



Arrhythmias & Heart Failure
New Insights & Technological Advances

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Ablation Index :

A new standard for Safety and Efficacy

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Disclosures

Dr Franck Halimi

I have the following potential conflicts of interest to report:

Consulting:

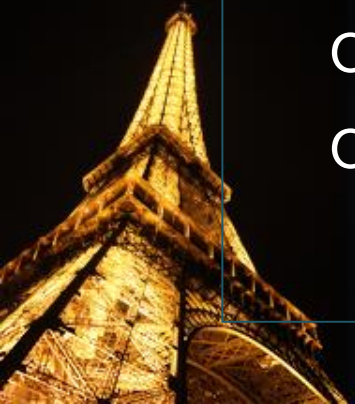
- Medtronic, Saint Jude Medical, Boston Scientific, Biotronik, Johnson & Johnson

Employment in industry: 0

Shareholder in a healthcare company: 0

Owner of a healthcare company: 0

Other(s): 0



Background: Contact force technology

- Has become a new standard for catheter ablation
 - AF ablation
- Evidences for
 - Better acute PVI and long term outcomes
 - Improved safety

Real-Time Contact Force Sensing for Pulmonary Vein Isolation in the Setting of Paroxysmal Atrial Fibrillation: Procedural and 1-Year Results

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and JEAN-PAUL ALBENQUE, M.D.*

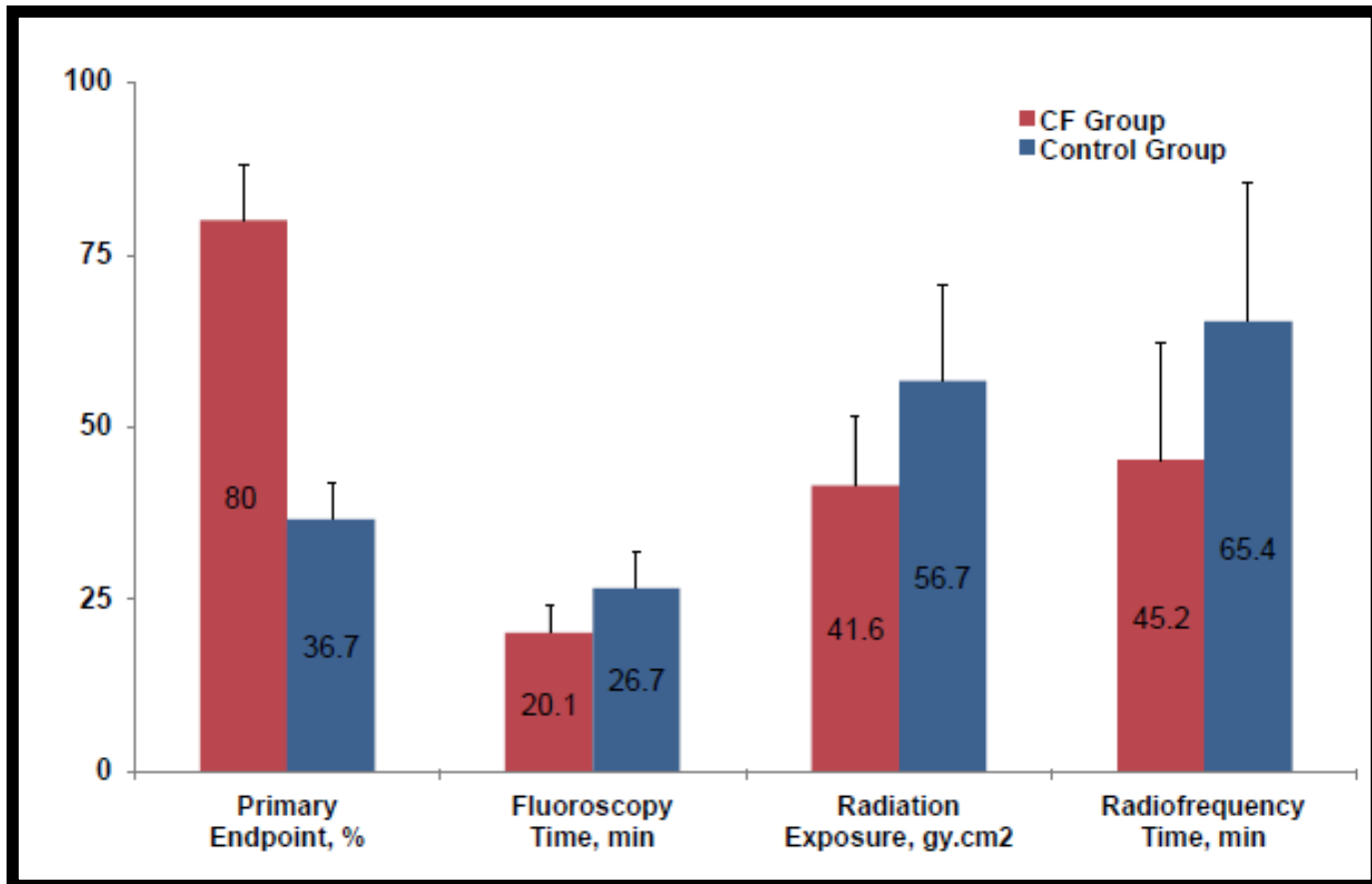
From the *Clinique Pasteur, Département de Rythmologie, Toulouse, France; †Paris Cardiovascular Research Center, Paris, France; and ‡Service de Cardiologie, Hôpital Privé Les Franciscaines, Nîmes, France

Real-Time Contact Force Sensing for Pulmonary Vein Isolation. Introduction: The additional benefit of contact force (CF) technology during pulmonary vein isolation (PVI) for paroxysmal atrial fibrillation (AF) to improve mid-term clinical outcome is unclear.

Methods and Results: Eligible patients with symptomatic paroxysmal AF were enrolled in this prospective trial, comparing circular antral catheter ablation (guided by Carto 3 System, Biosense Webster) using either a new open-irrigated CF catheter (SmartTouch Thermocool, Biosense Webster) (CF group) or a non-CF open-irrigated catheter (EZ Steer Thermocool, Biosense Webster) (control group). Overall, 30 patients were enrolled in each group, with a standardized 12-month follow-up, free of antiarrhythmic therapy. Demographic, cardiovascular and anatomic characteristics were similar in both groups. Though complete PVI was eventually achieved in all cases in both groups, success using an exclusive anatomic approach was 80.0% in CF group versus 36.7% in control group ($P < 0.0001$). CF use was associated with significant reductions in fluoroscopy exposure ($P < 0.01$) and radiofrequency time ($P = 0.01$). The incidence rates of AF recurrence were 10.5% (95% CI, 1.38–22.4) in the CF group, and 35.9% (95% CI, 12.4–59.4) in the control group (log rank test, $P = 0.04$). After adjustment on potential confounders, the use of CF catheter was found to be associated with a lower AF recurrence (OR 0.18, 95% CI 0.04–0.94, $P = 0.04$).

