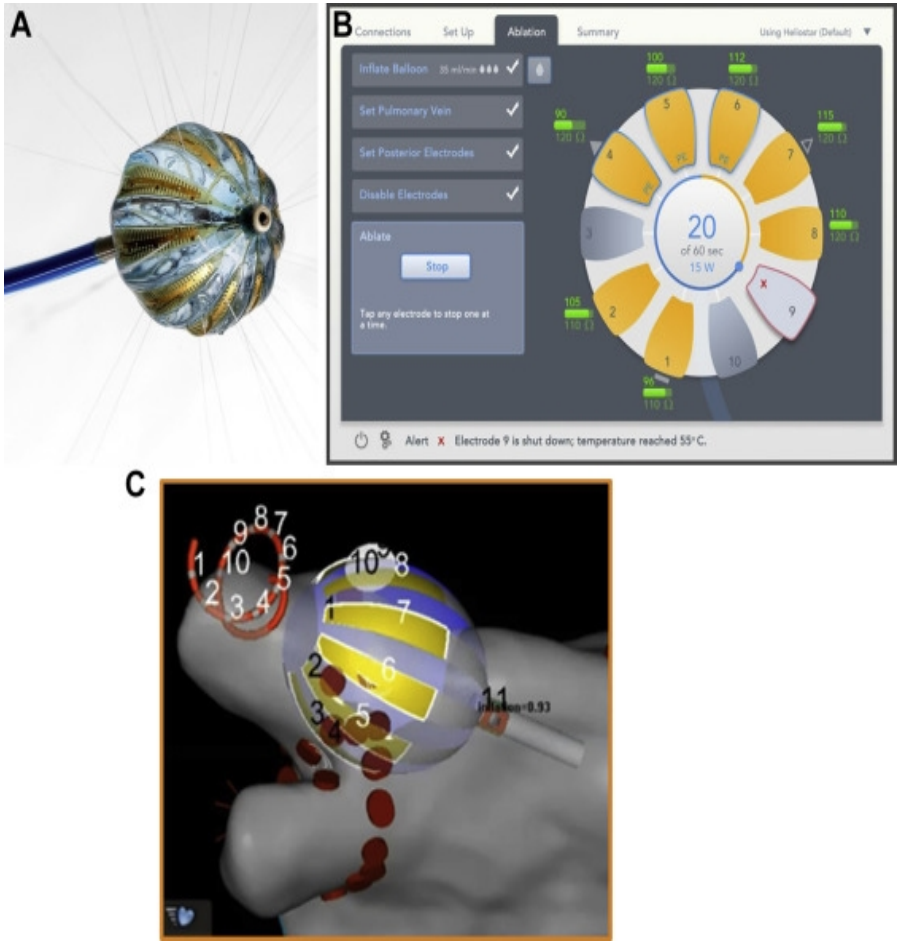
ABLASYON TEKNOLOJİLERİNDE YENİ NE VAR?

Dr. Gökhan Aksan

Samsun EAH Kardiyoloji Kliniği

Balloon Devices for Atrial Fibrillation Therapy

Heliostar



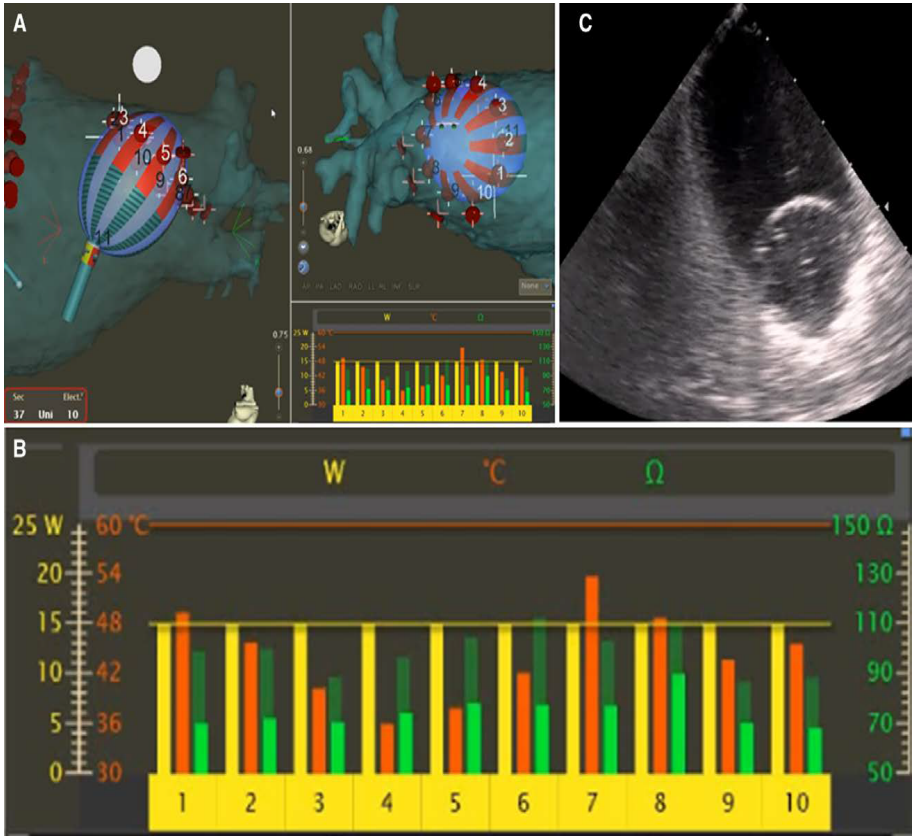
- Yeni kompliyan multielektrod RF balon kateter
- 10 adet irrigasyonlu altın elektrod
- Elektrodlarda bağımsız RF enerji uygulaması
- 28 mm sferik kompliyan balon
- Merkez lümen içinde 0.032 GW-balon konumlandırma
- Her elektrodda 4 delik irrigasyon
- CARTO-3 (Biosense) ile uyumlu
- 13.5 F deflectable sheath

Circulation: Arrhythmia and Electrophysiology

ORIGINAL ARTICLE

Pulmonary Vein Isolation With a Novel Multielectrode Radiofrequency Balloon Catheter That Allows Directionally Tailored Energy Delivery

Short-Term Outcomes From a Multicenter First-in-Human Study (RADIANCE)



- 39 hasta çalışmaya alındı (9 operatör)
- Ablasyon: Simultane 15 watt/35 ml/dk
- Posterior PV:30 sn; Anterior PV:60 sn
- İlk uygulamada başarı 79.6%

Erken rekonneksiyon (adenozin/isoproterenol) 4.7%

- Ortalama süre 101±29 dk, Balon yerleştirme 40±11 dk, floroskopi zamanı 17±10 dk, Ablasyon zamanı 36±17 dk
- RF balon uygulaması hasta başı 7.3±2.6
- 5 hastada özefagus eritem (+)
- İlk 3 ayda erken atrial aritmi rekürrensi 25.6%

ESC European Society of Cardiology
Europace (2021) **00**, 1–10
doi:10.1093/europace/euaa382

Safety, effectiveness, and quality of life following pulmonary vein isolation with a multi-electrode radiofrequency balloon catheter in paroxysmal atrial fibrillation: 1-year outcomes from SHINE

Pulmonary Vein Isolation with the Novel Radiofrequency Balloon in Paroxysmal Atrial Fibrillation Patients – The Multicentre SHINE Study

PATIENT ENROLLMENT

MULTICENTRE

6

EUROPEAN HOSPITALS

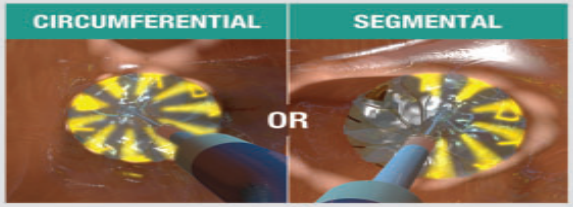
PATIENT INCLUSION

85

PATIENTS WITH SYMPTOMATIC PAROXYSMAL ATRIAL FIBRILLATION

Age 18-75 years
First-time ablation
LA diameter ≤50 mm, LVEF ≥40%

PULMONARY VEIN ISOLATION (PVI)



PROCEDURAL EFFICIENCY

99.7%
PVI WITH BALLOON ALONE

40.3MIN
BALLOON DWELL TIME, MEAN

87.6MIN
PROCEDURE TIME, MEAN

10.9MIN
FLUOROSCOPY TIME, MEAN

12 MONTHS FOLLOW-UP

SAFETY PROFILE

1.2%
PRIMARY ADVERSE EVENT
(n=1 Retroperitoneal bleed)

12-MONTH EFFECTIVENESS

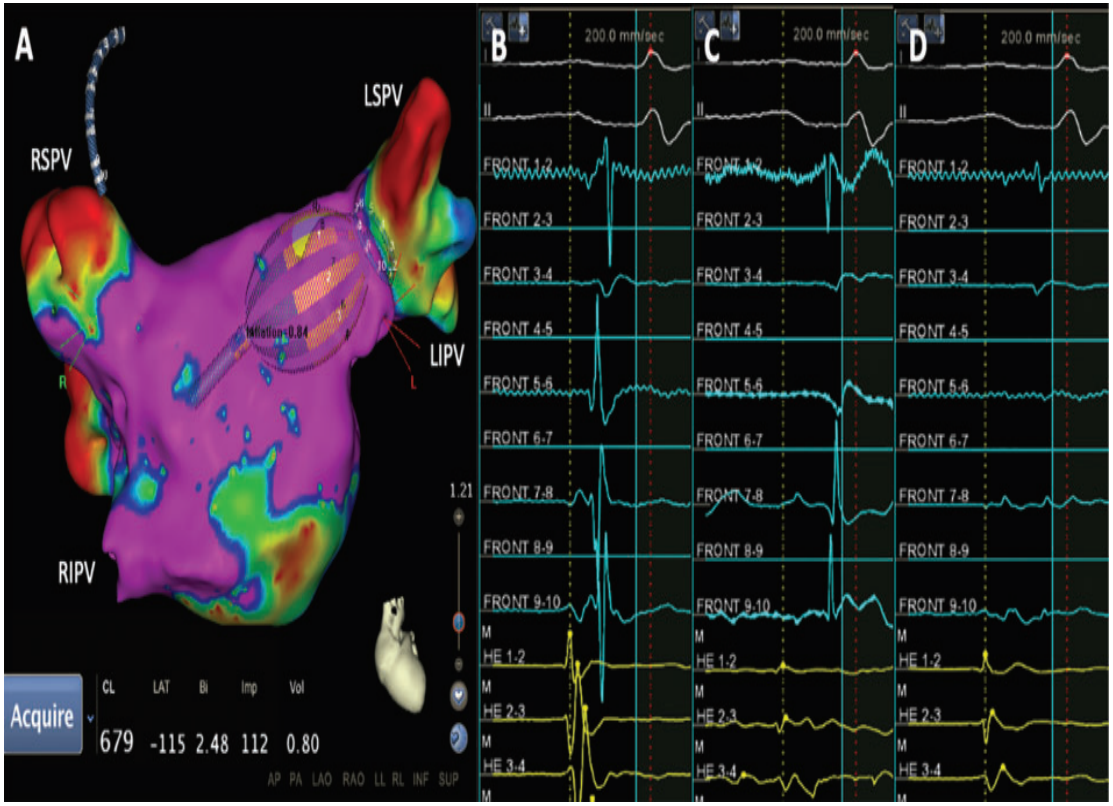
12-MONTH FREEDOM FROM SYMPTOMATIC ATRIAL ARRHYTHMIA RECURRENCE*

No significant site variation in 12-month freedom from symptomatic atrial arrhythmia recurrence

