Classification Systems For Characterizing Aortic Necks

David J Minion, MD

The Pericles Registry

PAPERS OF THE 135TH ASA ANNUAL MEETING

Collected World Experience About the Performance of the Snorkel/Chimney Endovascular Technique in the Treatment of Complex Aortic Pathologies

The PERICLES Registry

Konstantinos P. Donas, MD, Jason T. Lee, MD,† Mario Lachat, MD,‡ Giovanni Torsello, MD, PhD,§ and Frank J. Veith, MD,¶ on behalf of the PERICLES investigators*

Objectives: We sought to analyze the collected worldwide experience with use of snorkel/chimney endovascular aneurysm repair (EVAR) for complex abdominal aneurysm treatment.

Background: EVAR has largely replaced open surgery worldwide for anatomically suitable aortic aneurysms. Lack of availability of fenestrated and branched devices has encouraged an alternative strategy utilizing parallel or snorkel/chimney grafts (ch-EVAR).

Methods: Clinical and radiographic information was retrospectively reviewed and analyzed on 517 patients treated by ch-EVAR from 2008 from 2014 by prearranged defined and documented protocols.

Results: A total of 119 patients in US centers and 398 in European centers were treated during the study period. US centers preferentially used Zenith stent-grafts (54.2%) and European centers Endurant stent-grafts (62.2%) for the main body component. Overall 898 chimney grafts (49.2% balloon expandable, 39.6% self-expanding covered stents, and 11.2% balloon-expandable bare metal stents) were placed in 692 renal arteries, 156 superior mesenteric arteries (SMA), and 50 celiac arteries. At a mean follow-up of 17.1 months (range: 1–70 months), primary patency was 94%, with secondary patency of 95.3%. Overall survival of patients in this high-risk cohort for open repair at latest follow-up was 79%.

Conclusions: This global experience represents the largest series in the ch-EVAR literature and demonstrates comparable outcomes to those in published reports of branched/fenestrated devices, suggesting the appropriateness of broader applicability and the need for continued careful surveillance. These results support ch-EVAR as a valid off-the-shelf and immediately available alternative in the treatment of complex abdominal EVAR and provide impetus for the standardization of these techniques in the future.

Keywords: abdominal aortic aneurysm, endovascular, fenestrated, thoracoabdominal, vascular

(*Ann Surg* 2015;262:546–553)

From the *Department of Vascular Surgery, St. Franziskus-Hospital Münster, Münster, Germany; †Division of Vascular Surgery, Stanford University Medical Center, Stanford, CA; ‡Division of Vascular Surgery, University Hospital Zurich, Zurich, Switzerland; §Department of Vascular Surgery, St. Franziskus-Hospital Münster, and Clinic for Vascular and Endovascular Surgery, University of Münster, Münster, Germany; and ¶Division of Vascular Surgery, New York University Medical Center, New York, NY.

Presented at the 135th Annual Meeting of the American Surgical Association, April 23–25, 2015, San Diego, CA.

Disclosure: The authors have no disclosures, and there was no funding for this study.

PERICLES investigators are as follows: Ronald L. Dalman, MD, Kenneth Tran, MD, Stanford University Medical Center, Stanford, CA; Felice Pecoraro, MD, Zurich University Hospital, Zurich, Switzerland; Theodosios Bisdas, MD, St. Franziskus-Hospital Münster, Münster, Germany; Sven Seifert, MD, Mirko Essche, MD, Clinicum Chemnitz, Chemnitz, Germany; Daniele Gasparini, MD, Paolo Frigatti, MD, University Hospital S. Maria della Misericordia of Udine, Udine, Italy; Roberto Adovasio, MD, Fabio Pozzi Mucelli, MD, University Hospital Cattinara, Trieste, Italy; Scott M. Damrauer, MD, Hospital of the University of Pennsylvania, Philadelphia, PA; Edward Y. Woo, MD, Medstar Health, Washington, DC; Adam Beck, MD, Salvatore Scali, MD, University of Florida Medical Center, Gainsville, FL; David Minion, MD, University of Kentucky Medical Center, Lexington, KY; Juha Salenius, MD, Veljekka Suominen, MD, University of Tampere, Tampere, Finland; Nicola Mangialardi, MD, Sonia Ronchey, MD, Stefano Fazzini, MD, San Filippo Neri Hospital, Rome, Italy; Gaspar Mestres, MD, Vincent Ruambas, MD, University of Barcelona, Barcelona, Spain; and Nilo J Mosquera, MD, University of Ourense, Ourense, Spain.

Supplemental digital content is available for this article. Direct URL citation appears in the printed text and is provided in the HTML and PDF versions of this article on the journal's Web site (www.annalsofsurgery.com).

Reprints: Jason T. Lee, MD, Division of Vascular Surgery, Stanford University Medical Center, 300 Pasteur Dr, Ste H3600, Stanford, CA 94305. E-mail: jdee@stanford.edu.

ISSN: 0003-4932/15/26203-0546

DOI: 10.1097/SLA.0000000000001405

The snorkel/chimney technique is an endovascular therapeutic modality for branch revascularization in complex aortic pathologies that has gained increasing popularity since the first publications in 2003 and 2007.[1,2] These techniques have emerged from the basic idea of creating a "snorkel/chimney" conduit from available off-the-shelf stents deployed into target visceral branches from a parallel course adjacent to the main intra-aortic stent-graft. Initially proposed as a bailout technique for inadvertent coverage or emergent situations, this strategy has since been employed electively in juxta- or pararenal cases with the goal to preserve or restore normal blood flow into the involved branch or branches.[3–10]

The current body of published literature on snorkel/chimney endovascular aneurysm repair (ch-EVAR) consists mainly of case reports and single center series with limited numbers of patients and follow-up. Furthermore, the majority of patients were being treated for a wide variety of aortic pathologies using nonstandardized off-the-shelf devices and follow-up protocols. As a result, critics of the snorkel/chimney approach as a mainstream strategy claim that it remains difficult to obtain a clear picture of ch-EVAR outcomes and its potential applications. With fenestrated/branched solutions slowly being approved by the Food and Drug Administration as a purpose-specific and on-label solution to complex EVAR, concerns with ch-EVAR regarding overall technical success, gutter-related type Ia endoleaks, chimney stent patency, long-term renal dysfunction, and ch-EVAR durability make this approach an oft-debated treatment strategy. The purpose of this study was to collect and analyze a large sample of the world experience with ch-EVAR from centers with significant experience and standardized protocols for operative strategy and follow-up to provide the latest evidence regarding this treatment option for complex abdominal aortic aneurysms.

METHODS

The study was conducted to evaluate the PERformance of the chImney technique for the treatment of Complex aortic pathoLogiES

- 517 patients from 13 centers.
- Mean Follow-up of 17 Months
  - 94% Primary Patency of 898 Chimney grafts
  - Mean Sac Regression = 4.4 mm
  - No aortic ruptures
  - Overall survival of 79%

Donas, et al. Ann Surg. 2015 262:546-53

PAPERS OF THE 135TH ASA ANNUAL MEETING

Collected World Experience About the Performance of the Snorkel/Chimney Endovascular Technique in the Treatment of Complex Aortic Pathologies

The PERICLES Registry

Konstantinos P. Donas, MD, Jason T. Lee, MD,† Mario Lachat, MD,‡ Giovanni Torsello, MD, PhD,§ and Frank J. Veith, MD,¶ on behalf of the PERICLES investigators*

Objectives: We sought to analyze the collected worldwide experience with use of snorkel/chimney endovascular aneurysm repair (EVAR) for complex abdominal aneurysm treatment.

Background: EVAR has largely replaced open surgery worldwide for anatomically suitable aortic aneurysms. Lack of availability of fenestrated and branched devices has encouraged an alternative strategy utilizing parallel or snorkel/chimney grafts (ch-EVAR).

Methods: Clinical and radiographic information was retrospectively reviewed and analyzed on 517 patients treated by ch-EVAR from 2008 from 2014 by prearranged defined and documented protocols.

Results: A total of 119 patients in US centers and 398 in European centers were treated during the study period. US centers preferentially used Zenith stent-grafts (54.2%) and European centers Endurant stent-grafts (62.2%) for the main body component. Overall 898 chimney grafts (49.2% balloon expandable, 39.6% self-expanding covered stents, and 11.2% balloon-expandable bare metal stents) were placed in 692 renal arteries, 156 superior mesenteric arteries (SMA), and 50 celiac arteries. At a mean follow-up of 17.1 months (range: 1–70 months), primary patency was 94%, with secondary patency of 95.3%. Overall survival of patients in this high-risk cohort for open repair at latest follow-up was 79%.

Conclusions: This global experience represents the largest series in the ch-EVAR literature and demonstrates comparable outcomes to those in published reports of branched/fenestrated devices, suggesting the appropriateness of broader applicability and the need for continued careful surveillance. These results support ch-EVAR as a valid off-the-shelf and immediately available alternative in the treatment of complex abdominal EVAR and provide impetus for the standardization of these techniques in the future.

Keywords: abdominal aortic aneurysm, endovascular, fenestrated, thoracoabdominal, vascular

(*Ann Surg* 2015;262:546–553)

From the *Department of Vascular Surgery, St. Franziskus-Hospital Münster, Münster, Germany; †Division of Vascular Surgery, Stanford University Medical Center, Stanford, CA; ‡Division of Vascular Surgery, University Hospital Zurich, Zurich, Switzerland; §Department of Vascular Surgery, St. Franziskus-Hospital Münster, and Clinic for Vascular and Endovascular Surgery, University of Münster, Münster, Germany; and ¶Division of Vascular Surgery, New York University Medical Center, New York, NY.

