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Original Article

Initial Experience and Potential Advantages of AFX2 Bifurcated Endograft System: Comparative Case Series

EunAh Jo[1], Sanghyun Ahn[1], Seung-Kee Min[1], Hyejin Mo[1], Hwan-Jun Jae[2], and Saebeom Hur[2]

Departments of [1]Surgery and [2]Radiology, Seoul National University College of Medicine, Seoul, Korea

Purpose: The AFX2 endograft is a unibody, bifurcated stent graft that can be used to lower complications in certain patients. In this study, we retrospectively reviewed consecutive cases in which the AFX2 system was used to overcome the challenges of narrow distal aorta, as well as to reduce procedure time and contrast medium dose. Furthermore, we compared the results with matched patients treated using the Endurant II endograft system.

Materials and Methods: This was a retrospective observational study of nine patients with abdominal aortic aneurysm (AAA) who underwent endovascular aneurysm repair (EVAR) using the AFX2 device between June 2017 and April 2018 at Seoul National University Hospital. The patients had narrow distal aorta (n=3), reversed tapered neck (n=1), iliac artery aneurysm (n=2), chronic kidney disease patients (n=2), and impending rupture (n=1). Seven matched patients were treated using the Endurant II graft.

Results: In the AFX2 group, the mean procedure time was 87.2 minutes, mean blood loss volume was 157.7 mL, and mean volume of contrast medium used was 48.3 mL. In the Endurant II group, the mean procedure time was 140.0 minutes, mean blood loss volume was 175.0 mL, and mean volume of contrast medium used was 119.3 mL.

Conclusion: Our preliminary experiences with selected AAA patients treated using the AFX2 endovascular repair system showed good outcomes compared with similar patients treated using the Endurant II system. Therefore, the AFX2 may be a good option to perform EVAR in patients of advanced age who have chronic kidney failure or narrow distal aorta.

Key Words: Aortic aneurysm, Abdominal, Endovascular aortic aneurysm repair, AFX, Stent graft

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Corresponding author: Sanghyun Ahn
Department of Surgery, Seoul National University Hospital, 101 Daehak-ro, Jongno-gu, Seoul 03080, Korea
Tel: 82-2-2072-2817
Fax: 82-2-766-3975
E-mail: onlyjis@snu.ac.kr
https://orcid.org/0000-0003-2094-3586

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INTRODUCTION

Endovascular aneurysm repair (EVAR) is the primary method used to treat abdominal aortic aneurysm (AAA) [1]. However, the technique can be hindered by anatomical restrictions that make it difficult to apply stent grafts, causing adverse events such as migration and endoleak [2]. Therefore, endograft manufacturers are constantly designing new devices to eliminate these undesirable effects and reduce EVAR-related complications [3].

The AFX2 (Endoogix Inc., Irvine, CA, USA) was first introduced in Korea in the spring of 2017. It is a unibody,

bifurcated stent graft with proximal and limb extensions that can be fixed and sealed into both landing zones [4]. It is the only graft that is fixed to the aortic bifurcation; all others use infrarenal neck for fixation [5]. The LEOPARD trial showed that the AFX2 graft conferred fewer endoleaks, limb occlusions, and secondary interventions and that no type III endoleaks occurred when using the graft [6].

The Endurant II (Medtronic Cardiovascular, Santa Rosa, CA, USA) has long been the most commonly used graft in patients undergoing EVAR in Korea [7]. It has a modular, bifurcated stent composed of nitinol and a polyester graft. In contrast with the AFX2, which is fixed to the aortic bifurcation, the Endurant II graft has an M-shaped, wire stent architecture, as well as proximal springs with anchoring barbs that can actively fix the graft to the aortic neck [8].

This study was to assess preliminary results of the AFX2 stent graft in patients and to compare patients treated using the AFX2 stent graft with matched patients treated using the Endurant II stent graft.

