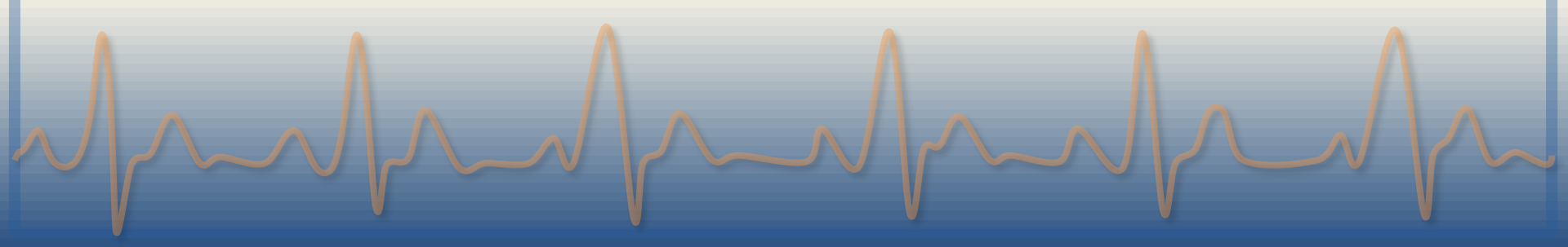


Should Carotid Stenting Volume Requirements Be Markedly Decreased or Eliminated? Yes, Given the Drop in Activity Resulting From a Lack of Reimbursement and No Data Showing They Are Necessary!

**Gary S. Roubin MD PhD.
Chairman. IMC. CREST 2 Trial.**

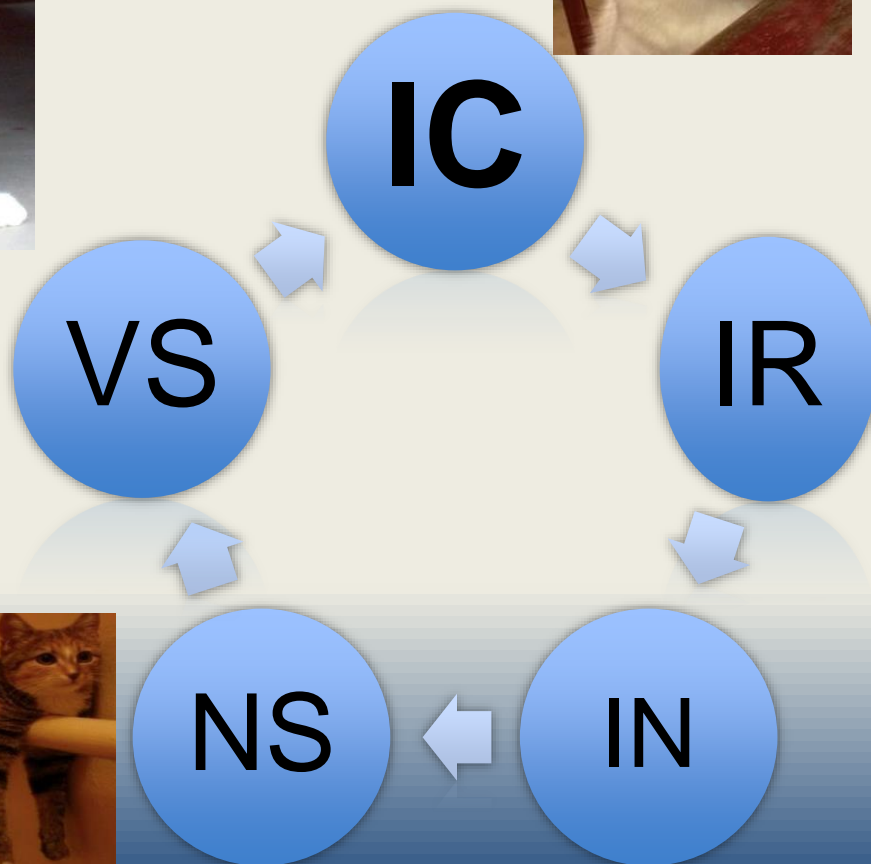
Conflicts of Interest.

