



Fenestrated Endovascular Aneurysm Repair versus Snorkel Endovascular Aneurysm Repair: Competing yet Complementary Strategies

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Juxtarenal/pararenal aortic aneurysms and type IV thoracoabdominal aneurysms pose particular technical challenges for endovascular repair as they involve the visceral segment in addition to insufficient infrarenal neck for the use of standard endovascular aneurysm repair (EVAR) devices. To overcome these challenges, complex EVAR techniques have been developed to extend the proximal landing zone cephalad with maintaining perfusion to vital aortic branches, thereby broadening the applicability of endografting from the infrarenal to the suprarenal aorta. Complex EVAR can be divided into two broad categories: fenestrated endovascular aneurysm repair (FEVAR) and snorkel EVAR. FEVAR is a valid procedure with the standardized procedure, although it remains as a relatively complex procedure with a learning curve. Given time constraints for the custom fenestrated graft, snorkel EVAR may be an alternative for complex repairs in symptomatic or ruptured patients for whom custom-made endografts may not be immediately available. This article discusses these two most commonly used complex EVAR strategies.

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INTRODUCTION

With the advent of endovascular techniques, endovascular aneurysm repair (EVAR) has largely replaced open surgical repair for anatomically suitable abdominal aortic aneurysm (AAA) [1-3]. However, approximately one-third of patients presenting with AAAs are deemed unsuitable for conventional EVAR because of anatomic constraints most often related to proximal neck anatomy [4,5]. In two-third of these patients with challenging anatomy, the proximal neck is less than the required 10 to 15 mm or is unsuitable as a proximal landing zone [6,7]. Complex AAAs, comprised of juxtarenal/pararenal AAAs and often grouped with type IV thoracoabdominal aneurysms (TAAAs), pose particular technical challenges for endovascular repair as they involve the visceral segment in addition to insufficient infrarenal

neck for the use of standard EVAR devices [8]. To overcome these challenges, complex EVAR techniques have been developed to extend the proximal landing zone cephalad with maintaining perfusion to vital aortic branches, thereby broadening the applicability of endografting from the infrarenal to the suprarenal aorta.

Complex EVAR can be divided into two broad categories: fenestrated endovascular aneurysm repair (FEVAR) and repair with debranching of the renovisceral branches using snorkel/chimney stent grafts followed by complete exclusion using a standard endograft (snorkel EVAR) [9]. This article discusses these two most commonly used complex EVAR strategies, with particular attention to several variables that may favor one strategy over the other.

FEVAR

FEVAR was first reported in 1999 for the treatment of a juxtarenal aortic aneurysm [10]. In 2001, Anderson et al. [11] published the first series of EVAR experience incorporating the renal and the superior mesenteric artery (SMA) with fenestrations in 13 patients with juxtarenal aortic aneurysm. In the United States (US), after a prospective trial at 14 United States academic centers, the Zenith Fenestrated stent graft (ZFEN; Cook Medical Inc., Bloomington, IN, USA) was approved by the US Food and Drug Administration (FDA) for commercial use in April 2012 [8].

Since the approval of the device, fenestrated stent grafts have been increasingly used to treat complex aortic aneurysms involving visceral branches [1,2,12]. Recently, O'Donnell et al. [9] analyzed all endovascular repairs of complex AAAs from 2014 to 2018 in the Vascular Quality Initiative (VQI). This study included all commercially available FEVAR, snorkel EVAR, and physician-modified endografts (PMEGs), exclusive of investigational device exemptions and clinical trial devices. There were 880 FEVAR (63%), 256 PMEGs (18%), and 260 snorkel EVAR (19%). While no change in aneurysm extent was noted, the length of proximal seal extended over time. In line with this finding, the number of centers managing complex AAAs using endovascular techniques expanded steadily from 39 in 2014 to 81 in 2017 [9].

