

HISTORICAL VIGNETTES IN VASCULAR SURGERY

Norman M. Rich, MD, Section Editor

Early endovascular grafts at Montefiore Hospital and their effect on vascular surgery

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Vascular surgery is very fortunate. It recognized the transition from open surgery to endovascular procedures as treatments for vascular disease early enough to adapt as a specialty. As a result, most vascular surgeons in North America became competent with endovascular techniques, and the survival of the specialty was assured. The endovascular graft program at Montefiore Hospital played a major role in vascular surgery's early recognition of the importance of the endovascular revolution. This article will review the history of this early endovascular graft program and how it influenced the specialty. (*J Vasc Surg* 2014;59:547-50.)

The Montefiore Division of Vascular Surgery had a long-standing interest in aggressive efforts to save lower limbs threatened by gangrene and critical limb ischemia.^{1,2} Many of the very distal reconstructive operations were based on unusually fine arteriography performed by our interventional radiology colleagues.¹ In addition, because of the high cardiopulmonary risk of many of our limb salvage patients and the multilevel nature of their arterial occlusive disease, we embraced percutaneous transluminal angioplasty and stenting of iliac and femoral arteries before most other surgical groups.^{1,2} In all regards, our Montefiore vascular surgeons were endovascular enthusiasts since the mid-1970s. However, up until 1992, all endovascular procedures except for intraoperative arteriography were performed by the interventional radiologists at our institution with full concurrence and support of the vascular surgeons.

In January 1987, at an International Interventional Meeting organized by Dr Barry Katzen in Miami, one of us (F.V.), who was attending because of interests in percutaneous transluminal angioplasty and stenting, heard a talk on stents and the possible future use of prosthetic graft-stent combinations to treat abdominal aortic aneurysms

(AAAs), a concept which had been proposed by Juan Parodi in 1976. This idea and the potential of endovascular treatment of AAAs was a topic of much discussion among the Montefiore vascular group, particularly as a way of treating AAA patients with serious comorbidities. This discussion intensified after Parodi and his colleagues performed the first clinical case on September 7, 1990, and published their initial clinical experience with endovascular aortic aneurysm repair (EVAR) in five patients.³

In August 1992, we were asked to care for a 76-year-old man who had a painful 7.5-cm AAA in addition to oxygen-dependent pulmonary insufficiency and severe inoperable coronary artery disease with recurrent ventricular arrhythmias. The patient was mentally alert and wanted his AAA fixed, but was deemed by all who evaluated him to be a prohibitively high risk for an open AAA repair. At that time, EVAR procedures had only been performed in Argentina. Since we had been recently discussing Parodi's work, an endovascular graft repair was quickly considered. The patient appeared to have favorable anatomy for an EVAR procedure, with a long infrarenal neck, a well-defined distal neck, and large straight iliac arteries.⁴ So one of us (F.V.) and another Montefiore vascular surgeon, Dr Michael L. Marin, who played a major role in the institution's endovascular graft program, considered journeying to Buenos Aires to learn the procedure and return to Montefiore to perform it.

Dr Parodi was called and indicated that he had no immediate cases planned, but said that he might come to New York City to present his work at our Annual Symposium, and at that time, he might help us perform the EVAR procedure on our patient. Arteriograms and computed tomographic scans were sent to Dr Parodi and then discussed with him by Dr Marin at an interventional cardiology meeting in Milwaukee. At that meeting, it was decided that the patient was a good candidate. However, many logistic issues were left unresolved. One was getting

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permission from Johnson & Johnson Interventional Systems (JJIS) to use a large Palmaz stent since JJIS had the rights to both Palmaz's and Parodi's patents. The company was concerned that our use of a large Palmaz stent without an Investigational Device Exemption would impair the company's ability to get Food and Drug Administration approval to implant Palmaz-Schatz stents in the coronary arteries.

This issue was extensively discussed at a meeting between Drs Veith and Marin and Marvin Woodall, President of JJIS, and Paul Marshall, Director of New Products for JJIS. The meeting, which was sometimes heated and lasted over 4 hours, took place at a restaurant in the Newark Airport Marriott. After many negative statements from the JJIS team, the issue was finally resolved by having JJIS, which would never let us use their large unapproved Palmaz stent (P 5014), agree to let us use a similar one that was manufactured in Argentina by a company owned by Carlos Sommer.

Next, funds for bringing the Argentinian team to the U.S. had to be obtained. The team consisted of Juan Parodi, Claudio Schonholz, a talented interventional radiologist, and Hector Barone, an engineer who made and assembled the various components of the delivery system and stent graft. Funds for travel and hotel expenses for the team for their stay in New York were obtained from a grant from the James Hilton Manning and Emma Austin Manning Foundation.

Our digital C-arm fluoroscope to be used in the operating room for the procedure was one that had been discarded by an interventional cardiology animal laboratory. When Drs Parodi and Schonholz saw the primitive nature of this instrument, they hesitated to perform the procedure, but were convinced to do so because of their previous commitment and the patient's dire condition.

