PFA in over 2K Patients for Paroxysmal and Persistent Atrial Fibrillation in Single Center

Petr Neužil, Jan Petrů, Jan Škoda, Moritoshi Funasako, Lucie Šedivá, Milan Chovanec, Pavel Hála, Štěpán Královec

Nemocnice Na Homolce , Praha

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Pulsed Field Ablation (PFA)

First-in-Human Acute Clinical Data (HRS-2018)

- 7 patients: epicardial system (surgical approach, box lesion)
- 15 patients: endocardial system (over-the-wire PVI catheter)
  - ➢ 100% acute isolation (endo), no acute SAEs

Epicardial Cohort (n = 7)		Endocardial Cohort (n = 15)
N/A	Procedure time	67.0 ± 10.5
N/A	Mapping time	41.4 ± 9.3
50.7 ± 19.5	Catheter time	26.0 ± 4.3
25.0 ± 17.5	Ablation time	19.0 ± 2.5
6.6 ± 3.8	Fluoroscopy time	12.3 ± 4.0
6/7 (86)	Isolation success	15/15 (100)

VY.Reddy, J.Koruth, P.Jais et al, *JACC EP* 4:987-995 (2018)

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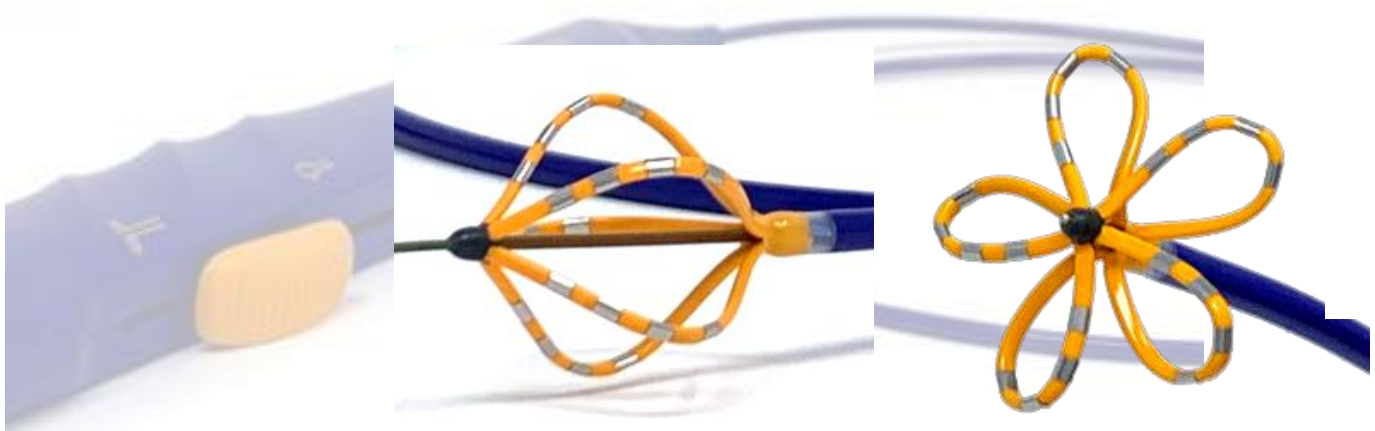
Durable PVI proven with one system

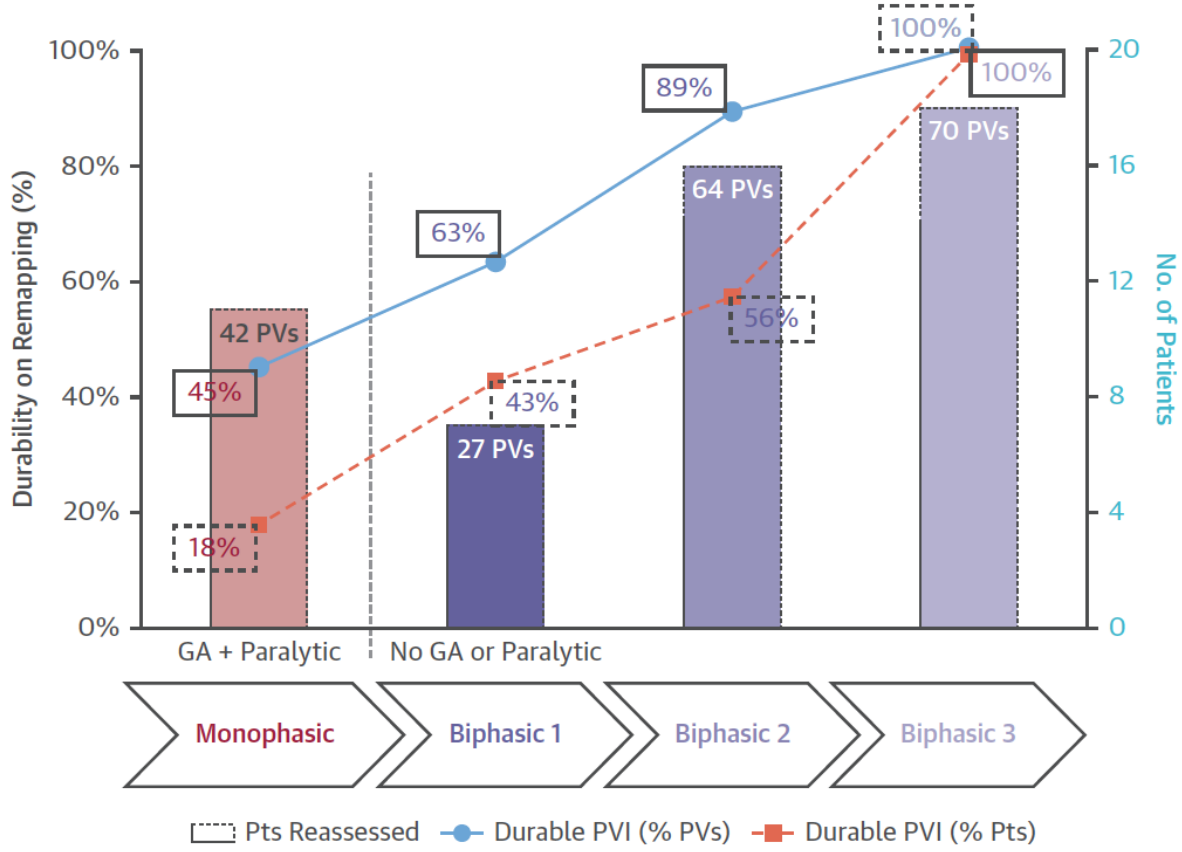
- Biphasic, bipolar PFA
- 5-spline OTW catheter

- Extensive prospective remapping performed to assess lesion durability



Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation

Vivek Y. Reddy, MD,[a,b] Petr Neuzil, MD, PhD,[a] Jacob S. Koruth, MD,[b] Jan Petru, MD,[a] Moritoshi Funosako, MD,[a] Hubert Cochet, MD,[c] Lucie Sediva, MD,[a] Milan Chovanec, MD,[a] Srinivas R. Dukkipati, MD,[b] Pierre Jais, MD[c]



Reddy VY, Neuzil P, Koruth JS, et al.: *J Am Coll Cardiol*. 2019;74:315-26.

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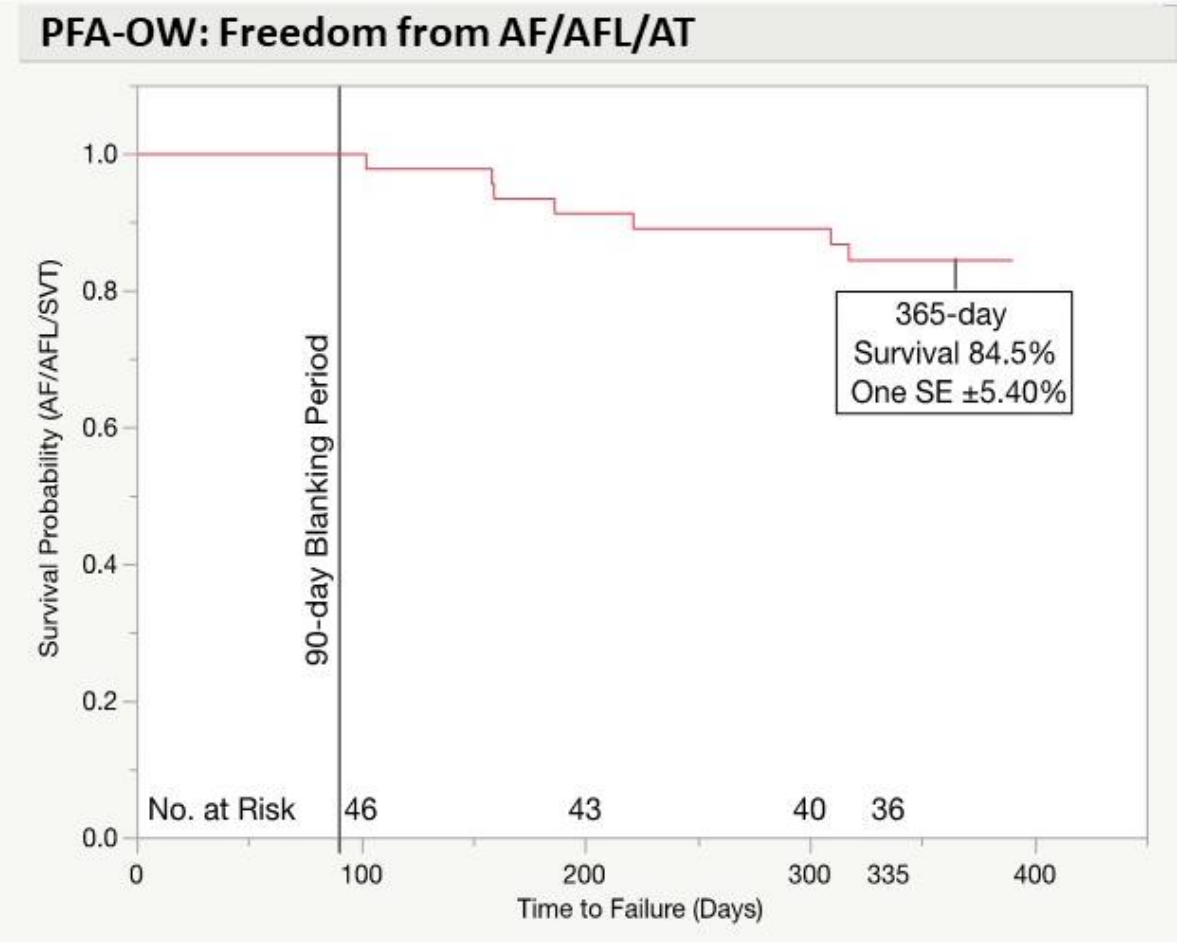
Durable PV Isolation

Data from Optimized Biphasic Waveform Study

121 PAF pts

49 Optimized Waveform



- 100% acute success

- **44/49 pts remapped**
- **96% durable at 81 days (69-98 IQR)**
  - **166/173 PVs**

- **Freedom from AF/AFL/AT: 84,5±5,4%**
- **Recurrent AF/AFL/AT did occur in 7 patients, however:**

  - **Remap protocol showed majority (6/7) had durable PVI at remap**
  - **Suggests extra-PV source for AF initiation?**

Reddy VY, Dukkipati SR, Neuzil P, et al. Pulsed Field Ablation of Paroxysmal Atrial Fibrillation: 1-Year Outcomes of IMPULSE, PEFCAT, and PEFCAT II. *JACC Clin Electrophysiol*. 2021;7(5):614-627. doi:10.1016/j.jacep.2021.02.014

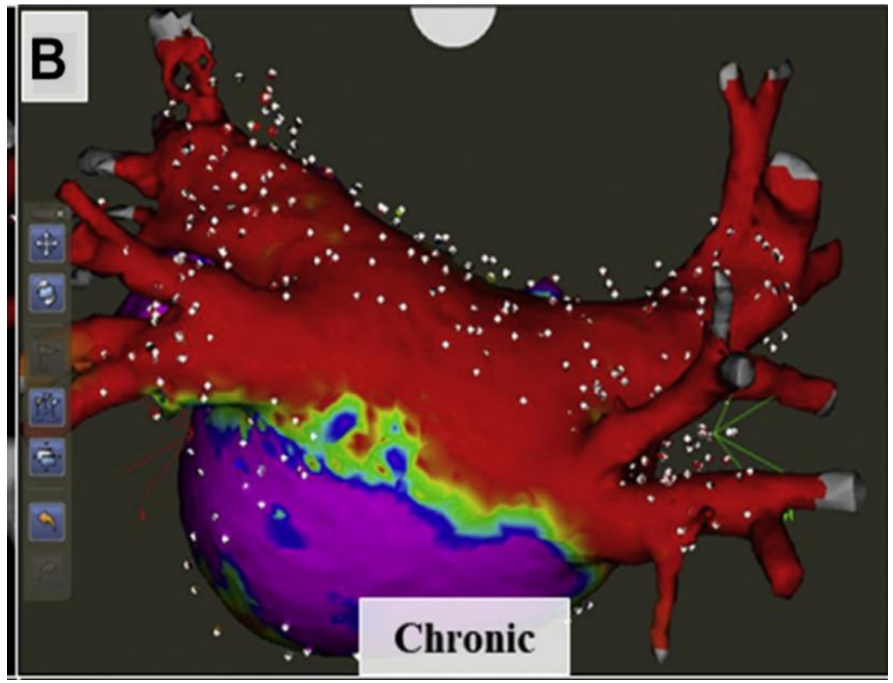
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 76, NO. 9, 2020

Pulsed Field Ablation in Patients With Persistent Atrial Fibrillation

Vivek Y. Reddy, MD,[a,b] Ante Anic, MD,[c] Jacob Koruth, MD,[b] Jan Petru, MD,[a] Moritoshi Funasako, MD,[a] Kentaro Minami, MD,[a] Toni Breskovic, MD, PhD,[c] Ivan Sikiric, MD,[c] Srinivas R. Dukkipati, MD,[b] Iwanari Kawamura, MD,[b] Petr Neuzil, MD, PhD[a]

ne
y:

Remapování po 3M	n	%
Počet pacientů	22/25	88
Izolace plicních žil	82/85	96
Box léze zadní stěny	21/22	95
Blok vedení na CT istmu	9/12	75



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Pulsed Field Ablation in Patients With Persistent Atrial Fibrillation

