

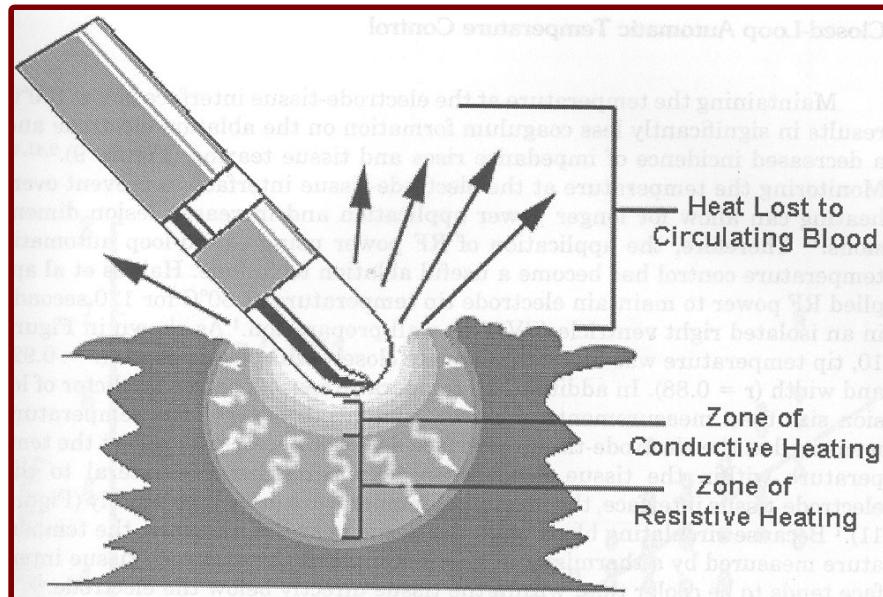
Il diamante: materiale innovativo per il trattamento ablativo

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UO Complessa di Cardiologia
Ospedale dell'Angelo, Mestre-Venezia



Radiofrequency Energy for Cardiac Ablation

Thermal injury determining coagulation necrosis:



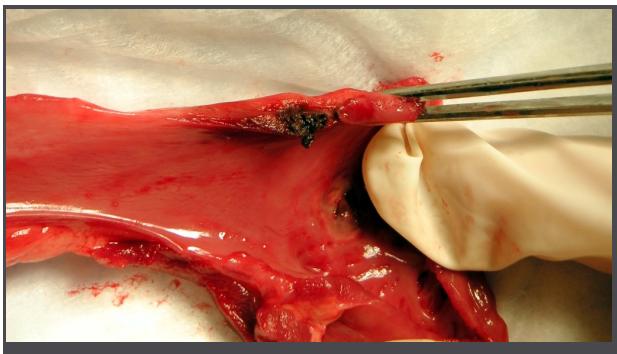
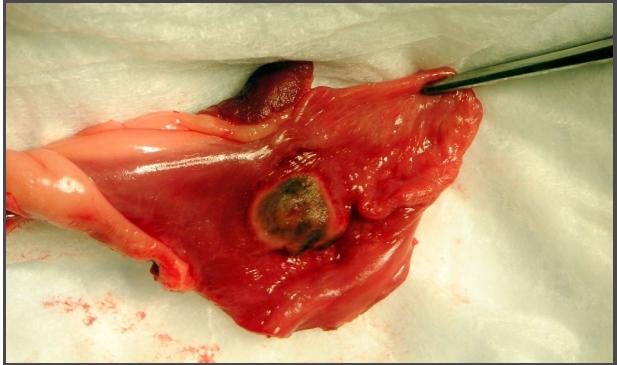
- ✓ Endothelium disruption
- ✓ Intimal thickening
- ✓ Proliferation of elastic laminae



➤ Coagulum and Char formation

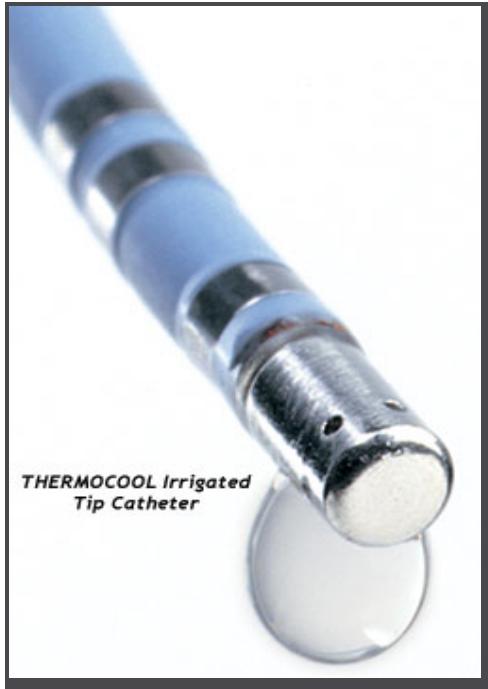


RF lesion and charring after pop ablation

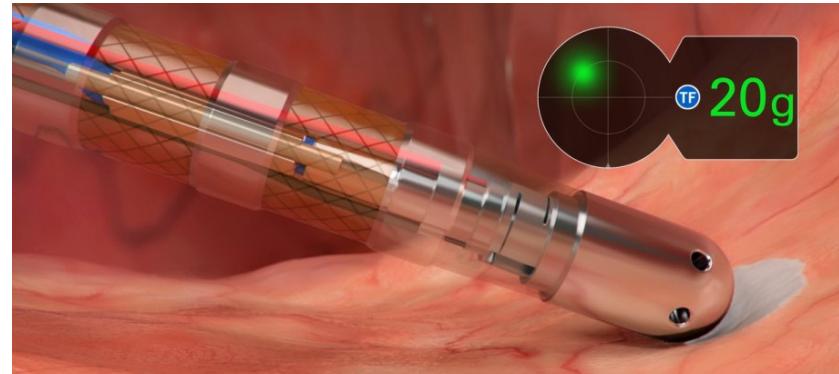




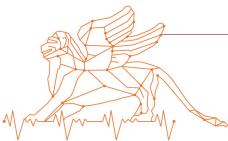
Ablation catheters with active cooling and contact force sensor