After obtaining institutional review board approval and with the informed consent of the patient and his wife, his EVAR procedure was performed under local anesthesia on November 22, 1992. A 22-mm knitted Dacron graft was sewn to a large balloon-expandable (Palmaz-like) stent (Fig 1). The endograft, within a large sheath,^{3,4} was guided into position fluoroscopically so that the single proximal stent was mostly within the 2.5-cm non-aneurysmal neck of the AAA. The sheath was retracted and the stent deployed by inflation of the balloon on which it was mounted.⁴ No distal stent was employed. Despite that, aneurysm exclusion was demonstrated by intraoperative angiography. The prominent AAA pulse was markedly reduced, and the patient's pain was totally relieved. The next morning, the patient had eaten a full breakfast and was sitting up in a chair reading a magazine. He looked far better than any other open AAA repair patient we had ever seen. Postoperative computed tomographic scans and ultrasonography confirmed exclusion of the aneurysm lumen.⁴ The patient was discharged 4 days after his procedure, had no abdominal pain, and did well until he died from his cardiac and rhythm problems 9 months later.

This first U.S. EVAR had a profound effect on not only the Montefiore Vascular Surgery Division but also vascular

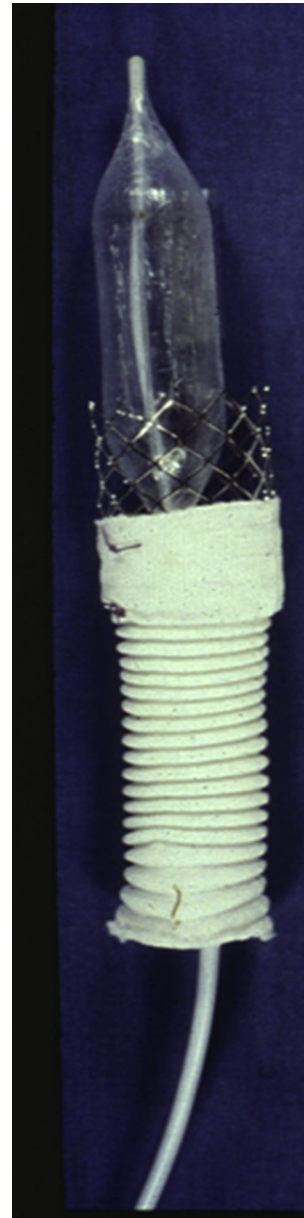


Fig 1. A model similar to the endograft used in the first U.S. endovascular aneurysm repair (EVAR) patient. A Dacron graft was hand-sewn to a large Palmaz-like balloon expandable stent. The compressed stent was mounted on a minimally compliant balloon, which was expanded in the abdominal aortic aneurysm (AAA) neck to fix the proximal end of the endograft to the normal-sized aortic neck.

surgery in the U.S. and around the world. The Montefiore vascular surgeons, in collaboration with our interventional radiologists and Argentinian colleagues, embarked on a program of endovascular grafting for the treatment of aneurysms, traumatic arterial lesions, and aorto-iliac and femoral occlusive disease. We used modifications of Parodi's surgeon-made stent grafts or endografts, which consisted of

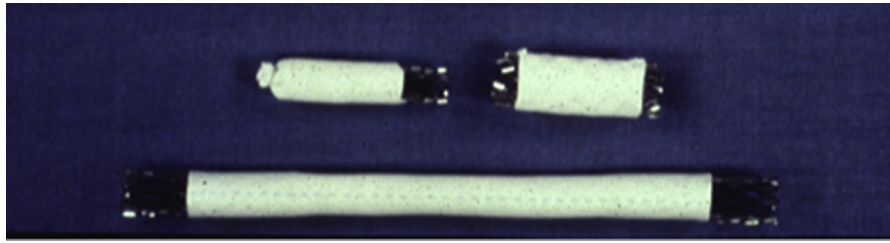


Fig 2. Early surgeon-made stent grafts based on Parodi's concepts. **Top left,** An occlusion device consisting of a Palmaz stent covered by a polytetrafluoroethylene (PTFE) graft closed at one end by ligatures. This was used for occluding the common iliac artery opposite to an aortofemoral or aortoiliac endograft in an abdominal aortic aneurysm (AAA) repair.^{5,8} **Top right,** A covered stent fabricated by hand-sewing a PTFE graft to a balloon-expandable Palmaz stent, used for treating arterial injuries (eg, of the subclavian artery).⁷ **Bottom,** A PTFE graft with a Palmaz stent at either end, used for some long iliac or popliteal aneurysms.¹⁰

modified commercially available polytetrafluoroethylene grafts with various sized Palmaz stents sewn to them (Fig 2). The stent components of these endografts were mounted on balloon catheters, compressed within a variety of simple hollow tubes or sheaths, then inserted over previously placed guidewires and guided into position under fluoroscopic control. Once in place, the sheaths or insertion tubes were retracted and the stents deployed by balloon inflation. Sometimes, the distal end of these grafts were fixed with a second stent. More often, the distal end of the endograft was fixed within the host artery with an endoluminal hand-sewn suture anastomosis (Fig 3).⁵⁻⁷