Presented at the 135th Annual Meeting of the American Surgical Association, April 23–25, 2015, San Diego, CA.

Disclosure: The authors have no disclosures, and there was no funding for this study.

PERICLES investigators are as follows: Ronald L. Dalman, MD, Kenneth Tran, MD, Stanford University Medical Center, Stanford, CA; Felice Pecoraro, MD, Zurich University Hospital, Zurich, Switzerland; Theodosios Bisdas, MD, St. Franziskus-Hospital Münster, Münster, Germany; Sven Setifer, MD, Mirko Esche, MD, Clinicum Chemnitz, Chemnitz, Germany; Daniele Gasparini, MD, Paolo Frigatti, MD, University Hospital S. Maria della Misericordia of Udine, Udine, Italy; Roberto Advanto, MD, Fabio Pozzi Mucelli, MD, University Hospital Cattinara, Trieste, Italy; Scott M. Damrauer, MD, Hospital of the University of Pennsylvania, Philadelphia, PA; Edward Y. Woo, MD, Medstar Health, Washington, DC; Adam Beck, MD, Salvatore Scali, MD, University of Florida Medical Center, Gainsville, FL; David Minion, MD, University of Kentucky Medical Center, Lexington, KY; Juha Salenius, MD, Veljekka Suominen, MD, University of Tampere, Tampere, Finland; Nicola Mangialardi, MD, Sonia Ronchey, MD, Stefano Fazzini, MD, San Filippo Neri Hospital, Rome, Italy; Gaspar Mestres, MD, Vincent Ruambas, MD, University of Barcelona, Barcelona, Spain; and Nilo J. Mosquera, MD, University of Ourense, Ourense, Spain.

Supplemental digital content is available for this article. Direct URL citation appears in the printed text and is provided in the HTML and PDF versions of this article on the journal's Web site (www.annalsofsurgery.com).

Reprints: Jason T. Lee, MD, Division of Vascular Surgery, Stanford University Medical Center, 300 Pasteur Dr, Ste H3600, Stanford, CA 94305. E-mail: jdlee@stanford.edu.

ISSN: 0003-4932/15/26203-0546

DOI: 10.1097/SLA.0000000000001405

METHODS

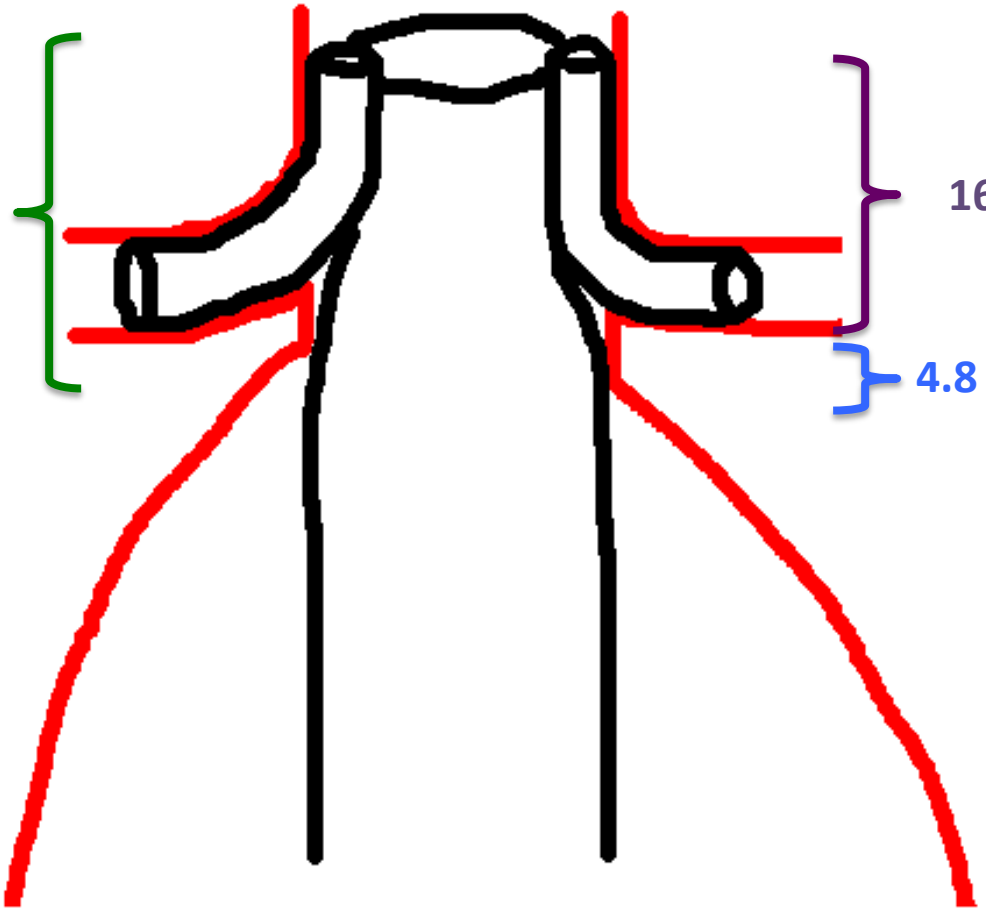
The study was conducted to evaluate the PERformance of the chIMney technique for the treatment of Complex aortic pathoLogiES

The Pericles Registry

- Type IA Endoleaks
  - Intra-operative = 7.9%
  - Late/Persistent = 2.9%
- Average Seal Length = 21 mm
- Average Infrarenal neck = 4.8 mm

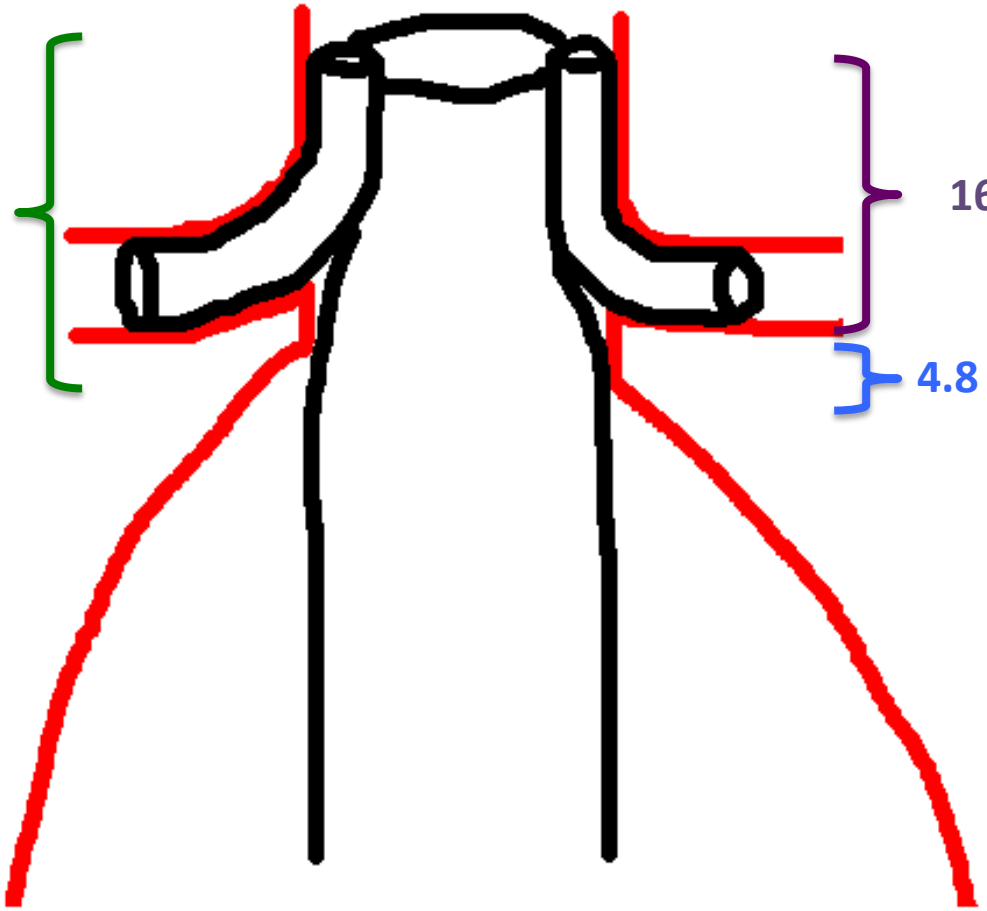
Donas, et al. Ann Surg. 2015 262:546-53

Average Pericles Neck



Defining Boundary Parameters

Minimal Neck Requirements?



