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Improved Midterm Outcomes Using Standard Devices and EndoAnchors for Endovascular Repair of Abdominal Aortic Aneurysms with Hyperangulated Necks

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Abstract
Purpose Loss of fixation and seal represent a key problem when undertaking endovascular repair of abdominal aortic aneurysms (AAA) with hyperangulated necks (HAN). This study assesses the outcomes following the use of adjunct endostapling to supplement proximal aorto-prosthetic fixation in patients who have AAAs with HAN.
Methods A retrospective review of a prospective database of 42 patients with HAN (> 60°) who underwent endovascular aneurysm repair (EVAR) with supplementary endostapling was undertaken. Primary outcomes assessed were: change in post-EVAR neck angulation at first post-procedure scan, freedom from type 1 endoleaks, migration and reintervention for proximal seal complications. Secondary parameters included assessment for neck dilatation, sac size changes and EndoAnchor distribution patterns.
Results In total, 42 patients underwent EVAR between 2013 and 2019. There was one 30-day mortality resulting in 41 patients (34 male, 7 females aged 76.8 ± 8.9 years)) being analysed; 251 EndoAnchors were deployed in total, averaging 6 ± 2 per patient; 38 such cases were primary deployments. Neck angulation was 76.9 ± 14 degrees pre-EVAR and 50.2 ± 14.5 degrees post-procedure ($p < .001$, paired T test). Mean follow-up time was 18.5 (95% CI 13.3–23.9) months. One patient had persistent type Ia endoleak, successfully banded. There was 6.8 ± 10.2 mm sac size reduction ($p < .001$, paired T test). There were no other neck-related reinterventions, despite continued neck dilatation (3.2 ± 3.7 mm, $p < .001$, paired T test).
Conclusion This study suggests successful EVAR with adjunct endostapling for AAA with hyperangulated necks, with significant sac shrinkage and low rates of endoleaks, migration and reinterventions. More data are needed to consider influencing current instructions for use.

Keywords Abdominal aortic aneurysm (AAA) · Endovascular aneurysm repair (EVAR) · EndoAnchors · Endostapling · Hostile neck anatomy · post-operative complications

Introduction

Hostile anatomical conditions at endovascular aneurysm repair (EVAR) for abdominal aortic aneurysms (AAAs) can result in unsuitability for conventional infrarenal EVAR or compromise against device instructions for use (IFU), resulting in a non-durable result. Endostapling is a recognised technique for reinforcing fixation and seal [1], with recent terminology such as EndoSuture(d) Aneurysm Repair (ESAR) [2, 3] now added to the lexicon. This collaborative study specifically examines hostile neck anatomy in the context of hyperangulated necks, typically defined in the literature as a neck angle exceeding 60° [4], and whether using targeted adjunct fixation with the Heli-FX EndoAnchor (EA) system (Medtronic Ltd.,

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Minneapolis, USA) at infrarenal EVAR for AAAs with hyperangulated necks can achieve acceptable sealing augmentation and prevent complications such as type Ia endoleaks and migration, the recognised typical complications in this scenario.

Materials and Methods

A retrospective analysis of a prospective database of 42 patients who underwent planned EVAR with supplementary endostapling for AAAs with hyperangulated necks (herein specifically referring to the β-angle) [5], defined as $> 60°$, was undertaken in two academic vascular centres with endostapling experience at EVAR and TEVAR. This includes one patient with Marfan syndrome. Patients underwent endostapling in a radial clockface fashion as typical (Fig. 1), but also supplementary columnar endostapling along the outer curve of the neck, to counter the pulling away forces that would contribute to loss of seal. These were done either on a lateral basis for a laterally curving outer curve (Fig. 2A), or anteriorly for necks that were hyperangulated along a sagittal plane (Fig. 2B). Data collected included device details, patient demographics and neck anatomical characteristics which are presented in Table 1. Primary outcomes assessed were change in neck angulation at first post-procedure scan, freedom from type Ia endoleakage and migration (defined as > 5 mm caudal displacement), and also reinterventions for endoleak-related complications. Other parameters assessed include neck diameter changes, sac size changes and EndoAnchor deployment patterns. Follow-up imaging was undertaken on a standardised chronological protocol in the early post-procedure phase (< 6 weeks), at 6 months and then annually thereafter. Neck diameter was assessed as the average inner-to-inner aortic diameter from the first postoperative scan as in other such analyses [6] and then for comparison against similar parameters in the most recent CTA or, where abdominal radiographs were used, against the outer-to-outer diameter of the aortic endoprosthesis as these two designated measurement parameters would be the closest, i.e. as the device is deployed into the inner aortic wall. Measurements were all done by a single assessor at each centre (AC, ARV) in order to minimise inter-operator variability, using local Picture Archiving and Communications System (PACS) software.

