Why is Proper Planning Essential for Long Term Success, and how Durable are the Chosen Solutions?

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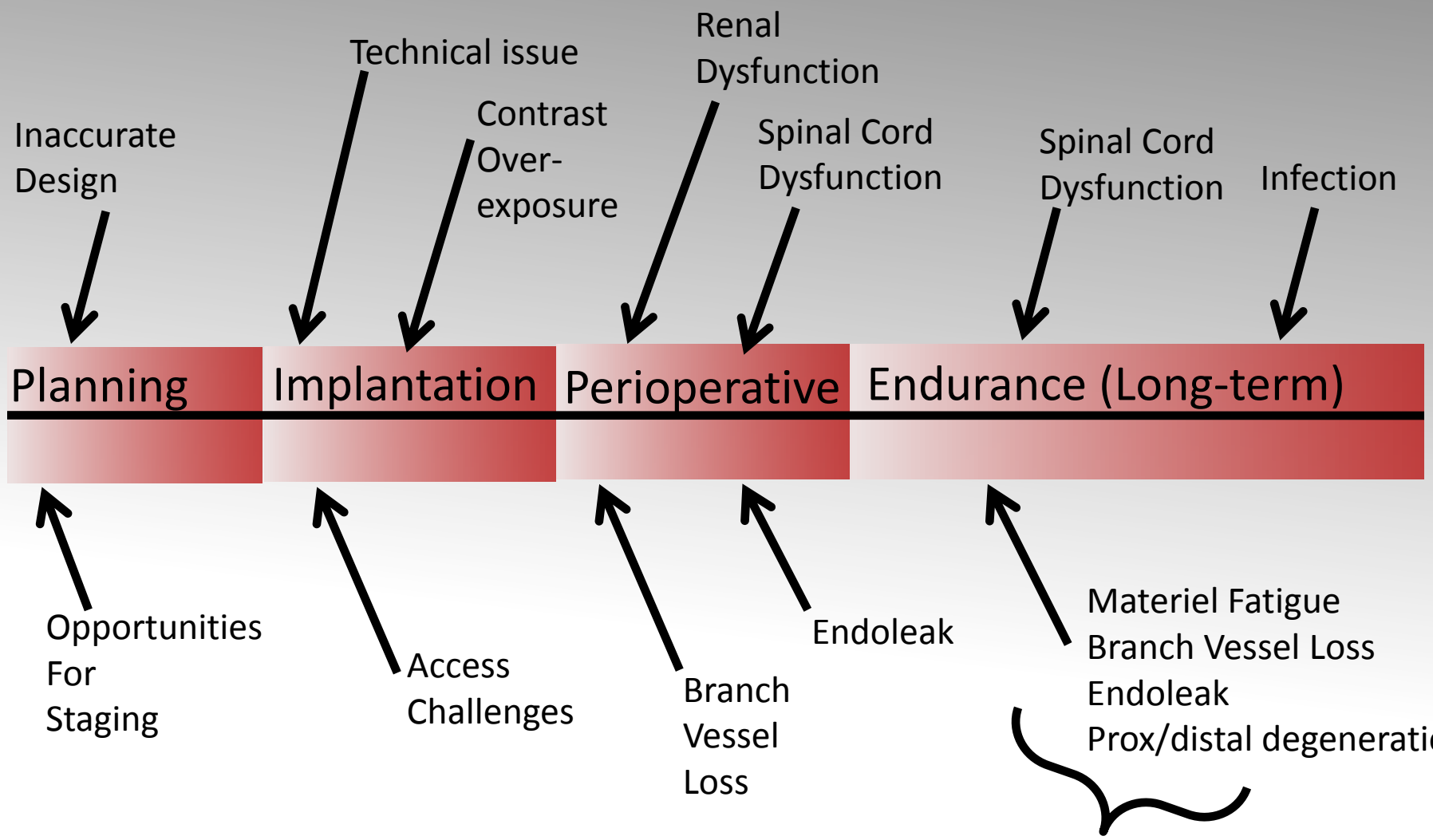
Disclosures

- Siemens Imaging Inc
  - Speaking and Consultation
- Cook Medical Inc
  - Proctorship and Consultation
- Maquet, Inc
  - Speaking

Why is Proper Planning Essential for Long Term Success?

- Good planning improves durability
- Planning, and therefore durability, are directly related to experience
- Experience improves outcome.

The Lifespan of a Complex Endograft…



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THE GREAT FORCE EXERTED on a STENT GRAFT is TIME

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Good Planning Improves Durability

From the Society for Vascular Surgery

Type Ia endoleaks after fenestrated and branched endografts may lead to component instability and increased aortic mortality

Adrian O'Callaghan, Roy K. Greenberg, MD, Matthew J. Eagleton, MD, James Bena MS, and Tara Marie Mastracci, MD, *Cleveland, Ohio*

Objectives: Fenestrated and branched endografts allow for proximal sealing zone extension into or above the visceral aorta to optimize landing in healthy aorta. We describe the incidence, causes, and implications of proximal endoleak development in patients undergoing complex endovascular aortic aneurysm repair.

Methods: All patients undergoing a fenestrated/branched repair were entered onto a prospective database, and this analysis included all those with at least one postoperative contrast computed tomography scan. Preoperative and postoperative three-dimensional imaging was reanalyzed to characterize morphology and identify endoleak. A blinded assessor used the preoperative imaging to resize the repairs in the endoleak group and a matched cohort of patients without endoleak. The outcome measures were proximal endoleak development, mortality, and component stability, and a comparison was made with all patients undergoing complex aortic repair.

Results: From 2001 to July 2013, 969 patients underwent repair in a physician-sponsored investigational device exemption trial. Excluded were 24 emergency patients and 21 patients without requisite imaging, leaving 924 available for analysis. A proximal type Ia endoleak developed in 26 patients (2.8%). Poor choice of landing zone was implicated in most cases, with an area of sealing in the visceral aorta, compared with the thoracic aorta, being significantly associated with endoleak development ($P < .01$). Aortic-related mortality was significantly higher in the endoleak group (26.9%) than in the group without endoleak (6.2%; $P = .001$). These patients also experienced a higher incidence of component instability of 30.8% compared with 9.6% in patients without type Ia endoleak ($P < .01$).

Conclusions: Fenestrated/branched endovascular repair has a low incidence of sealing zone failure despite the increased complexity. However, development of a proximal endoleak destabilizes the repair and leads to increased mortality. Increasing complexity of design seems to improve the long-term outcome for patients requiring complex aortic repair. (J Vasc Surg 2014;■:1-7.)

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Type Ia Endoleaks Over time

- 924 patients: 26 type Ia endoleaks over 12 years (2.8%)
  - Poor choice of landing zone (in visceral aorta) was significantly associated with endoleak development
  - Aortic related mortality higher in endoleak group (26.9%) compared with non-endoleak group (9.6%)

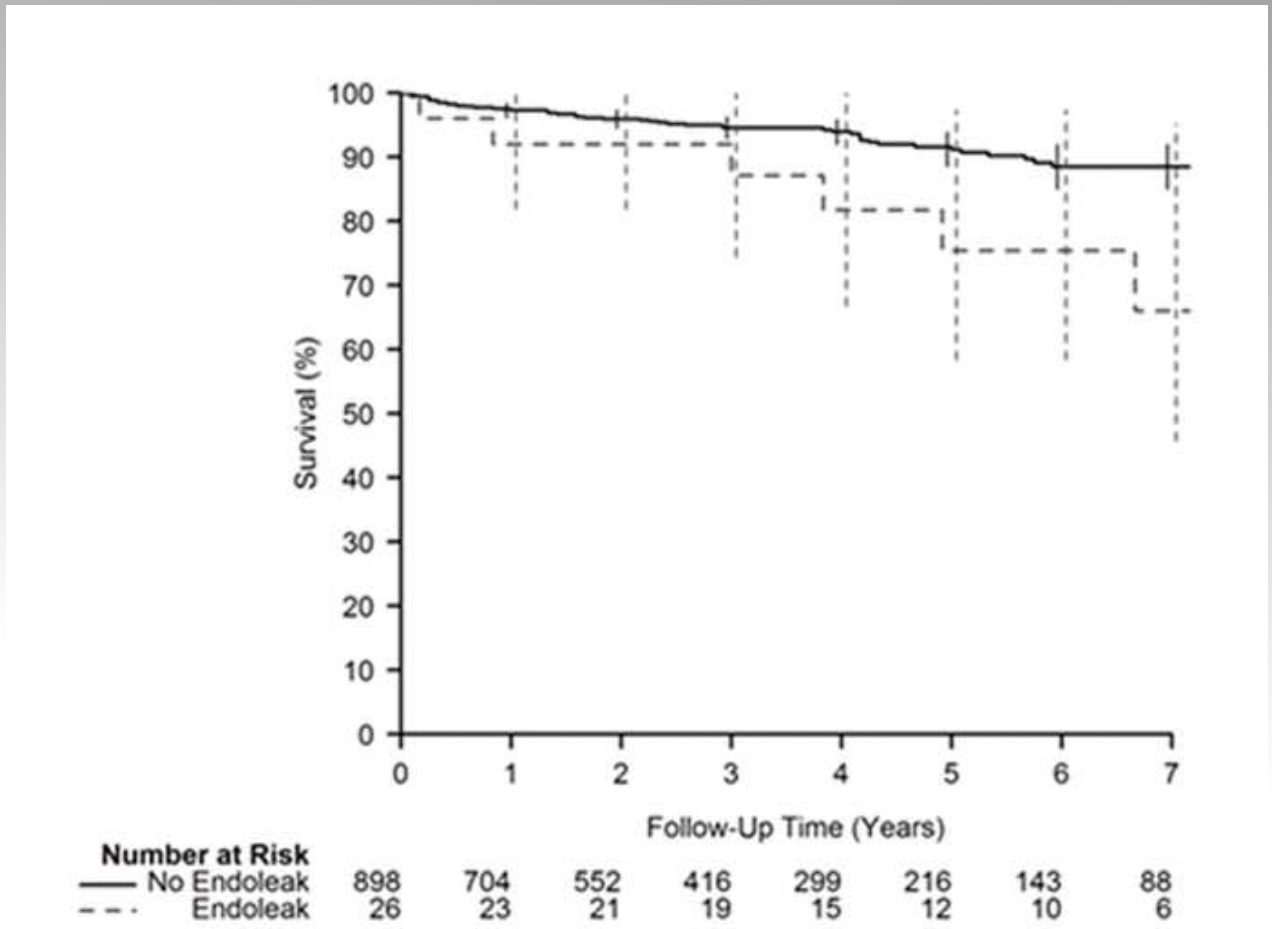
O'Callaghan et al, JVS 2015

Type Ia Endoleaks over Time

- 924 patients: 26 type Ia endoleaks over 12 years (2.8%)
  - Component instability (branch stent failure, loss of seal in branch, type II endoleak) 30.8% compared with 9.6% (p-0.003)
  - Non parallel neck (>10% diameter change across the proximal seal zone) was significantly more likely to lead to sealing failure (9/26, 42.9% versus 2/75, 2.7%, p<0.001

