From the Society for Clinical Vascular Surgery

Use of the Zenith Fenestrated platform to rescue failing endovascular and open aortic reconstructions is safe and technically feasible

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ABSTRACT

Objective: Proximal neck dilation is a serious long-term complication directly causing the failure of endovascular aneurysm repair (EVAR) and open surgical repair (OSR) of abdominal aortic aneurysms. However, the implantation of a fenestrated device presents the opportunity for proximal extension of the aortic reconstruction into a healthy segment while maintaining patency of the visceral vessels. The objective of this investigation was to report perioperative and follow-up outcomes using the Zenith Fenestrated (ZFEN; Cook Medical, Bloomington, Ind) aortic stent system in salvaging previous aortic repairs undergoing type IA endoleak or aneurysmal degeneration of the proximal neck.

Methods: We performed a retrospective review of a prospectively maintained institutional database capturing all fenestrated EVAR (FEVAR) cases with the ZFEN platform. Fenestrated cases were classified as primary FEVAR or reoperative FEVAR (rFEVAR) after previous EVAR or OSR. Cohort comparisons were performed using Fisher exact tests and Student *t*-tests for categorical and continuous variables, respectively.

Results: Between October 2012 and March 2017, a total of 103 patients diagnosed with abdominal aortic aneurysm with an inadequate proximal seal zone for traditional EVAR were treated with ZFEN. In 12 patients, FEVAR was performed as a reoperation after previous EVAR (n = 6) or OSR (n = 6). The indications for rFEVAR were proximal neck dilation (>55 mm) after OSR (n = 6), type IA endoleak after EVAR (n = 5), and proximal neck dilation after EVAR without endoleak (n = 1). No difference in ability to achieve technical success was observed between primary FEVAR and rFEVAR (97.8% vs 100%; $P = 1.00$). In addition, there were no differences in estimated blood loss (363 vs 500 mL; $P = .25$) and intraoperative use of contrast material (97.3 vs 104.0 mL; $P = .55$). However, a significant increase in fluoroscopy time (61.1 vs 79.8 minutes; $P = .04$), radiation exposure (415.9 vs 606.3 rad; $P = .02$), and operative time (228.4 vs 287.6 minutes; $P = .03$) in the rFEVAR cohort was observed. In the 30-day perioperative period, there were no significant differences with regard to mortality (2.2% vs 0%; $P = 1.0$), major adverse cardiovascular events (5.5% vs 0%, $P = 1.0$), and stent-related adverse events (2.2% vs 0%; $P = 1.0$). There were no differences in rates of perioperative (5.5% vs 0%; $P = 1.0$) or follow-up reintervention after a mean follow-up duration of 20.8 months (18.6% vs 25.0%; $P = .70$).

Conclusions: FEVAR with the ZFEN platform of failed and failing aortic reconstructions due to disease progression is safe and feasible without increased morbidity and mortality in select patients. These preliminary results support the inclusion of ZFEN as a treatment option for aortic reintervention. (J Vasc Surg 2018;■:1-6.)

Keywords: Abdominal aortic aneurysm; Reintervention; Zenith Fenestrated endograft; FEVAR; Rescue

Disease progression in the form of proximal neck dilation is a common cause of endoleak and need for reintervention during the follow-up of the surgically repaired abdominal aortic aneurysm patient.[1] Whereas the treatment may be simple proximal endovascular extension in those aneurysms with an adequate neck, short-neck (≤10 mm) aneurysms cannot achieve a proximal seal without coverage of the visceral vessels by traditional endovascular techniques.[2] Unfortunately, significantly higher rates of morbidity and mortality are associated with open surgical rescue.[3] Therefore, reoperative fenestrated endovascular aneurysm repair (rFEVAR) represents a unique, minimally invasive technique to extend the proximal landing zone into the healthy paravisceral aorta without jeopardizing mesenteric and renal arterial blood flow. This retrospective review was

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Author conflict of interest: A.F. is a proctor and consultant for Cook Medical but does not receive any personal remuneration.

Presented in a plenary podium presentation at the Forty-sixth Annual Symposium of the Society for Clinical Vascular Surgery, Las Vegas, Nev, March 17-21, 2018.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

https://doi.org/10.1016/j.jvs.2018.01.038

performed to assess our perioperative and follow-up outcomes of primary FEVAR vs rFEVAR with the Zenith Fenestrated (ZFEN; Cook Medical, Bloomington, Ind) platform to report safety and feasibility.