We generally used these endografts in patients for whom no other standard endovascular or open surgical treatment option was available because of local or systemic risk factors. These included high-risk AAAs, ruptured AAAs, aneurysms in other locations difficult to reach by open exposures, very difficult limb salvage patients usually after multiple previous failures, and difficult traumatic arterial injuries like subclavian disruptions and arteriovenous fistulas.⁵⁻¹⁰ Even in these challenging circumstances, these primitive surgeon-made endografts proved to be surprisingly successful. The procedures proved to be easier and less stressful on the patients undergoing them than we had anticipated, even though our endovascular skills were still not advanced.⁵⁻¹⁰

Because of the relative prominence of our Montefiore vascular group, we were asked to speak on these early endograft experiences quite often. Surprisingly, although we ourselves remained skeptical in our presentations, others hearing them were even more dubious about our results. Indeed, we were often greeted with disbelief, and the opinion of some was that, even if these procedures worked sometimes, vascular surgeons should not be doing them.

Our attitude was just the opposite. We were convinced that vascular treatment was undergoing a revolution: the endo-revolution. We further believed that, if vascular surgeons did not recognize that this was happening and embrace endovascular skills and techniques, they would rapidly be replaced by interventionalists in cardiology and radiology, and vascular surgery would become extinct as a specialty.^{11,12}

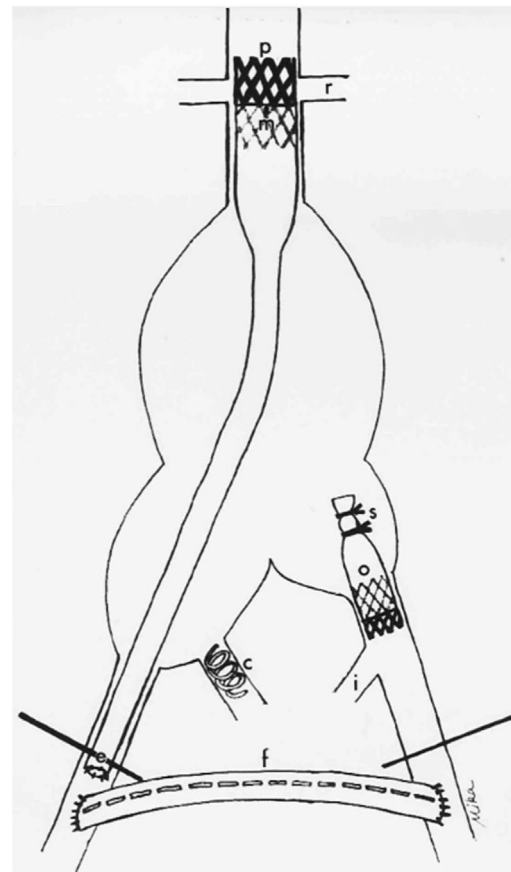


Fig 3. Schematic configuration of a unilateral aortofemoral endograft used for treating complex and ruptured abdominal aortic aneurysms (AAAs). Note the large Palmaz stent (*p*) is partly covered (*m*) and partly uncovered. The open portion of the stent covers the renal arteries (*r*) for secure fixation. An endovascular anastomosis (*e*) fixes the distal end of the endograft within the common femoral artery. The endograft is dilated (not shown) to entirely fill the lumen of the femoral and external iliac artery. When a common iliac aneurysm is present, the ipsilateral hypogastric artery is occluded by coils (*c*). The contralateral common iliac artery is occluded by a covered stent (*o*) closed at one end by ligatures (*s*). The procedure is completed by performing a femorofemoral bypass (*f*).^{5,8}

One of us (F.V.) had the good fortune in 1994 and 1996 to be President of two important vascular societies. The theme of the Presidential Addresses before these two societies was that vascular surgeons must recognize the importance of this endovascular revolution and embrace it. Considerable resistance to this was present, at first. Now, however, it is almost universally recognized, and endovascular procedures make up the majority of many vascular surgical practices. Interestingly, even the predictions of an endovascular enthusiast of the late 1990s¹² proved to be short of the mark. With the remarkable creativity of all vascular specialists, it is now likely that more than 90% of the open operations vascular surgeons performed in the mid-1980s will be replaced by endovascular procedures. Even the small proportion of remaining open operations will probably be made simpler or better by using endovascular techniques for a portion of the procedure.¹³

What happened at Montefiore in November 1992 certainly led to an epiphany for our entire vascular group about the nature of vascular treatment in the future. In subsequent years, that epiphany has fortunately spread to the rest of vascular surgery, albeit sometimes slowly. We believe that early recognition and adoption of endovascular treatments by vascular surgeons everywhere will contribute greatly to the survival and prosperity of the specialty.

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