- 1. Cook Inc.**
- 2. Essential Medical Inc.**
- 3. The Medicines Co.**

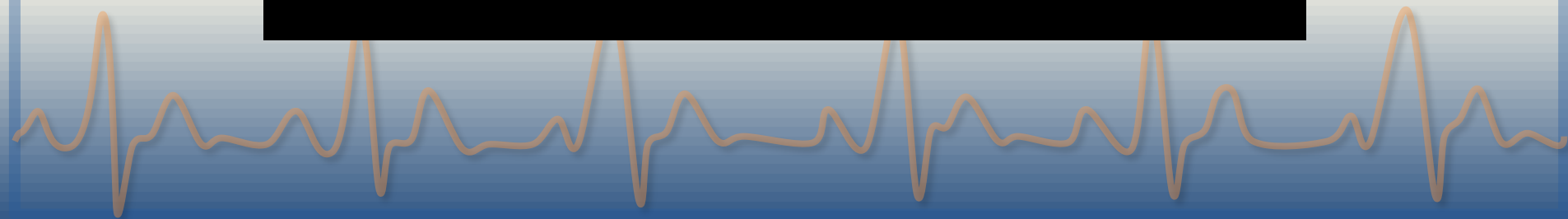
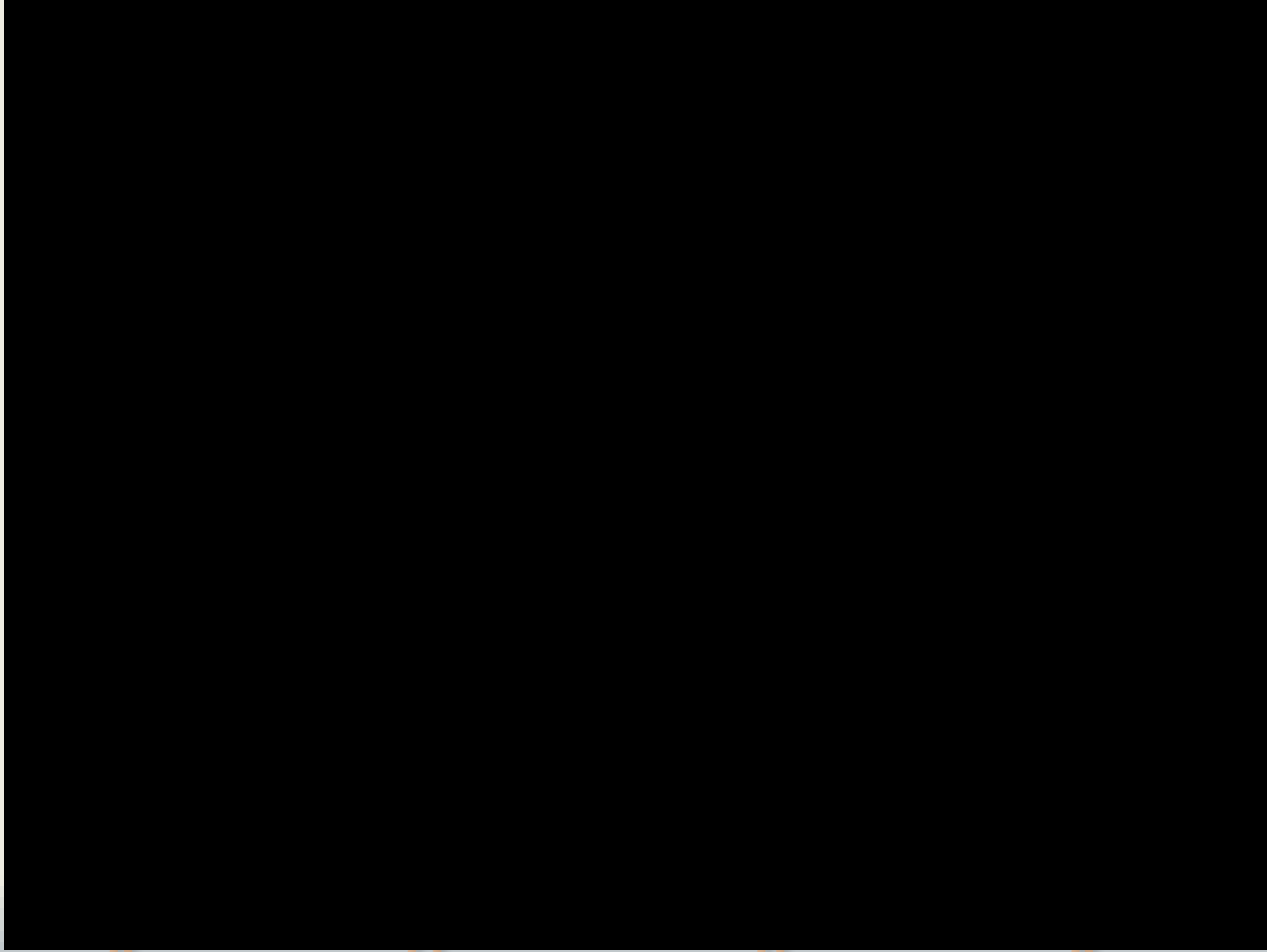




