Update on Venous Valvuloplasty
Is there a role and how to do it.

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Introduction

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 [3, 25]. Treatment options to correct deep venous insufficiency, then, have to be looked at.

There is evidence 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 - 80 % of patients at 5 years post-operation.[1, 2, 3, 4]

Venous valve reconstruction for chronic venous insufficiency was introduced by Kistner 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 recalcitrant non-healing leg ulcer as a ‘last resort treatment’, despite multiple superficial/perforator vein surgeries, compression therapy and medical management.

MATERIAL & METHODS:

Between October 1994 and November 1999, of 162 patients who underwent deep vein reconstructions in our department, 137 patients (169 limbs) were included in this prospective study. The mean age of this patient group was 38.7 years (range 17-75 yrs) with a male: female ratio of 2.18: 1. In the 169 limbs, there were a total of 411 previous superficial/perforator surgeries performed in the past. 24 Limbs had single surgery performed, 83 limbs had 2 surgeries and 62 limbs had 3 or more surgeries performed before presenting as recalcitrant, recurrent venous ulceration. Majority of the procedures 284/411 (69%) were superficial vein + perforator surgeries in combination, Perforator surgery alone was for 96/411(23.35%) and superficial surgery alone included 31/411(7.54%).

Diagnosis of deep vein pathology was ascertained by ascending and descending venography and with colour duplex Doppler assessment in all patients.

Criteria for inclusion in this study was as follows:

1).Patients with CEAP C6 Ulceration of Leg greater than or equal to 3 cms. diameter.

2).Evidence of severe deep venous reflux - Grade III/IV reflux on descending venogram and Valve Closure Time (VCT) > 3 secs. by standing Duplex scan with patient performing Valsalva manoevre.

3).Failure of Conservative Therapy for more than 3 months – with Class II/III compression stockings + Daflon

4).Previous Superficial or perforator vein surgery(ies)with no current duplex recorded superficial or perforator vein incompetence

5).Open surgical demonstration of a repairable, refluxive valve

Patients with colour duplex scan or venographic (ascending or descending) findings of concomitant superficial vein reflux or perforator incompetence in association with deep venous reflux , existence of a coagulopathy (on pre-operative coagulopathy screening), presence of mixed disease (obstructions with reflux), fixed equinus deformity of the ankle or operative findings of valveless syndrome were excluded from this study.

Primary refluxive disease 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[5] was used in 52 patients (60 limbs / 97 valves), Raju's transverse technique[8] in 1 patient (1 limb / 2 valves), Sottiurai "T" technique[7] in 3 patients (4 limbs / 4 valves) and the Tripathi 'Trapdoor' technique[17] was employed 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 use 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). Multi-level (2-3) reconstructions were performed in 37 limbs.
41 patients had secondary valvular defects involving 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), Femoral or popliteal vein ligation was carried out in 6 patients (9 limbs).
All patients were anticoagulated with Enoxaparine 1mg/kg body weight b.i.d for 3 days and oral anticoagulation was started on post-op. day 1 and continued for 3 months during which INR was maintained between 2.5 and 3.0.
All patients had regular clinical examinations for leg ulcer healing assessments and colour-duplex scans at follow-up at 1, 3, 6, 12 and 24 months after vein valve reconstruction. The repaired valve stations were evaluated for endpoints i.e. competence (valve closure time) and patency.
Post-operatively, all patients underwent calf muscle strengthening physiotherapy, and complied with compression therapy with 3-layer crepe bandaging or class II compression stocking until ulcer healed completely.

RESULTS:

Two-year results of external valvuloplasty showed ulcer healing in 6/12 (50%) legs with maintenance of competency at only 6/19 (31.5%) valve stations. Furthermore, external repairs had better outcomes with 5/9 (55.56%) leg ulcer healing compared to transcommissural valvular repairs with 1/3 (33.3%) but the results were statistically not significant ($p>0.05$).
Overall, internal valvuloplasty was the most durable valve repair procedure with 2-year leg ulcer healing rates of 61/90 (67.7%) and valve station competency of 115/144 (79.8%).
The new Trapdoor Valvuloplasty technique also showed 19/25 (76%) ulcer healing rates and valve station competency of 34/41 (82.9%). There were 7 valves in our early experience where valve leaflet trauma occurred during vertical venotomy and these were repaired with CV8 PTFE sutures.3 of these valves had post-operative thrombosis and 4 (57.1%) valves remained competent at 2 years. It was also noted that single–level repairs had a lower ulcer healing rate 29/53 (54.7%) than multi-level repairs 27/37 (72.9%) ($P=0.002$). 65.5% of limbs whose ulcers healed had one or more valves competent at two years. Of the 105 valves that underwent single level repair, 62 (59.04%) valves were competent (VCT<0.5 secs.) with an ulcer healing in 54.7% limbs. Of the 74 valves that had

multilevel repairs, 59 (79.7 %) valves were competent (VCT<0.5 secs) with ulcer healing in 72.9% limbs (P<0.05).

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 single valve (46.1%) (P=0.002).

43.1%of limbs whose ulcers healed had one or more valves competent at two years. Of the 18 valve segments that underwent single level repair, 7 (38.9%) valves were competent (VCT<0.5 secs.) with an ulcer healing in 46.1% limbs. Of the 20 valve segments (43 valves) that had multilevel repairs, 24 (55.81 %) valves were competent (VCT<0.5 secs) with ulcer healing in 57% limbs (P<0.2).

