

From the American Venous Forum

Postthrombotic or non-postthrombotic severe venous insufficiency: Impact of removal of superficial venous reflux with or without subcutaneous fasciotomy

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Background: Severe chronic venous insufficiency is often associated with therapy-resistant or recurrent venous leg ulcers, either as a result of deep vein thrombosis (DVT)- (postthrombotic syndrome [PTS]) or superficial venous insufficiency (SVI). Frequently present dermatoliposclerosis affects the skin as well as the subcutaneous and subfascial structures, which may impact tissue pressures and compromise skin perfusion. This study was undertaken to measure tissue pressures in PTS and SVI limbs and to evaluate the impact of removal of superficial venous reflux with or without concomitant subcutaneous fasciotomy.

Material: In eight patients with recurrent, therapy-resistant venous leg ulcers, due to PTS (11 limbs, 12 ulcers) and 14 patients with severe SVI (14 limbs, 14 ulcers), subcutaneous fasciotomy was performed in addition to removal of superficial reflux. They were compared with eight patients with PTS (11 limbs, 11 ulcers) and 10 patients with SVI (13 limbs, 13 ulcers) who did not have fasciotomy in addition to removal of their superficial venous reflux. Intramuscular (i.m.) and subcutaneous (s.c.) tissue pressures and transcutaneous oxygen tension (TcPO₂) were measured prior to, immediately after, and 3 months following the surgical intervention. Healing of ulcer (spontaneous or by skin grafting) at 3 months was also observed.

Results: There were no statistical differences between the groups regarding gender and age distribution or ulcer age at the time of surgery. All patients had in addition to surgery compression stockings class II (30 mm Hg). The i.m. tissue pressure was higher in patients with PTS compared with SVI patients, while s.c. tissue pressure and TcPO₂ did not differ between the groups. When fasciotomy was performed, i.m. and s.c. tissue pressures decreased and TcPO₂ increased significantly. Without fasciotomy, only s.c. tissue pressure decreased first at 3 months postoperatively. In the SVI-group, i.m. tissue pressure was significantly decreased at 3 months in the group without fasciotomy.

Conclusions: Patients with severe chronic venous insufficiency with therapy-resistant or recurrent ulcer disease due to deep and superficial insufficiency have higher i.m. tissue pressures than patients with only superficial venous reflux, even though both groups have higher i.m. and s.c. tissue pressures compared with normal values. Eradication of all superficial reflux lowers s.c. tissue pressure, while additional fasciotomy lowers both i.m. and s.c. tissue pressures and increases TcPO₂, which seems to promote ulcer healing. (*J Vasc Surg* 2007;46:316-21.)

Chronic venous insufficiency is a common disease estimated to affect 10% to 35% of the entire US population and that 4% of people older than 65 years of age have active venous ulcers. The high prevalence of the disease has been calculated to cost more than 1 billion US dollars yearly.¹

Venous ulcer formation is commonly thought to be the result of venous hypertension, which may occur either as a venous reflux in the superficial or deep venous system or combination of the two or as a result of venous outflow tract obstruction.^{2,3} The development of venous hypertension initiates a cascade of pathologic events resulting in

development of varicose veins, lower limb edema, dermatoliposclerosis, and finally venous ulcer formation.⁴

Treatment of venous ulcers falls into two categories: conservative therapy and surgical treatment. Conservative therapy and prevention of new ulcers include control of edema and venous hypertension by adequate compression therapy⁵ and systemic drug therapy, such as micronized purified flavonoid fraction (Daflon 500 mg; Servier, Paris, France).⁶

Since an estimated 85% of patients with leg ulcers have reflux in superficial veins, a surgical intervention with eradication of the superficial reflux is frequently indicated. These veins can be ligated, removed, or obliterated by surgery, sclerotherapy, and/or endovenous obliteration by either radiofrequency or laser.^{7,8}

If severe deep vein reflux exists, deep vein reconstruction to obtain proximal control of the reflux can be performed for selected patients in specialized centers.⁹ Patients with resistant, recurrent or large ulcers may require additional wound bed preparation and skin grafting.

When compartment pressure exceeds recumbent tibial vein pressure, tibial veins may be impaired.¹⁰ Increasing

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Competition of interest: none.

