From the Society for Vascular Surgery

Aortic neck evolution after endovascular repair with TriVascular Ovation stent graft

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Objective: **Aortic neck dilation has been reported after endovascular aneurysm repair (EVAR) with self-expanding devices. With a core laboratory analysis of morphologic changes, this study evaluated midterm results of aortic neck evolution after EVAR by endograft with no chronic outward force.**

Methods: **This was a multicenter registry of all patients undergoing EVAR with the Ovation endograft (TriVascular, Santa Rosa, Calif). Inclusion criteria were at least 24 months of follow-up. Standard computed tomography (CT) scans were reviewed centrally using a dedicated software with multiplanar and volume reconstructions. Proximal aortic neck was segmented into zone A (suprarenal aorta/fixation area), zone B (infrarenal aorta, from lowest renal artery to the first polymer-filled ring), and zone C (infrarenal aorta, at level of the first polymer-filled ring/sealing zone). Images were analyzed for neck enlargement (≥2 mm), graft migration (≥3 mm), endoleak, barb detachment, neck bulging, and patency of the celiac trunk and superior mesenteric and renal arteries.**

Results: **Inclusion criteria were met in 161 patients (mean age, 75.2 years; 92% male). During a mean follow-up period of 32 months (range, 24-50), 17 patients died (no abdominal aortic aneurysm-related death). Primary clinical success at 2 years was 95.1% (defined as absence of aneurysm-related death, type I or type III endoleak, graft infection or thrombosis, aneurysm expansion >5 mm, aneurysm rupture, or conversion to open repair). Assisted primary clinical success was 100%. CT scan images at a minimum follow-up of 2 years were available in 89 cases. Patency of visceral arteries at the level of suprarenal fixation (zone A) was 100%. Neither graft migration nor barb detachment or neck bulging was observed. None of the patients had significant neck enlargement. The mean change in the diameter was 0.18 ± 0.22 mm at zone A, −0.32 ± 0.87 mm at zone B, and −0.06 ± 0.97 mm at zone C. Changes at zone B correlated significantly with changes at zone C (correlation coefficient, 0.183; $P = .05$), whereas no correlation was found with zone A (correlation coefficient, 0.000; $P = 1.0$).**

Conclusions: **No aortic neck dilation occurred in this series at CT scan after a minimum 24-month follow-up. This may suggest that aortic neck evolution is not associated with EVAR at midterm follow-up when an endograft with no chronic outward radial force is implanted. (J Vasc Surg 2016;63:8-15.)**

A continuous aortic enlargement at the level of the infrarenal aortic neck has been reported after endovascular aneurysm repair (EVAR) of abdominal aortic aneurysm (AAA).[1-3] Current concepts about the reason for this phenomenon remain poorly understood, although it is known that the amount of proximal device oversizing with self-expanding stent grafts (SESGs) influences neck progression.[4,5] Once deployed, SESGs continue to expand until the nominal diameter is reached,[6] unless tissue resistance limits expansion.[7] It has been reported that when aortic neck dilation occurs, it is related to adverse midterm outcomes.[8,9]

A new stent graft has recently been introduced to the market, carrying a new sealing technology that is not based on chronic expanding force. The Ovation endograft (TriVascular, Santa Rosa, Calif), with its new concept of sealing by nonexpansive circumferential apposition of polymer-filled rings to aortic wall, creates no chronic outward force at the infrarenal aortic level. This sealing mechanism, which is completely different from that obtained by SESGs, promises to isolate the aortic neck from blood pressure, thus preventing aortic neck evolution over time.[10,11]

This study assessed midterm clinical outcomes after EVAR with the Ovation stent graft in a series of patients with a minimum follow-up of 24 months. With a core laboratory analysis of morphologic changes, this research evaluated aortic neck evolution at 2 years after EVAR by endograft with no chronic outward force.