MATERIALS AND METHODS

A retrospective observational study was initially conducted in nine selected patients with AAA (patients A-I) who underwent EVAR using the AFX2 from June 2017 to April 2018 at Seoul National University Hospital. Three of these patients had narrow distal aorta, one had a reversed tapered aortic neck, two had isolated iliac artery aneurysm, two had chronic kidney disease, and one had impending rupture.

The study was approved by the Institutional Review Board (IRB) for Research at the Seoul National University Hospital (IRB no. 1904-126-1029). The need for informed consent was waived due to the retrospective nature of the study.

Seven comparative patients (patients 1-7) who were treated in the same center and time period and who had similar age, underlying diseases, and aneurysm characteristics underwent EVAR with the Endurant II stent graft. One of these patients had narrow distal aorta, one had a reversed tapered aortic neck, one had isolated iliac artery aneurysm, two had chronic kidney disease, and two had impending rupture. The stent graft (AFX2 or Endurant II) was selected either arbitrarily or based on the surgeon's preference.

The final population of this analysis comprised 16 patients: nine in the AFX2 group and seven in the Endurant II group. Patients' data, including demographics, preoperative risk factors, operative time, volume of contrast medium used, outcomes, and complications were retrospectively collected from the electronic medical records.

Pre-sizing and planning were undertaken with a computer-based software. In all procedures, percutaneous access was achieved through both femoral arteries, with the patients under general anesthesia, and all were carried out in an adequately equipped operating room that included a C-arm unit. For all patients, postoperative surveillance included physical examination and computed tomography (CT) angiography imaging within 1 month of surgery.

The guidelines of the Society for Vascular Surgery/American Association for Vascular Surgery were used as a reporting standard [9]. In both groups, technical success was defined as successful deployment of the endograft and completion of the procedure with no type I or III endoleaks and without the need for a secondary intervention within the first 24 hours. Clinical success was defined as the absence of the following adverse events during the follow-up period of 2 months: (1) aneurysm expansion >5 mm, (2) type I or III endoleaks, (3) aneurysm rupture, (4) conversion to open surgery, (5) graft infection, migration, or thrombosis, and (6) aneurysm-related death during follow-up periods of two months. Contrast-induced nephropathy was defined as an impairment in renal function measured as either a 25% increase in serum creatinine from baseline or a 0.5-mg/dL increase in absolute serum creatinine level 48 to 72 hours after intravenous administration of contrast medium [10]. Narrow distal aorta is defined in Asians when the diameter measures 16 mm or smaller [7]. Reversed tapered neck was defined as gradual neck dilatation of ≥2 mm within the first 10 mm after the most caudal renal artery [11].

Continuous data are expressed as mean±standard deviation, while categorical data are presented as absolute values and percentages (%). Statistical analyses were conducted using IBM SPSS Statistics ver. 20.0 software (IBM Co., Armonk, NY, USA). P-values <0.05 were considered statistically significant. Continuous variables were compared using the Mann–Whitney U test, while categorical variables were compared using the two-sided Fisher exact test.

RESULTS

There was no significant difference in baseline characteristics between the AFX2 and Endurant II groups (Table 1). Table 2 shows that the duration of AFX2 procedure was significantly shorter (87.2 vs. 140 minutes) and that the AFX2 required less contrast medium (48.3 vs. 119.3 mL).

1) Narrow distal aorta

Three patients in the AFX2 group and one in the Endurant II group had narrow distal aorta. Patients A, B, and C were treated using AFX2 graft system, whereas patient 1

