

SINGLE-SHOT PFA

Curva di apprendimento delle diverse tecnologie PFA a singolo impulso

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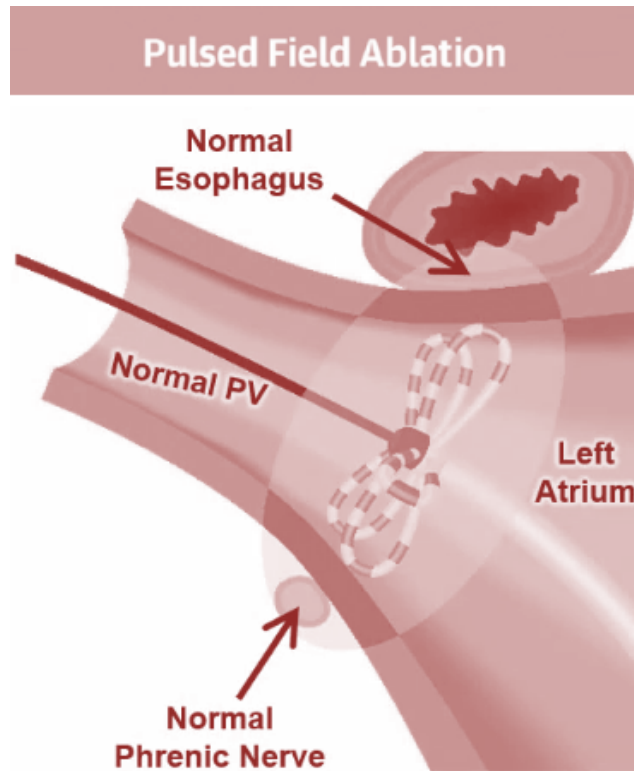
Introduzione

La **PFA** (Pulsed Field Ablation) è una tecnologia che utilizza un'energia non termica altamente selettiva per trattare la fibrillazione atriale.

A differenza dei tradizionali metodi ablativi basati sulla distruzione per via termica (radiofrequenza o crioenergia), la PFA si fonda sul principio dell'elettroporazione cellulare mediante impulsi elettrici.

La PFA presenta un'eccezionale specificità per il tessuto del miocardio, isolando in sicurezza le vene polmonari.

Questa tecnologia all'avanguardia si sta rapidamente affermando in tutto il mondo come terapia sicura di prima linea per il trattamento della fibrillazione atriale parossistica e persistente.

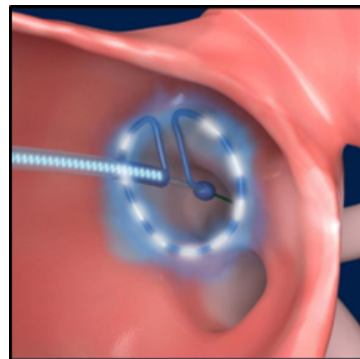
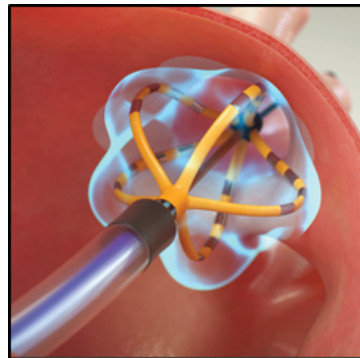


Il Paradigma Single Shot

La Pulsed Field Ablation (PFA) ha rivoluzionato il trattamento della Fibrillazione Atriale.

Sfrutta un'ablazione non termica altamente selettiva per il tessuto miocardico

La procedura è eccezionalmente rapida, sicura ed efficace, azzerando virtualmente il rischio di danni collaterali a esofago e nervo frenico.



