

# Endovascular Aneurysm Repair in Conical Proximal Aortic Neck Anatomy: Impact of a Conformable Endograft on Proximal Sealing Outcomes

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**Background:** Conical proximal aortic neck anatomy has traditionally been considered a hostile feature for endovascular aneurysm repair (EVAR) due to concerns regarding inadequate proximal sealing and increased rates of type Ia endoleak. However, the independent impact of conical morphology and the potential mitigating role of modern conformable endografts remain debated. This study evaluates short- and mid-term outcomes of EVAR in patients with conical neck anatomy, with a specific focus on the effectiveness of the GORE Excluder Conformable endograft.

**Methods:** We performed a retrospective analysis of prospectively collected data including all consecutive patients undergoing elective EVAR for infrarenal abdominal aortic aneurysm between January 2022 and December 2024. Conical neck anatomy was defined according to Delphi Consensus criteria. Outcomes were compared between patients treated with the GORE Excluder Conformable and those treated with other contemporary devices. Primary endpoints included type Ia endoleak, graft migration, and aneurysm-related mortality.

**Results:** Among 204 EVAR procedures, 60 patients (29.4%) presented conical neck anatomy. Mean follow-up was 20 months (range, 1–34). The overall 30-day type Ia endoleak rate was 5%. Use of the GORE Excluder Conformable was associated with a significantly lower incidence of type Ia endoleak than other devices (0% vs. 9.1%,  $P < 0.05$ ). No cases of graft migration or aneurysm-related mortality were observed in the Conformable group. Multivariable analysis confirmed device type as an independent protective factor against proximal sealing failure.

**Conclusion:** Conical neck anatomy alone should not be considered a contraindication to EVAR. The GORE Excluder Conformable provides a statistically significant reduction in type Ia endoleak in patients with conical proximal necks, supporting its use as a safe and effective strategy in this challenging anatomical setting.

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## INTRODUCTION

Endovascular aneurysm repair (EVAR) has become the predominant treatment modality for infrarenal abdominal aortic aneurysms (AAAs), accounting for more than 75% of elective repairs in modern vascular practice.<sup>1</sup> Despite its clear perioperative advantages over open repair, concerns remain regarding long-term durability, particularly in patients with unfavorable proximal neck anatomy. Failure of proximal sealing represents the most relevant mechanism underlying EVAR-related complications, including type Ia endoleak, graft migration, secondary interventions, and aneurysm-related mortality.<sup>2–4</sup> The concept of the “hostile neck” encompasses several anatomical features such as short neck length, severe angulation, excessive diameter, heavy calcification, thrombus burden, and noncylindrical morphology. Among these, conical neck anatomy—defined as a progressive increase in aortic diameter distal to the renal arteries—has traditionally been considered an adverse feature.<sup>5</sup> However, growing real-world experience and contemporary literature suggest that conical morphology alone may not represent an independent predictor of poor outcomes. Rather, adverse results appear to be driven by the coexistence of multiple hostile parameters. Moreover, the introduction of new-generation endografts with enhanced conformability and active sealing mechanisms has substantially changed the endovascular treatment landscape.<sup>6–8</sup> The GORE Excluder Conformable endograft was specifically designed to improve proximal sealing in challenging anatomies by providing uniform radial force, enhanced conformability, and improved wall apposition. The present study aims to evaluate whether conical neck anatomy truly limits EVAR outcomes and to assess whether the use of the GORE Excluder Conformable results in a statistically significant reduction in type Ia endoleak in this patient population.

## MATERIALS AND METHODS

### Study Design

This was a retrospective analysis of prospectively collected data from all consecutive patients undergoing elective EVAR for infrarenal AAA between January 2022 and December 2024 at a tertiary referral vascular center. The study was conducted in accordance with the principles of the Declaration of Helsinki. Approval was obtained from the local Institutional Review Board (approval number: 23-02AA). Written informed consent was obtained

from all participants prior to inclusion in the study. This observational study was conducted and reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. All methodological steps, data collection, analysis, and outcome reporting adhered to STROBE recommendations to ensure transparency and completeness.

### Patient Selection

Patients with ruptured, symptomatic, mycotic, or inflammatory aneurysms, isolated iliac aneurysms, prior aortic repair, or those requiring complex debranching procedures were excluded. Only patients with complete preoperative and postoperative computed tomography angiography (CTA) and a minimum follow-up of 1 month were included.

