Feature

Five-Year Experience of Valvular Reconstructions for Nonhealing Leg Ulceration due to Deep Venous Reflux: Lessons Learned

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ABSTRACT **Deep venous reflux is responsible for considerable morbidity in the form of venous leg ulceration and remains a significant health problem. Deep venous reconstructions have been looked upon as controversial in the past. To clarify the role of deep vein valve surgery in venous surgery, we report the lessons learned from clinical and imaging results of a 5-year experience of deep venous valve reconstructions. From 1994 to 1999, 137 patients (169 limbs) underwent deep vein reconstructions for nonhealing venous leg ulcers of CEAP C6 class, as a "last resort" treatment. End points of the study were leg ulcer healing, and vein valve station patency and competency. All end points were looked at on a follow-up of a minimal 2-year period following the valve reconstructions. External valvuloplasty showed ulcer healing in 50% of limbs with maintenance of competency at only 31% of valve stations. Internal valvuloplasty was the most durable valve repair procedure, with 2-year leg ulcer healing rates of 67% and valve station competency of 79%. For**

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secondary incompetence, valve transplants showed a significant deterioration in valve patency (58%) and competence (47%) at 2 years, with 55.3% leg ulcer healing. Single-level repairs or single valve transplants had much lower ulcer healing rates than multiple-level repairs or valve transplants with multiple valve stations. Important lessons learned from this study are: 1) Valvular reconstruction for refluxive disease is effective in healing venous ulcers that defy conservative management and superficial/perforator venous surgery. 2) These procedures appear more promising for primary than for secondary incompetence. 3) Multiple-level or multiple-valve reconstructions yield superior results to single-level repairs, challenging the "gatekeeper" concept.

Keywords **Deep venous valve reflux, valvuloplasty, venous ulcer**

Venous ulceration in the gaiter area of legs occurs as a consequence of unabated, persistent chronic venous insufficiency. This is due to valvular deficiency of superficial, perforator, or deep veins, alone or in combination. Most venous ulcers heal rapidly after superficial vein surgery if the deep venous system is not involved. However, the results are not good when deep veins are involved.[1,2] Thus, treatment options to correct deep venous insufficiency have to be examined.

Evidence suggests that surgical treatment of deep vein valvular reflux leading to severe chronic venous insufficiency provides long-term relief of symptoms and heals venous leg ulcers in 65% to 80% of patients at 5 years postoperation.[1,3–5] Kistner introduced venous valve reconstruction for chronic venous insufficiency as early as in 1968.[6] However, deep venous valvular reconstructions have not become popular and maintain an aura of controversy due to a lack of comparative studies between conservative and surgical therapy. Furthermore, previous studies have included patients with valvular surgery performed with additional superficial and perforator vein surgery, making it difficult to assess whether the benefits of such therapies were due to valve repairs or superficial/perforator surgery.

This study was undertaken to further justify the role of deep venous valvular reconstructions in chronic venous insufficiency in patients who had a recalcitrant nonhealing leg ulcer as a "last resort treatment," despite

multiple superficial/perforator vein surgeries, compression therapy, and medical management.

MATERIALS AND METHODS

Between October 1994 and November 1999, 137 patients (169 limbs) out of 162 patients who underwent deep vein reconstructions in our department met the inclusion criteria and were included in this prospective study. The mean age of this patient group was 38.7 years (range 17 to 75 years), with a male:female ratio of 2.18:1. In the 169 limbs, 411 superficial/perforator surgeries had been previously performed; 24 limbs had a single surgery performed, 83 limbs had two surgeries, and 62 limbs had three or more surgeries performed before presenting as recalcitrant, recurrent venous ulceration. Of the 411 procedures, 284 (69%) were a combination of superficial vein and perforator surgeries; perforator surgery alone was for 96 (23.35%), and superficial surgery alone included 31 (7.54%).

The diagnosis of deep vein pathology was ascertained by ascending and descending venography and with color duplex Doppler assessment in all patients. The patients were then categorized into two groups: a primary refluxive group, where incompetent valves could be identified on imaging and had absence of wall thickness or any intraluminal vein wall defects; and a secondary refluxive group, where there was a past history of deep vein thrombosis and the patients had vein wall thickening and intraluminal trabeculae.

