Strut Failure in the Body of the Zenith Abdominal Endoprosthesis

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Objectives. Endovascular repair of abdominal aortic aneurysm is a technology that has undergone rapid technological evolution with a number of different types of grafts developed and concern has been the structural integrity of the metallic endoskeleton. We describe our experiences of strut failure in the Zenith abdominal aneurysm endograft device.

Design/materials/methods. Eighty-four patients have undergone endovascular repair of their abdominal aortic aneurysm at Christchurch Hospital from 1996 to 2005, all with the Zenith endoprosthesis. All available plain radiographs of the endoprosthesis (AP and lateral planes) were reviewed retrospectively, by a single experience observer, to assess strut failure.

Results. Three cases of strut failure in second-generation grafts were identified, each in the inferior body of the graft above the iliac bifurcation. There was no clear evidence that these strut failures were associated with clinical complications.

Conclusion. This is the first time that strut failure in the Zenith abdominal endoprosthesis has been reported. Whilst in each of our three cases this does not appear to have been of clinical significance, these findings re-iterate the necessity of life-long surveillance of this technology.

Keywords: Aortic aneurysm; Zenith; Stent-graft; Strut failure; Follow-up; Endovascular.

Introduction

Endovascular repair of abdominal aortic aneurysms was first described in 1991 by Parodi et al. using a straight Dacron stent.1 With all new medical technologies there is an obligation to monitor patients carefully, allowing early detection of device failure.

Many device-related complications associated with endoluminal exclusion of abdominal aortic aneurysms (AAA) have been reported, including loss of integrity of the metallic endoskeleton. Review of the literature revealed no reported incidences in the Zenith endoprosthesis. We report the first published cases with Zenith graft strut failure, which occurred in three patients at our institution.

Materials and Methods

At our institution, endoluminal repair of AAA commenced in 1996. Until now (2005), all patients except one have received a Zenith (Cook Incorporated, Bloomington, IN, USA) stent-graft of second-generation.

All repairs were entered onto a database that facilitates recall for imaging surveillance, in addition to clinical audit. From 1996 to 2005, 84 patients were entered in the database, 66 of whom are currently undergoing surveillance. Eighteen patients are not in the programme as 12 patients are deceased, one is terminally ill, two have withdrawn from surveillance and three are awaiting their inaugural scan.

We routinely survey all our endoluminal aortic stent-grafts with a combination of CT and/or colour Doppler ultrasound (CDU) imaging according to a rigid protocol. In addition, in 2003 plain anterior–posterior (AP) and lateral abdominal radiographs were introduced into this protocol, to be carried out at the same time as other imaging. The abdominal radiographs were introduced to allow detection of strut failure and graft migration. Hence, from the database we have identified a cohort of 70 patients who have had plain radiograph imaging of their stent-graft. These patients form the basis of this paper.

For monitoring of graft integrity we routinely obtain AP and lateral plain abdominal radiographs,
with additional oblique views taken only if the initial views give reason for concern. In the beginning of the surveillance program, plain radiographs were reviewed by the general pool of abdominal radiologists; however, one of the three strut failures in our series was missed initially and was only noted on a second reading when all studies were reviewed for this paper. This has led to the entire CT, ultrasound and plain radiograph AAA follow-ups now being reviewed by one specialist Vascular Radiologist (Professor Tim Buckenham).

Results

The patient cohort comprised 65 men and five women, aged 57–88 years (median 77 years), with pre-implantation AAA diameters of 42–80 mm (median 58 mm) [maximum AP diameter in the transverse plane from CDU] and a follow-up time of 0–90 months (median 39 months). They have undergone a total of 1612 abdominal radiographs, range 1–7 per patient (median 2). Three patients were found to have strut failure, these cases are described below.

Case 1

This 79-year-old man had an uncomplicated endoluminal repair of his 65 mm AAA in 1998. He was commenced on the CT screening program after the procedure and subsequent measurement of the aneurysmal sac showed a maximal diameter of 70 mm in 2001. No significant abnormality was detected until 2002 when CT scanning revealed a type 2 endoleak via the inferior mesenteric artery (IMA) with sac expansion. This was treated successfully via endoluminal coiling and occlusion of the IMA origin. Further sac measurements have shown ongoing shrinkage with maximal sac diameters of 64 mm in 2003 and 63 mm in both 2004 and 2005.

Plain radiographs of the endoluminal device in Jan 2003 revealed a strut failure in the distal body ring at the site of the previously repaired endoleak (Fig. 1). No association between the endoleak and strut failure was thought to exist. Subsequent radiographs, with the most recent in February 2005, have shown no new strut failures and no change in the appearance of the known strut failure.

Case 2

This 72-year-old man had an endoluminal repair performed in Feb 1998 for a 61 mm AAA. The procedure was complicated by difficulty in passage of the short limb and an angioplasty was required. Due to insufficient overlap between the stent and short limb a 50 mm extension piece was required. No evidence of endoleak was seen at the end of the procedure. CT scanning in 1999 showed no abnormality; sac size at this time was 40 mm. Plain abdominal radiographs in June 1999 showed no strut failure. CT scanning June 2000 showed no abnormality and a stable sac size. The patient represented acutely in late 2000 with an acute retroperitoneal haemorrhage, which was attributed to a contained AAA leak. The patient was treated conservatively due to comorbidities precluding repair.

A CT in February 2001 revealed the aneurysmal sac to be 40 mm in diameter and the presence of a small endoleak of unknown type. Arteriography in August 2001 showed a left iliac limb endoleak at the junction of the graft (type III). The patient had a left iliac limb covered stent replacement with successful exclusion of the endoleak. CT scanning in 2002 showed a sac size of 43 mm and no endoleak.

