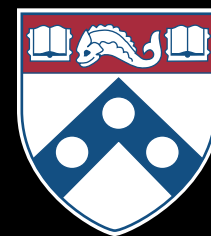


Contact Force Sensor: Crucial Tool or Nice Toy?

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Disclosures

- *Honoraria and consultant for Biosense Webster*
- *Honoraria from Boston Scientific*



Outline

- Available contact force technologies.
- Clinical studies assessing safety and efficacy.
 - What have we learned
- Development of guidelines for CF including lesion index real-time measurements.
 - What to look forward to



Why Contact Force?

Power (W)

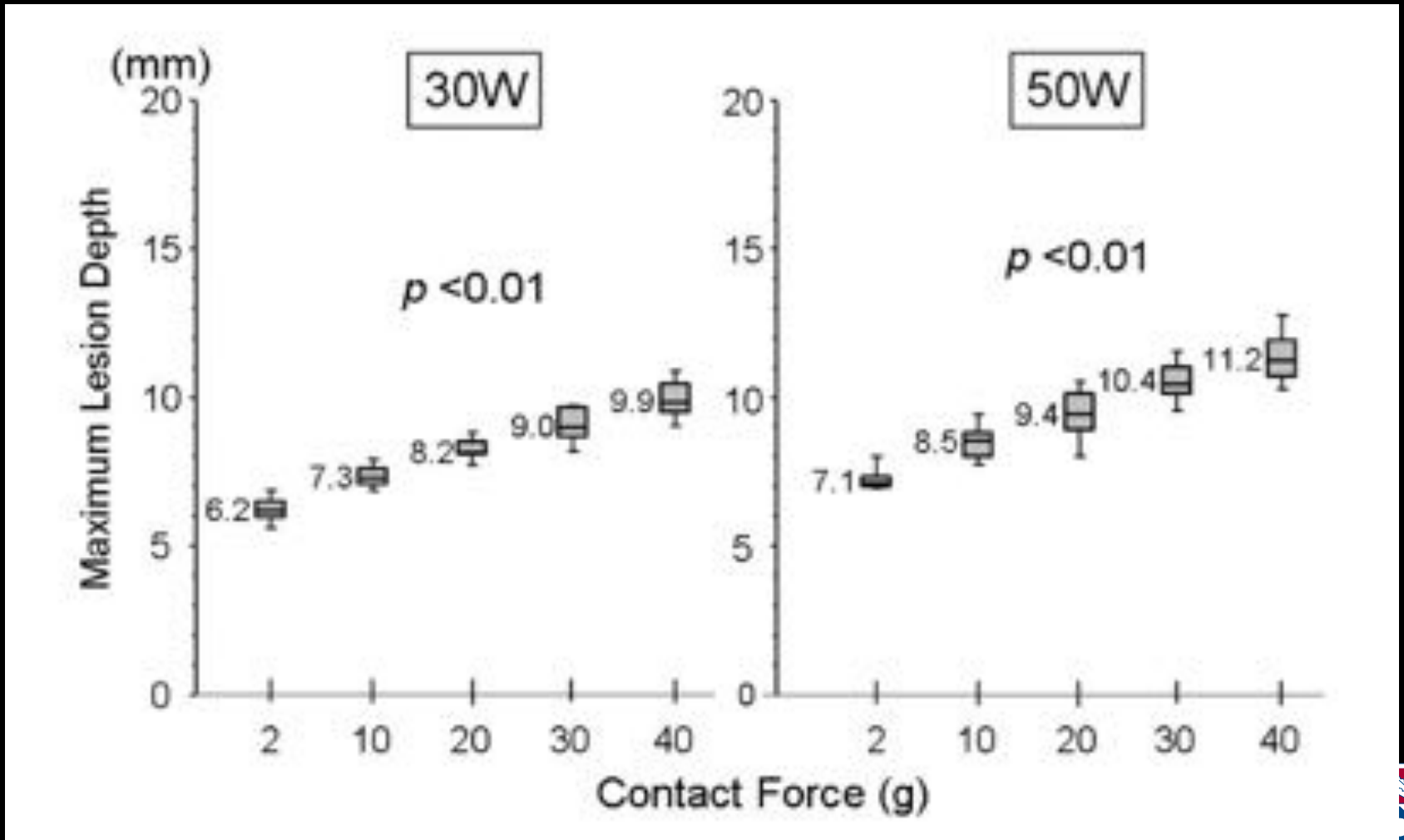
Duration (s)