Fenestrated device usually consists of three components: a proximal fenestrated component, a distal bifurcated component, and one contralateral limb (Fig. 1) [13]. Fenestrated stent graft components are provided with custom-made fenestrations and scallops. The flow to vital aortic branches is preserved through fenestrations. The most commonly used configuration includes small fenestrations (8x6 mm)

for the renal arteries and a scallop (10-mm wide, 12-mm deep) for the SMA. Using a combination of fenestrations and scallops, the proximal landing zone can be extended to the suprarenal aorta, whilst maintaining the patency of the renal and visceral arteries (Fig. 2) [14]. Hence, the absence of an infrarenal neck is no longer a limiting factor. In addition, this composite three-part system allows some sliding between the fenestrated tube and the bifurcated component, which in turn helps to avoid traction on the fenestrations with subsequent risk of crushing the renal arteries [15].

Current anatomic and clinical indications for primary FEVAR include short-necked (4 to 14 mm in length) and juxtarenal/pararenal AAAs. This strategy can also be used to repair previous failed open surgery or EVAR [16]. The

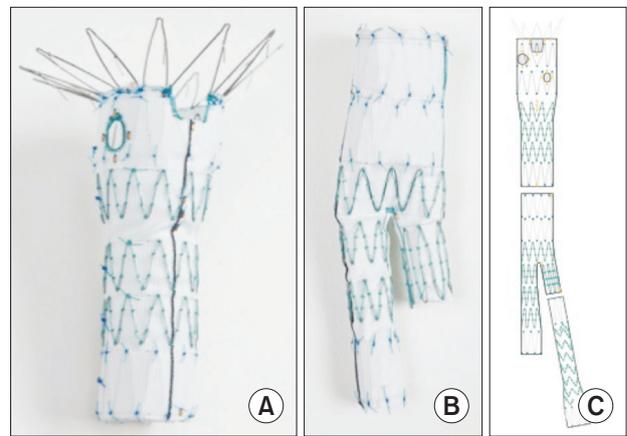


Fig. 1. Zenith fenestrated stent graft (Cook Medical Inc.) consisting of a fenestrated proximal component (A), a bifurcated distal component (B), and a contralateral iliac limb extensions (C). Images from the Cook Medical Inc. with original copyright holder's permission.



Fig. 2. Intraoperative angiogram showing standard Zenith Fenestrated (ZFEN): pre-deployment (A), at completion (B).

technique of implantation of fenestrated stent graft to treat juxtarenal AAAs has been previously described in the literature [15,17,18]. Of note, compared with standard EVAR, FEVAR requires a better access vessel that is large and healthy enough to allow not only insertion of the delivery system, but also repositioning and reorientation to achieve successful catheterization of the target vessels through the fenestrations. Additionally, the anatomy of the target vessels must also be adequate to achieve insertion and sealing with a stent graft. Thus, small caliber (<4 mm), extensive arteriosclerotic disease, early bifurcation and sharp downward take-off are unfavorable anatomic characteristics of a target vessel because catheterization is more difficult [15].

With the increasing application of the FEVAR approach, much data have been collected and outcomes have been assessed. Critical issues that need to be addressed when evaluating FEVAR outcomes include patency of visceral branches, endoleaks, reinterventions, changes in renal function, and prevention of aneurysm rupture. The results of the United States Zenith Fenestrated trial showed a low mortality rate of 1.5% with no aneurysm rupture and with a low rate of renal artery occlusion (4%) [8]. Type Ia endoleak occurred in only one patient at 3 years due to enlargement of the aortic neck. These results have been replicated in systemic reviews, as well as multicenter and single-center series, with high rates of technical success and low morbidity (12%–16%) and mortality (2%–6%) [12,19–22]. Due to the inherent disease progression, approximately 2% to 3% of FEVAR patients will eventually develop a proximal type I endoleak given enough time [23]. Nevertheless, endoleaks from the attachment sites (type I and type III) has been reported to occur in less than 3% of patients [12,22].