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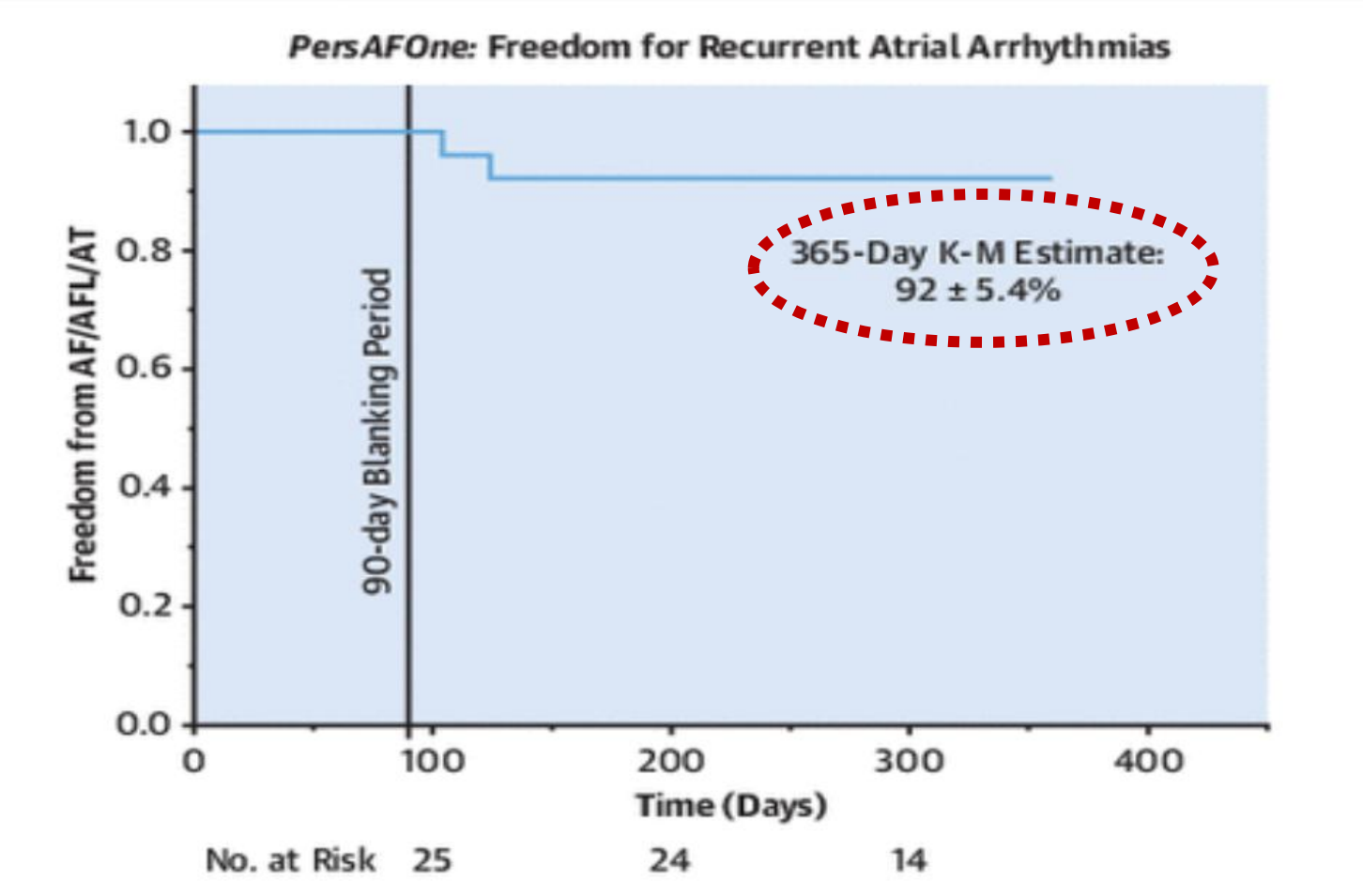

- **23/25 bez recidivy FS**

- TTM každý týden
- 24hod holter EKG 6 a 12m po ablaci

- 1 pac. léčen amiodaronem, ostatní bez AA

PFA : Homolka Clinical Practise

Strategy Related to Pefcat & Persafone Studies

- **No general anesthesia or paralytic**

Repeated boluses of Midazolam, Fentanyl, Propofol i.v.

- **No temporary pacing**

Atropin i.v. 1 mg single bolus. Nitrates i.v. , Phenylephrine (CTI only)

PFA strategy for paroxysmal AF – PVI:

2+2 (rotation by one quadrant) „BASKET“

2+2 (rotation by one quadrant) „OLIVE“ - Left Veins only

& 2+2 (rotation by one quadrant) „FLOWER“

PFA strategy for perzistent AF:

the same PVI + 2 lines on posterior LA wall :

2 app. in FLOWER configuration

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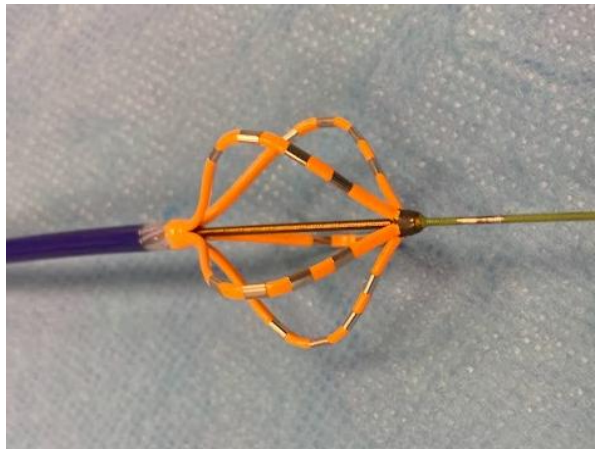
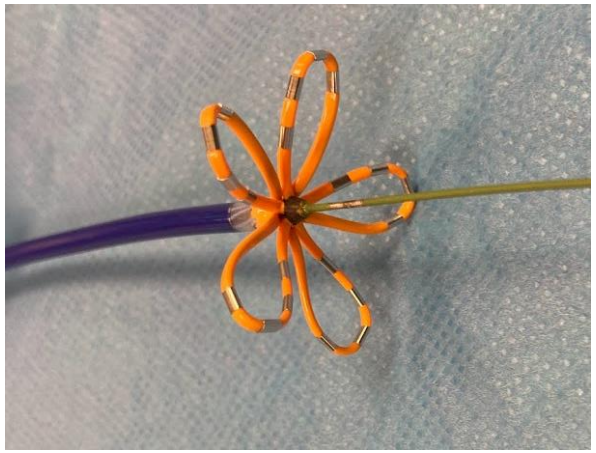
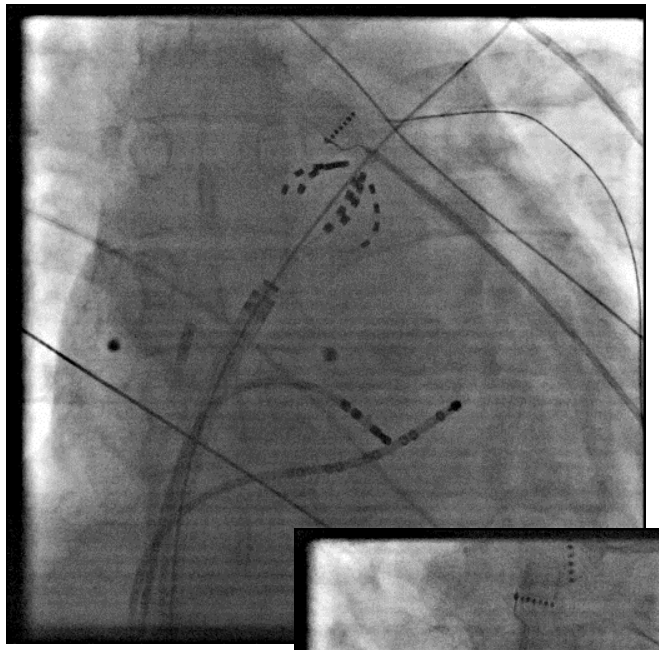
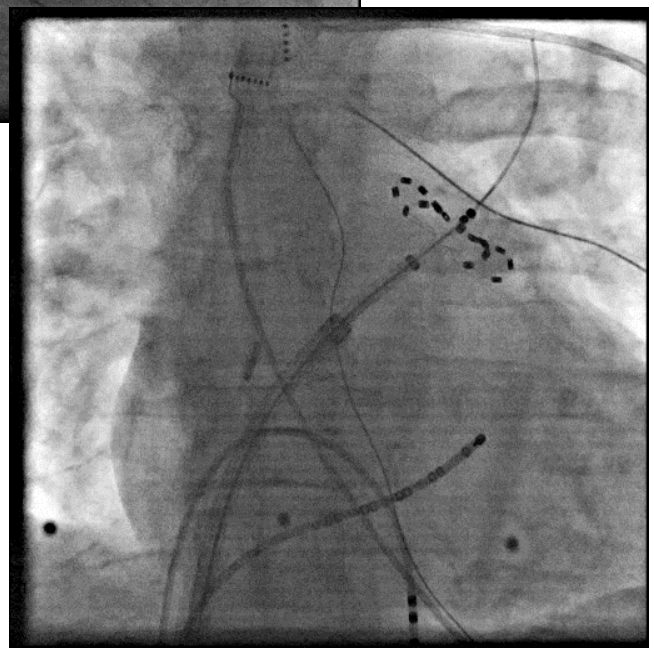
Biphasic PFA: First Clinical Experience