**Temperature
(°C)**

**Contact
Force (g)**



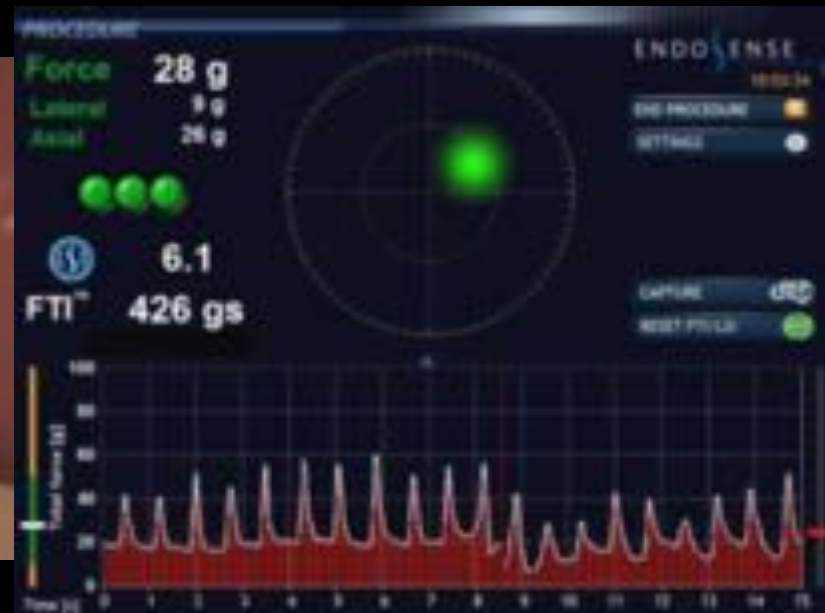
CF is a Major Determinant of Lesion Size



Real-Time CF Measurement

Tacticath Endosense

- Dedicated interface (Contact Force information)
- 50 Hz sampling rate (real-time highly accurate information)
- Only unidirectional



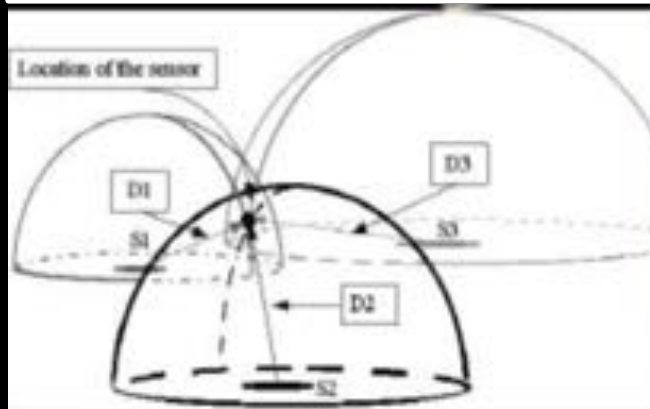
Real-Time CF Measurement

Thermocool SmartTouch



Sensors receive transmitter coils location signals and micro-movements of the spring

Transmitter coil in the tip sends location reference signal



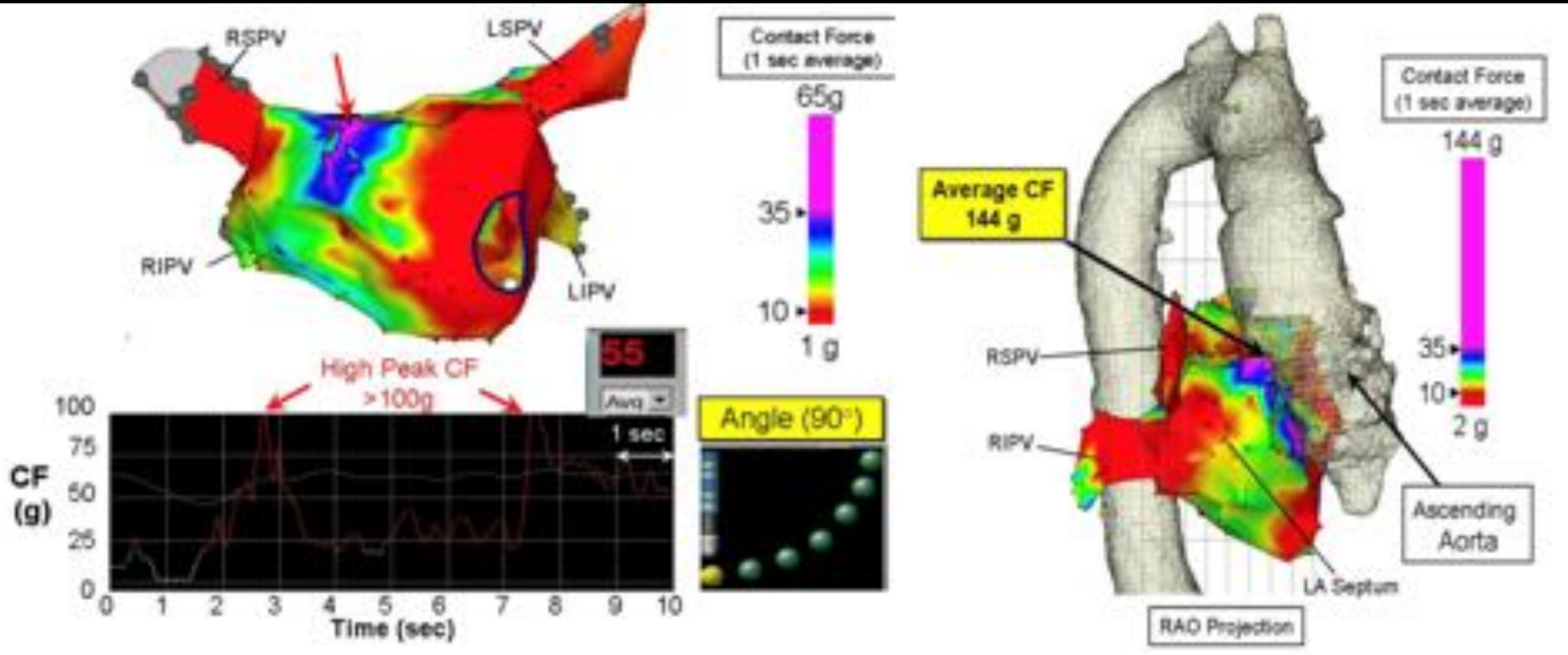
Precision spring allows small amount of electrode deflection

