

# Endovenous 980-nm laser treatment of saphenous veins in a series of 500 patients

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**Background:** In recent years, endovenous laser treatment (ELT) has been proposed to treat incompetent great saphenous veins (GSV). This study reports the long-term outcome of ELT in a series of 500 patients.

**Methods:** Incompetent GSV segments in 500 patients (436 women, 64 men) with a mean age of 52.6 years (range, 19 to 83 years) were treated with intraluminal ELT using a 980-nm diode laser (Pharaon, Osyris, France). The GSV diameter was measured by Duplex examination in an upright position in different GSV segments (1.5 cm below the saphenofemoral junction, crural segment, condylar segment, and sural segment). These measurements were used to determine the optimal linear endovenous energy density (LEED) for each segment. During treatment, patients were maintained in the Trendelenburg position. Patients were evaluated clinically and by duplex scanning at 1 and 8 days, 1 and 6 months, and at 1, 2, 3, and 4 years to assess treatment efficacy and adverse reactions.

**Results:** A total of 511 GSVs were treated. The mean diameter was 7.5 mm (range, 2.4 to 15.0). The LEED was tuned as a function of the initial GSV diameter measured in the orthostatic position, from 50 J/cm (3 mm) up to 120 J/cm (15 mm). At the 1-week follow-up, 9.3% of the patients reported moderate pain. In the immediate postoperative period, the closure rate was 98.0% and remained constant during the 4-year follow-up to reach 97.1%. After 1 year, a complete disappearance of the GSV or minimal residual fibrous cord was noted. Major complications have not been detected; in particular, no deep venous thrombosis. Ecchymoses were seen in 60%, transitory paresthesia was observed in 7%. There was no dyschromia, superficial burns, thrombophlebitis, or palpable indurations. Complementary phlebectomy was done in 98% of patients. Failures occurred only in large veins (saphenofemoral junction diameter >1.1 cm or for GSV truncular diameter >0.8 cm)

**Conclusion:** ELT of the incompetent GSV with a 980-nm diode laser appears to be an extremely safe technique, particularly when the energy applied is calculated as a function of the GSV diameter. It is associated with only minor effects. Currently, ELT has become the method of choice for treating superficial veins and has almost replaced the treatment of traditional ligation and stripping. (*J Vasc Surg* 2007;46:1242-7.)

Lower-extremity venous insufficiency is a common medical condition afflicting 25% of women and 15% of men in the United States and in Europe. Great saphenous vein (GSV) reflux is the most common underlying cause of significant varicose veins. Traditional treatment of GSV reflux has been surgical removal of the GSV<sup>1</sup>; however, recurrence in 30% to 60% of cases is reported,<sup>2</sup> and it is also associated with significant perioperative morbidity.

Less-invasive surgical treatments, including high ligation of the GSV at the saphenofemoral junction (SFJ), have been attempted in the hope that gravitational reflux would be controlled while the vein is preserved for possible use as a bypass graft. Unfortunately, ligation of the GSV alone usually results in recurrent varicose veins. Recurrence has been the rule even when high ligation has been combined with phlebectomy of varicose tributaries or retrograde sclerotherapy. Therefore, when it is determined that GSV reflux is the principal underlying problem, treatment

should involve eliminating this source of reflux with ablation of any associated incompetent venous segments.<sup>3</sup>

Although inadequate surgery of the saphenofemoral junction and progression of disease are mechanisms that explain some cases of recurrence, another important mechanism is neovascularization of the junction area after venous surgery. Histologic evidence has clearly shown that neovascularization is the principle cause of recurrence.<sup>4</sup>

Minimally invasive techniques have been developed within the last few years as alternatives to surgery in an attempt to reduce morbidity and improve recovery time. Endovenous laser treatment (ELT) is one of the most promising of these new techniques, and numerous studies have since demonstrated that it is safe and efficacious.

Several wavelengths have been proposed, respectively 810, 940, 980, 1064, and 1320 nm,<sup>5-9</sup> with 810, 940 and 980 nm the most commonly used. At these wavelengths, power is usually set between 10 and 15 W. The energy is administered endovenously, either in a pulsed fashion (pulse duration, 1 to 3 seconds) with fiber pullback in 3- to 5-mm increments every 2 seconds or continuously with a constant pullback of the laser fiber at a velocity of 1 to 3 mm/s. At these settings, the average linear endovenous energy density (LEED) that is commonly used to report the dose administered to the vein is 20 J/cm to 140 J/cm.<sup>10,11</sup> These doses induce heating of the vein wall, which is necessary to cause collagen contraction and de-

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Competition of interest: none.