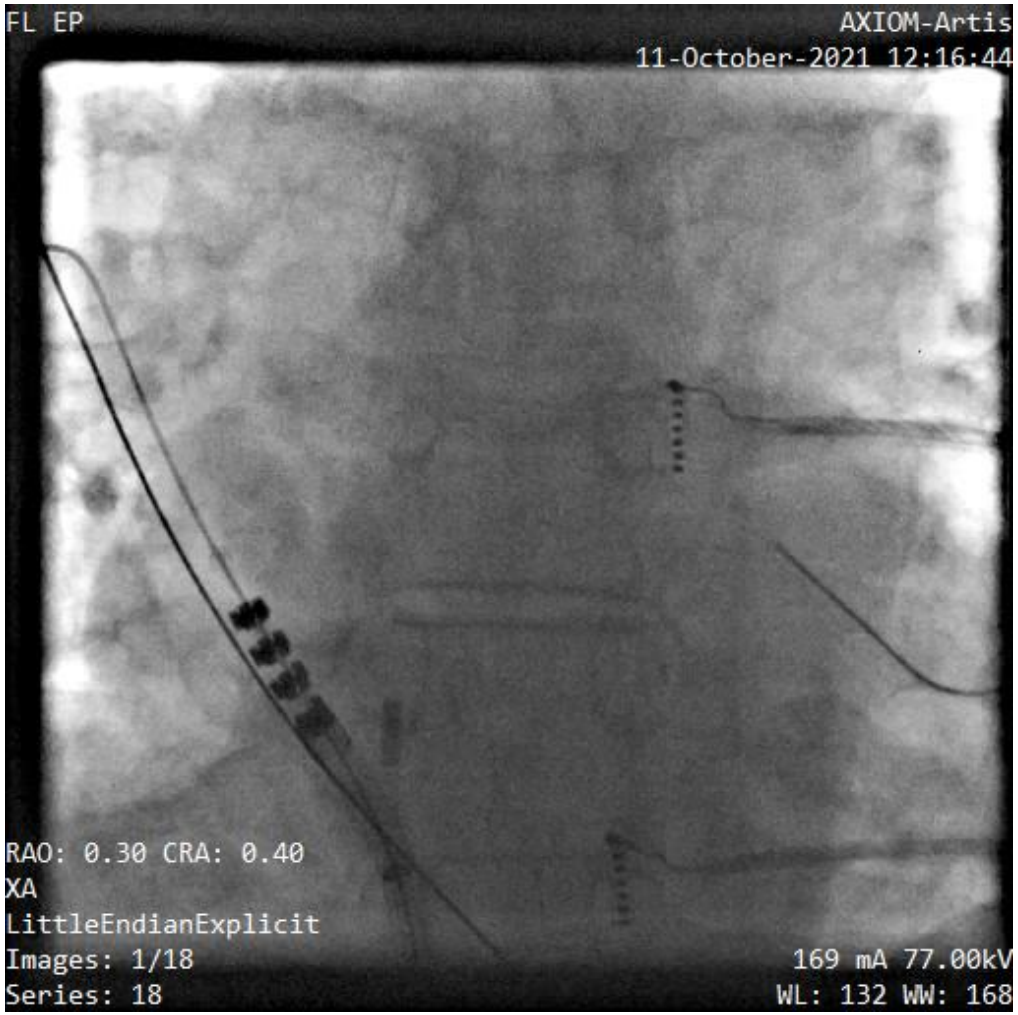


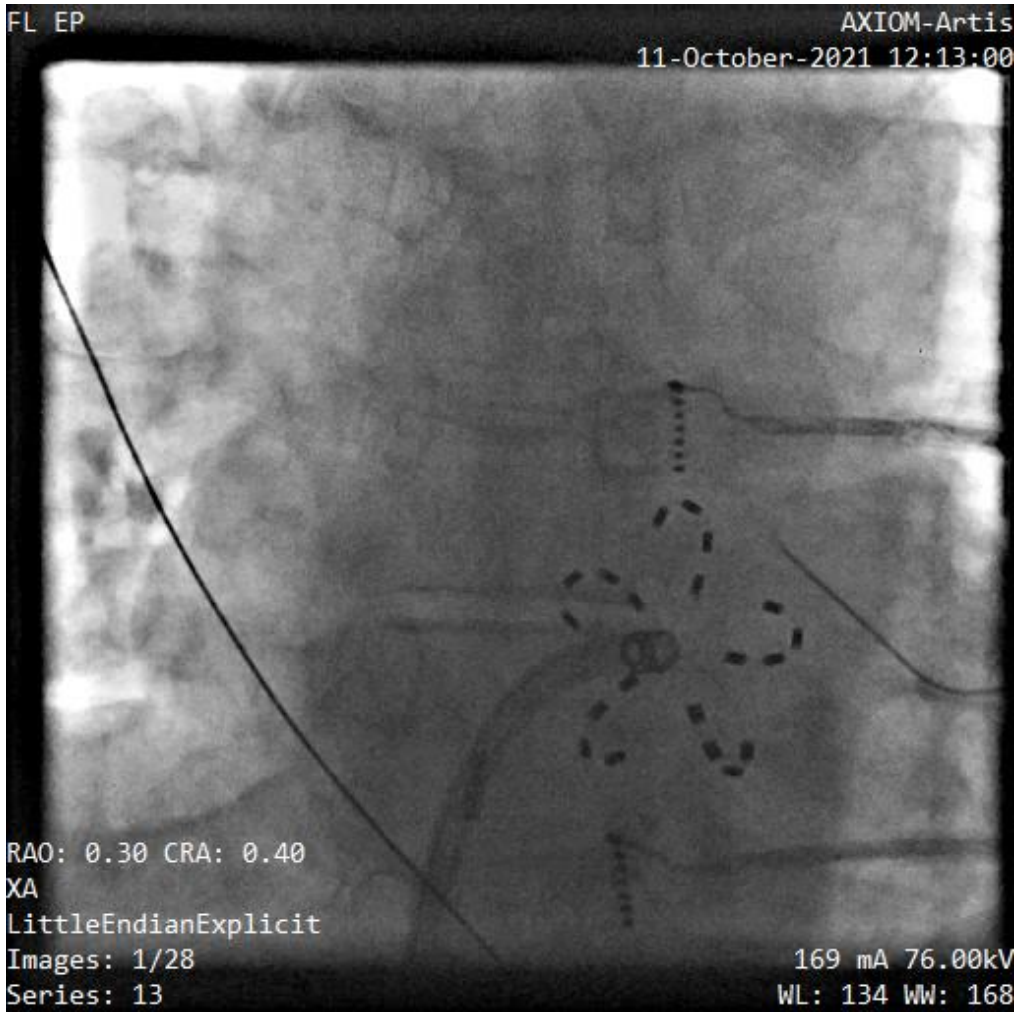




Pulsed Field Ablation

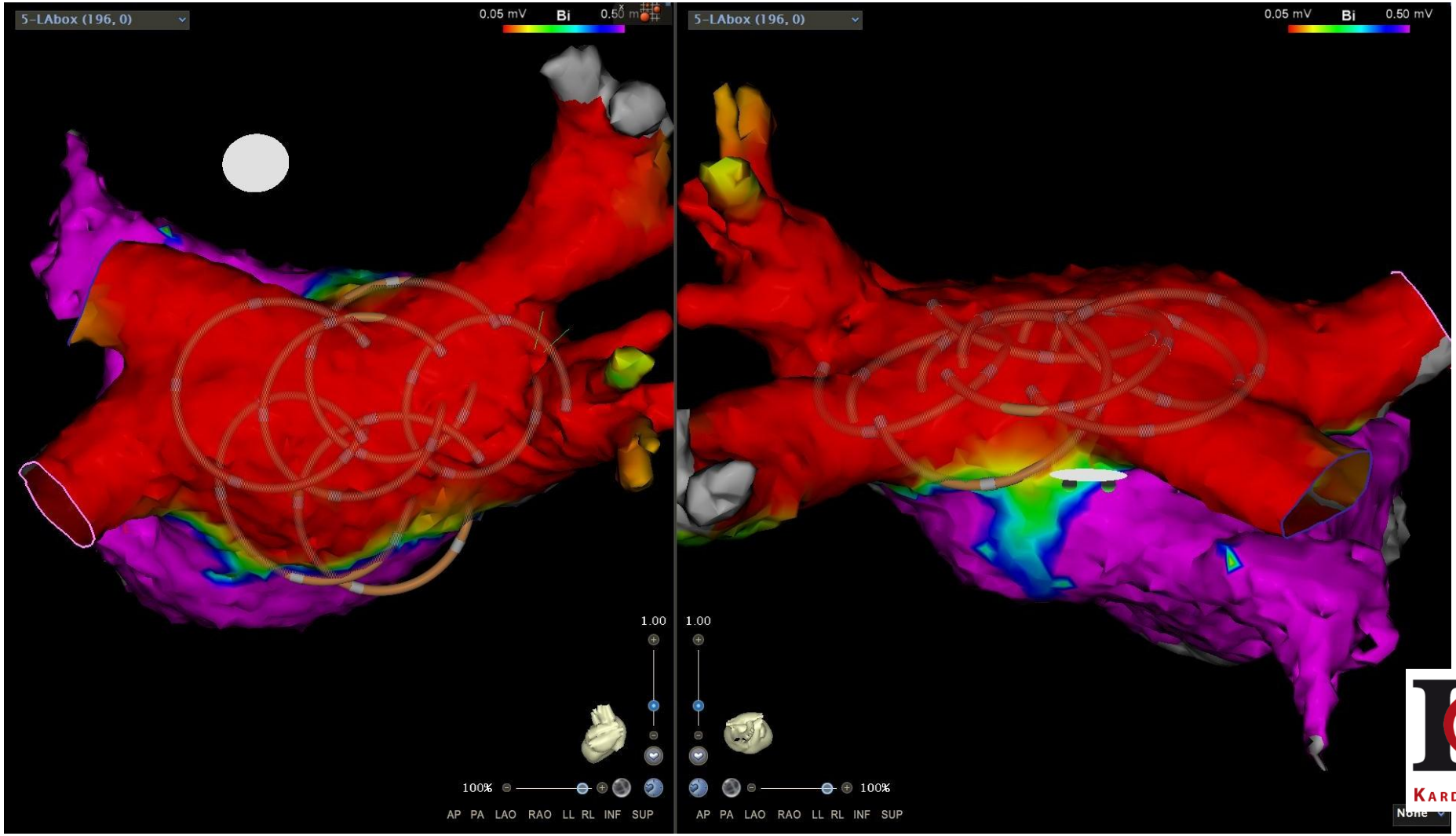
Posterior Wall Ablation on Fluoro





Pulsed Field Ablation

Posterior wall ablation



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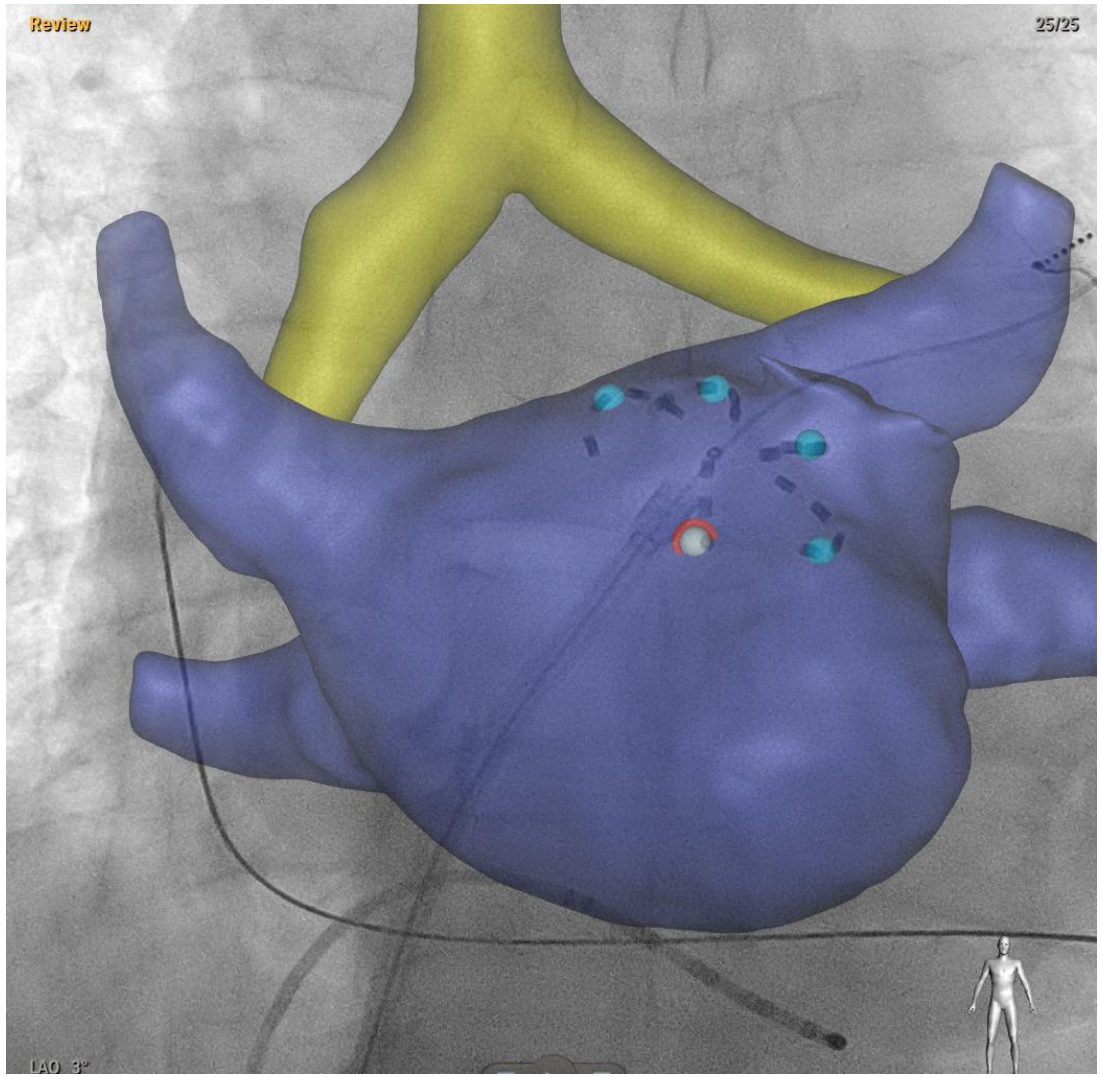
Pulsed Field Ablation

CT & Fluoro Integration



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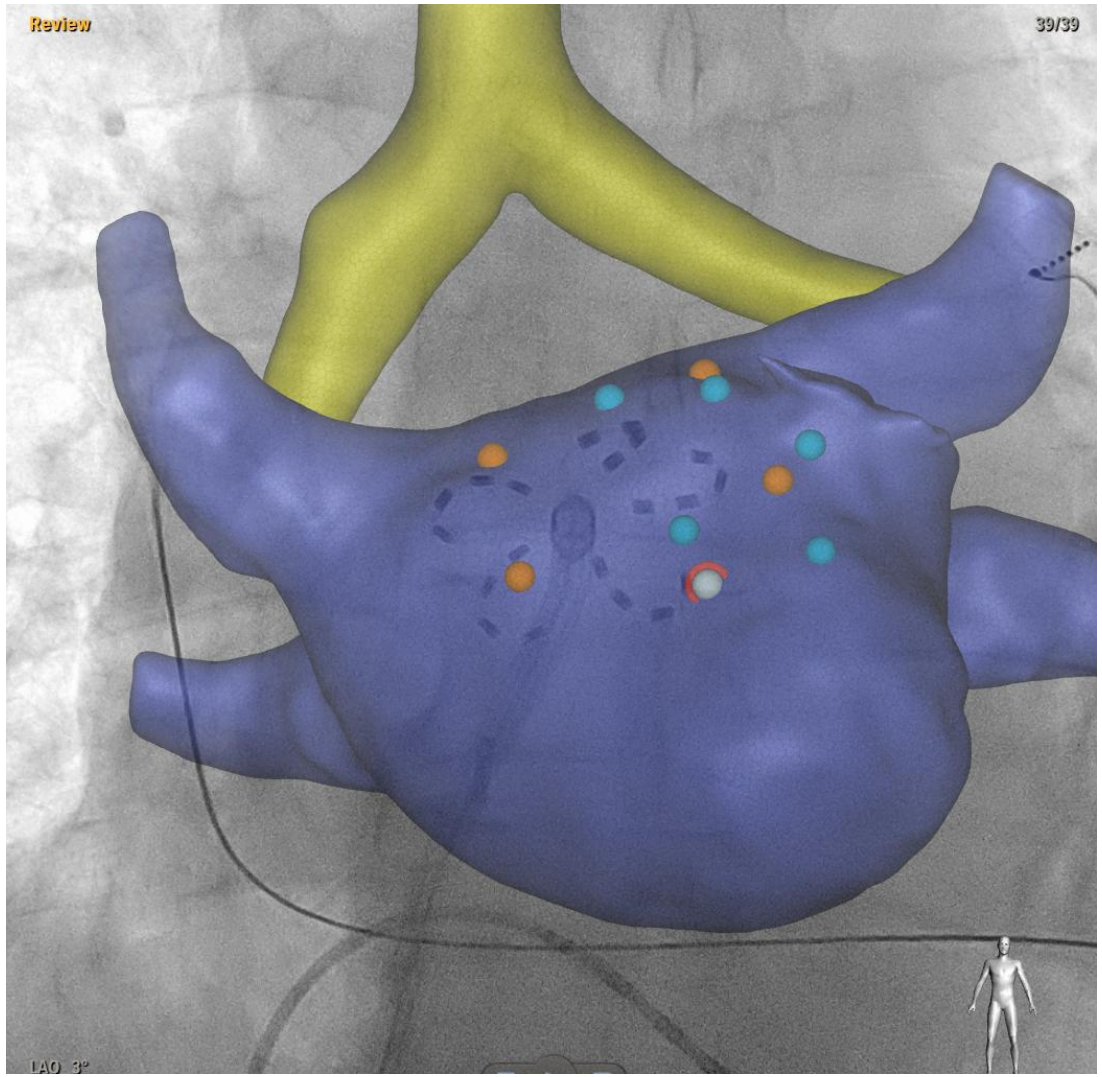