Criteria for inclusion in this study were as follows:

1. Patients with CEAP C6 ulceration of leg greater than or equal to 3 cm in diameter and present for more than 3 months duration, unhealed.
2. Evidence of severe, deep venous reflux, Kistner's Grade III/IV reflux on descending venogram and valve closure time (VCT) greater than 3 seconds; severe reflux associated with reflux velocities greater than 5 cm/sec by standing duplex scan with patient performing Valsalva maneuver.
3. Failure of conservative therapy for more than 3 months (Class II/III compression stockings plus Daflon).
4. Previous superficial or perforator vein surgery (ies) with no current duplex recording of superficial or perforator vein incompetence.
5. Open surgical demonstration of a repairable, refluxive valve.
6. Patients who had completed a follow-up of at least 2 years post-valve reconstruction.

Excluded from the study were patients with color duplex scan or venographic (ascending or descending) findings of concomitant superficial vein reflux or perforator incompetence in association with deep

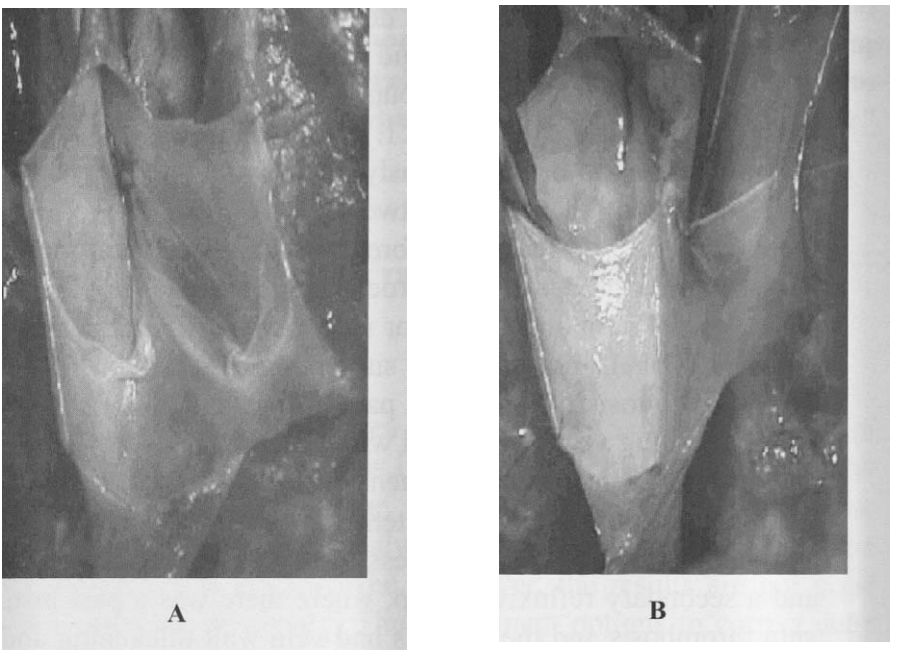


Fig. 1 (**A**) Valve architecture before valvuloplasty. (**B**) Valve architecture after valvuloplasty by Trapdoor technique.

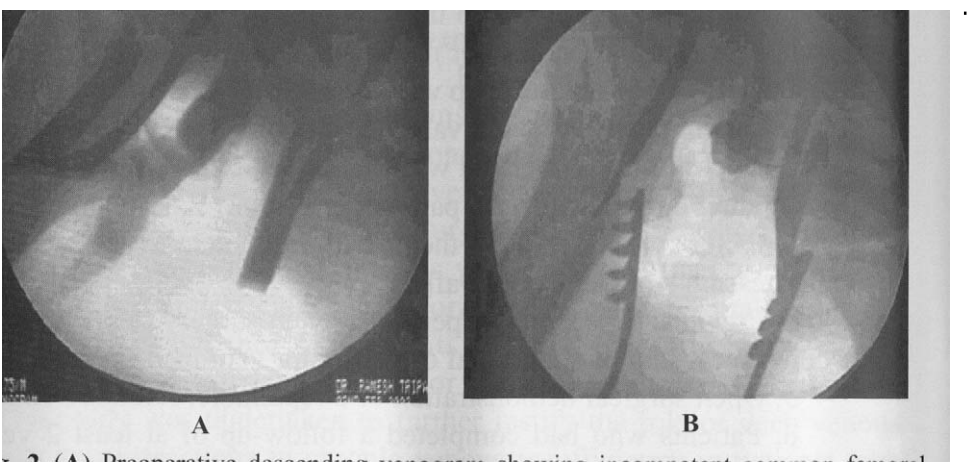
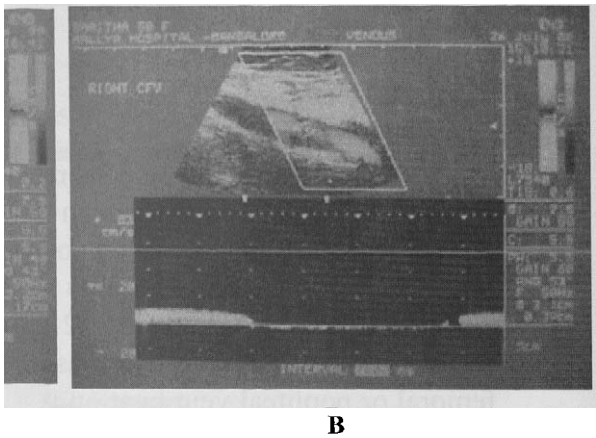


