

Finnish Multicenter Study on the Midterm Results of Use of the Zenith Stent-Graft in the Treatment of an Abdominal Aortic Aneurysm

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PURPOSE: To assess the midterm results of endovascular repair of abdominal aneurysm (AAA) with a Zenith stent-graft.

MATERIALS AND METHODS: Between January 2001 and December 2005, a Zenith stent-graft was employed for endovascular repair of an infrarenal AAA in 206 patients. The mean patient age (\pm standard deviation) was 73.2 years \pm 7.3. Bifurcated grafts were used in 196 patients (96.1%), aortouni-iliac grafts were used in seven patients (3.4%), and a tubular graft was used in one patient (0.5%). The mean follow-up period was 2.4 years \pm 1.7.

RESULTS: The 30-day mortality rate was 2.9%. The overall survival rates at 1-, 3-, and 5-year follow-up were 93.3%, 78.7%, and 64.5%, respectively. None of the patients died of AAA rupture. The primary and assisted technical success rates 1 week after endovascular aneurysm repair were 82.0% and 90.3%. The primary clinical success rates at the 1-, 3-, and 5-year follow-up were 90.6%, 85.6%, and 83.5%. Twenty-seven patients (13.1%) underwent a secondary intervention during the study period.

CONCLUSIONS: An 83% rate of freedom from repeat vascular intervention over a period of 5 years as well as an absence of structural failures or aneurysm ruptures demonstrates that a Zenith stent-graft is associated with good midterm results.

J Vasc Interv Radiol 2009; 20:448–454

Abbreviations: AAA = abdominal aortic aneurysm, CI = confidence interval, EVAR = endovascular aneurysm repair, GAS = Glasgow Aneurysm Score, IMA = inferior mesenteric artery, OR = odds ratio, SE = standard error

SINCE the first endovascular repair of an abdominal aortic aneurysm (AAA) reported by Parodi et al (1) in 1991, this technique has been increasingly used to

treat this condition. Large prospective studies have shown the early efficacy and safety of endovascular aneurysm repair (EVAR) (2,3) and, nowadays, it is widely accepted as an alternative to open surgery (4). However, the latter has been shown to be associated with durable, good long-term results (5,6), which EVAR must confront. Stent-grafts have developed from “homemade” endografts to different kinds of manufactured devices. This evolution has improved the results of EVAR (7). Among the stent-grafts currently in use, the Zenith system (Cook, Bloomington, Indiana) is one of the most employed (8). Indeed, the United Kingdom EVAR device-specific study favored the Zenith stent-graft over the Talent stent-graft (Medtronic, Minneapolis, Minnesota), although it was not a statistically signif-

icant trend (9). The Zenith stent-graft was introduced in clinical use in 1993 (10) and over time it has undergone several improvements (11). It is a fully stented, modular, bifurcated stent-graft with a proximal stainless steel Z stent that is completely uncovered to allow routine suprarenal implantation. The main graft and ancillary components are covered with woven polyester graft material. Detailed information about the device has been given elsewhere (11). Herein, we report the midterm results of implanting this stent-graft in a series of 206 patients with infrarenal AAA in three Finnish university hospitals.

MATERIALS AND METHODS

From January 2000 to December 2005, 206 patients underwent endovas-

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None of the authors have identified a conflict of interest.

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DOI: 10.1016/j.jvir.2008.12.410

cular repair of intact, asymptomatic AAAs with a Zenith stent-graft at the Oulu University Hospital (50 patients), Kuopio University Hospital (99 patients), and Helsinki University Hospital (57 patients). This is a retrospective, multicenter study with common data points within centers. Permission to use nationwide data was obtained from the Ministry of Social Affairs and Health. The institutional review board did not require their approval for this retrospective study.

Patients

In this study, we included only patients who underwent elective repair of an infrarenal AAA. Patients who underwent urgent repair of a symptomatic AAA or isolated repair of an aneurysm of the iliac artery were excluded from the study. During the study period, a few other commercially available stent-grafts were also used in all three institutions, but these patients were excluded from the study. The mean patient age was 73.2 years, and 181 of the 206 patients (87.9%) were men. The mean patient weight was 80.0 kilograms (kg) standard deviation 14.0 (median, 79.5 kg; range, 44–121 kg). The patients' characteristics are reported in **Table 1**. Operative risk was assessed according to the Glasgow Aneurysm Score (GAS) (12) by one of the authors by using complete patient files, including data from all the hospitals' departments. The GAS was calculated according to the following equation for elective procedures: risk score = (age in years) + (7 points for myocardial disease) + (10 points for cerebrovascular disease) + (14 points for renal disease). This has been previously validated with Eurostar patients undergoing EVAR (8). As shown by the high GAS (mean \pm standard deviation, 80.0 \pm 9.7; range 53–115), most of the patients had a significantly increased operative risk and thus were not fit for major open surgery.