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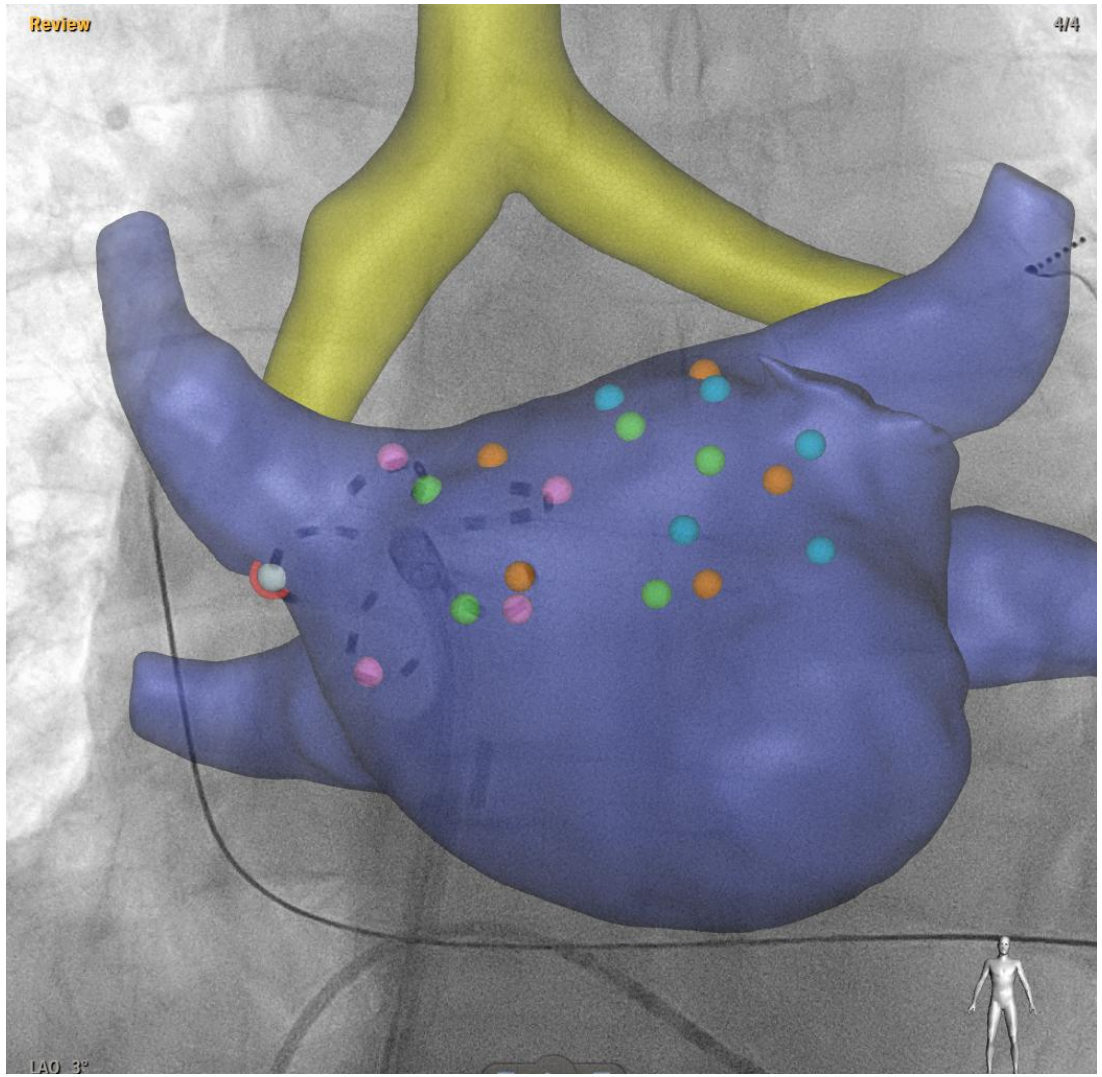

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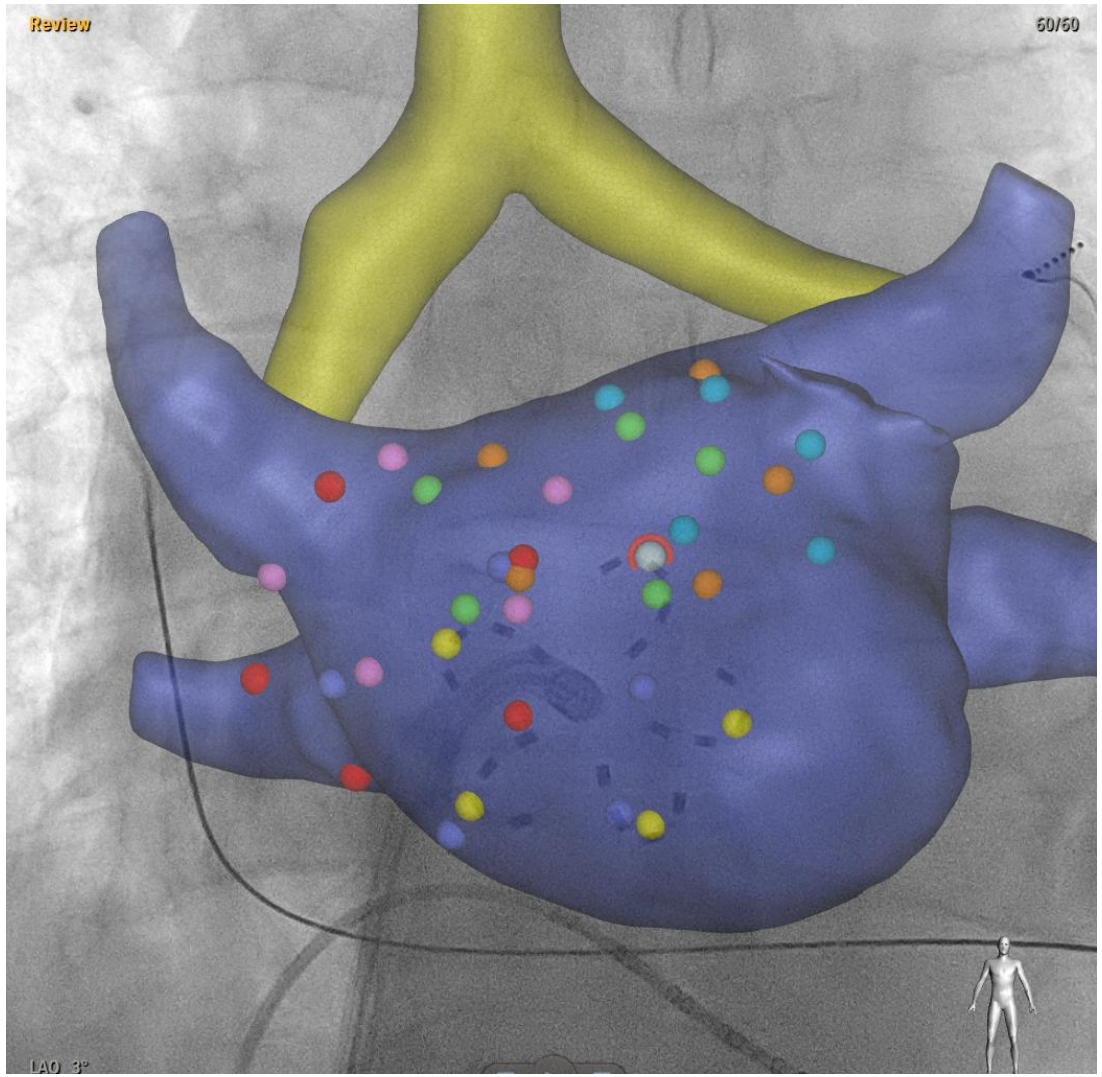

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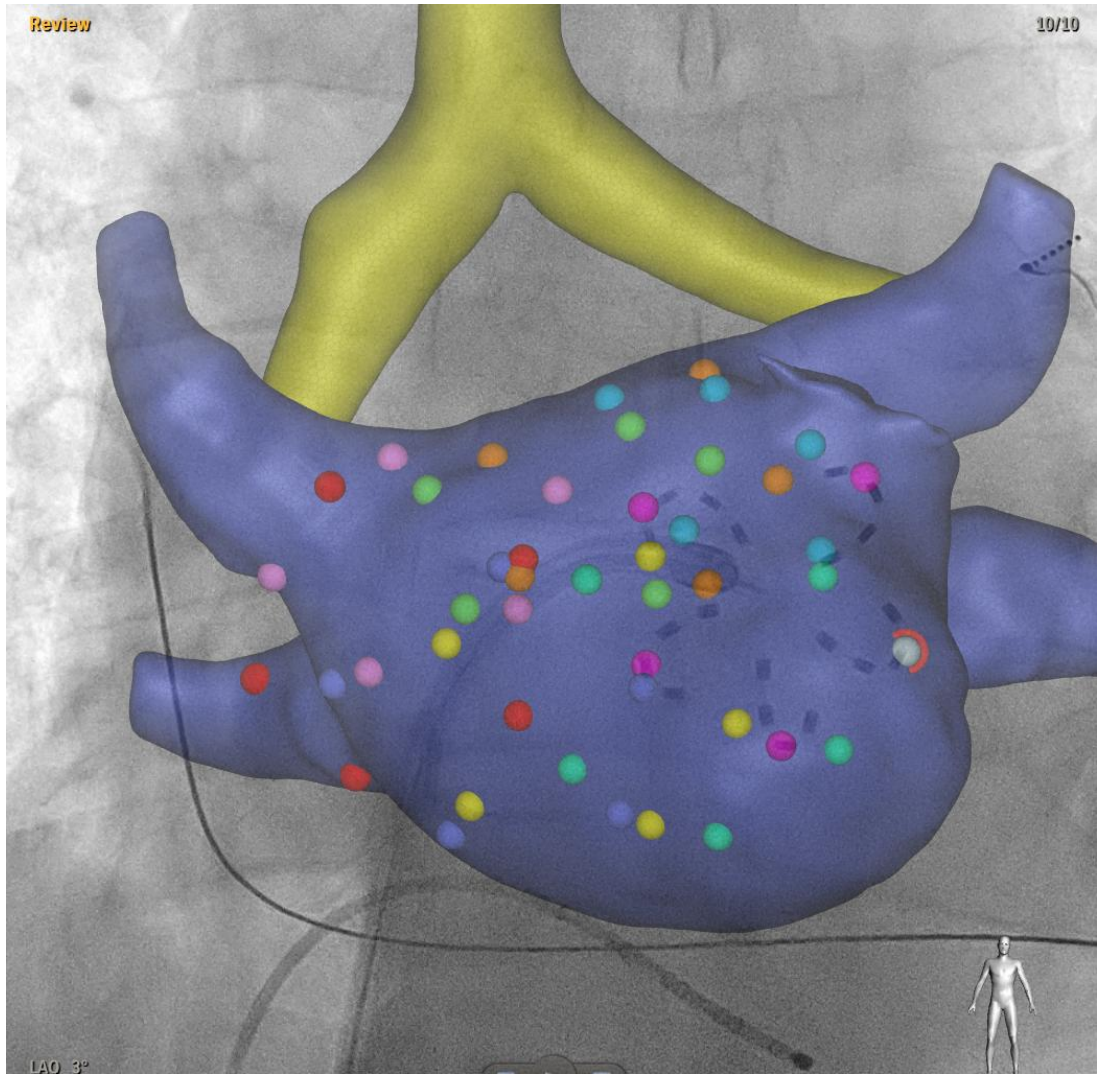

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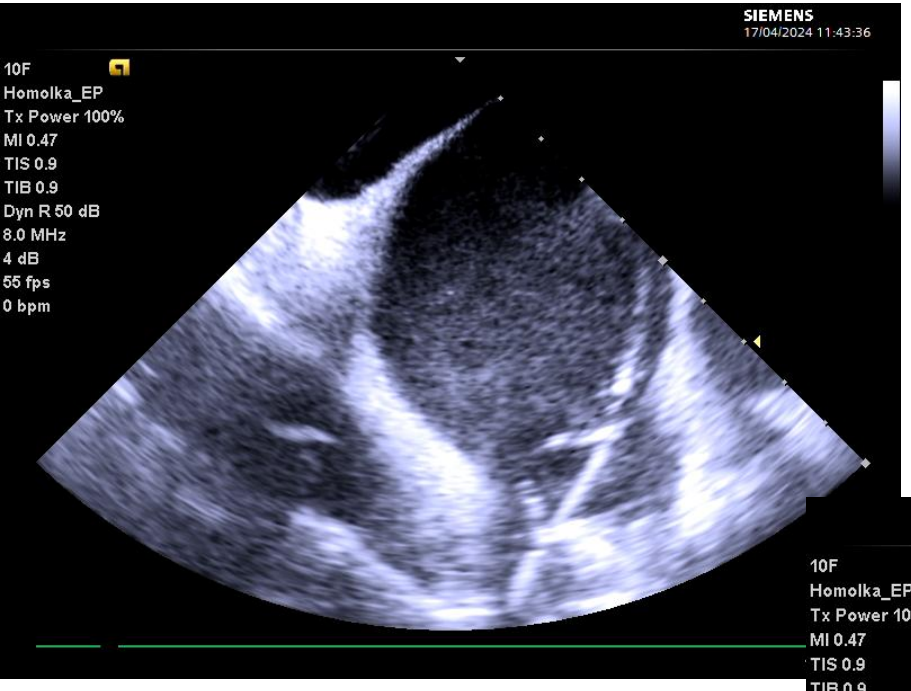
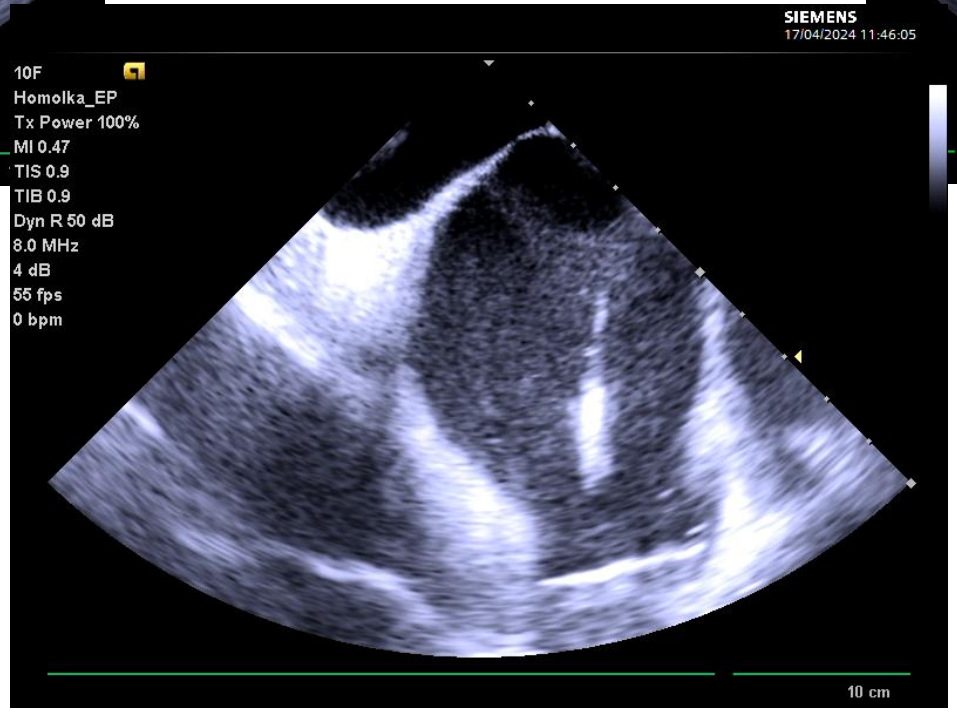
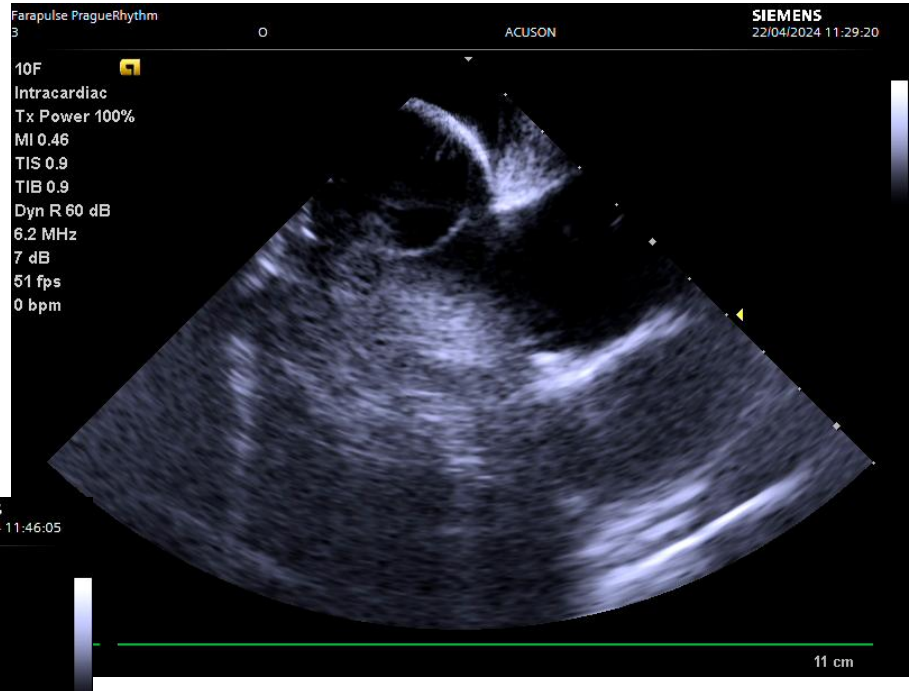
Farawave Pulsed Field Ablation

