"CLOSED" IN SITU VEIN INFRAINGUINAL BYPASS

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"CLOSED" IN SITU VEIN INFRAINGUINAL BYPASS

"gesloten" in situ infrainguinale bypass

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Co-promotor:	Dr C.H.A. Wittens

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Aan Parvin en mijn ouders,
voor Raïssa en Magda.

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Chapter 1

INTRODUCTION

1.1 Introduction

The autologous greater saphenous vein is considered to be the best bypass material for below knee femoropopliteal and femorocrural arterial reconstructions.

The history of the greater saphenous vein arterial bypass in humans started in 1949, with its first introduction by Kunlin.[1] Upto 1959, when Rob performed the first in situ saphenous vein bypass,[2] the reversed saphenous vein technique of Kunlin was the standard procedure. The first publication about the in situ bypass was written in 1962 by Karl Victor Hall.[3] After this preliminary report, several optimistic reports, written by Hall, Connolly, May and Samuel [4-7] followed. Despite the promissing results, the in situ bypass technique only achieved minimal popularity, mainly in Europe. It was not before Leather, Powers and Karmody published their historical publication in 1979 that the in situ bypass really was considered to be a worthy alternative for the "reversed" technique.[8] Their excellent results received worldwide attention and contributed to the adoption of the in situ bypass technique in many major vascular surgery departments during the early eighties (including those in the USA).

Hall's original in situ bypass technique can be briefly described as follows:[3] After exposure of the greater saphenous vein (GSV) via one long skin incision, the proximal end of the GSV was cut loose from the femoral vein and anastomosed end to side to the common femoral artery. Each of the competent vein valves was excised through a transverse venotomy and all vein side branches were ligated. At the end of the procedure, before the distal anastomosis was performed, a retrograde venography of the (arterialised) GSV was performed to discover hidden side branches. One of the disadvantages of Hall's original technique was the need for multiple, technically demanding, venotomies for valve excision. In 1968, Samuels et al. had already introduced a retrograde valvulotomy procedure.[7] In 1973 Skagseth and Hall introduced Hall's modification of Samuels original idea:[9] the Hall valvulotome. Before this, Connolly had introduced an antegrade "vein plunger" technique for treatment of the vein valves in the GSV, but this technique was not widely followed.[5]

Ever since the introduction of the in situ vein bypass, the question was whether this technique was better than the reversed saphenous vein technique. Theoretically the in situ vein bypass has the advantage that the vein is not removed from its bed.

The removal of the GSV from its bed for the reversed vein technique leads to disruption of the vasa vasorum of the vein and a temporary preservation in an ischaemic environment is necessary. This may cause endothelial damage, which can lead to early graft thrombosis.[10-12] Other degenerative changes of the vein attributed to its removal, are intimal thickening and atherosclerotic changes.[13] Another advantage claimed of the in situ vein technique compared to the reversed technique is the better diameter compatibility of the non-reversed GSV, especially if it is used for a femorocrural arterial reconstruction.[14] In spite of the theoretical advantages of the in situ vein technique compared to the reversed technique, the patency rates of both types of bypasses were not different in two randomised studies comparing both techniques.[15,16] Examples of currently reported excellent patency rates of in situ bypasses are: 84 - 92% at 15 months and 78 - 83% at 2 years.[17,18]

A disadvantage of both the reversed and the standard "open" in situ vein bypass technique, with surgical exposure of the GSV via one long skin incision, is the high incidence of postoperative wound complications. Wound complications after in situ bypass grafting are considered to be more threatening, due to its subcutaneous position, whereas reversed bypasses are usually tunnelled along the anatomical path of the arteries. In two retrospective studies dealing with postoperative wound complications after in situ bypasses the incidences found were 33% and 44%.[19,20] Deep wound complications, with bypass involvement may have serious consequences like graft failure, limb loss or death. Wound complications not involving the bypass usually have less serious consequences, but lead to prolonged wound observations and care, thus prolonging hospital stay and increasing hospital costs.[21] A logical step to reduce wound complications was the development of operating techniques with a reduced skin incision length. One method is to ligate the side branches of the GSV via separate small skin incisions instead of exposing the entire vein through a long skin incision. To allow this technique, the valvulotomy procedure has to be performed either "blindly" (without direct visualisation of the GSV) or under endoscopic control. The endoscopically controlled valvulotomy offers the advantage of direct visualisation of the completeness of the valvulotomy procedure.

However, Clair et al. showed in a randomised trial,[22] that endoscopically assisted valvulotomy did not result in a better bypass performance compared to valvulotomy without endoscopy during in situ bypass grafting using the Mills valvulotome.

Selective ligation of venous contributaries can be performed via separate small skin incisions after intraoperative localisation with angiography (with radiopacque markers), with a Doppler device or with colour-flow Duplex scanning.[23,24] Another option is to locate the side branches endoscopically. With these techniques, the need for one long skin incision is obviated, but several small skin incisions beside the incisions necessary for the anastomoses, remain.

The final step to a more "closed" technique, with reduced skin incision, involves the closure of the side branches of the vein from its lumen. The first publication in 1991 of intraluminal sidebranch occlusion was written by Stierli and Aeberhard.[25] In 5 patients a total number of 10 side branches were successfully coil embolised, using an "occluder valvulotome": a modified Mills' valvulotome with an integrated working channel allowing insertion of a catheter for coil embolisation of side branches. The coil embolisation was performed under angioscopic guidance. Rosenthal et al. described a series of "closed" in situ bypasses in 1992.[26] They used an electronically steerable nitinol catheter system to selectively, per-operatively catheterise and coil-embolise the side branches of the vein. Intraoperative coil-embolisation was performed under angioscopic and fluoroscopic control. In 46 patients a total number of 84 side branches were embolised with coils. In 39 patients (85%) additional small skin incisions were necessary to ligate or clip side branches that could not be embolised. The occurrence of postoperative open side branches (residual arterio-venous fistulas) was not mentioned in this preliminary report. Wound complications occurred in only 6% of the patients, but no details about the severity of the wound complications were given. The one year patency rate (13 grafts at risk), was 84%. The authors did not mention if this was primary or secondary patency.

In 1993 Chervu et al. described their initial experience in 3 patients in which they used a 6F or 7F tracker catheter for the coil embolisation procedure.[27] The operation time was seriously prolonged (1 to 5 hours increase) by the endovascular coil embolisation procedure. In two of these patients wound complications occurred and residual arterio-venous fistulas were seen twice. One graft occlusion occurred within the first postoperative year.

This rather disappointing result led to the recommendation that better instrumentation had to be available to allow more successful "closed" in situ bypass procedures.

Cikrit et al. used the same electronically steerable nitinol catheter system as used by Rosenthal in a series of 30 patients (31 limbs).[28] After the first 16 operations they abandoned the angioscopic control during valvulotomy and coil embolisation. Valvulotomy was then performed "blindly" and the peroperative coil-embolisation was performed under fluoroscopic control only. In 31 operations a total number of 97 side branches (3.2 per patient) were (coil) embolised. In seven patients (23%) an additional skin incision was necessary to ligate side branches that could not be embolised. In 39% of the cases residual arterio-venous fistulas were found and treated postoperatively. In 13% of the patients postoperative wound complications were reported. Early graft failure (within 30 days of the operation) was 6%. One year patency rates were not reported.

In Rotterdam, a "closed" in situ bypass technique was developed, using a variable valve cutter for the valvulotomy procedure and a co-axial embolisation catheter system for fluoroscopically controlled intraoperative coil embolisation of the side branches. *This new "closed" in situ bypass technique is the subject of this thesis.* The main questions evaluated in the next chapters are:

1. Is the "closed" in situ bypass technique developed in Rotterdam technically feasible?
2. What are the advantages (i.e. less wound complications) and disadvantages of a "closed" technique in comparison with the standard "open" technique?
3. Is the "closed" technique, compared to the standard "open" technique, cost-effective?
4. What are the consequences of residual arterio-venous fistulas after "closed" in situ bypass grafting?
5. What is the value of preoperative ultrasound mapping of the greater saphenous vein prior to "closed" in situ bypass grafting.

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Chapter 2

A NEW "CLOSED" IN SITU VEIN BYPASS TECHNIQUE

C.H.A. Wittens[1], L.C. van Dijk[2], N.A.J.J. du Bois[1] and H. van Urk[1].

Departments of Vascular Surgery[1] and Radiology[2]
University Hospital Rotterdam "Dijkzigt"
Dr Molewaterplein 40
3015 GD Rotterdam
The Netherlands

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2.1 Abstract

Aim: We have developed a new closed technique using a co-axial embolisation system for intraoperative coil embolisation of the side branches of in situ vein bypass grafts in order to avoid long incisions.

Technique: After completion of the proximal anastomosis, disruption of the valves and completion of the distal anastomosis, the catheter is introduced via a proximal side branch of the greater saphenous vein. Under fluoroscopic control the side branches are identified, selectively catheterised and an embolisation coil is positioned in each side branch.

Patients: In 14 patients (eight men, six women), 16 in situ bypasses were performed (12 below knee femoro-popliteal, 4 femoro-crural).

Results: Once mastered the embolisation procedure took less than one hour. In four cases persistent arterio-venous fistulas had to be treated in the postoperative period. Two major wound complications occurred and there were three early failures. One late failure occurred due to a rupture of the venous bypass 6 weeks postoperatively. The remaining 12 bypasses are patent, with a median follow-up of 16 (3 - 26) months.

Conclusion: These preliminary results suggest that the "closed" technique is feasible and that long term occlusion of AV-fistulas can be achieved without ligation via incisions.

Key Words: In Situ Bypass, Embolisation, Wound Complication.

2.2 Introduction

The in situ technique, using the greater saphenous vein as an arterial bypass in the lower extremity without reversing it, is the preferred technique in many clinics. After its introduction by Hall in 1962,[1] it took untill the early 1980s that the in situ technique gained more general acceptance.[2] Especially when long, very distal bypasses are required, the in situ technique excells because of its superior vein utility compared to the reversed technique.[3] Two specific procedures are inevitable during the in situ procedure: (1) The valves in the vein have to be rendered insufficient for which a number of valve cutting devices are available, and (2) The side branches of the vein have to be closed. Currently the side branches are ligated or clipped via one long or several short skin incisions. These long skin incisions can lead to a large percentage of wound complications.[4] Reifsnyder et al reported a wound complication rate of 44% after in situ bypass operations.[5]

We developed a new "closed" technique, using a co-axial catheter embolisation system for intraoperative coil embolisation of the side branches of the vein, obviating the need for a long or multiple short skin incisions. In this paper we present the first preliminary results of this technique.

2.3 Patients and methods

Patients: In 14 patients (eight men and six women), 16 "closed" in situ bypasses were performed. Indications were: severe disabling claudication in four legs; restpain in five legs; ulcer(s) and/or necrosis in seven legs. The proximal anastomosis was "end to side" to the common femoral artery in 12 legs; "end to end" to the proximal superficial femoral artery in two legs and "end to side" to an aorto-femoral prosthesis in two legs. The distal anastomosis was "end to end" or "end to side" to the infragenicular popliteal artery in 12 legs; "end to side" to the anterior tibial artery in three legs and "end to side" to the posterior tibial artery in one leg. At first a skin incision was made at the location of the (planned) distal anastomosis. The receiving artery and the greater saphenous vein were identified. A similar procedure was performed at the proximal anastomosis site.

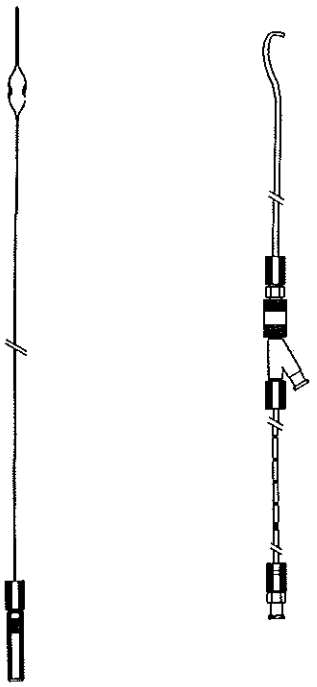

Fig. 2.1. A schematical drawing of the valvecutter and the co-axial embolisation catheter.

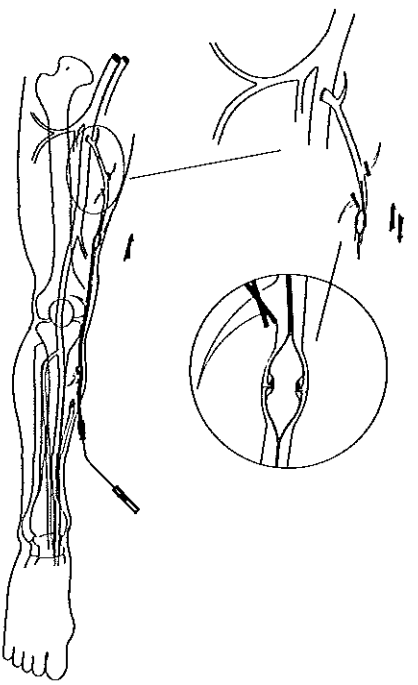

Fig. 2.2. A schematical drawing of the valvecutter as used during the operations.

