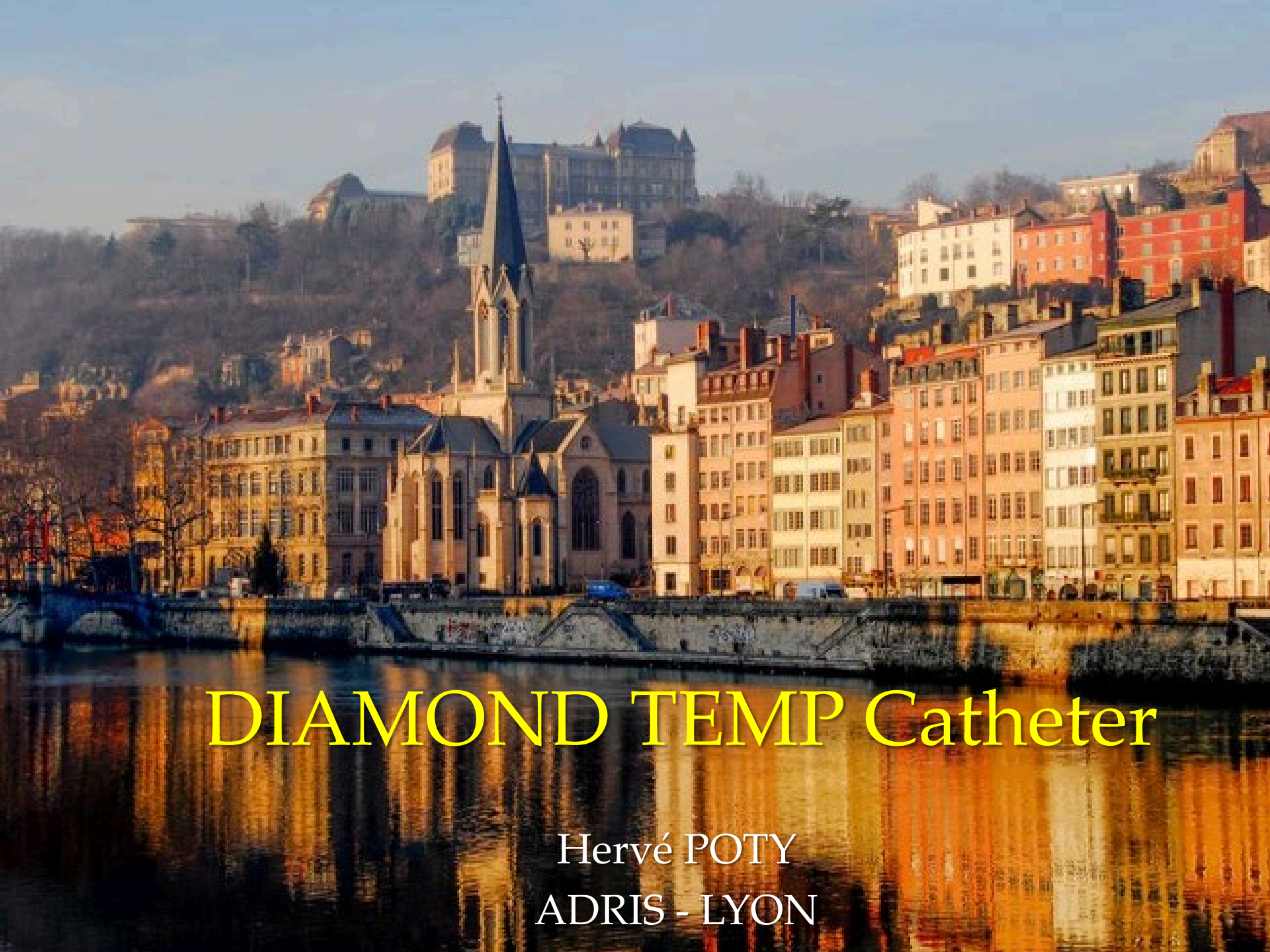


DIAMOND TEMP Catheter

Hervé POTY

ADRIS - LYON

Disclosure

- I have the following potential conflicts of interest to report:

  Consulting: ABBOTT, MEDTRONIC

Background

- Saline irrigation changed RF ablation by minimising char , but it complicates power titration by inhibiting Temperature feedback

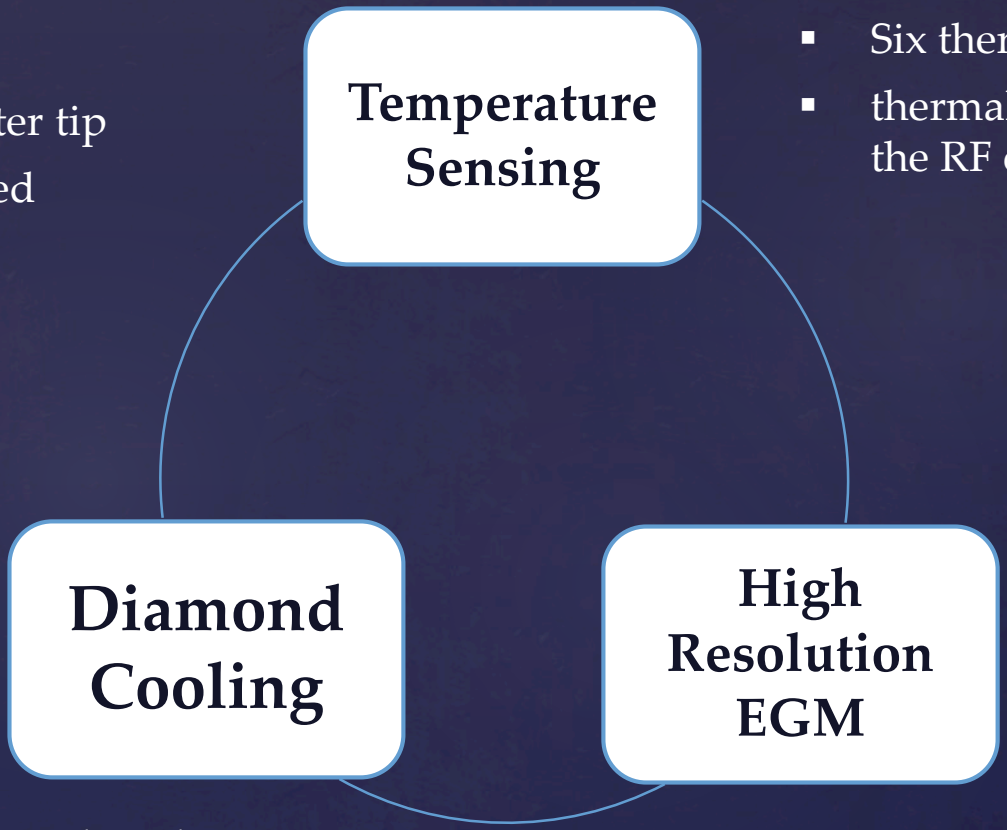
  Irrigated RF ablation is delivered in a power mode

- Point by point PVI ablation is challenging by faster procedure using Balloon

- Despite satisfactory PVI acute success, high percentage of long term PVI reconnection suggesting imperfect acute lesion

Design Overview: DiamondTemp™ Ablation System

- 7.5F,
- 4.1 mm catheter tip
- Saline-irrigated catheter

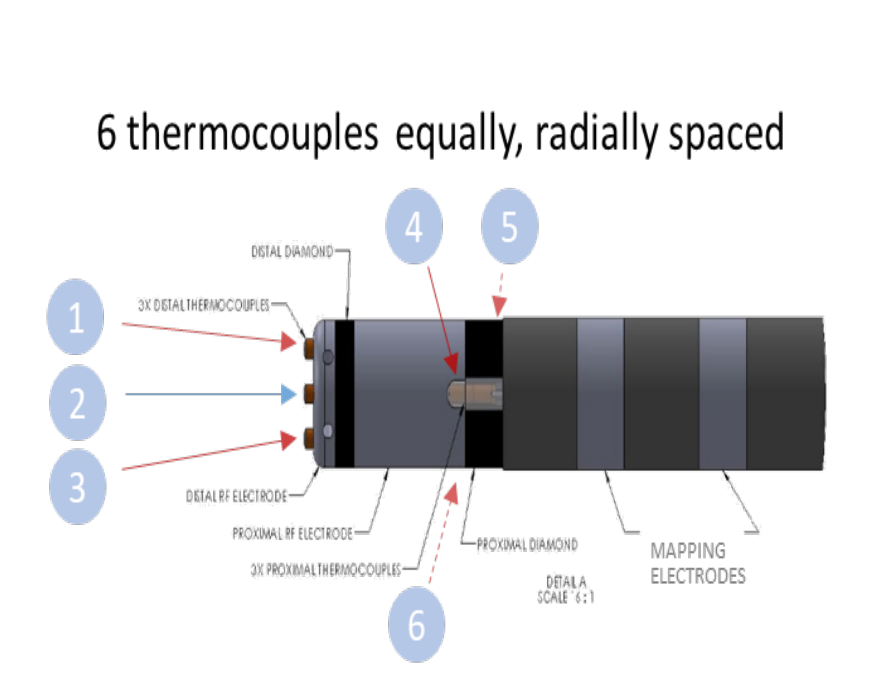


- Six thermocouples
- thermally isolated from the RF electrode

- Diamond network at the distal tip designed to provide heat shunting
- One flow rate : 8 ml/min

- Split tip providing localized, electrical information

Temperature-Controlled RF Ablation



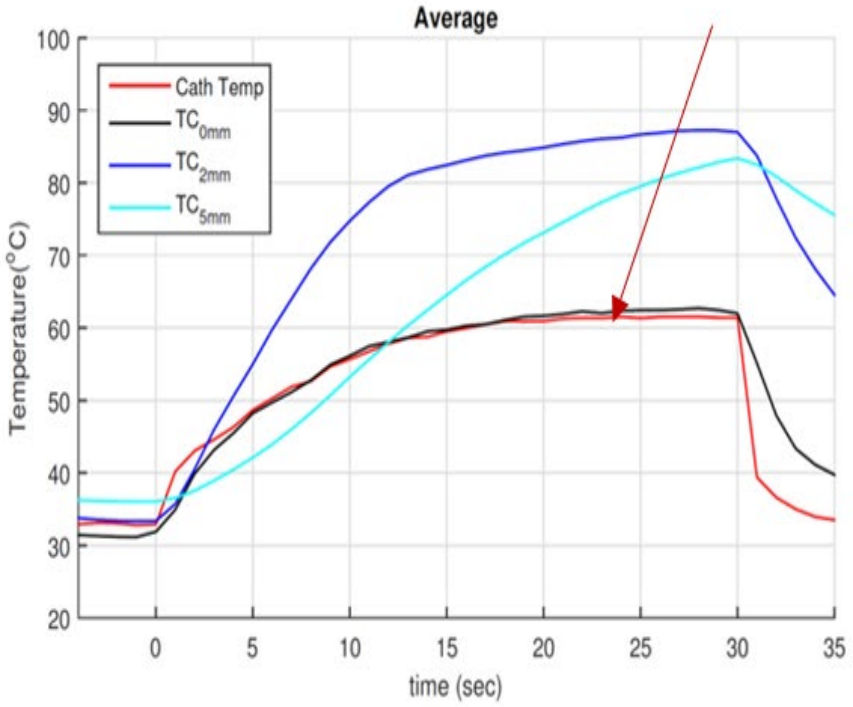
<u>Real-time temp monitoring</u>

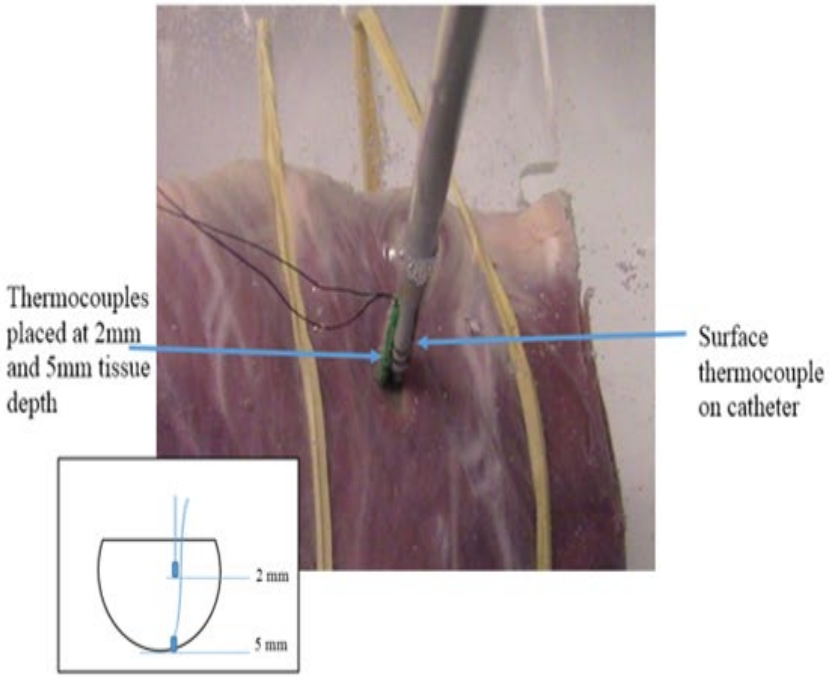
- Each sensor sampled Temperature every 20 ms
- System continuously monitors highest sensor temperature and **automatically controls the power** to that temperature

Temperature provides direct feedback of lesion creation.

