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Endoluminal Aortic Grafting With Renal and Superior Mesenteric Artery Incorporation By Graft Fenestration

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Purpose: To explore the use of juxta- and suprarenal aortic segments for endograft fixation in abdominal aortic aneurysm (AAA) patients and to develop methods of graft implantation that use endograft fenestrations to preserve renal and visceral vessel perfusion.

Methods: From August 1998 to May 2000, 13 AAA patients with unsuitable infrarenal aortic necks were treated with custom-designed endovascular grafts employing the juxta- and suprarenal aortic segments for proximal sealing. Flow to 33 renal and superior mesenteric arteries was maintained via graft fenestrations that were aligned by use of radiopaque graft markers. The fenestration-orifice interface for renal arteries was secured with modified balloon-expandable stents.

Results: All fenestrated grafts were deployed as planned, and all target vessels (33/33) were preserved. Two patients did not receive any stents, one being the first in the series and another who had incorporation of a renal accessory artery only. Without the use of transgraft stenting, 5 renal arteries would have been occluded by the endograft or poorly perfused.

Procedural success was 100%. No conversion to open operation or graft-related complications occurred. There was no primary endoleak in any patient by angiographic criteria. Two patients required additional surgical procedures related to access vessels. Periprocedural mortality at 30 days was nil. Follow-up ranging from 3 to 24 months on all patients has not demonstrated any proximal or distal endoleaks. One stented renal vessel has occluded; all other arteries remain patent at last examination.

Conclusions: This study has demonstrated the ability to successfully place a multifenestrated endoluminal graft in an aortic aneurysm using juxta- and suprarenal aortic segments to obtain a satisfactory seal. Stenting of the fenestration–renal ostium junction has helped to maintain renal patency.

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Key words: abdominal aortic aneurysm, aortic neck, endograft, Zenith system, Palmaz stent

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The past decade has seen the development of a number of devices and techniques whose purpose has been a less invasive approach to the treatment of arterial aneurysms.[1,2] Endoluminal graft exclusion has gained considerable popularity in a variety of vascular sites, most notably the infrarenal abdominal aorta.[3–5] As a consequence of the early experience gained in this field, many patients who could benefit from such an endovascular procedure are excluded, owing to unfavorable infrarenal aortic neck anatomy related to length, diameter, shape, angulation, or wall morphology.[6,7]

In this study we explored the potential for using the juxta- and suprarenal aortic segments for endograft fixation in abdominal aortic aneurysm (AAA) patients who had unsuitable aortic neck anatomy. Moreover, we have developed methods to incorporate renal and visceral arteries into endografts by precise alignment of graft fenestrations with vessel ostia, so as to maintain branch flow and avoid endograft migration.

METHODS

From the period August 1998 to March 2000, 13 AAA patients (10 men; average age 74 years, range 64–79) giving informed consent were entered into this study to investigate the possibility of using fenestrated aortic endografts for exclusion of aneurysms with suboptimal aortic neck anatomy. Aneurysm classification was based on criteria developed by the Society for Vascular Surgery/North American chapter of the International Society for Cardiovascular Surgery.[8] Eleven aneurysms were class IV; the other 2 were IIa. The average aneurysm diameter was 6.6 cm (range 51–97); aneurysm neck length ranged from 0 to 20 mm.

Endograft Construction

Graft design was dependent on good-quality spiral computed tomographic (CT) scanning, complemented by calibration angiography where necessary. Detailed evaluation of the aneurysm neck and side branch geometry was mandatory to ensure accurate placement of the fenestrations, so CT axial images were usually acquired at 1-mm intervals throughout this area of critical assessment.

The endograft used in this study was a customized endoluminal prosthesis based on the Zenith system (William A. Cook Australia Pty. Ltd., Brisbane, Australia), which uses a self-expanding modular design with an uncovered Gianturco Z-stent (William Cook Europe, Bjaeverskov, Denmark) for proximal fixation in the standard graft configuration.[9] The proximal anchor stent, which has multiple spikes at its upper end to enhance fixation, is designed for suprarenal implantation.

Customization of these stent-grafts involved the placement of fenestrations (Fig. 1A) to match renal and superior mesenteric artery (SMA) ostia that would be crossed by the endograft. Radiopaque markers were incorporated at the quarter-hour positions around the fenestrations to aid in accurate alignment with the arterial ostia. Moreover, anterior and posterior markers were placed on the graft body to indicate correct axial alignment. The endografts were constructed so that no internal stent wires crossed the renal fenestrations.

Fixation of the fenestration to the renal arteries was provided by implantation of modified balloon-expandable Palmaz P204 stents (Cordis Endovascular, Warren, NJ, USA) across the graft-ostium interface so that a portion of the stent protruded into the endograft lumen (Fig. 1B). This end of the stent had been refashioned by laser cutting to allow marked flaring to 90° over approximately one third of the stent's length. This feature produced better wall-graft contact and would facilitate future interventions to the renal artery should they become necessary. Approval to use the modified Palmaz stents was obtained on an individual patient usage basis from the Therapeutic Goods Administration, a regulatory body of the Australian Federal Government. The SMA fenestration was sized generously, and, because it was remote from the site of sealing, no transvessel stent fixation was required to improve alignment.

