Treatment of complex abdominal aortic aneurysms by a combination of endoluminal and extraluminal aortofemoral grafts

James May, MS, FRACS, FACS, Geoffrey White, FRACS, Richard Waugh, MB, BS, DDR, FRACR, Weiyun Yu, MB, BS, BSc, and John Harris, MS, FRACS, FACS, *Sydney, Australia*

Purpose: **The purpose of this study was to test the hypothesis that abdominal aortic aneurysms (AAA) whose morphology makes them unsuited for repair with an endoluminal tube graft can be treated by a combination of a transluminally placed aortofemoral graft and a femorofemoral crossover graft. In addition the technique involves either ligation or balloon occlusion of the contralateral common iliac and internal iliac arteries in such a manner that excludes the AAA from the circulation.**

Methods: **We report the use of this technique in three male patients with 6.4 to 7.0 cm diameter AAA. Two had renal impairment and cardiac function too poor to permit open repair, and the third had an unfavorable abdomen caused by previous surgery and the presence of a permanent colostomy. Each patient had an individually tailored Dacron tube graft constructed on the basis of preoperative arteriograms and computed tomography scans. The grafts were delivered transluminally into the aorta through a sheath in the iliac arteries and anchored proximally with a stainless steel stent under radiographic control. The grafts were then anastomosed distally to the femoral artery.**

Results: **Recovery was complicated by a midgraft stenosis corrected by percutaneous balloon dilation in one patient, an episode of pulmonary edema in the second and an unexplained pyrexia in the third. Follow-up with duplex scanning confirmed normal flow through the grafts and the presence of thrombus between the prosthetic graft and the aneurysmal sac.**

Conclusions: **We conclude that transluminal placement of an aortofemoral graft combined with a femorofemoral crossover graft is feasible in patients who are unsuited to repair with an endoluminal tube graft. The outcome with this technique is not known and requires further careful evaluation. (J VASC SURG 1994;19:924-33.)**

Currently there is great interest in endoluminal techniques for treatment of abdominal aortic aneurysms (AAA). The ideal method seems to be transluminal placement of a tube graft into the aorta, but variations in morphology of the aortic wall, particularly at the bifurcation, and associated aneurysms of the iliac arteries make many patients unsuitable candidates. We report three patients with AAA lacking a distal neck, two of whom had common iliac aneurysms in addition, who were treated by a combination of a transluminally placed aortofemoral graft and a femorofemoral crossover graft.

There have been several reports of experimental endoluminal grafts[1-5] preceding the first report of AAA endoluminal repair in human beings by Parodi et al.[6] He and his colleagues treated five patients with AAA by transfemoral intraluminal Dacron grafts anchored by modified stainless steel stents. These aneurysms were all of the fusiform variety with a discrete proximal neck between the renal arteries and the proximal extent of the aneurysm and a distal neck between the distal extent of the aneurysm and the bifurcation of the aorta. In three of the patients the proximal stent was used without a distal stent. In the other two patients, both ends of the Dacron graft were anchored by stents.

The three patients in this report were not suitable for treatment by an endoluminal tube graft tech-

From the Department of Vascular Surgery, Royal Prince Alfred Hospital and Department of Surgery, University of Sydney, Sydney.

Reprint requests: James May, MS, FRACS, FACS, Department of Surgery, University of Sydney, Sydney, NSW 2006, Australia.

0741-5214/94/$3.00 + 0 24/1/52315

nique, because of the lack of distal neck of the aneurysm. The technique described in this report is a modification of a method developed by Parodi,[10] whose experience preceeded the authors'.

PATIENTS AND METHODS

Endovascular repair of aneurysms with materials currently used in vascular surgery is approved by the Institutional Review Board. Food and Drug Administration approval of grafts and stents is not required in Australia. Informed consent was obtained from each patient. Laboratory and clinical experience in the use of intraluminal grafts for subclavian and aortic aneurysms has previously been reported by the authors.[7-9]

Graft preparation. The graft/stent devices used in the treatment of two of these three patients were identical except in length. Each device was constructed from two Dacron tubes (Fig. 1). The larger of the two was 18 mm–diameter knitted Dacron (Industrias HA Barone, Buenos Aires, Argentina). The proximal 15 mm of this graft was compliant and was constructed to allow stretching up to 24 mm in diameter. The diameter of the proximal necks of the aneurysms had been measured at 19.2 mm and 20.4 mm, respectively, on preoperative CT scans and aortograms. During arteriography a pigtail catheter with 1 cm markings was used to accurately calibrate the dimensions and avoid errors of parallax and magnification. The smaller of the two tubes was a woven Dacron graft (Bard Inc., C.R., Murray Hill, N.J.). Each graft was cut obliquely and joined with a continuous 5/0 Gore-tex suture.* The proximal graft measured 9 cm in length, and the smaller diameter grafts measured 13 cm and 20 cm, respectively, with the crimp fully extended in each. The larger grafts were supplied with stainless steel stents, 5.2 mm in diameter and 3.5 cm in length, to which they were attached by braided sutures at two opposing points on the circumference.