We were able to identify only 8% of valves in the secondary valvular incompetence group that underwent Axillary/Saphenous-femoral vein valve transplant procedure, which were amenable to internal valvuloplasty. The patency in this group was 63% and competency was 28%, with leg ulcer healing rate of only 33.3% indicating that when valves are damaged with thrombotic process, further operative trauma may not produce results comparable with those of primary incompetence.

The correlation between ulcer healing and duplex findings of valve patency and competence was stronger in the internal valvuloplasty group with multi valve repairs 72.9% ulcer healing with 78% valve competency compared with single valve repairs 54.7% ulcer healing with 63% valve competency.

The cumulative rate of clinical success at two 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.

COMPLICATIONS: Wound hematomas occurred in 17 limbs. Post-operative sero-sanguineous drainage more than 500 ml. in first three post-operative days requiring blood transfusion occurred in 9 patients.

Overall rate of post-operative thrombosis in the operated limb was 12.4% (21/169 limbs).There was a significant difference(P=0.001) between patients with post-operative DVT 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. One patient in the venous ligation group also had contralateral limb DVT, despite adequate anticoagulation. Valve resorption was seen in 11 valve stations 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 severity of chronic venous insufficiency [12]. 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[2]. Perforator incompetence is nearly always a result of deep valve reflux [2]. In chronic venous insufficiency, deep vein reflux occurs in 98% of patients, either alone or in combination of superficial or perforator vein incompetence [13]. Surgery of the insufficient superficial or perforator venous systems, in the presence of deep venous reflux, leads to poor healing of venous ulcers in a majority of patients [3]. Hence, this group in whom recurrence of leg ulceration is significant even after superficial and perforator vein surgery and the group which has deep venous reflux without superficial vein involvement, constitute a significant number of venous leg ulceration patients in whom deep venous valve reconstruction surgery becomes a last option.

This study presents results expressed at two 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 non-healing venous ulceration despite superficial and perforator vein surgery and trial of conservative management for more than 3 months on venotropic drugs and compression therapy.

In our study we demonstrated ulcer healing of 63.5% limbs in the primary refluxive disease and 47% in secondary refluxive disease. Sottiurai [3] has shown 80% ulcer healing in primary valvular reflux patients who underwent valvuloplasty and superficial venous surgery. He further showed 75% ulcer healing in secondary reflux patients 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 non-healing or recurrence of a majority of these leg ulcers.

The ideal site for repair of valve is still debated. Sottiurai and others believe that popliteal vein is the gatekeeper of the leg veins and recommend popliteal level repair. Kistner and Raju have recommended repair of common femoral vein or termination of superficial femoral level. In our study, we based the site of valve reconstruction at valve stations with maximum reflux. We used 2-level repairs in patients with grade III / IV reflux according to Kistner. We also found that patients who underwent multi-level repairs (irrespective of site chosen) had superior results to single-level repairs, irrespective of 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 the primary reflux group,

in our series, the ulcer healing rate has been 63% which is lower than that reported in other series [8,10,14,15, 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, our results of external repair have been better than trans-commissural repairs; contrary to other reports and this we believe is due to learning curve with Transcommissural valvuloplasty, which we have done as a blind guess procedure rather than with angioscopic control. External cuffing has now been abandoned in our practice as the results are not satisfactory and yield a high leg ulcer recurrence and often end up with fibrotic / thrombotic occlusion of vein valve stations.

Valve cusp injuries or defects can be effectively repaired with CV8 PTFE sutures as has been our experience. Out of the 7 valve cusps repaired, more than half of these remained competent at two years. The most common internal valvuloplasty technique we employed was the Kistner vertical venotomy valvuloplasty [9] in the early part of this study. After the development of "Trapdoor" valvuloplasty technique [17], this has become our exclusive technique due to its technical advantages. "Trapdoor" valvuloplasty technique yields a ulcer healing rate of 76% and valve competency of 83% at two years. This is in concordance with reported results of internal valvuloplasty in the literature.[18]

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 complete absence of valves or 'valve resorption'. This may be due to collagenolysis following trauma to valve leaflets or due to persistent distal reflux [19]. The real cause is however not known. In our study, multiple level repairs yielded better outcomes than single level repairs ($p < 0.002$) for primary reflux , in agreement with observations made by Raju in support of back-up repair [20] .

We observed post-operative thrombosis in 6.7% limbs in the primary reflux group and 25.4% limbs in the secondary reflux group. In the former group, DVT occurred at the site of valve repair in 62.5% limbs and remote site in 25% limbs and involving the whole femoro-popliteal system in 12.5%.In the latter group, DVT occurred at the site of valve repair in 53.85% limbs and remote site in 15.3% limbs and involving the whole femoro-popliteal system in 30.76%.The reporting of post-valve reconstruction DVT in literature is not common. According to Raju [10] this occurs in 4.5% where as Perrin [18] has reported 8.8% DVT after valvuloplasty and 29.7% after valve transplants. Our experience is therefore more in concordance with the Perrin experience. No pulmonary embolism was reported in our study. This thrombosis occurred in spite of adequate anticoagulation.