After the proximal anastomosis was completed, the arterial flow was restored down to the first competent valve in the greater saphenous vein.
The valves were disrupted with a newly designed variable valvecutter (Cook®) and than the distal anastomosis was completed. The co-axial embolisation catheter (Cook®) was introduced via a proximal side branch of the greater saphenous vein. Under fluoroscopic control the side branches were identified, selectively catheterised and an embolisation coil (Cook®) was positioned in each side branch (see figure 2.1, 2.2 and 2.3). At the end a completion angiogram was obtained before skin closure.

Follow-up up to 26 months consisted of regular colour Duplex scanning and Doppler systolic pressure ankle-arm index measurements. If these non-invasive tests indicated problems an angiogram was obtained.

2.4 Results

There was no postoperative mortality. In the 16 "closed" in situ bypass procedures, a total number of 122 side-branches were coil embolised (average eight per bypass).Three postoperative complications were evaluated: arterio-venous fistulas, bypass occlusions and wound problems (see table 2.1).
We observed that persistent coiled side-branches of the in situ bypass usually occlude within 1-2 weeks (figure 2.4). In two patients AV-fistulas causing problems were detected whithin the first week after the operation and had to be treated operatively: in one of these patients a fistula was clipped to treat local redness and pain of the skin; in the other patient an early occlusion of the bypass occurred due to inflow problems combined with four patent AV-fistulas. In eight patients AV-fistulas were detected by color duplex examination later in the follow-up period, of which only two had to be treated: In one patient three AV-fistulas with a significant shunt were coil embolised percutaneously in a separate session 2½ months postoperatively. In the other patient a patent arterio-venous fistula was detected by angiography 3 weeks postoperatively and treated surgically. In six patients small arterio-venous fistulas to the superficial venous system were left untreated because they were symptom-free.

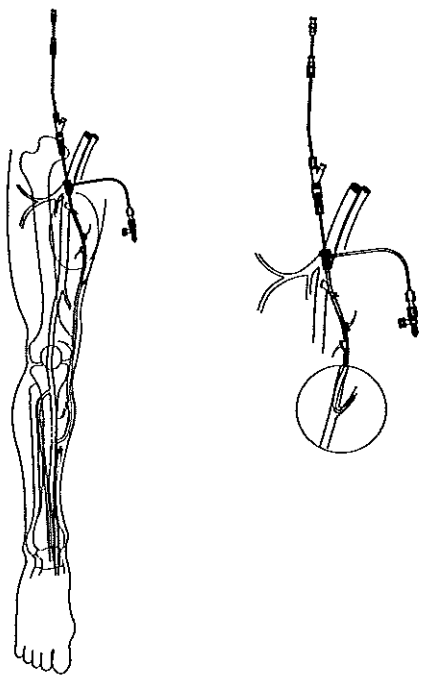

Fig. 2.3. A schematical drawing of the deposition of an embolisation coil in a side branch via the co-axial catheter.

Three early bypass occlusions occurred. One early occlusion occurred in the group of 12 infragenicular popliteal bypasses. This was due to a technical error at the distal anastomosis combined with a poor run-off.

Embolectomy with revision of the distal anastomosis 1 week after the first operation resulted in a patent bypass for only 1 day. After a second failed embolectomy a below knee amputation was performed two weeks after the first operation. The second early failure has already been mentioned and was caused by insufficient inflow and one large and three smaller remaining arterio-venous fistulas. These problems were treated operatively two weeks after the first operation and the bypass has remained patent since (follow-up 16 months). The third early occlusion occurred in the group of four femorocrural bypasses. In this case there was a distal triplication of the greater saphenous vein. After occlusion 1 week postoperatively a revision was performed using a short PTFE-graft. Nine months postoperatively this revised bypass occluded and was not reoperated, but upto now (19 months postoperatively) this has not resulted in an amputation.

Table 2.1 Summary of the results

	Distal anastomosis to popliteal artery (n = 12 bypasses)	Distal anastomosis to crural artery (n = 4 bypasses)
Occlusions	1	2
Early successful revision (< 1 month postoperative)	1	1
Late successful revision (> 1 month postoperative)	0	1
Major amputations	1	0
Arterio-Venous fistulas needing treatment	4	0
Follow-up of primary patent bypasses	10 bypasses: 16 months (range 3 - 26)	2 bypasses: 16 and 15 months
Follow-up of secondary patent bypasses	1 bypass: 16 months (revision 2 weeks, post first operation)	0

In 16 in situ bypass operations two major wound complications (13%) occurred. In one patient a haematoma had to be drained surgically and in another patient a wound dehiscence led to rupture of the bypass. A revision and transposition of the bypass had to be performed 6 weeks postoperatively. This revised bypass occluded 9 1/2 months postoperatively, but to date no amputation has been necessary.

Six minor wound complications were treated conservatively. With a median follow-up of 16 months (range 3 - 26), 10 bypasses to the infragenicular popliteal artery are patent (primary patency: 81%). One infragenicular femoro-popliteal bypass revised two weeks postoperatively is patent with a follow-up of 16 months (primary assisted patency: 92%). Two crural bypasses are patent with a follow-up of 16 and 15 months (primary patency: 50%).

2.5 Discussion

The in situ technique inevitably involves the occlusion of side branches of the greater saphenous vein. Currently these side branches are either ligated via multiple short incisions or via one long incision. In patients with occlusive arterial disease postoperative wound complications frequently occur [6,4] and longer skin-incisions may be related to an increased wound complication rate.

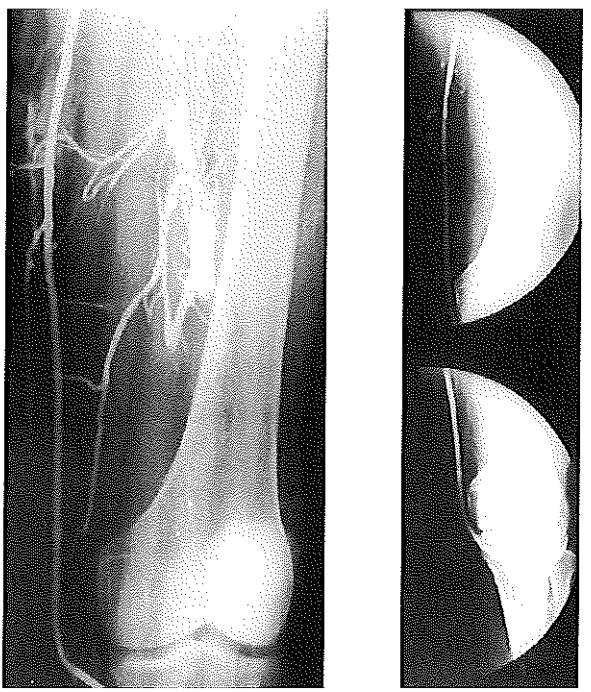

Fig. 2.4. Angiogram of an in situ bypass with coil embolised side branches: Left: peroperatively, Right: 1 month postoperatively.

The new technique described here, utilising a co-axial catheter for coil embolisation of the side branches of the greater saphenous vein, obviates the need for the long skin incision and therefore might diminish the frequency of wound complications.

Per-operative coil embolisation is new, but coil embolisation as a separate procedure for remaining arterio-venous fistulas with haemodynamically significant shunting after in situ bypass operations, has already been described.[7] One of the problems of this new technique is the occurrence of postoperative AV-fistula-related problems, e.g. haemodynamically significant shunting or impairment of skin blood flow. It is a matter of controversy which side branches have to be closed to prevent AV-fistula-related problems. There are three causes for the postoperative appearance of non-coiled AV-fistulas. First there are side branches with intact valves that can be "missed" under fluoroscopy because there is no blood flow from the greater saphenous vein into the side branch. These valves may be subsequently become incompetent due to the arterial pressure in the bypass. Secondly, small side branches are difficult to detect due to insufficient fluoroscopic material and therefore not coil-embolised, or when very small side branches are detected, they are not coil-embolised because they are not expected to cause problems. Postoperatively these small side-branches can enlarge under arterial pressure and cause late AV-fistula related problems. Thirdly some side branches mostly with an angle of more than 120^0, could not be coil-embolised. To avoid the development of persistent fistulas, we could try to visualise the side branches with intact valves by angioscopy or possibly peroperative Duplex scanning. Whether this is necessary remains uncertain because not all side branches with intact valves will cause AV-fistulas and even if they do, they do not always cause problems.

In this series, we tried to coil-embolise all side branches we could detect. In a new series, we plan to perform pre- and postoperative vein-mapping using colour Duplex scanning and by combining these findings with the per-operative angiography, we hope to identify side branches that will cause postoperative AV-fistulas related problems. Postoperative AV-fistulas in coiled side branches can theoretically occur, but we did not detect them. By optimising the fluoroscopy equipment and technique during the period of this pilot study, we have the impression, that toward the end of our learning curve the incidence of persisting AV-fistulas was diminishing.

Thorough follow-up and immediate correction if necessary will prevent major AV-fistula-related problems, e.g. skin necrosis and distal graft occlusion due to steal.

At this time 11 of the 12 below-knee femoro-popliteal and two of the four femoro-crural bypasses are patent. Only in one case bypass failure was probably related to the new technique, because occlusion occurred in a distal triplication of the greater saphenous vein below the knee. An anatomical variation of the greater saphenous vein, like a duplication or a triplication, hampers the coil embolisation of side-branches considerably and should therefore be considered as a contra-indication for this technique. Currently we perform Duplex investigation of the greater saphenous vein preoperatively to identify these anatomical variations. This vein-mapping, as advocated by Ruoff et al.,[8] is especially worthwhile in selecting patients for "closed" in situ bypass operations.

In these 16 in situ bypasses, two major and six minor wound complications occurred. Due to the significant learning curve required for this procedure, illustrated by the time the embolisation procedure took in the first patients (> 2 hours) and the last patients (< 1 hour), we think that this wound complication rate can be reduced.

The preliminary results of the new "closed" in situ bypass technique suggest that the technique is feasible. To establish the clinical value of this technique, with special attention to the wound complications and the occurrence of clinical relevant arterio-venous fistulas, a prospective randomised trial has been started.

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Chapter 3

A NEW "CLOSED" IN SITU VEIN BYPASS TECHNIQUE RESULTS IN A REDUCED WOUND COMPLICATION RATE

L.C. van Dijk[1,2], H. van Urk[1], N.A.J.J. du Bois[1], T.I. Yo[3], J. Koning[4], W.B.J. Jansen[4], and C.H.A. Wittens[5].

Departments of Vascular Surgery[1] and Radiology[2]
University Hospital Rotterdam "Dijkzigt", Rotterdam
Department of Surgery[3], St. Clara Hospital, Rotterdam
Department of Surgery[4], Reinier de Graaf Hospital, Delft
Department of Surgery[5], St. Franciscus Hospital, Rotterdam

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3.1 Abstract

Objectives: This prospective randomised multicentre trial was conducted to test whether a new "closed" technique for in situ vein bypass would result in a lower frequency of wound complications, without negative effects on patency rates and without an intolerable increase in residual arteriovenous fistulas compared to the conventional "open" technique.

Methods: We developed a new "closed" technique using a co-axial catheter embolisation system for intraoperative coil embolisation of side branches, in order to avoid long incisions.

Patients: In four centres, and 95 patients, 97 in situ bypasses were performed: 47 "closed" and 50 "open". Randomisation was stratified for below knee femoropopliteal bypasses (60) and femorocrural bypasses (37). Indications were disabling intermittant claudication (29), restpain (26) or ulcers and/or necrosis (42).

Results: Postoperative mortality was 2 % (one in the "closed", one in the "open" group). A total number of 16 (34%) wound complications (grade 1, 2 and 3) occurred in the closed group compared to 36 (72%) in the open group ($P < 0.05$). Deep wound complications (grade 2) occurred in six patients (13%) of the "closed" group, compared to 15 (30%) in the "open" group. In both groups three patients (6%) developed deep wound complications including the bypass area (grade 3). In the "closed" group, 20 patients needed additional treatment for arteriovenous fistulas, compared to four in the "open" group. One year patency rates did not show a statistically significant difference: primary patency rates were 65% and 61% and secundary patency rates were 86% and 76% respectively for the "closed" and "open" group.

