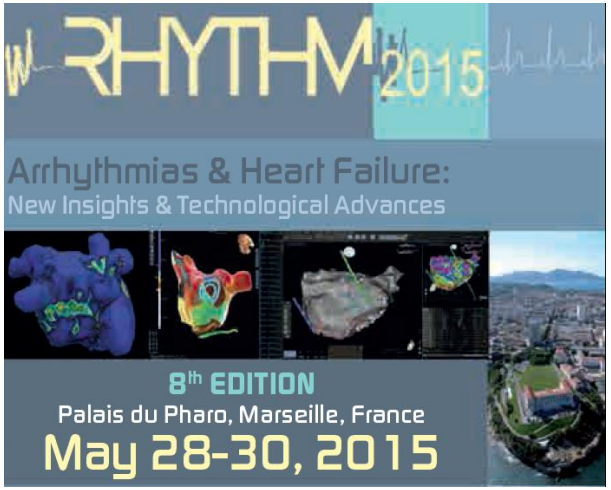
CONTACT FORCE TECHNOLOGY: Closing the Missing Gaps !

Dr Franck Halimi

H.P. Parly 2, Le Chesnay, France



Background

- RFCA was developed to treat cardiac arrhythmias
- Cardiac lesions have to be
  - Trans mural
  - Continuous (lines /PVI)
  - Irreversible
  - Safe
- CF technology combined with 3D systems is a major innovation in the field of point-by-point catheter ablation

Contact Force in AF ablation

- Allows accurate 3D geometry acquisition
  - Missing volumes
  - Real-time map modifications
- Facilitates catheter positioning
- Optimizes energy delivery between the ablation electrode and the endocardial atrial tissue
  - Force in grams
  - Force orientation
  - Stability
  - Lesion index
- Provides additional safety features

EndoSense / Tacticath Technology

A novel radiofrequency ablation catheter using contact force sensing: Toccata study

Karl-Heinz Kuck, MD, PhD, FHRS,* Vivek Y. Reddy, MD,† Boris Schmidt, MD,* Andrea Natale, MD, PhD, FHRS,‡ Petr Neuzil, MD, PhD,§ Nadir Saoudi, MD, PhD,‖ Josef Kautzner, MD, PhD,¶ Claudia Herrera, MD,# Gerhard Hindricks, MD, PhD,** Pierre Jaïs, MD, PhD,†† Hiroshi Nakagawa, MD, PhD,‡‡ Hendrik Lambert, PhD,§§ Dipen C. Shah, MD, PhD‖‖

*From the *Abt. Kardiologie, Asklepios Klinik St. Georg, Hamburg, Germany; †Cardiac Arrhythmia Service, Mount Sinai School of Medicine, New York, New York; ‡Texas Cardiac Arrhythmia Institute, St David's Medical Center, Austin, Texas; §Department of Cardiology, Na Homolce Hospital, Prague, Czech Republic; ‖Département Cardiologie, Centre Hospitalier Princesse Grace, Monaco, Monaco; ¶Department of Cardiology, Institute for Clinical and Experimental Medicine (IKEM), Prague, Czech Republic; #Rhythmologie, Herzzentrum Bad Krozingen, Bad Krozingen, Germany; **Abteilung für Rhythmologie, Herzzentrum Leipzig GmbH, Leipzig, Germany; ††Département Cardiologie, Hôpital Cardiologique du Haut-Lévêque, Bordeaux-Pessac Cedex, France; ‡‡Cardiac Arrhythmia Heart Rhythm Institute, University of Oklahoma Health Sciences Center, Oklahoma, Oklahoma; §§Endosense SA, Geneva, Switzerland; ‖‖Département de Cardiologie, Hôpital Universitaire de Genève, Geneva, Switzerland.*

OBJECTIVES The aim of this multicenter study was to evaluate the device- and procedure-related safety of a novel force-sensing radiofrequency (RF) ablation catheter capable of measuring the real-time contact force (CF) and to present CF data and its possible implications on patient safety.

BACKGROUND The clinical outcome of RF ablation for the treatment of cardiac arrhythmias may be affected by the CF between the catheter tip and the tissue. Insufficient CF may result in an ineffective lesion, whereas excessive CF may result in complications.

METHODS Seventy-seven patients (43 with right-sided supraventricular tachycardia [SVT] and 34 with atrial fibrillation [AF]) received percutaneous ablation with the novel studied catheter. The CF applied and safety events related to the procedure were reported.

RESULTS CF values at mapping ranged from 8 ± 8 to 60 ± 35 g and from 12 ± 10 to 39 ± 29 g in the SVT group and the LA group, respectively, showing a significant interinvestigator variability ($P < .0001$). High transient CFs (>100 g) were noted in 27 patients (79%) of the LA group. One device-related complication (tamponade, 3%) occurred in the AF group.

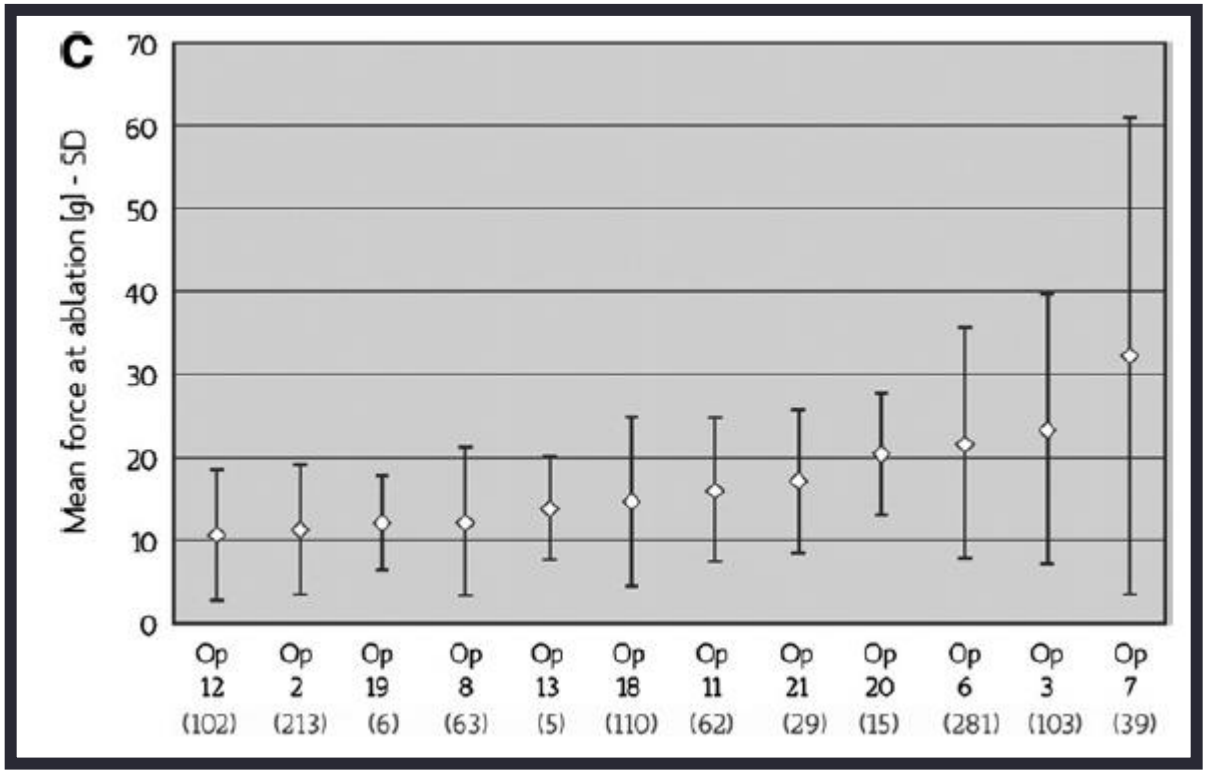
CONCLUSIONS Catheter ablation using real-time CF technology is safe for the treatment of SVT and AF. High CFs may occur during catheter manipulation and not just during ablation, suggesting that measuring CF may provide additional useful information to the operator for safe catheter manipulation. In the future, CF-sensing catheters may also increase the effectiveness of RF ablations by allowing better control of the RF lesion size.

KEYWORDS Ablation; Atrial fibrillation; Catheter ablation; Supraventricular tachycardia; Contact force

ABBREVIATIONS **AF** = atrial fibrillation; **AVNRT** = atrioventricular nodal reentry tachycardia; **CF** = contact force; **LA** = left atrium; **PVs** = pulmonary veins; **PVI** = pulmonary vein isolation; **RA** = right atrium; **RF** = radiofrequency; **SAEs** = serious adverse events; **SVT** = supraventricular tachycardia

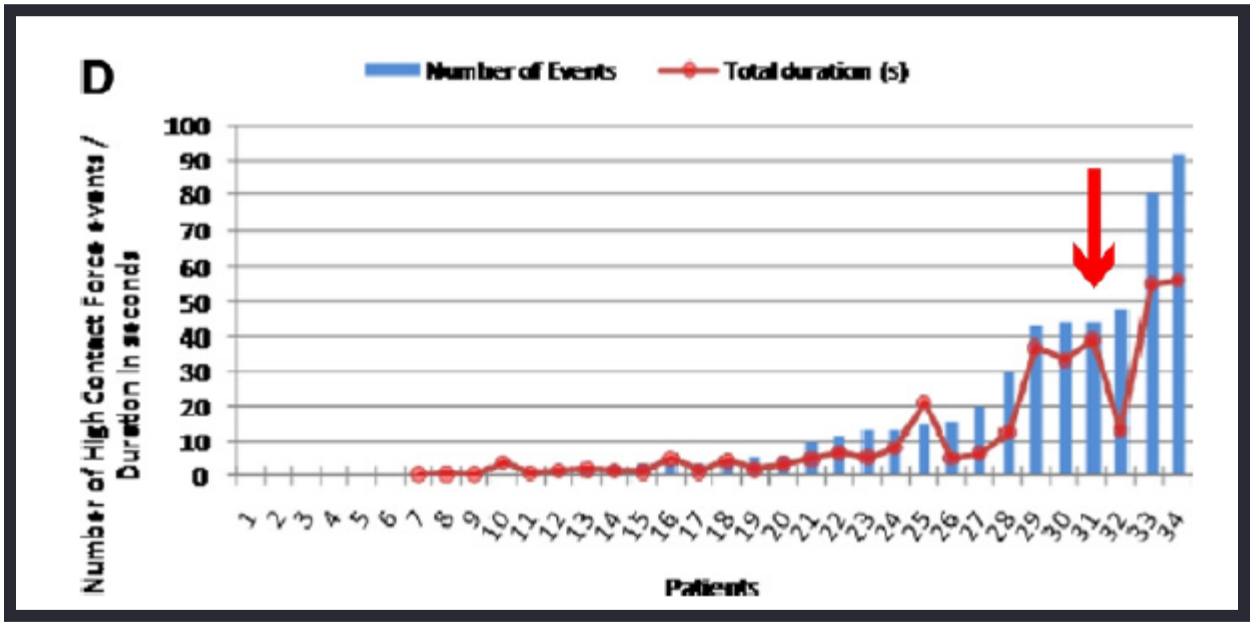
(Heart Rhythm 2012;9:18–23)

