

Early and late complications of silicone patch saphenoplasty at the saphenofemoral junction

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Background: To reduce the incidence of postoperative recurrence after great saphenous vein (GSV) surgery, various barrier techniques have been introduced, aiming at containment of postoperative neovascularization at the saphenofemoral junction in the groin. Interposition of a prosthetic barrier (patch saphenoplasty) may be useful for this purpose; however, the incidence of postoperative complications after patch saphenoplasty is unknown. A prospective study examined the incidence of complications after patch saphenoplasty in primary and repeat varicose vein surgery.

Methods: Silicone patch saphenoplasty was performed in a consecutive series of 462 limbs (primary GSV surgery in 380, repeat surgery in 82) in 387 patients. Early and late complications in the groin potentially related to patch saphenoplasty were registered at clinical follow-up after 1 week and at clinical and duplex ultrasound examination after 2 months, 1 year, and later in case of new symptoms.

Results: Complications occurred in 44 limbs (9.5%), 28 (7.4%) after primary GSV surgery and 16 (19.5%) after repeat surgery ($P < .01$). After repeat surgery, half of the complications were lymphatic problems. Nine limbs (2.0%) developed a complication after >2 months. Wound infection was registered in 13 limbs (2.8%), lymphocele or lymphedema in the groin or thigh in 15 limbs (3.2%), symptomatic or asymptomatic proximal venous thromboembolism in 14 limbs (3.0%), and swelling of the thigh due to important stenosis of the common femoral vein visible on duplex scan in 4 limbs (0.9%). Two of the latter remained symptomatic even after venoplasty and stenting of the pinpoint stenosis of the common femoral vein.

Conclusion: Patch saphenoplasty can cause early and late postoperative complications in the groin, which are usually minor. In exceptional cases, major complications may cause important morbidity and may be difficult to handle. (J Vasc Surg 2006;44:1285-90.)

Recurrence of varicose veins after surgery of the great saphenous vein (GSV) cannot always be attributed to technical inadequacy. Recent clinical studies have indicated that postoperative neovascularization may occur and can be detected on duplex ultrasound scans.¹⁻⁴ Tiny new venous vessels developing in the granulation tissue around the saphenofemoral junction (SFJ) may enlarge and connect to superficial veins, causing clinically obvious recurrence after a few years. In an attempt to improve the results of varicose vein surgery, various barrier techniques have been introduced, aiming at containment of postoperative neovascularization at the SFJ in the groin.⁵⁻¹¹ Interposition of a prosthetic barrier has also been called "patch saphenoplasty." Various patch materials have been used for this purpose: Mersilene mesh (Ethicon, Somerville, NJ), reinforced silicone sheeting, polytetrafluoroethylene (PTFE), and Dacron.

The potential benefit of silicone patch saphenoplasty in reducing postoperative neovascularization has been studied previously.^{9,11} A first prospective study demonstrated that at 1 year after operation, interposition of a silicone implant

significantly reduced the total incidence of postoperative neovascularization on duplex scans from 17% (35 of 212 limbs) to 6% (13 of 210 limbs).⁹ In a second study, silicone patch saphenoplasty has shown equally good clinical and duplex ultrasound results 5 years after repeat surgery.¹¹ Recurrent thigh varicosities were observed in 58% of limbs without patch and in 26% of limbs with patch. On duplex scan, neovascular vessels with a diameter ≥ 4 mm were present in 45% of limbs without and in 9% of limbs with patch.

Although the patch has clearly proven its benefit, it may also be associated with postoperative complications. It is well known that the use of foreign material in the human body may cause problems of infection, fistulization, rejection, and fibrosis. This can also be expected after patch implantation at the SFJ in the groin; however, the actual incidence of different complications after patch saphenoplasty is unknown. To address this issue, the present prospective study examined the incidence of adverse effects after patch implantation in the groin by recording the early and late complications in a single cohort of patients treated with this technique.