Conclusion: Our findings suggest a potential benefit of real-time CF sensing technology, in reducing AF recurrence during the first year after PVI. (*J Cardiovasc Electrophysiol*, Vol. pp. 1-8) 2013.

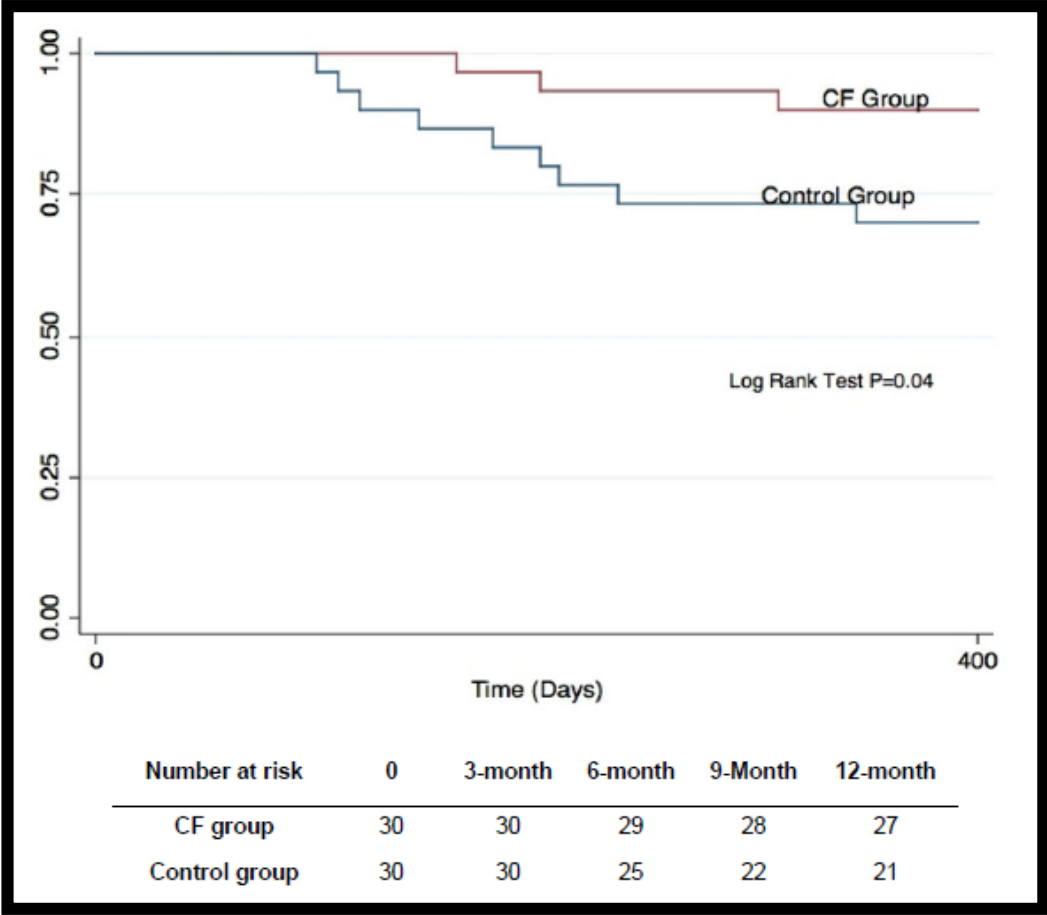
Primary and secondary acute endpoints in CF vs. Control group



Effective acute PVI using an anatomical approach (no lasso)

Proportion of pts free of AF during the 12-month FU (3 months blanking period)

Kaplan-Meier curve



Primary mid-term endpoint

Paroxysmal AF Catheter Ablation With a Contact Force Sensing Catheter

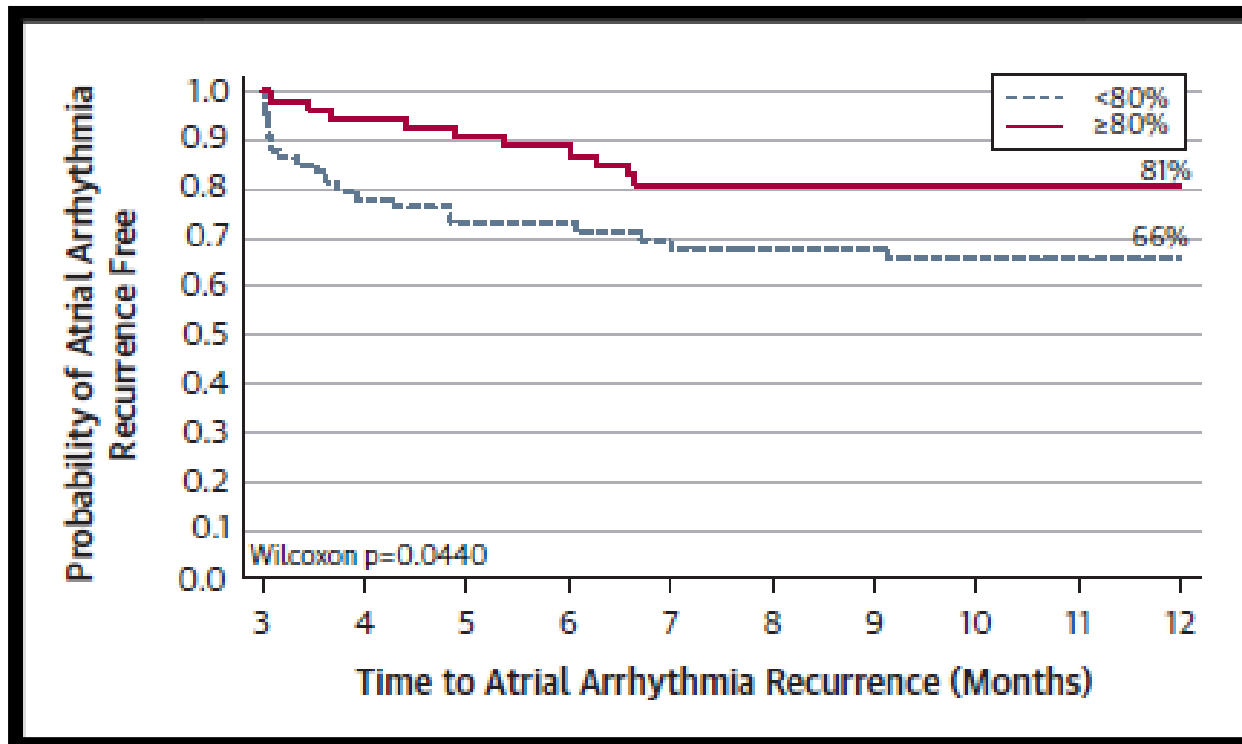
Results of the Prospective, Multicenter SMART-AF Trial