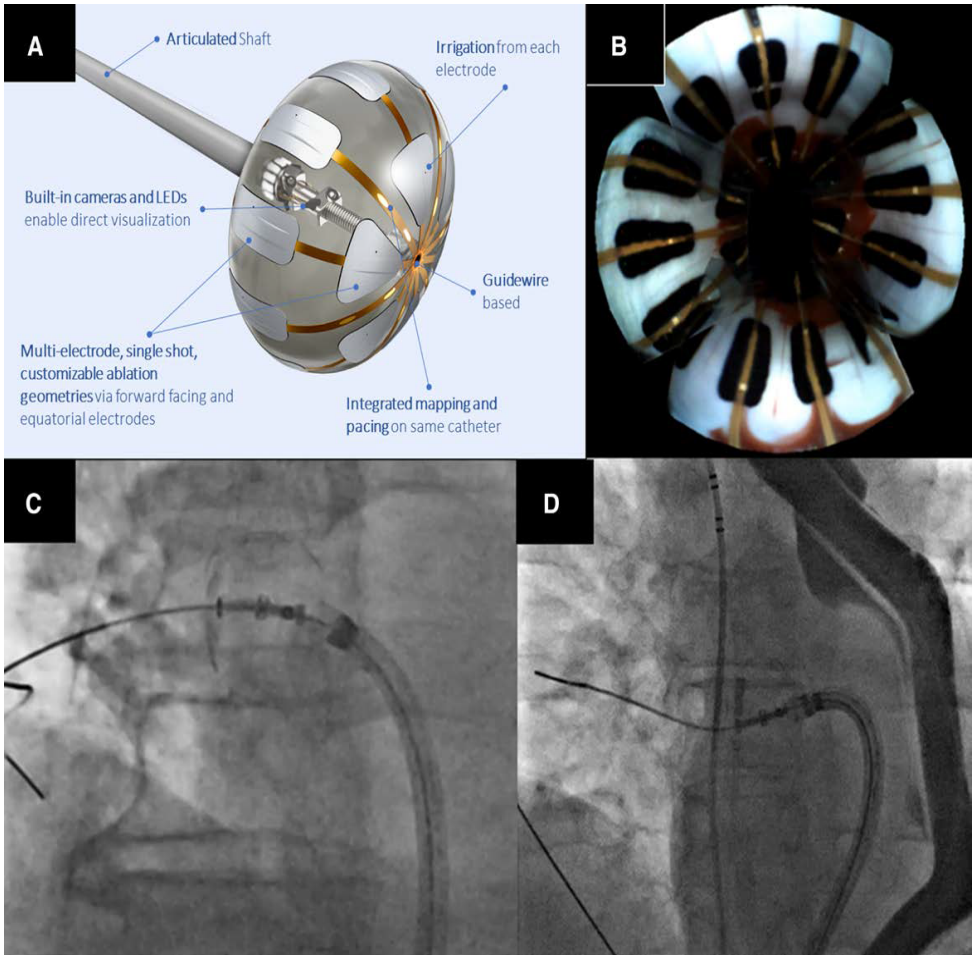
38.0% of patients on Class I/III AAD at 12 months, corresponding to a 32.8% decrease from baseline

*Based on binomial analysis with stringent arrhythmia monitoring

Heliostar


A
RSPV
LSPV
LIPV
RIPV
1.21
Acquire
CL LAT Bi Imp Vol
679 -115 2.48 112 0.80
AP PA LAO RAO LL RL INF SUP
B
C
D
200.0 mm/sec
II
FRONT 1-2
FRONT 2-3
FRONT 3-4
FRONT 4-5
FRONT 5-6
FRONT 6-7
FRONT 7-8
FRONT 8-9
FRONT 9-10
M
HE 1-2
HE 2-3
HE 3-4

Luminize



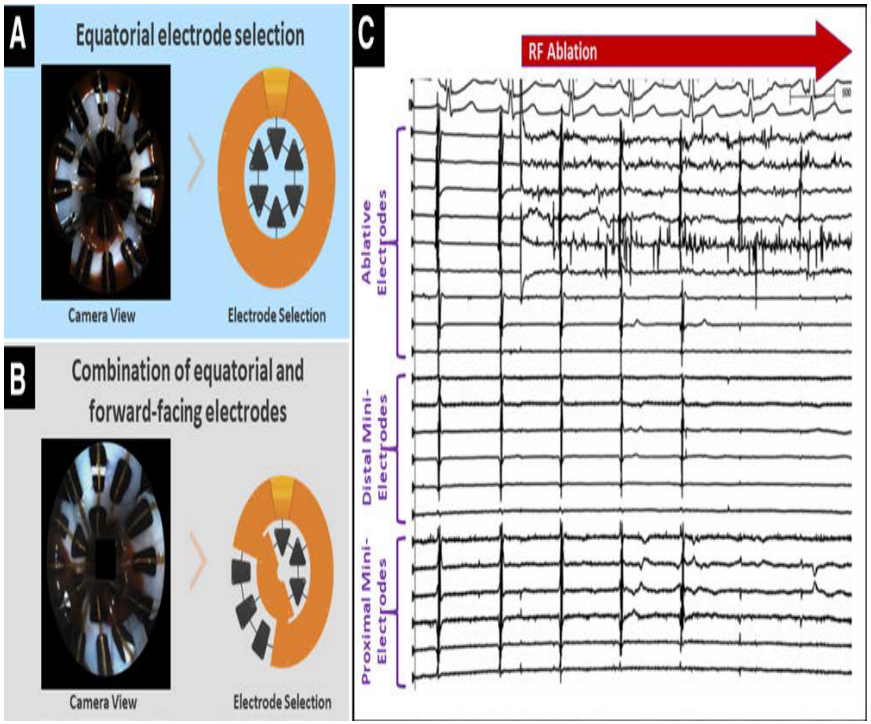
- Bi-directional, multielektrod, irrigasyonlu RF balon katater
- Boston Scientific
- Elektrodlarda bağımsız RF enerji uygulaması
- 28 mm çaplı balon
- 18 RF ablasyon elektrodu (6 ön-12 ekvator)
- Her RF elektroddan ayrı irrigasyon
- 12 sensing mini elektrod
- Balon içine entegre 4 CMOS kamera sistemi
- 13.3 deflectable sheath

Circulation: Arrhythmia and Electrophysiology

ORIGINAL ARTICLE

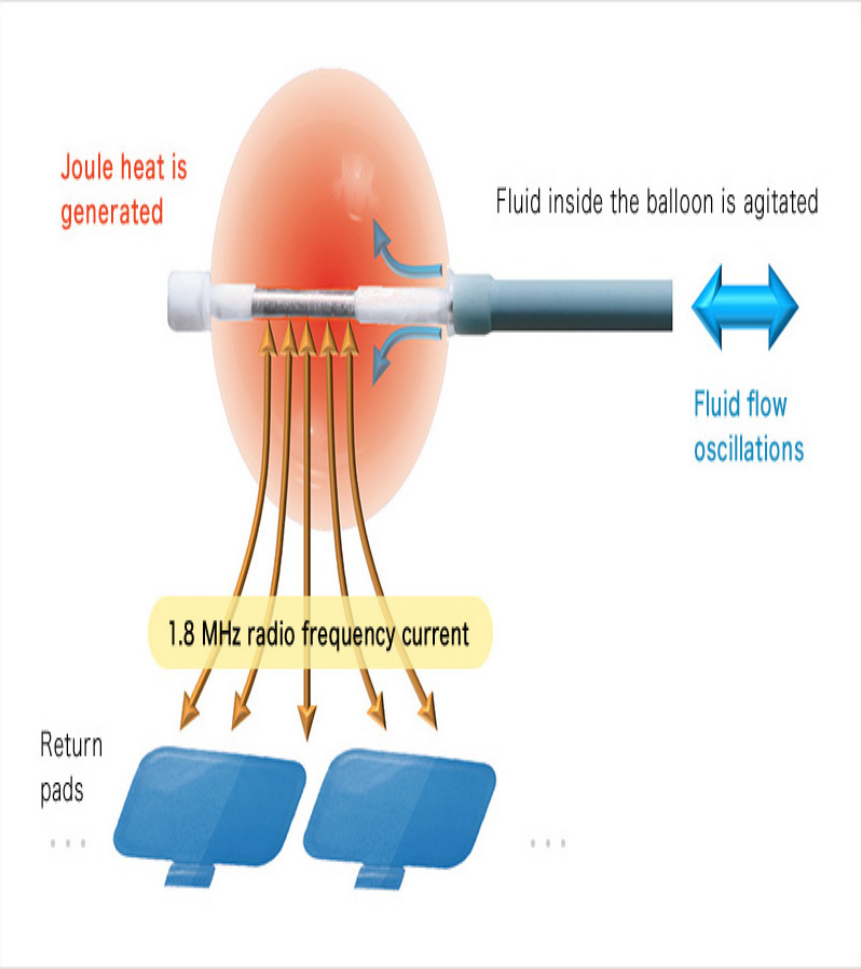
A Novel Visually Guided Radiofrequency Balloon Ablation Catheter for Pulmonary Vein Isolation