METHODS

Patients. The study was approved by the local ethics committee (University Hospital Antwerp, Edegem, Belgium). During the period 1997 to 2001, silicone patch saphenoplasty was used in a consecutive series of 462 limbs in 387 patients (96 men, 291 female; mean age \pm SD, 50 \pm

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Competition of interest: none.

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13 years) with varicose veins of the GSV. Bilateral surgery was done in 75 patients (16%), usually with a 1-week interval between the two operations. All patients included underwent a preoperative duplex scan of the deep and superficial venous system. At our department, all duplex ultrasound scans are performed by vascular technologists. All patients were operated on by a single surgeon (M. D. M.) in the Department of Vascular Surgery of the University Hospital Antwerp.

Antibiotic prophylaxis was given only in patients with pre-existing skin ulceration. Subcutaneous injections of nadroparin (0.3 mL; if >100 kg, 0.4 mL) were prescribed once a day during the first postoperative week. Patients were instructed to wear elastic stockings for 3 to 4 weeks after surgery.

Surgical procedure. In the groin, high ligation with above-knee stripping was performed in 347 limbs (75%). The technique of high ligation consisted of flush ligation at the SFJ using a single ligature (no transfixion) with non-resorbable, braided polyester (Mersuture 2-0, Ethicon). All collaterals ending directly into the common femoral vein (CFV) ≤ 1 cm of the SFJ were separately ligated with polyglactin (Vicryl 3-0, Ethicon).

Saphenofemoral incompetence in 33 limbs (7%) was associated with isolated insufficiency of the anterior accessory GSV without concomitant insufficiency of the main GSV trunk in the thigh. In those selected cases, only high ligation was performed with stepwise removal of the anterior accessory GSV, without stripping of the main trunk of the GSV in the thigh.

In 82 limbs (18%) with recurrent saphenofemoral incompetence, operation included re-exploration of the groin (the second in 69 limbs second, the third in 13 limbs). The inguinal incision was made parallel with the skin crease at least 1 cm above the previous incision, and after dissection of the medial border of the common femoral artery, the CFV was exposed just underneath the inguinal ligament to approach the SFJ without having to cross the scar tissue and varicose veins.¹¹

The technique of patch saphenoplasty used at our center has been previously described.^{9,11} A rectangular piece (2 × 3 cm) of reinforced 0.175-mm-thick silicone sheeting (Perthese Silicone Sheeting, Laboratoire Pérouse Implant, Bornel, France) was fixed on the saphenous stump in the groin. The patch was then tucked under the cribriform fascia, and the opening in this fascia was closed with two or three separate stitches (polyglactin 3-0), to maintain the patch in close apposition to the CFV. In some cases of GSV repeat surgery, the silicone patch had to be fixed directly to the deep vein with four stitches (polypropylene 5-0), one at each corner of the patch, because no cribriform fascia was left.

Follow-up and registration of postoperative complications. Routine postoperative follow-up consisted of a control visit 1 week postoperatively for removal of the stitches and a first clinical control after 1 week. Then patients were instructed to contact us if symptoms consistent with deep vein thrombosis (DVT) or wound problems occurred before the next follow-up appointment. This was

scheduled 2 months after operation and included complete clinical evaluation and duplex ultrasound scan of the operated leg(s) to verify if high ligation had been performed correctly and to control the deep venous system.

Early complications in the groin were registered: wound infection, lymphocele, lymphedema in the groin or thigh, symptomatic or asymptomatic proximal venous thromboembolism, and swelling of the thigh due to stenosis of the CFV visible on duplex scan. Complications unrelated to groin surgery, including saphenous or sural nerve injury, delayed wound healing or hematoma in the lower leg, and calf vein thrombosis, were not included in the present registry.

