

Surgical Management of Complications Following Endoluminal Grafting of Abdominal Aortic Aneurysms

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Objective: The aim of this study was to report the outcome of endoluminal grafting of abdominal aortic aneurysms (AAA) with special reference to complications.

Methods: Between May 1992 and August 1994 endoluminal repair of aneurysms was undertaken in 61 patients. In 53 the aneurysm was aortic and these are the basis of this report. In patients with AAA all procedures were elective and were performed in the operating room with the patient draped for an open repair in the event of failed endoluminal repair. The configuration of the endografts was tubular 36, tapered aortoiliac/aortofemoral 12 and bifurcated 5. Radiographic guidance was used to pass the endografts into the aorta via a delivery sheath introduced through the femoral or iliac arteries.

Results: Successful endoluminal repair of AAA was achieved in 43 of 53(81%) patients. In the remaining 10 patients, endoluminal repair was abandoned in favour of an open repair. There were 17(32%) local/vascular and 13(25%) systemic/remote complications. The sum of these complications occurring in successful endoluminal repairs and those complications leading to failure of endoluminal repair was 40(75%). There were two cardiac deaths within 30 days in patients undergoing endoluminal repair (both procedure related) and four late deaths (unrelated to aneurysm repair). Three of the late deaths were in patients undergoing endoluminal repair and one endoluminal converted to open repair.

Conclusion: Endoluminal repair of AAA in our experience has a low perioperative (<30 days) mortality rate (3.7%) but a high morbidity rate (75%). It is recommended that complications be classified into three groups: systemic/remote and local/vascular (following successful endoluminal repair) plus those complications leading to failure of endoluminal repair. The first group is composed of medical complications while the latter two groups comprise those surgical complications directly related to the endoluminal technique.

Introduction

There are now three groups with an experience of endoluminal AAA repair exceeding 50 patients each. These are Parodi and colleagues (Parodi, personal communication),^{1,2} the authors of the present paper^{3,4} and Endovascular Technologies (EVT), a California-based company, who are conducting a multicentre, FDA-approved pilot study and randomised trial at 15 centres within the U.S.A. and five outside the U.S.A. (T. Koller, personal communication).

All three groups have clearly established the feasibility of endoluminal aneurysm repair. However, the risks and long-term outcome remain unclear. With the enthusiasm that accompanies any new technology there is a tendency for these to be overlooked. With this in mind we present our experience of endoluminal AAA with special emphasis on the complications

that we have encountered and their surgical management.

Material and Methods

Endovascular repair of aneurysms with materials currently used in vascular surgery is approved by the Institutional Review Board. Informed consent was obtained from each patient. Laboratory and clinical experience in the use of endoluminal grafts for aneurysms has previously been reported by the authors.^{3,4,5-17,21}

Since May 1992 endoluminal repair of aneurysms was undertaken in 61 patients. The aneurysm was aortic ($n = 53$), iliac ($n = 7$) and subclavian ($n = 1$). In the aortic group there were 49 males and four females with a mean age of 70 years. In a previous publication³ the authors have classified AAA into Type I (those with a proximal neck of length 2 cm or greater and

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distal neck of length 1.5 cm or greater and iliac arteries of diameter 8 mm or greater) and Type II (any AAA not fitting the above criteria). In 29 patients the aneurysms were Type I and in 24 patients Type II. The mean diameter of the aneurysms was 5.2 cm (Type I) and 5.8 cm (Type II). Twenty-four patients had serious medical co-morbidities which led to them being rejected for open operation at other medical centres

Table 1. Medical co-morbidities leading to rejection for open surgical repair in 24 patients

Poor left ventricular function (+ renal impairment in 3)	16
Renal failure requiring dialysis	1
Bilateral thoracoplasties for tuberculosis	1
Chronic obstructive airways disease on oxygen 16 hours per day	1
Chronic liver disease (hepatitis C) with thrombocytopaenia	1
Hostile abdomen	4
<i>Total</i>	24

(Table 1).