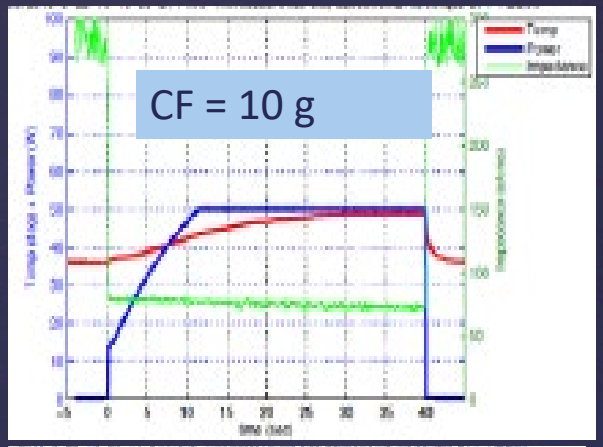
Real-time and Accurate tissue interface temperature recording (test in bench model)

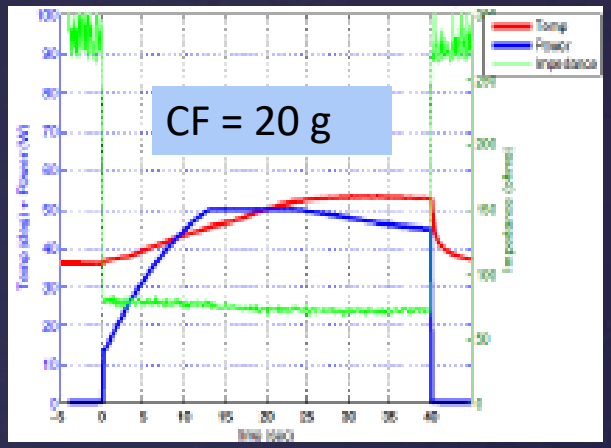
Temperature recorded from sensor is the same as external thermocouples during RF ablation

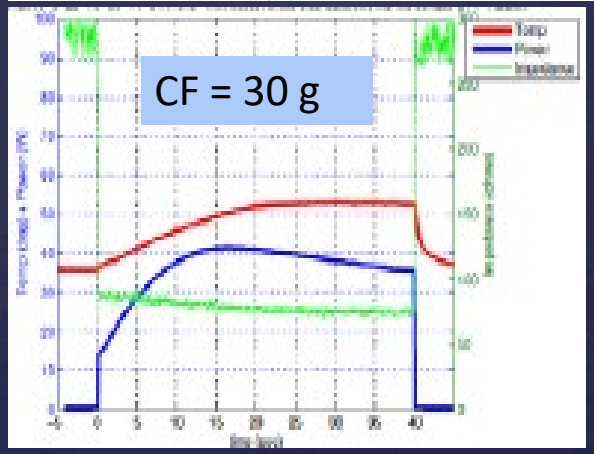


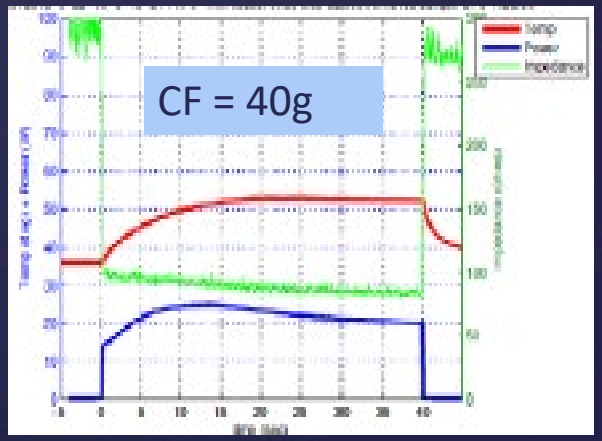


Real-Time Temperature control
Adjustment of POWER relative to Contact force (CF)





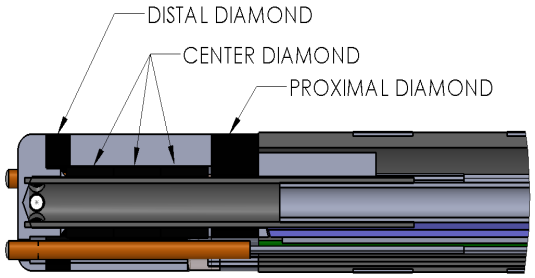




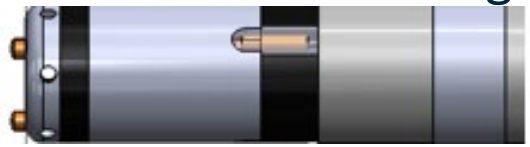
Power – blue
Temp – red

As contact improves, less power (blue line) is needed to reach the same temperature target (red line)

Diamond Cooling Mechanism



Diamond Cooling



Thermal diffusivity of common EP Catheter RF Electrodes

Pt/Ir - 4.5 mm^2/s
Gold – 127 mm^2/s
Steel – 4.2 mm^2/s
CVD Diamond - 800 - 1800 mm^2/s

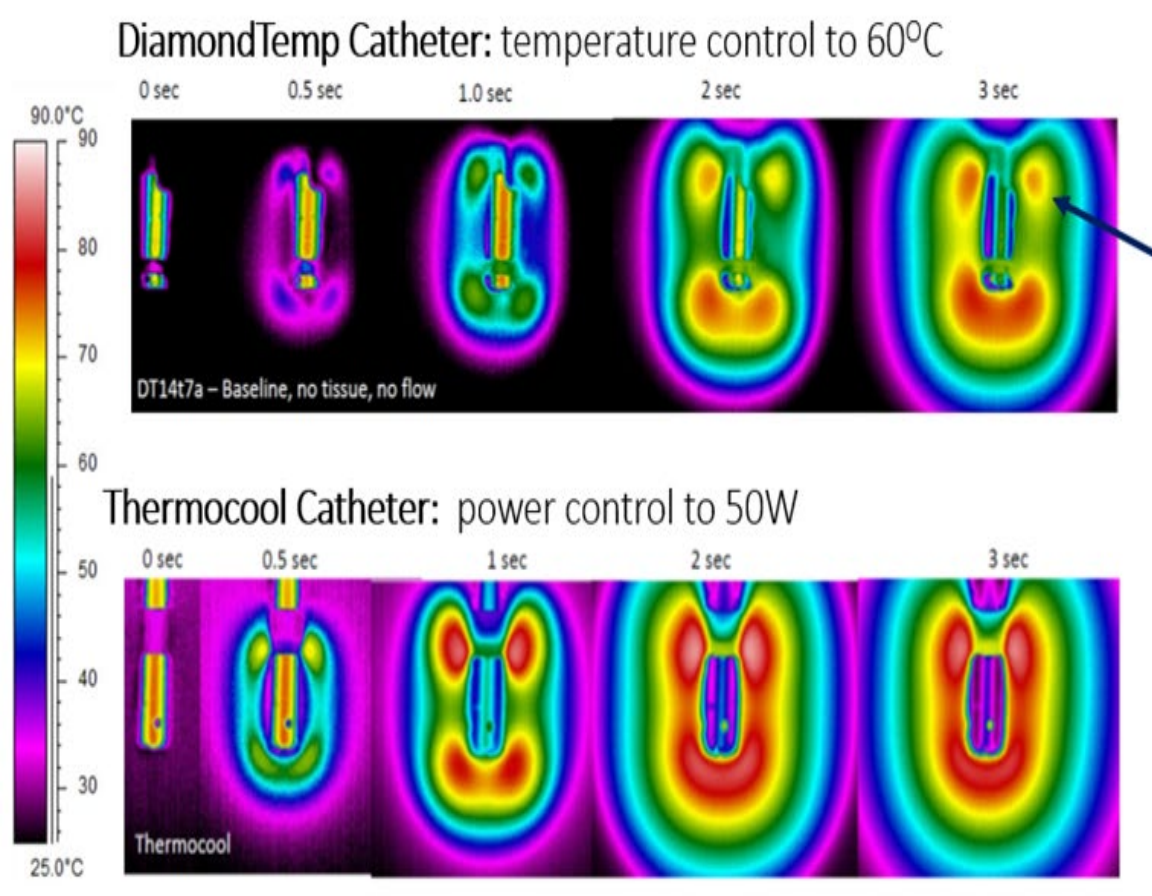
- The tip is manufactured with platinum/iridium and diamond components
- A network of industrial diamond designed to act as heat shunting material
- Extremely high thermal diffusivity , allows quick conduction of thermal energy

Heat and cooling transfer is **200-400 times faster** with diamond vs platinum/iridium[1].

[1]Brown; Marco (1958). Introduction to Heat Transfer (3rd ed.). McGraw-Hill. and Eckert; Drake (1959). Heat and Mass Transfer. McGraw-Hill. ISBN 978-0-89116-553-8. cited in Holman, J.P. (2002). Heat Transfer (9th ed.). McGraw-Hill. ISBN 978-0-07-029639-8.

Diamond Cooling

Comparison of Tip temperature with a conventionnal open irrigated catheter

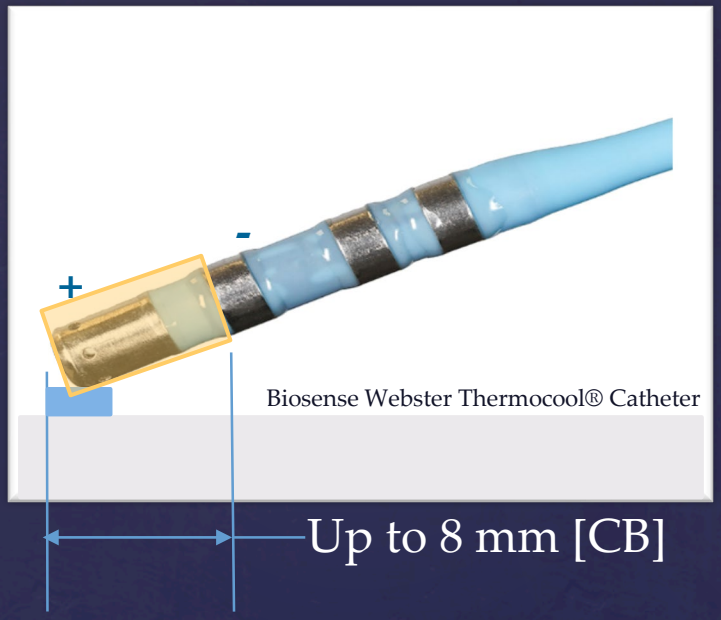


IR shows significant reduction in hot spots at the proximal edge of the tip in comparison to a conventional open-irrigated catheter due to the diamond tip cooling

As saline flows through the diamond network, very little heat is retained , thereby reducing hotspots at catheter tip

High Resolution Electrode

Conventional Electrodes
(bipolar mapping/pacing)



Center of mapping
Center of ablation

DiamondTemp Split distal tip
(bipolar mapping/pacing)

Center of mapping
Center of ablation

Recording of highly localized signals at the center of ablation
(with minimal far field artifact)

High Resolution Electrogram (HRE) linked to this new tip design

Comparison of 2 catheters (DT and CB) placed at the same place just inside the isolated RIPV

- No signal on HRE → indicates tip is inside PV (not in LA)
- Well-defined signal on Common bipole → falsely indicating tip is in LA , which could lead to create a lesion in PV

DiamondTemp RF Generator

9% impedance drop

Temp >50°C

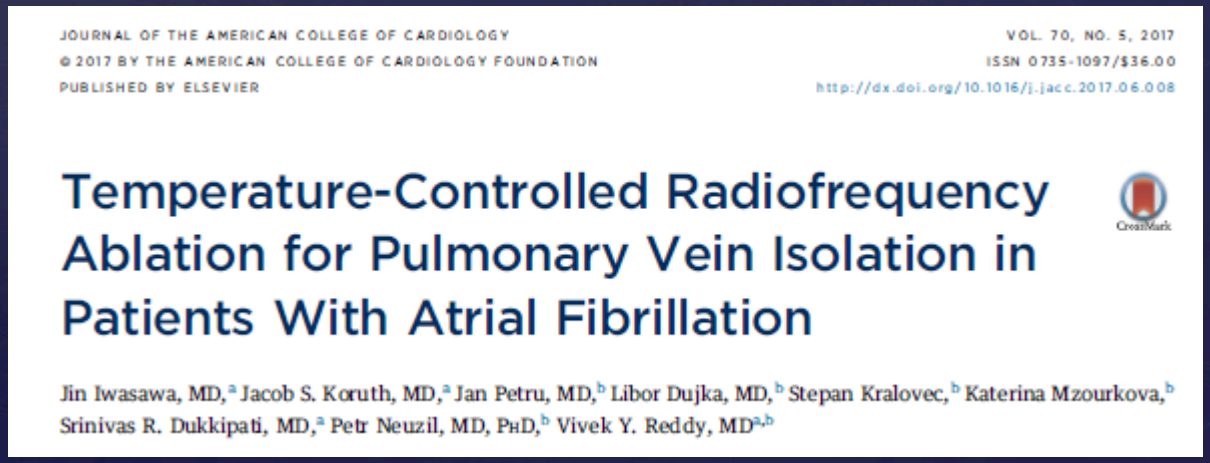
Abl 1-2 EGM attenuation

Summary of Benefits of DiamondTemp Ablation System

- **Direct measurement of lesion formation , given by Temperature**
  - ✓ Temperature at Electrode-Tissue Interface
  - ✓ Attenuation of High Resolution EGM during ablation
- Very efficient at delivering RF energy
  - ✓ Low distal flow rate : higher % of energy delivered to the tissue ,
- Contact Force Sensing is not needed with Temperature control
  - Generator adjusts Power to reach therapeutic T°
  - If contact force is low, more power delivered to compensate