Data were populated in Microsoft Excel for statistical analysis within Minitab 19 for Windows. Categorical variables are presented as counts and percentages. Continuous variables are presented as mean/median ± standard deviation/range. Matched parametric data were analysed using paired *t* tests. The threshold of statistical

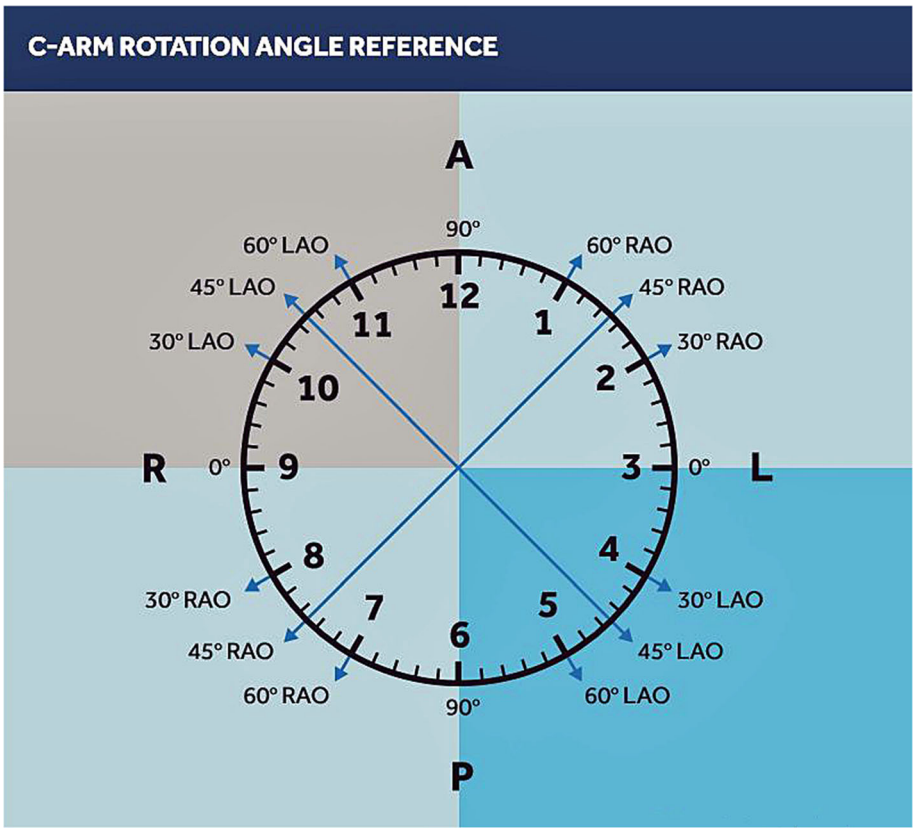

Fig. 1 Indicating the clockface positions for EndoAnchor deployment (reproduced with permission of Medtronic)

