

Neovalve construction in deep venous incompetence

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Objectives: The purpose of this study is to assess the outcome of neovalve construction in two consecutive series of patients affected by postthrombotic syndrome and valve agenesis. The technique was modified in the second series so as to correct a cause of failure.

Methods: Between December 2000 and June 2007, 40 neovalve constructions were carried out in 36 patients (19 males, 17 females, median age 57, range, 29-82) affected by deep venous insufficiency. Thirty-two patients were affected by postthrombotic syndrome and 4 by valve agenesis. The 32 patients with postthrombotic syndrome were selected from among 76 patients with resistant ulcers classified C_{6,S} E_S A_{S,D,P} P_{R,RO} and the 4 patients with valve agenesis were selected from among 28 affected by resistant ulcers classified as C_{6,S} E_C A_{S,D,P} P_R. The patients were subdivided into 2 groups. The first group included 19 operations performed in the period between December 2000 and December 2004, with a median follow-up of 54 months (range, 31-78). The second group included 21 patients operated on between January 2005 and June 2007, with a median follow-up of 5 months (range, 2-29). In the second group, a surgical variation was applied in order to prevent flap collapse and to maintain the continence of the neovalve.

Results: In the first series, ulcer healing was observed in 16 cases out of 19 (84%). Recurrent ulcers were observed in one case after 3 years. Valve competence was ascertained in 13 cases per 803 patient-months (1.6/100 patient-months). With regard to the second series, competence was achieved in all cases with a cumulative rate of 21 per 228 patient-months (9.2/100 patient-months). In the second series, the ulcer failed to heal in one case and recurred in two cases, with an intention-to-treat ulcer recurrence rate of three cases per 209 patient-months. Postoperative deep-venous thrombosis was observed in 3 patients in the first series. None was detected in the second series. The mortality rate was 0 and in neither group was pulmonary embolism detected.

Conclusion: The modified technique applied to the second group seemed to improve valve continence results significantly. However, a longer follow-up period is required for the latter group to validate this technical enhancement. (*J Vasc Surg* 2009;49:156-62.)

Severe chronic venous insufficiency is a widely recognized cause of incapacity. Significant symptoms and trophic lesions markedly reduce the quality of life of patients affected. The most serious forms are those related to pathologies affecting the deep venous system, predominantly of postthrombotic origin¹ and, to a lesser extent, primary and congenital types.² Compression therapy is the chief way of treating these patients,³ but it is not always possible to achieve complete control of the situation, and in selected patients various treatments can be indicated to restore axial flow or to neutralize reflux. In cases of valve insufficiency, the correction of reflux consists principally in reconstructing the valve or creating an anti-reflux mechanism. This goal can be achieved using various techniques,⁴ among which neovalve construction, as we have previously described in detail.^{5,6} The efficacy of the neovalve as an anti-reflux mechanism has been demonstrated in the short-to-medium term.⁶ However, it was unclear why, in some cases, neovalves that proved technically efficient at intraop-

erative checks and at immediate postoperative venography failed within a short period after the operation. Venographic findings of these cases suggested that the probable cause lay in parietal re-adhesion. Accordingly, we began treating a second series of patients, modifying the technique as described below and obtaining improved results.

METHODS AND MATERIALS

Patient selection. From December 2000 to June 2007, 40 consecutive neovalve construction operations were performed in 36 patients (19 male, 17 female, median age 57, range, 29-82) affected by deep venous insufficiency. Five were bicuspid and 35 were monocuspid.

These operations were subdivided into 2 groups, based on a technical variation. The first series included 19 operations in 17 patients (9 males, 8 females, median age 55, range, 34-79 years) performed in the period between December 2000 and December 2004. The second series included 21 operations in 21 patients (12 males, 9 females, median age 59, range, 29-82). Two patients underwent operations to both lower limbs and, therefore, fall into both groups, belonging to the first series for one limb, and to the second series as regards to the second limb. The two groups of patients do not present significant statistical differences. Patient demographics are shown in Table I. All patients were classified according to CEAP classification.

