HISTORICAL VIGNETTES IN VASCULAR SURGERY

Norman M. Rich, MD, Section Editor

The first Gore-Tex femoral-popliteal bypass

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In scientific investigation, "Who's on First" is often an ongoing debate when it comes to medical discoveries and scientific priority.[1] Surgeons embrace the idea of being first to perform an operation, particularly if history later shines upon it a favorable light.

Is it important to be first? The Olympic games initiated by ancient Greeks made heroes out of those who came in *first* in an event. In a presentation to the 25th Anniversary Veith Symposium on "*Firsts" in Vascular Surgery: Who Did What "First,"* Rich gave the subject an in-depth examination. He found that history is replete with claims of *first*. Many of these claims were associated with controversy.[2] *Firsts* in vascular surgery are numerous. It is generally acknowledged that William Harvey was the first to discover circulation. The Chinese, however, claimed they discovered the concept of blood circulation some 2000 years before Harvey.[3] Similarly, coronary arteriosclerosis is often regarded as a Western disease, yet a recent report has found coronary arteriosclerotic disease existed in China >2200 years ago.[4]

Besides "first operations," there are also "famous operations." Harold Ellis, in his book *Famous Operations,* divided the "famous operation" into three types: type I is the breakthrough operation. A type II operation may be insignificant itself, but it marks the introduction of some important point in surgical technique. Finally, the type III operation depends entirely on the patient; the operation itself may be routine, but the patient is a famous person, thus an operation, an act between the surgeon and the patient, does carry extra meaning and significance.[5]

Among all first operations, none can surpass the "blue baby" operation by Blalock and Taussig, performed at the Johns Hopkins Hospital on November 29, 1944.[6] To qualify as a first operation, DeBakey emphasized that the patient must survive the operation.[7] One such example is the homograft replacement of an abdominal aortic aneurysm. Dubost of France did the operation on March 29, 1951. It was later known that Schafer and Dardin, of Kansas, did the same operation on March 2, 1951, 27 days before Dubost. However, their patient died 29 days after the operation, 1 day short of the magic 30 days to be counted as a "survival."[8] Schafer and Dardin thus became just a footnote in the history of aneurysm surgery.

A first operation also depends on the date of the report in the medical literature. The clearest example involves the most common open arterial operation, carotid endarterectomy, with multiple surgeons claiming to have been first to perform the procedure. Eastcott, Pickering, and Rob reported the first carotid surgery on May 19, 1954, and the report usually has been cited as the first operation. However, in a 19-year follow-up report by DeBakey in 1975, it appears that DeBakey did the procedure on August 7, 1953, some 9 months before Eastcott et al. In the quest for being the first in carotid endarterectomy, Dr Denton Cooley introduced his publication on the history of carotid endarterectomy with the quote by Ralph Waldo Emerson[9]: "Every child of the Saxon race is educated to wish to be first. It is our system."

Thus, the first Gore-Tex (W. L. Gore and Associates, Flagstaff, Ariz) femoral popliteal bypass reported here is both the product of a natural desire and an interesting and important landmark in surgical history.

CASE REPORT

An elderly diabetic woman presented to our office in Norfolk, Virginia, with critical lower extremity ischemia <1 year after I entered clinical practice in 1974. She had the additional challenge of having had a ligation and stripping of bilateral lower extremity saphenous varicosities many years before. Angiography revealed an occluded superficial femoral artery, a patent popliteal artery segment below the knee, and limited runoff. The profunda was patent but small.

My partner, Dr Jock Wheeler (later Dean of Eastern Virginia Medical School), and I had encountered this type of situation on several occasions, and it was always a dilemma. We had used an expanded polytetrafluoroethylene (PTFE) IMPRA graft (Impra Inc, Tempe, Ariz) for a femoral-tibial bypass several months earlier. The graft thrombosed in the early postoperative phase, and an attempt at thrombectomy with a Fogarty catheter resulted

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in a longitudinal split in the graft over its entire length. In view of this experience, we were not inclined to try another PTFE graft. And yet, our dilemma remained.

We had heard that another new prosthetic graft made of PTFE had been produced by the W. L. Gore Company. The company was quickly contacted. They were aware of the problems with burst/hoop strength of the PTFE graft because a few of their sample grafts had developed graft aneurysms (personal communication, W. L. Gore Company, August 1975), later formally reported by Campbell et al.[10] This had prompted them to recall all of their sample grafts. By July 31, 1975, the W. L. Gore Company had re-engineered the graft by reinforcement with a thin outer sheath, which resolved the issue of hoop strength. This activity predated the requirement for U.S. Food and Drug Administration approval of new devices; these changes were all in-house modifications.

