Intraoperative angioscopy may improve the outcome of in situ saphenous vein bypass grafting: A prospective study

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Objective: **To find out whether intraoperative angioscopic assistance has any effect on graft outcome in patients with critical leg ischemia.**

Material and Methods: **One hundred one patients requiring a below-knee bypass were assigned to undergo in situ saphenous vein bypass with or without intraoperative angioscopic assistance; otherwise treated similarly including preoperative duplex vein mapping, intraoperative graft flow measurements, and angiography. Data on operative details, morbidity, hospital stay, and graft patency were collected prospectively and compared. All patients were followed up for 12 months.**

Results: **The group that underwent angioscopy (A) and the control group (B) were similar in all respects, except for the number of patients enrolled in the groups (32 and 69, respectively). Angioscopy revealed incompletely destructed valves in 34 patients (range, 0 to 5; mean 1), undiagnosed vein branches in 111 patients (mean 4.3), and partly occluding thrombus in 5 patients. The number of postoperative arteriovenous fistulas with signs of failing graft and a need for angiographic or surgical reintervention were significantly higher in group B ($P < .0001$). The 1-year primary patency rate was significantly better in group A ($P < .01$), but the primary assisted and secondary patency rates did not differ between the groups.**

Conclusions: **Angioscopic assistance has an impact on primary graft patency, minimizes the risk for graft failure and thus reduces the need for reintervention by allowing identification of persistent saphenous vein branches, incomplete valve destruction, and partly occluding graft thrombus without adding extra operative time. (J Vasc Surg 2002;35:759-65.)**

Autogenous vein grafts in situ provide a superb conduit for distal bypasses. However, the longevity is, apart from poor vein quality and technical errors during surgery, threatened by postoperative arteriovenous fistulas or later development of stenosis. Preoperative duplex scanning of the vein has been shown to be valuable in the assessment of postthrombotic stenosis or occlusion and varicosities of the proposed graft, information that is important for the preoperative decision whether the vein is useful as a bypass graft.[1,2] Furthermore, it has been shown to be an excellent method to localize the tributaries that should be ligated through multiple skin incisions during surgery.[3] Angioscopy has not gained full recognition, but it has been demonstrated that poor vein quality and unligated tributaries could be identified by angioscopy.[4-7] However, whether angioscopic assistance improves the graft outcome in patients with critical ischemia is debated. This prospective study was designed to evaluate whether angioscopy has any impact on primary graft patency, can minimize the risk of failing graft caused by postoperative arteriovenous fistulas or stenosis, and thereby reduce the need for reintervention.

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Competition of interest: nil.

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0741-5214/2002/$35.00 + 0 **24/1/119240**

doi:10.1067/mva.2002.120374

PATIENTS AND METHODS

Patients requiring femorodistal arterial reconstruction between January 1996 and December 1998 at the Division of Vascular Surgery, Lund University Hospital, were, if a suitable vein was present, assigned to undergo saphenous vein bypass in situ. In all cases the indication for surgery was critical leg ischemia, according to the classification of Fontaine III and IV,[8] and all patients who underwent operation during this period were included in this prospective nonrandomized study. They were divided into two groups: A, angioscopy (ie, with intraoperative angioscopic assistance) and B, no angioscopy.

All patients underwent a standardized preoperative workup (clinical examination, pressure measurements with calculation of ankle-brachial pressure index [ABPI] and angiography). Demographic data, risk factors and clinical status are listed in Table I. With the patient in the standing position, mapping of the saphenous vein was done before surgery with color-flow duplex scanning (GE Vingmed System 5, Horton, Norway), and the size of the vein, number of branches, and defects or anomalies were recorded.

Surgical procedure and intraoperative investigations and protocol. All patients received antibiotic pro-

Table I. Patients' characteristics and indication for operation

	A (n = 32)	B (n = 69)
Age (y)		
Median	74	74
Range	(53-91)	(47–88)
Sex (male)	20 (63%)	38 (55%)
Diabetes		
Total	17 (53%)	34 (49%)
Insulin dependent	11	25
Smoking	16 (50%)	35 (51%)
Cerebrocardiovascular disease	18 (57%)	52 (75%)*
Nephrosclerosis / uremia	3 (9%)	9 (13%)
Any previous peripheral vascular surgery	4 (13%)	14 (20%)
Rest pain	30 (94%)	65 (94%)
Ischemic ulcer/gangrene	23 (71%)	50 (72%)

*P < .01.