Conclusion: These results indicate that a "closed" technique reduces wound complication rate, without negative effects on the short term patency rates. The "closed" technique results in an increased number of postoperative treatments for residual arterio-venous fistulas.

Key words: In Situ Bypass, Wound Complications, Coil Embolisation, Closed Technique, Randomised Controlled Trial.

3.2 Introduction

Using the in situ vein bypass technique, one long incision or several short incisions are necessary in order to ligate the side branches of the greater saphenous vein, not infrequently leading to wound healing problems. As previously reported,[1] we have developed a new "closed" in situ bypass technique, using a co-axial catheter embolisation system for intraoperative coil embolisation of the side branches of the vein, obviating the need for one long or multiple short, skin incisions. Our pilot study showed a wound complication rate of 50 % (13% major, 37% minor) compared to Reifsnyder et al., who found a wound complication rate of 44% after conventional in situ bypass operations.[2] We wondered whether the reason for this failure to reduce the wound complication rate was that the peroperative embolisation procedure had a long learning curve. To test our hypothesis that this new technique would indeed result in a lower wound complication rate without a negative effect on patency rates and without an intolerable incidence of postoperative residual arteriovenous fistulas, we conducted a multi-centre prospective randomised trial to compare the new "closed" technique with the conventional "open" technique.

3.3 Patients and Methods

In four centres and 112 patients, 114 limbs were preoperatively randomised: 57 to the new "closed" technique and 57 to the "open" technique. Patients were randomised after informed consent was obtained. Criteria for randomisation were: lower extremity atherosclerotic disease resulting in disabling claudication, restpain or ulcers/necrosis for which an in situ bypass was planned. Stratification was done within centre and randomisation was stratified for below knee femoropopliteal bypasses and femorocrural bypasses. Peroperatively 17 operations were converted to other procedures, resulting in 97 in situ bypasses that could be analysed: 47 "closed" and 50 "open" (60 femoropopliteal and 37 femorocrural). Patient characteristics are summarised in table 3.1.

Indications for surgery were disabling intermittant claudication (29), restpain (26) or ulcers and/or necrosis (42). The risk factors and indications distribution between both groups was not statistically significant.

Table 3.1 Patient characteristics

	Closed (n = 47)	*Open* (n = 50)
Female	28 %	38 %
Male	72 %	62 %
Age (years)	71	72
Diabetes	15 %	28 %
Smoking	53 %	36 %
Hypertension	30 %	30 %
Ischaemic heart disease	30 %	40 %
Fontaine II	36 %	26 %
Fontaine III	24 %	28 %
Fontaine IV	40 %	46 %
Redo - procedures	13 %	6 %

Patients receiving the "closed" technique were operated as described in the pilot study of Wittens et al. [1] After exposure of the artery and the vein below the knee and in the groin the proximal anastomosis between the greater saphenous vein and a femoral artery was performed. The first side branch of the vein was preserved to hold the introducer sheet for the embolisation catheter. A "blind" valvulotomy was performed via the incision for the distal anastomosis using a variable valvecutter (Cook®). This valvecutter was advanced up to the groin and gradually pulled back, allowing arterial flow along the disrupted valves. This procedure was repeated once with the valvecutter rotated over 90°. Subsequently, the distal anastomosis was made. A coaxial embolisation catheter (Cook®) was advanced over a guide wire via the side branch. Using fluoroscopy and half diluted contrast medium, the side branches were identified and subsequently coil embolised, beginning distally and ending proximally.

During the "open" technique, the greater saphenous vein was exposed over the entire length needed for the bypass via one long incision. Valvulotomy was performed under vision and the side branches were clipped or ligated.
At the end of the procedure a completion angiogram was made. All skin incisions were closed with staples. The site of the distal anastomoses is shown in table 3.2.

Table 3.2 Distal anastomosis

	Closed (N = 47)		*Open* (N = 50)	
Below knee popliteal	26	(55 %)	29	(58 %)
Tibioperoneal	3	(6 %)	1	(2 %)
Anterior tibial	4	(8 %)	8	(16 %)
Posterior tibial	11	(23 %)	8	(16 %)
Peroneal	3	(6 %)	4	(8 %)

Wound observations were performed daily by the senior house officer and regularly by the staff surgeon. Beside these observations a second wound inspection was performed by the Infection Control Practitioners of the Departments of Hygiene and Infection Control. Wound complications were classified according the grades described by Szilagyi et al. [3]: grade 1: superficial, involving the dermis, grade 2: also including the subcutis and deeper layers, but not the bypass area, grade 3: deep, including the bypass area. Wound complication sites were defined as follows: groin (proximal anastomosis site), upper leg, lower leg (not the distal anastomosis site), distal anastomosis site.
After hospital discharge, wound inspection was performed during visits to the outpatient clinics by the resident or the surgeon.

Bypass patency and occurrence of open side branches or arteriovenous fistulas (AVF) was monitored by colour Duplex before discharge and at 3 monthly intervals.

Statistics: The chi-squared test was used to calculate *p*-values for differences in wound complication rate and the Kaplan Meier method was used to estimate the probability of patency. Possible differences in patency rates were checked using the log-rank test. A P-value < 0.05 was considered statistically significant.

3.4 Results

In 17 of the 114 randomised patients the planned in situ bypass was not performed. In 11 patients the diameter of the greater saphenous vein was too small (<=2 mm). In five patients the planned proximal or receiving distal artery was considered inadequate for anastomosis. One patient refused operation after randomisation. In the "closed" group 47 patients and in the "open" group 50 patients received an in situ bypass.

Early postoperative mortality (< 1 month) was 2 %. One patient in the "closed" group died 5 days postoperatively after a major stroke. One patient in the "open" group died 2 days postoperatively of congestive heart failure during emergency surgery for a rupture of the proximal bypass anastomosis. One patient of the "open" group died 47 days postoperatively (7 days after discharge) because of a rupture of the bypass caused by a deep wound infection. Four patients died during follow-up of causes unrelated to the bypass surgery.

In three patients (6%) peroperative complications were caused by the valvulotomy procedure during the "closed" technique. In one patient the valvecutter

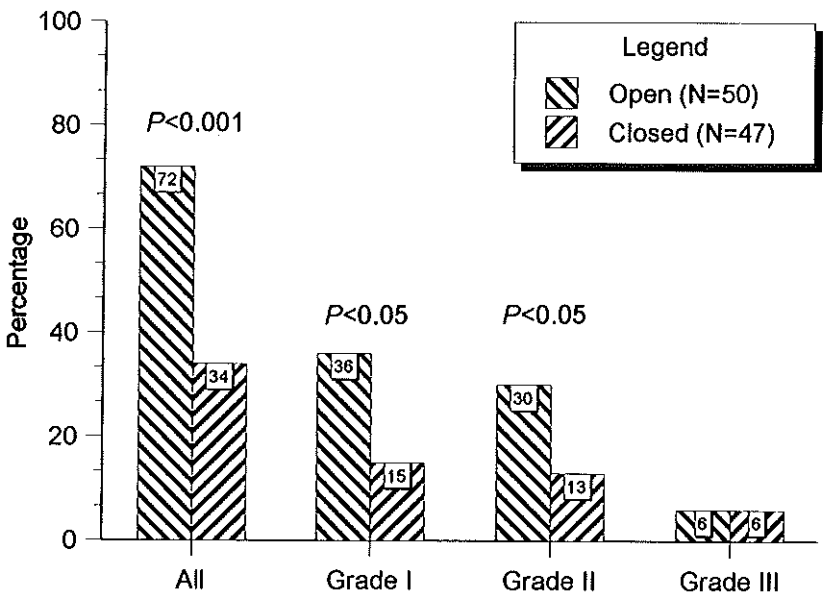

Fig. 3.1. Wound complication rates

entered the deep venous system and caused valve damage of the superficial femoral vein. Up to now (2 months postoperatively) this has not caused any symptoms. In two patients (4%) the valvecutter got stuck in a side-branch and had to be recovered by a separate incision and venotomy. This may have caused early graft occlusion in one patient. In three (6%) patients a 2 mm Hall valvecutter was used because of the small diameter (< 2.5 mm) of the vein.

In 47 "closed" in situ bypass operations 272 side branches were coil embolised (average of six per patient). In two (4%) patients none of the side branches could be coil embolised because the embolisation catheter could not be manipulated in the vein, due to its small diameter combined with spasm. In these cases side branches were ligated via small skin incisions. In three (6%) patients additional skin incisions were necessary, because these side branches could also not be coil embolised due to the small diameter (< 3.0 mm) of the greater saphenous vein.

Wound complication rates are shown in figure 3.1. A total number of 16 (34%) wound complications occurred in the closed group compared to 36 (72%) in the open group ($P < 0.001$). Superficial wound complications (grade 1) occurred in seven patients (15%) in the "closed" and 18 patients (36%) in the "open" group. Deep wound complications (grade 2) occurred in six patients (13%) of the "closed" group, compared to 15 (30%) in the "open" group ($P < 0.05$). In both groups 3 patients (6%) developed deep wound complications reaching to the bypass (grade 3). Wound complication localisations are shown in table 3.3. In this study no influence of "redo" procedures or diabetes could be detected on wound complication rates.

In one centre morbidity was evaluated by analysing the wound healing time. In 47 patients (23 "closed" and 24 "open" in situ bypasses) a mean wound healing time of 18 days for the "closed" group and 42 days for the "open" group was seen ($P < 0.001$). Mean hospital stay was 20 (SD: 13) days for the "closed" group and 24 (SD: 13) days for the "open" group.

Open side branches or arteriovenous fistulas (AVF) were detected with colour Duplex in 27 (56%) patients receiving a "closed" in situ bypass. In 20 (42%) of these patients AVF were ligated or embolised in a second procedure, because skin symptoms occurred or bypass patency was considered to be threatened by the AVF. In the "open" group AVF were detected in 4 patients (8%) and treated.

Patency rates (SD < 10%) are shown in figures 3.2 and 3.3. In four (8%) patients in the "closed" group and 9 (18%) patients in the "open" group early bypass occlusions occurred within 1 month after surgery. The one year primary patency rate was 65% in the "closed" group and 61% (NS) in the "open" group. The one year primary assisted patency was 76% and 68% and the 1-year secondary patency was 86% and 76% (N.S.) for the "closed" and "open" group respectively. Nine major amputations had to be performed within 1 year, four (8%) in the "closed" group and five (10%) in the "open" group.

3.5 Discussion

The in situ bypass technique is the preferred method for arterial reconstruction when the distal anastomosis is below knee level in many clinics. The major disadvantage of the "open" in situ bypass technique, exposing the entire vein via one long skin incision, is the high incidence of wound complications. We found an overall wound complication incidence of 34% in the "closed" group compared to 72% in the "open" group: a statistically significant difference.

Table 3.3 Wound complication locations

	Closed (N = 47)			*Open* (N = 50)		
	Grade			Grade		
	I	II	III	I	II	III
Groin	3	1	1	5	7	0
Upper leg	2	1	1	5	6	1
Lower leg	0	0	0	6	7	1
Distal anastomosis site	3	5	1	6	4	1

The four patients in the "closed" group with a wound complication in the *upper leg* (table 3.3) developed this complication at the site of the skin incision for the postoperative treatment of a residual AVF. A possible problem, caused by the catheter manipulations, could be an increased incidence of groin wound

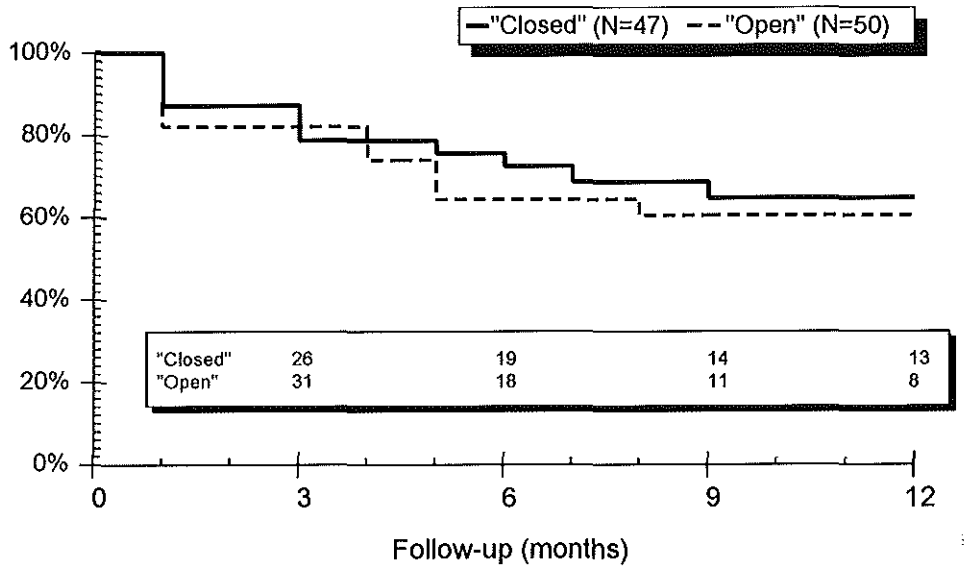

Fig. 3.2. Primary patency. Numbers of grafts at risk are shown in the box.

complications in the "closed" group. As shown in table 3.3, this was not the case.