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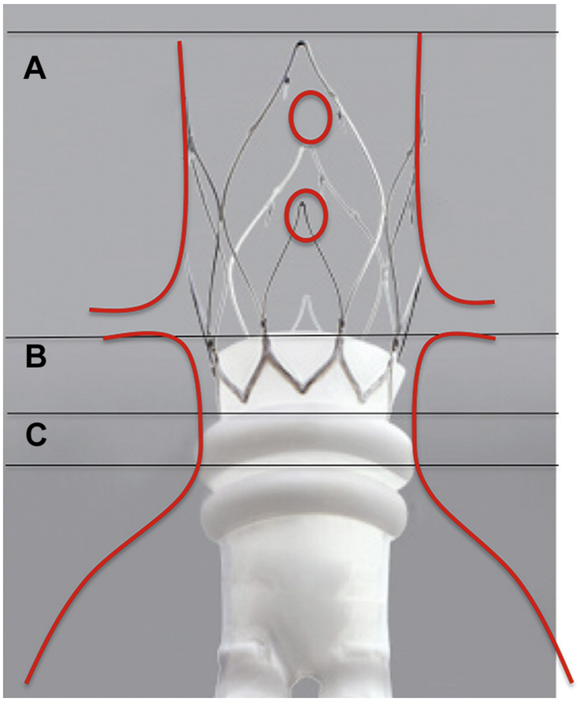


Fig 1. Aortic neck segmentation into three zones: *zone A*, suprarenal aorta/fixation area; *zone B*, infrarenal aorta, from lowest renal artery to the first polymer-filled ring; and *zone C*, infrarenal aorta, at level of the first polymer-filled ring/sealing zone.

Table I. Baseline demographics and aneurysm characteristics in the total population (N = 161)

Age, years (range)	75.2 ± 3 (52-88)
Men	148 (92)
Hypertension	94 (62)
Chronic ischemic heart disease	57 (35)
Diabetes	35 (22)
Renal insufficiency	3 (2)
AAA diameter, mm	57.7 ± 9
Neck thrombus >50% of circumference	51 (32)
Neck calcification >50% of circumference	15 (9)

AAA, Abdominal aortic aneurysm.
Categorical data are presented as number (%).

Table II. Clinical success at 2 years

Primary clinical success	95%
Aneurysm-related death	0
Type I or type III endoleak[a]	3 (2%)
Aneurysm expansion[a]	0
Graft infection	0
Graft thrombosis[a]	4 (3%)
Conversion to open repair	0
Assisted primary clinical success	100%
Aneurysm-related death	0
Type I or type III endoleak[a]	0
Aneurysm expansion[a]	0
Graft infection	0
Graft thrombosis[a]	0
Conversion to open repair	0

[a]Assessed by computed tomography (CT) or ultrasound follow-up.

METHODS

In November 2014, we performed a retrospective data collection of patients who had undergone implantation of a TriVascular Ovation stent graft for AAA at least 24 months previously. Patients with mycotic aneurysm or prior aortic reconstructive surgery were excluded. The study followed the Declaration of Helsinki on medical protocol, and informed consent was approved by the Institutional Review Board.

A total of 13 centers in Italy were enrolled as participants in the TriVascular Ovation Italian Study (Appendix). Each participant center was asked to collect data of clinical status at preoperative and at last follow-up visits. Standard computed tomography (CT) scans available at a minimum 24-month follow-up were collected and sent for blind reading to a centralized core laboratory.

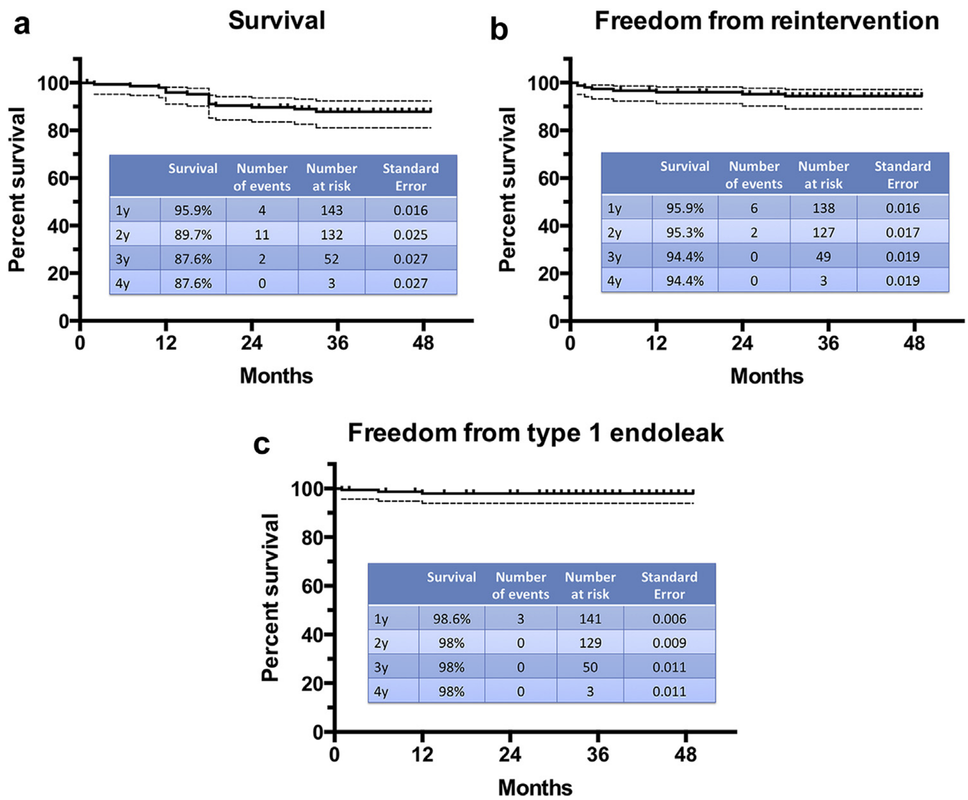
Full data sets and cross-sectional images of contrast-enhanced CT scans performed before EVAR, at first postoperative month, and at last follow-up interval were reported in the central database for the core laboratory review of morphologic changes. All images were in Digital Imaging and Communications in Medicine format.