"When do you need it?" they replied when I asked to see the graft.

"As soon as possible," I said.

Within a few days, Jack Hoover, a new associate with W. L. Gore, was in our office with unsterilized samples of the graft, which looked reasonable and handled well. We ordered six 6-mm reinforced grafts and two 7-mm to 4-mm grafts on August 25, 1975,[11] which arrived 2 days later. On August 28, 1975, we performed a below-knee femoral-popliteal bypass with a 6-mm reinforced Gore-Tex graft, which was sterilized on site. The anastomoses were performed with 5-0 Prolene (Ethicon, Somerville, NJ) suture on an RB-1 taper needle. When the occlusive clamps were released, the anastomoses leaked through the needle holes like the sprinkler head on a watering pot. We had seen this with the IMPRA graft and were not overly alarmed. We quickly reversed the heparin given before anastomotic construction, sprinkled thrombin powder over the bleeding anastomoses, and applied careful pressure. Over the next 5 to 10 minutes, hemostasis was regained.

The patient did well postoperatively, and limb salvage was achieved with a patent graft for several years. Hoover informed us later that this was the first use of the reinforced Gore-Tex graft: Ours had been their first order.[11]

BYPASS: A REVOLUTIONARY CONCEPT

In 1976, Campbell et al[12] reported a small series of patients with femoral-popliteal Gore-Tex bypass grafts.[12] This prompted us to organize our experience. By 1977, we had a series of some 30 patients with reasonable short-term results. These results were submitted for publication, but rejected. Subsequently, the series was presented at the Virginia Surgical Society meeting (because we were the only full-time vascular surgeons in the state, there was no state vascular society at that time). After the presentation, there was only one question: "Are anticoagulants needed postoperatively?" Otherwise, there were no comments or discussion.

The bypass principle, described by Jeger in 1913, was one of the most revolutionary concepts in the history of vascular surgery.[13] Interestingly, Jeger never performed a bypass. This concept allowed vascular surgeons to aggressively attack segmental arterial occlusive disease. The discovery of a fabric graft material by Voorhees, in 1951, allowed the bypass principle to flourish.[14] The DeBakey-led Baylor group used the Dacron graft (DuPont, Wilmington, Del) to replace aneurysms or to bypass occlusive disease in the aortoiliac position, which helped the growth of the era of reconstructive arterial surgery. However, the use of prosthetic grafts in limb salvage for critical ischemia secondary to severe infrainguinal arterial occlusive disease remained a serious issue because the results were not ideal.

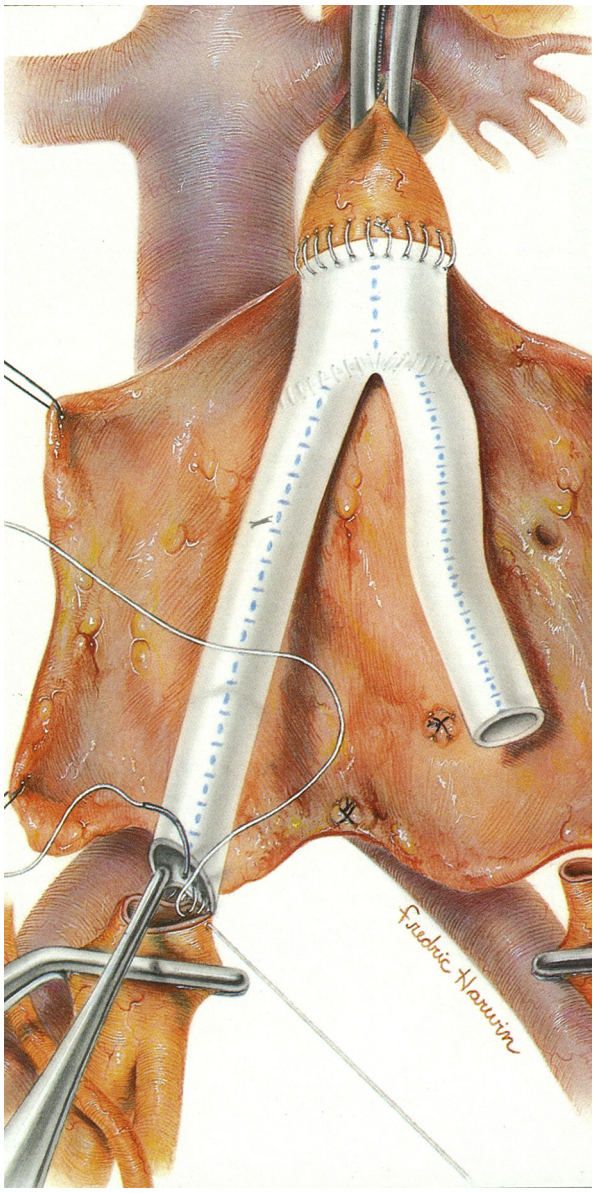

Fig. Illustration shows a Gore-Tex graft being placed.