Clinical Relevance of DiamondTemp Ablation System

Study	TRAC-AF
Indication	Paroxysmal Atrial Fibrillation
Study Design	Prospective, single-arm, multi-center, non-blinded, feasibility study
Primary Endpoint	• Safety: Serious adverse events through 30 days • Effectiveness: Acute pulmonary vein isolation (PVI)
EP at 3 mths	Durable PVI isolation
Total Subjects	70 patients (35 pts DT, 35 pts Control group)
Investigators	Petr Neuzil, Vivek Reddy



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

Jin Iwasawa, MD,[a] Jacob S. Koruth, MD,[a] Jan Petru, MD,[b] Libor Dujka, MD,[b] Stepan Kralovec,[b] Katerina Mzourkova,[b] Srinivas R. Dukkipati, MD,[a] Petr Neuzil, MD, PhD,[b] Vivek Y. Reddy, MD[a,b]

TRAC-AF

METHODS

- Pre-clinically, 6 pigs underwent Temp Control ablation (60°C/50 W) until ~80% electrogram amplitude reduction was observed.
- For the single-center clinical feasibility study, 35 patients underwent PV isolation with the DiamondTemp catheter.

  35 pts treated with a Force-sensing catheter were considered the control group.

RESULTS

- In the pre-clinical porcine study, Transmurality was observed in (92.7%) of the lesions, mean time/lesion : 13 sec
- In the clinical study:
  - All PVs were successfully isolated; one pericardial effusion did occur in the DiamondTemp arm.
  - Significantly shorter RF application duration (26 min vs 89 min), and acute dormant PV reconduction (0 vs 14%) were observed for the DiamondTemp group
  - At 3 months, PVI remained 85% of PV pairs , 75 % pts with the DiamondTemp

CONCLUSION

Temperature-controlled irrigated ablation can produce rapid, efficient, and durable PV isolation.

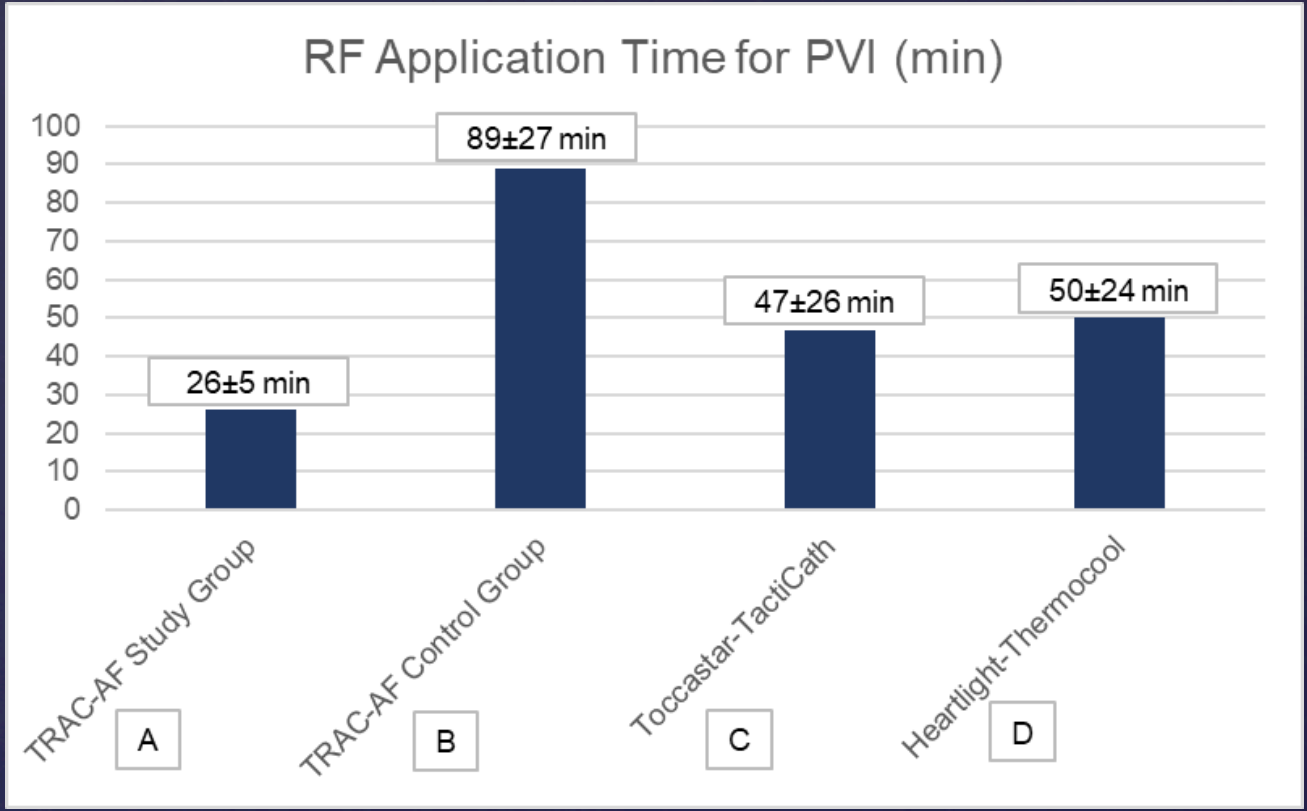
[1]Iwasawa J, et al. Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With Atrial Fibrillation. *J Am Coll Cardiol*. 2017 Aug 1;70(5):542-553.

TRAC-AF

	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

TRAC-AF

Temperature-controlled irrigated ablation can produce rapid PV isolation



Comparisons	Significance
A vs B	p<0.001
A vs C	p<0.001
A vs D	p<0.001

Image adapted from Iwasawa et al.[1]

[1]Iwasawa J, et al. Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With Atrial Fibrillation. *J Am Coll Cardiol*. 2017 Aug 1;70(5):542-553.

TRAC AF Starek EHJ 2019

- Prospective multicenter trial (New York, Prague , Toulouse)
- 70 pts with drug refractory, symptomatic paroxysmal A Fibrillation
- only ablated with the diamond temp catheter
- Point by point VPI in temperature control mode until 75-80% EGM reduction

- Results
- VPI in 100% pts
- Mean RF duration /point : 17 sec
- Mean RF ablation time : 19.8 ± 8.6 min
- Adverse events : pericardial effusion in 1 pt
- Freedom from AF at 6 and 12 Months; 73% (49/67) and 74 % (26/35)

DIAMOND AF

	DIAMOND-AF
Patient Population	Paroxysmal Atrial Fibrillation
Design	480 subjects, randomized 1:1 vs TactiCath™ Quartz Contact Force Ablation Catheter (Abbott)
Status	Active, enrollment complete
Objectives	Establish the safety and effectiveness of the DiamondTemp System for the treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation in patients.

Inclusion Criteria: At least 2 episodes of Parox AFib in the previous 12 mths
Exclusion Criteria:
-LA diameter > 55
-EF < 35%
-BMI > 40

DIAMOND Study (Paroxysmal AF)

Ablation Goal

PVI (entrance and exit block) with a 20 min waiting period

Ablation duration determined in

- Diamond Temp group:

by monitoring **Temperature curve , attenuation of high resolution EGM (75-80% reduction) and impedance drop of 10 ohms**

- **Tacticath group:**

In our group by LSI 5,5 anterior and 4,5 posterior with 30-35 watt preset power (by 2 operators)

Adenosine for 81 % pts with reablation in case of reconduction

Follow up

- **Trans Tel monitor: every 15 days after blanking period of 3 mths or in case of symptoms any time**
- **Clinic Visit , 12 Lead EKG and 24h Holter monitor at 3 - 6 - 12 months**

Diamond AF (Tonkin cohort)

	Tacticath	DiamondTemp	p value
Patients	29	29	
Age , % Male	66 ±9 (72%)	66 ±10 (52%)	
PVI acute success	100 %	100 %	
Pericardial effusion	2	2	
drained	0	1	
Procedure duration(mins)	98,5 ±18	99,3 ±24	
RF duration (mins)	22,3	15,8	p 0.01
Fluoro duration (mins)	8,3	11,3	
LPVI duration (mins)	17,3 ±5	17,1 ±9	
LPVI nb of applications	27	26	
RPVI duration (mins)	19,2 ±5	18,3 ±5	
RPVI nb of applications	35	33	
Saline infusion	822 cc	293 cc	p 0.01
VP reconduction/ATP	5/25 (20%)	2/22 (9 %)	
Recurrence at 12 mths	4 (13%)	2 (7%)	p 0.67

FASTR-AF

The FASTR RF Generator utilizes a faster power ramp to reach tissue temperature faster

Prospective, single-arm trial, multicenter trial
Presented at HRS 2019

ACUTE PROCEDURE RESULTS

	Paroxysmal (N=33)	Persistent (N=27)
RF Applications (PVI + Linear/Substrate)	56.2 ± 22.1	95.6 ± 45.6
Total RF Time (min)	9.4 ± 3.0	19.1 ± 9.2
Ave. Ablation Duration (sec)	10.8 ± 3.5	12.3 ± 3.7
Ave. Power (W)	47.3 ± 3.1	47.9 ± 2.6
Ave. Temperature (°C)	50.8 ± 3.0	51.7 ± 3.4
Fluid Infused (mL)	196.8 ± 51.2	321.8 ± 149
Procedure Time (h:mm)	1:41 ± 0:32	2:07 ± 0:32
Fluoro Time (min)	9.1 ± 5.3	10.9 ± 6.2*

[1]Neužil et al. First-in-Man FASTR-AF Study: Novel Temperature-Controlled FAST Ablation System to Rapidly Create Lesions for the Treatment of Persistent and Paroxysmal Atrial Fibrillation. HRS 2019.

DIAMOND AF 2

	DIAMOND-AF II
Patient Population	Persistent Atrial Fibrillation
Design	300 subjects, single arm
Status	Active, enrolling
Objectives	Establish the safety and effectiveness of the DiamondTemp Ablation System (fastr generator) for the treatment of drug refractory, symptomatic persistent atrial fibrillation in patients.

Inclusion Criteria: Symptomatic Persistent AFib > 7 days and less than 12 monthes
Exclusion Criteria:
-LA diameter > 55
-EF < 35%
-BMI > 40

Diamond AF2 (Persistent AF)

Tonkin cohort

	DiamondTemp
Patients	41
Age , % Male	67 ± 6 (80%)
AF duration	7.5 ± 3.2
LA diameter	42 ± 6
PVI acute success	100 %
Linear lesion/ CAFE Ablation	35 (85%)
Adverse Events	1 (2,44%)
TIA	1
Procedure	1h49 ± 18
PVI duration (mins)	30 ± 5
RF duration (mins)	15,8
Fluoro duration (mins)	11,9
Saline infusion	252 ml
Recurrence at 6 mths	3 (7%)

CONCLUSIONS

- Despite the absence of contact force sensing , Diamond Temp Catheter provides safe lesion with less irrigation flow.
- Due to accuracy of tissue Temperature recording and an improved assessement of lesion titration using electrogram attenuation, DT catheter gives an effective lesion with less RF ablation time.
- Theses preliminary results need however to be confirmed by the ongoing studies.