When the fenestrated endograft was loaded on its delivery sheath, the proximal stent prongs were compressed in a top cap that was connected to a locking wire. The graft was longitudinally folded and "zipped" along

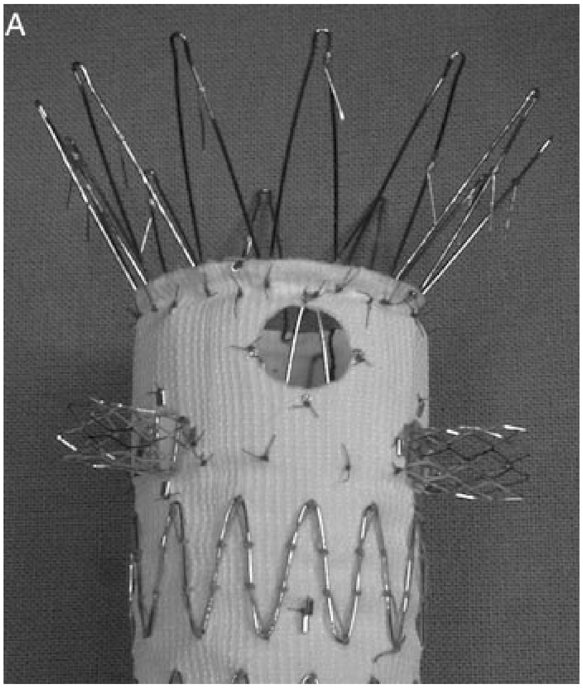
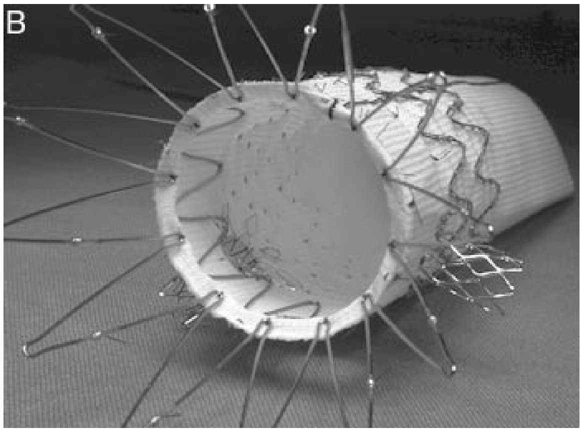


Figure 1 ◆ (A) View of a triple fenestrated graft showing the barbs on the uncovered proximal anchor stent and the modified Palmaz P204 stents deployed through their respective fenestrations for renal fixation. Note the radiopaque markers placed around each fenestration. **(B)** On this internal view, one can appreciate the 90° flaring of each luminal stent end. Note that no Gianturco stent struts cross either renal orifice in this case. This differs from the nonfenestrated version of this graft, in which struts invariably cross the renal vessels.



its posterior aspect with restraining ties that were attached to another trigger wire. This vitally important design feature limited the initial expansion of the endograft when it was released from the delivery sheath, which allowed maneuvering of a lower profile device both longitudinally and axially in the neck.

Implantation Technique

Patients were treated under general or epidural anesthesia, according to the judgment of the anesthetist. Renal output was carefully monitored during each procedure by an indwelling urinary catheter, and a continuous intravenous regime of aminophylline was given before, during, and after the procedure to maintain renal perfusion and reduce the risk of contrast-induced nephrotoxicity. High-resolution imaging was used for all procedures (Advantx, GE Medical Systems, Milwaukee, WI, USA); no cases were performed in an operating theatre using portable imaging equipment.

Once the patient was anesthetized, both femoral arteries were surgically exposed. The main body of the graft was delivered over a 0.035-inch wire through the selected femoral artery and positioned in relation to a previously placed external renal vessel marker wire. Axial orientation was obtained by aligning the anteroposterior (AP) markers and the marker on the short graft limb, thus ensuring the graft was not rotated 180° from its intended deployment position. Partial withdrawal of the sheath (Fig. 2) released the 2 upper graft stents to allow better viewing of the fenestration markers, but the anchoring stent remained capped. Release of the next stent usually exposed the AP markers on the graft body; at this stage, further rotational adjustments were still possible to position the fenestrations. The sheath was then withdrawn further to deploy the short limb, but the graft remained fixed in the cap proximally and the sheath distally over the long graft limb.

The contralateral femoral vessel was used to catheterize the short limb in a manner common to other modular systems. In those cases involving bilateral renal fixation, two 8-F, standard-length Avanti (Cordis Europe, Roden, The Netherlands) sheaths were placed, one

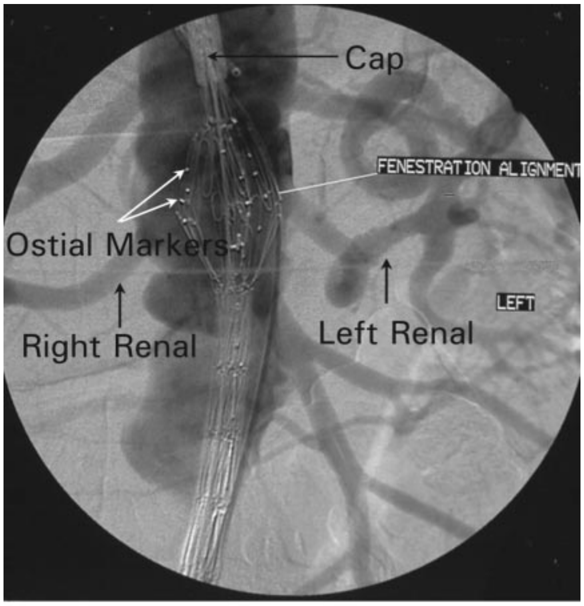


Figure 2 ◆ To initially orient the endograft, the sheath is partially withdrawn to deploy the 2 upper stents of the endograft body. The fenestration markers are now visible, to aid in alignment with the renal ostia. The bare top anchor stent remains encased in the cap until final positioning is obtained.

