◆CLINICAL INVESTIGATION ◆

Endovascular Repair of Abdominal Aortic Aneurysms With Reverse Taper Neck Anatomy Using the Endurant Stent-Graft: Analysis of Stent-Graft Oversizing

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Purpose: To evaluate endovascular repair of infrarenal abdominal aortic aneurysms (AAA) using the Endurant stent-graft and compare the outcomes of patients with different neck anatomies, particularly as pertains to stent-graft oversizing.
Methods: A retrospective review was conducted of 75 consecutive patients (69 men; mean age 75 years) undergoing endovascular AAA repair using the Endurant Stent Graft System from December 2008 to September 2011. The mean AAA size was 57±10 mm (range 51–92), with a mean proximal neck length of 33±10 mm (9–127) and a mean infrarenal neck angulation of 25°±15° (0°–91°). Patients were stratified according to neck anatomy [reverse taper (n=22) vs. inside (n=44) and outside (n=9) the Instructions for Use (IFU) criteria]. Standard safety and efficacy outcome measures were augmented by measurements of the percent oversizing at the proximal and distal neck and volumes of the proximal neck and stent-graft.
Results: Technical success was 100% in all groups, with no early or late type Ia endoleak detected in any group. Procedure time, contrast volumes, and radiation dosages were comparable in all groups. The reverse taper neck group had stent-graft diameters and volumes that were significantly larger (p=0.007) than the other groups. The proximal neck oversizing of the endograft was significantly greater (p=0.008) in the reverse taper neck group (42.9%±17.5%) compared to the within the IFU group (30.1%±11.7%). Over a mean follow-up of 20 months (range 14–46), there were no aneurysm-related deaths and 9 type II endoleaks (5 in the reverse taper neck group; overall, 3 were treated and 6 resolved spontaneously). The outside the IFU group suffered no endoleak of any type and had no secondary interventions.
Conclusion: The Endurant stent-graft can be utilized with acceptable results in more challenging neck anatomies, such as those with a reverse taper, as long as there is adequate oversizing of the stent-graft.

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Key words: endovascular aneurysm repair, stent-graft, abdominal aortic aneurysm, aorta, anatomy, neck anatomy, endoleak, oversizing, reverse taper neck

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The Endurant stent-graft, which was designed to conform to complex anatomical variations of the aorta,[1] has demonstrated effectiveness and versatility over midterm follow-up in the Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE),[2] as well as case series from individual institutions.[3–12] Furthermore, these findings were established both according to the criteria in the Instructions for Use (IFU), as well as in situations outside the scope of the IFU, such as in "hostile neck." The "reverse taper neck," a significant diameter increase caudally along the proximal aortic neck, is not included in the IFU for this device. This type of contoured neck has been associated with an increased risk of type Ia endoleak, likely owing to reduced wall-endograft contact along the proximal seal zone and the altered hemodynamic forces in the area of the graft not in contact with the wall.[13] Thus, the presence of a reverse taper neck increases the risk for proximal endoleak, device failure, and late migration.[14]

Since the early days of endografting,[15,16] oversizing of the proximal endograft in relation to the normal aortic neck diameter has been deemed essential to ensure an adequate seal,[15–20] particularly in short, irregular, and angulated necks. Typically, the degree of oversizing recommended by stent-graft manufacturers is 10% to 20%, but oversizing to 30% or more has been employed.[17–20] In their classification system for aneurysm neck morphology to aid in stent-graft planning, McDonnell et al.[21] suggested that oversizing to the most distal and largest diameter in a reverse taper neck would reduce the risk of a proximal endoleak.

Because there have been few reports regarding the use of the Endurant stent-graft in the reverse taper neck and none analyzing stent-graft oversizing, we sought to evaluate the application of the Endurant stent-graft in patients with proximal aortic neck anatomy considered outside the IFU criteria, with specific attention to the degree of stent-graft oversizing.

METHODS

Study Design

A retrospective review was conducted of consecutive patients undergoing endovascular repair using the Endurant Stent Graft System (Medtronic Endovascular, Santa Rosa, CA, USA) from December 2008 to September 2011 at two hospitals in Western Australia. Both hospitals approved the study, and all patients consented to the collection and analysis of demographic and outcome data. All patients were asymptomatic, and all procedures were performed electively. Every patient had either an infrarenal AAA with or without a common iliac artery aneurysm of a size appropriate for intervention.[2] The demographic characteristics of each patient were collected prospectively onto the department database.