Maintaining branch vessel patency is one of the keys to long-term FEVAR success. Midterm branch vessel patency rates in recent literature range from 93% to 98% (at 3–5 years) [24–27]. Mastracci et al. [28] conducted the largest study to date that evaluated the durability of branch vessels after FEVAR. This study included not only short-necked and juxtarenal AAAs, but also more extensive TAAAs. Patency of fenestrated branches was greater than 98% at 5 years. Secondary procedures were performed in only 0.6% of celiac arteries, 4% of SMA, 6% of right renal artery, and 5% of left renal arteries. The 5-year freedom from branch vessel reintervention rate was 89%.

Considering the manipulation of the renal arteries, as well as the use of contrast media used during the procedure and in the repeated follow-up imaging, renal dysfunction following FEVAR has been one of the greatest concerns. According to the long-term data from the Cleveland Clinic, permanent renal function deterioration occurs in 4% to 8% of patients, which is comparable with open repair [29]. In

the published literature, the need for hemodialysis after FEVAR ranges from 0% to 6% and varies based on the extent and complexity of the aneurysm repaired [19,22–24].

Beyond anatomic limitations and technical difficulties, there are some disadvantages. First, there is the need for customized devices, requiring a delay of 4 to 6 weeks for device manufacturing, thereby precluding the treatment of patients requiring urgent interventions [30]. To overcome this obstacle, PMEGs have been described with good outcomes [31]. This approach involves creation of fenestrations on a back table with commercially available aortic stent grafts to suit the patient's anatomy. However, this is an off-label use of devices, technically challenging, and, above all, the long-term implications on the durability of the modified device are unknown [32].

Second, due to its design constraints, two-thirds of patients with complex AAAs are not candidate for the ZFEN device, which is the only currently commercially available device in the United States. The maximum of two fenestrations and the use of single-diameter scallops limit the ability to achieve sealing zones above the SMA or celiac axis [33]. Thus, effort has been placed on the creation of off-the-shelf fenestrated devices, and trials of those devices are ongoing in the US [9]. The Ventana Engologix (Endologix, Irvine, CA, USA) design applies the concept of movable fenestrations, with 85% visceral artery incorporation [34]. The p-branch design (Cook Medical Inc.) uses pivot fenestrations with two possible designs that incorporate the visceral arteries in 80% of patients [35]. Mendes et al. [36] recently reported the anatomic feasibility of the aforementioned two off-the-shelf fenestrated stent grafts in 390 patients treated for juxtarenal/pararenal AAAs. In their report, only 42% and 49% of patients met anatomic recommendations for the Ventana fenestrated system (Endologix) and p-branch design, respectively. Thus, additional design options are still desired.

SNORKEL EVAR

The main alternative strategy to compare with FEVAR is the use of snorkel grafts. The term 'snorkel' was given because the imagery of the curved distal end and the straighter proximal end, when deployed into final position, looks like snorkels, and is used interchangeably with 'chimney' [37]. The snorkel technique, first described by Greenberg and colleagues, was originally developed as a rescue procedure of renal arteries accidentally covered by a main aortic endograft during regular EVAR. To maintain sufficient blood flow, in this technique, stent grafts are placed in the inadvertently obstructed artery in a parallel course adjacent to the main aortic stent graft. In doing so,

the stent graft (snorkel graft) travels in the cranial direction with the proximal portion extending beyond the proximal edge of the main aortic stent graft. This extension of the proximal edge in turn makes it possible to achieve a stable proximal suprarenal proximal landing zone [38]. Resultantly, the snorkel graft lies between the main aortic endograft and the aortic wall. This configuration, however, conduces to the inevitable zones of potentially suboptimal conformation, which are called 'gutters' [39].

Beyond extending the proximal landing zone in a short or no-neck aortic aneurysm, it has the several additional advantages. The most significant advantage is its immediate availability using immediately available off-the-shelf endograft devices [40]. The ability to use off-the-shelf devices designed for smaller access confers another advantage. The use of low-profile devices also helps lower the cost of snorkel EVAR compared to that of FEVAR [41]. In addition, compared to FEVAR where there is a learning curve, this approach is relatively easier due to cannulation of branches without first going through another device/fenestration. Furthermore, the typical downward angle of most renal and visceral vessels makes things easier with the snorkel EVAR strategy.

