AF ablation evolution with Higher Power Settings

LYON, Médipôle – Clinique Protestante

A.D.R.I.S

Disclosure

I have the following potential conflicts of interest to report

Consulting : Abbott, Medtronic

What can we expect from higher energy ablation?

- Interest?
  - Lesion and temperature LPHD / HPSD?
  - Impedance role
  - Contact / energy role

- How can we evaluate the quality of the lesion?
  - LSI

- Our experience

Summary

- What are we doing now?

    Consensus, usual practice, company recommandations

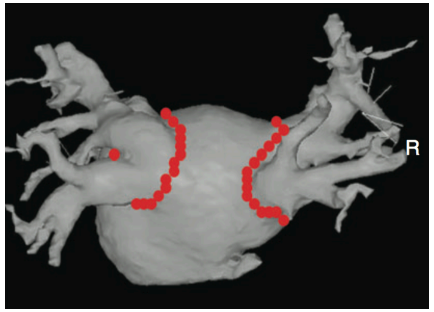
- What can we expect from higher energy ablation?
- Studies results (animal and human):

    Power, time, impedance, LSI

- Our experience
- Conclusion

What are we doing now?

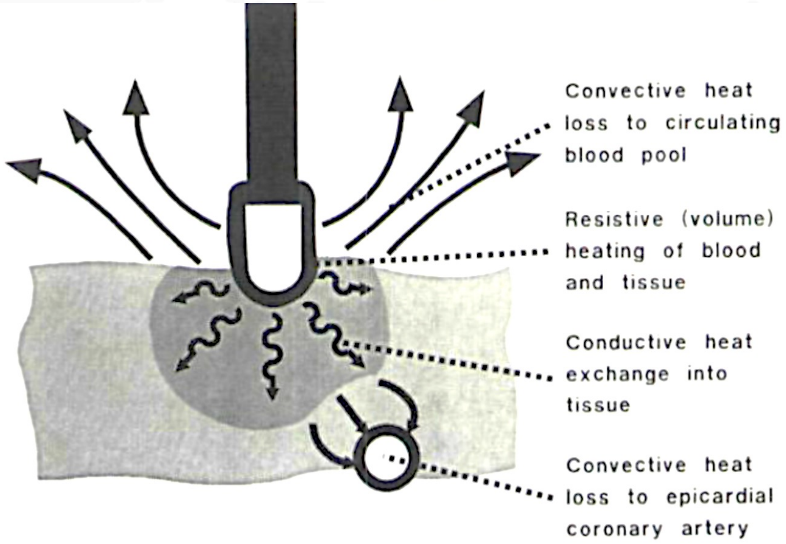
AF treatment consensus



- PV isolation is the most effective rythm control strategy for patients undergoing AF.
- PV isolation has become the standard catheter-based ablation strategy. It is used now to do antrum and jointed lesions.
- Several factors are important to create effective radiofrequency (RF) lesions, such as the RF power, contact force, ablation time, stability and impedance.

The Biophysics of Radiofrequency Catheter Ablation in the Heart: The Importance of Temperature Monitoring

DAVID E. HAINES



What are we doing now?

Recommandations from industry (IFU): less than 30 W

	ABBOTT (Tacticath SE ®)	BIOSENSE (Smarttouch ®)	BOSTON (Intellanav ®)
POWER	10-30 W max 50 W	15-30 W max 50 W	15-20 W max 50 W
Contact force	10-30 g (target 20 g)	No specified	local impedance
Application time	Not specified	30-120 sec	< 60 sec
Temperature	37-50 °	< 40 °	< 50 °
Irrigation flow	17-30 ml/mn	8 ml/mn	17 ml/mn

To date, many centers prefer to perform RF ablation using a power of 25–30W for durations of approximately 20–30 seconds at each point.

What are we doing now?

2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation

Heart Rhythm, Vol 14, No 10, October 2017

Ablation strategies to be considered for use in conjunction with PV isolation	When performing AF ablation with a force-sensing RF ablation catheter, a minimal targeted contact force of 5 to 10 grams is reasonable.	IIa	→No power recommandation
Strategies to reduce the risks of AF ablation	It is recommended that RF power be reduced when creating lesions along the posterior wall near the esophagus.	I	
	It is reasonable to use an esophageal temperature probe during AF ablation procedures to monitor esophageal temperature and help guide energy delivery.	IIa	→Safety recommandations

What can we expect from higher energy ablation?

TARGETS for ablation procedure

Depend on
- RF Power
- Contact force
- Stability
- Ablation time
- Impedance

For transmural lesion (> 2 mm)

New tool LSI, LI

EFFICACITY

REDUCE Time procedure

- Reduce RF time
- Reduced fluoroscopy time
- Reduced fluid volume infused

SAFETY

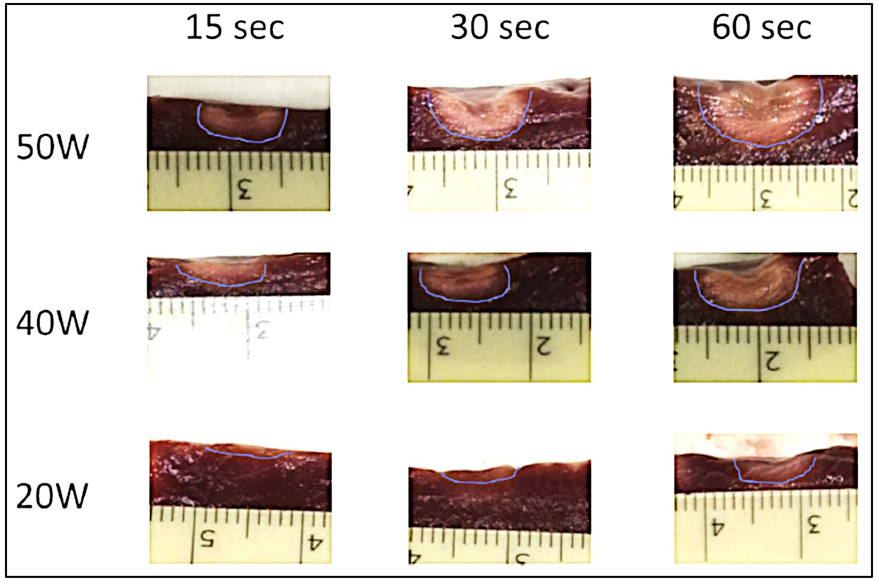
Avoid major adverse events :

- Esophageal injury
- Perforation
- Tamponnade
- Stroke

A high power–short duration strategy of radiofrequency ablation aims to deliver targeted heating to the atrial wall, while reducing the risk of collateral tissue damage

Animal studies results

Ex vivo viable bovine myocardium



Greater power delivery and longer radiofrequency time increased ablation lesion size.
Power delivery has the most contributory effect.

Longer Duration Versus Increasing Power During Radiofrequency Ablation Yields Different Ablation Lesion Characteristics

Ryan T. Borne, MD, William H. Sauer, MD, Matthew M. Zipse, MD, Lijun Zheng, MS, Wendy Tzou, MD, Duy T. Nguyen, MD

In vivo porcine myocardium, irrigated catheter, 10 g CF

TABLE 2 Ablation Lesion Characteristics and Parameters for Low Power/Long Duration and High Power/Low Duration in the In Vivo Model

	50 W/5 s	20 W/30 s	p Value
Volume, mm^3	35.3 ± 9.9	44.2 ± 17.9	0.07
Average maximum depth, mm	2.0 ± 0.2	2.9 ± 0.6	<0.01
Maximum diameter, mm	6.8 ± 0.8	6.2 ± 1.5	0.11
Impedance reduction, Ω	20 ± 7	14 ± 7	0.01
Force, g	16 ± 1	16 ± 2	0.88

For in vivo models,
50 W/5 s ablation lesions yielded similar volumes
but significantly less depth than 20 W/30 s ablation lesions

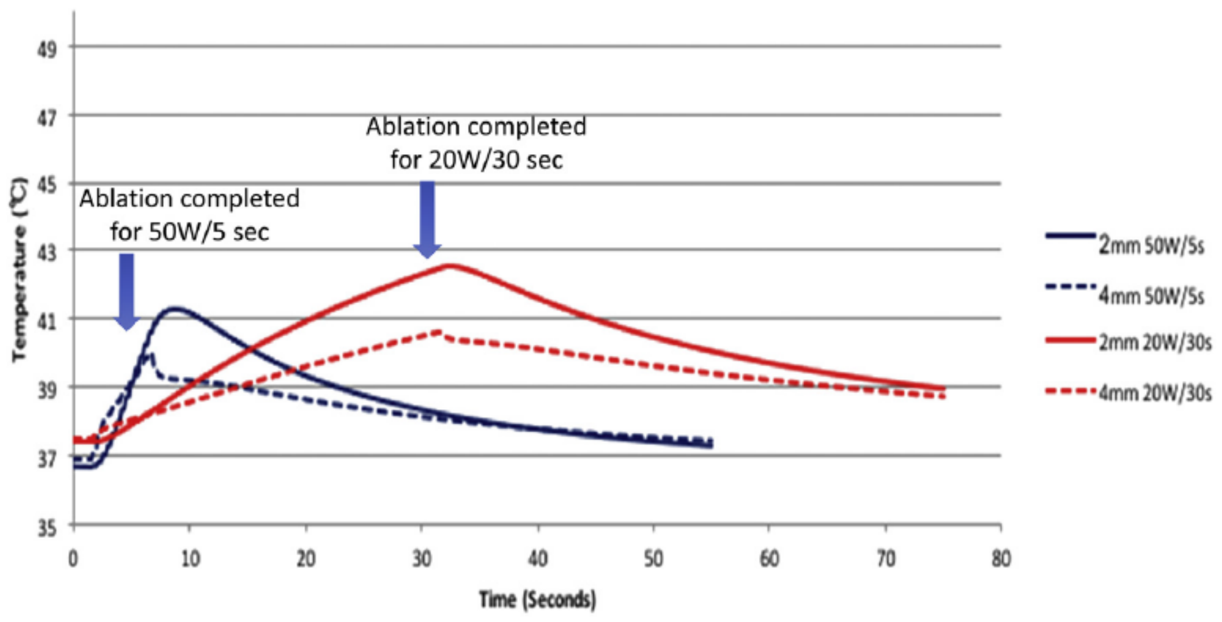
Borne et al. Clinical Electrophysiology 2018

Animal studies results

Longer Duration Versus Increasing Power During Radiofrequency Ablation Yields Different Ablation Lesion Characteristics

Ryan T. Borne, MD, William H. Sauer, MD, Matthew M. Zipse, MD, Lijun Zheng, MS, Wendy Tzou, MD, Duy T. Nguyen, MD

FIGURE 3 Temperature Curves for In Vivo Models of Low Power/Long Duration and High Power/Low Duration in the In Vivo Model



- **Peak temperatures were not significantly different at 2 and 4 mm with 50 W/5 s compared with 20 W/30 s.**
- In addition, the temperature–time integral (area under the curve) was smaller for 50 W/5 s at both 2 mm and 4 mm depths, 2,129C–s vs. 2,237C–s ($p < 0.01$) and 2,111C–s vs. 2,178C–s ($p < 0.01$), compared with those for 20 W/30 s.