One-Year Outcomes of the Multicenter AF-FICIENT I Trial



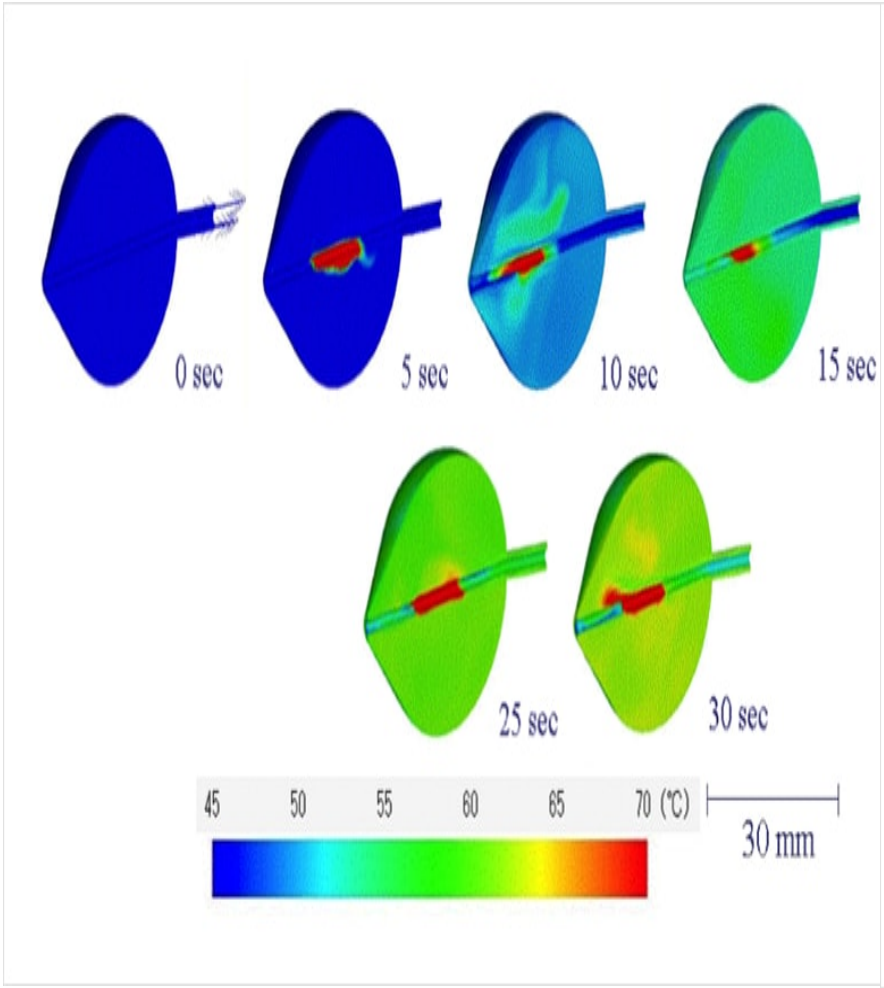
- 60 saniye 8-10 watt
- Total ablasyon zamanı ortalama 30 dk (20-53)
- Total prosedür zamanı ortalama 85 dk ve floroskopi zamanı ortalama 14dk.
- Hasta başı RF uygulama 9±4
- Sadece RF balon ile başarı 99.4%
- 1 yıllık takipte 77.5% oranında AT/AF/AFL izlenmedi.

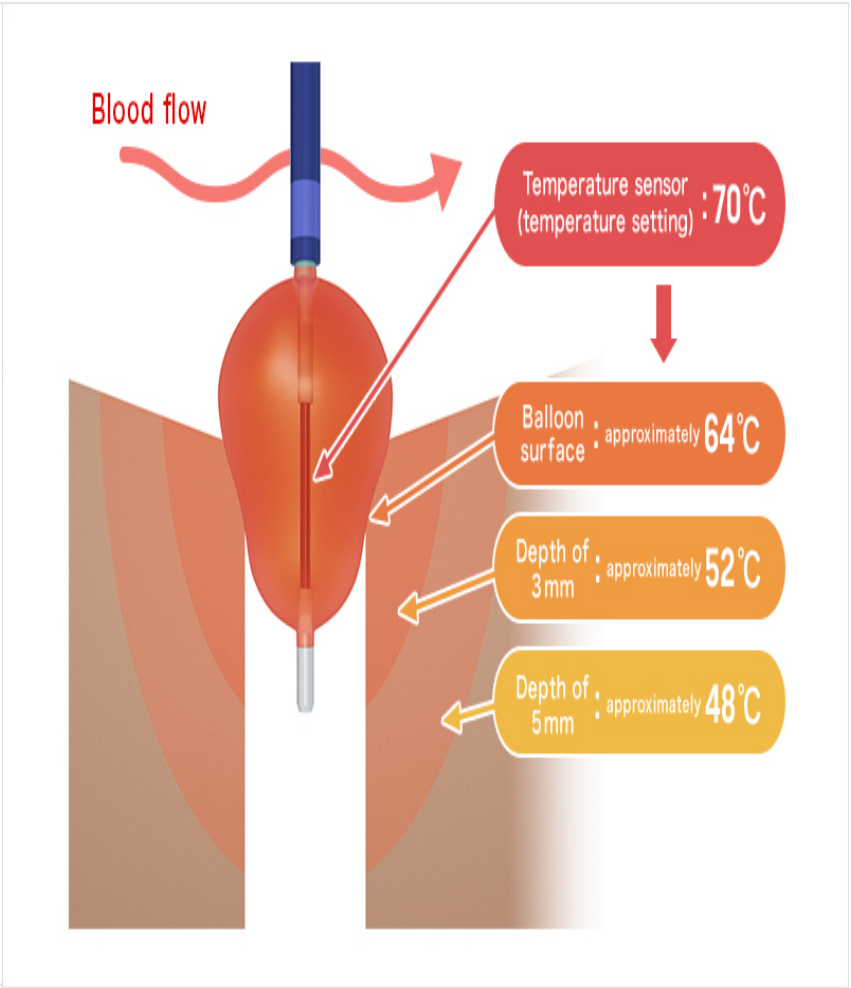
RF Hot Balloon



- Flexible, kompliyan balon kateter
- SATAKE-Hot Balloon (Toray Industries,Inc.,Tokyo, Japan)
- Balonun içinde RF enerji veren coil elektrod
- Balon merkezi ısısını gösteren coil elektrod yanındaki thermocouple
- Balon içinde 1/1 oranında salin ve kontrast (önerilen 10-20 ml)
- 26-33 mm ye balon genişlemesi
- 13-F deflectable sheath

RF Hot Balloon





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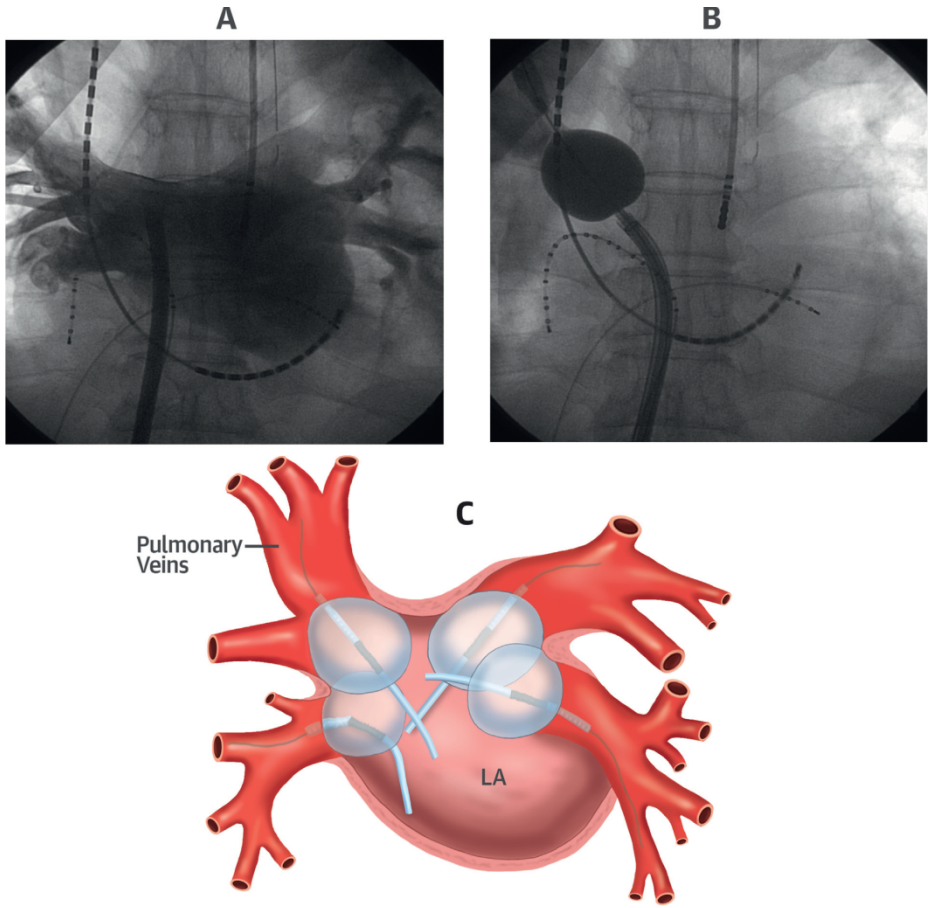
ISSN 0735-109
http://dx.doi.org/10.1016/j.jacc.2016.10.03