Like in FEVAR, the length of the proximal landing zone will prescribe which renal and/or visceral vessels require debranching, and thus the number of snorkel grafts required. Unfortunately, however, there is no consensus exists for the maximum number of stent graft that can be employed without compromising the integrity of the procedure. Also, there is the lack of standardization of the technique, with no recommendation as to the most appropriate type of snorkel graft or the best combinations of aortic stent graft and snorkel graft [32,40]. Studies are ongoing to try to identify the best combinations of aortic and branch stent-grafts to minimize theoretical gutter concerns.

In vitro testing by Troisi et al. [42], the combination of Endurant stent graft (Medtronic, Santa Rosa, CA, USA) as a standard aortic device and balloon-expandable covered stent Advanta/iCAST V12 (Atrium Medical, Hudson, NH, USA) as snorkels was shown to be an effective combination in minimizing the presence of gutters. This combination was investigated in the PROTAGORAS study, which included a total of 187 snorkel grafts deployed for the 128 patients with pararenal pathologies. After 2-year radiologic follow-up, the investigators reported that this combination is associated with significant pathologic sac regression and low incidence of new type Ia endoleaks requiring reintervention. Further, the results from this study indicated creation of a proximal landing zone of >15 mm might be sufficient to reduce the risk for late type Ia endoleak and the need for subsequent reintervention. In this study, primary

snorkel graft patency was 95.7%, and freedom from snorkel graft-related reinterventions was 93.1% [43].

Another combination that has been suggested in the literature is the use of the Excluder endograft (W.L. Gore & Associates, Flagstaff, AZ, USA) combined with self-expanding covered stents like the Viabahn (W.L. Gore & Associates). It has shown that the Excluder device has similar radial force to the Viabahn, so that it wraps around the snorkel graft more harmoniously and thereby minimizing the risk for persistent gutters [44]. Additionally, in a geometric study of various snorkel graft configurations in an in-vitro juxtarenal aneurysm model, the authors demonstrated the Viabahn is more compressible than the iCAST and thus facilitates a better wrap-around the aortic endograft body, thereby achieving a better seal around the gutter [45]. This combination was used in recent studies, which showed promising results [46,47].

With regard to balloon-expandable versus self-expanding stent grafts used in snorkel procedures, Donas's group compared these two types of stent grafts. In their study, 46 target vessels (43 renal arteries, 3 superior mesenteric arteries) were revascularized by the balloon-expandable Advanta and 81 target vessels (64 renal arteries, 11 superior mesenteric arteries, 6 celiac trunks) by the self-expanding Viabahn. Overall, one type Ia endoleak was detected in the Advanta group, whereas 5 type Ia endoleaks were present in the Viabahn group. The authors claimed that this difference was less important because only one of them was persistent and was able to be treated by proximal extension with a cuff. The patency of Advanta group was 97.8% and that of the Viabahn group was 100% in the entire follow-up. Also no patient suffered from a persistent deterioration of the renal function [48].

The technical success and short-term outcomes of snorkel EVAR are well published [46-50]. The largest collected world experience of snorkel EVAR was recently published from the PERICLES registry [51], which included 898 snorkel grafts in 517 patients in 13 centers worldwide. Snorkel EVAR were performed for a pararenal AAA in patients who have anatomic contraindication to FEVAR and/or with an aneurysm requiring immediate repair. Only three (0.6%) late-onset type Ia endoleaks, which were judged to be gutter-related endoleaks, were detected at 6-month but successfully treated by neck lengthening. A 30-day mortality rate of 4.9%, a persistent type Ia endoleak rate of 0.4%, and primary patency of 94% during a mean follow-up of 17.1 months were reported. These numbers are nearly identical to the results from the PROTAGORAS study and also comparable with published results from series of fenestrated grafts.