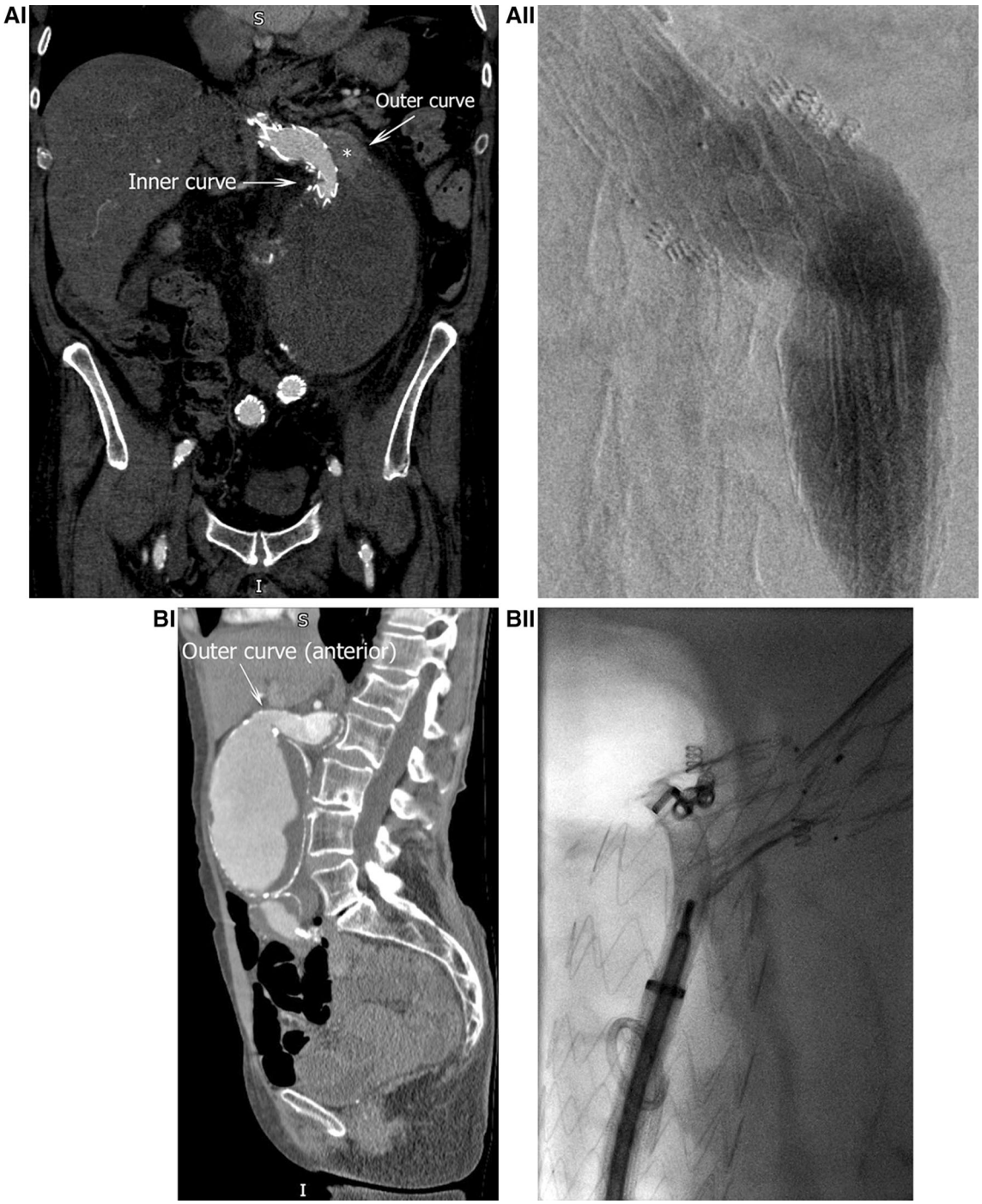

Fig. 2 Columnar endostapling along outer curve (**A**) (**i**) lateral hyperangulated neck with the endograft 'pulling away' from the outer curve of the neck resulting in a type Ia endoleak (*), which is then is then abolished by (**ii**) re-establishing aorto-prosthetic apposition by columnar endostapling along the 3 o'clock position, (**B**) (**i**) sagittal hyperangulated neck, (**ii**) emphasis on endostapling at the 12 o'clock position to fix the outer curve

significance was $p < 0.05$. Relationships between independent and linked outcome variables were compared using linear regression modelling. A distribution analysis of the variable follow-up using the Kaplan–Meier method was undertaken to identify the numbers at risk at each annual follow-up interval, generating a life table-based time series plot to present freedom from type I endoleak and migration.

Table 1 Summary of relevant patient and neck characteristics

Criterion	Details	
	Numerical details	Remarks
Patients and indications	41	One patient excluded
Primary	35	Planned EVAR with endostapling
Intact	30	– (cuffs used, $n = 3$)
Ruptured	5	–
Secondary	6	To treat type Ia endoleak (cuffs used, $n = 4$)
Sex (M/F)	33/8	–
Age (mean, SD)	76.8 (8.9)	–
Other factors		
Genetic aortic syndrome	1	1 patient with Marfan syndrome treated at age 55 years in 2014
Baseline anatomical characteristics		
Sac size (mm; mean, SD)	71.7 (16)	–
Neck characteristics (mean, SD)		–
Neck length (mm)	19.18(12)	–
Neck diameter (mm)	24.5(4.3)	–
Preoperative neck angulation (°)	76.95(14.0)	–