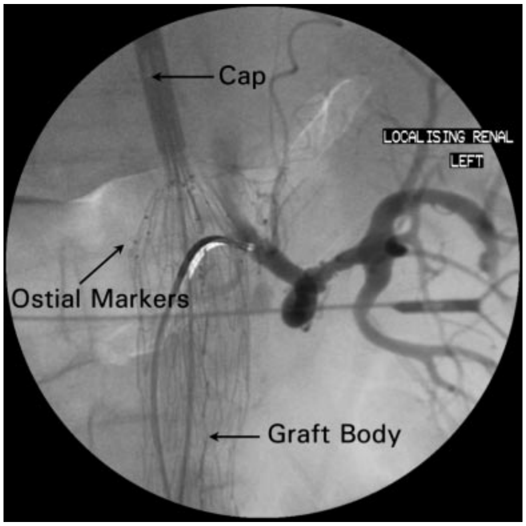


Figure 3 ◆ The sheath has now been withdrawn farther, to partially expand the graft body down to the short limb cuff, through which the selective catheters have been inserted to engage the renal ostia.

distal and one proximal, through separate punctures in the common femoral artery. Short limb engagement was usually achieved with either a 5-F Hinck or JB2 catheter (Cordis).

Catheterization of the renal vessels was carried out from within the graft lumen, most commonly by use of a 5-F IMA or Cobra 2 catheter (Cordis). Glyceryl trinitrate was injected into each renal artery upon successful catheterization, to control any vessel spasm prior to wire placement. A 0.035-inch Glidewire (Terumo Corporation, Tokyo, Japan) was used to engage the renal ostium, and the catheters were advanced as far as possible into the renal vessels (Fig. 3).

The Glidewire was exchanged for 180-cm-long Rosen J (1.5-mm) wires, to give more secure access for the next stages of delivery. Cardiac 8-F, 55-cm-long MPA1 guiding catheters (Cordis) were introduced over the Rosen wires within each renal artery (Fig. 4A). A 4-cm-long Opta angioplasty balloon (Cordis) was tracked over the Rosen wire through the short limb and graft fenestration into each renal artery (Fig. 4B). Balloon size was matched to each renal vessel so that no significant radial force was applied to the artery. Each balloon was inflated to 2 to 4 atm to act as a rail allowing accurate alignment of graft fenestrations and renal ostia while the graft was ''unzipped'' and the cap released. Further graft positioning was now no longer possible.

The modified P204 Palmaz stents were usually mounted on the initial Opta balloons so that the stent was in the center of the balloon with the nonmodified end toward the tip. The image intensifier was rotated to bring all the fenestration markers into a single plane (at this point the x-ray beam was tangential to the vessel ostium, facilitating accurate stent placement) (Fig. 5). The stent was maneuvered into the ostium so that the modified one third of the stent remained within the body of the graft. Caution and accuracy were paramount during stent positioning, since the modified end tended to flare readily because it had no radial strength. Attempts to pull back the stent after delivery from the guider usually resulted in snagging and premature flaring.

With the stent in position, the balloon was inflated to 6 to 8 atm to implant the stent within the renal artery and begin the flare (Fig. 6),