21 mm Total Seal

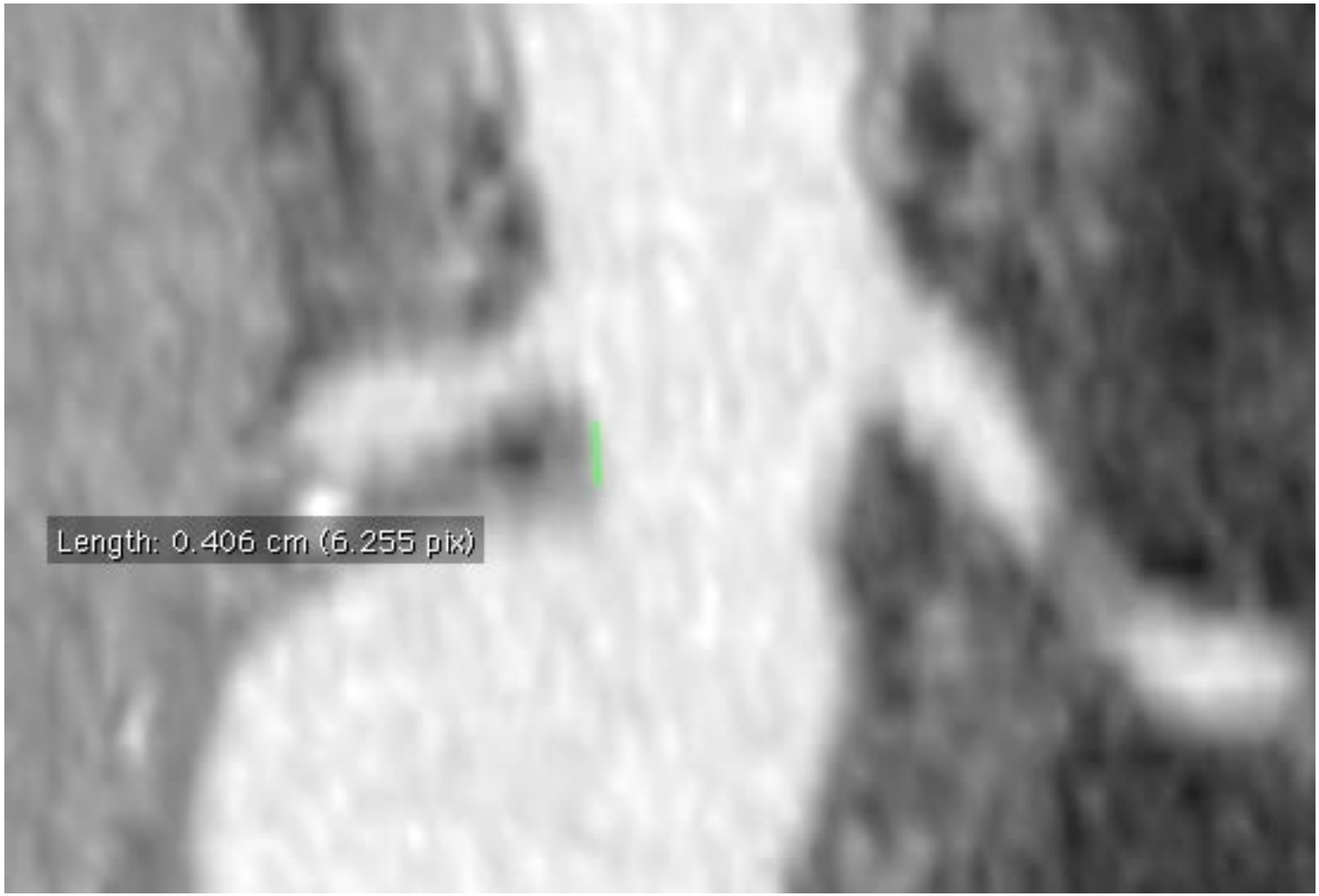
16mm “Parallel” Seal

4.8 mm “Standard” Seal

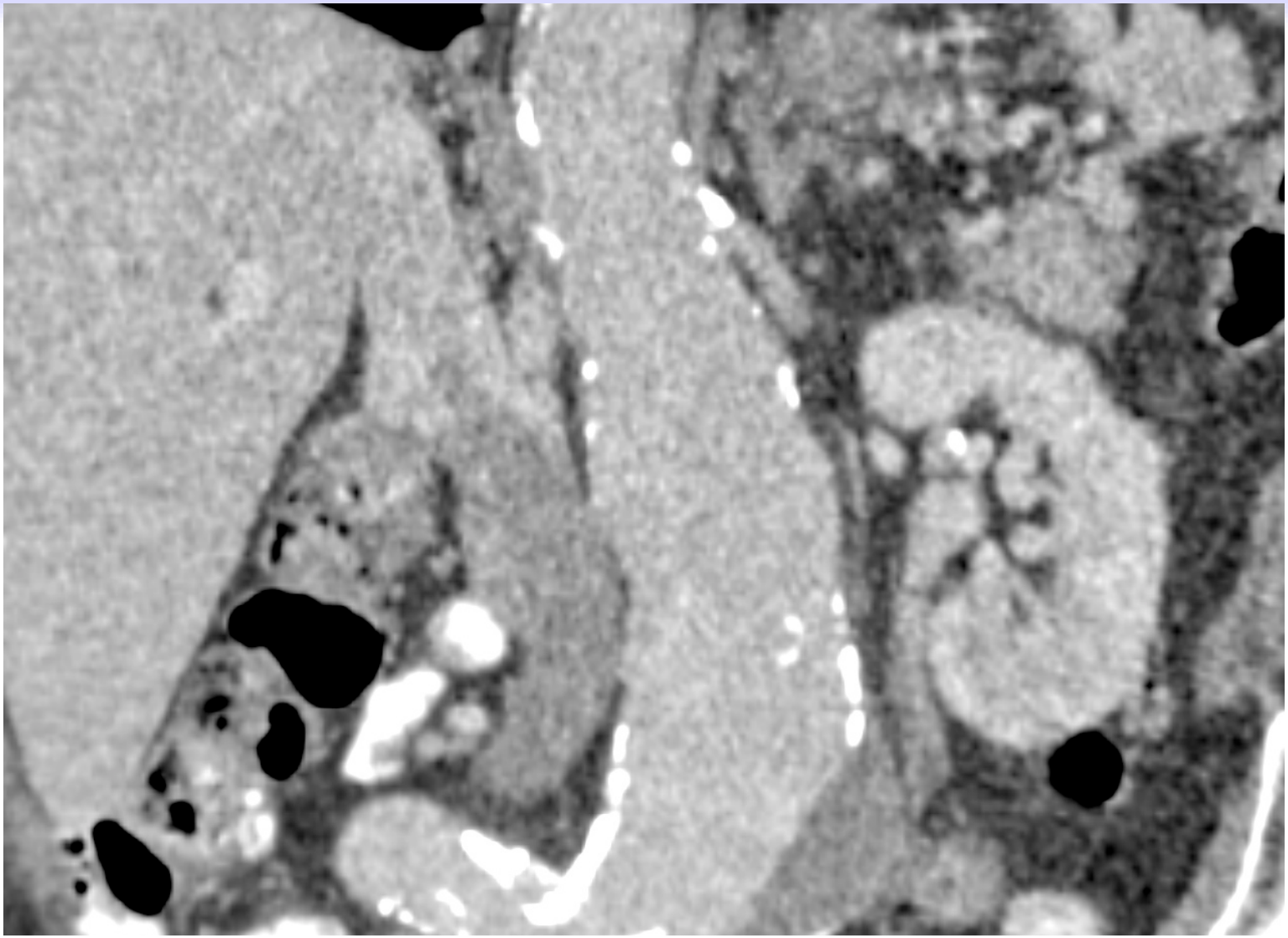
?

What Constitutes “Neck” Length?

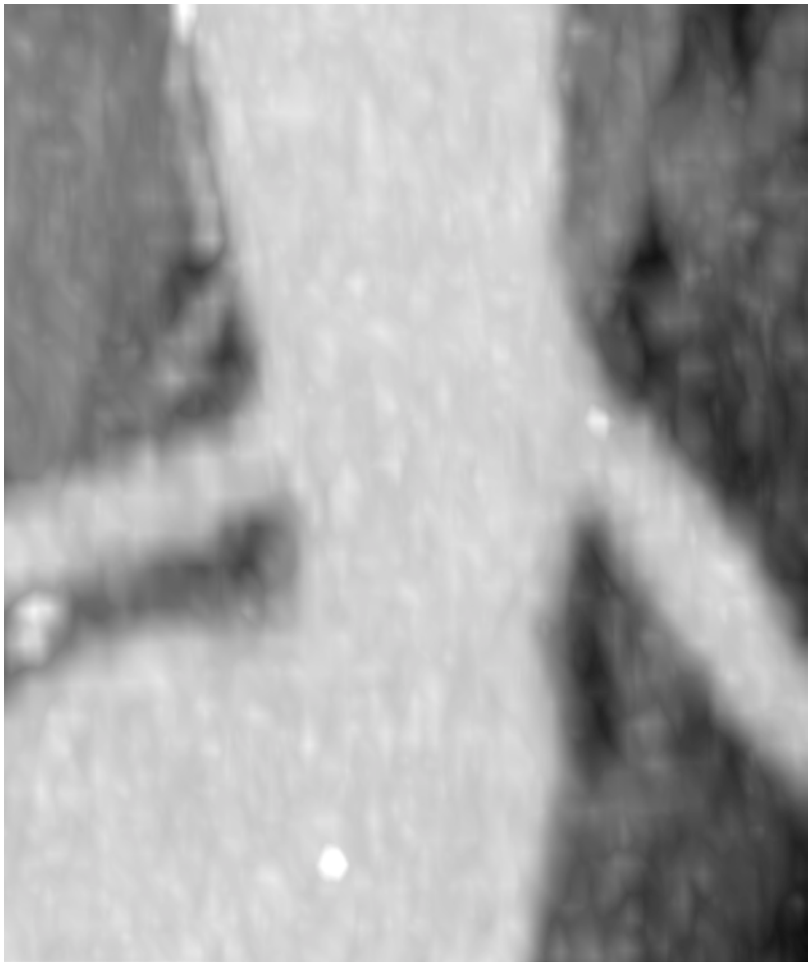
Abrupt Transition



Gradual Increasing Diameter



Two Very Different Neck Qualities



Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair

Elliot L. Chaikof, MD, PhD, Mark F. Fillinger, MD, Jon S. Matsumura, MD, Robert B. Rutherford, MD, Geoffrey H. White, MD, Jan D. Blankensteijn, MD, Victor M. Bernhard, MD, Peter L. Harris, MD, K. Craig Kent, MD, James May, MD, Frank J. Veith, MD, and Christopher K. Zarins, MD