Table 1. Baseline characteristics

Variable	AFX2 (n=9)	Endurant II (n=7)	Total (n=16)	P-value
Age (y)	74±4.98	77±5.13	76±5.04	0.23
Sex				
Female	1 (11.9)	0 (0.0)	1 (6.3)	0.84
Male	8 (88.9)	7 (100.0)	15 (93.8)	0.16
Perioperative risk factors				
Cerebrovascular disease	2 (22.2)	1 (14.3)	3 (18.8)	0.98
Coronary artery disease	4 (44.4)	2 (28.6)	6 (37.5)	0.76
Diabetes	1 (11.1)	1 (14.3)	2 (12.5)	0.99
Hypertension	6 (66.7)	3 (42.9)	9 (56.3)	0.91
Chronic renal failure	2 (22.2)	3 (42.9)	5 (31.3)	0.71
AAA anatomy (mm)				
Max aneurysm diameter	52.28±13.61	60.81±11.72	55.92±13.51	0.11
Aortic neck length	28.19±12.36	16±15.62	23.18±14.92	0.08

Values are presented as mean±standard deviation or number (%).
AAA, abdominal aortic aneurysm.

Table 2. Procedure-related characteristics

Perioperative characteristic	AFX2 (n=9)	Endurant II (n=7)	Total (n=16)	P-value
Procedure duration time (min)	87.2±20.9	140.0±56.1	110.3±47.2	0.04
Estimated blood loss (mL)	157.7±148.5	175.0±202.4	165.3±168.0	0.42
Total contrast media used (mL)	48.3±23.4	119.3±58.0	79.4±54.3	0.00
Total fluoroscopic time (min)	64.4±26.0	80.0±42.2	71.3±33.9	0.33
Length of hospital stay (d)	9.4±3.8	25.0±42.0	16.2±27.9	0.24
Serum creatinine (mg/dL)			-	-
Preoperative	1.3±0.5	1.3±0.7		
Postoperative[a]	1.2±1.5	1.6±1.1		

Values are presented as mean±standard deviation.
-, not available.
[a]Peak value in the 72-hour postoperative period.

was treated using the Endurant II graft. The narrow distal aorta diameters of these patients were as follows: patient A, 13.6 mm; patient B, 12.8 mm; patient C, 8.9 mm; patient 1, 13.5 mm. The follow-up CT images showed patency of the stent lumen, even in these patients with narrow distal aorta. All patients achieved technical success (Fig. 1).

2) Reversed tapered neck

One patient (patient D) in the AFX2 group and one (patient 2) in the Endurant II group had reversed tapered neck (Fig. 2A). Technical success was achieved in patient D, and no complications occurred in the 1 month follow-up period. This patient also had severe beta angulation, which was overcome using the telescopic technique. The main body and distal graft were first placed at the aortic bifurcation; followed by proximal extensions that could be manipulated to be placed exactly under the renal arteries.

However, with the Endurant II graft, the proximal main body had to be placed first—directly below the renal arteries—to prevent type Ia endoleak and migration. This resulted in a partial overlap of the orifice of the right renal artery, which was revealed on the final angiography. Therefore, the surgeon placed a renal stent to prevent stenosis or occlusion. However, this additional stent insertion resulted in occlusion of the access site (branchial artery).

3) Iliac artery aneurysm

Patient E had an aneurysm of the right common iliac aorta (CIA) measuring 43 mm and of the left internal iliac artery (IIA) measuring 66 mm (Fig. 2B). Patient F had a right CIA aneurysm of 39 mm. Both patients were treated using the AFX2 graft. Patient E had the left IIA embolized