Our Experience in AF ablation with Diamond Temp

- 85 pts
- 100 % PVI
- Complications: 3 pts (3,5%)

- 2 pericardial effusion , 1 was drained percuteanously
- 1 TIA

TRAC-AF

TABLE 1 Porcine Atrial Ablation Parameters (N = 64)

Ablation time, s	13.3 ± 6.0
Mean power, W	34.1 ± 7.2
Max power, W	39.4 ± 8.5
Voltage change, %	74.9 ± 12.0
Impedance change, Ω	10.6 ± 11.5
Temp distal average, °C	45.2 ± 6.1
Temp proximal average, °C	46.5 ± 4.3
Lesion length, mm	5.9 ± 2.9
Lesion width, mm	4.9 ± 2.1
Lesion area, mm^2	23.4 ± 14.1

DIAMOND AF : Follow up protocol

Follow up and Testing Schedule

Assessments/ Activities	Baseline Evaluation	Ablation Procedure	Blanking Period (Ablation procedure – 3 months post procedure)				Effectiveness Evaluation Period (3 months -12 months post procedure)		
			Pre-Discharge	7-Day Follow-Up (± 3 days) Phone	1-Month Follow-Up (± 5 days)	Repeat Ablation Procedure	3-Month Follow-Up (±21 days)	6-Month Follow- up (± 28 days)	12- Month Follow- up (± 45 days)
Eligibility Screening	X								
Informed Consent	X								
Patient Demographics	X								
Medical History	X								
Limited Physical Exam (vitals)	X		X		X	X[A]	X	X	X
12-lead ECG		X	X		X	X[A]	X	X	X
TEE or TTE	X[B]								
TEE, TTE or ICE		X[C]				X[C]			
NIH Stroke Scale	X		X			X[A]			X
Procedural Data		X				X[A]			
Event Monitor Recording			X[D]	X[D]	X[D]		X	X	X
24 hr. Holter Monitor								X	X
Cardiac Medication Changes	X	X	X	X	X	X[A]	X	X	X
Protocol Deviations	X	X	X	X	X	X[A]	X	X	X
Adverse Events	X	X	X	X	X	X[A]	X	X	X
AF Quality of Life Survey (AFEQT)	X					X[A]		X	X

[A] Only required if a repeat ablation procedure performed. 1 repeat ablation procedure is allowed during Blanking Period.

[B] TEE only required if subject does not have imaging data to determine LA diameter, LVEF for eligibility within 180d of ablation procedure

[C] TTE, TEE or ICE required pre-procedure to rule out LA thrombus if CHA2DS2-VASc score is ≥ 2, if LA diameter ≥4.6 or if pre-procedure anticoagulation requirements are not met

[D] Event monitor recording only required if subject is experiencing symptoms during blanking period

Temperature Controlled Irrigated RF Ablation
-A Novel Approach to Create Rapid Transmural Atrial Lesions-

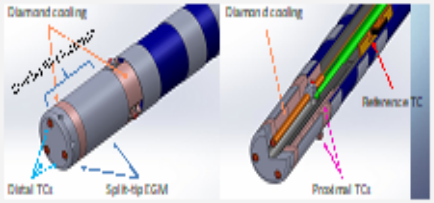
Jin Iwasawa, MD, Subbarao Choudry, MD, Noelle Langan, MD, William Whang, MD, Marc. A Miller, MD, Jacob S. Koruth, MD, Srinivas R. Dukkipati, MD, Vivek Y. Reddy, MD.

Helmsley Center for Electrophysiology, Mount Sinai Hospital, New York, NY

Introduction

Saline irrigation revolutionized RF ablation by minimizing char, but complicated power titration by inhibiting temperature feedback. We investigated a novel RF catheter with:

- a diamond embedded tip for rapid cooling by virtue of its high thermal diffusivity (saline irrigation at 8 ml/min)
- six surface thermocouples that reflect tissue temperature, thereby allowing 'temp-controlled' irrigated ablation
- a composite-tip for high resolution electrograms
- bipolar impedance-based tissue contact assessment



The electrode segment is comprised of a two part composite ablation tip electrode and two ring electrodes. The catheter has a distal ablation tip electrode that is 4.1 mm long with a 3 mm spacing between the tip and first ring electrode. The spacing between the two ring electrodes is 2mm. Also embedded near the tip electrodes are 3 thermocouples at the distal end, and 3 thermocouples in the proximal end used to monitor surface temperatures during RF ablation.

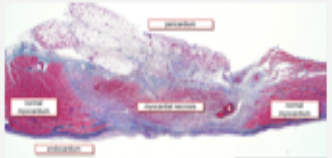
Methods

- In 6 swine, *in vivo* atrial lesions were delivered in temp-control mode (goal temp=60°C & 50W limit) until a 75-80% reduction in the split-tip EGM amplitude was observed.
- Impedance, power, temperatures, duration, and contact (scale 0-9) were continually recorded.
- After sacrifice, the hearts underwent pathological exam.

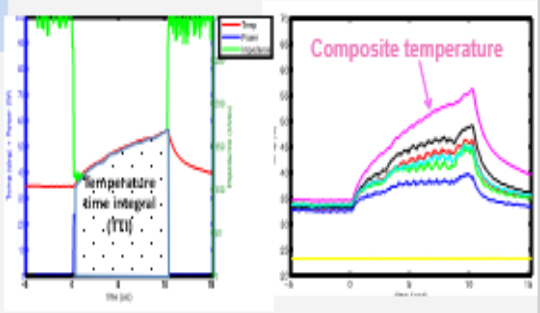
Results

- Of 70 total lesions, histological examination was performed on 55 identified lesions.
- Transmurality occurred in 51/55 lesions (93%) with RF duration of only 13.5 ± 5.7 sec/lesion.
- No steam pops or char formation occurred.

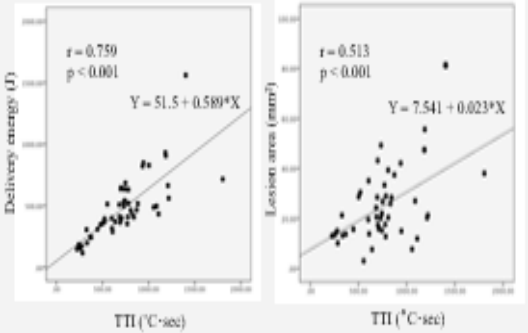
	(n=55)
Ablation time (sec)	13.5 ± 5.7
Contact Score	5.7 ± 1.7
Mean Power (W)	34.1 ± 7.4
Max temp composite (W)	57.7 ± 4.0
Voltage change (%)	76.1 ± 10.8
Impedance change (ohm)	11.1 ± 12.1
Temp distal average (°C)	45.4 ± 6.4
Temp proximal average (°C)	46.8 ± 4.4
Lesion length (mm)	6.5 ± 2.9
Lesion width (mm)	4.6 ± 1.5
Lesion area (mm^2)	24.5 ± 14.5



Histology stain with Masson's trichrome: Shown is a histological sample of excised myocardium from ablated atria. There is a lesion of transmural injury of the atrial myocardium. Because of ~1 wk survival, fibrotic replacement is incomplete, accounting for the necrotic core.



Temperature time integral (TTI) was defined as the area under the composite temperature curve



Conclusions

- This novel irrigated RF catheter allows for closed-loop temperature-controlled ablation to rapidly create predominantly transmural lesions in ~13 sec without steam pops or char formation.

Disclosures: Dr. Reddy serves as a consultant to and has received research grant support from Advanced Cardiac Therapeutics, Inc.

Poster presented at the Heart Rhythm Society Meeting May 2017, Chicago, IL

Rapid Pulmonary Vein Isolation Using a Novel Diamond Tip Temperature Controlled Irrigated RF Catheter: First-in-human Clinical Experience

Jin Iwasawa, MD, Jacob S. Koruth, MD, Petr Neuzil, MD, PhD, Jan Petru,MD, Stepan Kralovec, Srinivas R. Dukkipati, MD, Vivek Y. Reddy, MD

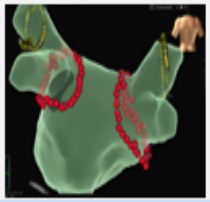
Helmsley Center for Electrophysiology, Mount Sinai Hospital, New York, NY & Homolka Hospital, Prague, Czech Republic

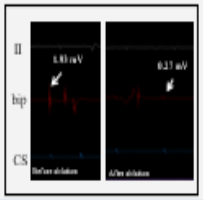
Introduction

- A novel irrigated RF catheter with a diamond tip and six surface thermocouples allows for accurate catheter-tissue interface temperature measurement during ablation.
- This feature allows for efficient closed-loop temp-controlled RF delivery to tissue despite saline irrigation.
- Additionally, it has a split-tip electrode to permit rapid lesion assessment by virtue of its high resolution-electrogram recording capability

Methods

- Thirty-five patients (24 men, 60 ± 10 years) with symptomatic, drug-refractory atrial fibrillation were prospectively enrolled at a single center as part of the *TRAC- AF* study (NCT 02821351)
- Herein, we present data on the first 35 pts enrolled in *TRAC-AF*; additional patients are being enrolling in this study
- After AF ablation, patients were scheduled for a pre-specified remapping procedure at 3 months regardless of symptomatology
- RF ablation was performed under the temperature control mode. (Temperature 60°C, 75-80% reduction in the high resolution EGM amplitude, saline irrigation flow rate of 8 ml/min)
- Acute procedural outcomes were compared with a historical control group who underwent PV isolation with a Thermocool-SmartTouch (force-sensing) irrigated RF catheter (n=35 pts).



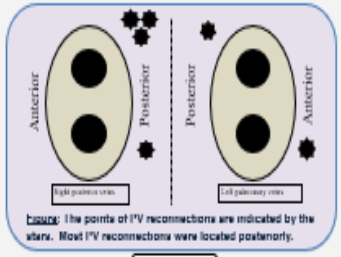


Results

	ACT (n=35)	SmartTouch (n=35)	p value
Age	60±10	63±11	0.312
Male sex	24 (69%)	28 (80%)	0.274
LVEF (%)	64±4	63±12	0.371
LAD (mm)	44±4	40±5	0.052
AF duration (month)	42±34	46±44	0.682
Hypertension	27 (77%)	17 (49%)	0.019
Heart failure	0 (0%)	1 (3%)	0.307
Diabetes mellitus	6 (17%)	3 (9%)	0.253
Stroke	1 (3%)	3 (9%)	0.296
CAD	5 (14%)	7 (20%)	0.490
Medication			
Class I	16 (46%)	8 (22%)	0.044
Class II	16 (46%)	25 (71%)	0.029
Class III	9 (26%)	14 (40%)	0.203
Class IV	3 (9%)	2 (6%)	0.500

	ACT (n=35)	SmartTouch (n=35)	p value
No. of Left PV ablation points	37.9±8.8	60.2±18.2	< 0.001
No. of Right PV ablation points	46.1±9.5	91.3±26.0	< 0.001
Total ablation point	83.6±13.2	151.6±38.2	< 0.001
Total RF application time per point (s)	18.8±1.9	35.1±4.1	< 0.001
Total RF application time (min)	26.3±5.2	89.2±27.2	< 0.001
Fluoroscopic time (min)	11.2±8.5	18.3±6.2	< 0.001
Average impedance drop (Ω)	13.1± 3.5	8.1±2.1	< 0.001
Average power (W)	36.3±2.6	29.8±1.7	< 0.001

- Dormant conduction (by Adenosine infusion at the end of the procedure) was not seen in any (0%) of the 35 pts (137 PV) in the study group. But in Controls, dormant conduction was unmasked in 5 of 35 pts (14%) and 5 /134 PV (3.7%) (p=0.024)
- Of the 35 patients in the study group, 23 pts (66%) underwent PV remapping at a mean of 128 ± 57 days post-ablation.
- PV reconnections were observed in 6/23 patients, or 9/89 individual PVs



35 patients

AF recurrence at 6 month follow up In 7/35 pts (20%)

19/20 PVs were electrically isolated (n=5)

Remapping study was not performed (n=2)

Conclusions

- This first-in-man series demonstrates that safe, rapid, durable PV isolation is achievable with this novel closed-loop temperature-controlled irrigated RF ablation catheter.

Disclosures: Dr. Reddy serves as a consultant to and has received research grant support from Advanced Cardiac Therapeutics, Inc. Dr. Neuzil has received research grant support from Advanced Cardiac Therapeutics, Inc.

Poster presented at the Heart Rhythm Society Meeting
May 2017, Chicago, IL

TRAC-AF

METHODS

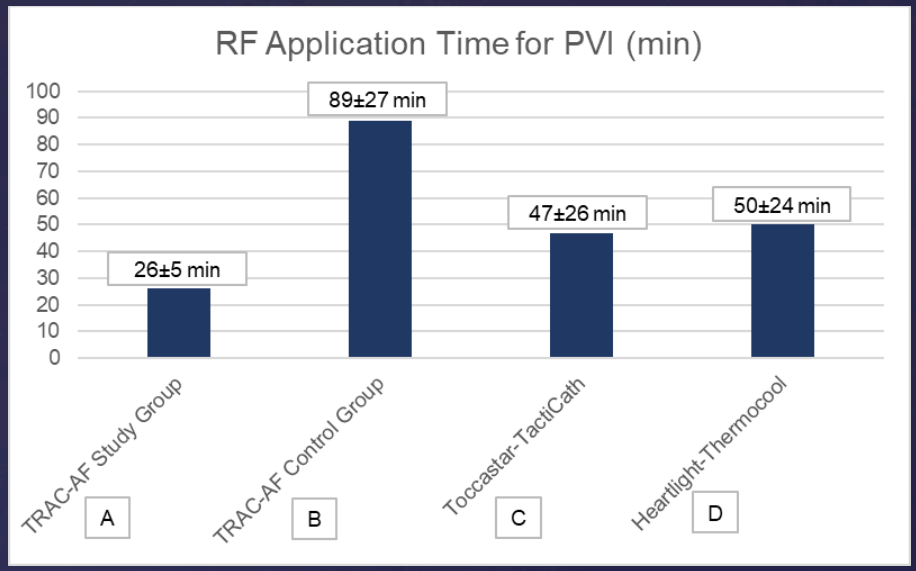
Pre-clinically, 6 pigs underwent temperature-controlled ablation (60°C/50 W) until ~80% electrogram amplitude reduction was observed.