Results

In total, 42 patients underwent EVAR between 2013 and 2019 for infrarenal AAAs that had a neck angle > 60°. Mean follow-up period was 18.5 (95% CI 13.0–23.9) months. There was one 30-day mortality from graft infection, resulting in 41 patients (34 male, 7 females aged 76.8 ± 8.9 years) being available for analysis. Devices used included Zenith Flex (Cook Aortic Interventions, Bloomington, USA; $n = 9$), Zenith LP (Cook Aortic Interventions; $n = 2$) Alpha (Cook Aortic Interventions; $n = 5$), Endurant (Medtronic; $n = 19$), Excluder C3 (WL Gore & Associates, AZ, USA; $n = 6$). Cuffs were used for proximal extension in 7 patients, primarily when the main aortic body was felt to have dropped ($n = 3$), or secondarily to treat a type Ia endoleak ($n = 4$). In the primary group, there was no residual type Ia endoleak after cuff extension, whilst there was one failure to achieve proximal seal in the latter, described below. The mean length of stay for the entire group was 5 ± 4 days.

A total of 251 EndoAnchors were implanted at a mean 6 ± 2 per patient. Choice of numbers deployed was arbitrary (though deployment positions were planned) based on operator choice, with regression modelling showing no correlation with neck angulation even when analysed in hindsight ($p = 0.99$, $R^2 = 0$). Most of the EAs were positioned (according to clock face in descending order) at 3 o'clock ($n = 47$), 9 o'clock ($n = 46$), 2 ($n = 32$), 4 ($n = 24$), 8 ($n = 26$), 10 ($n = 26$) 1:30 ($n = 5$), 4:30 ($n = 9$), 10:30 ($n = 19$), 12 and 6 o'clock positions ($n = 8$), 7:30 ($n = 1$), each (Fig. 3). A total of 35 such cases were primary and 6 for secondary indications, namely type Ia endoleak. Of the latter, endostapling was successful in 5, with 1 patient needing supplementary open aortic neck banding. Mean neck length was 19.18 ± 11.99 mm. There were no EndoAnchor-related complications. Pre-EVAR neck angles were 76.9 ± 14 degrees (typically classed as 'severe' [7]), reducing to 50.2 ± 14.5 degrees post-procedure ($p < 0.001$, paired T test; Fig. 4). Resumption of the hyperangulated state was not noted to occur throughout the follow-up period in any patient.

One patient had persistent type Ia endoleak despite an endostapled cuff that required open surgical banding which was successful. Freedom from type 1a endoleak and migration at any time are therefore 97.5% and 100%, respectively (Fig. 5). Anatomical trends in the AAAs are represented in Fig. 6A, B; sac size shrinkage occurred in 31 (75.6%) of patients, with a mean overall reduction of 6.8 ± 10 mm ($p = 0.001$; paired T test). Neck diameters indicated a trend towards continued dilatation (mean increase 3.2 ± 3.7 mm, $p = 0.001$; paired T test), representing a median neck dilatation rate of 0.11 mm/month (IQR 0.3) equating to around 1.3 mm per year (Fig. 6).

The salient results including complications are summarised in Table 2.