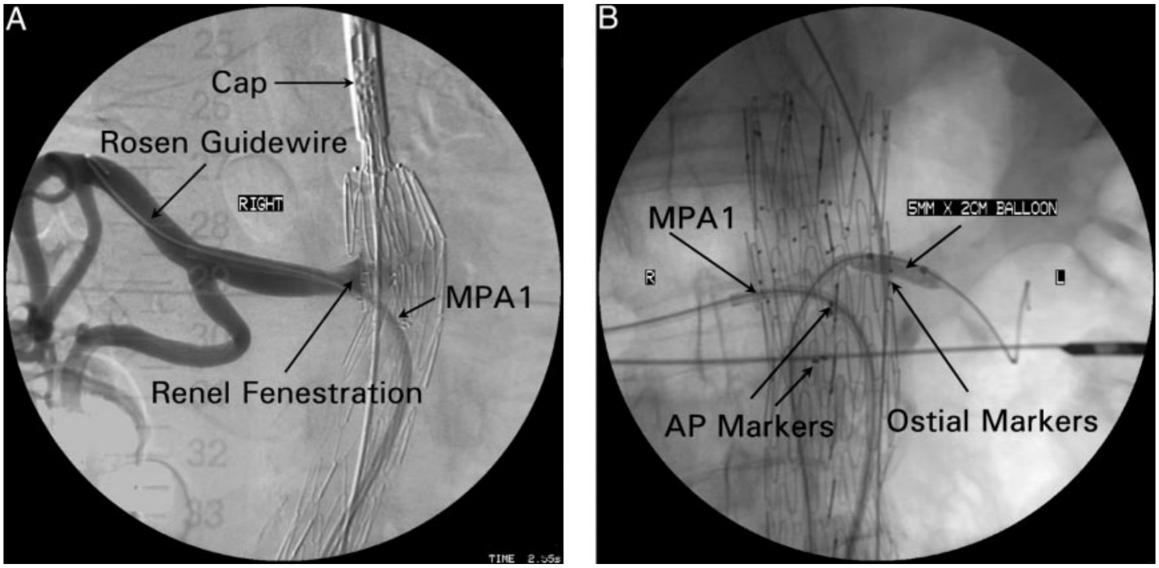


Figure 4 ◆ **(A)** The Glidewires were exchanged for a Rosen J-wire in each renal artery, and MPA1 guiding catheters were introduced. **(B)** Inflated angioplasty balloons anchor or "railroad" the fenestration-ostium junctions as the endograft is fully deployed. In this image after cap release, the MPA1 guide catheter is immediately behind the balloon in the left renal artery. Note, in this case, that the balloon is 2 cm long; the use of 4-cm-long balloons was an improvement introduced later in the series. In the right renal artery, the MPA1 catheter has already been advanced over the balloon shaft into the renal artery for safe stent delivery.

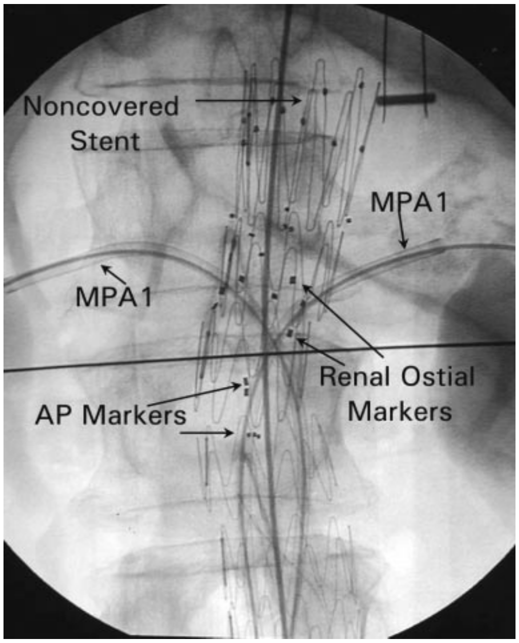


Figure 5 ◆ Both 8-F MPA1 guiding catheters have been introduced to facilitate stent placement. This image comes from an endograft made later in the series with an improved ostial and anteroposterior marker system.

which was improved with an 8- or 10-mm balloon. Because of the angles involved, the lower struts of the stent tended to show better flaring at this time. The second stent was positioned and flared in similar fashion.

Stent flaring was completed with the large compliant balloon supplied with the endograft. A sheath change to a 14-F size was necessary to insert the balloon, which was ideally placed coaxially over the wire in the more proximal renal artery (Fig. 7). The guidewire was withdrawn and advanced cephalad. The balloon was now situated in the graft lumen, where it was inflated and allowed to roll upward, completing the flare on both stents (recall that the lower struts flared easily with the smaller profile angioplasty balloons used in the initial dilation) (Fig. 8). With the renal stents deployed, the cap was retrieved and the extension leg for the short limb placed. Once the remainder of the procedure was completed, biplanar completion angiography confirmed vessel patency and verified a satisfactory seal with no endoleak.

All follow-up diagnostic imaging and re-

Figure 6 ◆ A Palmaz stent has been deployed across the fenestration-ostium junction so that the flared end of the stent remains in the endograft lumen. The ''railroad'' balloon remains in the left renal artery. Note the back flush of contrast from selective right-sided injection into the left renal artery, suggesting good fenestration alignment even prior to stenting.

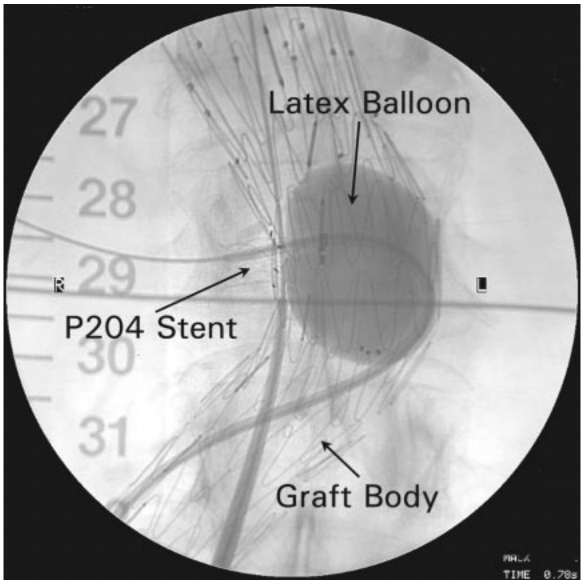


Figure 7 ◆ In this image from another patient, the large compliant balloon has been delivered coaxially over the Rosen guidewire via a 14-F sheath to the level of the renal ostia. At this stage, the balloon shaft is in the right renal artery.