The third graft/stent device consisted of a commercially available bifurcated woven Dacron graft (22 mm diameter with 10 mm–diameter limbs) (Bard Inc., C.R) and a stainless steel stent similar to that used in the previous two cases. The body of the graft was attached to the stent in a similar manner to the previous two cases. One limb of the graft was amputated and the resulting defect in the graft repaired with 5/0 Gore-tex suture. The remaining limb of the graft was cut to give the whole graft an overall length of 30 cm with the crimp fully extended.

*Gore-tex is a trademark of W.L. Gore & Associates, Elkton, Md.

The diameter of the neck of the aneurysm had been measured on preoperative arteriography and CT scanning at 22 mm.

The stents were mounted on a 30-mm–diameter balloon catheter (BALT Extrusion, Montmorency, France, or William A Cook, Queensland, Australia). The graft was furled around the stent and balloon catheter in the transverse configuration of the letter S. The graft/stent device and the balloon catheter were then loaded into a 21F internal diameter Teflon sheath (William A Cook) and advanced until the tip of the balloon protruded from the opposite end of the sheath (Fig. 2).

Case report 1. A 79-year-old male patient was admitted with an infrarenal AAA. It measured 6.4 cm in maximal diameter on CT scanning and had increased in diameter from 5.2 cm on CT scanning performed 18 months previously. He had been rejected for surgical repair of his aneurysm because of poor cardiac function. He had been receiving treatment for congestive heart failure for 4 years. Coronary angiography demonstrated triple vessel disease that was technically suitable for bypass grafting. This was precluded, however, by severe left ventricular dysfunction (gated heart pool ejection fraction less than 20%). He was referred for possible endoluminal repair of his aneurysm. Investigation revealed that his hematologic and biochemical parameters were within normal limits, with the exception of his serum creatinine, which was 140 mg/dl (Normal range 80 to 100 mg/dl). Aortography and CT scanning demonstrated a 2 cm–long neck between the renal arteries and the commencement of the aneurysm (Fig. 3). Close examination of the calcium within the walls of the aneurysm showed that the aneurysm extended to and involved the bifurcation of the aorta. The apparent distal neck of the aneurysm seen on the aortogram was due to mural thrombus, confirmed by CT scanning, just above the bifurcation of the aorta (Fig. 4). Endovascular repair of the aneurysm with a stent-anchored aortofemoral graft, combined with detachable balloon occlusion of contralateral common iliac artery and femorofemoral crossover graft was planned.

The operation was performed with the patient receiving general anesthetic and being placed in the supine position on a radiolucent table. The abdomen was prepared and draped in addition to the upper thighs in the event that access proximal to the planned femoral arteriotomy was required.

A retrograde aortogram was performed via a percutaneous approach to the left femoral artery. The positions of the renal arteries, the proximal extent of

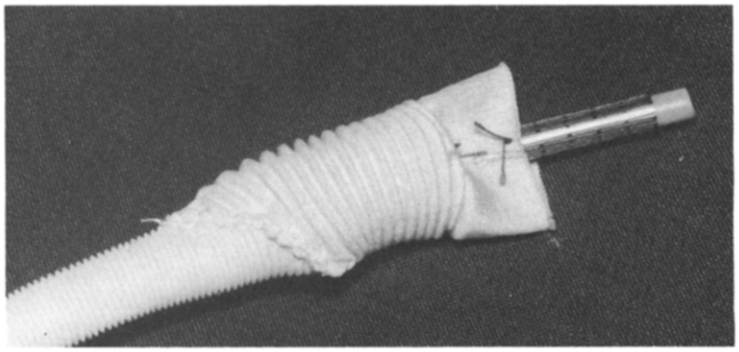

Fig. 1. Device consists of two Dacron tube grafts sutured together obliquely and stainless steel stent sutured to larger diameter graft.

