ADVANCES IN CARDIAC ELECTROPHYSIOLOGY

PVI with multielectrode RF catheter: long term outcome of the PVAC GOLD catheter

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di rilievo nazionale ad alta specializzazione

PHASED RF TECHNOLOGY

ContactIQ

effective contact = f (power + temperature)

Next Generation PVAC®

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GENius Contact IQ®

- **ContactIQ®** provides precise management of power and temperature to simplify decision-making and ablation effectiveness assessment
- **Effective contact** displayed by target temperature and power >3W - Green bars
- **Only effective contact** (heating time) per electrode **displayed**

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New User Interface Enhances Decision Making

- *De Greef et al* have demonstrated that good power and good temperature produces effective lesions[1]
- New ContactIQ user interface highlights electrodes with both good power and good temperature
- Users' impressions of the new user interface have been strong. According to a recent survey,

Green Bar
50 - 65°C +
Power ≥ 3W

Yellow Bar/Black Box
50 - 65°C + Power
< 3W

Yellow Bar/ White Box
< 50°C

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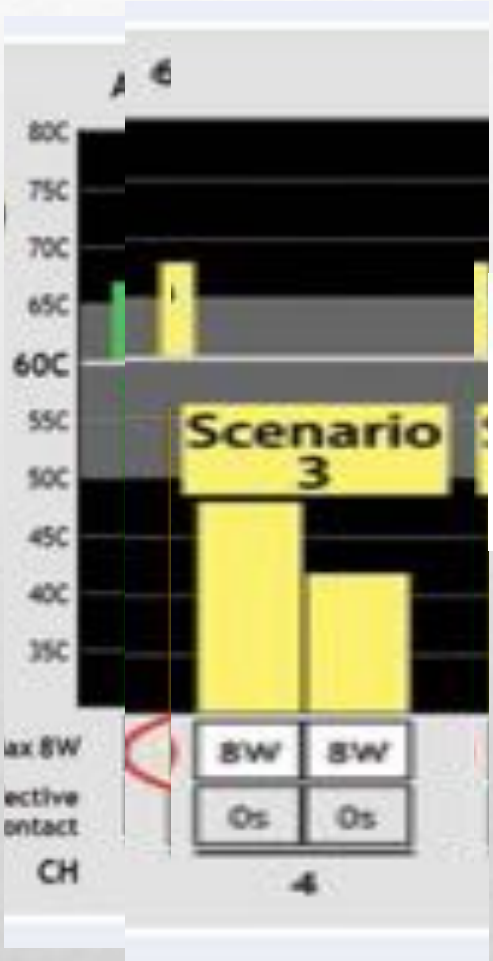
De Greef Y, Tavernier R, Schwagten B, De Keulenaer G, Stockman D, Duytschaever.
Impact of Radio-Frequency Characteristics on Acute Pulmonary Vein Reconnection and Clinical Outcome after PVAC Ablation. J Cardiovasc Electrophysiol. 20 Sept 2012

New User Interface Enhances Decision Making



Scenario 3: **INEFFECTIVE** Lesion Creation: **Low/No Contact**

- Yellow bars < 45 °C suggest tissue contact is minimal
- Max power delivery of 8 W suggests **Limited Tissue Contact**
- Gently **INCREASING** contact pressure may increase temperature to green range

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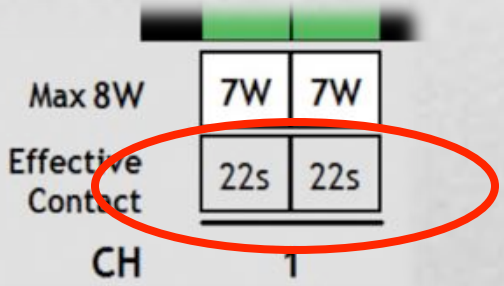
GENius Contact IQ®

Temp. > 48°c + power > 3W = enhance long term outcome (LESION)

Effective contact = green bar

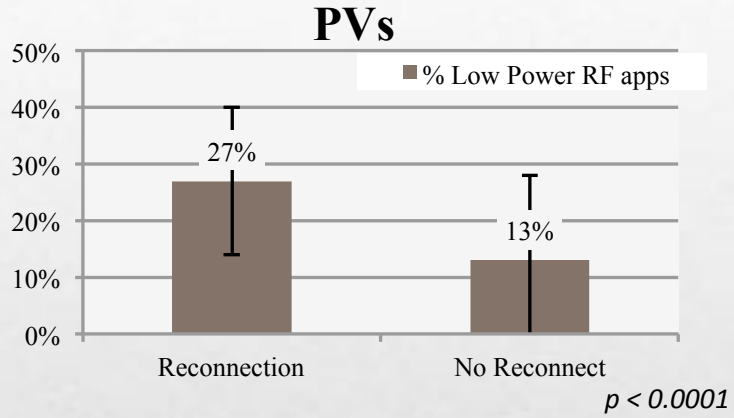


99% ppv for making lesion with 30 sds. of effective contact

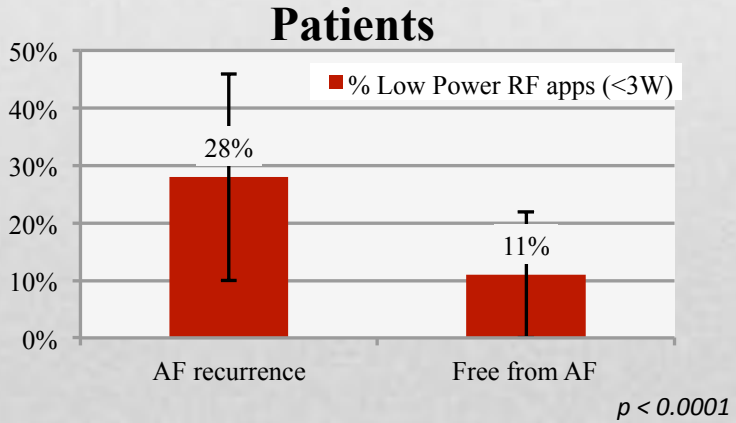
[1] De Greef Y et al. Impact of radiofrequency characteristics on acute pulmonary vein reconnection and clinical outcome following PVAC ablation. doi:10.1111/jce.12021

Contact Recognition Improves Outcomes
Combination of power and temperature is predictive of outcomes

PV Isolation after 1hr & Adenosine Challenge	% Low Power RF apps (>48°, <3W)
Reconnection	27% ± 13%
No Reconnection	13% ± 15%



Patient Outcome @ 12 months (n=80)	% Low Power RF apps (>48°, <3W)
AF recurrence	28% ± 18%
Free from AF	11% ± 11%



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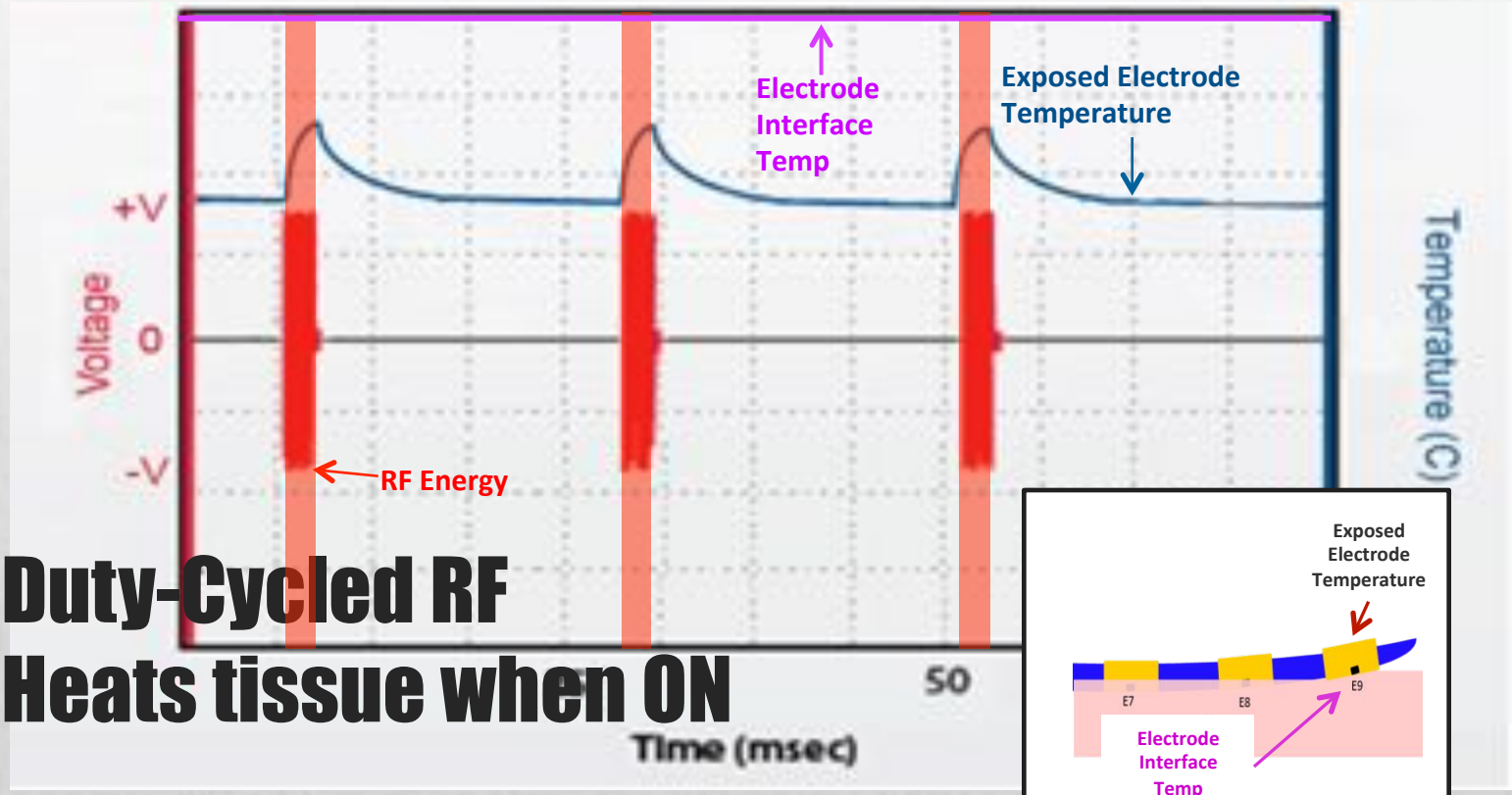
De Greef Y; Tavernier R; Schwagten B; De Keulenaer G; Stockman D; Duytschaever. Impact of Radio-Frequency Characteristics on Acute Pulmonary Vein Reconnection and Clinical Outcome after PVAC Ablation. *O007*. PACE, 2011; Vol 34: 1309-1310.

