


# Geometric Remodeling of the Perirenal Aortic Neck at and Adjacent to the Double Sealing Ring of the Anaconda Stent-Graft After Endovascular Aneurysm Repair

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## Abstract

**Purpose:** To evaluate if the radial force of the double sealing ring of the Anaconda stent-graft induces dilatation in the perirenal aortic neck adjacent to the rings. **Materials and Methods:** This study evaluated the serial electrocardiogram-gated computed tomography scans of 15 abdominal aortic aneurysm patients (mean age  $72.8 \pm 3.7$  years; 14 men) who were treated electively using an Anaconda stent-graft. Follow-up scans were conducted before discharge and at 1, 6, 12, and 24 months after endovascular repair. Diameter and area were assessed perpendicular to the aortic centerline along the perirenal aortic neck, which was subdivided into 3 zones: the suprastent, the stent, and the infrastent zones. Measurements were performed independently by 2 experienced observers using dedicated 3-dimensional image processing software. **Results:** Between discharge and the 2-year follow-up the diameter and area remained stable in the suprastent zone [average diameter change:  $-0.1 \pm 0.4$  mm ( $-0.4\% \pm 1.7\%$ ),  $p=0.893$ ; average area change:  $-2.9 \pm 17.2$  mm<sup>2</sup> ( $-0.7\% \pm 3.4\%$ ),  $p=0.946$ ], increased in the stent zone [average diameter change:  $+1.9 \pm 1.0$  mm ( $+7.3\% \pm 4.0\%$ ),  $p<0.001$ ; average area change:  $+84.3 \pm 48.3$  mm<sup>2</sup> ( $+15.5\% \pm 8.7\%$ ),  $p<0.001$ ], and diverged in the infrastent zone [average diameter change:  $-0.8 \pm 2.2$  mm ( $-2.3\% \pm 7.4\%$ ),  $p>0.99$ ; average area change:  $-34.6 \pm 102.3$  mm<sup>2</sup> ( $-4.1\% \pm 14.8\%$ ),  $p>0.99$ ; increased in 4 patients, decreased in 9 patients]. **Conclusion:** After Anaconda implantation the infrarenal aortic neck accommodated to the expansion of the sealing rings at the stent zone. Below the stent zone the neck diameter decreased in the majority of patients, while an increase was related to downstream displacement of the main body. A decrease in size in the infrastent zone may contribute to durable sealing and fixation. A personalized follow-up scheme based on geometric neck remodeling should be feasible if our observations are confirmed in larger, long-term studies.

## Keywords

abdominal aortic aneurysm, aortic neck dilatation, endograft, endovascular aneurysm repair, fixation, geometry, neck remodeling, sealing rings, stent-graft

## Introduction

Aortic neck dilatation (AND) after endovascular aneurysm repair (EVAR) is a major concern for the durability of an effective proximal seal between the stent-graft and the aortic wall.<sup>1–3</sup> AND appeared to be present in nearly 25% of EVAR patients according to a recent pooled analysis.<sup>2</sup> Controversy surrounds the cause and clinical relevance of AND,<sup>1–3</sup> especially since this phenomenon is seen with both open and endovascular repair of abdominal aortic aneurysm (AAA).<sup>4</sup> AND after EVAR has been associated with migration and type Ia endoleak,<sup>5–9</sup> which encompass the most common reasons for reinterventions,<sup>10–12</sup> though others did not show this relation.<sup>13–16</sup> Oversizing of self-expanding

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stent-grafts may to some extent be the reason for AND.<sup>2</sup> Additionally, the evolution of the aortic neck may differ per stent-graft design depending on the sealing and fixation properties.

The Anaconda AAA stent-graft system (Terumo Aortic, Inchinnan, Scotland, UK) differs from most other devices in its proximal dual rings for sealing and fixation. Once deployed in the infrarenal neck, the 2 nitinol stent-rings assume the shape of a saddle, with peaks and valleys as a result of compression against the aortic wall. The stent-rings exert a continuing outward radial force on the aortic wall, which has been shown to result in proximal ring expansion to near-nominal size during the first 6 to 12 months after EVAR, irrespective of oversize.<sup>17</sup> Recently, Vukovic et al<sup>18</sup> confirmed this finding, reporting significant proximal landing zone dilatation after EVAR using the Anaconda. Still, it remained unclear whether the dilatation was localized at the level of the sealing rings, leaving the remaining portion of the neck unaffected, or whether the complete neck may have been affected. Such differentiation is imperative to understand the clinical significance of AND and to be able to identify patients at risk of migration and type Ia endoleak.

In the present study, we continue analysis of a previously reported patient cohort<sup>17</sup> to seek full understanding of abdominal aortic neck remodeling after Anaconda stent-graft implantation by investigating the geometric evolution of the entire perirenal neck segment above, at, and below the 2 fixation and sealing rings.

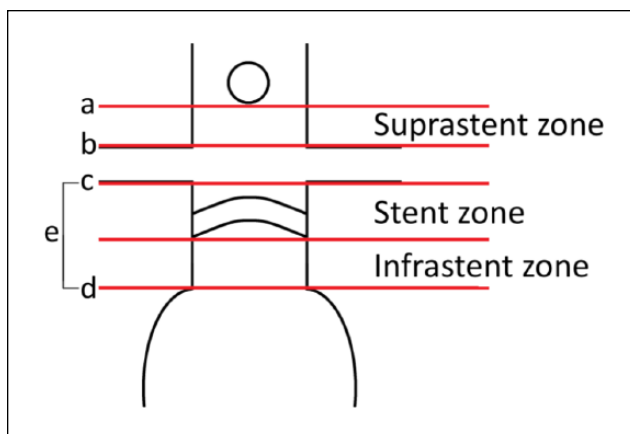
## Materials and Methods

### Study Design and Patient Sample

The present study evaluated 15 asymptomatic patients (mean age  $72.8 \pm 3.7$  years; 14 men) with an infrarenal AAA who underwent elective EVAR between April 2014 and May 2015 with an Anaconda AAA stent-graft and had at least 12 months of imaging follow-up. Details of the patient sample, including preoperative anatomical characteristics by standard computed tomography angiography (CTA) imaging, and the image acquisition protocol were reported in a prior publication about the evolution of the Anaconda proximal sealing rings.<sup>17</sup>

Sizes of the stent-graft body ranged from 25.5 to 34 mm. The device was oversized by 17% to 47% (mean 31%) based on inner wall diameters from static preoperative CTA scans. (In our practice, oversize was substantially increased particularly in case of unfavorable neck anatomy to increase the adaptive capacity of the sealing rings and intentional nonperpendicular placement with regard to the flow axis in angulated necks.)