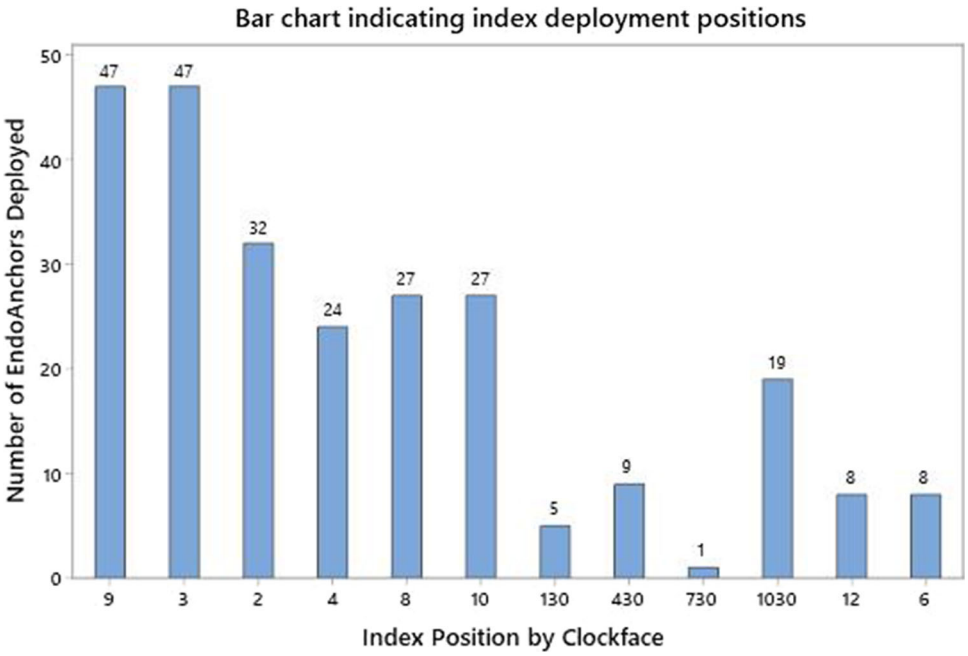

Fig. 3 Bar chart outlining numbers of EndoAnchors deployed in index positions

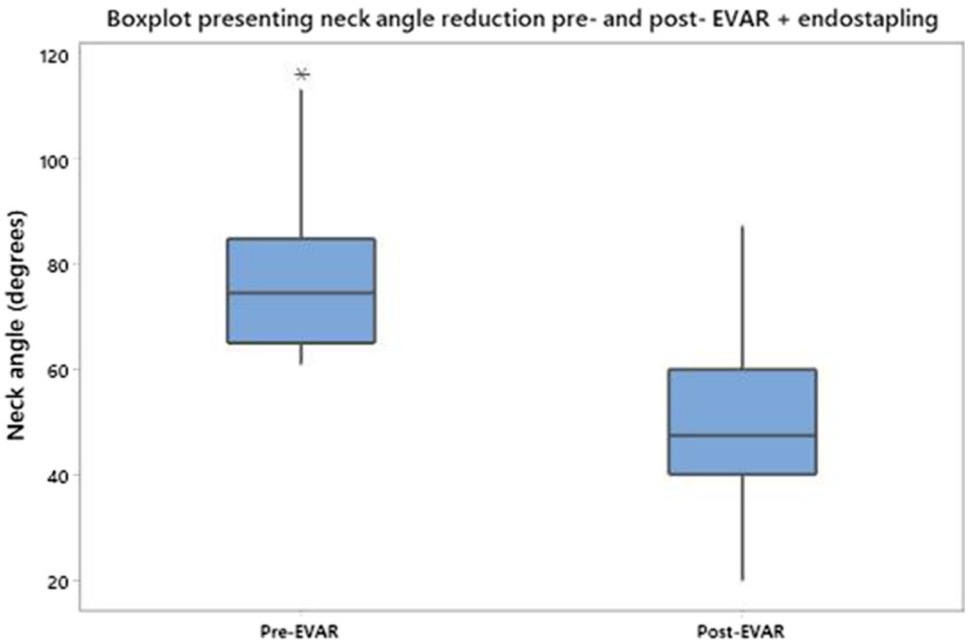

Fig. 4 Trends in pre- and post-procedure neck angulation after EVAR indicating the net reduction

Discussion

Most aortic prostheses are limited to deployment into an AAA with an infrarenal neck angle of $< 60°$, with a high risk of seal and migration-related complications beyond this [8]. Suprarenal hyperangulation is usually relevant in terms of device selection but is not really germane to sealing aspects as such, particularly where EndoAnchors are used. First-generation devices were felt to be at higher risk of migration [8], but even with modern devices licensed for use up to 90° a 3% risk of migration has been identified [9]. Currently, the only devices that have an IFU that accepts a 60°–90° neck angulation are the Aorfix device (Lombard Medical, Didcot, UK) [10] and the more recent Conformable C3 device (WL Gore & Associates) [11].

The Heli-FX EndoAnchor System has been devised for usage with several endograft systems [12, 13]. The initial promise of this adjunct system [14] seems to be borne out by the good midterm results of the ongoing ANCHOR registry, including in the context of HAN [15]. Other endovascular anchoring devices that were in development

