Influence of endograft oversizing on device migration, endoleak, aneurysm shrinkage, and aortic neck dilation: Results from the Zenith multicenter trial

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Background: **Generous endograft oversizing has been associated with propensity for aortic neck dilation and subsequent device migration in endografts without suprarenal fixation. Effects of variable oversizing of endografts with suprarenal fixation have been poorly studied.**

Methods: **Three hundred fifty-one patients underwent endovascular AAA repair (EVAR) in a prospective multicenter trial using the Zenith AAA Endovascular Graft, a fully supported bifurcated 3-piece endograft with barb-enhanced suprarenal stent fixation. Blinded core-laboratory measurement of variables was prospectively recorded at predischarge and at 1, 6, 12, and 24 months after the procedure. Potential influence of endograft oversizing on subsequent aortic neck dilation (minor axis), aneurysm shrinkage (major axis), device migration, endoleak, rupture, open conversion, and death were retrospectively studied. Data are given as mean ± SEM.**

Results: **Risk of endograft migration (>5mm) at 12 months was 2.3% (6/261). However, patients with endograft oversizing of >30% had a 14% (4/29) migration risk compared with those oversized ≤30% (0.9%, 2/232), $P < .002$. There was zero device migration by the SVS definition (>10 mm or clinical event). Device oversizing >30% was associated with decreased AAA sac shrinkage (48% vs 77%) and with increased sac enlargement (9.5% vs 0.6%) at 24 months when compared with oversizing of ≤30%, respectively ($P = .001$). Incidence rate of any endoleak at 12 and 24 months was 8.2% (21/256) and 7.1% (12/169), respectively. Oversizing of endografts by >30% was associated with an increased type II endoleak rate (11 vs 4.7%) that failed to reach statistical significance ($P = .27$). Aortic neck diameters increased significantly by 6 months ($P < .001$) but then stabilized through 24 months; the absolute changes at 1 (n = 298), 6 (n = 278), 12 (n = 264), and 24 months (n = 171) were 0.66 ± 0.10 mm (3.0%), 1.32 ± 0.11 mm (5.6%), 1.38 ± 0.12 mm (5.9%), and 1.44 ± 0.16 mm (6.1%), respectively. Linear regression analysis demonstrated no correlation between endograft oversizing and aortic neck dilation at 12 ($P = .86$) or 24 months ($P = .64$).**

Conclusions: **Device migration and endoleaks were very infrequent after treatment with the Zenith AAA Endovascular Graft. However, endograft oversizing of >30% was associated with an ~14-fold increase in device migration (>5 mm) at 12 months and with a ~16-fold increased risk of AAA expansion at 24 months. Although further follow-up will be essential to assess whether these early associations continue, avoidance of excessive endograft oversizing is recommended.**
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Precise sizing of aortic endografts increasingly has been recognized as an important element in attaining optimal early and late outcomes after endovascular abdominal aortic aneurysm repair (EVAR). In particular, the increased risk of type I endoleaks with inadequate oversizing has been emphasized. Mohan et al[1] found that the risk of type I endoleaks was significantly increased with oversizing of <10%. Using a model derived from these clinical data, they predicted a reduced type I endoleak rate with 10% to 20% device oversizing.[1]

Most endograft manufacturers indeed recommend a device oversize of 10% to 20% greater than the minor axis of the aortic neck. This degree of oversizing generally translates into use of an endograft that is 3 to 5 mm larger than the adventitia-to-adventitia measurement of the minor-axis aortic neck diameter. However, greater amounts of oversizing have been selectively used for a variety of reasons, including the perception that larger oversizing might be beneficial for treatment of challenging aortic neck anatomy.[2] However, Conners et al[3] found an association of >20% device oversizing with late aortic neck dilation and subsequent endograft migration. In that study, a self-expanding, modular, fully nitinol-supported device without hook or barb fixation had been employed.[3] It is unknown whether other endograft designs will react similarly to generous oversizing.

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*See Appendix.

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The purpose of this study was to examine the potential influence of device oversizing on subsequent endograft migration, aneurysm sac changes, endoleak, and aortic neck dilation using a fully supported trimodular device with suprarenal barb-enhanced fixation.