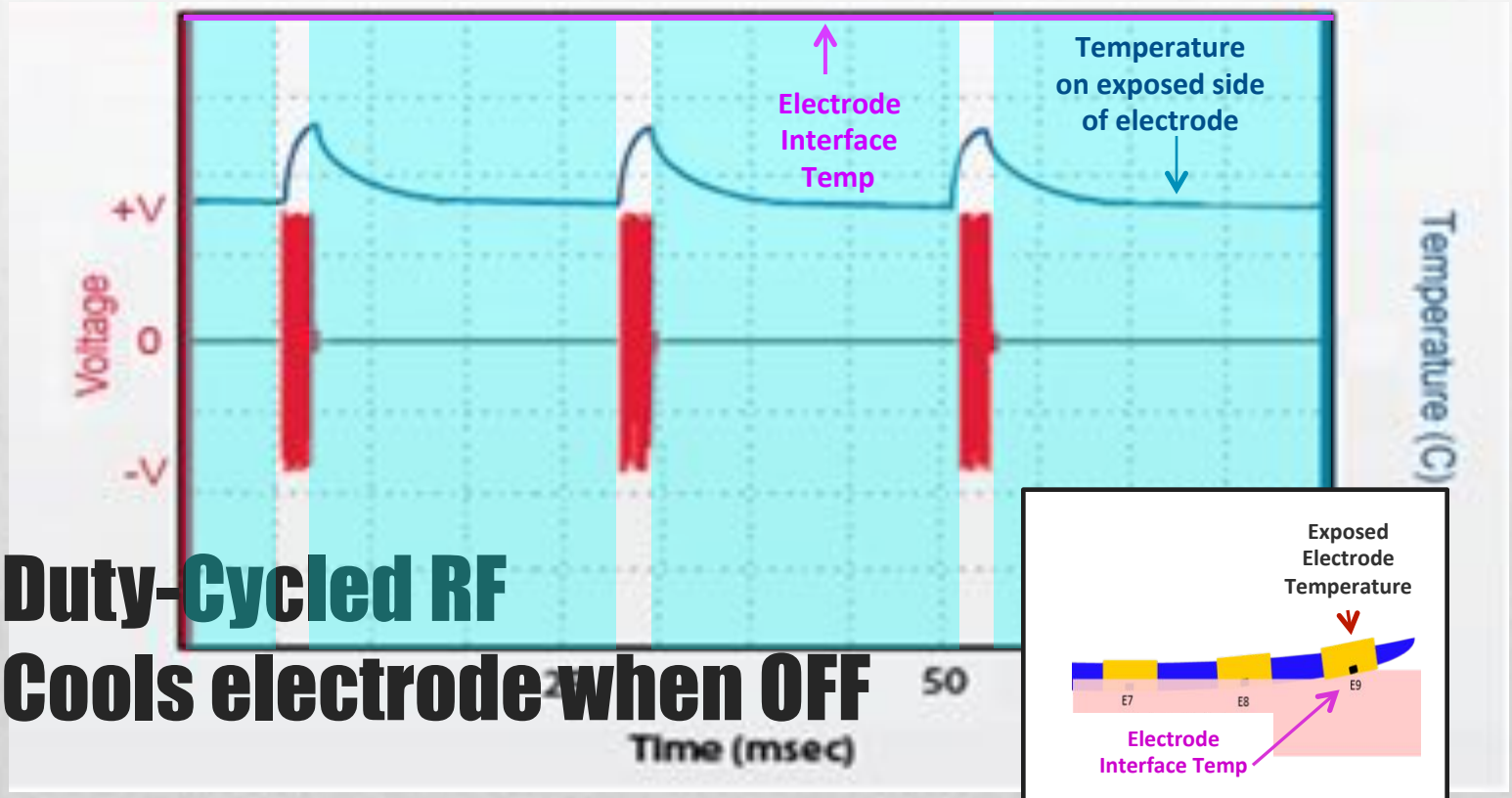
** Note: data shown is the average Temp & Power during ablation duration*

RF ‘ON’ – Electrode Delivers Current, Tissue Heats



Duty-Cycled RF
Heats tissue when ON

RF ‘OFF’ – Electrode Cooling Pulls Heat from Surface, Tissue at Depth Holds and Conducts Heat