Images analysis and measurements. Images were reviewed centrally by the same vascular surgeon (G.d.D.) using a dedicated software with multiplanar and volume reconstructions (OsiriX MD v.6.5.1 64-bit; Pixmeo Sarl, Bernex, Switzerland). For determination of intraobserver variability, the observer analyzed 20 randomly selected CT scans with an interval of 2 weeks, measuring each scan twice. Scans were obtained 1 cm above the celiac artery to the femoral artery. All vessel measurements were performed after centerline lumen (CLL) reconstructions. CLL was created by manual segmentation of the aorta on each axial slice.

For the postprocedural analysis, the proximal aortic neck was segmented into three zones (Fig 1):

- Zone A (suprarenal aorta/fixation area) from upper limit of suprarenal stent to a tangent horizontal plane passing through the most cranial point of the circumference of the lowermost renal artery ostium;
- Zone B (infrarenal aorta) from a tangent horizontal plane passing through the most distal point of the circumference of the lowermost renal artery ostium to a tangent horizontal plane passing through the most cranial point of the first polymer-filled ring;
- Zone C (infrarenal aorta/sealing zone) at the level of the first polymer-filled ring.

These three zones were examined separately, and then a comparison between preoperative and postoperative images was performed, with the distance from the lowest renal artery as reference for the analysis of morphologic changes of each single zone.



	Survival	Number of events	Number at risk	Standard Error
1y	95.9%	4	143	0.016
2y	89.7%	11	132	0.025
3y	87.6%	2	52	0.027
4y	87.6%	0	3	0.027

	Survival	Number of events	Number at risk	Standard Error
1y	95.9%	6	138	0.016
2y	95.3%	2	127	0.017
3y	94.4%	0	49	0.019
4y	94.4%	0	3	0.019

	Survival	Number of events	Number at risk	Standard Error
1y	98.6%	3	141	0.006
2y	98%	0	129	0.009
3y	98%	0	50	0.011
4y	98%	0	3	0.011

Fig 2. Kaplan-Meier estimates of cumulative patient survival **(a)**, freedom from reintervention **(b)**, and freedom from type I endoleak **(c)** during follow-up. The *lines* above and below the centerline represent the 95% confidence interval.

Diameter of the aorta at three defined zones, presence of thrombus, graft migration, stent graft patency and integrity, evidence of endoleak, barb detachment, neck bulging (ventral, lateral, and posterior), and patency of celiac trunk and superior mesenteric and renal arteries were assessed.

Definitions. Reporting is according to the guidelines from the Society for Vascular Surgery/American Association for Vascular Surgery Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery.[12] Primary clinical success, primary assisted clinical success, and secondary clinical success are defined accordingly.

Aortic neck dilation is defined as an increase in the diameter of 2 mm or more in comparing preoperative with last follow-up CT scan.

The aortic size is measured as the outer diameter at CLL analysis. Stent migration is defined as an increase of 3 mm or more in the distance between the lowest renal artery and the proximal end of the stent graft in comparing the first with the last follow-up CT scan.