Operators are Different

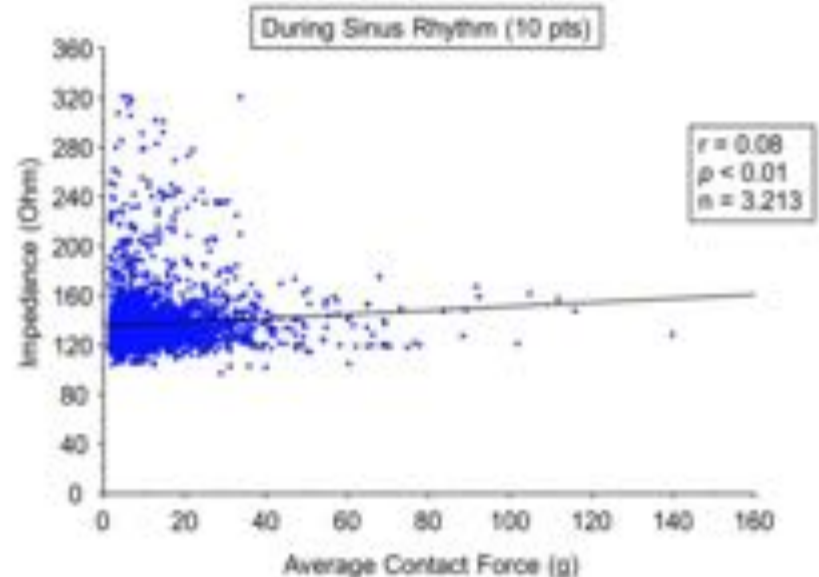
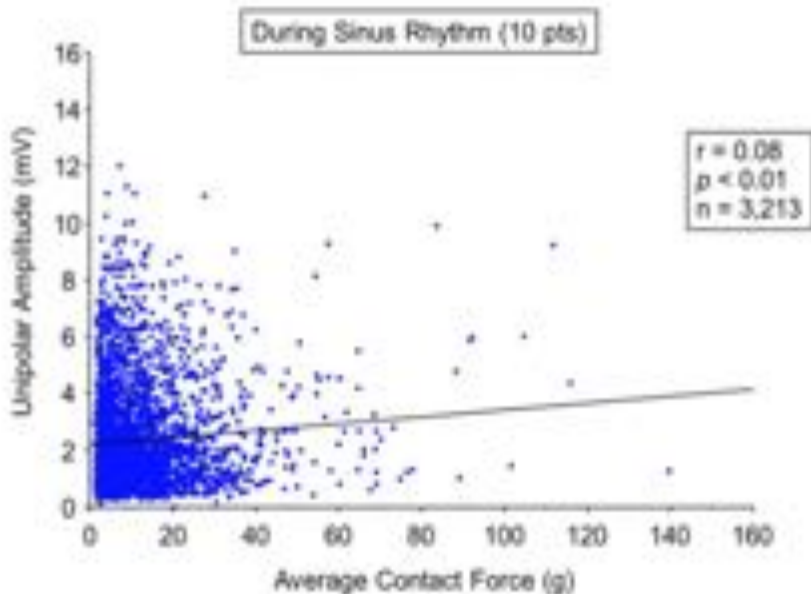
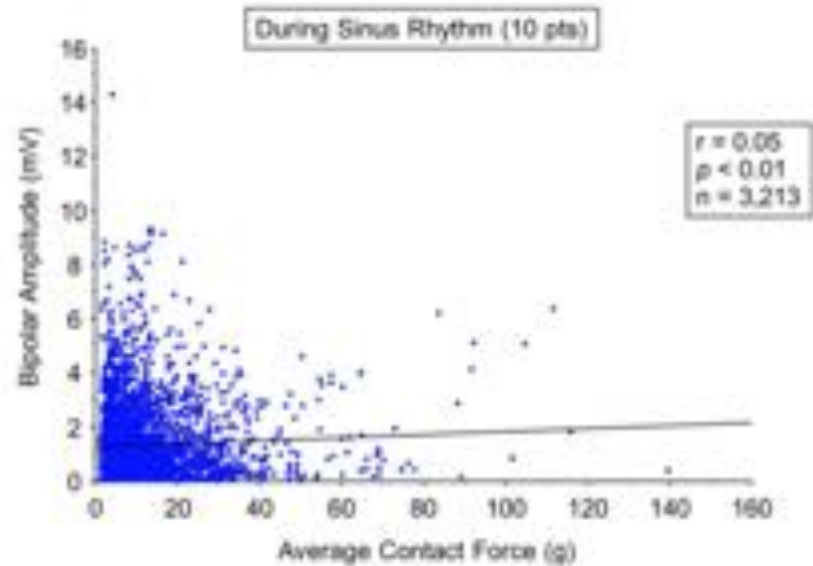
TOCCATA Study