Fig. 2 (**A**) Preoperative descending venogram showing incompetent common femoral bein valve. (**B**) Post valve repair descending venogram showing vale competence with outline of competent cusps.



A B

Fig. 3 Duplex scans pre- and postvalvuloplasty showing abolition of reflux following value repair. (**A**). Prevalvuloplasty showing reflux. (**B**) Post-valvuloplasty showing no valvular reflux.

venous reflux, segmental deep venous reflux, existence of a coagulopathy (on preoperative full coagulopathy screening), noncorrelation of duplex and venographic findings, presence of mixed disease (total or partial deep vein obstructions, with or without reflux), fixed equinus deformity of the ankle, or operative findings of valveless syndrome (among the primary refluxive disease).

Primary Refluxive Disease

Primary refluxive disease (resulting from dysplasia or hypoplasia or redundancy of valves) was present in 96 patients (118 limbs).

We performed external valvuloplasty in 12 limbs (19 valves): 9 limbs (16 valves) by external technique as described by Kistner, and 3 limbs (3 valves) by trans-commissural technique.

Internal valvuloplasty was undertaken in 90 limbs (144 valves): Kistner's vertical venotomy technique[7] was used in 52 patients (60 limbs/97 valves), Raju's transverse technique[8] in 1 patient (1 limb/2 valves), Sottiurai's "T" technique[9] in 3 patients (4 limbs/4 valves) and the Tripathi "Trapdoor" technique[10] (Fig. 1A and 1B) was used in 17 patients (25 limbs/41 valves).

External supports were used in 16 limbs (16 valves). In the beginning of our study, we used Dacron (3 limbs/3 valves) and PTFE grafts (5 limbs/5 valves) as external supports, but lately we used the External Valve Support (W.L. Gore and Associates, Flagstaff, Arizona) (2 limbs/2 valves) and PTFE Pericardial membranes (W.L. Gore and Associates, Flagstaff,

Arizona) (6 limbs/6 valves). Multiple-level (2 to 3) reconstructions were performed in 37 limbs.

Secondary Reflux Disease

Secondary valvular defects resulting from valve damage following venous thrombosis occurred in 41 patients and involved 51 limbs. Axillary-femoral vein or sapheno-femoral vein valve transplant was performed for 29 patients (35 limbs) and 3 patients (3 limbs), respectively (1-valve segment in 14 limbs and 2-valve segments in 24 limbs). Sapheno-femoral venous transposition was performed in 3 patients (4 limbs), and femoral or popliteal vein ligation was done in 6 patients (9 limbs).