Open Irrigation Catheter

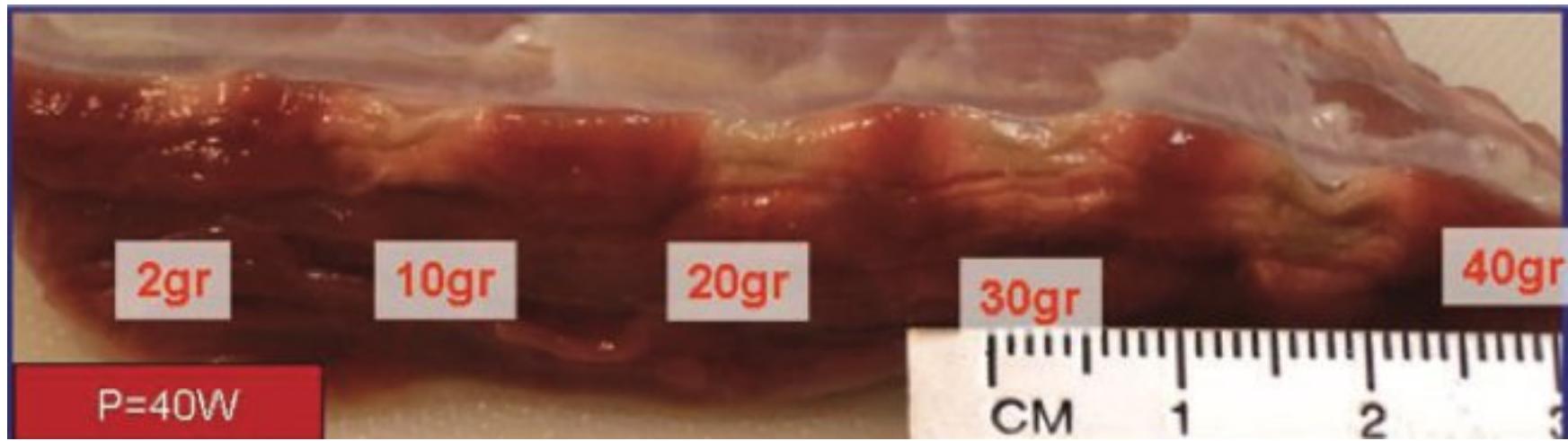


Contact Force Catheter



Importance of Catheter Contact Force During Irrigated Radiofrequency Ablation

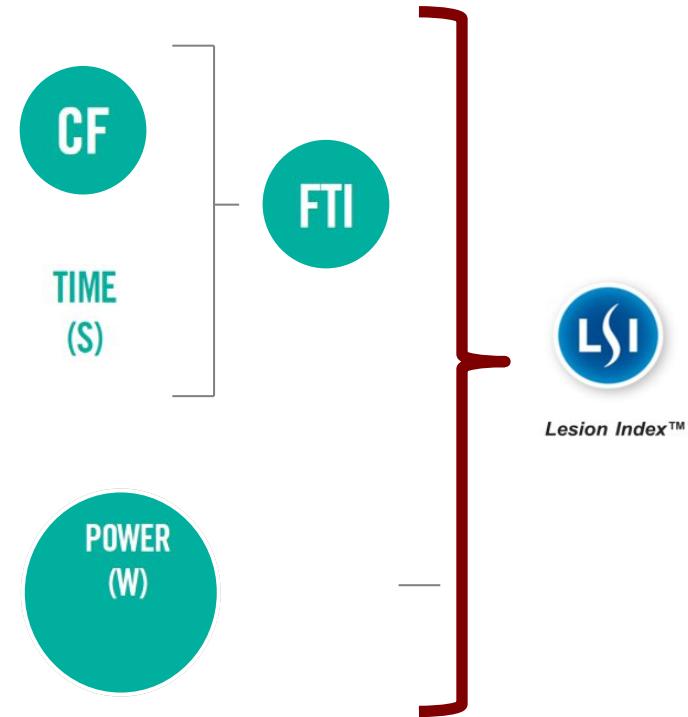
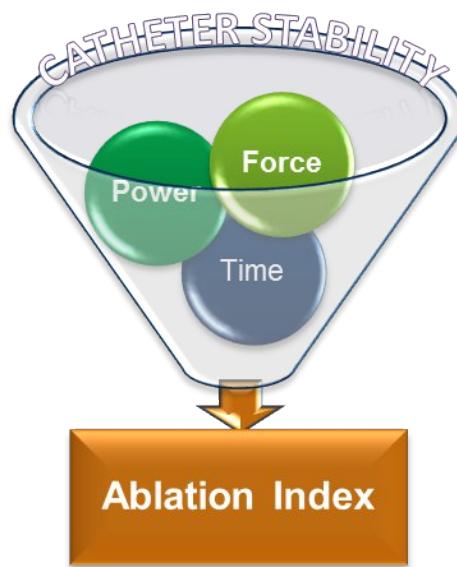
Width of RF lesion and pops versus electrode-tissue contact:



Thiagalingam et al. J Cardiovasc Electrophysiol. 2010;21: 806-11
Shah et al J Cardiovasc Electrophysiol, 2010;21:1038-43



Lesion Index



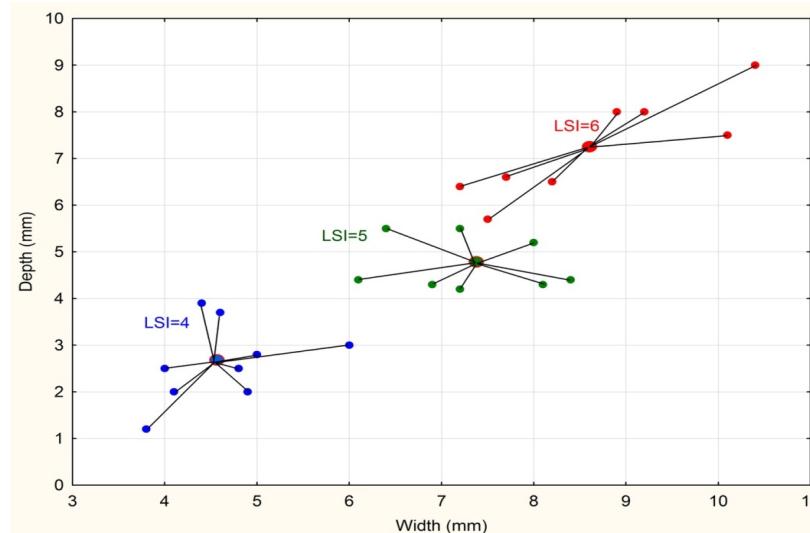


In-vivo Lesion Index (LSI) validation in percutaneous radiofrequency catheter ablation

Sakis Themistoclakis¹, MD, Vittorio Calzolari², MD, Luca De Mattia², MD, Antonio Dello Russo³, MD, Paolo China¹, MD, Michela Casella³, MD, Stefano Indiani⁴, MSc, Igor Caporaso⁴, MSc, CCRP, Alessandro Addis⁵, DVM, PhD and Claudio Tondo³, MD, PhD

- ✓ A strong linear correlation between LSI and lesion width ($r=0.87$, $p<0.00001$) and depth ($r=0.89$, $p<0.00001$)
- ✓ No steam-pops or char formation

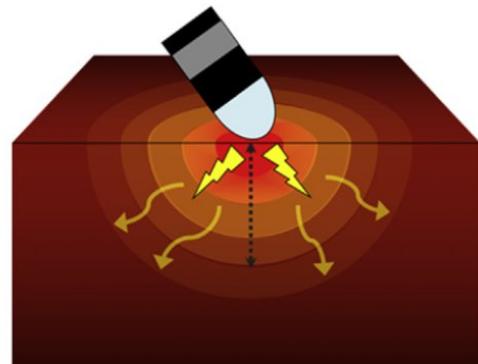
LSI has been identified as the **only significant predictor** of lesion width ($p<0.001$) and depth ($p<0.001$) in non-transmural lesions among ablation parameters by a **multiple linear regression** analysis with forward stepwise approach.



