Natural History of Composite Sequential Bypass

Ten Years’ Experience

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Background: We previously reported 48-month patency rates of composite sequential bypass (CSB) approaching 60%. Yet, extended patency and limb salvage rates are unknown.

Hypothesis: Long-term patency and limb salvage rates of CSB are affected by sex, bypass configuration, and warfarin therapy.

Design: Medical records of all patients who underwent CSB during a 10-year period were retrospectively reviewed.

Setting: A referral center for the Chicago, Ill, region.

Patients: One hundred consecutive patients (mean age, 68.8 years; 57% were men and 49% had diabetes) undergoing 102 CSBs for limb salvage (ulcer, 43%; rest pain, 39%; and gangrene, 18%) from January 1986 to January 1996 were identified.

Interventions: Warfarin was used after surgery by 72% of patients and aspirin was used by the remainder of them.

Main Outcome Measures: Life table primary patency and limb salvage rates were compared for sex, diabetes mellitus status, location of distal prosthetic anastomosis (above knee vs below knee), and anticoagulation drug therapy (warfarin sodium vs aspirin) with log-rank statistics.

Results: Primary patency of CSB was 56% at 24 months, 29% at 48 months, and 20% at 84 months (SE < 10%; mean follow-up, 19.6 months [range, 1.0-110.0 months]). Limb salvage rates were 64% at 24 months, 30% at 48 months, and 23% at 84 months (SE < 10%); 66% and 90% of patients had failed grafts requiring amputation by 3 months and 1 year, respectively.

Conclusions: Composite sequential bypass for limb salvage provides reasonable 2-year patency. However, patency rates steadily declined from year 2 to year 5. After CSB failure, limb salvage rates are poor, with 90% of patients progressing to amputation within 1 year.

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The autogenous greater saphenous vein remains the preferred conduit for infrageniculate arterial bypass procedures. When performed successfully, this form of bypass restores blood flow to the ischemic lower extremity and, with appropriate monitoring and follow-up, excellent primary and secondary patency can be achieved. Sufficient lengths of autogenous conduit are not available in as much as 30% of patients. Alternative conduits include prosthetic grafts, remote sources of vein (arm vein, lesser saphenous vein, etc), or a combination of prosthetic graft and autogenous vein. Furthermore, the use of short segments of vein in combination with polytetrafluoroethylene (PTFE) has become increasingly popular for the formation of anastomotic patches or cuffs. We used composite sequential bypass (CSB), as first described by DeLaurentis and Friedmann, as a possible technique to overcome the poor patency rates of infrageniculate prosthetic reconstructions. Although earlier published 3-year primary patency rates range from 35% to 50%, the long-term patency and limb salvage rates of this form of reconstruction are largely unknown. Therefore, we undertook this study to determine those rates using CSB arterial reconstruction. In addition, we attempted to determine the impact that location of the intermediate anastomosis, sex, and role of anticoagulation medication therapy have on patency.

RESULTS

Patients ranged in age from 30 to 91 years (mean, 69 years). The CSB was per-
PATIENTS AND METHODS

Medical records and results of blood flow studies were reviewed for 100 consecutive patients identified in the Northwestern Vascular Surgery database as having undergone 102 CSB procedures at Northwestern Memorial Hospital, Chicago, Ill, between January 1985 and January 1996. All bypass procedures included a PTFE bypass graft to the popliteal artery, with an intermediate anastomosis either above or below the knee and with a second venous graft that extended to an infrageniculate artery to form the distal anastomosis. Configuration of the synthetic conduit to the autogenous vein was an end-to-side proximal anastomosis of the vein graft from the hood of the distal anastomosis of the PTFE graft (Figure 1). Other types of composite bypasses such as cuffed and patched distal anastomoses, iliac popliteal-tibial bypasses, and axillary popliteal-tibial bypasses, were excluded from this analysis.