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 4, NO. 7, 2018 JULY

Animal studies results

Five seconds of 50–60 W radio frequency atrial ablations were transmural and safe: an *in vitro* mechanistic assessment and force-controlled *in vivo* validation

Evidence of overheating was confirmed in the in vivo experiments where the complications in short-duration ablation especially **steam pops were observed only at 40W/30 sec and at 70 and 80W/5sec ablations and not at 50 and 60W. Lung lesions were observed only at 40 W/30 s and 80 W/5 s settings. No perforation or tamponade was observed in any of the ablations**

40W to 80 W in 5 sec compared with 40W in 30 sec, 10 g CF, 30 ml/mn

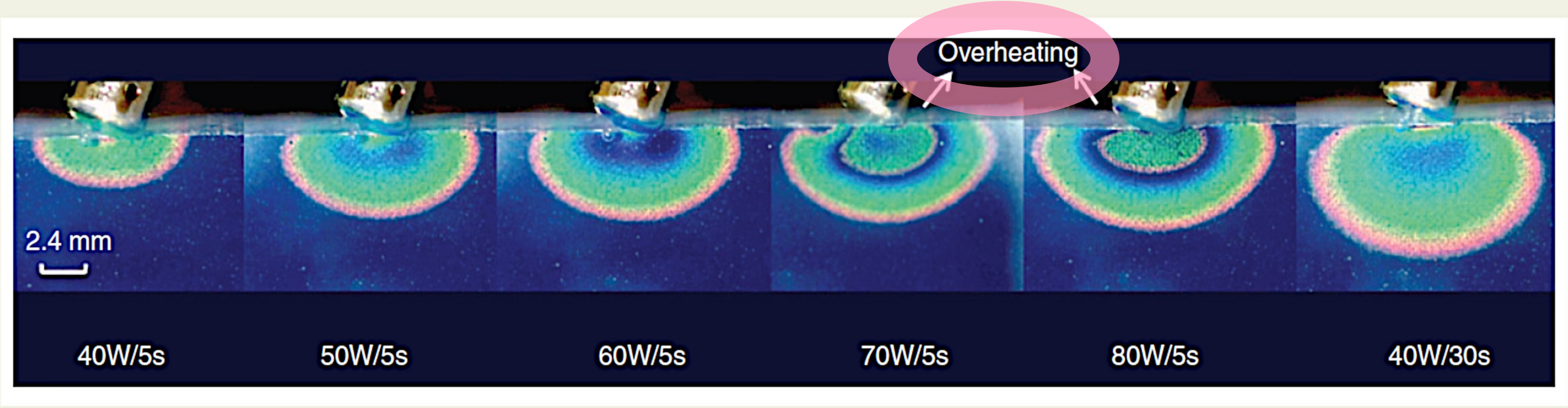
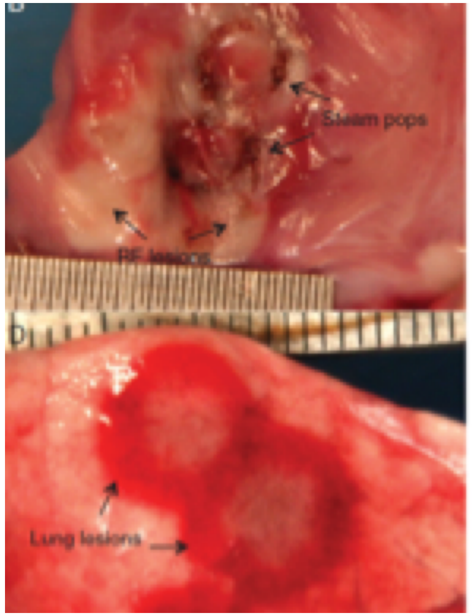


Figure 2 *In vitro* ablations in the myocardial phantom. Standard ablation of 40 W/30 s was compared with 40–80 W for 5 s. The critical depth of 2 mm was achieved by all ablations, except for 40 W/5 s setting. Overheating was observed in short-duration ablations of 70 and 80 W and was absent in 40 W/30 s.



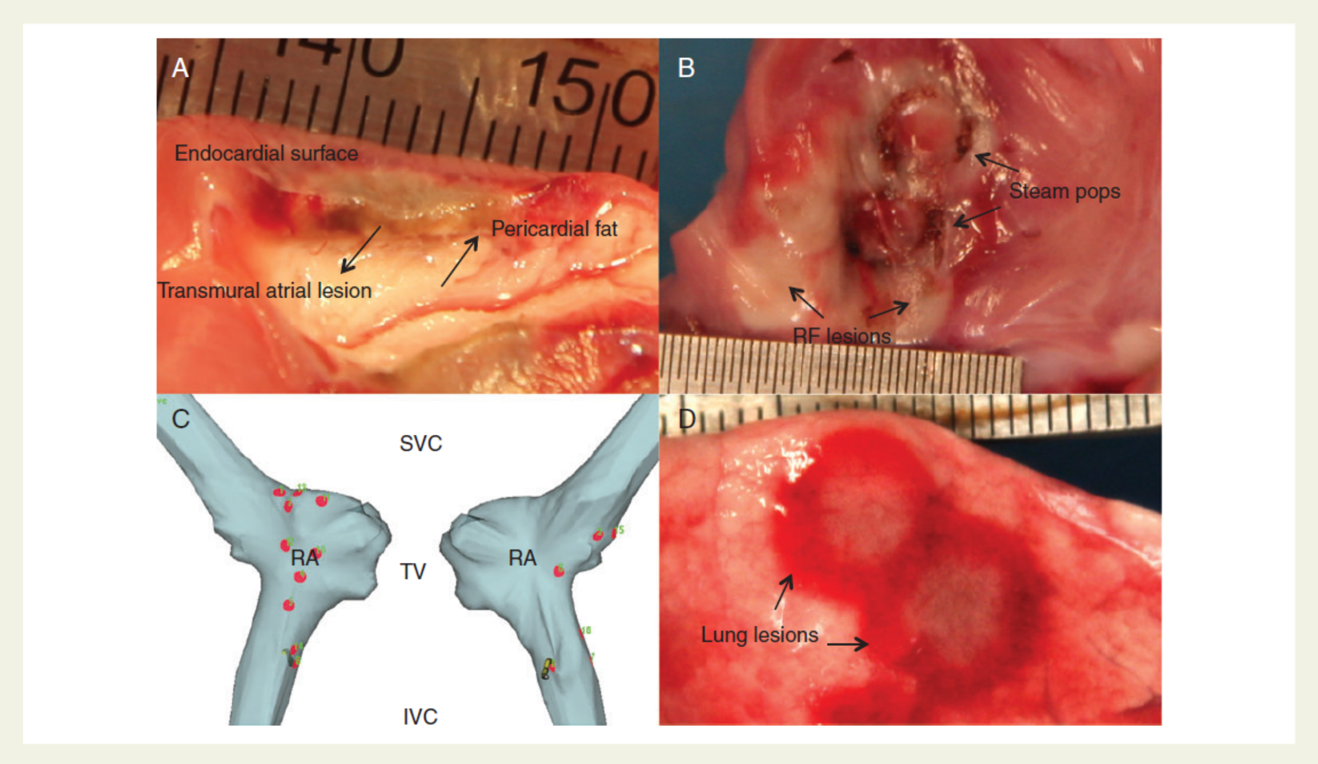
Abhishek Bhaskaran et al. Europace 2016.

Animal studies results

Five seconds of 50–60 W radio frequency atrial ablations were transmural and safe: an *in vitro* mechanistic assessment and force-controlled *in vivo* validation

Abhishek Bhaskaran[1,2]*, William Chik[1,2], Jim Pouliopoulos[1,2], Chrishan Nalliah[1,2], Pierre Qian[1,2], Tony Barry[1,2,3], Fazlur Nadri[1,2], Rahul Samanta[1,2], Ying Tran[4], Stuart Thomas[1,2], Pramesh Kovoor[1,2], and Aravinda Thiagalingam[1,2]

40W to 80 5 sec, 40W 30 sec



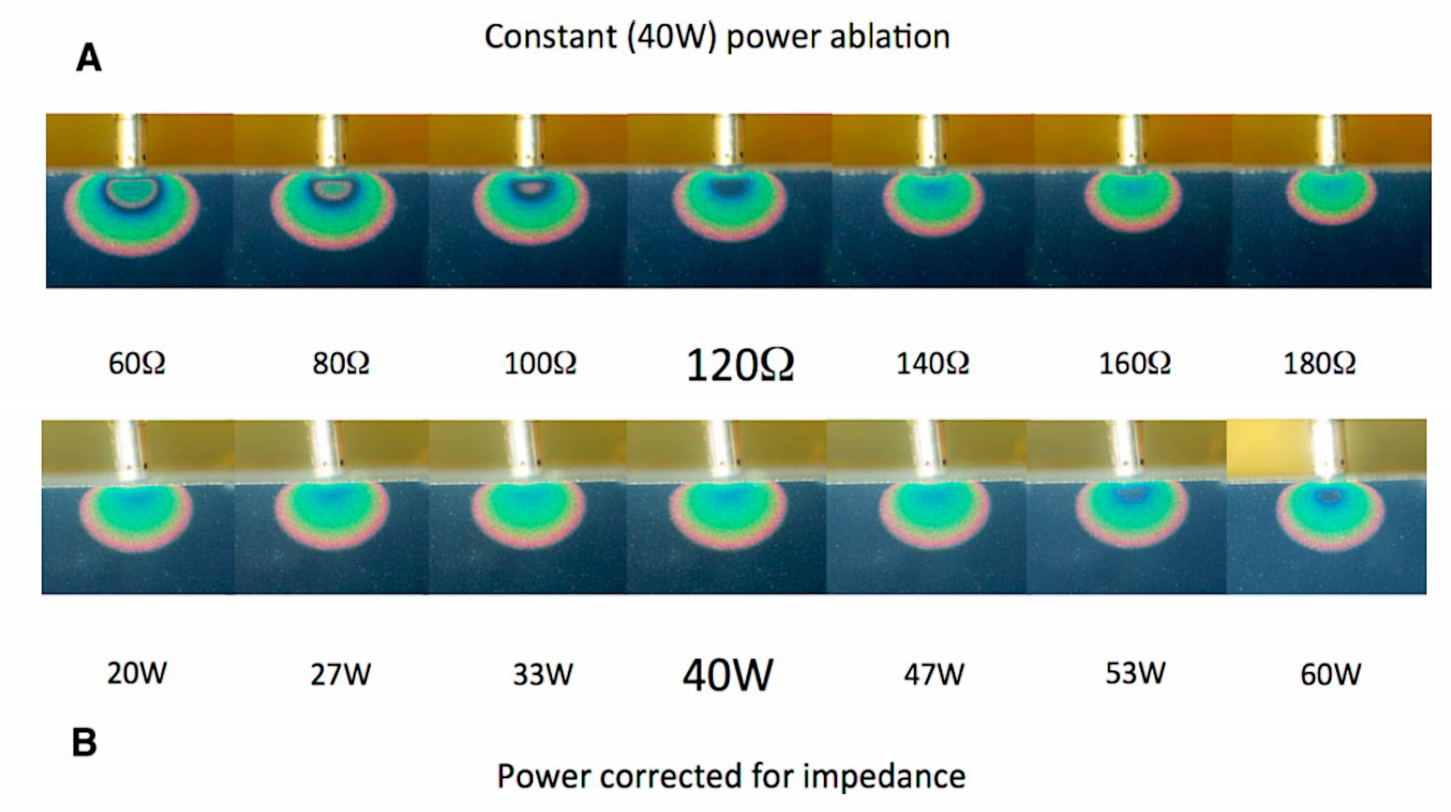
- « In the current study, lung lesions were present in the ablations of 40 W/30 s but not during short-duration ablations at 50 or 60 W. This could be explained by the fact that ablations at 50 W for 5 s deliver at most 250 J, while those at 40 W/30 s could deliver up to 1200 J to the atrial myocardium, providing the potential to cause tissue
- overheating. »
- 30 s is too much for lesion creations.

Europace Feb 2016

Studies results

Circuit Impedance Could Be a Crucial Factor Influencing Radiofrequency Ablation Efficacy and Safety: A Myocardial Phantom Study of the Problem and Its Correction

In Vitro myocardial phantom model comprised a solidified gel in which a thermochromic sheet was embedded



Pay attention to Impedance

The lesion volume was 72.0 mm^3 ± 4.8% and 44.7 mm^3 ± 4.6% higher at 80 Ω and 100 Ω compared to 120 W.