IMAGING AND FOLLOW-UP

In the operating theater, all patients underwent a strip test and an intraoperative descending venogram (Fig. 2A and 2B) followed postoperatively by regular clinical examinations for leg ulcer healing assessments and color-duplex scans (Fig. 3A and 3B) at follow-up at 1, 3, 6, 9, 12, and 24 months to show valve competency following valve repair (Fig. 2A and 2B)

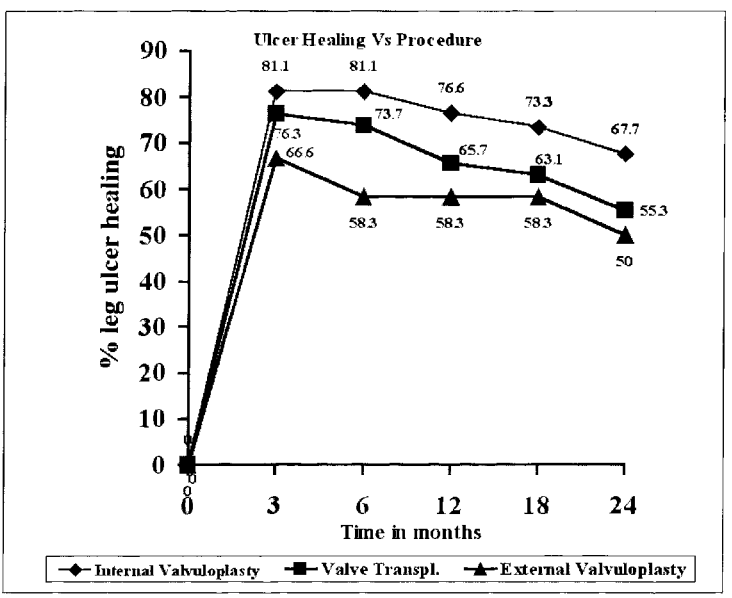


Fig. 4 Correlation between ulcer healing and type of valvular reconstruction.

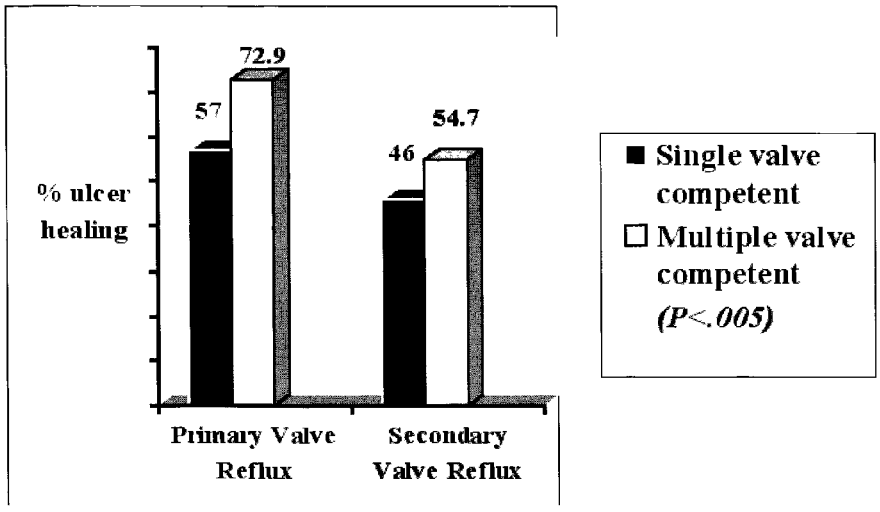


Fig. 5 Correlation between ulcer healing and valve competency.

The repaired valve stations were evaluated for endpoints, that is competence (valve closure time) and patency. All patients were anticoagulated with Enoxaparine (1 mg/kg body weight b.i.d. for 3 days), and oral anticoagulation was started on postoperative day 1 and continued for 3 months, during which the INR was maintained at between 2.5 and 3.0. Postoperatively, all patients underwent calf muscle strengthening physiotherapy and complied with compression therapy with 3-layer crepe bandaging or a class II compression stocking until the ulcer healed completely.

STATISTICAL ANALYSIS

The Student t test, χ-square test, the Fisher exact test, or multivariate analysis with a stepwise Cox proportional test was used for analysis of comparison of percentages. Survival curves were calculated using the Kaplan-Meier product limit method and their differences and comparisons were assessed by log-rank test with the standard limit of significance set at $P < .05$.