Since the beginning of carotid stenting all the “cats” wanted “IN” on the act! An unprecedented assault on a potentially safe, minimally invasive, efficacious and outpatient procedure !



Video



Herding Cats!

After two decades of mentoring, teaching, demonstrating, lecturing, studying and publishing on good patient selection and technique – I am astonished that a large percentage of operators regard less of stated volume and experience are “clueless”! On how to perform safe efficacious carotid stenting.

How do I know this?

How important is experience and volume ?

Credentialing process for CREST 2 BY the IMC.

	A	B	C	D	E	F	G	H
186	Univ of Colorado	No	R. Kevin Rogers	2.10.2015	Approved			W. Gray
187	LeBauer CV Research	No	Jonathon Berry	2.24.2015	Approved	Yes, 5	3.31.2015	B. Katzen
188	Alexian Brothers	Satellite	Sarah Johnson	2.24.2015	Conditionally Approved	Yes, 10-15	Additional cases G. Roubin	C. White
189	Sparrow Clinical Inst.	No	Joel Cohn	3.31.2015	Conditionally Approved	Yes, 10		G. Roubin
190	Sparrow Clinical Inst.		Syed Hussain	4.7.2015	Conditionally Approved	Yes, 20		G. Roubin
191	Sparrow Clinical Inst.		Dale Leffler	4.14.2015	Conditionally Approved	Yes, 10		G. Roubin
192	University of Cincinnati		Andrew Ringer	3.31.2015	Conditionally Approved	Yes, 10-15		K. Rosenfield
193	L'Enfant Jesus	No	Genevieve Milot	3.17.2015	Conditionally Approved	Yes, 10		T. Jovin
194	MJUSC	RCC	Claudio Schonholz	2.17.2015	Conditionally Approved	Yes, 3		D. Heck
195	Ohio State University	RCC	Barry George	3.31.2015	Conditionally Approved	Yes, 5		C. White
196	Ohio State University		Jean Starr	3.31.2015	Conditionally Approved	Yes, 10-15		C. White
197	Ohio State University		Ciaran Powers	3.31.2015	Denied			C. White
198	Ohio State University		Michael Go	3.31.2015	Denied			C. White
199	Palo Alto	No	Wei Zhou	3.3.2015	Conditionally Approved	Yes, 15-20		C. White
200	UT Texas	RCC	Richard Smalling	4.7.2015	Approved	Yes, 3	Approved 7.28.15 - G. Roubin 3 additional	T. Jovin
201	UT Texas		Ali Azzizadeh	4.7.2015	Conditionally Approved	Yes, 15-20		T. Jovin
202	UT Texas		Peng Chen	3.31.2015	Conditionally Approved	Yes, 5-10		T. Jovin
203	St. Francis	No	George Petrossian	4.7.2015	Approved			D. Heck
204	Case Western Univ	RCC	Preet Kang	5.12.2015	Conditionally Approved	Yes, 10		G. Roubin
205	St. Louis University	No	Randall Edgell	5.5.2015	Conditionally Approved	Yes, 5-10		N. Hopkins
206	St. Louis University		Donald Jacobs	6.16.2015	Conditionally Approved	Yes, 5	9.22.15; deferred Additional cases Roubin	D. Heck
207	University of Michigan	RCC	Enrique Criado	4.28.2015	Conditionally Approved	Yes, 15	Silk Road.	C. White
208	Unity Point Des Moines	No	Douglas Massop	5.12.2015	Conditionally Approved	Yes, 15		G. Roubin
209	Overlake Hospital	Satellite	Abhineet Chowdhary	4.21.2015	Denied			D. Heck
210	Mount Sinai Miami Beach	No	Robert Beasley	4.21.2015	Approved	Yes, 2	5.12.2015 G. Dabus	T. Jovin