The next control visit with duplex scanning was performed after 1 year. This duplex scan focused in particular on the presence or absence of postoperative neovascularization at the SFJ ligation site, distinguishing tiny neovascular veins (diameter <4 mm) from larger neovascular veins (diameter ≥ 4 mm).^{9,11} Patients were invited to come back only in case of new problems later on. A systematic yearly follow-up with a duplex ultrasound scan was not feasible because of National Health Office recommendations restricting the number of ultrasound examinations.

All complications registered >2 months postoperatively were classified as late complications. These included late wound infection with development of a seroma around the patch, late symptomatic DVT at the level of the CFV, and late symptomatic swelling of the thigh due to stenosis of the CFV.

Incidence of complications after primary GSV surgery and repeat surgery was compared using χ^2 analysis. Statistical analysis was performed using Prism 4 (GraphPad Software Inc, San Diego, Calif). Statistical significance was accepted at $P < .01$.

RESULTS

The early and late complications registered in 462 included limbs are summarized in the Table. The global incidence of complications was significantly higher after repeat surgery than after primary GSV surgery (19.5% vs 7.4%, $P < .01$). In four of nine limbs, early postoperative wound infection in the groin resolved quickly with oral antibiotic treatment. In three limbs, the patch had to be removed to solve the problem, and in two more, the patch was evacuated spontaneously through a wound fistula after 4 and 6 weeks, respectively.

Wound culture indicated infection with *Staphylococcus aureus* in seven of the nine patients. Two of nine patients with wound infection had diabetes mellitus, and three had a body mass index of >35. In three limbs, preoperative *Candida* infection in the groin was suspected to be a predisposing factor for wound infection. Later, a seroma developed in the groin in four patients, for which the patch had to be removed after 4 months, 10 months, 2 years, and 4 years, respectively.

Lymphatic problems were registered in 15 limbs. Lymphocele usually disappeared after evacuation of the lymphatic fluid with one or two punctures. Lymphedema in the

Table. Complications after primary and repeat varicose vein surgery

Complications	All limbs (n = 462) (%)	Primary surgery (n = 380)	Repeat surgery (n = 82)	P*
Infectious problems	13 (2.8)	8	5	.047
Early groin infection	9	5	4	
Late groin infection	4	3	1	
Lymphatic problems	15 (3.2)	7	8	<.001
Lymphocele	9	3	6	
Lymphedema	6	4	2	
Venous thromboembolism	14 (3.0)	13	1	.292
Early				
Symptomatic PE + DVT	2	2	0	
Symptomatic DVT	4	3	1	
Asymptomatic partial DVT	5	5	0	
Late				
Symptomatic DVT	3	3	0	
Stenosis CFV	4 (0.9)	2	2	.09
Early symptomatic	2	0	2	
Late symptomatic	2	2	0	
Total limbs with complications	44 (9.5)*	28 (7.4) [†]	16 (19.5)	<.001

PE, Pulmonary embolism; DVT, deep vein thrombosis; CFV, common femoral vein.

*Significance of difference between primary and repeat surgery.

[†]Two limbs had both venous thromboembolism and late CFV stenosis.

groin or thigh resolved quickly after a few sessions of manual lymphatic drainage.

Venous thromboembolism with symptomatic pulmonary embolism developed in one 52-year-old woman 3 weeks after the operation and in another 44-year-old woman with thrombophilia. After the operation, symptoms of proximal DVT developed in four patients, two with a history of DVT. Duplex scan revealed the presence of thrombus at least at the level of the CFV and the distal external iliac vein in all four. In one of these patients, a 51-year-old woman with a history of iliac DVT at the contralateral leg and underlying heterozygous factor V Leiden mutation, DVT developed in the operated leg along with thrombophlebitis of the crossover pubic collateral veins. Another patient, who had been taking long-term oral anticoagulants because of a previous DVT and a cardiac pacemaker, had a new DVT postoperatively, despite prophylaxis with high-dose low-molecular-weight heparin. In three of four patients with proximal DVT, oral anticoagulant treatment for 6 months resulted in complete recanalization, without recurrent DVT in the following 5 years.