Patients were followed according to study protocol for 2 years after EVAR by noncontrast electrocardiogram (ECG)-gated CT scans before discharge and after 1, 6, 12, and 24



**Figure 1.** Subdivision of measurements (a-e) into 3 zones: (1) suprastent zone, (2) stent zone, (3) infrastent zone.

months of follow-up. The predischarge scans were conducted within 3 days after the EVAR procedure. Duplex ultrasound examinations were complementary to the non-contrast CT scans to follow the exclusion of the aneurysm. After 2 years, patients were followed by duplex ultrasound examinations and plain radiography according to standard practice.

The patient data were prospectively collected in a database registered on *Trialregister.nl* (NTR4276). The study protocol was approved by the institutional review board of the Medisch Spectrum Twente. Written informed consent was obtained for each subject before participation.

### Image Postprocessing and Analysis

Prior to image analysis, the ECG-gated phases of each scan were averaged according to a previously published protocol to obtain time-averaged CT volumes with improved signal-to-noise ratio (SNR) compared with the reduced SNR of the individual phases.<sup>17</sup> The time-averaged CT volumes, representing mid cardiac cycle, were analyzed using 3-dimensional image analysis software (Aquarius Intuition version 4.4; TeraRecon, San Mateo, CA, USA) by 2 independent experienced observers blinded to each other's outcomes. Outer-to-outer diameter and area were assessed along the perirenal aortic neck in cross sectional planes perpendicular to the center lumen line (CLL) at predefined levels (Figure 1): (a) just below the superior mesenteric artery, (b) upper edge of the highest renal artery, (c) lower edge of the lowermost renal artery (baseline), (d) just before the initial origin of the aneurysm (a fixed distance from baseline), and (e) every 5 mm below baseline down to the initial origin of the aneurysm.

Although the Anaconda AAA stent-graft is an infrarenal fixating and sealing device, suprarenal measurements were performed to assess potential suprarenal remodeling not related to the presence of the stent-graft. At each level, ellipses

**Table 1.** Overview of Device-Related Complications During Follow-up.

Event	Patient	Months After EVAR	Intervention
Type II endoleak	#9	42	Coil embolization
Migration	#21	1	None; 10-mm migration with adequate AAA exclusion
Limb occlusion	#2	27	Recanalization and endolining
	#2	47	Thrombectomy
	#3	27	Recanalization and endolining

Abbreviations: AAA, abdominal aortic aneurysm; EVAR, endovascular aneurysm repair.

were drawn on the outer wall to assess area and minimum and maximum diameters, that is, minor and major axes of the ellipses, respectively. The minimum and maximum diameters were used to compute the average diameter, hereafter referred to as diameter. The measurements were subdivided into 3 aortic zones: the suprastent-ring zone, the stent-ring sealing zone, and the infrastent-ring zone, hereafter referred to as the suprastent, the stent, and the infrastent zones (Figure 1). The suprastent zone included the suprarenal measurements, the stent zone included the infrarenal measurements starting from baseline down to the level of the most caudal point of the dual rings at 2 years follow-up, and the infrastent zone included the measurements below the stent zone down to the level of the origin of the aneurysm in the predischarge CT scan. Additionally, aneurysm sac diameters and downstream displacement of the dual rings were assessed.

### Statistical Analysis

Data are presented as mean  $\pm$  standard deviation (range) or as median [interquartile range Q1, Q3] for normally or non-normally distributed data, respectively. Measurements were compared between time points by use of a linear mixed model repeated-measures analysis for normally distributed data and the Friedman test with post hoc Wilcoxon signed-rank tests for nonnormally distributed data. The autoregressive covariance model was found to be most appropriate for the repeated measures data in the mixed models. Bonferroni corrections were applied.

Correlations between changes in aortic size in the different aortic zones were tested using the 2-tailed Pearson correlation coefficient (PCC). Additionally, correlations were tested between the change in a zone and the change in aneurysm sac size and between the change in a zone and the oversizing percentage.

Interobserver variability in measuring diameter and area was analyzed with the repeatability coefficient (RC) and the intraclass correlation coefficient (ICC). RC was calculated as 1.96 times the standard deviation of the differences between repeated measurements, according to the method of Bland and Altman.<sup>19</sup> The ICC was tested with a 2-way mixed model by absolute agreement. Mean values of the observers were used for further analysis. The threshold of statistical significance was  $p < 0.05$  [ $p < 0.01$

for Wilcoxon signed-rank tests to correct for multiple comparisons (type I error)]. All statistical analyses were performed with SPSS Statistics (version 24.0; IBM Corporation, Armonk, NY, USA).

### Results

No type I or III endoleak was reported during a mean follow-up of  $48.6 \pm 3.4$  months (range 44–55) for any of the patients in the study. One type II endoleak, 1 device migration, and 3 limb occlusions (2 patients) occurred (Table 1).

All measurements showed excellent agreement between observers (ICC 0.95–0.98,  $p < 0.001$ ). The mean differences between repeated measurements of diameter, area, and device position, respectively, were  $0.0 \pm 0.7$  mm ( $0.0\% \pm 2.4\%$ ),  $0.9 \pm 31.6$  mm<sup>2</sup> ( $0.3\% \pm 4.6\%$ ), and  $0.1 \pm 1.2$  mm ( $0.7\% \pm 6.0\%$ ), with RCs of 1.4 mm (4.7%), 61.9 mm<sup>2</sup> (9.0%), and 2.4 mm (11.6%).