"The overheated volume was four times bigger when impedance was reduced from 100 to 80 Ohms"

Conclusion

The lesion and overheated dimensions were significantly larger at lower impedance during irrigated RF ablations and the lesion size was smaller at high impedance ablations.

This could be particularly important for patients with low BMI
So be careful, adapt power !

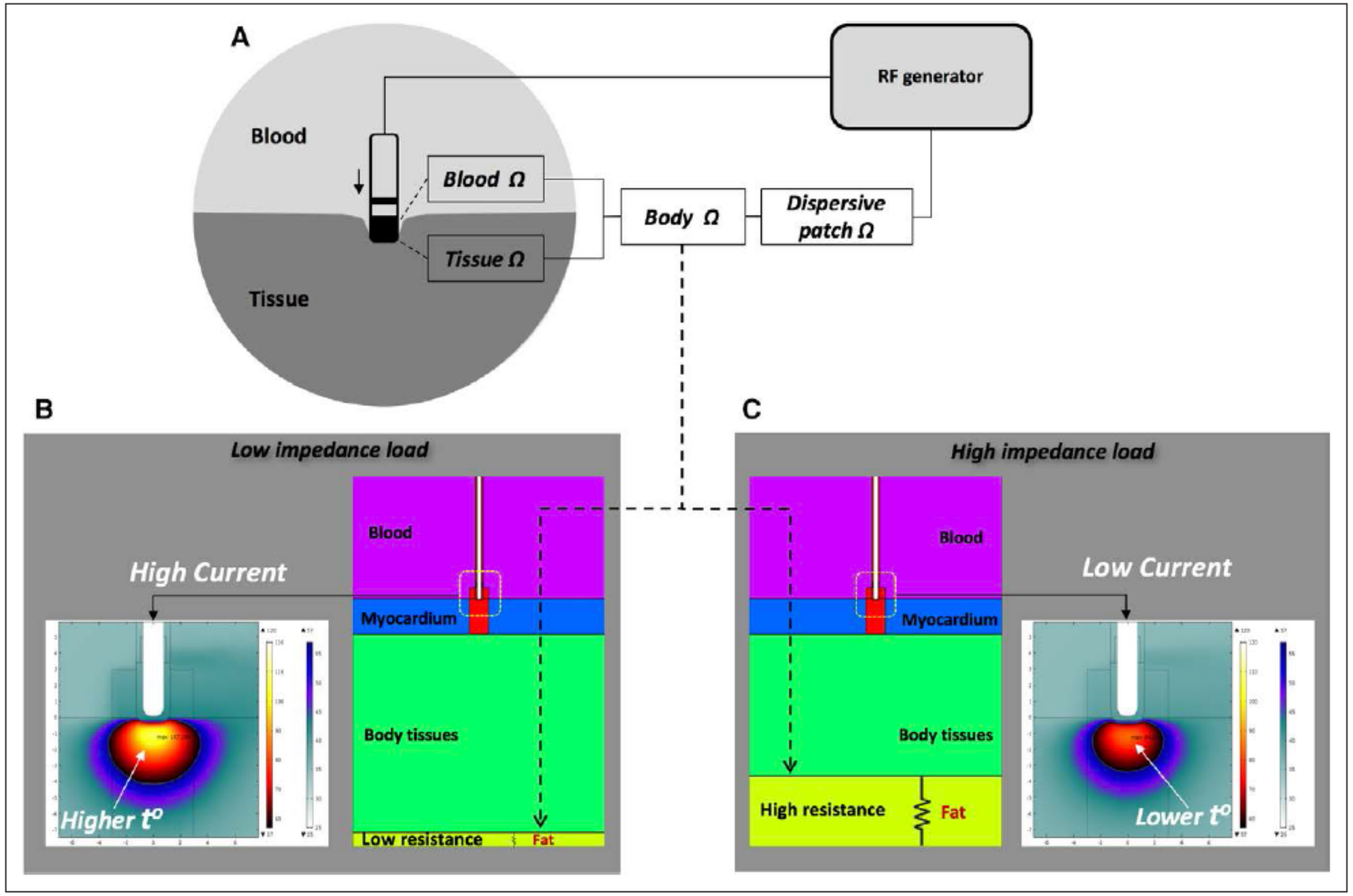
Abhishek Bhaskaran et al.Cardiovasc Electrophysiol, Vol. 27, 2016

Animal studies results

Effect of Baseline Impedance on Ablation Lesion Dimensions

A Multimodality Concept Validation From Physics to Clinical Experience

Michael Barkagan, MD*
Markus Rottmann, MSc, PhD*
Eran Leshem, MD
Changyu Shen, PhD
Alfred E. Buxton, MD
Elad Anter, MD



Impedance a crucial factor

"Radiofrequency ablation in a power control mode results in variable lesion dimensions that are partially related to differences in baseline impedance and current output."

Circ Arrhythm Electrophysiol. 2018;11:e006690. DOI: 10.1161/CIRCEP.118.006690

Clinical studies results

Low complication rates using high power (45–50 W) for short duration for atrial fibrillation ablations

Roger A. Winkle, MD, FHRS,* Sanghamitra Mohanty, MD,† Rob A. Patrawala, MD, FHRS,* R. Hardwin Mead, MD, FHRS,* Melissa H. Kong, MD, FHRS,* Gregory Engel, MD,* Jonathan Salcedo, MD, FHRS,* Chintan G. Trivedi, MD,† Carola Gianni, MD,† Pierre Jais, MD,‡ Andrea Natale, MD, FHRS,† John D. Day, MD, FHRS§

Results

Patient population

4 experienced centers 2006-2017

Patient demographics are summarized in Table 1. A total of 13,974 ablations were performed in 10,284 patients (average patient age 64 ± 11 years, male gender 68%, average left atrial size 4.4 ± 0.7 cm). AF was paroxysmal in 37%, persistent in 42%, and longstanding in 20%. The patients had failed an average of 1.4 ± 0.7 antiarrhythmic drugs. Hypertension was present in 54%, diabetes in 15%, and a previous stroke or transient ischemic attack had occurred in 7.0%. The average CHA_2DS_2-VASc score was 2.1 ± 1.4.

- → All centers used irrigated-tip catheters at a RF power of **45–50 W for short durations of 5–15 seconds** in the left atrium other than on the posterior wall
- → Posterior wall: 45-50 Watt for 2-10 sec
- → PW 2538 pts 35 W/20 sec
- → Esophageal monitoring.

- → Procedure time : 116 +/- 41 mn
- → Fluoroscopy time : 33+/-6 mn
- → RF time : 39 +/- 30 mn

Winkle et al. Heart Rhythm, Vol 16, No 2, 2019

Clinical studies results

Total complication rate : 0,51 %

Table 2 Per procedure complications

Complication	Total no.	Percent of ablations	Outcome
Pericardial tamponade	33	0.24	26 tapped, 7 surgery
Strokes in first 48 hours	6	0.043	1 death, 1 with residual
Strokes 48 hours to 30 days	6	0.043	None with residuals
PV stenosis requiring intervention	2	0.014	Both treated successfully
Phrenic nerve paralysis	2	0.014	Both recovered
Left atrial steam pops	2	0.014	No consequences
Catheter char	0	0.00	
Atrioesophageal fistula high-power posterior wall	1	0.0087	Survived with surgery
Atrioesophageal fistula lower-power posterior wall	3	0.12	1 death 2 survived with surgery

PV = pulmonary vein.

Low complication rates using high power (45–50 W) for short duration for atrial fibrillation ablations

Roger A. Winkle, MD, FHRS,* Sanghamitra Mohanty, MD,† Rob A. Patrawala, MD, FHRS,

Conclusion

AF ablations can be performed at 45–50 W for short durations with very low complication rates. High-power, short-duration ablations have the potential to shorten procedural and total RF times and create more localized and durable lesions.

The extremely low complication rate reported in this study could encourage physicians to consider the use of short-duration / high power ablation

Winkle et al. Heart Rhythm, Vol 16, No 2, 2019

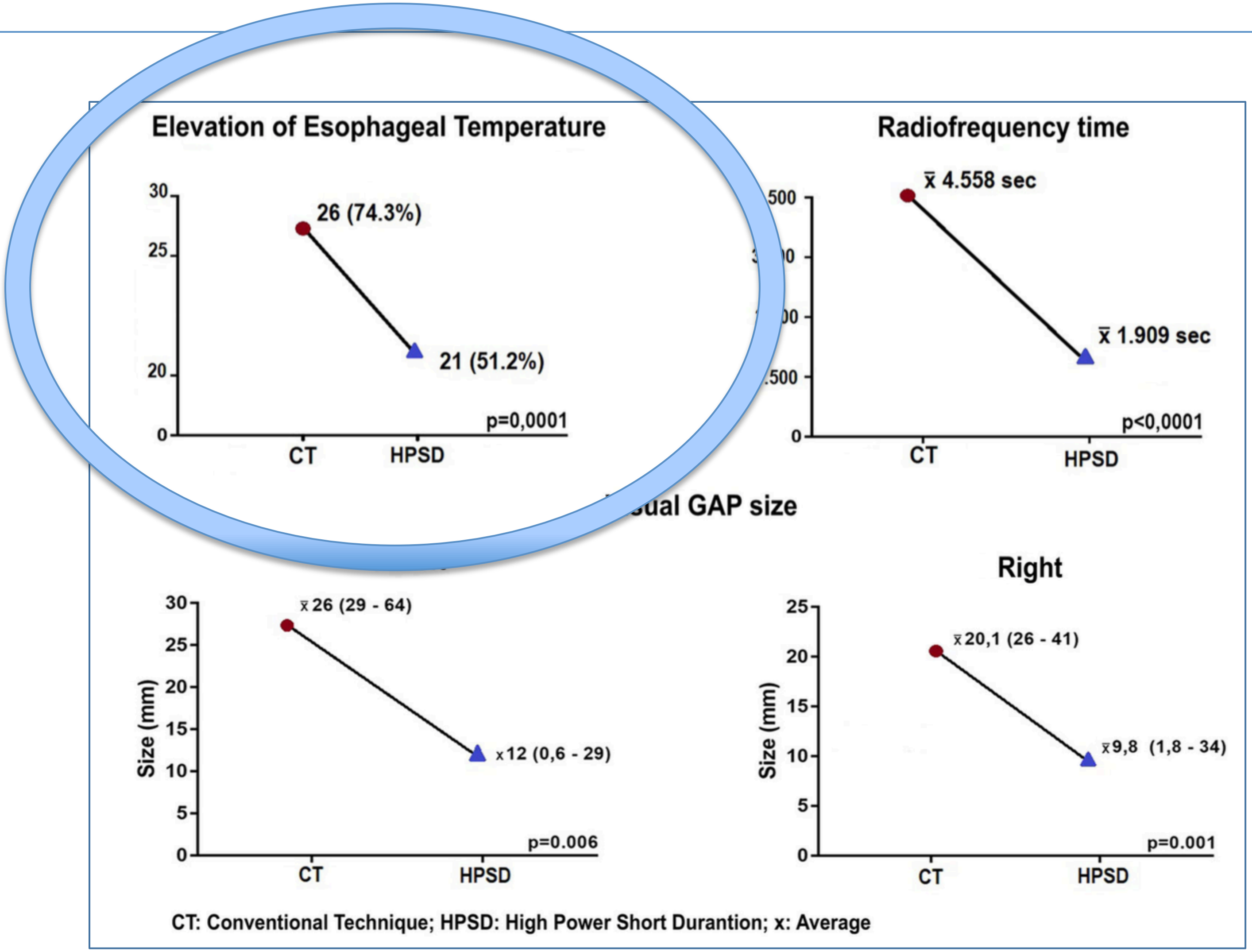
Clinical studies results

Study	Patients	Low Power	High Power	Procedure time (mn)	RF time (sec)	X ray (mn)	AF free (%)	Complica-tions
Nilsson 2006	90 (45/45) Retrospective	30W/ max 120 sec	**45 W/ 20 sec** Thermocool	127/**94** PV isolation	36/**19 mn**	73/**55**	74/**76** 15 months	1/1 TIA
Kanj 2007	121 (62/59) Randomized	30 W/ ?	**50 W/ ?** Thermocool	90/**58** Left instrument ation	-	53/**28**	68/**82** 6 months	50 W more pops, pericardial, gastro
Winkle 2018	51 Prospective	-	**50 W/ average 11,2 sec/10-40 g** Tacticath	101+/-19	**885 +/-258 sec (15 min)**	-	**86 parox 76 persist** 24 months	0
Vassalo 2019	76 (35/41) Retrospective	30 W/ 10-30g/ 30 sec	**50W/10-20 g/6 sec 45 W post** Tacticath	148/**106**	4558/ **1909 Sec (31 mn)**	8,5/**8,8**	69/ **83** 12 months	0

→High power output tends to be efficient and to be safe with short lesion times. It seems to reduce RF time.

