

KOMBINACE RF/PF ENERGIE MŘÍŽKOVÝM KATETREM SPHERE-9 PŘI KATETRIZAČNÍ ABLACI PERZISTENTNÍ FIBRILACE SÍNÍ, JEDNOROČNÍ VÝSLEDKY Z JEDNOHO CENTRA

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Kardiologické odd. Nemocnice Na Homolce

*Cardiac EP - Mount Sinai Hospital NY, USA



Studie Affera RF/PF

Mřížkový katetr Sphere-9, RFA:

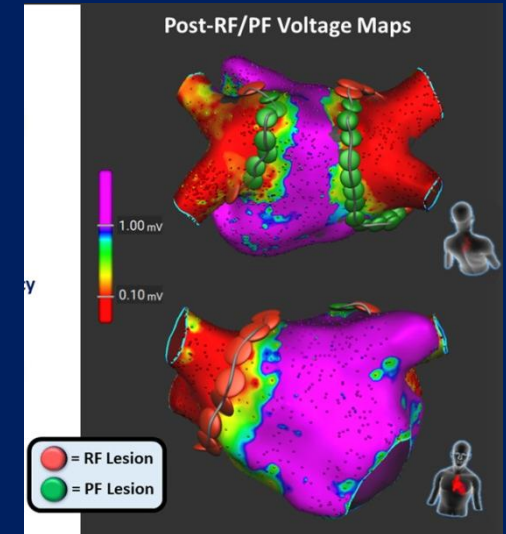
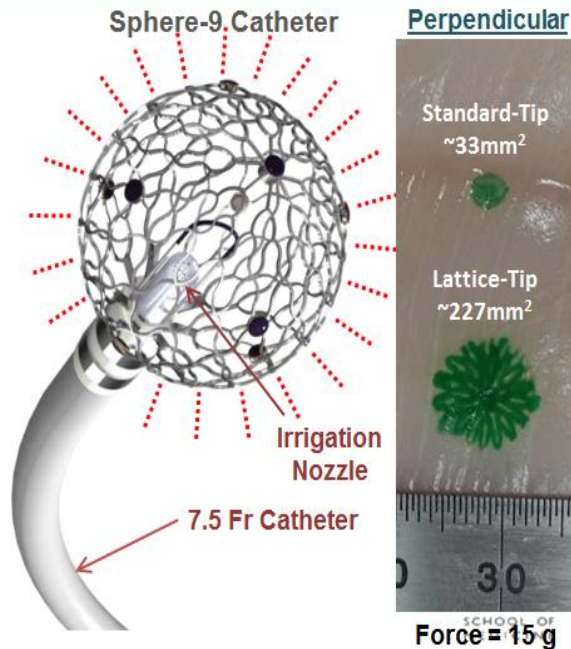
Temp-Controlled Ablation with *Large Thermal Footprint*

- Lattice tip – 9mm diameter
- Nine nodes on surface:
 - Mini-electrodes
 - Surface Thermocouples
- RF Energy from complete tip
- Irrigation from central nozzle
- Integrated Mapping System

Mapping System



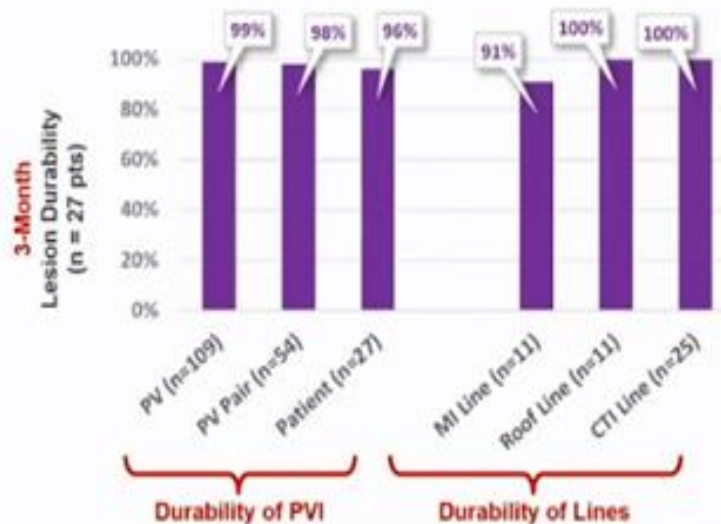
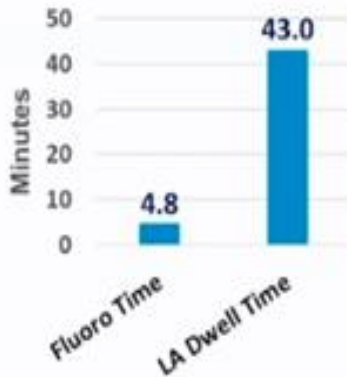
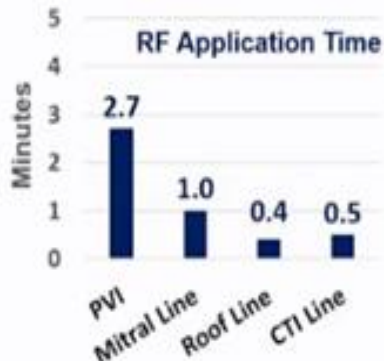
Integrated Pump & Generator