Table 2 presents the evolution of the diameter and area of the different aortic zones and the change with respect to the predischarge scan. Figure 2 provides a graphical representation of diameter changes and downstream displacement during follow-up. Two of the 15 patients did not complete the 2-year scan (1 voluntary withdrawal and 1 aneurysm-unrelated death). The average position of the most caudal point of the dual rings changed from  $20.5 \pm 6.8$  mm below baseline at discharge to  $23.5 \pm 7.3$  mm below baseline at 2 years, with a median change of 2.8 mm downstream ( $p = 0.006$ ; Figure 2B).

#### Suprastent Zone

The median diameter and area of the suprastent zone at discharge were 25.5 mm and 511.9 mm<sup>2</sup>, respectively. The average change from discharge in diameter and area at 2 years was  $-0.1 \pm 0.4$  mm ( $-0.4\% \pm 1.7\%$ ,  $p = 0.893$ ) and  $-2.9 \pm 17.2$  mm<sup>2</sup> ( $-0.7 \pm 3.4\%$ ,  $p = 0.946$ ), respectively. No significant changes were noted for any of the successive follow-up scans.

#### Stent Zone

The average diameter and area of the stent zone at discharge were  $26.2 \pm 2.0$  mm and  $544.2 \pm 84.5$  mm<sup>2</sup>, respectively. Diameter and area increased significantly between discharge

**Table 2.** Evolution of Aortic Diameter and Area by Aortic Zone.<sup>a</sup>

Aortic Zone	Discharge (n=15)	1 Month (n=15)	6 Months (n=15)	12 Months (n=15)	24 Months (n=13)
<b>Suprastent</b>					
Diameter, mm	25.5 [24.5, 27.7]	25.0 [24.3, 27.3]	25.5 [24.7, 27.3]	25.3 [24.6, 27.4]	25.6 [24.7, 28.5]
Δ Diameter, mm	—	-0.2±0.4 (-1.1 to 0.5) p=0.073	-0.1±0.5 (-0.9 to 0.6) p=0.890	-0.1±0.5 (-0.8 to 0.7) p=0.303	-0.1±0.4 (-1.3 to 0.4) p=0.893
Δ Diameter, %	—	-0.8±1.7 (-4.4 to 1.9)	-0.2±1.7 (-3.4 to 1.9)	-0.5±1.7 (-3.2 to 2.2)	-0.4±1.7 (-4.9 to 1.4)
Area, mm <sup>2</sup>	511.9 [468.8, 602.1]	492.2 [465.8, 585.4]	509.9 [477.2, 586.4]	502.1 [475.2, 589.4]	515.7 [478.7, 638.0]
Δ Area, mm <sup>2</sup>	—	-8.1±17.2 (-41.3 to 16.5) p=0.107	-1.5±18.9 (-37.1 to 29.8) p=0.934	-4.9±19.1 (-35.3 to 33.9) p=0.389	-2.9±17.2 (-47.1 to 17.0) p=0.946
Δ Area, %	—	-1.6±3.2 (-8.2 to 3.5)	-0.4±3.4 (-6.4 to 4.5)	-1.0±3.4 (-6.9 to 4.5)	-0.7±3.4 (-9.3 to 2.7)
<b>Stent</b>					
Diameter, mm	26.2±2.0 (22.9-30.2)	27.2±1.9 (24.0-31.0)	27.7±2.2 (24.5-31.4)	27.9±2.2 (25.1-31.7)	28.1±2.2 (25.1-33.1)
Δ Diameter, mm	—	1.0±0.6 (0.0-2.0) p<0.001	1.4±0.8 (0.0-2.8) p<0.001	1.6±0.8 (0.3-2.7) p<0.001	1.9±1.0 (0.7-4.0) p<0.001
Δ Diameter, %	—	3.8±2.3 (-0.0 to 8.4)	5.6±3.2 (-0.0 to 11.9)	6.3±3.2 (1.1-10.3)	7.3±4.0 (2.6-14.0)
Area, mm <sup>2</sup>	544.2±84.5 (412.8-717.2)	584.4±83.8 (453.6-756.1)	605.7±94.0 (472.0-773.4)	614.3±98.2 (491.5-788.0)	626.7±95.3 (492.9-859.5)
Δ Area, mm <sup>2</sup>	—	40.2±23.0 (0.3-75.5) p<0.001	61.5±32.7 (1.6-110.4) p<0.001	70.1±36.3 (11.8-122.1) p<0.001	84.3±48.3 (30.7-193.6) p<0.001
Δ Area, %	—	7.8±4.8 (-0.0 to 17.7)	11.7±6.7 (0.1-25.4)	13.3±6.9 (2.3-22.2)	15.5±8.7 (5.8-30.6)
<b>Infrastent</b>					
Diameter, mm	28.3±2.6 (22.6-33.3)	29.0±2.5 (23.0-33.8)	27.6±2.1 (22.6-30.5)	27.6±2.2 (22.8-30.4)	27.7±2.4 (25.0-31.7)
Δ Diameter, mm	—	0.7±0.8 (-0.4 to 2.6) p=0.038	-0.7±1.7 (-3.9 to 2.1) p=0.319	-0.8±2.0 (-4.9 to 3.6) p=0.647	-0.8±2.2 (-4.8 to 3.4) p>0.99
Δ Diameter, %	—	2.7±2.9 (-1.5 to 10.0)	-2.3±5.6 (-12.1 to 8.0)	-2.4±6.7 (-14.6 to 13.6)	-2.3±7.4 (-14.3 to 12.9)
Area, mm <sup>2</sup>	634.2±114.7 (401.3-872.3)	667.2±110.0 (415.4-895.5)	597.5±88.5 (401.6-732.6)	599.4±94.0 (408.4-719.4)	606.3±106.2 (489.7-780.0)
Δ Area, mm <sup>2</sup>	—	33.0±34.0 (-20.6 to 114.8) p=0.073	-36.7±86.4 (-232.4 to 93.4) p=0.283	-34.8±92.2 (-237.2 to 161.9) p=0.792	-34.6±102.3 (-232.9 to 151.6) p>0.99
Δ Area, %	—	5.6±5.9 (-2.7 to 20.6)	-4.6±11.6 (-26.6 to 16.8)	-4.2±13.3 (-27.1 to 29.1)	-4.1±14.8 (-26.6 to 27.2)