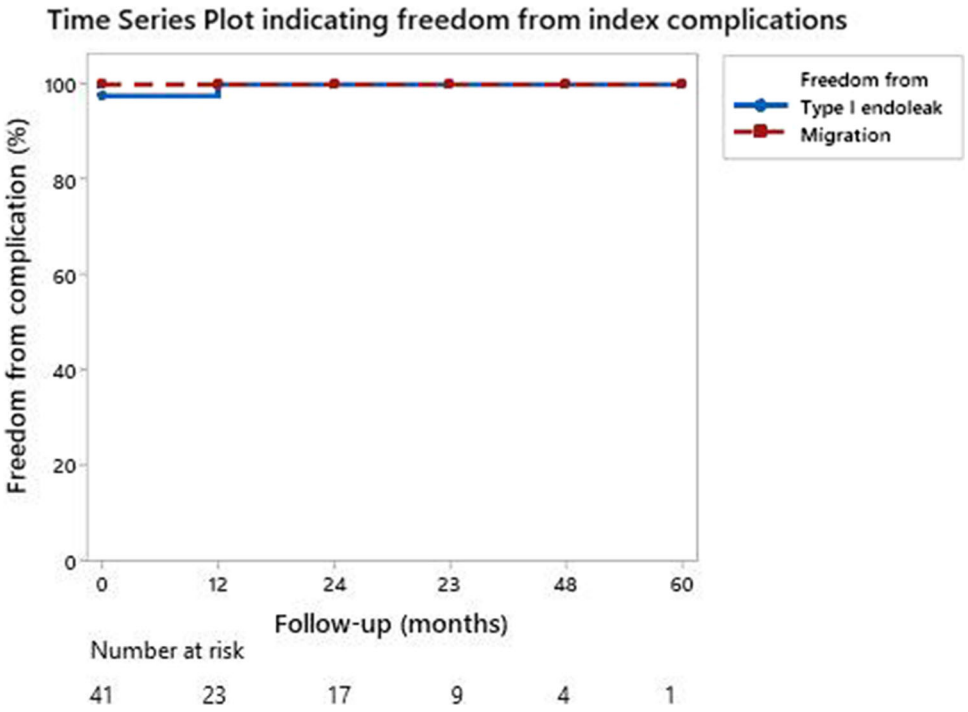

Fig. 5 Indicating freedom from index complications, namely type Ia endoleakage and migration

include the EndoRefix system (Lombard Medical) that is not available for use as clinical trials have been suspended [16]. There are no device-related contraindications for EndoAnchor usage, except with fragile PTFE-based devices such as the Powerlink system (Endologix, Irvine, USA). Furthermore, there are no neck angulation-related contraindications, and thus, adjunct endostapling for AAAs with HAN constitutes standard practice in our institutions. The number of EndoAnchors employed per patient is in keeping with recommendations for optimal fixation [17, 18].

IFUs for most EVAR devices have remained both ill-defined and static [13]—with fleeting references to endostapling in the recent European Guidelines for management of AAAs [19]. The only recent radical changes to IFU for EVAR are where the acceptable neck length for EVAR with primary endostapling has been changed to 4–10 mm for the Endurant device [2, 20]. It therefore seems device manufacturers have not been responsive overall to the presence of adjunct fixation technology even though it is firstly not very new [1] and secondly has proven fixation characteristics in terms of high resistive pullout forces [17] with corroborative data affirming the scope for reducing migration and endoleakage.

High sac regression rates with endostapling as indicated in other studies [21, 22] have been reflected in our results. A higher number of lateral EndoAnchors have been implanted (i.e. at 9 and 3 o'clock), linking to the higher incidence of lateral angulation in this series. Mechanical fixation of aortic neck to the endograft may resist post-EVAR effects such as longitudinal shrinkage, endograft shortening and stent-graft displacement secondary to proximal external compression [8]. Though all devices using radial force for proximal fixation seem to cause neck dilatation [23], the suggestion that endostapling has a protective effect is also borne out by our own results, which suggests some neck expansion albeit slower than published studies [24]. Primary endostapling also reduces the need for adjunct techniques such as bending stiff wires prior to deployment (given that the effect is lost immediately with removal of such wires) [8] or use of reinforcing balloon-expandable stents, such as the Palmaz XL (Cordis Corporation, a Johnson & Johnson company, FL, USA) [8].

Endoleak and/or migration rate in EVAR for AAAs with hyperangulated necks has been described [7]. Meta-analyses do not specifically analyse HAN-related adjunct procedures, but combine it under an umbrella of hostile neck conditions [25]. More specific allusions come from the EUROSTAR registry [4] where HAN is linked to neck dilatation, proximal type I endoleakage and reintervention rates. Historical series report complications as high as 70% where neck angle is > 60 degrees [26], but these are for older generations of devices and at that time without considering the possible role of EndoAnchors. Other criteria that have typically affected device migration—where this has been specifically studied—include short neck length (beside device choice) but not neck diameter, with migration rates as high as 70% at 4 years [6]. Relative to this study, we used the stricter threshold for migration i.e.