Affera RF – procedurální výsledky

First-in-Human 3-Center RFA Study

Procedural Performance (n=65) & Lesion Durability (n=27)

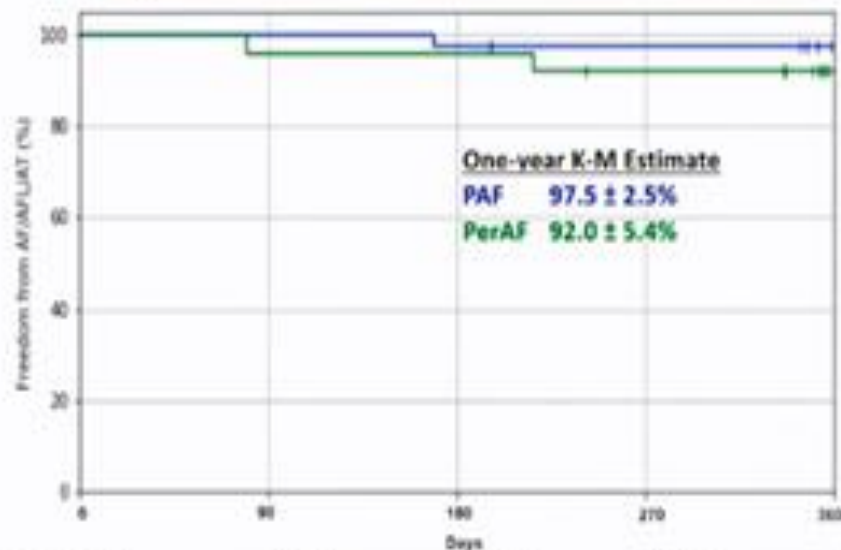


Affera RF – klinické výsledky

AF/AFL/AT Recurrence at 1 Year in PAF vs PerAF

- Mean follow-up: 391 ± 54 days
- Compliance with monitoring
 - 77% overall
 - 91% with the 12mo Holter
- 85% stopped Class I/III AAD by 12mo
- Short-/Long-term safety excellent
 - No atrio-esophageal fistula
 - No stroke / systemic embolism
 - No PV Stenosis
 - No pericardial tamponade
 - No phrenic nerve injury

Kaplan-Meier Freedom from AF/AFL/AT



At Risk	Day 0	Day 90	Day 180	Day 270
PAF	40	40	39	38
PerAF	25	24	24	22



POINT SINAI
SCHOOL OF
MEDICINE



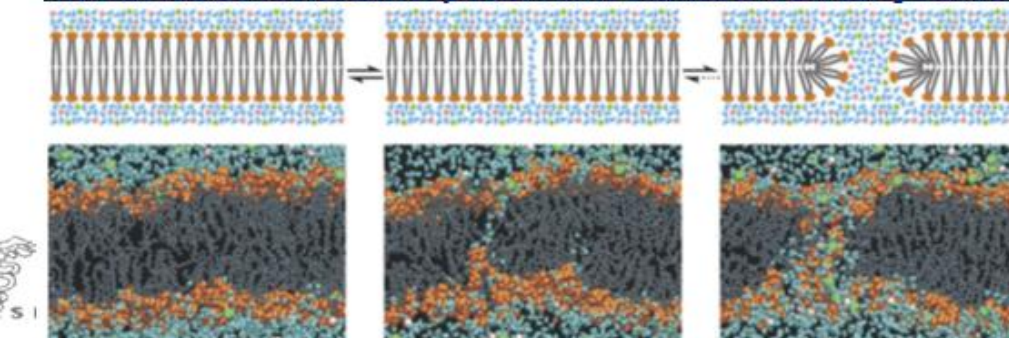
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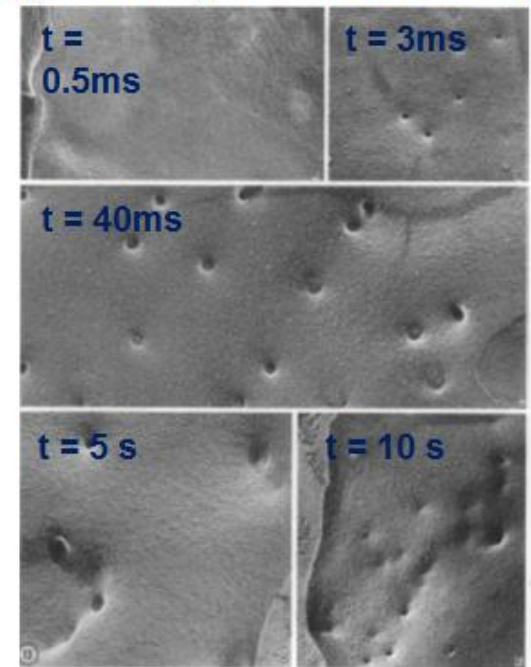
Mřížkový katetr Sphere-9, PFA:

- Application of intermittent, high-intensity electric fields for micro- (or nano-) seconds
- Destabilizing electric potential results in cellular and tissue electroporation
- Formation of nanoscale cell membrane defects
- Pore formation leads to permeabilization