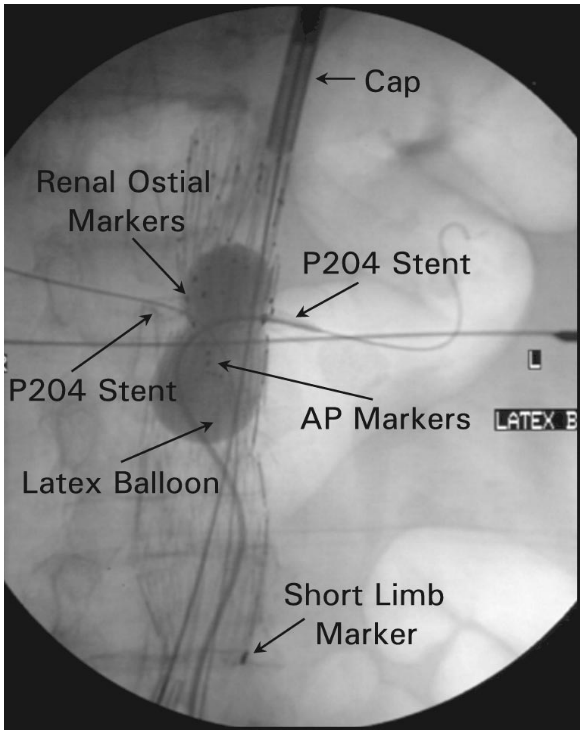


Figure 8 ◆ The latex balloon, which is coaxially mounted on the left Rosen guidewire at this point, is inflated within the endograft at the level of the renal ostia to complete the flare of the Palmaz stents, securing the stents against the endograft wall and providing unimpeded access to the renal arteries in future.

porting was conducted by an independent radiology group located in another facility; none of the reporting radiologists were involved in the primary procedure.

RESULTS

Completion angiography documented satisfactory exclusion of the aneurysm sac in all patients for a 100% technical success rate. In all, 33 side branch vessels were targeted for incorporation by fenestration (Table 1); 3 endografts had 4 fenestrations (Fig. 9). All were successfully perfused after endograft implantation. Stenting was reserved for the 20 main renal arteries only, but our first patient had undergone stenting for renal artery stenosis 2 years previously. We elected not to implant an additional stent inside the first because of concern for a high metal–vessel wall ratio.

Table 1
Thirteen AAA Patients Undergoing Endoluminal Grafting With Branch Vessel Incorporation By Fenestration

					Target Vessels for Fenestration						
Patient	Age/Sex	Aneurysm Size (mm)	Neck Length (mm)	Aneurysm Class*	Right Renal	Left Renal	SMA	Accessory Renal	Total Targeted/ Successfully Perfused	Type I Endoleak	Type II Endoleak
KR	77/M	78	6	IV		1†			1/1	No	No
LD	61/M	97	4	IV	1	1			2/2	No	No
CM	84/M	65	20	IIa‡	1	1	1		3/3	No	No
JL	79/F	58	4	IV			1		1/1	No	No
RT	76/M	55	0	IV		1	1	1	3/3	No	No
SW	78/F	64	0	IV	1	1			2/2	No	No
AS	73/F	51	5	IV	1		1		2/2	No	Yes
FG	59/M	53	19	IIa§				1	1/1	No	No
KP	73/M	60	2	IV	1	1	1	1	4/4	No	No
RE	80/M	60	0	IV	1	1	1	1	4/4	No	No
AJ	78/M	77	4	IV	1	1	1	1	4/4	No	No
HT	74/M	75	1	IV	1	1	1		3/3	No	No
DM	70/M	71	0	IV	1	1	1		3/3	No	Yes
					9	10	9	5	33/33	0	2

* SVS/ISCVS classification.[8]

† Renal artery not stented;

‡ Radiolucent material throughout the neck: rejected for endoluminal grafting but referred for possible fenestrated graft;

§ Accessory renal artery in infrarenal neck.

In a second patient late in the series, a right lower pole renal artery arising from an otherwise adequate infrarenal neck was fenestrated but not stented, owing to its small size (Fig. 10) and the satisfactory neck length. Two patients had solitary kidneys; another had a high-grade renal artery stenosis that was treated with a modified stent at the time of graft implantation.

There were no perioperative deaths. Two patients suffered occlusion of the left internal iliac artery because of distal graft limb misplacement, but patency of the other side was maintained in both cases. One patient required a local femoral artery endarterectomy and patch graft at the access site because of previous vascular surgery. Another patient experienced intraprocedural occlusion of a graft limb extension, which was resolved by femorofemoral crossover grafting. Moreover, this same patient developed significant postprocedural renal impairment owing to a major electrical failure that halted the procedure during a critical stage before renal artery implantation. During this 90-minute period, there was no kidney perfusion. Renal function returned to preprocedural levels after 6 days.

One patient, who inadvertently had not received any antiplatelet therapy after stenting, presented to another medical center 3 weeks postprocedure with a right renal artery occlusion. Because the nature of the problem was not immediately realized, the delay rendered the renal artery unsalvageable. His renal function deteriorated in relation to baseline but improved slowly, although not completely; dialysis was not required. This patient has had 3 further admissions for acute myocardial ischemia in the 4 months since endografting.

To date, all patients remain alive and well, without need for secondary intervention. Follow-up by contrast-enhanced spiral CT or duplex scanning has not shown any evidence of proximal or distal endoleaks. Retroleaks (type II) from a lumbar vessel have been reported in 2 patients. Renal function remains stable in all patients, with the exception of the one with renal artery occlusion. No patient has required renal dialysis, but the follow-up period for most patients remains short. Aneurysm