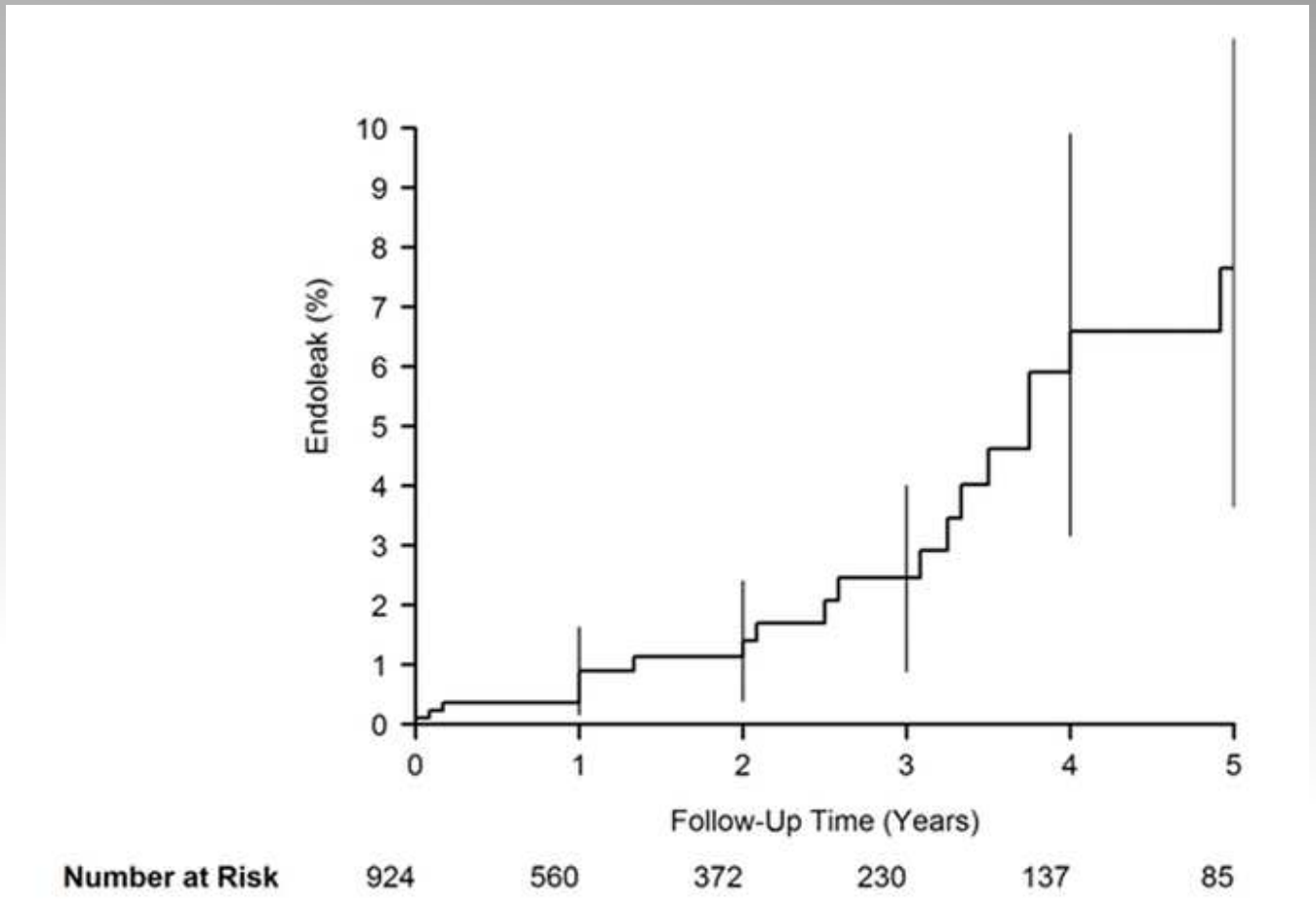
O'Callaghan et al, JVS 2015

Endoleak Association With Survival



O'Callaghan et al, JVS 2015

Endoleak rate over time.
Technical success does not mean durability



O'Callaghan et al, JVS 2015

Synchronous and Metachronous Aneurysms

		Pre 1995	2000 – 2009
Synchronous	Proximal (ascending, arch)	9%	14%
	Other Aortic Segment	6%	7%
Metachronous	Proximal (prior repair)	12%	14%
	AAA	24%	20%

Hollier et al, Ann Vasc Surg 1995
Piazza et al, A[illegible] Surg 201[illegible]