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0741-5214/\$32.00

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doi:10.1016/j.jvs.2007.08.028

struction of endothelium. This stimulates vein wall thickening, leading to luminal contraction, venous thrombosis, and vein fibrosis.<sup>12</sup>

Tumescent anesthesia is always delivered, so patients feel no pain during ELT ablation at the suggested or commonly used laser settings. This tumescent anesthesia has the two functions of compressing and reducing the diameter of the veins as well as acting as a protective barrier, minimizing the risk of heat-related damage to adjacent tissues.<sup>13,14</sup> The discomfort felt by patients occurs 5 to 8 days after the procedure and is related to the inflammation resulting from successful endovenous ablation (ie, wall thickening).<sup>15</sup> It is not related to the presence or degree of ecchymosis nor is it the result of nontarget laser damage to perivenous tissue.

This study reports the effectiveness and safety of ELT of the GSV from a large number of patients from S.E.L. Angéio-Phlébo Interventionnelle, Lomme, France with long-term follow-up results.

## MATERIALS AND METHODS

**Patient selection.** Directed history and physical examination, including an evaluation by duplex ultrasound imaging of the superficial venous system, was performed on limbs of subjects with GSV. Study inclusion criteria included varicose veins caused by SFJ incompetence with GSV reflux as demonstrated by duplex ultrasound imaging, age at least 18 years, and ability to return for scheduled follow-up examinations for 12, 24, 36, and 48 months after endovenous laser treatment. Exclusion criteria included nonpalpable pedal pulses, cardiovascular disease, inability to ambulate, deep venous thrombosis (DVT), general poor health; pregnancy, nursing, or plans to become pregnant during the course of participation in the investigation; and extremely tortuous GSVs that would not allow endovenous catheterization and passage of the laser fiber as identified on pretreatment venous duplex US mapping.

After initial consultation and evaluation, subjects meeting the appropriate criteria were offered surgery vs ELT. Nearly all subjects chose ELT rather than surgical ligation and stripping. The study protocol was approved by our local ethics committee. All patients gave written informed consent before treatment.

**Protocol.** This prospective cohort observational study included 500 patients (436 women, 64 men) with a mean age of 52.6 years (range, 19 to 83 years) who underwent ELT of incompetent GSV segments with 980-nm diode laser energy delivered intraluminally. To reduce the amount of blood inside the vein, the patients were maintained in Trendelenburg position in which the patient is on an elevated and inclined plane at 20° with the head down and legs and feet over the edge of the table.<sup>16</sup>

**Procedure.** Duplex ultrasonography (Aloka 3500, Decines, France) was performed in the upright position to map incompetent sources of venous reflux and then to mark the skin overlying the incompetent portion of the GSV starting at the SFJ. GSV diameter was measured in upright position in different locations (1.5 cm below the

SFJ, crural segment, condylar segment and sural segment) to select the appropriate LEED for each segment.

In an outpatient special procedure room in the hospital, the patient was placed in the Trendelenburg position for treatment of the GSV. The target extremity was sterilely prepared and draped. Under ultrasound guidance through a sterile ultrasound probe cover, the GSV was visualized at the knee level. The saphenous vein was percutaneously punctured with a 21-gauge needle under ultrasound guidance. A 5F microintroducer guidewire was threaded through the needle, followed by the introducer. A 0.035-inch guidewire was passed under ultrasound guidance up to the SFJ, and a 5F introducer was placed over the guidewire. A 600- $\mu$ m optical fiber (Osyfibre: PH-980-15-600-3, Osyris, Hellemmes, France) connected to a 980-nm diode laser (Pharaon, Osyris, Hellemmes, France) was passed through the introducer to the SFJ. Its position was verified by ultrasound imaging and by visualization of the aiming beam through the skin.

Duplex control was used to guide the injection of 7- to 8-mL aliquots of a solution containing 10 mL of lidocaine (1%) with epinephrine, 10 mL of lidocaine (1%) without epinephrine, and an additional 60 mL of physiologic serum. The injections were performed into the fascial space surrounding the vein at intervals down its length.