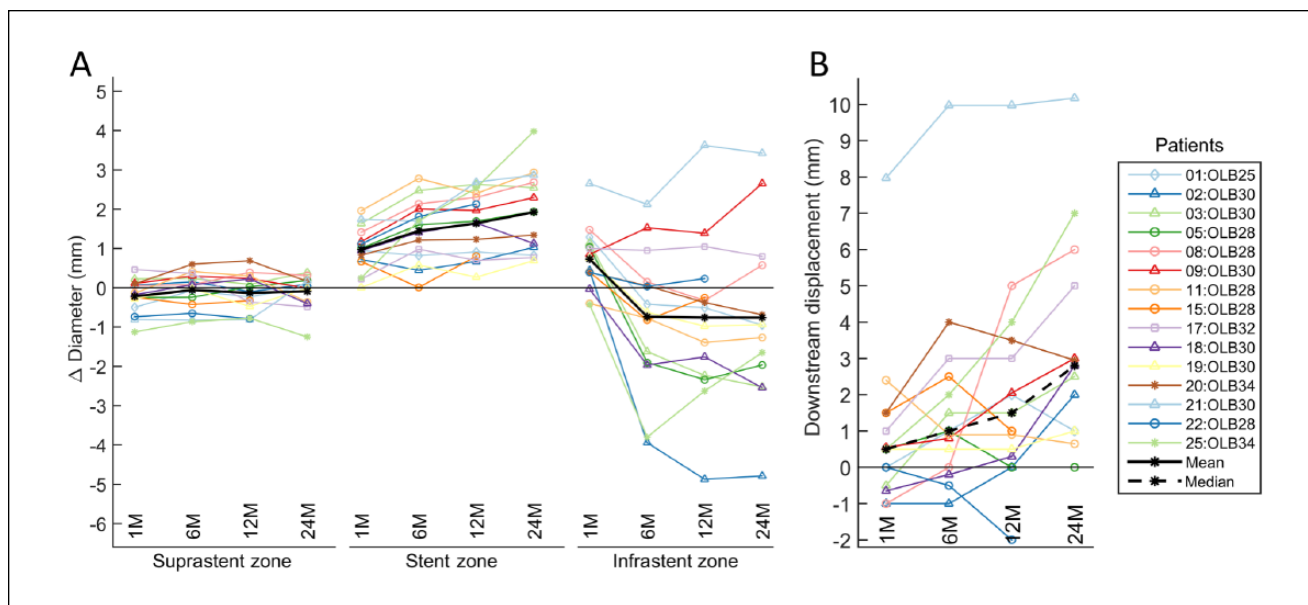
<sup>a</sup>Data are presented as the means ± standard deviation (range) or as median [interquartile range Q1, Q3] as appropriate for the distribution of the data.

and successive scans ( $p<0.001$ ). The average change from discharge to 2 years' follow-up was  $+1.9\pm 1.0$  mm ( $+7.3\%\pm 4.0\%$ ,  $p<0.001$ ) and  $+84.3\pm 48.3$  mm<sup>2</sup> ( $+15.5\%\pm 8.7\%$ ,  $p<0.001$ ), respectively. Between successive time points, the average percentage increase was greatest between discharge and 1 month by  $+3.8\%\pm 2.3\%$  in diameter and  $+7.8\%\pm 4.8\%$  in area ( $p<0.001$ ). From 1 month, the average increase between successive time points was below 2% in diameter and below 4% in area.

From 6 months, the increase between time points was not significant (diameter  $p>0.160$ ; area  $p>0.136$ ). Neck diameters in the stent zone did not exceed the main body stent-graft diameter.

### Infrastent Zone

In the infrastent zone, mean diameter and area were  $28.3\pm 2.6$  mm and  $634.2\pm 114.7$  mm<sup>2</sup> at discharge, respectively. At 1



**Figure 2.** (A) Change in diameter of the 3 aortic zones and (B) downstream displacement of the dual rings during the 2-year follow-up period. M, months; OLB, main body device size.

month, mean diameter had significantly increased by  $0.7 \pm 0.8$  mm ( $2.7\% \pm 2.9\%$ ,  $p=0.038$ ). From 1 to 6 months a significant decrease was observed in diameter and area by  $1.5 \pm 1.4$  mm ( $4.9\% \pm 4.4\%$ ,  $p<0.001$ ) and  $69.7 \pm 73.8$  mm<sup>2</sup> ( $9.7\% \pm 8.9\%$ ,  $p<0.001$ ), respectively. The average change after 2 years was  $-0.8 \pm 2.2$  mm ( $-2.3\% \pm 7.4\%$ ,  $p>0.99$ ) and  $-34.6 \pm 102.3$  mm<sup>2</sup> ( $-4.1\% \pm 14.8\%$ ,  $p>0.99$ ), respectively. After 2 years, diameters had decreased in 9 patients and increased in 4 patients. A case example (#2) presenting an evident decrease in size in the infrastent zone is shown in Figure 3.