This sample of patients was selected from among 353 patients observed from January 2000 and classified as C6s (Fig 1, online only). All patients underwent duplex scanning as-

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Table I. Patient demographics

	First series procedures n = 19	Second series procedures n = 21	P
Mean age ± SD	54 ± 12.3	58 ± 14.5	.249
Age range	34-79	29-82	—
Male:female	9:8	12:9	.775
Postthrombotic:congenital aplasia	16:1	18:3	.342
Median follow-up (months)	54	5	<.000
Follow-up (months) range	31-78	2-29	—
DVT (%)	3 (16%)	0	.06
Pulmonary embolism	0	0	—
Minor complications (seromas, hematomas)	4	3	.787
Ulcer healing (%)	16 (84%)	20 (95%)	.489
Median period of healing (weeks)	13	10	.112
Period of healing (weeks) range	4-19	3-18	—

DVT, Deep venous thrombosis.

assessment with precise mapping of the superficial, deep, and perforator system. When a deep venous reflux was identified on ultrasound scan evaluation,⁷ air plethysmography,⁸ and in cases of associated segmental obstruction, occlusion plethysmography was performed. Ultrasound scanning was conducted using the standard technique, with patients in the standing position. The reflux was detected with the sleeve placed at calf level, and subsequently with the patient in the supine position we performed the exploration of the entire axis. All patients with deep venous reflux were then submitted to ascending and descending venography, using the crossover technique.⁹ Of these, 246 patients were excluded from deep venous system surgery in favor of conservative therapy and/or superficial-vein and perforator treatment.^{10,11}

Selection criteria. All patients presented a deep venous reflux assessed at Kistner grade IV by using descending venography and duplex scanning.

The CEAP classification was C_{6,S} E_S A_{P,D} P_R in 32 patients and C_{6,S} E_C A_D P_R in 4 patients affected by valve agenesis. The patients affected by postthrombotic syndrome had presented deep venous thrombosis (DVT) almost 10 years previously. All patients presented an ulcer resistant to conservative therapy and superficial and/or perforator treatments. The ulcer had been active for at least 5 years or had been recurrent in the same period on more than three occasions. This meant that the ulcer had been present for a total of at least 3 years and was a source of major discomfort for the patients.

Criteria for exclusion from neovalve surgery were:

- severely limited ambulation¹²
- thrombophilic syndrome
- contraindication to anticoagulant therapy
- severe comorbidity
- feasibility of standard techniques (femoral transposition,¹³ valve transplant^{14,15})

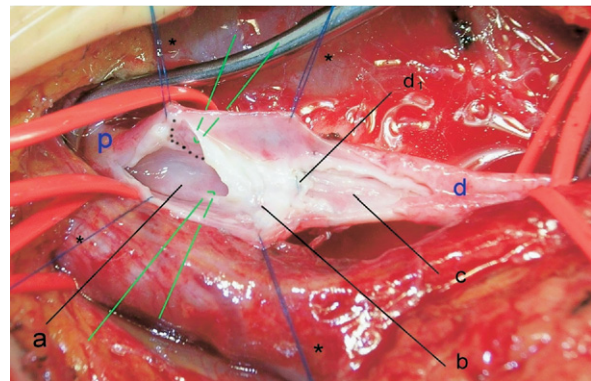


Fig 2. Neovalve construction in postthrombotic syndrome. *p*, proximal; *d*, distal; *a*, posterior area with endothelium intact; *b*, neovalve; *c*, area of endophlebectomy; *d1*, end of dissection; *, suspension stitches; *dotted line*, line of dissection; *green line*, direction and position of the stitched to maintain the valve in semi-open position.

Operations are performed under spinal (36) or general anesthesia (4). Short-time antibiotic prophylactics are applied (Cefuroxime per body weight). The position of the patient on the operating table is supine, with the limb slightly flexed. A lengthwise incision, approximately 10 centimeters long, is made along the projection of the femoral vein. The valve reconstruction site is decided on the basis of preoperative inquiries but definitive confirmation comes only during intraoperative exploration. The vessel dissection must be sufficient to ensure an adequate control of the vein. Heparin is administered endovenously so as to obtain full anticoagulation, and after activated clotting time (ACT) assessment, the phlebotomy is performed. The phlebotomy can be either longitudinal, T-shaped, or transversal, depending on the anatomical conditions encountered. Once the site for the intimal dissection is established, in accordance with the parietal thickness and how the vein-wall thickening itself is distributed, we proceed to a dissection of the valve flap after endophlebectomy (Fig 2). This dissection is made using an ophthalmic scalpel or microsurgical scissors. The depth of the valve is calculated empirically, checking that the flap is sufficiently wide to occlude the lumen completely. Whether a bicuspid or monocuspid valve is reconstructed depends on the circumferential distribution of the thrombotic thickening, though this does not imply variations of a technical nature. At this point, the technical variation that determines the difference between the two series comes into play.