The laser fiber was delivered endovenously 1 to 2 cm below the SFJ and along the course of the GSV. The laser fiber and catheter were slowly withdrawn in 3-mm increments using a graduated scale. The parameter was 10 W in continuous mode with bursts of laser energy. LEED was tuned as a function of the GSV diameters measured in the upright position for each segment: 1.5 cm below the SFJ, crural segment, condylar segment, and leg segment. The LEED applied was 50 J/cm for GSV diameters between 2 and 4.5 mm, 70 J/cm for 4.5 to 7 mm, 90 J/cm for 7 mm to 10mm, and up to 120 J/cm for larger diameters. Consequently, the pulse duration was adjusted for each individual GSV segment from 1.2 seconds (2 mm) up to 6 seconds (>10 mm). The last pulse was controlled by duplex ultrasound imaging to avoid any skin burn and delayed healing. Concomitant ambulatory phlebectomy was done in 98% of the patients in this series.

Venous compression was applied postoperatively for 24 hours by irremovable compression bandage. The patients were also asked to wear full-thigh class 3 compression stockings during the day for 3 weeks. Patients were instructed to walk immediately after the procedure and to continue their normal daily activities with vigorous workouts. All patients received the nonsteroidal anti-inflammatory drug piroxicam (Feldene, Pfizer, New York, NY) for 5 days.

**Follow-up examinations.** Patients were re-examined at day 1 after the procedure, at 1 week, at 1 and 6 months, and at 1, 2, 3, and 4 years. Patients received duplex scanning and were re-evaluated functionally and clinically. Treatment-related side effects and complications were recorded. Symptoms of interest were the presence of ecchy-

**Table I.** Clinical results during 4 years of follow-up

Follow-up period	GSVs, No.	Successful treatment, %
1 day	511	98
8 days	511	98
1 month	509	98.4
6 months	466	95.7
1 year	408	96.8
2 years	269	97.8
3 years	141	99.3
4 years	34	97.1

GSV, Great saphenous veins.

mosis, palpable induration, phlebitic reaction, and pain. The duration of all symptoms was recorded.

**Statistical analysis.** Univariate Kaplan-Meier life-table analysis was used to calculate failure rate, and the 95% confidence interval of the survival rate was also computed. Statistical analysis was performed using SAS 9.1 software (SAS Institute Inc, Cary, NC).

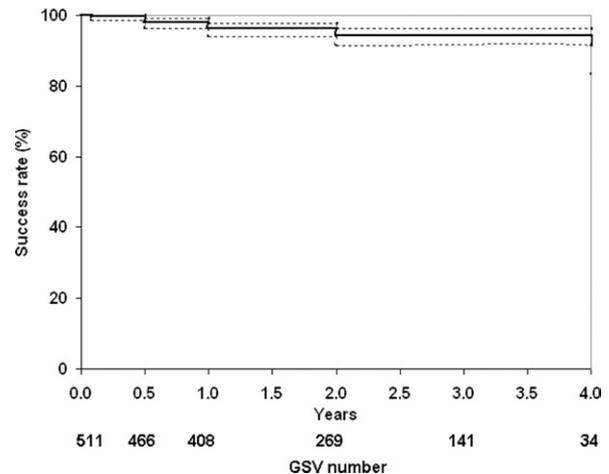
## RESULTS

Of the 500 patients who underwent ELT of the GSV, 436 were women and 64 were men, and their median age was 52.6 years (range, 19 to 83 years). A total of 511 limbs were treated, and according to the CEAP classification of venous disorders, 388 were C2EpAS2 (GSV above the knee) and 123 were C2EpAS3 (GSV below the knee).

The mean GSV diameter, measured in the orthostatic position, was  $5.88 \pm 2.23$  mm (range, 2.4 to 15.0 mm). The mean length of GSV treated was  $32.2 \pm 14.4$  cm (range, 15 to 86 cm). In the immediate postoperative period, successful occlusion, defined as vein occlusion with absence of flow, was noted in 501 GSVs (98%). This initial success rate remained almost constant during the follow-up period to reach 97.1% at 4 years (Table I, Fig). A total disappearance of the GSV or minimal residual cord was noted in 40% of patients at the 6-month follow-up, mainly in younger patients. At 1 year, a complete disappearance of the GSV or minimal residual fibrous cord was noted for all patients.