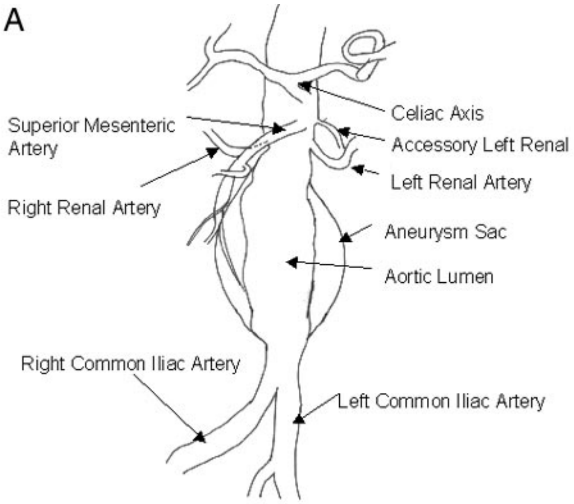


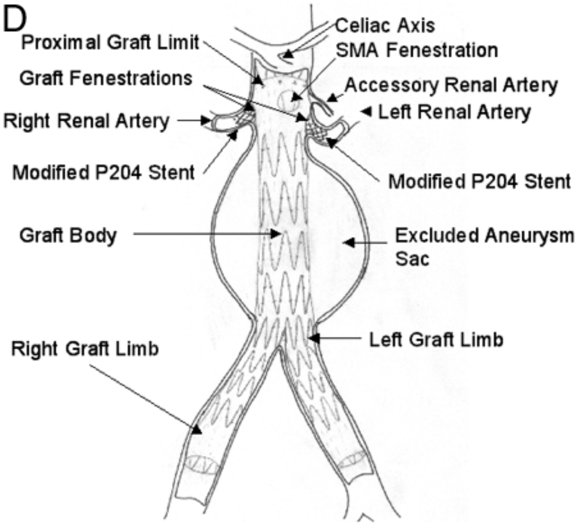
Figure 9 ◆ Diagrammatic representation **(A)** and preprocedural angiogram **(B)** of an infrarenal abdominal aortic aneurysm unsuitable for endoluminal grafting owing to absence of a significant neck below the right renal artery. Note also the superior mesenteric artery (SMA) origin near to the accessory and main left renal arteries. This side branch configuration would be easier to accommodate by including the SMA in a fenestration rather than by attempting to avoid it with subsequent risk of occlusion by graft material. **(C)** A lateral view of this area also shows that there is a posterior bulge of the aorta at this level.

size has decreased in the first 3 patients; the initial patient has demonstrated a 2-cm decrease in transverse diameter at his 24-month follow-up.

DISCUSSION

The introduction into clinical practice of endoluminal aortic grafting by Parodi et al.[1] in 1990 opened a new era in the treatment of aneurysmal disease. However, early work in this field using balloon-expandable tube grafts gave rise to a new set of problems and terminologies not previously encountered in the many years of successful surgical treatment of abdominal aortic aneurysms.

The term endoleak, for example, was adopted to signify continued perfusion of the aneurysm sac following endograft implantation,[10] which in turn spawned a classification system for such leaks.[11–13] Early tube grafts seemed to be plagued with a tendency to develop both distal and proximal type I endoleaks,[14] this being more noticeable with grafts



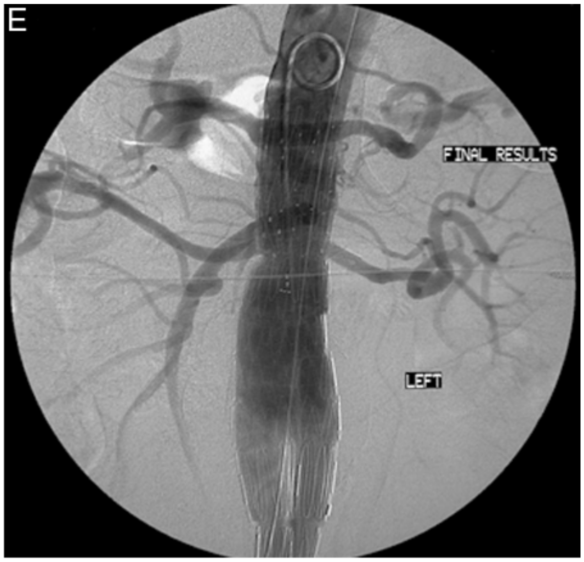
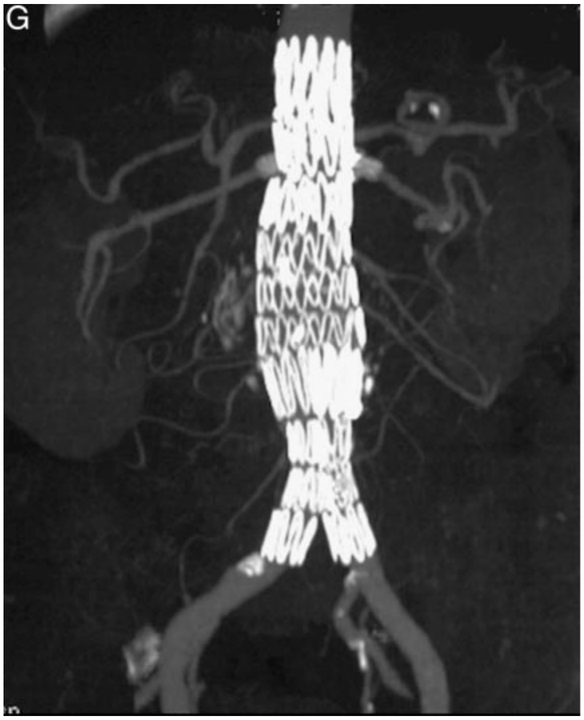


Figure 9 continued. ◆ A quadruple fenestrated graft, shown in a cutaway drawing **(D),** was created and implanted. Note that the upper limit of the graft fabric is immediately below the celiac axis, which is crossed by the uncovered Gianturco stent. The anteroposterior **(E)** and lateral **(F)** completion angiograms document the patency of all vessels, including the left accessory renal artery; there is no evidence of a primary endoleak. The graft has been slightly oversized to accommodate the bulge in the neck.

using balloon-expandable stents for proximal and distal fixation. Failure to obtain a seal at the distal neck tended to be more common, such leaks appearing both at the time of implantation and secondarily during follow-up. Systems employing self-expanding stent fixation appeared to offer a better solution in relation to late endoleaks,[14] and, with the advent of aortomonoiliac[15] and bifurcated[3–5] systems, some problems with the distal aortic neck seemed to be solved.