Atomic-Level Molecular Dynamics Simulation of Electroporation

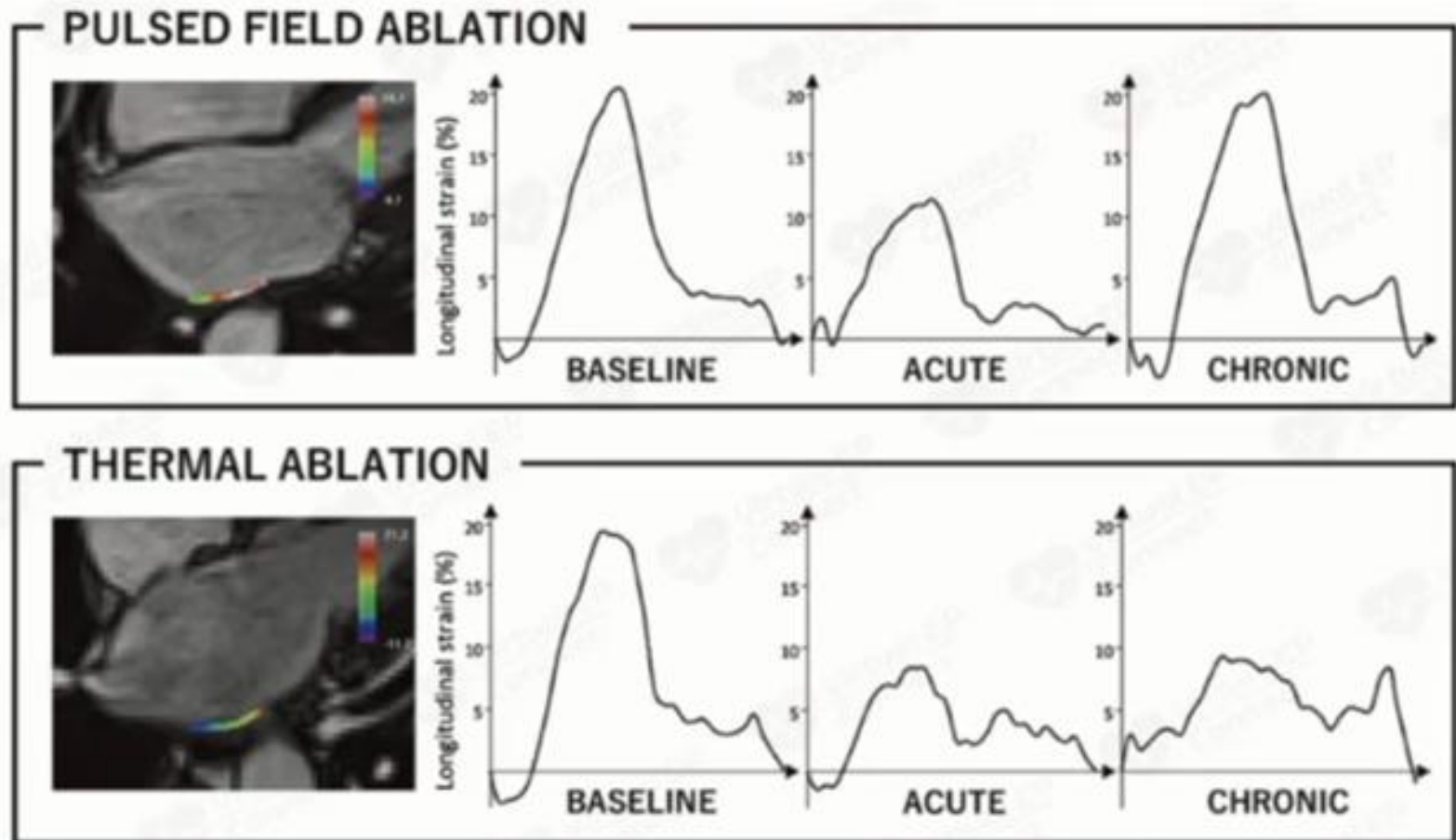


RBC Membranes after IRE: Rapid-freezing electron microscopy



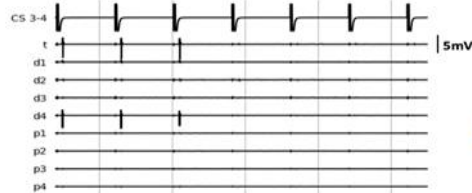
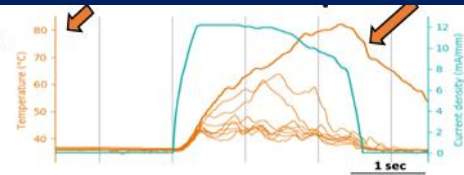
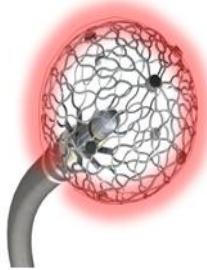
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Benefity PFA: logitudinální strain LA