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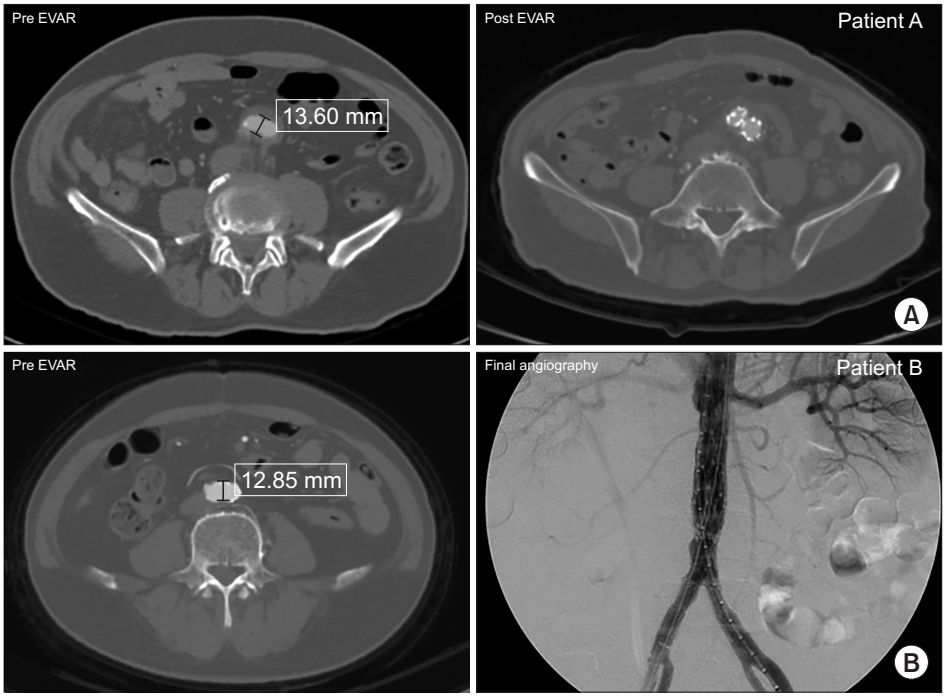

Fig. 1. Distal narrow aorta. Follow-up computed tomography after the AFX2 was deployed to 12 mm and 13 mm in the distal narrow aorta (A). The lumens of both limbs are patent. Both limbs are also shown well on the procedural angiography (B). EVAR, endovascular aneurysm repair.

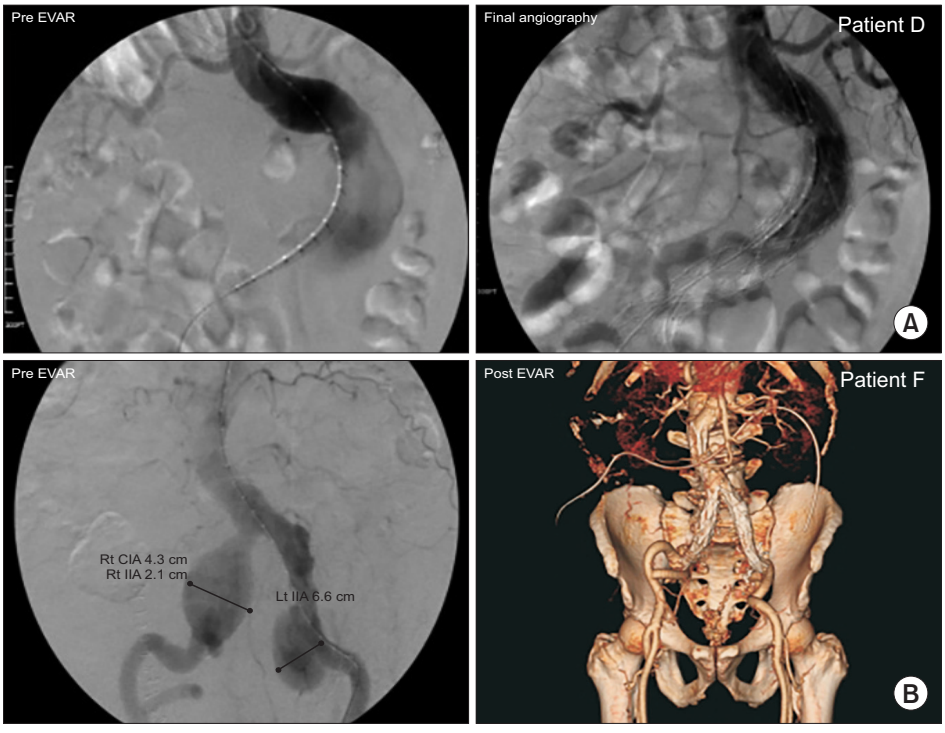

Fig. 2. Reverse tapered neck and iliac artery aneurysm. The telescope method, in which the proximal body was stacked up, was used in patient with severe angled-neck anatomy. There are no endoleaks, and the natural curve is preserved (A). The role of the AFX2 endograft in bilateral iliac aneurysm is remarkable. The proximal neck can be preserved, and a single bifurcated body is sufficient to cover the aneurysm. EVAR, endovascular aneurysm repair; CIA, common iliac aorta; IIA, internal iliac artery.

and the right CIA bypassed. Patient F had the right IIA embolized.