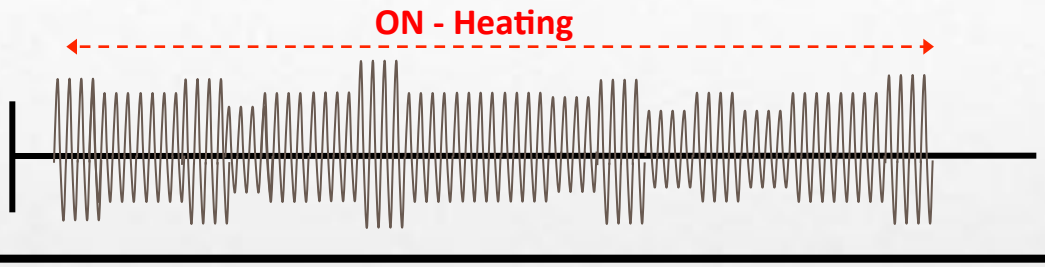


Duty-Cycled RF
Cools electrode when OFF

RF Power Delivery

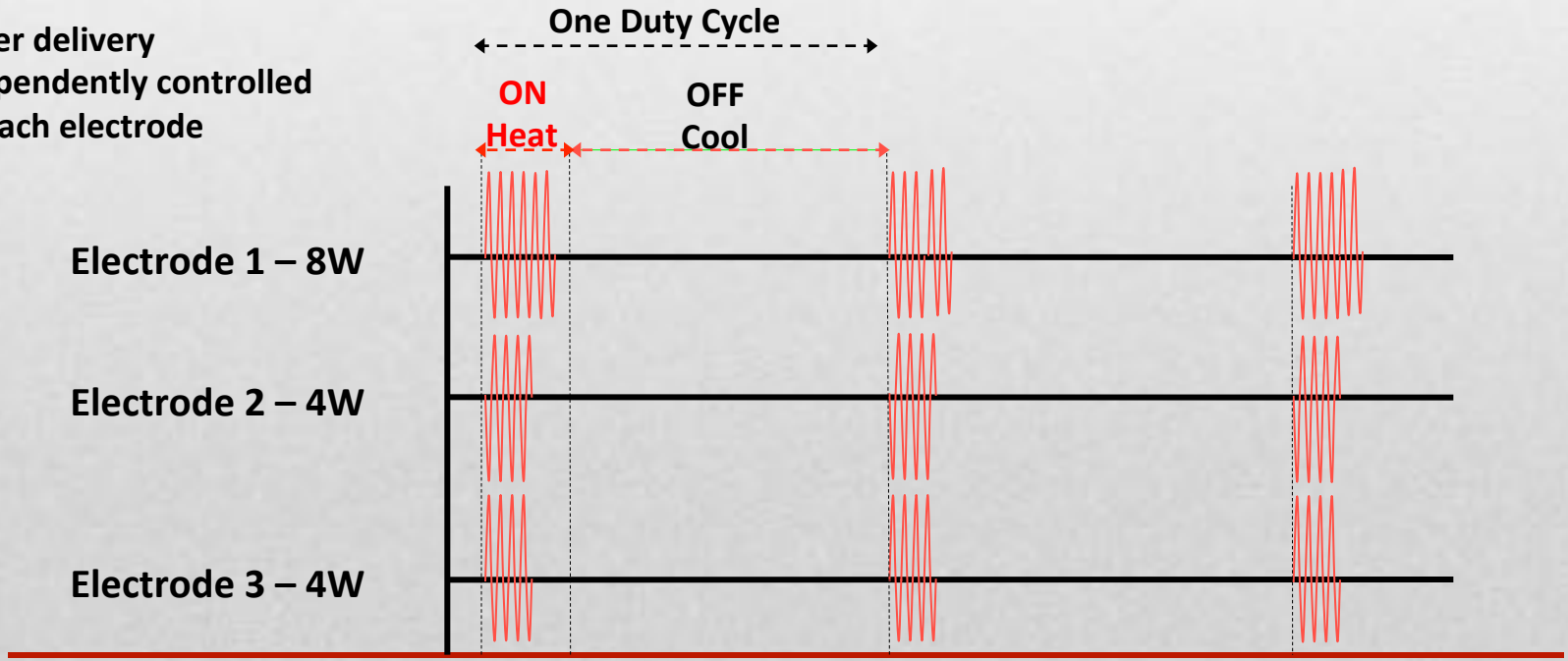
Duty-Cycled vs. Conventional

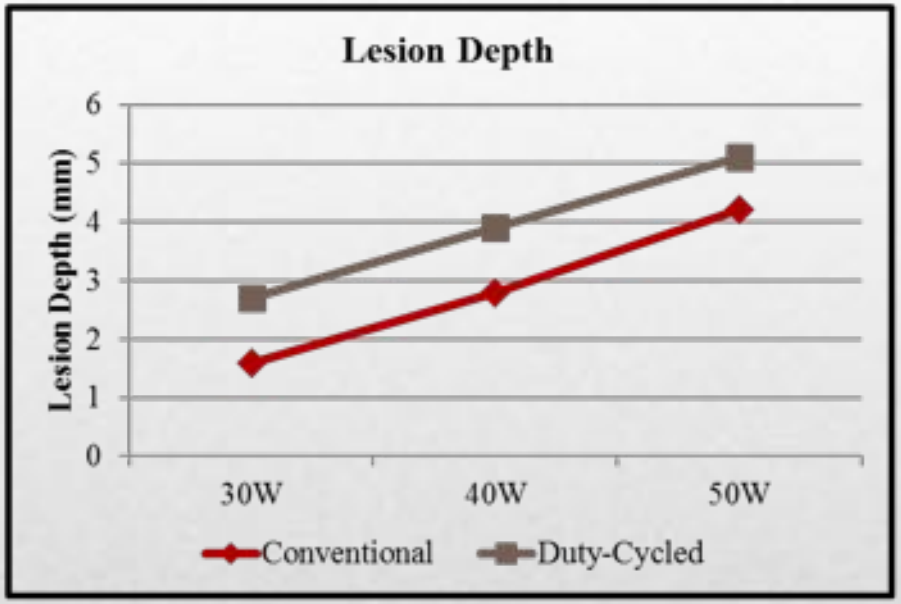
Conventional RF

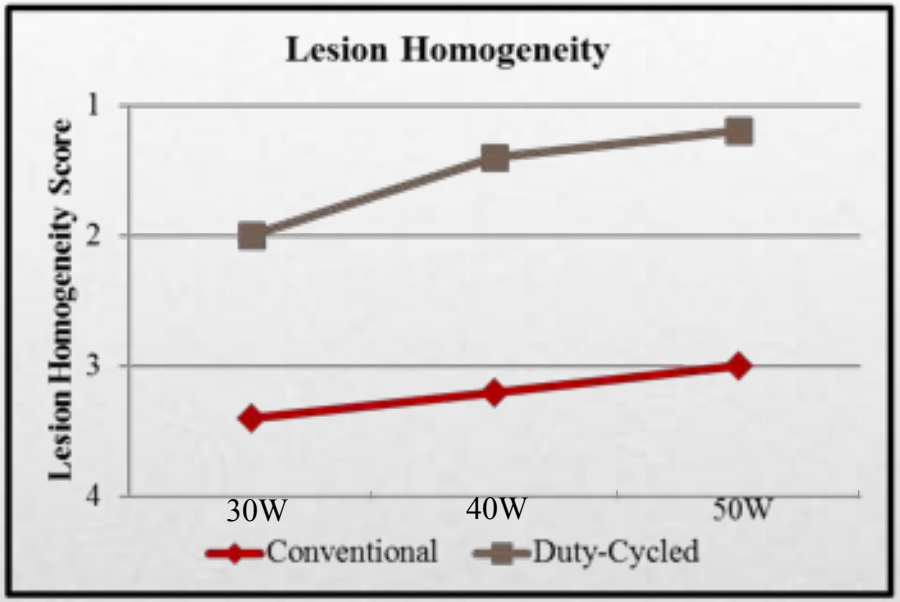


Duty-Cycled RF

Power delivery independently controlled for each electrode







Score 1: Smooth borderline to tissue without fluctuation in depth
Score 4: Lack of continuity with gaps

- Myocardial tissue has a high thermic storage capacity requiring 3 times as much time to cool as it does to heat from RF energy
- Electrodes can be OFF without tissue losing enough heat to affect lesion size and shape

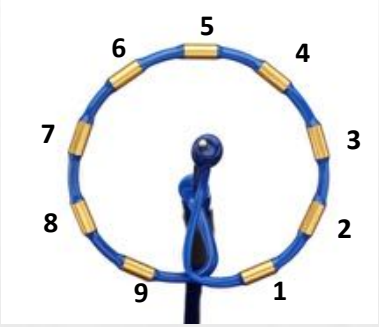
Duty-Cycled Energy Creates Deeper, More Homogenous Lesions

Adapted from Erdogan A et al. *Homogeneity and diameter of linear lesions induced with multipolar ablation catheters: In vitro and in vivo comparison of Pulsed vs continuous radiofrequency energy delivery.* JICE 4, 655-661 (2000)

PVAC GOLD

- Eliminate 1:10 electrode interaction
- Gold thermal conductivity (4x greater than platinum) allows more uniform heating and faster cooling than platinum providing precise temperature control across the electrode
- Improved uniformity of electrode contact force
- Over-the-wire design provides stability in all anatomies

Gold



9 Electrodes

3.75mm Spacing

20° Forward Tilt

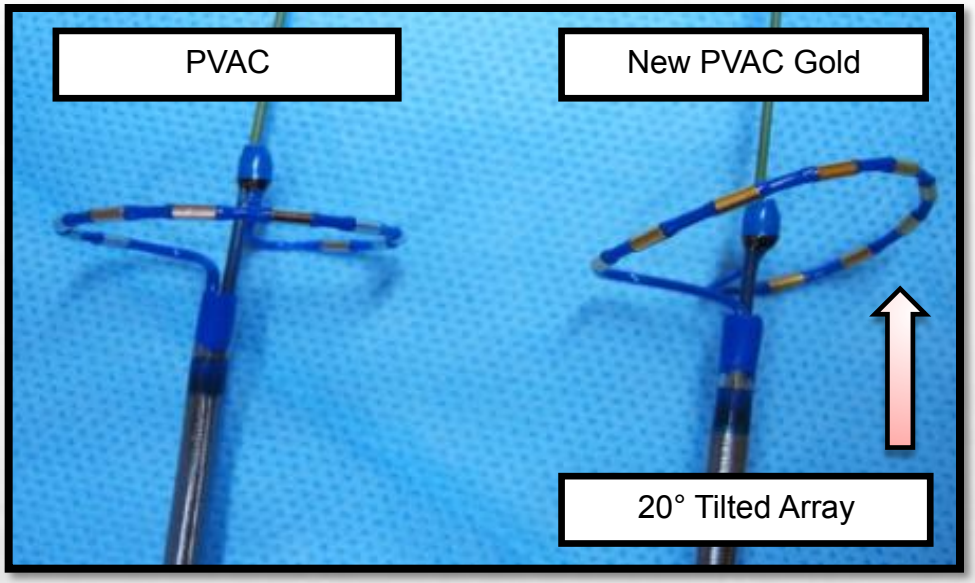
Platinum

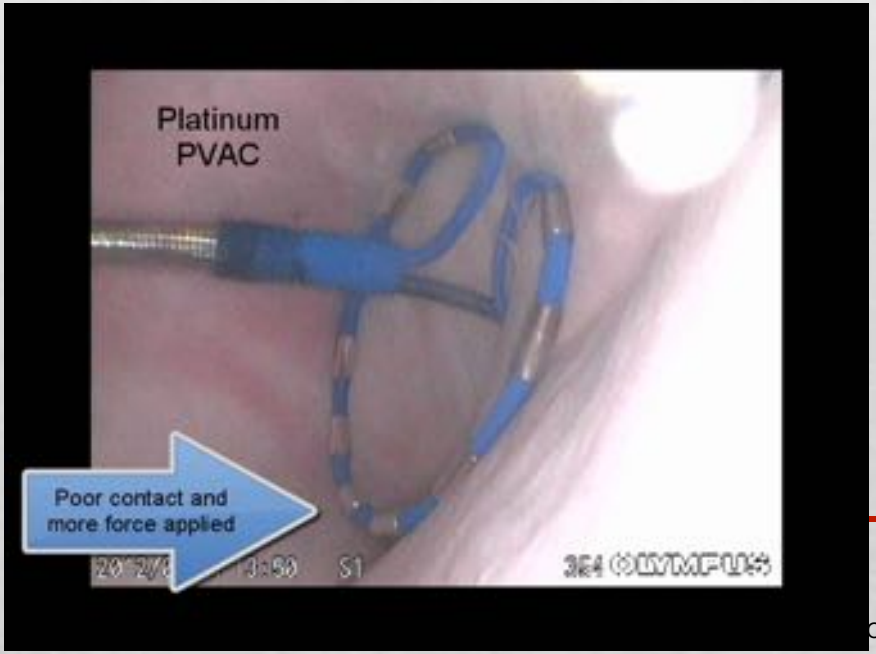
10 Electrodes

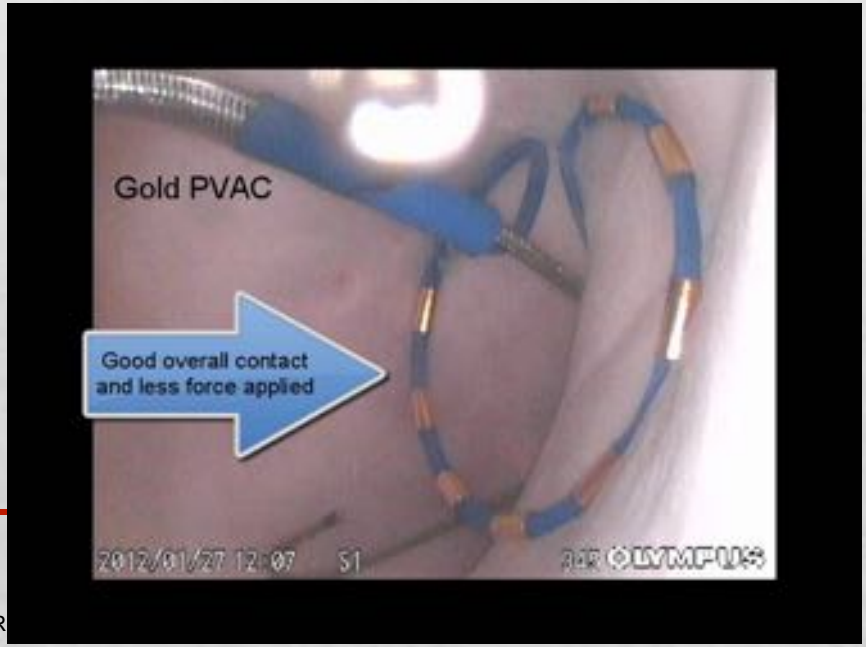
3mm Spacing

Perpendicular

Next Generation PVAC®







Comparison of Gold Versus Platinum Electrodes on Myocardial Lesion Size Using Radiofrequency Energy