Barb detachment is defined as malapposition of a proximal uncovered stent barb to the aortic wall. Neck bulging is defined by the increase of neck diameter in a quadrant defined by the convexity of the suprarenal angle, despite maintenance of adequate endograft apposition to aortic wall in the remaining quadrants on surveillance imaging.

Clinical success is defined as successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, type I or type III endoleak, graft infection or thrombosis, aneurysm expansion (diameter >5 mm or volume >5%), aneurysm rupture, or conversion to open repair.

AAA-related adverse event is defined as a composite of the following: direct (type I or type III) or undetermined type endoleaks, aneurysm sac growth, migration, device integrity failure, AAA-related death, late postimplantation AAA rupture, or any AAA-related secondary intervention.

Secondary interventions are performed to resolve or to prevent a possible complication. These included endovascular procedures (proximal cuff and stent implant, distal extension implant, catheter-based thrombolysis, iliac angioplasty, coil or glue embolization of aortic branch vessels) as well as surgical procedures (balloon thrombectomy, femorofemoral crossover, conversion to open repair, open or laparoscopic ligation of collaterals).

End points. The primary study end point was freedom from neck dilation at zones B and C. Secondary end points were primary clinical success, freedom from type Ia endoleak, freedom from reinterventions, freedom from neck dilation at zone A, and patency rate of celiac trunk and superior mesenteric and renal arteries.

Statistical analysis. The data were expressed as mean and standard deviation or as median and interquartile range (IQR), depending on the type of distribution. Box plots were used for graphic representation of changes in diameters.

To assess correlations, the Pearson coefficient was used in case of assumption that both X and Y values were sampled from populations that follow a gaussian distribution. The Spearman nonparametric correlation was used to assess correlation when there was not the assumption about the distribution of the values, as the calculations were based on ranks and not on the actual values.

The Kaplan-Meier method was used to construct survival curves to calculate survival, freedom from reintervention, freedom from rupture, and freedom from type Ia endoleak.

Intraobserver variability was assessed using Cohen κ test of concordance.[13] A κ value of 0.61 to 0.80 indicated good agreement, and 0.81 to 1.0 indicated excellent agreement.

All statistical analyses were performed with the Statistical Package for the Social Sciences (SPSS) software (version 13; SPSS Inc, Chicago, Ill) and GraphPad Prism (GraphPad, San Diego, Calif).

RESULTS

Inclusion criteria were met in 161 patients (mean age, 75.2 ± 3 years; 92% male). The interval study period was from December 2010 to November 2012. Table I shows baseline demographics and aneurysm characteristics. Primary technical success on an intention-to-treat basis was 98.1% (two type Ia endoleaks, one graft occlusion). Assisted primary technical success was 99.3%, considering that two of three primary technical failures were corrected intraoperatively (one type Ia endoleak correction by balloon-expandable stent implantation, one intraoperative femorofemoral bypass for iliac graft occlusion). The remaining technical failure consisted of a little type Ia endoleak, which was considered at low risk of sac pressurization and surveyed in the follow-up period. The perioperative mortality was 0%.

During a median follow-up period of 32 months (range, 24-50), 17 patients died (no AAA-related death), and 15 patients were lost to follow-up. Primary clinical success at 2 years was 95.1% (defined as absence of aneurysm-related death, type I or type III endoleak, graft infection or thrombosis, aneurysm expansion >5 mm, aneurysm rupture, or conversion to open repair). Assisted primary clinical success at 2 years was 100% (Table II).

The survival curve at 1 year, 2 years, and 4 years was, respectively, 95.9%, 89.7%, and 87.6% (Fig 2, *a*). During follow-up, reintervention was performed in eight cases, including treatment for type Ia endoleak in three cases (one aortic cuff, one balloon-expandable stent, one coil and glue embolization), iliac limb occlusion in four cases (one bypass, three surgical thrombectomies with stenting), and type II endoleak in one case (coil embolization). Life-table analysis showed freedom from reintervention at 1 year, 2 years, and 4 years of 95.9%, 95.3%, and 94.4% (Fig 2, *b*) and from type Ia endoleak at 1 year, 2 years, and 4 years of 98.6%, 98%, and 98% (Fig 2, *c*).

CT scan analysis at 2 years

CT scan images at a minimum follow-up of 2 years were available in 89 cases. Thirty-five CT scans (39.3%) were performed at a 2-year visit, 41 (46%) between the second and the third year, and 13 others (14.6%) later than 3 years after stent graft implantation (median, 28 months; range, 24-50).