In contrast, patient 3 had a bilateral CIA aneurysm of 22.95 mm on the right side and 20 mm on the left, with a growing AAA. In both groups, technical success was achieved. However, the procedure time was more than double with patient 3 with 200 minutes, compared to patient E with 60 minutes and patient F with 95 minutes.

4) Dose of contrast medium

The mean preoperative and postoperative creatinine levels of both groups are shown in Table 2. The AFX2 patient group showed no significant change in serum creatinine

level (1.34 mg/dL before surgery, 1.24 mg/dL afterwards), whereas the Endurant II patient group showed an increase from 1.29 to 1.59 mg/dL.

In both groups, patients with chronic renal failure (patients G, H, 4, and 5) were noted and the amount of contrast medium was reduced as much as possible. Preoperative serum creatinine levels of patients in the AFX group (patients G and H) were 2.2 and 1.6 mg/dL, respectively, whereas postoperative levels were 2.0 and 1.6 mg/dL (Fig. 3A). Preoperative serum creatinine levels of patients in the Endurant II group (patients 4 and 5) were 1.64 and 2.78 mg/dL, respectively, whereas postoperative levels were 3.49 and 2.99 mg/dL, showing mild elevation.

5) Impending rupture

Patient 1, who was treated using the AFX2 graft, had shown a sudden increase in aneurysm diameter of 26 mm over 2 months (Fig. 3B). Patients 6 and 7, who were treated using the Endurant II, both had an aneurysm size of >86.6 mm. The procedure time of patient 1 was 100 minutes, whereas that of patients 6 and 7 was 200 and 205 minutes, respectively. Patients 1 and 7 had technical success, but patient 6 experienced intra- and postoperative bleeding, resulting in multi-organ failure and death.

Patient outcomes up to July 31, 2019, were further reviewed. On average, the first follow-up visit occurred 6 to 8 months after surgery, while follow-up CT was taken annually after the first postoperative CT. Of the nine patients in the AFX2 group, one had a type II endoleak in the 1-year follow-up CT, one did not show up to the outpatient clinic after discharge, and one died during follow-up due to advancement of their underlying cancer. No other endoleaks, occlusions, or complications related to EVAR were found in the other patients. In comparison, of the seven patients in the Endurant II group, four showed type II endoleak in the 1-year follow-up CT and two did not attend follow-up.

DISCUSSION

After the AFX2 was introduced in Korea in the spring of 2017, we reviewed its benefits and applied it in appropriate patients with AAA.

Distal aortic diameters of <18 mm are considered as narrow distal aorta [12], although Asian patients are often defined as having narrow distal aorta at diameters of <16 mm [7]. In such cases, EVAR using a conventional graft can result in compression in one limb extension, causing occlusion of the graft at the distal aorta [13]. The AFX2 endograft is suitable in this situation, because there is no limb competition. With conventional endografts, the two limb extensions must both be deployed in the narrow distal aorta, and they subsequently compete with each other [12]. However, the bifurcation is preserved in the AFX2 endograft system, and long-term results have shown no subsequent aortoiliac occlusions occur, including Leriche