METHODS

This study was a retrospective analysis of multicenter data that was prospectively collected by a core-laboratory facility. Patients for EVAR were enrolled in the Zenith multicenter clinical trial. (For a list of the Zenith investigators, see the Appendix.) There were 3 EVAR cohorts: standard–medical risk group, high–medical risk group, and a "roll-in" group, consisting of patients with either standard or high medical risk. All groups had to conform to similar anatomic inclusion criteria and were thus pooled for purposes of this study. Detailed inclusion and exclusion criteria have been detailed elsewhere.[4] Briefly, anatomic inclusion in the trial required an aortic neck of $\geq$15 mm in length and $\leq$28 mm in diameter, with $\leq$10% change in diameter in the first 15 mm of the neck. Angulation of the aortic neck to the aneurysm sac or the suprarenal aorta was limited to $<60°$ and $<45°$, respectively.

The Zenith AAA Endovascular Graft is a bifurcated 3-piece device. It has a bare suprarenal stent with 10 to 12 barbs for enhanced fixation. It is fully supported with self-expanding Z-stents, placed on the inside of the Dacron material at the aortic and iliac fixation sites, and on the exterior of the device in the remainder of the body and limbs. The 5 available body lengths are designed to place the bifurcation of the device close to the iliac artery bifurcation. Aortic component devices are available in sizes from 22 to 32 mm, delivered through preloaded 18- to 20-Fr. sheaths. Iliac diameters extend to 24 mm, allowing treatment of ectatic common iliac vessels.

Anatomic patient selection was rigorously controlled by physician film reviewers who had no clinical interaction with the patient. Candidates were rejected from inclusion in the study if they did not fall within the previously described anatomic criteria. The suggested device oversizing at the aortic neck was 10% to 15%. The graft size that was implanted was based upon the collaboration between the national study proctors and investigator at each site. However, the site investigator made the final determination of all device sizing, including aortic oversizing.

Patients underwent computed tomography (CT) scanning postoperatively (within 7 days), then at 1, 6, and 12 months, and yearly thereafter. The study protocol mandated a CT slice thickness of $\leq$3 mm. CTs with and without intravenous contrast were required. Anatomic measurements used in this study were made by the study core laboratory personnel. Potential variation in measurement between investigative sites and the core laboratory was not examined.

Axial CT images were assessed on computer workstations (NIH Image), and measurements were performed electronically. A physician reviewer evaluated all chosen table positions against the entire CT as well as the outline of the vessel. Thus, all measurements were reviewed by a minimum of two people. Formal measurement of interobserver and intraobserver variability was not performed. Other imaging modalities (arteriograms, CT arteriograms, magnetic resonance arteriograms, and 3-D CT reconstructions) were not routinely required. Aortic neck diameter was measured in its minor axis from adventitia to adventitia. This measurement was taken at the ostium of the lowest renal artery. AAA sac size was measured at its major axis. The initial postoperative CT measurement of AAA size was employed as the baseline for subsequent comparison for changes is AAA sac size. Potential migration of the endograft was assessed by measuring the distance between the top of the bare suprarenal stent and the lowest renal artery. In cases in which the ostium of the lowest renal artery was seen in more than 1 cut, the image representing the more caudal aspect of the vessel was employed. The junction of the uncovered suprarenal stent and the covered portion of the endograft could not be reliably seen on axial CTs. Therefore, direct measurement of the distance between the lowest renal artery and the covered portion of the device was not possible.

Continuous and dichotomous measures were assessed using independent 2-sample t tests and Yates-corrected Pearson χ^2 tests, respectively. Change with time was assessed with multivariate repeated-measures ANOVA. Multivariate logistic regression was performed to assess predicate factors of outcome. All analyses were performed using Systat version 10.2 (SPSS, Chicago, IL). A P value of $<.05$ was considered significant.

The study design of this trial was a collaborative effort of the national primary investigators (R.K.G. and T.A.M.C.) and Cook, Inc, the study sponsor. Cook was also involved with data collection. The primary author (W.C.S.) and coauthors had unfettered access to all raw and tabulated data, including the source-imaging studies. Thus, the authors of this paper are solely responsible for the data analysis and interpretation, manuscript preparation, and timing of the manuscript's oral presentation and ultimate publication.