For the single-center clinical feasibility study, 35 patients underwent PV isolation with the DiamondTemp catheter.

35 pts treated with a standard force-sensing catheter were considered the control group.

RESULTS

- In the pre-clinical porcine study, transmurality was observed in (92.7%) of the lesions.
- In the clinical study:
  - All PVs were successfully isolated without char or thrombus formation for either group; one pericardial effusion did occur in the DiamondTemp arm.
  - Significantly shorter RF application duration, fluoro time, and acute dormant PV reconduction were observed for the DiamondTemp group ($p < 0.001$, $p<0.001$, and $p=0.024$ respectively).
  - At 3 months, 84.8% of the PV pairs treated with the DiamondTemp catheter remained isolated.



Comparisons	Significance
A vs B	p<0.001
A vs C	p<0.001
A vs D	p<0.001

Image adapted from Iwasawa et al.[1]

CONCLUSION

Temperature-controlled irrigated ablation can produce rapid, efficient, and durable PV isolation.

[1]Iwasawa J, et al. Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With Atrial Fibrillation. *J Am Coll Cardiol*. 2017 Aug 1;70(5):542-553.

C-PO03-16 / C-PO03-16 - Temperature Controlled Irrigated RF Ablation: A Novel Approach to Create Rapid Transmural Atrial Lesions

May 11, 2017, 2:00 PM - 4:30 PM | EPicenter - Exhibit Hall

Authors

Jin Iwasawa, MD, Jacob S. Koruth, MD, Yoshinari Enomoto, MD, Subbarao Choudry, MD, William Whang, MD, Marc A. Miller, MD, Srinivas Dukkipati, MD and Vivek Y. Reddy, MD. Mount Sinai School of Medicine, New York, NY, Mount Sinai Hospital, New York, NY

Disclosures

J. Iwasawa: None. **J.S. Koruth:** I - Research Grants; **0**; ACT. **Y. Enomoto:** None. **S. Choudry:** None. **W. Whang:** None. **M.A. Miller:** None. **S. Dukkipati:** None. **V.Y. Reddy:** A - Compensation for Services; **2**; ACT. C - Equity Interests/Stock Options – Non-Public; **0**; ACT.

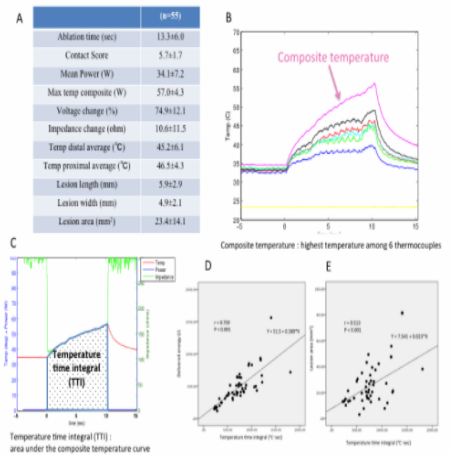
Abstract

Introduction: Saline irrigation revolutionized radiofrequency (RF) ablation by minimizing char, but complicated power titration. We investigated a novel RF catheter with: 1) a diamond embedded tip for rapid cooling by virtue of its high thermal diffusivity (irrigation at 8 ml/min), 2) 6 surface thermocouples to reflect tissue temp, thereby allowing 'temp-controlled' irrigated RF ablation, 3) a split tip for high resolution EGMs, and 4) bipolar impedance-based tissue contact assessment.

Methods: In 6 swine, *in vivo* atrial lesions were delivered in temp-control mode (60°C/50W) until 80% reduction in the EGM amplitude. Impedance, power, temp, duration, and contact (scale 0–9) were continually recorded.

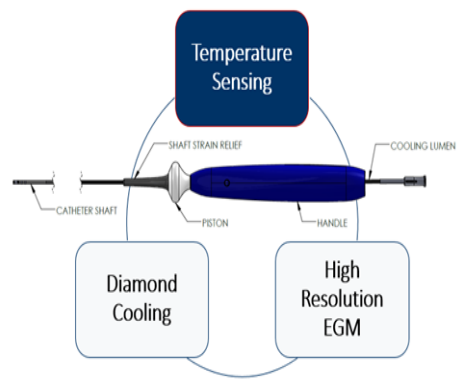
Results: Of 70 delivered lesions, histology was performed on 55 identified lesions. Transmurality occurred in 51/55 (93%) lesions with RF duration of only 13.3±6.0 sec (power 34.1±7.2W). The mean EGM reduction was 74.9±12.0%. The lesions measured 5.9±2.9 and 4.9±2.1 mm along the long and short axes. The contact score was 5.9±1.9 and the impedance drop was 10.6±11.5Ω. The highest recorded composite temp was 57.0±4.3°C (Panel B). When the temp time integral (TTI) was defined as the area under the composite temp curve (Panel C), significant correlation was seen between TTI and delivered energy ($r=0.759$, $p<0.001$) and between energy delivery and lesion area ($r=0.513$, $p<0.001$) (Panel D, E). No steam pops or char were observed.

Conclusion: This novel irrigated RF catheter allows for temp-controlled ablation to create adequate sized, predominantly transmural lesions in ~13s without steam pops or char formation.

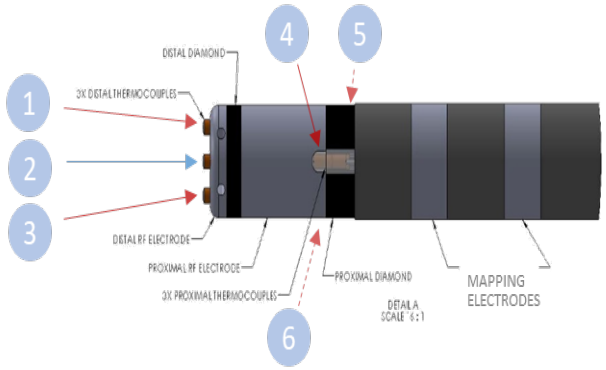


Temperature Sensing

Real-time and accurate tissue interface temperature recording

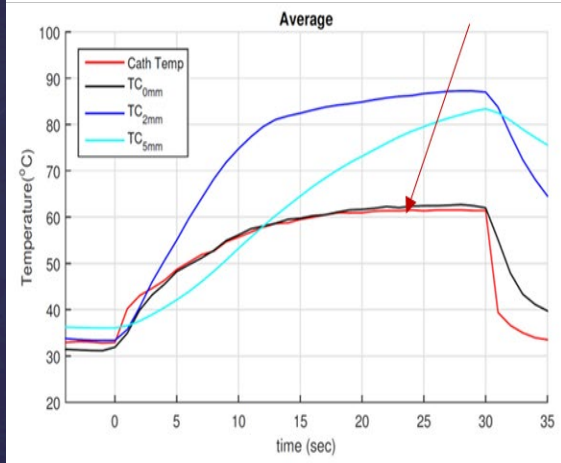


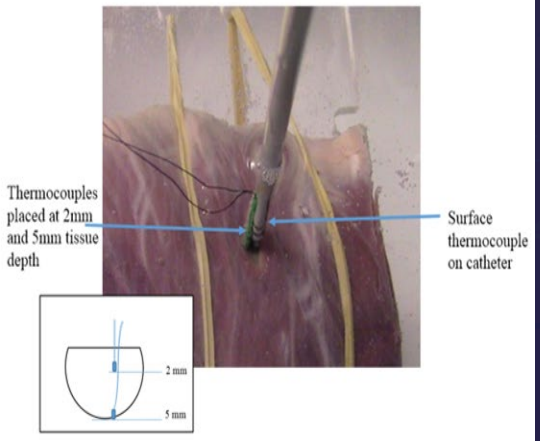
6 thermocouples equally, radially spaced



Thermocouples 5 and 6 not shown in image

Temperature recorded from sensor is the same as external thermocouples during RF ablation





- Temperature from each sensor sampled many times per second
- System continuously monitors highest sensor temperature and **automatically controls the power** to that temperature
- Controls temperature within a tight set range

C-PO05-139 / C-PO05-139 - Rapid pulmonary vein isolation using a novel diamond tip temperature controlled irrigated RF catheter: First-in-man Clinical Experience

May 12, 2017, 2:00 PM - 4:30 PM | EPicenter - Exhibit Hall

Authors

Jin Iwasawa, MD, Jacob S. Koruth, MD, Petr Neuzil, MD, PhD, Jan Petru, MD, Stepan Kralovec, No Degree, Srinivas Dukkipati, MD and Vivek Y. Reddy, MD. mountsinai medical center, New York, NY, Mount Sinai School of Medicine, New York, NY, Na Homolce Hospital, Prague 5, Czech Republic, Na Homolce Hospital, prague 5, Czech Republic

Disclosures

J. Iwasawa: None. **J.S. Koruth:** I - Research Grants; **0**; ACT. **P. Neuzil:** None. **J. Petru:** None. **S. Kralovec:** None. **S. Dukkipati:** None. **V.Y. Reddy:** A - Compensation for Services; **2**; ACT. C - Equity Interests/Stock Options – Non-Public; **0**; ACT.

Abstract

Introduction: A novel irrigated radiofrequency (RF) catheter with a diamond tip (high thermal diffusivity for rapid cooling) and 6 surface thermocouples (to reflect tissue temp) allows one to perform rapid temp-controlled irrigated ablation (DiamondTemp; ACT Inc). High resolution-EGMs from a split-tip electrode permits lesion assessment. We prospectively studied this catheter for pulmonary vein isolation (PVI). **Methods:** Atrial fibrillation (AF) pts (n=35, 24 men, 60±10 yrs) were enrolled at a single center (Grp1). Point-by-point PVI was performed in temp-control mode (60°C/50W) for an 80% reduction in the split-tip EGM amplitude. Outcomes were compared with a control group undergoing PVI with a Smartouch catheter (n=35; Grp2). At 3 months, pts underwent remapping to assess for PVI durability. **Results:** All PVs were successfully isolated in both groups. Mean RF time for PVI was reduced by 70% (26.5±5.2 vs 89.2±27.2 min; p<0.001), fluoroscopy times were shorter (11.2±8.5 vs 19.5±6.8 min; p<0.001), and dormant conduction rates were lower (0/35 vs 5/35 pts; p=0.024) in Grp 1 vs 2. There was one occurrence of pericardial effusion 8 hrs post-procedure and no occurrences of char, steam pop or embolism in Grp 1. Of pts undergoing remapping (23/35) at 128±57 days, durable PVI was present in 90% of PVs (80 of 89). At 3 months follow up, 7 of 35 (20%) pts had recurrent AF. These pts were remapped; 19 of 20 PVs were persistently isolated, indicating non-PV AF triggers. **Conclusion:** This first-in-man series demonstrates that safe, rapid, durable PVI is achievable with this novel temp-controlled irrigated RF ablation catheter.

	ACT (n=35)	Smart Touch (n=35)	P value
Left ablation point	37.9 ± 8.8	60.2 ± 18.2	< 0.001
Right ablation point	46.1 ± 9.5	91.3 ± 26.0	< 0.001
Total ablation point	83.6 ± 13.2	151.6 ± 38.2	< 0.001
Left RF application time per point (s)	17.6 ± 1.9	33.8 ± 5.4	< 0.001
Right RF application time per point (s)	19.7 ± 2.4	35.8 ± 4.2	< 0.001
Total RF application time per point (s)	18.8 ± 1.9	35.1 ± 4.1	< 0.001
Left RF application time (min)	11.2 ± 3.3	34.4 ± 13.1	< 0.001
Right RF application time (min)	15.1 ± 3.7	54.8 ± 17.9	< 0.001
Total RF application time (min)	26.3 ± 5.2	89.2 ± 27.2	< 0.001
Fluoroscopic time (min)	11.2 ± 8.5	19.5 ± 6.8	< 0.001
Average impedance drop (Ω)	8.1 ± 2.1	9.4 ± 2.5	0.028
Average power (W)	36.3 ± 2.6	31.2 ± 2.5	< 0.001

PO02-123 / PO02-123 - A novel RF ablation catheter design improves lesion formation and monitoring

May 5, 2016, 9:00 AM - 12:00 PM | EPicenter, Hall D

Authors

Boaz Avitall, MD, PHD, FHRS, Arthur A. Kalinski, BS, Raj Subramaniam, PhD, Joe Koblish, BS and Dorin Panescu, PhD. University of Illinois, Chicago, IL, Advanced Cardiac Therapeutics, Santa Clara, CA

Disclosures

B. Avitall: A - Compensation for Services; **1**; ACT. I - Research Grants; **4**; ACT. **A.A. Kalinski:** None. **R. Subramaniam:** K - Salary; **5**; ACT. **J. Koblish:** K - Salary; **5**; ACT. **D. Panescu:** K - Salary; **5**; ACT.