Table II. Result of preoperative vascular workup

	A	B
Vein-mapping	26 (80%)	62 (90%)
Vein diameter ≤3 mm	17 (65%)	45 (73%)
Vein branches		
Median	8	8
Range	(4-16)	(3-15)
ABPI	28 (88%)	56 (82%)
ABPI < 0.4 all patients	15 (54%)	34 (61%)
Diabetes	15/5 (33%)	25/9 (36%)
No diabetes	13/10 (77%)	31/25 (81%)
Angiography/runoff	32	69
1 artery	26 (81%)	52 (75%)
2 arteries	6 (19%)	15 (22%)
3 arteries	0	2 (3%)

phylaxis with cloxacillin (Ekvacillin; Astra, Södertälje, Sweden) 2 g intravenously administered three times, starting just before surgery and at 8-hour intervals. The proximal and distal anastomotic areas of the arteries were exposed, as were the corresponding segments of the saphenous vein. Before the vein was clamped, heparin 5000 units was given intravenously, and the most proximal cusps were cut under direct vision after division at the saphenofemoral junction. The proximal anastomosis was performed end-to-side at the common femoral bifurcation. The vein was exposed to arterial pressure and divided distally, and a valvulotome (Vascutech Expandable LeMaitre, Badsachen, Germany) was introduced from the distal end. Valvulotomy was performed by pulling the device through the vein at least twice or until no "cut" was felt in the instrument. Vein branches that were mapped before operation were then visualized through multiple skin incisions and ligated.

In group A a 7F introducer was inserted into a branch close to the proximal end of the saphenous vein. A 1.9- or 2.3-mm angioscope (Baxter, Irvine, Calif) connected to a camera and light source (Storz, Tuttlingen, Germany) was introduced into the vein (group A, angioscopy). Ringer's lactate solution with heparin 1 U/mL was used for irrigation and infused via an infusion pump controlled by a foot pedal, and the graft was inspected in an antegrade direction. During angioscopy the distal end of the vein was left open so that the irrigation fluid could go out distally, thus preventing fluid overload. The quality of the graft, the number of residual valves and branches, stenotic areas, or other defects in the vein, fresh thrombi, and instrumental damage to the vein were recorded, as were the time used for the investigation and the volume of irrigation fluid used. Found branches were ligated immediately after angioscopy. The bypass was completed after angioscopy in group A and after valvulotomy in group B by performing the distal anastomosis end to side.

After restoration of blood flow, a 3- or 5-mm flow probe was placed over the graft close to the proximal anastomosis, and a transit time flowmeter (CardioMed/Medi-Stim, Grefsen, Norway) was used to assess patency and to identify additional branches. This was done by digital occlusion of the graft on different levels from the probe. Continuous proximal flow in spite of vein compression indicated an overlooked branch, which was identified and ligated.

Finally intraoperative angiography (Stenoscop, Loncin, Belgium) was performed to assess patency, to control the anastomosis and runoff, and to detect overlooked fistulas. These were ligated, and other defects were corrected and recorded. After completion of the reconstruction, the final blood flow in the graft was measured and recorded, as was the operating time and blood loss. The procedures were performed by two staff surgeons or by a vascular fellow assisted by the surgeon, all of whom were familiar with the operation and had some angioscopic experience.

Postoperative follow-up and protocol. Data from the postoperative period included reoperations, wound problems, hospital stay, and early graft occlusion. Postoperative clinical examination was performed at 1 and 12 months. A postoperative graft surveillance program was followed and performed at 1, 3, 6, 9, and 12 months and included ABPI measurements and color-flow duplex scanning investigations (GE Vingmed System 5) by use of a 10-MHz probe. Two trained vascular laboratory technologists performed all duplex scanning and ankle-pressure measurements. Angiographic examination was performed if one of the following signs for failing graft was present: recurrent symptoms of leg ischemia, patent fistulas causing a decrease in the graft flow > 50% distal to the fistulas, significant graft stenosis where the peak systolic velocity ratio was > 3.0, or decrease of the ABPI by > 0.2.