With accumulating clinical experience,



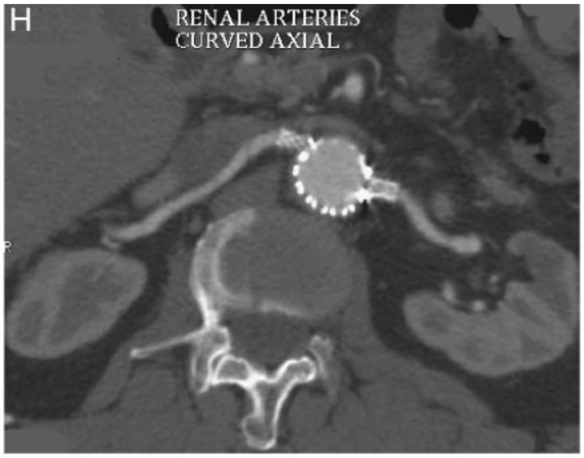


Figure 9 continued. ◆ Both renal arteries are well perfused **(G)**, and the modified P204 stents are clearly seen protruding beyond the metallic framework of the graft. Subsequent computed tomographic scanning at 7-month follow-up has shown an excellent seal, with continued perfusion of all vessels. In the axial view **(H)**, the patency of the renal vessels is easily verified. Note that there is also preservation of the hypogastric artery.

guidelines suggesting appropriate patient selection were developed.[6] Lower profile delivery systems overcame some problems with smaller access vessels,[16] and the use of suprarenal stent fixation has arguably helped to surmount some difficulties associated with the aortic neck, including distal migration and endoleak.[17–20] To date, however, there remains the need for an adequate length of suitable quality infrarenal aorta to permit adequate sealing of the aneurysm sac. Neck length <2 cm has been associated with a higher incidence of proximal endoleak.[13] Although some protocols stipulate a minimum neck length of 1 cm as sufficient to produce an adequate seal at implantation,[21] the long-term outcome remains tenuous. In such circumstances, continued neck dilatation and graft migration[22] may lead to later development of a proximal type I endoleak.

In an ongoing effort to overcome some of the problems with an inadequate infrarenal neck, several authors have reported anecdotal experience with fenestrated stent-grafts in recent years.[18,23–26] Our experience is perhaps the largest to date and has involved endografts with up to 4 fenestrations for aortic side branches. Because this was an evolutionary study, minor refinements in both the technique and the graft system were made during the course of the study, but no major changes were necessary in the primary graft design. Sophisticated imaging techniques allowed accurate anatomical assessment and measurement for these grafts, with spatial relationships of aortic branch vessel ostia captured in both coronal and axial views. These measurements were then incorporated into a custom graft design that featured a capped bare proximal stent and partial endograft expansion in vivo to facilitate final positioning in both longitudinal and rotational directions. Transgraft catheterization of the renal vessels gave confirmation of correct orientation prior to transvessel stenting, cap release, and final deployment.

Renal artery stents appear to be suitable for final ostial-graft alignment and fixation. Flaring of the luminal segment of the stents improves fenestration edge–aortic wall contact over the long term and allows subsequent renal artery interventions. Firm fixation of the fenestration to the vessel ostium should maintain this relationship despite aneurysm