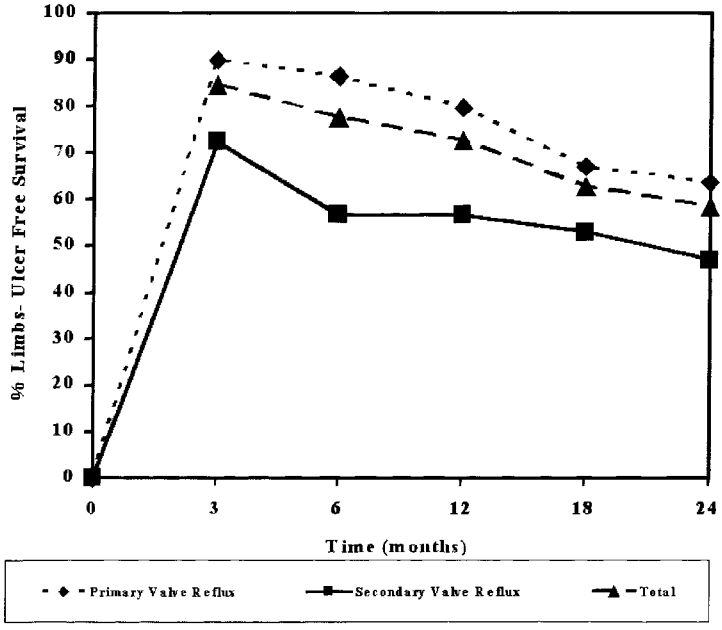
RESULTS

Two-year results of external valvuloplasty showed ulcer healing in 6 of 12 (50%) legs, with maintenance of competency at only 6 of 19 (31.5%) valve

stations. Furthermore, external repairs had better outcomes, with 5 of 9 (55.56%) leg ulcers healing compared to transcommissural valvular repairs, with 1 of 3 (33.3%). Overall, internal valvuloplasty was the most durable valve repair procedure, with 2-year leg ulcer healing rates of 61 of 90 (67.7%) and valve station competency of 115 of 144 (79.8%).

The new trapdoor valvuloplasty technique (Fig. 1A and 1B) also showed a 19 of 25 (76%) ulcer healing rate and a valve station competency of 34 of 41 (82.9%). In seven valves in our early experience, valve leaflet trauma occurred during vertical venotomy and these were repaired with CV8 PTFE sutures. Three of these valves had postoperative thrombosis, and four valves (57.1%) remained competent at 2 years.

Single-level repairs had a lower ulcer healing rate (29/53, 54.7%) than multiple-level repairs (27/37, 72.9%; $P = .002$), and in 65.5% of limbs with ulcers that had healed, one or more valves was competent at 2 years. Of the 105 valves that underwent single-level repair, 62 (59.04%) valves were competent (VCT < 0.5 seconds) with an ulcer healing in 54.7% limbs. Of the 74 valves that had multiple-level repairs, 59 (79.7 %) valves (one or



Months	3	6	12	18	24
Primary Valve Reflux	89.8	86.4	79.6	66.9	63.5
Secondary Valve Reflux	72.5	56.8	56.8	52.9	47.05
Total	84.6	77.5	72.7	62.7	58.5

Fig. 6 Correlation between ulcer healing and type of pathology.

more valves competent in the operated leg) were competent (VCT < 0.5 seconds) with ulcer healing in 72.9% limbs ($P < .05$).

For secondary incompetence, valve transplants showed a significant early deterioration in valve patency and competence, which at 2 years were 57.8% and 47.3%, respectively, with 55.3% leg ulcer healing. Also, valve transplants with multiple valve stations had better leg ulcer healing (57%) than vein valve segments with a single valve (46.1%) ($P = .002$). One or more valves was competent at 2 years in 43.1% of limbs whose ulcers healed. Of the 18 valve segments that underwent single-level repair, 7 (38.9%) valves were competent (VCT < 0.5 seconds), with an ulcer healing in 46.1% limbs. Of the 20 valve segments (43 valves) that had multiple-level repairs, 24 (55.81%) valves were competent (VCT < 0.5 seconds) with ulcer healing in 57% limbs ($P < .2$).

The correlation between ulcer healing and duplex findings of valve patency and competence was stronger in the internal valvuloplasty group (Fig. 4 and Fig. 5) with multiple-valve repairs (72.9% ulcer healing with 78% valve competency) compared with single valve repairs (54.7% ulcer healing with 63% valve competency) ($P < .005$).

The overall rate of clinical success at 2 years, defined by ulcer recurrence-free survival, was 63.5% for primary refluxive disease and 47% for secondary refluxive disease, when all procedures are taken into account (Fig. 6).