RESULTS

Three hundred fifty-one patients were treated with the Zenith AAA Endovascular Graft in a multicenter FDA phase II trial. These patients included all standard-risk, high medical–risk, and "roll-in" cohorts. Of these, the large majority (88%, 309) had endograft oversizing of $\leq$30%, whereas 12% (41) had endografts that were oversized by $>$30%. There were 1 or more patients in whom the endograft was oversized by $>$30% at 13 of 15 investigative sites (range, 0 to 7 patients). One patient received a custom device and was excluded from these analyses.

Migration. By recently revised Society for Vascular Surgery reporting standards, migration is considered to be $>$10-mm movement of the device or any endograft displacement with associated need for a secondary procedure.[5] By this definition, endograft migration was zero (0/261) at 12 months. However, more modest caudal migration ($>$5

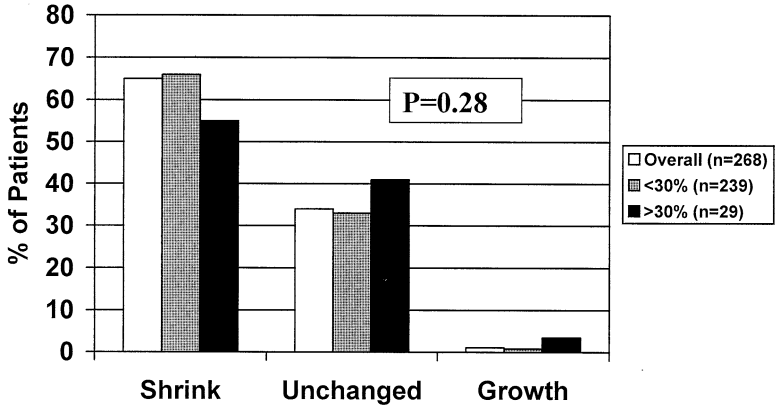

Fig 1. Effect of device oversizing (≤30% vs >30%) on AAA sac behavior at 12 months. AAA shrinkage (*Shrink*) was considered >5 mm reduction, *Unchanged* was −5 to +5 mm change, and *Growth* was >5 mm increase in size.

Table I. Possible anatomic risk factors for endograft migration (>5 mm) at 12 months

Risk factor	*No migration*	*Migration (>5 mm)*	*Odds ratio (95% confidence limits)*	P *value (statistic)*
Neck diameter, mean ± SEM (n)	24.5 ± 0.2 (253)	24.3 ± 0.6 (6)	0.972 (0.72, 1.31)	.85 (*t* test)
Neck length, mean ± SEM (n)	33.3 ± 1.0 (254)	24.6 ± 7.0 (6)	0.952 (0.89, 1.02)	.17 (*t* test)
Neck angulation, mean ± SEM (n)	21.2 ± 1.1 (210)	27.3 ± 6.1 (4)	1.023 (0.97, 1.08)	.44 (*t* test)
Neck shape, % (n)				.67 (Fisher's exact test)
Funnel	0.8 (2/255)	0 (0/6)	NA	
Inverted funnel	6.7 (17/255)	0 (0/6)	NA	
Irregular[§]	9.4 (24/255)	17 (1/6)	1.77 (0.20, 15.76)*	
Parallel	83 (212/255)	83 (5/6)		
Endograft oversizing, % (n)				.0016[†] (Fisher exact test)
≤30%	99 (230/232)	0.9 (2/232)		
>30%	86 (25/29)	14 (4/29)	18.4 (3.22, 106.01)[‡]	

NA, Not applicable.
*Odds ratio comparing irregular with parallel.
[†]Multivariate analysis confirmed endograft oversizing as the sole predictor for device migration at 12 months.
[‡]Odds ratio comparing ≤30% to >30%.
[§]Asymmetric bulge.

mm) was noted in 2.3 % (6/261) of patients at 12 months. No cranial migration was observed. Endograft oversizing of >30% was associated with a ~14-fold increase in the risk of device migration (>5 mm) at this time point: 14% (4/29) incidence vs 0.9% (2/232) with ≤30% oversizing (P = .002). No patient with migration had clinical sequelae or need for a secondary procedure. A single barb fracture was seen in 1 patient with migration. Possible associated anatomic risk factors for migration were also examined (Table I). At 12 months, endograft oversizing was the only predictor of device migration (> 5 mm) with univariate and multivariate analysis. There were no significant differences in aortic neck length, diameter, angulation, or shape in patients with or without migration.