CF is Site Dependent



CF Cannot be Predicted by EGMs Characteristics



22% of Lesions Without CF DO NOT Create Lesions

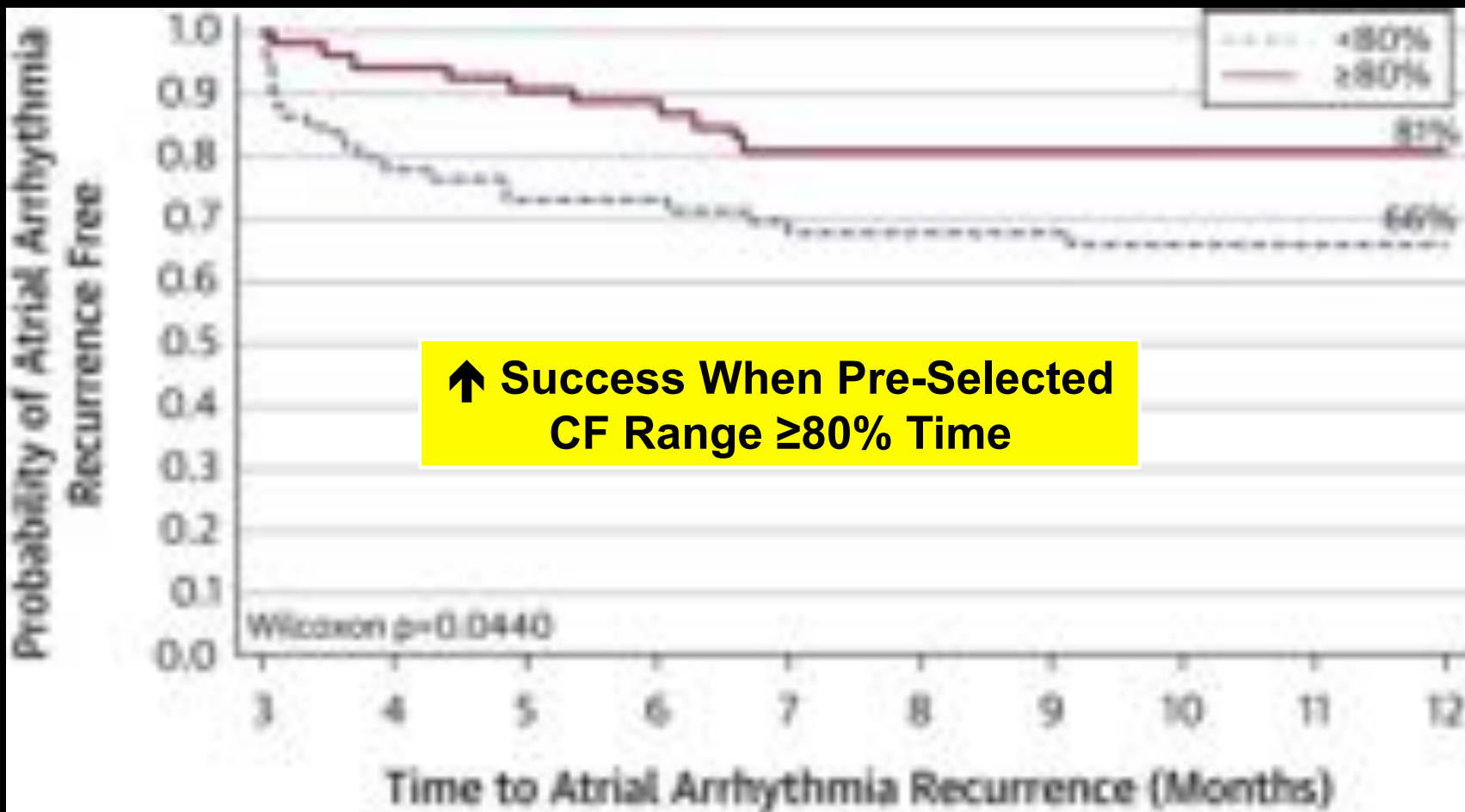
- Ventricular ablations in sheep model, 30W, 60s
- Experienced operator, confirming impression of good contact based on tactile feed-back, fluoroscopy and EGMs.
- 100% of lesions detected if CF > 10g and FTI >500 gs
- FTI most accurate parameter to predict lesion size
- 22% of endocardial RF applications that were thought to have good contact did not result in lesion formation.