Prospective randomization is a fundamental feature of clinical trial design because this process provides a mechanism for equal distribution among treatment arms of all factors, both recognized and hidden, that might modify outcome. Although an acceptable substitute for randomization does not exist, in the area of endovascular therapy for abdominal aortic aneurysm, practical considerations often limit the use of randomization. In this regard, adjusting for case severity mix provides a mechanism to obtain some measure of confidence in comparing the outcomes of two or more treatment protocols pursued within a single clinical trial or reported by separate investigators. Relevant examples include comparing outcomes of two or more different devices undergoing separate clinical trials; analyzing results of the same technical approach reported by different investigators; and gauging the effect of an adjunctive measure, improved device, or enhanced deployment system. Thus, it would be inappropriate to compare the outcomes of endograft repair between two studies if one was populated with healthy patients and relatively small aneurysms and the other treated more complex aneurysms among patients with significant comorbidities. The objective of adjusting for case variability is best achieved with severity scoring schemes incorporating all factors known to affect the outcome being assessed. Although scoring schemes that attempt to define the severity of associated medical comorbidities and anatomic factors have been reported for lower-extremity peripheral vascular[1] and venous disease,[2] comparable systems that are appropriate for endovascular aneurysm repair have yet to be proposed. In this report, comorbidity and anatomic schemes are offered as an initial effort to develop useful tools for the comparative analysis of data related to endovascular treatment of aortic aneurysms.

From the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/American Association for Vascular Surgery.

Competition of interest: ELC has been paid a consulting fee and received clinical research funding from Guidant. His family owns shares in the company. MFF has received a speaking fee from Medtronic. HSM has been paid a consulting fee and has received clinical research funding from Guidant, Medtronic, and WL Gore. He has also received research support from Boston Scientific. VME is a consultant to and owns stock in Guidant. JM has been paid a consulting fee by Medtronic. CZ has been paid a consulting fee by Medtronic and owns shares in the company.

Reprint requests: Elliot L. Chaikof, MD, PhD, 1639 Pierce Dr, Room 5105, Emory University, Atlanta, GA 30322 (e-mail: echaikof@emory.edu).

J Vasc Surg 2002;35:1061-6.

0741-5214/2002/$35.00 + 0 24/1/123991
doi:10.1067/mva.2002.123991

A GENERAL APPROACH FOR CATEGORIZATION AND WEIGHTING OF DISEASE SEVERITY

Optimally the design of a disease severity scoring scheme should grade each of the factors known or generally presumed to affect the outcome of endovascular repair and combine these into an overall score. In principle, factors affecting outcome can be separated into the following two general groups: (1) anatomic factors that affect technical success (successful access, accurate deployment, complete exclusion) and its durability (freedom from endoleak and secondary procedures); and (2) medical comorbidities that influence systemic morbidity and initial and late mortality. There is an advantage to scoring these two sets of factors separately, so as to allow correlation with the reported rates of technical success, persistent or recurrent endoleak, and secondary intervention on the one hand, and morbidity and mortality rates on the other. Use of such schemes, however, dictates that factors be described in sufficient detail for use of uniform grades, such as the Society for Vascular Surgery/American Association for Vascular Surgery (SVS/AAVS) 0 to 3 scale corresponding to absent, mild, moderate, and severe. With the preceding considerations in mind, a Comorbity Severity Score and an Anatomic Factor Severity Score are proposed. *Scoring all of the factors affecting outcome may seem complex when viewed in toto, but in a given report, it is probably unnecessary for all scores to be included.* One need apply only those scores that pertain to the outcome measures being investigated and reported, particularly those that affect an outcome for which a significant difference is claimed. Nevertheless, all of the scoring schemes are included in this report for the advantage of collecting prospective data in a manner that facilitates later analysis.

RISK STRATIFICATION BASED UPON COMORBID MEDICAL CONDITIONS: A COMORBIDITY SEVERITY SCORE

Cardiac deaths, related primarily to coronary artery disease, dominate the early and late mortality rates for both open surgery and endovascular aneurysm repair, accounting for the majority of deaths. As a consequence, at least seven scoring systems have been developed for assessing the relationship of bundled clinical parameters as a measure of cardiac risk. For example, Eagle's five clinical "markers" of cardiac disease (age >70 years, diabetes, history or Q-wave

Anatomic Severity Scoring Systems

- Shown to have utility in predicting adverse outcomes.
- Are they adequate for defining boundary parameters?

Chaikof, et al. J Vasc Surg. 2002; 35:1061-6

Antiquated?

Table III. Definition, grading, and categorization of an initial morphologic state

Attribute	*Absent = 0*	*Mild = 1*	*Moderate = 2*	*Severe = 3*
Aortic neck				
Length (L)	$L > 25$ mm	$15 < L < 25$ mm	$10 < L < 15$ mm	$L < 10$ mm
Diameter (d)	$d < 24$ mm	$24 < d < 26$ mm	$26 < d < 28$ mm	$d > 28$ mm
Angle	$> 150°$	$150° <$ angle $< 135°$	$135° <$ angle $< 120°$	Angle $< 120°$
Calcification/thrombus	$< 25\%$	25-50%	$> 50\%$	–
Aortic aneurysm				
Angulation and tortuosity				
Aortic tortuosity index (T)	$T < 1.05$	$1.05 < T < 1.15$	$1.15 < T < 1.2$	$T > 1.2$
Aortic angle (Φ)	160° to 180°	140° to 159°	120° to 139°	$< 120°$
Thrombus	0	$< 25\%$	25%-50%	>50%
Aortic branch vessels	No vessels	1 lumbar/IMA	2 vessels $d < 4$ mm	2 vessels IMA $d > 4$ mm
Pelvic perfusion	Patent bilateral IIA	Single IIA occlusion	Single IIA occlusion Contralateral IIA > 50% stenosis	Bilateral IIA occlusion
Iliac artery				
Calcification	None	<25% vessel length	25%-50% vessel length	>50% vessel length
Diameter/occlusive disease	$d > 10$ mm No occlusive disease	$8 < d < 10$ mm No stenosis <7 mm diameter or >3 cm long	$7 < d < 8$ mm Focal stenosis <7 mm diameter and <3 cm in length	$d < 7$ mm Stenosis < 7 mm diameter and >3 cm in length More than one focal stenosis < 7 mm diameter
Angulation and tortuosity				
Iliac tortuosity index (τ)	$\tau < 1.25$	$1.25 < \tau < 1.5$	$1.5 < \tau < 1.6$	$\tau > 1.6$
Iliac angle (ϕ)	160° to 180°	121° to 159°	90° to 120°	$< 90°$
Iliac artery sealing zone				
Length (L)	$L > 30$ mm	$20 < L < 30$ mm	$10 < L < 20$ mm	$L < 10$ mm
Diameter (d)	$d < 12.5$ mm	$12.5 < d < 14.5$ mm	$14.5 < d < 17$ mm	$d > 17$ mm

IIA, Internal iliac artery; *IMA*, inferior mesenteric artery.

Chaikof, et al. J Vasc Surg. 2002; 35:1061-6

A New Classification and Reporting System for Aortic Neck

Four Grades of Neck Quality

- Grade A = Healthy
- Grade B = Adequate
- Grade C = Marginal
- Grade D = Diseased

Variables For Determining Quality?