Presented at the Nineteenth Annual Meeting of the American Venous Forum, San Diego, Calif, February 14-17, 2007.

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CME article

0741-5214/\$32.00

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doi:10.1016/j.jvs.2007.03.046

compartment pressure leads to progressive local venous hypertension, decreased arteriovenous pressure gradient, and cessation of capillary flow, which may result in ischemia and necrosis of the skin.

Fasciotomy relieves pain, normalizes intramuscular pressure, and increases muscle blood flow and skeletal muscle metabolism in chronic anterior tibial compartment syndrome,¹¹ which might be beneficial for ulcer healing if the intramuscular tissue pressure is high.

Surgical procedures with lower limb's fascia as the target structure have a long tradition. Kondoleon, in 1912, described a lateral skin incision and resection of a broad, 5 to 7 cm long strip of the fascia and the superjacent dermal tissue.¹² Linton's operation used a long skin incision with incision of the fascia and dissection of all accessible perforator veins.¹³ The essential drawback of these methods were long operation time, considerable tissue trauma, and wound healing problems within dermatoliposclerotic skin. The paratibial fasciotomy¹⁴ avoids the side effects of previous surgical techniques, but the clinical impact of subcutaneous fasciotomy has not so far been fully understood.

Severe chronic venous insufficiency is often associated with therapy-resistant or recurrent venous leg ulcers and dermatoliposclerosis, which affect the skin as well as the subcutaneous and subfascial structures. This may impact tissue pressures and, thus, compromise skin perfusion.

This study was undertaken to measure tissue pressures in patients with postthrombotic syndrome (PTS) and in patients with severe primary venous insufficiency in order to evaluate the impact of removal of superficial venous reflux with or without concomitant subcutaneous fasciotomy.

PATIENTS AND METHODS

Between October 1, 2003 and October 1, 2006, 40 patients with recurrent, therapy-resistant active venous leg ulcers (CEAP, C6)¹⁵ and a venous clinical severity score (VCSS)¹⁶ of 15 ± 2 , underwent surgical eradication of all superficial reflux (high ligation and stripping of the great [98%] and/or small saphenous [10%] veins, phlebectomy and/or open ligation of incontinent perforating veins [88%] in accordance with a preoperative Duplex-Doppler evaluation). Reflux in the superficial, deep, and perforators veins was evaluated with duplex ultrasonographic scanning (Agilent, SONOS 4500; Phillips, Eindhoven, The Netherlands), in standing position to define anatomy and pathophysiology of the venous insufficiency. Reflux was defined as retrograde flow more than 0.5 seconds after calf compression or Valsalva maneuver. PTS was defined as patients with deep venous reflux with a previous documented history of deep vein thrombosis. Venous obstruction was ruled out by Duplex Doppler scanning, and no patients with primary deep venous reflux were included in this series. One surgeon (JC) performed all operations. There were 16 patients (22 limbs, 23 venous ulcers) with PTS with a concomitant reflux in the deep venous system. None of the patients had venous outflow obstruction. Twenty-four patients (27 limbs, 27 venous ulcers) had only severe

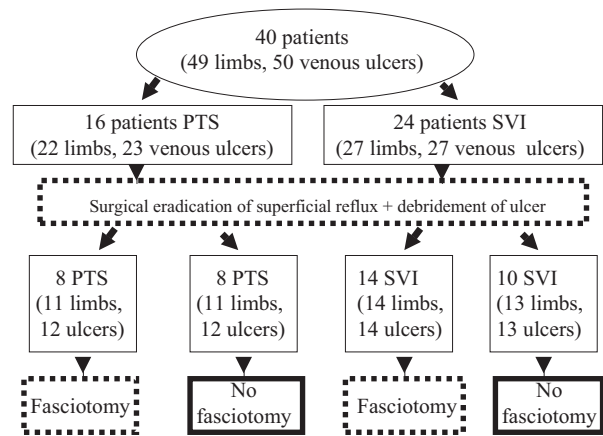


Fig 1. Schematic presentation of study design, groups and subgroups according to underlying pathology, and treatment modalities in 40 patients (49 limbs with severe chronic venous insufficiency and 50 therapy resistant or recurrent venous ulcers).

superficial venous insufficiency (SVI), with no reflux in the deep venous system.