Differenti cateteri



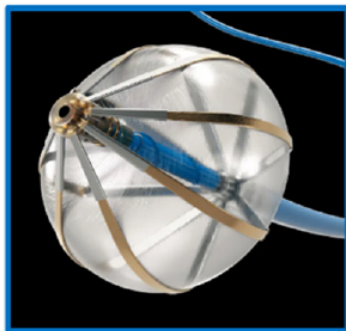
VARIPULSE™



FARAPULSE™



PulseSelect™



Volt™



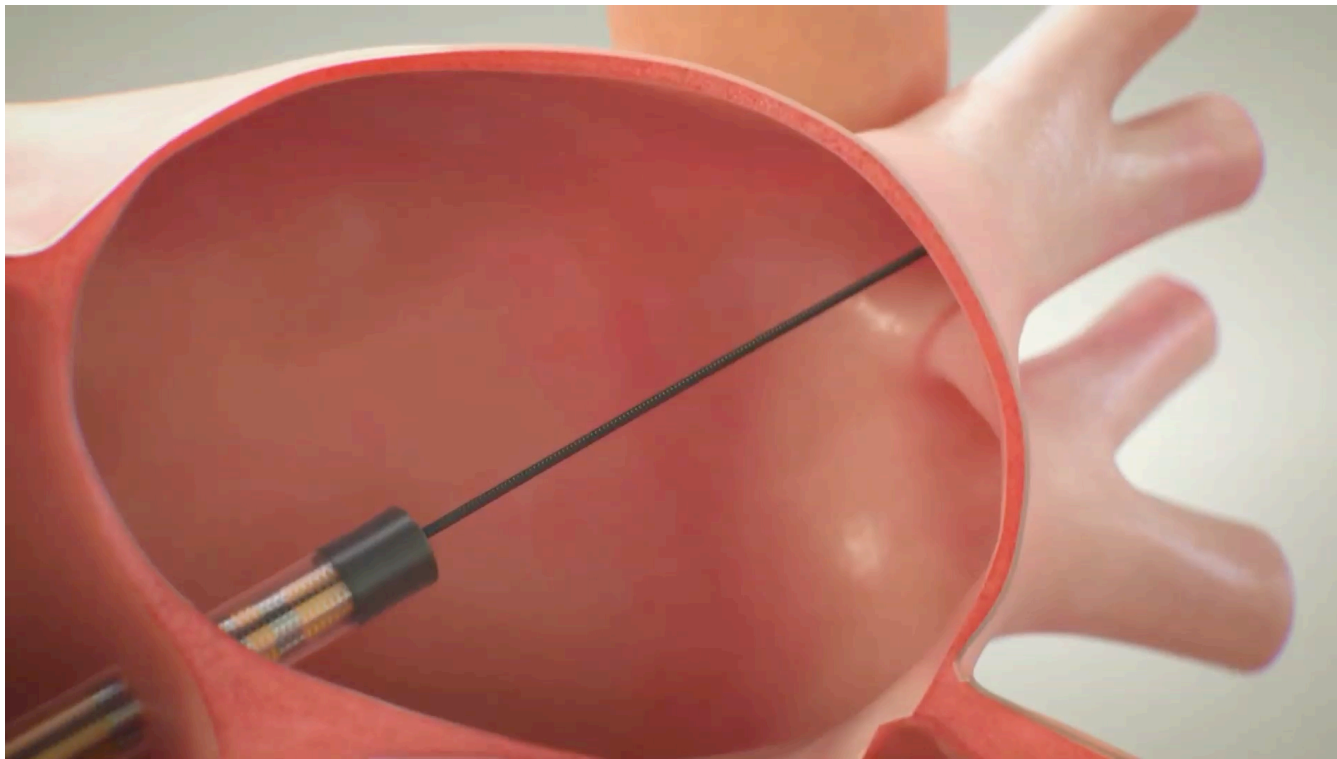
Sphere-9™



Sphere-360™



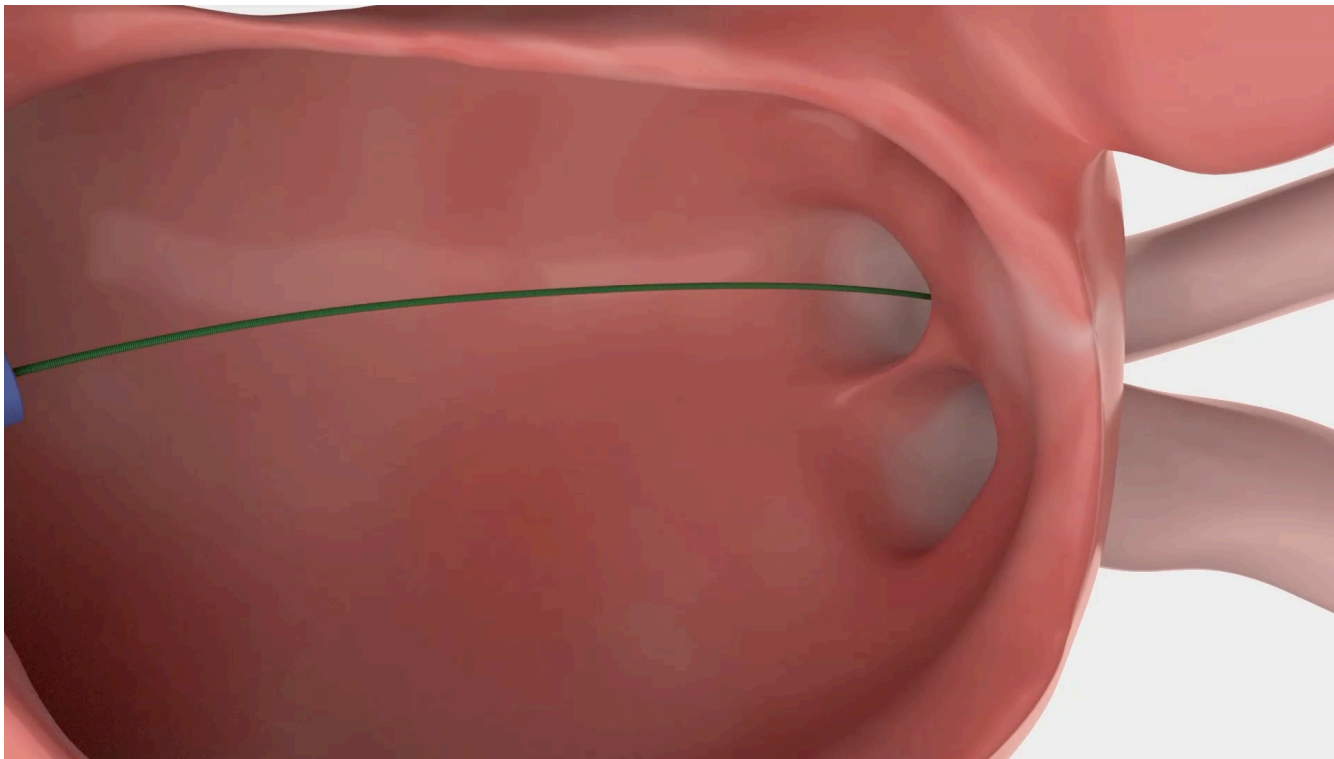
FARAPULSE - Boston Scientific



Due applicazioni per quattro posizioni - 8 applicazioni per vena



PulseSelect - Medtronic

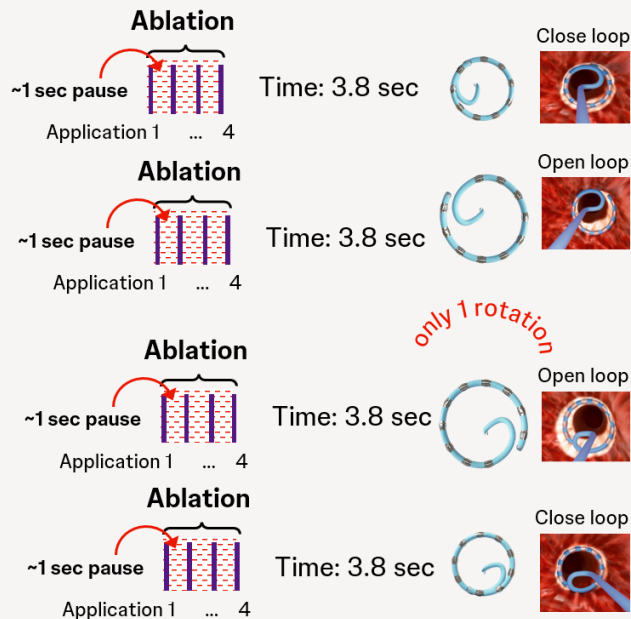


Una applicazione per otto posizioni - 8 applicazioni per vena



4 PF Ablations per vein^{1,2}

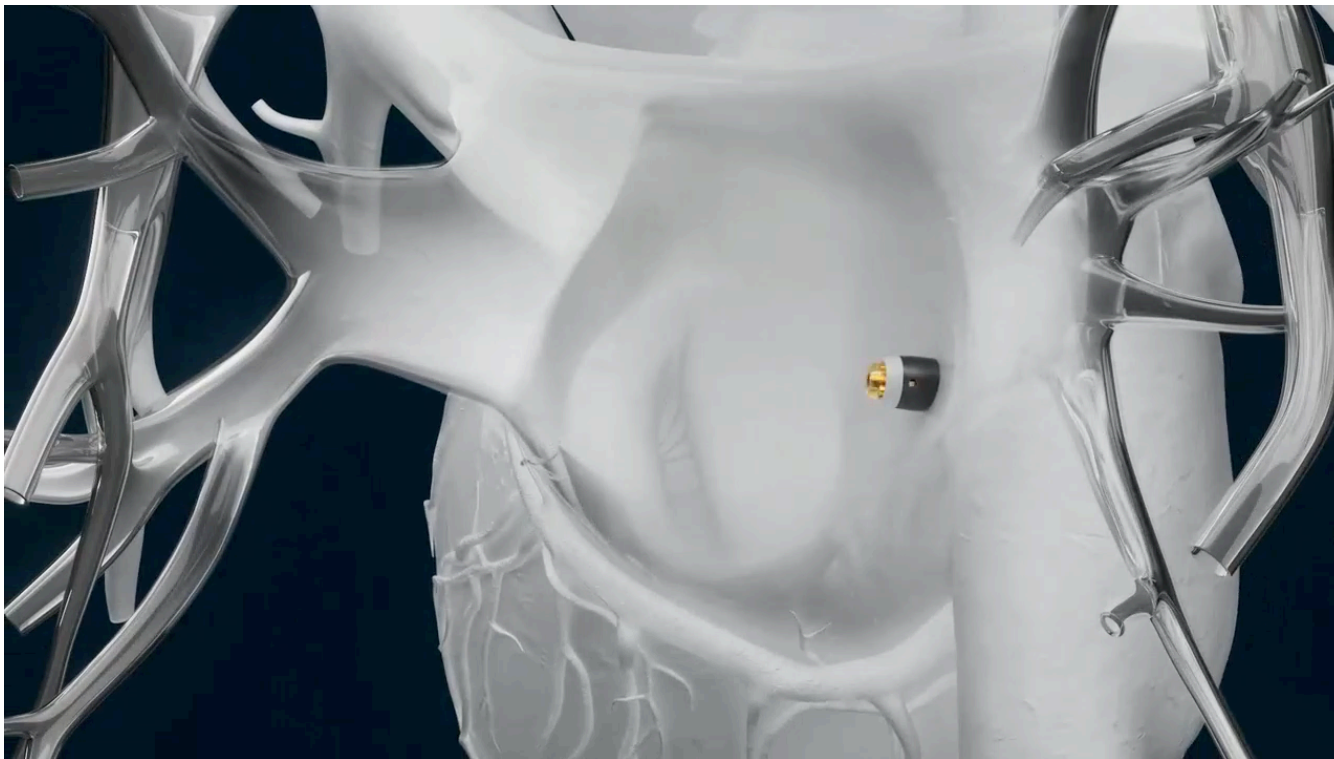
TOTAL TIME ABLATION PVI = 3.8 sec x 4ablations x 4 veins ≈ 60sec



Una applicazione per quattro posizioni - 4 applicazioni per vena



Volt - Abbott

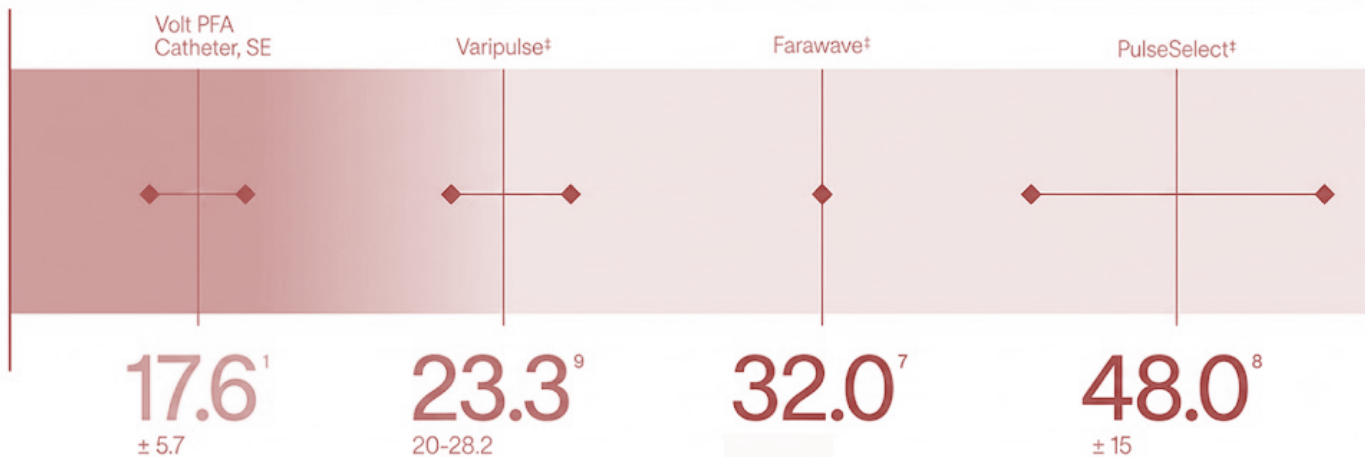


Uno-due applicazioni per due posizioni - 2-4 applicazioni per vena



Numero di applicazioni

Applications per patient



Aspetti che rendono la PFA più semplice rispetto alle tecniche tradizionali:

1) minor dipendenza dall'abilità manuale

- con RF si devono: creare lesioni continue, mantenere forza di contatto
-

2) riduzione passaggi procedurali

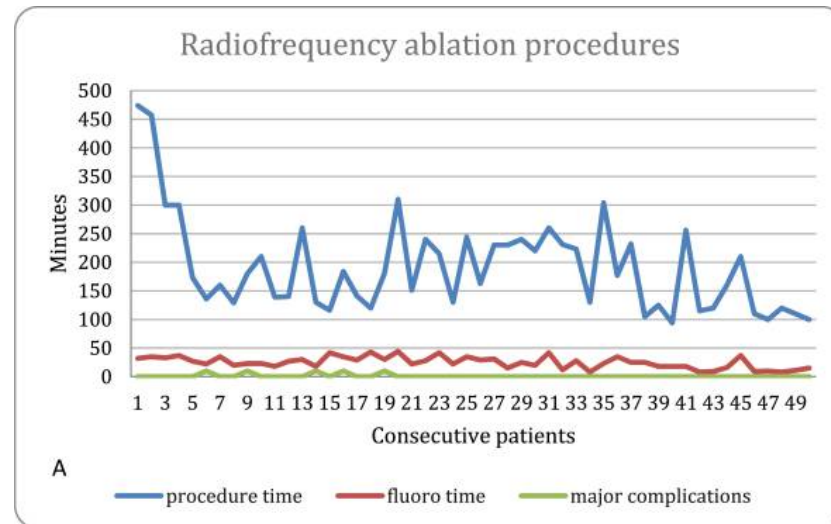
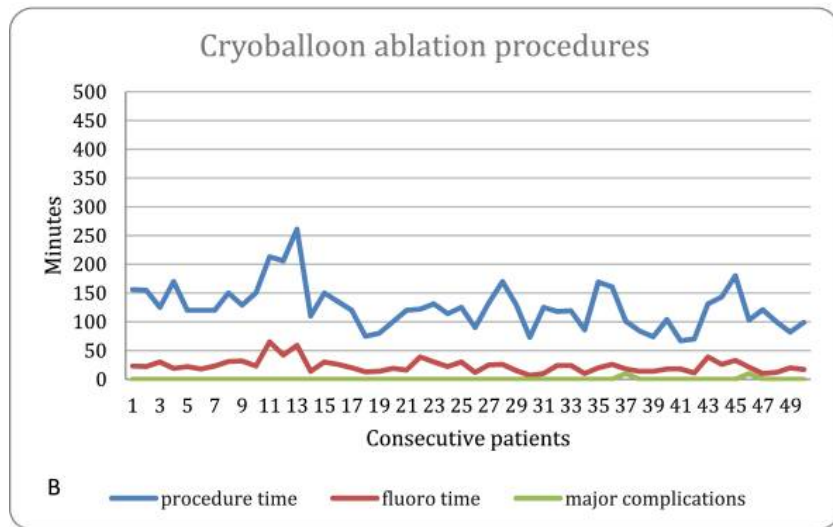
- meno applicazioni
- minor necessità di rimappaggio
- tempi inferiori di navigazione intracardiaca

1) profilo di sicurezza favorevole

- assenza di danno esofageo
- assenza stenosi polmonari
- assenza lesioni frenico
- minor formazione di coaguli dovuti al surriscaldamento



Durata procedure Cryo vs RF



Velagic V, Prepolec I, Pasara V, Puljevic M, Puljevic D, Planinc I, Samardzic J, Milicic D. Learning curves in atrial fibrillation ablation - A comparison between second generation cryoballoon and contact force sensing radiofrequency catheters. Indian Pacing Electrophysiol J. 2020 Nov-Dec;20(6):273-280. doi: 10.1016/j.ipej.2020.09.003. Epub 2020 Sep 30. PMID: 33007406; PMCID: PMC7691769.



Le procedure Farapulse sono molto rapide

STUDY	PROCEDURAL TIME	FLUOROSCOPIC TIME
MANIFEST PF	MEAN <u>61 MINUTES</u>	MEAN <u>13.7 MINUTES</u>
EU-PORIA	MEDIAN W/EAM <u>45 MINUTES</u>	MEAN <u>14 MINUTES</u>
5S FRANKFURT	MEAN <u>38 MINUTES</u>	MEAN <u>8 MINUTES</u>
FAST AND FOURIUS	MEAN <u>27.4 MINUTES</u>	MEAN <u>6 MINUTES</u>



Pulsed Field Ablation-Based Pulmonary Vein Isolation Using a Simplified Single-Access Single-Catheter Approach

— The Fast and Furious PFA Study —

Roland R. Tilz, MD; Julia Vogler, MD; Bettina Kirstein, MD; Charlotte Eitel, MD;
Huong-Lan Phan, MD; Sorin Ștefan Popescu, MD; Sascha Hatahet, MD;
Niels Große, MD; Behnam Subin, MD; Lisbeth Delgado Lopez, MD;
Karl-Heinz Kuck, MD; Christian-H. Heeger, MD

Table 2. Procedural Data

No. of patients	50
No. of pulmonary veins	196
RF ablation touch-up, n (%)	0 (0)
Isolated pulmonary veins, n (%)	196/196 (100)
WACA-PVI, n (%)	50 (100)
Single access, n (%)	50 (100)
PFA applications/patient, n (%)	40±0.6
Procedure duration, min	27.4±6.6
Fluoroscopy time, min	6.0±2.0
Dose-area product, cGy*cm ²	308±147
LA dwelling time, min	14.4±5.5
Contrast medium, mL	42.3±11.6

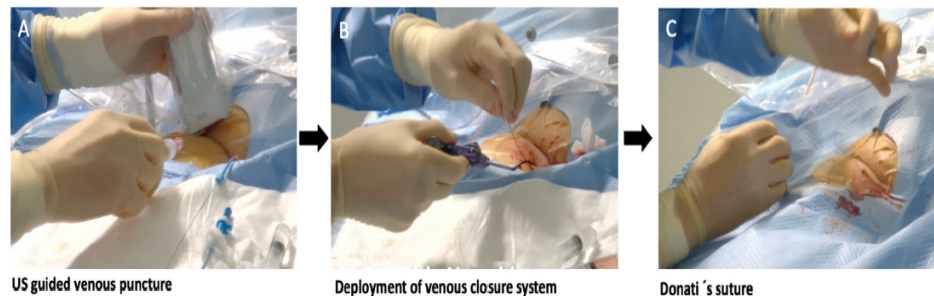
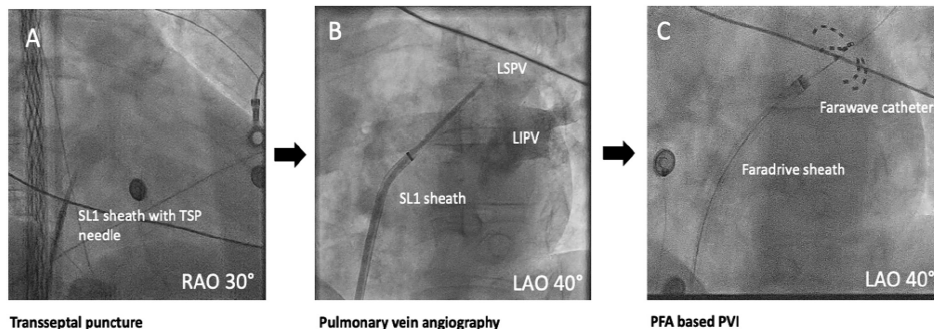
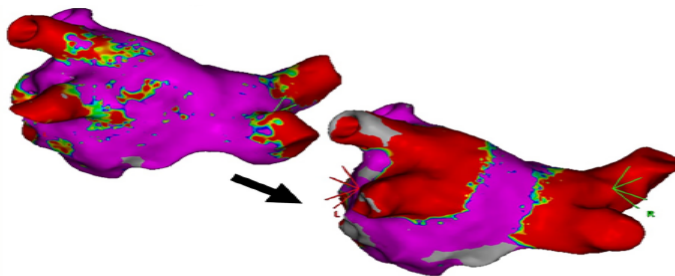
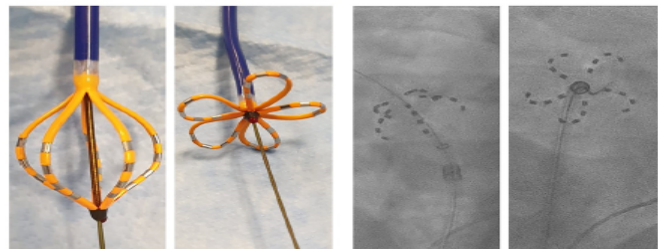


Figure 1. Venous access and closure workflow. (A) Single ultrasound-guided venous puncture. (B) Deployment of a suture-based venous closure system. (C) Removal of sheath, tightening of previously deployed closure system and Donati's suture.



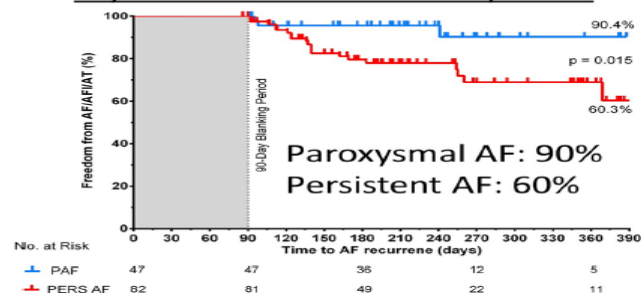
Pulsed-field ablation-based pulmonary vein isolation: acute safety, efficacy and short-term follow-up in a multi-center real world scenario

Marc D. Lemoine^{1,2} · Thomas Fink³ · Celine Mencke^{1,2} · Ruben Schleberger^{1,2} · Ilaria My^{1,2} · Julius Obergassel^{1,2}

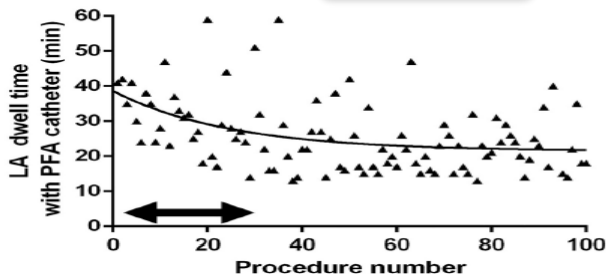


138 pazienti (38% parox)