All procedures were elective and were performed in the operating room with the patient draped for an open operation in the event of failed endoluminal repair. An on-table angiogram was used to identify the renal arteries and the aortic bifurcation. Radiographic guidance was used to pass the endografts into the aorta via a delivery sheath introduced through the femoral or iliac arteries. The configuration of the grafts was tubular (36), tapered aortoiliac/aortofemoral (12) and bifurcated (5). The grafts were anchored in the methods devised by Parodi² (10), White and Yu¹⁴ (32), Chuter¹⁸ (1) and the Endovascular Technologies (EVT) grafting system¹⁹ (10). The methods of endograft delivery and deployment have been described in detail in previous publications.^{5,14,18,19}

An on-table angiogram was performed at the completion of each procedure. All patients have been followed up by clinical examination, Duplex scan and computerised tomogram (CT) scan with contrast before discharge, at 6 months, 12 months and then annually. Complications have been recorded and classified in the manner recommended by the Ad Hoc Committee on Reporting Standards.²⁰

Results

Endoluminal repair was achieved in 43 of 53(81%) patients with AAA and terminated in favour of an open repair in the remaining 10 patients. The causes of failed endoluminal repair are listed in Table 2 and have been analysed in detail together with suggestions for their avoidance in a previous publication.¹⁶

Table 2. Causes of failed endoluminal repair of AAA

Problems with access	2
Balloon malfunction	1
Stent dislodgement	3
Graft thrombosis	1
Inability to deploy the contralateral limb of a bifurcated graft/twist in ipsilateral limb	3

There were two cardiac deaths within 30 days in patients undergoing endoluminal repair—both procedure related. There have been four late deaths, one of which was cardiac, one due to liver failure, one due to hepatoma and one following spontaneous rupture of the oesophagus.

Complications

The 30 complications have been classified into 17 local/vascular and 13 systemic/remote and are sum-

Table 3. Complications following endoluminal AAA repair

<i>Local/Vascular</i>	
Femoral artery repair	3
Perforation of iliac artery	2
Graft stenosis	2
Common iliac artery occlusion	1
Proximal leak (corrected)	1
Distal leak (corrected)	2
Distal leak (persistent)	1
Bleeding (return to OR)	1
Bleeding (haematoma)	1
Lymph fistula	2
Wound infection	1
<i>Total</i>	17
<i>Systemic/remote (Severity/outcome)*</i>	
Renal insufficiency	
obstructive (postoperative retention) (1)	1
contrast media induced (1,1,1,2,2)	5
Cardiac	
congestive failure (2,2)	2
myocardial infarction (2,2,3)	3
cardiac arrhythmia (1)	1
Stroke/TIA (1)	1
<i>Total</i>	13

marised in Table 3. These represent 32% and 25% respectively of total patients undergoing endoluminal repair.

Local/vascular complications

Femoral artery damage Femoral artery damage at the access site occurred in three patients. Two of these occurred early in our experience and resulted from

misguided attempts to pass a 24F delivery sheath through 6–7 mm diameter femoral and iliac arteries. Both injuries required vein patch repairs. Both patients have been followed-up regularly with clinical examination and in the non-invasive vascular laboratory. Ankle/brachial pressure indices were unchanged from before operation. The third patient was noted to have an ischaemic leg (category 2²⁰) at the completion of a successful endoluminal tube graft repair via a femoral arteriotomy. On reopening the arteriotomy, the artery was found to be thrombosed. A large calcified posterior plaque had become detached and moved in such a manner as to block the origins of both profunda and superficial femoral arteries. Thrombectomy of the superficial femoral artery and endarterectomy of the common femoral artery restored the circulation of the leg to its preoperative state.

