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A fenestrated, double-barrel technique for proximal reintervention after open or endovascular abdominal aortic aneurysm repair

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ABSTRACT

Objective: Proximal endovascular reintervention after prior endovascular aortic repair (EVAR) or open abdominal aortic aneurysm repair (OR) can be challenging due to the short distance to the visceral branches. We present a novel solution to allow the use of the commercially available ZFEN device using a double-barrel, kissing-limb technique.

Methods: Patients who underwent fenestrated repair for proximal failure after EVAR or OR were identified. The ZFEN device is deployed above the prior graft flow divider. Once the visceral branches are secured, kissing limbs are used to connect with the prior graft limbs. The distal diameter of the standard ZFEN is 24 mm, accommodating two 20 mm components according to the formula $2\pi D_{LIMB} = \pi D_{ZFEN} + 2D_{ZFEN}$.

Results: Of 235 patients who underwent repair using ZFEN from 2012 to 2021 at a single institution, 28 were treated for proximal failure of prior repairs, with 13 treated using the double-barrel technique (8 EVAR, 5 OR). The distance from the flow divider to the lowest renal artery was 67 ± 24.4 mm (range, 39-128 mm), and the distance to the superior mesenteric artery (SMA) was 87 ± 30.5 mm (range, 60-164 mm). Technical success was 100%. Seven patients had standard ZFEN builds (2 renal small fenestrations, SMA large fen/scallop). The minimum distance to the lowest renal artery and SMA to accommodate a standard ZFEN build was 56 and 60 mm, respectively. Four patients required adjunctive snorkel grafts and two required laser fenestrations. Two patients had gutter leaks at 1 month that self-resolved; one patient developed a late type 1a endoleak. Freedom from reintervention was 90%, 72%, and 48% at 1, 2, and 3 years, respectively.

Conclusions: This double-barrel technique allows for distal seal of commercial ZFEN devices into prior open or endovascular repairs with good technical success. Long-term outcomes remain to be quantified. (J Vasc Surg Cases Innov Tech 2023;9:1-6.)

Keywords: Aortic aneurysm; Endovascular; Fenestrated/branched repair

Repair of infrarenal abdominal aortic aneurysms can be achieved by either open surgical repair (OR) or endovascular aortic repair (EVAR); the latter has become increasingly prevalent in recent years.[1] Failure at the proximal end of the repair can occur with either approach, resulting from technical failures, graft-related issues, or continued aneurysmal degeneration.[2-6] This clinical scenario can be associated with important and potentially devastating outcomes such as anastomotic pseudoaneurysms in OR patients, and type 1a endoleak with sac expansion and rupture after EVAR.[7] With patients surviving longer than ever after abdominal aortic aneurysm repair, these late complications are becoming commonplace in modern aortic practice.[8]

Endovascular intervention to address proximal failure of prior OR/EVAR is a challenging problem due to encroachment on the visceral aortic segment. Any repair at this level needs to incorporate the renovisceral vessels using either branched or fenestrated devices[5,6] or parallel grafting techniques.[9] One of the technical issues is connecting the new endovascular graft to the prior repair, made difficult by the short distance between the lowest visceral branches and the flow divider of the prior EVAR or aorto-bi-iliac graft. Traditionally, the main body of an open surgical graft was trimmed as short as possible before performing the proximal anastomosis; first-generation EVAR devices were modeled after this, with very short distances to the flow divider as well. This precludes the use of most bifurcated endovascular grafts for revision and does not allow for adequate overlap and seal between the new graft and the prior implant.

The Cook Zenith Fenestrated device (ZFEN; Cook Medical) is the only commercially available fenestrated device in the United States. Although it is indicated for repair of short neck and juxtarenal aneurysms and could potentially be used for such proximal failures, several design restrictions and its need for a distal bifurcated

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piece limit its utility. Physician-modified endografts (PMEGs) may be used, though subject to institutional restrictions and surgeon familiarity with this technique, and custom fenestrated/branched (F/BEVAR) devices are not universally available. We therefore describe and report outcomes on a novel technique to overcome some of these obstacles, which allows for the use of ZFEN in this scenario using a double-barrel, kissing-limb technique to bridge to the prior repair with sufficient overlap and seal. We also attempt to define the minimum required distance from the flow divider to the visceral branches to employ this strategy for fenestrated repair of prior EVAR or OR using the commercially available ZFEN graft.