This study was approved by the Institutional Review Board and patient consent was obtained. The mean age was 63 ± 18 years, (ranging from 25 to 91 years). There were 23 men (58%) and 17 women (42%) and 6 patients had diabetes. Mean body mass index was 27 ± 4.4 kg/m². The ulcer size was between 2 x 3 cm and 10 x 20 cm. The mean duration of the ulcers at time of surgery was 3.3 years. Of the total of 50 venous ulcers, 20 ulcers had previously failed skin graft transplantation and of these, 16 had undergone more than one skin graft intervention. There were no statistical differences in demographic parameters or type of superficial venous surgical interventions performed between the groups (PTS vs SVI). All ulcers underwent debridement at the end of the venous surgical procedure.

Eight PTS-patients and 14 SVI-patients had, in addition to the removal of the superficial venous reflux, a para-tibial subcutaneous fasciotomy (Fig 1). All surgical procedures and patient characteristics were comparable between the subgroups. All patients included in this study had normal ankle-brachial pressure indices (0.8-1.1) and all peripheral arteries had palpable pulses.

Intramuscular and subcutaneous tissue pressure measurements. Intramuscular and subcutaneous tissues pressure measurements were performed in all patients in standing position using a 19-gauge needle connected to a saline-filled tubing, which was connected to a pressure transducer and recorder (Datex, Helsinki, Finland). The needle was placed first into the subcutaneous tissue about 15 cm below the knee joint. The zero level was taken on the level of the tip of the needle, and pressure was measured at rest during 4 minutes. Thereafter, the needle was placed into the posterior compartment and the tissue pressure was recorded. Tissue pressure measurements were repeated in the same manner on day one postoperatively and at 3 months.

Table I. Intramuscular (i.m.) and subcutaneous (s.c.) tissue pressures and, transcutaneous oxygen tension (TcPO₂), in patients with therapy resistant or recurrent venous leg ulcers due to postthrombotic syndrome (PTS) or severe superficial venous insufficiency (SVI)

Parameter	Postthrombotic syndrome	P value	Superficial venous insufficiency	Normal values
I.m. tissue pressure, mm Hg	28.7 ± 6.6	P < .001	20.1 ± 4.4	9.6 ± 5.6*
S.c. tissue pressure, mm Hg	9.5 ± 4.4	n.s.	10.4 ± 2.9	0.4 ± 2.6†
TcPO ₂ , mm Hg	15.2 ± 4.5	n.s.	14.3 ± 4.6	70.6 ± 8.9‡

n.s., Nonsignificant statistical difference.

Mean ± SD.

*reference 22, †reference 23, ‡reference 25.

Transcutaneous oxygen tension (TcPO₂) was measured at the upper edge of the ulcer pre- and 10 days postoperatively. The same location was used for pre- and postoperative measurements. Transcutaneous oxygen measurements were obtained with a device (Kontron Instruments, Ameda, Switzerland) set at a temperature of 44°C. Reference values are given in Table I.

Subcutaneous fasciotomy. The fasciotomy is performed through a small 1 cm skin incision paratibial on the medial side of the limb in healthy cutaneous areas so that wound-healing disorders are avoided. The fascia is opened and with a long Metzenbaum-scissor and the fascia is slit open all the way down to the medial ankle. Remaining close to the tibial bone is emphasized in order to avoid lesions of the posterior tibial artery as well as subcutaneous lymph vessels. If bleeding occurs, a suction-drain is placed, while if the bleeding is only minimal, no drain is placed. An intradermal suture and steri-strips closed the skin wound. A compression bandage was immediately applied.

Patients were followed on a regular basis to observe ulcer healing. All patients had, in addition to surgery, compression stockings (Sigvaris, class II, 30 mm Hg; Canzone & CIE AG, St Gallen, Switzerland). None of the patients had graduated compression support greater than class II stockings following surgery.

Twenty venous ulcers (the larger ulcers) had mesh skin graft transplantation 1 to 2 weeks following the venous surgical procedure, while 30 venous ulcers were left for primary healing.