CTI Position on ICE







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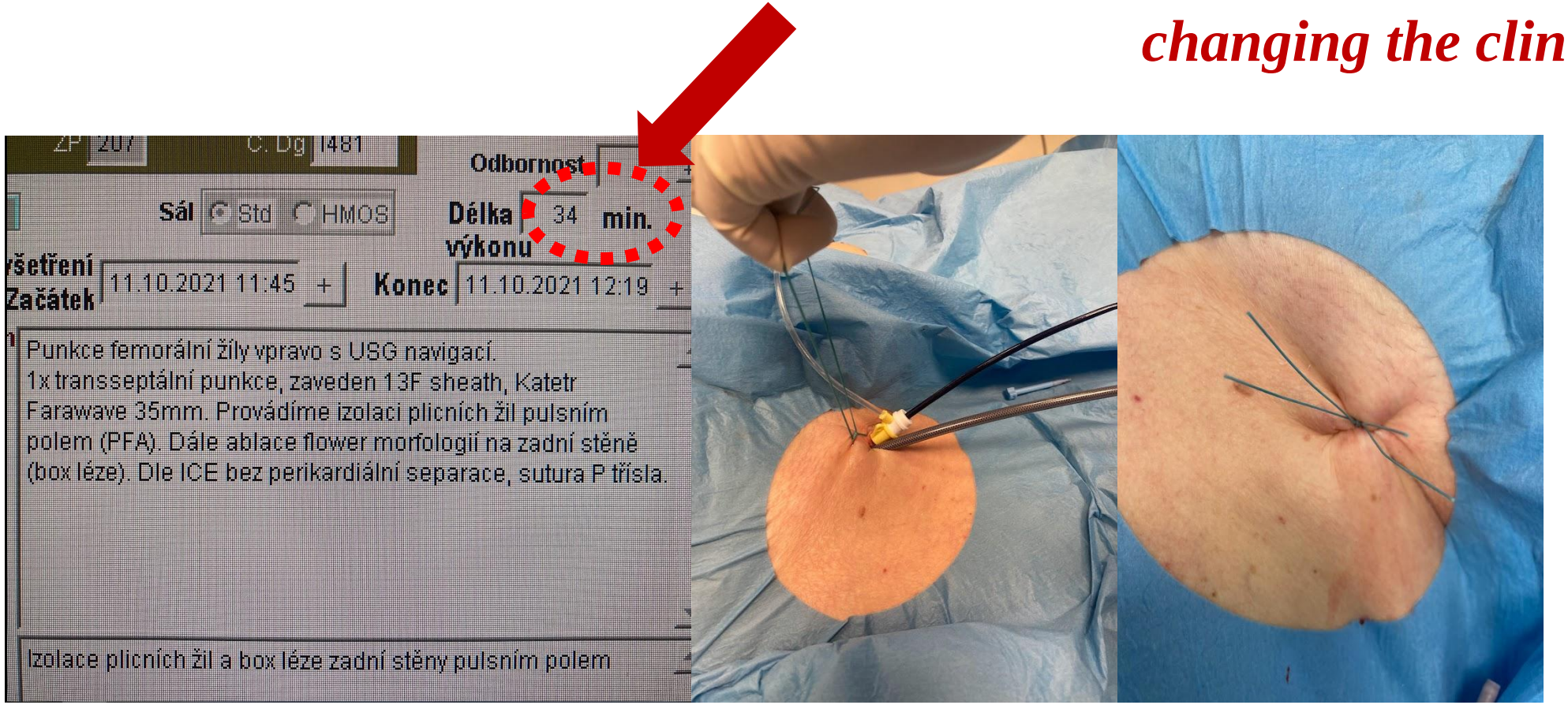
Perzistent AFib

changing the clinical practise



1.Single groin puncture

2. No general anesthesia

3.No mapping system need

4. Outpatient based procedure

PFA : NNH Real Clinical Data

2.125 patients (1.354 M / 798 F), average age 66,7 ± 11,3 years ,BMI 28,9 ± 4,8

LA DIAMETER	**43mm (30-66)**
LV EF	**58,2 ± 9,5%**

Hypertension	***63%***
DM	***15 %***
CAD	***2 %***
CHF	***11,2 %***
Stroke/TIA	***8,2 %***
Ø CHA_2DS_2-VASc	***2,2***

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PFA : NNH Real Clinical Data

GA: *46 pts,* Single transseptal: *100 %*, PVI: *100 %*

PAROXYSMAL AF *(1153 pts)* :

PFA ≤ 3,2 min elapsed delivery/patient

„Skin to skin“	*procedure time*	*34,8 ± 8,9 min*
	fluoro time	*4,9 ± 6,6 min*

..

PERZISTENT AF *(841 pts)* :

„Skin to skin“	*procedure time*	*59,7 ± 17.8 min*
	fluoro time	*6,4 ± 5,2 min*

Long-standing PERZISTENT AF *(132 pts)* :

„Skin to skin“	*procedure time*	*68,8 ± 21.8 min*
	fluoro time	*6,8 ± 4,4 min*

ATRIAL TACHYCARDIA *(8 pts)* :

„Skin to skin“	*procedure time*	*72,4 ± 23.5 min*
	fluoro time	*7,2 ± 4,8 min*

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PFA : NNH Real Clinical Data

Single transseptal: *100 %*, PVI: *100 %*

Ablation strategy: *100 %*

PVI was done in: 2.119 pts = ***99,7 %***,

LA posterior wall in: 1.371 pts = ***64,5 %***,

Mitral isthmus in: 431 pts = ***20,3 %***,

Cavo-tricuspid isthmus in: 650 pts = ***30,5 %***,

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PFA : NNH Real Clinical Data

2.125 patients (1.354 M / 798 F), average age 66,7 ± 11,3 years ,BMI 28,9 ± 4,8

Complications:

Stroke/TIA	*3/2*
Pericardial effusion	*5*
No intervention	*5*
Vascular	*31*
Hematoma	*25*
Pseudoaneurysm	*6*
A-V fistula	*4*
Phrenic Pulsy/Injury	*0/0*
Esophageal injury	*0*

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PFA : NNH Real Clinical Data

2.125 patients (1.354 M / 798 F), average age 66,7 ± 11,3 years ,BMI 28,9 ± 4,8

Follow-Up (Ø 17,8 months):

Freedom from all atrial arrhythmias: ***88,1 ± 4,8%***

(by repeated Holters and ECGs for all types of atrial arrhythmias).

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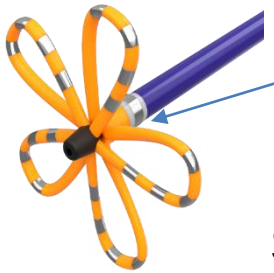
Faravawe NAV

EAM Integration

FARAWAVE NAV Catheter



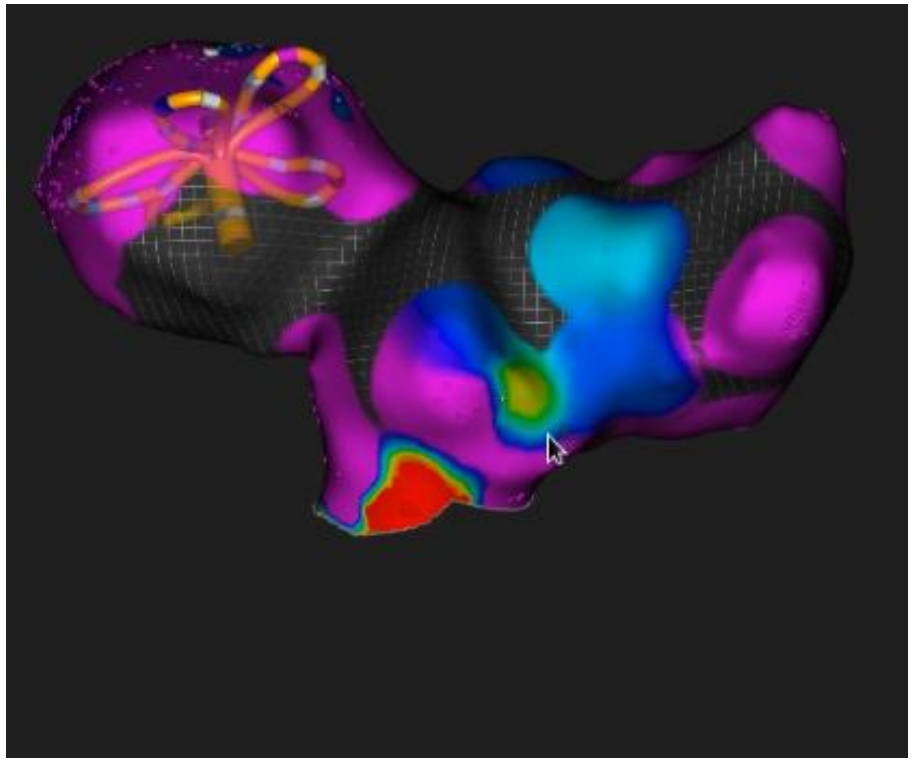
Nav sensor and shaft electrode for shape detection

Shaft marker for FARADRIVE sheath

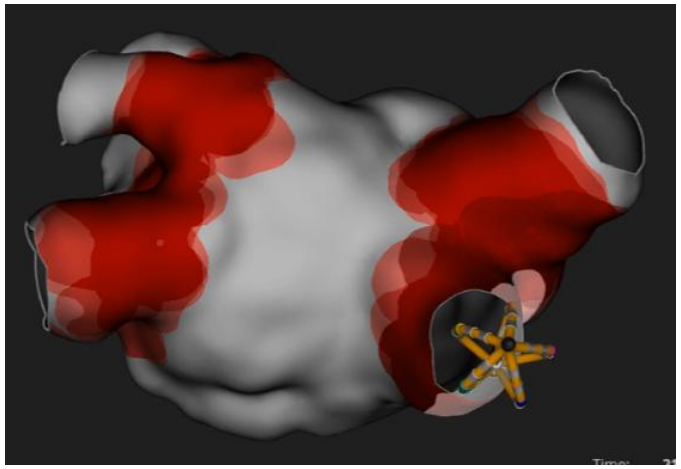
Improved deployment

RHYTHMIA integration

Mapping System Module



PFA tagging



Conclusions

„Take home message“

- Our center acute and mid-term Follow-Up outcomes with PFA FaraPulse confirmed highly efficient & safe data from all main studies for both types paroxysmal and perzistent Afib with minimal recurrence of atrial fibrillation and atrial tachycardias as well

- This PFA strategy indicated real potential to change out daily clinical practise for management of patients with atrial fibrillation

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Virtual EP
Connect
1:11:36

Závěry

- Acute outcomes with lattice-tip PF/RFA: A highly efficient & safe procedure for both PVI (rivals “one-shots”) and for linear lesions (no comparator)

- But, two important questions/limitations:
  1. *How durable are these lesions?*
  2. *What are the clinical outcomes?*