Abstract

Introduction: A novel Temperature Controlled Irrigation catheter (TCI) designed to provide high fidelity localized recording, increase accuracy of RF tip to tissue temperature (T) and high efficiency heat dissipation was tested vs. a standard 4mm irrigated tip ablation catheter (IT). The TCI ablation electrode is composed of an irrigated distal tip (1mm), 0.5mm space and high efficiency heat transfer proximal ring (3mm). Three T sensors are distributed around each electrode surface and the RF generator adjusts the power to the highest measured T.

Methods: RF lesions were placed in all heart chambers in 3 TCI and 6 IT canines. RF application time was titrated to maximal electrogram attenuation for TCI and 60 sec control used with the IT with irrigation flow TCI-8cc/min and IT-15cc/min. Pre/post ablation EGM, pacing threshold and complications such as char, tissue shredding and esophageal injury collected for each lesion. Following tetrazolium staining lesion dimensions and histology were done.

Results: TCI vs. IT generated the same or larger lesions in both the A and V with lower irrigation flow, higher power and true temperature settings, while titrating RF application time to max EGM reduction. The TCI catheter was more sensitive to lesion formation with significantly greater EGM reduction and pacing threshold increase. The TCI vs. IT had 1 vs. 4 lesions with char and no other complications noted.

Table: Results and Settings	Power (W)	Temp (°C)	RF Time (sec)	Length (mm)	Width (mm)	Depth (mm)	%EGM Δ	Pace TH mA
Atria								
TCI (N=30)	35.7±11	65	31±10	9.4±2.5	7.2±1.8	1.7±1	72±19	14.5±3.6
IT 60 sec (N=62)	30	33.9±1.7	60	7.1±2.4$	6.8±2.1NS	1.7±1NS	52±25$	4.7±3.6$
Ventricle								
TCI (N=11)	44.8±8	65	44±10	9.6±2.2	7.3±1.3	6.1±1.8	78±15	15.3±5
IT 60 sec (N=25)	30	34.1±1.6	60	7.7±1.5*	7.1±1.8NS	4.9±2.0NS	37±16$	2.1±2.4$

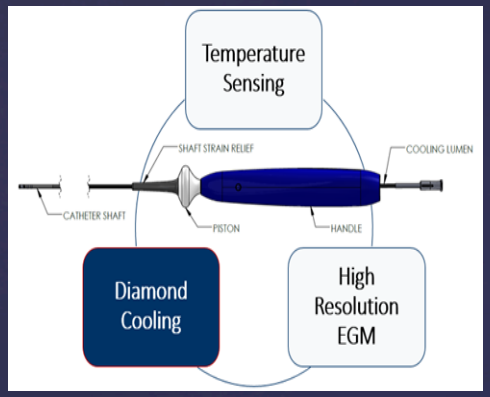
Statistics: IT vs. TCI: NS=p>0.05, *=p<0.05, #=p<0.01, $=p<0.001

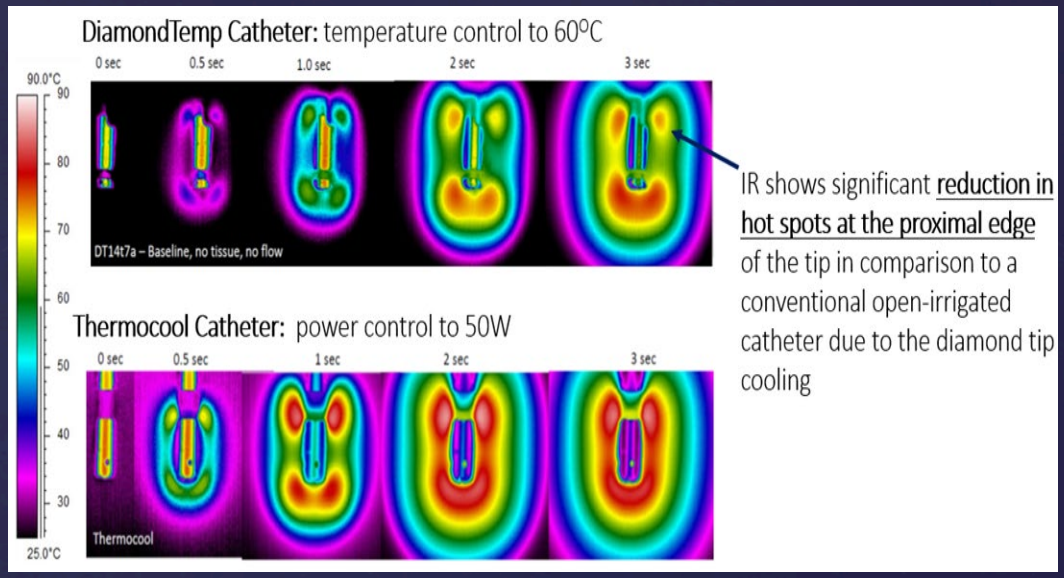
Conclusions: The TCI catheter vs. the IT provides:

1. Greater accuracy of tissue temperature recordings.
2. Safe lesion formation with less irrigation flow,
3. Improved assessment of lesion maturation using the EGM attenuation during RF application and pace threshold increase.

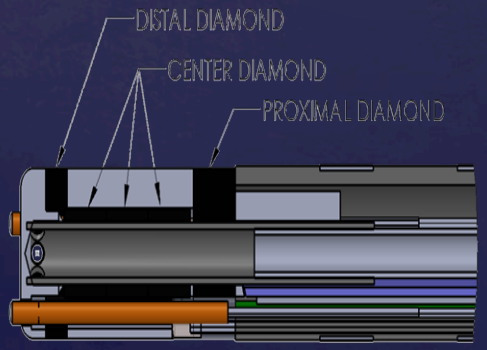
Diamond Cooling

As saline flows through the diamond network, very little heat is retained thereby reducing hotspots at catheter tip





Cross Section of Catheter Tip

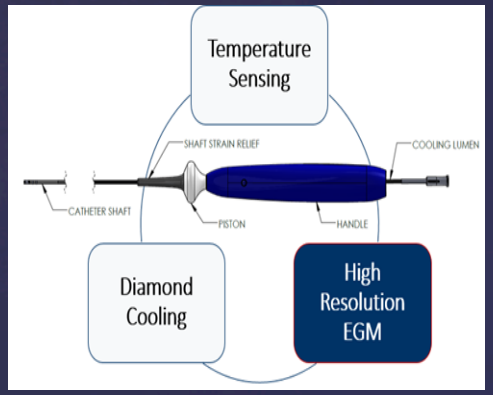


Platinum / Iridium Tip with Diamond Network

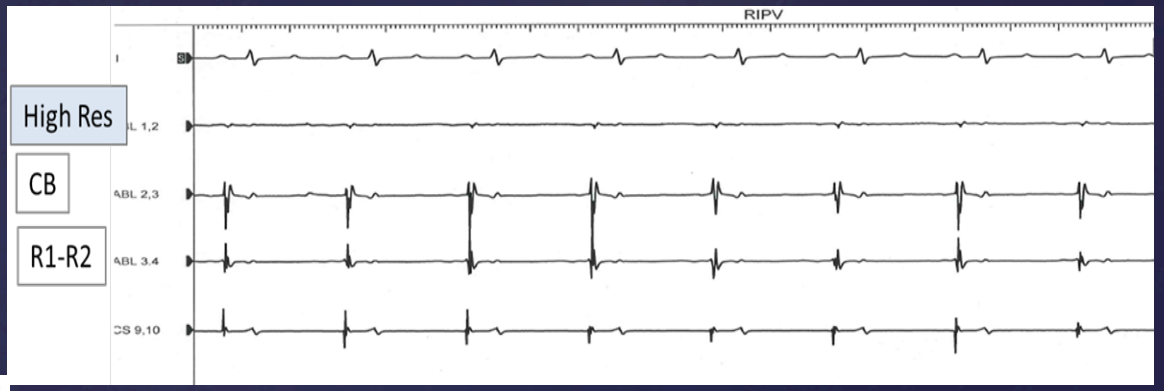
- Diamond network - **extremely high thermal diffusivity**
- Allows quick conduction of thermal energy through the **diamond shunt**

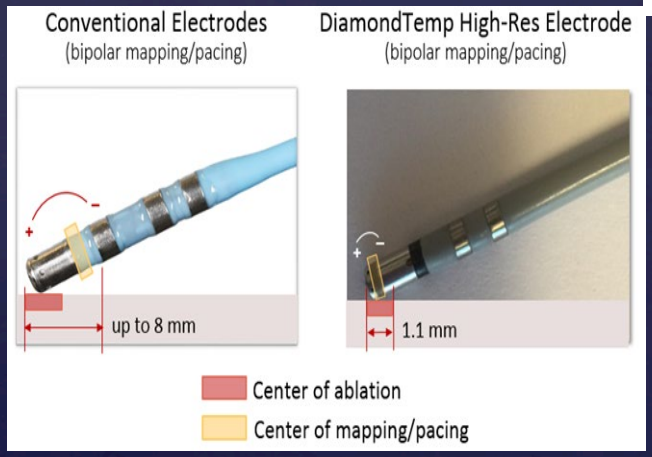
High Resolution Electrogram (HRE)

Novel tip design that allow for precise, localized, high resolution EGM recording



DiamondTemp Catheter placed just inside the RIPV





- **Note:** there is no signal on HRE

→ indicates tip is inside PV or not in left atrium

- In contrast, the common bipole shows a well-defined signal, falsely indicating tip is in left atrium which could lead to a lesion created unintentionally in PV

TRAC-AF

DiamondTemp TempeRAture-Controlled and Contact Sensing RF Ablation Clinical Trial for Atrial Fibrillation[1]

AIM

Evaluate the preclinical and clinical performance of the novel DiamondTemp Ablation System (EPIX Therapeutics, Sunnyvale, CA).

METHODS

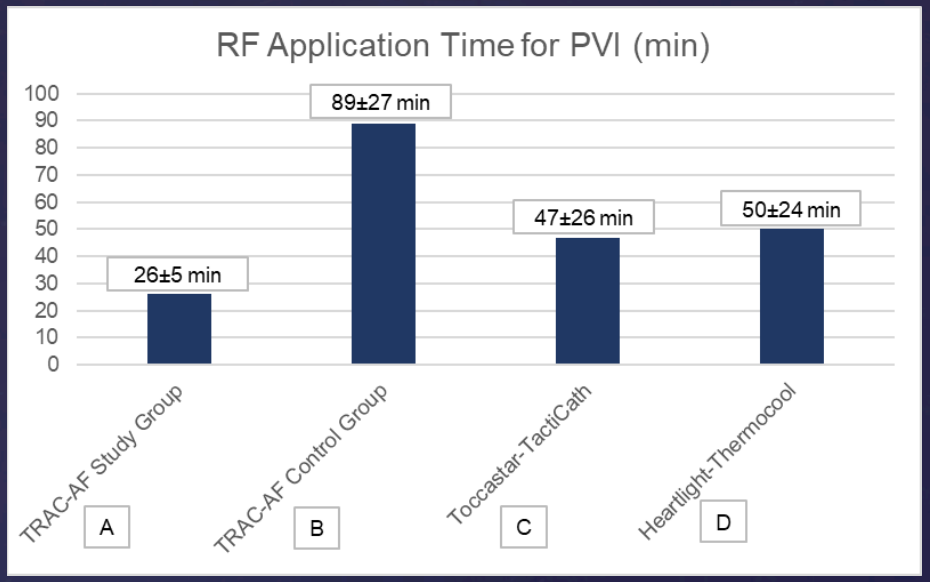
Pre-clinically, 6 pigs underwent temperature-controlled ablation (60°C/50 W) until ~80% electrogram amplitude reduction was observed.

For the single-center clinical feasibility study, 35 patients underwent PV isolation with the DiamondTemp catheter.

35 pts treated with a standard force-sensing catheter were considered the control group.

RESULTS

- In the pre-clinical porcine study, transmurality was observed in (92.7%) of the lesions.
- In the clinical study:
  - All PVs were successfully isolated without char or thrombus formation for either group; one pericardial effusion (etiology unknown) did occur in the DiamondTemp arm.
  - Significantly shorter RF application duration, fluoro time, and acute dormant PV reconduction were observed for the DiamondTemp group ($p < 0.001$, $p<0.001$, and $p=0.024$ respectively).
  - At 3 months, 84.8% of the PV pairs treated with the DiamondTemp catheter remained isolated.



Comparisons	Significance
A vs B	p<0.001
A vs C	p<0.001
A vs D	p<0.001

Image adapted from Iwasawa et al.[1]

CONCLUSION

Temperature-controlled irrigated ablation can produce rapid, efficient, and durable PV isolation.

[1]Iwasawa J, et al. Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With Atrial Fibrillation. *J Am Coll Cardiol*. 2017 Aug 1;70(5):542-553.