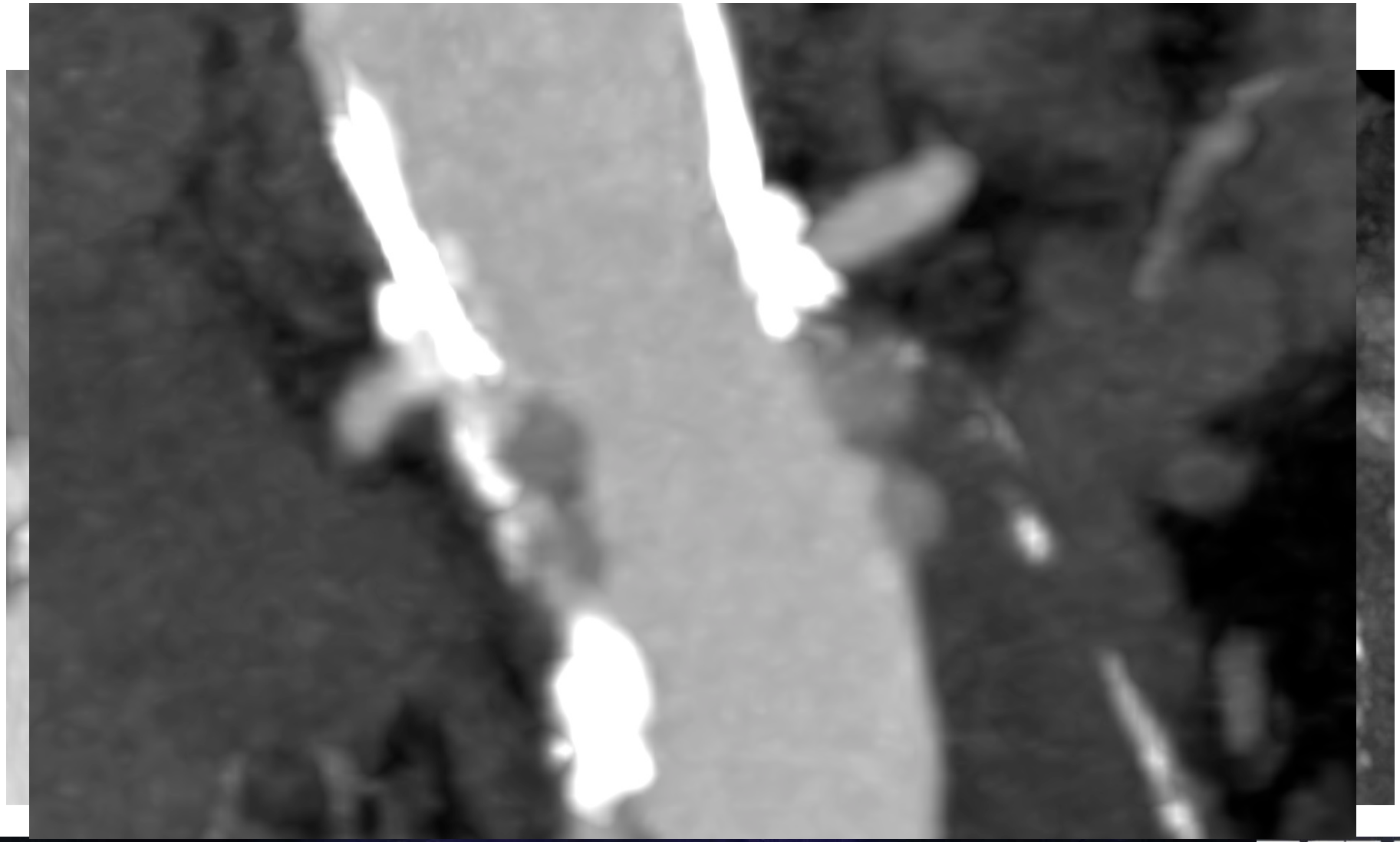
- Reverse Taper
- Calcification
- Atheroma
- Thrombus

Combine As One (C/A/T)

Neck Quality (Worse of the Two)

	Reverse Taper	Calcification/Atheroma/Thrombus
Grade A (Healthy)	None	< 1 mm Thick AND < 10% Circumference
Grade B (Adequate)	<2 mm	< 2 mm Thick AND < 40% Circumference, but not Grade A
Grade C (Marginal)	2-5 mm	2-5 mm Thick OR >40% Circumference
Grade D (Diseased)	>5 mm	2-5 mm Thick AND >40% Circumference, or >5 mm Thick any % Circumference