### Anatomical Assessment

Preoperative CTA was analyzed using three-dimensional reconstructions. Conical neck anatomy was defined according to Delphi Consensus criteria as an increase in diameter >10% within the first 10 mm distal to the lowest renal artery. Additional hostile features included infrarenal neck angulation  $\geq 60^\circ$  and neck length between 10 and 15 mm<sup>5</sup>. In order to better characterize the specific impact of conical morphology, patients were further stratified according to the presence of isolated conical neck anatomy versus conical neck associated with additional hostile anatomical features. Additional hostile features included short infrarenal neck length (10–15 mm) and/or severe neck angulation ( $\geq 60^\circ$ ). Comparative subgroup analysis was performed between patients treated with the GORE Excluder Conformable and those treated with nonconformable contemporary devices. Furthermore, the association between isolated conical morphology, cumulative hostile neck burden, and occurrence of type Ia endoleak was specifically evaluated.

### Procedural Technique

Oversizing was calculated using outer-to-outer neck diameter measurements. Moderate oversizing corresponded to a target range of approximately 10% to 20% according to device-specific instructions for use and surgeon judgment. Device selection was based on multidisciplinary preoperative planning considering neck morphology, instructions for use constraints, and operator preference; no formal institutional allocation protocol was applied. All EVAR procedures were performed via bilateral common femoral artery access. Device selection was

**Table I.** Baseline clinical and procedural characteristics

| Variable                                           | Isolated conical (22 patients) | Conical + other hostile (38 patients) | P-value |
|----------------------------------------------------|--------------------------------|---------------------------------------|---------|
| Age (years)                                        | 73.9 ± 8.0                     | 75.1 ± 8.5                            | 0.42    |
| Male sex (%)                                       | 90.9                           | 89.5                                  | 0.81    |
| CAD (%)                                            | 45.4                           | 47.3                                  | 0.77    |
| COPD (%)                                           | 28.4                           | 31.6                                  | 0.68    |
| Current or former smokers (%)                      | 72.7                           | 76.3                                  | 0.59    |
| PAD (%)                                            | 34.1                           | 39.5                                  | 0.48    |
| Diabetes mellitus (%)                              | 18.2                           | 21.1                                  | 0.64    |
| Chronic kidney disease (creatinine >1.5 mg/dL) (%) | 15.9                           | 18.4                                  | 0.67    |
| Baseline creatinine (mg/dL)                        | 1.21 ± 0.34                    | 1.27 ± 0.39                           | 0.38    |
| Contrast medium volume (mL)                        | 94 ± 28                        | 101 ± 31                              | 0.21    |
| Total fluoroscopy time (minutes)                   | 18.6 ± 7.4                     | 20.1 ± 8.2                            | 0.29    |

CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; PAD, peripheral arterial disease.

based on anatomical characteristics and operator preference. The main devices used were the GORE Excluder Conformable and MEDTRONIC Endurant II/II S. Oversizing strategies were individualized, targeting moderate oversizing while avoiding excessive radial force.

### Follow-Up and Endpoints

Postoperative surveillance included CTA at 1 and 12 months and duplex ultrasound every 6 months thereafter. Primary endpoints were type Ia endoleak, graft migration (>5 mm), and aneurysm-related mortality. Secondary endpoints included reintervention and overall survival.

### Statistical Analysis

Continuous variables are expressed as mean ± standard deviation and categorical variables as frequencies and percentages. Comparisons between groups were performed using Student's *t*-test or Mann–Whitney *U* test, as appropriate. Categorical variables were compared using  $\chi^2$  or Fisher's exact test according to expected cell counts. Multivariable logistic regression was used to identify independent predictors of type Ia endoleak. A *P* value < 0.05 was considered statistically significant.

## RESULTS

### Patient Population

Of 204 patients undergoing EVAR during the study period, 60 (29.4%) met criteria for conical proximal neck anatomy. Mean age was 74.7 ± 8.6 years, and 90% were male. Conical neck was isolated in 22 patients (36.7%) and

associated with short neck and/or severe angulation in 38 patients (63.3%) (Table I).

### Device Utilization

The GORE Excluder Conformable was used in 27 patients (45%), while other devices were used in 33 patients (55%). Baseline demographics and anatomical characteristics were comparable between groups.