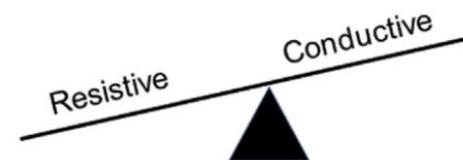
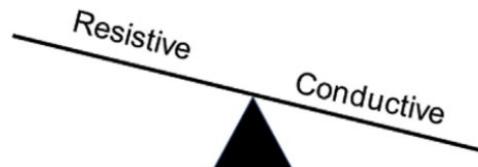


High-power and short-duration ablation for PVI Biophysical Characterization

A Standard

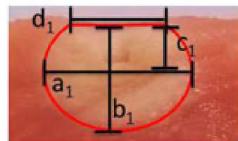


B High-Power Short-Duration

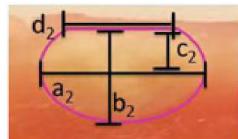




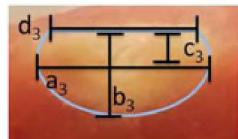
High-power short-duration versus standard RF ablation: insights on lesion metrics



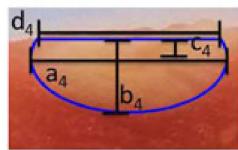
Standard 30W, 30s, 15-20g
 $a_1 = 8.9 \pm 0.6\text{mm}$ $c_1 = 2.2 \pm 0.5\text{mm}$
 $b_1 = 5.7 \pm 0.6\text{mm}$ $d_1 = 7.5 \pm 0.6\text{mm}$
Volume₁ = 271±46mm³



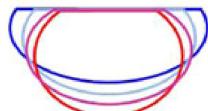
HPSD 50W, 13s, 15-20g
 $a_2 = 10.2 \pm 0.5\text{mm}$ $c_2 = 1.0 \pm 0.4\text{mm}$
 $b_2 = 4.7 \pm 0.6\text{mm}$ $d_2 = 8.9 \pm 0.4\text{mm}$
Volume₂ = 274±34mm³



HPSD 60W, 10s, 15-20g
 $a_3 = 10.4 \pm 0.6\text{mm}$ $c_3 = 0.6 \pm 0.3\text{mm}$
 $b_3 = 4.3 \pm 0.5\text{mm}$ $d_3 = 9.4 \pm 0.5\text{mm}$
Volume₃ = 259±36mm³



HPSD 70W, 7s, 15-20g
 $a_4 = 11.2 \pm 0.5\text{mm}$ $c_4 = 0.6 \pm 0.2\text{mm}$
 $b_4 = 3.9 \pm 0.5\text{mm}$ $d_4 = 10.3 \pm 0.6\text{mm}$
Volume₄ = 272±40mm³



Overlay view of schematic lesion geometries
(30W 30s red, 50W 13s purple,
60W 10s light blue, 70W 7s blue)

HPSD vs Standard RF applications:

- similar lesion volumes
- different lesion geometry (larger maximum diameter and smaller lesion depth)

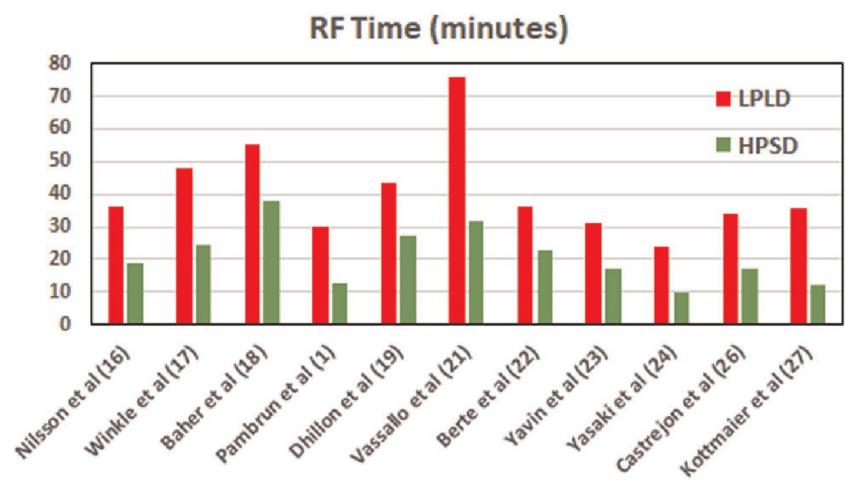
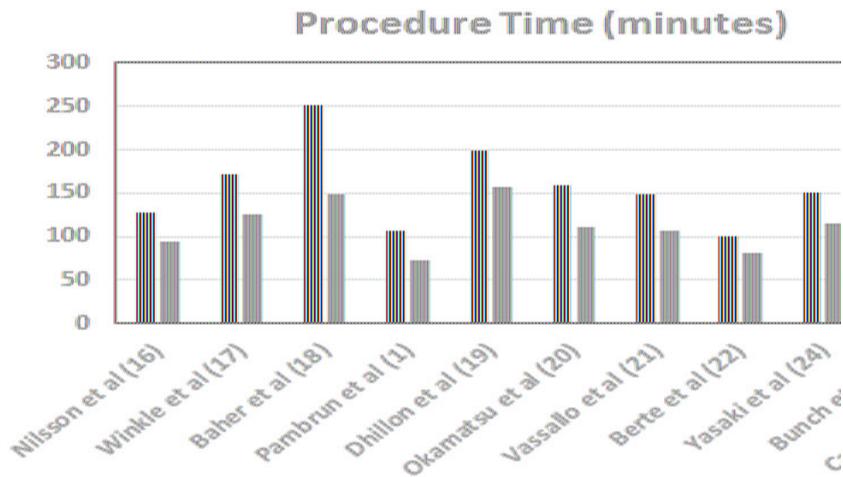


High-power short-duration vs low-power long-duration AF ablation: Clinical Studies

Study	Year published	# LPLD patients	# HPSD patients	AF type	Multi-center	Contact force or noncontact force	LPLD power/time surrogate	HPSD power/time surrogate
Nilsson et al. ¹⁶	2006	45	45	mixed	No	NCF	30 W/120 s	45 W/20 s
Winkle et al. ¹⁷	2011	42	666	mixed	No	NCF	40 W/3-10 s	50 W/3-10 s
Baher et al. ¹⁸	2018	113	574	mixed	No	CF and NCF	≤35 W/10-30 s	50 W/5 s
Pambrun et al. ¹	2019	50	50	paroxysmal	Yes	CF	25-30 W/15.7 s	40-50 W/8.5 s
							Unipolar SM	Unipolar SM
Dhillon et al. ¹⁹	2019	50	50	paroxysmal	Yes	CF	25 W PW, 30 W	30 W PW, 40 W
							AI	AI
Okamatsu et al. ²⁰	2019	20	20	mixed	No	CF	20 W PW, 30 W/18-19 s	30 W E, 40 W PW, 50 W/10 s
							AI	AI
Vassallo et al. ²¹	2019	35	41	mixed	No	CF	30 W/30 s	45 W PW, 50 W/6 s
Berte et al. ²²	2019	94	80	mixed	No	CF	25 W PW, 35 W	35 W PW, 45 W
							AI, CLOSE Protocol	AI, CLOSE Protocol
Yavin et al. ²³	2020	112	112	mixed	No	CF	20-40 W/20-30 s	45-50 W/8-15 s
Yasaki et al. ²⁴	2020	32	32	mixed	No	CF and NCF	25-40 W	50 W
							Unipolar SM	Unipolar SM
Bunch et al. ²⁵	2020	402	402	mixed	No	CF and NCF	30 W/5 s PW, 30 W/20-30 s	50 W/2-3 s PW, 5-15 s
Castrejon-Castrejon et al. ²⁶	2020	48	48	mixed	No	NCF LPSD CF HPSD	30 W/30 s	50 W LSI or AI
Kottmaier et al. ²⁷	2020	100	97	paroxysmal	No	NCF	30-40 W/20-40 s	70 W/5 s PW, 70 W/7 s



High-power short-duration vs low-power long-duration AF ablation: Clinical Studies