Endo Card		Epi Card	
ThermoC (n=80)	TactiCath (n=80)	ThermoC (n=68)	TactiCath (n=72)
78%	98%	90%	100%
p < 0.001		p=0.02	
Lesions detected			

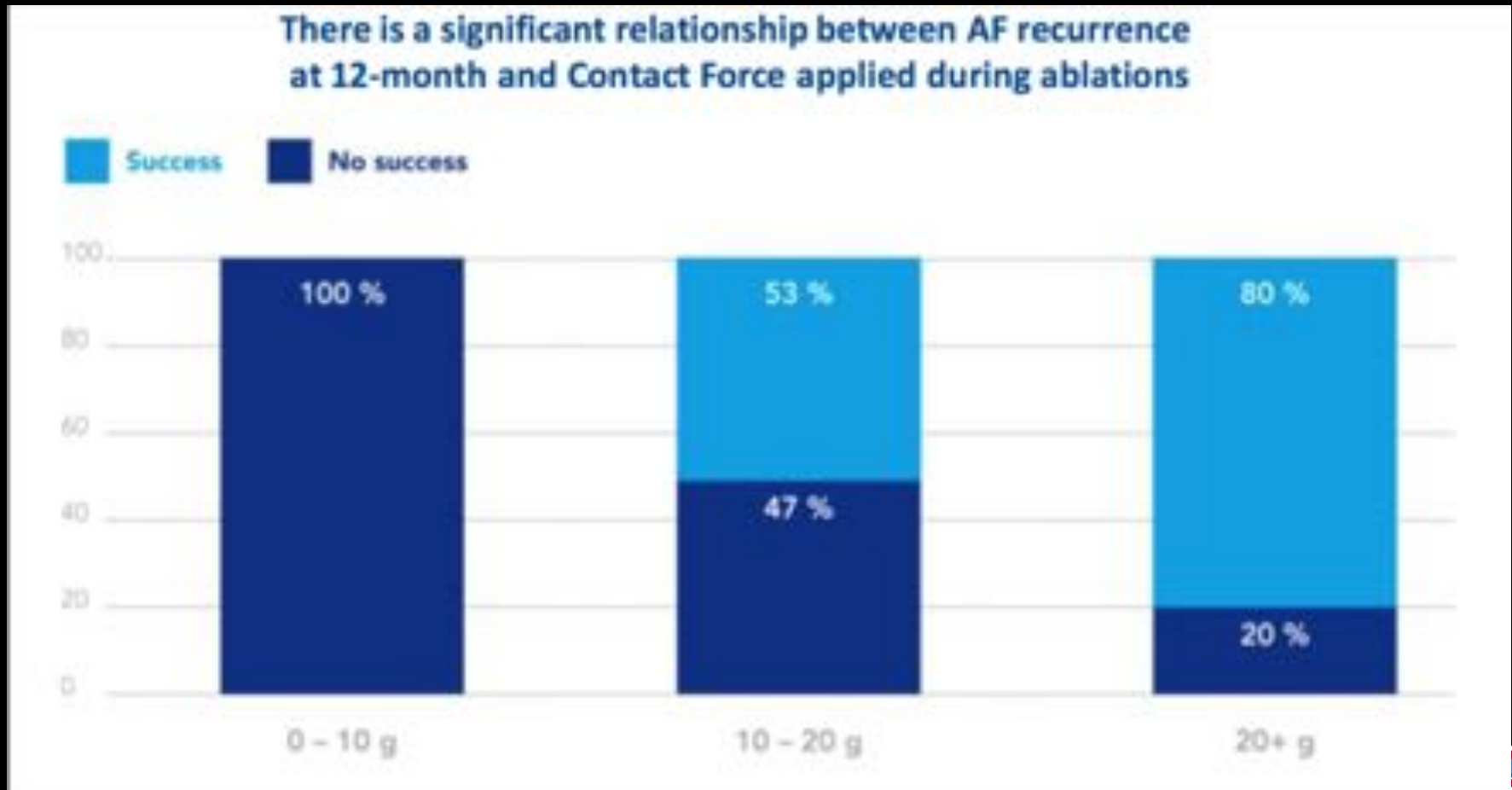