To minimise a potential observer bias, with regard to reporting wound complications, we asked infection control practitioners from the Department of Hygiene and Infection Control in each participating centre, to perform the wound inspections and to score the severity of infections.

Our wound complication rate of 34% and 72% respectively seems rather high compared to complication rates reported in literature (Schwartz et al.[5]: 33%; Reifsnyder et al. [2]: 44%; Johnson et al.[6] : 33%). However, it has been shown that wound complication rates tend to be underestimated if surgeons report their own complications [4]. This is especially true for retrospective studies, due to the inherent lack of reliable information. All above mentioned studies were retrospective. We consider the high incidence of wound complications observed in our patients to be a reflection of the prospective nature of this study which focused on objective reporting of wound complications.

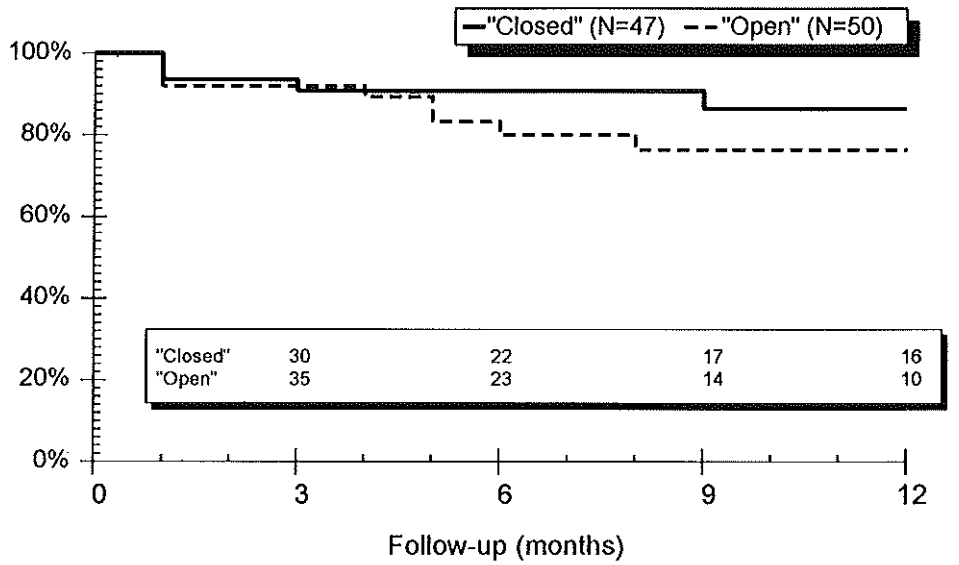

Fig. 3.3. Secondary patency. Numbers of grafts at risk are shown in the box.

In our series, the reduction in wound complication rates did not result in a significant reduction of hospital stay. The other factors influencing hospital stay, like re-interventions, concomitant diseases, rehabilitation in the hospital and social factors probably masked the benefit of the reduction of wound complications. The results in a subgroup showing a significant reduction in wound healing time in the "closed" group indicates a decreased need for outpatient wound care.

Our technique of peroperative coil embolisation under fluoroscopic control can be compared with the electronically steerable nitinol catheter system described by Rosenthal et al.[7] and Cikrit et al.[8] Cikrit et al. used the electronically steerable nitinol catheter first under angioscopic and fluoroscopic control and later under fluoroscopic control only. Their catheter seems very elegant, especially for catheterisation of difficult, sharp angled side branches. However they also needed extra skin incisions in several patients (27%) to ligate side branches. In experienced hands the co-axial catheter that we used enables catheterisation of almost all difficult angled side branches.

In our series a small diameter of the vein was the main cause of failure to embolise side branches. This observation has led us to conclude that a small vein diameter (< 3 mm) is a contraindication for a "closed" in situ bypass procedure. Patients with a small diameter vein could be preoperatively selected by ultrasound examination.

In the "closed" group of our series the average number of peroperatively coil-embolised side branches was six per patient. Cikrit et al.[8] described their experience in a group of 30 patients with a comparable "closed" in situ bypass technique. They coil embolised an average of 3-4 side branches per limb. This number seems comparable with our experience. LeMaitre[9] states that he has never clipped more than six side branches with a "semi-closed" technique.

The time loss caused by the embolisation technique can be minimal if the operating team and the fluoroscopy technician are familiar with the technique. Time loss caused by the embolisation procedure was not recorded in the protocol of this study. However, one centre did record the time loss due to the embolisation procedure and found the mean operating time to be 25 minutes longer for the "closed" procedure compared to the "open" procedure.

In our series 42% of the patients receiving a "closed" in situ bypass were treated in the early postoperative period for AVF. We believe that by gaining experience in the embolisation technique and by using optimal fluoroscopy equipment, the frequency of reinterventions needed for AVF can be reduced, but perhaps not to a level comparable with the "open" technique. Chang et al.[10] have shown that in the majority of patients AVF's do not affect distal bypass flow and patency. A conservative approach to these fistulas is therefore justifiable. Partly because of a lack of generally accepted treatment criteria, we probably unnecessarily treated too many residual AVF's especially in the early phase of the trial. In the series of Cikrit et al.[8] 39% of the patients underwent a re-intervention for treatment of AVF.

The ultimate criterium to judge the value of a new or modified surgical technique for bypass surgery is undoubtedly the long-term patency rate. The follow-up on our series of patients only allows the calculation of 1-year patency rates (SD < 10%). At 1 year we found no statistically significant difference in patency between the "closed" and the "open" technique. We feel that this suggests that the extra catheter manipulation, which is necessary to perform the "closed" technique, does not result in a reduced patency rate.

Therefore we conclude that the "closed" technique for in situ femorodistal bypasses leads to a significant reduction in wound complications without a negative effect on graft performance, although a disadvantage of the "closed" technique is the increased need for treatment of residual AVF's compared to the "open" technique. As the "closed" technique is in line with the general trend towards "less invasive" surgery, we consider the "closed" bypass procedure to be a worthwhile acquisition for the vascular surgeon. This opinion will have to be corroborated by longer follow-up and other prospective studies.

3.6 Acknowledgements

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Chapter 4

COMPARISON OF COST AFFECTING PARAMETERS AND COSTS OF THE "CLOSED" AND "OPEN" IN SITU BYPASS TECHNIQUE

Lukas C. van Dijk[1], Rob Seerden[2], Hero van Urk[3], and Cees H.A. Wittens.[4]

Departments of Radiology[1], Finance[2] and Vascular Surgery[3]
of the University Hospital Rotterdam "Dijkzigt".
Department of Surgery,[4] St Franciscus Gasthuis.
Rotterdam, The Netherlands.

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4.1 Abstract

Objectives: The "closed" in situ vein infrainguinal bypass results in a reduction of wound complications compared to the "open" technique. This clear advantage is partly diminished by extra costs for the "closed" procedure and a larger percentage of residual AV-fistulas. This study analyses costs related to "closed" and "open" procedure in a randomised group of patients.

Methods: The cost affecting parameters: 1. duration of operation; 2. length of hospital stay; and 3. number of patients treated for residual AV-fistulas, were analysed in a randomised group of 73 patients (35 "closed" and 38 "open") in two centres. In addition, costs of the operation, nursing care and treatment of AV-fistulas were analysed.

Results: The "closed" and "open" group showed a median duration of operation of 210 (range 105-570) and 154 (range 90-355) minutes ($P < 0.05$), length of hospital stay of 16 (range 5-51) and 25 (range 12-65) days ($P < 0.01$), and a percentage of patients treated for residual AV-fistulas of 40% and 5% respectively ($P < 0.01$). The "closed" operation was US$ 798 more expensive than the "open". Median nursing care costs were US$ 2664 less for the "closed" group. Mean estimated costs for treatment of AV-fistulas was US$ 9 in the "open" and US$ 167 in the "closed" group.

Conclusion: The "closed" in situ vein bypass technique is cost-effective in comparison with the "open" technique.

Key words: In Situ Bypass, Costs Analysis, Embolisation, Peripheral Vascular Disease, Atherosclerosis.

4.2 Introduction

Several studies have shown that vascular surgical reconstructions with a distal anastomosis in the lower leg are cost effective for treatment of critical ischaemia in the lower extremity, compared to primary amputation.[1,2] One of the preferred operating techniques for vascular reconstruction in the lower extremity is the in situ vein bypass technique. The problem of the standard or "open" in situ bypass technique is the high incidence of postoperative wound complications, which has been reported by Reifsnyder et al. as being 44%.[3] Recently "closed" in situ bypass techniques have been developed to reduce the length of the skin incision and thereby reduce the number of postoperative wound complications.[4,5] Rosenthal et al. showed a decrease in wound complication rate and a reduction of the length of hospital stay in a group of patients receiving a "closed" in situ bypass compared to a concurrently operated group of patients receiving an "open" in situ bypass.[6] In a prospective randomised study we showed that the "closed" technique resulted in a significant reduction in postoperative wound complications compared to the "open" technique.[7] However despite this clear advantage, we have the impression that this technique is currently not widely used. One of the reasons could be the extra costs of the disposable materials needed for this technique. In addition to this, the operation time is reported to be prolonged[8] and the percentage of patients in which additional procedures in the early postoperative period are necessary for residual arteriovenous fistulas is reported to be 6 - 42 % in 3 studies.[7,9,10] These consequences of the "closed" technique could result in increased costs compared to the "open" technique. On the other hand, if lower wound complication rates would result in a reduced length of hospital stay, the "closed" technique could indeed be cost-effective.

The purpose of this study was to compare three important cost affecting parameters in the "closed" and "open" technique in a randomised group of patients:

1. the duration of operation
2. the length of hospital stay
3. the number of patients treated postoperatively for residual AV-fistulas.

A cost analysis of the operation, nursing care costs and costs of treatment of residual AV-fistulas was performed to illustrate the effect of the differences of the cost affecting parameters on the costs.

4.3 Patients and Methods

Patients

From May 1st 1992 to June 30th 1994, in 2 centres 73 patients (49 male, 24 female) were randomised for the "closed" or "open" technique, after informed consent had been obtained. The randomisation was stratified per centre, therefore an even distribution of "open" and "closed" procedures was realised per centre. The surgeons were randomised with the patients i.e. none of the five vascular surgeons involved in this study were excluded for either technique. During the embolisation procedure of a "closed" in situ bypass operation a surgeon experienced in this embolisation technique assisted the main operator. The study was performed with approval of the ethical committees of both hospitals. Thirty-five "closed" and 38 "open" procedures were analysed in this study. Patient characteristics, indications for operation and the locations of the distal anastomoses are shown in table 4.1, 4.2 and 4.3. Risk factors were equally distributed.

Table 4.1 Patient characteristics

	Closed (N 35)	*Open* (N 38)
Female	23%	42%
Male	77%	58%
Age (years)	71	71
Diabetes	14%	32%
Smoking	51%	37%
Hypertension	34%	37%
Ischaemic heart disease	37%	34%

Operation technique

During the "open" technique the valvulotomy procedure and the ligation of the venous tributaries was performed "a vue" after exposure of the entire vein via one long skin incision.

The "closed" technique as described by Wittens et al.[5] was used. The valvulotomy procedure was performed "blindly" with a disposable valvecutter with a variable diameter (Vavacut, Cook Europe, Denmark) and the side branches of the vein were embolised with coils via a co-axial embolisation catheter (Cook Europe, Denmark) under fluoroscopic control.

Table 4.2 Indication for operation

	Closed (N=35)		*Open* (N =38)	
	N	%	N	%
Disabling intermittent claudication	13	(37)	13	(34)
Rest pain	8	(23)	8	(21)
Ulcers and/or necrosis	14	(40)	17	(45)

Cost affecting parameters

Three cost affecting parameters were analysed: 1. duration of operation measured from the first skin incision to the last skin closure, 2. length of hospital stay counted from day 1 = operation day to the day of discharge and 3. number of patients receiving treatment for residual AV-fistulas.

Table 4.3 Distal anastomosis technique

	Closed (N = 35)	*Open* (N = 38)
Popliteal artery b.k.	21	23
Tibioperoneal trunk	2	1
Anterior tibial artery	3	6
Posterior tibial artery	6	7
Peroneal artery	3	1

Cost analyses

For calculation of the median costs of the operation and nursing care, the financial data of a subgroup of 26 patients operated in one of the two centres (University Hospital Rotterdam) were used. Because we were interested in differences between two comparable operation techniques, only direct costs of manpower and materials were included.