Andrea Natale, MD,*†‡§||¶ Vivek Y. Reddy, MD,# George Monir, MD,** David J. Wilber, MD,†† Bruce D. Lindsay, MD,‡‡
H. Thomas McElderry, MD,§§ Charan Kantipudi, MD,||| Moussa C. Mansour, MD,¶¶ Daniel P. Melby, MD,##
Douglas L. Packer, MD,*** Hiroshi Nakagawa, MD,††† Baohui Zhang, MS, SM,††† Robert B. Stagg, PhD,†††
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Time to first AF / atrial flutter / atrial tach recurrence through 12 months FU

Kaplan-Meier curve



Investigators working in their selected ranges

What are the missing information to create consistent and safe lesions ?

- Catheter stability
 - Lesion continuity
- } **Visitag***
-
- Amount of energy for each RF pulse ?
 - Contact force magnitude
 - Power settings
 - RF duration
- } **Ablation Index***

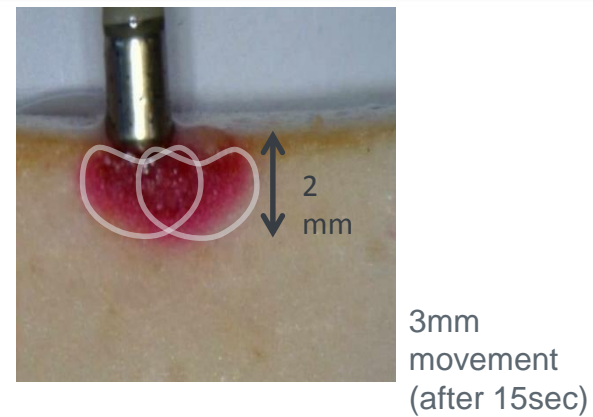
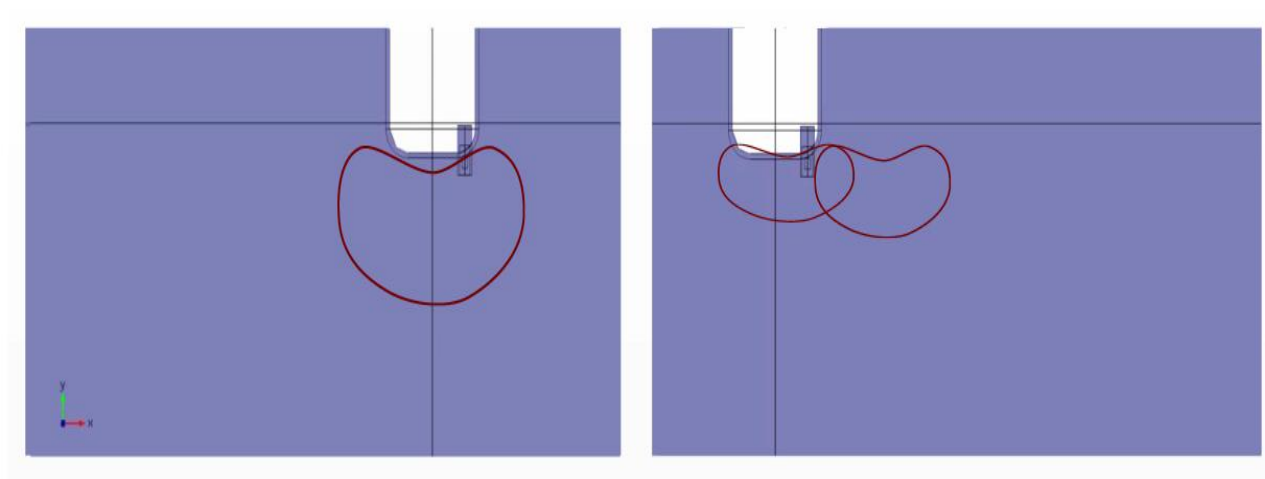
Catheter stability assessed by CARTO 3 Visitag* Module

- Visitag* are automatic tags that give valuable information on
 - Catheter stability in mm (respiration gating)
 - Minimum application time in sec
 - Predefined range of contact force in grams