At routine control duplex scan 2 months after the operation, the vascular technologist observed a partial DVT at the level of the CFV in five limbs without symptoms. Symptoms of calf edema developed in one of these patients after 1 year. Unexpectedly symptomatic late proximal DVT developed in three more patients, one after 13 months, one after 3 years, and another patient, with a history of swelling of the thigh (>7 cm) since an interim pregnancy, after 4 years. Duplex scan showed excessive scar tissue surrounding the patch causing an acoustic shadow at the level of the CFV in all three.

In four exceptional cases, patch saphenoplasty led to symptomatic stenosis of the CFV. In two of these cases, swelling of the thigh developed a few weeks after repeat

surgery, and duplex scan revealed narrowing of the CFV without thrombosis. Conservative treatment with lymphatic drainage massage and compression stocking was prescribed. In one of these patients, an angioplasty with 10 mm × 47 mm stenting (Wallstent, Boston Scientific, Natick, Mass) was successfully performed 1 year after the operation because of persisting problems (Fig 1).

More than 5 years after the operation, a pinpoint stenosis of the CFV developed exactly at the site of patch implantation in two other patients, who had a postoperative proximal DVT (one early and one after 3 years, both already mentioned). This caused a typical clinical picture: both young women had a chronic swelling of the thigh (+5 cm, sometimes up to a +10 cm circumference) and experienced important venous claudication in the thigh, causing permanent disability.

In one 41-year-old woman (G3P3), angioplasty of the left CFV was performed 6 years after patch saphenoplasty with placement of a 9 mm × 60 mm Astron stent (BIOTRONIK GmbH & Co, KG, Berlin, Germany) but with only temporary improvement. In addition, 6 months later the groin was re-explored, because of persisting groin pain and swelling of the thigh. There was a remarkable presence of excessive scar tissue in the groin, which was extremely tough and very adherent to the CFV up to its posterior wall. The silicone implant was folded up in the middle of this scar tissue and was finally removed (Fig 2). Once the CFV was dissected free completely, a longitudinal venotomy was made at its anterior side and a saphenous vein patch was inserted to enlarge the CFV at this site. After this surgical intervention, the pain in the groin disappeared but intermittent swelling of the thigh continued to remain a problem in this patient.

The other woman (36 years old, G4P4) with CFV stenosis also underwent a re-exploration of the right groin,

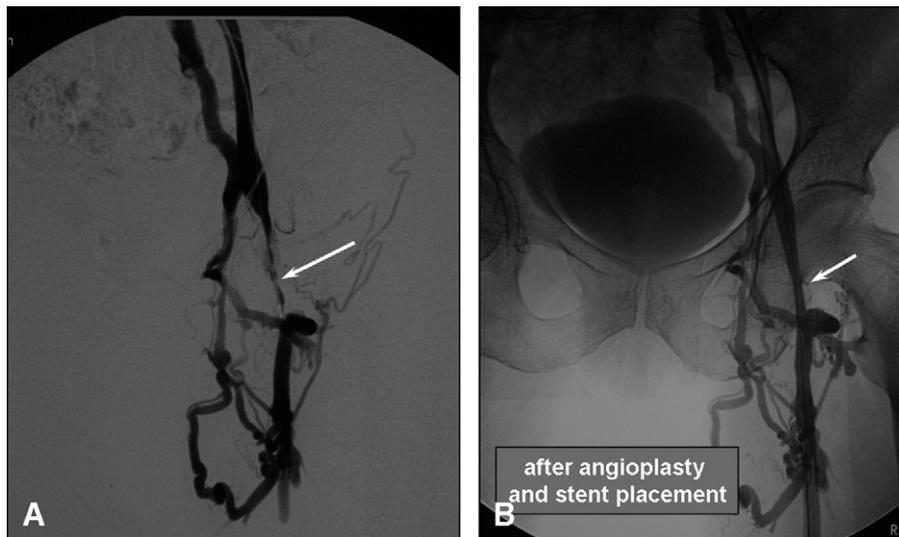


Fig 1. A, Venography illustrates a postoperative stenosis of the common femoral vein after repeat surgery 1 year earlier in a 61-year-old woman with symptomatic swelling of the left thigh. Symptoms started 3 weeks after surgery and gradually deteriorated. B, Control venography after angioplasty and stent placement.