Cost analyses of the operation was composed of 2 parts: 1. a price per minute personnel costs and 2. costs of disposable materials. Cost analyses of nursing care was composed of the personal costs (including doctor's fees) and costs of disposable materials per day of hospitalisation.

Mean direct costs for treatment of residual AV-fistulas were estimated. Mean costs of surgical ligation was based on the assumption of an average duration of the procedure of 30 minutes and US$ 90 costs for disposable materials. Mean costs of postoperative percutaneous coil embolisation of AV-fistulas was based on an average duration of the procedure of 120 minutes and US$ 320 costs for disposable materials. For both methods of treatment the direct costs per minute calculated for the "open" in situ bypass operation was used.

All cost calculations were based on financial data of 1994 and calculated in Dutch Guilders (Conversion rate in this study: 1 US$ = 1.70 Dutch Guilders).

Statistics

Possible differences were tested for statistical significance by calculation of the p-value using the Mann-Whitney test. For the numbers of patients treated postoperatively for residual AV-fistulas the chi-squared test with Yates correction was used.

4.4 Results

Cost affecting parameters

The median duration of operation, the median length of hospital stay and the number of patients treated for residual AV-fistulas are shown in table 4.4. The median duration of operation of the "closed" procedure was 56 minutes longer than the "open" procedure ($P < 0.05$). The median length of hospital stay was 9 days less for the "closed" group ($P < 0.01$).

The percentage of patients treated postoperatively for residual AV-fistulas after "closed" in situ bypass grafting was 40% compared to 5% after "open" procedures ($P < 0.01$).

Table 4.4 Median cost affecting parameters

	Closed (N = 35)	*Open* (N = 38)
Duration of operation (minutes)	210 range 105 - 570	154 range 90 - 355
	$P < 0.05$	
Length of hospital stay (days)	16 range 5 - 51	25 range 12 - 65
	$P < 0.01$	
Residual AV-fistulas treated postoperatively	14 (40%)	2 (5%)
	$P < 0.01$	

Cost analysis

Operation: the personal costs per minute operating time were US$ 2.86 for the "closed" group and US$ 2.83 for the "open" group. The mean price of disposable materials was US$ 818 for the "closed" group and US$ 185 for the "open" group. The disposable set we used for the "closed" procedure, consisting of the co-axial embolisation catheter with guide wire, 10 embolisation coils and a valvecutter (Cook Europe, Denmark), costed US$ 588. The difference in operation costs between the 2 groups was US$ 798 per operation in favour of the "open" technique. Table 4.5 shows the median costs of the operation, nursing care and treatment of residual AV-fistulas.

Table 4.5 Median direct costs

	Closed (N = 35)	*Open* (N = 38)
Operation costs (US $)	1419	621
Nursing care costs (US $)	4736	7400
Treatment costs of AVF* (US$)	167	9

* estimated values

The mean costs of nursing care were US$ 296 per patient day of hospitalisation. The difference in nursing care costs was US$ 2664 per patient in favour of the "closed" technique. The estimated direct costs for treatment of residual AV-fistulas were US$ 175 for surgical ligation and US$ 660 for percutaneous coil embolisation per procedure. In the "open" group 2 patients were treated surgically. In the "closed" group 7 patients were treated percutaneously and 7 surgically. Therefore the mean costs for AV-fistula treatment per patient were US$ 9 in the "open" and US$ 167 in the "closed" group.

4.4 Discussion

In this study of a randomised group of patients we found a statistically significant shorter length of hospital stay for patients after a "closed" in situ bypass compared to an "open" in situ bypass ($P < 0.01$). However, the duration of the operative procedure was longer ($P < 0.05$) and the number of patients treated for residual AV-fistulas larger ($P < 0.01$). The effects on the costs of different types of treatment cannot be analysed reliably by using hospital charges.[11,12] To illustrate the economic effects of these differences, we calculated the direct costs of te operation and nursing care costs of the median patient in each group. The costs for treatment of residual AV-fistulas were estimated. Costs of equipment and overheads were expected to be equal, therefore these indirect costs were not taken into account in this study. In our hospital the average indirect costs per bed per day on the surgical ward was US$ 270 and the average costs per minute operating time US$ 1.93. Since these costs are less than half of the total costs, their influence would not essentially alter the outcome of the relative differences in costs. This study indicates that the median direct costs of the "closed" operation were US$ 798 more compared to the "open" technique, mainly due to the disposable materials and the increased duration of the operating time. The slightly higher price per operation minute in the "closed" group was caused by the additional time the radiology technician was needed during the embolisation procedures. The 9 days shorter hospital stay in the "closed" group results in a median nursing care cost reduction of US$ 2664. It is reasonable to assume that the shorter hospital stay was mainly caused by the lower frequency

of wound complications. The length of hospital stay was in both groups relatively long due to concomitant diseases. We did not take into account additional nursing costs after patient discharge. It is reasonable to assume that nursing care costs at home are higher after "open" in situ bypasses since mean total wound healing time is reported to be significantly longer, namely 42 days after "open" procedures compared to 18 days after "closed" procedures.[7]

The advantages of the "closed" technique could be diminished by the costs involved with treatment of residual AV-fistulas. In this study 40% of the patients received additional treatment for residual AV-fistulas. Our recent experiences however indicate that only 6% of the patients need treatment for residual AV-fistulas after "closed" in situ bypass grafting.[10] If in this study only 6% of the patients had been treated for residual AV-fistulas instead of 40%, this treatment would account for an even smaller percentage of the total costs. We did not calculate the costs of AV-fistula treatment, since they strongly depend on the treatment modality. One of the options, percutaneous coil embolisation as described by Kalman et al.,[13] is an expensive procedure with high costs depending on technique and different types of embolisation catheters and materials. Surgical ligation however, especially when performed on an outpatient basis, is a less expensive procedure. Although we realise that estimation of costs is not exact and prone to bias, we estimated the costs for treatment of residual AV-fistulas in this study. We think that we did not underestimate these costs. Moreover the disadvantage in terms of treatment costs for AV-fistulas in the "closed" group could have been less if all residual AV-fistulas had been treated surgically. The net result of operation costs, nursing care costs and costs for treatment of residual AV-fistulas for the median patient would be US$ 6322 for a "closed" and US$ 8030 for an "open" in situ bypass. A net difference in favour of the "closed" technique of US$ 1708.

In conclusion we have shown that the "closed" in situ vein bypass technique is cost-effective compared to the standard "open" technique.

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Chapter 5

RESIDUAL ARTERIO-VENOUS FISTULAS AFTER "CLOSED" IN SITU BYPASS GRAFTING: AN OVERRATED PROBLEM

Lukas C. van Dijk[1], Hero van Urk[2], Johan S. Laméris[1] and Cees H.A. Wittens[3].

Departments of Radiology[1] and Vascular Surgery [2]
University Hospital Rotterdam "Dijkzigt" and
Department of Surgery[3], St Franciscus Gasthuis.
Rotterdam, The Netherlands.

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5.1 Abstract

Objectives: To reduce wound complication rates after in situ vein infrainguinal bypass grafting, "closed" techniques, using per-operative endovascular coil embolisation of side branches, have been developed. These techniques are associated with postoperative treatment of residual AV-fistulas in up to 40% of the patients. The purpose of this study was to evaluate the incidence and consequences of residual AV-fistulas after "closed" in situ bypass grafting.

Methods: In 34 patients, 35 "closed" in situ bypass operations were performed. Postoperative assessment of residual AV-fistulas and bypass patency was performed with duplex scanning.

Results: Postoperative mortality was 3%. During 35 "closed" in situ bypass procedures 216 side branches were coil-embolised. Postoperatively 39 AV-fistulas (15% of the total number of 216+39=255 side branches) were detected. Of these, thirteen (5%) closed spontaneously. Fifteen (6%) remained unchanged and eleven (4%) were treated. In 3 patients 4 asymptomatic residual AV-fistulas were treated. Only in 4 patients 7 symptomatic AV-fistulas were treated for: decreased distal bypass flow in 1; persistent leg edema in 1; pain and redness of the skin in 2.

One year primary patency was 80% (SE 8.4%). In none of 6 bypass occlusions residual AV-fistulas had been detected during follow-up.

Conclusion: Residual AV-fistulas detected following "closed" in situ bypass grafting only need treatment if they are symptomatic; in this study only in 6% of the patients.

Key words: In Situ Bypass, Arterio-Venous Fistulas, Saphenous Vein, Endovascular, Coil Embolisation.

5.2 Introduction

The in situ vein infrainguinal bypass is one of the preferred techniques for treatment of lower extremity ischaemia. The standard "open" technique, using ligation of the side branches via a long skin incision, is associated with wound complication rates up to 44%.[1,2] To reduce the number of postoperative wound complications, "closed" in situ bypass techniques, using per-operative endovascular coil embolisation of vein side branches, have been developed.[3,4] A disadvantage of these "closed" techniques seems the high incidence of postoperative residual AV-fistulas. Cikret et al.,[5] who used the electronically steerable nitinol catheter system as first used by Rosenthal et al.,[3] reported that 39% of the patients were treated for residual AV-fistulas after "closed" in situ bypass grafting. We reported that 42% of the patients were treated for residual AV-fistulas after "closed" in situ bypass grafting, using a co-axial catheter system in a randomised study comparing the "closed" technique to the "open" technique.[6] Rosenthal et al. however only treated 6% residual AV-fistulas after refinement of the electronically steerable nitinol catheter and increased operator experience with the "closed" technique.[7]

The purpose of this study was to evaluate the incidence and consequences of residual AV-fistulas after "closed" in situ bypass grafting using a co-axial catheter system for per-operative endovascular coil embolisation of the vein side branches.

5.3 Patients and Methods

From June 1992 to March 1996, 35 "closed" in situ bypasses were performed in 34 patients (23 male, 11 female) in the St Franciscus Gasthuis Rotterdam. Mean age was 73 years (range 55 - 90). The indications for operation were non-healing ulcers or necrosis in 16, rest pain in 7 and life-style-limiting/disabling claudication in 11 patients. Fourteen (41%) patients had a smoking history, 17 (50%) had ischaemic heart disease, 17 (50%) had hypertension and 6 (18%) were diabetic. Seventeen femorodistal popliteal and 18 femorocrural bypasses were performed.

The "closed" in situ bypass technique used was described by Wittens et al.[4] The main characteristics of this method were: the valvulotomy procedure was performed

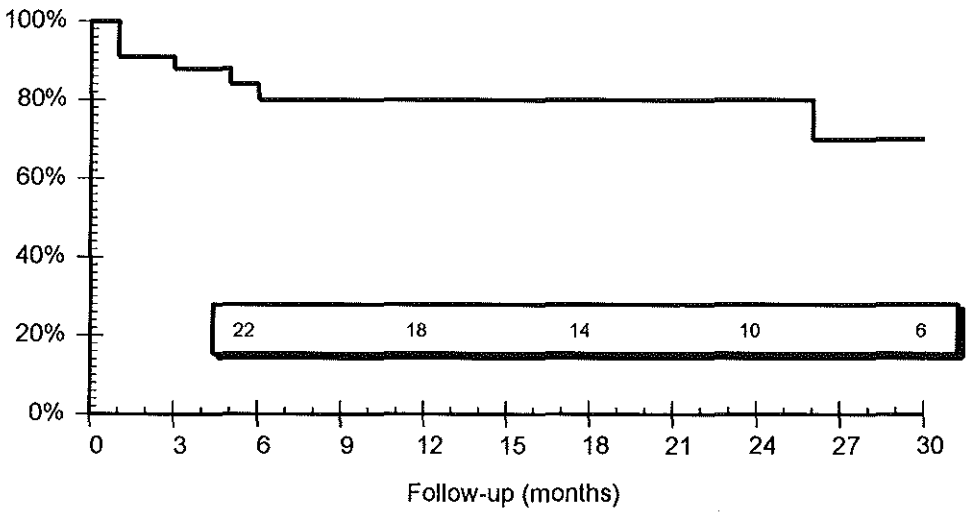

Fig. 5.1. Primary patency rates. Numbers in the box indicate bypasses at risk.

"blindly" with a disposable variable valvecutter; the side branches of the vein were coil embolised via a co-axial embolisation catheter under fluoroscopic control. The disposable materials needed for this procedure: valvecutter, embolisation catheter and 10 embolisation coils, are commercially available as a set (Cook Europe, Denmark).

During the follow-up period duplex scanning was performed within 4 weeks after the operation, every 3 months postoperatively in the first year and every half year thereafter for assessment of graft patency and occurrence of AV-fistulas. The Kaplan Meier life table method was used to estimate the probability of bypass patency. Primary patency rates were calculated without taking into account operations and/or interventions for treatment of residual AV-fistula.