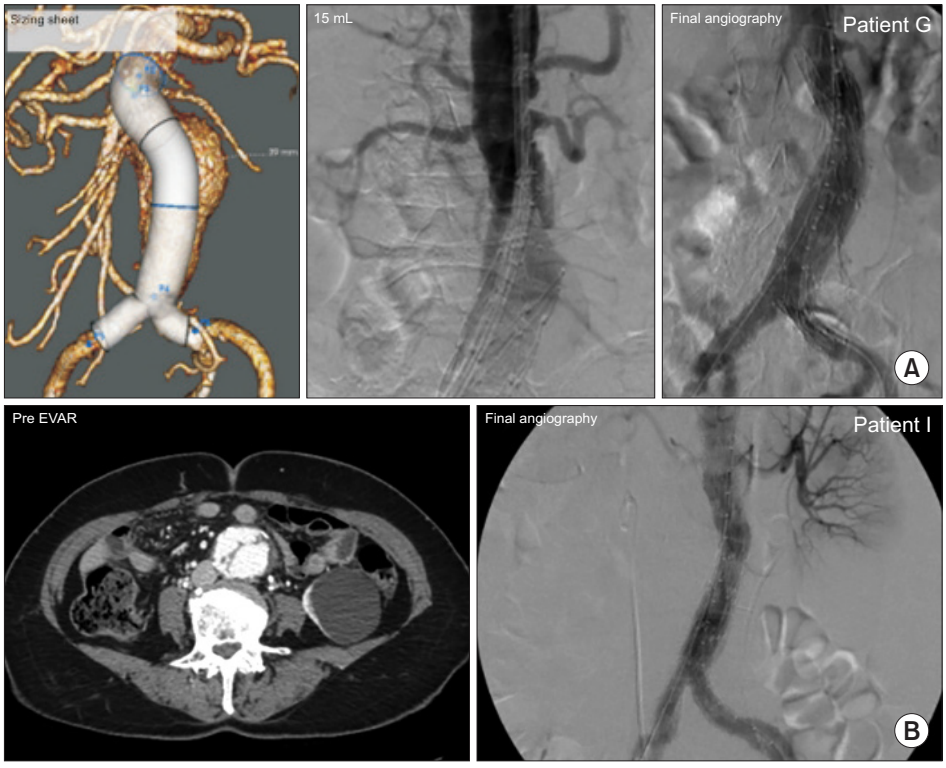

Fig. 3. Reduced dose of contrast medium and impending rupture. Through the specific planning program of the AFX2 device, the size can be chosen accurately. Therefore, contrast medium to check the orifice of the renal artery can be reduced, and final angiography shows a patent renal artery (A). The reduced dose of contrast can reduce nephrotoxicity. There is no gate cannulation in the AFX2 graft, and deployment of the bifurcated body is sufficient to seal the aneurysm rupture (B). EVAR, endovascular aneurysm repair

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syndrome [14]. Therefore, we advocate the use of the AFX2 endograft in patients with narrow distal aorta.

Reversed tapered neck is one of the most significant hostile aortic neck anatomies; it affects the seal between the device and aorta, resulting in early type Ia endoleak [11]. The AFX2 has a unique design at the proximal and distal ends called ActiveSeal, which has fabric-stent apposition beyond the stent frame, allowing for oversizing without excessive radial force. Furthermore, the AFX2 has the largest instructions for use oversizing range, which is applicable to various neck anatomies [5]. The Endurant II graft is also effective in patients with reversed tapered neck [15]. Therefore, the choice of the stent graft to be used in patients with hostile neck anatomies depends on the surgeon's preference and experience.

The AFX2 system was also used in two patients with iliac artery aneurysms in this study. One significant advantage of the AFX2 is that it does not require an adjunctive proximal component to save the renal arteries, unlike conventional grafts; this allows the number of stents deployed to be reduced. Furthermore, limb extension can customized to the patient's anatomy to accommodate a range of iliac diameters [16]. Thus, the AFX2 endograft is especially beneficial in patients with isolated iliac aneurysms [15].