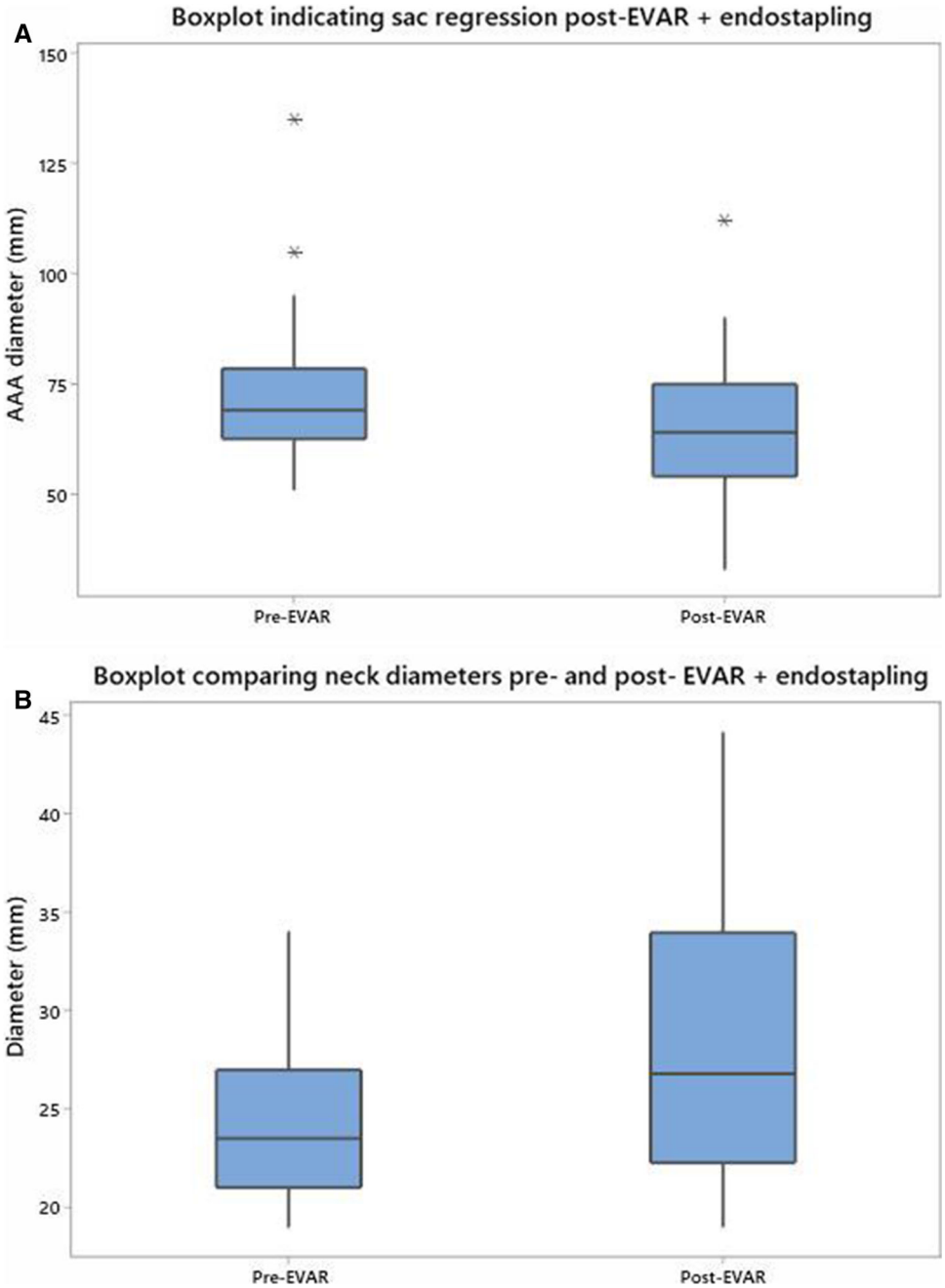

Fig. 6 Highlighting (**A**) sac size comparisons and (**B**) neck diameter trends pre- and post-EVAR

≥ 5 mm as opposed to the more relaxed threshold of 10 mm [6, 8].