For secondary valvular reflux, valve transplants have been used from axillary / brachial venous segments or from the opposite GSV. An attempt was been 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 ($p<0.003$) when multiple valve segments were used compared to single valve segment transplants. There was also a marked reduction of early and mid (3-9 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 DVT was extensive. Overall, valve transplantation results in our study showed 58% patency, 47% competency and 55.3% ulcer healing which favourably compares to other series.[2, 18, 21, 22, 23, 24]

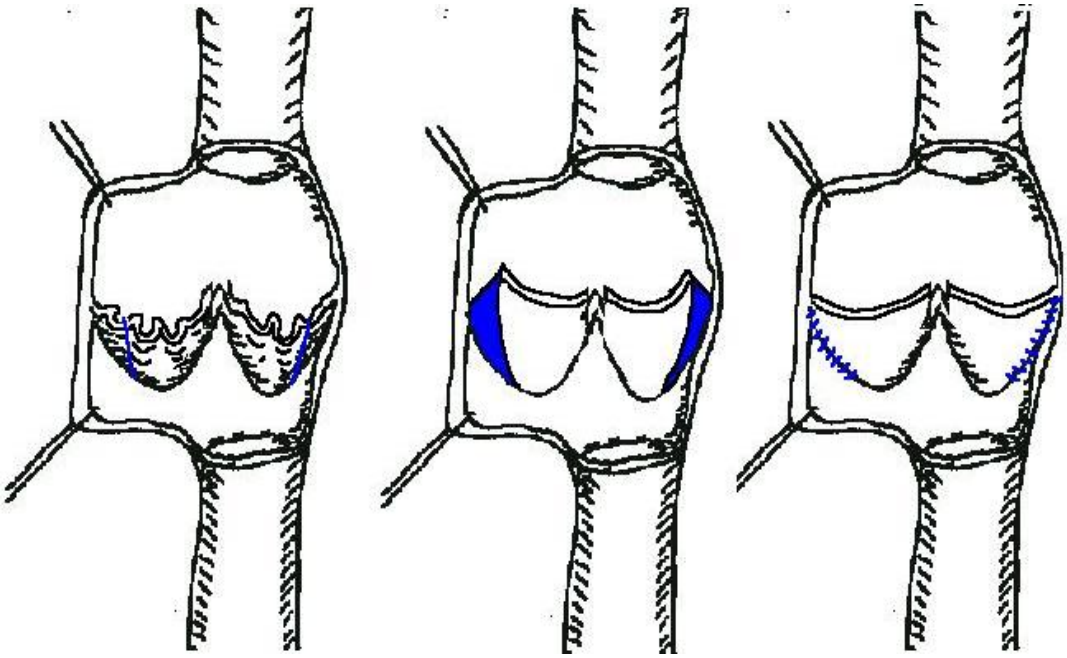
There was a correlation between ulcer healing and duplex findings of valve patency and competence only in the primary reflux group which underwent internal valvuloplasty-with multi valve repairs (72.9% ulcer healing with 78% valve competency) compared with single valve repairs (54.7% ulcer healing with 63% valve competency) $p<0.05$. The other deep venous valve repair groups did not show statistically significant correlation.

The early results of this series indicate that valvular reconstruction is more durable when performed for primary refluxive disease and if 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 having the need to use compression stockings in the leg.

Recent Advances

We have recently introduced a new concept in treating very severely redundant valves which are difficult to plicate at the commissures because the current valvuloplasty techniques result in bulky valve remnants left behind at the commissures causing increased thrombogenic potential at the valve station level.

To obviate this problem, we have embarked upon excision of redundant valve and stitching of the valve border to the vein valve and we have been technically able to provide a water tight repair with good competency following this repair. This technique is called “Reduction Valvuloplasty”(Figure below).



REFERENCES

1) 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.

2) 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.

3) Sottiurai VS. Surgical correction of recurrent venous ulcer. J Cardiovasc Surg 1991; 32: 104-109.

4) 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.

5) Kistner R. Surgical repair of incompetent femoral vein valve. Arch Surg 1975; 110: 1336-1342.

6) Kistner R. Surgical repair of a venous valve. Straub Clinic Proceedings 1968; 34: 41-43

7) Sottiurai VS. Technique in direct venous valvuloplasty. J Vasc Surg 1988; 8: 646 - 648

8) Raju S. Venous insufficiency of the lower limb and stasis ulceration.Changing concepts and management. Ann Surg 1983 ; 197: 688 - 697.

9) 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.

10) Raju S, Fredericks RK, Neglen PN, Bass JD . Durability of venous valve reconstruction techniques for "primary" and postthrombotic reflux. J Vasc Surg 1996, 23: 357-66

11) Kistner RL. Surgical technique of external venous valve repair. Pro.Straub Pacific Health Found.,1990, 55 :15.