CF in the left atrium



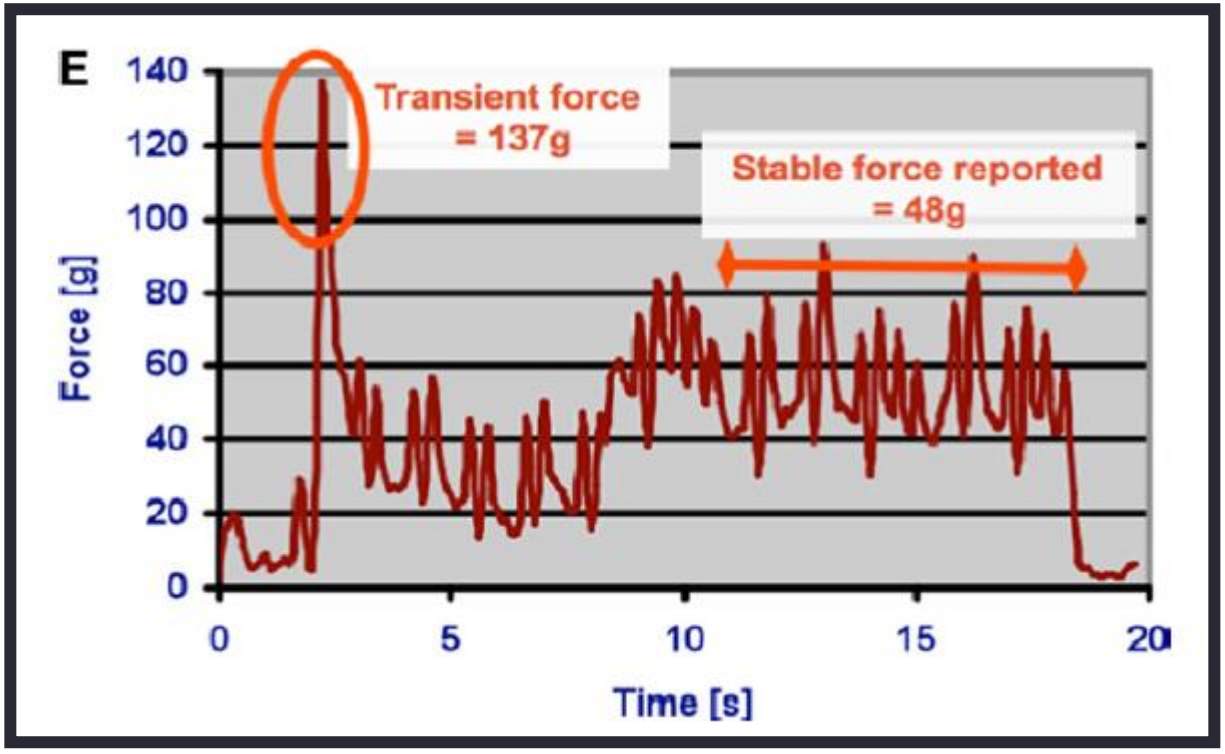
High transient CF > 100 g in the LA group

High CF events



Red arrow indicates tamponade

Real-time CF in pt with tamponade



CF variability = heart contraction and respiration cycle

Conclusions

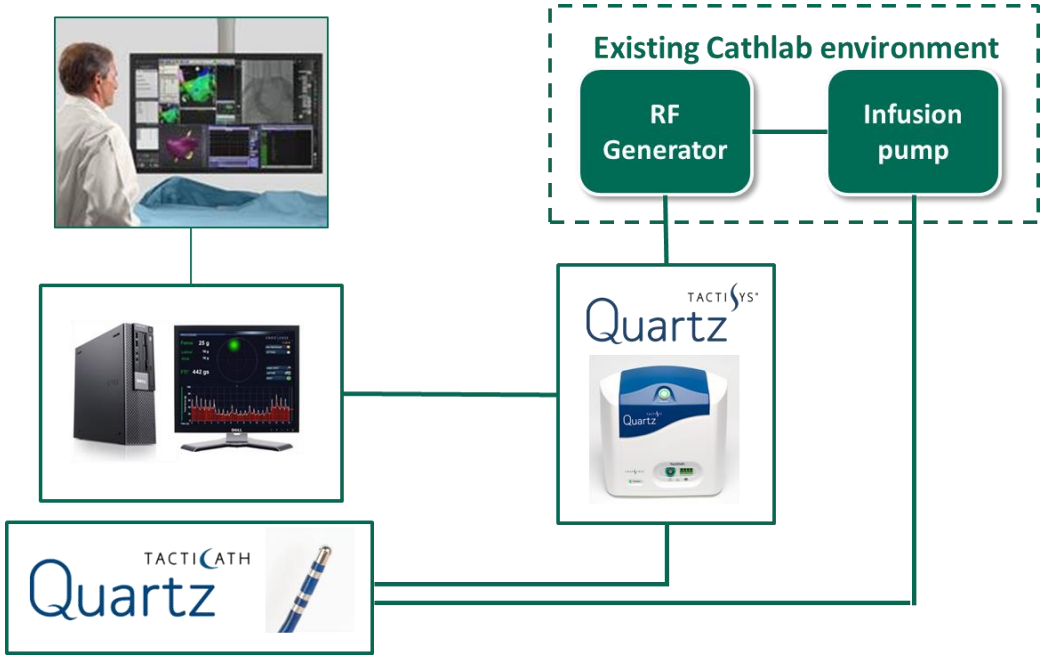
In conclusion, the CF catheter is as safe as conventional irrigated RF catheters. Assessment of CF showed marked inter- and intrainvestigator variability. High CF values may occur during manipulation and not just during ablation. This suggests that the ability to measure CF may provide additional useful information to the operator for safe catheter manipulation. In the future, CF-sensing catheters may increase the safety and effectiveness of RF ablation procedures by preventing the use of inappropriately high CF and by allowing better control of the RF lesion size.

TactiCath* System

TactiSys* Quartz Interface

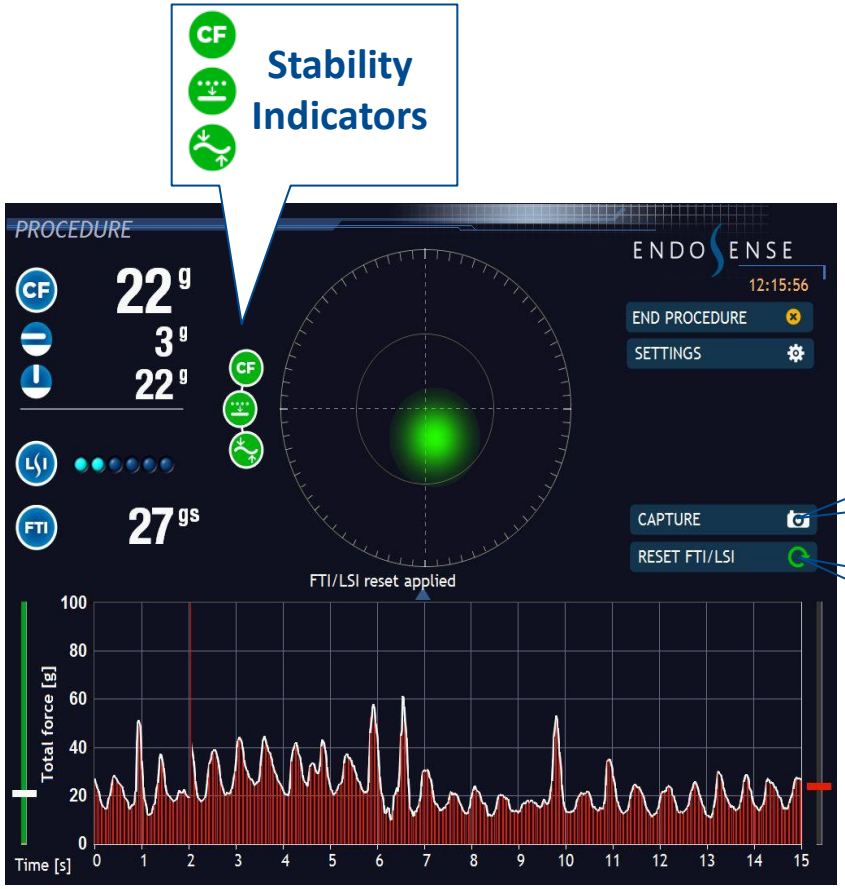
Dedicated RF Catheter

Computer software



Saint Jude Medical

TactiSoft* Interface



Saint Jude Medical

Introducing Force Time Integral (FTI) and Lesion Index (LSI)

Saint Jude Medical

Electrical Reconnection After Pulmonary Vein Isolation Is Contingent on Contact Force During Initial Treatment