In a fourth patient a successful endoluminal tube graft repair of an AAA had been achieved. Access was via an arteriotomy in a small aneurysm in the left common femoral artery. On withdrawal of the delivery sheath it was considered to be a safer option to replace the femoral aneurysm with a Dacron tube graft rather than close the arteriotomy.

Graft stenosis Graft stenoses occurred in two patients where endoluminal grafts of 10 mm diameter had been placed within iliac arteries of the same diameter. Post-procedure on-table aortograms showed normal flow through both grafts. A postoperative Duplex scan on the first patient demonstrated a small longitudinal

infolding of that portion of the graft within the common iliac artery (Fig. 1). This was not thought to be significant at the time, as the flow was normal on Duplex scan and clinically femoral pulses were palpable. Twelve days after operation, over a period of 3 hours, however, the patient developed weakness of both lower limbs and signs of ischaemia (category 2²⁰).

An aortogram performed via the right brachial artery demonstrated a stenosis in the endoluminal aortofemoral graft corresponding to that section of the graft lying within the right common iliac artery (Fig. 2). The stenosis was corrected by percutaneous balloon dilatation using sequentially 6 mm diameter and 10 mm diameter balloons (Fig. 3a, b). Follow up with Duplex scan demonstrated normal flow in his endoluminal and cross-over grafts.

The second patient had a similar problem following an endoluminal aortofemoral graft. In the first month after discharge he was readmitted with acute ischaemia of the right leg. In the absence of femoral pulses, urgent operation was undertaken. The endoluminal aortofemoral graft was found to be thrombosed over that section lying within the common and external iliac arteries. It was not possible to re-establish flow with a balloon catheter. An extraperitoneal approach to the right common iliac artery was made allowing this artery to be opened and flow re-established by means of an extraluminal graft running from the previously narrowed aortoiliac graft down to the common femoral artery. This procedure successfully restored flow to the lower extremities. The



Fig. 1. Duplex scan of endoluminal aortofemoral graft showing infolding of the graft (arrow) just before entering the common iliac artery.

patient had a myocardial infarction three days later which resulted in his death.

Perforation of iliac artery Perforation of the iliac artery occurred in two patients. Both were caused by the delivery sheath. The first patient had previous irradiation for bladder cancer, and the field included the iliac arteries. The delivery sheath was introduced transfemorally into the aorta with difficulty. Tachycardia and falling blood pressure indicated blood loss due to perforation. The blood loss was controlled via an iliac incision and the perforated external iliac artery ligated. A Dacron tube graft was placed end-to-side to the common iliac artery and brought down to be used as a conduit for the delivery sheath, which permitted successful placement of a tube endograft in the aorta. After withdrawal of the introducing sheath, the Dacron conduit was transected at the appropriate length and anastomosed end to side to the common femoral artery to revascularise the lower limb. This patient is also listed in the local/vascular complications for return to the operating room for bleeding. No specific bleeding site was identified and the patient retained his endoluminal graft.

The second patient in which perforation of the iliac arteries occurred was one of the few women who fulfilled the criteria for endoluminal AAA repair. The introducing sheath was successfully placed in the aorta and a tube endograft was deployed immediately below the renal arteries. During withdrawal of the 24F delivery sheath the external iliac artery was avulsed from its origin. A similar procedure in the previous

case involving control of bleeding and placement of a Dacron graft from the common iliac to common femoral artery allowed successful revascularisation of the lower limb and retention of the aortic endograft. In addition to the two patients with perforation of the iliac artery there was a further patient who started to bleed heavily from the external iliac artery beneath the inguinal ligament following withdrawal through the femoral arteriotomy, of the introducing sheath. An extraperitoneal approach to the external iliac artery above the inguinal ligament was required to control



Fig. 2. Aortogram demonstrating stenosis in an endoluminal aortofemoral graft. Note revascularisation of left lower limb by femoro-femoral cross over graft.