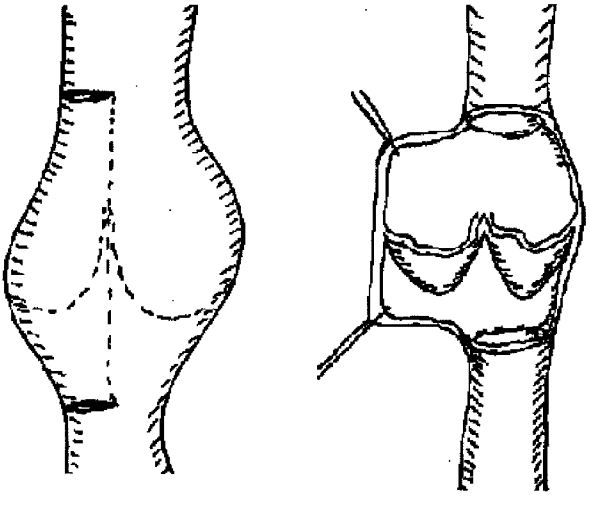


Fig. 7 Surgical exposure for Trapdoor valvuloplasty.

COMPLICATIONS

Wound hematomas occurred in 17 limbs. In the first three postoperative days, nine patients required blood transfusions when postoperative serosanguineous drainage of more than 500 mL occurred.

The overall rate of postoperative thrombosis in the operated limb was 12.4% (21/169 limbs). A significant difference ($P = .001$) existed between patients with postoperative deep vein thrombosis, which

occurred in 6.7% (8/118) limbs with procedures for primary refluxive disease and in 25.4% (13/51) limbs with secondary reflux surgeries. Early post-postoperative deep vein thrombosis (within 10 days of surgery) occurred in 85.71% (18/21) and 92.3% (12/13) of limbs in the secondary group. This may have been related to technical problems during the valve surgeries, the small caliber of the veins involved, and the small size of axillary veins seen in the Indian patient population. One patient in the venous ligation group also had contralateral limb deep vein thrombosis, despite adequate anticoagulation.

"Valve resorption" (absence of valves at the site of a surgically competent valve repair on duplex scan on follow-up) was seen in 11 valve stations that were undergoing repair for primary reflux. Wound infections occurred in 12 limbs (7.1%). All healed with conservative management. There was no mortality in this study.

DISCUSSION

Volume of reflux is one of the most important determinants of the severity of chronic venous insufficiency.[11] Stasis-induced symptoms and signs in chronic venous hypertension in deep vein refluxive disease are more than likely due to large volume reflux. The compensatory mechanisms like calf-pump action and perforator valve function gradually deteriorate with increased deep vein reflux.[4] Perforator incompetence may be a result of deep valve reflux.[4] In chronic venous insufficiency, deep vein reflux occurs in 98% of patients, either alone or in combination with superficial or perforator vein incompetence.[12] Surgery of the insufficient superficial or perforator venous systems, in the presence of deep venous reflux, leads to poor healing of venous ulcers in most patients.[1] Hence, this group, in whom recurrence of leg ulceration is significant even after superficial and perforator vein surgery, and the group that has deep venous reflux without superficial vein involvement, constitute a significant number of venous leg ulcerations patients in whom deep venous valve reconstruction surgery becomes a last option.

This study presents results expressed at 2 years in a continuing long-term follow-up of all patients with venous leg ulcerations due to deep venous reflux. These patients' CEAP C6 had nonhealing venous ulceration despite superficial and perforator vein surgery and a trial of conservative management for more than 3 months on venotropic drugs and compression therapy.

Our study demonstrated ulcer healing of 63.5% limbs in the primary refluxive disease and 47% in secondary refluxive disease. Sottiurai[1] has shown 80% ulcer healing in patients with primary valvular reflux who underwent valvuloplasty and superficial venous surgery. He further showed 75% ulcer healing in patients with secondary reflux who underwent vein valve transplant in combination with superficial venous surgery. These comparative data suggest that when deep vein reflux is associated with superficial venous incompetence, superficial venous surgery alone for these patients will result in nonhealing or recurrence of most of these leg ulcers.

The ideal site for valve repair is still debated. Sottiurai and others believe that the popliteal vein is the gatekeeper of the leg veins and recommend popliteal level repair. Kistner and Raju have recommended repair of the common femoral vein or termination of the superficial femoral level. We based the site of valve reconstruction at valve stations with maximum reflux. We used 2-level repairs in patients with Kistner grade IV reflux. We also found that patients who underwent multiple-level repairs (irrespective of the site chosen) had superior results to single-level repairs, irrespective of the sites of repair. The gatekeeper concept may therefore not be as important as has been emphasized in the past.