METHODS

We retrospectively reviewed our prospectively maintained, institutional ZFEN database to identify patients in whom FEVAR was performed for proximal failure of prior endovascular or open infrarenal repair. The patients treated with the double-barrel technique were then analyzed. Technical success was defined as successful implantation of the fenestrated device, cannulation and stenting of all intended visceral targets, and bridging to the prior repair with the double-barrel stents, as well as successful aneurysm exclusion. The primary outcome measures were endoleak and freedom from reintervention. Follow-up imaging was obtained using our standard protocol, with computed tomography angiogram and/or duplex ultrasound imaging performed at 30 days, 6 months, 1 year, and yearly thereafter. The study was approved by our local institutional review board, and because of the retrospective nature of the study, informed consent was not required.

We also attempted to define the minimum distance between the visceral arteries and the flow divider of the prior repair, in order to generalize the applicability of this technique. The diameter ratio was calculated at the first postoperative computed tomography scan, using the methods described by Groot Jebbink et al,[10] to estimate the "fit" of the double-barrel stents into the main device; the ratio is calculated by dividing the major axis length by the minor, with larger ratios representing a more elliptical shape.[10] We also used our previously described formula to assure that two barrels fit inside a larger barrel without gutter leak either by circumference covered or area filled.[11,12]

Statistical analysis was performed using Stata 16.0. Descriptive statistics were used to analyze patient demographics, comorbidities, and clinical outcomes. All measurements were performed using 3D rendering software (Intuition; TeraRecon) by the same user (JRS) to limit interobserver variability.

Description of technique. The fenestrated device was generally designed such that its distal end would sit just above the flow divider of the prior repair. "Standard build" was defined as having two small fenestrations for the renal arteries, which were bridged with covered stents, and an unstented large fenestration or scallop for the superior mesenteric artery (SMA). Other configurations were referred to as "nonstandard builds." After obtaining bilateral femoral access, the ZFEN main body was advanced into position and deployed. The visceral targets were then cannulated and stented from the contralateral femoral access using standard methods. Once the visceral branches were secured and the proximal graft had been balloon-molded, attention was turned to bridging to the prior repair. The distal diameter of the commercially available ZFEN device is 24 mm, which accommodates two 20 mm limbs according to the formula $2\pi D_{LIMB} = \pi D_{ZFEN} + 2D_{ZFEN}$ and leaves no gutters (Fig 1). To fill the space completely, the left side of this equation must be equal to or greater than the right. The two limbs were positioned side by side and deployed simultaneously to create the double-barrel configuration (Fig 2, *A*). A kissing-balloon technique can then be used to simultaneously mold the limbs to ensure equal visual positioning of the two limbs (Fig 2, *B*). Finally, each side is extended as needed to fully seal into the prior repair. A 3D reconstruction of the final repair is shown in Fig 3. Patients were all discharged on dual antiplatelet therapy for 6 weeks.

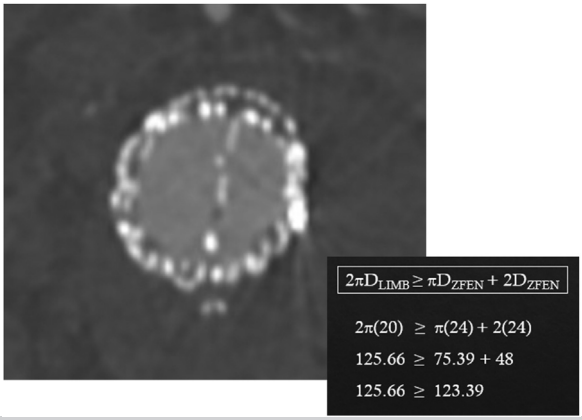

Fig 1. Double-barrel configuration and rationale. Two 20 mm limbs fill the distal end of the 24 mm ZFEN device without gutters, according to the formula $2\pi D_{LIMB} = \pi D_{ZFEN} + 2D_{ZFEN}$. The calculation proof is shown.