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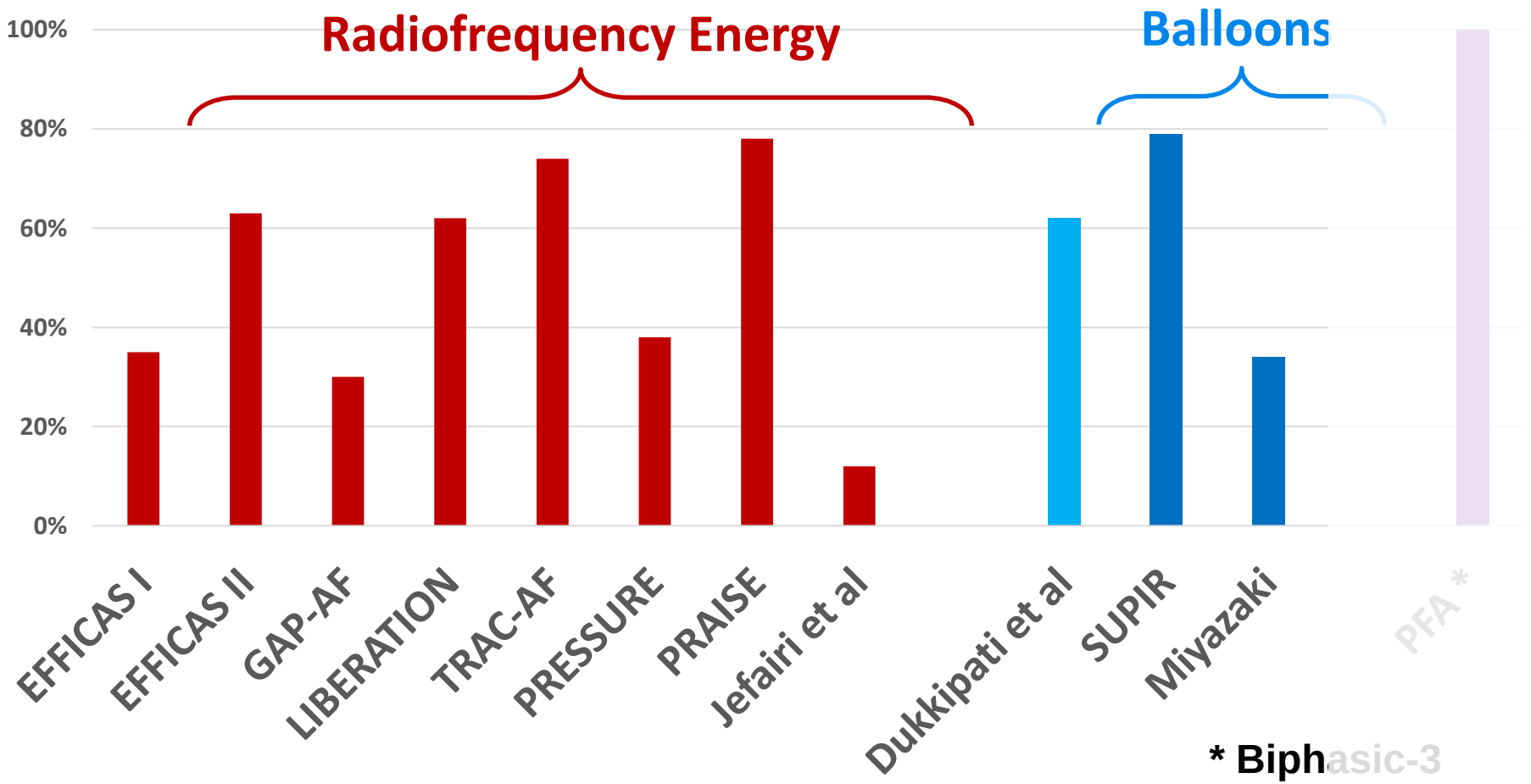
Durable PV Isolation

Data from Protocol-Driven Remap Studies

Patients with all PVs Durably Isolated



* Biphasic-3

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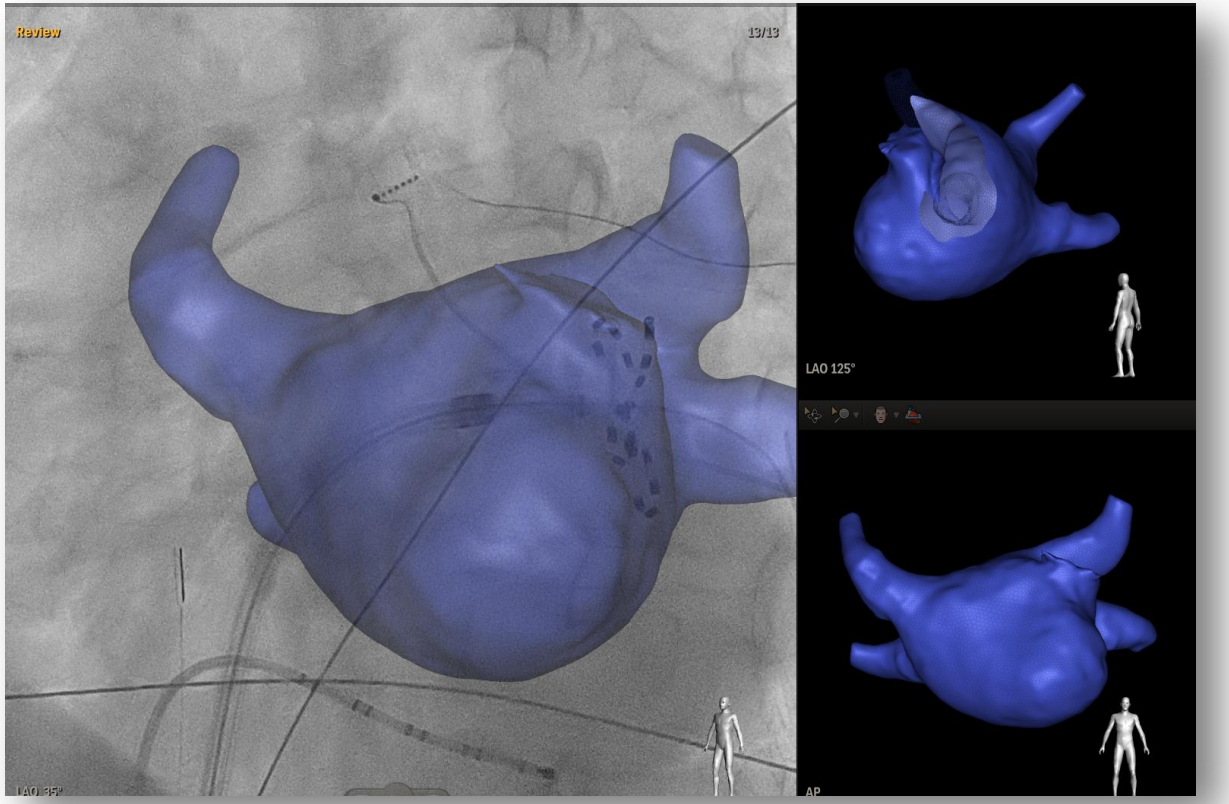
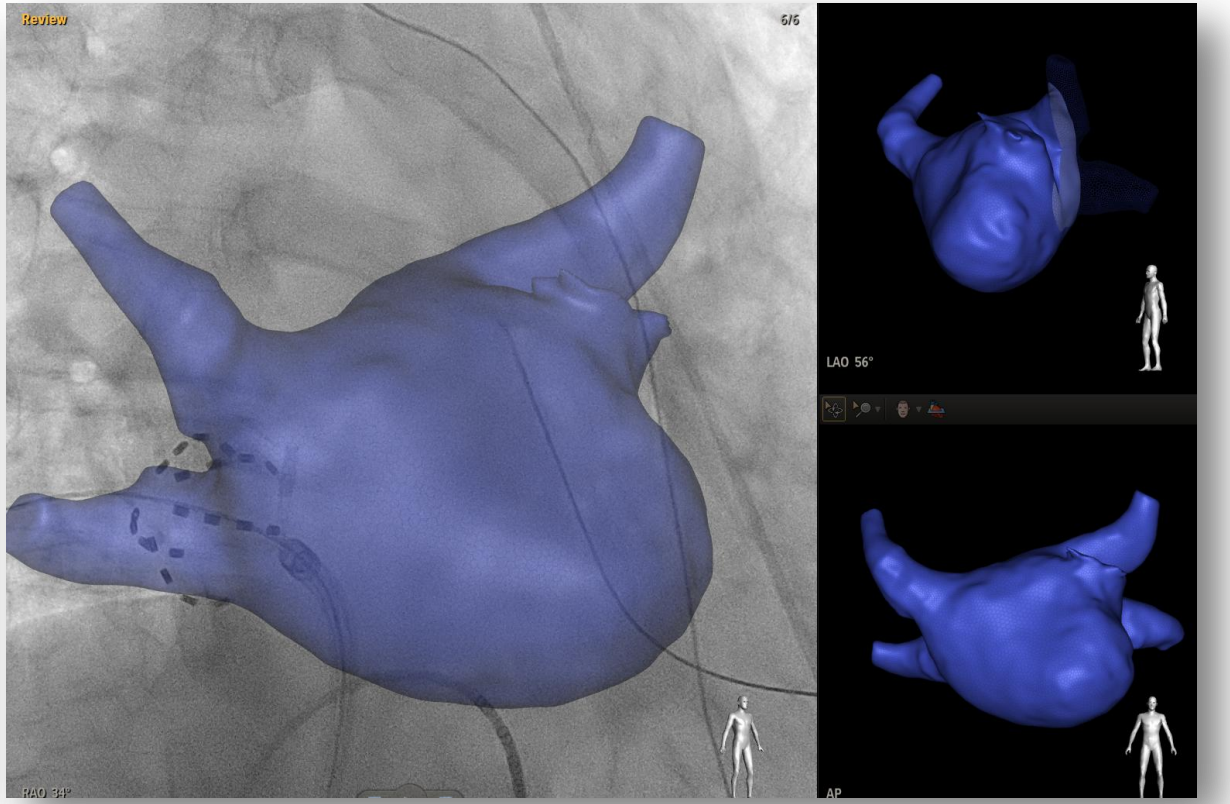
Klinická praxe pro perzistující FS

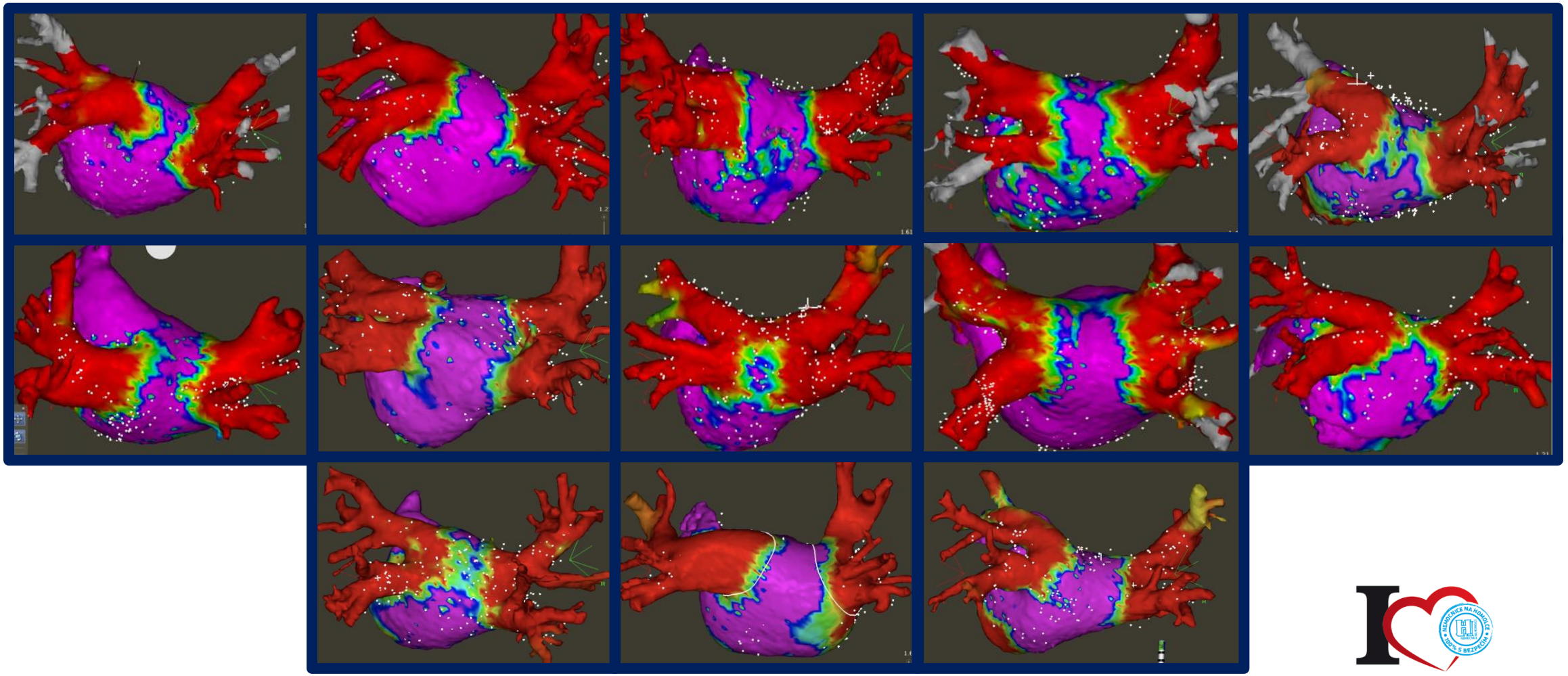
- duben 2021 – září 2021: IPV + box léze zadní stěny
- 18 pac., Ø délka výkonů: **73,2 min**





Pulsed Field Ablation

Addressing Varying Anatomies



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Klinická praxe pro perzistující FS

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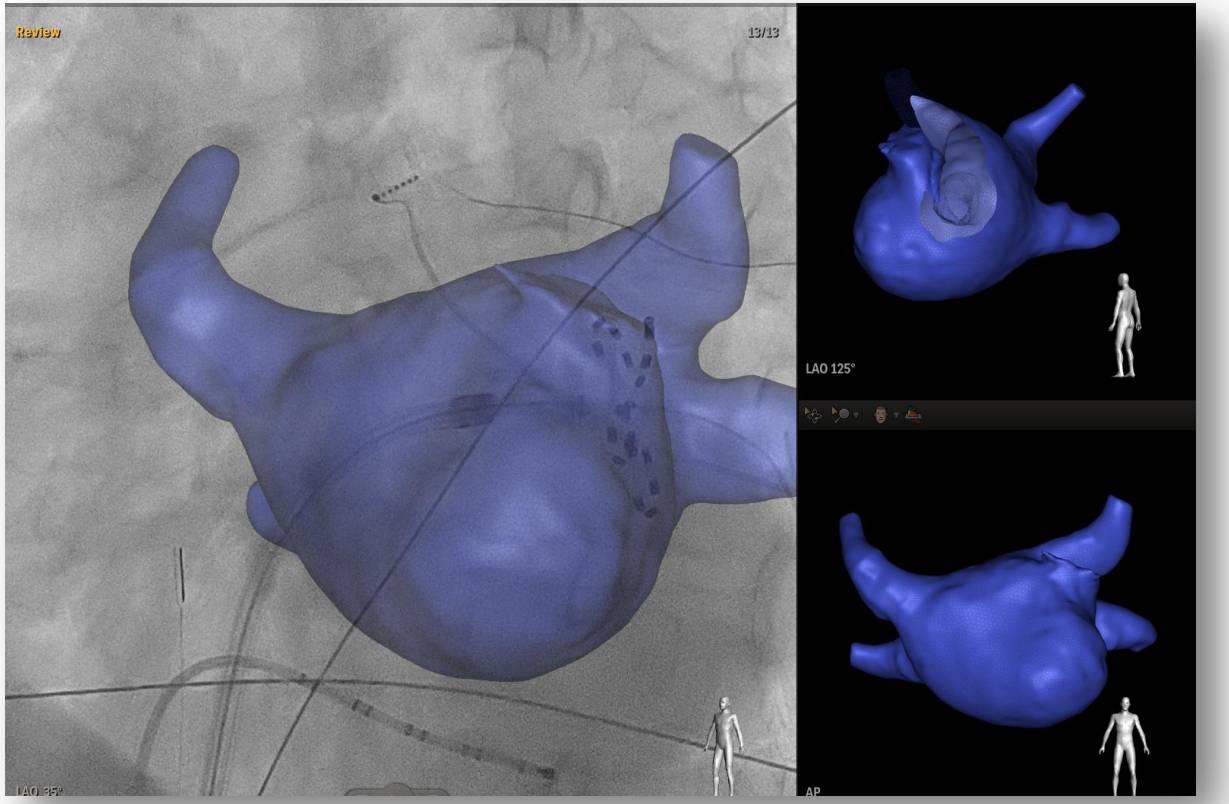