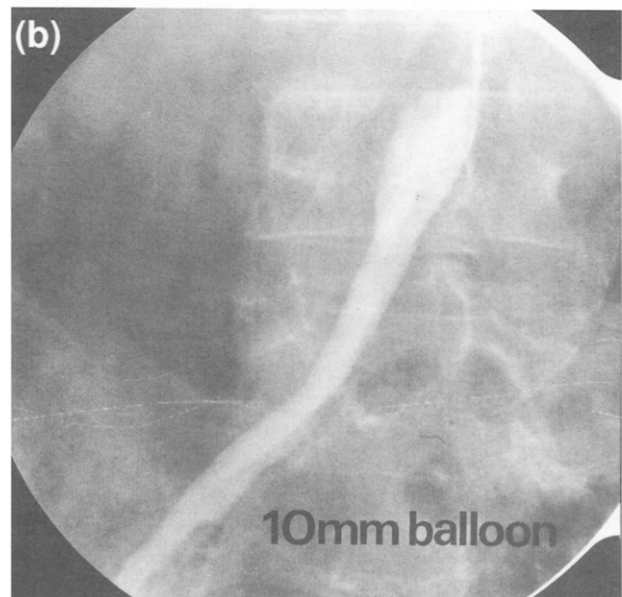
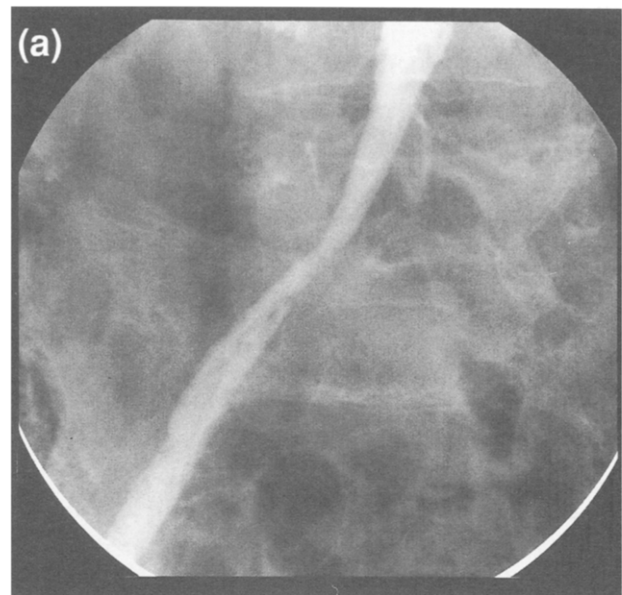


Fig. 3. (a) Close up view of stenosis demonstrated in Fig. 2 before percutaneous dilatation. (b) Angiogram following 10 mm balloon dilatation.

the bleeding and allow suture repair of the bleeding point. No graft was required.

Iliac artery obstruction Obstruction of the common iliac artery was observed in one patient. A tube endograft was placed successfully in the aorta via a left-sided transfemoral approach. The post-procedure angiogram demonstrated that the AAA had been excluded from the circulation but also demonstrated that the right common iliac artery was obstructed. The obstruction appeared to be due to compression of the contralateral atheromatous common iliac artery by the delivery sheath rather than an inappropriately placed inferior attachment device in the endograft. It was possible to pass a guidewire through the obstructed iliac artery into and beyond the endograft by the percutaneous route. Balloon dilatation followed by deployment of a Palmaz 8 mm stent (Johnson & Johnson Warren NJ) restored normal flow through the right iliac arterial system. Despite the presence of a right femoral pulse of normal amplitude, the patient developed paresis and ischaemia (category 2²⁰) in the leg. Femoral artery bypass and fasciotomy were required in the first 48 hours post-aneurysm repair. Cardiac arrest, pulmonary oedema and renal failure led to death on the twelfth day postoperatively.