Tissue pressures, transcutaneous oxygen tension, and ulcer healing were compared pre- and postoperatively and at 3 months following the intervention between patients with PTS and patients with SVI and the immediate impact of additional subcutaneous fasciotomy was evaluated.

Statistics. Data are presented as the mean ± standard deviation. Continuous variables were analyzed with Student t test and categorical variables using χ^2 test. $P < .05$ was considered statistically significant.

RESULTS

The preoperative intramuscular tissue pressure was recorded significantly higher in patients with PTS compared with patients with only SVI, while subcutaneous tissue pressures and transcutaneous oxygen tension did not differ significantly (Table I).

Eradication of SVI did not alter intramuscular tissue pressure in either group, while subcutaneous tissue pressure dropped significantly in SVI-group (Table II). These observations remained valid also at 3 months following surgery.

Additional subcutaneous fasciotomy significantly decreased both intramuscular and subcutaneous tissue pressures and increased transcutaneous oxygen tension in both groups (Table II). Also, these observations remained valid also at 3 months following surgery. There were no differences in transcutaneous oxygen tension comparing patients who had only saphenous vein removal with those who in addition had ligation of incompetent perforating veins.

Ulcer healing with or without skin graft transplantation following eradication of superficial venous reflux was seen in 11/24 ulcers (46%). In this group, the venous severity score decreased at 3 months to 6 ± 3 . When subcutaneous fasciotomy was added as surgical adjuvant therapy, ulcer healing was significantly better, 25/26 ulcers (96%), $P < .007$, up to 3 months postoperatively, and the venous severity score was clearly lower, 2 ± 1 . Ulcer healing was slightly better in the SVI group compared with the PTS patients (Table III).

DISCUSSION

The best treatment for advanced chronic venous insufficiency, often associated with recurrent or therapy-resistant venous leg ulcers, remains controversial. The role of deep, superficial, and perforating venous systems are yet unclear. It has been demonstrated that chronic venous insufficiency can begin in any vein and location in the lower limb, but it is observed most often in the superficial venous system. More than 85% of patients with chronic venous insufficiency have disease in their superficial veins. It now clear that vein wall damage and varicose vein development occur in ascending, descending, or multicentric manner.¹⁷

The development of venous hypertension is secondary to primary valve reflux in the majority of patients, while outflow obstruction in association with venous ulcer formation represents only 1% to 6% of patients.² Patients with PTS in this series all had patent, but incompetent deep veins.

The importance of a SVI has recently been reported.

Puggioni and coworkers recently demonstrated that in patients with concomitant deep and superficial venous re-

Table II. Intramuscular (i.m.) and subcutaneous (s.c.) tissue pressures and, transcutaneous oxygen tension (TcPO₂), prior to and after eradication of superficial venous reflux in patients with therapy resistant or recurrent venous leg ulcers due to postthrombotic syndrome (PTS) or severe superficial venous insufficiency (SVI)

<i>I.m. mm Hg</i>	<i>PTS with fasciotomy</i>	<i>P value</i>	<i>PTS without fasciotomy</i>	<i>SVI with fasciotomy</i>	<i>P value</i>	<i>SVI without fasciotomy</i>
Preop.	29.0 ± 7.0	n.s.	28.5 ± 6.6	20.0 ± 4.0	n.s.	19.7 ± 5.1
P value	< .001		n.s.	< .001		n.s.
Postop.	7.5 ± 3.8	< .001	27.3 ± 5.9	4.3 ± 1.8	< .001	19.3 ± 5.5
P value	n.s.		n.s.	n.s.		.049
3 months	6.9 ± 3.6	< .001	25.5 ± 7.8	4.0 ± 1.6	< .001	16.3 ± 7.8
s.c. mm Hg	PTS with fasciotomy	P value	PTS without fasciotomy	SVI with fasciotomy	P value	SVI without fasciotomy
Preop.	9.0 ± 3.4	n.s.	8.9 ± 4.1	10.6 ± 2.8	n.s.	10.2 ± 3.3
P value	< .001		n.s.	< .001		< .001
Postop.	0.5 ± 0.9	< .001	7.4 ± 3.2	0.5 ± 0.6	< .001	5.9 ± 1.8
P value	n.s.		.002	n.s.		.003
3 months	1.4 ± 1.6	< .001	5.0 ± 1.2	0.5 ± 0.7	< .001	4.2 ± 0.6
TcPO ₂ , mm Hg	PTS with fasciotomy	P value	PTS without fasciotomy	SVI with fasciotomy	P value	SVI without fasciotomy
Preop.	15.2 ± 4.5	n.s.	14.8 ± 4.6	13.3 ± 4.5	n.s.	14.2 ± 5.2
P value	< .001		P < .001	< .001		P < .001
Postop.	38.2 ± 8.6	P < .001	27.6 ± 7.9	39.8 ± 8.3	P < .001	26.5 ± 9.1
10 days						
P value	P < .001		n.s.	P < .001		n.s.
3 months	49.6 ± 6.7	P < .001	26 ± 8.2	47.4 ± 6.2	P < .001	24.4 ± 11.1