The analysis of failures (Table II) shows that the first group of patients with early failures (2- and 4-year follow-up) may have been due to inadequate initial treatments; however, most recurrences were seen at 6 months. In this series, failures occurred only in large veins (SFJ diameter >1.1 cm in diameter for GSV truncular diameter >0.8 cm in diameter). In three patients who had early failure, closure was noted at the 1-month follow-up. For these three patients, SFJ diameter was 9 mm and GSV truncular diameter was 6.5 mm.

Major complications have not been detected; in particular, no DVT. Ecchymoses were seen in 60%, with a median duration of 2 weeks. Transitory paresthesia was observed in 7% of treated legs, with a median duration of 2 weeks (maximum duration,  $\leq 4$  weeks). At 1-week follow-up, moderate pain was reported in 9.3% of the patients, and



**Fig.** Success rates. The numbers along the axis represent the numbers of veins available for analysis at intervals through the study. The dotted lines represent 95% confidence intervals. GSV, Great saphenous vein.

they received analgesics for 1 more week. No dyschromia, superficial burns, thrombophlebitis, or palpable indurations were observed.

The compliance rate for class 3 compression was 100% at 1 week and 70% at 3 weeks. This rate was assessed using a patient questionnaire at the 1-month follow-up.

## DISCUSSION

Valvular incompetence of the GSV is the most common contributor to primary varicose veins. ELT of the GSV has been widely accepted, and numerous studies have been published. Studies with >400 patients and with a 4-year follow-up are very limited, however:

- In 2003, Min et al<sup>3</sup> published results on 499 GSV in 423 subjects with varicose veins treated during a 3-year period with an 810-nm diode laser. Successful occlusion of the GSV, defined as absence of flow on color Doppler imaging, was noted in 490 of 499 GSVs (98.2%) after initial treatment, and 113 of 121 limbs (93.4%) followed up for 2 years have remained closed, with the treated portions of the GSVs not visible on duplex imaging. Forty subjects have been followed up for 3 years and no new recurrences were seen at 2 or 3 years that were not present at the 1-year follow-up.<sup>3</sup>
- In 2005, Duran presented a study including 517 GSV in 426 patients with a 24-month follow-up. Among 112 GSV followed up at least 24 months, 98% remained closed or reabsorbed.<sup>17</sup>
- In 2006, the Italian Endovenous-laser Working Group<sup>18</sup> reported a cooperative multicenter clinical study in 1050 patients (1076 limbs) during a 6-year period but with only a 3-year follow up for all the centers using duplex scanning. Thus far, the total occlusion rate has been 97%.
- In 2007, Sadick and Wasser<sup>19</sup> reported their 4-year experience with ELT plus ambulatory phlebectomy for

**Table II.** Patients with immediate and late failures

Patient	1 day	8 days	1 month	6 months	1 year	2 years	3 years	4 years	SFJ diameter, mm	GSV troncular diameter, mm
1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	13.0	8.0
2	Yes	Yes	Yes	Yes	Yes	Yes	...	...	13.0	8.0
3	Yes	Yes	Yes	Yes	Yes	Yes	...	...	12.0	8.0
4	Yes	Yes	Yes	Yes	Yes	Yes	...	...	12.0	7.5
5	Yes	Yes	Yes	Yes	Yes	Yes	...	...	12.0	8.0
6	No	No	No	Yes	Yes	Yes	...	...	9.5	7.5
7	Yes	Yes	No	No	No	...	...	...	8.5	6.08
8	No	No	No	Yes	Yes	...	...	...	12.0	8.0
9	No	No	No	Yes	Yes	...	...	...	11.0	8.0
10	No	No	No	Yes	Yes	...	...	...	10.0	7.0
11	No	No	No	Yes	Yes	...	...	...	9.0	6.0
12	No	No	No	Yes	Yes	...	...	...	10.0	8.5
13	No	No	No	Yes	Yes	...	...	...	13.0	8.0
14	No	No	No	Yes	Yes	...	...	...	11.0	8.0
15	Yes	Yes	Yes	Yes	...	...	...	...	15.0	8.0
16	No	No	No	Yes	...	...	...	...	11.0	7.0
17	No	No	No	Yes	...	...	...	...	13.0	8.0
18	Yes	Yes	Yes	Yes	...	...	...	...	15.0	8.5
19	No	Yes	Yes	Yes	...	...	...	...	12.5	7.0
20	No	No	No	Yes	...	...	...	...	11.5	8.0
21	No	No	No	Yes	...	...	...	...	13.0	8.0
22	Yes	Yes	No	...	...	...	...	...	8.5	6.5
23	Yes	No	No	...	...	...	...	...	9.5	6.5
Total	10	10	8	20	13	6	1	1		