1-year freedom from arrhythmia



Learning curve: ~30 patients



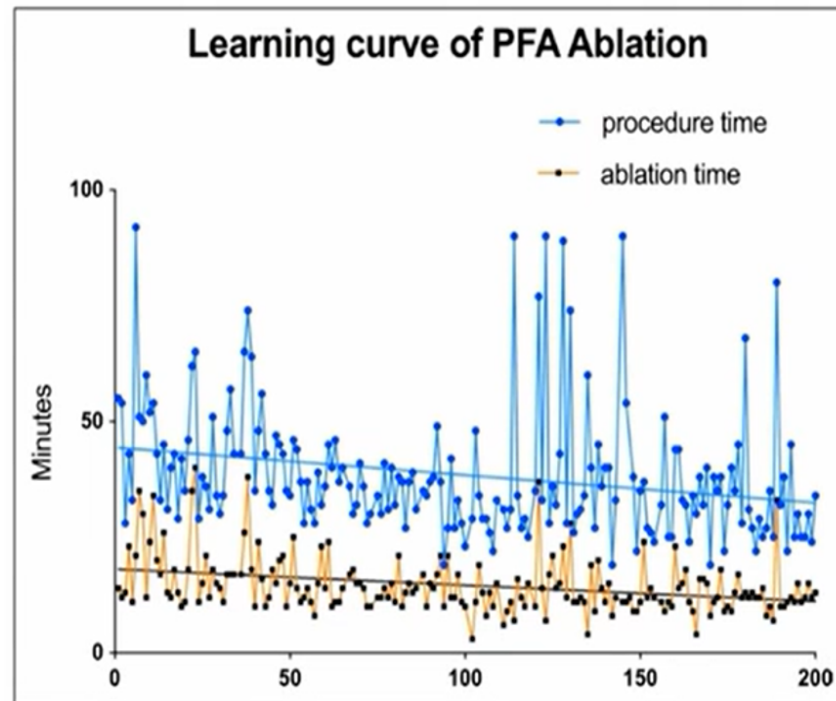
1 Box posteriore



5S Study: Safe and Simple Single Shot Pulmonary Vein Isolation With Pulsed Field Ablation Using Sedation

Boris Schmidt¹, MD; Stefano Bordignon², MD; Shota Tohoku, MD; Shaojie Chen, MD; Fabrizio Bologna³, MD; Lukas Urbanek, MD; Francesco Pansera⁴, MD; Matthias Ernst, MD; K.R. Julian Chun⁵, MD

	Phase 1	Phase 2	P value
Procedural characteristics, n	25 Pts, 98 PV	166 Pts, 650 PVs	
Duration of overall procedure, mins			
Mean±SD, n	46±14	38±14	0.004*
Median (min-max)	43 (28-92)	35 (19-90)	
Overall fluoroscopy time, mins			
Mean±SD, n	11±5	8±4	0.001*
Median (min-max)	9.9 (5.1-22.9)	7.5 (3.9-27.9)	
Number of catheters used			
1, n (%)	24 (96%)	166 (100%)	
2, n (%)	1 (4%)	0 (0%)	
Catheter size (31/35 mm), n (%)	14/11 (56%/44%)	82/84 (49%/51%)	
Number of veins attempted, n	98	650	...
Number of applications, per vein	8±1	8±0	
Single-shot isolation, n (%)	95 (97%)	649 (100%)	0.007†
Patients with all PVs single-shot isolation, n (%)	22 (88%)	165 (99%)	0.006†



Beyond the learning curve: How operator experience affects pulsed-field ablation outcomes 

Thomas Kueffer, PhD,¹ Raphael King, BMed,¹ Jens Maurhofer, MD,¹ Salik ur Rehman Iqbal, MD,¹ Gregor Thalmann, MD,¹ Nikola A. Kozuharov, MD,¹ Oskar Galuszka, MD,¹ Helge Servatius, MD,¹ Andreas Haeberlin, MD, PhD,^{1,2} Fabian Noti, MD,¹ Hildegard Tanner, MD,¹ Laurent Roten, MD,¹ Tobias Reichlin, MD¹

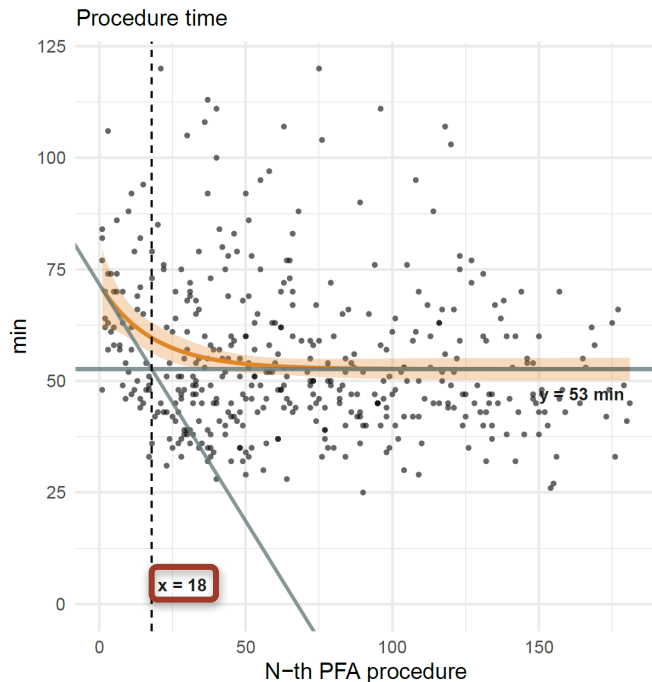
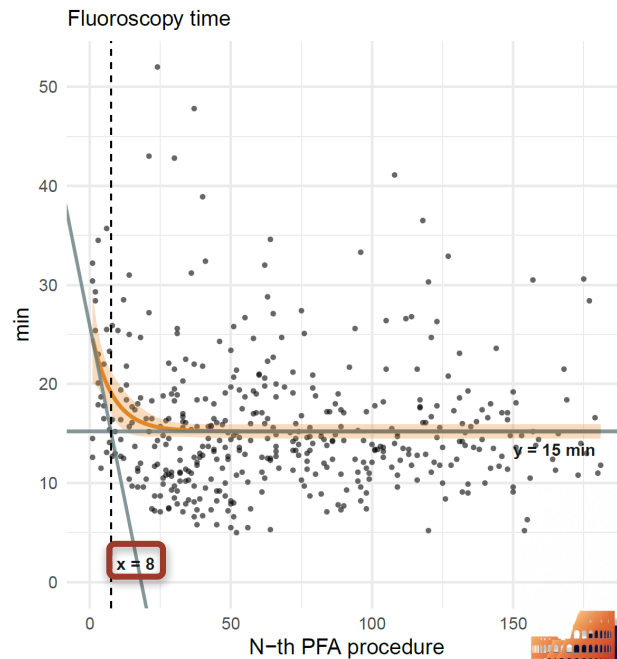


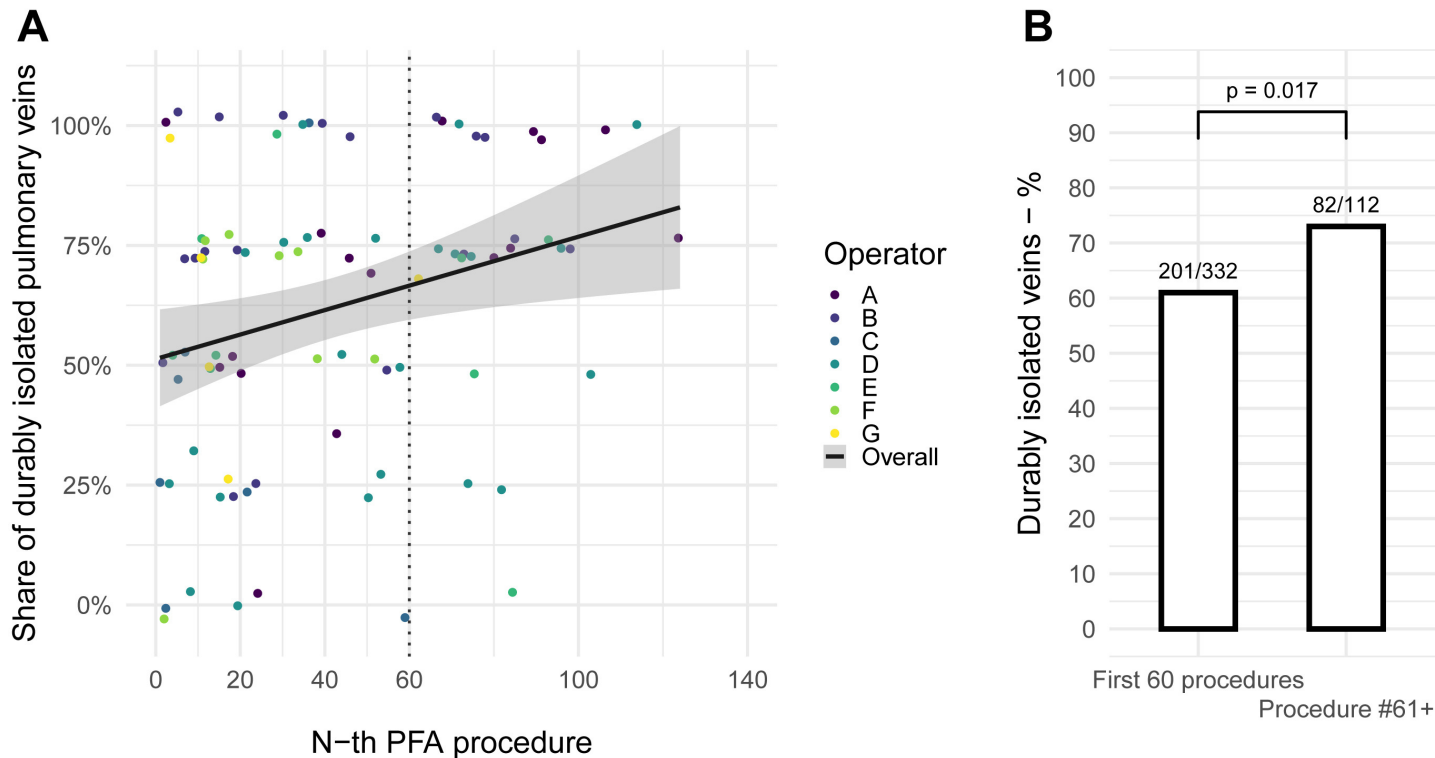
Table 2 Periprocedural safety and follow-up data

