermatosclerosis, and ulceration

Risk factors include older age, family history, female gender, standing occupation, obesity, and history of phlebitis or thrombosis
1566 men and women, 18-64yoa, 13 year FU
Annual Incidence of VV Development 1.35%;
   Men 1.31%, Women 1.39%
18-34 yoa 0.73%; 35-44 1.23%; 45-54 1.62%; 55-64 1.93%
Underwt 1.06%; Normal 1.28%; Overwt 1.41%; Obese 1.54%
No Family Hx 1.07%; Positive Family Hx 1.60%
No Preg 1.24%; Up to 4 pregnancies 2.11%

**Edinburgh Vein Study, AVF Feb 2011**
3072 men and women, 18-79yos, 6.6 year FU
Annual Incidence of VV Development 2.1%
   No difference Men vs. Women
   <39 yoa 1.16%; >59 yoa, 2.8%

Annual Incidence of Development CVI 2%
   C0, C1 to Higher Cstage 3.4% (Age, Obesity, Reflux)
   C2 to Higher Cstage, NSVVV 3.0%, SVV 4.8% (Age, BMI, Swelling)
Corona on Foot Edge, Mild 1.67%, Severe 5.23%

**Bonn Vein Study, AVF Feb 2011**
Etiology and Management of VV

- Patients may have isolated superficial insufficiency or combined superficial and deep insufficiency. At present, however, the effect of deep insufficiency on the outcomes and complications of laser ablation is unknown.

- Indications for varicose vein treatment:
  - Pain over the varicosities
  - History of phlebitis
  - Bleeding

- Varicose veins associated with superficial saphenous vein reflux are treated with saphenous vein ablation with or without stab phlebectomy

- Options for ablation include:
  - Endovenous laser therapy (EVLT)
  - Radiofrequency ablation (RFA)
  - Foam sclerotherapy
  - Open ligation and stripping; Powered Phlebectomy
Venous Insufficiency Protocol

Varicosities (C2)

Duplex Testing

Compression Stockings (20-30 mm/Hg)

Relief?

Y

N

Exercise, Skin care, wt loss, diet

Superficial reflux

Y

N

VA + VVE

VVE

VVE = varicose vein excision
Success = ulcer healed
VA = vein ablation
C2-C6, CEAP clinical classification
Open Surgery
Invaginated axial saphenectomy by a semirigid stripper: Perforate-invaginate stripping

Open Surgery

ClosureFast

ClosureFAST Catheter

RFGPlus RF Generator

ClosurePLUS Catheter
1. Catheter tip positioned 2cm distal to the saphenofemoral junction. Tumescent fluid is administered.

2. 7cm vein segment treated all at once during 20-second treatment cycle. Additional vein segments treated serially.

3. Catheter shaft markings allow fast and accurate catheter re-positioning between treatment cycles. No energy is delivered during re-positioning.

4. Treatment of 45cm vein length takes 3 to 5 minutes (seven treatment segments).
While combined insufficiency could result from postthrombotic deep venous insufficiency combined with primary superficial insufficiency, the more common presentation is progressive primary venous insufficiency.

In the overload theory, superficial insufficiency develops due to a milieu of inflammation and damage of valves and venous dilation, thought to be secondary to chronic ambulatory venous hypertension in the superficial system.

Reflux and varicosities in the superficial system lead to increased blood return to the deep system. Eventually the capacitance of these vessels is exhausted and deep valvular reflux develops due to the inability of the valve leaflets to coapt properly.


It therefore makes intuitive sense that eradication of the incompetent superficial vessels would allow the deep system to return to a normal physiologic state and deep reflux would improve or even cease.
Comparison of surgery in chronic venous ulcers in a controlled trial

Jamie R Barwell, Colin E Davies, Jane Usher, Clare Wakely, Jonathan J Earnshaw, Keith R Poskitt

Figure 1: Kaplan-Meier analysis of ulcer recurrence by reflux pattern
Long term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial

Manjit S Gohel, specialist registrar,1 Jamie R Barwell, consultant vascular and transplant surgeon,2 Maxine Taylor, leg ulcer nurse specialist,3 Terry Chant, vascular nurse specialist,3 Chris Foy, medical statistician,4 Jonathan J Earnshaw, consultant surgeon,5 Brian P Heather, consultant surgeon,5 David C Mitchell, consultant surgeon,5 Mark R Whyman, consultant surgeon,5 Keith P Passfield, consultant surgeon