Additionally, the association of a flared aortic neck with device oversizing was examined. Patients with flared aortic necks were defined as those with ≥3 mm aortic neck enlargement that measured 15 mm caudal to the lowest renal artery ostium. There was a 15% (45/305) and 27% (11/41) rate of flared aortic necks in patients with ≤30% and >30% device oversizing, respectively (P = .08). There was no significant relationship between a flared neck and neck dilation at 12 months (P = .09) or at 24 months (P = .40) by linear regression analysis.

AAA shrinkage. At 12 months, the entire cohort (Fig 1), 65% (174/268) experienced significant shrinkage (>5 mm sac reduction), 34 % (91/268) remained unchanged (−5 to + 5 mm), and 1.1 % (3/268) enlarged (>5 mm).[4] At 24 months (Fig 2), there was a 73% (128/175), 25% (44/175), and 1.7% (3/175) rate of shrinkage, stability, and growth, respectively. Endograft oversizing by >30% was associated with a lower shrink rate (48% vs 77%) and with a ~16-fold higher expansion rate (9.5% vs 0.6%) at 24 months that was significant (P = .001; Fig 2).

Aortic neck dilation. When compared with the preoperative measurements, there was no significant increase in neck diameter at the immediate postimplant measurement (0.07 ± 0.12 mm, P = .57). When compared with the immediate postimplant diameter, there was significant aortic neck dilation by 6 months (1.3 mm, P < .001) that

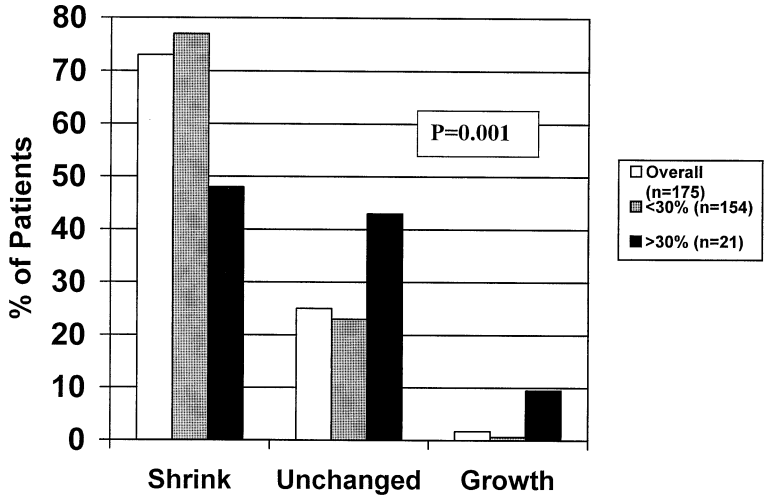

Fig 2. Effect of device oversizing (≤30% vs >30%) on AAA sac behavior at 24 months. AAA shrinkage (*Shrink*) was considered >5 mm reduction, *Unchanged* was −5 to +5 mm change, and *Growth* was >5 mm increase in size.

Table II. Changes in aortic neck diameter

	Follow-up (mo)			
Parameter	*1*	*6*	*12*	*24*
n	298	278	264	171
% Change (mean ± SEM)	3.0 ± 0.4	5.6 ± 0.4	5.9 ± 0.5	6.1 ± 0.7
Absolute change (mm)	0.7 ± 0.1	1.3 ± 0.1	1.4 ± 0.1	1.4 ± 0.2

then plateaued through 24 months (Table 2). Percentage of device oversizing did not correlate with aortic neck dilation at 12 months (r^2 = 0; P = .86) or 24 months (r^2=0.001; P = .69) by linear regression.

Endoleak. Risk of any endoleak was 8.2 % (21/256) at 12 months and 7.1 % (12/169) at 24 months. Most of these endoleaks were type II. Risk of a type I or III endoleak was 1.9% (5/256) at 12 months and 0 (0/169) at 24 months.[4] Potential effect of device oversizing is shown in Table III. There was a >50% higher incidence rate of type II endoleaks with >30% device oversizing (4.8% vs 11%) that did not achieve statistical significance at 12 (P = .17) or 24 months (P = .27).