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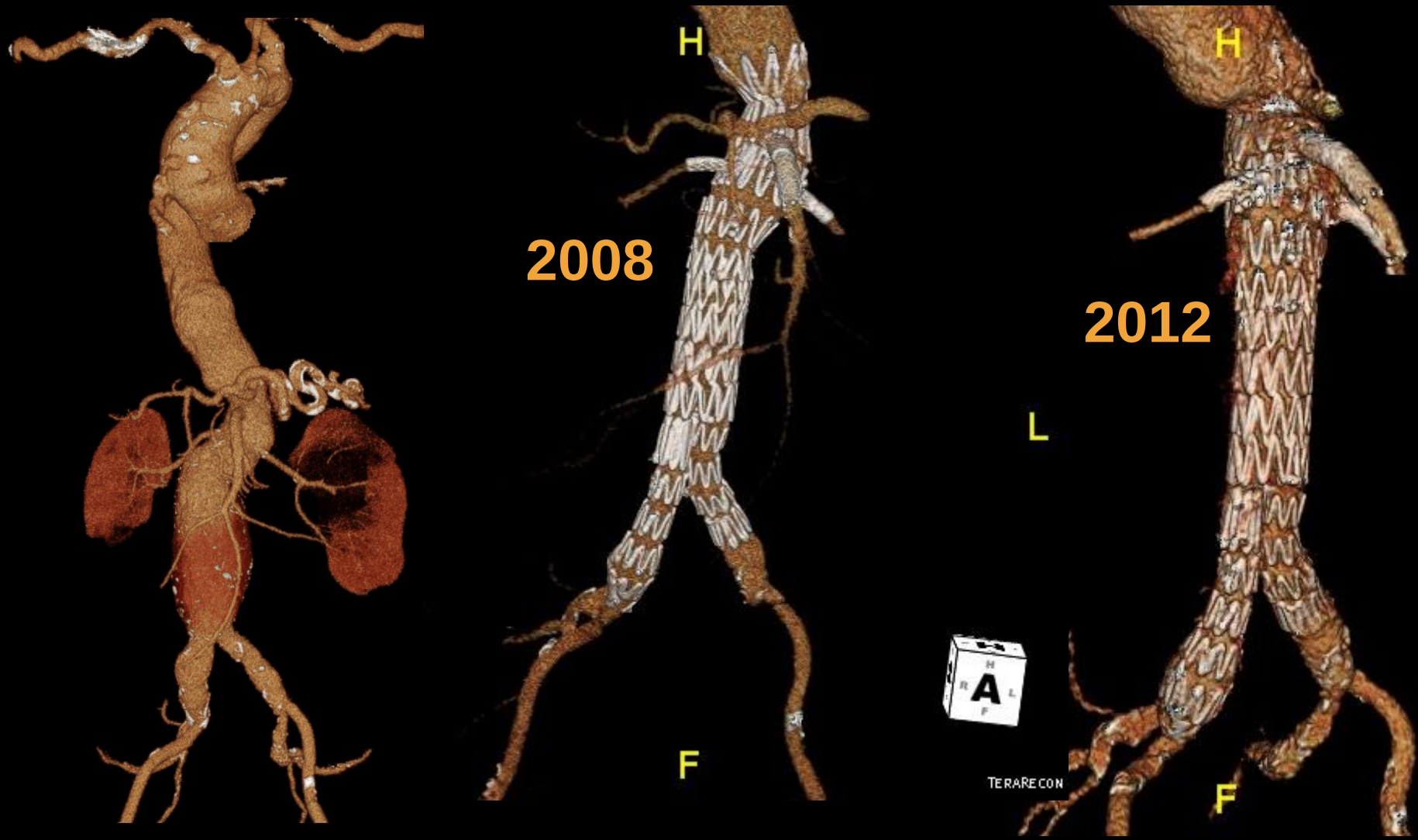
H
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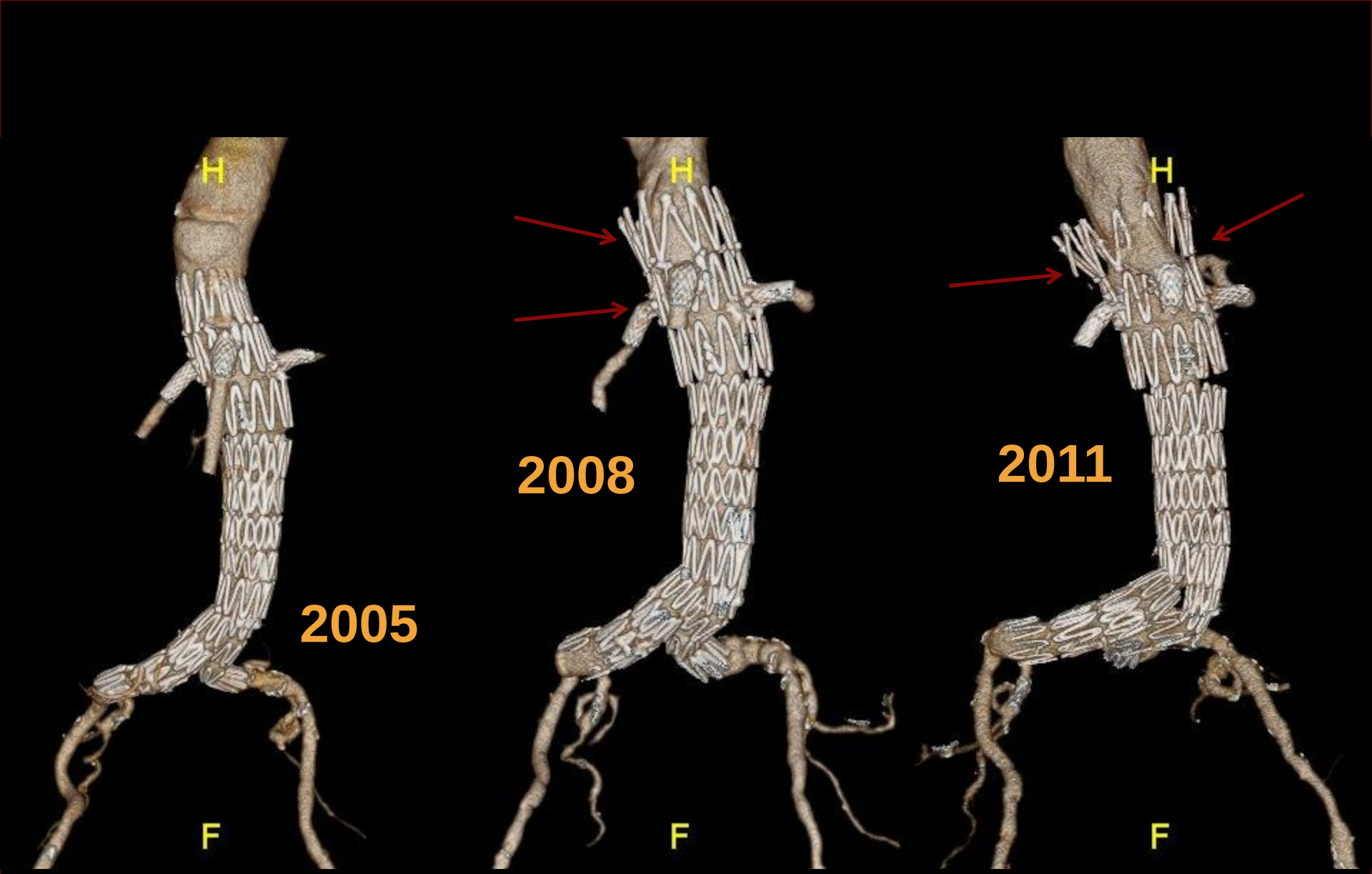
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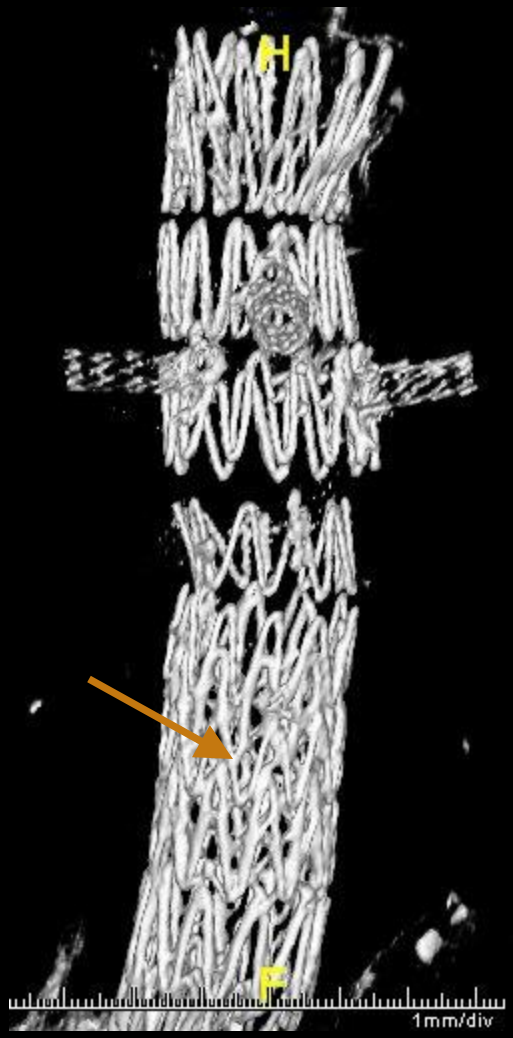
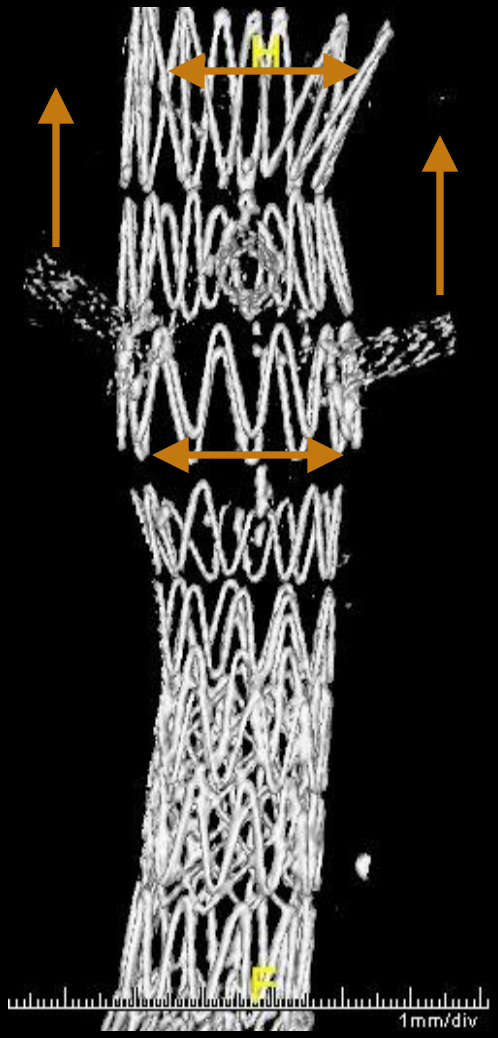
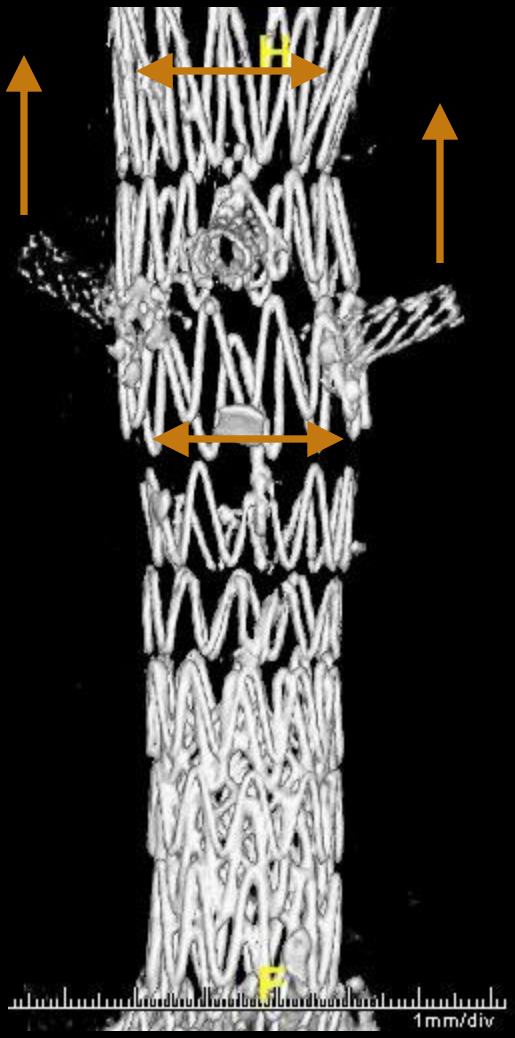
2011