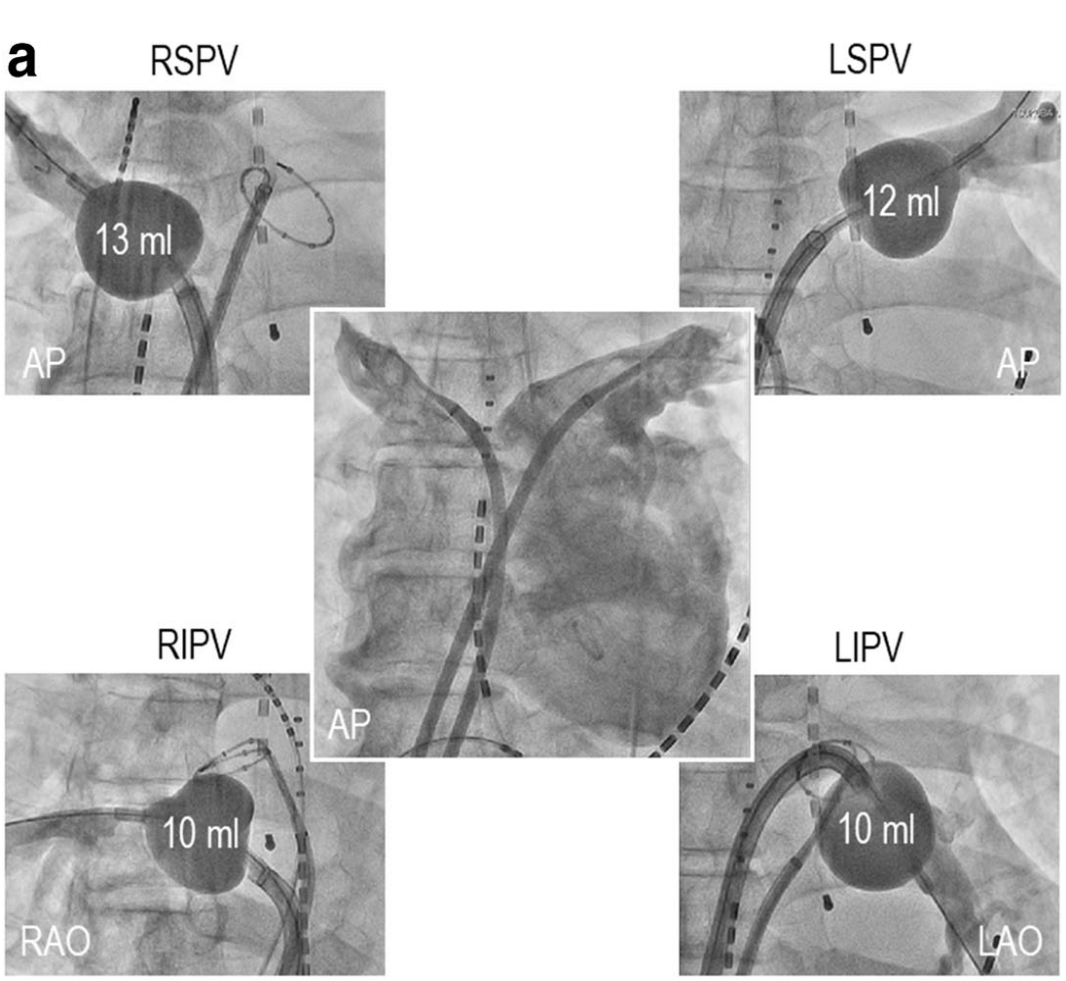
HotBalloon Ablation of the Pulmonary Veins for Paroxysmal AF

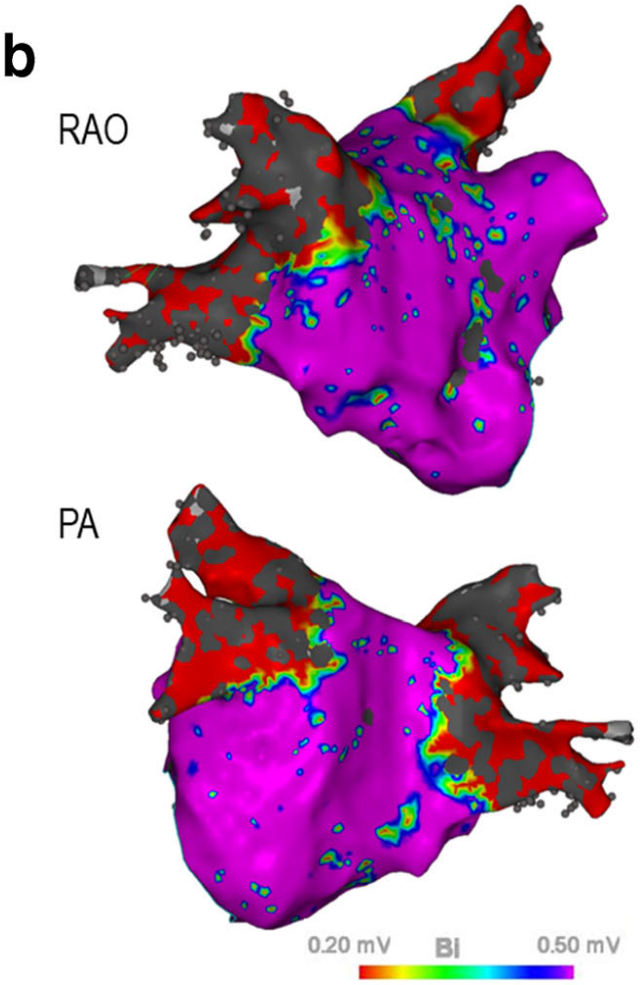
A Multicenter Randomized Trial in Japan



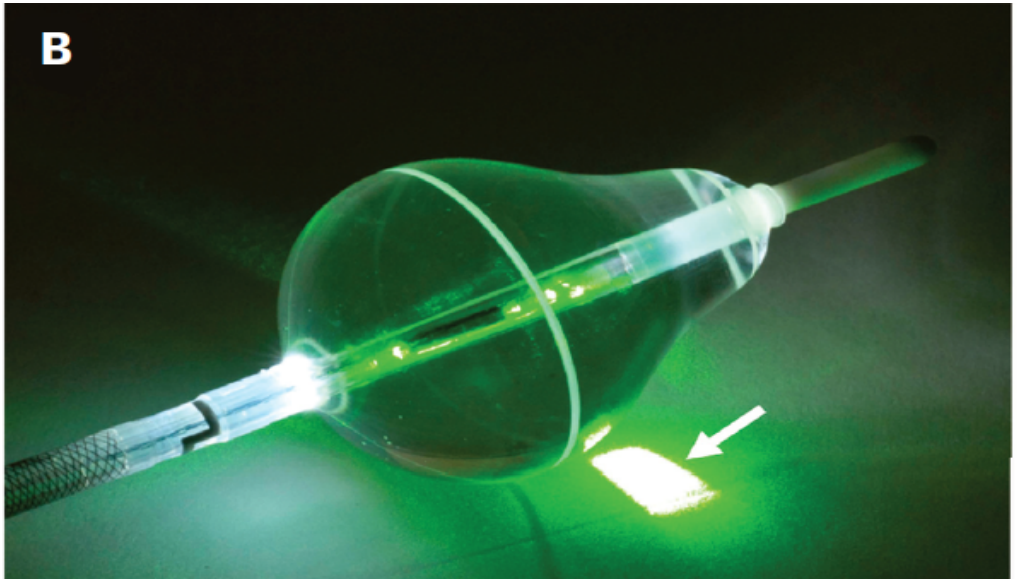
- Akut PVI başarı oranı 98.0%
- 9 aylık takipte 59.0% oranında AT/AF/AFL izlenmedi.
- PV stenosis 5.2%
- Frenik sinir hasarı 3.7%
- Toplam floroskopi zamanı 49.4±26.6
- Toplam işlem süresi 113.9±31.9

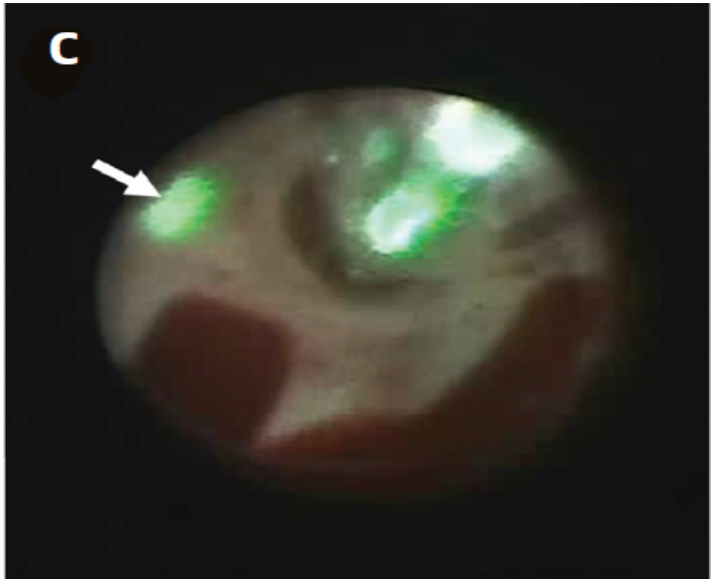
RF Hot Balloon





Heart Light





- Visually guided laser balloon (VGLB) (Heart Light, Cardiofocus)
- Flexible tip, kompliyan balon kateter (balon şaftı radyoopak marker içerir)
- 12-F deflectable sheath
- Balon kateterin merkezinde 2F endoskop ile hedef dokunun görüntülenmesi
- Merkez şaftı balonu soğutmak için dolaşan deuterium oxide (D2O) lümenleri içermektedir.
- 980 nm dalga boyunda diyot laser enerji ile ablasyon yapmaktadır (near infrared)
- Bu Işık yayı balon yüzeyi boyunca herhangi bir bölgeye ablasyon için yönlendirilebilir.