Results From the EFFICAS I Study

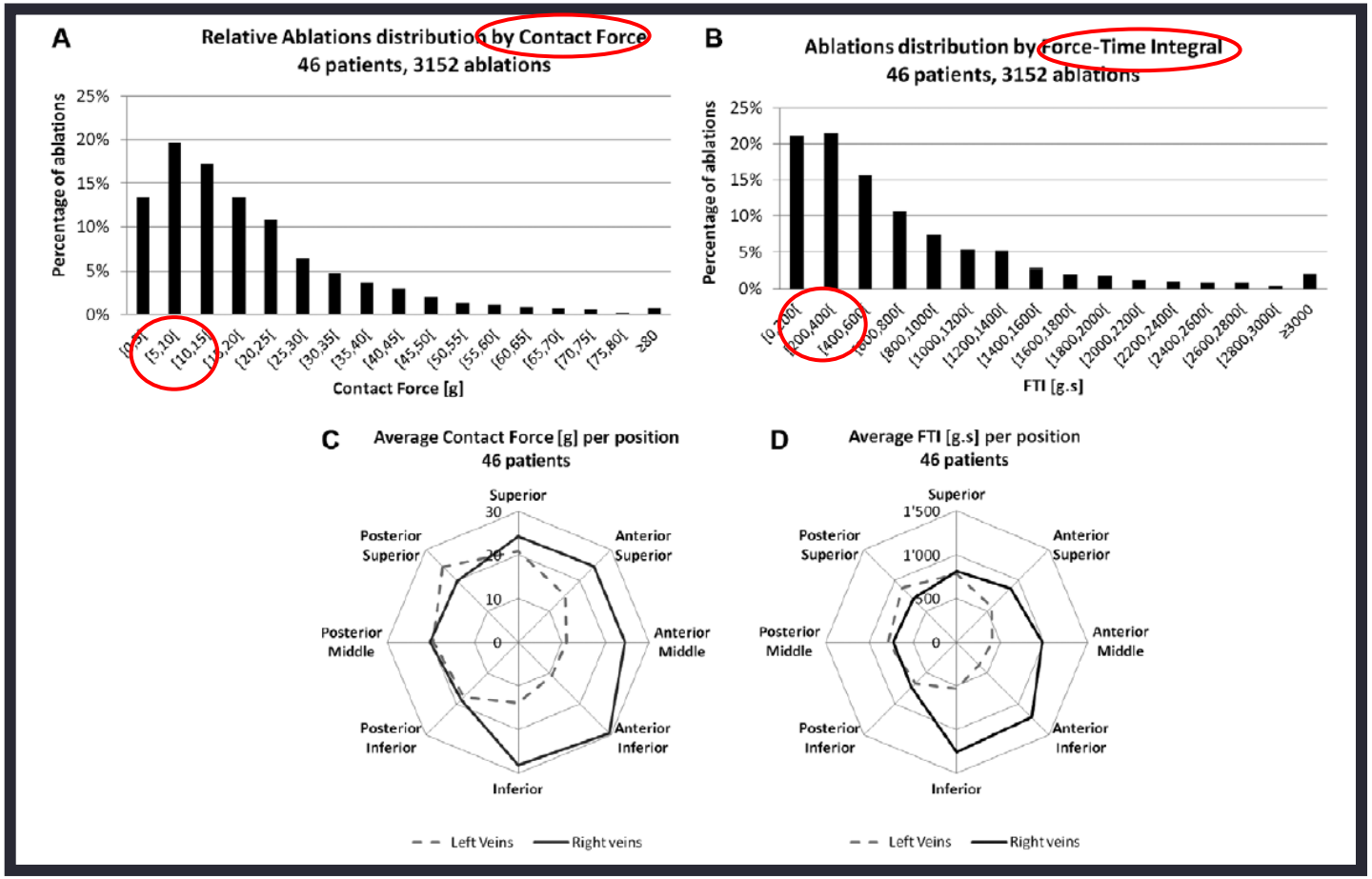
Petr Neuzil, MD, PhD; Vivek Y. Reddy, MD; Josef Kautzner, MD, PhD; Jan Petru, MD; Dan Wichterle, MD, PhD; Dipen Shah, MD; Hendrik Lambert, PhD; Aude Yulzari, MSc; Erik Wissner, MD; Karl-Heinz Kuck, MD, PhD, FHRS

Background—Pulmonary vein isolation is the most prevalent approach for catheter ablation of paroxysmal atrial fibrillation. Long-term success of the procedure is diminished by arrhythmia recurrences occurring predominantly because of reconnections in previously isolated pulmonary veins. The aim of the EFFICAS I multicenter study was to demonstrate the correlation between contact force (CF) parameters during initial procedure and the incidence of isolation gaps (gap) at 3-month follow-up.

Method and Results—A radiofrequency ablation catheter with integrated CF sensor (TactiCath, Endosense, Geneva, Switzerland) was used to perform pulmonary vein isolation in 46 patients with paroxysmal atrial fibrillation. During the ablation procedure, the operator was blinded to CF information. At follow-up, an interventional diagnostic procedure was performed to assess gap location as correlated to index procedure ablation parameters. At follow-up, 65% (26/40) of patients showed ≥1 gaps. Ablations with minimum Force–Time Integral (FTI) <400 gs showed increased likelihood for reconnection ($P<0.001$). Reconnection correlated strongly with minimum CF ($P<0.0001$) and minimum FTI ($P=0.0007$) at the site of gap. Gap occurrence showed a strong trend with lower average CF and average FTI. CF and FTI are generally higher on the right side, although the left anterior segment presents a unique challenge to achieve stable position with good CF.

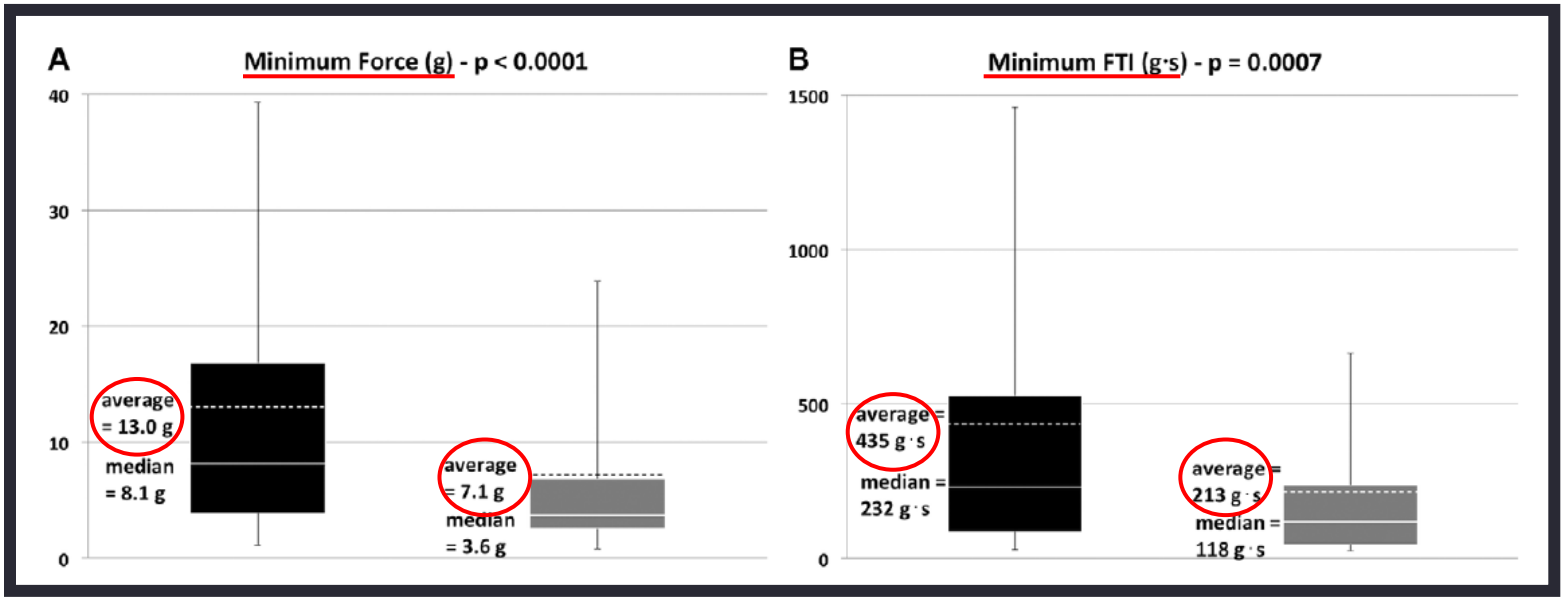
Conclusions—Minimum CF and minimum FTI values are strong predictors of gap formation. Optimal CF parameter recommendations are a target CF of 20 g and a minimum FTI of 400 gs for each new lesion. (***Circ Arrhythm Electrophysiol*. 2013;6:327-333.**)

Distribution of force at index procedure

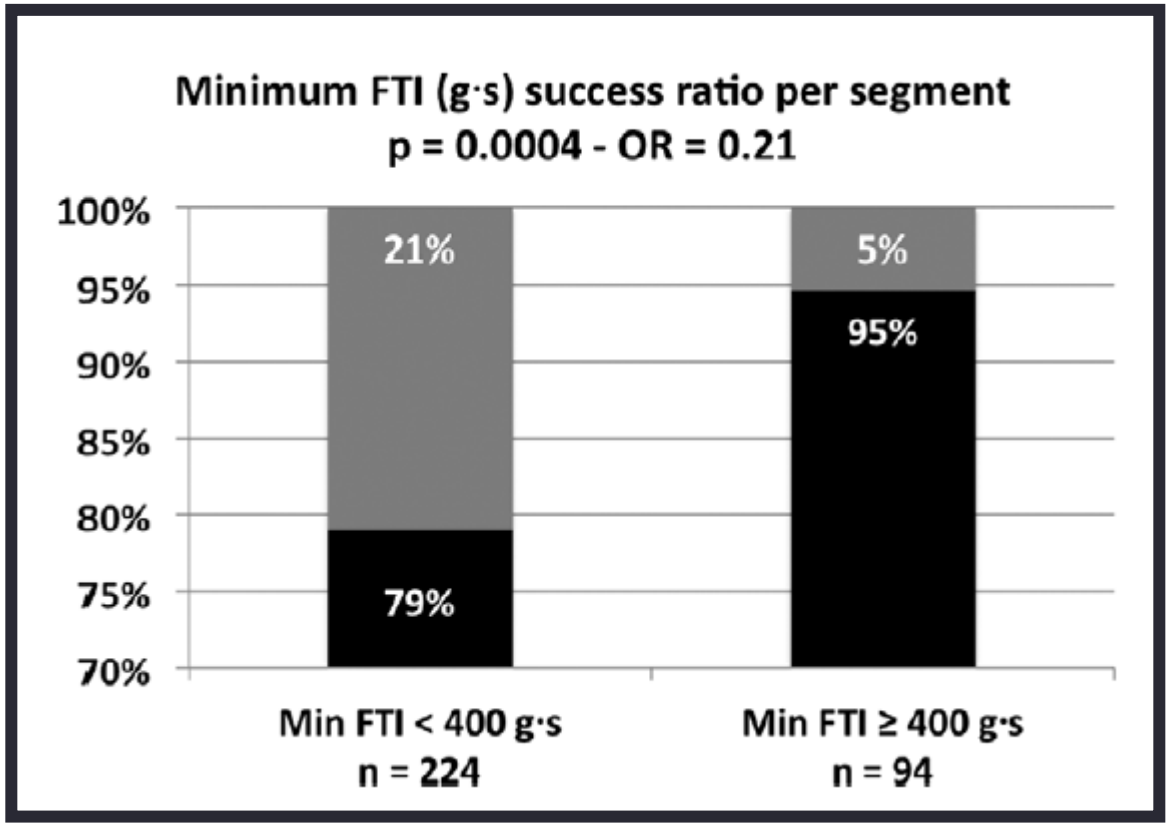


Anterior segment of the left veins +++

Force discriminators for segments with isolation vs. gaps at 3 months FU



Minimum FTI success ratio



Conclusion

Invasive electrophysiological assessment of conduction gaps at PVI ablation sites at 3-month follow-up has shown that the minimum CF and minimum FTI values obtained at the index procedure ablations correlate strongly with subsequent gap formation. The 3-month ablation outcome at any segment is only as effective as the minimum FTI of any ablation delivered in that segment, particularly when the ablation is <400 gs. CF stability is required before ablation to minimize the risk of unstable contact and ineffective lesions, particularly in the left anterior segment. To achieve durable successful PVI, a target CF of 20 g is recommended, with an absolute minimum CF of 10 g and an absolute minimum FTI of 400 gs per individual ablation lesion.