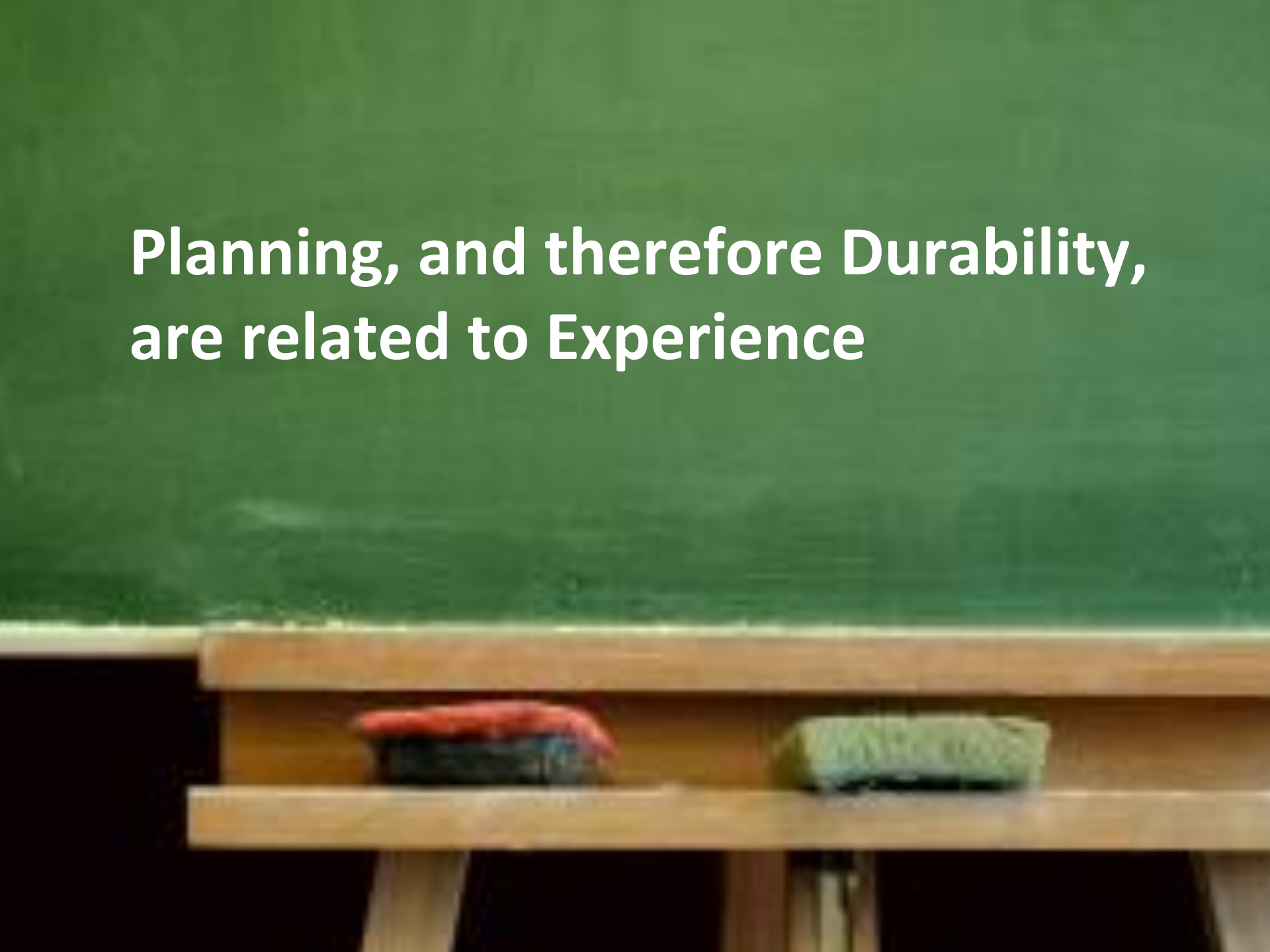
2005



2006



2007


Planning, and therefore Durability,
are related to Experience

Variability in CT Interpretation

Inter-observer Variability in Sizing Fenestrated and/or Branched Aortic Stent-grafts

H. Banno [a,*], H. Kobeiter [b], J. Brossier [a], J. Marzelle [a], E. Presles [c], J.-P. Becquemin [a]

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[b] Department of Radiology, Henri Mondor Hospital, University Paris XII, Creteil, France
[c] Department of Clinical Research, Saint-Étienne University Hospital, St-Étienne, France

WHAT THIS PAPER ADDS

The current study is the first large-scale analysis, focused on inter-observer variability in sizing fenestrated and/or branched aortic stent-grafts. The agreements between core laboratory and each rater were all moderate to perfect; however, there were some significant discrepancies, which may affect clinical results. These discrepancies should be taken into account in sizing fenestrated and/or branched stent-grafts.

Background: Several studies have examined inter-observer variability in measurements for standard EVAR, but little is known about measurements for complex aortic aneurysm.
Methods: Two independent observers reviewed all preoperative CT scans of 268 patients in a French trial of fenestrated and/or branched aortic stent-grafts (f/b-EVAR). Those data were compared with those obtained (1) by investigators (extent of aneurysm, target vessel stenosis, and aortic diameters), and (2) from manufacturers (proximal landing zone, device diameter, and target vessel position). We assessed the reproducibility using kappa statistics for qualitative data and both Bland—Altman plot and Passing—Bablok regression analysis for quantitative data.
Results: Reproducibility was moderate to almost perfect for all factors. However, a few critical discrepancies were found, such as target vessel clock position (≥45 minutes) and location (≥5 mm), level of proximal landing zone, and diameters of the endograft.
Conclusions: This is the first large-scale analysis focused on inter-observer variability in sizing for f/b-EVAR. The measurement data showed good agreement, but there were some critical discrepancies between observers that may affect clinical results.

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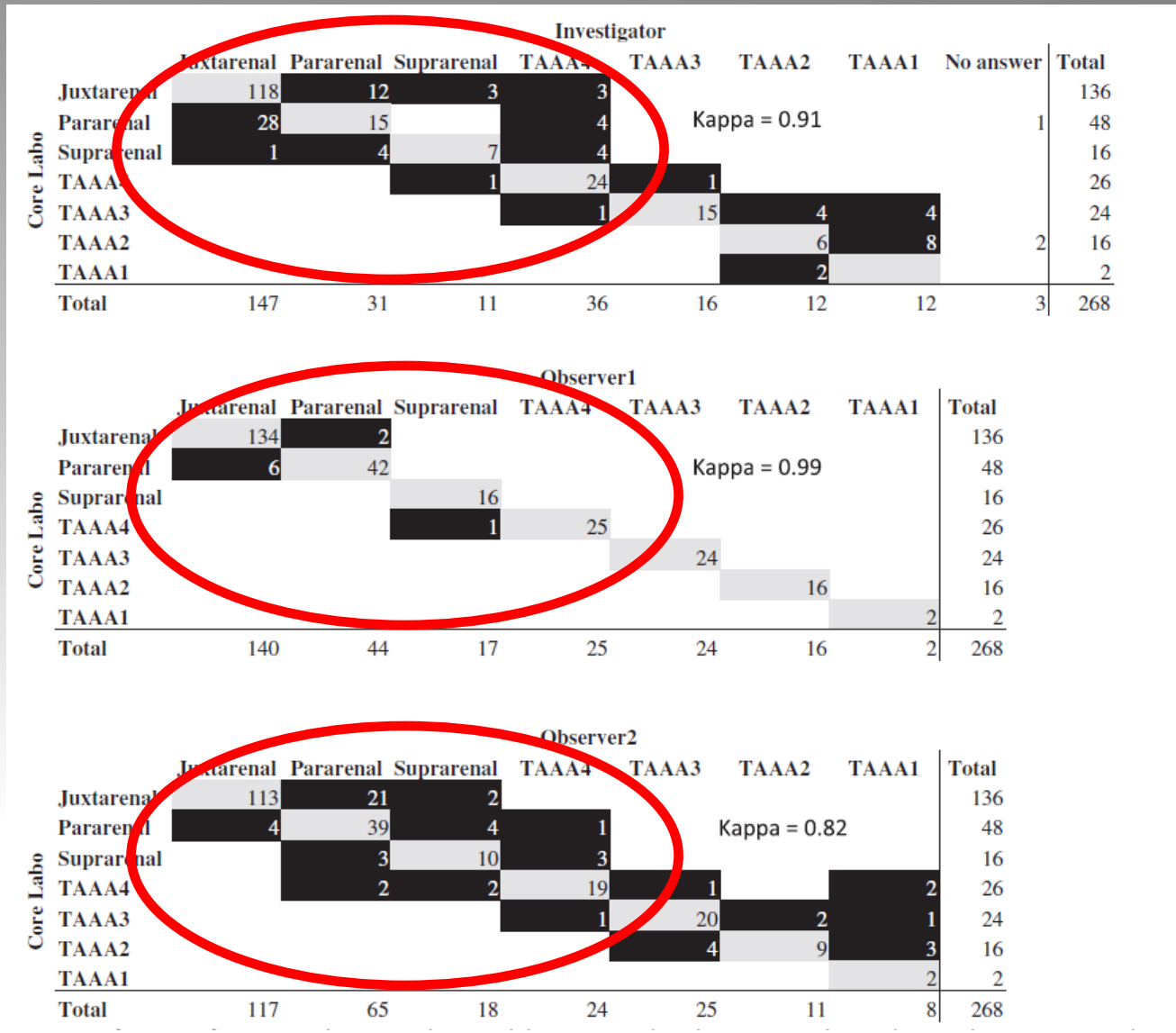
Extent of Aneurysm



Investigator

Core Labo	Juxtarenal	Pararenal	Suprarenal	TAAA4	TAAA3	TAAA2	TAAA1	No answer	Total
Juxtarenal	118	12	3	3					136
Pararenal	28	15		4				1	48
Suprarenal	1	4	7	4					16
TAAA4			1	24	1				26
TAAA3				1	15	4	4		24
TAAA2						6	8	2	16
TAAA1						2			2
Total	147	31	11	36	16	12	12	3	268

Kappa = 0.91

Observer1

Core Labo	Juxtarenal	Pararenal	Suprarenal	TAAA4	TAAA3	TAAA2	TAAA1	Total
Juxtarenal	134	2						136
Pararenal	6	42						48
Suprarenal			16					16
TAAA4			1	25				26
TAAA3					24			24
TAAA2						16		16
TAAA1							2	2
Total	140	44	17	25	24	16	2	268

