Shuttering of the superior mesenteric artery during fenestrated endovascular aneurysm repair

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Objective: Shuttering occurs when a scallop or fenestration does not align perfectly with the target vessel ostium and is potentially minimized by stenting. The current United States Food and Drug Administration-approved fenestrated endovascular aneurysm repair (f-EVAR) device is most commonly configured with an unstented superior mesenteric artery (SMA) scallop, thereby subjecting the SMA to risk of partial coverage. We aimed to describe the incidence, severity, and clinical effect of SMA shuttering during f-EVAR.

Methods: Patients undergoing f-EVAR using the commercially available Zenith (Cook Medical, Bloomington, Ind) fenestrated stent graft system containing an SMA scallop at our institution between September 2012 and January 2014 were included for analysis. Corrected multiplanar reformatted images on postoperative computed tomographic angiography were reviewed to measure SMA shuttering, defined as the percentage of scallop misalignment relative to the SMA ostial diameter.

Results: Of the 28 f-EVAR cases performed at our institution during the study period, 18 patients (78% male) had an SMA scallop and were included in this analysis. The median age was 78 years (interquartile range [IQR], 72-81 years), and the median abdominal aortic aneurysm size was 61 mm (IQR, 56-64 mm). Fifty-one vessels were targeted (18 SMA scallops, 32 renal fenestrations, 1 renal snorkel), with covered stents placed in all fenestrations. Target vessel catheterization and successful branch stent deployment was achieved in 100% of patients. SMA shuttering measured on postoperative computed tomographic angiography of any amount occurred in 50% of patients (range of SMA shuttering, 12%-40%). The severity of SMA shuttering varied: one patient had 11% to 20%, four had 21% to 30%, and four had 31 to 40%. When compared with patients without shuttering, patients with any SMA shuttering were noted to have a shorter infra-SMA neck length (17 vs 25 mm; P = .007), higher volume of intraprocedural contrast administration (100 vs 66 mL; P = .001), and had a trend toward longer procedural durations (240 vs 188 minutes; P = .09). No association was found between SMA shuttering and the preoperative measured clock position of the visceral vessels, percentage of device oversizing, number of target vessels per patient, aortic diameter at the SMA or seal zone, aneurysm neck morphology, infrarenal neck length, scallop width, or SMA ostial diameter. No acute or chronic events of mesenteric ischemia were noted during a median clinical follow-up period of 11 months (IQR, 5-14 months).

Conclusions: Even with the custom design of currently available fenestrated technology, shuttering of the SMA occurred in one-half of the patients in our cohort, although no clinical events were noted. Further details of the incidence, magnitude, and tolerance of SMA shuttering during f-EVAR are warranted to fully understand the clinical implication of this radiographic finding. Future design considerations for advanced EVAR should take into account SMA shuttering to further refine operative planning. (J Vasc Surg 2014;60:900-7.)

Fenestrated endovascular aneurysm repair (f-EVAR) represents an innovative and technically demanding approach to the treatment of short-neck and juxtarenal abdominal aneurysms (JAAs). Although f-EVAR was first reported in 1999, ¹ experience in the United States (U.S.) remains in its relative infancy, with relatively few centers having access to the clinical trials or investigational device exemption-sponsored trials. Only after the recent approval of the Zenith fenestrated endovascular (ZFEN) abdominal

April 2012 has increasing experience been reported in the U.S., with a number of published series demonstrating favorable early and midterm results using this advanced EVAR technique.²⁻⁵

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soluttering occurs when a scallop or renestration does not align perfectly with the target vessel ostium and is potentially minimized by the use of stenting. The term shuttering has not been previously described nor quantified in the literature, and theoretically could range from 0% (perfect alignment) to 100% (complete coverage of the scallop/fenestration). The currently approved f-EVAR platform is most commonly constructed with an unstented superior mesenteric artery (SMA) scallop, thereby subjecting the SMA to the risk of partial coverage during device deployment.

Although poorly defined and not mentioned to any significance in the literature, the theoretical clinical sequelae of SMA shuttering would be branch vessel ischemia and possible visceral malperfusion. Adverse events

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Presented at the Forty-second Annual Symposium of the Society for Clinical Vascular Surgery, Carlsbad, Calif, March 18-22, 2014.

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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/\$36.00

Copyright © 2014 by the Society for Vascular Surgery. http://dx.doi.org/10.1016/j.jvs.2014.04.055 secondary to SMA shuttering may be unpredictable, ranging from entirely asymptomatic to the development of life-threatening mesenteric ischemia. In the world's largest experience with f-EVAR from the Cleveland Clinic, concern was raised recently about unsupported scallops at the SMA, and a recommendation was offered to stent all scallop configurations.⁵ Given the extreme paucity of imaging data regarding shuttering during complex aneurysm repair, we aimed to describe the incidence, severity, and clinical impact of SMA shuttering during f-EVAR.