Role of stability

June 2012 | Cardiostim 2012 - Nice, France

EFFICAS 2 RESULTS: CONTACT FORCE, FTI, LESION CONTINUITY ROLES AT PVI

P. Neuzil, E. Wissner, J. Kautzner, R. Cihak, P. Peichl, D. Wichterle, J. Petru, J. Skoda, H. Lambert, A. Yulzari, K.H. Kuck.

INTRODUCTION:

The EFFICAS multi-center study series assessed the role of contact force (CF) parameters during RF ablation for durable PV isolation (PVI). Electrical reconnection (gap) results from lack of transmurality or due to discontinuous lesion sets. In EFFICAS I (EFF1) operators were blinded to CF and study showed a significant correlation between low Force Time Integral (FTI) and gap formation. In EFFICAS II (EFF2) operators used CF and FTI to optimize lesion creation.

METHODS AND RESULTS:

In EFF1 & EFF2, 5 operators enrolled 26 pts (1670 ablations) and 24 pts (1294 ablations) respectively, who received an initial procedure using a CF sensing catheter (TactiCath®, Endosense) for circumferential PVI and a 3-month (M) invasive follow up to pinpoint gap location. CF guidelines in EFF2 advised ablations with a stable catheter position (8 segments per PV line) were collected for each ablation. Continuity of each PV lesion set was quantified using a 'Jump Index' (JI) that calculates how often the catheter is moved for ablation to non-contiguous locations. Each jump to a non-adjacent site increases the JI for the PV line. JI < 6 (Low-JI) is associated with good continuity and JI ε 6 (High-JI) with poor continuity, potentially due to anatomy, respiration, etc. Gaps detected at 3M were correlated with CF, FTI and with JI at index procedure.

There was a significant reduction of PV lines with gaps from 29% in EFF1 (n=20) to 0% in EFF2 (n=27) for PV lines with Low-JI (p=0.005). For PV lines with High-JI there was no difference in gap rate (50% vs 53%, p = NS), suggesting that both conditions of CF and of catheter continuity need to be fulfilled. Gap formation in EFF1 correlated with both low FTI (213 ± 325 vs 436 ± 599, p <0.001) and with JI (5.9 ± 3.0 vs 10.3 ± 4.1, p=0.0001).

CONCLUSION:

Efficas studies show that two parameters, Min FTI and JI predict gap at 3M and are most likely associated with lesion continuity and transmurality. Both must be fulfilled to achieve durable isolation at 3M. For contiguous lesion sets, the use of CF information results in significant improvement in PV isolation and may enable to achieve 100% durable isolation.

Contact force and force-time integral in atrial radiofrequency ablation predict transmurality of lesions

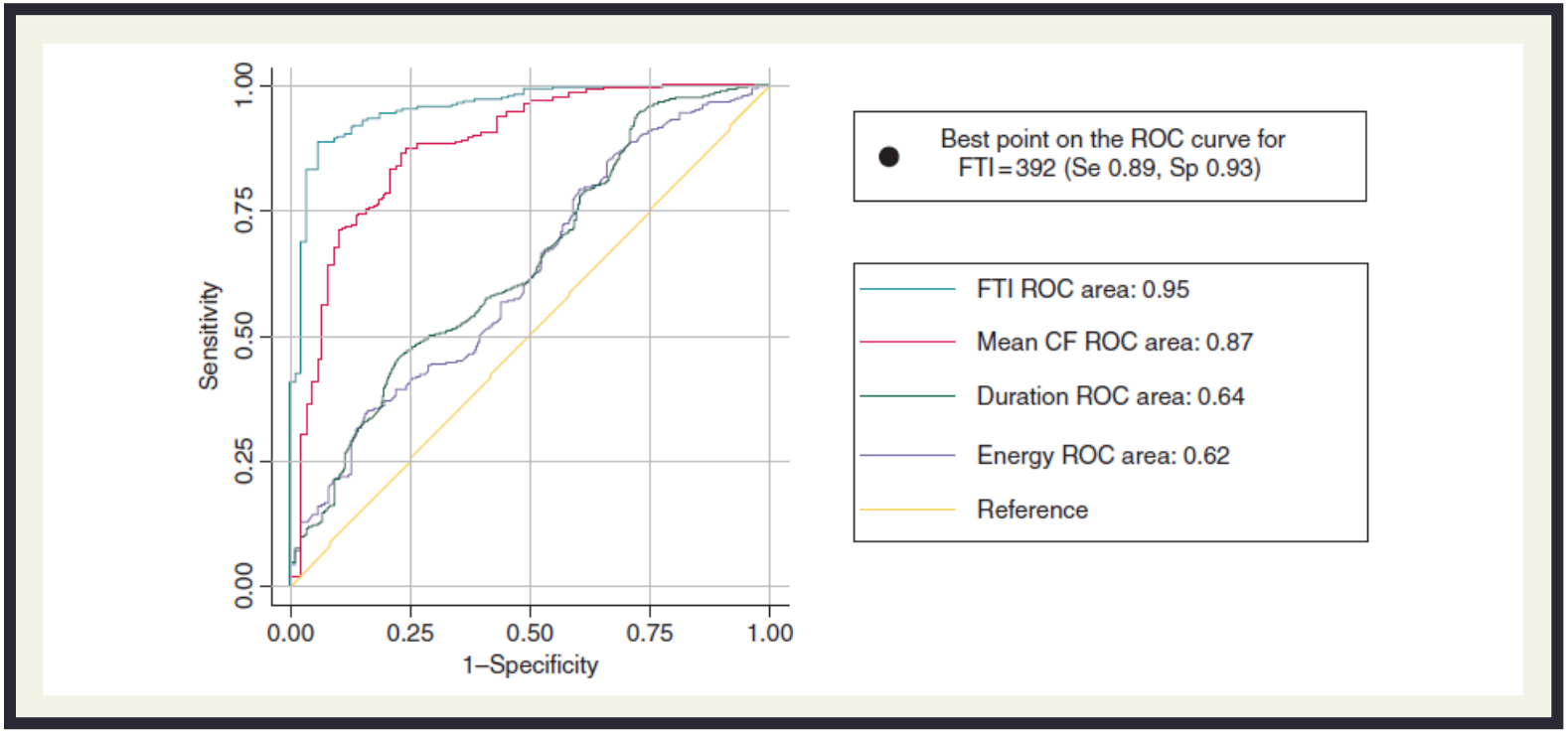
Fabien Squara[1,2†], Decebal Gabriel Latcu[1†*], Youssef Massaad[1], Marouane Mahjoub[1], Sok-Sithikun Bun[1], and Nadir Saoudi[1]

[1]Cardiologie, Centre Hospitalier Princesse Grace, Avenue Pasteur, 98000, Monaco; and [2]Cardiology Department, Pasteur University Hospital, 06000 Nice, France

Received 6 November 2013; accepted after revision 10 March 2014

Europace (2014) **16**, 660–667
doi:10.1093/europace/euu068

FTI is the best predictor of lesion transmurality



Clinical Impact of a New Open-Irrigated Radiofrequency Catheter with Direct Force Measurement on Atrial Fibrillation Ablation

MARTIN MARTINEK, M.D., CHRISTINE LEMES, M.D., ELISABETH SIGMUND, M.D., MICHAEL DERNDORFER, M.D., JOSEF AICHINGER, M.D., SIEGMUND WINTER, M.D., HANS-JOACHIM NESSER, M.D., and HELMUT PÜRERFELLNER, M.D.

From the Department of Cardiology, Elisabethinen University Teaching Hospital of the Universities Innsbruck and Graz, Linz, Austria

Background: *Electrode-tissue contact is crucial for adequate lesion formation in radiofrequency catheter ablation (RFCA).*

Objective: *We assessed the impact of direct catheter force measurement on acute procedural parameters during RFCA of atrial fibrillation (AF).*

Methods: *Fifty consecutive patients (28 male) with paroxysmal AF who underwent their first procedure of circumferential pulmonary vein (PV) isolation (PVI) were assigned to either RFCA using (1) a standard 3.5-mm open-irrigated-tip catheter or (2) a catheter with contact force measurement capabilities. Using the endpoint of PVI with entry and exit block, acute procedural parameters were assessed.*

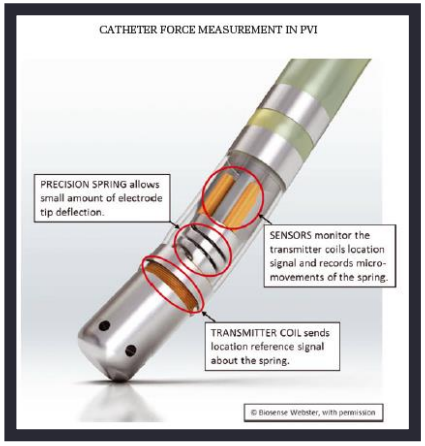
Results: *Procedural data showed a remarkable decline in ablation time (radiofrequency time needed for PVI) from 50.5 ± 15.9 to 39.0 ± 11.0 minutes (P = 0.007) with a reduction in overall procedure duration from 185 ± 46 to 154 ± 39 minutes (P = 0.022). In parallel, the total energy delivered could be significantly reduced from 70,926 ± 19,470 to 58,511 ± 14,655 Ws (P = 0.019). The number of acute PV reconnections declined from 36% to 12% (P = 0.095).*

Conclusions: *The use of contact force sensing technology is able to significantly reduce ablation and procedure times in PVI. In addition, energy delivery is substantially reduced by avoiding radiofrequency ablation in positions with insufficient surface contact. Procedural efficacy and safety of this new feature have to be evaluated in larger cohorts. (PACE 2012;00:1–7)*