Importance of stability on ablation size

10 g 30 sec 25 W ablation

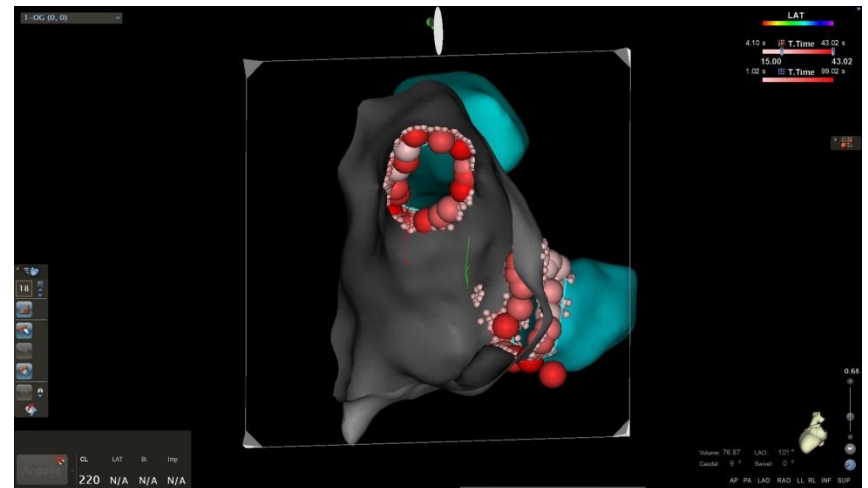
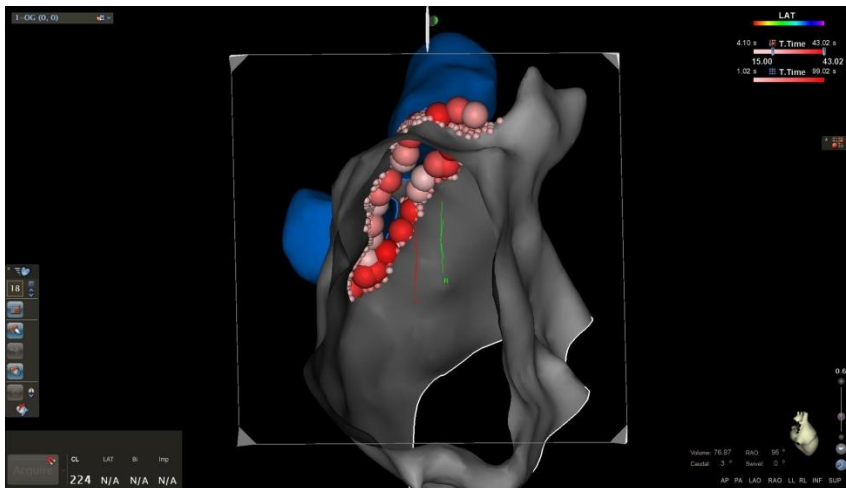
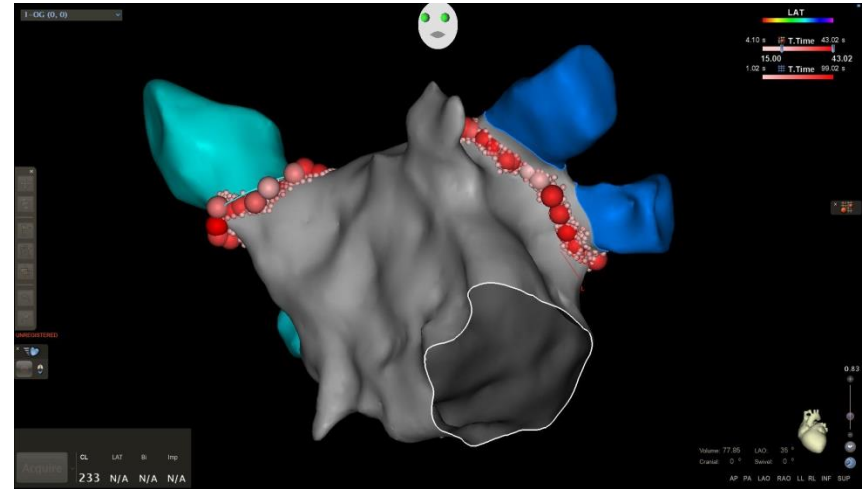
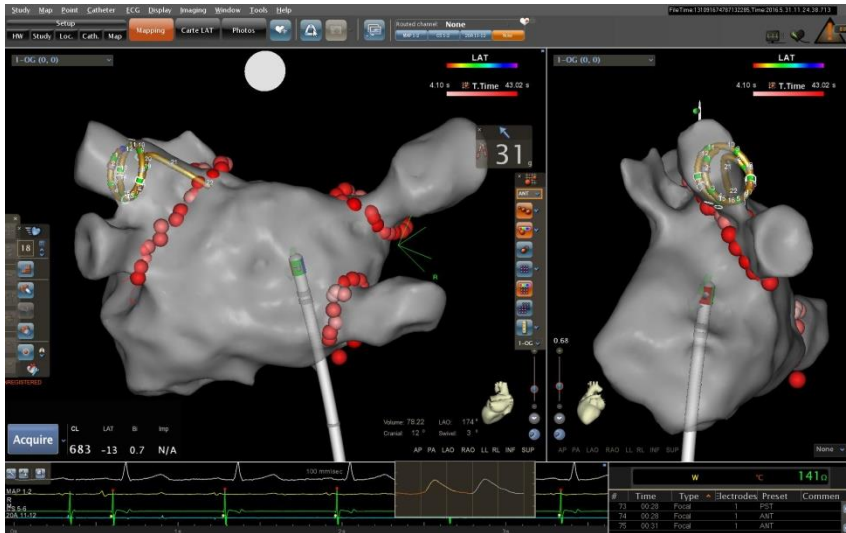


Lesion continuity with Visitag*

Contiguous tags to avoid gaps

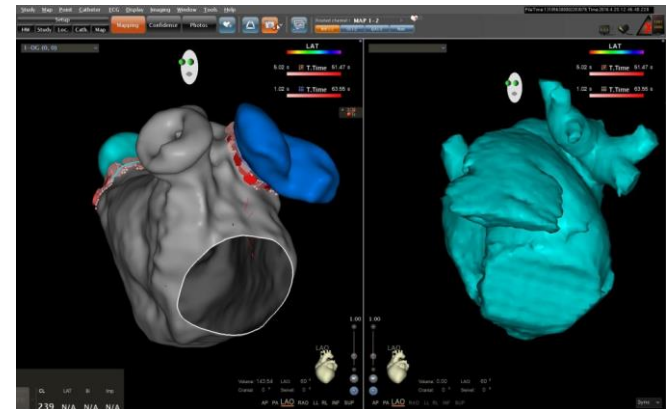


Linear lesions using 3D tags (floating points)