SMART-AF

Prospective Nonrandomized



Outcomes Improve With CF

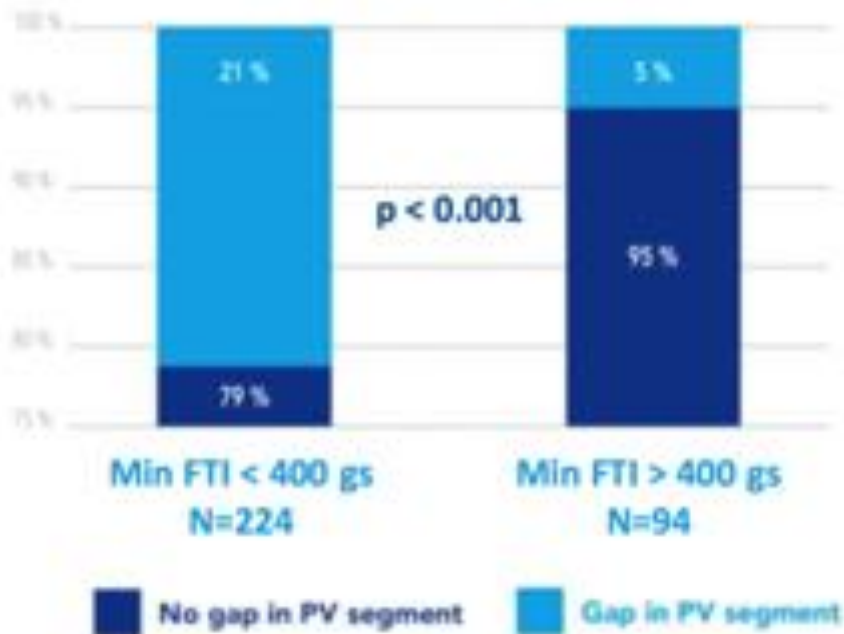
TOCCATA Study



EFFICAS I – OUTCOME

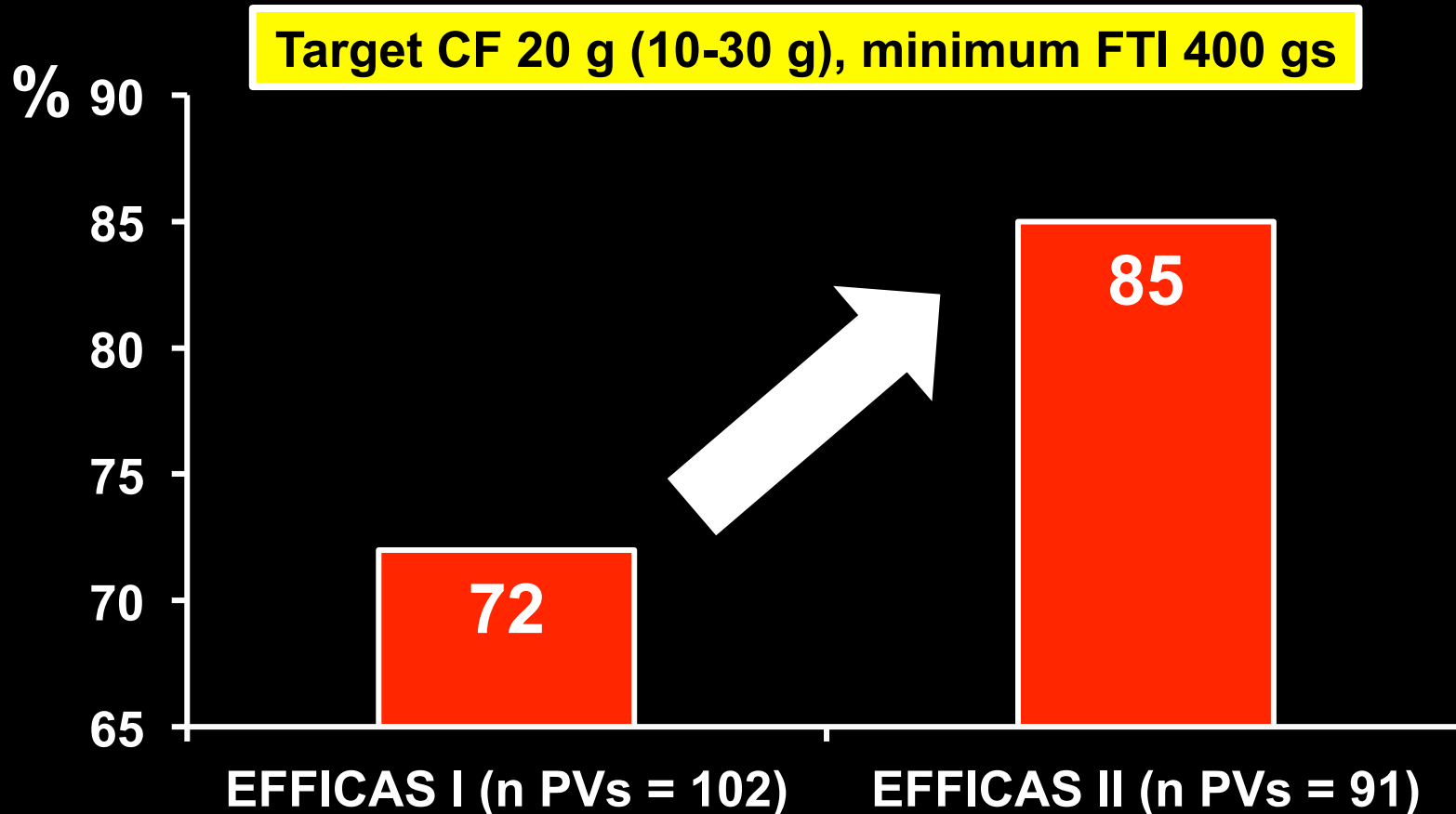