In the second series, the free edge of the flap is fixed to the vein wall by applying a 7/0 suture (Fig 3). This stitch limits the degree to which the flap can obtrude into the vessel and fixes it in a semi-open position (Fig 4). In this way, reattachment to the original vein wall is prevented. When the valve has been reconstructed, the phlebotomy below the reconstruction site is sutured, the vessel is declamped, and the flap is assessed in its working position.

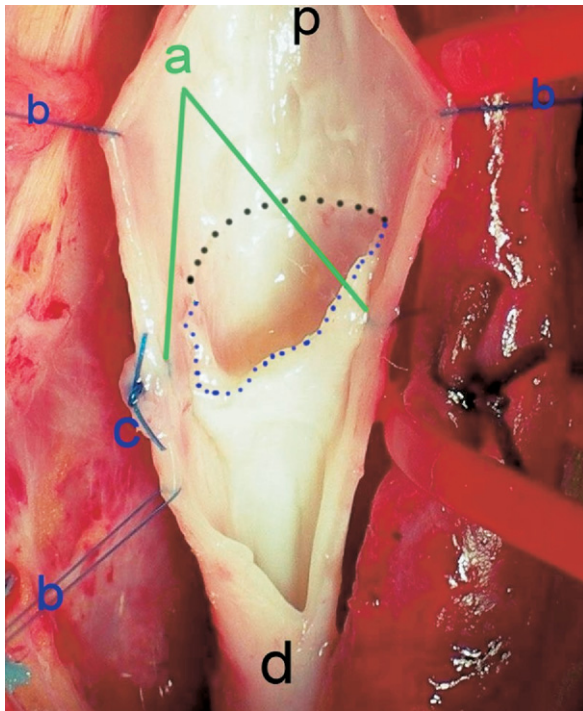


Fig 3. Neovale construction in post-thrombotic syndrome. *p*, proximal; *d*, distal; *c*, collateral ligature; *b*, suspension stitches; dotted black line, line of dissection; dotted blue line, free edge of neovale; *a*, sites of stitches fixing the flap in a semi-open position.

The valve bulge is visible through the distal phlebotomy, which is still open, enabling us to check its size and competence (Fig 5). At the conclusion of the operation, both groups of patients underwent compression therapy with a foot-thigh elastic stocking at 35 mm Hg or with short stretch bandaging. Anticoagulation therapy with endovenous heparin takes place on day 2 after the operation, and is then replaced by low-molecular-weight heparin (LMWH) for a period of 30 days. Subsequently, antiplatelet treatment (clopidogrel 75 mg daily) continues for 6 months, associated with compression therapy. This therapeutic approach, which replaces coagulation by means of oral anticoagulants, was introduced in June 2004, when evidence of postoperative thrombosis proved insignificant. Active movement is resumed early on, during the first postoperative day.

Statistical analysis. Demographic information was tabulated for all patients and measurements were expressed as mean \pm standard deviations. Univariate analysis between the two series was performed by χ^2 test for the discrete variables and by Student's *t* test for the continuous ones. The effect of the technical enhancement applied to the second series on neovale patency, neovale competence, ulcer healing, and ulcer recurrence was examined. All analyses were performed using the SPSS 11.0 statistical package (SPSS Inc, Chicago, Ill).