Variable	Overall, N = 1008	First 20 procedures, n = 224	>20 procedures, n = 784	P value
Procedure time	71.0 [51.0–99.2]	89.0 [69.0–115.2]	67.0 [49.0–91.0]	<.001
Procedure time in procedures with 3D mapping, min	95.0 [78.0–120.0]	101.0 [82.0–126.0]	91.0 [75.0–119.0]	.006
Procedure time in procedures without 3D mapping, min	54.0 [45.0–70.0]	63.0 [50.5–74.0]	53.5 [45.0–69.2]	.003
Fluoroscopy time, min	17.1 [13.0–24.5]	22.5 [15.7–29.0]	16.1 [12.4–22.0]	<.001



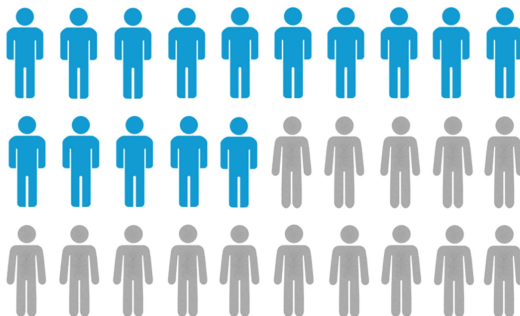
Durabilità migliora con l'esperienza

PV-durability increases with more experience



Insights into Early Adoption and Learning Curve of Pulsed Field Ablation in the U.S.: The Prospective Multicenter DISRUPT-AF Registry

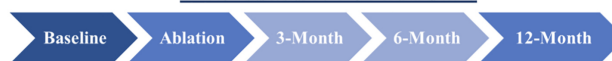
DISRUPT-AF Registry
April 2024



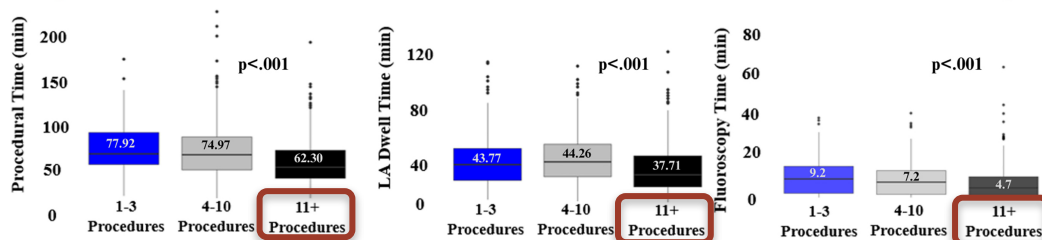
Prospective Cohort:
1,076 patients
PAF:
592 patients
Non-PAF:
482 patients

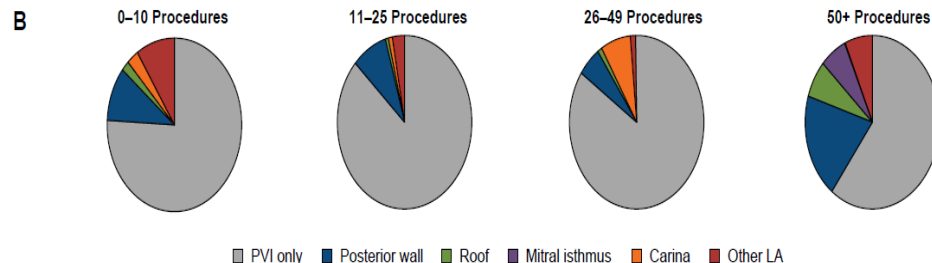
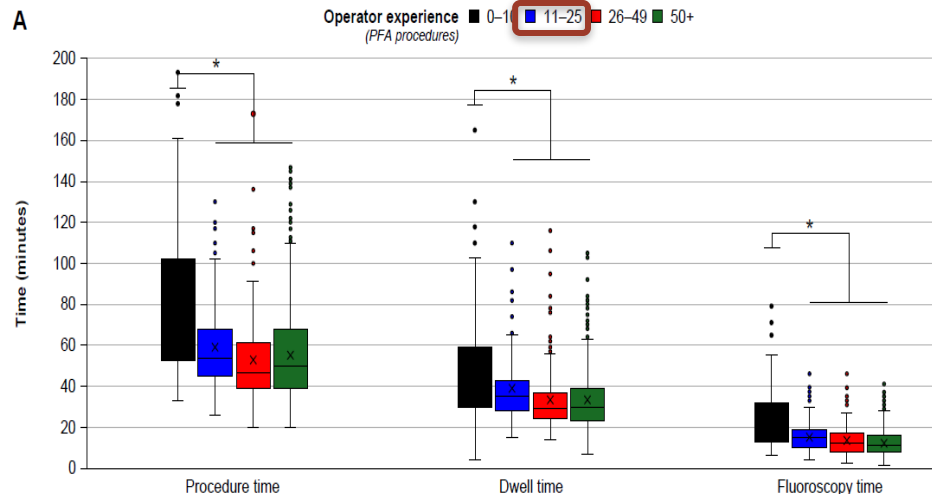
Target:
5,000 patients
40 sites

Data Collection Time Points



Learning Curve





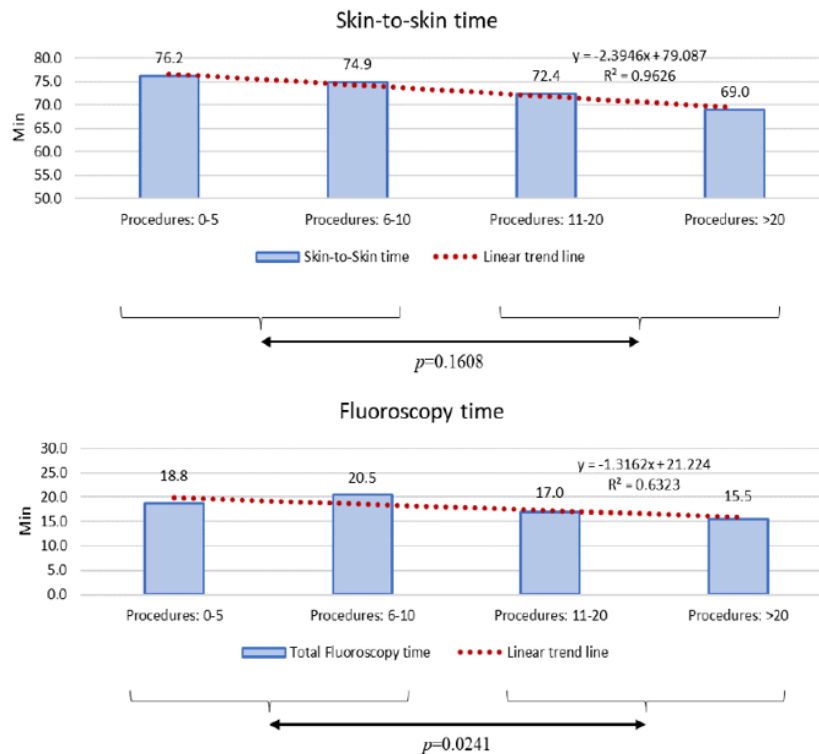
Real-world experience with the pentaspline pulsed field ablation system: one-year outcomes of the FARADISE registry

Lucas V.A. Boersma ^{1*}, Gábor Széplaki ², Antonio Dello Russo ³, Ignacio García-Bolao ⁴, Michael Efremidis⁵, Nándor Szegedi ⁶, Stephan Willems ⁷, Haris Haqqani ⁸, Estelle Gandjbakhch ⁹, Francesco Solimene ¹⁰, George Andrikopoulos ¹¹, Martin Fiala¹², Pascal Defaye ¹³, Armin Luik ¹⁴, Patrick Lugenbiel ¹⁵, Lars Eckardt ¹⁶, Alexandre Ouss ¹⁷, Jean-Manuel Herzet ¹⁸, Javier Ramos Maqueda¹⁹, Sélim Abbey²⁰, Joaquín Osca ²¹, Azlan Hussin²², Nele Cielen²³, Madeline Johnson ²³, Elizabeth M. Albrecht²³, Brad S. Sutton²³, and Johan Vijgen ²⁴; On Behalf of the FARADISE Investigators



National workflow experience with pulsed field ablation for atrial fibrillation: learning curve, efficiency, and safety

Antonio Bisignani¹ · Marco Schiavone² · Francesco Solimene^{3,4} · Antonio Dello Russo^{4,5} · Pasquale Filannino⁶ · Michele Magnocavallo¹ · Claudio Tondo² · Vincenzo Schillaci³ · Michela Casella^{5,7} · Andrea Petretta⁶ · Pietro Rossi¹ · Gaetano Fassini² · Antonio Rossillo⁸ · Ruggero Maggio⁹ · Sakis Themistoclakis¹⁰ · Claudio Pandozi¹¹ · Marco Polselli¹ · Fabrizio Tundo² · Alberto Arestia³ · Paolo Compagnucci^{4,5} · Annelisa Valente Perrone¹² · Maurizio Malacrida¹² · Saverio Iacopino⁶ · Stefano Bianchi¹