If a stenosis (>70%) or a patent fistula was observed at angiographic investigation, a revision procedure was performed, either as an immediate percutaneous transluminal angioplasty (PTA) or a transluminal "coiling" of the fistula or later as an open surgical procedure.[9,10] In case of an insignificant stenosis or a patent arteriovenous fistula

(AVF) with an insignificant flow steal, no further intervention was undertaken, but subsequent surveillance duplex examinations were performed at reduced intervals.

Data analysis. The patients were followed up for 12 months and primary assisted patency rates were calculated by Kaplan-Meier survival estimates, and the data were compared with log-rank test. Nonparametric variables were presented as median, and the significance of any difference was calculated with the Mann-Whitney test. Categorical parameters were compared by use of χ^2 analysis. *P* values < .05 were considered significant.

RESULTS

In the study 101 patients were enrolled: 32 patients in the angioscopy group A and 69 in the control (no angioscopy) group B. The intention was to include 100 patients, 50 in each group. We used the angioscope in every second patient; no other criteria for selection was used. Problems with our angioscopic equipment made angioscopy impossible for a period during the study. Because of European community regulations we could not repair our equipment or get new equipment, which meant that the condition of this equipment decided in which group patients were included, rather than the operating surgeon or random selection. Therefore there are significantly fewer patients in the angioscopy group.

One patient from each group did not complete the surveillance program as scheduled. However, their grafts were patent at 1 year. Demographic data depicted in Table I were all similar in the two groups, with the exception of cerebrocardiovascular disease, which was seen slightly more often in group B.

Preoperative angiography showed only one distal runoff artery in approximately 80% of the patients and no difference between the groups (Table II). The percentage of patients who underwent preoperative vein mapping did not differ between the groups. The scanning time was 15 minutes per patient. The vein diameter varied but was <3 mm in some part in approximately 70%, and the number of tributaries was similar in both groups. All veins were considered suitable for use as a bypass graft. No operation was prematurely finished as a result of a vein being considered useless at surgery. ABPI was < 0.4 in 54% and 61% in the respective groups. If patients with diabetes were excluded, ABPI was <0.4 in almost 80% (Table II).

The proximal anastomosis was in most cases performed at the bifurcation of the common femoral artery, although in a few cases it was performed at the proximal part of the superficial femoral artery or the deep femoral artery. The distal anastomoses were constructed below the knee and approximately 60% to a crural or pedal artery (Table E I, online only). The quality of the arteries and the veins assessed by the two surgeons did not differ between the two groups.

During angioscopy 172 saphenous vein branches (of these 111 in premapped veins), 34 residual valves (17 patients), and 5 partially occluding thrombi were found. In three cases the angioscope damaged the vein because of varicose or postthrombotic disease. Angioscopic data are presented in Table III.

By flowmetry further branches were found in both groups, although significantly more were found in group B (*P* > .01). However, a few were found during intraoperative angiography; more were found in group B, although the difference was not significant. Adding the number of unligated branches found by flowmetry and angiography resulted in a convincing difference (*P* < .005) between the two groups (Table IV). The median number of vein branches in patients who underwent premapping found by all investigative modalities was 14 and 11 in groups A and B, respectively (*P* < .05). Further residual valve cusps found by flowmetry or angiography was none in group A and four in B (Table IV).

The operating time was similar, but the intraoperative blood loss was less in group B (430 and 320 mL, respectively; *P* < .05). There were no differences between the groups regarding the number of reoperations, postoperative local complications (hematoma, infections, wound necrosis, edema), or postoperative hospital stay (Table E II, online only).

Criteria for failing graft were present in two patients in group A because of graft stenosis and in 18 and 10 patients in group B because of AVFs and stenosis, respectively (Table V). The difference in the number of significant AVF between the groups was statistically significant (*P* < .0001), as was the difference in the total number of primary failing graft, regardless of cause.

The AVF in group B (18 grafts) that were judged as hemodynamically significant were all scheduled for treatment but one. Six grafts occluded—four while waiting for investigation and one was not diagnosed until after graft failure. The last patient was opposed to any further investigation because of absence of symptoms. However, shortly thereafter the graft occluded, and symptoms of critical ischemia recurred. In spite of thrombolysis none of these grafts could be saved (Table V). Four of the 12 treated patients later had development of stenosis distal to the occluded AVF.

The two primary graft stenoses in group A and six in group B were successfully treated by PTA (Table V). Three grafts in group B occluded before scheduled treatment and could not be reopened.