HP-SD versus LP-LD AF ablation

1st pass isolation and acute reconnection rate

Study	LPLD (% 1st pass isolation)	HPSD (% 1st pass isolation)	p Value	LPLD (acute reconnection)	HPSD (acute reconnection)	p Value
Nilsson et al. ¹⁶	Not given	Not given	Not given	Not given	Not given	Not given
Winkle et al. ¹⁷	Not given	Not given	Not given	Not given	Not given	Not given
Baher et al. ¹⁸	Not given	Not given	Not given	Not given	Not given	Not given
Pambrun et al. ¹	73%	92%	<.001	17%	2%	<.001
Dhillon et al. ¹⁹	34%	82%	<.001	24%	14%	.015
Okamatsu et al. ²⁰	55%	85%	.002	10%	0%	.03
Vassallo et al. ²¹	Not given	Not given	Not given	Not given	Not given	Not given
Berte et al. ²²	87%	88.5%	.254	21%	13%	.16
Yavin et al. ²³	83.0%	90.2%	.006	12.5%	6.2%	.02
Yasaki et al. ²⁴	Not given	Not given	Not given	63%	26%	<.0001
Bunch et al. ²⁵	Not given	Not given	Not given	Not given	Not given	Not given
Castrejon-Castrejon et al. ²⁶	39%	57%	.01	7%	5%	.56
Kottmaier et al. ²⁷	Not given	Not given	Not given	55.0%	13.4%	<.001
61.8% Average		82.5% Average		26.2% Average		9.9% Average



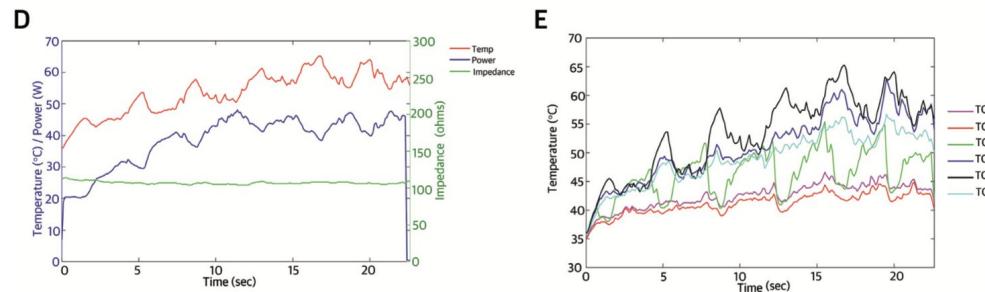
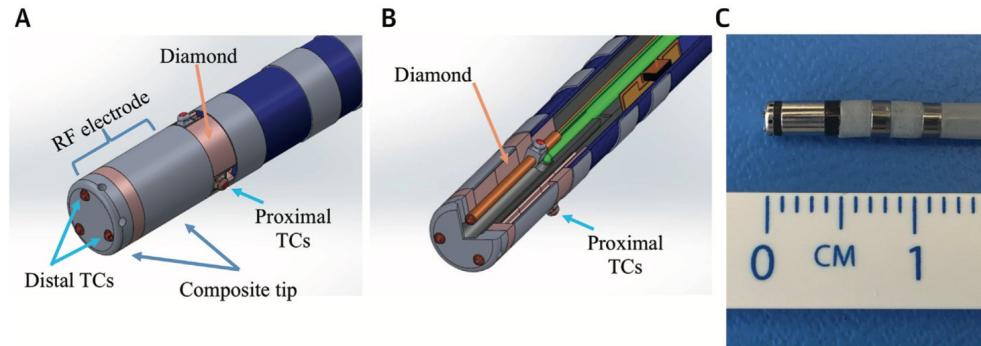
HP-SD versus LP-LD AF ablation

Outcome and complication rate

Study	Follow-up duration	LPLD (AF free)	HPSD (AF free)	p Value	LPLD (% complications)	HPSD (% complications)	p Value
Nilsson et al. ¹⁶	15 ± 7 months	38% ^a	32% ^a	NS	2.22%	2.22%	1.000
Winkle et al. ¹⁷	1 year	45.2%	59.7%	<.001	1.79%	1.33%	.785
Baher et al. ¹⁸	2.5 Years	59%	58%	.571	Esophageal only	Esophageal only	N.S.
Pambrun et al. ¹	1 year	90%	88%	.75	3%	2%	.645
Dhillon et al. ¹⁹	1 year	64%	78%	.186	6%	0%	.039
Okamatsu et al. ²⁰	12 months	80%	100%	.95	10%	0%	.090
Vassallo et al. ²¹	1 year	68.6%	82.9%	.14	0%	0%	1.000
Berte et al. ²²	6 months	83%	82%	.93	1.3%	1%	.39
Yavin et al. ²³	Not given	69.6%	79.5%	not given	1.67%	0%	.095
Yasaki et al. ²⁴	10 months	68%	71%	.99	0%	3.10%	.091
Bunch et al. ²⁵	3 years	(66.3%) on and off AADs	(61.4%) on and off AADs	.07	Not given	Not given	Not given
Castrejon-Castrejon et al. ²⁶	Not given	Not given	Not given	Not given	7%	0%	.115
Kottmaier et al. ²⁷	1 year	65.1%	83.1%	<.013	17%	13%	.482
		66.4% Average off AAD	74.0% Average off AAD			4.5% Average	2.1% Average



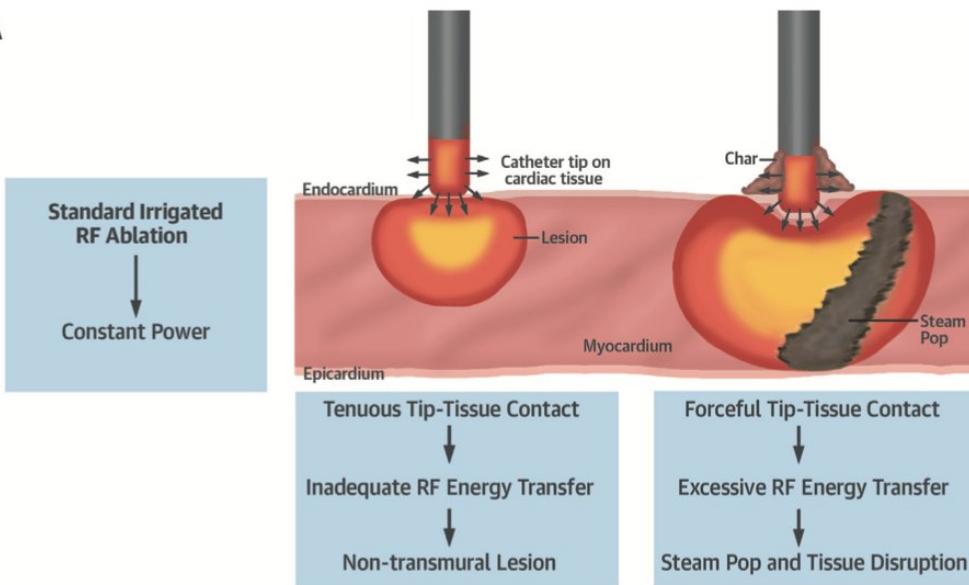
Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With Atrial Fibrillation