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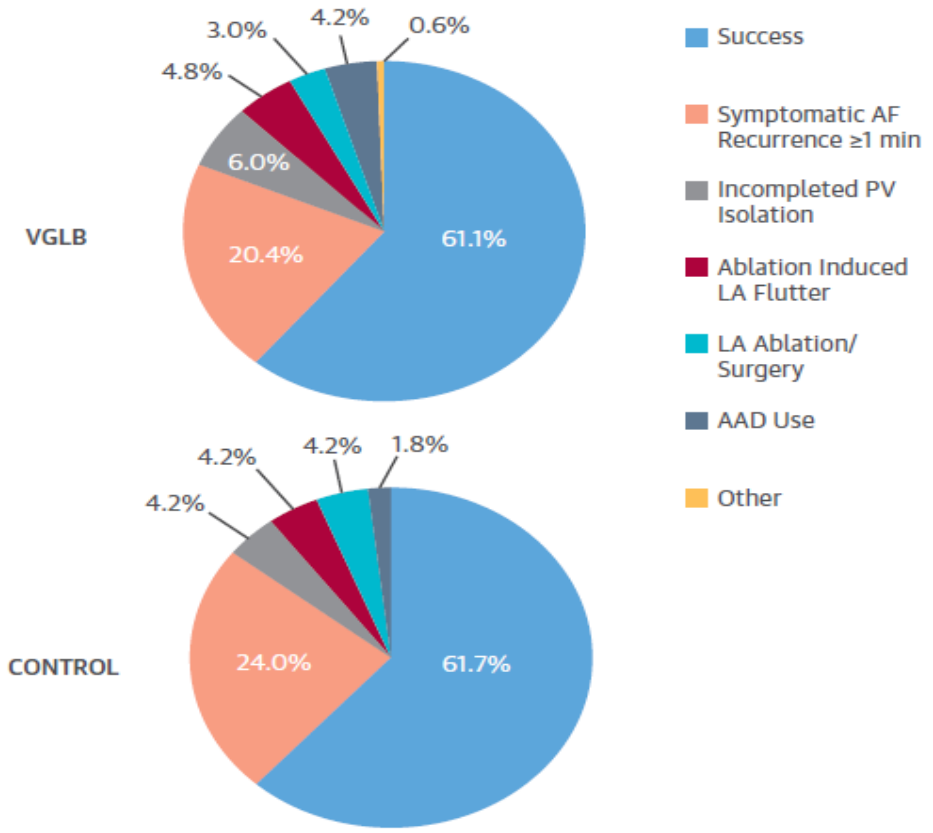
http://dx.doi.org/10.1016/j.jacc.2015.07.036

Pulmonary Vein Isolation Using the Visually Guided Laser Balloon

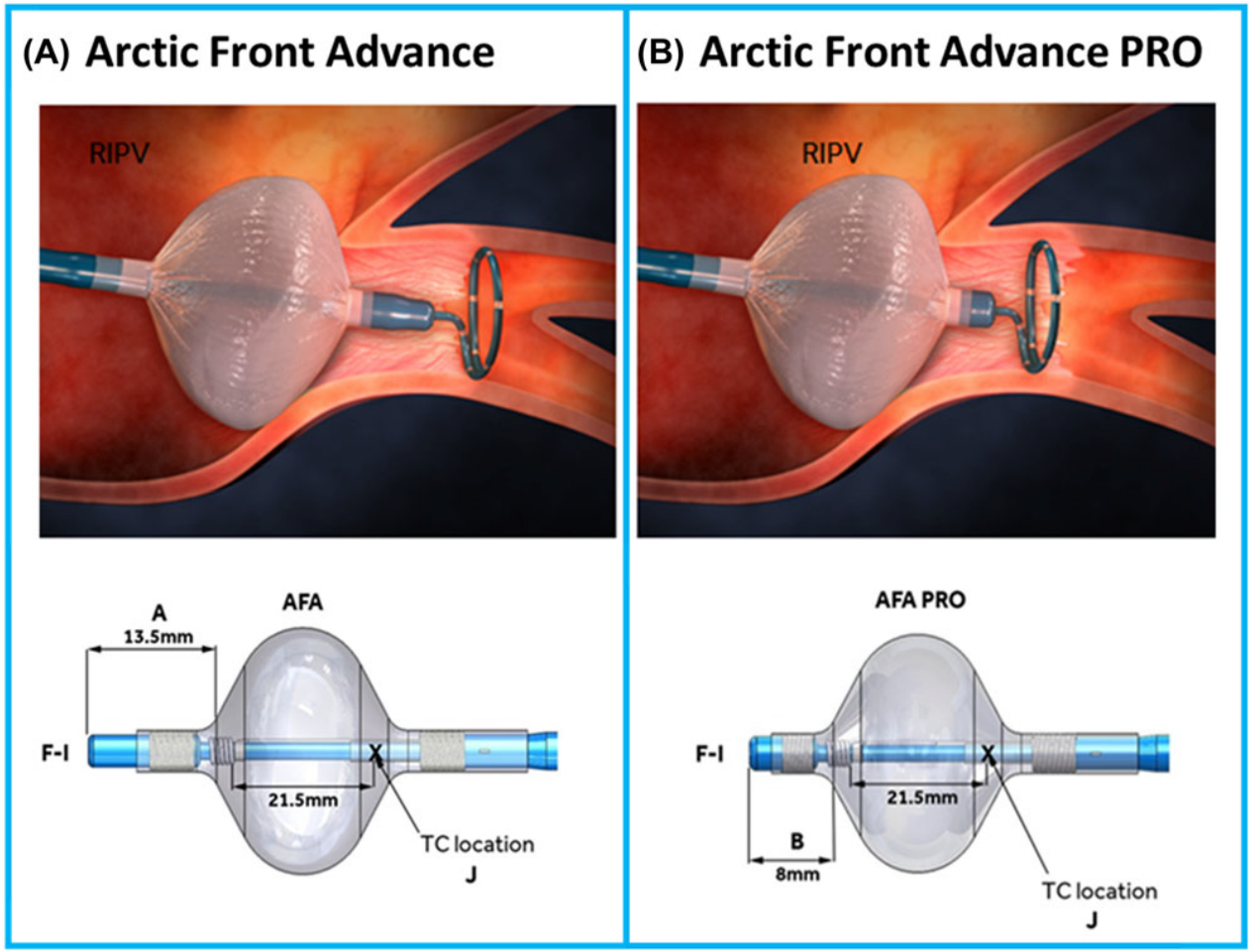
A Prospective, Multicenter, and Randomized Comparison to Standard Radiofrequency Ablation

FIGURE 3 Causes for Primary Efficacy Endpoint Failure



- Laser enerji 8.5 Wx20 saniye (7,10,12 W az sıklıkla)
- Akut PV isolasyonu VGLB grubunda 97.7%
- 12 aylık takipte AT/AF/AFL VGLB grubunda 61% oranında izlenmedi.
- Prosedür zamanı 236±52.8 (kontrol grubuna göre anlamlı uzun)
- Ablasyon zamanı 173.8±46.6 (Thermocool KA kontrol grubuna göre anlamlı uzun)
- Frenik sinir hasarı 3.5% (P=0.05)
- PV stenosis 0%

Arctic Front Advance PRO

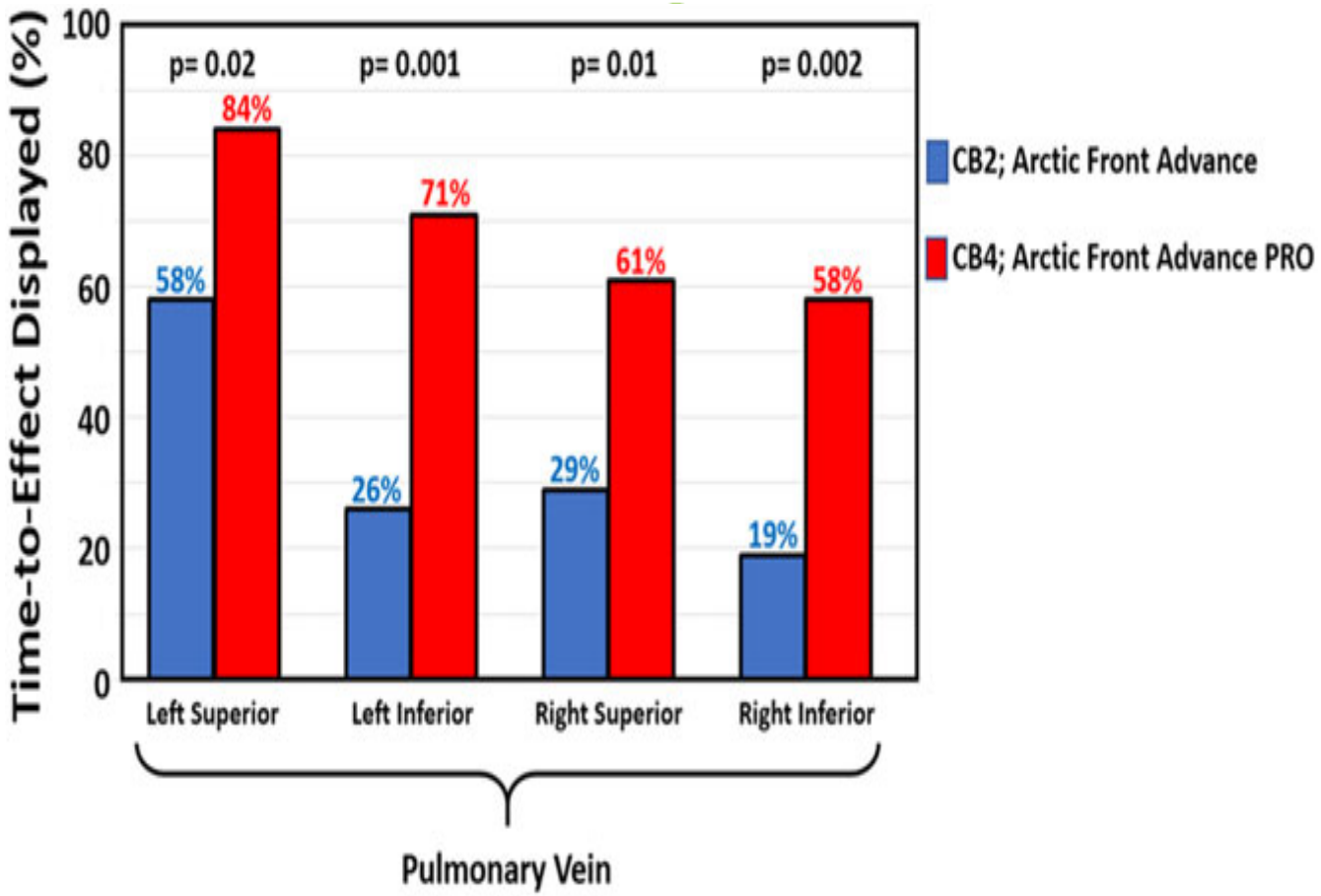


Received: 2 April 2019 | Revised: 22 April 2019 | Accepted: 29 April 2019
DOI: 10.1111/pace.13718