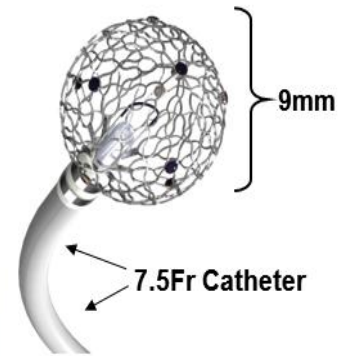
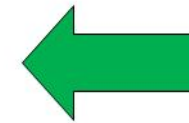
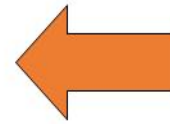
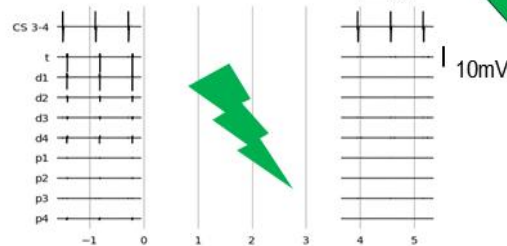
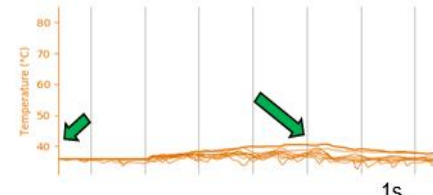
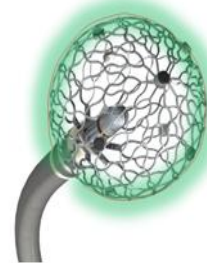


Studie Affera RF/PF Mřížkový katetr Sphere-9:

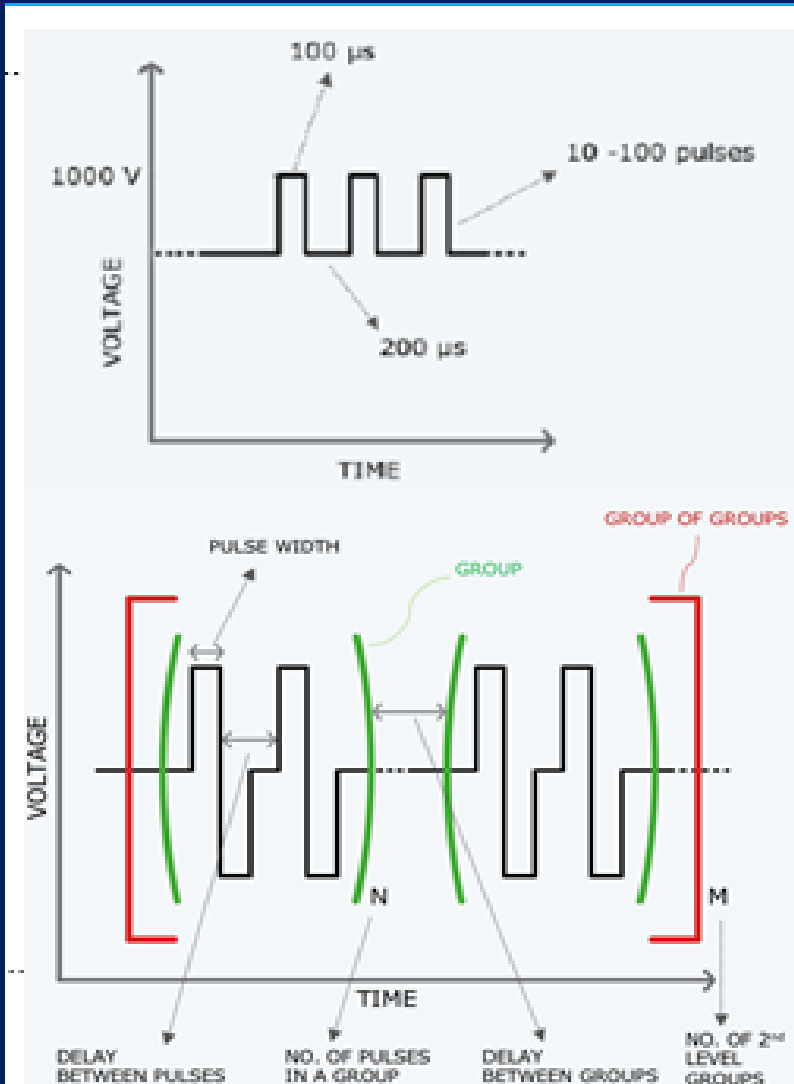
RF Ablation



PF Ablation



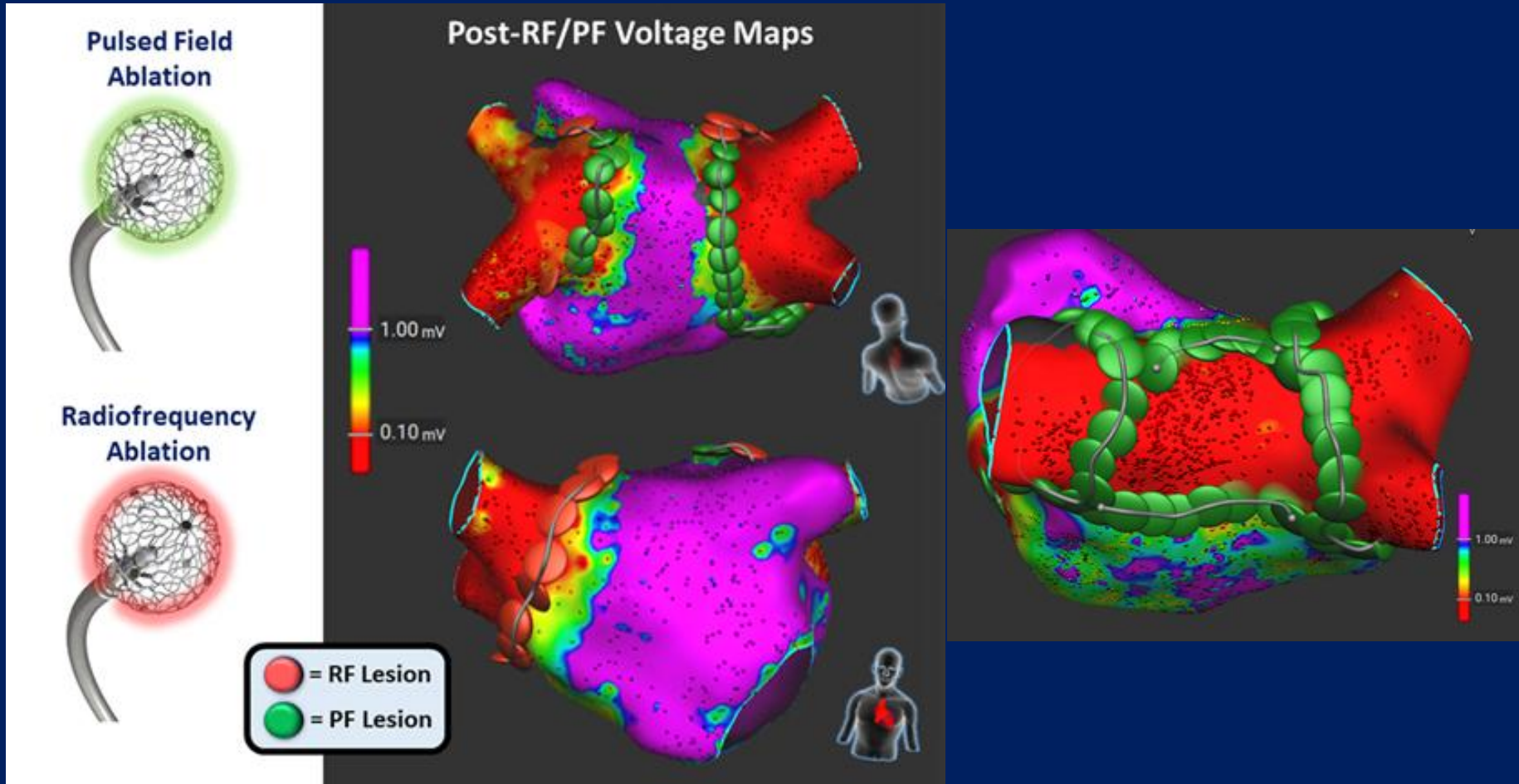
PFA setup – „recept“



Electrode geometry
Electrode count
Electrode spacing
Pulse duration
Pulse count
Pulse amplitude
Pulse precision
Target cell proximity
Target cell orientation
Target cell size
Tissue resistivity
Etc...

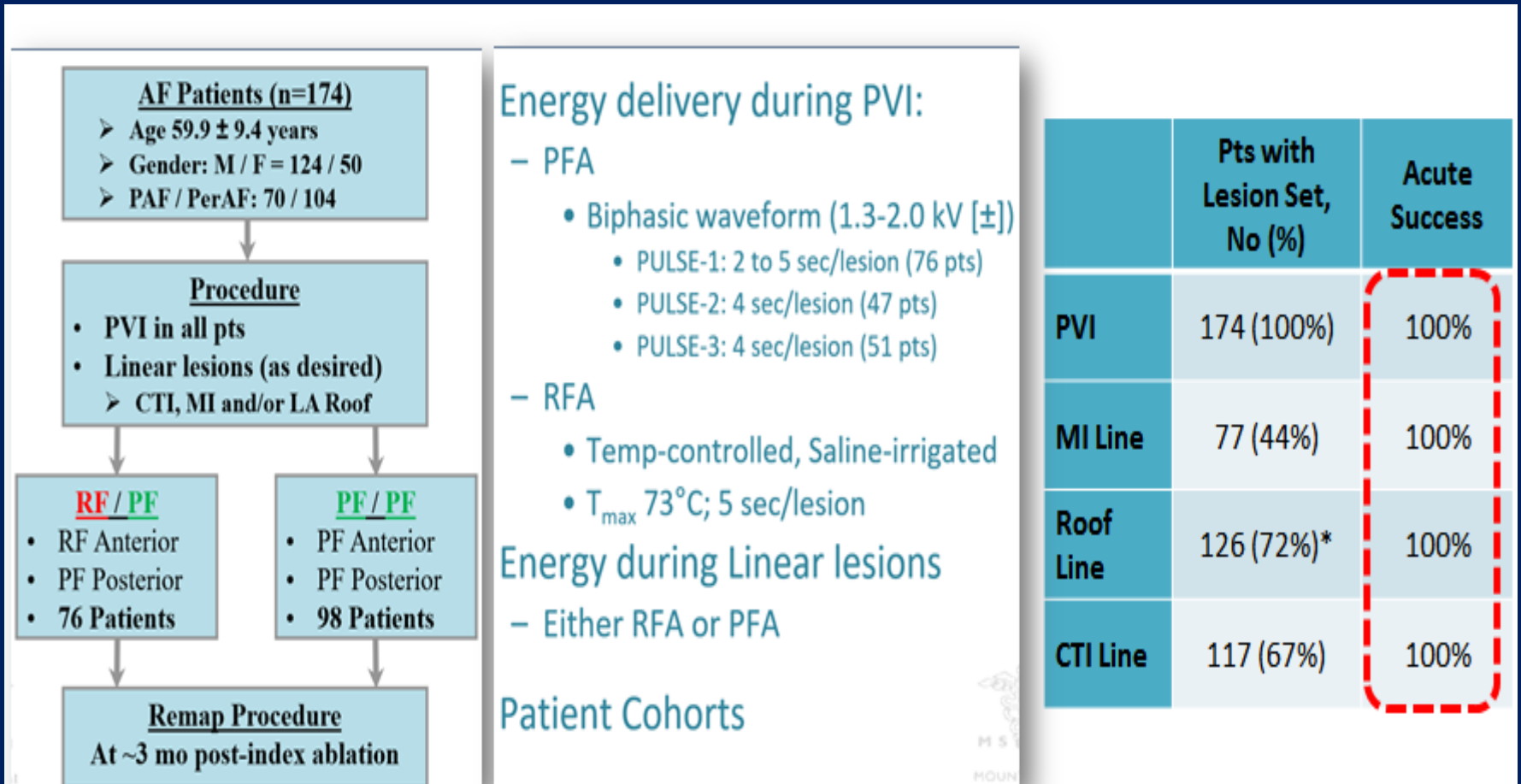
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IPV: post.PF ant.RF, linie roof-PF, mi-RF, CTi-RF