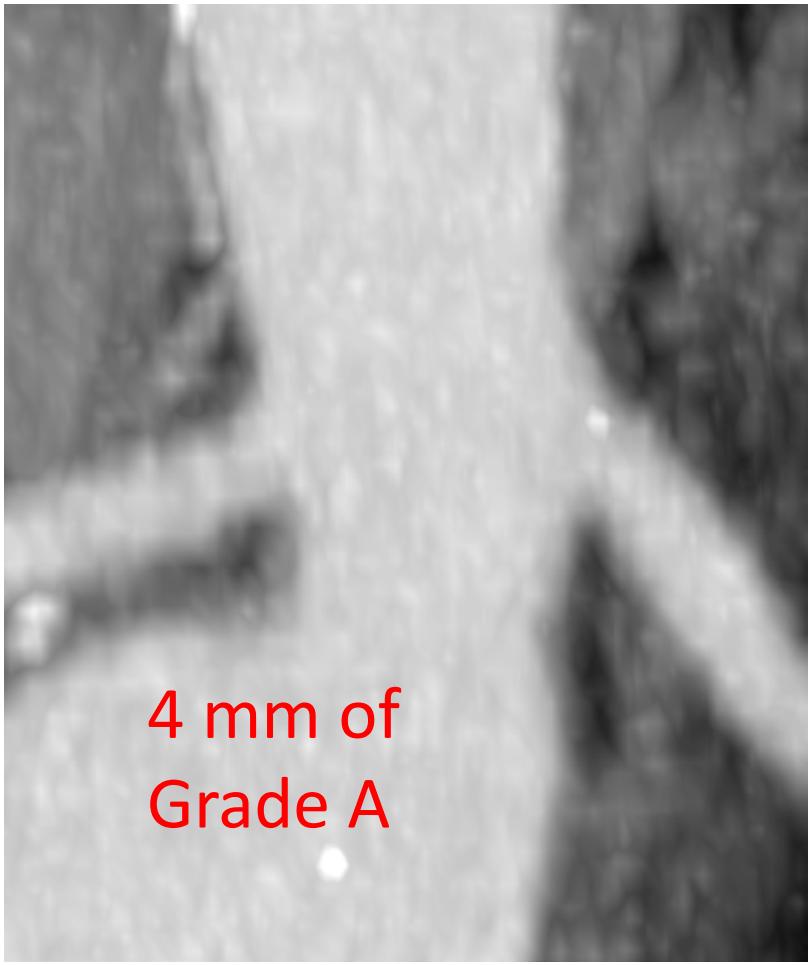
Two Very Different Neck Qualities

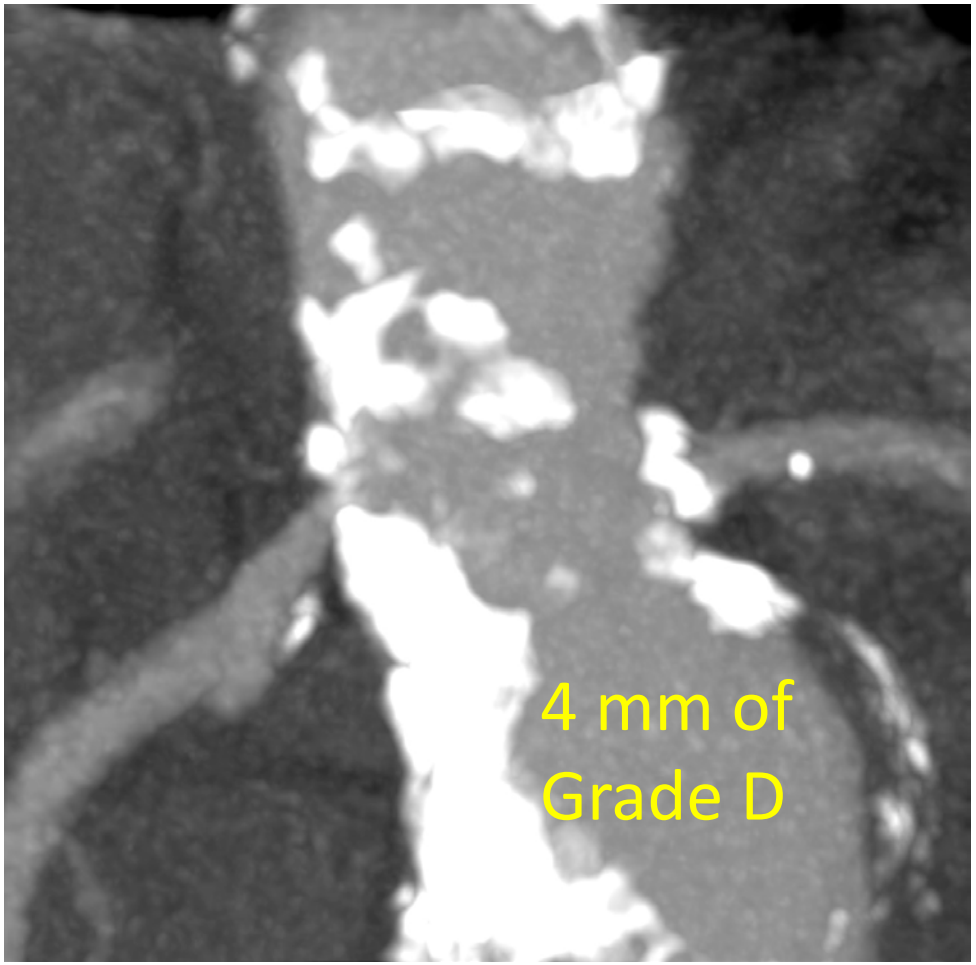


Variables that are Independent of Quality

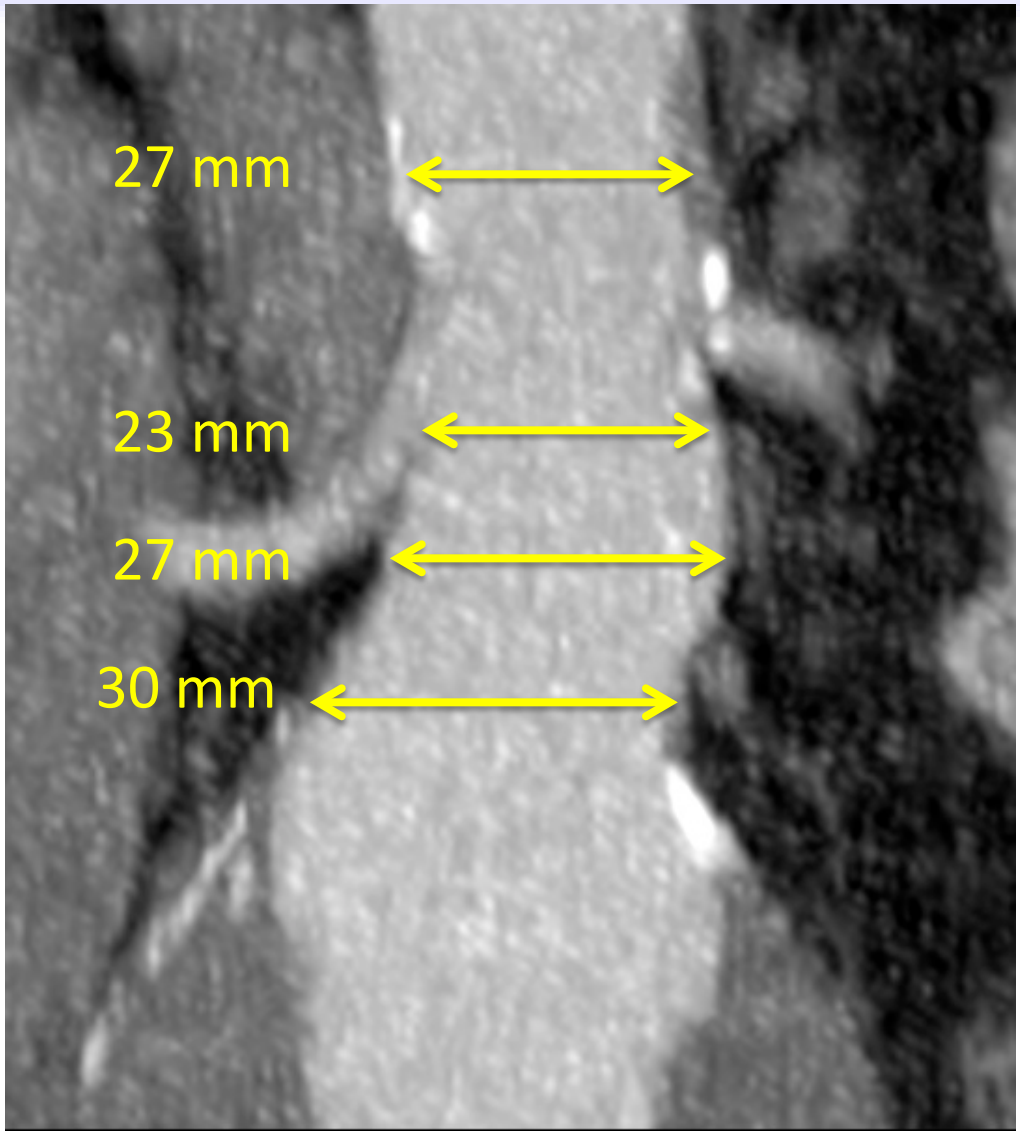
- Diameter
- Length
- Angulation

Two Very Different Neck Qualities





Determining Length of Reverse Tapered Necks



- Based on Sealing Diameter of the Aortic Endograft

  (Endograft Diameter minus 2 mm)

Reporting

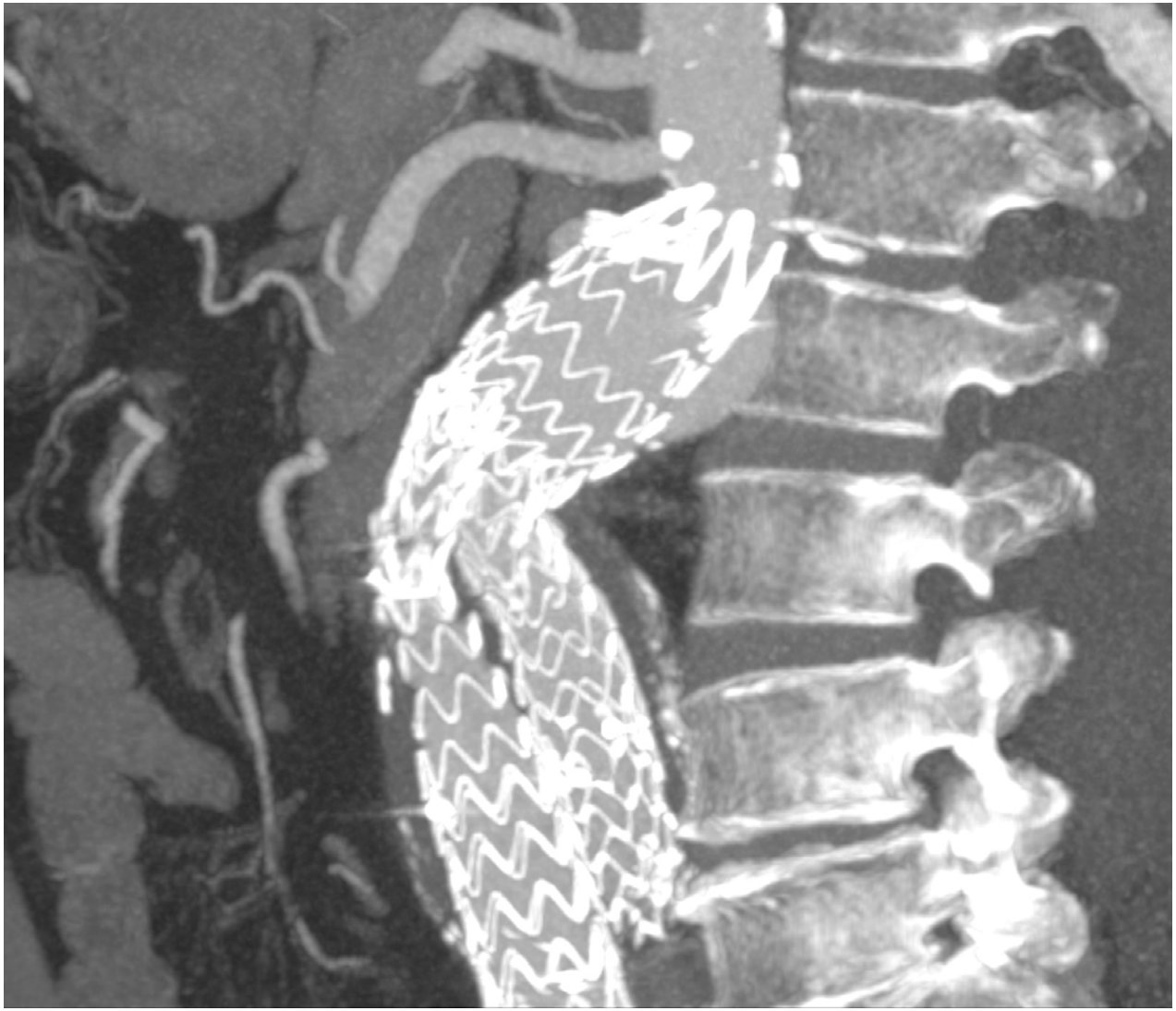
- A seal zone may be comprised of multiple segments of varying grade.
  - For instances, the first 5 mm may be Grade A, the next 5 mm may be Grade B, the next 5 mm may be Grade C, or any other number of combinations.
- However, additional segments should only be reported in short necks.
  - If at least 15 mm of a Grade A and/or Grade B seal zone is present, then additional Grade C or D segments should be considered irrelevant and not reported.
- If a seal zone is to be subdivided into multiple grades, then the segments should be listed from proximal to distal.
  - The center line length of each segment should be reported
  - As well as the aortic diameter at the most proximal and distal points of each segment.