5.4 Results

Postoperative mortality was 3%: one patient died in the first week following the operation because of cardiac failure. In 35 "closed" in situ bypasses a total number of 216 side branches (mean 6.2 per patient) were coil-embolised during the "closed" in situ bypass procedure. The mean follow-up was 21 months (range 1-48). Bypass patency rates are shown in figure 5.1. The 1-year primary patency rate was 80% (SE 8.4%). During the follow-up period 6 bypasses occluded. In none of these patients residual AV-fistulas had been detected during follow-up before occlusion. Postoperatively in 21 of the 35 bypasses a total number of 39 AV-fistulas were detected. The total number of vein side branches detected intraoperatively and postoperatively therefore is 255. In other words 15% (39) of the total number of side branches were seen as postoperatively detected AV-fistulas. Figure 5.2 shows the outcome of these AV-fistulas. A total number of thirteen (5%) AV-fistulas in twelve patients closed spontaneously after a mean follow-up period of 8 months (range 1-30). Fifteen AV-fistulas (6%) in nine patients remained unchanged for a mean follow-up period of 13 months (range 1-22) and eleven (4%)

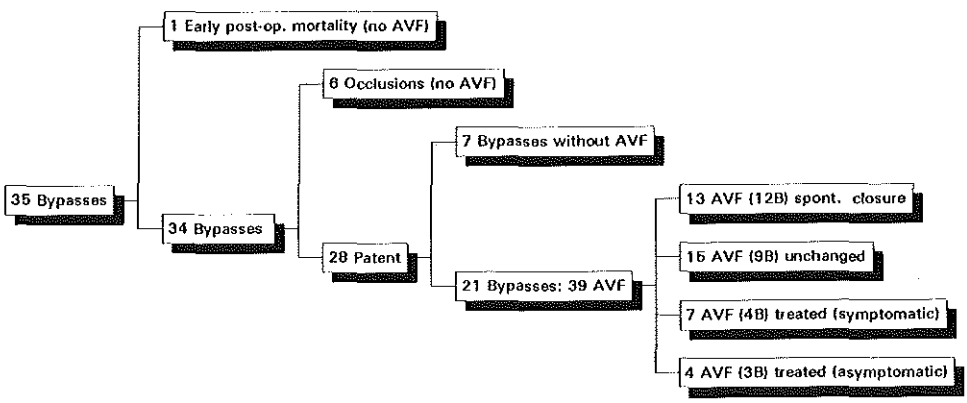

Fig. 5.2. Results of follow-up of 35 bypasses. AVF = AV-fistulas, B = bypasses.

were treated: In 3 patients 4 asymptomatic residual AV-fistulas were treated; in two patients 1 week and in one patient 1 month postoperatively. Seven symptomatic AV-fistulas in 4 patients were treated. Reasons for treatment were: 2 AV-fistulas caused continuous retrograde diastolic flow distally in 1 patient and were treated 8 months postoperatively. After this treatment the retrograde diastolic bypass flow disappeared. Two AV-fistulas were associated with persistent leg edema in 1 patient and treated successfully 3 months postoperatively; pain and redness of the skin was caused by 3 AV-fistulas in 2 patients and treated successfully 2 days postoperatively.

All but 3 residual AV-fistulas were detected at the first Duplex examination within one month postoperatively. In one patient an AV-fistula was detected at the first examination and 3 additional AV-fistulas were detected 2 months later. These 4 AV-fistulas remained asymptomatic for the follow-up period of 23 months.

5.6 Discussion

Management of residual AV-fistulas after in situ bypass grafting seems a controversial issue. Symptoms attributed to residual AV-fistulas are bypass occlusion, diminished bypass function, leg edema and skin symptoms.[8] In this study no bypass occlusion was associated with detected residual AV-fistulas. However, other investigators have reported that residual AV-fistulas can cause bypass occlusion, especially of the segment distal to the AV-fistula.[9-11] In this study Duplex scanning showed continuous retrograde diastolic flow in a bypass segment distal of 2 large residual AV-fistulas in one patient. Treatment of these AV-fistulas restored normal blood flow. Leopold et al. reported similar experiences with treatment of impaired bypass function, without occlusion, by closure of residual AV-fistulas.[12]

In one patient in our study, persistent leg edema was associated with residual AV-fistulas and treated successfully by AV-fistula ligation. Chang et al. reported successful treatment of persistent leg edema by closure of residual AV-fistulas in 4 patients after 216 in situ bypasses.[8]

Besides bypass failure and leg edema, symptoms attributed to residual AV-fistulas are redness and tenderness of a focal skin area. These AV-fistulas with a connection to the skin tend to occlude spontaneously.[8]

Therefore a conservative attitude towards these AV-fistulas is a good option. We started probably unnecessarily to obliterate all residual AV-fistulas suffering skin redness and pain. However, after two patients we changed our policy to a more conservative attitude and treated skin symptoms by application of a compressive bandage. Symptoms subsided in all patients within one week. Accordingly we did not close any other AV-fistulas for this reason. Leather et al. reported an incidence of only 1 patient with skin necrosis after 1038 in situ bypasses.[13] In the early phase after the introduction of "closed" in situ bypass grafting, we treated 3 patients for AV-fistulas that were asymptomatic. This policy was also changed to a more conservative approach, after which no asymptomatic residual AV-fistulas were treated anymore.

The incidence of residual AV-fistulas detected in this study is rather high. Rosenthal et al. reported that 6% (3 patients) of the patients were postoperatively treated for residual AV-fistulas with a diameter larger than 2 mm's. Numbers of smaller residual AV-fistulas were not mentioned. Rosenthal's group had coil-embolised 258 side branches during 53 "closed" in situ bypass procedures (average of 4.9 side branches per bypass).[6] In this study we coil-embolised an average of 6.2 side branches per bypass operation. We think that the technical differences of the embolisation catheters are not a logical explanation for the difference in residual AV-fistulas incidence. Theoretically the electronically steerable nitinol catheter as used by Rosenthal et al. (CRI, Catheter Research, Inc., Indianapolis) is ideal for selective catheterisation, also of difficult angled side branches. We learned that with a co-axial system (Cook Europe, Denmark) it is also possible to selectively catheterise difficult angled side branches. A probable explanation for the different incidence of *detected* residual AV-fistulas could be that we also detected AV-fistulas smaller than 2 mm's. Small tributaries might have been missed during intraoperative fluoroscopy due to sufficient valves at the orifice. These sufficient valves can dilate under arterial pressure and become insufficient, after which they remain as residual AV-fistulas.

After gaining some experience with the "closed" technique, we developed a policy not to aim at closure of all vein side branches in all cases: side branches that were very small or were difficult to catheterise and coil embolise within 10 minutes per-operatively were left open, because we had the impression that usually these side branches had no consequences.

An advantage of this policy is that the per-operative embolisation procedure took only 20 - 40 minutes, since no time was lost with prolonged attempts for catheterisation of small side branches and/or additional skin incisions for surgical ligation. In this series one third of the AV-fistulas occluded spontaneously and 15 of the persistent fistulas remained asymptomatic during follow-up. As we already mentioned, only 4 patients with residual AV-fistulas were treated for symptoms. The 2 patients with local skin redness and pain probably could have been treated conservatively. Therefore it is reasonable to assume that only after 2 (6%) of the 35 bypasses, residual AV-fistulas needed treatment. No AV-fistula related occlusions occurred and bypass patency rates were comparable to other series of "closed" and "open" in situ bypasses.[6,14,15] Therefore it is probably not necessary to strive for in situ bypass techniques that result in the complete absence of postoperative residual AV-fistulas. Because asymptomatic AV-fistulas do not threaten bypass patency, specific follow-up for detection of AV-fistulas seems unnecessary.

In conclusion, we have shown that the incidence of detected residual AV-fistulas after "closed" in situ bypass grafting was 15% of the total number of vein side branches. When residual AV-fistulas are detected after "closed" in situ bypass grafting, they only need treatment in a minority of patients (6%) namely if they are symptomatic.

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Chapter 6

THE VALUE OF PREOPERATIVE ULTRASOUND MAPPING OF THE GREATER SAPHENOUS VEIN PRIOR TO "CLOSED" IN SITU BYPASS OPERATIONS

Lukas C. van Dijk[1], Cees H.A. Wittens[2], Herman Pieterman[1] and Hero van Urk[3].

Departments of Radiology[1] and Vascular Surgery[3],
University Hospital Rotterdam "Dijkzigt", Rotterdam
Department of Surgery[2], St. Franciscus Hospital, Rotterdam
The Netherlands

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6.1 Abstract

Objective: The aim of this study was to test preoperative ultrasound mapping for the detection of duplications and narrow vein segments of the greater saphenous vein (GSV) used as bypass for occlusive arterial disease surgery.

Patients and Methods: In 44 patients preoperative ultrasound findings of duplications and lumen assessment of the GSV were compared to the intraoperative findings.

Results: In nine patients (20%) the preoperative ultrasound examination showed a duplication. Preoperative ultrasound had missed a duplication in two cases but had instead shown a narrow segment in both. The preoperative ultrasound assessment of lumen diameter showed a narrow lumen segment in 10 of the 44 patients. In one patient a intraoperatively narrow lumen had not been seen on preoperative ultrasound.

Conclusion: Preoperative ultrasound mapping of the GSV is a sensitive tool for detection of duplications and narrow vein segments. Since these anatomical variations are important to be known by the vascular surgeon, before performing a "closed" in situ bypass operation, preoperative vein mapping should be considered when planning such a procedure.

Key words: Ultrasound Studies, Saphenous Vein; Veins, Greater Saphenous; Veins, US study, Veins, Surgery

6.2 Introduction

It is generally accepted that autologous vein is the preferred bypass material for surgical arterial reconstruction in the lower extremity since it offers the best patency rates. Usually the greater saphenous vein (GSV) is chosen if it is of sufficient quality to serve as an arterial bypass. The GSV can either be used "reversed" or "in situ". When the reversed technique is chosen, the GSV is removed over the length necessary for the bypass. Subsequently the vein is anastomosed reversed, i.e. the distal end is anastomosed proximally and vice versa. Reversal is necessary because the valves in the vein would otherwise hamper the arterial blood flow. All side branches of the vein are ligated during the removal of the vein. As the name "in situ" suggests, this technique, in contrast to the reversed technique, leaves the GSV in its anatomical place. To achieve an adequate bypass, this technique requires that the valves in the vein are rendered insufficient and the side branches of the vein ligated. Usually this technique is performed "open", i.e. the GSV is exposed over the entire length needed for the bypass. This "open" technique leads to a high number of postoperative wound complications: Reifsnyder et al. reported 44% wound complications in a retrospective study [1].

Recently modifications of the "in situ" bypass technique have been proposed to reduce the length of the skin incision and thereby the number of wound complications [2,3]. Two procedures are necessary for these "closed" in situ bypass techniques: 1) the blind cutting of the valves of the greater saphenous vein (GSV) and 2) intraoperative coil embolisation of the side branches of the GSV. In a previous article, we noted that two anatomical aspects of the GSV in particular are important determinants for a successful "closed" in situ bypass procedure, namely, the occurrence of duplications and narrow segments of the GSV [3].

B-mode ultrasound scanning as described by Leopold et al. [4] is considered the best way to perform preoperative examination of the GSV. The aim of this study was to test the efficacy of preoperative ultrasound mapping of the GSV for detection of duplications and narrow vein segments.

6.3 Patients and Methods

In 44 patients with arterial obstructive disease, in which a venous bypass with a below knee distal anastomosis was planned, preoperative ultrasound examination of the GSV was performed less than one week prior to surgery. Characteristics and indications for the arterial reconstruction are shown in Table 6.1. An in situ bypass ("open" or "closed") was performed. In 3 patients however a "semi-closed" procedure was performed, i.e. the side-branches were ligated via separate small skin incisions, because the operator was not yet familiarised with the "closed" technique. The reversed GSV technique was used if the ipsilateral GSV was not available or considered inadequate intraoperatively and the contra lateral GSV was acceptable. A prosthetic bypass was used if no adequate GSV was available at all. Veins of other parts of the body were not used. Also no composed grafts were used in this study. Table 6.2 shows the numbers of the different operative procedures.

Table 6.1 Patient characteristics and indications for surgery.