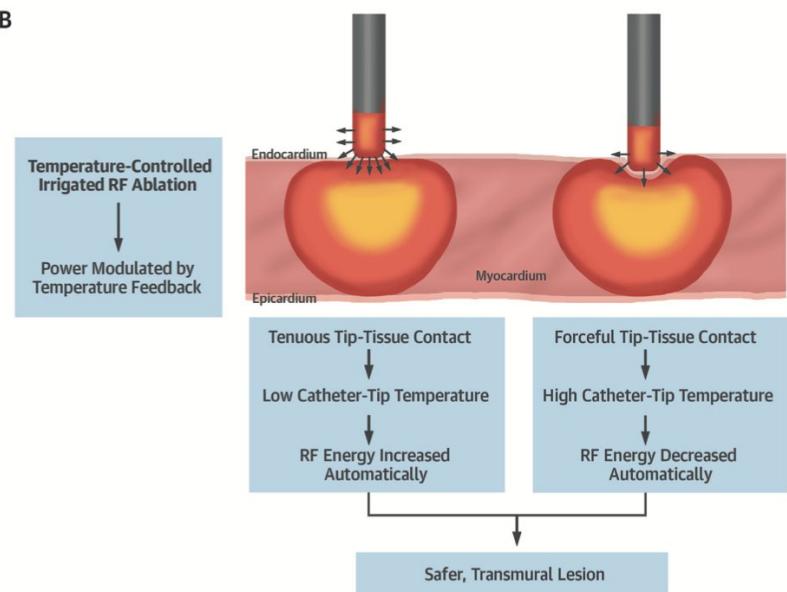


Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With Atrial Fibrillation

A

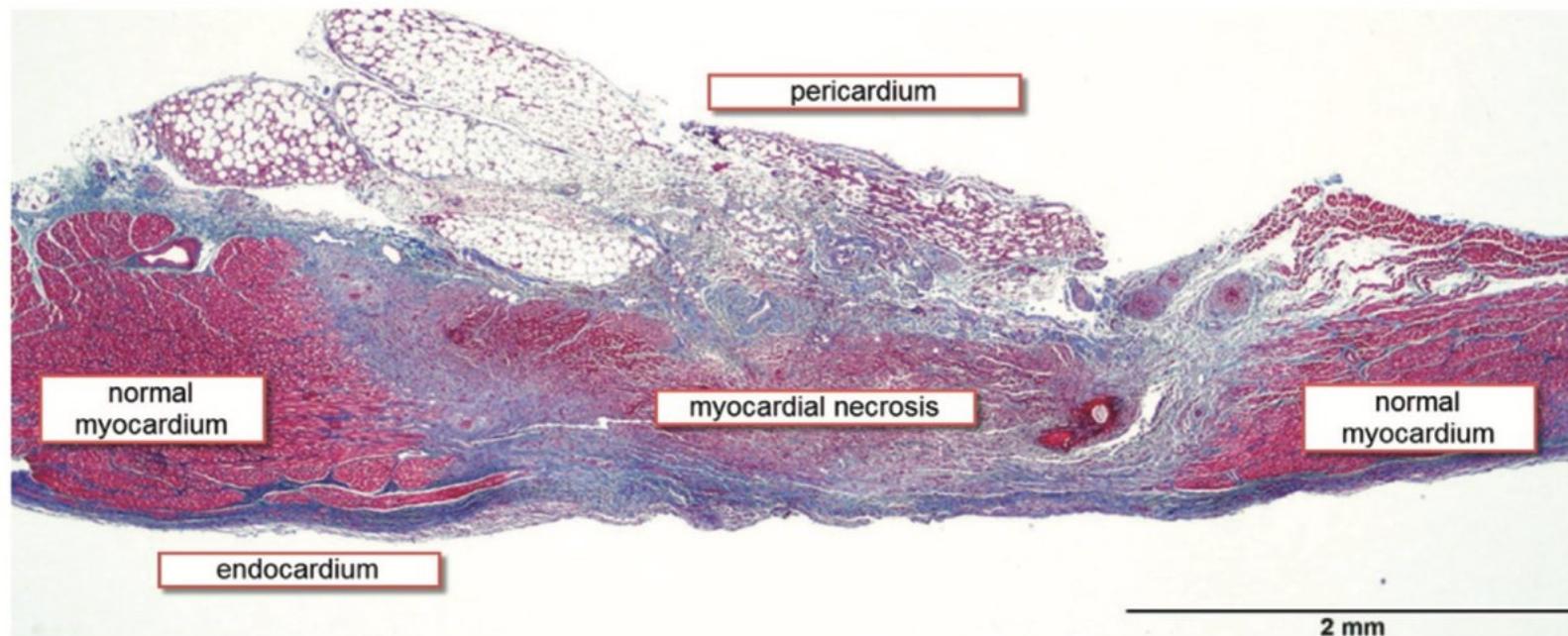


B





Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With Atrial Fibrillation





Temperature-controlled irrigated ablation

TABLE 3 Procedural Details

	Study Group (n = 35)	Control Group (n = 35)	p Value
No. of ablation lesions per patient	83.6 ± 13.2	151.6 ± 38.2	<0.001
Left PV lesion set	37.9 ± 8.8	60.2 ± 18.2	<0.001
Right PV lesion set	46.1 ± 9.5	91.3 ± 26.0	<0.001
RF application time per point, s	18.8 ± 1.9	35.1 ± 4.1	<0.001
Left PV lesion set	17.6 ± 1.9	33.8 ± 5.4	<0.001
Right PV lesion set	19.7 ± 2.4	35.8 ± 4.2	<0.001
Total RF application time per patient, min	26.3 ± 5.2	89.2 ± 27.2	<0.001
Left PV lesion set	11.2 ± 3.3	34.4 ± 13.1	<0.001
Right PV lesion set	15.1 ± 3.7	54.8 ± 17.9	<0.001
Fluoroscopy time, min	11.2 ± 8.5	19.5 ± 6.8	<0.001
Average impedance drop, Ω	13.1 ± 3.5	8.1 ± 2.1	<0.001
Average power, W	36.3 ± 2.6	31.2 ± 2.5	<0.001

- dormant conduction with adenosine provocation: 0
- durable isolation rates: (3 months remap) 89.9% on a per PV basis.

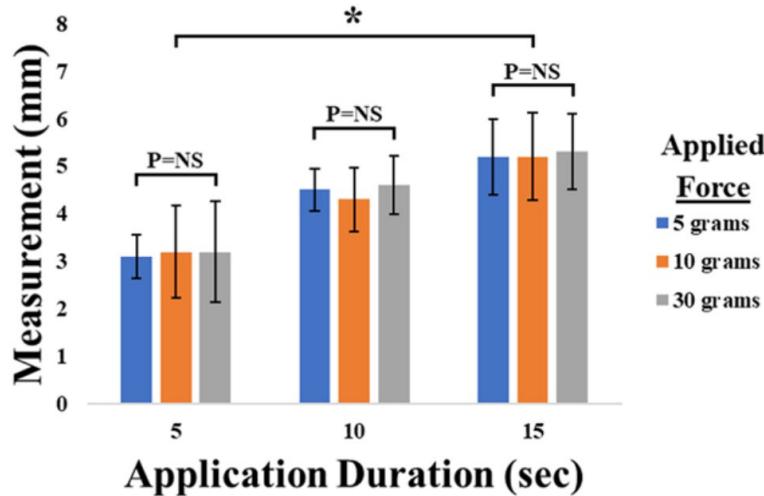
At 6-month follow-up, AF was recorded on the event recorder in 7 of 35 patients (20%).

Five of these patients with clinical recurrence were remapped; however, 19 of 20 PVs in these 5 patients had been durably isolated, suggesting a non-PV trigger

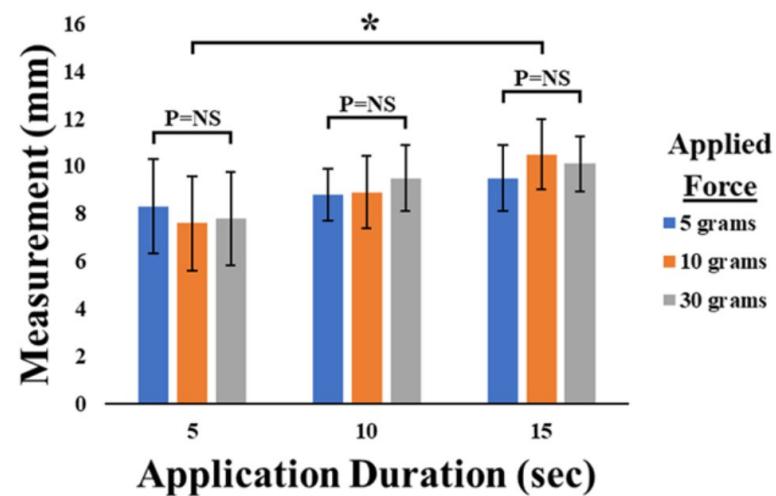


Assessing the Relationship of Applied Force and Ablation Duration on Lesion Size Using a Diamond Tip Catheter Ablation System