Grade H

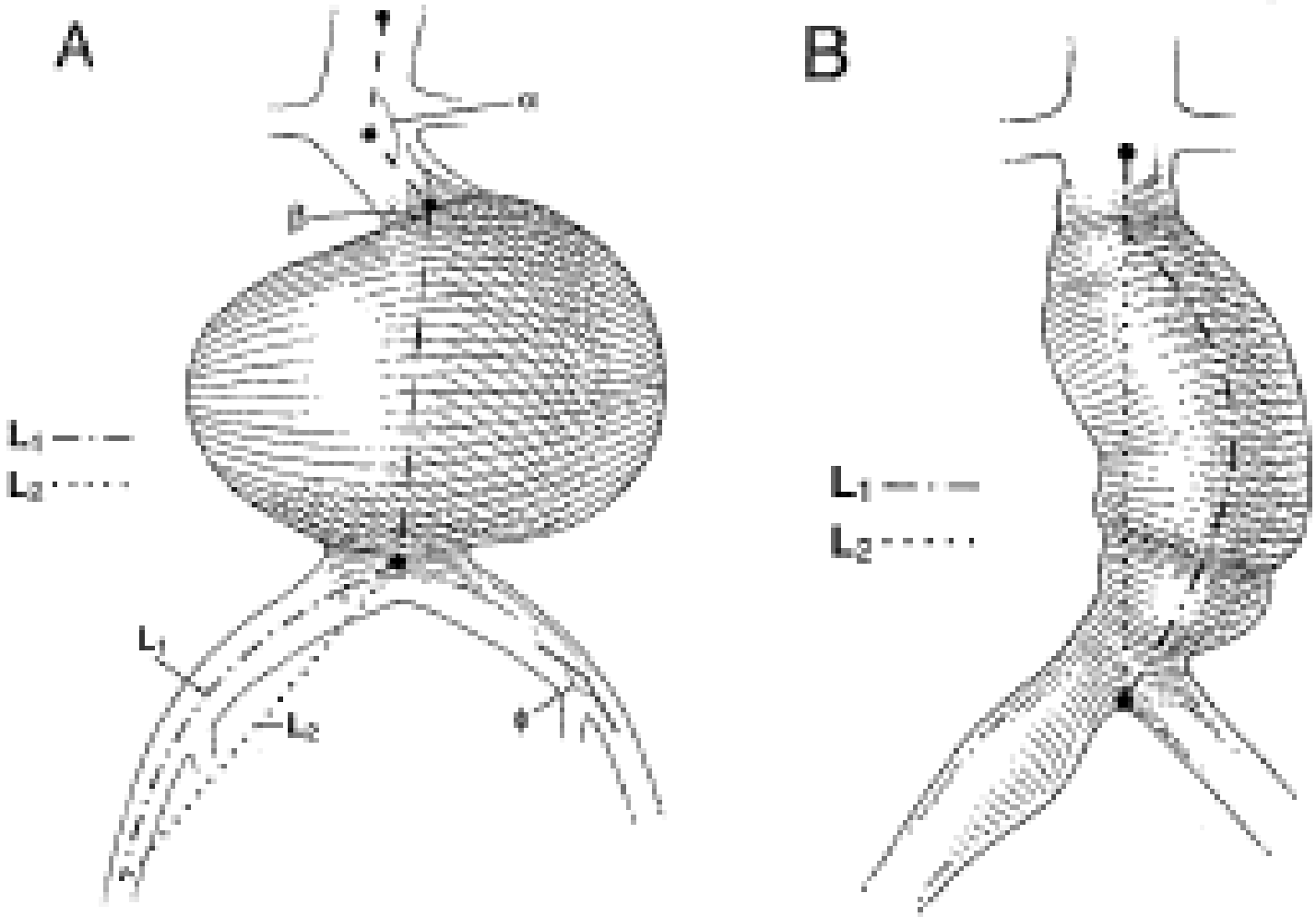
If a second, more distal seal zone is present (hourglass shape), then that segment will be reported as Grade H and documented in terms of centerline length, smallest aortic diameter, and length from the lowest renal artery.

Again, Grade H segments will be considered irrelevant (and not reported) if at least 15 mm of a Grade A or B seal zone is present.