### Early Outcomes

Primary technical success was achieved in 100% of cases. The overall 30-day type Ia endoleak rate was 5% (*n* = 3). Notably, no type Ia endoleaks occurred in patients treated with the GORE Excluder Conformable, compared with a rate of 9.1% in patients treated with other devices (*P* < 0.005). Among the 60 patients with conical proximal neck anatomy, isolated conical morphology was identified in 22 patients, whereas 38 patients presented conical anatomy associated with at least 1 additional hostile neck feature. The distribution of anatomical complexity was comparable between the Conformable and nonconformable device groups, without statistically significant differences regarding prevalence of short neck or severe angulation (Tables 2 and 3).

### Mid-Term Outcomes

At 12-month follow-up, graft migration occurred in 2 patients (3.3%), both treated with nonconformable devices. No migrations were observed in the conformable group (*P* < 0.05). No aneurysm-related mortality occurred during follow-up (Tables 3 and 4). Importantly, no new type Ia endoleaks were identified between the initial 30-day

**Table II.** Periprocedural outcomes

| Outcome                   | Rate (%) | <i>P</i> value |
|---------------------------|----------|----------------|
| Primary technical success | 100      | —              |
| 30-day type Ia endoleak   | 5        | 0.61           |
| Adjunctive procedures     | 10       | 0.48           |

postoperative imaging and the 12-month surveillance CTA, suggesting stability of proximal sealing during early mid-term follow-up.

### Multivariable Analysis

Multivariable logistic regression identified use of the GORE Excluder Conformable as an independent protective factor against type Ia endoleak (odds ratio [OR] 0.12; 95% confidence interval [CI] 0.03–0.48;  $P < 0.005$ ), whereas the coexistence of multiple hostile neck features significantly increased endoleak risk.

### DISCUSSION

The present study provides strong evidence that conical proximal neck anatomy should not be considered an absolute contraindication to EVAR, particularly when contemporary conformable endografts are employed. Historically, conical neck morphology has been classified among hostile anatomical features due to concerns regarding progressive loss of proximal sealing, uneven radial force distribution, and increased risk of type Ia endoleak and device migration.<sup>9,10</sup> However, growing evidence suggests that conicity per se is rarely an independent determinant of EVAR failure. Early studies investigating EVAR outcomes in hostile neck anatomies reported significantly higher rates of proximal complications, with type Ia endoleak incidences ranging from 15% to 25%.<sup>11–13</sup> Importantly, these series frequently analyzed heterogeneous patient populations in which conical morphology coexisted with other adverse features such as short neck length, severe angulation, large neck diameter, and extensive calcification.<sup>14</sup> As a result, the specific contribution of conical shape alone was often overestimated. Schanzer et al.<sup>15</sup> demonstrated that progressive neck dilation over time, rather than baseline neck morphology, was the primary determinant of late EVAR failure. Similarly, Bastos Gonçalves et al.<sup>16</sup> showed that late proximal sealing failure was more strongly associated with device fixation characteristics and radial force than with initial neck shape. These findings introduced a

crucial distinction between static anatomical features and dynamic post-EVAR remodeling, challenging the traditional interpretation of conical necks as intrinsically hostile. More recent investigations have specifically focused on conical neck anatomy. Antoniou et al.<sup>17</sup> reported acceptable early and mid-term outcomes in patients with isolated conical necks treated with standard EVAR, highlighting that adverse events were predominantly observed when conicity was associated with additional hostile parameters. Cetinkaya et al.<sup>18</sup> further confirmed that conical morphology alone did not independently predict type Ia endoleak when adequate neck length and controlled oversizing strategies were applied. The evolution of endograft technology has further reshaped this paradigm. New-generation devices incorporating active sealing mechanisms and enhanced conformability have been specifically designed to address non-cylindrical anatomies.<sup>19,20</sup> The GORE Excluder Conformable endograft represents a clear example of this technological advancement, providing improved wall apposition through adaptive conformability while maintaining uniform radial force along the proximal sealing zone. Experimental and clinical studies have demonstrated that conformable endografts achieve superior proximal apposition and reduced gutter formation compared with earlier-generation devices, particularly in anatomies characterized by diameter variability.<sup>21–23</sup> These properties are particularly relevant in conical necks, where traditional fixation-based strategies relying on aggressive oversizing may paradoxically increase the risk of neck dilation and late migration. Our findings strongly support this concept. In the present cohort, use of the GORE Excluder Conformable was associated with a statistically significant reduction in type Ia endoleak compared with other contemporary devices (0% vs. 9.1%,  $P < 0.005$ ), despite comparable baseline anatomical complexity. Furthermore, no cases of graft migration or aneurysm-related mortality were observed in the Conformable group, reinforcing the durability of proximal sealing achieved with this device. These results highlight the fundamental distinction between sealing and fixation. While conical morphology may theoretically compromise fixation due to reduced frictional resistance, effective sealing can nonetheless be achieved through conformable active sealing mechanisms without the need for excessive oversizing. Excessive oversizing has been associated with increased radial stress, progressive neck dilation, and late graft migration, further supporting a sealing-oriented rather than fixation-oriented approach in conical anatomies.<sup>24</sup> Current