A Thigh - Lesion Depth



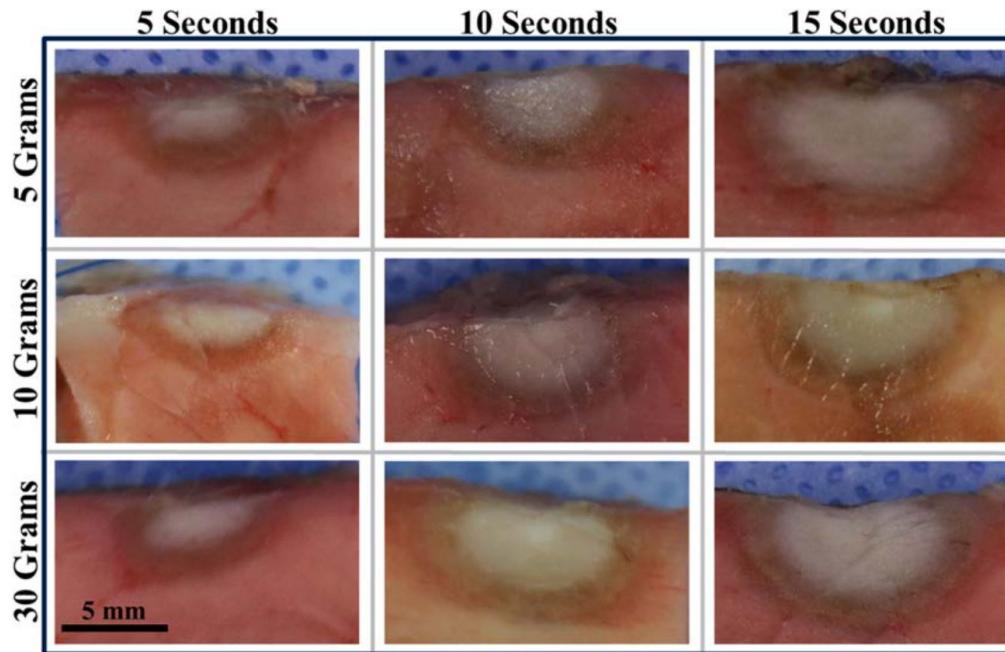
B Thigh - Lesion Width



* p<0.001

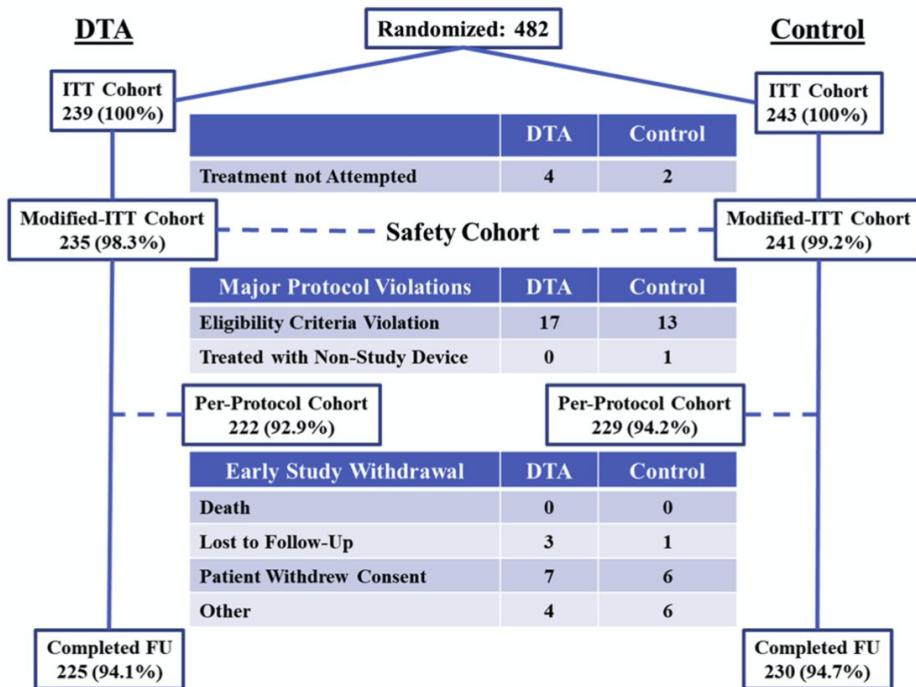


Assessing the Relationship of Applied Force and Ablation Duration on Lesion Size Using a Diamond Tip Catheter Ablation System





A Novel Temperature-Controlled RF Catheter Ablation System Used to Treat Patients With Paroxysmal AF: DIAMOND AF Trial



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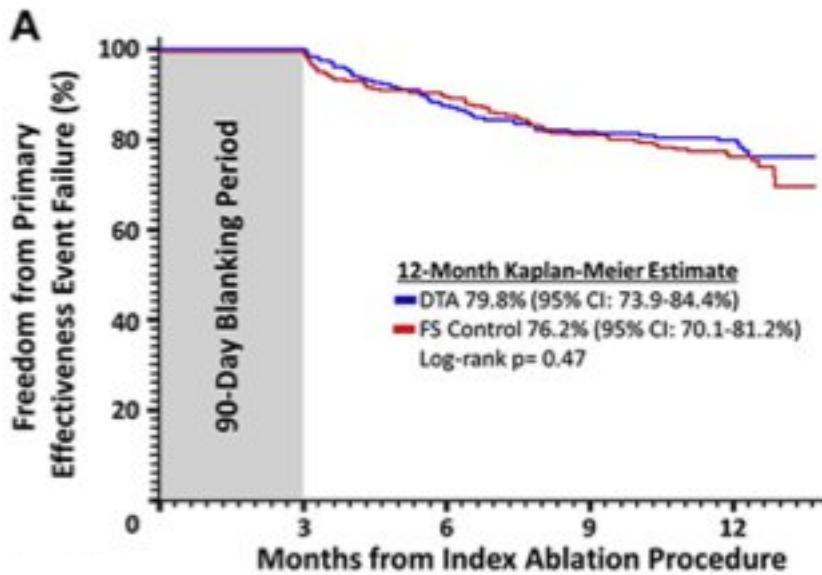
DIAMOND AF Trial

TABLE 2 Characteristics of the Index Ablation Procedures

	DTA (n = 239)	Control (n = 243)	p Value
Procedural durations			
Total procedure, min*	109.7 ± 46.2	115.4 ± 50.8	0.20
Fluoroscopy, min	12.7 ± 10.2	12.8 ± 9.4	0.85
LA dwell, min†	83.1 ± 34.0	91.4 ± 60.9	0.07
Total RF, min	17.9 ± 8.1	29.8 ± 14.0	<0.001
Ablations performed‡			
Successful PVI	239 (100.0)	241 (99.2)	0.16
CTI ablation	74 (31.0)	69 (28.4)	0.54
Additional left-sided targets	6 (2.5)	8 (3.3)	0.61
Additional right-sided targets	2 (0.8)	4 (1.7)	0.42
Other ablation targets	8 (3.3)	9 (3.7)	0.83
Ablation data			
No. of ablations per procedure	74.2 ± 33.0	71.1 ± 39.8	0.36
Individual ablation duration, s	14.7 ± 5.3	32.6 ± 25.3	<0.001
Fluid infusion, ml	332.2 ± 120.8	785.2 ± 351.5	<0.001
Maximum power delivered, W	52.9 ± 2.1	34.3 ± 5.4	<0.001
Average power delivered, W	40.2 ± 4.9	32.3 ± 29.3	<0.001
Maximum temperature, °C	64.7 ± 5.0	40.9 ± 2.6	<0.001
Average temperature, °C	47.6 ± 3.1	35.4 ± 27.0	<0.001
Average contact force	NA	14.4 ± 13.2	NA
Acute procedural confirmation			
Acute reconnection	45 (18.8)	45 (18.5)	0.93
Adenosine administration	85 (35.6)	90 (37.0)	0.76
Isoproterenol administration	27 (11.3)	30 (12.3)	0.73