Patients screened for study (n=1418)

Excluded (n=653): 
- Ankle brachial pressure index < 0.85 (n=276)
- No superficial reflux (n=270)
- Occluded deep veins (n=41)
- Incomplete duplex imaging (n=29)
- Unable to consent (n=13)
- Unfit for surgery (n=10)
- Compression impractical (n=8)
- Malignant ulcer (n=6)

Eligible patients (n=765)

Consented to randomisation (n=500)

Compressed group (n=258) 
- No surgery (n=255)
- Requested surgery (n=3)

Compressed plus surgery group (n=242) 
- Refused surgery (n=47)
- Had surgery (n=195)

Legs remaining healed (%) 

Compressed plus surgery 
- Analysed for healing rate (n=185)
- Healed during study (n=153)

Compressed alone 
- Analysed for recurrence rate (n=226)
- Healed during study (n=130)

P=0.331
Endovenous Laser Ablation Improves Venous Outcomes Irrespective of the Presence of Deep Venous Insufficiency


Section of Vascular Surgery and the Division of Interventional Radiology, University of Michigan, Ann Arbor, MI
Methods

- 460 limbs and 364 patients underwent EVLT or EVLT plus stab phlebectomy (EVLTP) from January 2005 through August 2007
- 810 nm laser 14W continuous mode
- Preoperative duplex testing evaluated valve closure times at SFJ, CFV, and PV; > 500 msec considered abnormal
- 200 mL of tumescent anesthesia
- Ablation was initiated either proximal to the first branch of the great saphenous vein in the groin or 2 cm from the saphenofemoral junction
- Legs were dressed with either a nonstretch Comprilan dressing, a stretch ACE wrap, or a combination of both
Demographics

- 364 patients and 460 limbs
- Average length of followup was 7.5 ± 6.2 months (range 0 to 35.6 months)

Table I. Demographics of patients with and without deep venous insufficiency

<table>
<thead>
<tr>
<th>Variable</th>
<th>DVI</th>
<th>No DVI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, average ± SD (range), y</td>
<td>50.6 ± 12.2 (16-81)</td>
<td>51.1 ± 12.2 (27-90)</td>
<td>.671</td>
</tr>
<tr>
<td>Female, No. (%)</td>
<td>241 (77.5)</td>
<td>103 (78.0)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>DVT risk factors, median (IQR) No.</td>
<td>4 (3-6)</td>
<td>4 (3-7)</td>
<td>.578</td>
</tr>
<tr>
<td>Right side, No. (%)</td>
<td>160 (51.4)</td>
<td>54 (40.9%)</td>
<td>.048</td>
</tr>
<tr>
<td>Bilateral EVLT, a same setting, No. (%)</td>
<td>31 (10)</td>
<td>11 (8.3%)</td>
<td>.723</td>
</tr>
<tr>
<td>EVAP stabs, median (IQR) No. b</td>
<td>30 (24-37)</td>
<td>26 (21-31)</td>
<td>.097</td>
</tr>
</tbody>
</table>

DVI, Deep venous insufficiency; EVA, endovenous laser ablation; EVAP, endovenous laser ablation with phlebectomy; IQR, interquartile range.

aEVLT (Endovenous Laser Treatment) system, Diomed Inc, Andover, Mass.
bData are for patients who underwent phlebectomy concomitantly with EVA.
# CEAP Scores

## Clinical Score

<table>
<thead>
<tr>
<th>C1: Telangiectasics</th>
<th>1.6%</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2: Venous varicosities</td>
<td>52.6%</td>
</tr>
<tr>
<td>C3: Edema</td>
<td>15.6%</td>
</tr>
<tr>
<td>C4: Skin changes</td>
<td>20.1%</td>
</tr>
<tr>
<td>C5: Healed ulcer</td>
<td>7.4%</td>
</tr>
<tr>
<td>C6: Active ulcer</td>
<td>2.7%</td>
</tr>
<tr>
<td>Symptomatic disease</td>
<td>98.4%</td>
</tr>
</tbody>
</table>

## Etiology

<table>
<thead>
<tr>
<th>Type</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Primary etiology</td>
<td>95.0%</td>
</tr>
<tr>
<td>Secondary etiology</td>
<td>4.1%</td>
</tr>
<tr>
<td>Congenital etiology</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