211	Providence Hospital	No	Jamal Zarghami	4.28.2015	Conditionally Approved	Yes, 15		T. Jovin
212	Providence Hospital		Marcel Zughaib	4.28.2015	Conditionally Approved	Yes, 3		T. Jovin
213	Providence Hospital		Patrick Alexander	4.28.2015	Conditionally Approved	Yes, 15		T. Jovin
214	Desert Regional	No	Mohammed Taqi	4.28.2015	Approved			B. Jankowitz
215	St. Joseph's Stockton	No	Surrender Raina	5.12.2015	Conditionally Approved	Yes, 3		D. Heck
216	St. Joseph's Stockton		Venkata Emami	5.12.2015	Conditionally Approved	Yes, 10		D. Heck
217	SUNY Buffalo	No	Nick Hopkins	5.12.2015	Approved			G. Roubin
218	SUNY Buffalo		Elad Levy	5.12.2015	Approved			G. Roubin
219	SUNY Buffalo		Kenneth Snyder	5.12.2015	Approved			G. Roubin
220	SUNY Buffalo		Adnan Siddiqui	5.12.2015	Approved			G. Roubin
221	Huntington Memorial	Satellite	Steven Katz	5.12.2015	Conditionally Approved	Yes, 15		T. Jovin
222	University of Minnesota	RCC	Ramachandra Tummala	5.12.2015	Approved			N. Hopkins
223	University of Miami	RCC	Dileep Yavagal	7.14.2015	Conditionally Approved	Yes, 5		T. Jovin
224	University of Washington	RCC	Basavaraj Ghodke	5.19.2015	C2R only	Yes, 20-25 CAS		C. White
225	Morton Plant	No	Eric Lopez del Valle	5.26.2015	Approved	Yes, 2	Additional cases - Jankowitz 9.1.15	C. White
226	Stanford	RCC	Jason Lee	7.7.2015	Deferred			C. White
227	University of Pennsylvania	RCC	Ron Fairman	7.7.2015	Conditionally Approved	Yes, 15-20		D. Heck
228	University of Pennsylvania		Robert Hurst	6.9.2015	Denied			B. Jankowitz
229	Arizona Heart Hospital	No	Venkata Ramaiah	5.19.2015	Denied			B. Jankowitz
230	Arizona Heart Hospital		Raul Malhotra	5.19.2015	Conditionally Approved	Yes, 15		B. Jankowitz
231	Franciscan St. Francis Health	No	William Berg	5.26.2015	Approved	Yes, 3	9.22.15 Additional cases - Dabus	D. Heck
232	Gundersen	Satellite	Mouhammed Kabbani	5.19.2015	Approved	Yes, 10	Additional cases Roubin 8.18.15	T. Jovin
233	Maine Medical	No	Robert Ecker	6.2.2015	Approved			B. Jankowitz
234	Maine Medical		Christopher Baker	6.2.2015	Approved			B. Jankowitz
235	Thomas Jefferson	No	Robert Rosenwasser	6.2.2015	Conditionally Approved	Yes, 15		G. Roubin
236	Thomas Jefferson		Pascal Jabbour	6.9.2015	Deferred			G. Roubin
237	Thomas Jefferson		Stavropola Tjoumakaris	6.9.2015	Deferred			G. Roubin
238	Rush	Satellite	Jeffrey Snell	5.26.2015	Deferred			G. Roubin
239	Deborah Heart and Lung	No	Jon George	6.9.2015	Denied			B. Gray
240	Deborah Heart and Lung		Richard Kovach	6.9.2015	Conditionally Approved	Yes, 15	8/4 requested 5 more.... Additional case	B. Gray
241	Duke	No	Fernando Gonzalez	6.9.2015	Conditionally Approved	Yes, 15		B. Jankowitz
242	Bryan Heart	No	Robert Hibbard	6.30.2015	Conditionally Approved	Yes, 20		N. Hopkins
243	University of Massachusetts	Satellite	Ajay Wakhloo	6.23.2015	Conditionally Approved	Yes, 10		B. Jankowitz
244	University of Massachusetts		Ajit Puri	6.23.2015	Conditionally Approved	Yes, 10		B. Jankowitz