The technique of composite sequential grafting was used only when an autogenous vein of sufficient quality was not available. Surgical exposure of the individual vessels that were used for inflow and outflow followed standard principles. If possible, the PTFE portion was tunneled deeply in the thigh in an attempt to protect the graft from wound complications. Completion angiography was routinely used.

Patients were monitored as outpatients by following a standard practice pattern that included an office visit within 2 weeks of discharge, at 3 months, and then every 6 months. Arterial Doppler examinations were performed before and after surgery and then concurrently with the outpatient follow-up appointments. A decline of greater than 13% in the ankle-brachial index was used to determine graft failure or stenosis. That finding or the clinical suggestion of failed or failing bypass grafts prompted urgent arteriographic evaluation.

Life table patency rates were determined according to the methods recommended by Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS/ISCVS) guidelines for reporting the patency of infrageniculate grafts in lower extremity ischemia.14 Patency comparisons between subgroups used log-rank statistical analysis.

Follow-up of 1 to 110 months (mean, 19.6 months) was available from the time of surgery to the time of occlusion, last known patency, or death. No perioperative deaths (within 30 days of surgery) occurred. Primary patency of CSB was 56% at 24 months and 20% at 84 months (SE < 10%). The limb salvage rate was 23.1% at 84 months (SE < 10%) (Table and Figure 2). Sixty-six percent and 90% of patients with failed grafts required amputation by 3 months and 1 year, respectively.

Patency rates for grafts placed above or below the knee (P = .89), did not differ in patients with vs without diabetes (P = .57), or in men vs women (P = .60). Patency rates for patients treated with warfarin (15% at 84 months) (Figure 3) did not significantly differ from those of patients treated with aspirin alone (32% at 84 months) (P = .10).

The autogenous saphenous vein remains the conduit of choice for lower extremity bypass procedures, particularly to the tibial vessels. Previous experience with prosthetic grafts to tibial vessels demonstrated poor long-term patency. Veith et al.16 in a randomized study, found a 2-year patency of 22% and a 4-year patency of 12% for tibial PTFE grafts. Similar results were reported by Whittemore et al.,17 who found a 12% 5-year patency rate for PTFE grafts to tibial vessels. In 1991, Londrey and colleagues18 from the University of Southern Illinois reported no patent PTFE grafts to tibial vessels at 5 years. In an effort to avoid using all-prosthetic grafts to tibial vessels, several authors3,19 reported the use of spliced arm veins and alternative inflow sources. Furthermore, arteriovenous fistulae and various cuffs and boots at the distal anastomosis have been devised to enhance the long-term patency of long PTFE grafts.20 In addition, long-term anticoagulation medication therapy has been used to improve long-term patency of all-prosthetic infrapopliteal grafts.21

We report the largest series of patients undergoing CSB grafts with the longest follow-up (84 months). We found that patency at 4 years was nearly 30%, with 20% of the grafts functioning at 84 months. Anticoagulation drug therapy, sex, and location of the intermediate anastomosis did not affect long-term outcome.

The CSB graft described by DeLaurentis and Freidmann11 differs from a straight composite graft. A CSB graft is constructed using an intermediate anastomosis to the popliteal artery above or below the knee, with a long spatulated proximal anastomosis of the vein graft to the pros-
thetic graft. Perhaps it is this long intermediate anastomosis between the vein and prosthetic material that increases the patency of this configuration over that of a straight composite graft. In the original description of our experience by Flinn et al in 1984, 59 patients underwent CSB grafting for an overall patency at 2 years of 80%. In an intermediate study, McCarthy et al reported 1- and 4-year patencies of 72% and 40%, respectively. The current study encompasses all previous ones, but with a much larger number of patients. The venous conduit for the distal anastomosis was usually obtained from the ipsilateral lesser saphenous vein or venous segment of an upper extremity.