n.s., Non-statistical significant difference
Mean ± SD.

Table III. Venous leg ulcer healing, spontaneous or after mesh skin graft transplantation, in patients with postthrombotic syndrome (PTS) or severe superficial venous insufficiency (SVI) following surgical eradication of superficial insufficiency with or without additional subcutaneous fasciotomy

<i>Parameters</i>	<i>PTS with fasciotomy N = 12 ulcers</i>	<i>PTS without fasciotomy N = 11 ulcers</i>	<i>SVI with fasciotomy N = 14 ulcers</i>	<i>SVI without fasciotomy N = 13 ulcers</i>
Venous ulcer healed by successful skin graft	8/8 100%	2/4 50%	4/4 100%	2/4 50%
Venous ulcer healed without skin graft	3/4 75%	2/7 29%	10/10 100%	5/9 56%
Total healed ulcers	11/12 92%*	4/11 36%*	14/14 100%†	7/13 53%†
	*P value	P = .049	†P value	P = .042

*Statistical comparison between PTS with fasciotomy and without was P = 0.049.

†Statistical comparison between SVI with and without fasciotomy was P = 0.042.

flux, saphenous vein ablation resulted in normalization of deep reflux in 1/3 of patients.¹⁸

The Effect of Surgery and Compression on Healing and Recurrence (ESCHAR) study have demonstrated that surgical correction of superficial reflux reduces 12-month ulcer recurrence, and that most patients with chronic venous ulceration will benefit from eradication of superficial reflux in addition to elastic compression stockings.¹⁹ However, while surgical ablation of superficial reflux did not improve immediate venous ulcer healing, which was also the observations in our series, the ESCHAR study revealed a significant reduction in recurrence of venous ulcers.

The significance of incompetent perforating veins remains a controversial issue. Some have suggested that incompetent perforators do not contribute to venous hypertension; whereas others have suggested they play a major role.¹ Some recent clinical studies have demonstrated positive effects of reflux surgery including subfascial endoscopic perforating vein surgery (SEPS).^{20,21}

The role of the fascia and adjacent intramuscular and subcutaneous compartments in the development and sub-

sequent healing or failure to heal of venous ulcers has not been fully evaluated. An increased compartment pressure leads to progressive local venous hypertension but may also affect the arteriovenous pressure gradient with cessation of capillary flow as a result, which is contradictory to wound healing.¹⁰

Intramuscular pressures in the anterior tibial and superficial posterior compartments of the lower limb in healthy volunteers was reported in 1982.²² Furthermore, significantly elevated subcutaneous and intramuscular tissue pressures have been found in patients with primary lymphedema.²³ Markedly elevated subcutaneous and intramuscular tissue pressures have also been reported in the post-phlebotic limb.²⁴

Failure to heal or recurrent venous ulcer disease often related to venous hypertension may also be due to an impaired capillary circulation. Measurement of TcPO₂ has gained worldwide acceptance as a simple and effective method of evaluating cutaneous blood flow in settings where skin viability and the adequacy of skin blood flow are of major concern. In this series, it was clearly demonstrated

that the capillary circulation at the edge of the venous ulcer was well below the threshold generally regarded as critical, 20 mm Hg.