CREST2 Interventional Management Committee.

Gary S Roubin MD, PhD. Chair.

Thomas Brott MD

Barry Katzen MD

William Gray MD

BK Lau MD

Donald Heck MD

Jon Matsumura MD

Nick Hopkins MD

Kenneth Rosenfield MD

Tudor Jovin MD

Christopher White MD

CREST 2 Interventional Management Committee.

Credentialing process:

If you have a career experience of more than 50 cases (fellowship experience considered) please submit your last 25 cases with data sheet and confirmation procedure reports.

252 Operators.

6,300 Procedure reports and 252 data sheets reviewed and considered on weekly 1 hour conference calls.

81 Approved for RCT.

134 Moved to more cases in C2R.

Top 10 Most Egregious Reasons preventing immediate access to RCT.

- 1. Stenting elderly patients without regard for adverse anatomy and cerebral function.**
- 2. Ignoring fundamentals of patient selection concerning arch anatomy, tortuosity, calcification and lesion length and complexity.**
- 3. Failing to use optimal pre procedure DAP and statin therapy.**
- 4. Disregard for optimal anticoagulation therapy.**
- 5. Disregard for properly defined symptom status and lesion severity.**

- 6. Pre dilating with oversized balloons.**
- 7. Routinely using 40 mm long undersized stents.**
- 8. Utilizing general anesthesia or heavy sedation.**
- 9. Post dilating aggressively and /or with balloons > 5mm in diameter and more than a single inflation.**
- 10. Lengthy EPD and Fluro times and
Not documenting neurological status post procedure.**