METHODS

Patients and inclusion criteria. The present study included a retrospective review of all consecutive patients with complex AAAs treated by f-EVAR using the commercially available ZFEN endovascular AAA endograft at our institution between September 2012 and January 2014. All patients were enrolled in our complex EVAR protocol approved by our local Institution Review Board and informed consent was obtained from all patients. Aneurysm extent included short-necked infrarenal, juxtarenal, pararenal, and type IV thoracoabdominal aortic aneurysms.

All patients were considered medically or anatomically unsuitable for conventional EVAR. Only patients undergoing f-EVAR with a main body device containing a SMA scallop and those with available postoperative cross-sectional imaging were included for analysis. Exclusion criteria included any procedure involving a fenestrated device constructed without an SMA scallop, as well as any f-EVAR associated with SMA stenting or use of a periscope or snorkel technique involving the SMA. Also excluded were patients without available postoperative imaging.

Device description. The ZFEN endovascular device has a modular design consisting of two primary components: a proximal main body graft and a distal bifurcated main body graft that often requires at least one iliac limb extension to complete most procedures. Each component is composed of full-thickness woven polyester fabric and self-expanding stainless steel stents that are secured together as a composite endograft using braided polyester and monofilament polypropylene suture. The proximal main body component may accommodate a combination of up to three fenestrations or scallops, thereby maintaining visceral arterial patency and facilitating a more proximal sealing position compared with standard EVAR devices. The two most common endograft configurations involve one scallop or fenestration for an asymmetrically vertically positioned renal artery or two renal fenestrations and one scallop for the SMA.

A scallop represents a U-shaped gap within the proximal fabric of the stent graft; all scallops are 10-mm wide and 6-mm to 12-mm in height, custom ordered by the implanting physician, with the most common choice being a 12-mm height. In contrast, fenestrations are circular or elliptical holes within the proximal main body fabric. The fenestrations are either small with an elliptical shape (6-mm width and a height of 6 or 8 mm) and fit entirely between the struts of the seal stent or are large with a

circular shape (diameters measuring 8, 10, or 12 mm) that when constructed do cross struts of the seal stent. In accordance with the instructions for use for this device, it is recommended that all vessels accommodated by a small fenestration be stented to optimize and secure proper alignment of the fenestration with the ostium of the visceral vessel. Stenting for vessels accommodated by a scallop is optional and not recommended in vessels accommodated by a large fenestration.

Technical details regarding implantation of fenestrated endovascular AAA devices have been previously described.^{2,6,7} In brief, the technique begins preoperatively with custom design of the scallop and fenestrations relative to clock positions and at chosen distances from the proximal edge of fabric. During the actual procedure, the proximal main body is introduced, with proper rotational orientation confirmed by the overlap of an anterior row of vertical and posterior row of horizontal markers to form a cross. Correct orientation is also confirmed with reference to the circumferential radiopaque markers of the renal fenestrations and SMA scallop, and in our practice lined up with prewired renal vessels. Selective catheterization of the target visceral vessels is performed at this time and confirmed using a small injection of contrast medium. Sheaths are advanced into all target vessels, and stents are prepositioned within the sheaths, where applicable, before endograft deployment.

Our practice is to place covered stents within target vessels accommodated by small fenestrations. We do not routinely stent target vessels accommodated by scallops or large fenestrations. The proximal main body graft is deployed at this time and balloon-molded to the juxtarenal neck. The visceral stents are then deployed and flared approximately one-third of the stent graft length (usually ~ 5 mm) within the aortic lumen to enhance fixation and minimize risk of endoleak. Completion angiography after assembly and deployment of all modular components is performed to document target vessel patency and presence of any endoleak.

Calculation of SMA shuttering. High-resolution computed tomographic angiography (CTA) of the abdomen and pelvis was obtained in all patients preoperatively and ≤30 days postoperatively. Additional postoperative imaging at 6 and 12 months, and annually thereafter, was pursued unless prohibited by severe renal insufficiency, in which case duplex ultrasound imaging and noncontrast CT was substituted.

A dedicated three-dimensional workstation (TeraRecon, San Mateo, Calif) with semiautomated centerline of flow reconstruction was used to characterize visceral segment geometry. Corrected multiplanar images from postoperative scans were reviewed as a group by all three authors to measure the degree of SMA shuttering, defined as the percentage of scallop misalignment relative to the SMA ostial diameter (Fig 1). The position of the scallop relative to the ostium of the SMA was verified in coronal and sagittal orientations, and misalignment was often most notable in the lateral direction, although we did not specifically measure vertical shuttering. The craniocaudal

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