A second episode of failing graft, caused by stenosis, was seen in six patients in group B, and five were successfully treated by PTA (Table V). The increase in ABPI in patent grafts 1 year after operation was 0.6 in both groups (Table E III, online only).

In three patients in group A and two in group B, wound dehiscence caused by massive leg edema, local skin necrosis, and infection over the distal anastomosis resulted in graft occlusion. It was not possible to reopen those grafts.

The 1-year primary patency rate was 69% in group A, which was significantly higher than the 42% in group B (*P* < .01). The primary assisted patency rate was 72% and 70% in groups A and B, respectively, with no statistically significant difference (Figs 1 and 2).

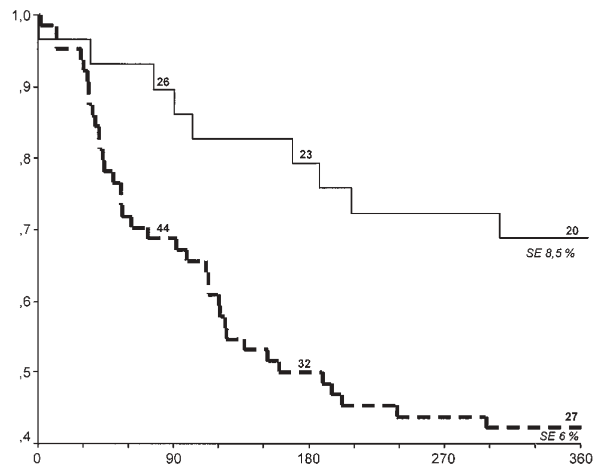

Fig 1. One-year primary patency rate. There is significant difference between group A *(solid line)* and group B *(dashed line)* ($P < .01$). Numbers represent grafts available for follow-up at 3, 6, and 12 months. Standard error < 10% at 12 months for both groups.

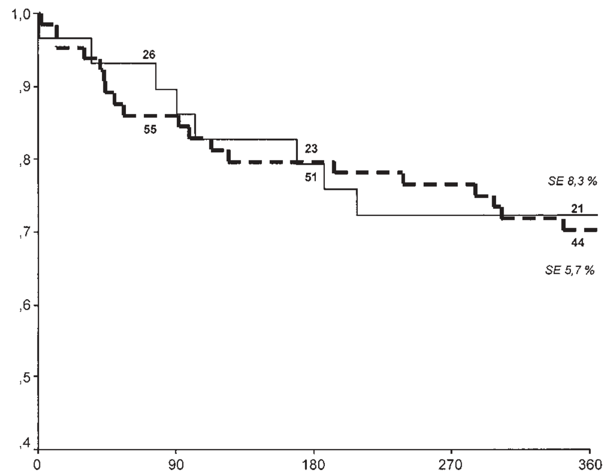

Fig 2. One-year primary assisted patency rate. There is no difference between groups A *(solid line)* and B *(dashed line)*. Numbers represent grafts available for follow-up at 3, 6, and 12 months. Standard error < 10% at 12 months for both groups.

Table III. *Result of angioscopic investigation*

Angioscopy (n = 32)	*Total*	*Median/mean*
Irrigation fluid		
mL		550
Range		(200-1000)
Residual valve cusps (n = 17)	34	2
Branches		
Total	172	
Only premapped veins (n = 26)	111	4.3
Thrombi	5	
Vein damage	3*	

*One was caused by varicose vein (12 months patent), two were due to fibrous changes (one occluded, one patient died at <1 year).

Seven grafts in the angioscopic group and 20 in group B occluded during the surveillance period. Early deaths (within 30 days) included three patients in each group, and the 1-year mortality rate was 10% in both groups. All but two (in group B) had patent grafts at the time of death. The amputation rate was 16% and 7% in groups A and B ($P = .17$), respectively, all of which had occluded grafts.