METHODS

This investigation was approved by the Indiana University Institutional Review Board (No. 1311843883) and conducted in accordance with the principles outlined in the latest iteration of the Declaration of Helsinki.[4] The need for informed consent was not required by the protocol and was therefore waived. A retrospective analysis of a prospectively maintained institutional FEVAR database capturing all ZFENs implanted at Indiana University Health Hospitals (Indianapolis, Ind) from October 2012 to March 2017 was completed. Demographics, comorbidities, surgical history, intraoperative details, and postoperative outcomes were tabulated. Patients with previous endovascular aneurysm repair (EVAR) or open surgical repair (OSR) were combined for the purposes of statistical analysis. Continuous variables are presented as a mean ± standard deviation and compared using Student *t*-tests; Fisher exact tests were performed for categorical variables.

Preoperative. At the time of initial evaluation of the patient, computed tomography angiography (CTA) with three-dimensional reconstruction for aortic anatomy and ZFEN device design was completed on an Aquarius workstation (TeraRecon, Foster City, Calif). In this time period, all patients who could have a ZFEN fitted into the previously reconstructed abdominal aorta were offered rFEVAR preferentially. If the decision was made to proceed with FEVAR, preoperative risk, at minimum, was assessed with electrocardiography and a clinical pulmonary risk screening. Patients at high risk of cardiac or pulmonary complications were referred for pulmonary function or cardiac stress testing to be clinically optimized before the procedure.

Intraoperative. All FEVAR procedures during the study period were performed under general anesthesia in a hybrid operating room equipped with a floor-mounted C-arm (Artis zeego; Siemens Medical Solutions, Malvern, Pa). Percutaneous arterial access was obtained (Perclose; Abbott Vascular, Santa Clara, Calif) under ultrasound and fluoroscopic guidance unless the patient demonstrated anterior femoral artery wall calcification or had a previous groin dissection. Systemic anticoagulation was initiated at a dose of 100 units/kg to maintain activated clotting times >250 seconds for the duration of the case.

After cannulation of the visceral vessels through the main body fenestrations, iCAST (Atrium Medical, Hudson, NH) covered stents were deployed and the intra-aortic portion flared to minimize the potential for type III endoleaks. Superior mesenteric artery (SMA) scallops and unsupported large fenestrations were not routinely stented in our experience. If the distal landing zone of the visceral stent was particularly tortuous or angulated, a bare-metal stent was deployed to extend the distal zone to a more linear target. Technical success was defined as case completion without evidence of a type I or type III endoleak in the setting of the successful deployment of the main body, cannulation of the contralateral gate, and successful stenting of all target fenestrations.[5]

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective, single-center, cohort study
- **Take Home Message:** Use of the Cook Zenith Fenestrated (ZFEN) device in 12 patients with failed previous endovascular aneurysm repair (EVAR) or open repair of an infrarenal aortic aneurysm resulted in similar technical success, mortality, reinterventions, and adverse events compared with primary ZFEN procedures but did require more contrast material and fluoroscopy time.
- **Recommendation:** This study suggests that use of the ZFEN device for failed EVAR and open aneurysm repairs is as safe as primary fenestrated EVAR procedures.

Postoperative. All patients were started on dual antiplatelet therapy (clopidogrel 75 mg daily, aspirin 81 mg daily) for 3 months before transitioning to lifelong aspirin. Follow-up with CTA and serum creatinine concentration was scheduled at 4 weeks, 6 months, and 12 months, followed by annual visits after the first year. In this investigation, major complications were defined as a composite of stent thrombosis (by CTA or renal duplex ultrasound), bowel ischemia, myocardial infarction, spinal cord ischemia, renal failure requiring hemodialysis, and stroke. Bowel ischemia was further defined as bloody diarrhea in the presence of mucosal changes on endoscopy.

RESULTS

Demographics and comorbidities. From 2012 to 2017 at our institution, 103 ZFENs were implanted in the same number of patients. Twelve (11.7%) of these cases were performed as an aortic reoperation after previous EVAR (n = 6) or OSR (n = 6; Table I). The indications for reintervention were proximal neck dilation (>55 mm) after OSR (n = 6), type IA endoleak after EVAR (n = 5), and proximal neck dilation after EVAR without evidence of endoleak (n = 1). The baseline demographics and comorbidities of the cohorts are detailed in Table II.

Operative details. Between the two cohorts, we observed increased technical difficulty (Table III) of rFEVAR using a composite surrogate of visceral vessels