An enlargement of  $>2.5$  mm in the infrastent zone diameter was found after 2 years in 2 patients (Figure 2): the patient with a type II endoleak 3.5 years after EVAR and the patient with a 10-mm caudal displacement of the dual rings 2 years after EVAR. This displacement had mainly occurred during the first month, after which the position stabilized. The type II endoleak was treated successfully by coil embolization. The device migration was treated conservatively. No device-related complications occurred. The aneurysm sac diameter remained stable. Because of the displacement, the infrastent zone comprised only the measurements at the initial origin of the aneurysm. In this patient, the device was oversized by 38% and was placed inclined in a 55° infrarenally angulated aorta with a straight, 23-mm-long, 22-mm-diameter neck that had no thrombus and 20% circumferential calcification. The infrastent neck diameters did not evolve beyond the main body device diameter.

In 2 other cases (#8, #25), the size of the infrastent zone increased from 12 and 6 months, respectively, after an initial decrease in size, resulting in a minor ( $<1$  mm) enlargement at last follow-up in 1 case (Figure 2A). This increase

in size developed with a downstream displacement of the dual rings in both cases, resulting in 6- and 7-mm caudal displacements, respectively, at 24 months (Figure 2B). Still, the aneurysm sac diameter had regressed by  $\geq 20$  mm. The pertinent main bodies were oversized by 28% and 36%, respectively. The infrarenal straight necks measured 26 and 41 mm in length by 21 and 25 mm in diameter and 0° and 100° in infrarenal neck angulation, respectively, with no thrombus and minor calcification.

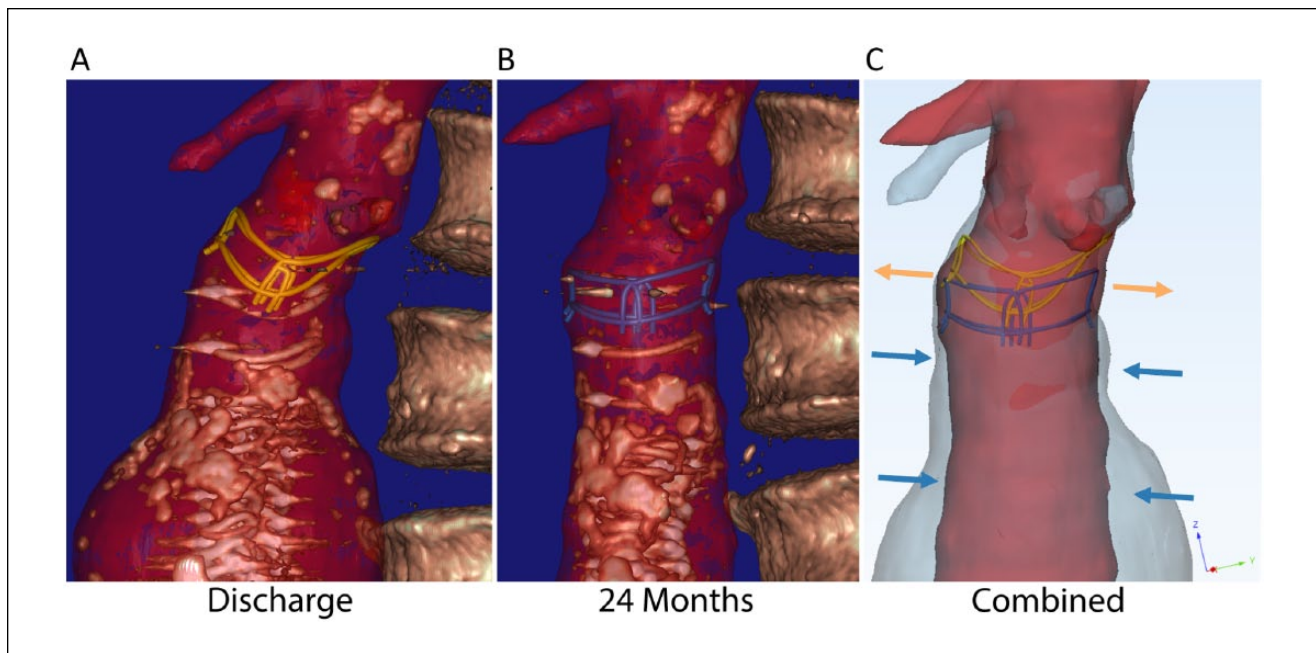
### Correlations

There was no correlation between changes in the stent zone and changes in the infrastent zone (1 year: PCC 0.18,  $p=0.513$ ; 2 years: PCC 0.23,  $p=0.447$ ). The change in diameter in the infrastent zone correlated positively with the change in aneurysm sac diameter at 1 year (PCC 0.69,  $p=0.005$ ; Figure 4A) and 2 years (PCC 0.68,  $p=0.011$ ; Figure 4C). There was no correlation between the change in aneurysm sac diameter and the change in diameter in the stent zone at 1 year (PCC  $-0.01$ ,  $p=0.965$ ; Figure 4B) or 2 years (PCC  $-0.06$ ,  $p=0.848$ ; Figure 4D).

The oversizing percentages correlated positively with the percent change in diameter in the stent zone 1 year (PCC 0.54,  $p=0.037$ ) and 2 years (PCC 0.61,  $p=0.029$ ) after EVAR, but no correlation was found for the infrastent zone (1 year: PCC 0.32,  $p=0.247$ ; 2 years: PCC 0.48,  $p=0.095$ ).

### Discussion

This study shows different remodeling of the perirenal aorta at the suprastent, stent, and infrastent zones after



**Figure 3.** A clinical case (#2) demonstrating a decrease in aortic neck size in the infrastent zone after endovascular aneurysm repair (EVAR). Computed tomography scan segmentations of the aorta (outer wall) and the proximal sealing rings (A) at discharge and (B) 2 years after EVAR were rigidly aligned using Mimics and 3-Matic based on vascular landmarks (C). Proximal ring-stent models were based on prior work.<sup>17</sup> Arrows indicate size increase (orange) or decrease (blue). The axes of the coordinate system (C) denote the x- (left-right), y- (anteroposterior), and z- (superior-inferior) directions.