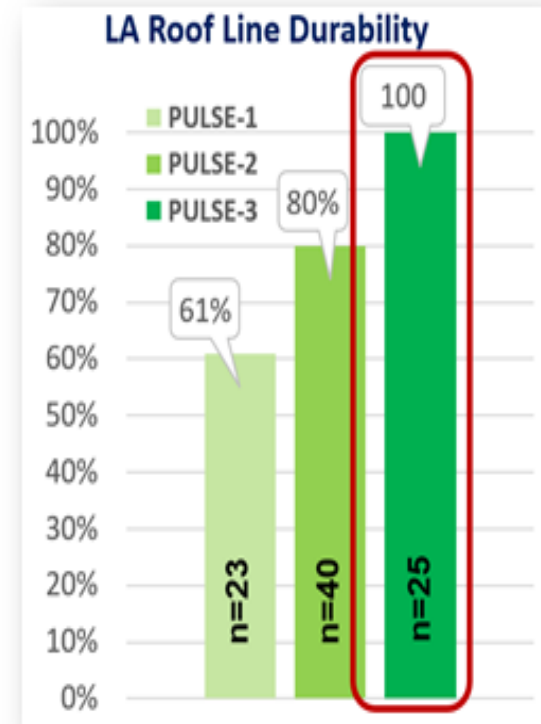
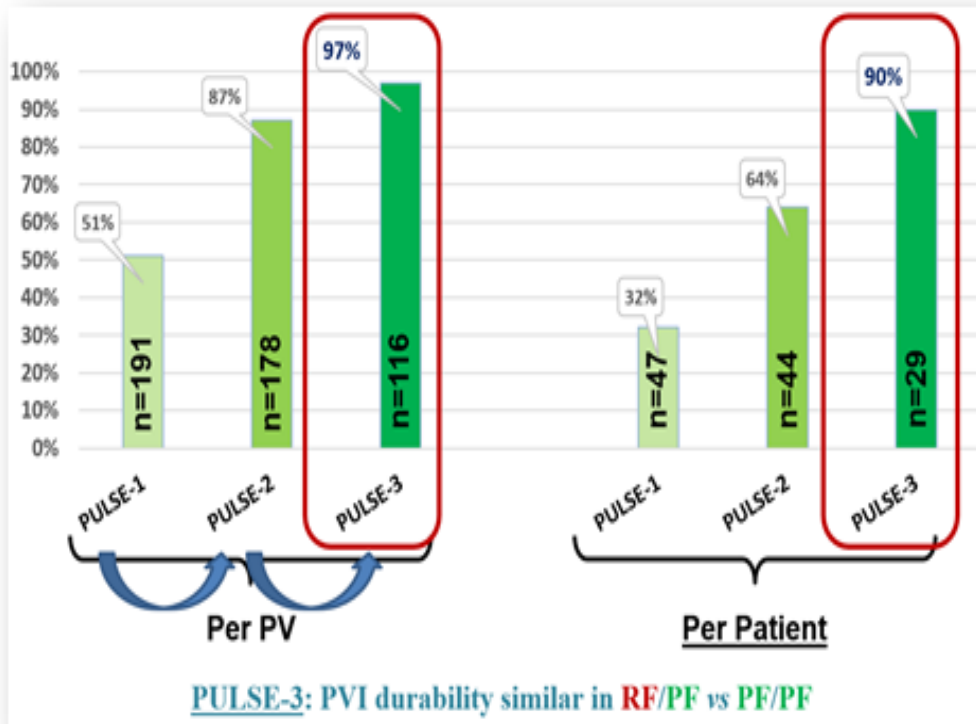
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Parox./Perzist. FiS: výkon a 3M remapování 3-centra, prospektivní, nerandomizovaná