Role of the FTI

Relationship between Min FTI and % of gap in PV segments

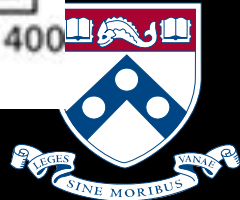
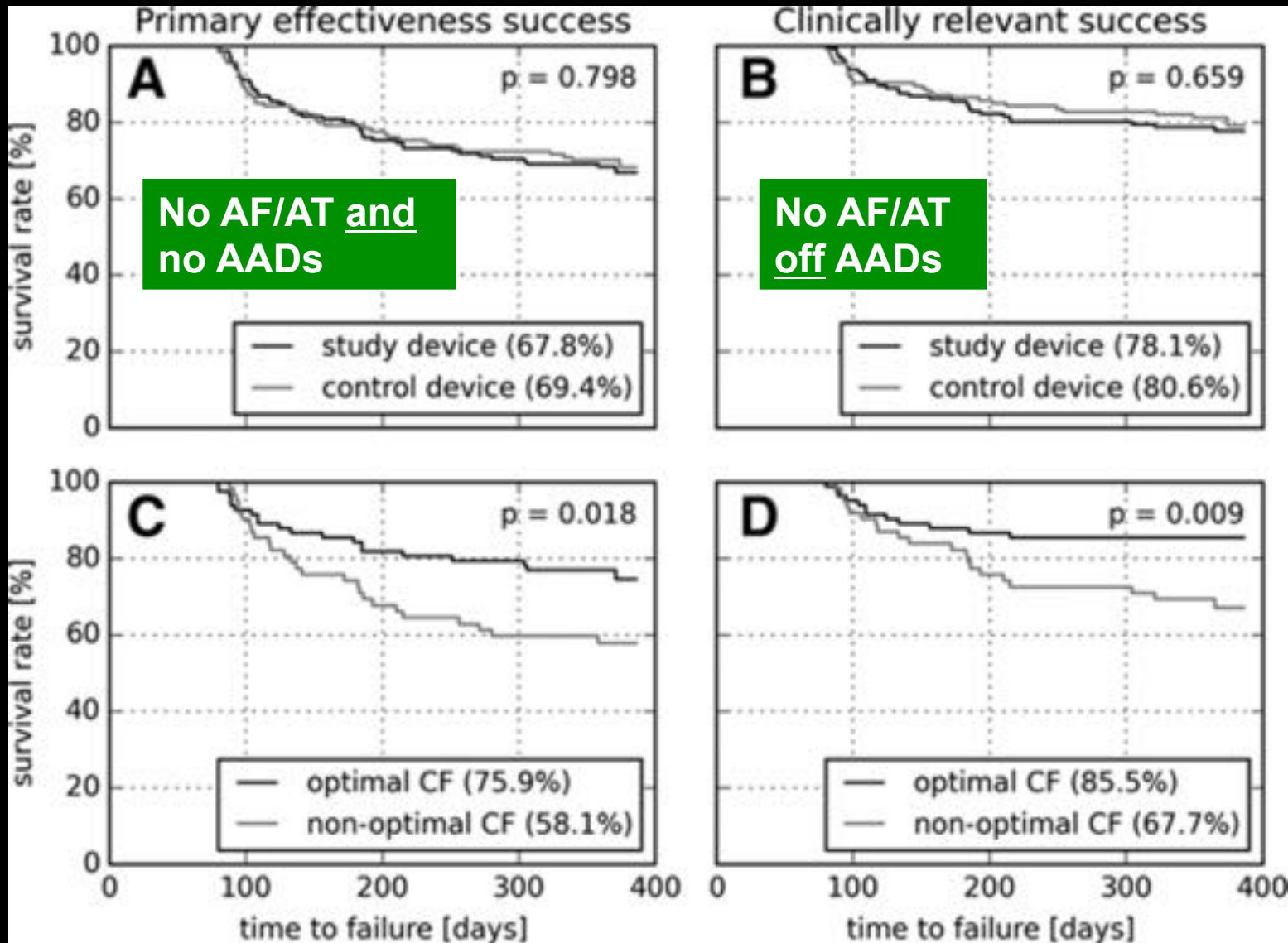