Anatomical Evaluation

All patients underwent preoperative computed tomographic angiography (CTA) to accurately define the arterial anatomy for selection of the appropriately sized endograft. Measurements were performed on a TeraRecon workstation using the latest Aquarius iNtuition software (TeraRecon Inc., San Mateo, CA, USA). All measurements were performed by a vascular surgeon (B.P.M.) with experience in sizing aortic aneurysms for stent-graft repair and were independently verified by a second vascular surgeon (V.V.). The proximal and distal neck diameters (inner-to-inner wall), infrarenal neck length, and supra- and infrarenal angulation were measured, and the presence of neck calcification or thrombus was determined.

Definitions and Calculations

A standard neck was defined as one with non-significant calcification and/or thrombus that satisfied both length and angulation criteria for the IFU for the Endurant stent-graft (Table 1), namely a length $\geq$10 mm with $\leq$60° infrarenal and $\leq$45° suprarenal angulation OR $\geq$15 mm if the angulation was $\leq$75° infrarenal and $\leq$60° suprarenal. A reverse taper proximal neck (Fig. 1) was one in which there was an increase in axial diameter $\geq$2 mm for every 5 mm distal from the most caudal renal artery, specifically, a diameter greater than the proximal sealing zone of the stent-graft.

TABLE 1
Instructions for Use

Proximal neck ≥10 mm in length with non-significant calcification and/or non-significant thrombus with ≤60° infrarenal and ≤45° suprarenal angulation.
Proximal neck ≥15 mm in length with non-significant calcification and/or non-significant thrombus with ≤75° infrarenal and ≤60° suprarenal angulation.
Aortic neck diameters ranging from 19 to 32 mm.
Distal fixation length ≥15 mm.
Iliac diameters ranging from 8 to 25 mm.
Adequate iliac or femoral access.
Morphology suitable for aneurysm repair.

An infrarenal proximal aortic neck ≤10 mm long, i.e., a distance ≤10 mm from the most caudal renal artery to the start of the aneurysm bulge, was considered a short neck. An aortic neck with an angle ≥60° within the first 20 mm from the most caudal renal artery defined an angulated neck.

Patients who fit the anatomical criteria for the proximal neck as determined by the manufacturer (standard neck) were compared to those with neck anatomy outside of the IFU and to those with reverse taper necks.

The volume of the proximal neck was approximated utilizing the formula for the volume of a frustum (truncated cylindrical cone in which a plane parallel to the base cuts off the apex; Fig. 2). This was compared to the volume of the cylindrical segment of the proximal stent-graft over the same length.

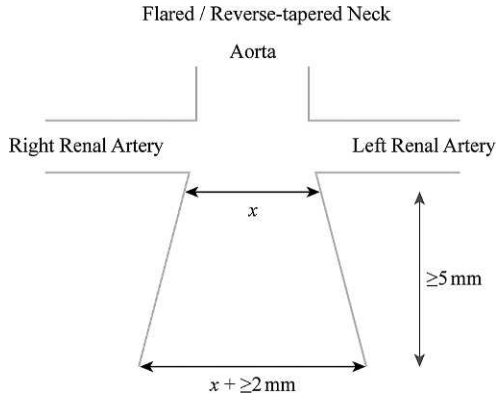

Figure 1 ◆ Schematic representation of a flared neck, which is defined as an increase in the proximal diameter ≥2 mm over a distance of ≥5 mm distal to the most caudal renal artery. *X* is the maximum diameter of the aortic neck just caudal to the lowest renal artery.

Patient Cohort

In the observation period, 75 patients (69 men; mean age 75 years) underwent endovascular repair using the Endurant stent-graft (Table 2). The mean AAA size was 57±10 mm (range 51–92), with a mean proximal neck length of 33±10 mm (9–127) and a mean infrarenal neck angulation of 25°±15° (0°–91°). More than a third (31, 41.3%) of the patients had a reverse taper neck (22, 29.3%) or were outside the IFU based on the proximal neck anatomy (9, 12.0%).