Clinical studies results

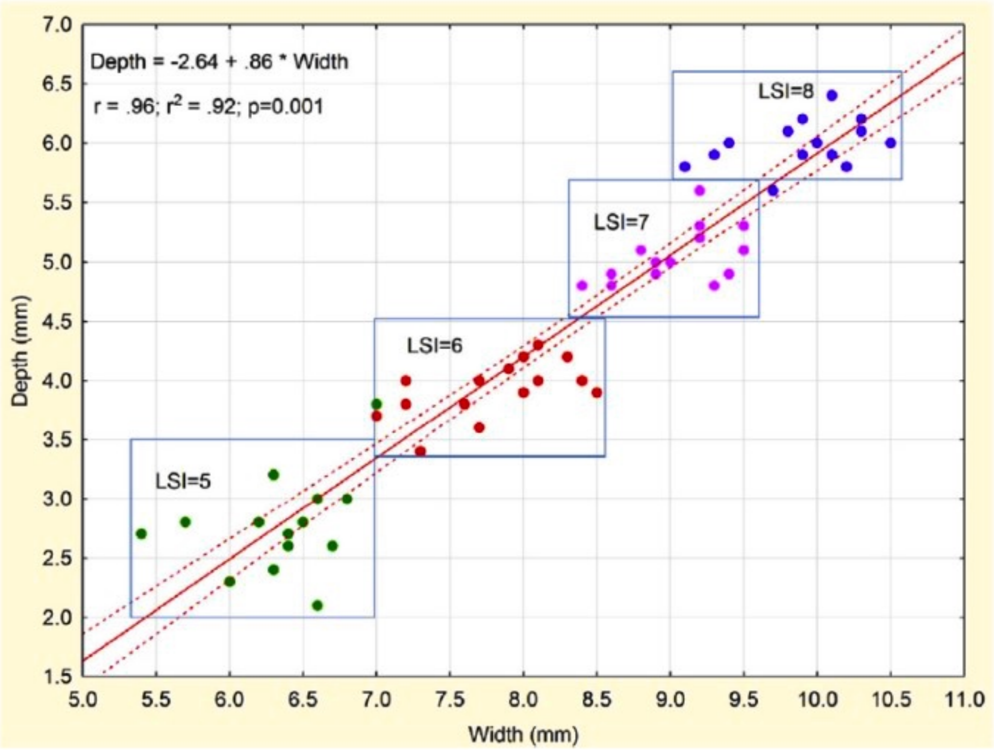
→ Less elevation of esophageal temperature in HPSD group



Vassalo et al. J Cardiovasco Electrophysiol 2019

LSI studies: integration of contact force, energy, time and impedance.

In Vitro Validation of the Lesion Size Index to Predict Lesion Width and Depth After Irrigated Radiofrequency Ablation in a Porcine Model



Lesion Size Index developped by Abbott is calculated by the formula:

LSI = CF (g) ×Current (mA) ×Time (sec)

$$LSI\,(F,\ I,\ t) = k_1 * \left(f_2\left(1 - e^{-F/f_1}\right) + f_0\right) * i_2\left(1 - e^{-(I/i_1)^2}\right) * \left\{(1 - k_0) + k_0\left[\left(1 - e^{-t/\tau}\right)/\left(1 - e^{-60/\tau}\right)\right]\right\}$$

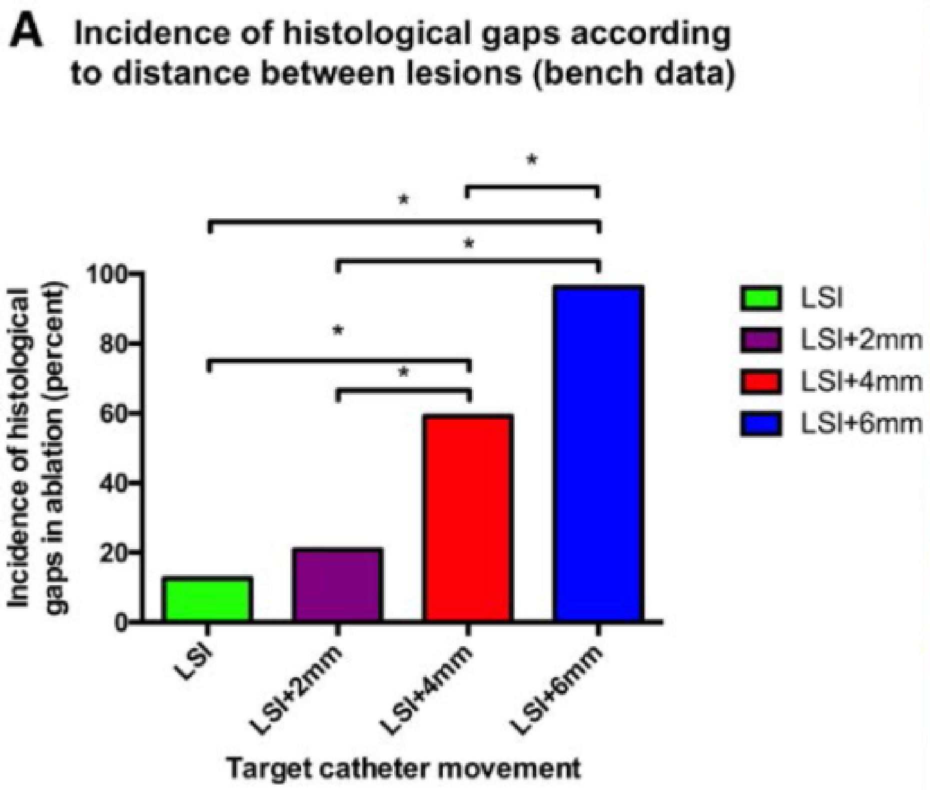
LSI was found to be highly predictive of RF lesion width and depth in the in vitro model.

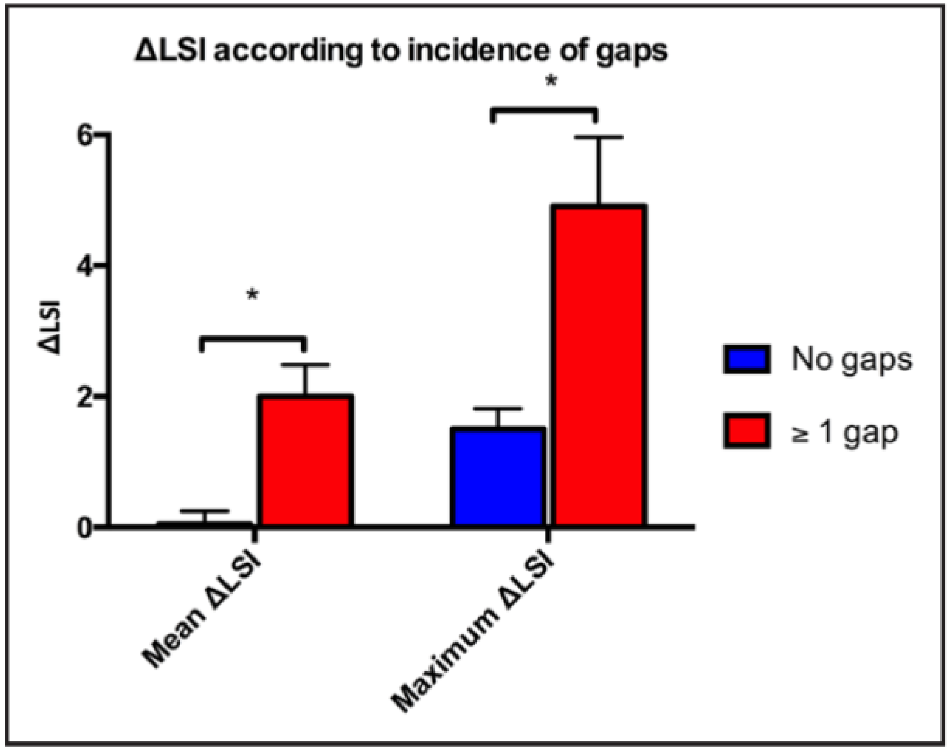
A useful solution to predict lesion size that allows better efficacity and safety with HPSD ablation

Calzolari et al. JACC 2017

LSI studies

Continuous, transmural ablation is facilitated by the use of Lesion Index™ to guide lesion placement in a porcine recovery model. John Whitaker et al





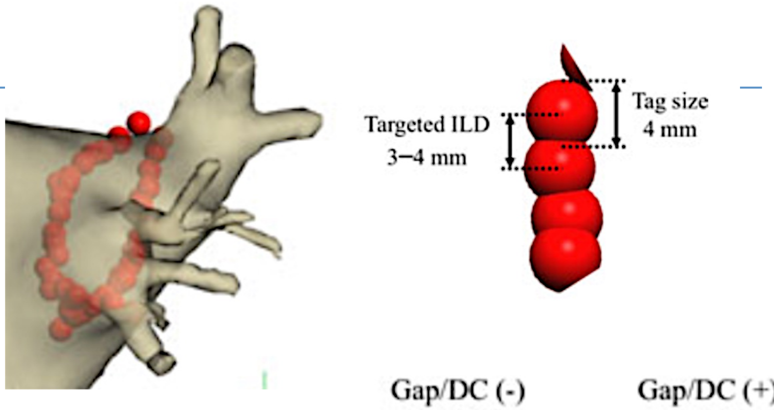
- When delivered lesions have LSI **values between 4 and 5**, the ΔLSI metric may be used retrospectively to predict the presence of gaps. Used in this way, **ΔLSI values of ≤1.5 mm were associated with no gaps** in transmural atrial ablation.

→*Circ Arrhythm Electrophysiol.* 2018

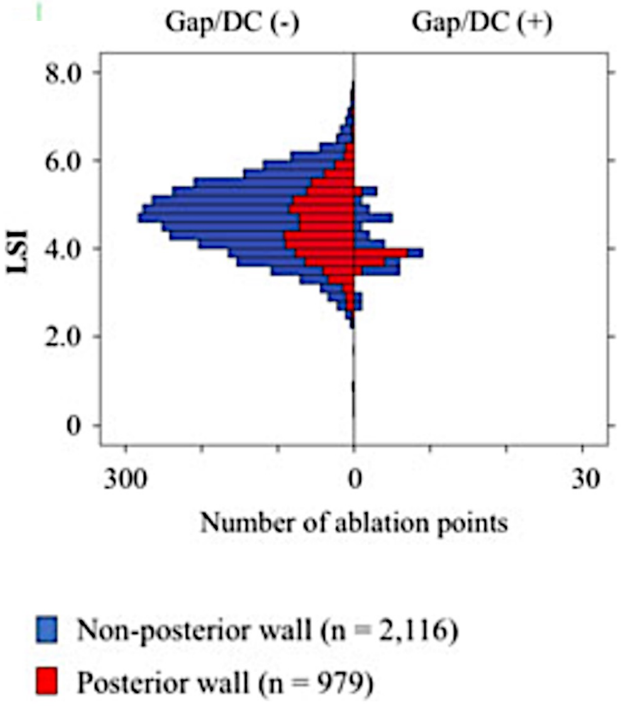
LSI studies

Optimal lesion size index to prevent conduction gap during pulmonary vein isolation

Naomi Kanamori MD[1,2] | Takeshi Kato MD, PhD[1] | Satoru Sakagami MD, PhD[2] |



Between December 2016 and October 2017. The CF parameters, force-time integral (FTI), and LSI for 3095 ablation points in 34 patients were evaluated. 25- 35 W, 10-30 g.
No complication



→ The LSI can be used to predict gaps/DC during the PVI procedure.
→ An **LSI of 5.2** may be a suitable target for effective lesion formation.
→ An **LSI of 4.0** may be acceptable in the posterior wall, especially in areas adjacent to the esophagus.