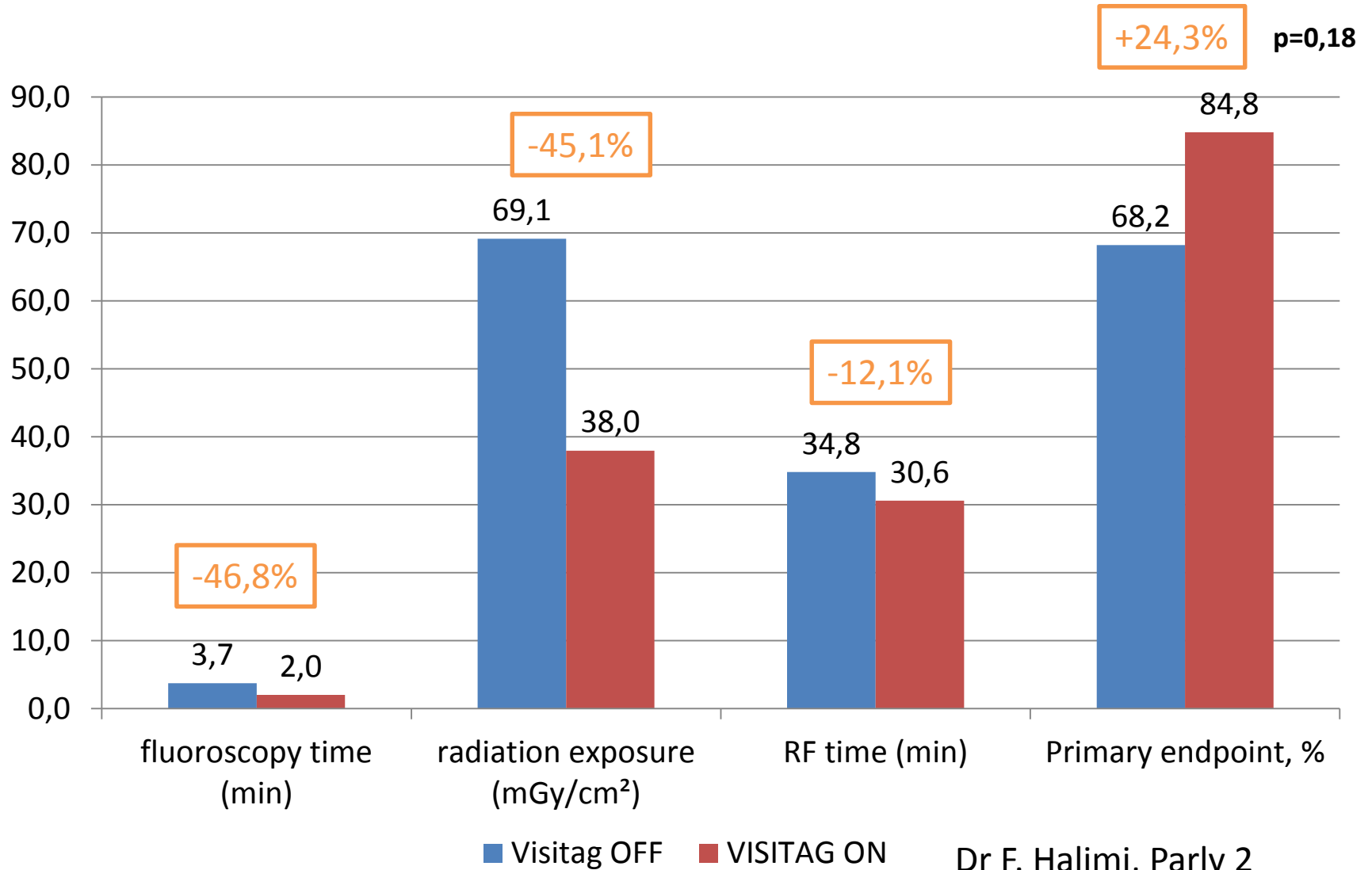


Visitag* Study (ongoing)

- Single operator, Single center (Parly 2)
- Consecutive PAF, 1st procedure
- CARTO 3 and SmartTouch* catheters
- Inclusion 07/2012 to 07/2015
- **2 groups :**
 - CF / Visitag* OFF : 22 pts
 - CF / Visitag* ON : 33 pts
- **Follow-up :**
 - Clinical FU
 - 24h-Holter at 3, 6 and 12 months



Visitag* Study Results



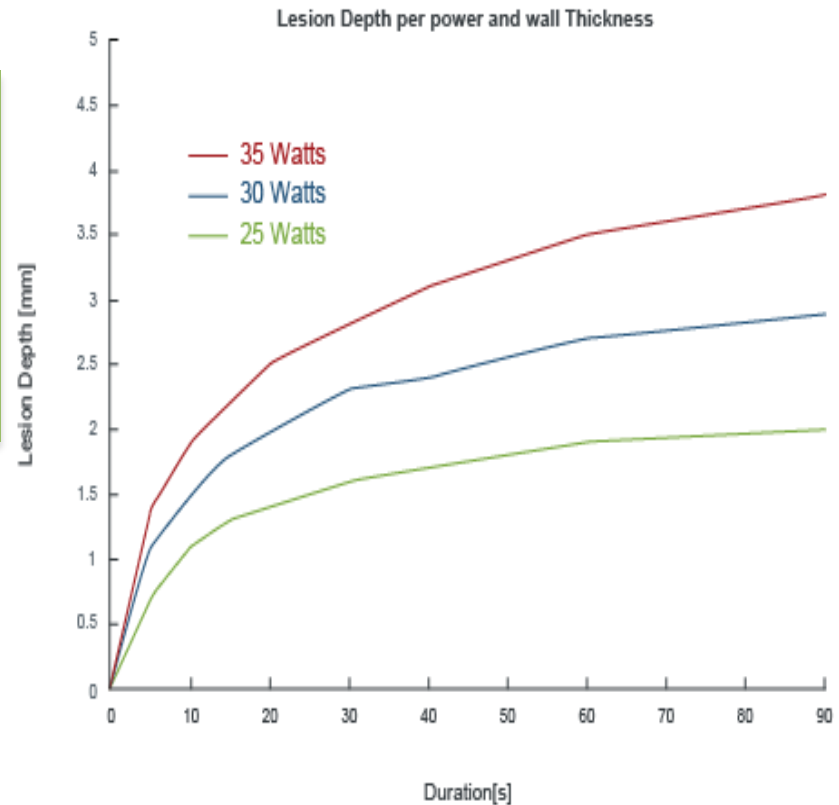
The CARTO 3 Ablation Index*

- Provides automatic composite tag combining
 - Contact force
 - Power
 - Application time
 - (catheter in a stable position)

Ablation Depth VS. Time with constant contact force

Using an irrigated catheter, Lesion Depth as function of RF Duration – for different power levels – represents non-linear progression.

Contact Force is constant.