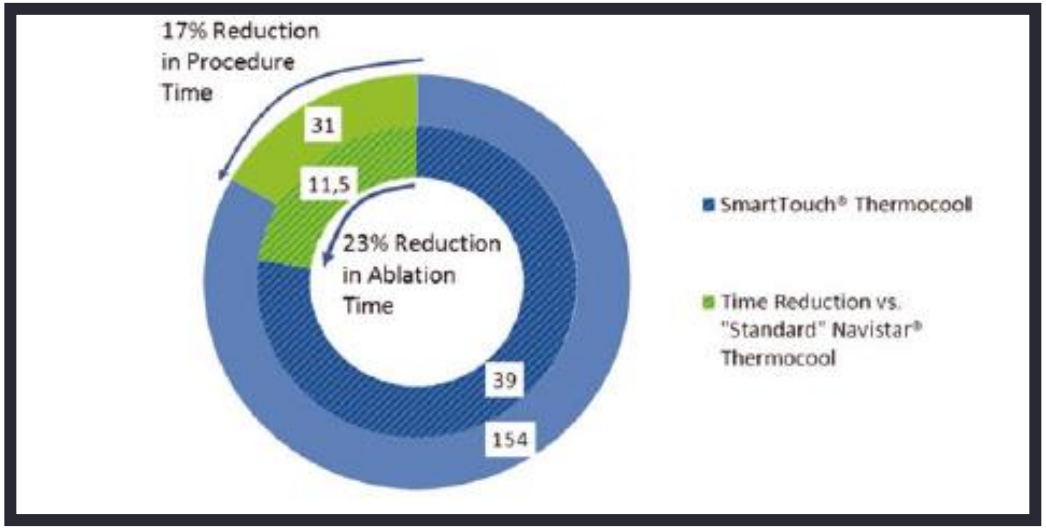
Acute PVI

Procedural Parameters			
	"Standard" Navistar® Thermocool (Biosense Webster)	SmartTouch® Thermocool (Biosense Webster)	P
Ablation time (minutes)	50.5 ± 15.9	39.0 ± 11.0	0.007
Procedure duration (minutes)	185 ± 46	154 ± 39	0.022
Total energy delivered (Ws)	70,926 ± 19,470	58,510 ± 14,655	0.019
Maximum power delivered (W)	30.2 ± 2.3	31.0 ± 4.3	0.418
Fluoro duration (minutes)	28.6 ± 17.4	23.6 ± 13.1	0.312
Acute pulmonary vein reconnection	9/25 (36%)	3/25 (12%)	0.095
Mean INR at day of procedure	2.5 ± 0.6	2.3 ± 0.5	0.334
Mean ACT value during procedure (seconds)	331 ± 39	345 ± 36	0.368

INR = international normalized ratio; ACT = activated clotting time.



SmartTouch* catheter



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

ELOI MARIJON, M.D., PH.D.,*,† SAMIA FAZAA, M.D.,* KUMAR NARAYANAN, M.D.,† BENOIT GUY-MOYAT, M.D.,* ABDESLAM BOUZEMAN, M.D.,*,† RUI PROVIDENCIA, M.D., M.S.,* FREDERIC TREGUER, M.D., M.S.,* NICOLAS COMBES, M.D., M.S.,* AGUSTIN BORTONE, M.D.,‡ SERGE BOVEDA, M.D.,* STEPHANE COMBES, M.D., M.S.,* and JEAN-PAUL ALBENQUE, M.D.*

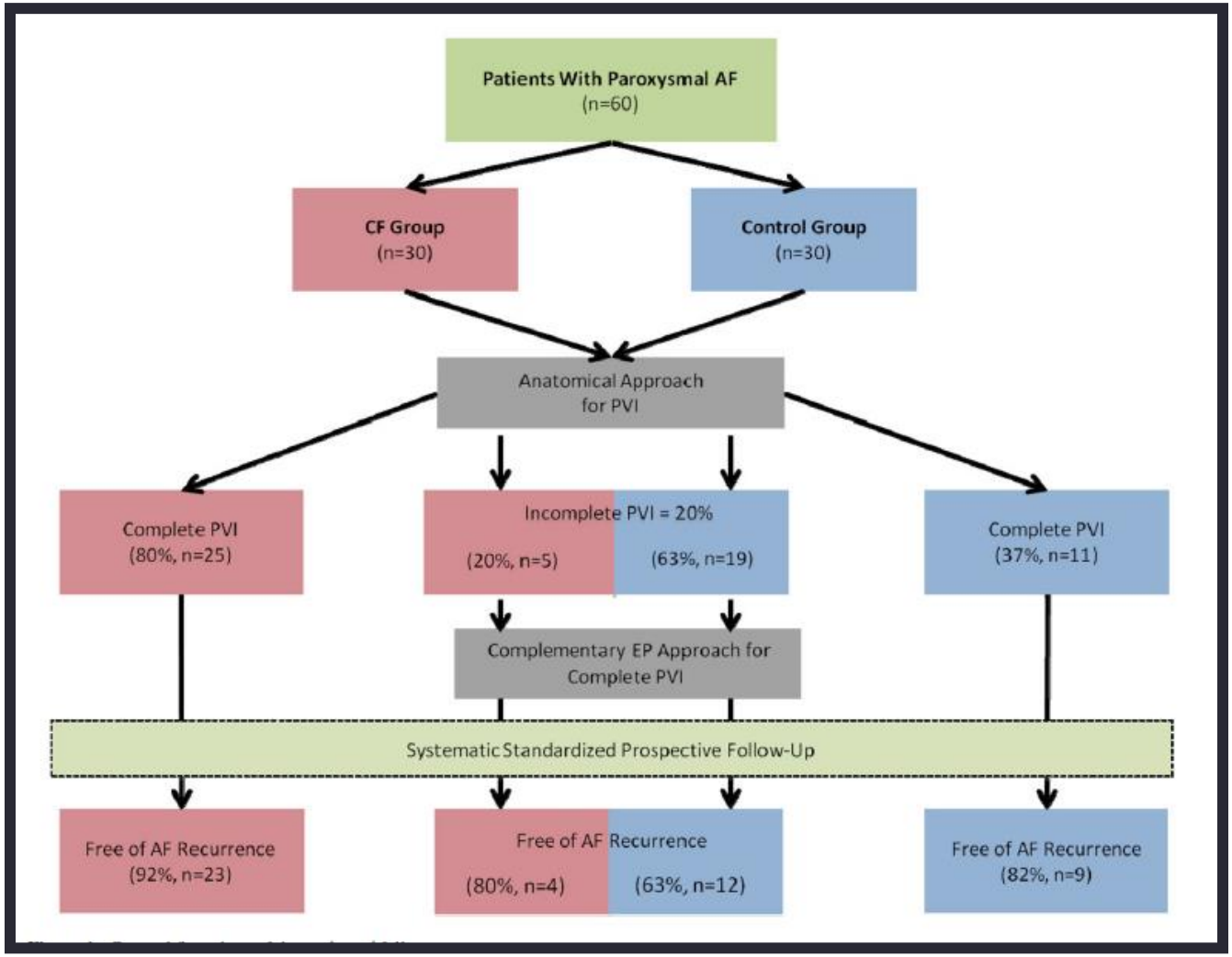
From the *Clinique Pasteur, Département de Rythmologie, Toulouse, France; †Paris Cardiovascular Research Center, Paris, France; and ‡Service de Cardiologie, Hôpital Privé Les Franciscaines, Nîmes, France

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.**

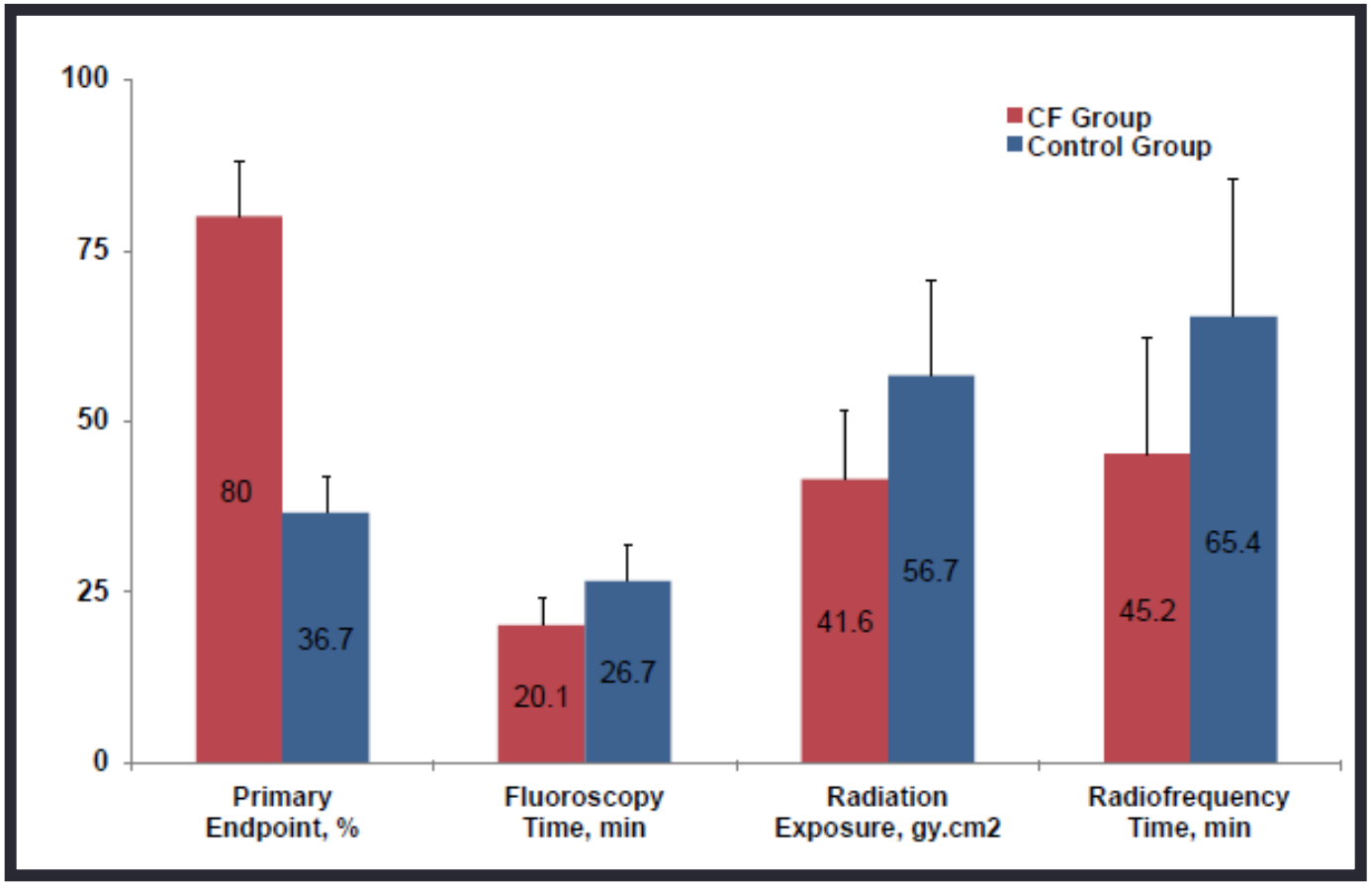
Methods and Results: **Eligible patients with symptomatic paroxysmal AF were enrolled in this prospective trial, comparing circular antral catheter ablation (guided by Carto 3 System, Biosense Webster) using either a new open-irrigated CF catheter (SmartTouch Thermocool, Biosense Webster) (CF group) 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