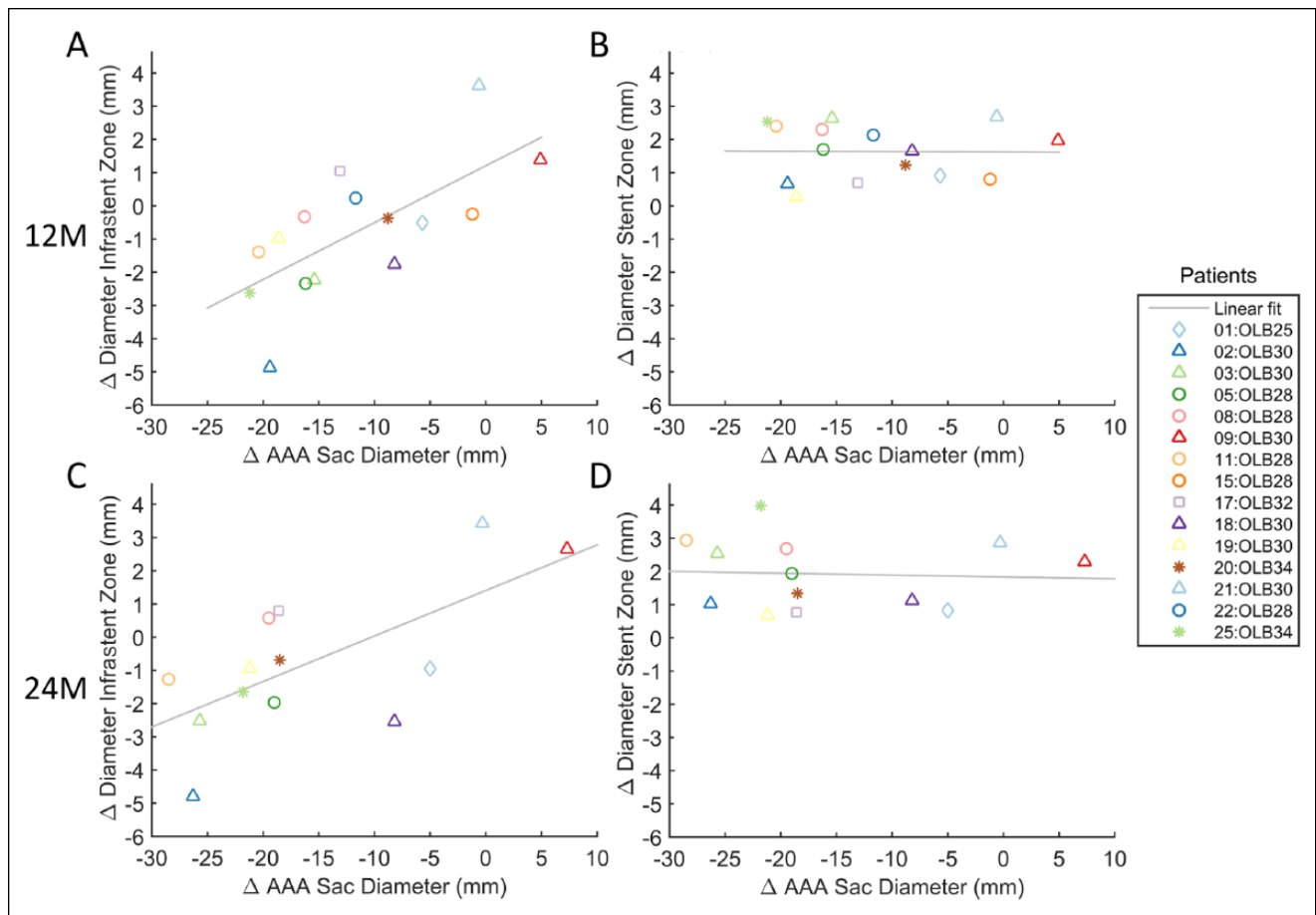
Anaconda implantation. While diameter and area increased in the stent zone of the infrarenal neck as a result of radial expansion of the nitinol sealing rings, a decrease was found in most patients in the infrastent neck zone during the 2-year follow-up.

In line with our present observations in the stent zone, a recent retrospective study by Vukovic et al<sup>18</sup> reported a 2- to 4-mm increase in aortic diameter at the level of the upper and lower rings within 1 year after Anaconda implantation. This study suggested that the expansion of the Anaconda sealing rings leads to infrarenal neck expansion, stent-graft migration, and endoleak, even though diameters remained unchanged after 1 year. Additionally, the degree of ring flattening was below average in the patients with a type Ia endoleak, showing that in these cases the rings actually expanded less compared to most other patients. In our current study, the infrastent measurements showed that the proximal ring expansion had generally not affected the entire infrarenal neck segment despite a 31% mean device oversize but had promoted diameter reduction of the neck below the nitinol sealing rings, which may in fact contribute to durable sealing and fixation. In contrast, 2 studies that investigated diameter changes at the distal end of the neck in various body-supported stent-grafts (Medtronic Talent, Cook Zenith, and Gore Excluder) did not evidence a reduction in size at the distal neck but rather growth, despite aneurysmal regression.<sup>20,21</sup>

Kret et al<sup>15</sup> recently evaluated aortic neck remodeling at and 10 mm below the lowermost renal artery for 26 Cook Zenith, 26 Gore Excluder, 22 Medtronic Endurant, 10 Endologix Powerlink, and 2 Endologix Ovation devices. Compared with the degree of neck dilation reported in this study at 2 years (mean change  $3.8 \pm 2.4$  mm,  $15.4\% \pm 10.1\%$ ), we observed a lower degree of neck dilatation at similar levels (mean change  $1.5 \pm 1.0$  mm,  $5.5\% \pm 3.8\%$ ) for the Anaconda device. Also, the clinical relevance of AND after EVAR is questionable since AND was not associated with adverse outcomes in multiple studies.<sup>13-16</sup> A study by Malas et al<sup>22</sup> on the performance of Lombard Medical's Aorfix stent-graft, an infrarenal fixating device that resembles the Anaconda but has an 8-mm proximal segment of concentric rings, showed that for this device the aortic neck dilated at 7 and 15 mm below the lowermost renal artery but without an increased risk of migration.