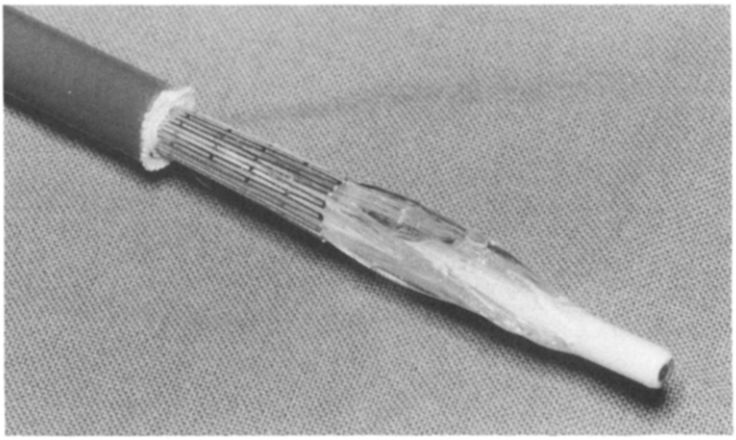

Fig. 2. Graft/stent device mounted on balloon catheter and packaged in inner 21F sheath ready for delivery into outer sheath.

the AAA, and the bifurcation of the aorta were carefully determined and marked with metallic clips on the patient's abdomen. A radiopaque ruler beneath the patient was also used as an additional reference point for these anatomic levels. The common femoral artery was exposed through a small vertical incision in the right groin. An Amplatz extra stiff guide wire (Cook, Inc., Bloomington, Ind.) was introduced into the right femoral artery and passed up to the descending thoracic aorta. An unsuccessful attempt was made to pass a 24F internal diameter Teflon sheath with its mandrel (William A Cook) through a right femoral arteriotomy into the aorta. The external iliac artery, which had been measured at 6.5 mm in diameter on the preoperative aortogram could not be dilated sufficiently to accommodate the sheath, which had an external diameter of 10 mm. Access via the iliac artery was then obtained with a method devised by Parodi.[10] This involved the use of a large-diameter Dacron graft as a temporary conduit to the common iliac artery. With Parodi's technique the graft is oversewn proximally and the excess is excised when it is no longer required as a conduit. In this case the conduit was retained to allow the aortofemoral graft to pass distally to the femoral artery. The distal right common iliac artery was exposed through an extraperitoneal approach in the right iliac fossa. A 14 mm, woven Dacron tube graft was sutured to an arteriotomy in the nonaneurysmal common iliac artery and delivered to the exterior by passing the graft deep to the inguinal ligament and out through the wound in the right groin. The 24F Teflon sheath and mandrel were then passed without difficulty over a guide wire through the Dacron graft into the distal aorta. The mandrel was removed and replaced with the 21F internal diameter Teflon

sheath containing its preloaded balloon catheter and graft stent device. Under radiographic control the balloon and graft/stent device were advanced in a cephalad direction from the end of the 21F Teflon sheath. The stent was deliberately positioned with its uncovered upper end overlapping the left renal artery origin by 0.5 cm. The stent was deployed by inflating the balloon to a diameter of 22 mm. During inflation of the balloon the patient's blood pressure was maintained at 80 mm Hg systolic by means of a nitroprusside infusion. After balloon deflation, the guide wire was removed, and aortography was performed through the central channel of the balloon catheter. This demonstrated a satisfactory seal between the graft and the neck of the aneurysm without escape of contrast into the aneurysmal sac. The 24F and 21F sheaths were removed, and the graft was extended down to the femoral arteriotomy by suturing on an additional segment of Dacron graft. The left lower limb was revascularized with a crossover 8 mm Gore-Tex graft from the Dacron graft in the right groin to the common femoral artery in the left groin. Both common iliac arteries were ligated, the left one at its origin and the right one distal to the site of attachment of the original 14 mm Dacron access graft (Fig. 5). Ligation of both common iliac arteries through a small right-sided extraperitoneal approach was facilitated by the patient's build but could be difficult in an obese patient. The blood loss of 3 L was returned to the patient by cell-saver and the operating time was 7 hours.

Outcome. The patient recovered and was extubated in the immediate postoperative period. His serum creatinine level rose to 230 mg/dl on the second postoperative day before returning to the preoperative level of 140 mg/dl on the fourth postoperative day.

The patient's convalescence was complicated by an episode of acute ischemia affecting both lower limbs on the tenth postoperative day. Urgent aortography was performed via the right brachial artery in the cubital fossa. This demonstrated stenosis in the composite aortic graft, just distal to the oblique suture line. This stenosis was corrected by balloon dilation, with a 6 mm balloon catheter followed by a 10 mm balloon catheter. Postdilation arteriography demonstrated restoration of the normal graft lumen. The ischemia in both legs rapidly reversed with return of ankle-brachial pressure indexes to postoperative levels. The patient was discharged 2 days later (the thirteenth postoperative day). Follow-up duplex scanning studies at 4 months confirmed normal blood flow through the graft and runoff arteries. Isolation of the aneurysm from the circulation and obliteration of the aneurysm sac by thrombus around the graft was also confirmed.