Intraobserver agreement was excellent (κ, 0.91).

Zone A. Patency of visceral arteries in zone A was 100%. In particular, the suprarenal bare stent of the Ovation endograft landed above the celiac trunk in 58.4% of cases. All visceral arteries (n = 325; 52 celiac trunks, 89 superior mesenteric arteries, 88 pairs of renal arteries, 1 single renal artery in a patient with previous nephrectomy, and 7 accessory renal arteries) were patent behind the bare stent struts, with no significant vessel lumen change in comparison to preoperative scans.

The absolute size in the diameter of zone A at last follow-up scan was 24.2 ± 2.9 mm. The mean change in the diameter at zone A was 0.18 ± 0.22 mm (standard error [SE], 0.02), with a nongaussian distribution and a median diameter increase of 0.1 mm (IQR, 0-0.3 mm; Fig 3).

Neither barb detachment nor ventral, lateral, or posterior neck bulging was observed at axial scan and multiplanar reconstructions.

Zones B and C. Sizes of the stent graft body ranged from 23 to 34 mm. The device was oversized by 10% to 20% in all cases. The mean stent graft landing distance to the lowest renal artery was 3.13 ± 4.25 mm (SE, 0.45), with a nongaussian distribution (median, 2 mm; IQR, 0-6 mm). In particular, landing distance was <5 mm in 65 patients (73.1%; Fig 4).

Neither stent graft migration nor neck enlargement was observed when the first and the last follow-up CT scans were compared.

At last follow-up scan, the absolute sizes in the diameters of zone B and zone C were 23.1 ± 3.4 mm and 25.2 ± 3.7 mm, respectively. The mean change was −0.32 ± 0.87 mm (SE, 0.09) in the diameters at zone B, with a nongaussian distribution, and the majority of cases had an absolute decrease in the diameter (median, 0.0 mm; IQR, 0 to −0.6 mm; Fig 5).

In zone C, the mean change in diameters was −0.06 ± 0.97 mm (SE, 0.1), with a gaussian distribution (median, 0.0 mm; IQR, +0.4 to −0.3 mm; Fig 6).

To investigate a possible correlation between baseline and last follow-up diameter changes, a Spearman correlation test between the three zones was performed. As shown in Table III and Figs 7 and 8, changes at zone B correlated significantly with changes at zone C (correlation coefficient, 0.183; $P = .05$), whereas no correlation was found with zone A (correlation coefficient, 0.000; $P = 1.0$).

DISCUSSION

Traditional SESGs require an infrarenal nonaneurysmal segment, the so-called aortic neck, to adequately seal the

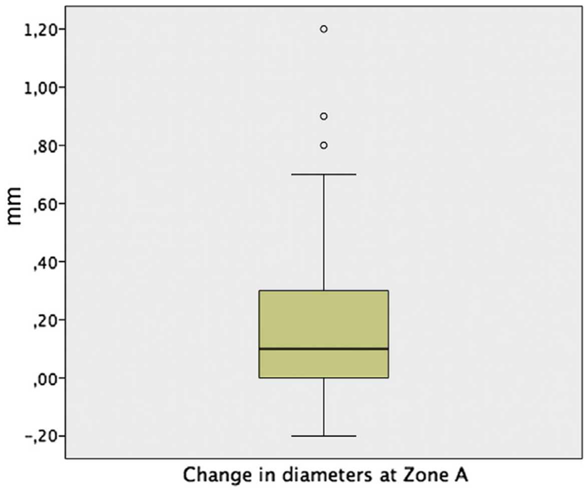


Fig 3. Zone A: changes in diameters over time. The *horizontal line* in the middle of the box indicates the median; the *top and bottom borders* of the box mark the 75th and 25th percentiles, respectively, and the *whiskers* mark the 90th and 10th percentiles.