Forty-nine percent of patients had diabetes. This high incidence represents the fact that most patients with diabetes will have an open popliteal segment for intermediate anastomosis to be performed. The high incidence of diabetes mellitus may also explain the high amputation rate after graft failure.

The limb salvage rate after CSB is lower than that seen with other bypasses. In most cases, limb salvage exceeds graft patency. Here, the limb salvage rate closely followed the graft patency rate. Amputation rapidly followed graft failure, with 90% of patients undergoing amputation at 1 year. The high amputation rate after failure of these grafts may reflect the end-stage nature of patients with multilevel disease.

Use of long-term anticoagulation medications, particularly warfarin, is controversial. Flinn and colleagues first reported a beneficial effect in maintaining long-term patency in prosthetic tibial bypass grafts in

| Life Table |
|---|---|---|---|---|---|---|
| Interval, mo | Bypasses at Risk, No. | Failed Grafts, No. | Duration, mo | Lost to Follow-up, No. | Deaths, No. | Interval Patency, % | Cumulative Patency, % SE, % |
| 0 | 102 | 2 | 0 | 0 | 0 | 0.98 | 1.00 |
| 3 | 101 | 4 | 2 | 4 | 4 | 0.96 | 0.96 |
| 6 | 87 | 8 | 1 | 5 | 4 | 0.90 | 0.86 |
| 9 | 69 | 6 | 2 | 1 | 1 | 0.91 | 0.78 |
| 12 | 59 | 6 | 1 | 1 | 0 | 0.89 | 0.70 |
| 15 | 51 | 0 | 2 | 2 | 1 | 1.00 | 0.70 |
| 18 | 46 | 1 | 0 | 0 | 0 | 0.98 | 0.68 |
| 21 | 45 | 4 | 2 | 1 | 2 | 0.90 | 0.62 |
| 24 | 36 | 3 | 1 | 2 | 0 | 0.91 | 0.56 |
| 27 | 30 | 2 | 1 | 0 | 0 | 0.93 | 0.52 |
| 30 | 27 | 0 | 0 | 1 | 0 | 1.00 | 0.52 |
| 33 | 28 | 1 | 2 | 0 | 1 | 0.96 | 0.50 |
| 36 | 22 | 3 | 0 | 0 | 0 | 0.86 | 0.43 |
| 42 | 19 | 2 | 0 | 3 | 0 | 0.88 | 0.38 |
| 48 | 14 | 3 | 0 | 1 | 0 | 0.77 | 0.29 |
| 54 | 10 | 1 | 0 | 0 | 0 | 0.90 | 0.26 |
| 60 | 9 | 0 | 0 | 0 | 0 | 1.00 | 0.26 |
| 66 | 9 | 2 | 0 | 0 | 0 | 0.78 | 0.20 |
| 72 | 7 | 0 | 1 | 1 | 1 | 1.00 | 0.20 |
| 78 | 5 | 0 | 0 | 1 | 1 | 1.00 | 0.20 |
| 84 | 3 | 0 | 0 | 0 | 0 | 1.00 | 0.20 |
| 90 | 2 | 0 | 0 | 0 | 1 | 1.00 | 0.20 |
| 96 | 1 | 0 | 0 | 0 | 0 | 1.00 | 0.20 |
| 104 | 1 | 0 | 0 | 0 | 0 | 1.00 | 0.20 |
| 110 | 1 | 0 | 0 | 0 | 0 | 1.00 | 0.20 |

**Figure 2.** Cumulative life table primary patency. The SE remained less than 10% until after 84 months.

**Figure 3.** Cumulative life table primary patency for composite sequential bypass, with and without long-term warfarin therapy. No statistically significant difference was noted between the 2 groups.
1988. Four-year patency of prostatic grafts was 37%, without significant adverse effects. Other studies by Papas et al° did not demonstrate any beneficial effect with long-term anticoagulation drug therapy. In the current study, use of warfarin did not enhance the patency rate for CSB grafts.