Naomi Kanamori et al. J Cardiovasc Electrophysiol. 2018 Dec.

LSI studies

Atrial fibrillation ablation using very short duration 50 W ablations and contact force sensing catheters

Roger A. Winkle[1,2] • Ryan Moskovitz[3] • R. Hardwin Mead[1] • Gregory Engel[1] • Melissa H. Kong[1] • William Fleming[1] • Jonathan Salcedo[1] • Rob A. Patrawala[1] • John H. Tranter[3] • Isaac Shai[3]

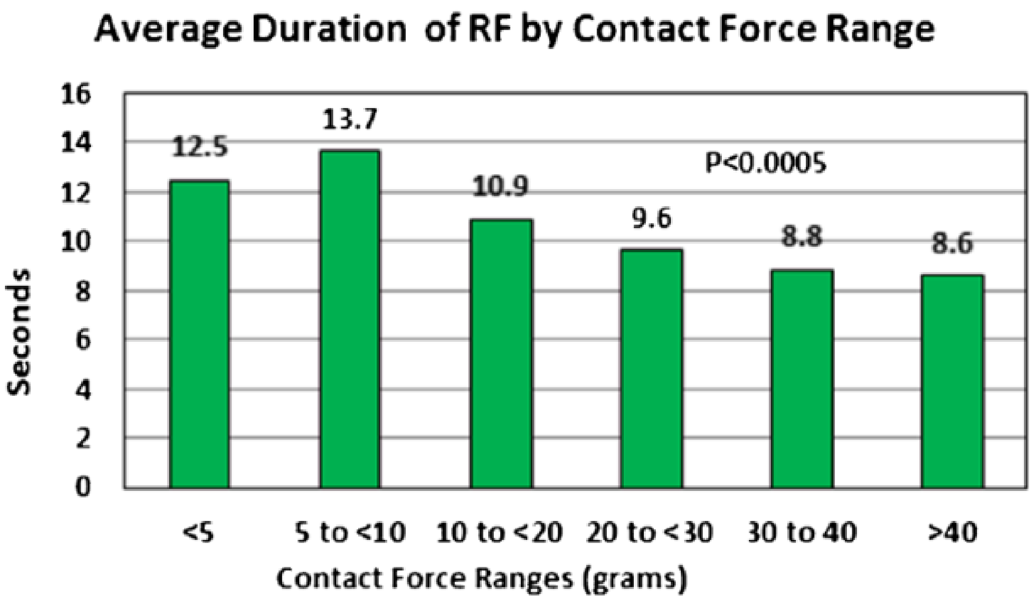
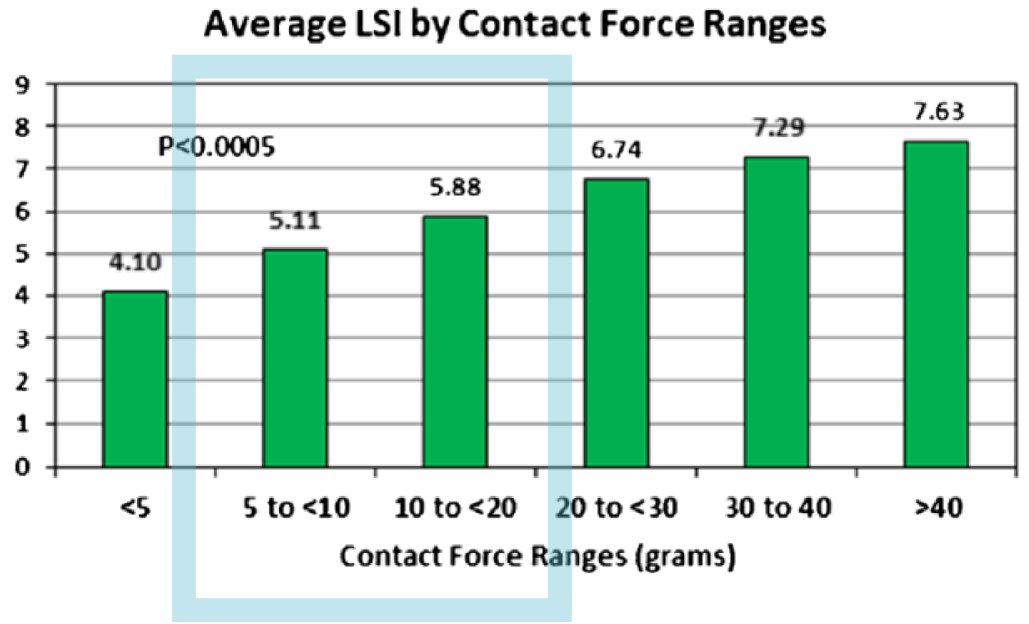


Fig. 2 The average duration of 50 W RF lesions by average CF ranges



Journal of Interventional Cardiac Electrophysiology 2018

LSI studies

Two Year, Single Center Clinical Outcome After Catheter Ablation For Paroxysmal Atrial Fibrillation Guided by Lesion Index

Sri Sundaram[1], William Choe[1], J. Ryan Jordan[1], Charles Boorman[2], Nate Mullins[2], Austin Davies[2], Austin Stucky[2], Sunil Nath[3]

Retrospective review of a cohort of 50 patients with PAF

Ablation lesions were delivered to achieve **a LSI value of 5.0 in posterior locations**, **5.5 in anterior locations and 6.0 in the region between the left atrial appendage and left superior pulmonary vein ridge.**

→ **86%** (43/50) were in normal rhythm **without recurrences** with a mean of **two years follow up**.

Mean procedure time was 134 ± 34 mins and the mean fluoroscopy time was 7.8 ± 3.2 mins.

This result is higher than previously reported with contact force catheters where the lesion formation was guided by the FTI alone.

2 pericardial effusion required percutaneous drainage

LSI can be used to guide the placement of durable lesion formation with RF ablation using CF catheters in patients with PAF.

Sundaram et al. Journal of atrial fibrillation 2018

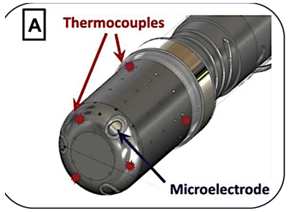
On evaluation

- **Q DOT (Boston): The vHPSD catheter is a novel contact force–sensing catheter optimized for temperature-controlled radiofrequency ablation with microelectrodes and 6 thermocouples for real-time temperature monitoring; the associated vHPSD algorithm modulates power to maintain target temperature during 90 W, 4 s lesions.**

QDOT-FAST trial : 52 patients first results at 3 mois show efficacity and safety

- **<u>Diamond: temperature controlled high power.</u>**

On evaluation



	Qdot ® Micro* 90 W	Tacticath SE ® 50 W
Number of patients	52 (parox ++)	51 (20 parox, 31 persist)
AF duration (months)	28,5	73,2
Sinus rythm rate	At 3 months 94%	At 3 months 94% parox 90% persitant
	At 1 year no result	At 1 year 86% parox 83% persistant
	At 2 years no result	At 2 years parox 86% persistant 72%
Procedure time	105 mn +/- 24	101 mn +/- 19,7
RF time	8,1 mn +/- ???	15 mn +/- 4,1
Major adverse events	0	0

*Q DOT: novel high power catheter developped by Biosense, optimized for temperature-controled RF ablation to maintain target temperature (60 °) during 90 W, 4 s lesions.
But to date we lack solid data, with results only at 3 month.

Reddy et al. The QDOT-FAST Trial . JACC 2019 ; Winkle et al. Journal of Interventional Cardiac Electrophysiology 2018

Our Experience with the Abbott solution

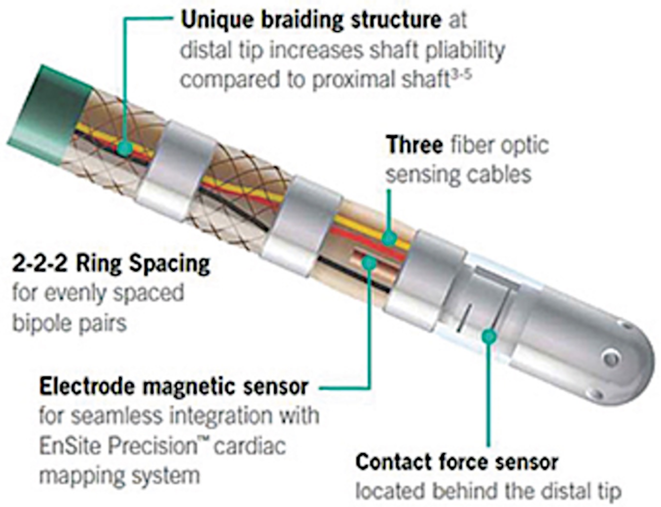
Material used:

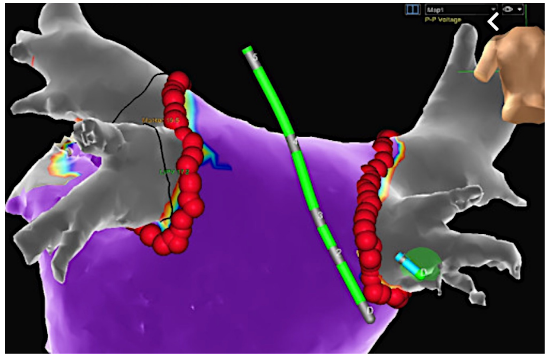
- Open irrigated tip Tacticath SE.
- Agilis steerable sheath for stability.
- 50 W in anterior, 40 W in posterior/ 40 ° cutoff/ irrigation 30 ml/mn

power raising in 2 sec/ CF 10- 20g.

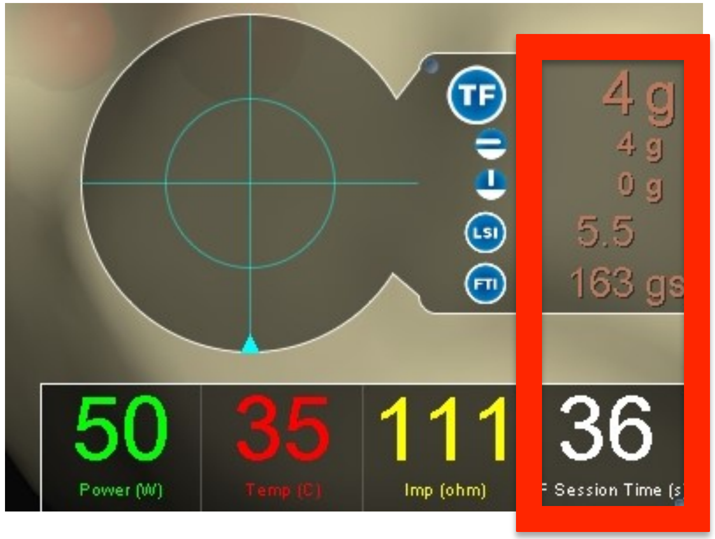
- LSI goal: 5,5 anterior

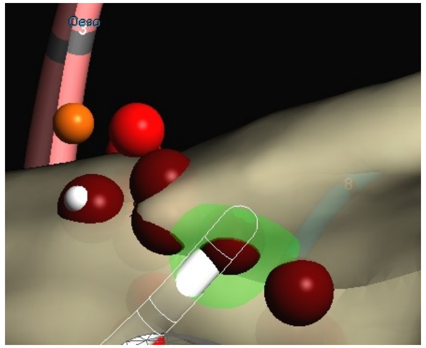
  4,5 posterior wall
- Esophageal probe Sensitherm: 39 ° alarm.