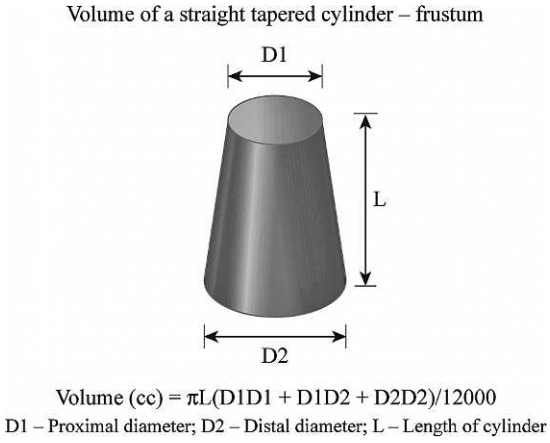

Figure 2 ◆ Schematic diagram and formula for the calculation of the volume of a frustum, which is the truncated portion of a solid cone that is left after cutting off a top section with a plane parallel to the base. To calculate its volume, the proximal aortic neck was assumed to be geometrically similar to a frustum.

TABLE 2
Demographic Data and Preoperative Risk Factors in the 3 Study Groups

	Outside IFU Neck (n=9)	Reverse Taper Neck (n=22)	Standard Neck (n=44)	p
Age, y	75.5 (52–86)	75.3 (56–88)	75 (53–90)	NS
Men	9 (100%)	20 (90.9%)	40 (90.9%)	NS
ASA				
I	0 (0%)	0 (0%)	0 (0%)	NS
II	2 (22.2%)	7 (31.8%)	7 (15.9%)	NS
III	4 (44.5%)	12 (54.6%)	27 (61.4%)	NS
IV	3 (33.3%)	3 (13.6%)	10 (22.7%)	NS
Comorbidities				
Hypertension	4 (44.4%)	15 (68.1%)	36 (81.8%)	NS
Angina	0 (0%)	3 (13.6%)	7 (15.9%)	NS
Myocardial infarction	0 (0%)	8 (36.6%)	14 (31.8%)	NS
Heart failure	1 (11.1%)	0 (0%)	4 (9.09%)	NS
Arrhythmia	2 (22.2%)	1 (4.5%)	7 (15.9%)	NS
Stroke	0 (0%)	4 (18.1%)	0 (0%)	0.005
TIA	0 (0%)	2 (9.1%)	2 (2.27%)	NS
PVD	1 (11.1%)	3 (13.6%)	13 (29.5%)	NS
Hypercholesterolemia	2 (22.2%)	9 (40.9%)	28 (63.6%)	NS
Diabetes mellitus	1 (11.1%)	5 (22.7%)	9 (20.4%)	NS
Asthma	1 (11.1%)	1 (4.5%)	3 (6.81%)	NS
COPD	1 (11.1%)	5 (22.7%)	7 (15.9%)	NS
Renal impairment	1 (11.1%)	5 (22.7%)	8 (18.1%)	NS
Dialysis	0 (0%)	1 (4.5%)	0 (0%)	NS
SCr, mmol/L	83.6 (63–112)	122 (58–534)	97 (58–186)	NS
Preoperative	83.6 (63–112)	122 (58–534)	97 (58–186)	NS
Postoperative	84.2 (61–112)	113 (64–241)	96 (50–145)	0.03

Continuous data are presented as the means (range); categorical data are given as the counts (percentage).
IFU: instructions for use, ASA: American Society of Anesthesiologists, TIA: transient ischemic attack, PVD: peripheral vascular disease, COPD: chronic obstructive pulmonary disease, SCr; serum creatinine, NS: not significant.

Operative Procedure

All patients underwent elective AAA stent-graft repair either under general or regional anesthesia. Common femoral arterial access was achieved either percutaneously or by open cutdown. Deployment of the Endurant stent-graft was performed according to the IFU. A Reliant balloon (Medtronic Endovascular) was used in all cases to mold the stent-grafts after deployment. The side through which the bifurcated stent-graft body was inserted (ipsilateral side), the length of the procedure, the screening time (from the arterial puncture to the removal of the last sheath), the type and volume of contrast, the radiation dosage, and the codes for all of the implanted stent-graft components, were recorded. The need for adjunctive procedures during the primary operation, such as the deployment of an aortic cuff, extra iliac components, or the use of other balloons, coils, or stents apart from the endograft, was also documented.