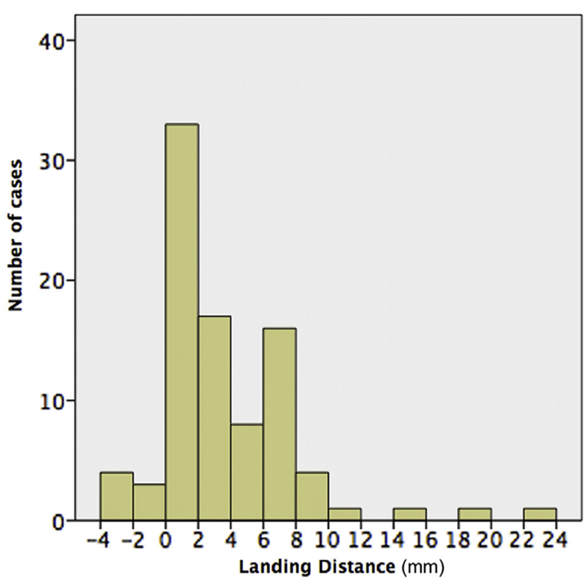


Fig 4. Stent graft landing distance to the lowest renal artery.

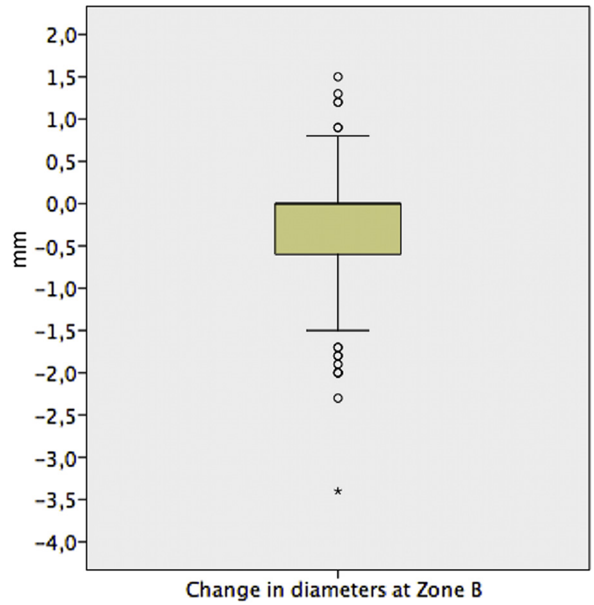


Fig 5. Zone B: changes in diameters over time. The *horizontal line* in the middle of the box indicates the median; the *top and bottom borders* of the box mark the 75th and 25th percentiles, respectively, and the *whiskers* mark the 90th and 10th percentiles.

aneurysm sac from chronic circulatory pressures. Sealing is obtained by oversizing of the stent (from 10% to 30%), in the prospect that the chronic radial force exerted longitudinally against the aortic wall will circumferentially prevent any leakage.

The Ovation technology is based on a new sealing concept that redefines the idea of aortic neck length. The polymer-filled sealing ring provides uniform, nonexpansive, continuous wall apposition that aims to isolate the aortic neck from circulatory pressures.

The sealing is not longitudinal and related to neck length, but circumferential and based on the apposition of the polymer-filled ring to the aortic wall at 13 mm below the lower renal artery. This makes the Ovation system the only stent graft approved by the U.S. Food and Drug Administration[14] for EVAR that is not restricted by the conventional measurement of aortic neck length. Actually, the Food and Drug Administration criteria for the use of the Ovation endograft are the presence of an inner wall diameter ≥16 mm and ≤30 mm at 13 mm below the inferior renal artery to allow correct apposition of rings to the aortic wall.

We reported for the first time in the literature midterm clinical outcomes from a series of patients treated with this new sealing technology, describing encouraging data (assisted primary clinical success rate at 2 years of 100%, estimated freedom from type I endoleak at 3 years of 98%). These results are fully in line with those reported for last-generation SESGs[15] (estimated freedom from type I and type III endoleak at 2 years of 96.9%).

With a core laboratory analysis of morphologic changes, this multicenter registry reported original data on aortic neck evolution after Ovation stent graft implantation in patients with at least 24-month CT follow-up. The segmentation of aortic neck (Fig 1) allowed us to investigate three zones independently. Zone A was studied to understand the evolution of the suprarenal aortic segment in the presence of a long nitinol stent (35 mm) landing above the ostium of superior mesenteric artery and celiac trunk. This position is unusual with other stent grafts. The diameter progression in this zone was irrelevant, and patency of the visceral vessels covered by the bare stent struts was