Plain radiographs of the graft in February 2004 revealed a strut failure in the inferior body ring of the main aortic graft. This has remained unchanged and was not associated with an endoleak. Ultrasonography in 2005 showed no further endoleak and a sac size of 39 mm.

Case 3

This patient underwent endoluminal repair of a 50 mm asymptomatic AAA in January 1999. At
insertion, note was made of some minor kinking at the posterior aspect of the stent in the mid-aortic region. There were otherwise no immediate complications and subsequent CT scans were unremarkable. In 2001, the aneurysm measured 32 mm, with no evidence of an endoleak. Ultrasound of in 2003 showed a sac size of 30 mm and the first plain radiograph of the stent at this time showed a strut fracture in the inferior ring of the main body of the stent. Further radiographs in 2004 showed no change in the strut appearances and further shrinkage of the sac to 28 mm.

Discussion

The Zenith endograft has evolved since its genesis in 1991. The first modular bifurcated graft was inserted in July 1994 with over 10,000 Zenith AAA grafts having subsequently been implanted. In December 1999, Zenith introduced their Tri-Fab system, which was again a modular system, but this time based on three individual components. The materials and introducer were unchanged; however, the stent-graft construction was altered with more flexibility in the legs and alteration of the stent height in the mid portion of the stent-graft. The current most popular model is a modular bifurcated system with an infrarenal body and suprarenal fixation via metallic tines. The body is continuous with two limbs, one of which is landed directly in the iliac of the accessed side. The contralateral limb is docked into the appropriate stump and landed in the contralateral iliac. The graft itself comprises a stainless steel endoskeleton with a Dacron outer sleeve. The sleeve is attached to the endoskeleton with sutures.

All of the patients in our series received the second-generation Zenith graft. UK experience of 269 patients receiving this model suggests a success rate of aneurysm exclusion of 94.1%, with 30 patients (11.8%) developing type II endoleak. A large US multi-center trial of the third-generation Zenith graft showed 0% migration less than or equal to 10 mm, 98.7% rate of aneurysm size stabilizing or decreasing and a 7.4% rate of all endoleaks. Despite the large number of implants, no strut failures have been reported, unlike other devices where this type of complication has been well documented.

The significance of the strut failures in our three cases is uncertain. In our series, 28% of patients had an endoleak and two out of the three strut failure patients had an endoleak, but the strut failure was unlikely to have an aetiological role. All strut failures were noted in the distal ring of the body and there was no associated fabric failure. All these strut failures were identified on AP and lateral plain radiographs, which we performed as a routine follow-up in addition to CT and ultrasound. The AP and lateral radiographs were introduced to the follow-up in 2003, when reports of strut failure were first published relating to other endoluminal prostheses used for the exclusion of abdominal aortic aneurysms. The three strut failures have been reported to Medsafe and TGA, but we are unable to find in the literature any other reports of strut failure relating to the second-generation Zenith graft.

Detection of the failures is not in itself a difficult task, however, it is a finding that needs to be specifically looked for. For this reason we believe single reading by specialist vascular radiologists is sufficient to monitor graft integrity. All of the strut failures were evident on bi-planar imaging and this appears to be adequate to monitor graft position and assess strut integrity.

In the medical literature there is little published research into the implications of strut failures in the clinical setting. Although this is a recognised phenomenon there have been a small number of reported cases with no clear adverse sequelae seen. From current review of the literature there is no clear association of generic strut failure with endoleak despite a number of different models of AAA stents exhibiting strut failures.

As we believe this is the first reported case series of strut failures in the Zenith graft it suggests there is a paucity of published data showing any association with strut failure in this graft type and significant clinical consequences. Despite the occurrence of endoleak at the site of our first patient’s strut failure we appreciate that this may be a coincidental finding. In each of our cases, further screening of the grafts has shown neither further strut failures nor alteration in graft morphology of position.

Correspondence with the manufacturers, Cook, suggests that up to 2% of the first/second-generation Zenith AAA grafts (those with 22 mm long stents) have shown stent fractures (letter from Henrik Gyllun, QC Manager, William Cook Europe ApS, March 6, 2003). The UK Medicines and Healthcare products Regulatory Agency refer to this letter in their website and also provide a summary of data on available endoprostheses, including the Zenith, from the Medical Devices Agency (see http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&useSecondary=true&ssDocName=CON019583 and http://www.mhra.gov.uk/home/groups/dts-bi/documents/websiteresources/con019585.pdf). All of these fractures were located in a similar position just above the bifurcation and no adverse events or clinical sequelae
have been reported in relation to the fractured stents. This is somewhat reassuring and it will be interesting to see if this known phenomenon of strut failure in the main body is seen in the third-generation models.

Despite the apparent lack of clinical consequence with strut failures in Zenith AAA grafts, it serves as a good illustration of the principle that endovascularly repaired AAA patients are indeed ‘patients for life’. AAA repair via endovascular means is becoming the norm rather than the exception in many institutions and as in any new technology long term data for all aspects of the procedure are still pending. As the consequences of mechanical device failure, i.e. strut failure, could be catastrophic it is seems prudent to regard the patients as necessitating ongoing follow-up, maybe even indefinitely. The nature of what is ‘appropriate’ follow-up is less clear. Due to the inherent artefact produced by CT scanning of metallic objects, as well as the spatial resolution obtained with axial scanning it has taken the introduction of abdominal X-ray screening in 2003 for the strut failures in our case series to become apparent. We have taken the conservative approach of yearly abdominal plain radiographs corresponding with our ultrasound screening as an initial policy. This may need adjusting as some of our cohort start to exceed a decade from their initial procedure. However, until there is either conclusive evidence that single strut failure is clinically insignificant or newer generation models of graft are shown to not exhibit the problem, it seems prudent to continue with our current screening policy.

References


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