The development of femoral bypass dates back to the early 20th century, yet it was Kunlin, in 1948, who caught the attention of vascular surgeons internationally when he reported a femoral-popliteal bypass using a saphenous vein graft.[13] The extension of the femoral bypass to the

Table. Chronology of development of infrainguinal bypass since Kunlin[a]

Date	*Surgeon*	*Development*
1951	E. Lowenberg	Saphenous vein, lateral approach
1958	J. J. McCaughan	Distal popliteal artery exposure
1959	G.C. Morris	Posterior approach—posterior tibial artery
1959	C. Rob	In situ vein graft
1960	E. C. Palma	Vein graft to posterior tibial artery
1961	J. J. McCaughan	Vein graft to posterior and anterior tibial artery, calf level
1966	J. J. McCaughan	Femoral to posterior tibial (ankle) vein graft
1966	H. E. Garrett	Bypass to distal posterior tibial artery
1967	J. A. Mannick	Bypass to isolated popliteal artery
1967	J. J. Ochsner	Dorsalis pedis
1968	H. E. Garrett	Tibial arteries at ankle level
1969	V. V. Kakkar	Cephalic vein
1971	D. A. DeLaurentis	Sequential graft
1972	W. A. Dale	Composite graft
1975	F. A. Reichle, R. Tyson	Peroneal artery
1988	E. Ascer, F. J. Veith, S.K. Gupta	Bypass to plantar artery

[a]Modified from Yao JS, Pearce WH. Preface. In: Yao JS, Pearce WH, eds. The ischemic extremity: advances in treatment. East Norwalk, CT: Appleton & Lange; 1995.

below-knee popliteal and tibial or peroneal arteries was slow to follow (Table). Improvement in technique was also very slow, although Cartier reported use of an in situ vein graft in 1960.[15] This technique failed to gain popularity until Leather et al[16] reported their experience in 1979, including some technical refinements. Despite this progress, autogenous tissue was still viewed as the ideal bypass graft. The need for an off-the-shelf prosthetic graft for femoral-popliteal bypass to be used when autogenous tissue was not available or in certain high-risk patients was widely acknowledged.

The expanded PTFE Gore-Tex tubular graft was first used as a venous prosthesis by Dr Ben Eiseman.[17] This is a fascinating story of serendipity, imagination, and friendship[18] that Chandler called a magical moment in vascular surgery.[19] The accidental discovery of the Gore-Tex graft is of interest because it led to renewed hope that a suitable vascular prosthetic graft for femoral arterial bypass had been found. Several investigators began to report the successful use of the PTFE graft in the arterial circulation.[20] However, it was the multicenter randomized trial by Veith et al[21] that firmly established the value of the PTFE graft in infrainguinal arterial reconstruction.

Other substitutes for the saphenous vein graft have been tried, including the human umbilical cord vein, mandril grafts, bovine grafts, cryopreserved grafts, and composite grafts. These grafts garnered scattered use, but none received the attention and wide application that the Gore-Tex graft did. Although the first use of a Gore-Tex graft for a femoral-popliteal bypass in 1975 received little initial attention, this graft went on to international application in >5 million cases and underwent several improvements (thin walled, stretch, and ringed; personal communication, W. L. Gore Company, April 2012). The Gore-Tex graft is not yet the ideal replacement for an autogenous saphenous vein, but it has been a substantial step forward.

On April 3, 1991, we implanted the first Gore-Tex Stretch graft in the aortobiiliac position (Fig), this time at the invitation of Don Lass, another W. L. Gore associate. The suture material for the anastomoses was 3-0 Gore-Tex, which offered a considerable improvement over the sutures used for the first femoral-popliteal bypass. Leaking after clamp release was minimal. This event, however, was not followed by the same explosive popularity as the Gore-Tex femoral-popliteal bypass graft placed 16 years earlier.

We are fully aware that being first does not always mean being best. These first two cases are reported as a footnote to a graft that was discovered accidentally, followed by worldwide acceptance and widespread application.

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