Incomplete seal between graft and aorta An incomplete seal between the graft and the aortic wall manifests itself in the on-table post-procedure aortogram as a leak of contrast from the lumen of the aorta into the aneurysmal sac. One such leak at the upper end of an endoluminal aortoiliac graft was successfully sealed by the introduction of a second stent which was completely covered by, and attached to, a Dacron graft (Fig. 4a-c).

Three further patients had a leak at the lower end of a tube endograft. Two of these were successfully sealed by a subsequent second endograft telescoped into the primary tube endograft (Fig. 5a, b). The third patient currently has a leak at the lower end of his endoluminal tube graft. The morphology of this aneurysm was well suited for transfemoral tube graft repair with proximal and distal necks of 2 cm in length. The leak is thought to be due to undersizing the diameter of the graft rather than deployment too far above the aortic bifurcation.

Wound complications A haematoma in the iliac fossa occurred in one patient following placement of an endoluminal aortoiliac graft via a conduit to the common iliac artery. This resolved spontaneously without operative intervention.

Two lymph fistulas have occurred following

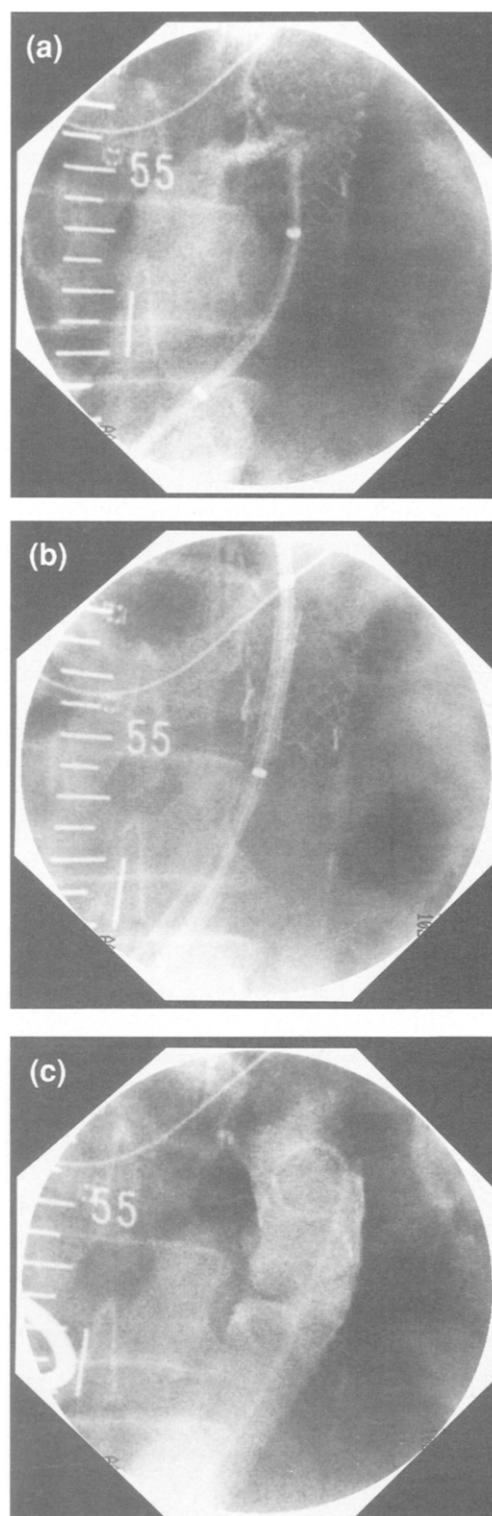


Fig. 4. (a) On-table post-procedure angiogram demonstrating a leak of contrast at the upper end of the graft from the lumen into the aneurysmal sac. (b) Angiogram showing the insertion of a second covered stent mounted on a balloon catheter prior to deployment. (c) Angiogram demonstrating that the leak of contrast has been sealed by the second covered stent.

Fig. 4. Reproduced with permission from the *Journal of Endovascular Surgery*.

transfemoral access. One patient was grossly obese and the other had a prolonged procedure due to heavy calcification in the iliac arteries.