12) Neglen P,Raju S : A rational approach to detect significant reflux using duplex Doppler scan and air plethysmography. J Vasc Surg 17 :590,1993

13) Morano JU,Raju S : Chronic venous insufficiency Assessment with descending venography.Radiology 174 :441,1990

14) Sottiurai VS : Supravalvular incision for valve repair in primary valvular insufficiency. In Atlas of Venous surgery,eds.J.J Bergan and R.L Kistner.W.B.Saunders, Philadelphia,1992, pp.137-145

15) Sottiurai VS : Current surgical approaches to venous hypertension and valvular reflux. Journal of International Angiology, 1996, 5, 49-54

16) Erilsson I,Almgren B,Nordgren L : Late results after venous valve repair. Journal of International Angiology, 1985, 4, 413-417

17) Tripathi R, Ktenidis K: Trapdoor Internal Valvuloplasty – a new technique for Primary Deep Vein Valvular Incompetence, European J of Vasc and Endovasc Surg ,2001,22, 86-89

18) Perrin M: Reconstructive surgery for deep venous reflux: a report on 144 cases, Cardiovasc Surg 2000, 8, 4, 246-255

19) Kistner RL : Can valves be preserved ? Hawaii Medical Journal, 59, 4, 128-129

20) Raju S : Surgical treatment of deep venous valvular incompetence, Vascular Surgery Ed.Rutherford R, W.B.Saunders,Philadelphia, 2000,pp 2043

21) Taheri SA : Vein valve transplantation.Vascular Surgery, 1997, 31, 278-281

22) O'Donnell TF: Popliteal vein transplantation for deep venous valvular reflux .In Venous Disorders,eds. J.J Bergan, J.S.T Yao .W.B Saunders,Philadelphia,1991,pp 273-295

23) 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 of Cardiovasc Surg, 1988, 29, 712-716

24) Taheri SA,Lazar S,Elias SM : Surgical treatment of post-phlebitic syndrome. Vascular Surgery,1982,16,123-127