Initial experience with pulsed field ablation for atrial fibrillation

Federico T. Magni  1,2*, Bart A. Mulder  1,

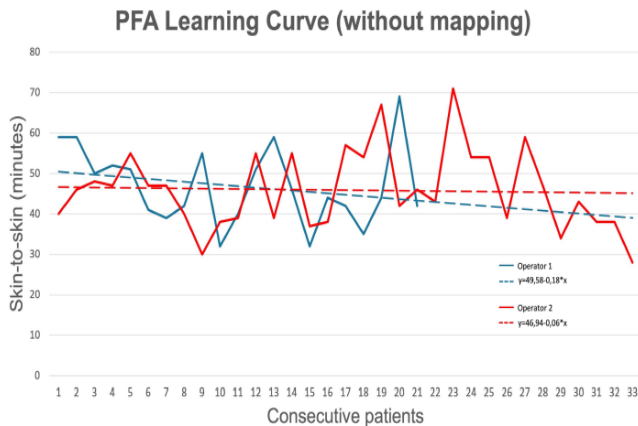
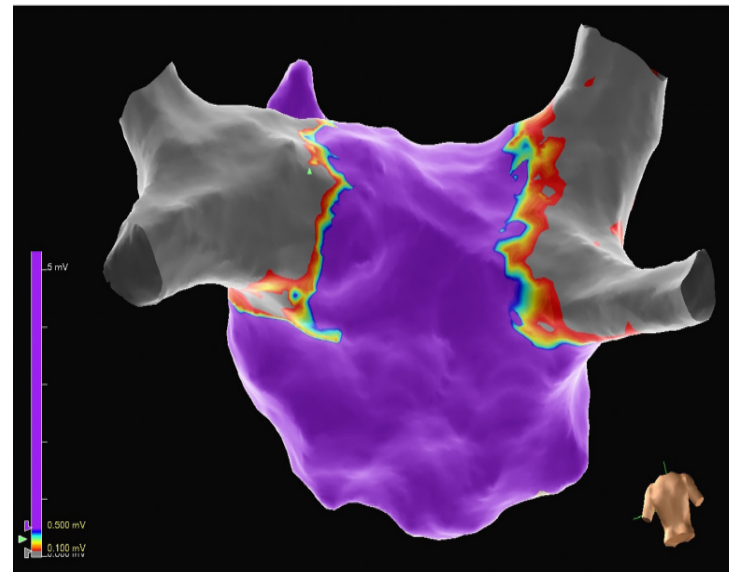


FIGURE 4

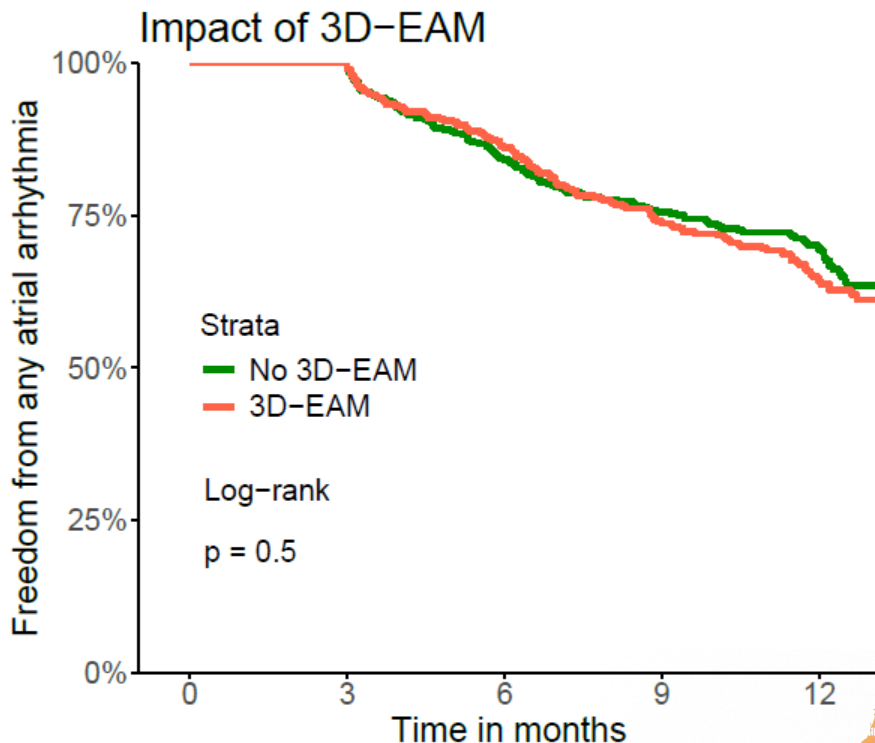
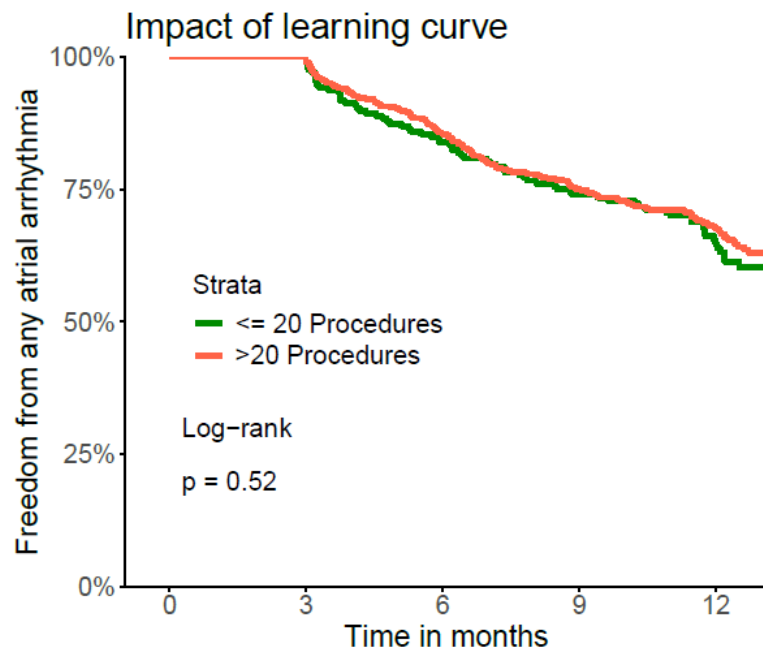
Learning curve for pulsed field ablation (of operators who performed > 20 procedures). Operator 1 (senior) had more than 10 years of experience with AF ablation, while Operator 2 (junior) had less than 5 years of experience with AF ablation.



Le procedure Farapulse sono efficaci indipendentemente da esperienza dell'operatore e utilizzo del mappaggio elettroanatomico

Beyond the learning curve: How operator experience affects pulsed-field ablation outcomes 

Thomas Kueffer, PhD,¹ Raphael King, BMed,¹ Jens Maurhofer, MD,¹ Salik ur Rehman Iqbal, MD,¹ Gregor Thalmann, MD,¹ Nikola A. Kozuharov, MD,¹ Oskar Galuszka, MD,¹ Helge Servatius, MD,¹ Andreas Haeberlin, MD, PhD,^{1,2} Fabian Noti, MD,¹ Hildegard Tanner, MD,¹ Laurent Roten, MD,¹ Tobias Reichlin, MD¹



Le procedure Farapulse in progressi utilizzatori Cryo e RF



7 European centers



42 operators



1233 AF patients treated with PFA



Acute efficacy



99.96% PVI
58 min procedure time

Acute safety

1.7% major complications
(1.1% pericardial tamponade,
0.41% stroke, 0.16% TIA)

Chronic efficacy

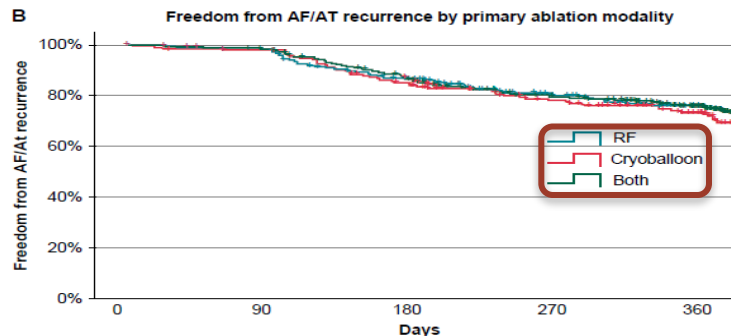
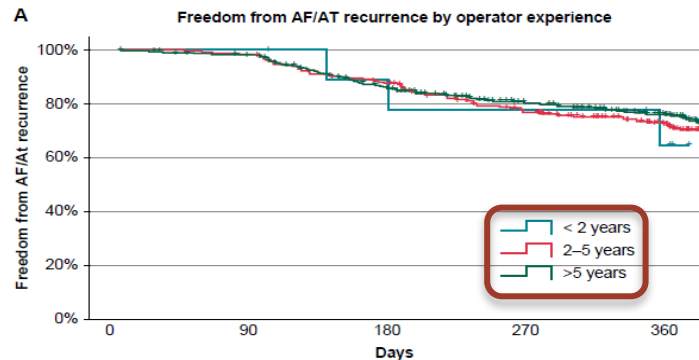
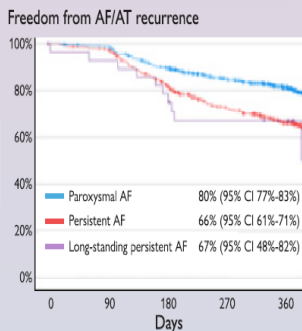


AF/AT-free survival at
365 days median follow up

80% in paroxysmal AF
66% in persistent AF

Reproducible results among
centers irrespective of
operator experience

Freedom from AF/AT recurrence by
AF indication (PFA index procedures)