RESULTS

Of 235 patients who underwent repair using ZFEN between 2012 and 2021, 28 (11.9%) were treated for proximal failure of a prior repair. The double-barrel technique was used in 13 of 28 of these patients (46.4%), though more recently this has become the primary strategy for this scenario and was used in 11 of the last 12 cases. Basic demographics of the double-barrel cohort are outlined in

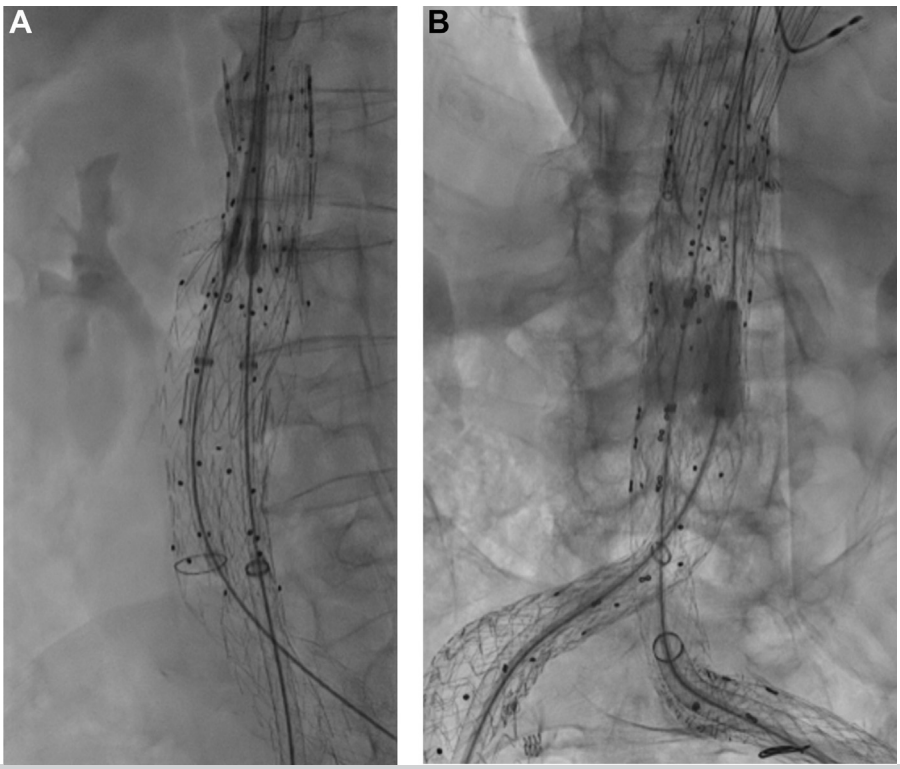

Fig 2. Deployment and kissing-balloon molding of double-barrel stents. **A,** The 2 limbs are deployed simultaneously to ensure that the proximal ends are even. **B,** Kissing balloons are used to mold and ensure seal.

the Table. Five patients (38.5%) had prior OR, whereas 8 (61.5%) had prior EVAR: 3 AneuRx (Medtronic), 3 Endurant (Medtronic), 1 Excluder (W.L. Gore), and 1 Ovation (TriVascular Inc).

Anatomic factors and devices. The distance from the flow divider of the prior repair to the lowest renal artery was 67 ± 24.4 mm (range, 39-128 mm), and the distance to the SMA was 87 ± 30.5 mm (range, 60-164 mm). Seven patients had standard ZFEN builds, whereas four patients required adjunctive snorkel grafts[13] and two required in situ laser fenestration[14] for one of the renals. Among patients with standard builds, the shortest distance to the lowest renal artery and the SMA was 56 and 60 mm, respectively. Patients with standard ZFEN builds were treated for juxtarenal aneurysms, whereas those requiring adjunctive chimneys or laser fenestrations were treated for the paravisceral aneurysm extent. In the latter, the adjunctive maneuvers were planned ahead of time and performed on the lower renal(s) to move the ZFEN higher and use the fenestrations for the more proximal branches. No true thoracoabdominal aneurysms were included in this series.

For the double-barrel components, in the first patient two 20 × 55 mm ESLE Iliac Leg Extensions (Cook Medical) were used; two patients then had flipped 20 mm Excluder Contralateral Leg Endoprostheses (W.L. Gore),[15] and the remaining 10 patients were treated with 20 × 82 mm Endurant Iliac Limb Extensions (Medtronic). Diameter ratios of the double-barrel configuration ranged between 1.60 (more spherical) and 2.11 (more elliptical), with a mean ratio of 1.92 ± 0.14.

Outcomes. Technical success was 100%. Average fluoroscopy time was 62 ± 11 minutes, and radiation exposure was 4310 ± 1387 mGy. Operative time was 161 ± 35 minutes, and 96 ± 24 mL of contrast was used.