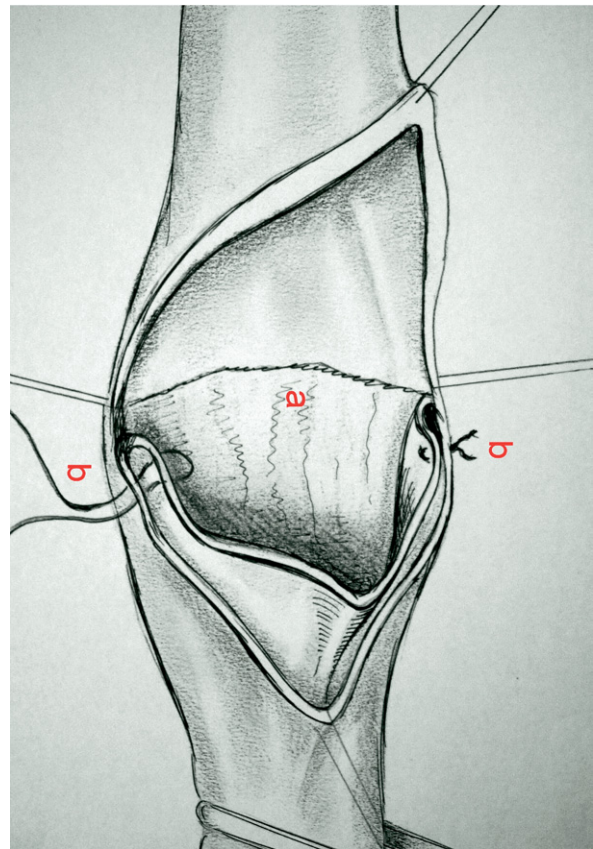


Fig 4. Stylized drawing of the creation of neovale by parietal dissection (*a*) and fixing stitches to avoid re-adhesion (*b*).

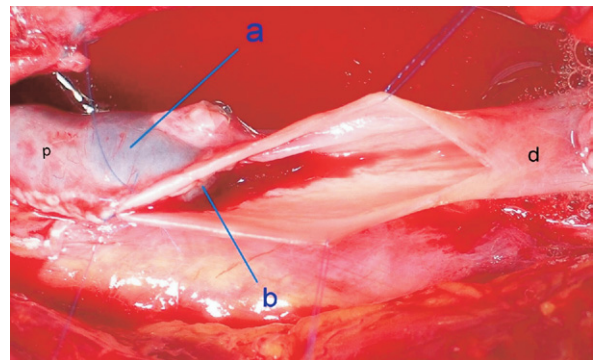


Fig 5. The suture is completed in the proximal part of the phlebotomy. Valve competence is checked. *a*, neovale site; *b*, neovale bulge visible through distal phlebotomy; *p*, proximal; *d*, distal.

RESULTS

The neovale construction technique was first applied in December 2000. At June 2007, the overall median follow-up period is 28.5 (range, 2-78). The first series presents a long-term follow-up (median 54 months, range, 31-78), while the patients of the second series have been

Table II. Plethysmographic parameters: preoperative and postoperative (at 1 month) values

<i>Plethysmographic parameters</i>	<i>n</i>	<i>Preoperative values, median (range)</i>	<i>Postoperative values, median (range)</i>
Venous filling index (mL/s)			
first series	19	12 (7.3-19.2)	2.6 (1.2-8.2)
second series	21	11.5 (6.1-33)	3.8 (1.4-6.4)
Ejection fraction (%)			
first series	19	34 (18-41)	51 (30-69)
second series	21	38 (20-56)	45 (35-68)
Venous filling index (mL/s)			
cumulative	40	11.9 (6.1-33)	2.8 (1.2-8.2)
Ejection fraction (%)			
cumulative	40	35 (18-56)	48.5 (30-69)

followed for a short/mid-term period (median 5 months, range, 2-29). During the follow-up period, neovalve competence, neovalve patency, and clinical outcome (ulcer healing/recurrence) were evaluated (Fig 7, online only).

After the operation, all patients were submitted daily to duplex scanning examination until discharge, and then scheduled for this diagnostic evaluation at 1 month, 6 months, 12 months, and yearly thereafter. Postoperative descending venography was performed in 37 limbs; 3 patients were submitted to a second postoperative venographic examination. Patients were also scheduled for air-plethysmography 1 month after surgery and yearly thereafter (Table II). The mortality rate was 0% and no major complication occurred.

The cumulative occurrence of minor complications was 17.5% (7/40), with no significant differences between the two series. There were 3 hematomas (2 requiring surgical hemostasis), 3 seromas, and 1 wound infection.

The cumulative patency rates were 16 cases per 919 patient-months (1.7/100 patient-months) and 21 per 228 patient-months (9.2/100 patient-months), respectively, in the first and second series. Two early DVTs were detected, but distal to the neovalve site and not affecting its function; one late femoro-popliteal DVT occurred in 1 female patient who resumed oral contraceptives. All DVT episodes occurred in patients of the first series, only one affecting the efficacy of the neovalve by occlusion. No pulmonary embolism was detected.