Follow-up Protocol and Endpoints

All patients underwent a standard post-implantation CTA, plain abdominal radiography, and clinical evaluation at 1 month, 6 months, 1 year, and annually thereafter. Prior to the CTA examination, all patients were stratified as either low [estimated glomerular filtration rate (eGFR) $>$60 mL/min/1.73 m^2], intermediate (eGFR between 30 and 60 mL/min/1.73 m^2), or high (eGFR $<$30 mL/min/1.73 m^2) risk for contrast use. If after 1 year of follow-up, the CT scan did not reveal any graft-related adverse events, then patients who were classified either high or intermedi-

TABLE 3
Preoperative AAA Morphological Assessments and Perioperative Data in the 3 Study Groups

	Outside IFU Neck (n=9)	Reverse Taper Neck (n=22)	Standard Neck (n=44)	p
Infrarenal neck length, mm	27.7±13.5 (9–48)	23.6±14.0 (9–76)	38.2±19.5 (13–127)	0.005
Neck diameter proximal, mm*	21.5±3.1 (18–28)	22.6±2.5 (19–28)	22.2±2.7 (18–29)	NS
Neck diameter distal, mm†	23.5±2.7 (20–28)	26.9±2.7 (22–32)	23.5±2.7 (20–31)	NS
Infrarenal neck angle, °	69.7±18.2 (30–91)	20.0±20.2 (0–75)	19.8±18.7 (0–50)	<0.001
Operative time, min	118.2±35.5 (60–170)	140.6±59.9 (55–300)	120.0±35.8 (75–245)	NS
Contrast volume, mL	170.0±51.4 (98–245)	168.6±64.2 (75–332)	141.0±49.0 (50–250)	NS
Screening time, min	36.1±16.6 (13–65)	31.5±14.7 (12–69)	25.9±8.6 (12–46)	0.03*
Radiation dosage, mGy*cm^2	370.1±212.5 (51–650)	418.0±542.5 (120-2502)	403.2±436.2 (66–2444)	NS
General anesthesia	7 (77.8%)	15 (68.2%)	36 (81.2%)	—
Percutaneous approach	6 (66.7%)	19 (86.4%)	39 (88.6%)	—
Use of proximal aortic cuff	2 (22.2%)	2 (9.1%)	0 (0%)	0.01
Technical success	100%	100%	100%	NS
Length of stay, d	5.8 (3–11)	8.2 (3–25)	5.7 (1–24)	NS

Continuous data are presented as the means ± standard deviation or median (range); categorical data are given as the counts (percentage).
AAA: abdominal aortic aneurysm, IFU: instructions for use, NS: not significant
* Just caudal to the lowest renal artery.
† At beginning of the aneurysm sac.

ate risk were followed only by abdominal ultrasound and plain abdominal radiography.

Primary outcome measures were the technical and clinical success of device deployment and aneurysm exclusion, respectively; the presence and type of endoleak on follow-up (early <30 days and late >30 days); endograft migration; and the presence of any aneurysm-related deaths. Secondary outcomes included surgical complications, the need for adjunctive endovascular procedures during primary deployment, and the occurrence and type of any of postoperative secondary interventions.

Statistical Analysis

Continuous data are presented as the means ± standard deviation or median (range); categorical data are given as the counts (percentage). A Student *t* test was used for comparison of continuous variables, and a chi-square analysis was used for comparison of nominal data. $P<0.05$ was considered to be statistically significant. Statistical analysis was performed using PASW Statistics (version 18; IBM Corporation, Somers, NY, USA).

RESULTS

Immediate Outcome

Intraoperative technical success was achieved in all cases. To obtain satisfactory seal at the aortic neck, 4 patients required an aortic cuff as an intraoperative adjunctive procedure. Of the 2 patients in the reverse taper neck group who required a cuff, the first patient had a type Ia endoleak that was resolved by an extension and coil deployment at the lower part of the neck. The second patient had a suboptimal suprarenal fixation across both renal arteries without endoleak. In the outside the IFU group, 2 patients had a proximal aortic cuff deployed during the initial procedure for short, highly angulated (>75°) necks.

No intraoperative conversion, migration, types I/III endoleak, major complication, or death occurred at the completion of the operations. The procedure times, contrast volumes, and radiation dosages were comparable in all groups (Table 3). However, screening time (puncture to sheath removal) was shorter in the standard neck group when compared to the reverse taper or outside the IFU neck groups (p=0.03).