There was no perioperative or 30-day mortality. Two patients (15.4%) had gutter leaks at 1-month follow-up, both of which resolved at the subsequent 6-month scan. One patient (7.7%) developed a late type 1a endoleak at 6 months, which is being followed as the patient is of advanced age and there has been no associated sac growth. Kaplan-Meier estimated freedom from reintervention was 90%, 72%, and 48% at 1, 2, and 3 years, respectively, with all reinterventions related to the renal branches. There was one occlusion of a renal chimney, which was not able to be salvaged. All other reinterventions were for restenosis, which were successful in restoring patency. The overall primary and secondary patency of the renal branches at the last follow-up was 92% and 100%, respectively. No patients required temporary or permanent renal replacement therapy. There were no limb occlusions noted.

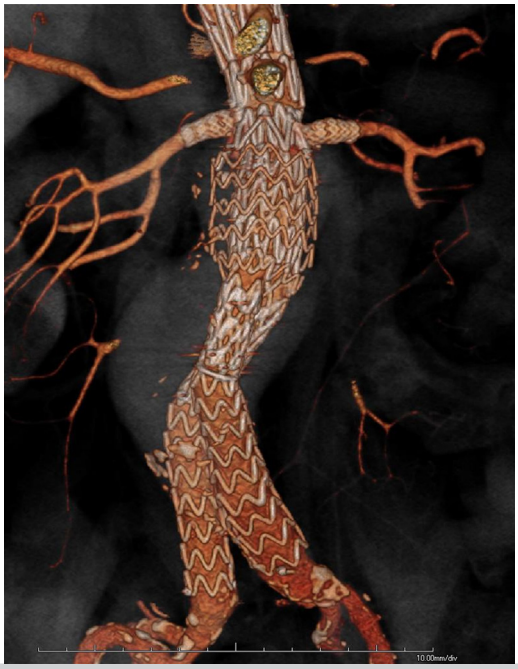

Fig 3. Completed double-barrel repair. A 3D rendering (Intuition; TeraRecon) demonstrating a completed double-barrel repair, with the proximal fenestrated component and visceral stents as well as the double-barrel limbs distally. The prior infrarenal endograft is seen, having been excommunicated from the new repair.

Table. Basic demographics and prior repairs

Variable	Value
Age	75.7 ± 8.8
Male sex	11 (84.6)
Comorbidities	
CAD	5 (38.5)
A-Fib	4 (30.8)
CHF	2 (15.4)
HTN	13 (100)
Hyperlipidemia	7 (53.8)
Smoking history	7 (53.8)
COPD	3 (23.1)
CKD	5 (38.5)
Prior CVA	1 (7.7)
PAD	1 (7.7)
Prior repair	
Open	5 (38.5)
EVAR	8 (61.5)
AneuRx	3 (37.5)
Endurant	3 (37.5)
Excluder	1 (12.5)
Ovation	1 (12.5)
Indication for intervention	
Type 1a endoleak	7 (53.8)
Proximal aneurysmal degeneration/pseudoaneurysm	6 (46.2)

CAD, Coronary artery disease; *CHF*, congestive heart failure; *CKD*, chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *CVA*, cerebrovascular accident; *EVAR*, endovascular aortic repair; *HTN*, hypertension; *PAD*, peripheral arterial disease.
Values expressed as mean ± standard deviation for continuous variables, and number (%) for categorical values.

DISCUSSION

We describe a novel technique for endovascular rescue of proximal failure in prior infrarenal aneurysm repair. The technique allows for the use of the commercial ZFEN device, in both prior open and endovascular repairs, so long as the fenestrated component can land above the flow divider. We defined this minimum required distance from the flow divider to the lowest renal artery as approximately 56 mm, though the actual distance will vary based on the size of the fenestrated graft, the number of sealing stents, and the location of the lower fenestration boundary. We achieved technical success in all cases, and reasonable short-term outcomes with no perioperative mortality and only two self-limited gutter leaks between the double-barrel limbs. The ability to seal the distal 24 mm body of the commercially available ZFEN device via these double barrels expands its use to include cases of proximal degeneration of prior open or endovascular repair.

Proximal failure of infrarenal aortic repair is a significant problem in modern vascular practice and can be caused by either device failure or the progression of disease.[13,16] Unchecked type 1a endoleaks from loss of proximal seal in EVAR can lead to continued pressurization of the aneurysm sac and ultimately rupture and death.[7] Although open repair remains a viable option in fit patients, it can be associated with significant morbidity and mortality,[17] making endovascular repair an attractive alternative. Good results have been described with F/BEVAR[18] in this context, but in the United States, these devices are limited to those with investigational device exemptions from the Food and Drug Administration. Interventionalists in the United States are therefore limited to alternative strategies with parallel grafting[9] or more recently using back table PMEG devices. Although PMEGs can certainly be used to treat these failures, data are lacking due to the inability to publish results in peer-reviewed journals. In addition, some hospitals do not allow physician modifications, as they may not be reimbursable and potentially open the door to medicolegal exposure.