WALTER N. SIMMONS, SEAN MACKEY, DING SHENG HE, and FRANK I. MARCUS

From the Cardiology Section, Department of Medicine, and the Department of Electrical and Computer Engineering, University of Arizona, College of Medicine, Tucson, Arizona

(PACE 1996; 19[Pt. I]:398–402)

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Platinum 71 $\frac{W}{mK}$

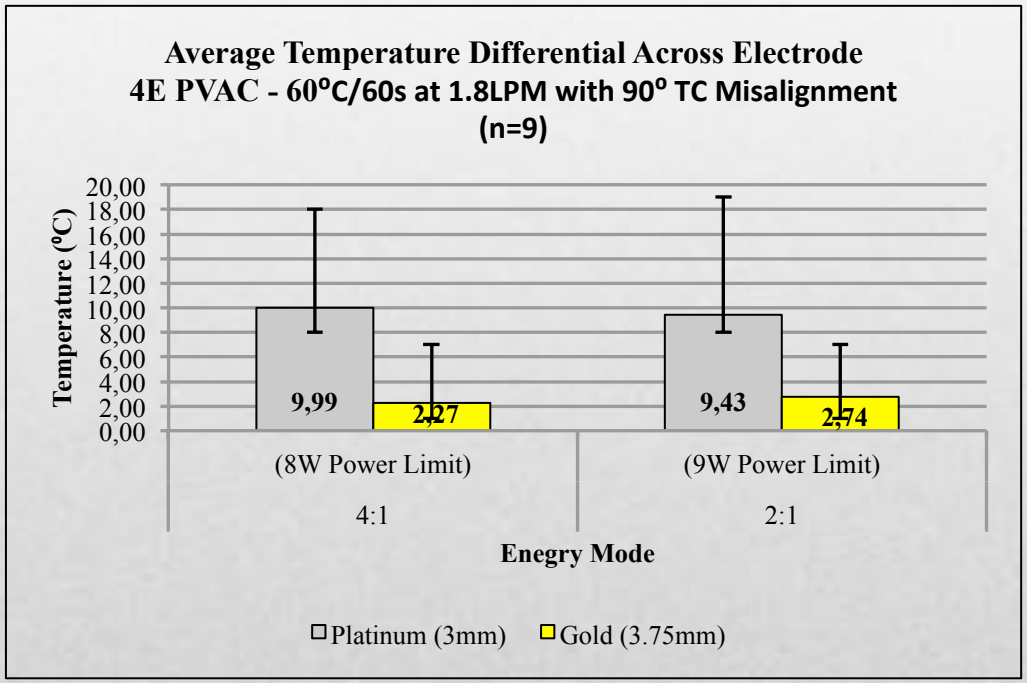
x 4

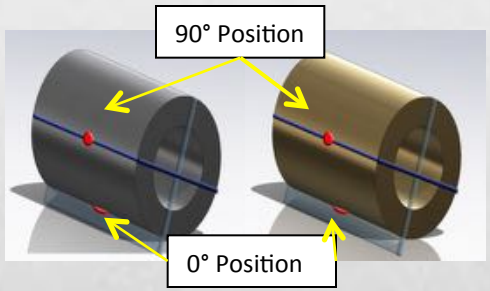
Gold 318 $\frac{W}{mK}$

Gold has 4 times greater thermal conductivity

Temperature Control

Temperature differential accross the electrode is less with gold than platinum in the in-vitro perfusion test set-up





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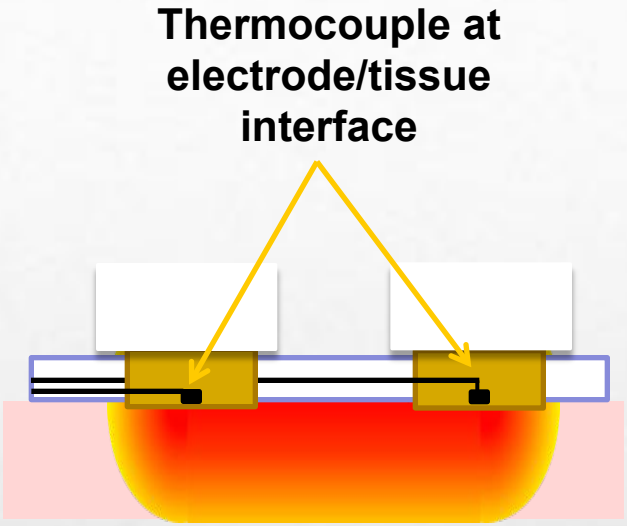
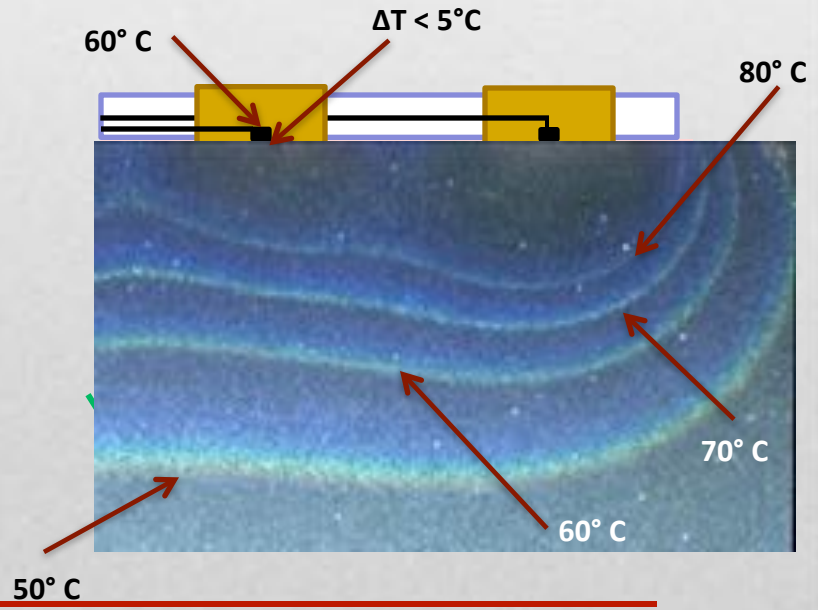
Temperature Control

Thermocouple placement

- Placed at electrode-tissue interface to improve accuracy of temperature measurement
- Temperature control using precise tissue interface temperature eliminates possibility of steam pops





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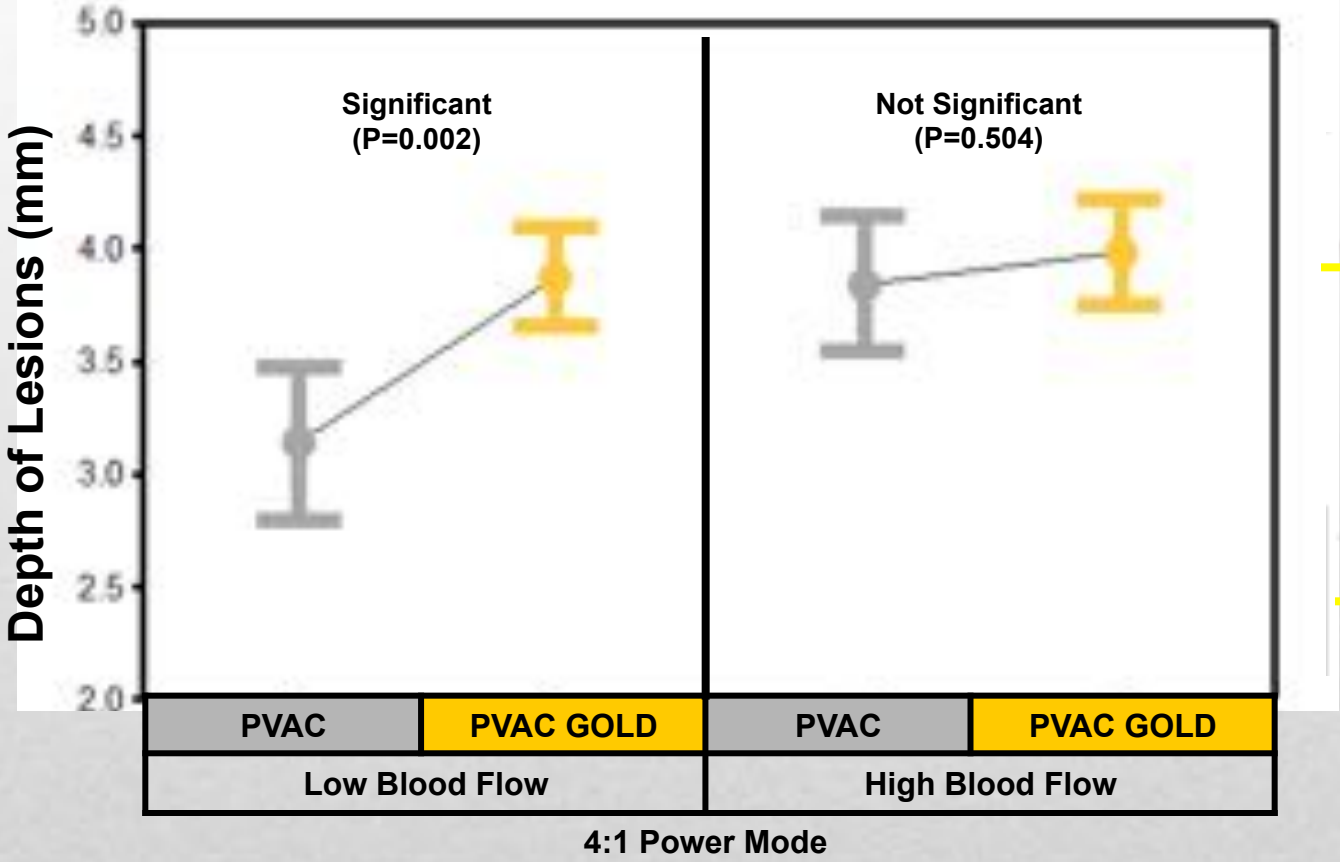
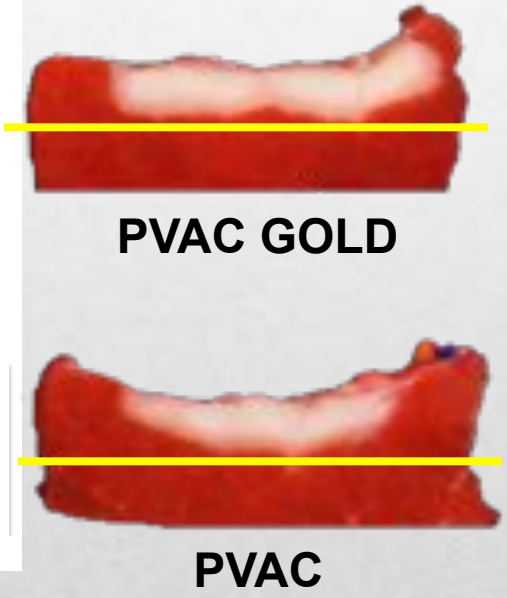
Better Lesions Under Low-Flow Conditions