Cumulative neovalve competence was assessed at 85%. The neovalve was considered competent when the reflux recorded just below it was less than 1 second. The competence rate differs considerably between the two series ($P[\log\text{-rank}].035$). In the first series, 6 neovalve failures were detected (two early failures, one neovalve disruption after DVT, and 3 flap collapses), with a cumulative neovalve competence assessed at 1.6/100 patient-months (13 cases per 803 patient-months). To date, no neovalve failure has been detected in the second series, with a cumulative neovalve competence assessed at 9.2/100 patient-months (21 cases per 228 patient-months).

Neovalve competence rates for patients of the first and the second series are demonstrated in Kaplan-Meier curves in Fig 6. Neovalve failure tends to occur more frequently

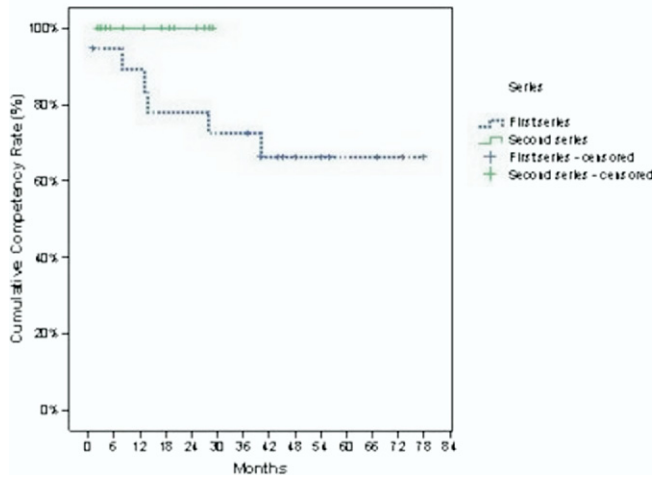
during the first and second postoperative year, while late deterioration patterns are still unknown.

In terms of the clinical outcome, cumulative ulcer healing was 7.7/100 patient-months (16 cases per 206 patient-months) in the first series and 30.7/100 patient-months (20 cases per 65 patient-months) in the second. Recurrence occurred in one case from the first series and in two cases from the second series with an intention-to-treat ulcer recurrence rate of 3 cases per 209 patient-months. The recurrence of the ulcer in the first series was related to deep reflux recurrence. One of the two second series cases was related to superficial venous reflux not present before deep venous surgery. The other was consequent to a local trauma. No significant difference in ulcer healing and ulcer recurrence rates was detected between the two groups (Fig 7).

DISCUSSION

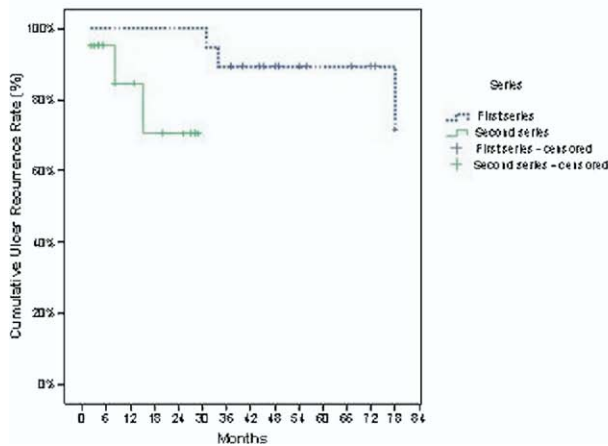
Corrective surgery in deep-venous reflux is not practiced often for reasons not quite known, though many consider it risky, others think it pointless, and still others judge it insufficiently validated in time. In actual fact, this type of surgery is generally non-aggressive and entails a low rate of complication.^{4,16,17} The results achieved partly fade in time due to the evolving nature of the malady, but the benefits accruing to over half the patients for a period of over 5 years are by no means negligible. Unfortunately, diagnostic procedures for pinpointing the hemodynamic implications of an obstructive process, particularly if it is linked to associated reflux, are still somewhat inadequate in this field. This has doubtless restricted indications for treatment. Endoluminal techniques, widespread at arterial level, are also totally neglected in the field of venous surgery,¹⁸ even though the restoration of permeability, performable in chronic obstructions,¹ yields gratifying results.^{19,20} Neutralizing obstructions does not resolve all reflux problems and the beneficial effects of corrective surgery in deep-venous reflux are well described.^{4,21}

Endoluminal techniques for the correction of refluxes are still at an experimental stage,^{21,22} and in the neutralization of subinguinal refluxes they still present a number of problems. In such cases, therefore, direct surgery is the only technique currently at our disposal but the indications are



Month	Limbs at risk (1 series)	Limbs at risk (2 series)
0	19	21
6	17	10
12	16	8
18	14	6
24	14	4
29	13	1
36	13	
42	10	
48	8	
54	7	
60	5	
66	5	
72	4	
78	3	

Fig 6. Cumulative competency rate (%).