A further patient had prolonged infection in both groin wounds following successful deployment of a bifurcated endoluminal graft. The organism cultured was *Staphylococcus aureus* and the length of hospital stay for the patient was 4 weeks.

Systemic/remote complications

Renal insufficiency was the commonest systemic complication observed. It occurred in five patients all of whom had renal impairment (mean serum creatinine 140 mmols/l) before operation. In three of these the serum creatinine rose over 4 to 5 days to a mean of 290 mmols/l before returning to the preoperative level over a further three to four days. In one of these patients the elevation in serum creatinine was accompanied by an acute episode of pulmonary oedema on day four requiring intubation and ventilation for 24 hours followed by recovery associated with improved renal function. In the fourth patient the serum creatinine rose more rapidly in the first two postoperative days and was accompanied by myocardial infarction and congestion cardiac failure. Haemodialysis was required on four occasions before renal function improved to the preoperative level. In the fifth patient, the serum creatinine rose from 120 mmols/l to 180 mmols/l over the first 48 hours in the postoperative

period. At this point, the patient who had an ischaemic limb (previously referred to under the heading of 'iliac artery obstruction') had a cardiac arrest. Renal function deteriorated further necessitating haemodialysis. He died 12 days after operation from a combination of renal, cardiac and metabolic causes. The renal insufficiency in all five cases was considered to be contrast-medium induced. The mean dose of contrast medium was 285 ml. A further patient developed urinary retention due to prostatic hypertrophy. Conservative management failed and he required transurethral resection of his prostate gland.

Congestive cardiac failure occurred in two patients. This was associated with renal insufficiency and was reversed with improvement in renal function. Three patients developed myocardial infarction in the immediate postoperative period. None required coronary angiography or surgical intervention. A further patient developed atrial fibrillation which responded to medication.

One patient developed a stroke due to infarction in the parietal area of the brain. Weakness in his left hand recovered rapidly but some residual personality change remains.

Discussion

Although endoluminal repair of AAA is less invasive than the standard transperitoneal operation, the morbidity associated with its performance must be taken