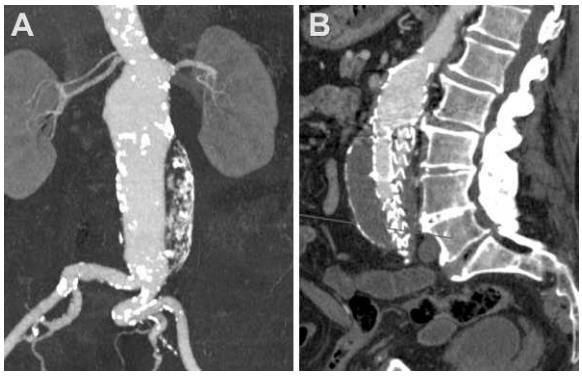

Figure 3 ◆ (**A**) Volume-rendered CTA displaying a short flared infrarenal aortic neck; both renal artery origins are calcified with >60% stenosis of the left renal artery. (**B**) CTA 1 month after implantation of an Endurant stent-graft. Oversizing >30% and coil deployment has ensured good apposition of the stent-graft in this case along the short flared proximal sealing zone, but a mild inversion of the suprarenal stent can be identified, with no adverse effect.

Follow-up

The mean follow-up was 20 months (range 14–46); 67 (89.3%) patients reached 1-year follow-up and 71 (94.7%) had at least one postoperative clinical evaluation with radiography and CTA. There were no type Ia endoleaks observed in any of the groups during follow-up. Among the 42 patients in the standard aortic neck group who had follow-up, 4 patients developed type II endoleaks within 6 months after implantation of the stent-graft. One of these underwent coil embolization of the inferior mesenteric artery (due to aneurysm growth), and the remainder of the type II endoleaks resolved spontaneously by 12 months. One patient had an acute graft limb occlusion that required an emergent crossover bypass. There were 2 late (>30 days) non-aneurysm-related deaths in this group (myocardial infarction and cancer, respectively).

Five of the 22 patients in the reverse taper neck group demonstrated type II endoleaks within 6 months of implantation. Two patients underwent successful coil embolization of the inferior mesenteric artery and the remainder resolved spontaneously. One patient had an acute graft limb occlusion requiring an emergent crossover bypass. There were 2 non-aneurysm-related deaths: one within 30 days and one at 6 months (Fig. 3).

The outside the IFU group suffered no endoleak of any type, and no secondary interventions had to be performed on these 9 patients. There was 1 non-aneurysm-related death (cardiac) within 3 months of surgery.

Stent-Graft Oversizing

Compared to the standard neck or outside the IFU groups, patients with a reverse taper neck had significantly greater oversizing of their Endurant stent-grafts at the proximal end of the seal zone (Table 4, $p<0.05$). At 20 mm distal to the most caudal renal artery (the distal end of the seal zone), there was no significant difference in the amount of stent-graft oversizing among the 3 groups.

TABLE 4
Proximal Dimensions of the Endurant Stent-Graft in the 3 Study Groups

	Outside IFU Neck (n=9)	Reverse Taper Neck (n=22)	Standard Neck (n=44)	p
Neck diameter oversizing, %				
Proximal	38.9±25.9 (17.9–86.5)	42.9±17.5 (21.4–86.5)	30.1±11.7 (8.2–60.0)	0.008
Distal	26.1±11.4 (1.02–48.1)	19.3±12.1 (0.0–48.2)	22.5±10.3 (4.2–52.4)	NS
Neck volume, mL*	7.1±2.8 (3.5–12.1)	8.8±2.7 (3.5–13.9)	8.2±2.05 (4.7–14.4)	NS
Stent-graft volume, mL*	11.9±3.87 (9.2–20.4)	14.6±4.3 (7.4–20.4)	12.0±3.5 (7.4–20.4)	0.007
Stent-graft volume oversizing, %	77.4±47.3 (36.0–171.5)	70±37.5 (20.0–172.0)	63.3±26.9 (14.1–143.6)	NS
Stent-graft diameter, mm	28 (25–36)	32 (25–36)	28 (25–36)	0.007

Continuous data are presented as the means ± standard deviation or median (range).
IFU: instructions for use, NS: not significant.
* Approximated value over the first 20 mm of the neck.