Our technique takes advantage of the Food and Drug Administration-approved and widely available ZFEN device, with which U.S. physicians are already familiar and for which good long-term data are available.[19] So long as the ZFEN device lands above the flow divider, the workflow for completing the fenestrated portion of the

procedure is identical to that for standard ZFEN implantation. Bridging to the prior device is also very straightforward, provided two operators are able to deploy the double-barrel limbs simultaneously and at the same level. We have transitioned to using 20 × 82 mm straight Medtronic limbs, particularly as their deployment is easily controlled for accuracy. The length is ideal also as it traverses across the flow divider into ipsilateral and contralateral gates of all prior infrarenal devices or open repair constructs. These self-expanding limbs fill the distal ZFEN body well and generally make a good elliptical "Double-D" shape without significant gutters (Fig 1).

Fortunately, the two gutter leaks seen at 6 months both spontaneously resolved. Although this is a limited series, it is encouraging that these did not persist and lead to downstream sequelae. Particularly because this technique is an alternative to proximal extension with parallel grafts, one may argue that we are simply trading one gutter issue for another. Indeed, the natural history of parallel graft gutters may also be relatively benign,[20] but a major advantage of this technique over traditional parallel strategies is that the renovisceral branches can be secured via fenestrations, avoiding some of the concerns related to chimney graft occlusions.[21,22] Late explantation for failure of this configuration always remains an option, but would be extremely difficult and unlikely to be feasible in the majority of these patients.

In calculating the optimal size for the double-barrel components, we previously developed the equation $2\pi D_{LIMB} = \pi D_{ZFEN} + 2D_{ZFEN}$.[11] When the left side of this equation is equal to or greater in value than the right, then the conformable self-expanding stents should fill the lumen of the larger device into which they are placed. We have also found that this general equation can be adapted to any similar situation where a double-barrel configuration may be needed. Just as two 20 mm limbs are needed to fill the 24 mm ZFEN lumen, this equation suggests that the devices needed are perhaps somewhat larger than one may predict. For example, two 14 mm devices would be needed to fill a 16 mm lumen, and two 28 mm devices to fill a 34 mm lumen. The clinical applicability of this remains to be seen, but it is a concept that could prove useful in various scenarios.

Our study has several limitations, primarily related to its retrospective nature and small size. Although we were able to achieve good technical and short-term success, the long-term durability of this configuration is unknown. The results from our high-volume single institution may also not be widely applicable to all users and hospitals, but we do feel that for experienced ZFEN users, this is a useful technique for these difficult situations. Caution should be taken in situations of severe angulation and tortuous neck anatomy. Finally, this technique helps solve this specific issue given the current device restrictions in the United States, but may become obsolete in the future with the widespread availability of custom F/BEVAR devices or if a converter from the commercially available device into a bifurcated graft becomes available.

CONCLUSIONS

The double-barrel technique allows for repair of proximal failure of prior open and endovascular infrarenal aortic aneurysm repair using the commercially available ZFEN device connecting it to any prior endovascular or open repair graft. Although technical and short-term success was high in this small cohort, more data are needed to quantify long-term outcomes.