Month	Limbs at risk (1 series)	Limbs at risk (2 series)
0	19	21
6	19	9
12	19	7
18	19	5
24	19	4
29	19	1
36	17	
42	15	
48	12	
54	10	
60	8	
66	8	
72	7	
78	5	

Fig 7. Cumulative ulcer recurrence rate (%).

still controversial,²³ above all in postthrombotic syndrome, where established reflux correction techniques do not always prove practicable. The search for alternative routes²⁴⁻²⁷ is what led us to the invention of the neovalve, performed without the use of extraneous material, but based exclusively on the recycling of thickened vein-wall tissue to fashion a flap.⁵ The flap is quite simply a pocket obtained by dissecting the vein wall: while not impeding the normal flow of blood, it is able to withstand the reflux. Initially, the flap was created in such a way as to leave it “flapping” freely inside the lumen like a flag, and this because our major concern was not to impede the flow, thus avoiding a thrombosis at the dissection site. Contrary to expectations, however, we ascertained a low incidence of venous thrombosis: only in one case did it occur at the neovalve site. In the first series, we encountered two early

thromboses below the valve reconstruction site and one late thrombosis at the femoro-popliteal level. None occurred in the second series.⁶

On the other hand, one possible complication leading to the early failure of the treatment may have been the re-adhesion of the flap to the vein wall. How else to explain why operations which, from the technical point of view were complete successes, failed to achieve our predefined goals? For this reason, we decided to modify the position of the flap, fixing it in the semi-open position so as to prevent it from sticking to the vein wall.

Accordingly, in the second consecutive series of patients the flap was fixed in such a way as to impede adhesion. This modified flap position is closer to the physiological position²⁸ than it was in the previous series of operations. The fact that no cases of thrombosis occurred in the second

series would seem to confirm the thesis that parietal dissection and fixing of a flap are of themselves not thrombotogenic. We do not know the precise dynamics of the flap: whether it floats in the lumen like a natural valve, or whether it closes due to the filling of the valve bulge, which pushes it towards the opposite side of the vein wall. This modified technique proves much simpler and safeguards against possible technical failures associated with inadequately fashioned flaps. It can be seen immediately if the anti-reflux function works, and in cases of non-functioning or inadequate flaps the defects can be corrected, thus reducing time spent in the theatre. Probably, the mechanism can be further improved and the procedure needs to be standardized. The mid-term results are particularly encouraging and it would be opportune to inquire into other elements such as the most suitable reconstruction site (even if this is often dictated by anatomical factors) or the possibility of creating anti-reflux mechanisms at various levels.

Valve reconstruction is limited by collateral factors such as parallel refluxes (axial femoral refluxes or reflexive profunda vein), which are a cause of early and late failure.²⁹ Correcting reflux syndrome should not, therefore, be based exclusively on neutralizing axial reflux but on a precise strategy aimed at neutralizing all refluxes, or at least the most significant refluxes based on a hierarchical order. It is the hierarchy of these refluxes that we are not in a position to determine, nor indeed where diagnostic inquiries fail. Hence, even the neutralization of a reflux in the principal axis can prove insufficient with time, despite being perfectly efficient with regard to the segment it addresses. We need to assess whether associated ligatures are opportune or whether additional techniques such as endophlebectomy are required.³⁰ This would aim at maintaining the benefits achieved by the neovalve in order to prevent a deterioration of results.

CONCLUSION

The role of corrective surgery in the deep vein system, either to obtain healing of ulcers resistant to conservative treatment or to resolve significant symptoms, is still a matter of some controversy.²³ Deep neovalve construction can be performed in highly selected patients with low complication rate, high competence rate, high ulcer healing rate, and low ulcer recurrence. The results have, in the short term, improved substantially with the new technique. In patients with a long history of chronic leg ulcers refractory to treatment, this is an important alternative treatment, when feasible.

AUTHOR CONTRIBUTIONS

Conception and design: ML, OM
Analysis and interpretation: OM, MG, GS
Data collection: ML, SG, GM, GS
Writing the article: ML, OM, SG
Critical revision of the article: OM
Final approval of the article: OM
Statistical analysis: ML

Obtained funding: OM

Overall responsibility: ML, OM

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Additional material for this article may be found online at www.jvascsurg.org.