FEVAR VERSUS SNORKEL EVAR

Few studies have compared the techniques, and some of studies have reported similar results when using FEVAR or snorkel EVAR with regard to technical success, target branch vessel patency, early mortality, type Ia endoleak, postoperative renal dysfunction, or need for secondary intervention [50,52,53]. Banno et al. [40] compared early-term and midterm results of FEVAR and snorkel EVAR with 80 patients undergoing FEVAR and 38 undergoing snorkel EVAR for juxtarenal or pararenal AAAs. The FEVAR and snorkel groups did not differ significantly in 30-day mortality (6.3% after FEVAR vs. 7.9% after snorkel), primary patency of the revascularized vessel rates (71.4% vs. 72.0%), or in moderate to severe complications (27.5% vs. 39.5%). Ducasse et al. [54] conducted a systematic search and included 227 patients (510 target vessels) in the FEVAR group and 126 patients (174 target vessels) in the snorkel EVAR group. The 30-day mortality rate (4.4% after FEVAR vs. 4.8% after snorkel), overall target vessel patency rate at 12-month (97.8% for FEVAR vs. 95.9% for snorkel), and the 12-month rates of type Ia endoleak (1.7% for FEVAR vs. 3.7% for snorkel) did not differ significantly between the techniques.

On the contrary, in the recent report from the O'Donnell group reporting early results from their study in the VQI (a three-arm study also including PMEGs), there was a trend toward higher rates of perioperative death after snorkel (3.4% for FEVAR vs. 2.7% for PMEG vs. 6.1% for snorkel; $P=0.13$), while rate of AKI remained similar (17% vs. 18% vs. 19%; $P=0.42$) [9]. Further, in this study, even after adjustment, snorkel was associated with significantly higher odds of stroke (odds ratio [OR], 7.3; $P=0.15$) and major adverse cardiac events (OR, 11.1; $P=0.005$). This trend was also shown in a previous meta-analysis study by Katsargyris et al. [50] comparing early results between snorkel EVAR and FEVAR for juxtarenal aortic aneurysms. This study indicated, although not statistically significant, FEVAR (2,465 vessels targeted) emerges with numerically better outcomes than snorkel EVAR (151 vessels targeted) for 30-day mortality (2.4% vs. 5.3%) and also for renal dysfunction (9.8% vs. 12%). In the same study, early proximal type Ia endoleak

was also lower after FEVAR compared to snorkel EVAR (4.3% vs. 10%, $P=0.002$).

Numerically inferior outcomes of snorkel EVAR in aforementioned studies certainly deserve further attention. Snorkel techniques have been advocated by some clinicians but remain unproven clinically and standardization is also lacking. On the other hand, FEVAR is a valid procedure with the standardized procedure. Ideally, direct comparison in a prospective randomized controlled trial would be needed to evaluate superiority of FEVAR over snorkel repair in standard surgical risk patients. Unfortunately, such trials are not feasible because of the different patient cohort.

CONCLUSION

With rapid technological advances and increasing operator experience, the use of EVAR in the management of complex aneurysms has expanded. Currently, FEVAR and snorkel EVAR represent the two most commonly utilized advanced endovascular techniques to overcome the obstacles of unfavorable hostile proximal neck anatomy. FEVAR is a valid procedure with the standardized procedure, although it remains as a relatively complex procedure with a learning curve. Given time constraints for the custom fenestrated graft, snorkel EVAR may be an alternative for complex repairs in symptomatic or ruptured patients for whom custom-made endografts may not be immediately available. Ultimately, with the long-term goal of achieving the most durable repair possible, both of these strategies should be in the armamentarium of surgeon treating complex aortic pathologies.

CONFLICTS OF INTEREST

William J. Yoon, M.D. is a paid consultant to Cook Medical Inc. He also has a consulting agreement contract with W.L. Gore.

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