The benefits of valvular reconstructions are superior in the primary reflux group compared to the secondary (post-thrombotic) reflux group. In our series, the ulcer healing rate in the primary reflux group has been 63%, which is lower than that reported in other series.[8,13–16] It is likely that the results of our series are not augmented by the contribution of the effects of superficial vein/perforator surgery, which have been done in conjunction with valvuloplasty in other series.

Regarding external valvuloplasty as described by Kistner,[17] our results of external repair have been better than transcommissural repairs, contrary to other reports. We believe this is due to the transcommissural valvuloplasty learning curve, which we have done as a blind guess procedure (without actually visualizing the valve) rather than with angioscopic control. We have abandoned external cuffing in our practice because the results are not satisfactory, yield a high leg ulcer recurrence, and often a fibrotic or thrombotic occlusion of the vein valve stations occurs.

Our experience has been that valve cusp injuries or defects can be effectively repaired with CV8 PTFE sutures. Out of the seven valve cusps repaired, more than half of these remained competent at 2 years. The most common internal valvuloplasty technique we employed was the Kistner

vertical venotomy valvuloplasty[18] in the early part of this study. Once the "trapdoor" valvuloplasty technique was developed (Fig. 7), it became our exclusive technique due to its technical advantages.[10] The "trapdoor" valvuloplasty technique yields a ulcer healing rate of 76% and valve competency of 83% at 2 years. This is in concordance with reported results of internal valvuloplasty in the literature.[19]

A curious phenomenon was observed on duplex follow-up scan in 11 valve stations of patients who developed loss of competence following internal valvuloplasty. These valves showed the complete absence of valves, or "valve resorption." This may be due to collagenolysis following trauma to valve leaflets or due to persistent distal reflux.[20] The real cause is, however, not known. In our study, multiple-level repairs yielded better outcomes than single-level repairs ($P < .002$) for primary reflux, in agreement with observations made by Raju in support of back-up repair.[21]

We observed postoperative thrombosis in 6.7% limbs in the primary reflux group and 25.4% limbs in the secondary reflux group. In the former group, deep vein thrombosis occurred at the site of valve repair in 62.5% limbs, in a remote site in 25% limbs, and involving the whole femoropopliteal system in 12.5%. In the latter group, deep vein thrombosis occurred at the site of valve repair in 53.85% limbs, at a remote site in 15.3% limbs, and involving the whole femoropopliteal system in 30.76%. The reporting of postvalvar reconstruction deep vein thrombosis in the literature is not common. According to Raju,[13] this occurs in 4.5% of cases, whereas Perrin[19] has reported 8.8% deep vein thrombosis after valvuloplasty and 29.7% after valve transplants. Our experience is more in concordance with the Perrin experience. No pulmonary embolism was reported in our study. These thromboses occurred in spite of adequate anticoagulation.

For secondary valvular reflux, valve transplants have been used from axillary or brachial venous segments, or from the opposite greater saphenous vein. An attempt was made to harvest a segment of vein with at least two competent valve stations, wherever possible. When the valves were incompetent, external or internal valvuloplasty was employed. The results of ulcer healing in our study improved ($P < .003$) when multiple valve segments were used compared to single valve segment transplants. There was also a marked reduction of early and mid (3 to 9 months) deterioration of valve function, especially total or partial occlusion of valve stations when ultra-thin PTFE pericardial membrane was used compared to our previous experience with using the PTFE/Dacron sleeve. It was possible to perform

trabeculectomy in some deep veins to improve outflow where the deep vein thrombosis was extensive. Overall, valve transplantation results in our study showed 58% patency, 47% competency, and 55.3% ulcer healing, which favorably compares to other series.[4,19,22-25]

There was a correlation between ulcer healing and duplex findings of valve patency and competence (Fig. 5) only in the primary reflux group that underwent internal valvuloplasty with multiple-valve repairs (72.9% ulcer healing with 78% valve competency) compared with single-valve repairs (54.7% ulcer healing with 63% valve competency) ($P < .005$). The other deep venous valve repair groups did not show a statistically significant correlation.