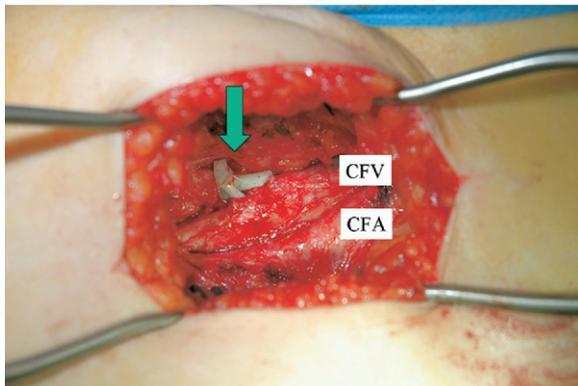


Fig 2. Re-exploration of the left groin 6.5 years after primary varicose vein surgery with patch saphenoplasty. After dissection through very tough scar tissue, the common femoral vein (CFV) and artery (CFA) are clearly visualized. The silicone patch (arrow) was found at the site of the previous saphenofemoral junction. It was folded instead of lying flat along the CFV, where it had been put to cover the ligated saphenofemoral junction and the anterior half of the CFV.

including removal of the patch and angioplasty of the CFV with a saphenous vein patch 4 years after initial GSV surgery. There was excessive scar tissue formation around the CFV. Two days later, a stent had to be inserted into the CFV because of occlusion of the venous reconstruction. Although a duplex ultrasound scan indicated good permeability of the venous stent, clinical improvement was only minimal, and the patient continues to experience chronic disabling leg edema.

After 1 year, duplex ultrasound results were obtained in 293 limbs after primary surgery and 59 limbs after repeat

surgery. This represented 362 of the 462 initially included limbs: five dropped out owing to patch removal and 95 were lost to follow-up. After primary surgery, neovascular veins <4 mm were seen in 10 limbs (3.4%), and neovascular veins \geq 4 mm in six limbs (2.0%). After repeat surgery, newly formed veins <4 mm were seen in eight limbs (8.5%) and larger new veins in five limbs (13.8%).

DISCUSSION

The present study focuses on the complications after GSV surgery, including high ligation and additional patch saphenoplasty, used with the aim of containing postoperative neovascularization. Complications related to the surgery in the groin occurred in 9.5% of limbs. To our knowledge, this is the first prospective study of postoperative complications after this type of operation. Obviously, the complications observed in the present study in patients undergoing patch saphenoplasty are not necessarily related to the patch procedure. Similar complications may also occur after standard varicose vein surgery and are inherent to the groin incision.

Unfortunately, little is known about postoperative complications in the groin after GSV surgery. A study of the literature is disappointing. Complications are usually only mentioned as such in surgical textbooks, described in case reports, and cited in other publications without clear figures about their incidence. Moreover, studies about the incidence of complications are usually based on retrospective analysis, which might lead to underestimation of the real problem.^{12,13}

In the present study, complications were significantly more common after re-explorations of the groin than after primary interventions. This confirms the general knowledge about repeat surgery in the groin, which earns its bad

reputation not only by being technically more demanding but also by causing enhanced postoperative morbidity and complications. After surgery for recurrent varicose veins, complications have been reported to occur in as much as 40% of limbs.¹⁴ Up to now, however, in reports on repeat surgery including patch saphenoplasty, only few exceptional wound problems in the groin were mentioned.^{8,10,11}

Infection of the groin incision was seen in 2.8% of limbs as an immediate postoperative infection and also as a low-grade infection with seroma formation around the silicone implant after several months and even years. The incidence of early surgical site infection was reported to be between 0.5% and 1.5% after varicose vein operations.^{15,16} In the present study, implantation of a prosthetic patch in the groin apparently increased the risk of infection. In particular, patients with diabetes and obese patients with intertrigo in the skin crease of the groin seemed to be prone to postoperative infection. There are no data in literature about late groin infection after varicose vein operations. In the present study, such late low-grade infections were probably related to the implantation of foreign material.