The wisdom to do the best
for your patient

**Technical and cognitive skills and
clinical and procedural judgment
can only be learnt by experience !**

**The wisdom derived from
experience requires the
challenges and failures ONLY
provided by procedural volume.**

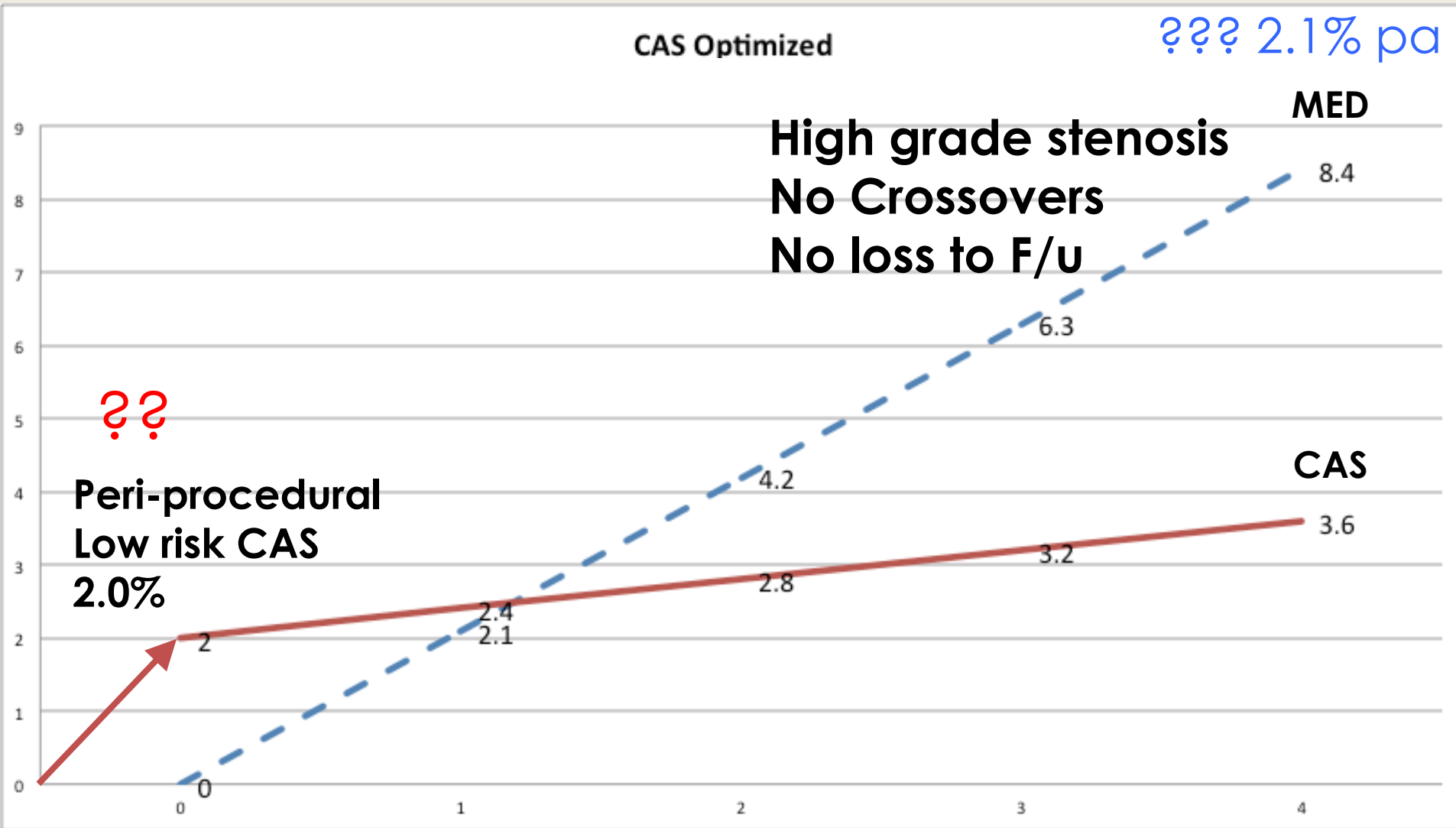
CREST2 Trial Credibility

High Grade Stenosis  Events in the Medical Arm

- Young patients.
Perfect 'Ideal' Anatomy  Events Stenting Arm

Skilled and experienced operators.

Trial Credibility



**Should Carotid Stenting Volume
Requirements Be Markedly
Decreased or Eliminated?**

A resounding NO!