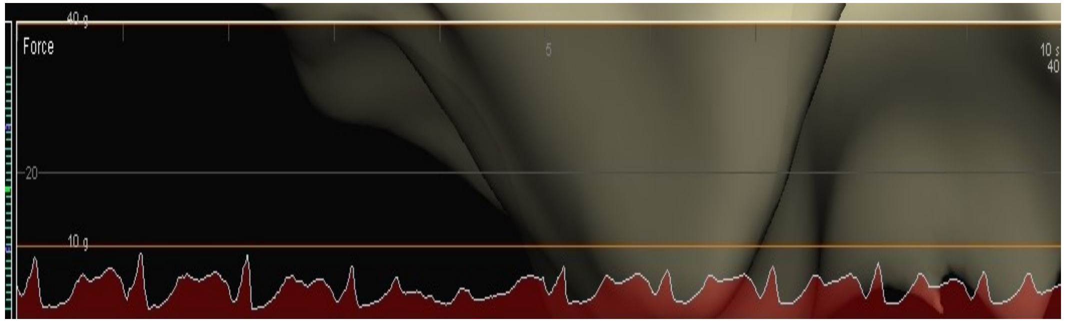




Experience: 50 W Low contact / Good contact. Same patient

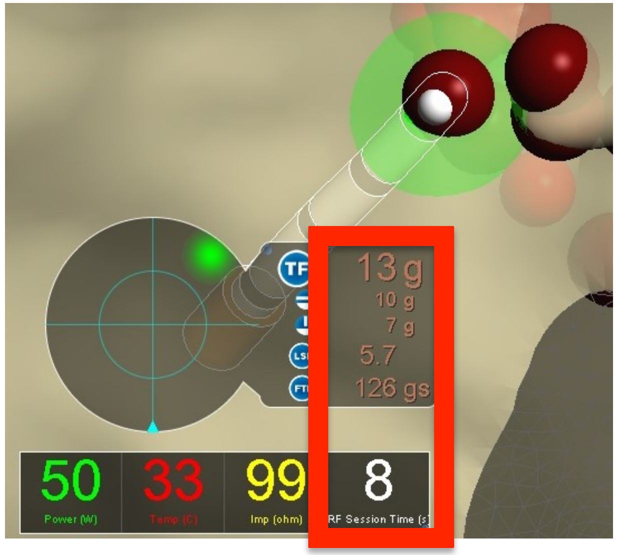






50 W, anterior

LSI of 5,5 in 36 sec with contact force between 3 and 8 grams.



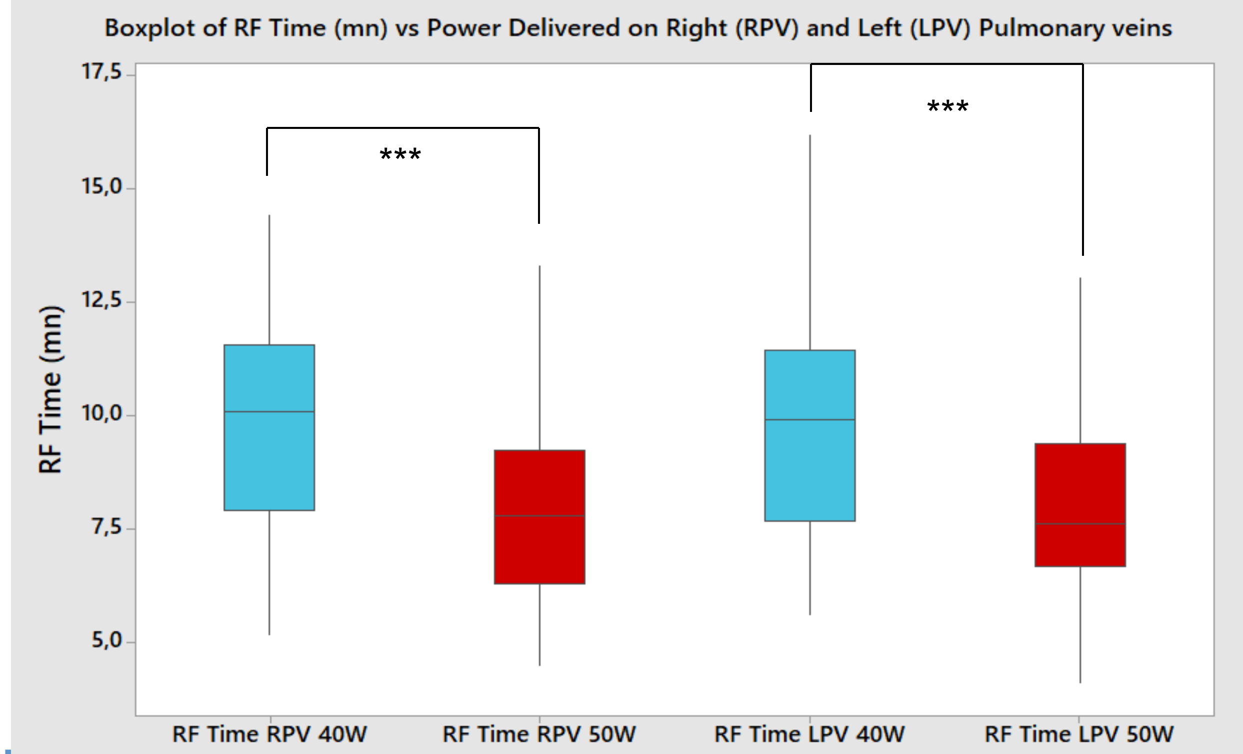
50 W, anterior

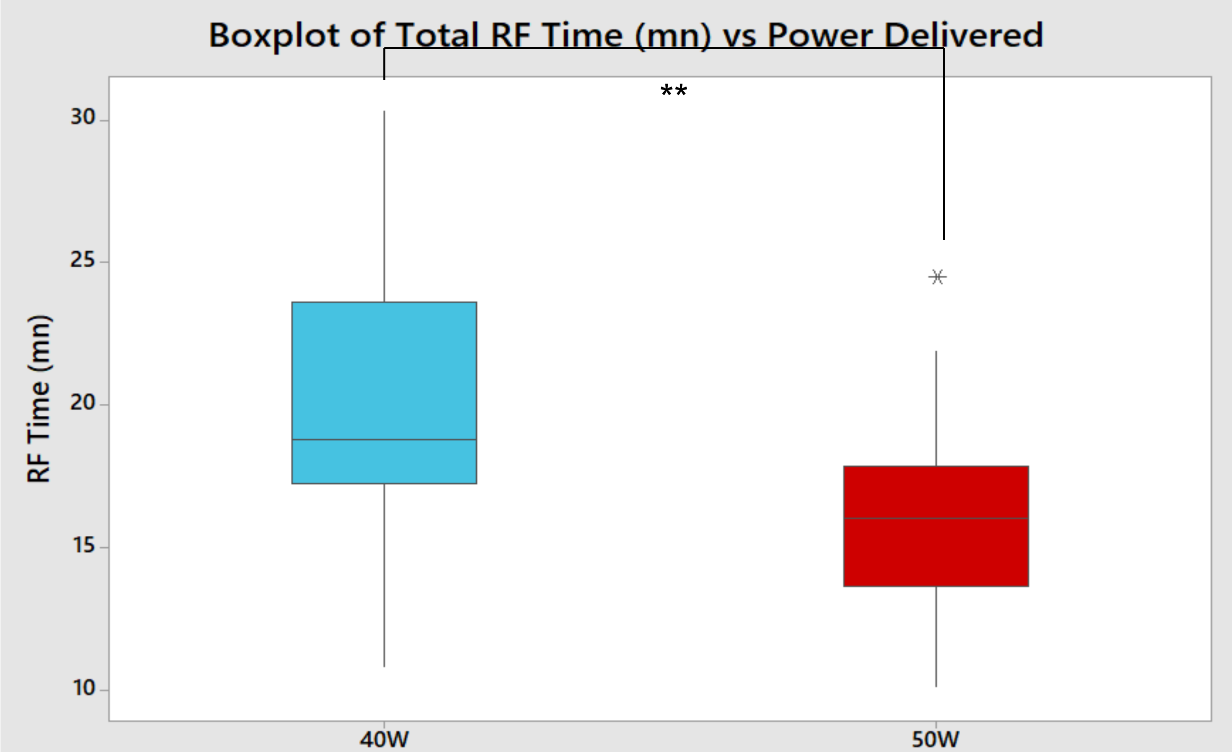
LSI of 5,7 in 8 sec with contact force between 10 and 30 grams.

Experience: RF Time at 40 and 50W, N= 56 (28/28)

We studied during the last two months retrospectively a cohort of **56** patients (28/28, 40 W- 50 W)
The RF time is significantly shorter on the PV **when the power is increased from 40 to 50W**