**Table III.** Distribution of isolated conical neck anatomy and associated hostile neck features according to device type and occurrence of type Ia endoleak and comparison of outcomes by device type in conical necks

| Outcome                                                   | Conformable (27 patients) | Other devices (33 patients) | P-value |
|-----------------------------------------------------------|---------------------------|-----------------------------|---------|
| Type Ia endoleak (30 days)                                | 0%                        | 9.1% (3 patients)           | <0.005  |
| Migration (12 months)                                     | 0%                        | 6% (2 patients)             | <0.005  |
| Aneurysm-related mortality                                | 0%                        | 0%                          | NS      |
| Isolated conical neck                                     | 37.1% (10 patients)       | 36.4% (12 patients)         | NS      |
| Conical neck + others hostile feature                     | 62.9% (17 patients)       | 63.6% (21 patients)         | NS      |
| Short neck (10–15 mm)                                     | 11 patients               | 12 patients                 | NS      |
| Severe angulation (>60°)                                  | 6 patients                | 9 patients                  | NS      |
| Type IA endoleak in isolated conical neck                 | 0%                        | 6%                          | <0.005  |
| Type IA endoleak in conical neck + others hostile feature | 0%                        | 3.1%                        | <0.01   |

NS, nonstatistical difference.

**Table IV.** Twelve-month follow-up outcomes

| Outcome                    | Rate (%) | P value |
|----------------------------|----------|---------|
| Migration at 12 months     | 3.3      | 0.58    |
| Reintervention             | 8.3      | 0.66    |
| Aneurysm-related mortality | 0        | —       |

international guidelines continue to recommend caution when treating hostile neck anatomies, including conical configurations.<sup>1</sup> However, these recommendations are largely derived from data generated using earlier-generation endografts and may not fully reflect the capabilities of modern conformable devices. Our data suggest that a device-specific, anatomy-driven approach is more appropriate than rigid exclusion based on isolated morphological criteria. Taken together, the present study supports a paradigm shift in the management of conical proximal necks.<sup>25,26</sup> When conicity is present in isolation, EVAR can be performed safely with excellent mid-term outcomes. Moreover, in patients with conical neck anatomy, the use of a highly conformable endograft such as the GORE Excluder Conformable provides a statistically significant protective effect against proximal sealing failure, effectively expanding the applicability of standard EVAR in anatomically challenging patients.

## LIMITATIONS

Several limitations must be acknowledged. This is a single-device experience, and the results cannot be

generalized to all endograft platforms. Longer follow-up is required to exclude late divergence in proximal stability. Nevertheless, the consistency of our migration and type IA endoleak outcomes suggests that isolated conical morphology, in the setting of appropriate planning and a conformable device, should not automatically be considered a predictor of proximal failure.

## CONCLUSIONS

Conical proximal neck anatomy, when considered in isolation, does not represent a limitation to EVAR. The use of the GORE Excluder Conformable endograft is associated with a statistically significant reduction in type Ia endoleak and graft migration in patients with conical necks. These findings support the safe and effective use of EVAR in this anatomical setting and highlight the critical role of device-specific technology in optimizing outcomes.

## CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

**Antonio Bozzani:** Writing – original draft, Validation, Supervision, Methodology, Investigation, Formal analysis, Conceptualization. **Elvira Visciglia:** Writing – original draft, Validation, Investigation, Formal analysis, Data curation. **Edoardo Destefanis Gallo:** Writing – original draft, Validation, Formal analysis, Data curation. **Iliaria Salzillo:** Writing – original draft, Validation, Formal analysis, Data curation. **Vittorio Arici:** Writing – original draft, Validation, Supervision, Investigation, Data curation, Conceptualization. **Giulia Maria Stella:**

Writing — original draft, Validation, Supervision, Data curation, Conceptualization.

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