INVITED COMMENTARY

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The quest for a substitute venous valve, which would function long-term and be readily available, has been extensive and often fruitless. A variety of synthetic, allograft, and even xenograft venous valves have been manufactured but to date have not been clinically successful. The only sporadically reported successes have been with valves made from autologous venous tissue obtained from distant sites or possible only under very restrictive conditions.

Dr Maleti and his associates have found a way to use readily available local autologous tissue (the inner vein wall even when postthrombotic) and a very delicate surgical technique to fashion, in most cases, a monocusp venous valve. The patients chosen to undergo this procedure had failed many other attempts to heal persistent venous ulcers and represent only about a tenth of such patients his group were treating. In the first series, the valve was dissected and the vein closed. Although 16 of 19 ulcers healed, the authors noted that six neovalves demonstrated reflux within a few years. Innovation requires observation and the imagination to envision a solution. Since the problem seemed to be re-adherence of the valve to the vein wall, two sutures were placed to keep the valve in the semi-open position. As mentioned in the text, this may

reflect more closely the normal physiologic position of a venous valve. The result has been a dramatic improvement in the neovalve competency rate from 1.6/100 patient months to 9.2/100 patient-months and an improved clinical ulcer healing rate of nearly fourfold.

Who would have thought that the vein wall could be dissected to make a flap resembling a valve without having the flap immediately resticking to the wall or result in complete venous thrombosis? Obviously, neither occurs in most cases and the authors had the insight and courage to test the hypothesis. The illustrations are superb, instructive, and clearly demonstrate the thickened post-thrombotic vein being worked on. The authors demonstrate the correct position to place sutures to keep the valve in the semi-open position. The results are well presented, concise, and confirm the fact that the neovalve works to prevent venous reflux and improve the clinical condition. I applaud the authors for an innovative approach to a very difficult clinical problem and for the scientific method employed in investigating the results. Adoption of the technique and confirmation of the results by other venous surgeons remains the final step for this new surgical technique.