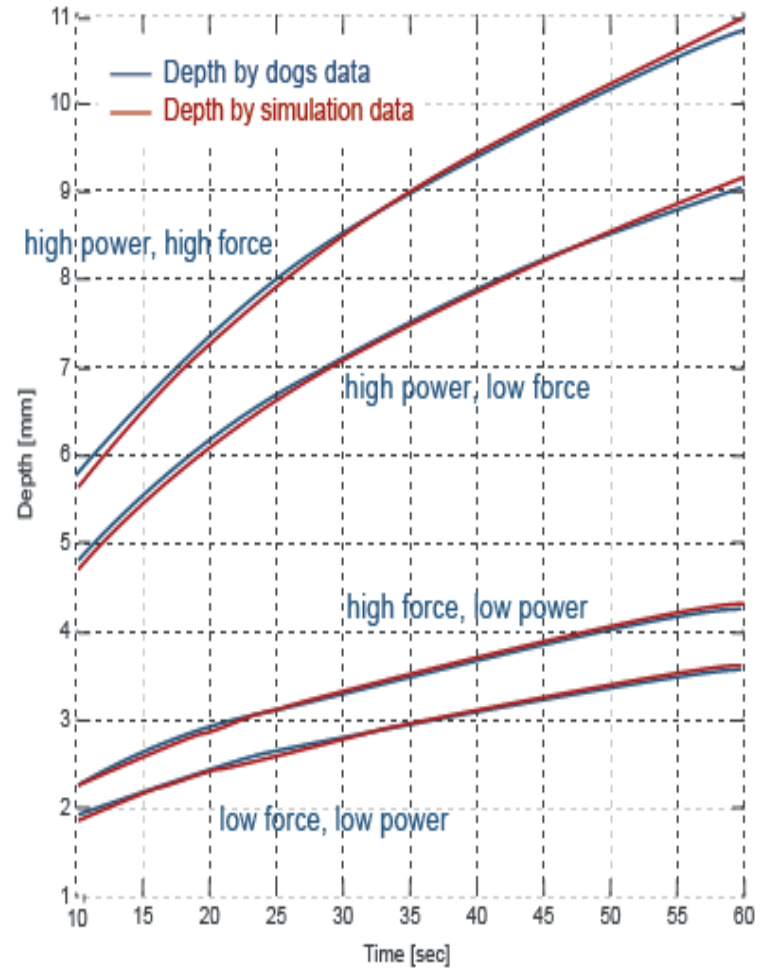


<http://www.mate.tue.nl/mate/pdfs/10447.pdf>

Experimental and Numerical Analysis of Lesion Growth during Cardiac Radiofrequency Ablation Sytске Foppen BMTE 09.14, April 2009

Lesion Depth by Time for Variable Power & Contact-Force

- The Animal Model and Simulated Model show similar behavior.
- The effect of increased power is more significant than contact force.
- The ablation Depth graphs reflect a non-linear relation with time for diverse Contact-Force and Power.



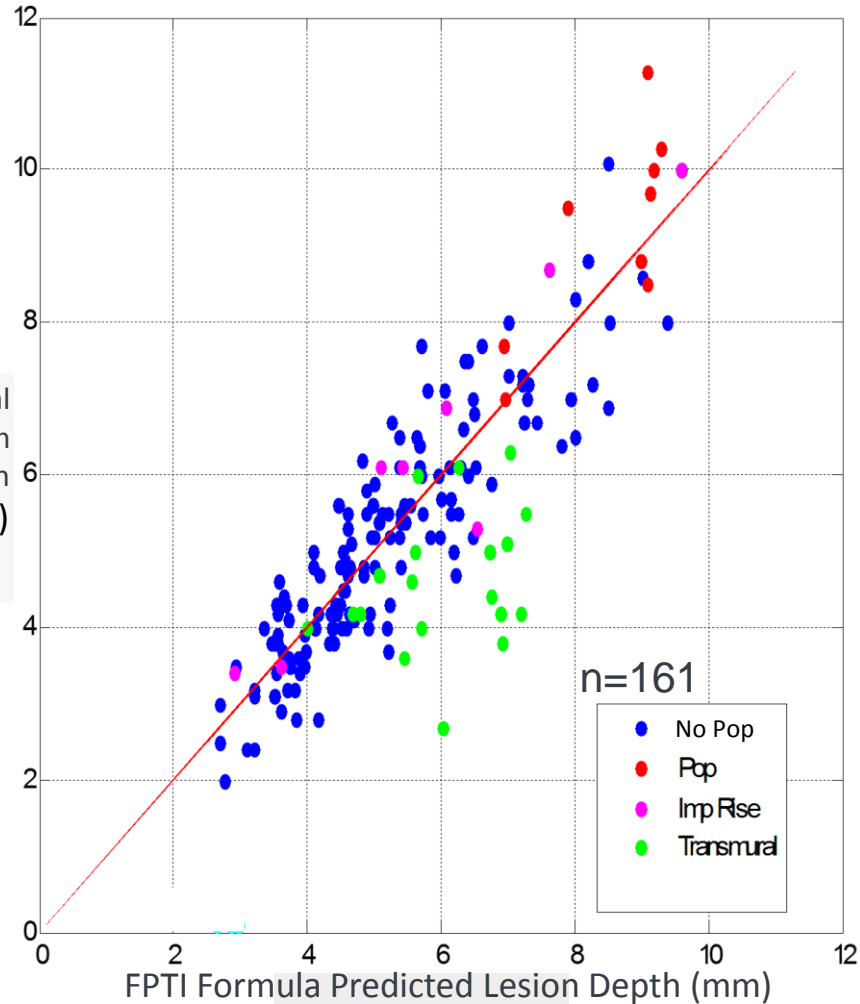
Ablation Index Formula versus Actual Lesion Depth

$$Index = \left(k * \int_0^t CF^a(\tau) P^b(\tau) d\tau \right)^c$$

CF: Contact Force,
P: RF Power,
t: Application Time

Accuracy
± 1mm
(90%)

Actual
Lesion
Depth
(mm)



(FPTI: Force Power Time Index)

Clinical Prospective Study

“High Incidence of Ipsilateral Pulmonary Vein Isolation by First Encirclement Using New Force-Power-Time Formula with Short Radiofrequency Time in Atrial Fibrillation Patients”

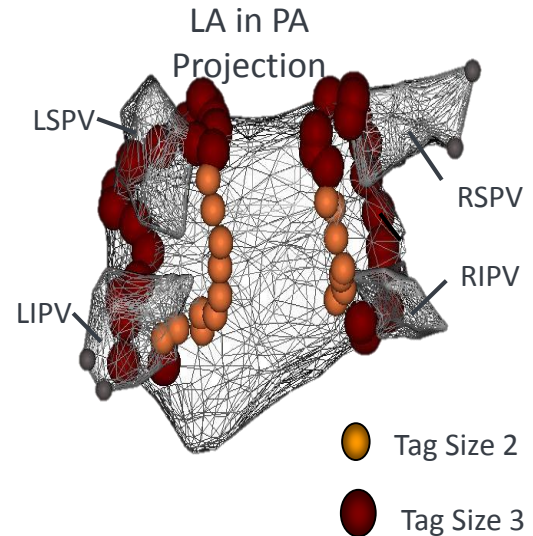
Methods:

43 PAF patients (2 centers) had PVI. Two Ablation Index target numbers were used:

- Anterior/superior segments (Represented by tag size 3 - Dark red)
- Posterior/inferior segments (Represented by tag size 2 - Orange)

RF was delivered until Force Power Time Index reached target number or esophageal temperature reached 40C.