The early results of this series indicate that valvular reconstruction is more durable when it is performed for primary refluxive disease (Fig. 4, Fig. 6) and if it is undertaken at multiple levels or using multiple valve segments. Most patients with successful valve reconstruction have successful healing of their venous ulcers, and they return back to active life, without needing to use compression stockings.

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REFERENCES

1. Sottiurai VS. Surgical correction of recurrent venous ulcer. J Cardiovasc Surg 1991; 32:104–109
2. Burnand KG, O'Donnell TF, Lea Thomas, Browse NL. The relative importance of incompetent communicating veins in the production of varicose veins and venous ulcers. Surgery, 1977;82:9
3. Masuda EM, Kistner RL. Long term results of venous valve reconstruction: a four-to-twenty-one-year follow-up. J Vasc Surg. 1994;19:391–403
4. Raju S, Fredricks R. Valve reconstruction procedures for non-obstructive venous insufficiency: rationale, techniques and results in 107 procedures with 2-8 year follow-up. J Vasc Surg 1988;7:301–310
5. Perrin M, Hitbrand B, Bayon JM. Results of valvuloplasty in patients presenting with deep venous insufficiency and recurring ulceration. Ann Vasc Surg 1999;13:524–532
6. Kistner R. Surgical repair of a venous valve. Straub Clinic Proceedings 1968; 34:41–43

7. Kistner R. Surgical repair of incompetent femoral vein valve. Arch Surg 1975; 110:1336–1342
8. Raju S. Venous insufficiency of the lower limb and stasis ulceration. Changing concepts and management. Ann Surg 1983;197:688–697
9. Sottiurai VS. Technique in direct venous valvuloplasty. J Vasc Surg 1988;8:646–648
10. Tripathi R, Ktenidis K. Trapdoor internal valvuloplasty – a new technique for primary deep vein valvular incompetence, Eur J Vasc Endovasc Surg 2001;22:86–89
11. Neglen P, Raju S. A rational approach to detect significant reflux using duplex Doppler scan and air plethysmography. J Vasc Surg 1993;17:590
12. Morano JU, Raju S. Chronic venous insufficiency assessment with descending venography radiology 1990;174:441
13. Raju S, Fredericks RK, Neglen PN, Bass JD. Durability of venous valve reconstruction techniques for "primary" and postthrombotic reflux. J Vasc Surg 1996;23: 357–366
14. Sottiurai VS. Supravalvular incision for valve repair in primary valvular insufficiency. In: Bergan JJ, Kistner RL, eds. Atlas of Venous Surgery. Philadelphia: W.B. Saunders; 1992:137–145
15. Sottiurai VS. Current surgical approaches to venous hypertension and valvular reflux. J Int Angiol, 1996;5:49–54
16. Erilsson I, Almgren B, Nordgren L. Late results after venous valve repair. J Int Angiol 1985;4:413–417
17. Kistner RL. Surgical technique of external venous valve repair. Pro.Straub Pacific Health Found 1990;55:15
18. Kistner RL, Ferris EB. Technique of surgical reconstruction of femoral vein valves. In Bergan JJ, Yao JST, eds. Operative Techniques in Vascular Surgery. New York: Grune & Stratton;1980:291–295
19. Perrin M. Reconstructive surgery for deep venous reflux: a report on 144 cases, Cardiovasc Surg 2000;8(4):246–255
20. Kistner RL. Can valves be preserved? Hawaii Med J 59(4):128–129
21. Raju S. Surgical treatment of deep venous valvular incompetence, In: Rutherford R, ed. Vascular Surgery. Philadelphia: W.B.Saunders;2000: 2043
22. Taheri SA. Vein valve transplantation. Vasc Surg 1997;31:278–281
23. O'Donnell TF. Popliteal vein transplantation for deep venous valvular reflux. In: Bergan JJ, Yao JST, eds.Venous Disorders. Philadelphia: W.B Saunders;1991: 273–295
24. Nash T. Long term results of vein valve transplants placed in the popliteal vein for intractable post-phlebitic venous ulcers and pre-ulcer skin changes. J Cardiovasc Surg 1988;29:712–716
25. Taheri SA, Lazar S, Elias SM. Surgical treatment of post–phlebitic syndrome. Vasc Surg 1982;16:123–127