25) 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

Trapdoor" Technique of Internal Venous Valvuloplasty

Fig.1 Strip Test a

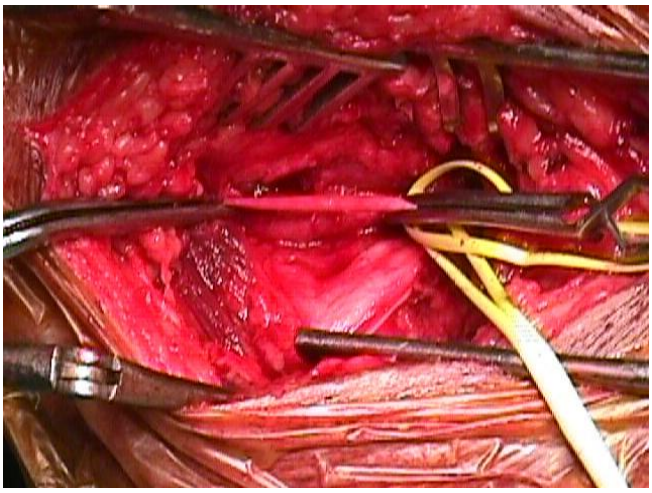


Fig.2 Strip Test b
showing incompetent deep vein valve with reflux

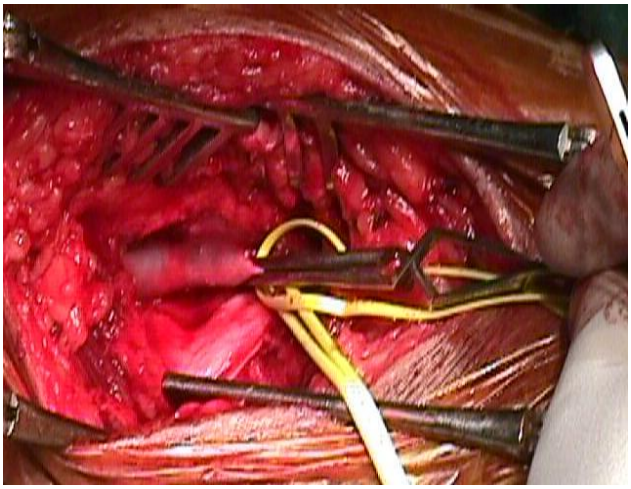


Fig.3 Identification of Valve Station

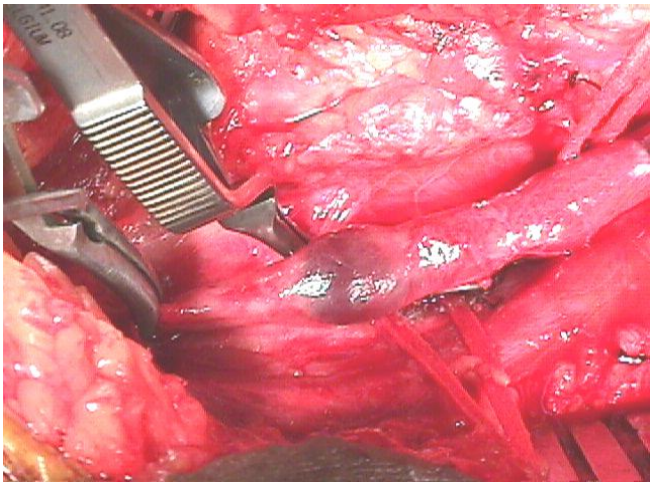


Fig.4 Adventitial dissection of Valve station

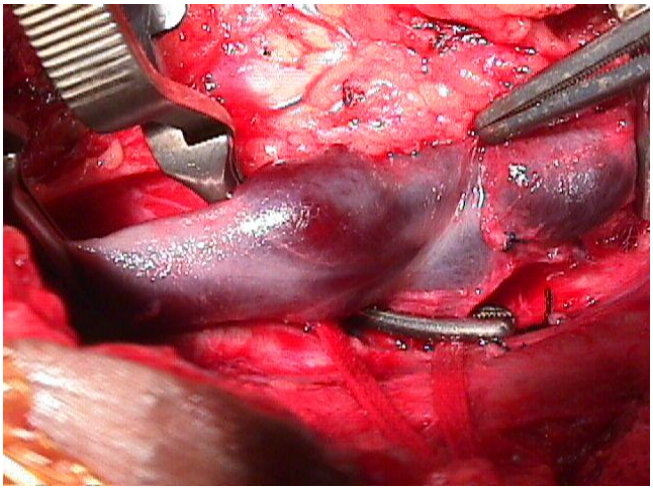


Fig.5 Transverse Venotomy

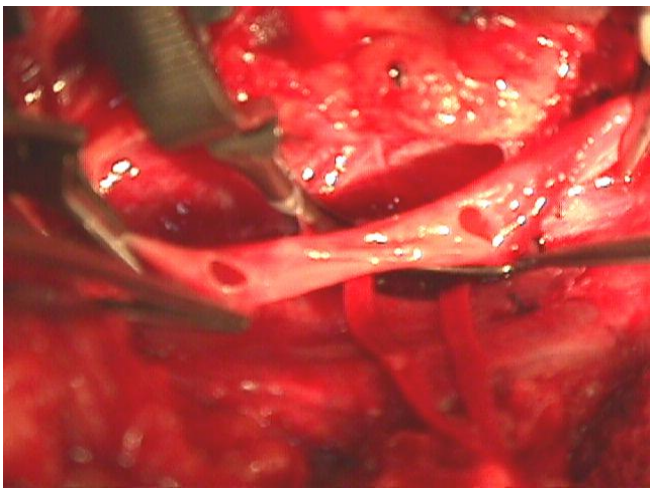


Fig.6
Diagrammatic Schema of Transverse Venotomy

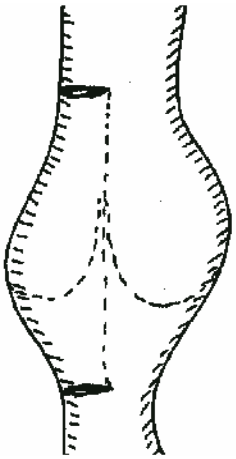


Fig.7 Vein Valve Retractor Forceps

Fig.8 Use of Vein Valve Retractor

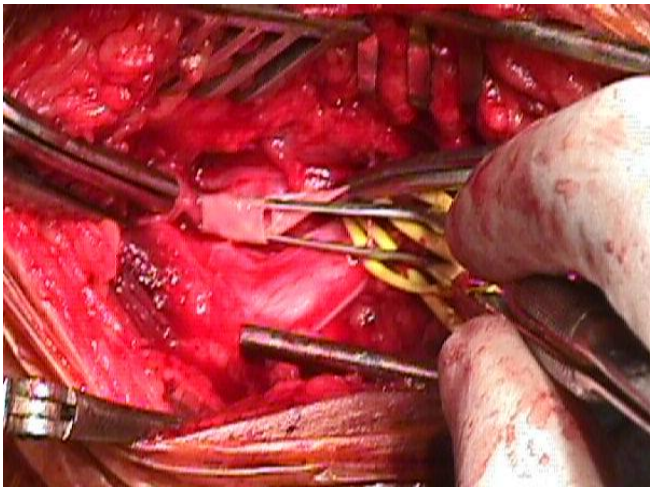


Fig.9 Opened “Trapdoor” with Vein Valve exposed

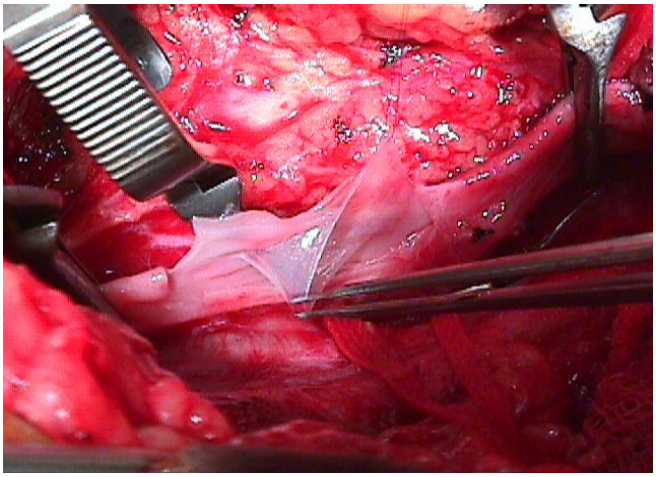


Fig.10 Diagrammatic Schema of “Trapdoor”