RF power was increased at low CF and decreased at high CF..



Results & Conclusions

Results

	Median	Range
Parameters per application	Contact force 15g	3-64g
	Power 35w	17-50w
	Time 28 sec	6-93 sec
Ip-PVsi Circum.	Length 12.2 cm	8-16.5 cm

Complete Ip - PVs isolation	77/86 (90%)
Adenosine reconnection	4/86 (5%)
Follow Up (2-11 months) no tachycardia	42/43 (98%)

Conclusions:

Ablation Index guidance produced complete ipsilateral PV isolation by a single encirclement in 90% using short RF time

Ablation Index* targeted values

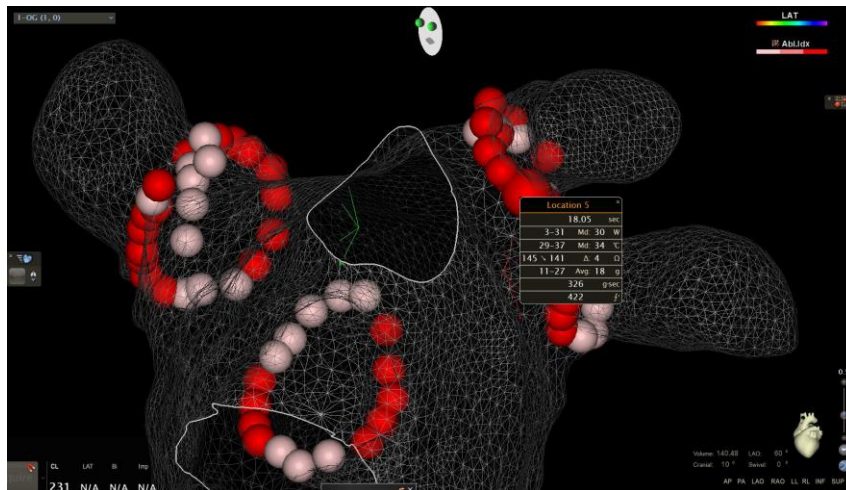
- At this point there are no predefined Ablation Index* values
- Each operator has to perform 10 blinded cases with retrospective Ablation Index* calculation per segment

My early experience

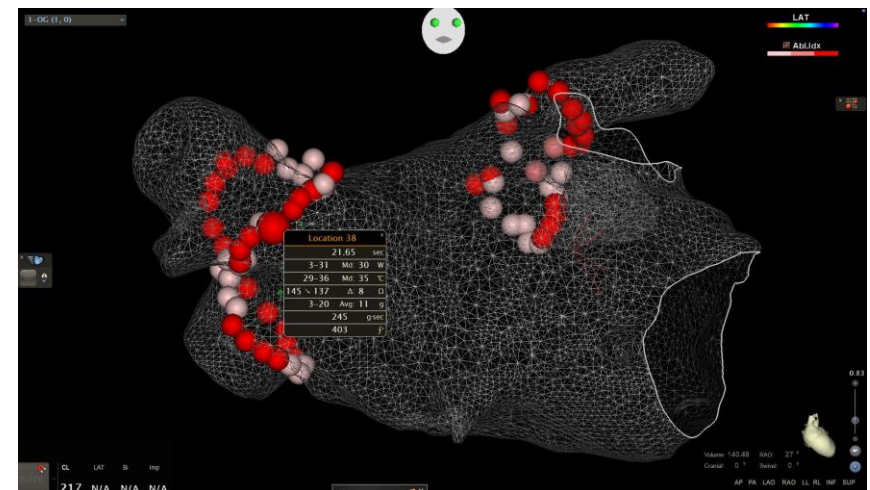
- 10 blinded cases
- 13 PAF (ongoing)
- Third group to the Visitag* Study
 - CF / Visitag* OFF
 - CF / Visitag* ON
 - CF / Ablation Index*
- 3D tags only (stability / lesion continuity)