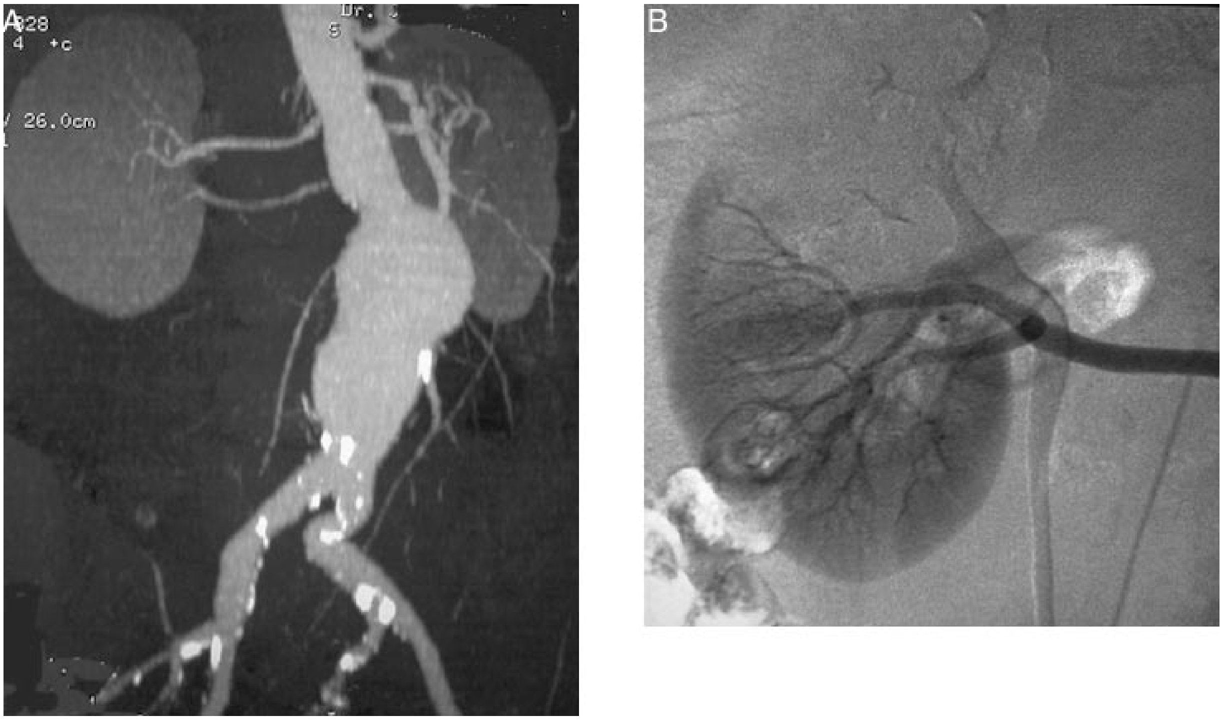
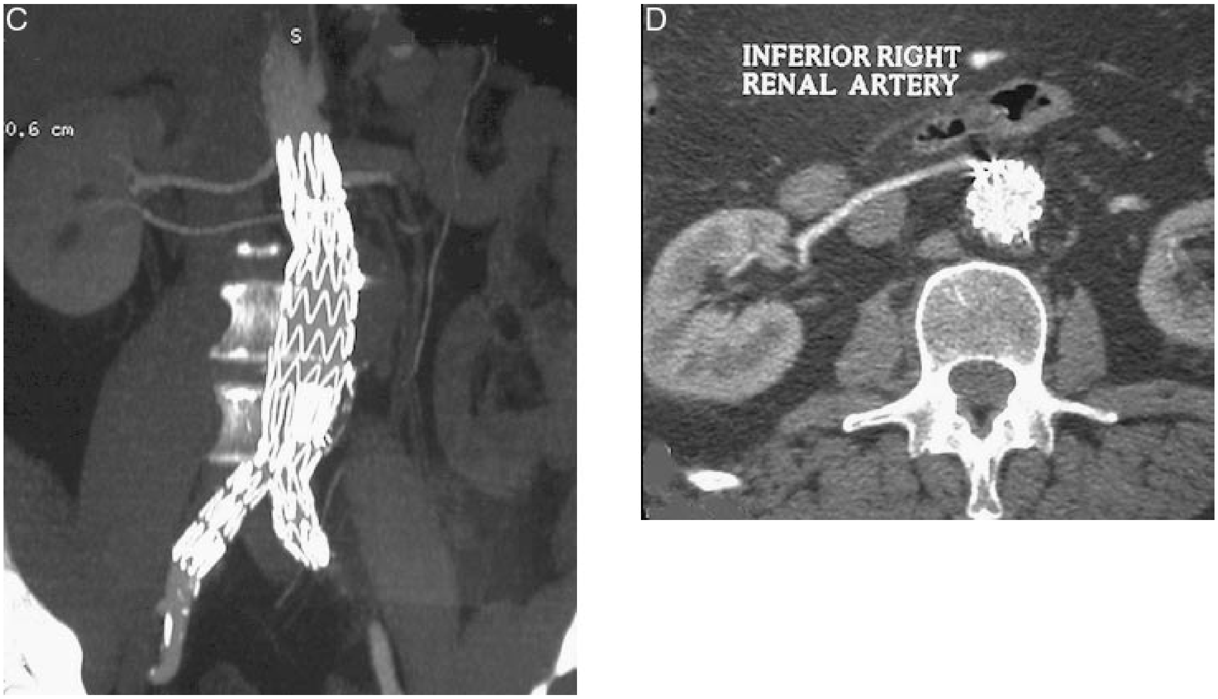


Figure 10 ◆ (A) Computed tomographic angiogram of a 59-year-old male with an otherwise good quality infrarenal aortic neck. The right renal has a dual blood supply with the lower pole artery arising within the neck. Application of a conventional endograft would occlude the accessory artery and threaten the considerable renal parenchyma perfused by it **(B)**. An endoluminal graft **(C)** with a fenestration was implanted to allow continued perfusion of the right lower pole renal artery, but stenting was not employed because of the relatively small size of the vessel. The bare Gianturco stent crosses both the right and left renal arteries; the Dacron fabric lies immediately below the left renal artery. **(D)** A contrast-enhanced axial image at the level of the right lower pole renal artery shows continued perfusion of this kidney segment through the endograft fenestration.



sac remodeling, thus preventing vessel occlusion or endoleak by a migrating graft. Although the hooks on the proximal stent prevent distal migration, they will not control proximal movement following sac remodeling. The stent fixation of the graft to the renal vessels was designed to produce a long-term, stable relationship between the graft fenestration and the vessel ostium. However, a modification of this technique using an endograft capable of recapture and repositioning could also be adapted to achieve similar results. Such a graft would overcome the objection of placing stent wires across the superior mesenteric and celiac vessels. Possible design improvements in both grafts and stents may ultimately lead to successful endoluminal treatment of suprarenal aneurysms.

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