DIAMOND AF Trial

**TABLE 4 Primary Safety Endpoints**

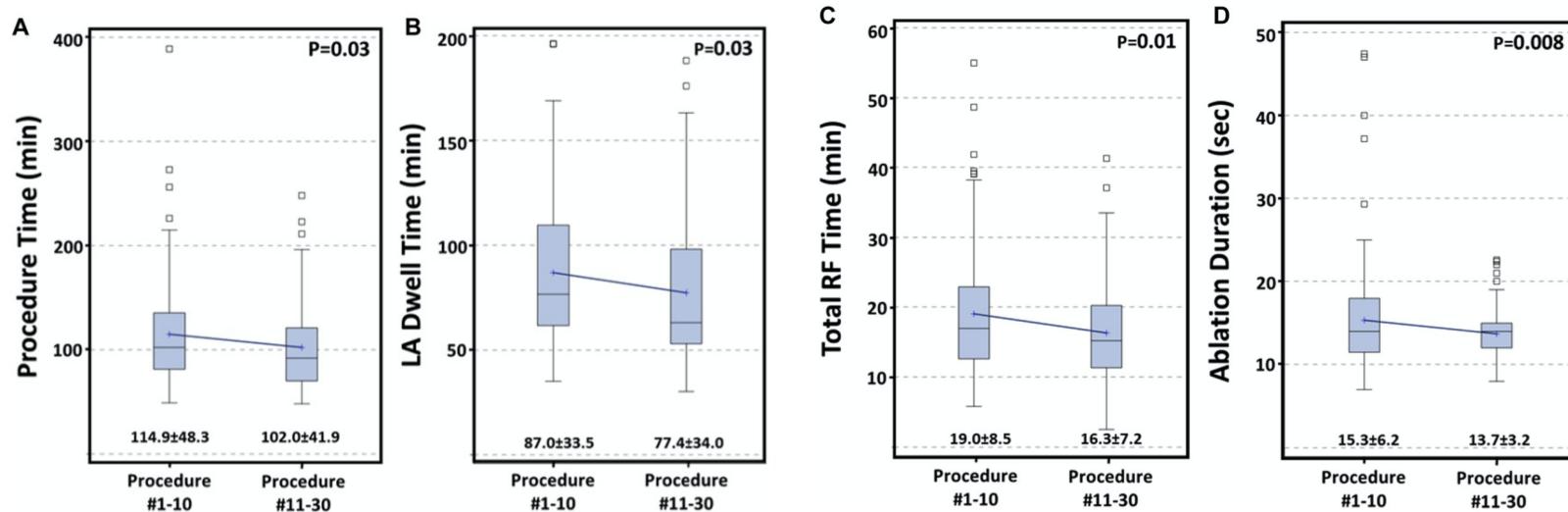
Serious Adverse Event	DTA (n = 239)	Control (n = 243)
Cardiac tamponade/perforation	2 (0.8)	2 (0.8)
Extended hospitalization	0	6 (2.5)
Pericarditis	0	1 (0.4)
Phrenic nerve paralysis	1 (0.4)	0
Pulmonary edema	0	1 (0.4)
Stroke post ablation	0	1 (0.4)
Transient ischemic attack	2 (0.8)	1 (0.4)
Vagal nerve injury	1 (0.4)	0
Vascular access complication	2 (0.8)	4 (1.6)
Bleeding complication	0	0
Myocardial infarction	0	0
Thromboembolism	0	0
Death	0	0
Atrioesophageal fistula	0	0
Pulmonary vein stenosis	0	0
Total	8 (3.3)	16 (6.6)

Effectiveness subanalysis showed 12-month freedom from atrial arrhythmias off class I and III AADs favored DTA compared with the control group (142 [59.4%] vs. 120 [49.4%], respectively; $p < 0.03$).



Temperature-controlled radiofrequency ablation for pulmonary vein isolation in patients with atrial fibrillation

DiamondTemp Ablation Procedural Efficiency Analysis:





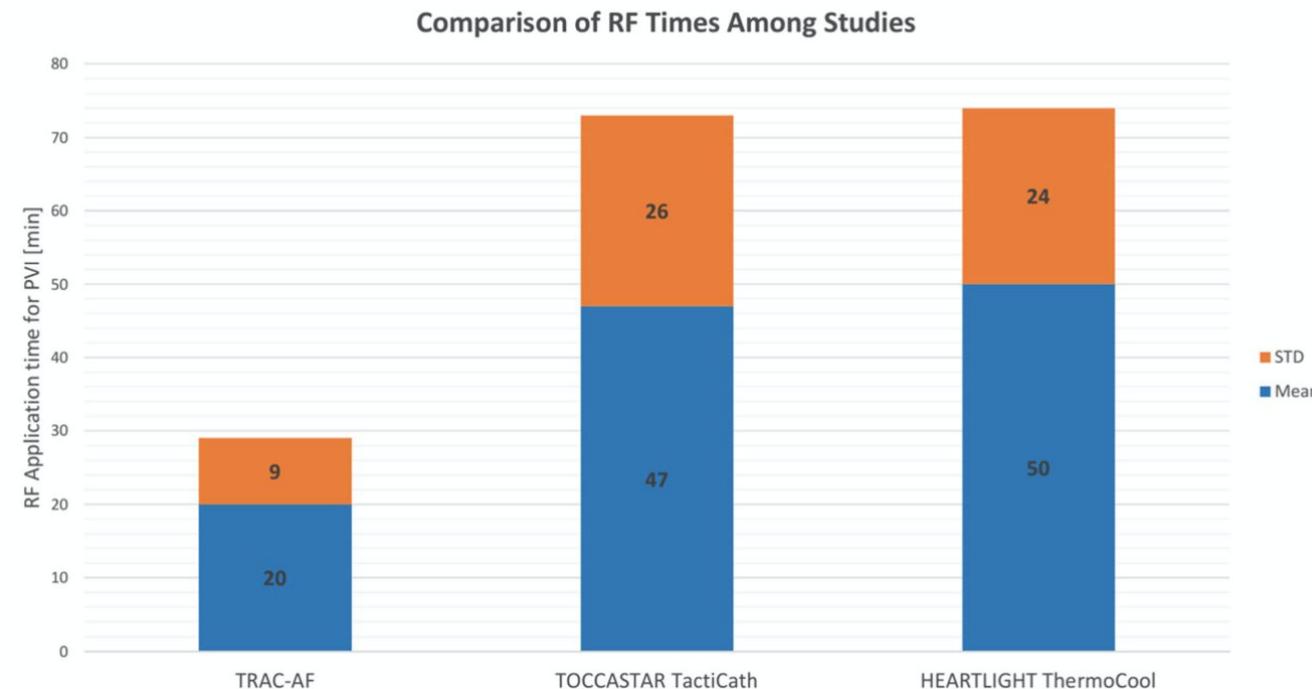
Efficacy and safety of novel temperature-controlled radiofrequency ablation system during pulmonary vein isolation in patients with paroxysmal atrial fibrillation: TRAC-AF study

Table 3 Procedure data ($n = 71$)