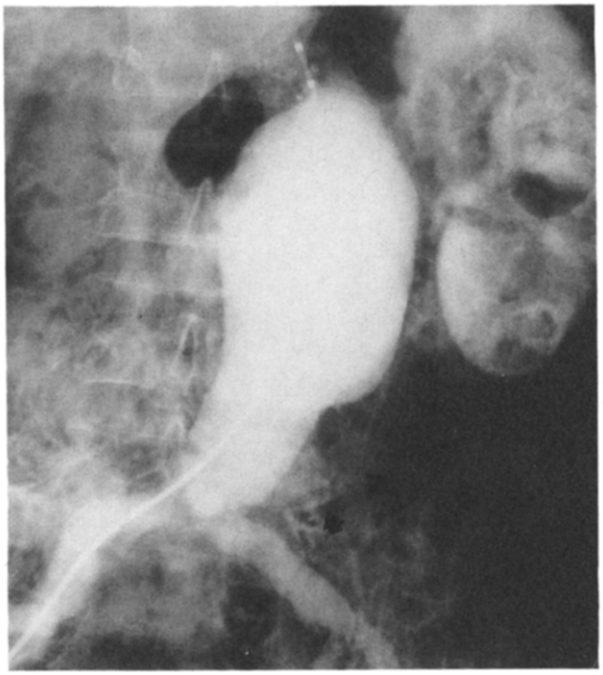

Fig. 3. Aortogram from case 1. Centimeter markers on upper end of catheter for accurate measurement of aneurysm. Calcification in aortic wall *(arrows)* demonstrate that aneurysm extends down to bifurcation.

Case report 2. A 76-year-old male patient was admitted with a 6.5 cm diameter infrarenal AAA. The patient had angina and underwent exercise dipyridamole thallium scanning, which demonstrated an area of redistribution. Coronary angiography disclosed triple vessel disease that was technically suitable for bypass grafting. Gated heart pool ejection fraction was less than 20%. The patient's cardiologist considered the combined risk of coronary artery bypass grafting and open repair of the AAA to be considerable and recommended transluminal repair in preference to the two open operations. Hematologic and biochemical parameters were within normal limits, with the exception of the serum creatinine level, which was 176 mg/dl. Aortography demonstrated that the aneurysm had a neck 2.2 cm in length between the renal arteries and the commencement of the aneurysm (Fig. 6). Together with a CT scan, it also demonstrated that the right common iliac artery

Fig. 4. CT scan 0.5 cm above aortic bifurcation from case 1, confirms extent of aneurysm and absence of distal neck.

was aneurysmal and the left common iliac artery was ectatic.

The operation was performed with the patient receiving general anesthetic and in the supine position. Draping and preliminary aortography were performed in a similar manner to the preceding case. Access to the aorta was gained through the left external iliac artery. This artery was exposed through a transverse incision below the inguinal ligament. Because of extreme tortuosity, the left external iliac artery was extensively mobilized in the manner devised by Parodi.[10] This allowed the excess in length of the tortuous artery to be delivered below the inguinal ligament and provided a straight passage into the aorta for the 24F sheath.

The graft/stent was delivered into the aorta, positioned, and deployed in a similar manner to the previous case. After withdrawal of the sheaths, the distal end of the aortofemoral graft was left protruding through the arteriotomy in the left external iliac artery. This artery was transected at this point, and an additional 3 cm of redundant artery distal to this point was excised. The distal end of the aortofemoral graft was anastomosed end-to-end to the free end of the common femoral artery, as shown in Fig. 7. There was no bleeding between the transected end of the left external iliac artery and the Dacron graft, but a ligature with minimal tension was applied to secure this potential opening. The right limb was revascularized by a femorofemoral crossover graft. The right common iliac artery was occluded with a detachable balloon (custom made in the Interventional Radiology Department, Royal Prince Alfred Hospital, Sydney, Australia) passed up the right external iliac artery and the left internal iliac artery was ligated extraperitoneally. On table intraoperative angiography confirmed the occlusion of the right common iliac was complete. The blood loss of 2½ l was returned to the patient by cell-saver and the operating time was 6½ hours.

Outcome. The patient recovered well and was extubated in the immediate postoperative period. The serum creatinine level rose to 357 mg/dl by the third postoperative day. At this point the patient had an acute episode of pulmonary edema requiring ventilation for 24 hours. The patient then made an uneventful recovery with his serum creatinine level falling to the preoperative level over the next 4 days.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.