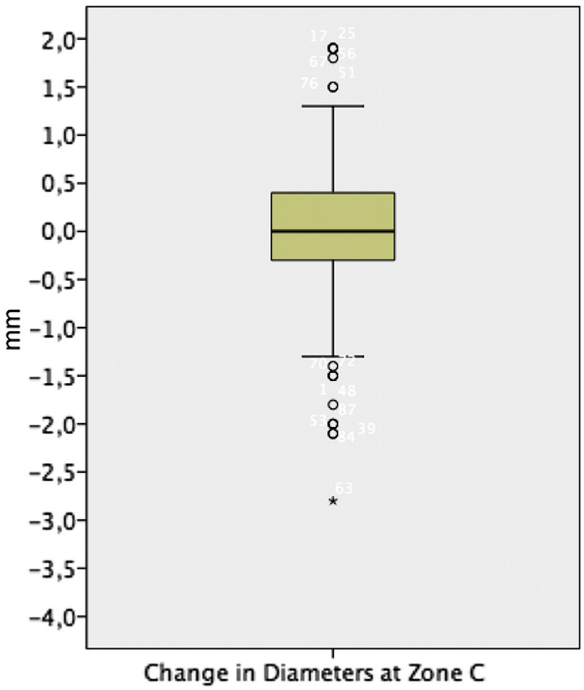


Fig 6. Zone C: changes in diameters over time. The *horizontal line* in the middle of the box indicates the median; the *top and bottom borders* of the box mark the 75th and 25th percentiles, respectively, and the *whiskers* mark the 90th and 10th percentiles.

Table III. Correlation test of diameter changes among aortic neck zones

	Changes at zone A	*Changes at zone B*	*Changes at zone C*
Change at zone B (Spearman test)			
Correlation coefficient	.000	1.000	.183
P (two tails)	1.000		.05
No.	89	89	89

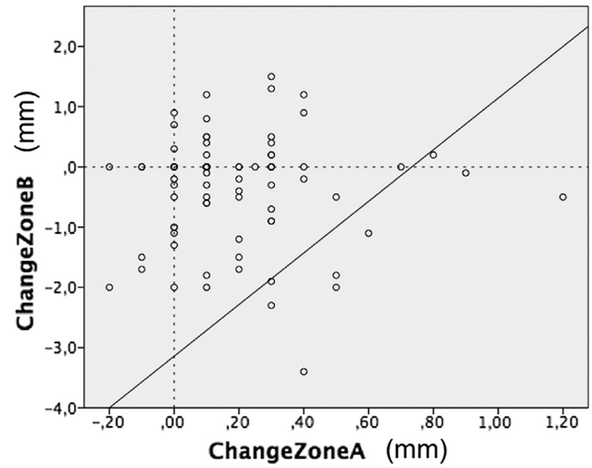


Fig 7. Spearman correlation test between changes at zone B and changes at zone A.

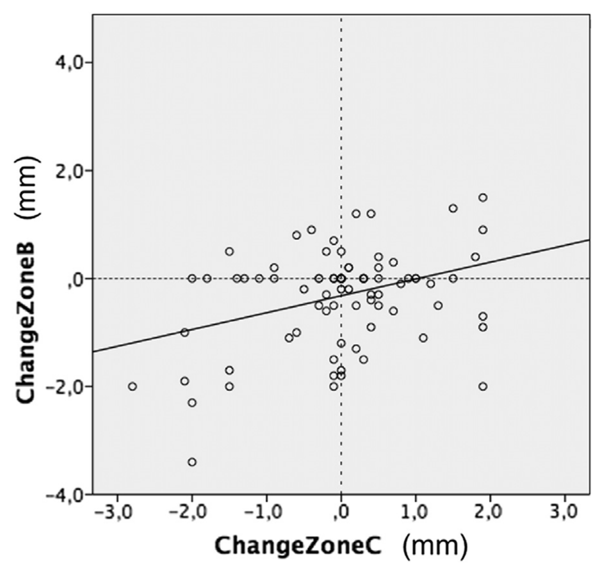


Fig 8. Spearman correlation test between changes at zone B and changes at zone C.

100%. In addition, the long suprarenal stent with robust hooks for fixation guaranteed a migration rate of 0% at 2 years, which is similar to that reported for the best-performing last-generation SESGs with both infrarenal[16] and suprarenal fixation.[17]

Analysis of zone B focused on the behavior of the infrarenal aortic segment that is above the sealing ring and, theoretically, may still be damaged by the circulatory pressure. Our data described an excellent performance of the aorta at this level (-0.32 ± 0.87 mm at 2 years), which let us hypothesize that no significant pressure is transmitted to the aortic wall and that this phenomenon may be related to the particular design of the stent graft in this zone. First, the distal end of the suprarenal nitinol stent is attached to the inner portion of the first ring. Then, when the polymer is injected, the nitinol stent is gently dislodged away from the aortic wall; therefore, it does not apply any chronic outward force. Second, the graft material in zone B is slightly free to move independently of the stent and may conform to the aortic wall ("mainsail effect"), preserving bloodstream between the fabric and the wall. As a result, aortic wall in zone B is protected from arterial pressure, and this may explain the regression of its diameter at 2 years.