Studie Affera RF/PF

Parox./Perzist. FiS: Durabilita: 3M remapování
3-centra, prospektivní, nerandomizovaná



Durability of Linear Lesions

Various combinations of RFA & PFA dosing strategies were tested

Only LA roof line used a "pure" PF-only strategy

Mitral Line: 67%

CTI Line: 86%

Studie Affera RF/PF

1R - VÝSLEDKY NAŠEHO CENTRA

Perzist. FiS N=55

- 55/86 perzistentní fibrilace síní, 62r, 13žen
- trvání FiS 7D - 1R
- EF $62 \pm 8\%$
- BMI $29,8 \pm 3$
- LA Plax $44,8 \pm 5\text{mm}$

Studie Affera RF/PF

1R - VÝSLEDKY NAŠEHO CENTRA

Perzist. FiS, N=55, rozsah a typ energie, CA

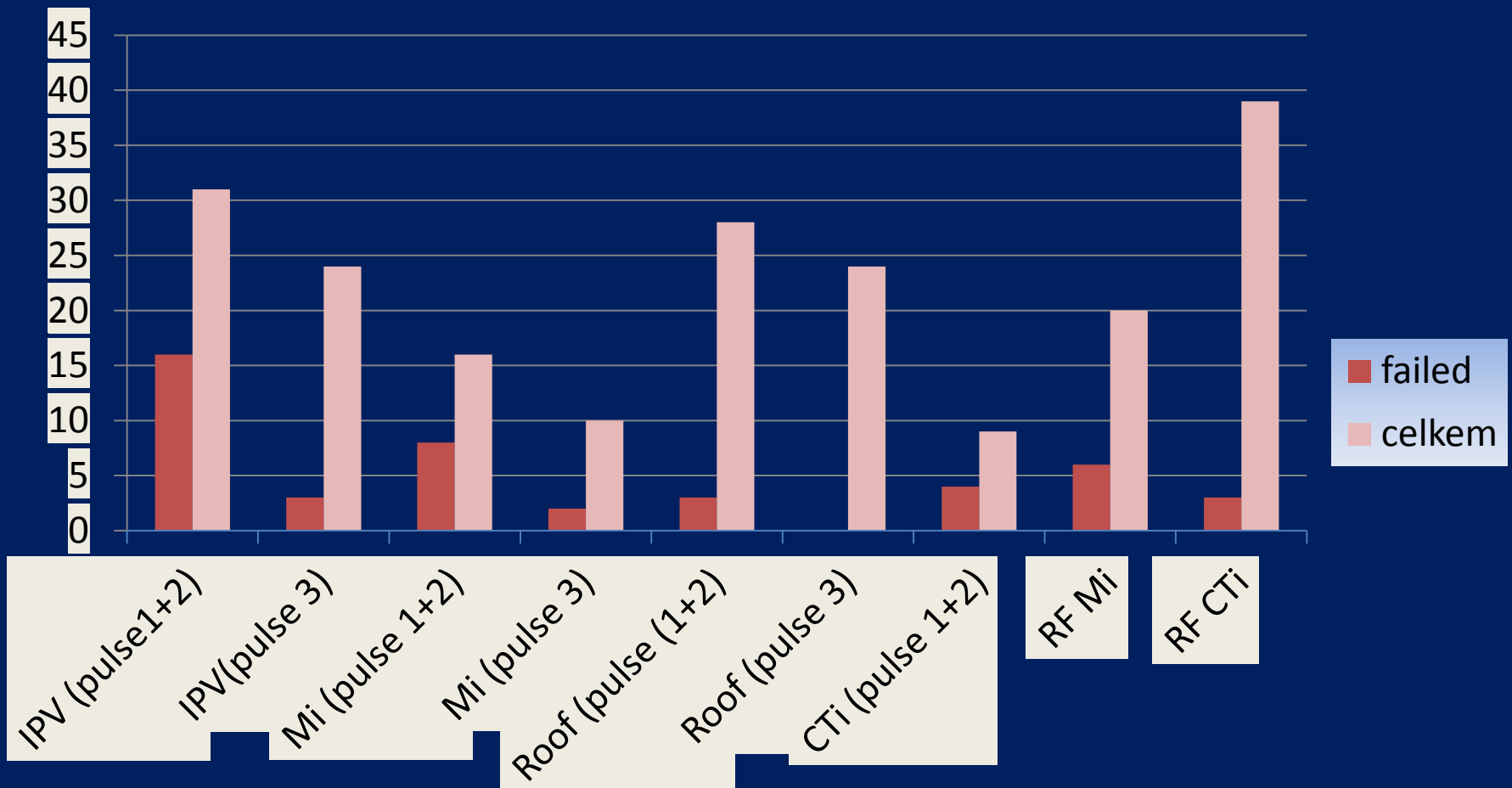
- 1. RF/PF (PF/PF) IPV, PF strop, PF Mi, RF CTi
– z toho 5x PF CS (nikdy RF CS) (25x)
- 2. RF Mi (bez CS) 18x
- 3. bez mitrální linie (8x)
- 4. bez mitrální ani stropní linie (jen IPV + Cti) 3x
- 5. PF box (3x)
- 6. PF CTi (11x)