The CSB graft offers a potential advantage by providing increased flow through the prosthetic graft limb and a vein graft–arterial interface at the distal anastomosis on the tibial artery. Despite this theoretical advantage, long-term patency is only modestly better than that for femoral-tibial bypass with PTFE alone. Recently, several authors reported extended long-term patency using distal anastomotic patches, boots, or cuffs. In a single-institution, randomized trial, Stonebridge et al° reported a doubling of the distal patency rate at 2 years, from 19% to 49%, using a Miller cuff but no anticoagulation medication. The exact mechanism by which a small venous interposition at the distal anastomosis enhances patency is unknown. Most likely, the enlargement created by the patch minimizes the effect of intimal hyperplasia. Thus, in one sense, CSB accomplishes the same goal as distal venous interposition. Intimal hyperplasia is minimized at the distal tibial anastomosis by an all-autogenous anastomosis, whereas graft-to-vein anastomosis is exaggerated by a long anastomosis at the intermediate anastomosis.

CONCLUSIONS

The CSB is an effective alternative to an all-prosthetic bypass graft to distal tibial vessels. Although the patency and limb salvage rates are inferior to an all-autogenous graft, they are better than historical controls for prosthetic tibial grafts. Patency rates for composite sequential graft size are similar to those for venous interposition grafts, cuffs, or boots. Use of anticoagulation medications does not seem to enhance patency, although it is difficult to draw firm conclusions regarding the use of warfarin because these patients were not randomized. The location of the intermediate anastomosis did not affect patency rates, and it seems that using the vein segment across the knee plays no role in maintaining long-term graft patency. To clearly understand the role of the CSB graft in relation to distal cuffs or arteriovenous fistulae, a randomized study is necessary.

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REFERENCES


DISCUSSION

William H. Baker, MD, Maywood, Ill: I am probably unbelievably qualified to discuss this article, since I have done at least 3 or 4 of these procedures in my career; this operation was popularized in our cardiac surgery units. Multiple anastomoses using 1 conduit were performed under the guise that another look. Am J Surg. 1971;121:382-397.

Again, these were not diabetic patients with necrotic legs. These dogs did not have separation of their vascular beds. Therefore, when we opened the distal bypass, we created a competitive flow, and the flow through the original anastomoses decreased.

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direct flow into the popliteal and a second bypass to the crural vessels? When will just a popliteal bypass suffice? Furthermore, I noticed in 1 of the previous papers by Dr Flinn that several of the distal limbs actually occluded and the patients did well. Did that occur in this series over the long term as well?

Dr Oppatt discussed other alternatives. We can construct a composite conduit of the lesser saphenous vein from 1 or both legs as well as arm veins. When is enough enough? In my opinion, once we start stringing together vein after vein, the results are not very good over time. We have been limiting our vein-vein anastomoses to probably 2.

You did note that historically there were some sequential bypasses that were done using a different technique. Drs Dale and Linton performed end-to-end PTFE-to-vein anastomoses; they reported dismal results. Dr Wheeler on the other hand has reported fairly decent results using this technique. More recently, Justin Miller and John Wolle from Australia and England, respectively, have pioneered a vein cuff technique in which PTFE is inserted onto a vein cuff at the distal anastomoses. Have you tried any of these operations and if so, how did they compare? One of the new members of your faculty, Dr Morasch, has his name on a paper in which there is a 60% 2-year graft patency with primary PTFE-vein cuff operations. You will note that in today’s review, Dr Oppatt did not separate out primary vs secondary operations, and that may be important.

Finally, you mentioned looking for vein whenever you could. How did you look for it? Did you rely purely on duplex examination or did you force yourself to explore veins even when the duplex told you that the vein may be of small diameter? Sometimes, we have not been impressed that the duplex is the know-all and where-all and that some small veins are actually distensible.