The anatomic criteria of all the patients were assessed with preoperative contrast medium-enhanced computed tomography (CT). One hundred twenty-two patients (59.2%) also underwent catheter angiography. Vascular surgeons and radiologists together determined their suitability for EVAR. The follow-up was planned as three-phase CT examinations before discharge, at 3 and 12 months, and annually thereafter. An-

teroposterior and lateral abdominal radiographs were obtained at the same time points. Causes of death were obtained from the hospitals' patient documents and from the Finnish Center of Statistics.

Operative Technique

The stent-grafts were installed via surgically exposed femoral arteries by using fluoroscopic guidance with large image field angiographic equipment. The procedure was carried out in all cases as a collaborative effort by vascular surgeons and interventional radiologists. Most of the inserted stent-grafts were Trifab version devices. Bifurcated grafts were used in 196 of the 204 patients (96.1%), aortouni-iliac grafts were used in seven patients (3.4%), and a tubular graft was used in one patient (0.5%). Aortouni-iliac grafts were used if another iliac artery was occluded or severely stenosed or if the contralateral limb was not successfully catheterized. The tubular stent-graft was used in a patient who had an AAA with a long distal neck. The proximal stent-graft was oversized 10%–20% compared with the outer diameter of the neck. In 26 of the 206 patients (12.6%), the aneurysm extended into the common iliac arteries. These patients underwent internal iliac embolization (24 unilateral, two bilateral) before placement of the stent-graft. In 41 of the 206 patients (19.9%), the inferior mesenteric artery (IMA) was embolized before placement of the stent-graft. A left lumbar artery at the L4 level, both lumbar arteries at the L4 level, and one accessory left renal artery were embolized in three of the 206 patients (1.5%). Indications for these preoperative coiling procedures varied among the three institutions. All but one of the coiling procedures were performed at Kuopio University Hospital. This is due to a policy of preoperative coiling of the patent inferior mesenteric artery adopted by this center. The type of anesthesia, procedure time, blood loss, fluoroscopy time, and amount of contrast medium administered were recorded.

Outcome End Points and Definitions

Immediate postoperative morbidity and mortality as well as late survival, prevalence of aneurysm rupture, en-

Table 1
Preoperative Patient Characteristics

Risk Factors	No. of Patients (n = 206)
Male sex	181 (87.9)
Diabetes	27 (13.1)
Smoking habit	116 (56.3)
Transient ischemic attack	11 (5.3)
Stroke	28 (13.6)
Coronary artery disease	111 (53.9)
Myocardial infarction	76 (36.9)
Previous coronary artery revascularization	61 (29.6)
Previous peripheral vascular interventions	19 (9.2)
Lower limb ischemia	21 (10.2)
Dyslipidemia	88 (42.7)
Hemo-/peritoneal dialysis	4 (1.9)
Atrial fibrillation	39 (18.9)
Chronic heart failure	31 (15.0)
Hypertension	115 (55.8)
Chronic obstructive pulmonary disease/asthma	51 (24.8)
Serum creatinine level >150 μ mol/L	11 (5.3)

Note.—The mean patient age was 73.2 years \pm 7.3, and the mean GAS was 80.0 \pm 9.7. Numbers in parentheses are percentages.

dograft patency, clinical success, technical success, prevalence of endoleak, and need for secondary procedures were evaluated as the main outcome measures by using the Society for Vascular Surgery/American Association for Vascular Surgery reporting standards (13).

Endograft patency is given as primary, assisted primary, or secondary patency. Primary patency was defined as a patent stent-graft without significant stenosis (>30%) or occlusion. Assisted primary patency was defined as a failing patent stent-graft that underwent further intervention such as stent placement to improve patency. Secondary patency was defined as a patent stent-graft after additional endovascular or surgical procedures.

Primary clinical success is reported on an intention-to-treat basis and considered a success if there was no need for additional procedures. Data from

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