PVAC GOLD produced deeper lesions versus PVAC under low flow conditions due to the improved cooling ability of gold[1]





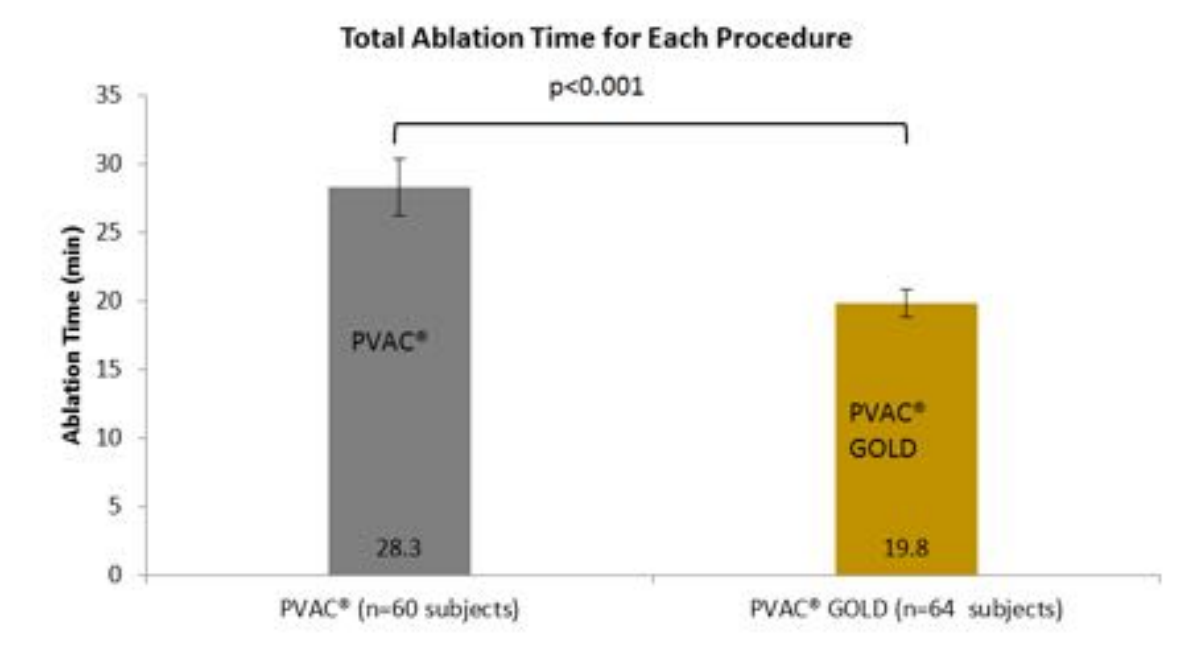
- **Coagulum**: no evidence was observed on catheter or thigh muscle.

1. Haines et al, Effect of Conductive Material on Passive Convective Cooling During Radiofrequency (RF) Catheter Ablation, HRS Abstracts 2014

PVAC GOLD is More Efficient than PVAC

Procedures were performed with 30% fewer RF applications with PVAC GOLD

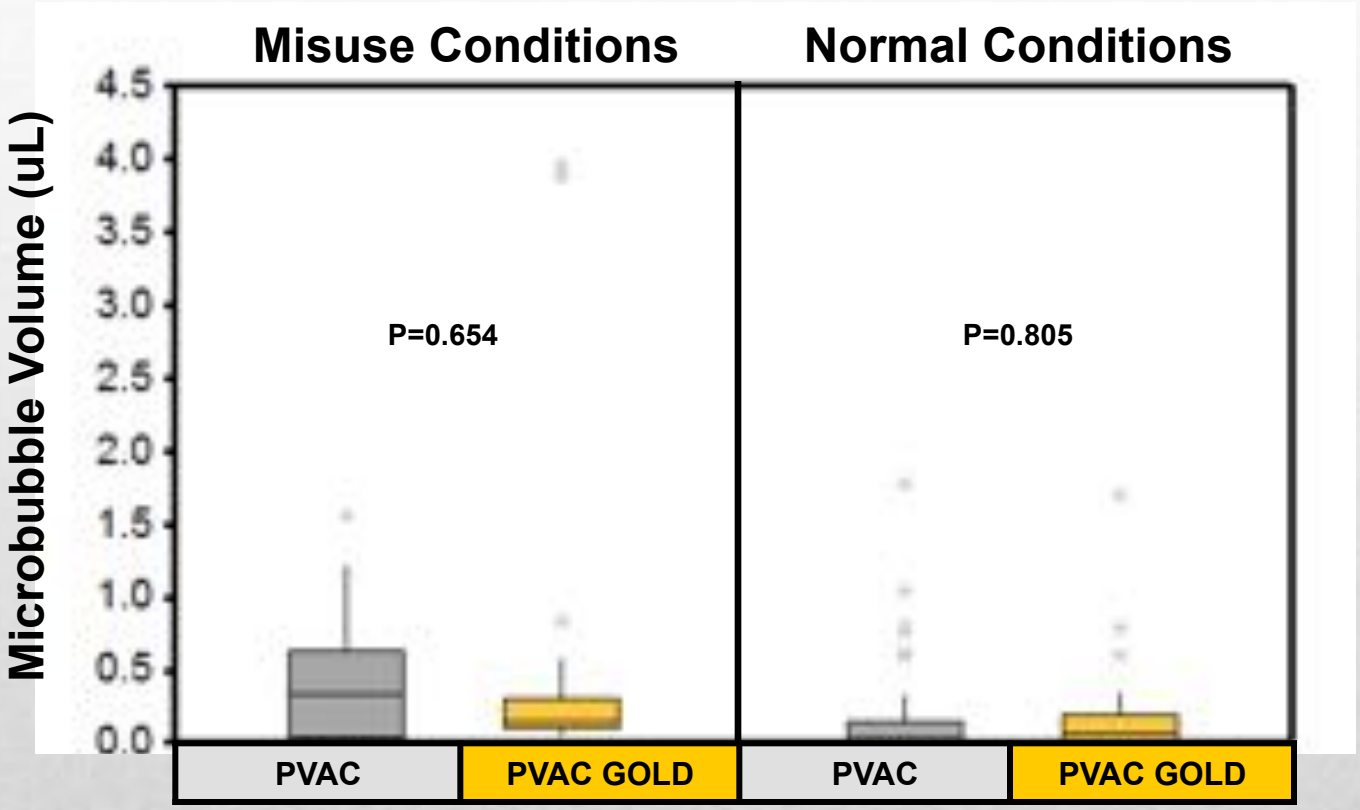
	ERACE	PRECISION GOLD
Procedure Time	100 ± 35 min	92 ± 25 min
LA Dwell Time	64 ± 27 min	59 ± 17 min
Fluoroscopy Time	-	16 ± 6 min
Average Effective Contact	32 secs	36 secs



1. De Greef et al, Improved Efficiency and Energy Delivery with Second Generation Multi-electrode Ablation System. Cardiostim abstract 2014.

Gas Production with Gold is the Same

Gold and platinum produce the same volume of microbubbles in both normal and misuse conditions[1]



- Misuse conditions include thermocouple misalignment and intermittent tissue contact
- Coagulum: non-adherent solid particles were not observed in any of the filters post ablation

1. Haines et al. Evaluation of gold/platinum electrode multipolar phased RF ablations in a swine model *In Vivo*: Microembolus production and energy delivery performance. ESC Poster 2012.