In patients with chronic kidney disease, such patients G and H in this study, the AFX2 system can minimize the amount of contrast medium used. After initial deployment at the aortic graft, the first 10 mL of contrast medium was used to identify the renal arteries, whereas the second and final 20 mL were used in the final angiography. The AFX2 system's precise sizing sheet, which uses automatic three-dimensional sizing software (Endosize; Therenva, Rennes, France), combined with independent proximal and distal control, enables predictable target deployment with minimal use of contrast medium [17].

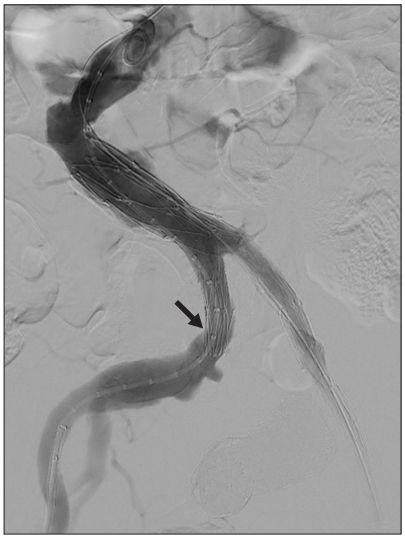

Fig. 4. Bird-beak configuration of patient treated with the AFX2 endograft.

In patients with impending ruptures or ruptured aneurysm, such as patients 1, 6, and 7, a fast and an efficient deployment of the endograft is critical [18]. Gate cannulation is the most time-consuming and rate-limiting step of the EVAR procedure that often causes delays in the deployment of the limb extension graft. Uniquely, the AFX2 does not require gate cannulation, and a single deployment of the bifurcated unibody is sufficient to block flow into the aneurysm [19].

Despite such advantages of the AFX2 endograft system, we came across a fatal flaw. The AFX2 is comparably rigid, causing problems at the distal edge that can result in bird-beak configurations (arrow in Fig. 4), indicating collapse, which eventually causes occlusion. Such failures occur more frequently in AAA with severe iliac tortuosity [20]. This graft stiffness is also a problem in cases of wide beta angulation. In our experience, the telescopic technique of the AFX2 stent can be used to overcome these limitations, although more research is needed [21].

There were several limitations to the present study. First, the number of cases was small and no long-term results were presented. Specifically, three of the 16 patients were lost to follow-up and one died due to advancement of their underlying cancer. However, the main purpose of this study was to share our initial experiences and show that the AFX2 graft can be used equally despite racial anatomical differences. Further studies should be undertaken to assess the benefits in a larger population, as well as the long-term results. Second, the 1:1 matching of the AFX2 graft to the Endurant II graft resulted in selection bias. Nonetheless, we presume that patients treated using the Endurant II graft would have shown good outcomes if they had been treated using the AFX2 graft.

CONCLUSION

Our preliminary experiences with AFX2 endovascular repair in selected patients with AAA (narrow distal aorta, chronic kidney disease, and isolated iliac aneurysms) showed good outcomes compared with those in similar patients treated using the Endurant II. Advantages of fixation to the aortic bifurcation are that it requires no gate cannulation or limb competition. The endograft can be deployed in less time with fewer steps. Therefore, the AFX2 could be an excellent option to implement EVAR in patients of advanced age who have chronic kidney failure or narrow distal aorta.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

ORCID

EunAh Jo
https://orcid.org/0000-0002-9324-4877
Sanghyun Ahn
https://orcid.org/0000-0003-2094-3586
Seung-Kee Min
https://orcid.org/0000-0002-1433-2562
Hyejin Mo
https://orcid.org/0000-0002-5383-0863
Hwan-Jun Jae
https://orcid.org/0000-0002-0328-3400
Saebeom Hur
https://orcid.org/0000-0003-0787-5101

AUTHOR CONTRIBUTIONS

Concept and design: SA. Analysis and interpretation: EAJ. Data collection: SA, HJJ, SH. Writing the article: EAJ. Critical revision of the article: SH. Final approval of the article: SKM. Statistical analysis: HM. Overall responsibility: SA.

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