Kappa = 0.99

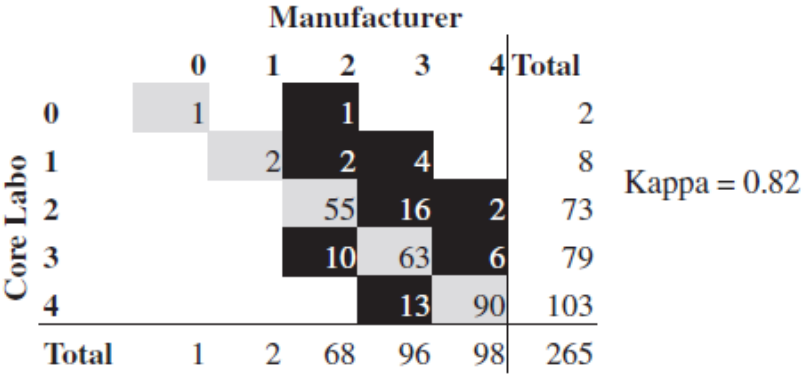
Observer2

Core Labo	Juxtarenal	Pararenal	Suprarenal	TAAA4	TAAA3	TAAA2	TAAA1	Total
Juxtarenal	113	21	2					136
Pararenal	4	39	4	1				48
Suprarenal		3	10	3				16
TAAA4		2	2	19	1		2	26
TAAA3				1	20	2	1	24
TAAA2					4	9	3	16
TAAA1							2	2
Total	117	65	18	24	25	11	8	268

Kappa = 0.82

Banno et al, EJVES 2015

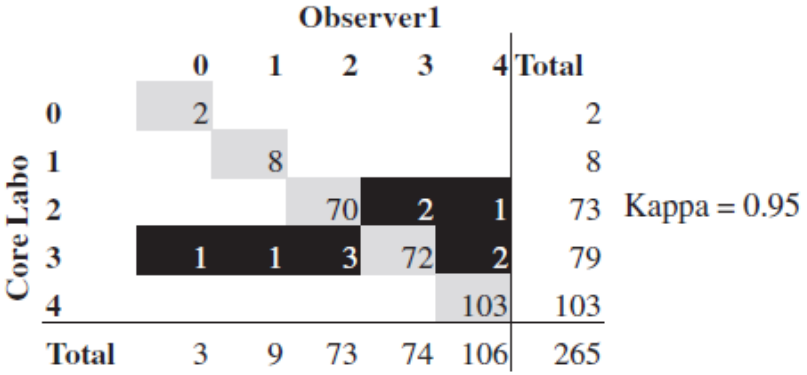
Proximal Landing Zone



Manufacturer

Core Labo	0	1	2	3	4	Total
0	1		1			2
1		2	2	4		8
2			55	16	2	73
3			10	63	6	79
4				13	90	103
Total	1	2	68	96	98	265

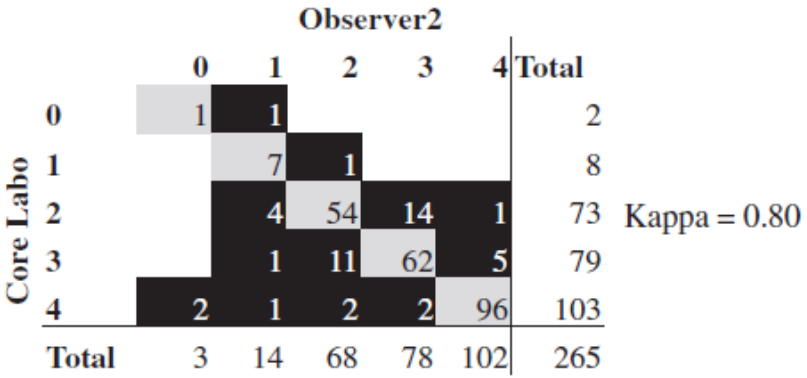
Kappa = 0.82



Observer1

Core Labo	0	1	2	3	4	Total
0	2					2
1		8				8
2			70	2	1	73
3	1	1	3	72	2	79
4					103	103
Total	3	9	73	74	106	265

Kappa = 0.95



Observer2

Core Labo	0	1	2	3	4	Total
0	1	1				2
1		7	1			8
2		4	54	14	1	73
3		1	11	62	5	79
4	2	1	2	2	96	103
Total	3	14	68	78	102	265

Kappa = 0.80

Banno et al, EJVES 2015

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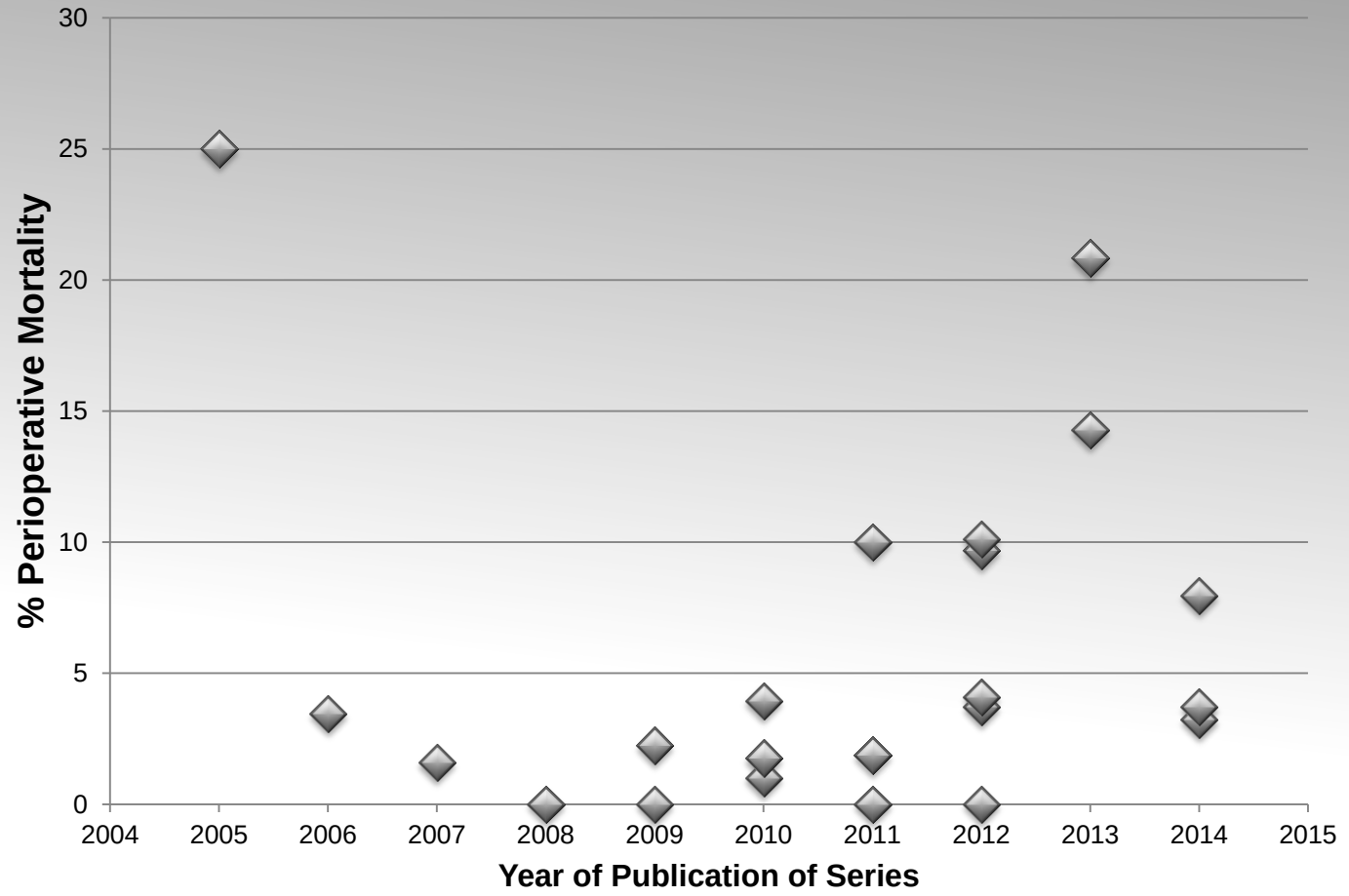
What does this mean?

- There is a great deal of room for interpretation of the critical measurements of CT aortography.