In this series, patients with PTS and secondary superficial reflux were found to have significantly higher intramuscular tissue pressures compared with the normal leg,²² although below the threshold for an acute compartment syndrome (more than 30 mm Hg). The intramuscular tissue pressure was also higher than in limbs with only superficial venous reflux.²⁴ Not surprisingly, subcutaneous tissue pressures as well as transcutaneous oxygen tension did not differ between the groups of patients with severe venous insufficiency and therapy-resistant or recurrent venous ulcer disease. The benefit from surgery, including eradication of superficial venous reflux combined with ulcer shaving and fasciectomy for healing of venous leg ulcers in the long term, has recently been reported.²⁶ Qvarfordt et al have shown that fasciotomy relieves pain, normalizes intramuscular pressure, and increases muscle blood flow and skeletal muscle metabolism in chronic anterior tibial compartment syndrome.²⁷ It was with this in mind that the addition of a para-tibial subcutaneous fasciotomy was evaluated and was found to be a safe surgical procedure, which together with eradication of as much of superficial reflux as possible, had an immediate positive impact on ulcer healing.²⁸ It is still unknown for how long a subcutaneous fasciotomy may remain efficient in this context. However, long-term result following subcutaneous fasciotomy has been reported to be excellent up to 2 years following the intervention in patients with chronic anterior compartment syndrome.²⁸ The benefit from surgery removing SVI for chronic leg ulcers in the long term has recently been reported.²⁹

Even though the immediate effect on ulcer healing has been clearly demonstrated, longer follow-up is necessary and is on-going. Other limitations of this study maybe that it is a single center study, nonrandomized study on a limited number of patients. However, all measurements, evaluations, and interventions were performed in a standard manner. One surgeon performed all interventions, and all therapies other than the surgical interventions were the same for all patients in the study. Dermatologist followed up on ulcer healing. More research into the area of recurrent venous ulcer disease is required, and development of specialized centers for the care of patients with venous leg ulcers has been shown cost-effective.³⁰

CONCLUSION

In conclusion, this study has shown that patients with severe chronic venous insufficiency with therapy-resistant or recurrent ulcer disease due to deep and superficial insufficiency have higher intramuscular (i.m.) tissue pressures than patients with only superficial venous reflux, even though both groups have higher i.m. and subcutaneous (s.c.) tissue pressures compared with the normal limb. Eradication of all superficial reflux lowers s.c. tissue pressure, while additional subcutaneous fasciotomy lowers

both i.m. and s.c. tissue pressures and increases TcPO₂, which seems to promote ulcer healing.

AUTHOR CONTRIBUTIONS

Conception and design: JC
Analysis and interpretation: JC
Data collection: JC
Writing the article: JC
Critical revision of the article: JC
Final approval of the article: JC
Statistical analysis: JC
Obtained funding: Not applicable
Overall responsibility: JC

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Submitted Feb 5, 2007; accepted Mar 20, 2007.

INVITED COMMENTARY

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This is an important article, which presents some new and useful information and explains some observed facts.

Many variables between groups such as age, gender, ulcer age, and posttreatment compression were eliminated. So, we have pure observations such as the fact that intra-muscular (i.m.) tissue pressure was higher in patients with post thrombotic syndrome (PTS) compared with superficial venous insufficiency (SVI) patients and that subcutaneous tissue pressure (s.c.) and TcPO₂ did not differ between the groups.

When fasciotomy was performed in chronic venous insufficiency (CVI) limbs, both i.m. and s.c. tissue pressures decreased, and TcPO₂ increased significantly. This means that there is a component of venous obstruction in the postthrombotic limbs, which causes increased tissue pressures. These

pressures interfere with tissue oxygenation, which by inference decrease healing potential and explain the resistance to healing that is seen in the postthrombotic limb. Without fasciotomy, only s.c. tissue pressure decreased at 3 months postoperatively, while i.m. pressures remained high in CVI limbs. This argues for selective fasciotomy at the time of surgical intervention in postthrombotic limbs.

Intramuscular tissue pressure decreased significantly at 3 months in the SVI-group even without fasciotomy. This means that subcutaneous tissue pressures are influenced chiefly by superficial reflux in limbs without previous thrombosis.

Obviously, this is a thoughtful study, carefully presented, and worthy of consideration in planning treatment for severe postthrombotic CVI.