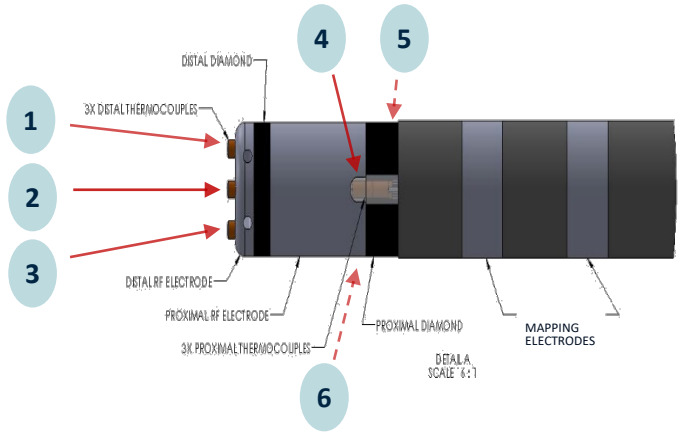
DiamondTemp™ Cardiac Ablation System

1. RF Generator
2. Irrigation Pump
3. Ablation Catheter
4. Catheter-to-RFG Cable (re-sterilizable 10x Autoclave)
5. GenConnect Cable
6. Irrigation Tubing Set

- Ablation duration determined by monitoring **temperature curve and localized, high resolution EGM**
- RF Generator **automatically adjusts power output** based on the temperature set-point
- **Compatible** with existing EP Cath-lab systems and with the EnSite™ Velocity™

Temperature-Controlled RF Ablation

Real-time temp monitoring for intelligent lesion formation



Thermocouples 5 and 6 not shown in image

6 thermocouples equally, radially spaced

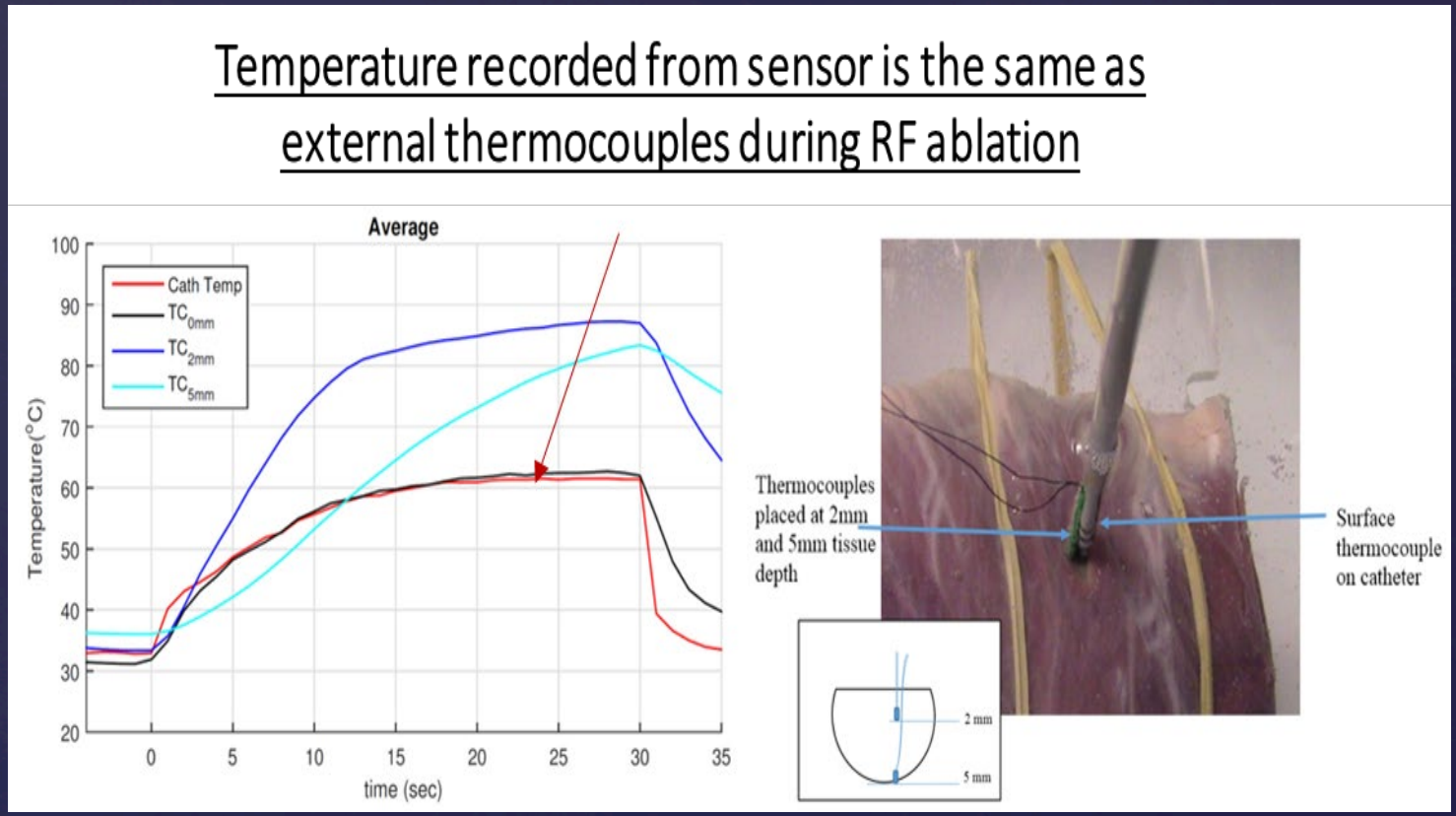
- System runs in temperature control mode
- Temperature from each sensor sampled every 20 milliseconds
- System continuously monitors highest sensor temperature and **automatically controls the power** to that temperature

Temperature provides direct feedback of lesion creation.
Irreversible tissue damage is created at **tissue temperatures >50°C**[1].

[1]Nath, S. et al. Basic Aspects of Radiofrequency Catheter Ablation. Journal of Cardiovascular Electrophysiology Vol. 5. No. 10. October 1994.

Temperature Sensing

Real-time and accurate tissue interface temperature recording



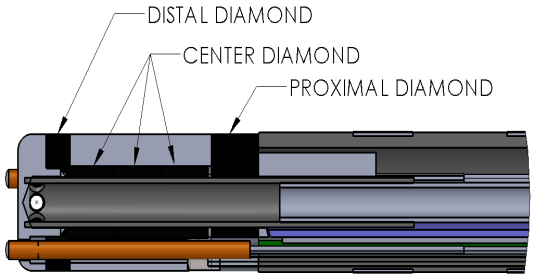
- Temperature from each sensor sampled many times per second
- System continuously monitors highest sensor temperature and **automatically controls the power** to that temperature
- Controls temperature within a tight set range

Topics

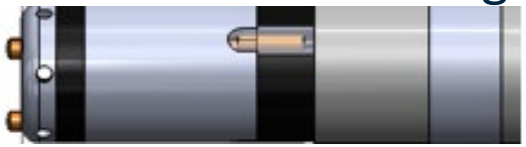
- Background
- Design Overview
  - Temperature Sensing
  - Diamond Cooling Mechanism
  - High Resolution EGMs
- Temperature vs Power Control in RF Ablation
- Clinical Relevance

DiamondTemp™ Cardiac Ablation System

Diamond Cooling Mechanism



Diamond Cooling



Thermal diffusivity of common EP Catheter RF Electrodes

Pt/Ir - 4.5 mm^2/s
Gold – 127 mm^2/s
Steel – 4.2 mm^2/s
CVD Diamond - 800 - 1800 mm^2/s

- The DiamondTemp Catheter tip is manufactured with platinum/iridium and diamond components
- A network of Chemical Vapor Deposit (CVD) industrial diamonds designed to act as heat shunting material
- Extremely high thermal diffusivity allows quick conduction of thermal energy through the diamond shunt network

Heat and cooling transfer is **200-400 times faster** with CVD diamond vs platinum/iridium[1].

[1]Brown; Marco (1958). Introduction to Heat Transfer (3rd ed.). McGraw-Hill. and Eckert; Drake (1959). Heat and Mass Transfer. McGraw-Hill. ISBN 978-0-89116-553-8. cited in Holman, J.P. (2002). Heat Transfer (9th ed.). McGraw-Hill. ISBN 978-0-07-029639-8.

Diamond AF1 (our experience)

	Tacticath	DiamondTemp
Patients	29	29
Age , % Male	66 ±9 (72%)	66 ±10 (52%)
PVI acute success	100 %	100 %
Epicardial effusion	2	2
Not drained	2	1
drained	0	1
Procedure duration (mins)	98,5 ±18	99,3 ±24
RF duration (mins)	22,3	15,8
Fluoro duration (mins)	8,3	11,3
LPVI duration (mins)	17,3 ±5	17,1 ±9
LPVI nb of applications	27	26
RPVI duration (mins)	19,2 ±5	18,3 ±5
RPVI nb of applications	35	33
Recurrence at 12 mths	4 (13%)	2 (7%)

Saline irrigation revolutionnized RF ablation by minimising char but it complicated power titration by inhibiting temperature feedback

Six thermocouples that reflect tissue temperature; allowing temp controlled irrigated ablation

Thermal feedback for energy titration
Small electrode improve assessement of lesion titration by ECG attenuation

Split tip irrigated catheter

Diamond embedded tip for Rapid cooling by virtue of its high thermal diffusivity

A Novel RF Ablation Catheter Design Improves Lesion Formation and Monitoring

Boaz Avitall[1], MD, PHD, FHRS , Arthur Kalinski[1],BS, Raj Subramaniam[2], PhD, Joe Koblish[2] , BS, and Dorin Panescu, PhD. [2]
University of Illinois at Chicago, Chicago, IL[1] Advanced Cardiac Therapeutics, Santa Clara, CA[2]

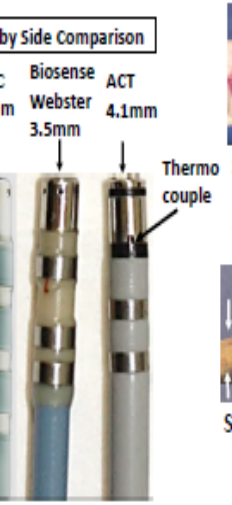
Introduction

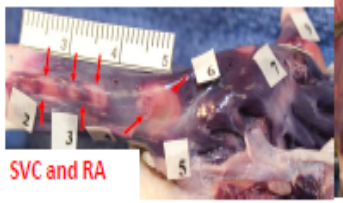
p irrigated RF ablation catheter (STI) designed to provide high
d recording, increase accuracy of RF tip to tissue temperature
fficiency heat dissipation. The STI catheter was tested vs. a
irrigated tip ablation catheter (IT).
n electrode is composed two electrodes. Irrigated distal tip
0.5mm space and high efficiency heat transfer proximal ring
T sensors are distributed around each electrode surface and
or adjusts the power to the highest measured T.

Methods

ere placed in both atria and ventricles in 3 STI and 6 IT canines.
lesions were done with the STI catheter with 77 lesions for IT
pplication time was titrated to maximal electrogram
for STI. Maximal attenuation was determined as the point
mplitudes decreased no further. A 60 sec. control was used
or comparison.
w was STI-8cc/min vs. IT-15cc/min. Pre/post ablation EGM,
hold and complications such as char, tissue shredding and
injury collected for each lesion. The tissues were stained with
blue, width, length and depth were measured.

Lesion and Catheter Pictures

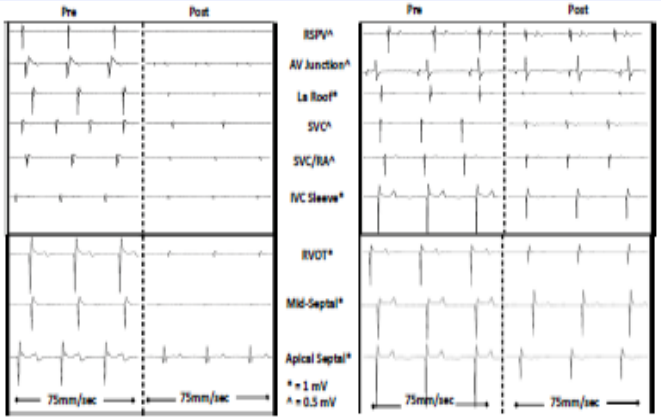




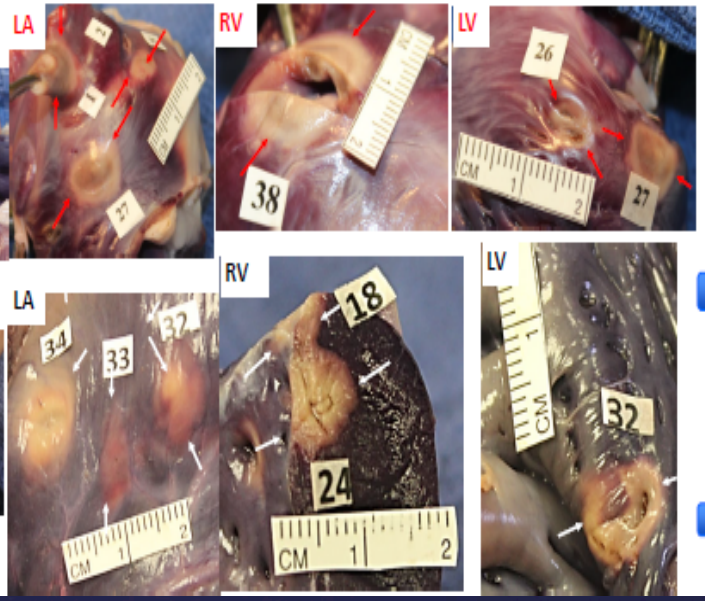
Split Tip Irrigated Catheter

4mm Irrigated Catheter

Split Tip Irrigated Catheter (STI) 4mm Irrigated Tip (TI)



The panels above are pre/post EGM amplitude with each catheter showing dramatic EGM reduction with STI vs. TI catheter. The panels below are the lesion generated with each catheter (red arrows STI white IT).