DISCUSSION

Different preoperative, intraoperative, and postoperative investigations, such as duplex vein mapping, intraoperative angiography, angioscopy, flow measurements, and specially designed surveillance programs, have been advocated to improve the surgical outcome of in situ distal bypass grafting.[10-13] The operative technique may thereby be refined, minimizing the risk for technical errors and also implying a possibility for an early correction, thus improving the operative results. It may also give an indication of the outcome of the procedure.[14-17]

Preoperative mapping is not a standard procedure, but Maini et al[3] described its advantages in 1993. When tributaries are localized before surgery, they can be ligated through small skin incisions before other intraoperative investigations are performed. Preoperative vein scanning also reduces postoperative wound complications, because several small skin incisions are used instead of a long incision to visualize the entire vein. Our experience of mapping agrees with that of Maini's group: early ligation of mapped branches, better angioscopic sight with less irrigation fluid, and easier diagnosis of fistulas by flowmetry and angiography.

Angioscopy has so far not gained full recognition. Some surgeons even find it unnecessary.[18] Others still consider it to be an excellent method for an intraoperative evaluation of the vein bypass, thereby reducing the risk for eventual graft failure.[19-21] Our results support this statement.

Maini et al[3] found that the length of hospital stay and wound complications were significantly reduced. However, in contrast to our study, they did not observe any impact on the 12-month primary patency rates.

Wilson et al[6,22] and others[23] have elucidated the relevance of the quality of the vein for the success of bypass grafting. On the basis of these studies, they also stated that using an angioscope with care did not cause significant disease for the later graft function. This is supported by other published series.[3,6,18] In a couple of cases in group A, we found changes in the vein wall indicating preexisting disease, such as fibrous strands or local fibrous stenosis, with anticipated negative effects on future graft function if not taken care of. This may explain why primary stenosis developed earlier in group B, where these preexisting defects were less likely to be visualized during surgery. Our data have not indicated any obvious risk for endothelial damage

Table IV. Number of fistulas and residual valve cusps found with flowmetry or angiography

	A *all (n = 32)* *premapped (n = 26)*	*B* *all (n = 69)* *premapped (n = 62)*
Flowmetry		
Fistulas		
All	39	158
Only premapped	31	140*
Median premapped	1	2*
Valve cusps (residual)	0	3
Angiography		
Fistulas		
All	10	48
Only premapped	9	42
Valve cusps (residual)	0	1
Flowmetry and angiography		
Fistulas		
All	49	206
Only premapped	40	182†
Median premapped	1	2†

Statistical calculations are made only on patients who underwent premapping.
*$P < .01$.
†$P < .005$.

Table V. Result of postoperative surveillance by duplex Doppler scanning and clinical inspection and treatment of AVF and stenosis by surgery, coiling, or PTA

	A (n = 32)			*B (n = 69)*		
Postoperative surveillance	*Fistula/stenosis*	*Grafts*	*Successful treatment**	*Fistula/stenosis*	*Grafts*	*Successful treatment**
AVF at 1 month	0	0	—	45	28	
Nonsignificant AVF/ spontaneous AVF occlusion	—	—		15	10	
Failing graft—primary						
Significant fistulas	0	0		30†	18	
Treated AVF coil/surgery	—	—		19	12	12
Stenosis distal to AVF	—	—		—	1	1
No treatment graft occlusion	—	—		11	6	0
Stenosis distal to AVF	—	—		—	2	0
Significant stenoses	2	2		10	10	
Days after surgery (range)	305-365			30-100		
Treated stenosis PTA/surgery	2	2	2	7	7	6
No treatment graft occlusion	—	—	—	—	3	0
Failing graft—secondary						
Stenosis	0	0	0	6	6	5
Days after surgery (range)				144-339		

Graft fistulas are found only in group B, and significant stenoses are more frequently seen in group B, but without significance.
*Defined as a patent graft.
†$P < .0001$.

caused by the angioscope and later graft failure. However, it is notable that the time elapsed from surgery to the occurrence of the stenosis was longer in group A than in group B. Interestingly, within the observation period restenoses were seen only in group B approximately 300 days after operation, that is at the time when the problem first arose in group A. A further indication that angioscopy probably has little or no negative long-term effects on the endothelium. In our study 10% of the grafts developed significant stenosis. Others have reported up to 30% graft stenosis within the first year.[24-27] The cause of vein graft stenosis in the in situ graft is not quite understood; however, several authors believe that there are predisposing factors such as vein size, tributaries, valve cusps, structure, and effect of the valvulotomy.[25,28-30]

In our two groups preoperative mapping did not indicate significant differences in vein diameter, number of tributaries, or abnormal structure. In group A the result of valvulotomy could be inspected and, in cases of incomplete valve destruction, immediately corrected. Obviously this was impossible in group B, and, if the number of incompletely cut valves was the same in both groups, only a small fraction of them were found by flowmetry or angiography. Is an incompletely disrupted valve cusp after all a focus for the formation of early stenosis as was found in group B? This could mean that the pathogenesis for strictures differs in the two groups. In light of our results the role of the cusps cannot with certainty be discarded. However, if residual valves are one of the causes, the effectiveness of the valvulotome must be questioned.