- Thus, experience, not science, helps a surgeon decide the best stent design


Experience Improves Outcomes

Perioperative Mortality, Year of Publication



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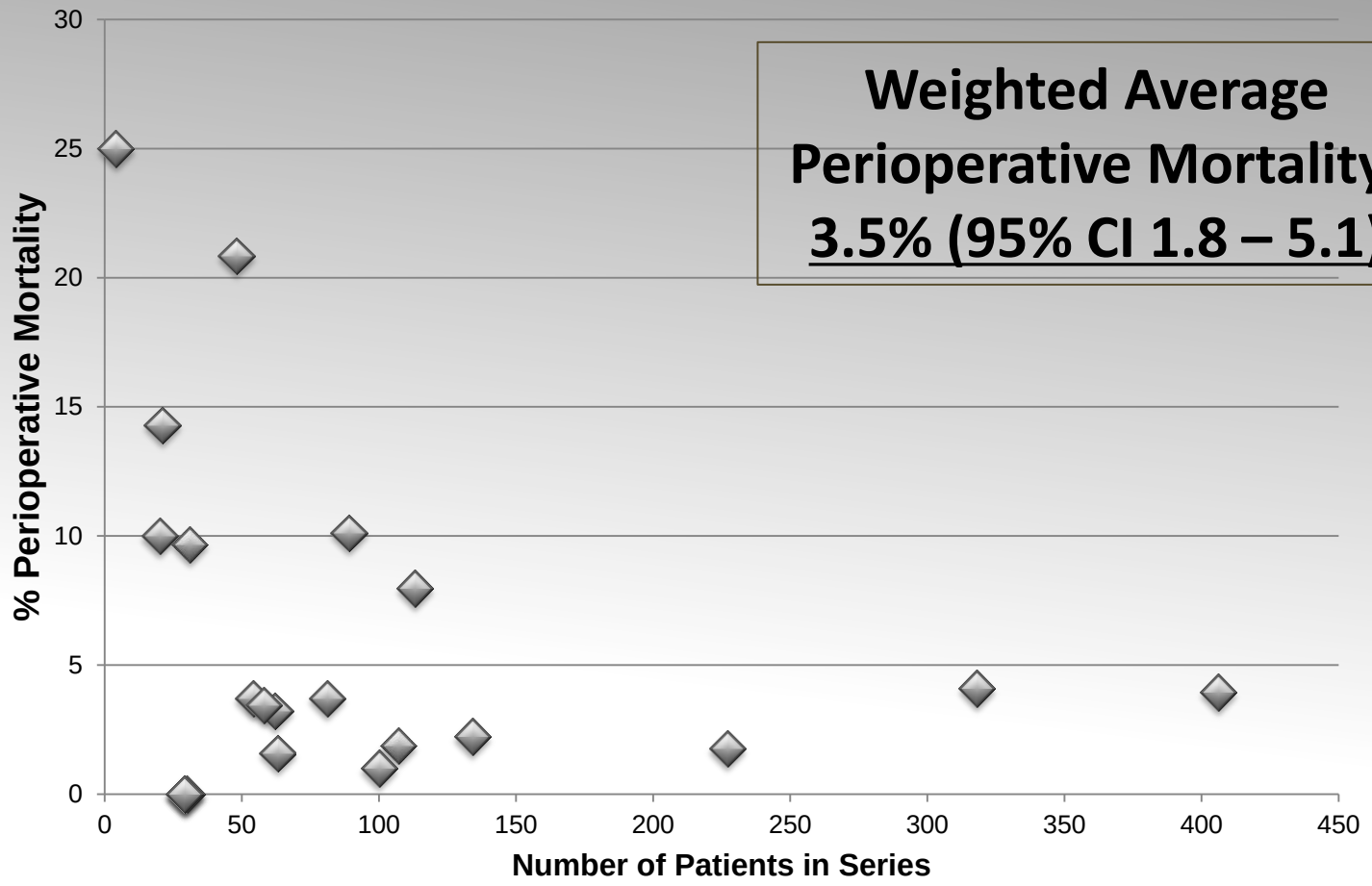
Perioperative Mortality: the literature



Weighted Average Perioperative Mortality: 3.5% (95% CI 1.8 – 5.1)

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From the Society for Vascular Surgery

Early versus late experience in fenestrated endovascular repair for abdominal aortic aneurysm

Magnus Sveinsson, MD,[a] Jonathan Sobocinski, MD, PhD,[b] Timothy Resch, MD, PhD,[a] Björn Sonesson, MD, PhD,[a] Nuno Dias, MD, PhD,[a] Stéphan Haulon, MD, PhD,[b] and Thorarinn Kristmundsson, MD, PhD,[a] *Malmö, Sweden, and Lille, France*

Objective: The objective of this study was to evaluate operative results and 1-year outcomes in early vs late experience after fenestrated endovascular aortic repair.

Methods: All patients treated in Malmö, Sweden, and in Lille, France, with fenestrated endovascular repair for abdominal aortic aneurysm were prospectively enrolled in a computerized database. Early experience was defined as the first 50 patients treated at each center. Data from early and late experience were retrospectively analyzed and compared for differences in operative results and 1-year outcomes.

Results: Early experience covered 4.7 years in Malmö and 4.5 years in Lille; late experience covered 5.6 years in Malmö and 3.7 years in Lille. A total of 288 patients were included. In the later phase, stent graft configuration was more complex because of increased number of fenestrations/scallops incorporated in the graft design (2.7 ± 0.8 vs 3.2 ± 0.7; $P < .001$). Despite this, volume of contrast material and radiation time decreased by 27% and 20%, respectively, whereas procedure time remained unchanged. At 1 year, a trend toward decreasing abdominal aortic aneurysm diameter was observed in the late group, but no differences were found in mortality, endoleaks, or target vessel patency between the groups.

Conclusions: With increasing experience, fenestrated endovascular aneurysm repair design has become more complicated, with more visceral vessels targeted for better proximal seal, while operative risk still remains low. Simultaneously, radiation time and volume of contrast material have been reduced, with possible long-term benefits for the patient. (J Vasc Surg 2015;■:1-7.)

Sveinsson et al, JVS 2015

Benefit of Experience

- Basic Assumption, 50 cases makes an expert.
- 288 patients total, grouped in to early and late experience

- Expertise results in
  - Increasing complexity of design
  - Similar perioperative outcomes
  - Lower radiation dose
  - Lower contrast dose

Sveinsson et al, JVS 2015

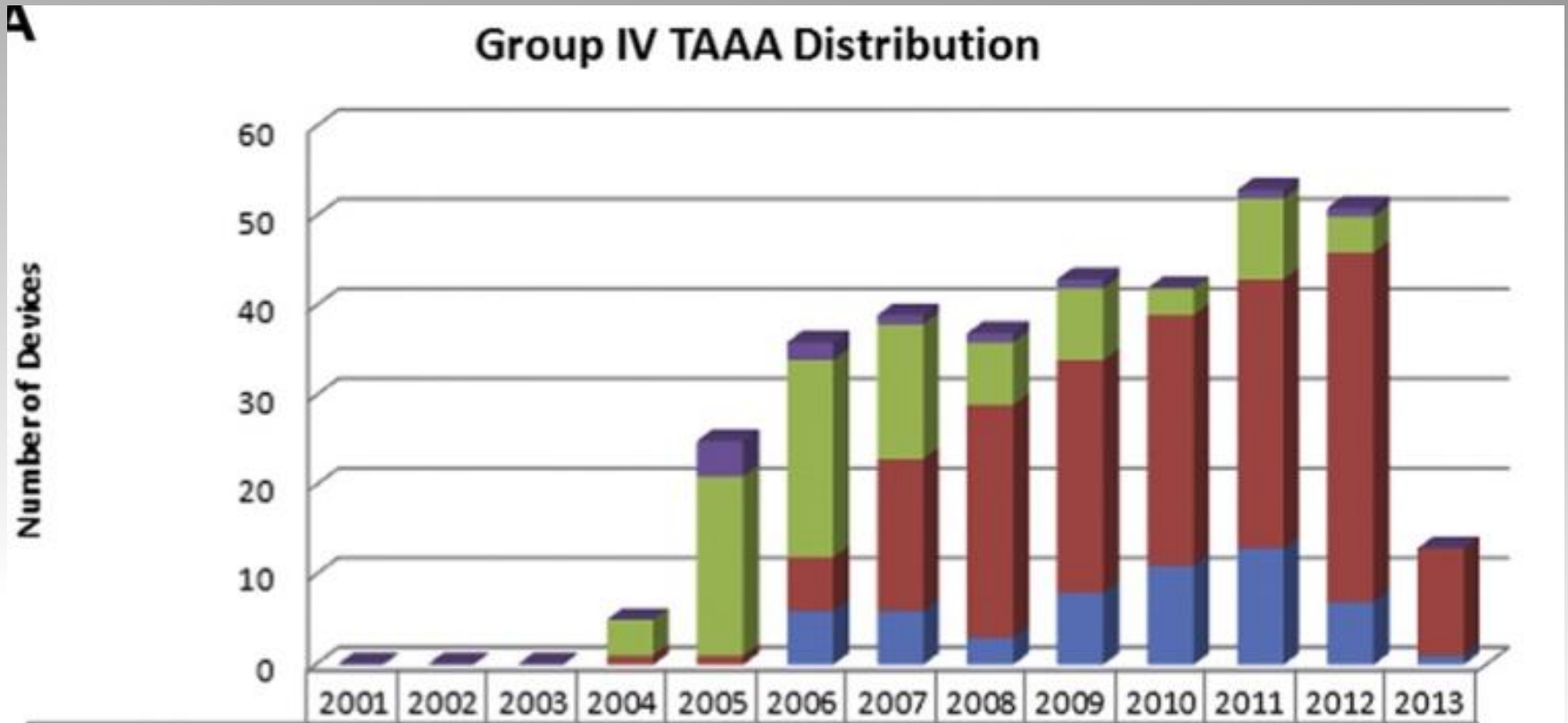
What changes with experience?

Over time, in good hands,

technical results may not vary, but the PLAN matures.