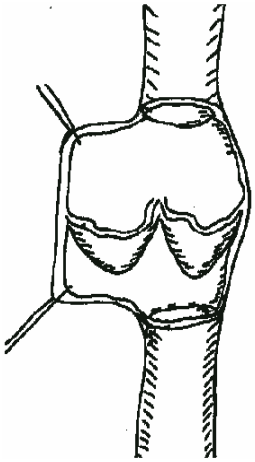


Fig.11 Posterior Commissure Apical Stitch

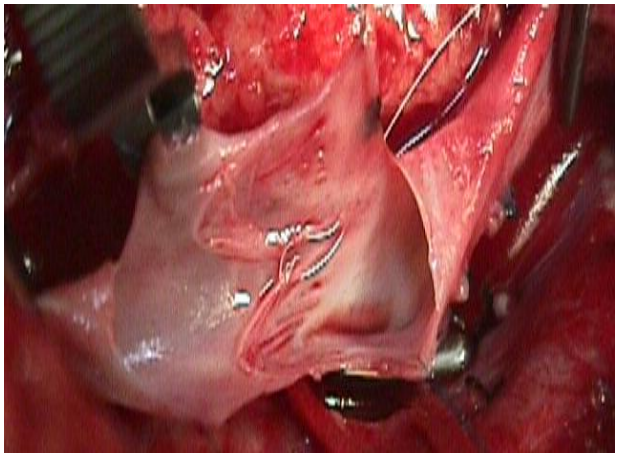


Fig.12 Valve cusps plicated till valve rim is straightened out

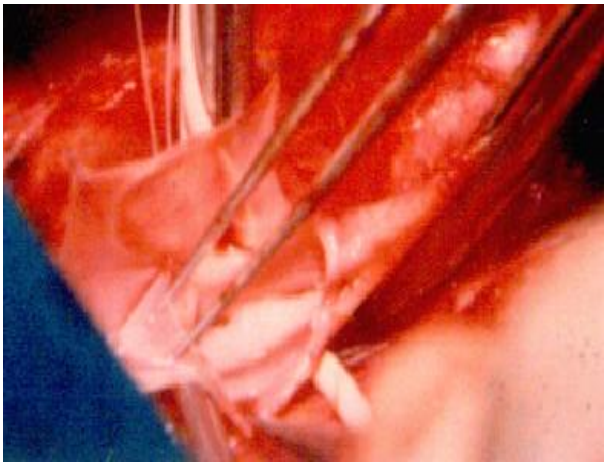


Fig.13 Valve Cusp abnormalities e.g hole in the valve cusp medially noted here and repaired

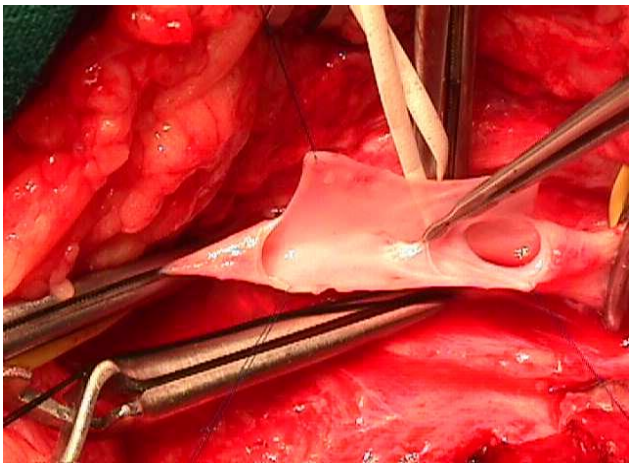


Fig.14 Completed valve plication

Fig.15 Open Technique of Competency Check

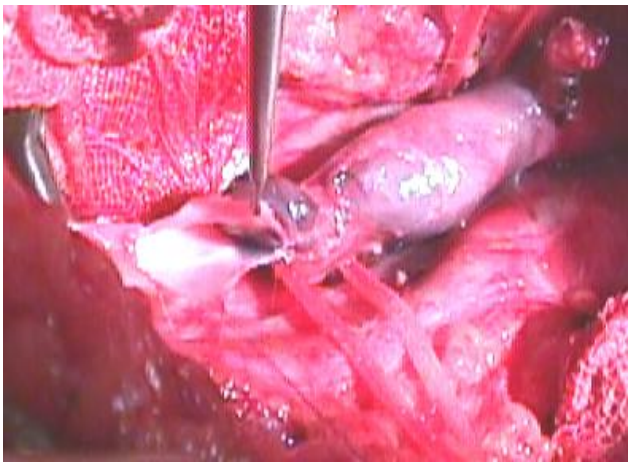


Fig.16 Closed Technique of Competency Check (Strip Test)

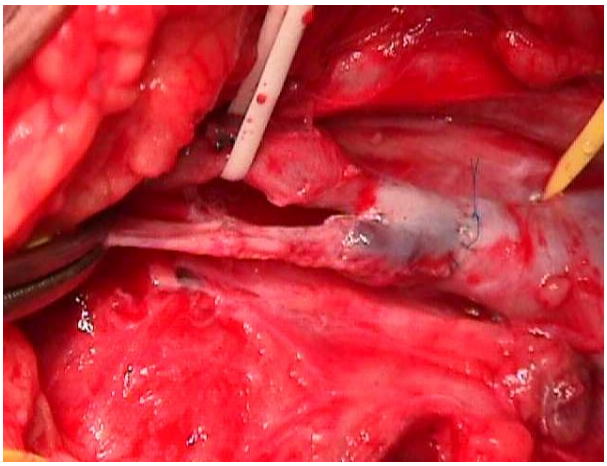
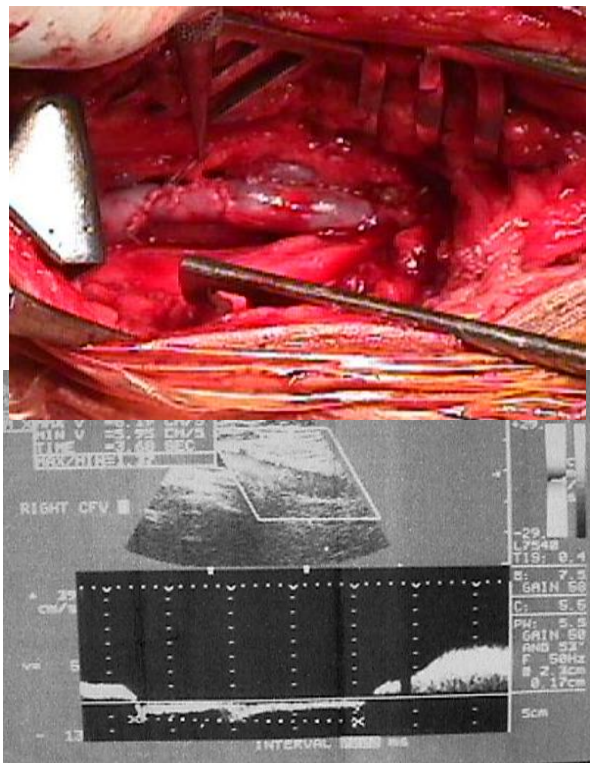