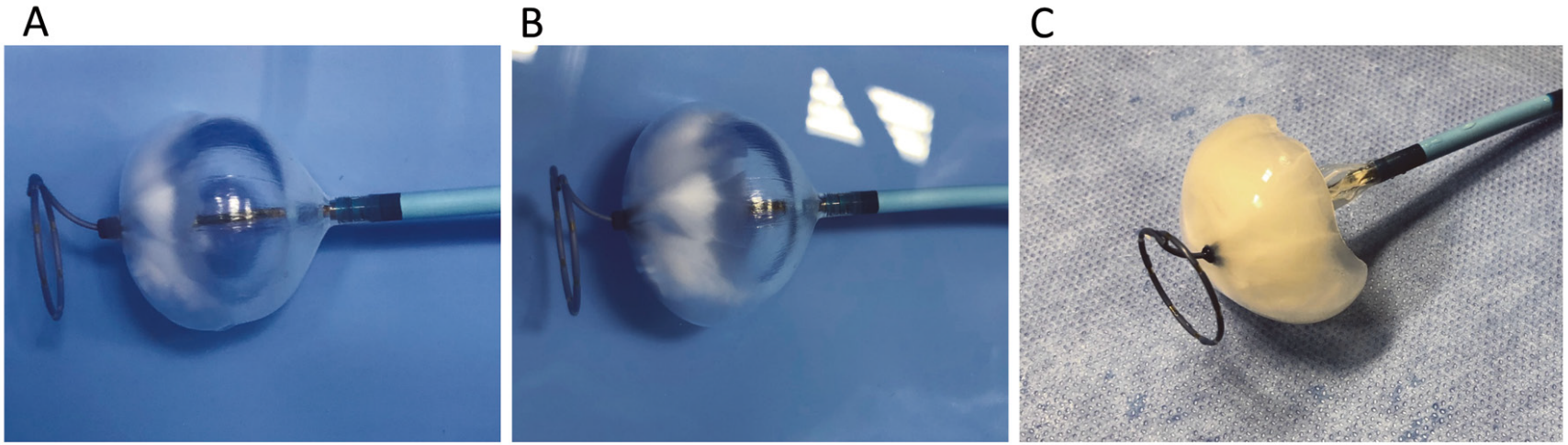
PACE WILEY

ELECTROPHYSIOLOGY

Acute outcome after a single cryoballoon ablation: Comparison between Arctic Front Advance and Arctic Front Advance PRO



POLARx



- Boston Scientific
- 15.9 F POLARSEATH (155 derece- distal defleksiyon)
- Balon çapı 28 mm
- Distal tip uzunluğu 5 veya 12 mm
- POLARMAP sirküler haritalama katateri (şaft kalınlığı 3F, 8 elektrod [1-6-1] ve loop diameter 20 mm)
- SMARTFREEZE konsol sistemi
- Komple distal hemisferde soğuma özelliği

Circulation Journal
Circ J 2021; 85: 1296–1304
doi:10.1253/circj.CJ-21-0094

ORIGINAL ARTICLE
Catheter Ablation

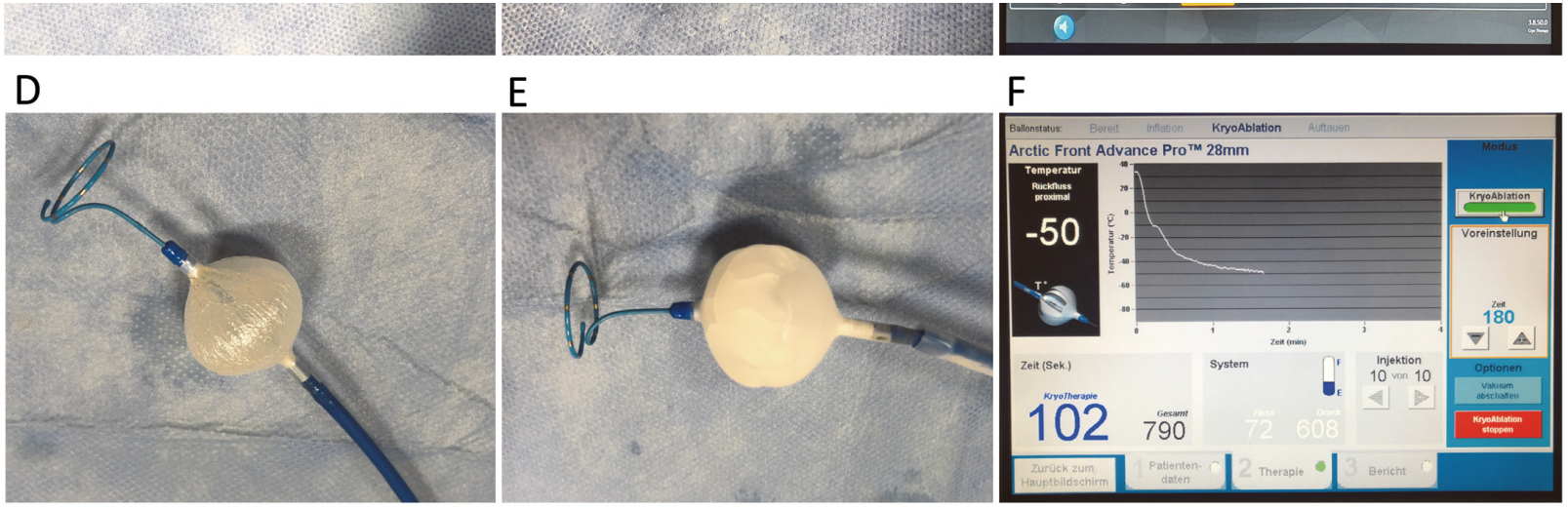
Novel Cryoballoon Ablation System for Single Shot Pulmonary Vein Isolation
— The Prospective ICE-AGE-X Study —

Received: 24 November 2020 | Revised: 19 December 2020 | Accepted: 2 January 2021
DOI: 10.1111/jce.14930

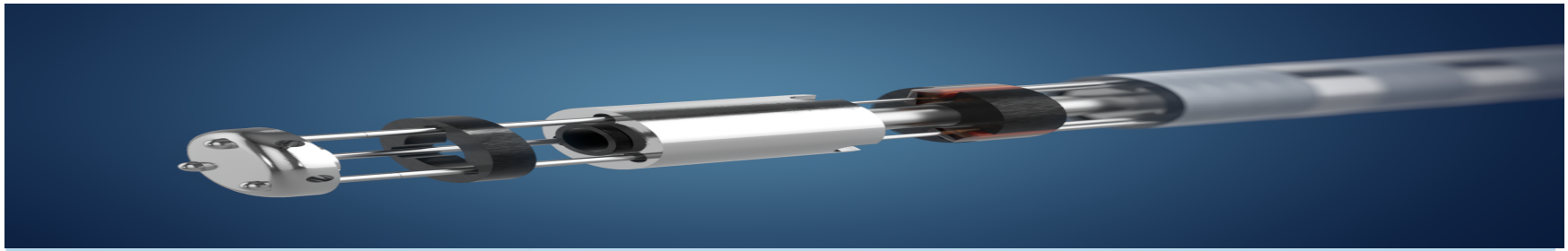
ORIGINAL ARTICLES

WILEY

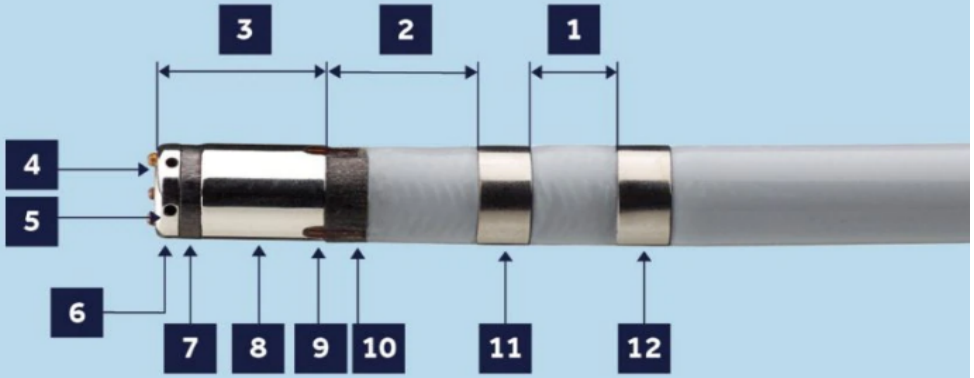
Cryoballoon atrial fibrillation ablation: Single-center safety and efficacy data using a novel cryoballoon technology compared to a historical balloon platform



DiamondTemp



1. 2.0 mm
2. 3.5 mm
3. 4.1 mm
4. 3x Distal Thermocouples
5. 6x Irrigation Ports
6. Distal RF Electrode – 0.6 mm
7. Distal Diamond – 0.5 mm
8. Proximal RF Electrode – 3.0 mm
9. 3x Proximal Thermocouples
10. Proximal Diamond
11. Distal Ring Electrode
12. Proximal Ring Electrode

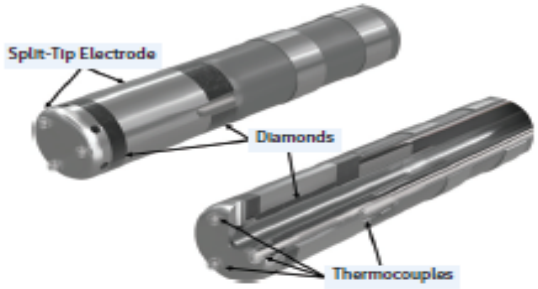


7.5 Fr Isı kontrolü ablasyon kateteri, 6 adet TC , her 20 msn de bir 6 TC dan ısı ölçümü yapılarak RF jeneratör tarafından optimal doku sıcaklığı için güç modülasyonu yapılır.