Nine patients were identified intraoperatively with a proximal Type I endoleak, as noted by the site. Per protocol, aggressive treatment of Type I (proximal or distal) and Type III endoleaks was required. Treatment for the proximal Type I endoleaks identified during the procedure was physician dependent and ranged from use of a molding balloon (5 patients), molding balloon and Zenith main body extension (1 patient), and Zenith main body extension and commercially available stent (1 patient). Additionally, 1 patient was not treated at the time of the procedure, and this patient's Type I endoleak resolved by the time of hospital discharge. One additional patient had an endoleak that remained at the time of hospital discharge.

Table III. Possible effect of endograft oversizing on endoleak

		Endograft oversizing, % (n)		
Endoleak type	*Follow-up (mo)*	*<30%*	*>30%*	P
All	12	7.9 (18/229)	11 (3/27)	.47
Type I & III	12	2.2 (5/229)	0 (0/27)	.99
Type II	12	4.8 (11/29)	11 (3/27)	.17
Type IV	12	0	0	NA
All	24	6.7 (10/150)	11 (2/19)	.63
Type I and III	24	0	0	NA
Type II	24	4.7 (7/150)	11 (2/19)	.27
Type IV	24	0	0	NA

NA, Not applicable.

Other end points. There was 1 late rupture in the entire cohort, occurring in the group whose endografts were oversized by ≤30% (0.3% [1/309] vs 0 [0/41], P = .99). Late open conversions were also infrequent and not statistically different between groups (1.3% [4/309] vs 2.4% [1/41], P = .99). There were no conversions to open repair in the first 30 days after EVAR. Finally, death at 12 months (6.1% [19/309] vs 7.3% [3/41], P = .99) and 24 months (12% [38/309] vs 20% [8/41], P = .30) was not different between those oversized ≤30% or >30%, respectively.

DISCUSSION

Potential influence of endograft oversizing on subsequent adverse events after EVAR was evaluated from prospectively collected multicenter data.

Oversizing and migration. Using this robust and impartial database, device migration at 12 months was found to be infrequent after treatment with the Zenith AAA Endovascular Graft. By the SVS definition of migration, there was zero incidence of endograft migration at 12

months. By a stricter definition of migration (>5 mm), 2.3% were noted to have caudal movement of the device at 12 months. Of these, ≤30% device oversizing was associated with a 0.9% (2/232) rate of migration, whereas there was a 14.1% (4/27) rate of migration in patients with >30% oversizing. These differences were highly significant ($P = .001$). Univariate and multivariate analysis of anatomic aortic neck characteristics failed to demonstrate any other significant variables that were associated with device migration.

Migration of the Zenith endograft has been an uncommon event in previous reports. In a single-center series from the University of California at San Francisco, no episodes of migration were seen after treatment of 116 patients with the Zenith endograft with a mean follow-up of 10.3 ± 9.8 months (range, 1 to 34 months).[6] The Nottingham group reported a 5-year experience (mean follow-up of 20.6 ± 14.9 months) with the Zenith endograft, with only a single episode of migration (1/94, 1.1%).[7] This case was associated with late aortic neck dilation. The 5-year cumulative migration rate in this study was 7% by Kaplan-Meier analysis.[7] Finally, Greenberg et al[8] reported on 528 patients treated in Europe, Australia, and the United States with a mean follow-up of 14 months (range, 1 to 36 months). In this large data set, 8 patients who had been treated with an earlier prototype of the device with fewer suprarenal barbs had migration at 2 to 3 years after implantation.[8]

Experimental studies have suggested that the suprarenal barb fixation of the Zenith endograft resists migration more rigorously than does many other endograft designs.[9] The mean displacement force in a cadaveric model for the Zenith device was 24 N. An endograft with infrarenal hooks required 12.5 N, whereas a third endograft relying on radial force required only 4.5 N of displacement force.[9] Aortic necks with larger diameters and significant angulation create greater static downward forces on the endograft, exceeding 8 to 12 N in some anatomic cases.[10] This dynamic flow modeling has been confirmed in the clinical observation of high migration rates in patients with large aortic necks after treatment with an endograft without active fixation.[11]