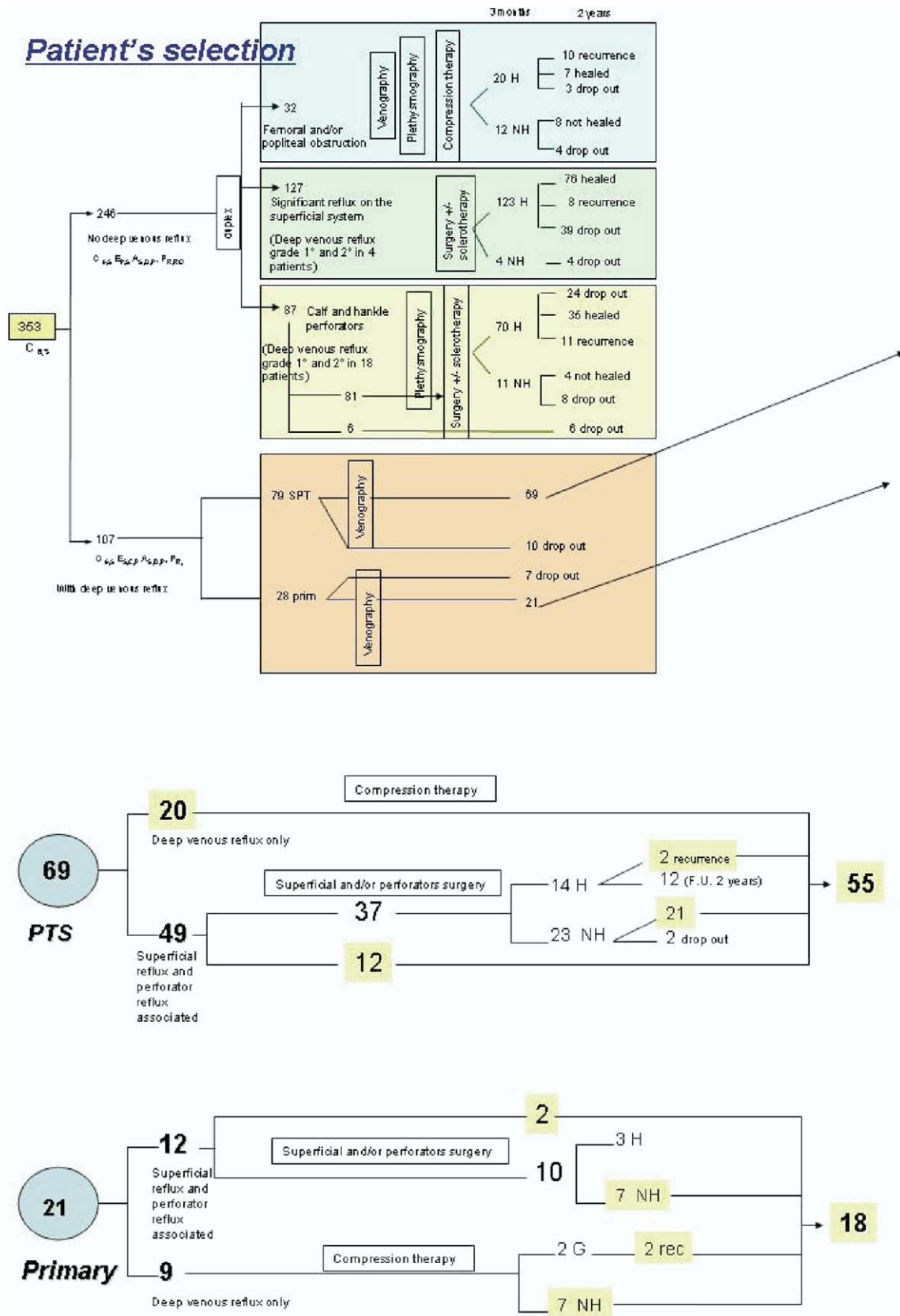


Fig 1, online only. Patient selection.

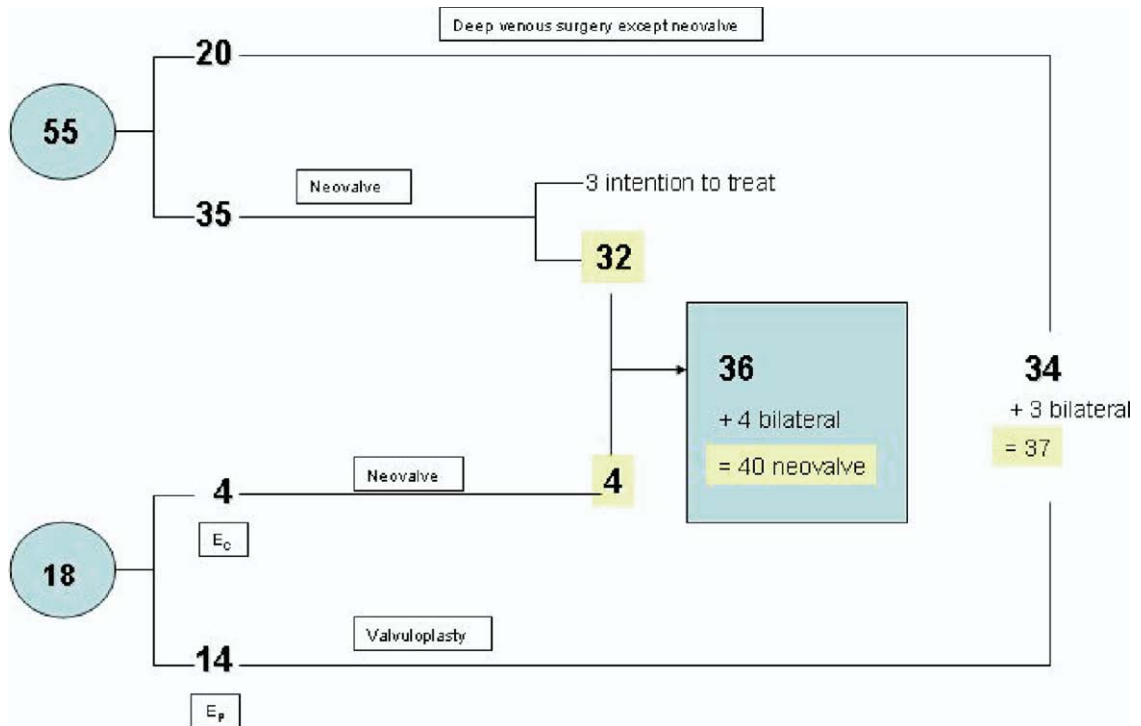


Fig 1, online only. Continued