ContactIQ Sensitivity and Specificity Results

Sensitivity

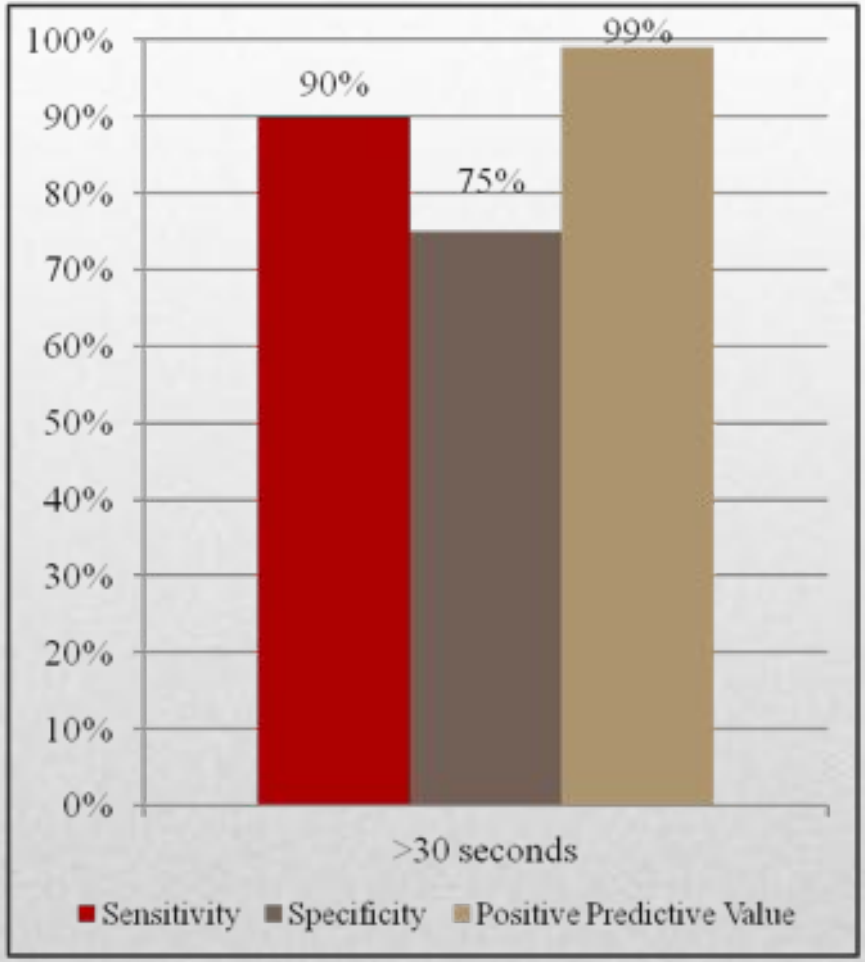
- Correctly identified a lesion was present at >30s and >45s

Specificity

- Correctly identified a lesion was not present at <30s and <45s

Positive Predictive Value (PPV)

- Percent of time a lesion is predicted and one is present



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Evaluation and Reduction of Asymptomatic Cerebral Embolism in Ablation of Atrial Fibrillation, but High Prevalence of Chronic Silent Infarction: Results of the ERACE Trial

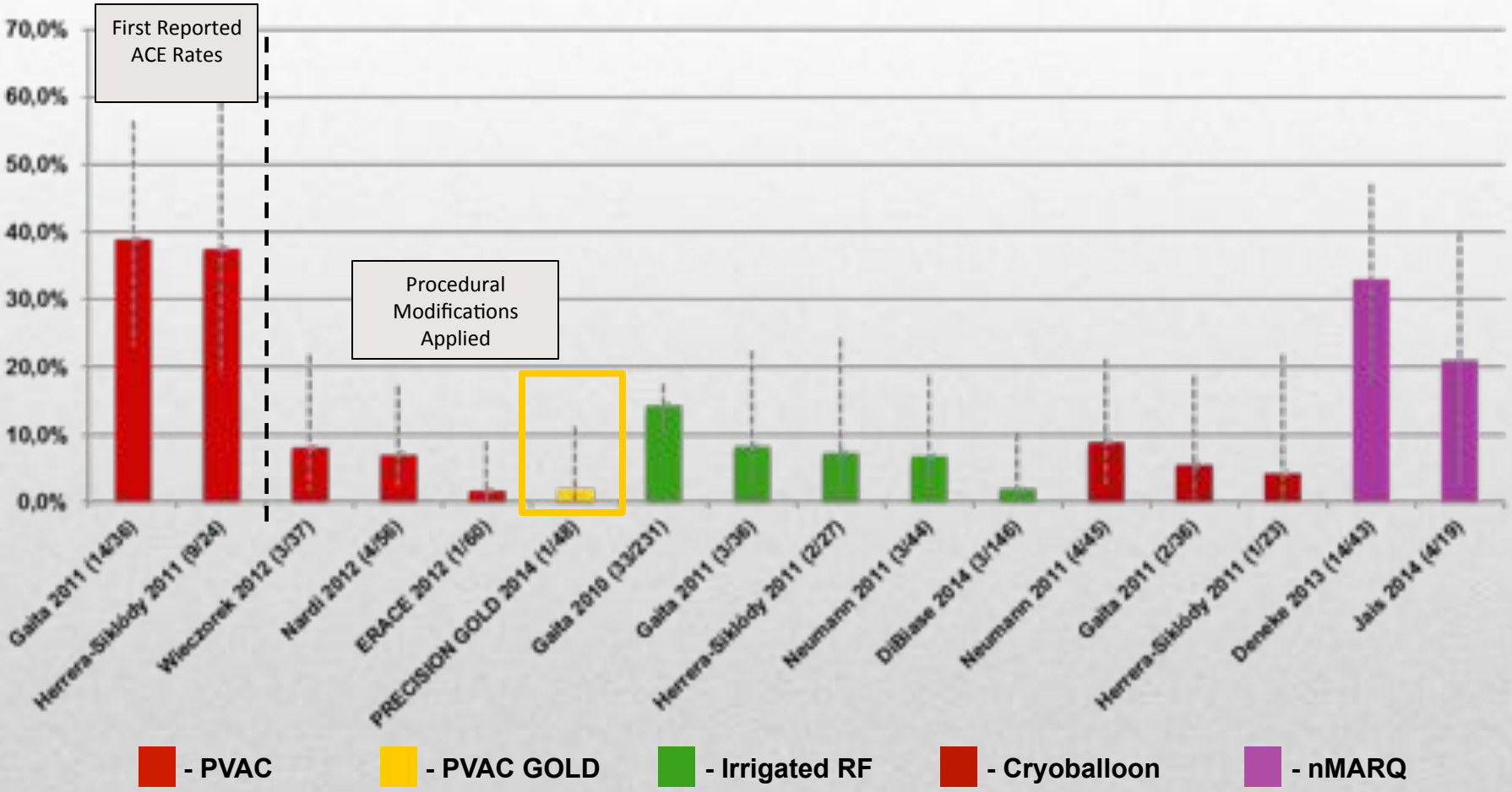
Atul Verma, Philippe Debruyne, Stefano Nardi, Thomas Deneke, Yves DeGreef, Stefan Spitzer, Jörn O. Balzer and Lucas Boersma

Circ Arrhythm Electrophysiol. published online August 27, 2013;
Circulation: Arrhythmia and Electrophysiology is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 1941-3149. Online ISSN: 1941-3084

Conclusions **-** Applying procedural changes to MER ablation significantly reduces the ACE incidence to 1.7%, which is on the low end of reported ACE rates of any technology.

PVAC GOLD ACE Rate is Consistent with Previously-Reported Microembolism Reductions

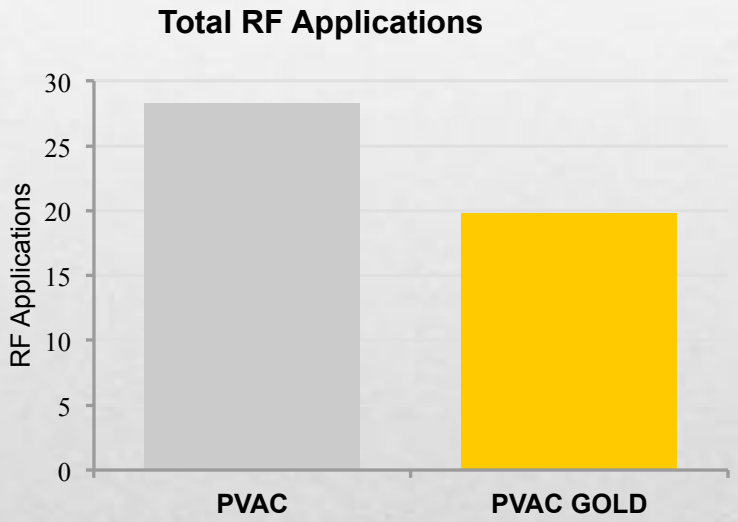


Caution: Clinical results across studies/protocols may not be comparable.
All studies included used 1.5T MRI scanner and used a consistent lesion definition as per Gaita/Herrera-Siklódy (DWI + ADC + FLAIR)

PVAC GOLD May Be More Efficient than PVAC

Comparing data from PRECISION GOLD (PVAC GOLD) and ERACE (PVAC) shows more Effective Contact and less RF applications with PVAC GOLD

	PRECISION GOLD	ERACE
Procedure time	92 ± 25 min	100 ± 35 min
LA dwell time	59 ± 17 min	64 ± 27 min
Fluoroscopy time	16 ± 6 min	-
Effective contact	36s	32s



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PVAC vs point by point PVI: follow up