Limitations

This study thus for the first time analyses the scope of adjunct endostapling at EVAR in AAAs with HAN, though this is limited by being a small series, with only isolated reports published prior [27–29]. Other limitations also include the lack of long-term follow-up for all patients beyond five years. However, these include the first usage in this scenario in a patient with Marfan syndrome who has remained free from both type Ia endoleakage and migrations at > 5 years. A perceived limitation may be the potential confounding effect of mixed devices using either supra- or infrarenal fixation, but this has not been shown to make a difference [30], and was thus not analysed. In addition, as all EndoAnchor deployment positions were planned, these would be in areas lacking in thrombus or calcification as per IFU, and we therefore feel these neck aspects do not confound the outcomes. In fact, it has been suggested that calcification is protective against neck

Table 2 Summary of results in the 41 analysed patients

Criterion	Outcome details	
	Result	Remarks
Sac data (mean, SD)	71.7(16)	Sac size reduction in 73.8%
Initial (mm)	64.7(15.4) ↓	↓ $p < .001$ (paired t test)
Final (mm)		
EAs deployed	251	Arbitrary numbers per patient as per operator choice ($R^2 = 0$, regression analysis)
Total	6(2)	
Per patient (mean, SD)	46 (18.3)	Typical deployments for lateral angulations
Index position deployments by clockface (n, %)	47 (18.5)	–
	32 (12.3)	–
9	24 (9.6)	–
3	26 (10.4)	–
2	26 (10.4)	–
4	5 (2)	–
8	9 (3.5)	–
10	1 (0.4)	–
1:30	19 (7.6)	Typical positions for anteroposterior angulations
4:30	8 (3.2)	
7:30	8 (3.2)	
10:30		
12		
6		
Neck characteristics (mean, SD)		
Neck angle pre-EVAR	76.95(14.0)°	29 lateral, 12 sagittal angulations
Neck angle post-EVAR	50.2(14.5)°	↓ $p < .001$ (paired t test)
Neck diameter (initial, mm)	24.5(4.0)	–
Neck diameter (final, mm)	27.6(6.0)	↑ $p < .001$ (paired t test)
Complication specifics (n)		
Type Ia endoleak	1[a] (2.4%)	1 patient needed banding despite cuff extension
Migration	0	
EA-related complications	0	–
Any other complication:	4 (9.75%)	–
AKI	1 (2.4%)	–
AKI	1 (2.4%)	Contrast-induced nephropathy
Limb thrombosis	1 (2.4%)	Axillofemoral bypass done
Stroke	1 (2.4%)	Recovered after carotid artery stenting
Type II endoleak needing treatment	1 (2.4%)	IMA and sac embolised

AKI acute kidney injury, *EA* EndoAnchor(s), *EVAR* endovascular aneurysm repair, *NS* not significant, *IMA* inferior mesenteric artery

dilatation [23]. We could not compare this to a control group without EndoAnchors, as most operators will choose now to either excessively oversize devices out of IFU (potentially accelerating the risk of late neck dilatation [23], an approach that we discourage), or opt for super-complex options like fenestrated/ branched/ chimney (F/B/Ch)EVAR; however, endostapled EVAR may offer equivalent safety in this context to ChEVAR at least [31]. This is despite the misconception that FEVAR is a 'solution' for HAN anatomy, whereas the IFU limits use of fenestrated devices such as the Zenith ZFEN (Cook Aortic Interventions) to a neck angle $< 45°$ [32]. Also, given the nature of Ch-EVAR, there is no related IFU.

We accept the combined effect of the individual contribution of endografts ± cuffs, which have their own inherent stiffness and unpredictable tissue incorporation

[7], but EndoAnchors certainly constrain the aortic tissue [33] on to the endograft fabric and prevent loss of apposition along the outer curve, which is the most prone area for failure to seal. The fact that there were 6 secondary interventions for type Ia endoleak who have remained endoleak-free is a possible indicator that primary usage could have been undertaken [34], but these patients were referred from elsewhere.

Conclusion

In conclusion, this study indicates the scope for a multiplanar approach to endostapling when dealing with hyperangulated neck anatomy at EVAR, specifically additional linear endostapling along a second line of fixation along the outer curve of the deployed device. Such adjunct techniques at EVAR to treat AAAs with hyperangulated necks may prevent migration and proximal endoleakage in the midterm at least and reduce the severe neck angulation to a more moderate one. Larger studies with longer duration of follow-up are needed to gauge the robustness of this approach, with a view to considering IFU changes to include primary endostapling in this scenario. This then also needs more uptake of primary endostapling by endovascular operators.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval For this type of study, formal consent is not required.

Informed Consent For this type of study, informed consent is not required.

Consent for Publication For this type of study, consent for publication is not required (there is no patient-identifying data).

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