Female	15
Male	29
Age	70
Diabetes	18%
Smoking	30%
Hypertension	25%
Ischaemic heart disease	41%
Fontaine II	15
Fontaine III	10
Fontaine IV	19

Note: Fontaine clasification:
Fontaine II: intermittant claudication (in all patients IIb walking distance < 100 m)
Fontaine III: rest pain
Fontaine IV: ulcus and/or necrosis

Table 6.2 Types of operative procedures performed

Types of surgical procedures (N = 44)			
	N		N
In situ femoropopliteal ✶	22	*Open*	12
		Closed	9
		Semi-closed	1
In situ femorocrural	13	*Open*	9
		Closed	2
		Semi-closed	2
Reversed femoropopliteal ✶	1		
Reversed femorocrural	2		
Prosthetic bypass	6		

✶ Note: Femoropopliteal bypasses always with a distal anastomosis below knee joint level

The preoperative ultrasound vein mapping was performed with a Dornier AI 3200 B-mode ultrasound scanner. A 7.5 MHz linear array transducer was used. Patients were examined with the leg in a vertical position: standing or sitting on a high chair with the examined leg dangling. If the ipsilateral vein was considered not suitable for a bypass, the contralateral GSV was also examined.

Table 6.3 Duplications of the greater saphenous vein. Preoperative ultrasound vein mapping findings compared to preoperative findings

Duplications (N = 44)		
	During operation	
Preoperative	Normal	Duplication
Normal	33	2
Duplication	3	6

Table 6.4 Diameter assessment of the greater saphenous vein. Preoperative ultrasound vein mapping findings compared to subjective intraoperative findings

Venous lumen assessment (N = 44)		
	During operation	
Preoperative	Normal	Narrow (<2mm)
Normal	33	1
Narrow (<2mm)	4	6

The preoperative ultrasound and intraoperative visual aspects of the GSV were described as follows: 1) the occurrence of duplications was scored; 2) the diameter of the vein was assessed for stenoses. The preoperative ultrasound criterion for a narrow segment was if the smallest venous lumen diameter < 2.0 mm. The intraoperative criterion was a subjective judgement of narrowness by the surgeon, without the use of a caliper or other measurement since only outer diameter and not lumen diameter was assessed intraoperatively.

The ultrasound findings were preoperatively available to the surgeon. There was an agreement that the findings on ultrasound were not to be considered a reason for not using the vein as a bypass without intraoperative inspection of the vein.

6.4 Results

In nine patients (20%) the preoperative ultrasound examination showed a duplication of the GSV (Table 6.3). Preoperative ultrasound had missed a duplication in two cases but had instead shown a narrow segment with a lumen < 2 mm in both.

The preoperative ultrasound assessment of lumen diameter showed a narrow lumen segment in 10 of the 44 patients (Table 6.4).

6.5 Discussion

Preoperative ultrasound mapping of the GSV allows visualisation of duplications and narrow segments of the GSV. With preoperative vein mapping duplications of the GSV were observed in 20%. Two duplications were missed with preoperative ultrasound. In both patients preoperative ultrasound had only shown a narrow vein segment, possibly one half of the duplicated segment. In three patients in which preoperative ultrasound showed a duplication, this was not visualised intraoperatively, possibly due to the fact that the duplicated part of the GSV was not explored totally and therefore the duplication could have been interpreted as being a side branch. If the preoperatively and intraoperatively demonstrated duplications are added, a total of 11 duplications in 44 legs (25%) were seen. This figure lies between the 42% seen by Leopold et al. [5] and the 18% found by Ruoff et al.[6]. Both however, only recorded the number of duplications seen with preoperative ultrasound vein mapping and did not mention any "missed" duplications encountered intraoperatively.

When planning intraoperative coil embolisation for a "closed" in situ bypass technique, requiring endovascular catheter manipulation, an accurate preoperative diameter assessment is essential since a lumen diameter of $\geq$ 3 mm is preferred [7,8]. The coil embolisation catheter we use has a 7 F (2.1 mm) diameter, therefore we consider a venous lumen diameter < 2 mm to be an absolute contra-indication for a closed in situ bypass. The preoperative assessment showed a venous lumen with the smallest diameter < 2 mm in 10 patients. Only in 1 patient a intraoperatively found narrow venous lumen was not anticipated preoperatively with ultrasound. In four patients a narrow vein anticipated preoperatively was not considered to be narrow during the operation. The diameter of the GSV was examined with the patients leg in a vertical position. This may explain the apparent overestimation of the occurrence of narrow segments, since Blebea et al. showed that the optimal position for venous mapping, leading to the largest measured vein diameters, is not the vertical position but supine in combination with the use of a high-thigh tourniquet[9].

Preoperative ultrasound vein mapping is a relatively inexpensive and unharmful investigation which can provide useful information when planning lower extremity vein bypass surgery. We have shown that the preoperative ultrasound mapping is a sensitive tool for the detection of duplications and narrow segments of the GSV.

Therefore this safe and inexpensive investigation should be considered before planning a "closed" in situ bypass procedure. Preoperative vein mapping can be performed with the leg in a vertical position as we did, but the supine position with use of a high-thigh tourniquet is to be preferred[9].

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Chapter 7

SUMMARY

SUMMARY

This thesis describes the results of a study of the value of a new "closed" in situ vein bypass technique developed in Rotterdam. The in situ bypass is one of the frequently used methods for treatment of severe atherosclerotic disease in the lower extremity. During in situ bypass operations, a vascular reconstruction is made of the ipsilateral autologous greater saphenous vein (GSV). The standard "open" in situ bypass technique, in which the entire GSV is exposed via a long skin incision, leads to a high incidence of postoperative wound complications. Because for the "closed" technique only 2 small skin incisions are necessary at the anastomotic sites, we expected that this technique would result in a reduction of postoperative wound complications.

Chapter 1, gives a short summary of the history of arterial reconstructions in the lower extremity with the use of the autologous GSV. Subsequently the different, recently developed, "closed" in situ vein bypass techniques are discussed. These techniques have in common, that the side branches of the GSV are per-operatively occluded with embolisation coils. The initial results of these techniques were varying: the "closed" techniques were feasible, but sometimes led to a substantial increase in the duration of the operation time and a high number of residual AV-fistulas.
At the end of the introduction the following questions are formulated:

1. Is the "closed" in situ bypass technically feasible?
2. What are the advantages of the "closed" technique (i.e. less wound complications) in comparison with the standard "open" technique and what are the disadvantages?
3. Are the extra costs involved with the "closed" technique compared to the standard "open" technique, economically justifiable?
4. What are the consequences of residual arteriovenous fistulas after "closed" in situ bypass grafting?
5. What is the value of preoperative ultrasound mapping of the greater saphenous vein prior to "closed" in situ bypass grafting.

Chapter 2, describes a "closed" in situ vein bypass technique developed in Rotterdam and the results of a pilot study of the first 16 bypasses. We developed a new closed technique using a co-axial catheter embolisation system for intraoperative coil embolisation of the vein contributories.

In 14 patients (8 men, 6 women), 16 in situ bypasses were performed (12 below knee femoropopliteal, 4 femorocrural). The embolisation procedure took - after a learning curve in the first patients - less than one hour. In 4 cases persistent arteriovenous fistulas had to be treated in the postoperative period. Two major wound complications occurred. Three early bypass failures were observed. One late failure occurred due to a rupture of the bypass 6 weeks postoperatively after a deep wound complication. The remaining 12 bypasses were patent, with a median follow-up of 16 (3 - 26) months. We concluded that these preliminary results suggest that the "closed" in situ vein bypass technique is feasible.

Chapter 3, describes the results of a multi-centre randomised trial. The new "closed" technique, introduced in the previous chapter, was compared to the standard "open" in situ bypass technique.

In 4 centres, in 95 patients, 97 in situ bypasses were performed: 47 "closed" and 50 "open". Patients were stratified for below knee femoropopliteal bypasses (60) and femorocrural bypasses (37). Indications for operation were disabling intermittent claudication (29), rest pain (26) or ulcers and/or necrosis (42).

Postoperative mortality was 2 % (1 in the "closed", 1 in the "open" group). A total number of 16 (34%) wound complications (grade 1, 2 and 3) occurred in the closed group compared to 36 (72%) in the open group ($P < 0.05$). Deep wound complications (grade 2) occurred in 6 patients (13%) of the "closed" group, compared to 15 (30%) in the "open" group. In both groups 3 patients (6%) developed deep wound complications including the bypass area (grade 3).

In the "closed" group 20 patients needed additional treatment for AV-fistulas, compared to 4 in the "open" group.

One year patency rates did not show a statistically significant difference: primary patency rates were 65% and 61% and secondary patency rates were 86% and 76% respectively for the "closed" and "open" group.

We concluded that these results indicate that a "closed" technique reduces wound complication rates, without negative effects on the short term patency rates.

However, following "closed" in situ bypass grafting, an increased number of residual AV-fistulas are detected that need treatment.

Chapter 4, describes a study, comparing important cost affecting parameters of the "closed" to the "open" in situ bypass technique. The "closed" in situ vein infrainguinal bypass, results in a reduction of wound complication rate and therefore probably nursing costs, compared to the "open" in situ bypass. This clear advantage is partly diminished by the extra costs involved with the "closed" procedure, caused by the additional disposable materials needed and the longer duration of the operation time. Besides that, a larger percentage of residual AV-fistulas are treated postoperatively after "closed" in situ bypass grafting.

In a randomised group of 73 patients (35 "closed" and 38 "open" in situ bypasses) from two centres, duration of operation, length of hospital stay and the percentage of patients treated for residual AV-fistulas, were analysed. In addition a cost analysis of the operation, nursing care and costs of treatment of residual AV-fistulas was performed to illustrate the effects of the differences between the "closed" and "open" group on the costs.

The median duration of the operation was 210 minutes (range 105-570) for the "closed" procedure and 154 minutes (range 90 - 355) for the "open" procedure ($P < 0.05$). The median length of hospital stay was 16 days (range 5-51) after a "closed" in situ bypass and 25 days (range 12 - 65) after an "open" in situ bypass ($P < 0.01$). The percentage of patients treated for residual AV-fistulas was 40% in the "closed" group and 5% in the "open" group ($P < 0.01$).

Cost calculations showed that the median "closed" operation was US$ 798 more expensive than the "open" operation. The median nursing care costs were US$ 2664 less for the "closed" group. The costs for treatment of residual AV-fistulas were not calculated since the amount strongly depends on the treatment modality. We estimated the costs for residual AV-fistula treatment to be US$ 175 for surgical ligation and US$ 660 for percutaneous embolisation.

We concluded that the "closed" in situ bypass technique is cost-effective compared to the "open" technique.

Chapter 5, describes our experiences with residual AV-fistulas following "closed" in situ bypass grafting. "Closed" in situ bypass techniques are associated with a relative high number of patients (up to 40%) treated postoperatively for residual AV-fistulas. The purpose of this study was to evaluate the consequences of detected residual AV-fistulas after "closed" in situ bypass grafting.

After 35 "closed" in situ vein bypass operations (in 34 patients) in which a total number of 216 side branches were coil-embolised, assessment of residual AV-fistulas and bypass patency was performed with duplex scanning. During follow-up a total number of 39 AV-fistulas (15% of the total number of 216+39=255 side branches) were detected in 21 of the 35 bypasses. Of these 39 AV-fistulas, thirteen (5%) closed spontaneously. Fifteen AV-fistulas (6%) remained unchanged and eleven (4%) were treated. In 3 patients 4 asymptomatic residual AV-fistulas were treated. Only in 4 patients a total number of 7 symptomatic AV-fistulas were treated for: decreased flow in the bypass segment distally of AV-fistulas in 1 patient; persistent leg edema in 1 patient; pain and redness of the skin in 2 patients.

The 1-year primary patency rate was 80% (SE 8.4%). In none of 6 bypass occlusions residual AV-fistulas had been detected during follow-up.

We concluded that residual AV-fistulas only need treatment if they are symptomatic (after 6% of "closed" in situ bypasses).

Chapter 6, describes our findings with preoperative ultrasound mapping of the greater saphenous vein (GSV) prior to in situ vein bypass grafting. During "closed" in situ bypass procedures, the valvulotomy procedure is performed "blindly" and the vein contributories are embolised with a catheter and embolisation coils. Anatomical variations like narrow lumen segments and duplications of the GSV increase the risk of complications or make "closed" in situ bypass grafting technically impossible.

In 44 patients preoperative ultrasound findings of 1. duplications and 2. lumen assessment of the GSV were compared to the intraoperative findings.

1. In 9 patients (20%) the preoperative ultrasound examination showed a duplication. Preoperative ultrasound had missed a duplication in 2 cases but had instead shown a narrow segment in both.
2. The preoperative ultrasound assessment of lumen diameter showed a narrow lumen segment in 10 of the 44 patients. In 1 patient an intraoperatively detected

narrow lumen had not been seen on preoperative ultrasound.

We concluded that preoperative ultrasound mapping of the GSV is a sensitive tool for detection of duplications and narrow vein segments. Since these anatomical variations are important to be known by the vascular surgeon before performing a "closed" in situ bypass operation, preoperative vein mapping should be considered when planning such a procedure.