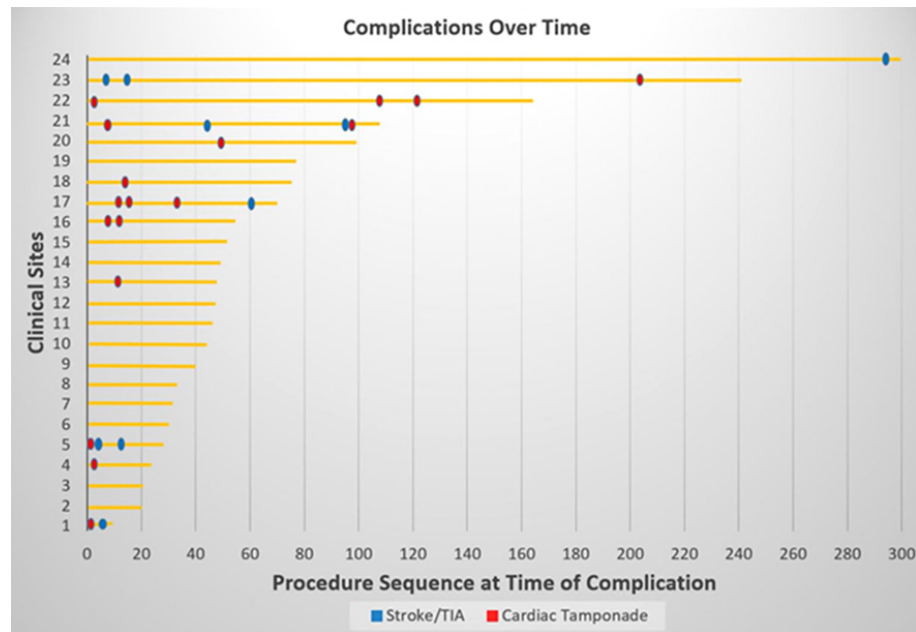


Studio EUPORIA

Table 5 Outcomes by operator primary ablation modality

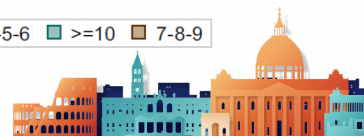
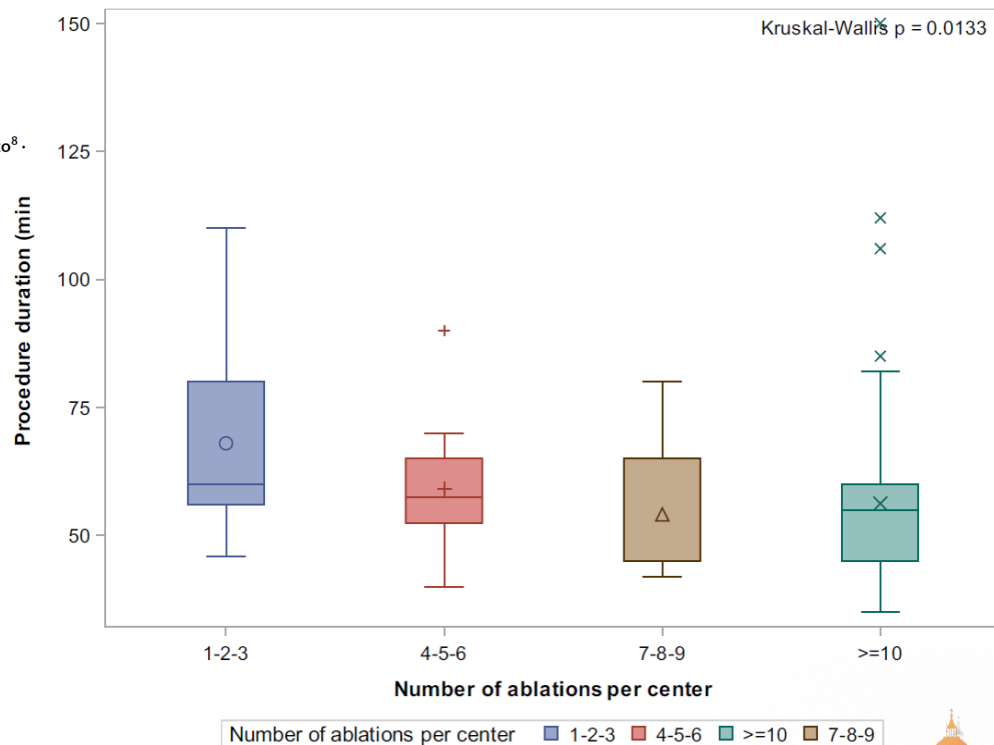
Primary ablation technology	Cryoballoon 13 operators 217 procedures	RF 11 operators 334 procedures	P-value
Procedure times			
Skin-to-skin procedure time, min	59 (50-75)	71 (45-106)	<0.0001
Fluoroscopy time, min	15 (11-21)	18 (13-25)	<0.0001
Safety			
Complications, n (%)	4 (1.8)	15 (4.5)	0.2409
Stroke/TIA, n (%)	1 (0.5)	3 (0.9)	0.7685
Pericardial tamponade, n (%)	0	9 (2.7)	0.0058
Efficacy			
PV reconnection rate, n (%)	33/98 (33.7)	62/162 (38.3)	0.0004
Freedom from AF/AT at 12 months, n (%)	155/217 (71.4)	252/334 (75.4)	

Studio MANIFEST



Acute outcomes and learning curve from the initial patients treated with the PulseSelect system: a real-world multicenter experience of pulsed field ablation

Giulio Molon¹ · Stefano Nardi² · Gianfranco Mitacchione³ · Antonio Dello Russo⁴ · Danilo Ricciardi⁵ · Roberto Mantovan⁶ · Luca Bontempi⁷ · Alessandro Costa¹ · Luigi Argenziano² · Edoardo Casali⁸ · Vincenzo Turco⁸ · Giuseppe Boriani⁸

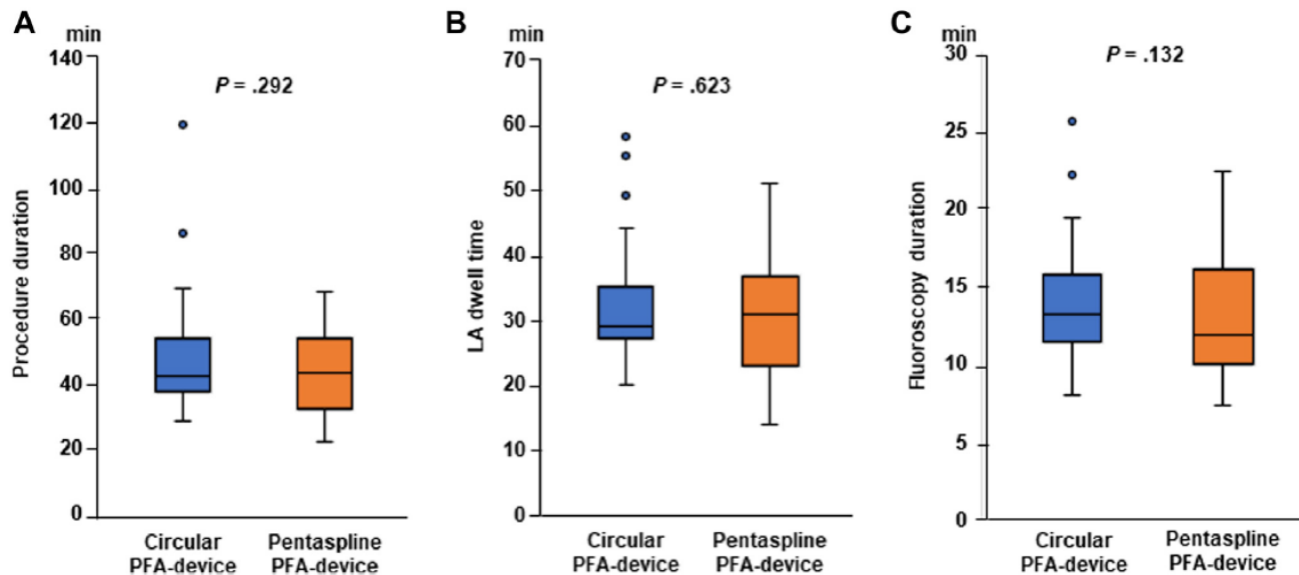


Comparative evaluation of 2 pulsed field ablation systems for atrial fibrillation: Insights from real-world clinical implementation and short-term outcomes 

Maura M. Zylla, MD, Christine Mages, MD, Ann-Kathrin Rahm, MD, Felix Wiedmann, MD, Patrick A. Schweizer, MD, Dierk Thomas, MD, FHRS, Norbert Frey, MD, Patrick Lugenbiel, MD

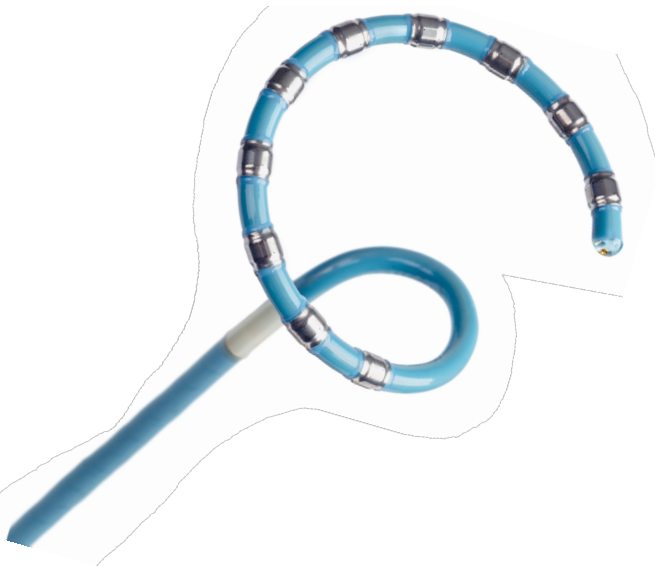
Table 2 Learning curve

	Procedures Number 1-10	Procedures Number 31-40	P value
Circular PFA catheter			
Procedure duration, min, median [P_{25} ; P_{75}]	49.0 [39.8; 53.0]	40.0 [35.0; 46.5]	.089
LA dwell time, min, median [P_{25} ; P_{75}]	32.5 [28.5; 46.8]	28.5 [23.8; 30.3]	.043
Fluoroscopy duration, min, median [P_{25} ; P_{75}]	16.1 [14.4; 19.3]	11.8 [9.9; 15.0]	.003



Evaluating the Safety Profile and Learning Curve With a Pulsed Field Ablation Variable Loop Circular Catheter in Procedures for AF: Observations From the VARIPURE Prospective, Multicenter, Postmarket Study