Fig.17 Vein Lumen after closure of “Trapdoor”



9 months- Post-operative Duplex showing abolition of reflux at valvuloplasty sitel

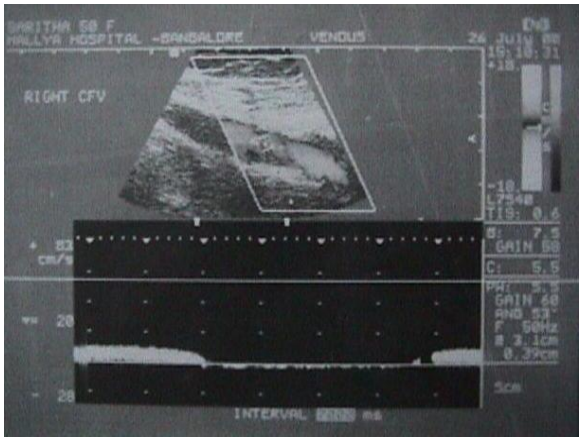


Fig.18

preoperative descending venogram showing incompetent common femoral vein valve

Fig.1b-post valve repair descending venogram showing valve competence with outline of competent cusps

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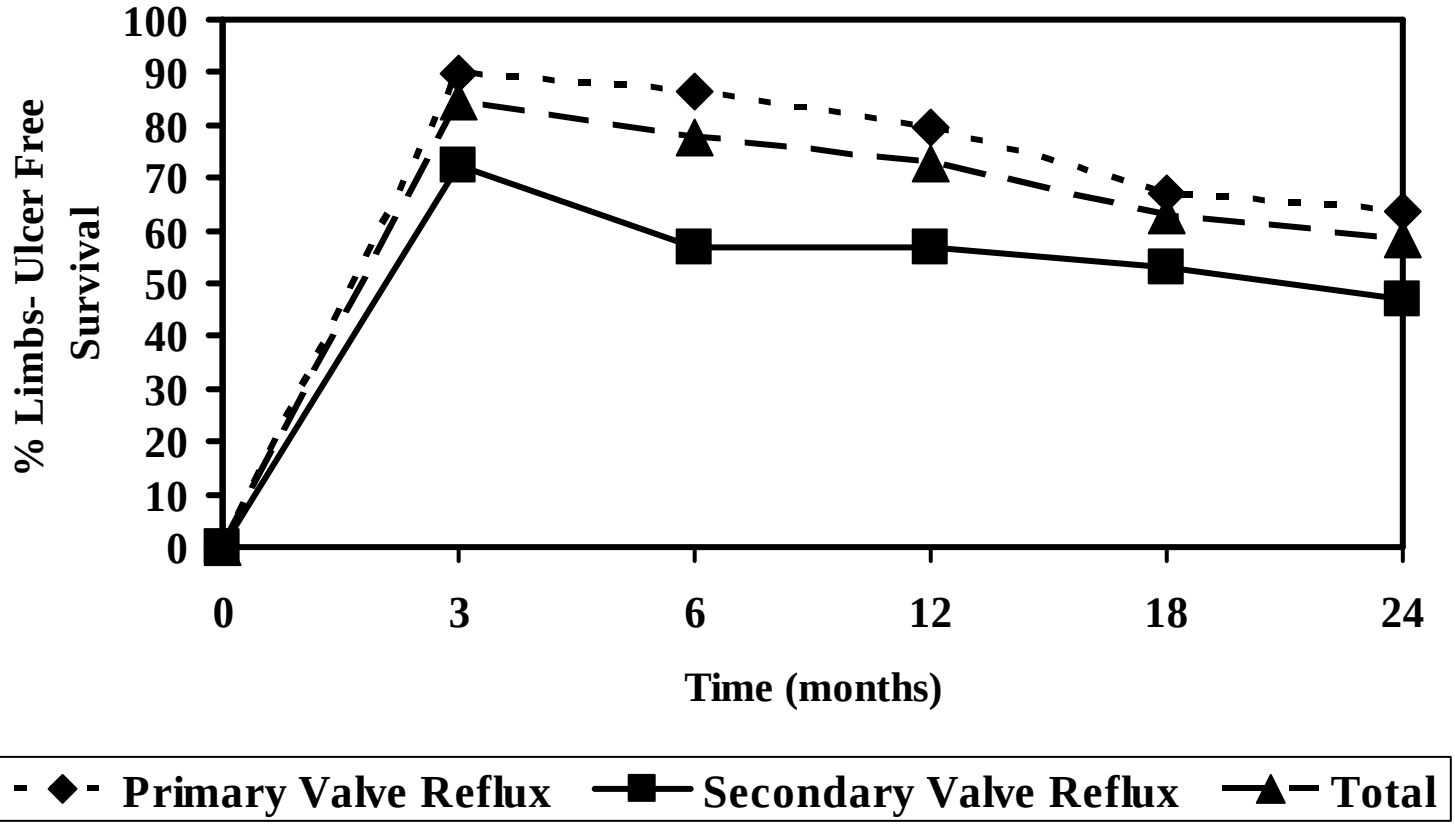