Lymphedema and lymphocele in the groin are mild complications that occurred in 3.2% of limbs after patch saphenoplasty. Although a postoperative lymphocele can cause a spectacular swelling in the groin, it normally disappears after one or two evacuating punctures. It is not very clear if the silicone patch itself can cause any lymphatic problem. The additional maneuver of closing the cribriform fascia may have led to lymphocele or lymphedema in primary operations. After repeat surgery, damage of the lymphatics is seen more frequently because of the more extensive dissection in scar tissue.¹⁴ The incidence of lymphatic complications in our study was significantly higher after repeat surgery than after primary surgery.

Venous thromboembolism is a relatively rare complication after varicose vein operations.^{12,13,17} A 5.3% incidence of DVT (proximal DVT of only 0.5%) after varicose vein surgery was recently reported, however, with minimal clinical short-term and long-term significance.¹⁸ In the present prospective study, the incidence of proximal DVT in the CFV or distal external iliac vein, or both, was definitely higher at 3%, despite systematic use of low-molecular-weight heparin prophylaxis during the first postoperative week.

A history of DVT or underlying thrombophilia was present in three (27%) of 11 patients with early venous thromboembolism. In the other cases of early DVT or stenosis of the CFV, it is possible that patch implantation contributed to these adverse reactions. The few cases of late DVT and late CFV stenosis question the long-term effect of the implanted patch. Excessive scar tissue formation immediately after the operation and later on, after several months or years, may somehow be induced by the foreign material in the groin. Local immune reactions might play a role in this fibrotic process, as has been described around silicone breast implants.¹⁹ It is not clear if the type of implanted material is significant. In the present study, the same patch material, reinforced silicone sheeting, has been used in all

operations. In other studies, PTFE has been used for the same purpose, apparently without thromboembolic or stenotic complications.^{6,8,10} A smaller number of patients was included in these series, however, and more studies are needed to clarify this issue.

To define the best indications for patch saphenoplasty, the potential benefit has to balance out the complication rates. In the present study, results of duplex scan after 1 year are comparable with those obtained in the two previous studies at our center, which demonstrated the efficacy of silicone patch saphenoplasty.^{9,11} After repeat surgery, patch saphenoplasty significantly reduced the incidence of postoperative neovascularization on duplex scans and also of recurrent thigh varicose veins after 5 years.¹¹ Therefore, the potential benefit of the patch might outweigh the risk of complications in patients with primary varicose veins and also, in particular, in patients with disabling recurrent varicose veins, which are known to have a higher tendency to redevelop recurrence.^{6,9} It has been suggested previously that patch saphenoplasty should rather be used in repeat procedures and not in standard operations for primary varicose veins.²⁰ Randomized controlled trials will be needed to clarify this further.

CONCLUSION

Patch saphenoplasty, a technique introduced to contain postoperative neovascularization in the groin after varicose vein surgery of the GSV, is not always a harmless procedure. It may be associated with a number of early and late postoperative complications in the groin, which are usually minor. In exceptional cases, however, these complications may lead to important morbidity and may be difficult to handle.

AUTHOR CONTRIBUTIONS

Conception and design: MDM, PVS

Analysis and interpretation: MDM

Data collection: MDM, CV, PL, JH

Writing the article: MDM, CV, SDH

Critical revision of the article: MDM, CPV, PRL, JMH, SDH, PVS

Final approval of the article: MDM, CPV, PRL, JMH, SDH, PVS

Statistical analysis: MDM, SDH

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Overall responsibility: MDM

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