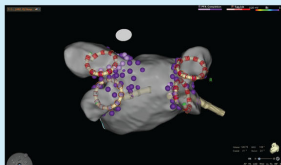
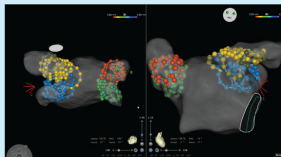
Francis Bessière¹, MD, PhD; Mads Brix Kronborg, MD, PhD; Philipp Sommer², MD; Alexandre Almorad³, MD; Gustavo Rodrigues⁴, MD; Daniel Scherr, MD; Frederic A. Sebag, MD; Tom De Potter⁵, MD, PhD; Massimo Grimaldi⁶, MD, PhD; Tobias Reichlin⁷, MD; Sebastian Knecht⁸, MD, PhD; Christian Sohns⁹, MD; Gian Battista Chierchia, MD; Kévin Gardey, MD; Sabine Ernst¹⁰, MD



VARIPURE Study

- Substudy of the SECURE study (ClinicalTrials.gov Identifier: NCT04750798)
- Observational, prospective, postmarket follow-up study evaluating ablation procedures performed with a novel biphasic PFA system with a VLCC (VARIPULSE, Biosense Webster, Inc, a part of Johnson & Johnson Medtech, Irvine, CA)

AF Ablation Procedure With the Novel PFA VLCC



40 operators from
13 European sites
enrolling patients



247 patients with AF enrolled
between April–October 2024
Aged 65.1±10.4 years;
59.1% male; 60.3% PAF

115 patients included in the
learning curve analysis
Aged 64.4±10.6 years;
57.4% male; 63.5% PAF

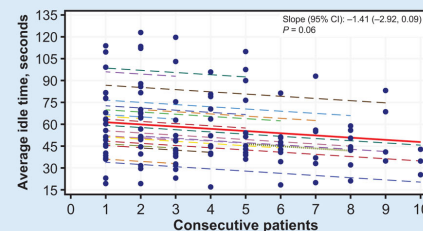
Safety

0 Serious device-related AEs, neurovascular events, ST modifications, or coronary spasms

Procedural Characteristics

Parameter ^a	All patients (N = 247)	LC analysis (n = 115) ^b
Procedure time, min	66.6 ± 21.7	64.5 ± 18.9
Preablation mapping time, min	8.5 ± 8.1	7.0 ± 5.2
Fluoroscopy time, min	5.6 ± 5.6	5.0 ± 4.5
LA dwell time, min	40.1 ± 16.7	40.1 ± 14.7
Total ablation duration, min ^c	30.9 ± 16.0	27.0 ± 11.3
Average idle time, seconds ^d	56.5 ± 25.3	56.3 ± 25.0

Learning Curve of Catheter Idle Time^{||}



How to Use a Variable Loop Circular Catheter to Perform Zero Fluoro Pulmonary Vein Isolation With Pulsed Field Ablation

William K. Chan^{1,2} | Melani Keshishi² | Tara Gomez³ | Umjeet S. Jolly¹

Workflow

1 Preparazione

GA · 2 sheaths · Eparina
200U/kg → ACT>350s

2 Mapping 3D

CARTOSOUND FAM (AI) · 4 VP
+ LAA · ~2 min

3 Accesso transsettale

Puntura RF-guidata sotto ICE ·
Small-curl VIZIGO 17mm

4 Ablazione

4 ablaz./VP (2 ostiali + 2
antrali) · 1800V · 3 appl. · TPI
filter

5 Verifica & chiusura

ICE finale · Protamina ·
Dimissione in giornata

40.5 min

Skin-to-Skin

2 min

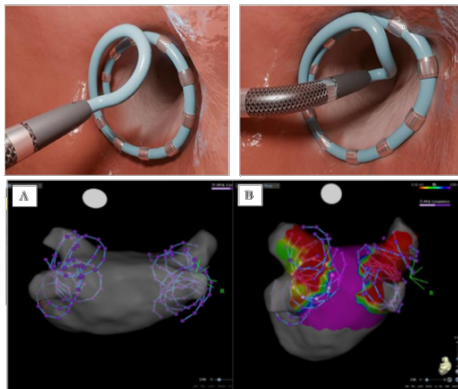
Mapping

100%

PVI acuta

3%

Recidiva 3 mesi



smaller right superior PV due to overlapping electrodes that could cause electrical interference. (Color figure can be viewed at wileyonlinelibrary.com)

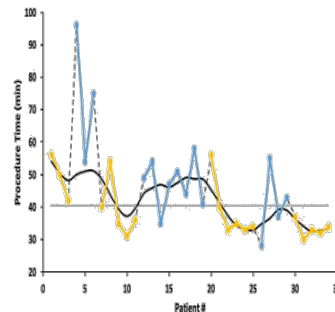


FIGURE 9 | Learning curve of total procedure time from skin-to-skin. Plots of procedure time with consecutive patients. The yellow line (Operator

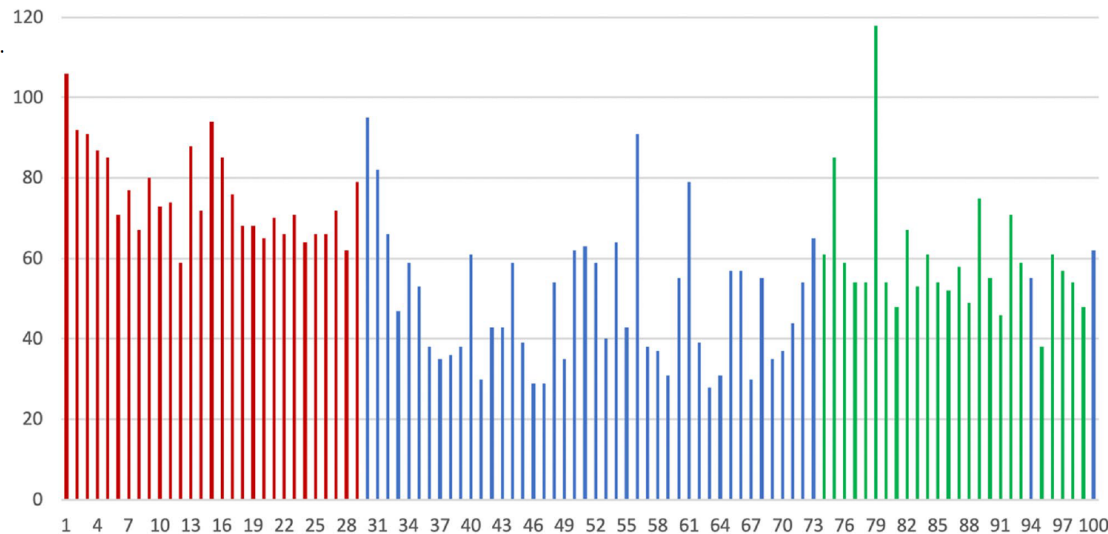
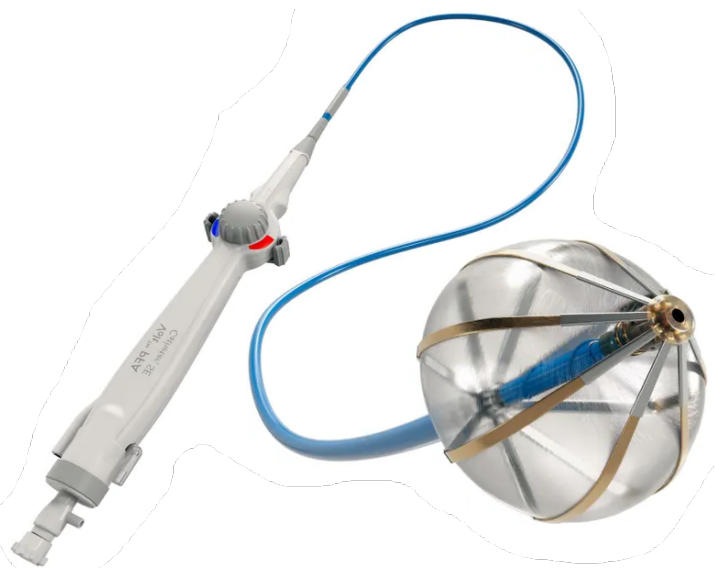
Fig. 9 – Curva apprendimento: <41 min costanti dopo 10 casi/operatore

Conclusioni

- 1a esperienza zero-fluoro, zero-exchange, ICE-guidata con VLCC
- 100% PVI acuta · 40.5 min · fino a 6 casi/giorno
- Curva di apprendimento rapida (10 casi) singolo catetere · no piombo · no imaging pre-proc
- 0 complicanze maggiori · 0 versamenti ·
- Dimissione in giornata · 3% recidiva FA a 3 mesi
- Validazione prospettica necessaria

Safety and performance of the novel balloon-in-basket pulsed field ablation system: initial 100-patient experience at a high-volume electrophysiology center

Roland Richard Tilz^{1,2} · Sascha Hatahet¹ · Charlotte Eitel¹ · Sorin Popescu^{1,2} · Roman Mamaev¹ · Kohei Ukita¹ · Mirco Küchler¹ · Suzanne de Waha¹ · Karl-Heinz Kuck¹ · Jan-Per Wenzel^{1,2}



Conclusioni

Rivoluzione Single Shot

*La PFA "single shot" ha rivoluzionato il trattamento della FA. Si conferma come una **procedura eccezionalmente rapida, sicura ed efficace***

Apprendimento rapido

*Essendo una procedura single shot, è di estrema facilità di apprendimento: bastano in media circa **10 procedure per abbattere e appiattire i tempi procedurali.***

Efficacia democratica

*Altamente **efficace anche in mani inesperte** con tassi di successo perfettamente sovrapponibili tra operatori alle prime armi ed esperti.*

Standardizzazione dei dati

La prima tecnologia a guidare gli studi è stata Farapulse (Boston), ma i dati preliminari ci indicano che i risultati sono estendibili anche agli altri cateteri.