Study flow chart: CF vs. non-CF catheter



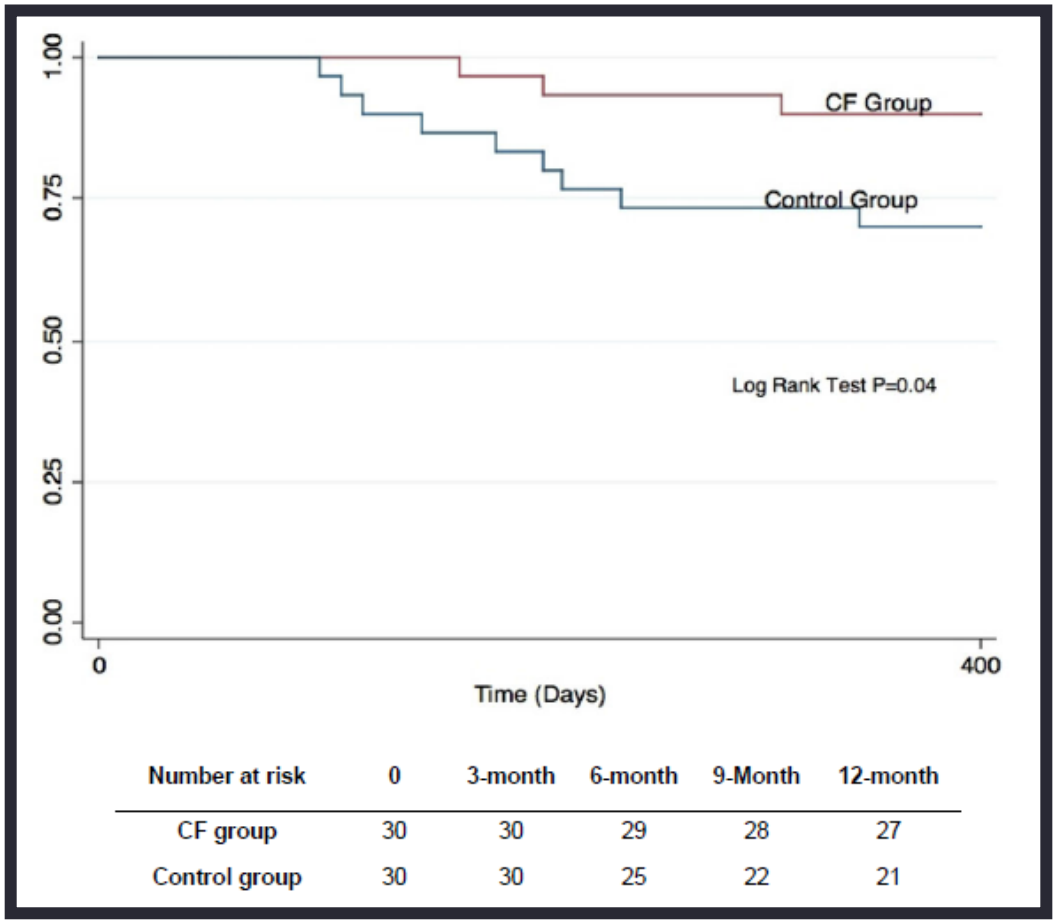
Primary and secondary acute endpoints in CF vs. Control group



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



Number at risk	0	3-month	6-month	9-Month	12-month
CF group	30	30	29	28	27
Control group	30	30	25	22	21

Primary mid-term endpoint

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. 64, NO. 7, 2014

ISSN 0735-1097/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jacc.2014.04.072

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,‡‡‡ Lee Ming Boo, PharmD,‡‡‡ Francis E. Marchlinski, MD§§§

BACKGROUND Catheter ablation is important for treatment of paroxysmal atrial fibrillation (PAF). Limited animal and human studies suggest a correlation between electrode-tissue contact and radiofrequency lesion generation.

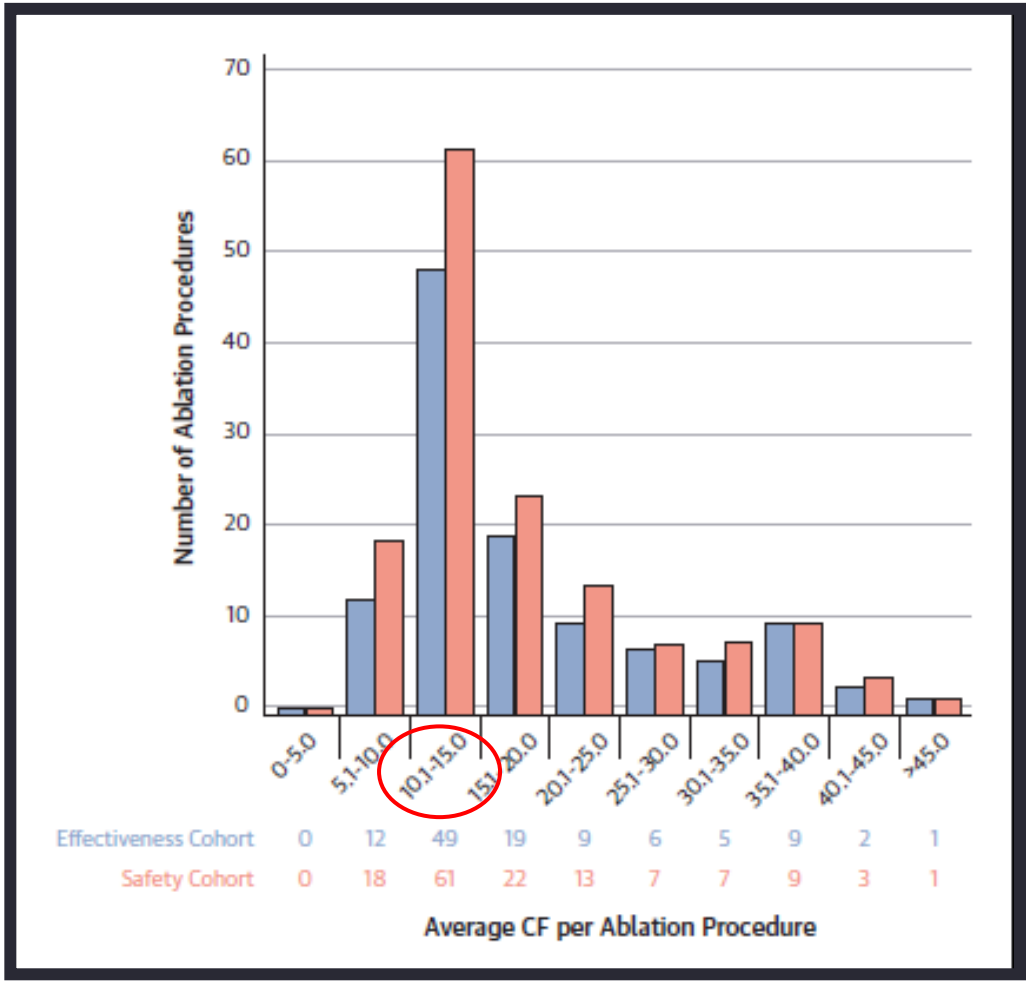
OBJECTIVES The study sought to assess the safety and effectiveness of an irrigated, contact force (CF)-sensing catheter in the treatment of drug refractory symptomatic PAF.

METHODS A prospective, multicenter, nonrandomized study was conducted. Enrollment criteria included: ≥3 symptomatic episodes of PAF within 6 months of enrollment and failure of ≥1 antiarrhythmic drug (Class I to IV). Ablation included pulmonary vein isolation with confirmed entrance block as procedural endpoint.

RESULTS A total of 172 patients were enrolled at 21 sites, where 161 patients had a study catheter inserted and 160 patients underwent radiofrequency application. Procedural-related serious adverse events occurring within 7 days of the procedure included tamponade (n = 4), pericarditis (n = 3), heart block (n = 1, prior to radiofrequency application), and vascular access complications (n = 4). By Kaplan-Meier analyses, 12-month freedom from atrial fibrillation/atrial flutter/atrial tachycardia recurrence was 72.5%. The average CF per procedure was 17.9 ± 9.4 g. When the CF employed was between investigator selected working ranges ≥80% of the time during therapy, outcomes were 4.25 times more likely to be successful (p = 0.0054; 95% confidence interval: 1.53 to 11.79).

CONCLUSIONS The SMART-AF trial demonstrated that this irrigated CF-sensing catheter is safe and effective for the treatment of drug refractory symptomatic PAF, with no unanticipated device-related adverse events. The increased percent of time within investigator-targeted CF ranges correlates with increased freedom from arrhythmia recurrence. Stable CF during radiofrequency application increases the likelihood of 12-month success. (THERMOCOOL® SMARTTOUCH® Catheter for Treatment of Symptomatic Paroxysmal Atrial Fibrillation; NCT01385202) (J Am Coll Cardiol 2014;64:647-56)

Distribution of average CF during RF



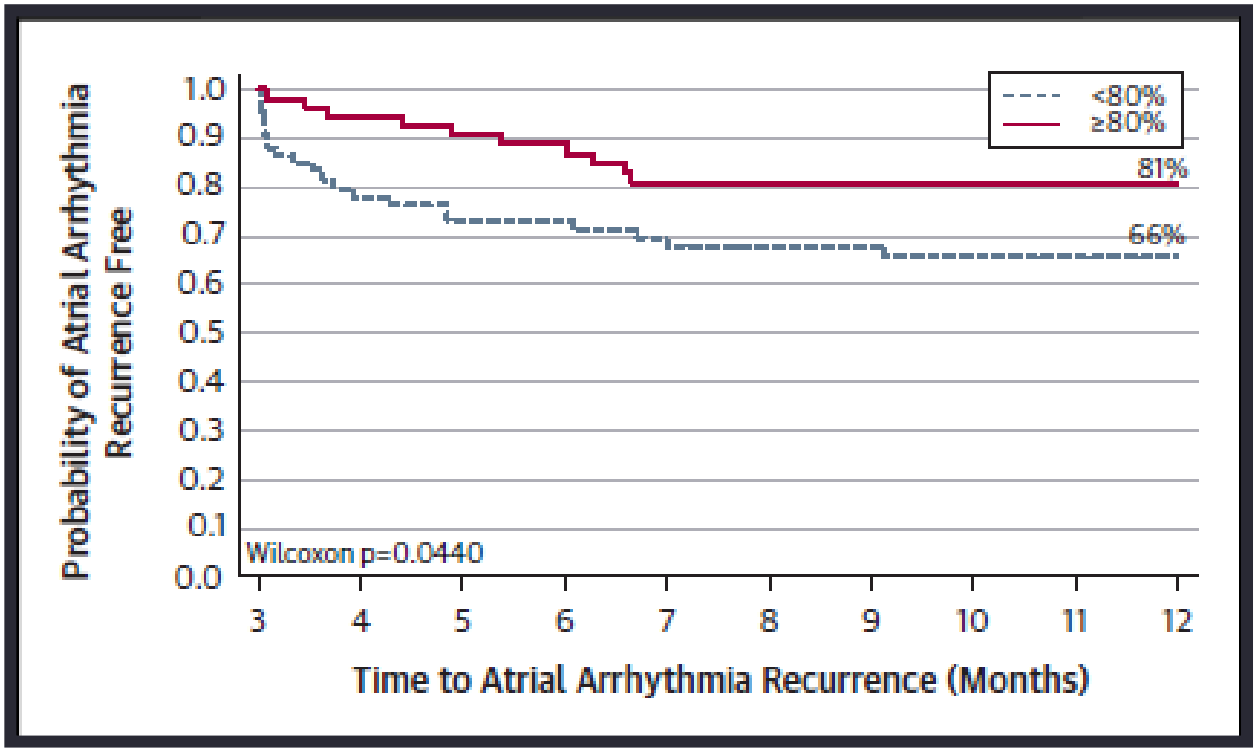
Twelve-month success rates with various types and forces of ablation catheters