- Doba výkonu 63 ± 20 min, skia 120 ± 83 sec, 5x Zero Flouro

Studie Affera RF/PF

Perzist FiS - VÝSLEDKY NAŠEHO CENTRA

3M remapování 53/55 pts



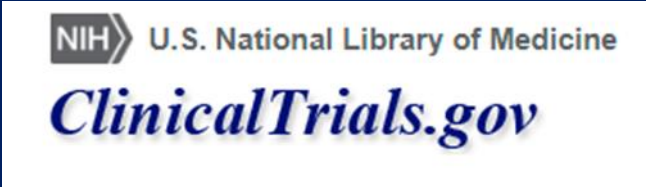
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1R - VÝSLEDKY NAŠEHO CENTRA

Perzist. FiS, N=55, **klinické recidivy FUP 1R**

	recidivy <u>do</u> <u>3M</u> remap+ABL	recidivy <u>po</u> <u>3M</u> remap+ABL	poznámka	MRI mozek nález do 3-4mm isch. lezí asympt. (DWI, FLAIR)
Pulse 1+2 (N= 31)	14/31 (45,1%)	8/31 (25.8%)	7 z 9 AT perimitr. ostatní reFiS	4/18 (22%) (kohorta 86 pts)
Pulse 3 (N=24)	1/24 (4.2%)	1/24 (4.2%)	AT-perimitr. po RF-Mi, jiný pac., norm. remapa	4/11 (36%) (kohorta 86 pts)

Affera RF/PF IDE-studie: RCT, perAF



Treatment of Persistent Atrial Fibrillation With Sphere-9 Catheter and Affera Mapping and Ablation System (SPHERE Per-AF)

ClinicalTrials.gov Identifier: NCT05120193

Study Description

Go to

Brief Summary:

This is a prospective, multicenter, randomized clinical evaluation of the Sphere-9 Mapping and Ablation Catheter with the **Affera** Mapping and Ablation System. Subjects will be randomly assigned 1:1 to receive treatment with either the Sphere-9 Mapping and Ablation Catheter and the **Affera** Mapping and Ablation System (investigational device) or the THERMOCOOL SMARTTOUCH® SF radiofrequency ablation catheter (control device).

Condition or disease ⓘ	Intervention/treatment ⓘ	Phase ⓘ
Atrial Fibrillation	Device: Mapping and Ablation	Not Applicable

Study Design

Go to

Study Type ⓘ : Interventional (Clinical Trial)

Estimated Enrollment ⓘ : 480 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Single (Participant)

Masking Description: Subjects will be blinded to treatment assignment

Primary Purpose: Treatment

Official Title: Treatment of Persistent Atrial Fibrillation With the Sphere-9 Mapping and Ablation Catheter and the **Affera** Mapping and Ablation System

Actual Study Start Date ⓘ : December 14, 2021

Estimated Primary Completion Date ⓘ : November 2023

Affera PF další studie: SpherePVI, parox.AF



Safety and Performance of the Affera SpherePVI™ Multi-Ablation System to Treat Paroxysmal Atrial Fibrillation (SpherePVI)

ClinicalTrials.gov Identifier: NCT05115214

Brief Summary:

A prospective, single-arm, multi-center study to evaluate the safety, performance, and effectiveness of the **Affera** SpherePVI™ Multi-Ablation System for treating paroxysmal atrial fibrillation.

Condition or disease ⓘ	Intervention/treatment ⓘ	Phase ⓘ
Atrial Fibrillation	Device: SpherePVI™ Catheter	Not Applicable

Study Design

Go to

Study Type ⓘ : Interventional (Clinical Trial)

Estimated Enrollment ⓘ : 50 participants

Allocation: N/A

Intervention Model: Single Group Assignment

Masking: None (Open Label)

Primary Purpose: Treatment

Official Title: A Safety and Performance Assessment of the **Affera** SpherePVI™ Multi-Ablation System to Treat Paroxysmal Atrial Fibrillation

Actual Study Start Date ⓘ : October 19, 2021

Estimated Primary Completion Date ⓘ : October 19, 2022

Estimated Study Completion Date ⓘ : October 19, 2023

Závěr:

- **Katetrizační ablace perzist FiS v kombinaci RF a PF ablace mřížkovým katetrem Sphere-9mm s EA mapováním prokazuje zejména po upgradu specifikace pulzní vlny velmi vysokou účinnost dle remapovacích výkonů i v jednoročním klinickém sledování, významně byly redukovány skiaskopické časy výkonu (0-2min).**
- **PF ablace mitrální linie endokardiálně je srovnatelně účinná jako RF energie systému Sphere-9mm, a lze zvažovat i vyšší PF účinnost při současné PF ablaci v koronárním sinu. V našem souboru jsme nezaznamenali výskyt koronárních spasmů.**
- **Použití RF energie jen v anteriorní části plicních žil se jeví dostatečně bezpečné v prevenci poškození jícnu, nezaznamenali jsme patologii bráničního nervu, zaznamenali jsme menšinový výskyt ojedinělých drobných lezí při MR mozku časně po výkonu, jejichž další zhodnocení je potřebné na větším souboru nemocných (AFFERA-IDE, RCT N=500),**