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 7, NO. 3, 2021

A Novel Temperature-Controlled Radiofrequency Catheter Ablation System Used to Treat Patients With Paroxysmal Atrial Fibrillation

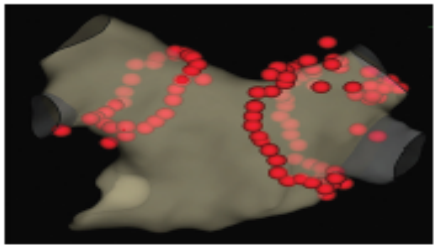
Prospective, Multicenter, Non-Inferiority, Randomized Controlled Trial (DIAMOND-AF)



DiamondTemp Ablation (DTA) Catheter

DTA Procedure

Crisp Electrograms

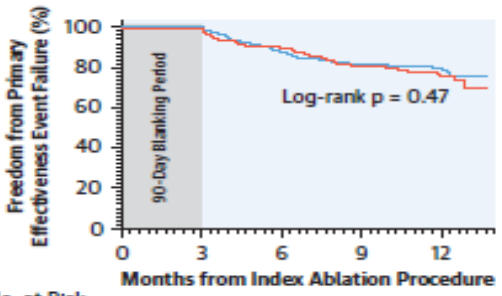


Ablation Map - PVI

DTA Clinical outcomes at 12 months

Primary Effectiveness Endpoint
DTA = 79.1% vs. Control 75.7%

Primary Safety Rate
DTA 3.3% vs. Control 6.6%



No. at Risk

DTA	239	234	200	185	117	9
FS Control	243	236	210	189	121	13

12-Month Kaplan-Meier Estimate

DTA 79.8% (95% CI: 73.9% - 84.4%)

FS Control 76.2% (95% CI: 70.1% - 81.2%)

Kautzner, J. et al. J Am Coll Cardiol EP. 2021;7(3):352-63.

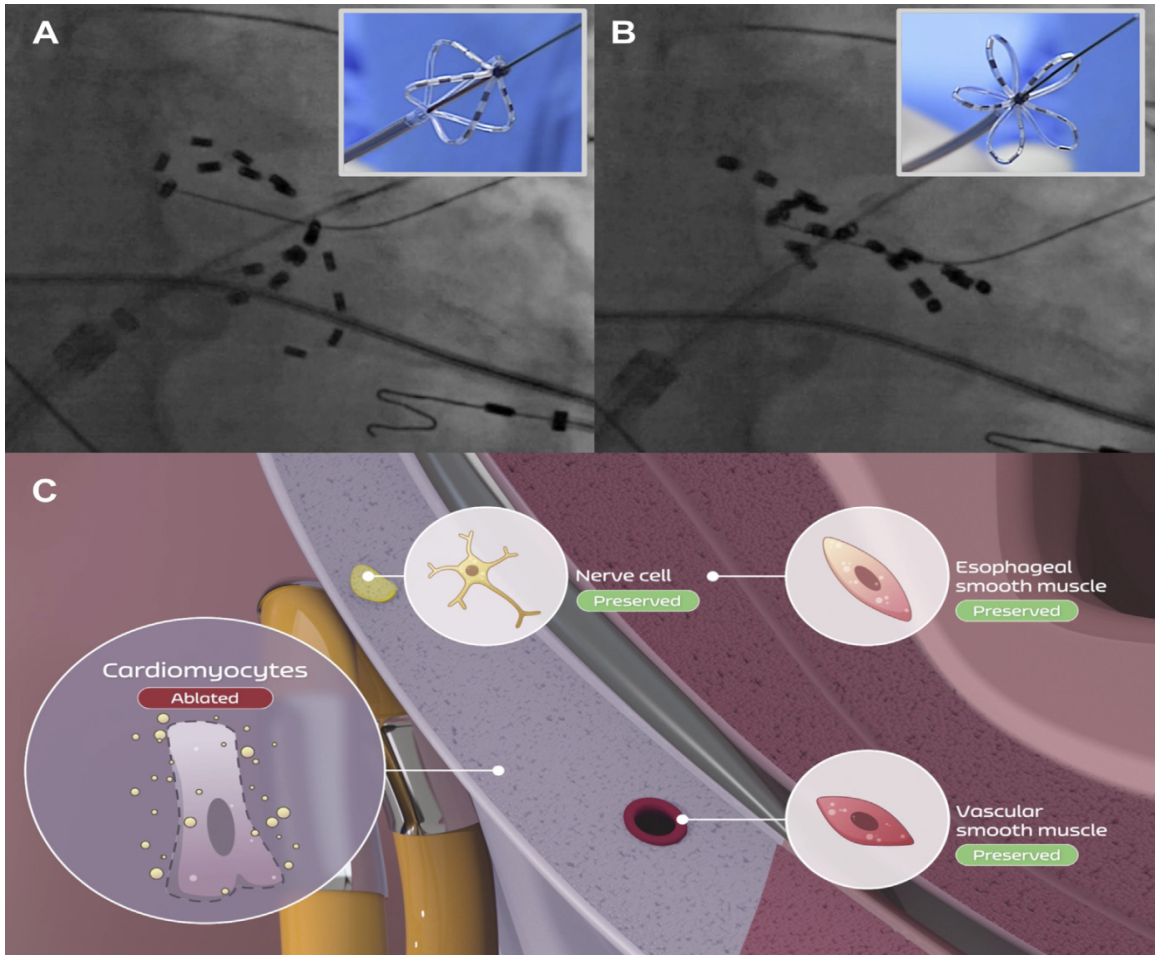
Electroporation

- Elektroporasyon elektrik alanlarını kullanarak yapılan, termal olmayan bir ablasyon tekniğidir.
- Hedeflenen hücrelerin hücre zarlarını yüksek voltajlı bir alana maruz bırakarak zarlarında nano delikler açmaya neden olur.
- Elektroporasyon yeterli voltaj altında hücresel apoptosis ve sonucunda da fibrozis e neden olmaktadır. (günler veya aylar içinde gelişebilir.)
- Irreversible elektroporasyon (IRE) Pulsed Field Ablation (PFA) olarak da anılmaktadır.

Avantajları ;

- daha hızlı ve efektif enerji verilmesi
- Doku seçiciliğinden dolayı frenik sinir ve özefagusta hasar olasılığını tamamen ortadan kaldırmasa da en aza indirmektedir.
- IRE esnasında sıvı elektrolizine bağlı çok kısa yarı ömre sahip mikrokabarcık oluşumu bildirilmesine rağmen hastalardaki şimdilik MRG verileri serebral lezyon oluşturmadıklarını göstermiştir.

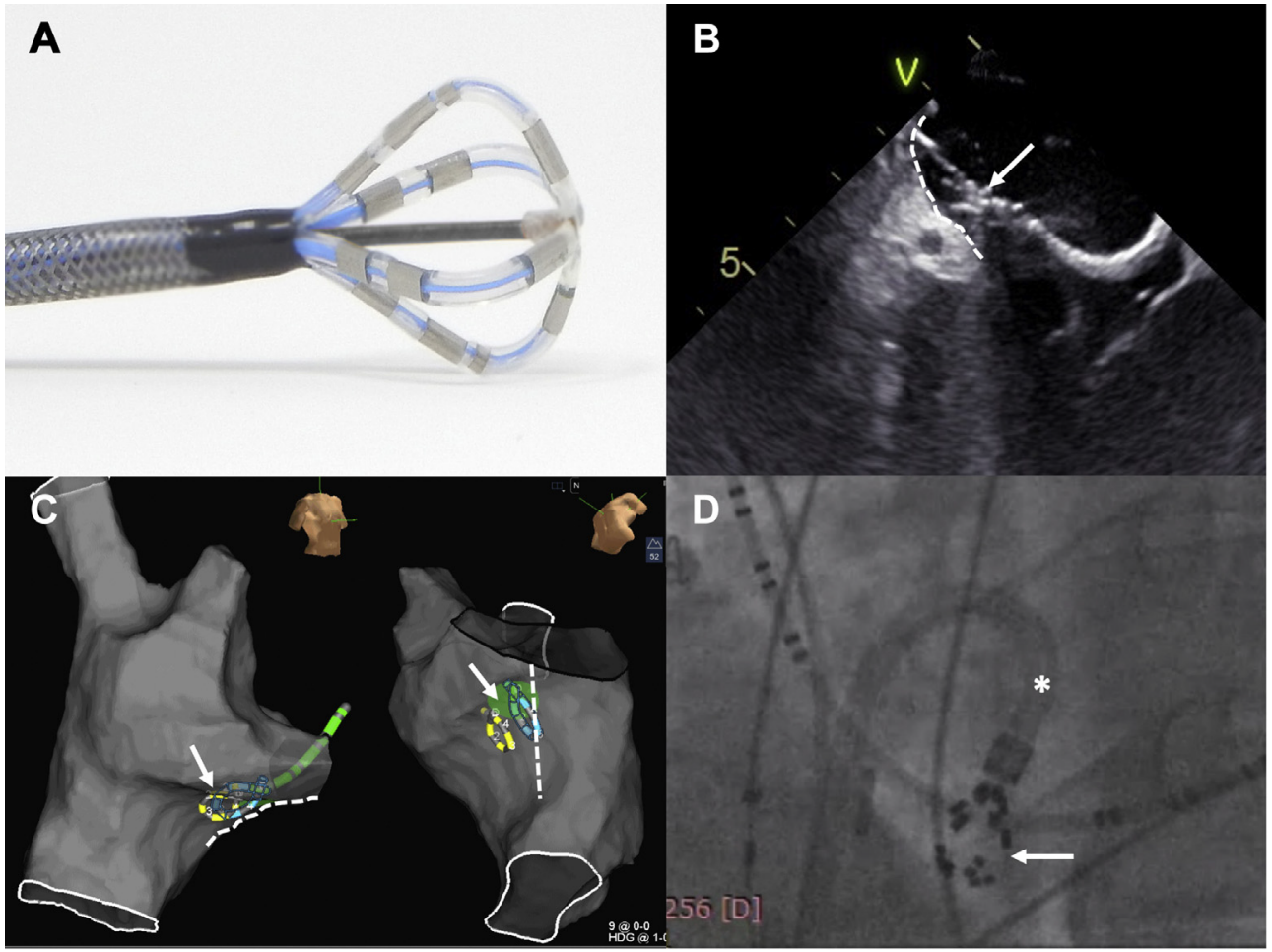
Pulse Field Ablation



•PFA jeneratör (Farastar), over the wire 12 F multielektrod PFA kateter (Farawave), 12 F steerable fokal PFA kateter (Faraflex), 13 F steerable sheath (Faradrive).