Dataset	No. of Pts	12-Month Success (AF/AT-free)
SMART-AF (≥80% time within preselected contact force range)	51	81%
SMART-AF (<80% time within preselected contact force range)	57	66%
Non Force-Sensing Open-Irrigated Catheter*	106	66%

Working range 5 to 40 g defined per center

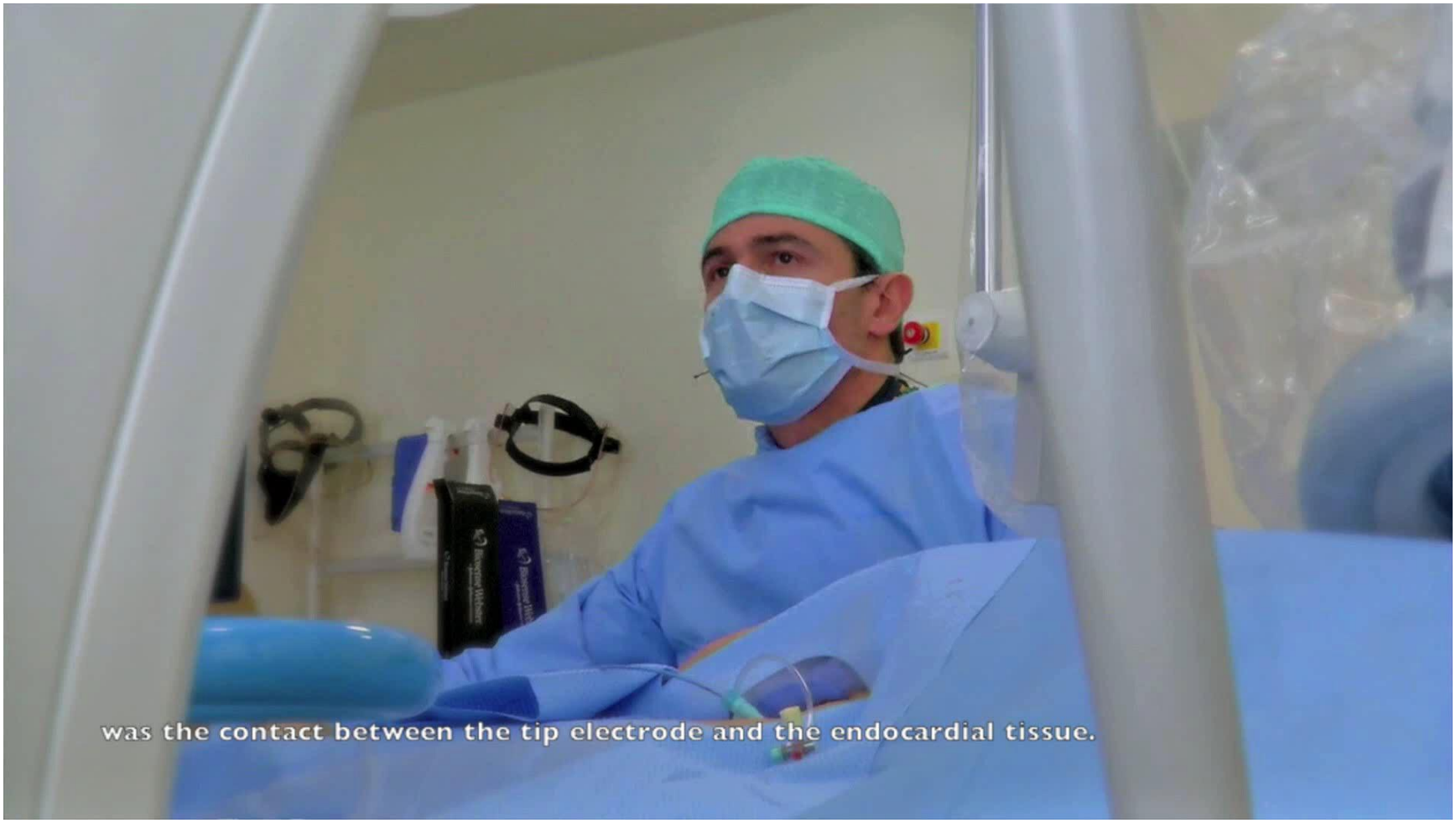
Time to first AF / atrial flutter / atrial tach recurrence through 12 months FU