*** : p < 0,05 ** : p < 0,01 *** : p < 0,001**

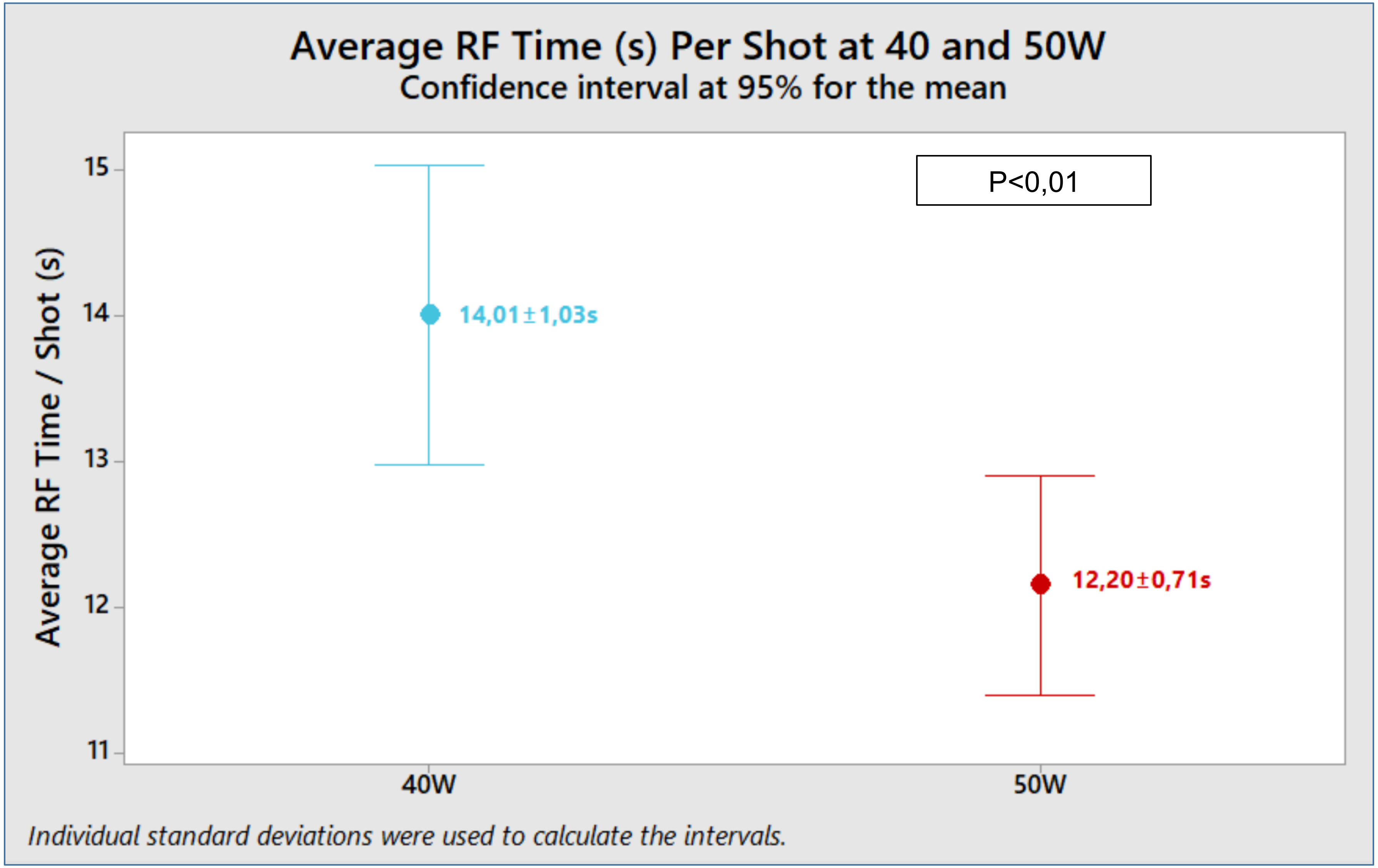




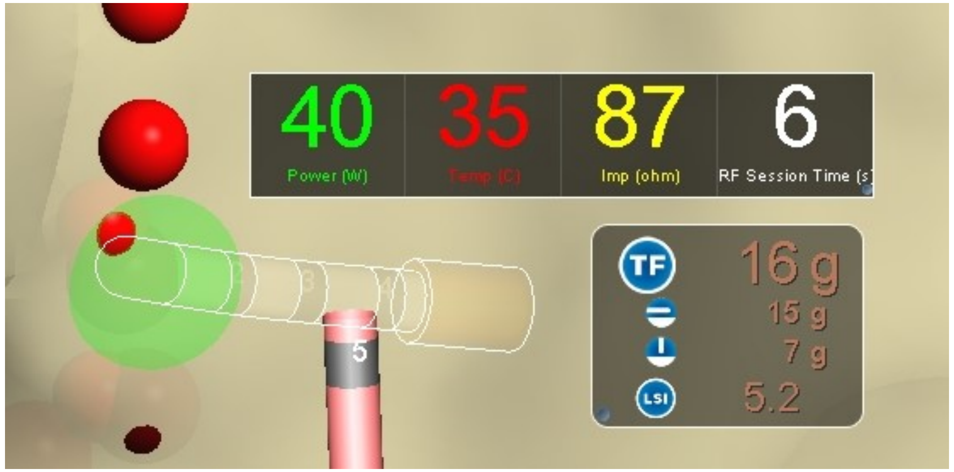
Average number of RF Shots			
40W		50W	
RPV	**LPV**	**RPV**	**LPV**
43	42	39	39
Total 85		Total **78**	

Average RF Time			
40W		50W	
RPV	**LPV**	**RPV**	**LPV**
9.8mn	10mn	8.0mn	8.1mn
Total 19,8 +/- 1,8 mn		Total **16 +/- 1,3 mn**	

At High power 50 Watt, average radiofrequency time **per shot is 12, 2 sec**



Experience: Low impedance



40 W, posterior of LSI 5.2 in 6 sec with contact **force between 10 and 20 grams.**

Low impedance base at 92 Ohms.

Experience: Low impedance

50 W, anterior LSI of 6,3 in 6 sec with contact force between 10 and 30 grams.

Low base impedance at 103 Ohms.

Experience: High impedance

50 W, anterior LSI of 5,5 in 11 sec with mean contact force of 14 grams.

Conclusion - Take Home Messages

- **High power short duration seems to be efficient and safe and may reduce procedure time.**
- **Correct lesions can be reached easily in less than 10-15 sec with sufficient contact.**
- **LSI is a very useful tool for higher power settings ablation with a targeted LSI of 5.2 on the anterior surface and of 4 on the posterior wall.**
- **When using high power, be cautious with low impedance and long duration lesions.**
- **However randomized, controlled clinical studies are still needed to support high power ablation at 50W and above in terms of efficacity and safety.**

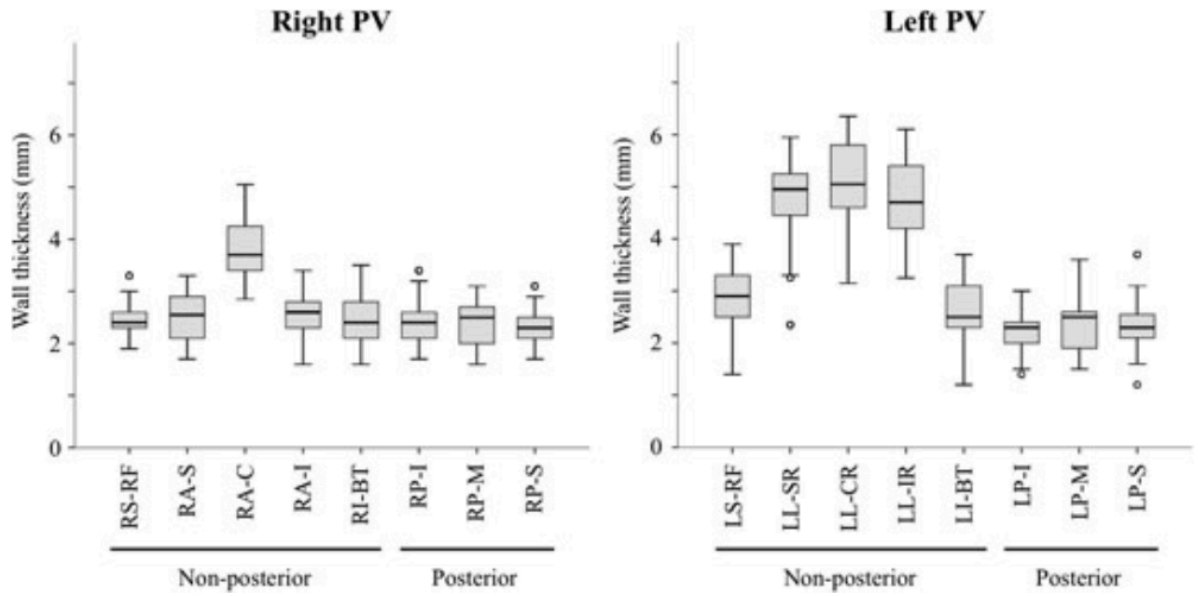


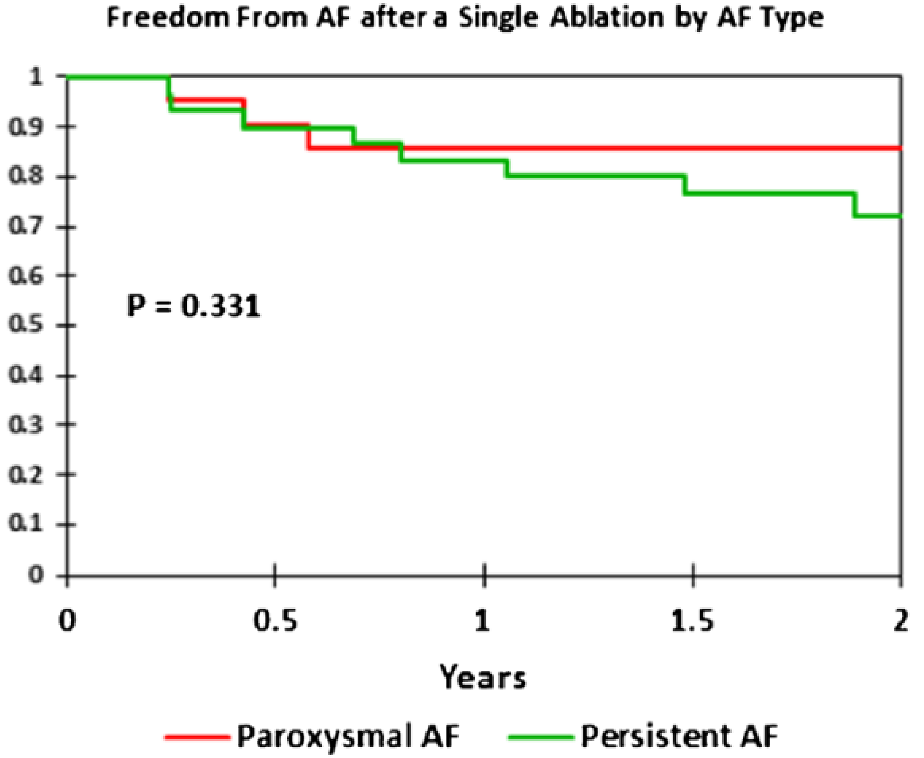
FIGURE 2 Myocardial wall thickness of the left atrium under the ablation line measured with multidetector CT. CT, computed tomography; LI-BT, left inferior bottom; LL-IR, left lateral inferior ridge; LL-CR, left lateral carina ridge; LL-SR, left lateral superior ridge; LP-I, left posterior inferior; LP-M, left posterior middle; LP-S, left posterior superior; LS-RF, left superior roof; PV, pulmonary vein; RA-C, right anterior carina; RA-I, right anterior inferior; RA-S, right anterior superior; RI-BT, right inferior bottom; RP-I, right posterior inferior; RP-M, right posterior middle; RP-S, right posterior superior; RS-RF, right superior roof

Atrial fibrillation ablation using very short duration 50 W ablations and contact force sensing catheters

LSI study

Roger A. Winkle[1,2] • Ryan Moskovitz[3] • R. Hardwin Mead[1] • Gregory Engel[1] • Melissa H. Kong[1] • William Fleming[1] • Jonathan Salcedo[1] • Rob A. Patrawala[1] • John H. Tranter[3] • Isaac Shai[3]

J Interv Card Electrophysiol (2018) 52:1–8



AF type	0 Years	0.5 Year	1 Years	1.5 Years	2 Years
Par AF	21	20	19	19	10
Per AF	30	28	26	24	12

51 patients with paroxysmal (n = 20) or persistent (n = 31) AF undergoing initial RF ablation.

50 W RF lesions average duration : 11,2 sec

For paroxysmal AF, the single procedure freedom from AF was 86% at 1 and 2 years. For persistent AF, it was 83% at 1 year and 72% at 2 years. There were no complications.