For those who don’t delve into these wonderful surgical mysteries, I must tell you that a 60% 2-year patency isn’t bad. If oncologists had an operation that would increase the quality of life in a person with limited life expectancy by 60%, they would gladly proceed to help patients. The Northwestern group is to be congratulated on getting such good results in this difficult group of patients.

Nathan L. Brightwell, MD, Colorado Springs, Colo: Autogenous saphenous vein remains the conduit of choice for lower extremity revascularization; however, in 20% to 30% of the patients the vein is unusable, absent, or thrombosed, as Dr Baker pointed out. Now the options are limited, particularly for bypasses to the lower leg vessels where prosthetic grafts have poor long-term patency.

This study details a large experience of patients undergoing composite sequential bypass graft procedures for limb salvage. The primary patency at 1 year is 56%, 29% for 4 years, and 20% for 7 years. When graft failure occurred, limb salvage was poor. In addition there was a high incidence of diabetics in this patient population.

I have the following questions. What was your method of graft surveillance? Did you use ankle-brachial indices, duplex scanning, or angiography? What are the complications associated with this procedure? Why is the limb salvage rate so low; it’s nearly the same as the patency rate. What about the secondary patency? Did you use thrombolytics or thrombectomy or a combination of the 2, and did you revise any of the grafts with the secondary procedures? Also, at the time of the secondary procedure, did you find intimal hyperplasia or progression of atherosclerotic disease as a cause for the occlusion?

Dr Pearce: This manuscript reviews a large experience with a bypass in a group of difficult patients and what was not said in the paper was that about 50% of these patients had had multiple previous procedures performed on that leg. Only in about 40% to 60% was this a primary procedure. So they had all had previous use of their saphenous vein in that leg.

Dr Baker’s first question was in response to the differences in the circulation beds. The cardiac surgeons for many years have done these kiss-and-run bypasses and when we did these initially with saphenous vein, we could demonstrate augmentation of flow through the main body of the graft. If you did a femoral-tibial bypass with an anastomosis at the popliteal artery and then went to the tibial vessels and put a flow probe on the more proximal part of the graft and clamped the distal vein graft to the tibial vessels, you saw a diminution of total flow. So there is in human beings, unlike the canine counterparts in Maywood, a separation of vascular beds. What’s interesting though is that in some cases you get into trouble with island ischemia. Following 1 of these very distal bypasses, you may find part of the posterior compartment dying with a bypass to the anterior tibial artery. It is not always a given that you will revascularize the leg successfully with 1 of these bypass procedures.

Dr Baker was also quite right and this also fits in with Dr Brightwell’s question about the mode of failure of these grafts. Many years ago, Dr Lester Sauvage showed us that PTFE grafts are thrombogenic and that they are fraught with hyperplasia at the distal anastomosis. Dr Baker was also right that you see some patients with the distal vein graft failed, which is almost always because the run-off has failed. You also have some patients with a patent proximal PTFE graft with failure of the distal vein graft. Here the failure is almost always loss of their run-off, either at the popliteal or the tibial vessels, and I think it is that group of patients who lose their legs quite rapidly after failure of their procedures. Then the final group, which is the most interesting to me, is when the PTFE fails and the vein graft stays open, which makes sense because the vein graft can tolerate very low flows. In these cases all we do is either use thrombolytic therapy or redo the bypass, and that has only occurred in 5 patients.

Some of the complications associated with this operation that are separate from other operations which we do to the tibial vessels include 2 anastomotic aneurysms that have occurred at the intermediate anastomosis. I have a patient in the hospital just yesterday whom we angiogramed who was about 4 years out from 1 of these composite sequential grafts and the anastomosis between the graft and the vein had come apart with aneurysm formation. The other complication is necrosis of the wound at the site of the lesser saphenous harvest. Basically when you lift the leg up to get the lesser saphenous, you put an incision distal in the leg and that incision often doesn’t heal. So we try not to use too many distal veins and Bill is also right, enough is enough. We will only splice 2 veins together.