Table 2 PVAC vs. point by point RF ablation in AF

	Technique	Patients (*N*)	Success %	FU duration
Paroxysmal atrial fibrillation (PAF)				
Bulava et al.[6]	PVAC	51	76	200 ± 13 days
	Point by point	51	71	
Khaykin et al.[7]	PVAC	31	67	6 months
	Point by point	19	54	
Beukema et al.[10]	PVAC	89	82	367 ± 139 days
	Point by point	96	80	
Choo et al.[8]	PVAC	30	73	6 months
	Point by point	43	49	
Tivig et al.[12]	PVAC	27	74	>12 months (+ or >?)
	Point by point	47	68	
Persistant atrial fibrillation (PERS) AF				
Choo et al.[8]	PVAC	8	50	6 months
	Point by point	28	25	
Tivig et al.[12]	PVAC/MAAC/MAASC	22	46	>12 months (> or =?)
	Point by point + substrate	23	61	
PAF + PERS AF				
Bittner et al.[9]	PVAC	40	72	254 ± 99 days
	Point by point	40	68	

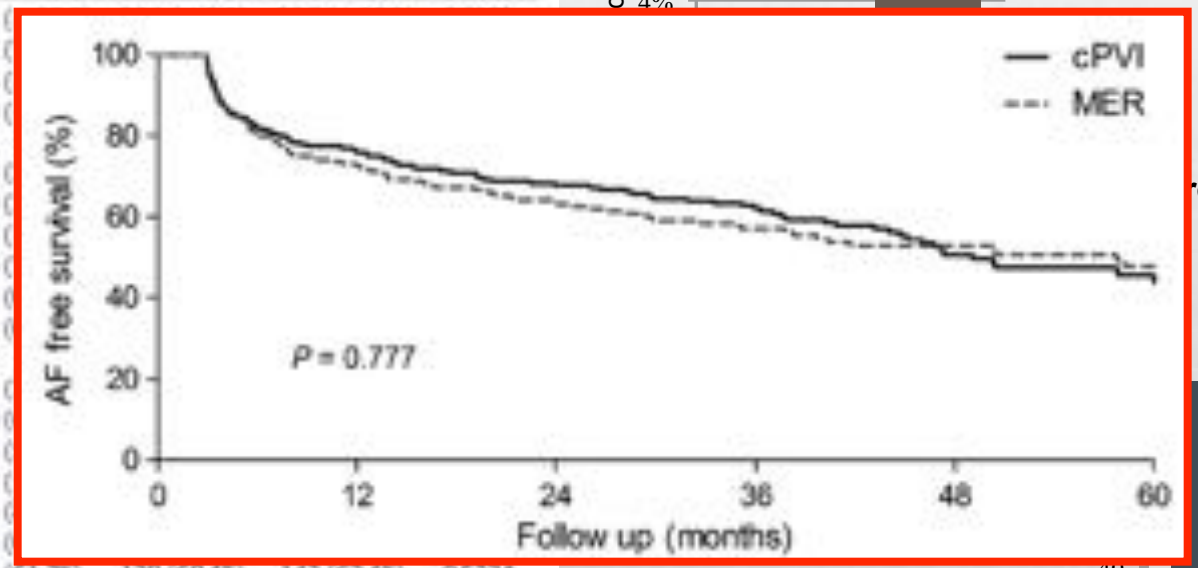
FU, follow-up.

Conventional radiofrequency catheter ablation compared to multi-electrode ablation for atrial fibrillation

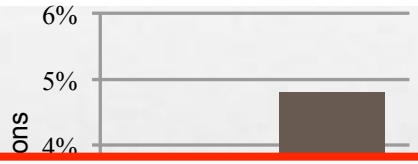
Pim Gal, Alissa E.S.M. Aarntzen, Jaap Jan J. Smit, Ahmet Adiyaman, Anand R. Ramdat Misier, Peter Paul H.M. Delnoy, Arif Elvan *

Department of Cardiology, Isala Klinieken, Zwolle, The Netherlands

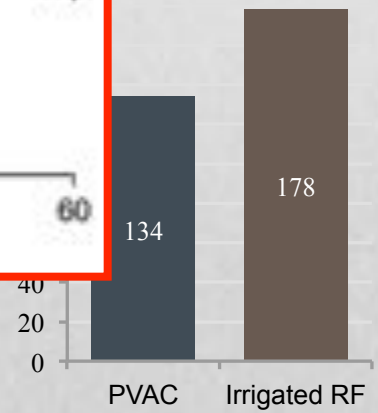
	Total group n = 460	cPVI n = 230	MER n = 230	P
Age (years)	56.3 (			
Gender men (%)	347 (			
BMI (kg/m^2)	27.6 (			
LA size in PSLAX (mm)	41.0 (			
CHA_2DS_2VASc score				
0	178 (			
1	160 (			
2	75 (			
3	36 (			
4	2 (			
5–7	1 (			
Co-morbidity (%)				
Hypertension	161 (			
Diabetes mellitus	30 (			
Previous TIA/stroke	25 (			
Structural heart disease	53 (			
Type AF: paroxysmal	375 (			
Failed AADs (range)	1.58 (			
Class I	282 (61.3%)	139 (60.4%)	143 (62.4%)	0.533†
Class III	329 (71.5%)	161 (70.0%)	168 (73.4%)	0.765†
AF duration (years)	8.3 (±5.1)	8.6 (±5.2)	7.9 (±5.0)	0.154*



Safety Profile



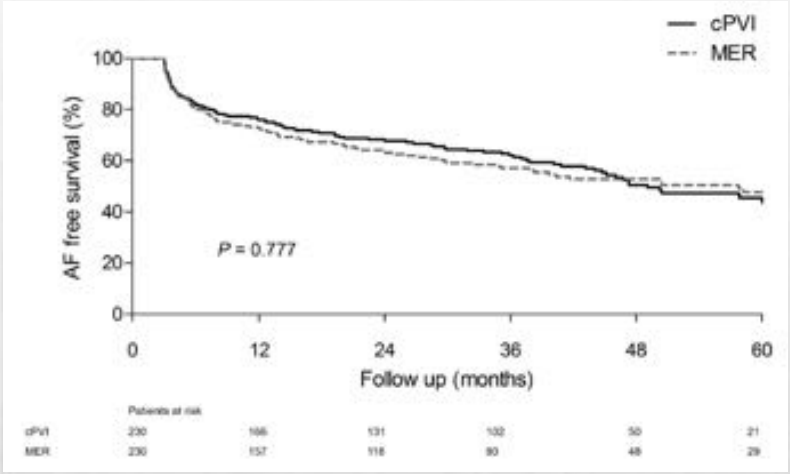
Procedure Time



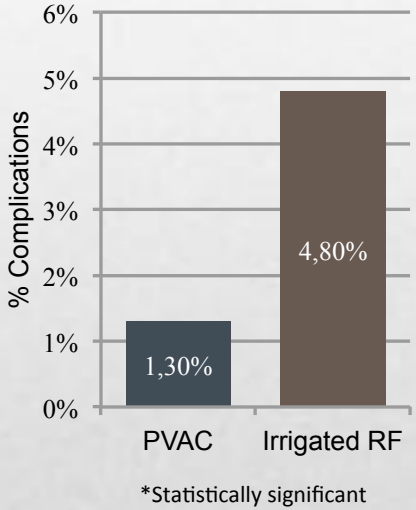
5 year Follow-Up with PVAC vs. Irrigated RF

Very long-term follow-up shows improved efficiency, improved safety and similar effectiveness with first-generation PVAC vs. Irrigated RF

Single Procedure Success off Drugs

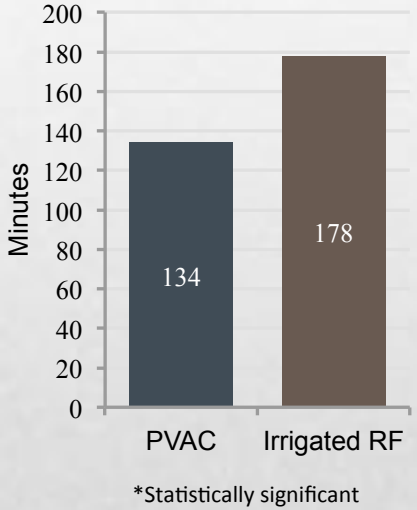


Safety Profile



*Statistically significant

Procedure Time



*Statistically significant

- PVAC **- Irrigated RF**

Gal P, et al, Conventional radiofrequency catheter ablation compared to multi-electrode ablation for atrial fibrillation. *Int J Cardiol*. Published online August 2014.