•20 elektrodlu (5 kollu her kol 4 elektrod) ablasyon kateteri

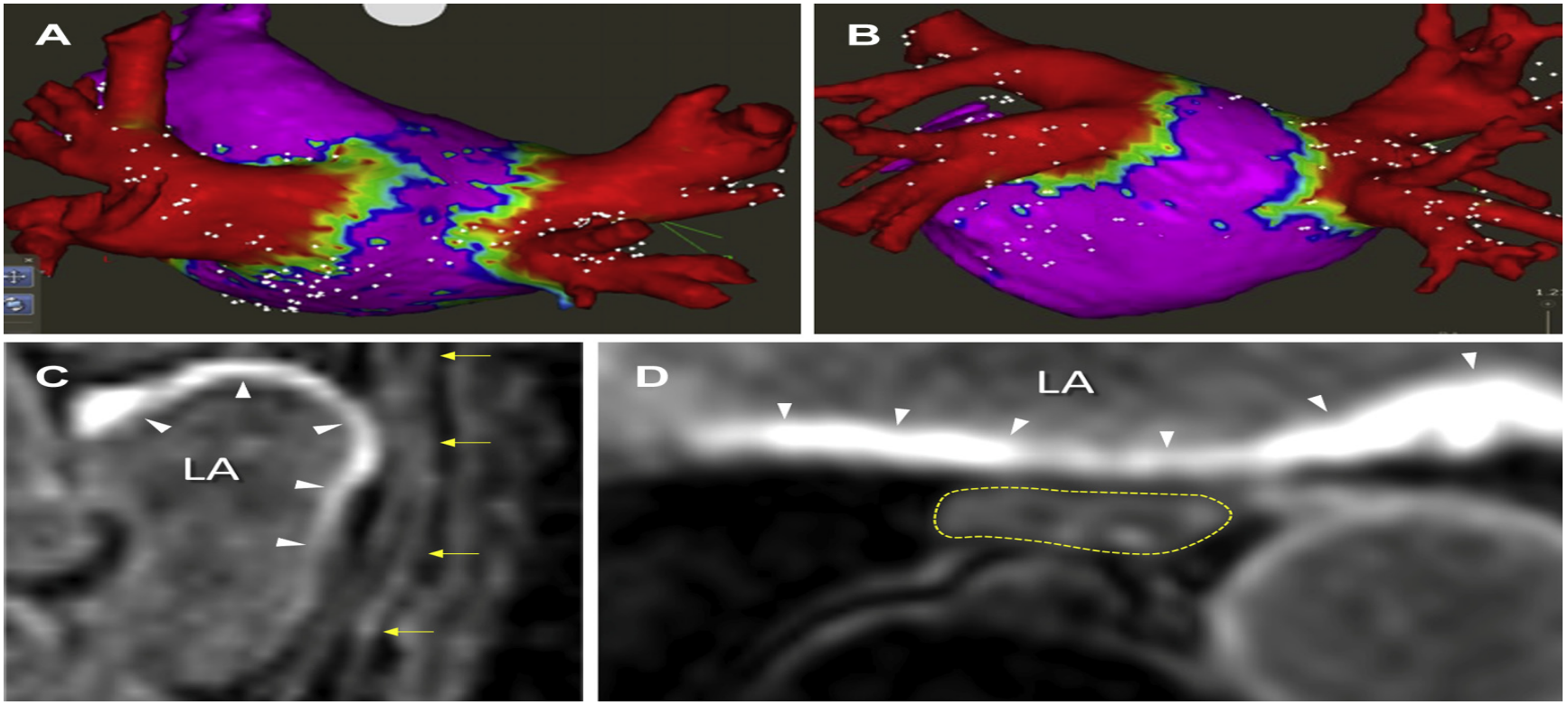
Pulse Field Ablation



JACC: CLINICAL ELECTROPHYSIOLOGY

Pulsed Field Ablation of Paroxysmal Atrial Fibrillation

1-Year Outcomes of IMPULSE, PEFCAT, and PEFCAT II



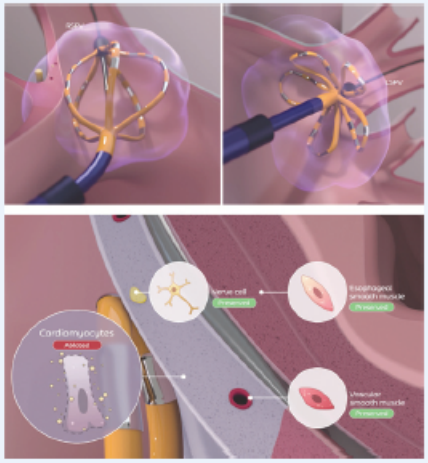
JACC: CLINICAL ELECTROPHYSIOLOGY

Pulsed Field Ablation of Paroxysmal Atrial Fibrillation

1-Year Outcomes of IMPULSE, PEFCAT, and PEFCAT II

CENTRAL ILLUSTRATION PFA for Paroxysmal AF

PFA Catheter & Mechanism of Ablation



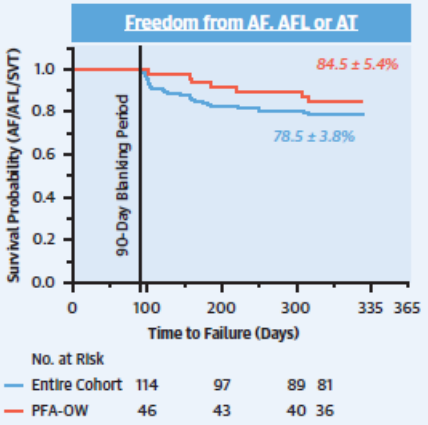
Safety

• Esophageal Damage	0%
◦ Esophageal Dysmotility	0%
◦ Atrioesophageal Fistula	0%
• Pulmonary Vein Stenosis	0%
• Phrenic Nerve Injury	0%
• Stroke	0%
◦ Transient Ischemic Attack	0.9%
• Pericardial Effusion	0.8%
• Vascular Injury	1.7%
• Death	0%

Efficacy

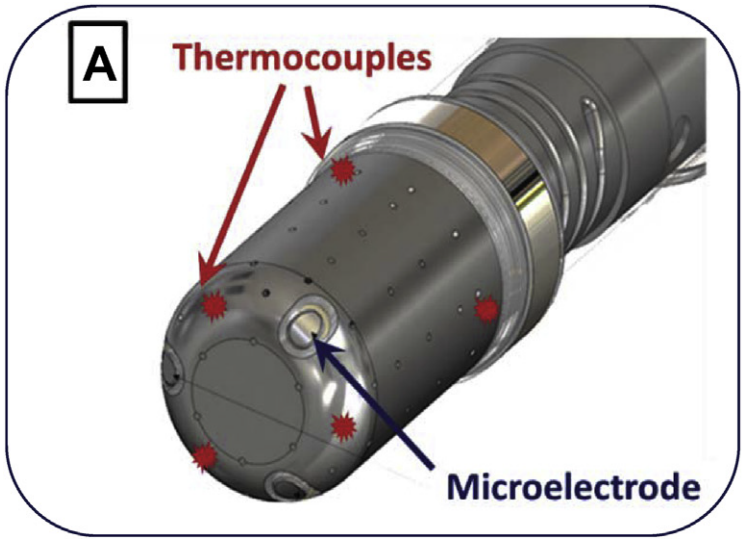
Durability of PV Isolation (Invasive Remapping)

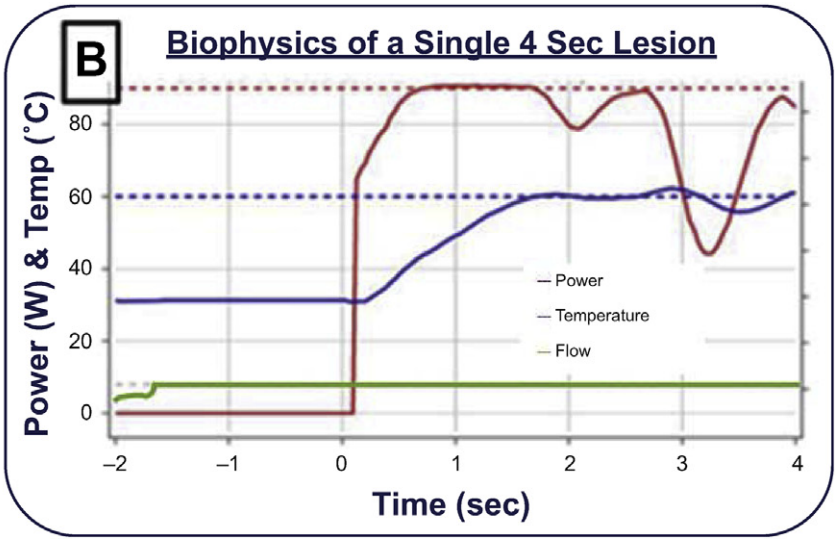
PFA Waveform	Per PV Basis		Per Pt Basis	
	No.%	Durable	No.%	Durable
All	429	84.8%	110	64.5%
PFA-OW	173	96.0%	44	84.1%



Reddy, V.Y. et al. J Am Coll Cardiol EP. 2021;7(5):614-27.

QDOT MICRO with QMODE+





6 tane thermocouple (3 proksimal 3 distal , 1 mm çaplı)

3 mikroelektrod (yüzey alanı 0.086 mm2, elektrodlar arası 1.5 mm)

66 gözenekli irrigasyon

•QMODE+: 90W/4sn

Temperature and flow controlled ablation/very high-power short-duration ablation vs Conventional power-controlled ablation: Comparison of focal and linear lesion characteristics

Table 2A. Focal lesions in the atria

	vHPSD (N=46) (90W/4s, 60□)	PC-Mode (N=46) (30W/30s)	P-values
Wall thickness, mm	2 [1.1-2.4]	2.1 [1.6-2.8]	0.31
Average contact force, g	18 [14-20.3]	16 [13-21.3]	0.35
Impedance drop, ohm	17.7 [14.5-21.0]	19.1 [13.8-25.7]	0.26
No lesion identified, n (%)	3 (6.5%)	8 (17.4%)	0.20
Surface lesion (length), mm	8.3 [6.4-9.7]	6.3 [5.2-7.7]	0.0002
Surface lesion (width), mm	6.0 [5.3-6.9]	4.6 [3.8-5.4]	<0.0001
Surface lesion (area), mm^2	39.4 [25.4-52.4]	23.6 [16.0-31.1]	0.0001
Transmurality, n (%)	41/46 (89.1%)	32/46 (69.6%)	0.04
Hemorrhage, mm	1.0 [1.0-2.0]	2.4 [1.2-3.2]	0.0007
Steam-pop, n (%)	1 (2.2%)	1 (2.2%)	1.0

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