The volume of the proximal neck approximated utilizing the formula for the volume of a frustum was not significantly different for the 3 groups of patients. There was, however, a significant difference in the volume of the grafts utilized in the reverse taper group, which was related to the larger diameter grafts deployed in this cohort (p=0.007). The reverse taper neck patients all had stent-grafts that were significantly larger in diameter: 32 mm compared to 28 mm for stent-grafts in patients with standard or outside the IFU necks.

DISCUSSION

Stent-graft oversizing ensures an adequate seal in the proximal landing zone, thus reducing the risk of distal migration and proximal endoleak.[16–21] Oversizing between 10% to 20% has been associated with a significant reduction in the proximal endoleak rate.[22] However, excessive oversizing (>20%) of the endoluminal device has been associated with continued neck dilatation,[23] late distal migration, and the so-called "guttering" effect secondary to graft infolding at the proximal graft-aorta seal zone, thus increasing the risk of a type Ia endoleak.[18] van Prehn et al.[19] performed a meta-analysis of 23 articles concerning proximal endograft oversizing. They reported conflicting outcomes in situations of >30% oversizing; in cases with up to 25% oversizing, there was a decrease in proximal endoleaks.

Sternberg et al.[18] reported that there was potentially an increase in distal migration in Zenith endografts that had been oversized >30%, but even in this subgroup, no type Ia endoleak was discovered. Of their >30% oversize patient cohort, almost a third had a reverse taper neck, but there was no significant relationship between a reverse taper neck and continued neck dilatation at 1 year. The degree of proximal endograft oversizing also did not correlate with aortic neck dilatation at 1 year.

We suggest that excessive oversizing, up to 30% and greater, is appropriate when planning endovascular AAA repair. Our data show a 0% type Ia endoleak rate, and no evidence of distal migration at 12 months in all subsets of aneurysms, specifically, within the IFU criteria and outside the IFU. We have demonstrated that moderate oversizing of the endograft to the most distal and largest aortic diameter in a reverse taper neck leads to an excessive percent oversizing in comparison to the proximal neck diameter. Despite this large proximal oversize, we did not see any evidence of guttering or failure to achieve a proximal seal. The same holds true for the highly angulated neck. The volume difference between the proximal stent-graft and proximal aortic neck was similar in all 3 groups examined. Thus, the amount of graft-wall interaction observed in a standard neck is similar to that observed in the reverse taper neck and others outside the IFU criteria.

We hold that the oversizing of the Endurant stent-graft system to the most distal neck diameter allows enhanced wall contact, thus improving the proximal seal from radial forces. We further propose that such an oversized Endurant stent-graft, coupled with the suprarenal barbed fixation, prevents distal migration. This excessive oversizing does not lead to the infolding effect that has been previously reported but apparently compensates for the flaring of the aortic wall and overcomes any significant angulation.

The use of the Endurant stent-graft system utilized outside of the recommended IFU did not lead to any aneurysm- or device-related complications. Although guidelines exist for the use of this stent-graft system, it is up to clinical practitioners to utilize their own judgment to balance between the extremely rigorous inclusion criteria that would exclude a large number of patients and the willingness to tolerate unacceptable anatomy, which could predispose patients to both early and delayed complications. Thus, expansion of the current indications for the oversizing of the Endurant endograft in particular situations would allow those patients with anatomical variants, who would normally be excluded from having a stent-graft, to undergo endoluminal repair. A frustum-shaped neck does not seem to exclude the use of a standard stent-graft with suprarenal fixation.

Limitations

First, the current study was a retrospective analysis of prospectively collected data. Second, a larger sample size and a randomized controlled trial would likely achieve more robust findings. The calculation of the volume of the proximal aortic neck is an approximation based on the assumption of a uniform geometric shape. Longer follow-up will also be important to determine the long-term outcomes of the use of the endograft outside of the IFU.

Conclusion

The results from our study add to the published literature regarding the positive benefits of utilizing the Endurant stent-graft in hostile proximal neck anatomy. Early and midterm outcomes indicate that the Endurant endograft may be utilized with acceptable results in more challenging anatomies, such as with reverse taper necks, as long as there is adequate oversizing of the graft. Skilled operators in high-volume centers should probably perform the endovascular management of this selected group of patients.

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