**Combined superficial and deep reflux**: 70.2%
Duration of occlusion

**Diagram:**
- X-axis: Time [months]
- Y-axis: Vessel Occlusion [%]
- Two lines represent DVI (Dashed line) and No DVI (Solid line).
- Key statistics:
  - DVI: 308 at risk, 144 occluded (99.5 ± 0.5%), 65 occluded (97.0 ± 1.6%), 22 occluded (97.0 ± 1.6%), 6 occluded (92.0 ± 5.1%), 1 occluded (92.0 ± 5.1%)
  - No DVI: 132 at risk, 70 occluded (96.8 ± 1.8%), 40 occluded (93.6 ± 2.9%), 13 occluded (90.9 ± 3.8%), 5 occluded (90.9 ± 3.8%), 1 occluded (90.9 ± 3.8%)
- P-value: 0.117
DVI Had No Effect on the Rate of Change of VCSS
Fate of Late Recannalizations

Less Improvement in VCSS noted in the Presence of Recannalization.

P = .04
Table 3
Postoperative Ecchymosis as Measured at Each Visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>Response (%)</th>
<th>CLF Response (%)</th>
<th>EVL Response (%)</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>48 Hours</td>
<td>None</td>
<td>30 (66.7)</td>
<td>8 (19.5)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td></td>
<td>0–25</td>
<td>15 (33.3)</td>
<td>13 (31.7)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25–50</td>
<td>0</td>
<td>14 (34.1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>50–75</td>
<td>0</td>
<td>5 (12.2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>75–100</td>
<td>0</td>
<td>1 (2.4)</td>
<td></td>
</tr>
<tr>
<td>1 Week</td>
<td>None</td>
<td>26 (65.0)</td>
<td>9 (25.7)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td></td>
<td>0–25</td>
<td>13 (32.5)</td>
<td>12 (34.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25–50</td>
<td>0</td>
<td>10 (28.6)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>50–75</td>
<td>1 (2.5)</td>
<td>4 (11.4)</td>
<td></td>
</tr>
<tr>
<td>2 Weeks</td>
<td>None</td>
<td>35 (81.4)</td>
<td>13 (33.3)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td></td>
<td>0–25</td>
<td>17 (40.3)</td>
<td>18 (46.2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25–50</td>
<td>1 (2.3)</td>
<td>6 (15.4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>50–75</td>
<td>0</td>
<td>2 (5.1)</td>
<td></td>
</tr>
<tr>
<td>1 Month</td>
<td>None</td>
<td>45 (97.8)</td>
<td>31 (77.5)</td>
<td>.0050</td>
</tr>
<tr>
<td></td>
<td>0–25</td>
<td>1 (2.2)</td>
<td>9 (22.5)</td>
<td></td>
</tr>
</tbody>
</table>

* Fisher exact test.

Radiofrequency Endovenous ClosureFAST versus Laser Ablation for the Treatment of Great Saphenous Reflux: A Multicenter, Single-blinded, Randomized Study (RECOVERY Study)

Jose I. Almeida, MD, RVT, John Kaufman, MD, Oliver Göckeritz, MD, Paramjit Chopra, MD, Martin T. Evans, MD, Daniel F. Hoehm, MD, Raymond G. Makhoul, MD, Tim Richards, MD, Christian Wenzel, MD, and Jeffrey K. Raines, PhD, RVT

J Vasc Interv Radiol 2009; 20:752–759

87 Veins, 69 Patients, ClosureFAST vs. 980-nm EVL, 5 American and 1 European Sites
Comparison of Radiofrequency Ablation to Endovenous Ablation of the Great Saphenous Vein

Brian S. Knipp, MD; Elaine Fellows, NP; William LaForge, RN; Susan A Blackburn, RN, MBA; Cathy Stabler, RN; Alysia Hogan; Jess R Bloom, RVT; John R. Rectenwald, MD; and Thomas W. Wakefield, MD

Section of Vascular Surgery, Department of Surgery, University of Michigan, Ann Arbor, MI
Methods