Kaplan-Meier curve

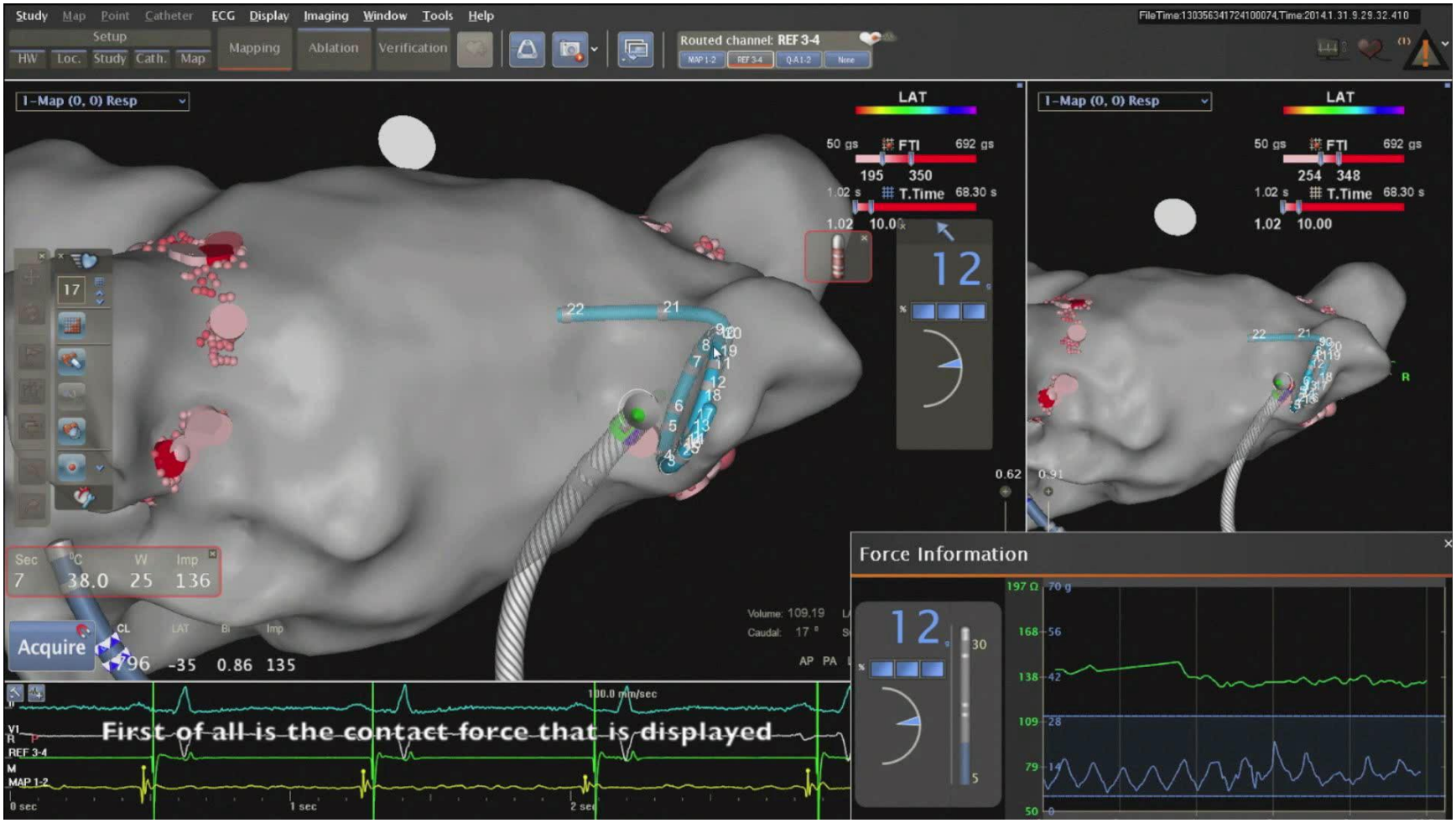


Investigators working in their selected ranges

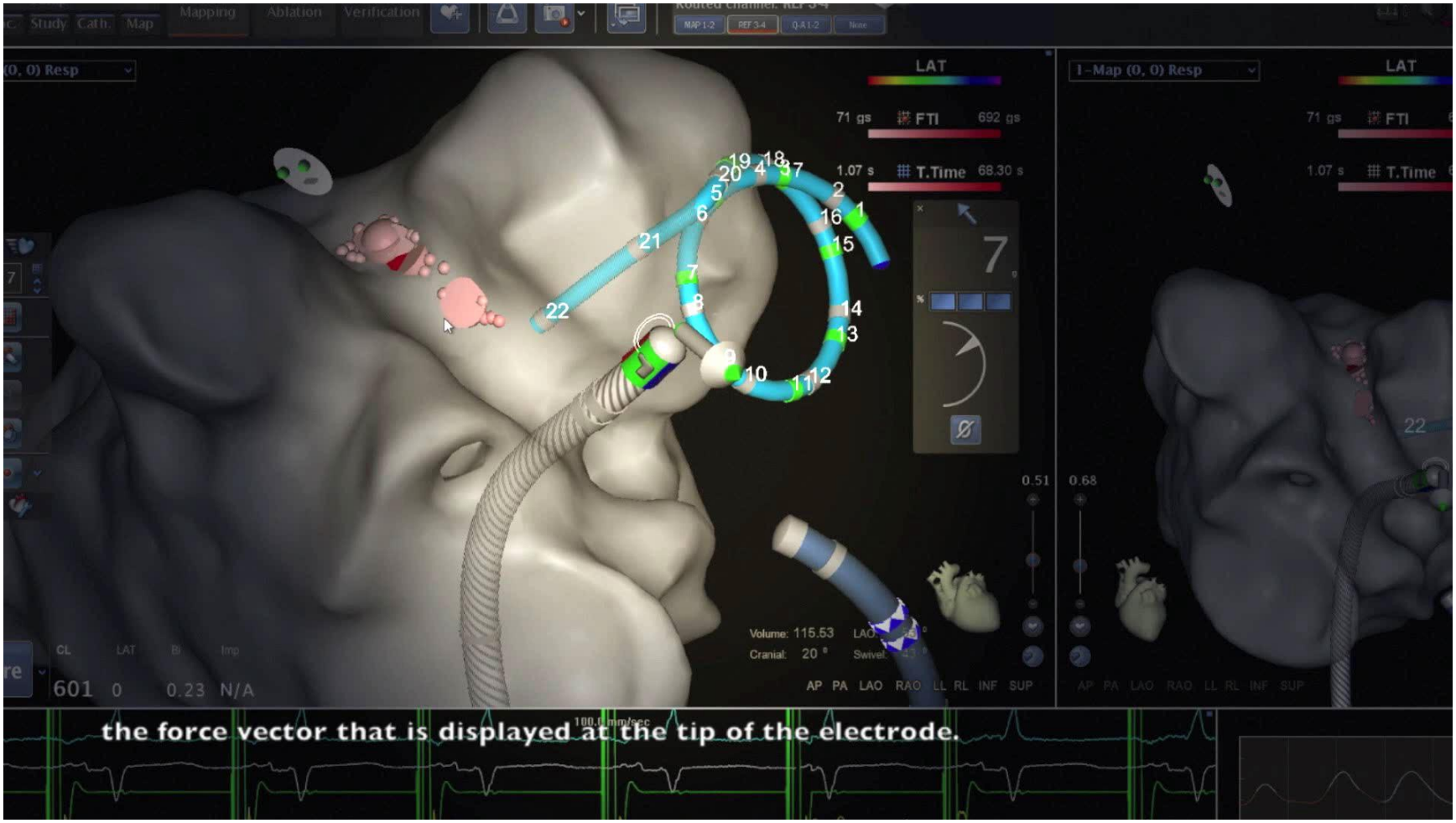
SmartTouch* technology



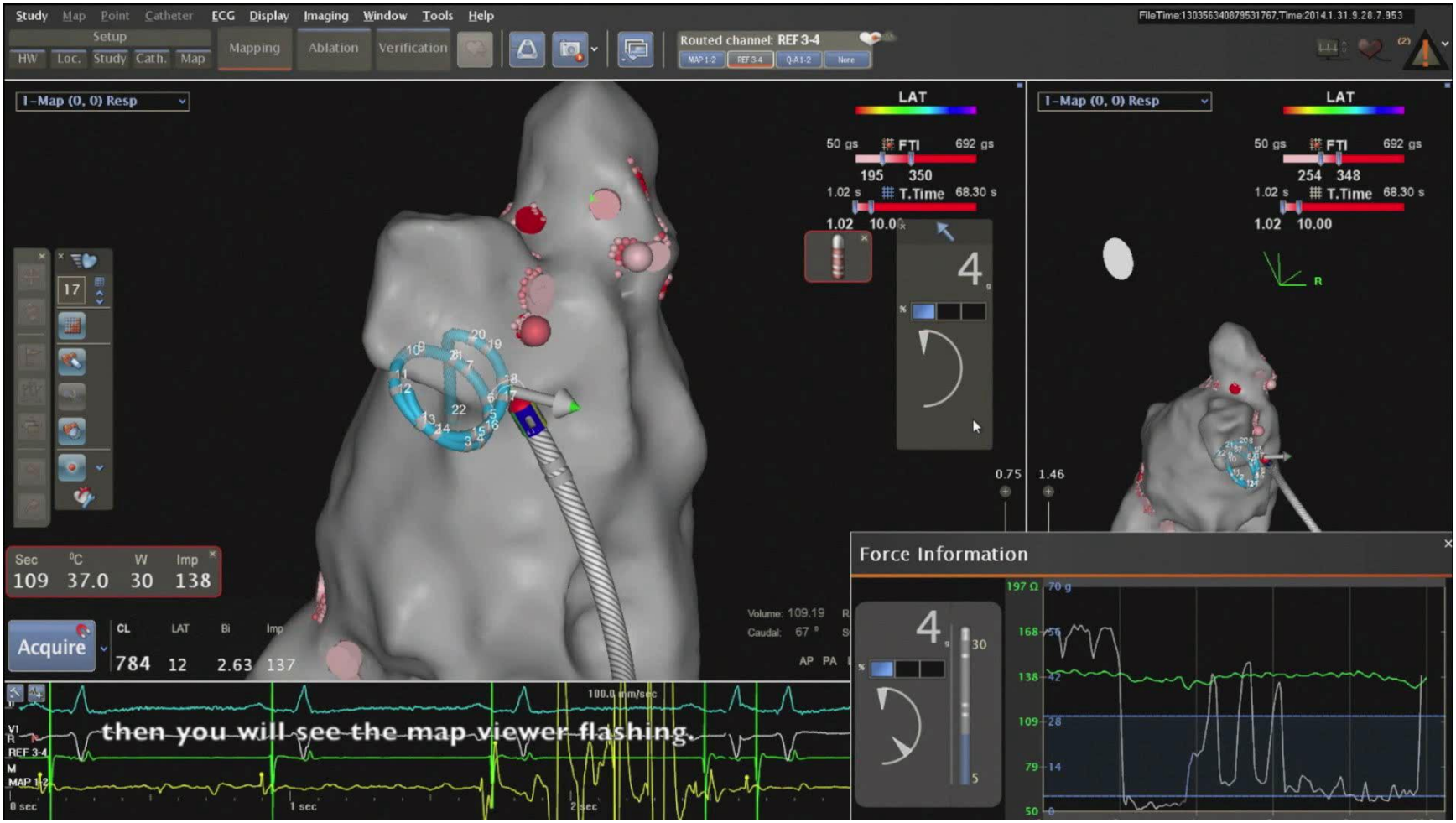
Contact force informations



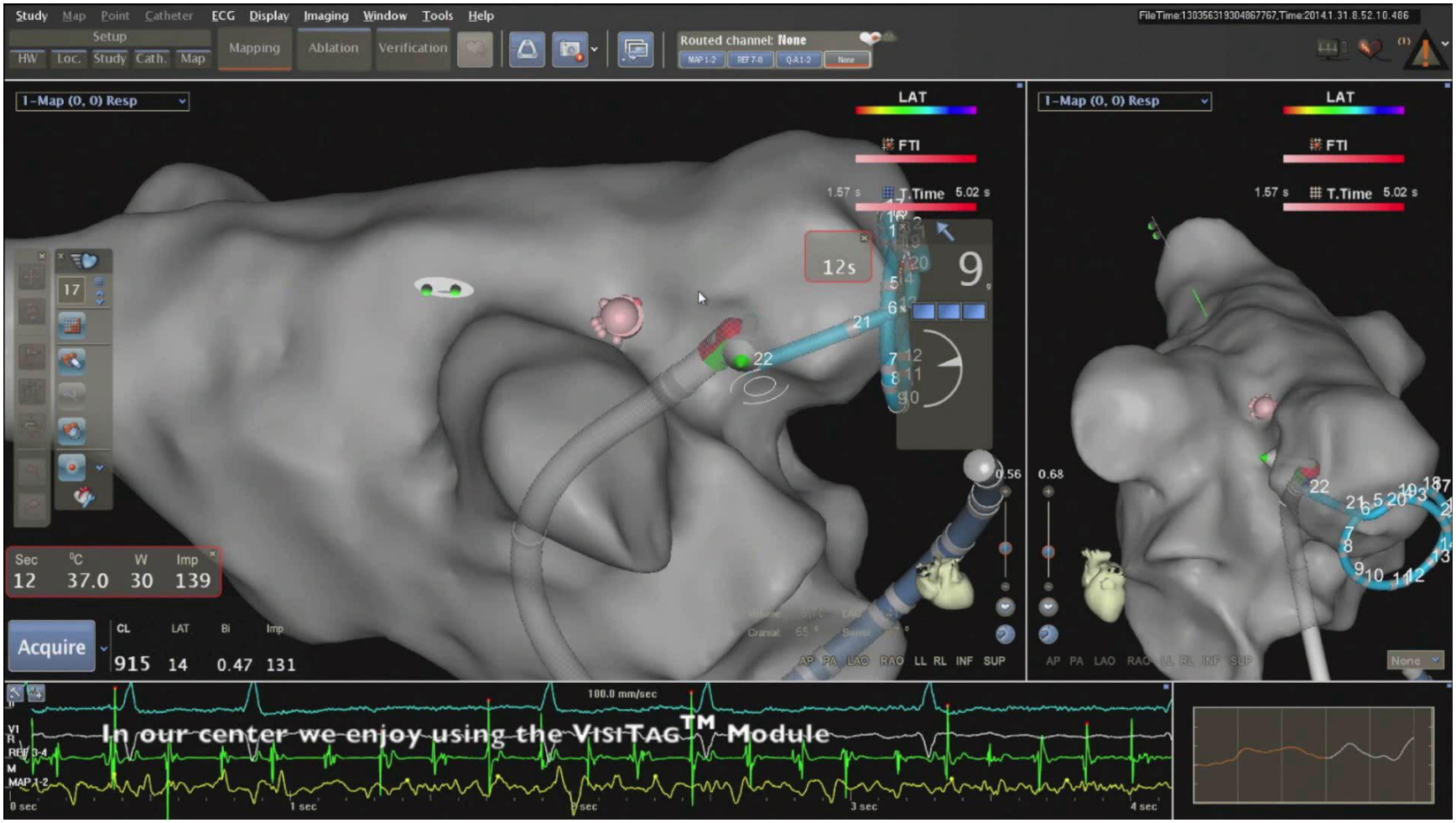
Force vector



Maximum force indicator



Visitag* module



Contact Force is a major innovation in AF ablation

- More accurate geometry acquisition
- Shorter procedure time
- Reduction in total RF delivery
- Decrease in fluoro duration and X-Ray exposure
- Better acute and long-term PVI
- Better 12-months outcomes after single AF ablation procedure
- Major additional safety informations