Eur J Vasc Endovasc Surg (2008) **36**, 653–660

Results of Endovascular Abdominal Aortic Aneurysm Repair with the Zenith stent-graft

W.T.G.J. Bos [a,*], I.F.J. Tielliu [a], C.J. Zeebregts [a], T.R. Prins [b], J.J.A.M. van den Dungen [a], E.L.G. Verhoeven [a,1]

[a] *Department of Surgery, Division of Vascular Surgery, University Medical Center Groningen, Groningen, P.O. Box 30 001, 9700 RB Groningen, The Netherlands*
[b] *Department of Radiology, University Medical Center Groningen, Groningen, The Netherlands*

Submitted 5 May 2008; accepted 12 July 2008
Available online 5 September 2008

KEYWORDS
Abdominal aneurysm;
Endovascular;
Zenith;
Mid-term;
Re-interventions

Abstract *Objective:* To evaluate single center results of the Zenith stent-graft for elective abdominal aortic aneurysm repair.
Methods: Data from all patients treated with a Zenith graft between March 1999 and December 2006 were retrospectively analyzed from a prospective database. Outcome measures were technical success, all-cause and aneurysm related mortality, late complications, and re-interventions.
Results: A total of 234 patients were included, of which 216 were male. Mean age was 72.1 ± 6.9 years. Mean diameter of the aneurysm was 60.9 ± 10 mm. Technical success rate was 98.3%. Thirty day mortality was 1.7%. Median follow-up was 26.9 months (range, 1–104). Overall survival was 92.2 ± 1.8% at 1 year, 87.2 ± 2.3% at 2 years, and 69.9 ± 4.6% at 5 years. During follow-up, one aneurysm ruptured due to limb disconnection, which was treated by bridging stent-grafting. Re-interventions were performed in 9.2% of the patients, with 79% by endovascular means. There was no mortality related to re-intervention.
Conclusions: Endovascular abdominal aortic aneurysm repair with the Zenith device provides excellent results with a low risk for aneurysm-related death and rupture, and a low re-intervention rate in the mid-term.

Introduction

Although early benefits of endovascular abdominal aortic aneurysm repair (EVAR) have been demonstrated in two randomized trials, the number of late complications and re-interventions remains an issue of debate.[1,2] First generation devices were associated with high rates of late

* Corresponding author. Tel.: +31 50 361 33 82; fax: +31 50 361 17 45.
E-mail address: w.t.g.j.bos@chir.umcg.nl (W.T.G.J. Bos).
[1] EV has received consulting fees and research funding from W.L. Gore & Associates and William Cook Europe.

1078-5884/$34
doi:10.1016/j.ejvs.2008.07.010

complications.[1,3] Later, the rate of secondary interventions seemed to decline, which was readily attributed to improved stent-graft design and better patient selection.[4,5]

The Zenith (Cook Inc, Bloomington, IN, USA) stent-graft is a third generation device that underwent very few changes over the years. It is available both in a custom-made two-part bifurcated device and in a standard three-part (aortic bifurcation + two iliac limbs) device. Although it has been used in more than 15 000 patients worldwide, there are still only few reports regarding the mid- and long-term follow-up.

The aim of this study was to report our single centre experience with the Zenith stent-graft.

Materials and Methods

The EVAR programme in our University Medical Center started in 1996. In the first years devices were mainly chosen based upon availability. From 1999 onwards several devices were commercially available allowing us to tailor device selection according to anatomical features of the aneurysm (e.g. Talent [Medtronic World Medical, Sunrise, FL, USA] for proximal necks with a large diameter, Excluder [W.L. Gore and Associates, Flagstaff, AZ, USA] for narrow and angulated iliac arteries because of the flexibility of the device, Zenith [Cook Inc, Bloomington, IN, USA] for short proximal necks in view of the suprarenal fixation of the bare stent with hooks and barbs). Since 2001 we have the availability of a full range of Zenith devices in stock. This, together with the versatility of the device in terms of distal diameter (10—24 mm) and lengths, is the reason why many patients were treated with a Zenith device.[6,7]

Patients

Between March 1999 and December 2006, a total of 379 patients underwent elective EVAR. The Zenith graft was selected in 234 patients. The device incorporates self-expanding stainless-steel Z stents attached to a polyester graft material. Features of the device are the suprarenal fixation and a controlled release mechanism of the bare top stent.[7,8]

Work-up

Pre-operative work-up consisted of a multi-slice computed tomography (CT) scan to evaluate the anatomy of the proximal and distal landing zones and the access through the femoral arteries. In selected cases, an additional angiography was performed. Evaluation of the indications for surgery and selection of the device was done by a team of senior staff members including an interventional radiologist.

Procedure

All procedures were performed in an operating theatre using a mobile image intensifier. Access to the femoral arteries was usually performed through surgical dissection, preferably under local anaesthesia. A description of the technique has been reported elsewhere.[9] Embolization of an internal iliac artery (IIA), if needed, was routinely performed during the same procedure. Patients received antibiotic prophylaxis (cefazoline 1 g) and heparin (5000 IU) intravenously.

Follow-up

From 1996 to January 1999, duplex ultrasound scanning, CTA (or MRA for suitable devices) and multiplanar abdominal radiography were performed before discharge of the patient. Follow-up included CTA or MRA, duplex ultrasound, and abdominal X-ray at 1, 3, 6, 12, 18, and 24 months, and yearly thereafter. From 1999 on, based on our clinical experience and emerging literature, but also due to logistical and stochastic burden for the patient, the protocol was simplified: duplex ultrasound scanning and multiplanar abdominal radiography were done before discharge. At 1 month, a contrast-enhanced CT-scan was performed. Routine follow-up thereafter consisted of duplex ultrasound scanning and multiplanar abdominal radiography at 6 months, 1 year and annually thereafter. CT-scan (or angiography) was only done on indication (endoleak, growth of aneurysm, migration >5 mm, kinking). All patients treated with the Zenith device were followed with the new protocol.[10—12] All patients were put on antiplatelet therapy after the procedure.

Definitions and statistics

Data were collected prospectively on intention-to-treat basis but analysed in a retrospective manner with SPSS 12.0 (SPSS, Chicago, IL, USA). Reporting standards for endovascular aortic aneurysm repair were used for definitions and analysis of endpoints.[13] Primary endpoints were technical success, all-cause and aneurysm related mortality and aneurysm rupture. The cause of death was determined by assessment of patient charts and by contacting the general practitioners and patients' relatives if necessary. Aneurysm related mortality was defined as death resulting from aneurysm rupture (as proven by autopsy, surgery or CT scan) or any death occurring within 30 days after the original procedure or a re-intervention. In case an autopsy was not available, we classified the death as probably unrelated if the clinical picture was consistent and documented with reliable observations during the terminal illness. When these criteria could not be met, the cause of death was considered indeterminate. Secondary endpoints were late complications including migration (>5 mm), endoleak, aneurysm sac diameter changes and re-intervention.

Primary technical success was defined as a successful introduction and deployment of the device in the absence of conversion or intra-operative mortality, type I or III endoleaks, or graft limb occlusion. When unplanned endovascular or surgical procedures were necessitated during the procedure or within 24 h, the terms assisted primary or secondary technical success, respectively, were used. Re-intervention was defined as any endovascular (transfemoral) or open surgical intervention (transfemoral or transabdominal) performed after the initial EVAR in order to maintain or restore the function of the endograft. When more than one re-intervention was necessary during follow-up, the classification of primary, secondary and tertiary