Interestingly, a recent study on aortic neck evolution after implantation of Endologix's Ovation stent-graft reported a slight decrease in diameters in the infrarenal segment above the polymer-filled sealing ring 2 years after EVAR.<sup>23</sup> Similar to the infrastent zone considered in the present study, this segment is free from outward radial force, which may have allowed aortic remodeling.

Remodeling of the distal neck may be related to remodeling mechanisms that also lead to aneurysm sac regression,<sup>24</sup> notably, reversal of aortic wall inflammation,<sup>25</sup>



**Figure 4.** Correlation between change in aneurysm sac diameter and change in aortic diameter in the (A, C) infrastent zone and the (B, D) stent zone after 1 (A, B) and 2 years (C, D) of follow-up. Negative values denote a decrease. The linear fit represents a least-squares fit for linear regression. AAA, abdominal aortic aneurysm; M, months; OLB, main body device size.

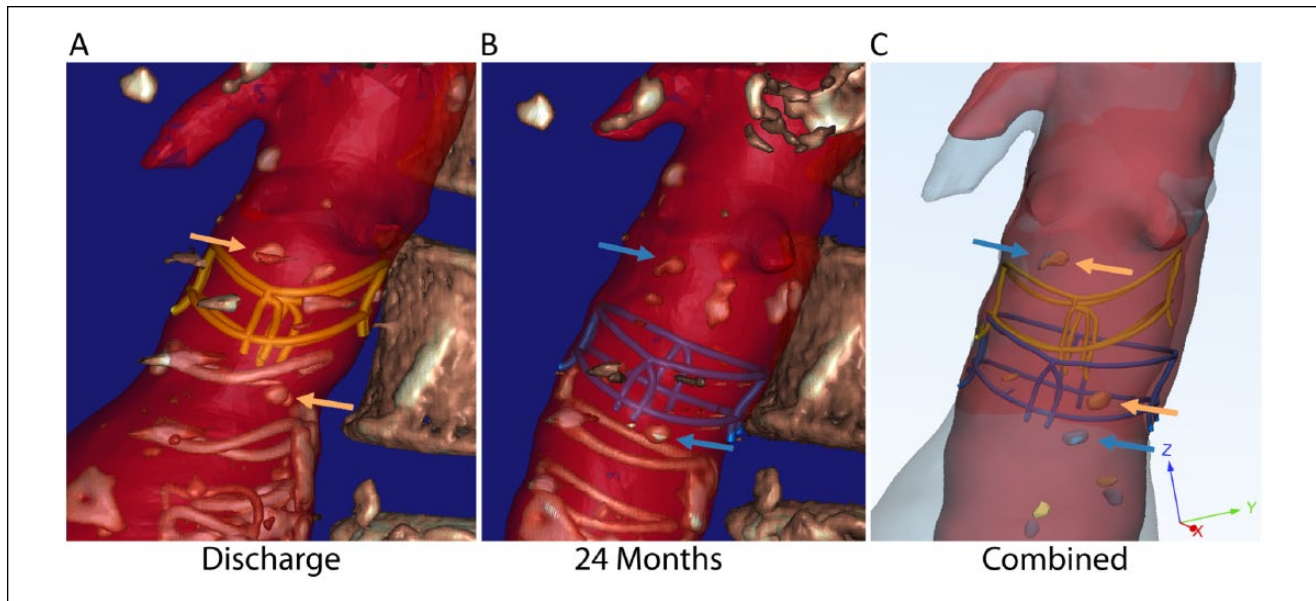
which involves tissue regeneration and shrinkage.<sup>26</sup> Additionally, the initial increase in infrastent neck size in the majority of patients after 1 month may be explained by the reconstructive phase of the inflammatory response, including granulation tissue formation, (myo)fibroblast proliferation, and collagen synthesis.<sup>26</sup>

Even though the incidence of Anaconda main body migration appears to be low,<sup>27–32</sup> Vukovic et al<sup>18</sup> reported continuous migration of the main body during follow-up. However, their definition of migration overestimates downward body displacement due to the expansion and flattening of the proximal saddle-shaped rings over time. The average 6-mm increase in distance between the superior mesenteric artery and the Anaconda upper ring was reported as main body migration, while an average 3-mm increase in renal artery to upper ring distance was found, which is similar to the displacement observed in our present study.

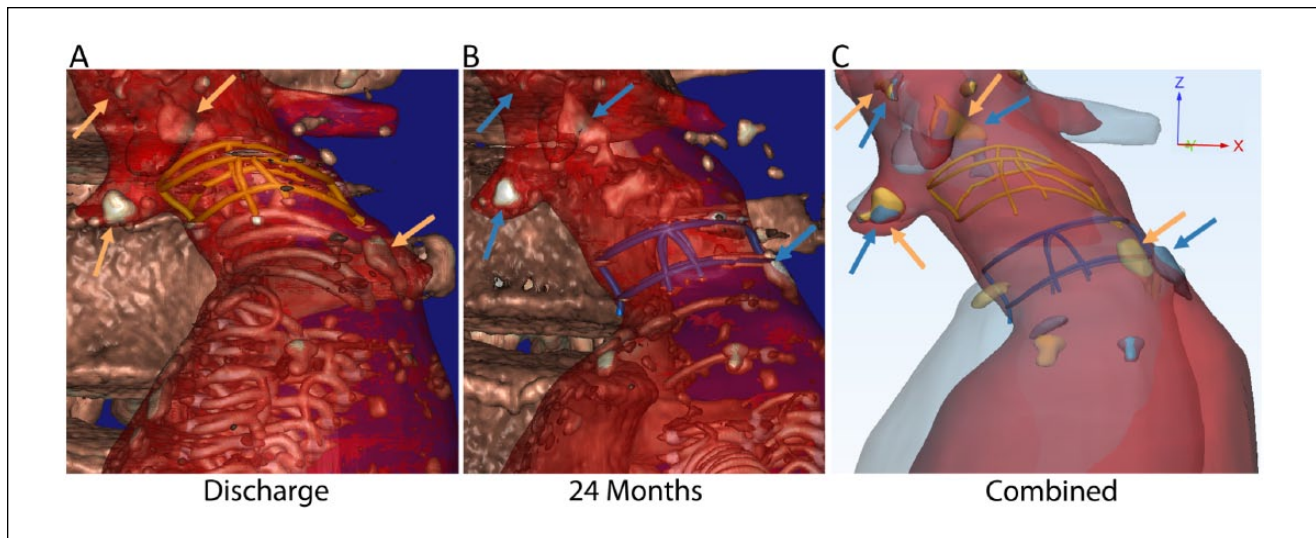
The downward movement of the peaks should not be considered migration, as it results from the adaptation of the sealing rings. We therefore use the lower valley of the dual