GSV, Great saphenous vein; SFJ, saphenofemoral junction.

the treatment of superficial venous incompetence. The recurrence rate was, respectively 5.9%, 3.6%, 3.4%, and 0% at 1, 2, 3, and 4 years of follow-up. In this study, however, only 90 patients (94 limbs) were treated, and results are reported for only three patients at 4 years.<sup>19</sup>

Thus, the present study is one of the largest studies performed in a single center with a 4-year follow-up.

The experience gained by our group through years has shown that the energy applied during treatment was the main determinant of success; hence, although not perfect, LEED remains our choice when comparing energy. We adapted LEED as a function of GSV diameter measured in upright position. Because thermal damage of the inner vein wall (tunica intima) is required to achieve the tissue alterations necessary to lead the vein to permanent occlusion, mathematic modeling of ELT has confirmed that LEED should be chosen as a function of the GSV diameter.<sup>20,21</sup>

In contrast to the mode of action of radiofrequency ablation as used in the VNUS closure system (VNUS Medical Technologies, Inc, San Jose, Calif), where a significant shrinkage of the vessel wall is observed, Proebstle et al<sup>22</sup> has clearly demonstrated that when performing ELT, permanent occlusion, reported at  $\geq 3$  months, can only be obtained by thermal damage of the tunica intima inner vein wall. This observation was confirmed by the histologic study performed by Corcos et al<sup>23</sup> after ELT with an 810-nm diode laser. They showed that when permanent occlusion was observed, the endothelium and intima were always damaged. The adventitia and the externa appeared to be involved in only a few of the specimens. They con-

cluded that that success was independent of the vessel wall thickness.<sup>23</sup>

The role of blood during the ELT must be considered. Because the presence of blood could reduce the light transmitted to the vein wall, it is usually recommended to reduce the amount of blood by emptying the vein lumen using leg elevation by Trendelenburg positioning, perisaphenous subcutaneous tumescent saline solution infiltration, and manual compression. If the laser light energy is entirely absorbed by the blood, the initial success rate is mainly due to a thrombotic effect, but the thrombus dissolution leads to a recanalization.<sup>11</sup>

The proper tumescent anesthetic technique is essential for this procedure to be safe and painless. With ultrasound guidance, only 300 to 400 mL of fluid is required. The procedure is painless, and a surrounding fascial envelope of the tumescent solution provides a margin of safety so heat damage to surrounding structures does not occur.<sup>24</sup>

The principal finding in this study is that ELT with a 980-nm diode laser system, when performed under tumescent local anesthesia, is a clinically feasible and well-tolerated technique. Because vein access is with a 21-gauge needle, it is truly minimal procedure that leaves a nearly invisible scar on the patient's skin.

The efficacy of ELT in obtaining early occlusion of the GSV is very satisfactory, with a 98.4% closure rate at the 1-month follow-up. These results are very similar to those reported by other teams. A 97% closure rate was obtained by Proebstle et al<sup>5</sup> with a similar follow-up. Min et al<sup>3</sup> reported a 97% closure rate 1 week after initial treatment.

At 2-year follow-up, the closure rate was 97.8% in our series and 93.4% in the Min et al series. Repeated treatments were sometimes performed, however, which is not the case in our study, where patients were only treated once. Sadick et al<sup>19</sup> obtained a closure rate of 96.4%. Duran<sup>17</sup> obtained a 24-month follow-up on 112 GSV (61 initially), among which 98% have remained closed. Disselhoff et al<sup>25</sup> reported that the treated GSV was not identifiable with duplex ultrasound in 89% and 90% of limbs at the 1- and 2-year follow-up, respectively. A complete disappearance of the GSV or minimal residual fibrous cord was noted in our study.