The etiology of increased migration (>5 mm) with >30% device oversizing is unclear. The multiple suprarenal barbs of the device are frequently transmural in the aorta, with forceful caudal movement causing aortic tears in experimental models.[9] This scenario is unlikely, as no suprarenal pseudoaneurysms have been seen in these patients. Migration of the device could infer failure of the barbs. However, isolated single-barb fractures have been seen in only a few patients. Moreover, the number of barbs (10-12) on the Zenith device was designed to provide redundant protection from migration. A second possible failure mode of the barbs would be initial failure of the barbs to penetrate the aorta. Routine use of a compliant "molding" balloon during implantation encourages engagement of the barbs. The downward orientation of the barbs may require 2 to 3 mm of device migration for full engagement of the aorta. Experimental models with Gianturco Z stent-based endografts have demonstrated folds in the proximal fabric with stent oversizing.[12] These folds or invaginations in the fabric grew larger with increases in stent oversizing. Although type I endoleaks would seem to be the greatest concern regarding such a phenomenon, theoretically fixation of the device could also be compromised.

Oversizing and aortic neck change. Changes in aortic neck diameter after EVAR could have important implications in long-term durability of this treatment. Significant dilation may lead to loss of seal or to fixation of the endograft, causing a proximal type I endoleak, caudal endograft migration, or both. The mechanisms of attaining a proximal seal and secure fixation differ significantly among endograft designs. The propensity for these severe adverse events after late aortic neck dilation could be device dependent, although this is speculative. Finally, the amount of late aortic neck dilation itself may be endograft dependent.

The present study found a small but significant change in aortic neck diameter at 6 months after implantation that then stabilized at 12 and 24 months. What factors might predispose to late aortic neck dilation? Conners et al[3] found a strong correlation with >20% device oversizing and subsequent late neck dilation at 2 and 3 years after treatment with a self-expanding, modular, fully nitinol-supported device. However, increased device oversizing did not appear to accelerate aortic neck dilation by the 2-year mark in the present study. The reasons for disparity of these observations are speculative. The most obvious explanation is that different endograft designs may have variable late effects on the aortic neck. However, other anatomic factors or differences in other patient characteristics cannot be excluded as contributing factors.

Oversizing and endoleak and shrinkage rates. Device oversizing by >30% had a negative impact on AAA sac behavior. At 24 months, the risk of AAA growth was elevated by ~16-fold (9.5% vs 0.6%), and the incidence of AAA shrinkage was decreased (48% vs 77%) in those with >30% and ≤30% oversizing, respectively. In previous studies with Zenith[13] and other endograft devices,[14] increased endoleak rates have been associated with a decrease in AAA shrinkage.

In the current study, endoleaks were infrequent after treatment with the Zenith device (8.2% and 7.1% at 12 and 24 months, respectively). This low endoleak rate compared favorably with that seen with other endografts. Endoleak rates at 12 and 24 months in AneuRx trial patients[15] were 13.9% and 16.7%, and in Excluder trial patients,[16] the rates were 17% and 20%, respectively. In the Zenith study, >30% device oversizing was associated with >50% increase in type II endoleaks that did not achieve statistical significance. There were no differences in the more troublesome type I endoleak, but it is possible that some of the increase in type II endoleaks may have actually been misclassified type I leaks. Thus, although it would appear intuitive that higher endoleak rates might negatively affect shrink rates, a robust statistical correlation is lacking. As such, the underlying

explanations for the striking negative effect of > 30% device oversizing on AAA sac behavior remain speculative.

Could the choice of >30% device oversizing simply be a marker for adverse anatomic characteristics that are known to negatively affect outcome? This study demonstrated no statistically significant differences in this area but did find some trends that ultimately could be clinically important. Those patients who experienced migration (>5 mm) at 12 months had shorter aortic necks (24.6 vs 33.3 mm, $P = .17$). Although this was not statistically significant, it is well known that the risk of migration increases with progressively shorter necks. There were a modestly greater percentage of patients with flared aortic necks in patients who had >30% device oversizing (27% vs 15%, $P = .08$). Patients with a flared aortic neck likely have a greater likelihood of late aortic neck dilation and resultant deleterious effects such as type I endoleaks or migration. Although this trend was not significant, further follow-up of possible such adverse anatomic findings is warranted.