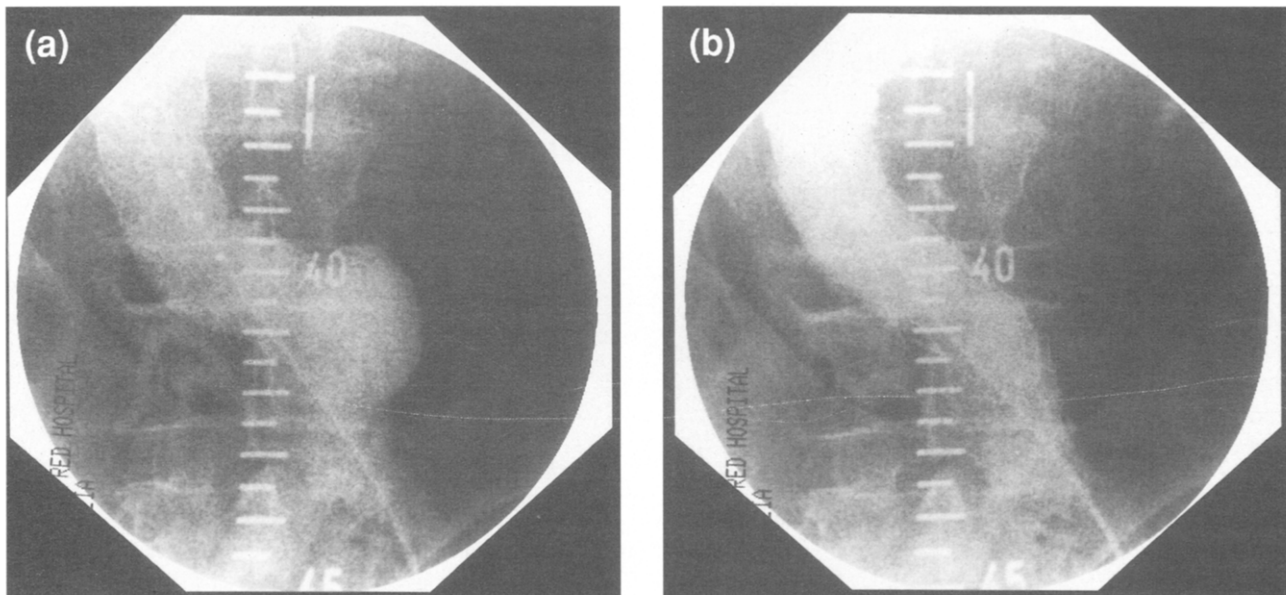


Fig. 5. (a) On-table pre-procedure angiogram confirming a known leak at the lower end of a tube endograft between the lumen and the aneurysmal sac. (b) On-table post-procedure angiogram demonstrating that the leak has been sealed by a second endograft telescoped into the primary tube endograft.

into account when assessing its merits. To obtain a clearer picture of the true morbidity those complications which lead to failure of endoluminal repair and conversion to open operation must be added to the complications occurring in those with successful endoluminal repairs listed above. When this is done it can be seen that the combined complication rate is a substantial 75%. One-third of these complications were systemic/remote and can be attributed to the general medical condition of the patients. It is also important to note that centres known to undertake endoluminal AAA repair attract a high proportion of patients with medical co-morbidities. Notwithstanding this, however, two-thirds of the complications are technical and are directly related to endoluminal method of AAA repair.

Those complications leading to failure of endoluminal repair are of a higher order of importance since many patients undergoing endoluminal repair have been rejected as unfit for open surgical repair at other medical centres. These patients are exposed to the combined risk of a failed endoluminal procedure followed by a standard open operation. The fact that there have been no perioperative (< 30 days) deaths in this group of at risk patients is a reflection of the quality of the anaesthetic and support services and an indication of how imprecise are our methods of risk assessment.

Some important lessons emerge from this experience. The first is the recognition that atheromatous calcified iliac arteries of 6–7 mm diameter are unlikely to dilate sufficiently to accommodate a 24F internal diameter sheath which has an external diameter of almost 10 mm. This statement refers to uniformly small iliac arteries not those of 9–10 mm diameter with a focal stenosis which may be made accessible by balloon dilatation as reported by Parodi.² It is also important to note that in general females have smaller iliac arteries than males. We have recently developed a 20F delivery sheath in an attempt to extend the endoluminal technique to a larger number of females.

With regard to perforation of the iliac arteries it would be anticipated that previous irradiation would make them more susceptible to perforation. It is also generally appreciated that there is a risk of arterial perforation during the introduction of a large sheath. What is less obvious, however, is that the external iliac artery can be so tightly stretched over the sheath that the whole artery can be avulsed from its origin as the sheath is withdrawn. It is also important to recognise that damage to the iliac arteries may occur during introduction of the sheath but bleeding may not

become apparent until withdrawal of the sheath and removal of its tamponading effect.

We have also identified some pitfalls in placing a graft within the lumen of the iliac arteries. The diameter of some commercially available grafts is not always as marked on the packet. Accuracy in this parameter has not previously been important, but now takes on added significance. We have also observed that an iliac artery measuring 10 mm in diameter will not accommodate a 10 mm diameter graft without the graft becoming invaginated into the centre of the lumen. This problem is further compounded by the fact that such invagination may not show up on a post procedure angiogram taken in only one plane (Fig. 6). This complication could be readily detected by intravascular ultrasound.