- 342 limbs and 278 patients underwent RFA or EVA with or without powered or stab phlebectomy from January 2007 through December 2009
- RFA: 120 degree heating in 20 second 7 cm segmental pullback cycles
- EVA: 810 nm laser 14W continuous mode
- Preoperative duplex testing evaluated valve closure times at SFJ, CFV, and PV; > 500 msec considered abnormal
- 300 mL of tumescent anesthesia
- Ablation was initiated either proximal to the first branch of the greater saphenous vein in the groin or 2 cm from the saphenofemoral junction
- Legs were dressed with either a nonstretch Comprilan dressing, a stretch ACE wrap, or a combination of both
- There were no immediate technical failures
## Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>RFA (n=184)</th>
<th>EVA (n=158)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>50.5 ± 12.4</td>
<td>51.0 ± 13.1</td>
<td>.244</td>
</tr>
<tr>
<td>Female</td>
<td>133 (72.3)</td>
<td>101 (63.9)</td>
<td>.104</td>
</tr>
<tr>
<td>BMI</td>
<td>30.3± 8.1</td>
<td>30.3± 8.1</td>
<td>.956</td>
</tr>
<tr>
<td>Left side</td>
<td>86 (46.7)</td>
<td>79 (50.0)</td>
<td>.588</td>
</tr>
<tr>
<td>Phlebectomy</td>
<td>92 (50.0)</td>
<td>88 (55.7)</td>
<td>.329</td>
</tr>
</tbody>
</table>
**CEAP Scores**

<table>
<thead>
<tr>
<th></th>
<th>All (n=342)</th>
<th>RFA (n=184)</th>
<th>EVA (n=158)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>C2</td>
<td>181 (52.9%)</td>
<td>100 (54.3%)</td>
<td>81 (51.3%)</td>
<td>.906</td>
</tr>
<tr>
<td>C3</td>
<td>94 (27.5%)</td>
<td>46 (25.0%)</td>
<td>48 (30.4%)</td>
<td></td>
</tr>
<tr>
<td>C4</td>
<td>34 (9.9%)</td>
<td>17 (9.2%)</td>
<td>17 (10.8%)</td>
<td></td>
</tr>
<tr>
<td>C5</td>
<td>9 (2.6%)</td>
<td>4 (2.2%)</td>
<td>5 (3.2%)</td>
<td></td>
</tr>
<tr>
<td>C6</td>
<td>24 (7.0%)</td>
<td>17 (9.2%)</td>
<td>7 (4.4%)</td>
<td></td>
</tr>
<tr>
<td>Symptomatic</td>
<td>342 (100%)</td>
<td>184 (100%)</td>
<td>158 (100%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Combined</td>
<td>270 (78.9%)</td>
<td>142 (77.2%)</td>
<td>128 (81.0%)</td>
<td>.426</td>
</tr>
</tbody>
</table>
Duration of occlusion

- There were two recannalization events, both in the EVA group without phlebectomy.
- Both events occurred at approximately 3 months postprocedure.
- The overall occlusion rate was 100% at 12 months for the RFA group and 98% at 29 months for the EVA group.
VCSS Improvement

P=.021
VCSS Improvement

- Preop VCSS
- VCSS 1 to 5

Baseline
- 0-30d
- 31-90d
- 91-180d
- 181-360d
- 361-720d

No phleb
- P = 0.059
- P = 0.011
- P < 0.001
- P < 0.001
- P = 0.042

Phleb
- P = 0.100

P-values are significant for the comparison between No phleb and Phleb groups at different time intervals.
• We feel it is appropriate to offer superficial venous ablation to all patients with combined superficial and deep venous insufficiency except in those patients in which the superficial system is compensating for persistent deep venous obstruction or severe postthrombotic changes.

• Patients with multisegment or distal deep reflux should, however, be counseled that superficial surgery is less likely to achieve complete benefit in their case.
Stab Phlebectomy

2-3 mm INCISIONS WITH ELEVEN BLADE OR 18 GUAGE NEEDLE

Crochet hooks vs PHLEBECTOMY hooks

HEMASTATS
Conventional vs. Powered Phlebectomy (Trivex)

Conventional Stab Avulsions 100 Limbs
Trivex 88 Limbs
FU 2, 6, 26, 52 weeks

Difference in Incisions: 29 vs. 5
Non-significant Operative Time: 85 vs. 67 m (most severe)

No Differences: Pain Score over 8 days;
Severe Bruising (7 vs. 9%), Cellulitis (3 vs. 2.3%), Numbness (25 vs. 18%) at 2 wks;
Nerve Injury (19 vs. 15.9%), Residual Veins (8 vs. 9.1%), Cosmetic Score,
Satisfaction at 6 wks
Cosmesis or Recurrence at 6 and 12 months

Trend for Decreased OR Time; Definite Decrease in Incisions