Sveinsson et al, JVS 2015

Technique *& Design* are subject to a learning curve



	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Renal IV	0	0	0	0	4	2	1	1	1	0	1	1	0
SMA IV	0	0	0	4	20	22	15	7	8	3	9	4	0
Celiac Scallop IV	0	0	0	1	1	6	17	26	26	28	30	39	12
Celiac Fen IV	0	0	0	0	0	6	6	3	8	11	13	7	1

Mastracci et al, JVS 2015

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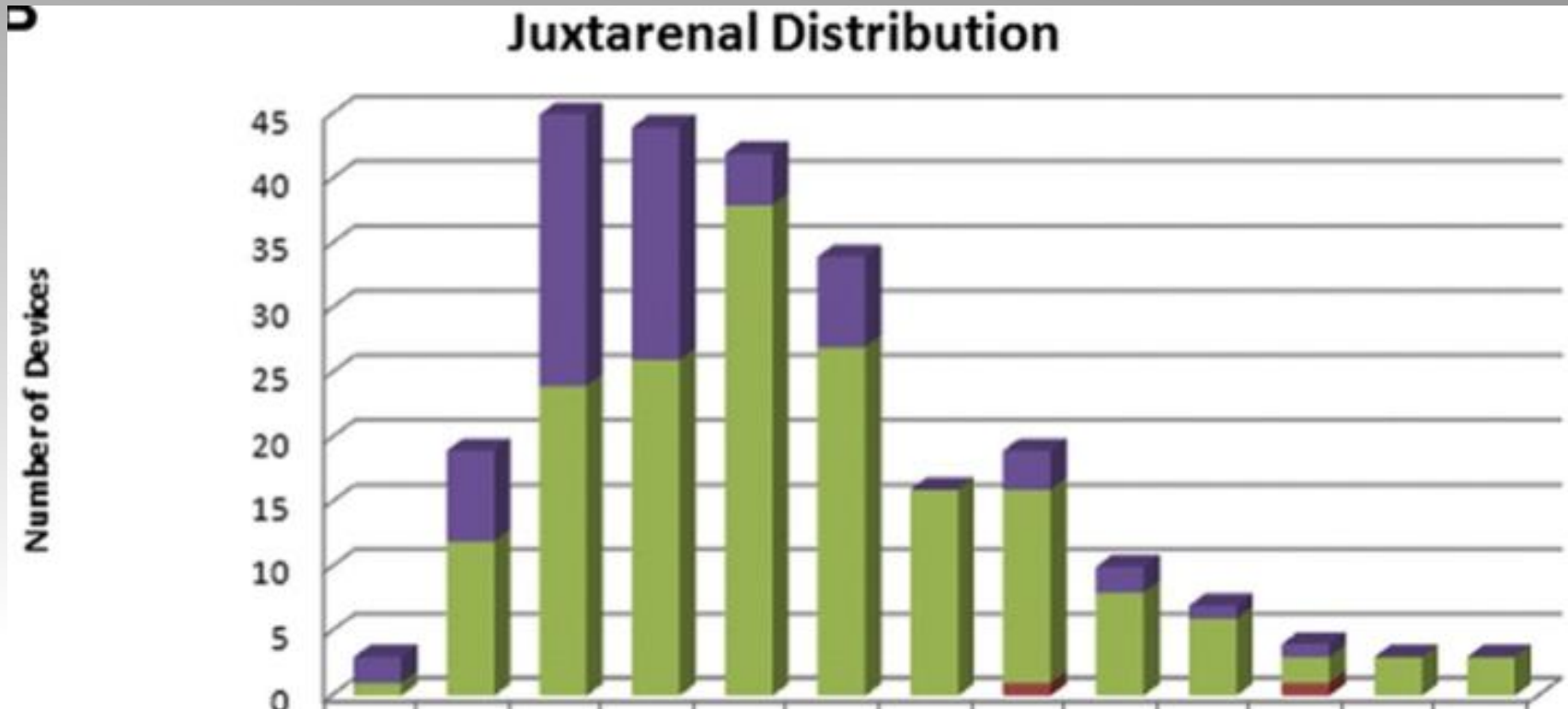
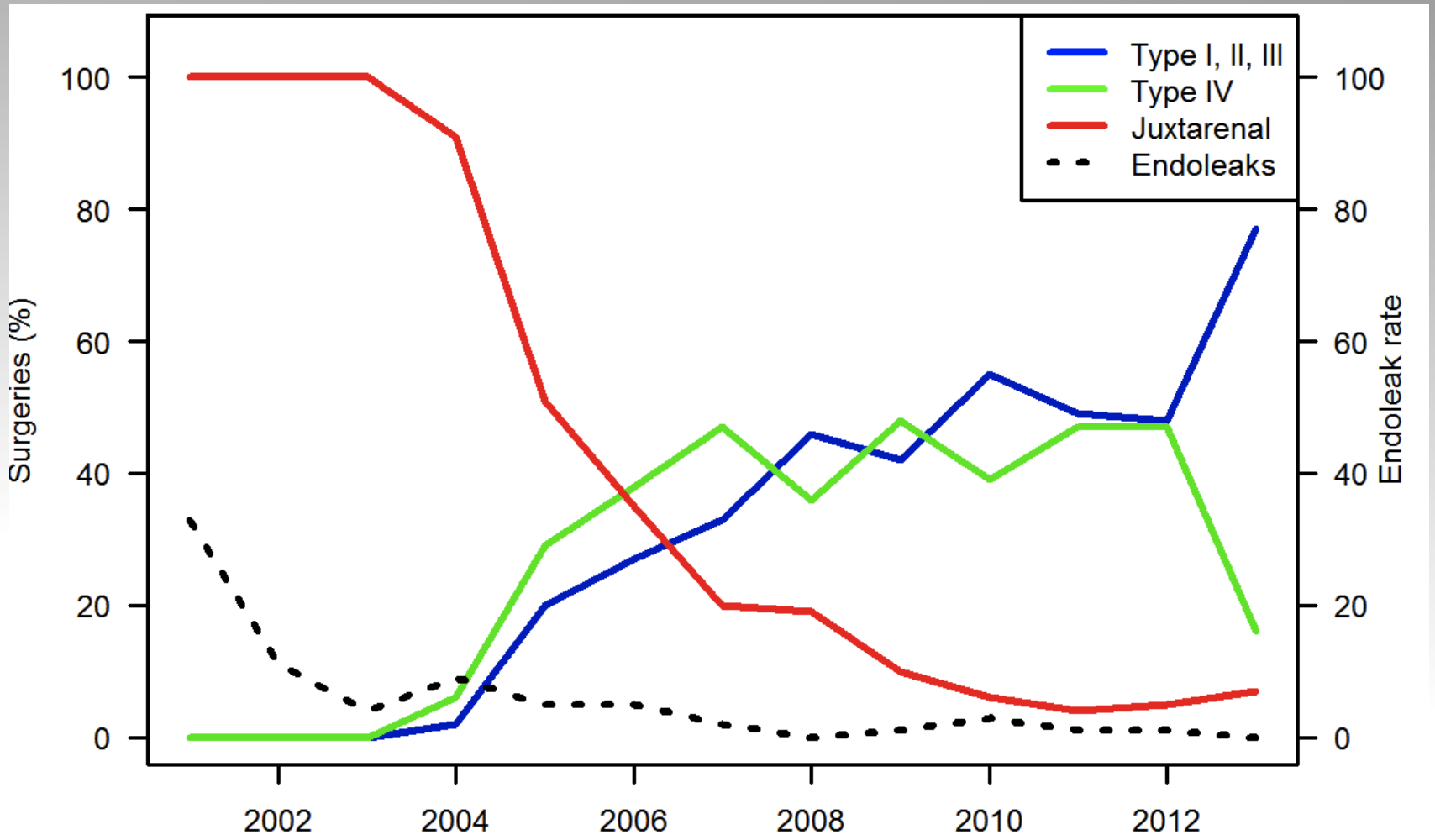
Technique *& Design* are subject to a learning curve



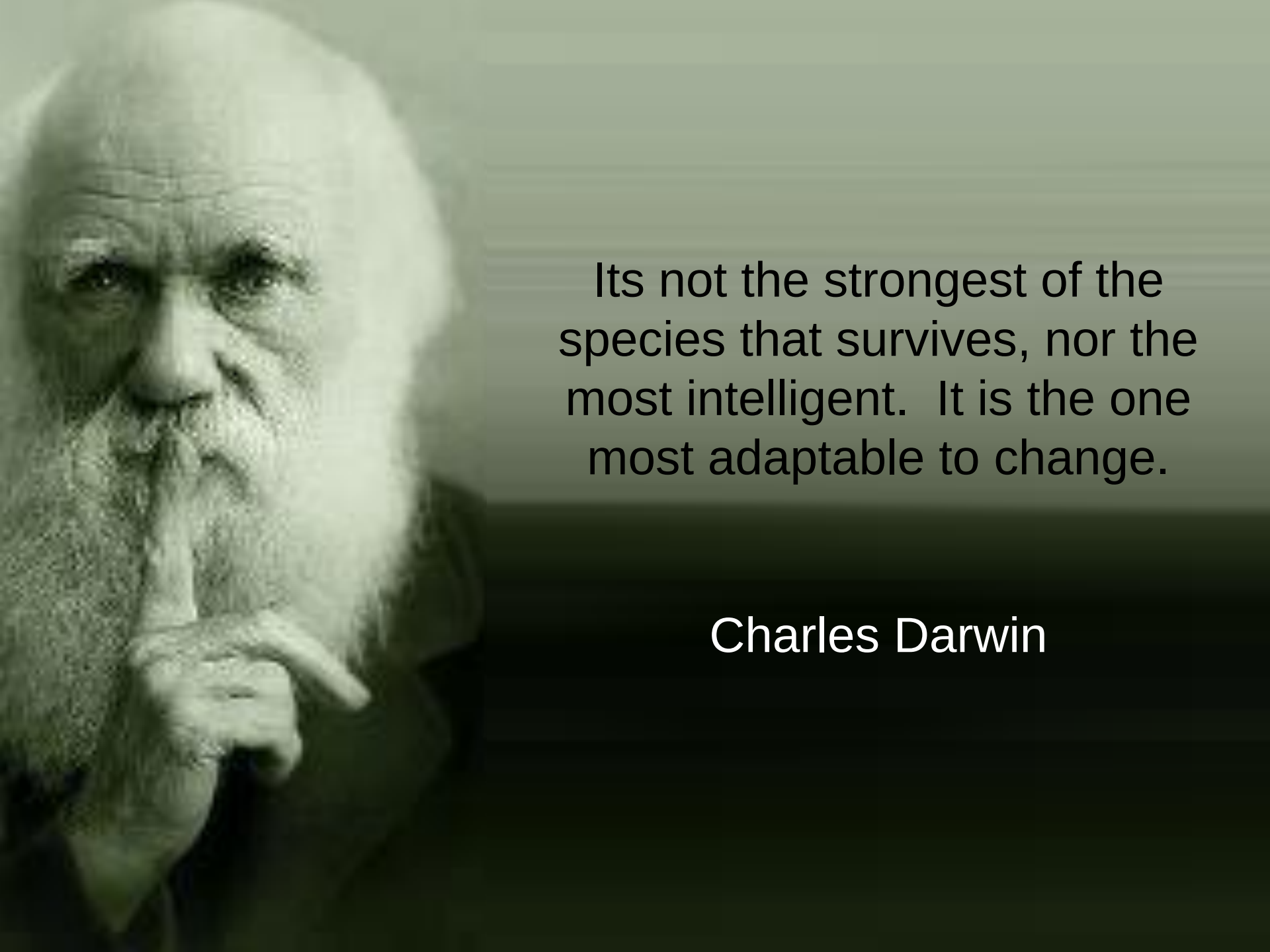
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Renal JR	2	7	21	18	4	7	0	3	2	1	1	0	0
SMA JR	1	12	24	26	38	27	16	15	8	6	2	3	3
Celiac Scallop JR	0	0	0	0	0	0	0	1	0	0	1	0	0
Celiac Fen JR	0	0	0	0	0	0	0	0	0	0	0	0	0