Stent graft deployment was extremely precise in the majority of cases in our series (<5 mm to the lowest renal artery in 73.1% of patients). Precision on deployment allows maximal coverage of the proximal aortic neck. Actually, the lower the deployment, the longer zone B is, meaning that neck protection is less. So we strongly recommend a precise stent graft deployment, as close as possible to the lowest renal artery, to preserve the benefit of proximal stent graft design.

Remarkably, our three cases of type I endoleaks corrected during the follow-up period were all in cases of less precise deployment (>5 mm to the lowest renal artery). Endoleaks were related to the minor apposition of the sealing ring to the arterial wall at the level of the unplanned landing (two at +7 mm, one at +10 mm to renal artery) and never to aortic neck dilation. Core laboratory analysis of these three cases revealed that preoperative planning advocated precise deployment and that an unplanned landing >3 mm would have resulted in poor sealing.

Results in zone C described no significant diameter changes at midterm follow-up (-0.006 ± 0.97 mm), confirming that no positive remodeling occurs in the absence of chronic radial force.

The home-made Parodi endograft essentially consisted of a tubular fabric graft attached at both ends by a large balloon-expandable Palmaz stent. Careful measurement of the proximal neck showed that neck dilation did not take place with the Parodi endograft.[18] In an early experience with the Montefiore endograft system, which is a balloon-expandable stent graft (BESG), Malas et al[19] reported neither neck evolution nor endograft migration at a mean follow-up of 31 months in a series of 77 patients. Also, second-generation BESGs revealed a migration rate of 0%.[20]

In a series of 241 patients, Dalainas et al[21] described that aortic neck dilation after EVAR is frequent and significantly correlated with SESGs (27.5%) in comparison to BESGs (7.1%).

All these data emphasize how aortic neck can definitely maintain its diameter when the radial force applied by the stent graft is lower than the recoil force of the elastic aortic wall. Nowadays, while BESGs have been removed from the market, the sealing technology of the TriVascular Ovation, which does not apply chronic outward force, may guarantee a similar phenomenon as suggested by the absence of neck dilation and migration in our study.

Finally, a correlation between suprarenal and infrarenal changes has been demonstrated for SESGs, with both a suprarenal or an infrarenal fixation,[5] which was not the case in our series. Changes of diameters in zone B did not correlate with changes in zone A, whereas they correlated significantly with changes in zone C. Although the analysis of such correlations may not draw any definitive conclusions, we can speculate that zone B and zone C are both fully protected by blood pressure and their diameters move synchronously (mainly in a negative remodeling trend) because of the absence of a chronic radial force, whereas zone A has its own independent behavior.

Limitations. This is a retrospective study whose findings are partially limited by the small size of the study cohort. All patients received ultrasound follow-up, and some of them (89 of 161) received CT scan on a case-by-case evaluation. This may have created a bias in selection of patients, although it is more likely that patients who did not receive CT control were those with more favorable outcome (ie, patients with complete sac exclusion and significant aneurysm shrinkage at ultrasound follow-up).

Moreover, some patients did not live long enough for the analysis of morphologic changes at 2 years. Nevertheless, it is significant that these patients did not die of aneurysm-related causes.

A further limitation was that a single observer performed all the CT analysis.

CONCLUSIONS

No aortic neck dilation occurred in patients treated with TriVascular Ovation stent graft at CT scan after a minimum 24-month follow-up. This may suggest that aortic neck evolution is not associated with EVAR at midterm follow-up when an endograft with no chronic outward radial force is implanted.

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AUTHOR CONTRIBUTIONS

Conception and design: GdD
Analysis and interpretation: GdD
Data collection: GdD, FS, LB, PC, RC, NM, GN, CS
Writing the article: GdD
Critical revision of the article: FS, LB, PC, RC, NM, GN
Final approval of the article: CS
Statistical analysis: GdD
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Overall responsibility: GdD

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APPENDIX.

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