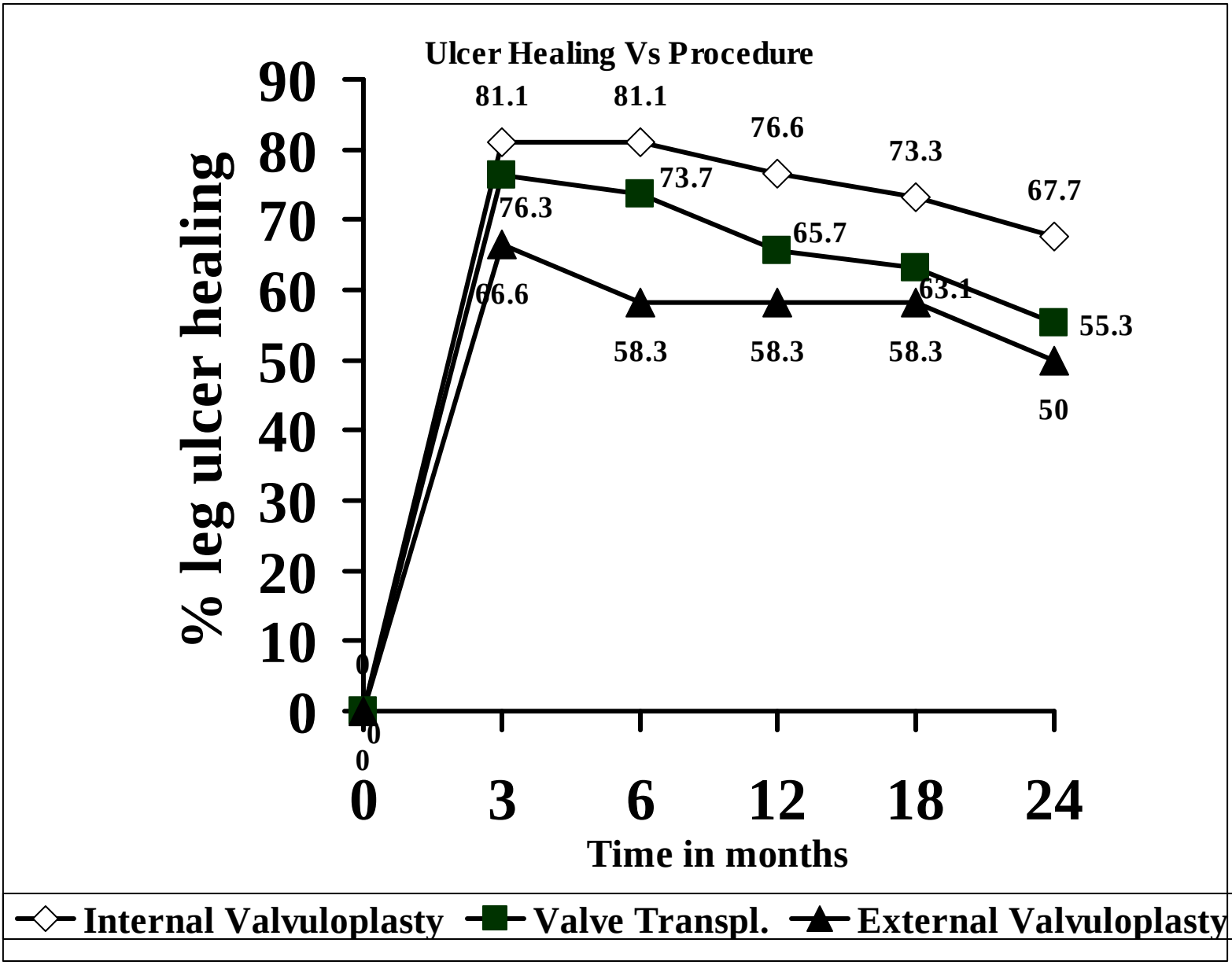
Graph I



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

Graph II


Ulcer Healing Vs Procedure
% leg ulcer healing
90
80
70
60
50
40
30
20
10
0
0
3
6
12
18
24
Time in months
81.1
81.1
76.6
73.3
67.7
73.7
76.3
65.7
63.1
55.3
66.6
58.3
58.3
58.3
50
0
0
0
Internal Valvuloplasty
Valve Transpl.
External Valvuloplasty

Graph III

Ulcer Healing Vs. Valve Competency