At 3-year follow-up, the total occlusion rate of GSV was 99.3%. This is similar to the 96.7% rate reported by Agus et al<sup>18</sup> and the 96.6% rate of Sadick et al<sup>19</sup> after 36 months. At 4 years, the closure rate was 97.1%. Sadick et al have obtained 100% occlusion, but with a follow-up on three patients only.<sup>19</sup>

In our series, recanalizations were only observed when SFJ diameter was >1.1 cm or for GSV troncular diameters >0.8 cm. This observation is in agreement with mathematic modeling demonstrating that higher energy should be necessary to treat a larger GSV diameter. Several authors have proposed to use higher LEED to improve the closure rate. Proebstle et al<sup>11</sup> observed that nonocclusion and early reopening of the GSV is energy-dependent.

Timperman et al<sup>26</sup> compared patients treated with an average energy delivered of 63.4 J/cm (range, 20.5 to 137.8 J/cm) and a second group treated with 46.6 J/cm (range, 25.7 to 78 J/cm). They showed that failures were mostly associated with the lower LEED. However, treatment failures were also identified in patients who received doses of  $\geq 80$  J/cm or more. Energy delivery for the failures was 120, 80, 110, 98, and 80 J/cm (mean J/cm [SD], 98 [18]), respectively.<sup>26</sup>

That failures were always observed when SFJ diameter was >1.1 cm or for GSV troncular diameter >0.8 cm, where the content of blood is very important even in the Trendelenburg position, confirms that laser irradiation was not sufficient to heat the vessel wall. One can hypothesize that blood remaining inside the lumen could absorb the laser light energy, limiting consequently the light transmitted to the vessel wall.

Side effects are also energy-dependent. Superficial burns and palpable indurations are sometimes associated with LEED >100 J/cm. In our study, LEED was chosen to obtain maximum efficiency but also to limit the treatment-related side effects and complications. No dyschromia, superficial burns, thrombophlebitis, or palpable indurations were reported in our study. These results confirm that our decision to adapt the LEED to the GSV diameter has led to a high rate of GSV closure while minimizing the side effects. The ecchymosis rate in our study was 60%, which is similar to the 61.7% rate reported by Sadick et al.<sup>19</sup> It also compares favorably with the ecchymosis rates observed by Proebstle et al<sup>27</sup> of 73.2% (940 nm, 15W, 1 second, pulsed), 78.2% (940 nm, 15W, continuous wave) and 81.2% (940 nm, 20W, continuous wave).

Most clinical studies published on ELT have not considered postprocedural pain. The difficulty with studies that evaluate pain is the significant variation in pain tolerance among patients. What may seem like "being sore" to one patient might be considered severe pain to another. Even objective measures such as carefully recording usage of pain medication can vary because patients have different pain tolerances. For example, Gibson et al<sup>28</sup> reported pain in 97% of treated patients, and in the series reported by Proebstle et al,<sup>27</sup> 72% of patients complained of pain. In their series, pain was treated with analgesics twice daily, and the median duration of pain and the demand for analgesics lasted usually 1 week (maximum duration, 2 weeks). In our series, analgesics were systematically given to the patients for 5 days, and at the 1-week follow-up, only 9.3% reported moderate pain.

Transitory paresthesia was observed in 7% of treated legs, with a median duration of 2 weeks. Huang et al<sup>29</sup> noted paresthesia in 7.2% of patients. In another study, Proebstle et al<sup>30</sup> reported an 11% incidence of paresthesia for 3 to 8 weeks after treatment, despite all patients being treated with low-molecular weight heparin and postoperative graduated compression for 8 days.

## CONCLUSION

ELT of the incompetent GSV with a 980-nm diode laser appears to be an extremely safe technique, particularly when the energy applied is calculated as a function of the GSV diameter. It is associated with only minor effects. Currently, ELT has become the method of choice for treating superficial veins and has almost replaced the traditional treatment of ligation and stripping.<sup>31,32</sup>

We acknowledge the contribution of Patrick Devos, PhD, Department of Biostatistics, University Hospital, Lille, France, for statistical analysis.

## AUTHOR CONTRIBUTIONS

Conception and design: JD, CG, SM  
Analysis and interpretation: JD, BW, SM  
Data collection: JD, CG  
Writing the article: SM  
Critical revision of the article: JD  
Final approval of the article: SM  
Statistical analysis: SM, BW  
Obtained funding: no funding  
Overall responsibility: JD, CG

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Submitted Jun 26, 2007; accepted Aug 18, 2007.