Parameter (per segment)	Median NO GAP N=266	Median WITH GAPS N=52	p-value
CF	19.5 g	15.5 g	p = 0.022
FTI	708 gs	627 gs	p = 0.090
Total number of ablations	6	9	p < 0.001
Min CF	8.1 g	3.6 g	p < 0.001
Min FTI	232 gs	118 gs	p < 0.001

Contact Force & Optimization of Catheter Contact Matters: EFFICAS II



TOCCASTAR RCT



TOCCASTAR vs. TOCCATA

Comparison of CF Indicators

Average CF [g] over all ablations



Percent Lesions with Low FTI (< 400 gs)



Percent Lesions with Low CF (< 5 g)



Intra-operator Variability in CF



Integrating Power to CF Information

Lesion Index (LSI™)

- Parameter to estimate lesion growth in real-time combining CF, ablation duration and RF power
- Models both electrical resistive and conductive thermal heating over time

Power (W)

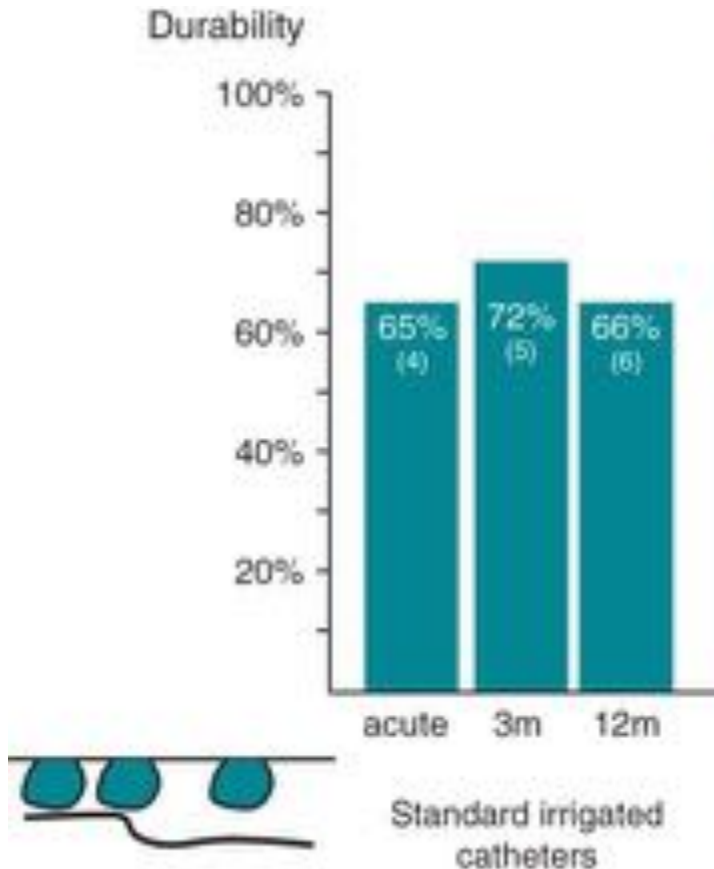
Duration (s)

CF (g)

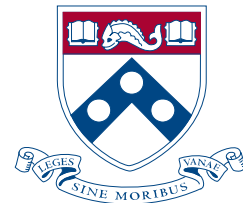
Still investigational!



Towards Lesion Size Index



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6. Wilber DJ et al. *JAMA* 2010;303:333–40
12. Marijon E et al. *J Cardiovasc Electrophysiol* 2014;25:130–7
14. Park CI et al. *J Cardiovasc Electrophysiol* 2014;25:701–8.
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Conclusions

- Contact force information has added significant value to the ablation armamentarium, with a potential for increase success rates and safety.
- Contact force guidelines are being developed from **retrospective analyses of data from clinical trials**
 - Target 20 g (range 10-30 g)
 - Min >10 g for any ablation point
 - Min >400 gs for any ablation point
- Prospective studies needed to better define lesion index guidelines