Flowmetry is not the method of choice to diagnose problems with incompletely divided leaflets. Those found in this study were a result of the exclusion of other causes for an extremely low flow in an otherwise good bypass graft. This suspicion was confirmed by angiography. Angiography is, however, inferior to angioscopy for detection of incomplete disruption of valve cusps or other intimal defects[6,31-33] but is a good complement for visualization of the distal anastomosis and the runoff situation.

The most striking result in our study is the complete absence of postoperative AVF in the angioscopy group. We believe it is important to ligate hemodynamically significant AFVs.[34,35] In spite of careful preoperative duplex scanning of the vein, we failed to visualize all branches. In group A these overlooked AVF were found and ligated. Probably, some insignificant branches were also ligated. This is indicated by the fact that there were significantly more branches in group A, even if the number of AVF found after operation in group B were added. Furthermore several AVF found during the postoperative surveillance program were considered hemodynamically insignificant. They all occluded spontaneously. Angioscopy may result in overtreatment of AVF with no hemodynamic significance, but we believe that this is justified by the fact that 18 (26%) patients in group B perhaps would not have needed a reintervention, neither surgical nor radiologic. Besides, reinterventions are both time consuming and costly. Lundell and Nyborg[34] reported 98 in situ bypasses, with 18% overlooked AVF that needed revision. Similar results are reported by van Dijk et al.[36] In a study with angioscopic assistance made by Rosenthal et al[37] the number of disregarded AVF was only 6%, a result that is in agreement with ours. During operation there is a risk for spasm in the branches temporarily abolishing their flow, making them difficult to find with flow measurement or angiography. In spite of papaverine injection into the graft, we did not detect further AVF.

Finally, it is known that some significant branches have competent valves in the orifice, readily seen with the angioscope in group A but impossible to diagnose and thus never taken care of in group B. With increasing flow and pressure in the graft, these valves eventually yielded, and an AVF was created.

Fluid volume administered to patients during angioscopy could be hazardous, especially when given to this group of elderly patients with a high frequency of heart disease.[18] We have reduced the flush volume by early ligation of the graft branches before angioscopy and by doing most of the investigation before the distal anastomosis was finished. Most of the irrigation fluid is thereby flushed through the distal end of the graft. The final angioscopic control is thereafter possible to do with a small amount of fluid.

Angioscopy revealed a lot of valve remnants, which would otherwise not have been found. We treated them during surgery, because we believed that would optimize flow. However, it is not known how many of these were of clinical significance. Whether the valvulotome used had any negative effect on the number of valve remnants is not possible to evaluate. Compared with other devices we have used, this valvulotome has been easy to handle, and no complications caused by the instrument, such as perforation or rupture, were recorded.

In conclusion we have confirmed the advantage of using angioscopy for in situ vein graft preparation. Angioscopy improved the primary graft patency rate by early detection of AVF, uncut valve cusps, and other defects and accordingly reduced the need for later reintervention. From our experience we consider angioscopy a good investigative modality, but more as a complement to flow measurement and angiography than a replacement.

With a more modern technique with angioscopic side branch occlusion during surgery, the number of skin incisions may be significantly reduced, with even fewer skin problems and also reduced operating times, as described by Rosenthal.[4] This study has also indicated that preoperative visualization and quality assessment of the vein with duplex Doppler scanning is invaluable in helping to make the angioscopic investigation faster and easier and thus has an unambiguous effect on the results of surgery.

Whether the valvulotome technique used in this study had any implication is difficult to evaluate. The finding of incompletely incised valves in both groups is open for speculation, and probably the perfect valvulotome is yet to be found.

We thank Christel Jungbeck and Karin Peterson, our two very competent vascular laboratory technologists, for their alertness and zeal.

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Submitted Feb 15, 2001; accepted July 17, 2001.

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