REFERENCES

1. Suckow BD, Goodney PP, Columbo JA, Kang R, Stone DH, Sedrakyan A, et al. National trends in open surgical, endovascular, and branched-fenestrated endovascular aortic aneurysm repair in medicare patients. J Vasc Surg 2018;67:1690-7.e1.
2. Schanzer A, Greenberg RK, Hevelone N, Robinson WP, Eslami MH, Goldberg RJ, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. Circulation 2011;123:2848-55.
3. Antoniou GA, Georgiadis GS, Antoniou SA, Kuhan G, Murray D. A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy. J Vasc Surg 2013;57:527-38.
4. Kaladji A, Daoudal A, Duménil A, Göksu C, Cardon A, Clochard E, et al. Predictive models of complications after endovascular aortic aneurysm repair. Ann Vasc Surg 2017;40:19-27.
5. Katsargyris A, Oikonomou K, Spinelli D, Houthoofd S, Verhoeven ELG. Fenestrated and branched stent-grafting after previous open or endovascular aortic surgery. J Cardiovasc Surg (Torino) 2014;55(Suppl 1):95-103.
6. Wang SK, Drucker NA, Sawchuk AP, Lemmon GW, Dalsing MC, Motaganahalli RL, et al. Use of the Zenith Fenestrated platform to rescue failing endovascular and open aortic reconstructions is safe and technically feasible. J Vasc Surg 2018;68:1017-22.
7. Deery SE, Ergul EA, Schermerhorn ML, Siracuse JJ, Schanzer A, Goodney PP, et al. Aneurysm sac expansion is independently associated with late mortality in patients treated with endovascular aneurysm repair. J Vasc Surg 2018;67:157-64.
8. Kouvelos G, Koutsoumpelis A, Lazaris A, Matsagkas M. Late open conversion after endovascular abdominal aortic aneurysm repair. J Vasc Surg 2015;61:1350-6.
9. Donas KP, Telve D, Torsello G, Pitoulias G, Schwindt A, Austermann M. Use of parallel grafts to save failed prior endovascular aortic aneurysm repair and type Ia endoleaks. J Vasc Surg 2015;62:578-84.
10. Groot Jebbink E, Grimme FAB, Goverde PCJM, van Oostayen JA, Slump CH, Reijnen MMPJ. Geometrical consequences of kissing stents and the covered endovascular reconstruction of the aortic bifurcation configuration in an in vitro model for endovascular reconstruction of aortic bifurcation. J Vasc Surg 2015;61:1306-11.
11. Casey K, Zayed M, Greenberg JI, Dalman RL, Lee JT. Endovascular repair of bilateral iliac artery aneurysms in a patient with Loeys-Dietz syndrome. Ann Vasc Surg 2012;26:107.e5-10.
12. DeRubertis BG, Quinones-Baldrich WJ, Greenberg JI, Jimenez JC, Lee JT. Results of a double-barrel technique with commercially available devices for hypogastric preservation during aortoiliac endovascular abdominal aortic aneurysm repair. J Vasc Surg 2012;56:1252-9.
13. Lee JT, Greenberg JI, Dalman RL. Early experience with the snorkel technique for juxtarenal aneurysms. J Vasc Surg 2012;55:935-46; discussion: 945-6.
14. McWilliams RG, Murphy M, Hartley D, Lawrence-Brown MMD, Harris PL. In situ stent-graft fenestration to preserve the left subclavian artery. J Endovasc Ther 2004;11:170-4.
15. Higashigawa T, Kato N, Hashimoto T, Inouchi M, Chino S, Yamamoto N, et al. Upside down use of Gore Excluder or Cook Zenith legs. Cardiovasc Intervent Radiol 2014;37:1068-72.

16. Martin Z, Greenberg RK, Mastracci TM, Eagleton MJ, O'Callaghan A, Bena J. Late rescue of proximal endograft failure using fenestrated and branched devices. J Vasc Surg 2014;59:1479-87.
17. Kelso RL, Lyden SP, Butler B, Greenberg RK, Eagleton MJ, Clair DG. Late conversion of aortic stent grafts. J Vasc Surg 2009;49:589-95.
18. Katsargyris A, Yazar O, Oikonomou K, Bekkema F, Tielliu I, Verhoeven ELG. Fenestrated stent-grafts for salvage of prior endovascular abdominal aortic aneurysm repair. Eur J Vasc Endovasc Surg 2013;46:49-56.
19. Oderich GS, Greenberg RK, Farber M, Lyden S, Sanchez L, Fairman R, et al. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. J Vasc Surg 2014;60:1420-8.e1-5.
20. Ullery BW, Tran K, Itoga NK, Dalman RL, Lee JT. Natural history of gutter-related type Ia endoleaks after snorkel/chimney endovascular aneurysm repair. J Vasc Surg 2017;65:981-90.
21. Scali ST, Feezor RJ, Chang CK, Waterman AL, Berceli SA, Huber TS, et al. Critical analysis of results after chimney endovascular aortic aneurysm repair raises cause for concern. J Vasc Surg 2014;60:865-74.e1.
22. Usai MV, Torsello G, Donas KP. Current evidence regarding chimney graft occlusions in the endovascular treatment of pararenal aortic pathologies: a systematic review with pooled data analysis. J Endovasc Ther 2015;22:396-400.

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