Phased multipolar radiofrequency pulmonary vein isolation is as effective and safe as conventional irrigated point-to-point ablation. A prospective randomised 1-year implantable cardiac monitoring device follow-up trial

Received: 11 April 2015 / Accepted: 29 July 2015

S. J. Podd[1] · A. N. Sulke[1] · C. Sugihara[1] · S. S. Furniss[1]

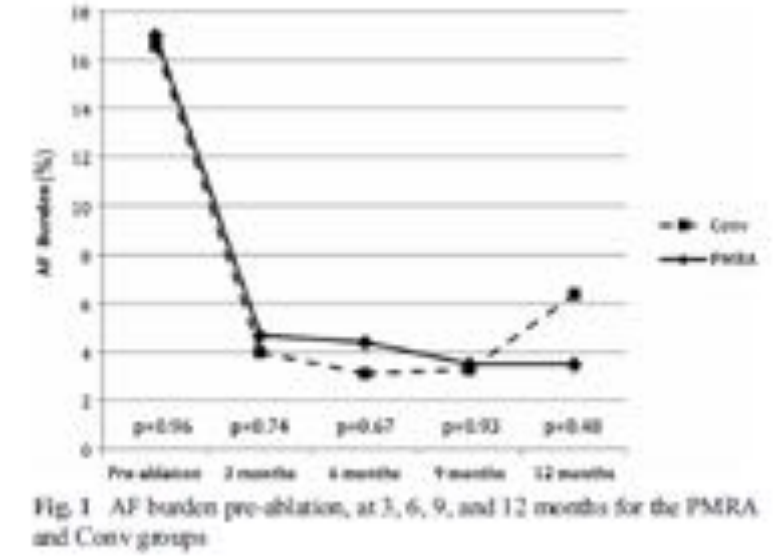
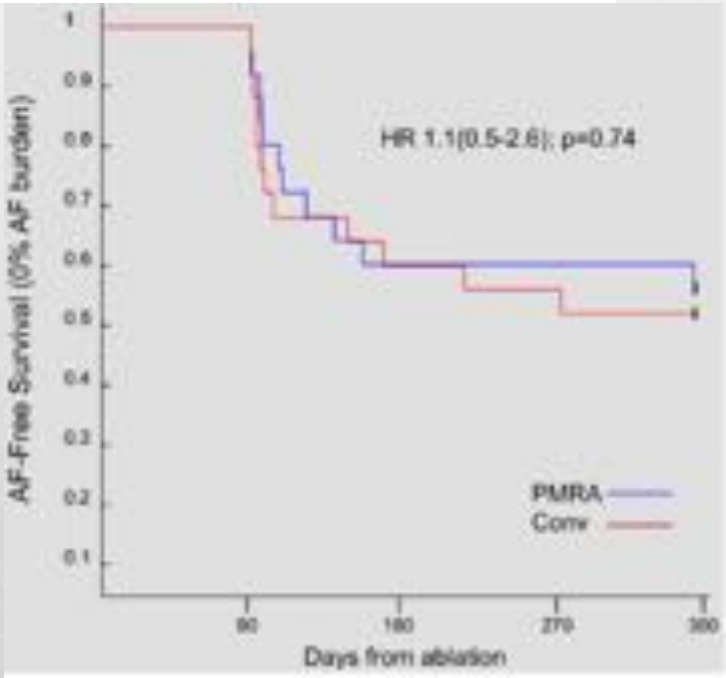


Fig. 1 AF burden pre-ablation, at 3, 6, 9, and 12 months for the PMRA and Conv groups



Procedural times were significantly shorter for the PMRA group (PMRA 79±19 min vs Conv 139±28 min, $p<0.001$).

Long-term Follow-Up of Ablation with Multiple Generations of Duty-Cycled Phased Radiofrequency Ablation Using a Subcutaneous Monitoring Device.

Giovanni Rovaris[1], et al.

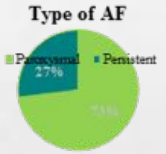
1 San Gerardo Hospital, Monza, Italy

Introduction

Multi-electrode radiofrequency (RF) ablation using phased, duty-cycled energy (PVAC, Medtronic, Minneapolis, USA) is a promising technique to treat atrial fibrillation that has reported equivalent freedom from AF as conventional point by point RF, with significantly reduced procedure times. Second-generation PVAC GOLD technology has recently been introduced, incorporating gold electrodes with potentially improved energy efficiency. At this point, few data are available on the acute procedural efficiency or the long-term freedom from AF with this novel device. Additionally, few data are available on freedom from AF when assessed with an implantable loop recorder, as opposed to a traditional Holter monitor. These highly sensitive devices may offer improved detection of AF at follow-up.

Methods

104 AF patients were ablated with PVAC and PVAC GOLD at our center between December 2010 and October 2014. 27% (28/104) were persistent. 71 subjects were ablated with the first-generation PVAC catheter and older versions of the GENius generator, 18 subjects were ablated with PVAC and the new GENius v15.1 generator and 15 subjects were ablated with the novel PVAC GOLD catheter and the new GENius 15.1 generator. 77% (80/104) subjects were followed with an implantable subcutaneous monitoring device to assess freedom from AF (Reveal, Medtronic, Minneapolis, USA)



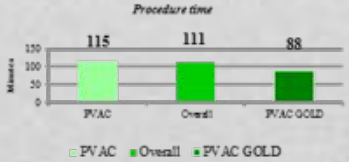
77% followed with ILR

Results

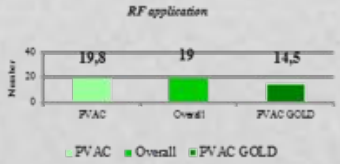
Baseline characteristics

	Overall	PVAC	PVAC GOLD
Age (years), mean±std	58±12	59±12	57±11
Gender (male), %	68%	66%	76%
Left Atrial Diameter (mm), mean±std	40,6±4,3	40,4±4,7	41,5±2,7

- Average procedure time was 111 ± 29 min. 115 min with PVAC and 88min with PVAC GOLD; p=0.0004.



- Average number of RF applications was 19 ± 6. 19.8 with PVAC and 14.5 with PVAC GOLD; p=0.0005.



- 2.9% adverse events occurred (3 vascular access complications).

- At an average follow-up of 27 ± 14 months, 74% (77/104) of patients were in sinus rhythm. At an average follow-up of 5 ± 2 months, 93% (14/15) of patients treated with the novel PVAC GOLD catheter were free from AF.

Conclusions

These data demonstrate strong clinical effectiveness of Phased RF technology at long-term follow-up using a highly sensitive implantable monitor. Furthermore, they suggest improved efficiency of the second-generation PVAC GOLD device versus the predicate PVAC catheter. .

Disclosure Information: No disclosure declared.

Long-term Follow-Up of Ablation with Multiple Generations of Duty-Cycled Phased Radiofrequency Ablation Using a Subcutaneous Monitoring Device.

Giovanni Rovaris[1], Elena Piazzi[1,] Sergio De Ceglia[1] et al.
1 San Gerardo Hospital, Monza, Italy

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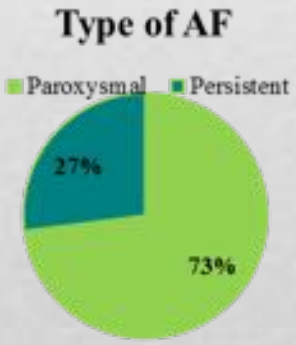

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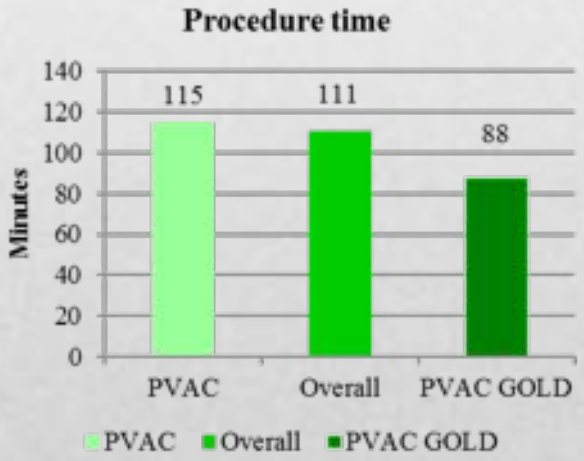

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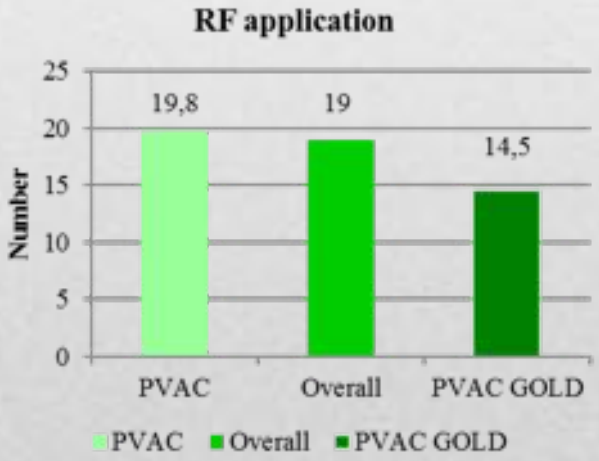

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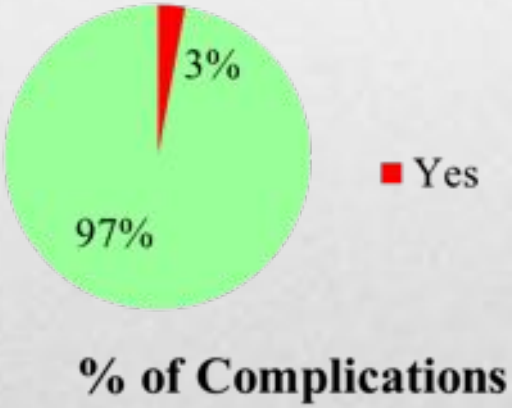

RESULTS

- At an average follow-up of 27 ± 14 months, 74% (77/104) of patients were in sinus rhythm.
- At an average follow-up of 5 ± 2 months, 93% (14/15) of patients treated with the novel PVAC GOLD catheter were free from AF.

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NEW STUDIES ONGOING

PVAC GOLD Versus Irrigated RF Single Tip Catheter With Contact FORCE Ablation of the Pulmonary Veins for Treatment of Drug Refractory Symptomatic Paroxysmal and Persistent Atrial Fibrillation (GOLD-FORCE)

GOLD AF Registry to Capture Real-World Insights Using Medtronic Phased RF Ablation to Treat Patients with Atrial Fibrillation

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Conclusions

Phased RF technology demonstrate strong clinical effectiveness at long term follow up using a highly sensitive implantable monitor.

The novel catheter designe of PVAC GOLD arrey and the Genius Contact IQ may improve :

- safety, reducing embolic events

- better tissue contact, with 20° forward tilt and the real contact with contact force

- reducing procedural time

- reducing application of energy

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