M Procedure time 101 min, RF : 895 sec

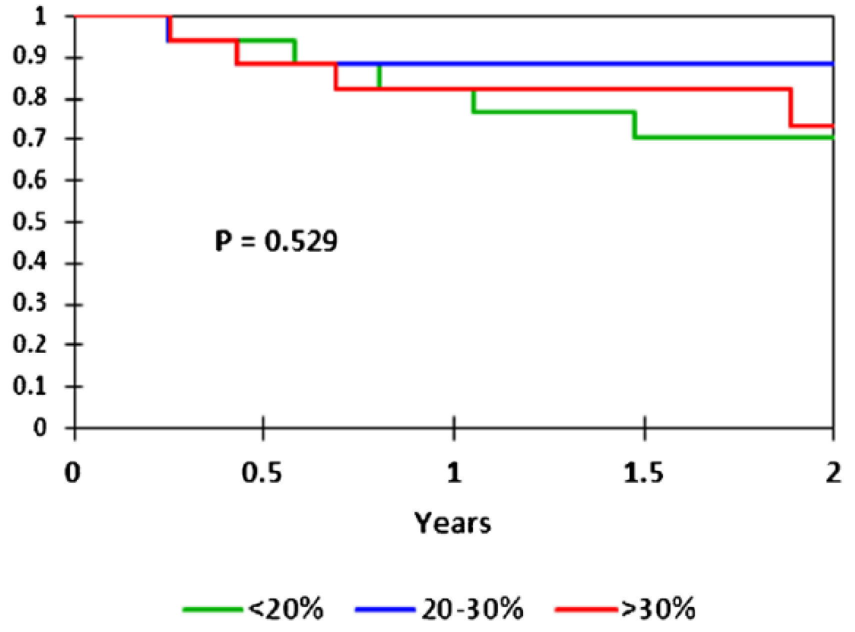
→Journal of Interventional Cardiac Electrophysiology (2018) 52:1–8

Atrial fibrillation ablation using very short duration 50 W ablations and contact force sensing catheters

LSI study

Roger A. Winkle[1,2] • Ryan Moskovitz[3] • R. Hardwin Mead[1] • Gregory Engel[1] • Melissa H. Kong[1] • William Fleming[1] • Jonathan Salcedo[1] • Rob A. Patrawala[1] • John H. Tranter[3] • Isaac Shai[3]

Freedom From AF after a Single Ablation by % of Ablation Lesions with Contact Force <10 Grams



% < 10 g	0 Years	0.5 Year	1 Years	1.5 Years	2 Years
<20%	17	17	15	13	10
20-30%	17	16	16	16	7
>30%	17	16	15	15	6

There were no difference in single procedure AF-free rates, suggesting that even the lesions created with < 10 g of force using 50 W, the majority of which were between 5 and 10 g (averaging 8.0 g of force), were making durable lesions.

Lesion Size and Safety Comparison Between the Novel Flex Ti on the FlexAbility Ablation Catheter and the Solid Tips on th ThermoCool and ThermoCool SF Ablation Catheters

JEFFREY R. WINTERFIELD, M.D.,* JAMES JENSEN, PH.D.,† THERESE GILBERT, B.S.,† FRANCIS MARCHLINSKI, M.D.,‡ ANDREA NATALE, M.D.,§ DOUGLAS PACKER, M.D.,¶ VIVEK REDDY, M.D.,# SRIJOY MAHAPATRA, M.D.,† and DAVID J. WILBER, M.D.*

From the *Loyola University Medical Center, Maywood, Illinois; †St. Jude Medical, St. Paul, Minnesota; ‡University of Pennsylvar Philadelphia, Pennsylvania; §Texas Cardiac Arrhythmia Institute, Austin, Texas; ¶Mayo Clinic, Rochester, Minnesota; and #Mount S Medical Center, New York, New York, USA

Flex Tip Comparative Ablation. ***Introduction:*** **Next-generation catheters have been developed to reduce irrigation volume and preserve power delivery. A novel design uses a flexible tip (FlexAbility™ catheter) that directs flow to the contact surface. Because of recent safety issues with new catheters, we undertook a study in a canine heart with 3 irrigated catheters to compare efficacy and safety.**

Methods: **Endocardial ablation was performed by 2 independent operators in 12 anesthetized canines with the FlexAbility (St. Jude Medical), ThermoCool™ (Biosense Webster), and ThermoCool™ SF (Biosense Webster) catheters. Endocardial RF lesions were delivered with each catheter in all 4 chambers of each animal for 52 ± 16 seconds. Each chamber was randomized to receive ablation from one catheter with recording of safety events. Cardiac pathology was performed with triphenyl tetrazolium chloride stain.**

Results: **Average lesion dimensions were not significantly different between the 3 catheters. FlexAbility™ demonstrated a lower risk of steam pops relative to ThermoCool SF (P-value = 0.013) despite equal mean power and radiofrequency time. High-temperature generator shutdowns were observed with FlexAbility™ but not with either ThermoCool catheter. High-temperature shutdowns were associated with larger average impedance drops (28.5 ohms vs. 19 ohms) without compromising lesion size.**

Conclusions: **The FlexAbility™ tip is safe and effective with no significant difference in lesion sizes compared to both standard ThermoCool and ThermoCool SF. FlexAbility™ has a significantly lower risk of steam pops compared to ThermoCool SF in a beating heart as defined predominantly by an abrupt rise of impedance.** *(J Cardiovasc Electrophysiol, Vol. 27, pp. 102-109, January 2016)*

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. ■, NO. ■, 2019

Pulmonary Vein Isolation With Very High Power, Short Duration, Temperature Controlled Lesions

The QDOT-FAST Trial

Vivek Y. Reddy, MD,[a,b] Massimo Grimaldi, MD,[c] Tom De Potter, MD,[d] Johan M. Vijgen, MD,[e] Alan Bulava, MD, PhD,[f] Mattias Francis Duytschaever, MD,[g] Martin Martinek, MD,[h] Andrea Natale, MD,[i] Sebastien Knecht, MD, PhD,[g] Petr Neuzil, MD, PhD,[b] Helmut Pürerfellner, MD[h]

ABSTRACT

OBJECTIVES This study sought to evaluate the safety and short-term performance of a novel catheter for very high power-short duration (vHPSD) ablation in the treatment of paroxysmal atrial fibrillation.

BACKGROUND The vHPSD catheter is a novel contact force-sensing catheter optimized for temperature-controlled radiofrequency ablation with microelectrodes and 6 thermocouples for real-time temperature monitoring; the associated vHPSD algorithm modulates power to maintain target temperature during 90 W, 4 s lesions.

METHODS The QDOT-FAST study (Clinical Study for Safety and Acute Performance Evaluation of the THERMOCOOL SMARTTOUCH SF-5D System Used With Fast Ablation Mode in Treatment of Patients With Paroxysmal Atrial Fibrillation) is a prospective, multicenter, single-arm study enrolling patients with symptomatic paroxysmal atrial fibrillation indicated for catheter-based pulmonary vein isolation. Primary endpoints were short-term effectiveness (confirmation of entrance block in all targeted pulmonary veins after adenosine/isoproterenol challenge) and short-term safety (primary adverse events). Participants were screened for silent cerebral lesions by magnetic resonance imaging. Patients were followed for 3 months post-ablation.

→ Heart Rhythm, Vol 16, No 2, February 2019

RESULTS A total of 52 patients underwent ablation and completed follow-up. Pulmonary vein isolation was achieved in all patients using the study catheter alone, with total procedure and fluoroscopy times of 105.2 ± 24.7 and 6.6 ± 8.2 min, respectively. Most patients (n = 49; 94.2%) were in sinus rhythm at 3 months. Two primary adverse events were reported: 1 pseudoaneurysm; and 1 asymptomatic thromboembolism. There were no deaths, stroke, atrioesophageal fistula, pulmonary vein stenosis, or unanticipated adverse device effects. Six patients had identified silent cerebral lesions—all classified as asymptomatic without clinical or neurologic deficits.

CONCLUSIONS This first-in-human study of a novel catheter with optimized temperature control demonstrated the clinical feasibility and safety of vHPSD ablation. Procedure and fluoroscopy times were substantially lower than historical standard ablation with point-by-point catheters. (Clinical Study for Safety and Acute Performance Evaluation of the THERMOCOOL SMARTTOUCH SF-5D System Used With Fast Ablation Mode in Treatment of Patients With Paroxysmal Atrial Fibrillation [QDOT-FAST]; NCT03459196) (J Am Coll Cardiol EP 2019;■:■-■) © 2019 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Safety And Necessity Of Thermal Esophageal Probes During Radiofrequency Ablation For The Treatment Of Atrial Fibrillation

Antonio Fasano, Prof Emeritus, , Luca Anfuso, MD, Stefano. Bozzi, MD, Claudio Pandozi, Prof

San Filippo Neri Hospital, Rome, Italy.

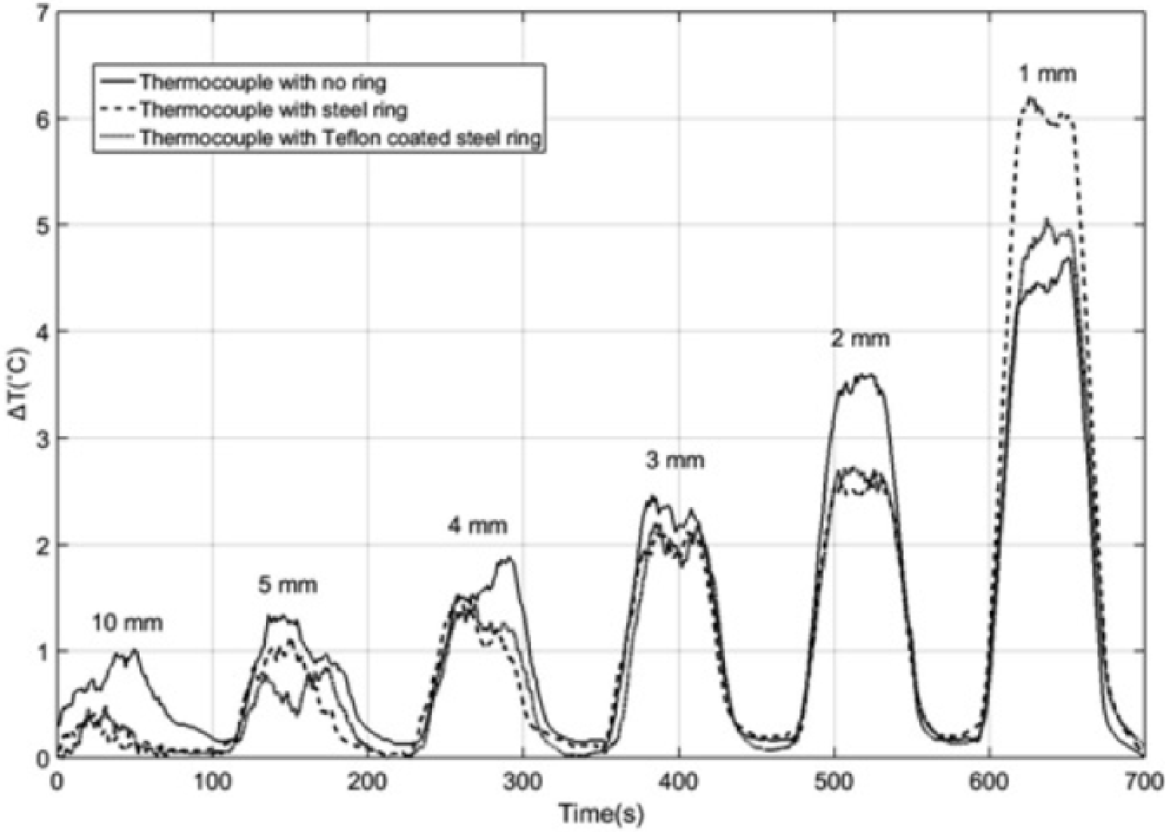


Figure 5: **Comparison of the thermal response of the three systems to a 1 min exposure to a 50W RF source**

Safety And Necessity Of Thermal Esophageal Probes During Radiofrequency Ablation For The Treatment Of Atrial Fibrillation

Antonio Fasano, Prof Emeritus, , Luca Anfuso, MD, Stefano. Bozzi, MD, Claudio Pandozi, Prof

San Filippo Neri Hospital, Rome, Italy.

Results: The direct interaction between the radiofrequency source and the probe sensors is found to be negligible. Numerical simulations show that the outer esophageal wall can be much warmer than the lumen. Theoretical heating curves are compared with the clinical data selecting the maximal slope as the reference quantity. The clinical values range between 0.01°C/s and 0.15°C/s agree with the computed predictions and demonstrate that reducing the esophagus-atrium distance by 1mm causes a slope increase of 0.06°C/s.

Conclusion: The use of esophageal thermal probes is absolutely safe and necessary in order to prevent the occurrence of thermal lesions. The model is reliable, and describes effectively the generated thermal field. The external esophageal temperature can be considerably higher than the luminal one.