Mastracci et al, JVS 2015

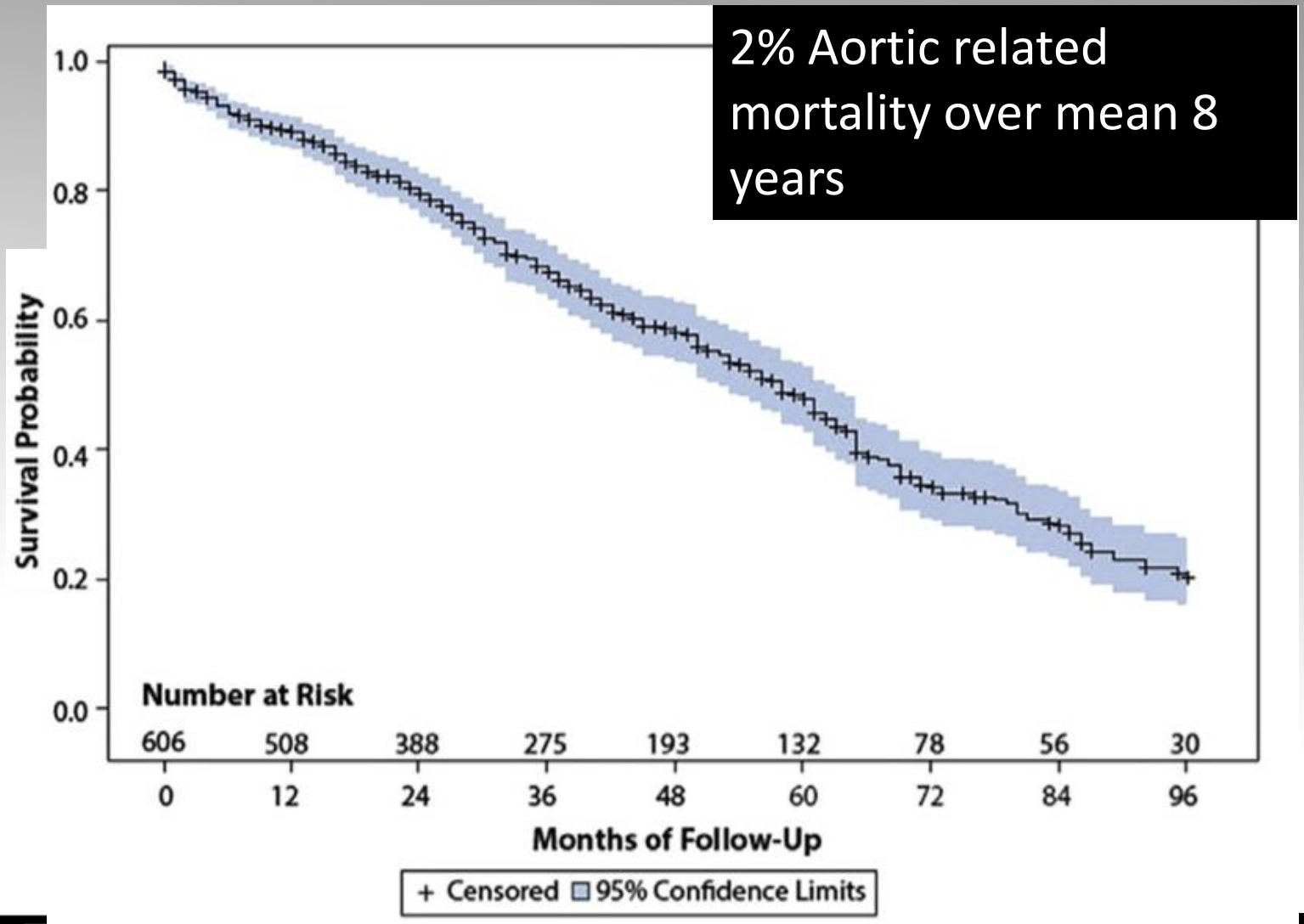
Endoleak Rate: Learning Curve



O'Callaghan et al, JVS 2015


Its not the strongest of the species that survives, nor the most intelligent. It is the one most adaptable to change.
Charles Darwin

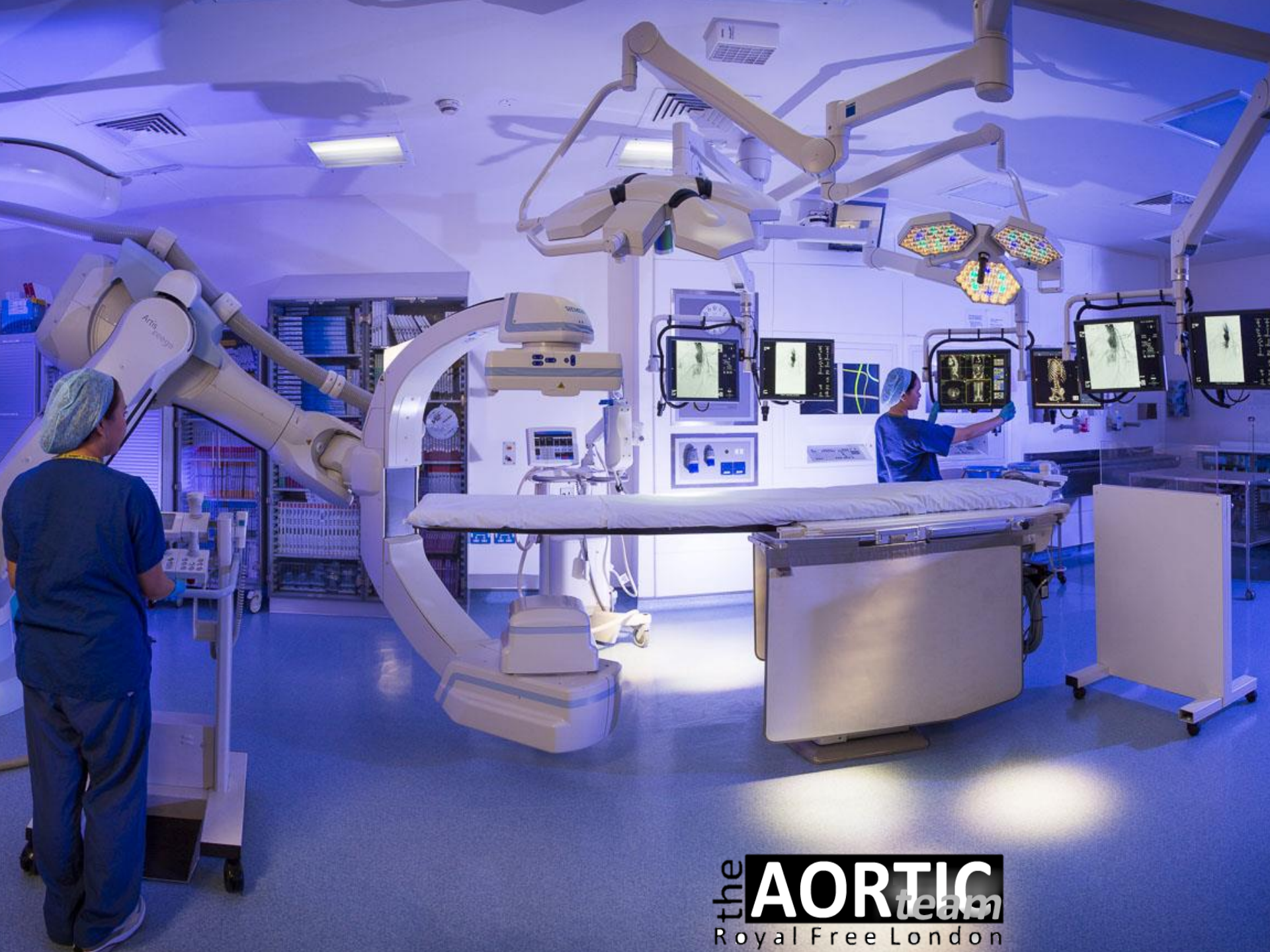
12 Year Experience with Fenestrated Grafts



Mastra [illegible] al, JVS 201[illegible]

How can you Plan for a Successful and Durable Repair?

- Combine the intelligence to appreciate a low signal to noise ratio with the humility to change course and evolve.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