Type I(H) Endoleak

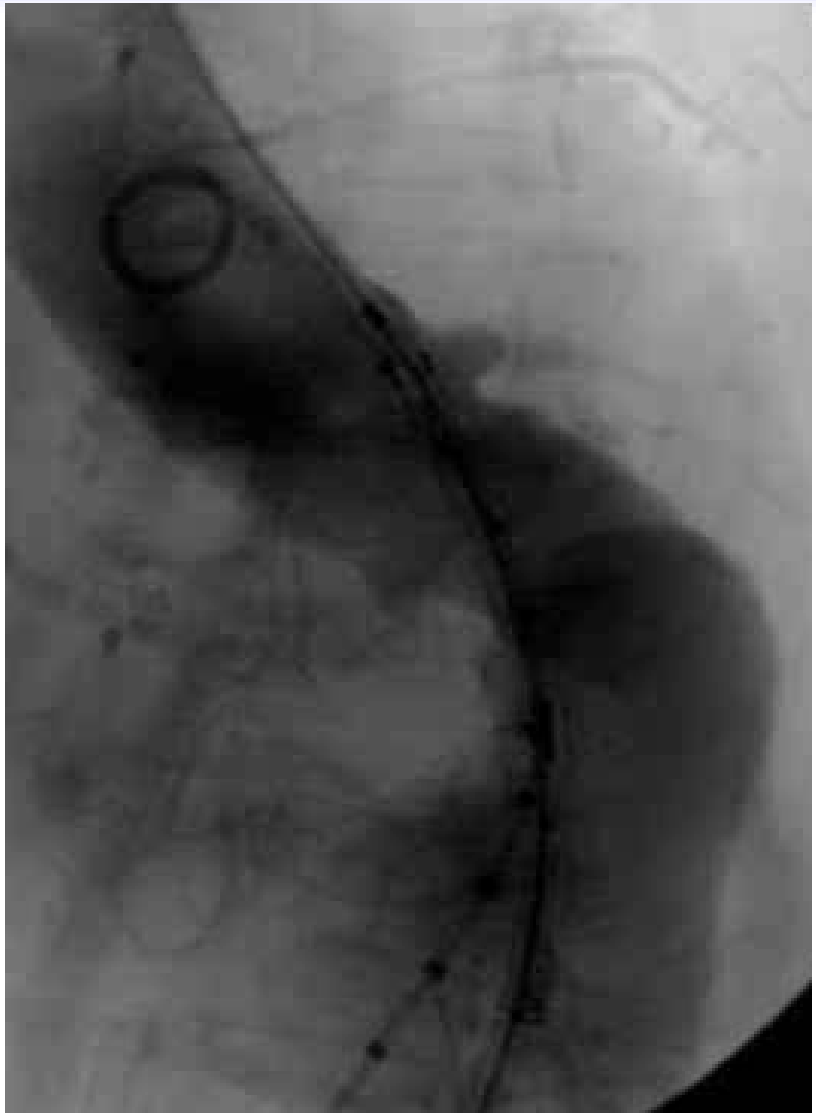


Measuring Angulation

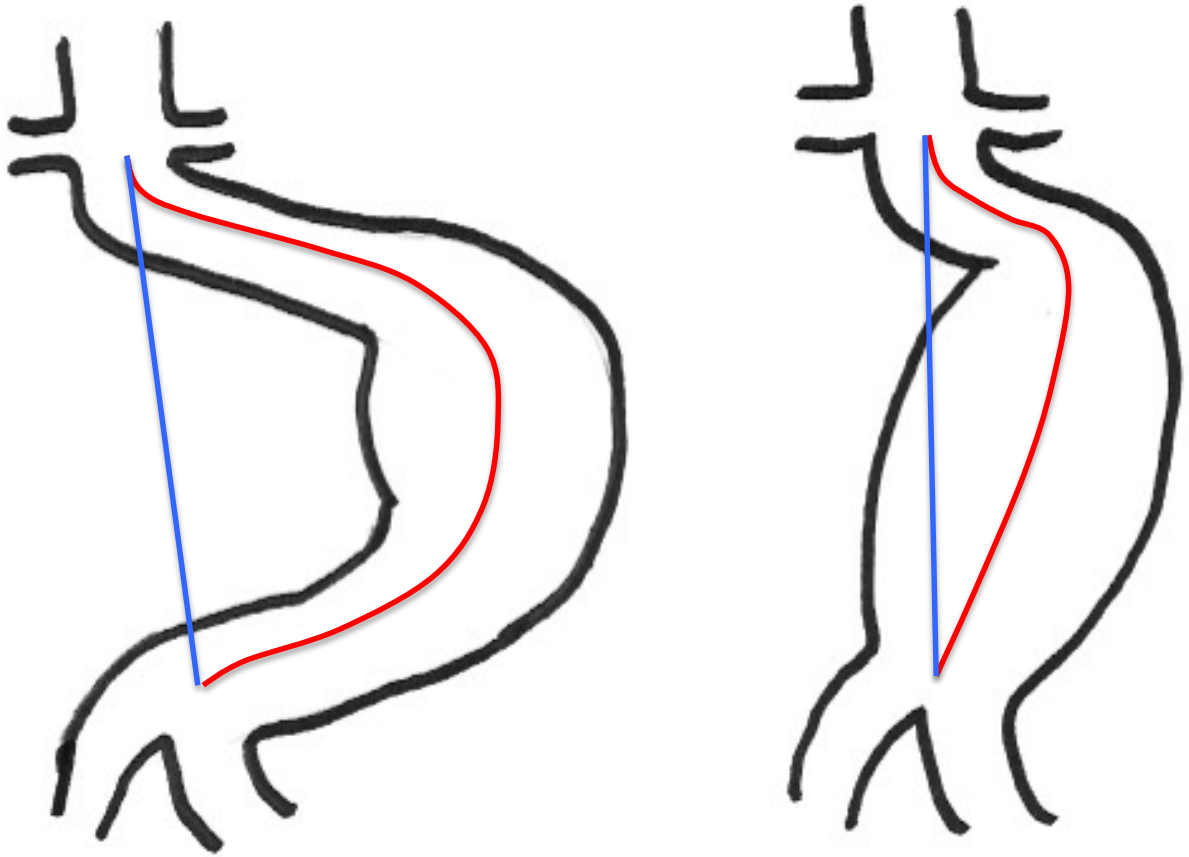


Chaikof, et al. J Vasc Surg. 2002; 35:1061-6

Overall Difficulty

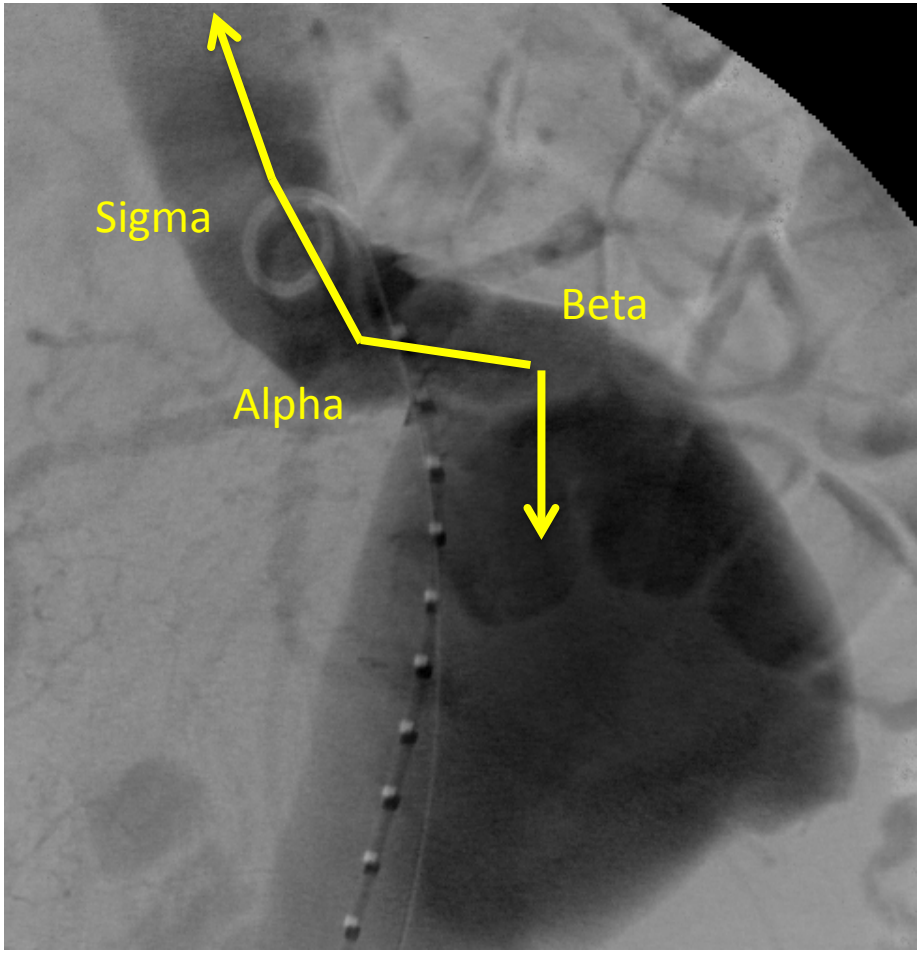


Tortuosity Index



L1 ÷ L2

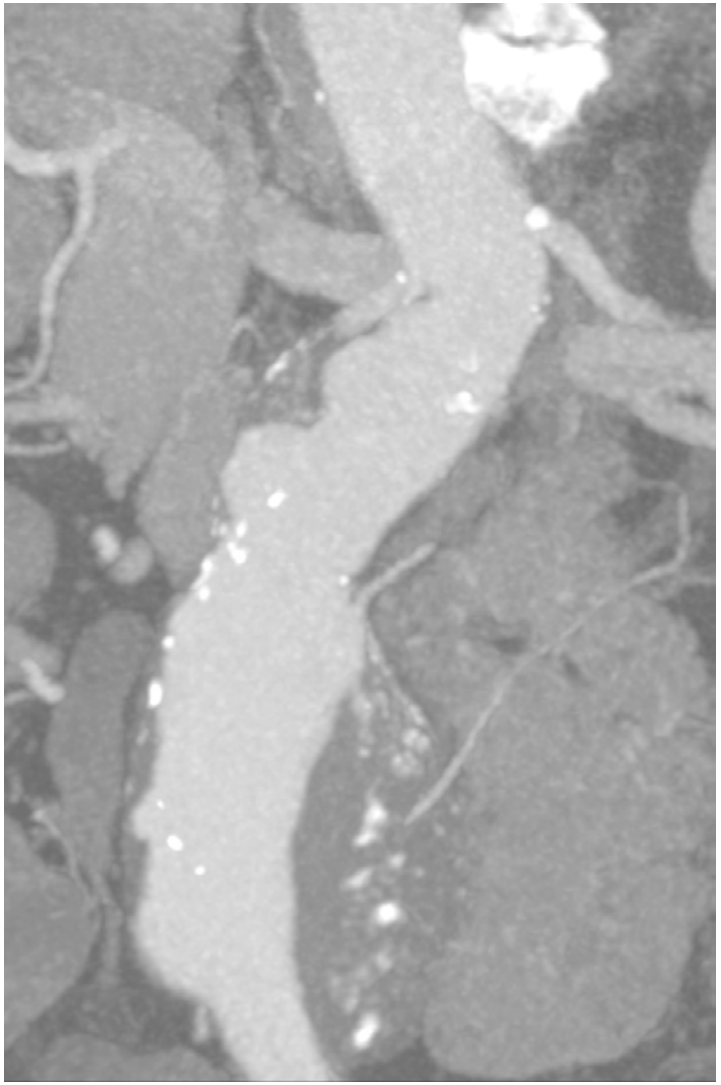
Angulation



- Alpha Angle
  - Immediate Suprarenal
  - Immediate Infrarenal
- Beta Angle
  - Immediate Infrarenal
  - Body of Aneurysm
- Alpha-Beta Distance
  - Length between the vertices of the the Alpha and Beta angles
- Sigma Angle
  - Immediate Suprarenal
  - Distal Thoracic

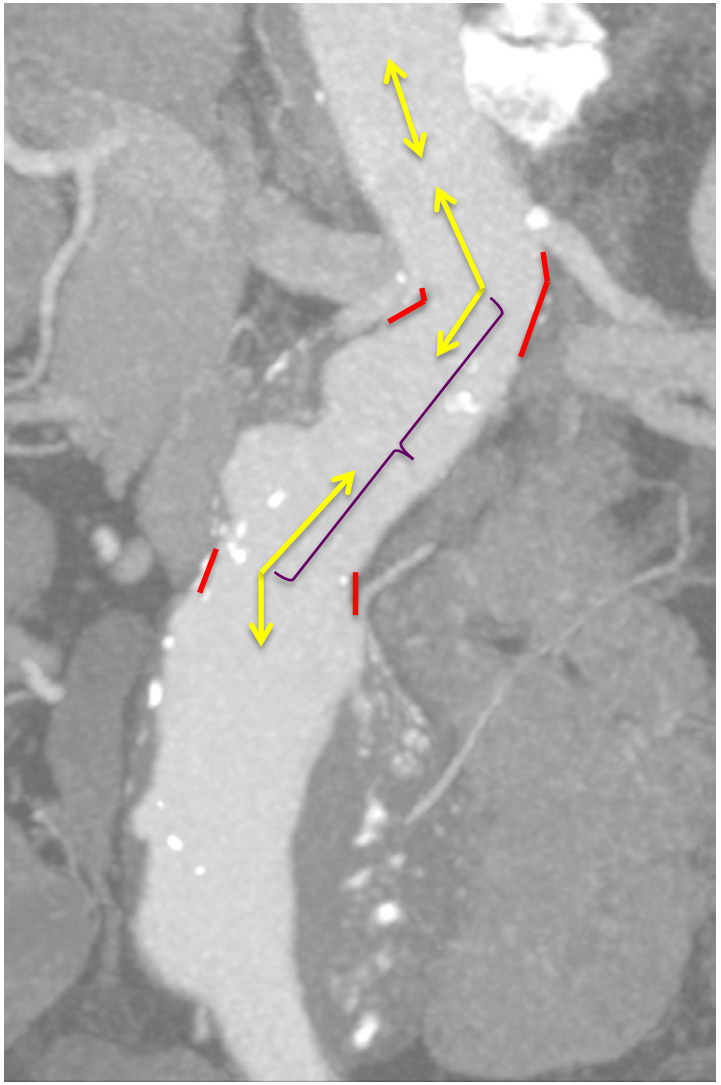
The Pericles Reporting System

- Grade A = 3 mm
- Grade D = 10 mm
- Grade H zone 6 cm distal to the renals
- Alpha angle = 60 degrees
- Beta angle = 40 degrees
- α-β distance = 6 cm
- Sigma Angle = 0 degrees



The Pericles Classification

- Grade A = 3 mm
- Grade D = 10 mm
- Grade H zone 6 cm distal to the renals
- Alpha angle = 60 degrees
- Beta angle = 40 degrees
- α-β distance = 6 cm
- Sigma Angle = 0 degrees



Neck Quality (Worse of the Two)

	Reverse Taper	Calcification/Atheroma/Thrombus
Grade A (Healthy)	None	< 1 mm Thick AND < 10% Circumference
Grade B (Adequate)	<2 mm	< 2 mm Thick AND < 40% Circumference, but not Grade A
Grade C (Marginal)	2-5 mm	2-5 mm Thick OR >40% Circumference
Grade D (Diseased)	>5 mm	2-5 mm Thick AND >40% Circumference, or >5 mm Thick any % Circumference

Appropriate Cut-Off Points?