The technique of using a covered stent or secondary endograft has been useful in avoiding a failed endoluminal repair due to communication between the aneurysmal sac and the aortic lumen, at the upper or lower end of the endograft. It may be used at the time of the initial endoluminal repair or subsequently for persistent leaks into the aneurysmal sac. We have found that CT scan with contrast to be the most sensitive method of identifying these leaks. Duplex scan and angiography may miss small amounts of contrast such as shown in Fig. 7. The significance of contrast appearing only in the periphery of the aneurysm and 3–4 cm from either end of the graft as in this case remains to be determined.

Wound infection and lymph fistula may be persistent problems but are not potentially dangerous because the majority of endoluminal repairs do not have any foreign graft material underlying the femoral wound.

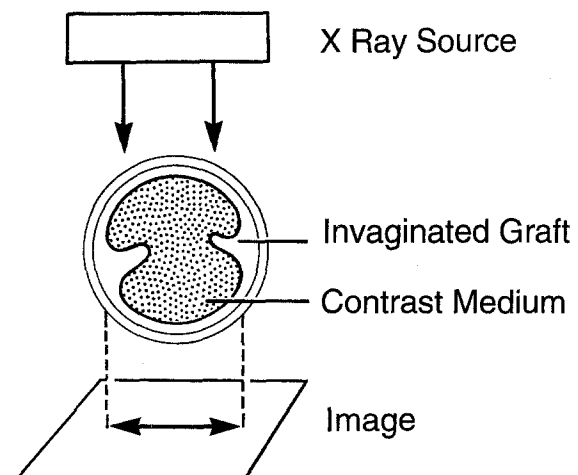


Fig. 6. Diagram illustrating the failure of single plane angiography to demonstrate invagination occurring in grafts placed within arteries.

It is noteworthy that so far in our experience no procedure has been complicated by microemboli. By contrast Parodi (personal communication) has experienced two instances in 50 cases, one of which resulted in the patient's death. We attribute this to two points of technique. Firstly the introduction of a regular guidewire into the thoracic aorta which is then exchanged for an extra stiff one. This minimises the risk of the extra stiff guidewire disturbing mural thrombus. Secondly a policy of making a single pass of the introducing sheath with its mandril to a position in the aorta superior to the renal arteries. From this point on, the mandril and sheath are removed in sequence, leaving the endograft positioned immediately below the renal arteries. At no point is the endograft advanced with any unprotected projections which might disrupt the mural thrombus.

Renal impairment, the commonest systemic/remote complication, has the potential for reduced incidence by more efficient use of contrast agent. This is particularly important in those patients with impaired renal function before operation. Cardiac events, the second commonest complication in this group will be difficult to reduce because so many patients with AAA also have advanced cardiac disease which is frequently inoperable.

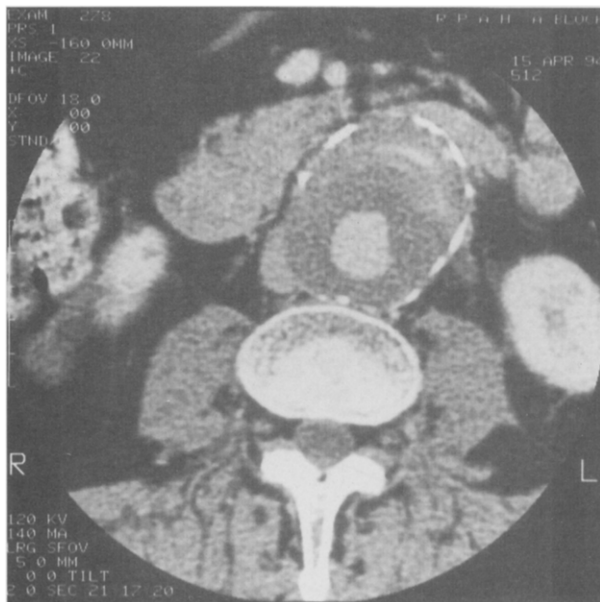


Fig. 7. CT scan with contrast seen within the endograft and in the periphery of the aneurysmal sac 3–4 cm from either end of the endograft.

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