My Ablation Index values per segment

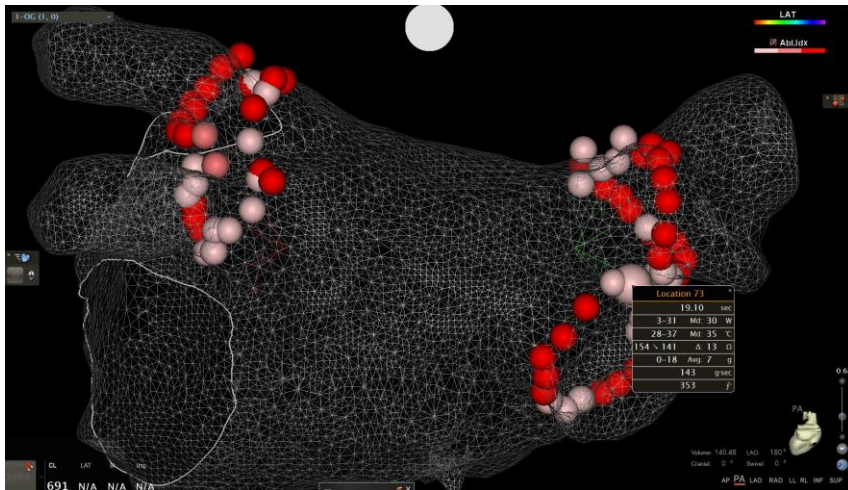
Ridge 420



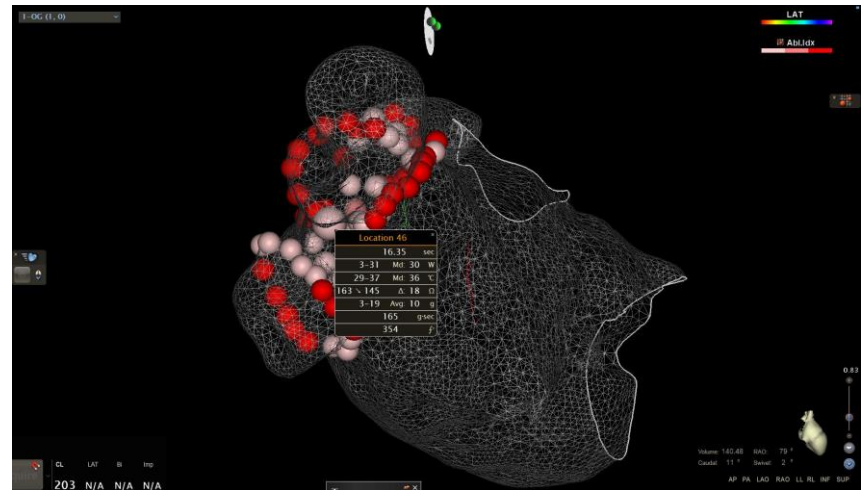
Anterior 400



Infero-sup / Carena 350



Posterior 320



First results: RF time

Variable	Visitag	N	Missing	Mean	S.D.
RF time (s)	No	25	0	1995	938
	Yes	49	0	1813	455
	Ablation Index	13	0	1587	350
	Total	87	0	1832	628

26 min

First results: X ray exposure

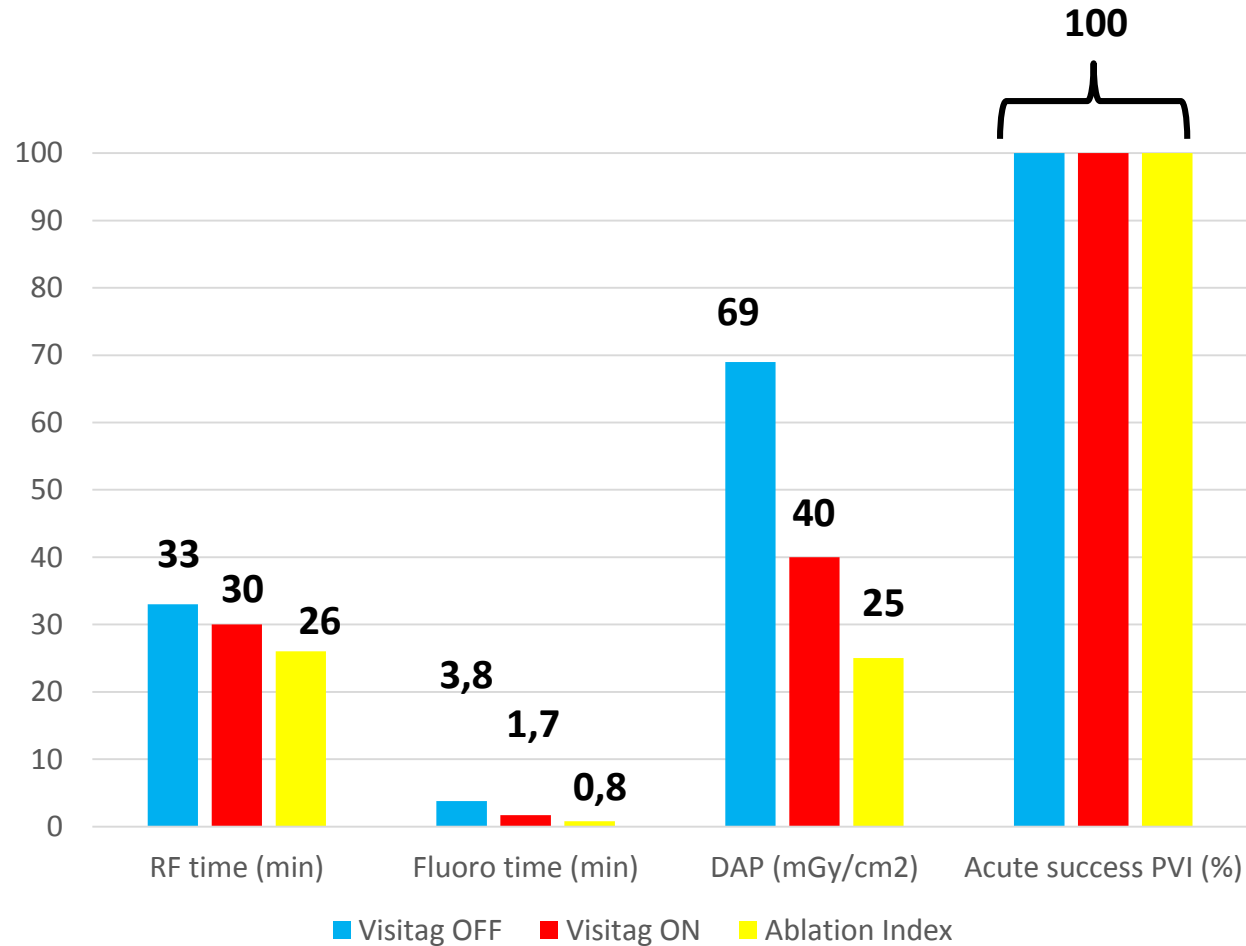
Fluoro (seconds)

Variable	Visitag	N	Missing	Mean	S.D.
Fluoroscopy time (s)	No	25	0	230	93
	Yes	49	0	102	49
	Ablation Index	13	0	49	16
	Total	87	0	131	90

Air Kerma (mGy/cm²)

Variable	Visitag	N	Missing	Mean	S.D.
Air Kerma, dose (mGy/cm ²)	No	23	2	69	36
	Yes	45	4	40	19
	Ablation Index	13	0	25	15
	Total	81	6	46	29

First Results with Ablation Index*



Conclusion 1

- Ablation Index* leads to a tailored RF strategy taking into consideration a combination of contact force and power to determine RF time for each stable application
 - Slight changes in procedure workflow
- Early results show
 - Reduction in RF delivery
 - Reduction in X Ray exposure
 - 100% of acute PVI

Conclusion 2

- There are strong evidences supporting that Ablation Index* provides high per-procedural efficacy and increased safety
- Results of the CLOSE Study will soon be published in Circulation with excellent long term outcomes after a single procedure