ring to examine body migration distances. In our present study, we measured >5-mm downstream displacement of the main body in 3 cases that developed with an increase in infrastent neck diameter, though not resulting in any type I or III endoleak. Besides severe infrarenal neck angulation (>90°) in 1 of the 3 cases, there were no clear predisposing neck characteristics that may explain the downstream displacement. To determine whether true device migration or axial remodeling had occurred in these cases, we additionally assessed the device displacement in relation to calcification landmarks in the neck. In 2 of the 3 cases, the distance from baseline to calcification landmarks near the sealing rings had increased by 4 to 5 mm, indicating that the neck remodeled axially under downward drag forces on the graft by the blood flow. In these cases, the true device migration actually constituted <5 mm. But more importantly, we observed an increase in neck length as a result of sac shrinkage. A case analysis is shown in Figure 5.

For the third case, we predominantly observed true migration, as elongation of the infrarenal neck was below 2



**Figure 5.** A case analysis (#8) by calcification landmarks to evaluate potential axial remodeling. By aligning (C) the vasculature (A) at discharge and (B) 2 years after endovascular aneurysm repair (EVAR), it is clear that besides device migration, the perirenal aortic neck remodeled axially. The infrarenal neck length increased as a result of sac shrinkage. The arrows indicate calcification landmarks at discharge (orange) and 2 years after EVAR (blue). The axes of the coordinate system (C) denote the x- (left-right), y- (anteroposterior), and z- (superior-inferior) directions.



**Figure 6.** Another case analysis (#21) by calcification landmarks demonstrated that the observed 10-mm main body displacement was predominantly caused by main body migration and not by axial remodeling of the aortic neck. Alignment (C) of the vasculature (A) at discharge and (B) 2 years after endovascular aneurysm repair (EVAR) shows that the position of a calcification pattern in the neck hardly changed. The arrows indicate calcification landmarks at discharge (orange) and 2 years after EVAR (blue). The axes of the coordinate system (C) denote the x- (left-right), y- (anteroposterior), and z- (superior-inferior) directions.

mm (Figure 6). Elongation of the aortic neck has also been observed by Litwinski et al,<sup>33</sup> who discussed these migration phenomena. Notably, in these 3 patients the proximal sealing ring had directly lost most of its saddle shape at the pre-discharge scan, despite ample oversize (>28%),

indicating an immediate expansion of the stent-rings. In fact, in a previous study of the same cohort<sup>17</sup> these patients had the highest (>94%) pre-discharge ring expansion percentages (diameter ring / nominal diameter ring  $\times$  100). Similarly, Schuurmann et al<sup>34</sup> found that the stent-graft had



already expanded substantially at the first postoperative scan in their migration group specifically. Perhaps in these cases the aortic wall was not able to withstand the radial force of the stent-rings due to insufficient elastic recoil, resulting in ring expansion, neck dilatation, and migration or elongation. In our clinic, we currently avoid excessive oversize and advise an oversizing percentage of 10% to 20% for necks within the instructions for use and with less than 60° infrarenal angulation. An in-depth individual assessment of the wall characteristics may be required in patient and device selection to identify such patients beforehand to allow for adequate treatment strategies.

### Limitations

The findings of the present study are limited by the small size of the study cohort and the lack of data regarding geometric changes beyond 2 years since patients were followed by duplex ultrasound examinations and plain radiography after that time. Nevertheless, reports from these non-CT examinations did not indicate any type I or III endoleak. Even though all changes from baseline in the stent zone were statistically significant, the size of the patient sample may have been too small to observe statistically significant changes in the other zones.

The strength of this investigation is that, to the best of our knowledge, no other study has reported in detail on size changes of the entire abdominal aortic neck segment. Thus, our data provide insight into neck remodeling after Anaconda implantation by differentiating between aortic zones. In addition, the repeatability of our measurements is similar to that reported by others.<sup>35,36</sup> Our study is unique in its approach because it longitudinally followed changes at standardized time points with a standardized thin-slice dynamic scan protocol that allowed measurements to be repeated adequately at various aortic levels and at the same time during the cardiac cycle.

### Conclusion

After EVAR using the Anaconda stent-graft, the infrarenal aortic neck accommodated to the expansion of the sealing rings at the stent sealing zone, but the neck below the stent zone decreased in size in the majority of patients. An evident increase in the infrastent zone was observed in one patient with 10-mm downstream displacement of the main body and in another patient, who developed a type II endoleak. The suprarenal aortic diameter remained unchanged. Increasing diameter in the infrastent zone seems to relate to downstream device displacement, which may suggest that a decrease in size in the infrastent zone contributes to durable sealing and fixation of the Anaconda double stent-ring. Patients presenting such infrarenal neck remodeling below the stent sealing zone may require less regular

follow-up, while patients presenting an increase may be prone to develop device migration and endoleak. A personalized follow-up scheme based on geometric neck remodeling after Anaconda implantation should be feasible if our observations are confirmed in larger, long-term studies.

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