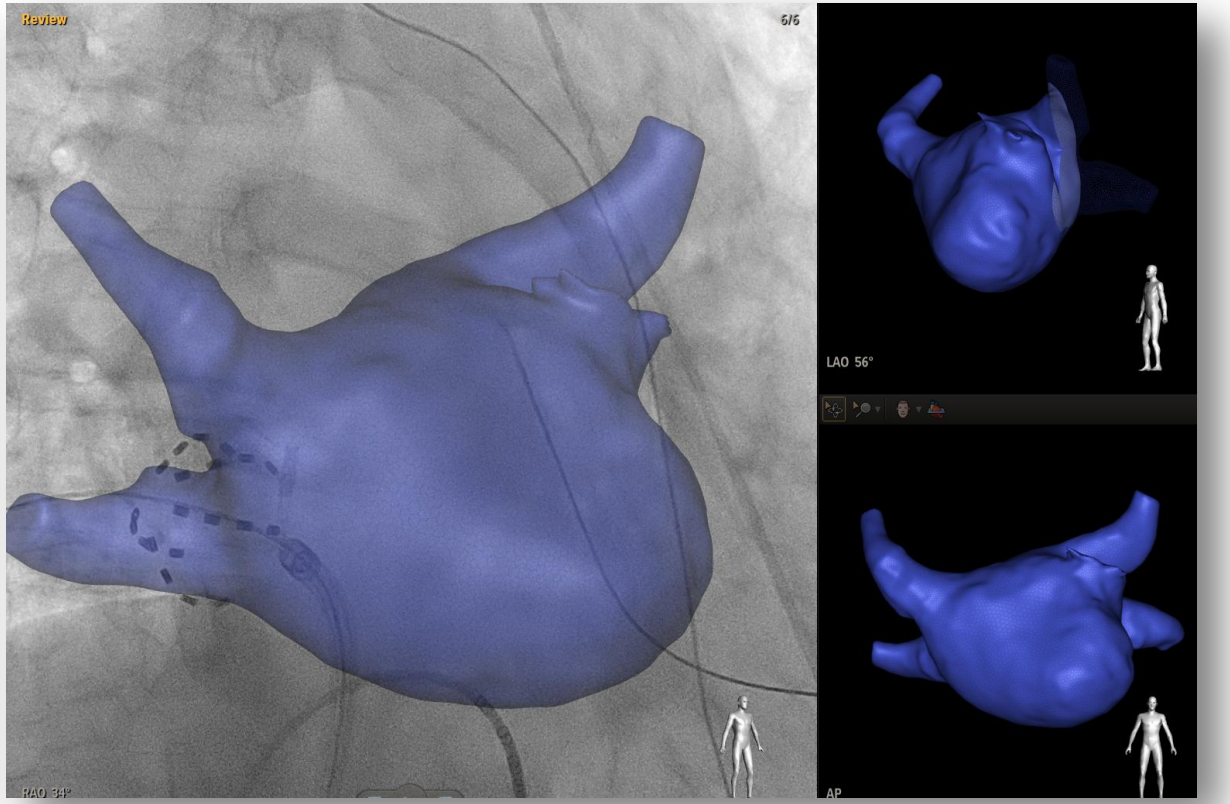

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Pulsed Field Ablation for Pulmonary Vein Isolation: Lesion Durability and Chronic Safety

Vivek Y Reddy, M.D.,[a,b] Petr Neuzil, M.D. Ph.D.,[a] Jacob S. Koruth, M.D.,[b] Jan Petru, M.D.,[a]
Moritoshi Funosako, M.D.,[a] Hubert Cochet, M.D.,[c] Lucie Sediva, M.D.,[a]
Milan Chovanec, M.D.,[a] Srinivas R. Dukkipati, M.D.[b] and Pierre Jais, M.D.[c]

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Pulsed Field Ablation (PFA)

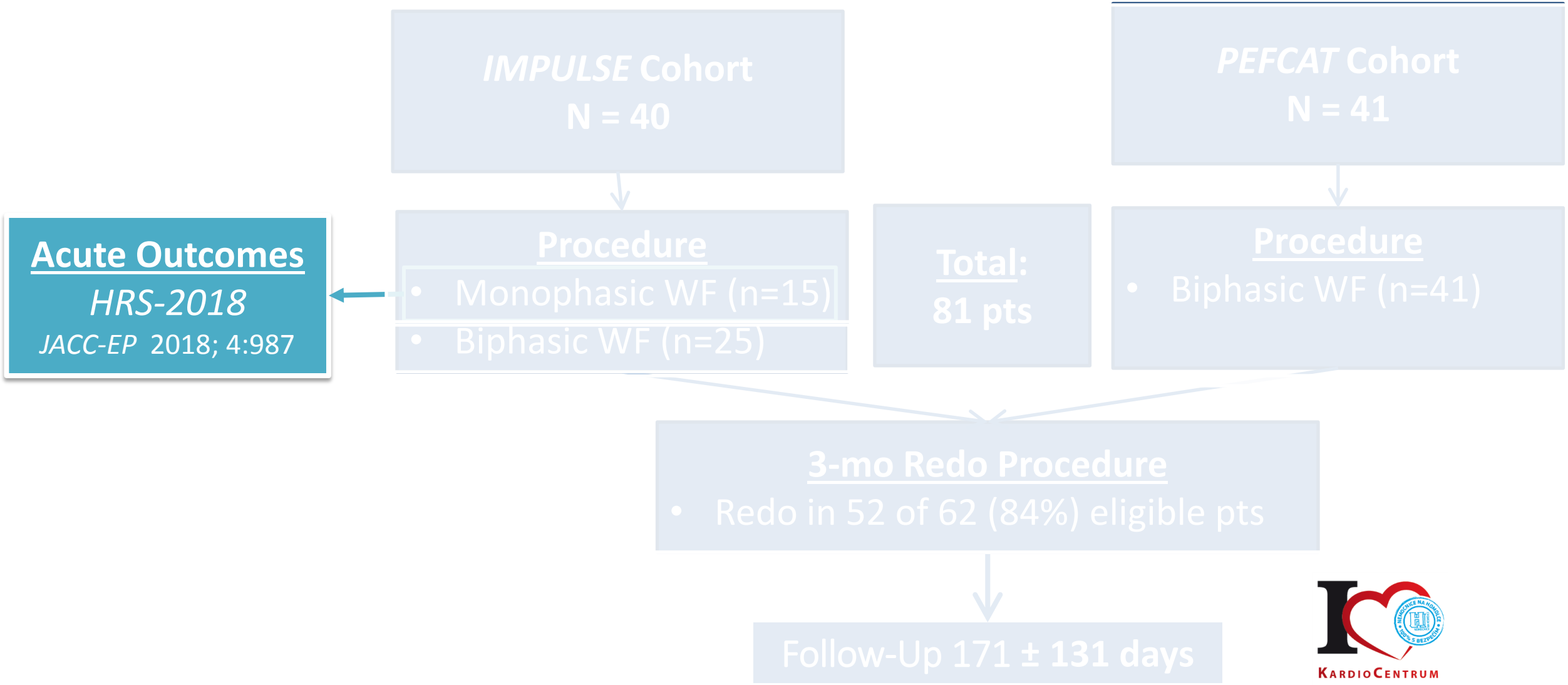
Fundamentals: Electroporation

- Application of intermittent, high-intensity electric fields for micro/nano- seconds
- Destabilizing electric potential results in cellular and tissue electroporation
- Formation of nanoscale cell membrane defects
- Pores leads to permeabilization & Cell death

E.Maor et al, *Heart Rhythm* DOI: https://doi.org/10.1016/j.hrthm.2019.01.012 (2018)
ML Yarmush et al, *Annu. Rev. Biomed. Eng.* 16:295–320 (2014)
Chang DC, Reese TS., *Biophys J.* 58:1–12 (1990)

IMPULSE & PEFCAT

Patient Flow



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IMPULSE & PEFCAT

Patient Baseline Characteristics

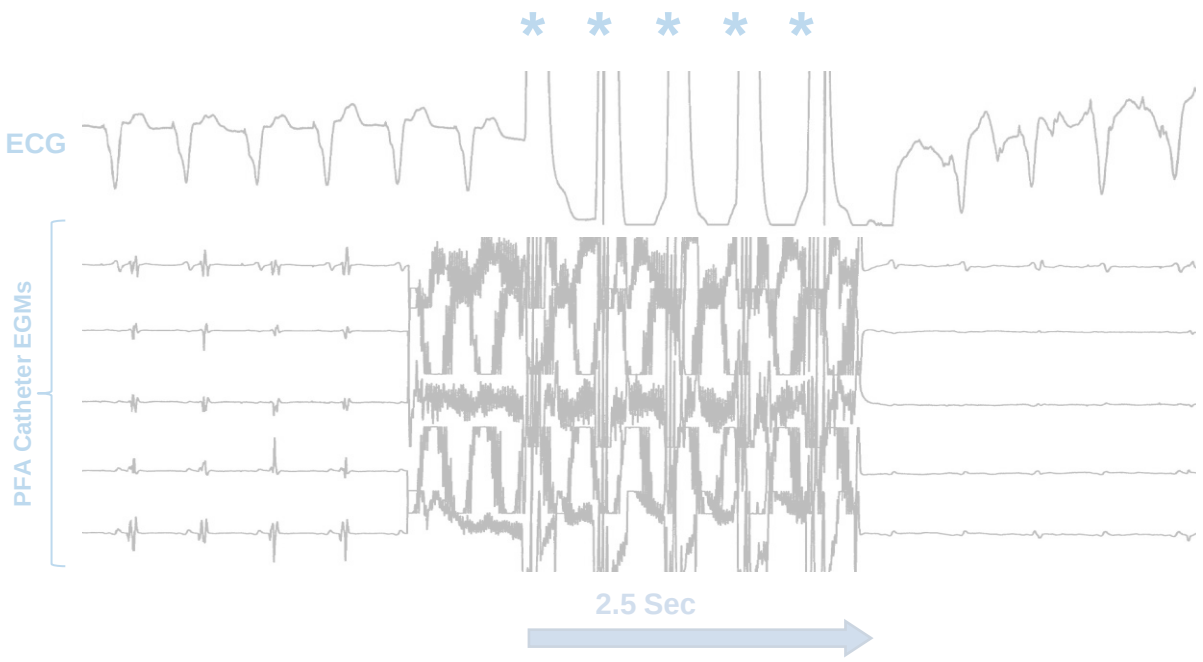
Characteristics	IMPULSE N=40	PEFCAT N=41	Total Cohort N=81
Age, years	58.5 ±9.0	57.6 ±12.1	58 ±10.7
Male, n (%)	28, (70%)	32, (78%)	60 (74%)
LA diameter, mm	41.0±4.3	41.4±5.6	41.2±5.0
LVEF, %	63.2±5%	63.3± 3.7%	63.3±4.3%
Hypertension, n (%)	20 (50%)	30 (73.2%)	50 (61.7%)
Diabetes, n (%)	3 (7.5%)	5 (12.2%)	8 (9.9%)
Stroke or TIA, n (%)	0 (0%)	3 (7.3%)	3 (3.7%)
CAD (MI / CABG), n (%)	1 (2.5%)	0 (0%)	1 (1.2%)