Chapter 8.

SAMENVATTING (SUMMARY IN DUTCH)

SAMENVATTING

Dit proefschrift beschrijft de resultaten van een onderzoek naar de waarde van een in Rotterdam ontwikkelde nieuwe "gesloten" in situ bypass techniek. De in situ bypass is een veelgebruikte methode voor behandeling van ernstig arterieel vaatlijden van het been. Bij de in situ bypass operatie wordt een vaatreconstructie verricht, waarbij gebruik gemaakt wordt van de ipsielaterale vena saphena magna (VSM). De gebruikelijke "open" techniek, waarbij de VSM via een lange huidincisie wordt vrijgelegd, leidt tot een hoog percentage post-operatieve wondcomplicaties. Aangezien bij de nieuwe "gesloten" techniek alleen kleine huidincisies nodig zijn ter plaatse van de anastomosen, was onze verwachting dat deze techniek zou leiden tot een reductie van het aantal post-operatieve wondcomplicaties.

Hoofdstuk 1, de introductie, beschrijft ten eerste kort de geschiedenis van de arteriële vaatreconstructie in het been, waarbij gebruik gemaakt wordt van de vena saphena magna (VSM). Vervolgens worden de verschillende, recent voorgestelde "gesloten" in situ bypass technieken belicht. Deze technieken hebben gemeen dat ze de zijtakken van de VSM met behulp van embolisatiecoils afsluiten. De initiële resultaten van de eerste onderzoekers op dit gebied waren wisselend; de "gesloten" technieken bleken uitvoerbaar, maar leidden soms tot een aanzienlijke verlenging van de operatieduur en tot een hoog aantal post-operatief opengebleven zijtakken ofwel persisterende arterio-veneuze (AV)-fistels van de bypass. Aan het eind van de inleiding worden de vraagstellingen van het door ons verrichte onderzoek uiteengezet, namelijk:

1. Is de door ons voorgestelde techniek bruikbaar?
2. Wat zijn de voor- en nadelen ten opzichte van de standaard "open" in situ bypass techniek?
3. Is de "gesloten" techniek economisch verantwoord in vergelijking met de "open" techniek?
4. Wat zijn de consequenties van persisterende arterio-veneuze fistels na de "gesloten" techniek.
5. Wat is de waarde van de echografische beoordeling van de vena saphena magna voorafgaand aan "gesloten" in situ bypass operaties.

Hoofdstuk 2 beschrijft de resultaten van de pilot studie: De in Rotterdam ontwikkelde "gesloten" techniek en de resultaten van de eerste 16 in situ bypasses worden beschreven. Wij maakten gebruik van een co-axiale embolisatiecatheter voor het per-operatief emboliseren van de zijtakken van de VSM.

Bij 14 patiënten werden 16 in situ bypasses vervaardigd; 12 femoro-popliteale (onder de knie) en 4 femoro-crurale reconstructies. De per-operatieve embolisatieprocedure kostte, na een leerperiode, minder dan 1 uur. In 4 gevallen werden in de post-operatieve fase alsnog opengebleven zijtakken van de vene (persisterende arterio-veneuze fistels) afgesloten. Bij 2 patiënten ontstond een belangrijke post-operatieve wondcomplicatie. Drie bypasses occludeerden in de vroege post-operatieve fase. In de latere fase, 6 weken post-operatief, ontstond een bypass ruptuur na een diepe wondcomplicatie. De overige 12 bypasses functioneerden goed met een mediane follow-up van 16 (3-26) maanden. Wij concludeerden dat deze eerste resultaten een goede bruikbaarheid van de "gesloten" in situ bypass techniek suggereerden.

Hoofdstuk 3 beschrijft de resultaten van een gerandomiseerde multi-center trial. De in het vorige hoofdstuk beschreven "gesloten" in situ bypass techniek werd vergeleken met de standaard "open" in situ bypass techniek.

In 4 ziekenhuizen werden bij 95 patiënten 97 (47 "gesloten", 50 "open") in situ bypasses verricht ter behandeling van ernstig invaliderende claudicatio intermittens (29), rustpijn (26) of weefselverlies (42). Er werd gestratificeerd voor "onder-de-knie" femoro-popliteale (60) en femoro-crurale (37) bypasses.

De post-operatieve mortaliteit was 2% (1 patiënt in de "gesloten" en 1 in de "open" groep). In de post-operatieve fase werden in de "gesloten" groep in totaal (graad 1, 2 en 3 tezamen) 16 (34%) wondcomplicaties gezien en in de "open" groep 36 (72%) ($P < 0,001$). Diepe, graad 2 wondcomplicaties werden bij 6 patiënten in de "gesloten" groep gezien en bij 15 patiënten in de "open" groep ($P < 0,05$). In beide groepen ontstond er bij 3 patiënten een graad 3 wondcomplicatie tot in het niveau van de bypass.

Bij 20 patiënten in de "gesloten" en 4 in de "open" groep werden in de post-operatieve fase opengebleven zijtakken (persisterende AV-fistels) afgesloten.

De 1-jaars patency rates lieten geen statistisch significant verschil zien: de primaire patency rates waren 65% en 61% en de secundaire patency rates waren

86% en 76% respectievelijk voor de "gesloten" en de "open" groep.

Uit deze resultaten concludeerden wij dat de "gesloten" techniek tot een significante daling van het aantal post-operatieve wondcomplicaties leidt. Na "gesloten" in situ bypasses moet echter rekening gehouden worden met een hoger aantal persisterende AV-fistels, die in een aantal gevallen alsnog behandeld moeten worden.

Hoofdstuk 4 beschrijft de vergelijking van een aantal belangrijke kostenbepalende aspecten van de "gesloten" ten opzichte van de "open" in situ bypass. De "gesloten" techniek leidt, in vergelijking met de "open" techniek, tot een vermindering van het aantal post-operatieve wondcomplicaties en daardoor vermoedelijk tot een vermindering van de opnamekosten. Dit voordeel wordt deels teniet gedaan door de extra kosten verbonden aan de "gesloten" techniek, veroorzaakt door de benodigde disposable materialen en de langere operatieduur. Daarnaast worden er meer patiënten post-operatief voor persisterende AV-fistels behandeld.

Het kostenaspect werd bestudeerd in 2 ziekenhuizen, waar bij 73 gerandomiseerde patiënten een in situ bypass verricht was (35 "gesloten" en 38 "open"). De duur van de operatie, de opnameduur en het percentage patiënten, waarbij post-operatief AV-fistels werden behandeld, werden vergeleken. Daarnaast werd ter illustratie van het effect van deze factoren op de kosten, een kostenanalyse van de operatie, de opname en de kosten voor behandeling van persisterende AV-fistels verricht.

De mediane duur van de operatie was 210 minuten (spreiding 105-570) voor de "gesloten" techniek en 154 minuten (spreiding 90-355) voor de "open" techniek ($P < 0,05$). De mediane opnameduur was 16 dagen (spreiding 5-51) na een "gesloten" en 25 dagen (spreiding 12-65) na een "open" in situ bypass ($P < 0,01$). Het percentage post-operatief behandelde patiënten voor persisterende AV-fistels was 40% in de "gesloten" en 5% in de "open" groep ($P < 0,01$).
Kostenberekeningen lieten zien dat de mediane directe kosten voor een "gesloten" in situ bypass operatie fl 1357,- hoger en voor de opname fl 4529,- lager lagen dan bij de "open" techniek. De kosten voor behandeling van persisterende AV-fistels werden niet berekend, aangezien de hoogte hiervan sterk afhangt van de gebruikte behandelmethode.

De geschatte kosten voor AV-fistel behandeling waren fl 300,- voor chirurgische ligatie en fl 1120,- voor percutane embolisatie.

De conclusie van deze studie was, dat de "gesloten" techniek tot een kostenbesparing leidt ten opzichte van de "open" techniek.

Hoofdstuk 5 beschrijft de consequenties van persisterende AV-fistels na "gesloten" in situ bypass operaties. De "gesloten" in situ bypass techniek heeft in een aantal studies geleid tot een relatief hoog percentage (tot 40%) post-operatieve behandelingen voor persisterende AV-fistels. Het doel van deze studie was om na te gaan welke consequenties de post-operatief gedetecteerde AV-fistels hadden.

Na 35 "gesloten" in situ bypasses (bij 34 patiënten), waarbij in totaal 216 zijtakken per-operatief geëmboliseerd waren, werd duplexonderzoek naar persisterende AV-fistels en doorgankelijkheid van de bypass verricht. Tijdens de follow-up werden bij 21 van de 35 bypasses in totaal 39 persisterende AV-fistels (15% van het totaal aantal van 216+39=255 zijtakken) ontdekt. Van deze AV-fistels occludeerden er dertien (5%) alsnog spontaan. Vijftien (6%) AV-fistels bleven stationair en elf (4%) werden behandeld. Bij 3 patiënten werden in totaal 4 asymptomatische AV-fistels behandeld. Bij 4 patiënten werden 7 symptomatische AV-fistels behandeld. Redenen voor behandeling waren: verminderde bloeddoorstroming in het deel van de bypass distaal van AV-fistels bij 1 patiënt; oedeem van het been bij 1 patiënt; roodheid en pijn van een locaal huidgebied bij 2 patiënten.

De 1-jaars patency rate van de bypasses was 80% (SE 8.4%). Bij geen van de tijdens de follow-up optredende bypassocclusies waren vooraf AV-fistels gedetecteerd.

Onze conclusie was dat persisterende AV-fistels slechts behandeld dienen te worden als ze symptomatisch zijn (na ongeveer 6% van de "gesloten" in situ bypasses).

Hoofdstuk 6 beschrijft onze ervaringen met pre-operatief echografisch onderzoek van de vena saphena magna (VSM) voor in situ bypass operaties. Bij de "gesloten" in situ bypass techniek zoals wij die gebruiken wordt de valvulotomieprocedure "blind" uitgevoerd en worden de zijtakken van de vene met behulp van een co-axiale catheter en coils geëmboliseerd.

Anatomische variaties als een vernauwd lumen van de vene en verdubbelingen vergroten het risico op complicaties of maken een "gesloten" procedure technisch onuitvoerbaar.

Bij 44 patiënten werd de VSM pre-operatief echografisch onderzocht op:
1) verdubbelingen of duplicaties en 2) nauwe segmenten.
De pre-operatieve bevindingen werden vergeleken met het aspect van de vene tijdens de operatie.

Resultaten:
1) Bij 9 patiënten (20%) liet pre-operatieve echografie een duplicatie van de VSM zien. Bij 2 patiënten was een duplicatie gemist, maar was de VSM als vernauwd beoordeeld.
2) De pre-operatieve beoordeling van de lumendiameter liet een vernauwd segment zien in 10 van de 44 patiënten. Bij 1 patiënt was een tijdens de operatie als vernauwd beoordeelde vene niet als vernauwd beoordeeld tijdens de pre-operatieve echografie.

Onze conclusie was dat pre-operatief echografisch onderzoek van de VSM een gevoelige methode is voor detectie van duplicaties en vernauwde segmenten. Aangezien deze anatomische variaties c.q. afwijkingen frequent voorkomen en bekend moeten zijn in verband met de technische uitvoerbaarheid van "gesloten" in situ bypass operaties, vinden wij dat dit onderzoek aan de ingreep vooraf zou moeten gaan.

Chapter 9

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Chapter 10

CURRICULUM VITAE

Lukas Carolus van Dijk

Geboren op 29 april 1964, te Amsterdam.
Gehuwd met Parvin C. Azimullah sinds 19 juni 1987.
Kinderen: Raïssa en Magda.

Opleiding:

1976 - 1982	Atheneum b, Petrus Canisius College, Alkmaar.
1982 - 1990	Studie Geneeskunde, Vrije Universiteit, Amsterdam. Doctoraalexamen 26 september 1986. Artsexamen 18 mei 1990.

Werkervaring en aanvullende opleiding:

1986 - 1987	Student-assistent fysiologie, Vrije Universiteit, Amsterdam.
1987 - 1988	Wetenschappelijk onderzoek cardio-vasculaire fysiologie Vrije Universiteit, Amsterdam, hoofd Prof. Dr N. Westerhof.
Oktober 1989	Elective clerkship "Trauma and Emergency Medicine", University of California Los Angeles, Los Angeles.
1990 - 1991	Militaire Dienst, Militair Geneeskundige Dienst Rotterdam en detachering Noord-Irak.
1991 - 1993	Arts-onderzoeker vaatchirurgie, Academisch Ziekenhuis Rotterdam "Dijkzigt", hoofd Prof. Dr H. van Urk.
1993 - heden	Arts-assistent Radiologie, Academisch Ziekenhuis Rotterdam opleiders: Prof. Dr H.E. Schütte en Prof. Dr J.S. Laméris.