No. of RF applications per patient	68.9 ± 24.8
Ablation duration (s)	19.6 ± 3.2
Average power (W)	36.5 ± 2.5
Max power (W)	50.7 ± 0.5
Temperature set-point (°C)	58.3 ± 1.7
Max temperature (°C)	65.0 ± 3.4
Average temperature (°C)	48.8 ± 2.2
Max impedance (Ω)	136.6 ± 32.2
Average impedance (Ω)	94.8 ± 8.6
Total RF ablation time (min)	20.6 ± 8.9
Total procedure time (mean)	159 ± 47.6
Total fluoroscopy time (min)	9.3 ± 6.1
Total fluid volume — ablation (ml)	331.7 ± 98.6



Efficacy and safety of novel temperature-controlled radiofrequency ablation system during pulmonary vein isolation in patients with paroxysmal atrial fibrillation: TRAC-AF study



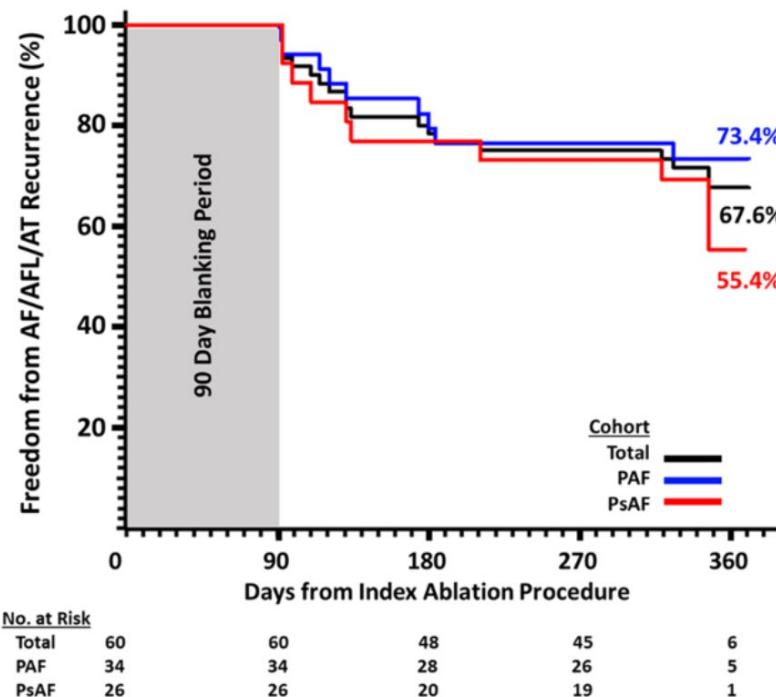


Radiofrequency ablation using the second-generation temperature-controlled diamond tip system in paroxysmal and persistent atrial fibrillation: results from FASTR-AF

Characteristic	Total (n=60)	PAF (n=34)	PsAF (n=26)	p-value
Procedural durations				
Total procedure, min *	90.8±31.6	76.9±21.9	108.8±33.6	<0.001
LA Dwell, min †	70.9±28.8	56.9±17.8	89.9±30.2	<0.001
Total RF, min	14.7±7.7	10.4±3.5	20.4±8.0	<0.001
Fluoroscopy, min	10.2±6.0	9.3±5.3	11.3±6.8	0.28
Ablations performed ‡‡				
Successful pulmonary vein isolation	60 (100.0%)	34 (100.0%)	26 (100.0%)	1.00
Non-PV ablation performed	26 (43.3%)	6 (17.6%)	20 (76.9%)	<0.001
Additional right-sided targets	17 (28.3%)	4 (11.8%)	13 (50.0%)	0.002
Cavotricuspid isthmus ablation	11 (18.3%)	4 (11.8%)	7 (26.9%)	0.18
Other right-sided targets	9 (15.0%)	0 (0.0%)	9 (15.0%)	<0.001
Additional left-sided targets	20 (33.3%)	2 (5.9%)	18 (69.2%)	<0.001
Posterior box isolation	9 (15.0%)	0 (0.0%)	9 (34.6%)	<0.001
Roof line	7 (11.7%)	0 (0.0%)	7 (26.9%)	0.002
Mitral isthmus line	9 (15.0%)	0 (0.0%)	9 (34.6%)	<0.001
Other left-sided targets	19 (31.7%)	2 (5.9%)	17 (65.4%)	<0.001
Ablation data				
Number of ablations per procedure	82.7±42.4	62.1±25.3	109.5±45.5	<0.001
Individual ablation duration, sec	10.7±3.6	10.3±3.3	11.2±3.8	0.03
Fluid Infusion, ml	284.7±111.5	231.1±59.5	354.8±125.1	<0.001
Maximum power delivered, W	56.1±0.6	55.9±0.5	56.4±0.7	0.01
Average power delivered, W	47.7±2.3	48.0±1.8	47.3±2.8	0.47
Maximum temperature, °C	67.1±2.9	66.4±2.6	68.1±3.1	0.05
Average temperature, °C	50.6±3.3	50.3±3.2	51.0±3.6	0.53



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DIAMOND-AFII trial

ClinicalTrials.gov

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DiamondTemp™ System for the Treatment of Persistent Atrial Fibrillation (Diamond-AFII)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.



ClinicalTrials.gov Identifier: NCT03643224

Recruitment Status [i](#) : Recruiting

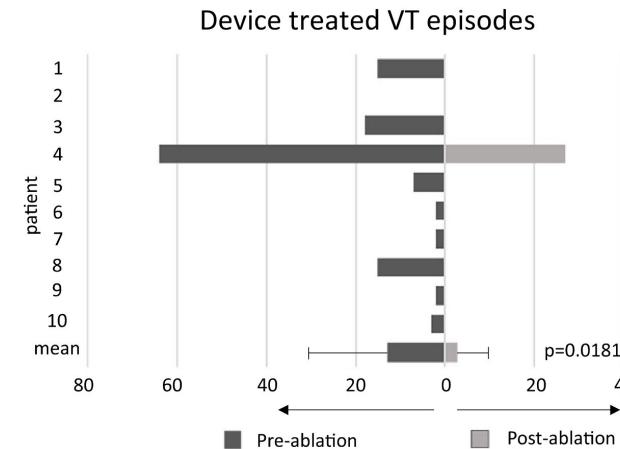
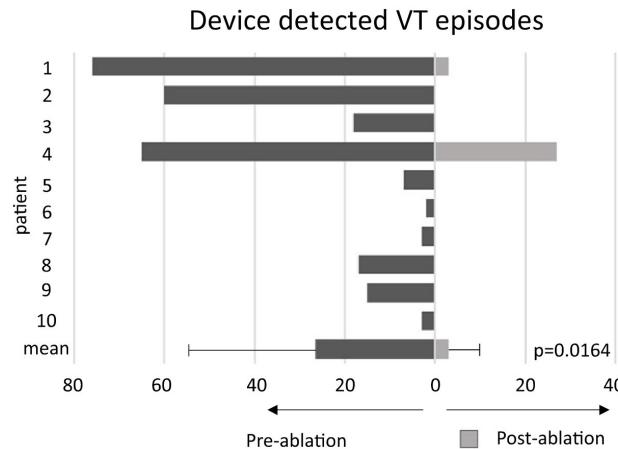
First Posted [i](#) : August 22, 2018

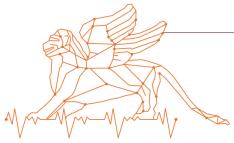
Last Update Posted [i](#) : July 8, 2022

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Initial experience of temperature-controlled irrigated radiofrequency ablation for ischaemic cardiomyopathy ventricular tachycardia ablation





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