Limitations. Conventional measurement of endograft migration could not be performed with this endograft. Direct measurement of the distance between the lowest renal artery and the endograft was not possible because CT could not reliably appreciate the end of the bare suprarenal stent and the beginning of the endograft. Thus, a surrogate measurement from the top of the suprarenal stent to the lowest renal artery was employed. This longer length may have increased the chance for relative inaccuracies in measurement of migration. However, the absence of any observed cranial migration would suggest that the measurement of caudal migration was not a random measurement error.

CONCLUSIONS

Device migration and endoleaks were very infrequent after treatment with the Zenith AAA Endovascular Graft. However, oversizing of >30% was associated with an increased rate of device migration at 12 months and with a negative effect on late AAA sac changes. Endoleak occurrence and late aortic neck dilation were not significantly changed by oversizing. The underlying etiology for increased caudal movement (of >5 mm) and AAA sac growth with generous oversizing is speculative. Although further follow-up will be essential to assess whether these early associations continue, avoidance of excessive endograft oversizing is recommended.

APPENDIX

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DISCUSSION

Dr Wesley S. Moore (Los Angeles, Calif). This was an excellent presentation and superbly analyzed; however, I'm still not totally convinced that the adverse effect of migration is related to the oversizing of the prosthesis. It is more likely related to the reasons that oversizing was selected to begin with.

You mentioned two possible reasons, including short neck or extreme angulation; perhaps there are more. These reasons for oversizing reflect the adverse effect based on patient selection rather than the generic consequence of oversizing per se. Clearly, there is no reason that one would want to excessively oversize unless you were trying to compensate for some particular adverse anatomic problem. Clearly there was a trend toward shorter necks in your series. Even though this trend wasn't statistically significant in your analysis, that may be a sample size problem and a type II error. Would you like to comment?

Dr Charles Sternbergh III. Thank you for those comments, and I couldn't agree more. We looked very hard for anatomic characteristics that might explain the correlation between >30% device oversizing and adverse events. As shown in this presentation, we could not identify any statistically significant associations; aortic neck length did trend shorter, although the differences were not statistically significant. The rate of endoleak was half of that in the patients who were oversized less than 30% than in the patients who were oversized greater than 30%, but this too was not statistically significant. Increased endoleak rates have correlated with a decrease in the chance of aneurysm shrinkage; but again, those trends were not significant.

Dr Jacob Buth (Eindhoven, The Netherlands). I also would like to congratulate Dr Sternbergh for an excellent paper. My question is this: How did you get to the threshold of 30%? Was this handpicked or was there any graphical or mathematical method used, like a ROC curve?

Dr Sternbergh. That's an excellent question. No, there were not ROC curves developed for this study. Thirty percent was chosen because it was double the size of the recommended maximum oversizing, which was 10% to 15%.

Dr David C. Brewster (Boston, Mass). Dr. Sternbergh, I'm a little surprised about migration with suprarenal hooks. I can understand where oversizing of a device without such fixation might be associated with a higher incidence of migration, but wouldn't one expect that suprarenal hook fixation would prevent that? And secondly, as a participant in the Zenith trial, the device selection was pretty tightly controlled, as I remember, by the sponsor, so why would 30% oversizing occur in certain patients if that wasn't desirable?

Dr Sternbergh. I'll start with your first question. I agree that any incidence of migration, frankly, was somewhat surprising based on the suprarenal barb fixation. But the data do suggest a small chance of migration (>25 mm) despite the suprarenal fixation.

In regard to the choice of oversizing, I, too, was surprised to find that a number of the patients had this excessive oversizing. And while I too recall that there was some significant oversight in terms of sizing of these devices, it was ultimately left to the discretion of the investigator.

Dr Piergiorgio Cao (Perugia, Italy). You report low incidence of migration, which is quite different from our experience. We had a higher incidence of migration with a different kind of endograft: the highest peak migration was after 2 years. You reported the results after 1 year. Do you have any other data after this interval?

And the second question is this: since you couldn't find any correlation between migration and neck dilatation, can you speculate where this migration is coming from? What is the cause since, you have no

Dr Sternbergh. I very much agree with you that migration is a time-dependent phenomenon and 12 months is fairly early. I don't have any available data yet on more long-term migration, but certainly that's going to be an important thing to keep an eye on. Your last question really is another question of why are these migrating. And the bottom line is that we don't know. We looked very hard for other anatomic characteristics that perhaps were the causative factor(s), and the >30% oversizing was simply a surrogate, but we could not find them.