RF Parameters and Lesion Characteristics

Table 1	Power (W)	Temp (°C)	RF Time (sec)	Length (mm)	Width (mm)	Depth (mm)	%EGM Δ	Pace TH mA
Atria								
STI (N=30)	35.7±11	65	31±10	9.4±2.5	7.2±1.8	1.7±1	72±19	14.3±3.6
IT 60 sec (N=62)	30	33.9±1.7	60	7.1±2.4$	6.8±2.1^{NS}	1.7±1^{NS}	52±25$	4.7±3.6$
Ventricle								
STI (N=11)	44.8±8	65	44±10	9.6±2.2	7.3±1.3	6.1±1.8	78±15	15.3±5
IT 60 sec (N=25)	30	34.1±1.6	60	7.7±1.5*	7.1±1.8^{NS}	4.9±2.0^{NS}	37±16$	2.1±2.4$

Statistics: IT vs. STI: NS=p>0.05, *=p<0.05, #=p<0.01, $=p<0.001

Results

- The Split Tip Irrigated catheter (STI) vs. the traditional Irrigated tip (IT) generated the same or larger lesions in both the atria and ventricles with lower irrigation flow, higher power and true temperature settings, while titrating RF application time.
- Electrodes provided high fidelity recordings that are sensitive to localized tissue EGMs.
- The STI catheter was more sensitive to lesion formation with significantly greater EGM reduction and pacing threshold increase when compared to standard 4.5mm irrigated tips.
- The STI vs. IT had 1 vs. 4 lesions with char and no other complications noted.

Conclusion

The STI catheter vs. the IT provides:

1. Greater accuracy of tissue temperature recordings.
2. Safe and effective lesion formation with less irrigation flow.
3. Improved assessment of lesion maturation and titration using the EGM attenuation during RF application.

Disclosures

Financial Support for this research was provided by Advanced Cardiac Therapeutics. Dr. Avitall is a consultant to ACT: Raj Subramaniam, Joe Koblish, and Dorin Panescu are employees of ACT

Poster presented at the Heart Rhythm Society MeetingMay 2016, San Francisco, CA

High Resolution Electrogram (HRE)

Novel tip design that allow for precise, localized, high resolution EGM recording

Comparison of 2 catheters (DT and CB) placed just inside the RIPV

- There is no signal on HRE → indicates tip is inside PV (not in LA)
- In contrast, the common bipole shows a well-defined signal,
  falsely indicating tip is in LA , which could lead to a lesion created unintentionally in PV

Study	**TRAC-AF**
Indication	Paroxysmal Atrial Fibrillation
Study Design	Prospective, single-arm, multi-center, non-blinded, feasibility study
Objective	Demonstrate safety/effectiveness of the DiamondTemp Ablation System for the treatment of paroxysmal AF
Primary Endpoint	• Safety: Serious adverse events through 30 days • Effectiveness: Acute pulmonary vein isolation (PVI)
Total Subjects	70 patients (35 pts DT, 35 pts control group)
Investigators	Petr Neuzil, (Na Homolce, Prague, CZ), Vivek Reddy

Primary effectiveness endpoint was achieved in all 70 subjects (100%) through the demonstration of PVI and confirmation 20 minutes after the last delivery of RF.

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

Jin Iwasawa, MD,[a] Jacob S. Koruth, MD,[a] Jan Petru, MD,[b] Libor Dujka, MD,[b] Stepan Kralovec,[b] Katerina Mzourkova,[b] Srinivas R. Dukkipati, MD,[a] Petr Neuzil, MD, PhD,[b] Vivek Y. Reddy, MD[a,b]

ABSTRACT

BACKGROUND Saline irrigation improved the safety of radiofrequency (RF) ablation, but the thermal feedback for energy titration is absent.

OBJECTIVES To allow temperature-controlled irrigated ablation, a novel irrigated RF catheter was designed with a diamond-embedded tip (for rapid cooling) and 6 surface thermocouples to reflect tissue temperature. High-resolution electrograms (EGMs) from the split-tip electrode allowed rapid lesion assessment. The authors evaluated the preclinical and clinical performance of this catheter for pulmonary vein (PV) isolation.

METHODS Using the DiamondTemp (DT) catheter, pigs (n = 6) underwent discrete atrial ablation in a temperature control mode (60°C/50 W) until there was ~80% EGM amplitude reduction. In a single-center clinical feasibility study, 35 patients underwent PV isolation with the DT catheter (study group); patients were planned for PV remapping after 3 months, regardless of symptomatology. A control group included 35 patients who underwent PV isolation with a standard force-sensing catheter.

RESULTS Porcine lesion histology revealed transmurality in 51 of 55 lesions (92.7%). In patients, all PVs were successfully isolated; no char or thrombus formation was observed. Compared with the control group, the study cohort had shorter mean RF application duration (26.3 ± 5.2 min vs. 89.2 ± 27.2 min; $p < 0.001$), shorter mean fluoroscopic time (11.2 ± 8.5 min vs. 19.5 ± 6.8 min; $p < 0.001$), and lower acute dormant PV reconduction (0 of 35 vs. 5 of 35; $p = 0.024$). At 3 months, 23 patients underwent remapping: 39 of 46 PV pairs (84.8%) remained durably isolated in 17 of these patients (73.9%).

CONCLUSIONS This first-in-human series demonstrated that temperature-controlled irrigated ablation produced rapid, efficient, and durable PV isolation. (ACT DiamondTemp Temperature-Controlled and Contact Sensing RF Ablation Clinical Trial for Atrial Fibrillation [TRAC-AF]; NCT02821351) (J Am Coll Cardiol 2017;70:542-53)

Iwasawa, J. et. al. Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients with Atrial Fibrillation. JACC. 2017 70(5):542-53

FASTR-AF

Evaluation of the Safety Profile of the DiamondTemp™ System for Fast Treatment of Patients With Atrial Fibrillation

The FASTR RF Generator utilizes a faster power ramp to reach tissue temperature faster

Prospective, single-arm trial performed at multiple centers in Europe, designed to demonstrate the feasibility of the FASTR-RF Generator.

RESULTS[1]

- patients with paroxysmal (n=33) or persistent (n=27) AF have been followed 6 months post-ablation
- Mean RF time for the paroxysmal and persistent pts were 9.4 (±3.0) and 19.1 (±9.2) mins, respectively.

ACUTE PROCEDURE RESULTS[1]

	Paroxysmal (N=33)	Persistent (N=27)
RF Applications (PVI + Linear/Substrate)	56.2 ± 22.1	95.6 ± 45.6
Total RF Time (min)	9.4 ± 3.0	19.1 ± 9.2
Ave. Ablation Duration (sec)	10.8 ± 3.5	12.3 ± 3.7
Ave. Power (W)	47.3 ± 3.1	47.9 ± 2.6
Ave. Temperature (°C)	50.8 ± 3.0	51.7 ± 3.4
Fluid Infused (mL)	196.8 ± 51.2	321.8 ± 149
Procedure Time (h:mm)	1:41 ± 0:32	2:07 ± 0:32
Fluoro Time (min)	9.1 ± 5.3	10.9 ± 6.2*

CONCLUSION[1]
safety profile and procedural effectiveness of the novel temperature-controlled DiamondTemp Ablation System with a FASTR generator for the treatment of paroxysmal and persistent AF.

[1]Neužil et al. First-in-Man FASTR-AF Study: Novel Temperature-Controlled FAST Ablation System to Rapidly Create Lesions for the Treatment of Persistent and Paroxysmal Atrial Fibrillation. HRS Scientific Sessions, 2019.

Diamond AF1 (Clinique du Tonkin experience)

	Tacticath	DiamondTemp
Patients	29	29
Age , % Male	66 ±9 (72%)	66 ±10 (52%)
PVI acute success	100 %	100 %
Pericardial effusion	2	2
Not drained	2	1
drained	0	1
Procedure duration (mins)	98,5 ±18	99,3 ±24
RF duration (mins)	22,3	15,8
Fluoro duration (mins)	8,3	11,3
LPVI duration (mins)	17,3 ±5	17,1 ±9
LPVI nb of applications	27	26
RPVI duration (mins)	19,2 ±5	18,3 ±5
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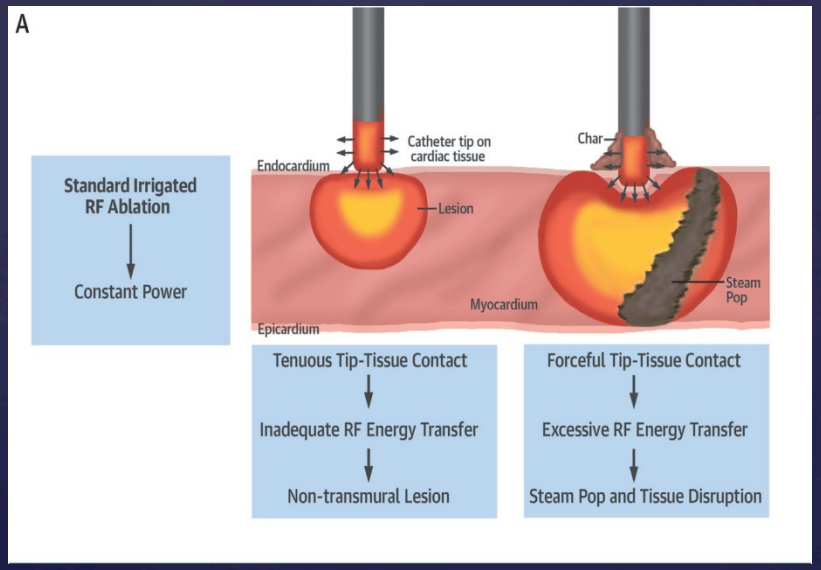
DIAMOND TEMP Catheter

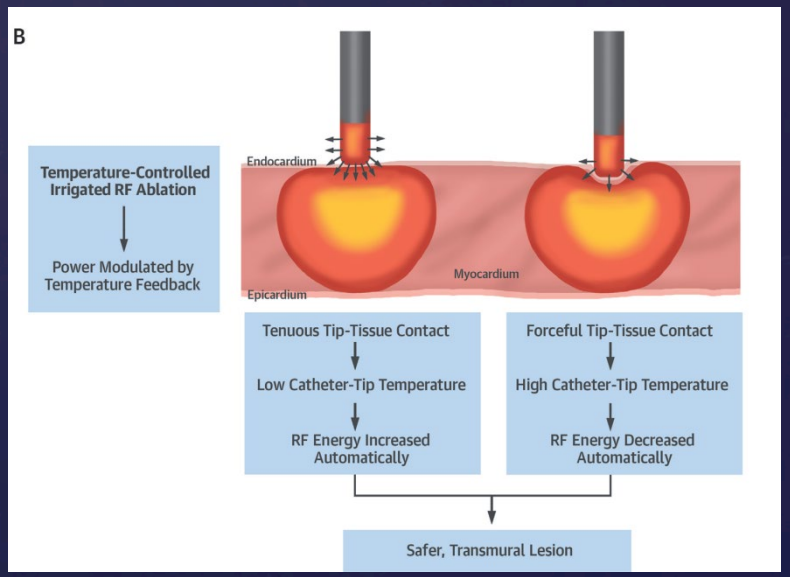
Hervé POTY
ADRIS - LYON

Background

Saline irrigation revolutionnized RF ablation by minimising char ,
but it complicated power titration by inhibiting Temperature feedback
Irrigated RF ablation is delivered in a power mode
Point by point PVI is challenging by rapid Balloon Procedure

<u>Comparison of a Power mode and Temperature mode</u>
(IWASAWA JACC 2017, 70 ; 5 : 542-53)





Temperature feedback loop appears essential for power titration to produce safe and transmural lesion

DIAMOND TEMP ABLATION CATHETER

- Background
- Design Overview
  - Temperature Sensing
  - Diamond Cooling Mechanism
  - High Resolution EGMs
- Clinical Relevance

  - Temperature vs Power Control in RF Ablation
  - Clinique du Tonkin Experience

DIAMOND AF Study

	DIAMOND-AF	DIAMOND-AF II
Patient Population	Paroxysmal Atrial Fibrillation	Persistent Atrial Fibrillation
Design	480 subjects, randomized 1:1 vs TactiCath™ Quartz Contact Force Ablation Catheter (Abbott)	300 subjects, single arm
Status	Active, enrollment complete	Active, enrolling
Objectives	Establish the safety and effectiveness of the DiamondTemp System for the treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation in patients.	Establish the safety and effectiveness of the DiamondTemp Ablation System for the treatment of drug refractory, symptomatic persistent atrial fibrillation in patients.

DIAMOND AF Studies

	DIAMOND-AF	DIAMOND-AF II
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