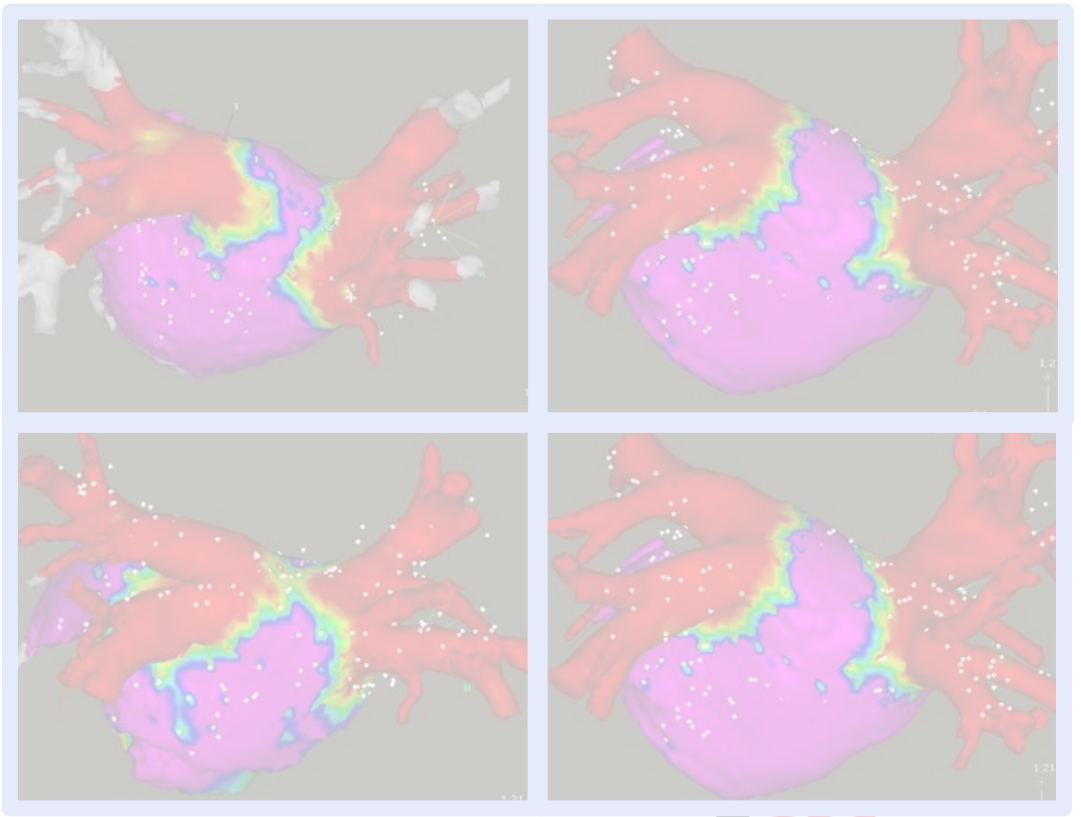
Biphasic PFA

FIH Clinical Experience

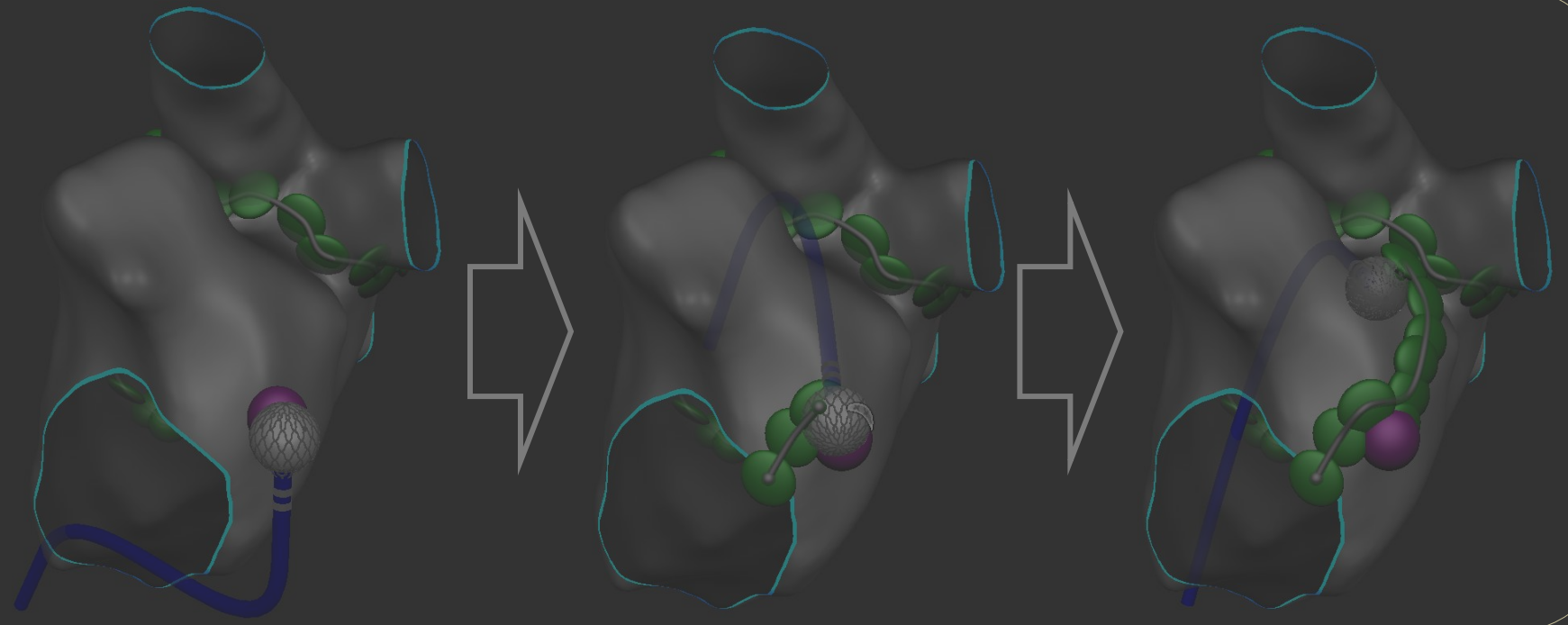
Improvements with biphasic delivery

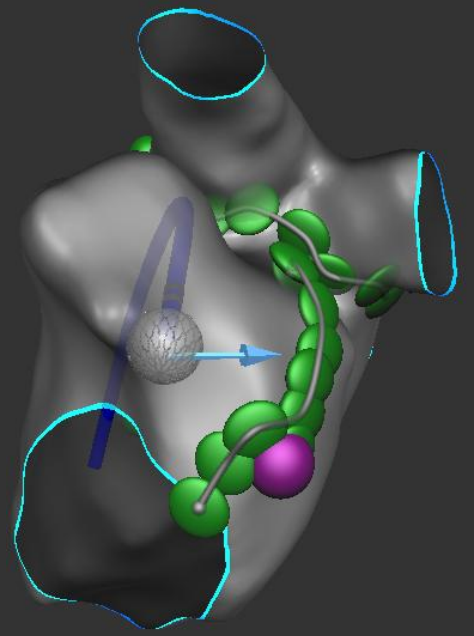
- No general anesthesia or paralytic (except 1st patient)
- Real-time EGM assessment with PFA catheter

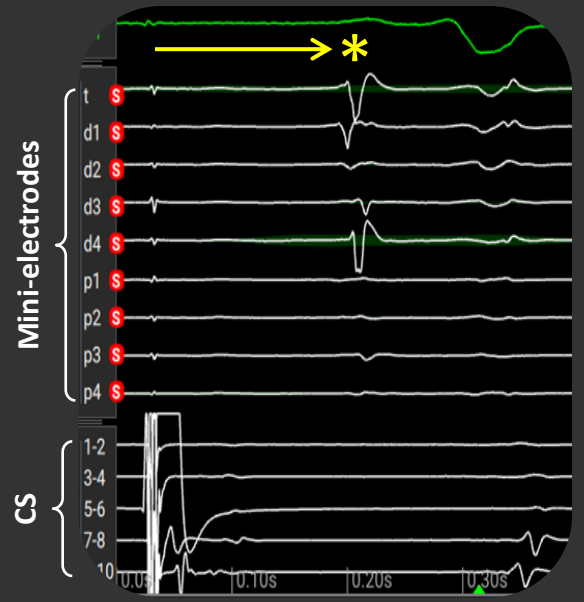


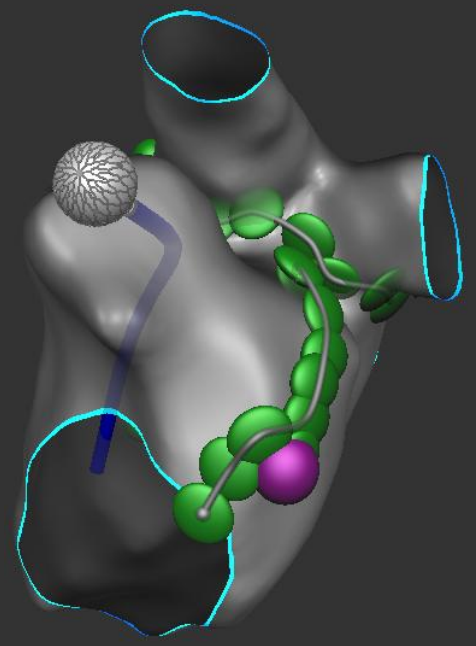


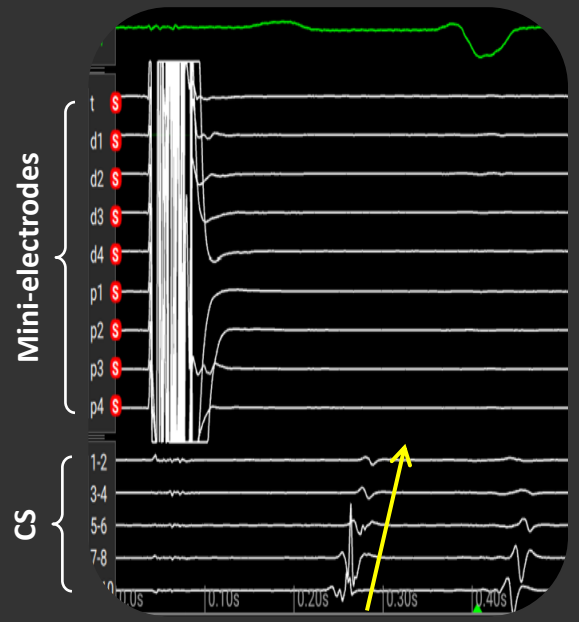
KardioCentrum






Mini-electrodes
t
d1
d2
d3
d4
p1
p2
p3
p4
CS
1-2
3-4
5-6
7-8
10
0.0s
0.1Us
0.2Us
0.3Us



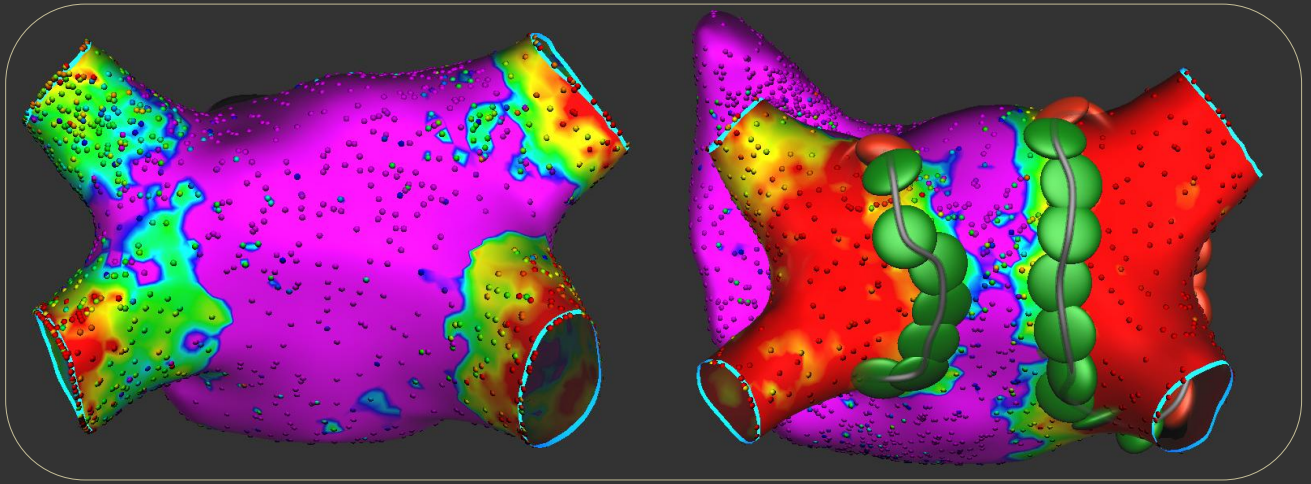

Mini-electrodes
t
d1
d2
d3
d4
p1
p2
p3
p4
CS
1-2
3-4
5-6
7-8
0.1Us
0.2Us
0.3Us
0.40s

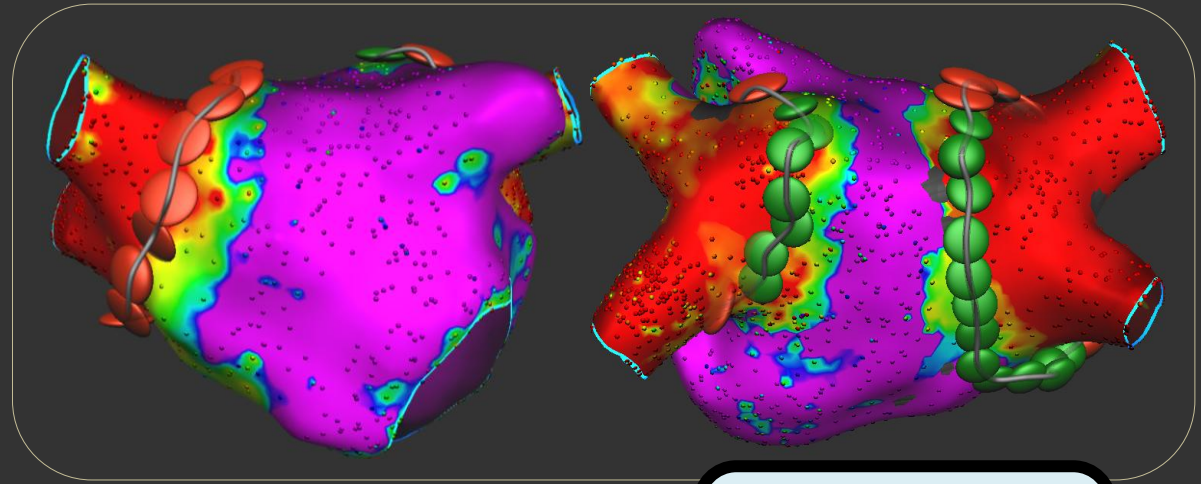
Patient Demographics

RF/PF vs PF/PF Cohort

Characteristic	Full AF Cohort (n = 76)	RF / PF Cohort (n = 40)	PF / PF Cohort (n = 36)
Age, mean ± SD, years	58.8 ± 9.9	57.0 ± 10.6	60.7 ± 8.9
Male, n (%)	50 / 76 (66%)	25 / 40 (63%)	25 / 36 (69%)
Body mass index, mean ± SD	29.8 ± 4.2	29.5 ± 4.1	30.2 ± 4.2
Medical History			
Paroxysmal AF, n (%)	55 / 76 (72%)	29 / 40 (73%)	26 / 36 (72%)
Persistent AF, n (%)	21 / 76 (28%)	11 / 40 (28%)	10 / 36 (28%)
Hypertension, n (%)	55 / 76 (72%)	32 / 40 (80%)	23 / 36 (64%)
Diabetes, n (%)	6 / 76 (8%)	3 / 40 (8%)	3 / 36 (8%)
LVEF, mean ± SD, %	58.1 ± 5.8	56.9 ± 5.3	59.4 ± 6.1
LA size, mean ± SD, mm	42.6 ± 5.3	41.8 ± 4.7	43.6 ± 5.8
Medications			
Warfarin, n (%)	19 / 76 (25%)	5 / 40 (13%)	14 / 36 (39%)
NOAC, n (%)	50 / 76 (66%)	32 / 40 (80%)	18 / 36 (50%)
Antiarrhythmic drugs, n (%)	72 / 76 (95%)	39 / 40 (98%)	33 / 36 (92%)

Post-RF/PF Ablation Mapping

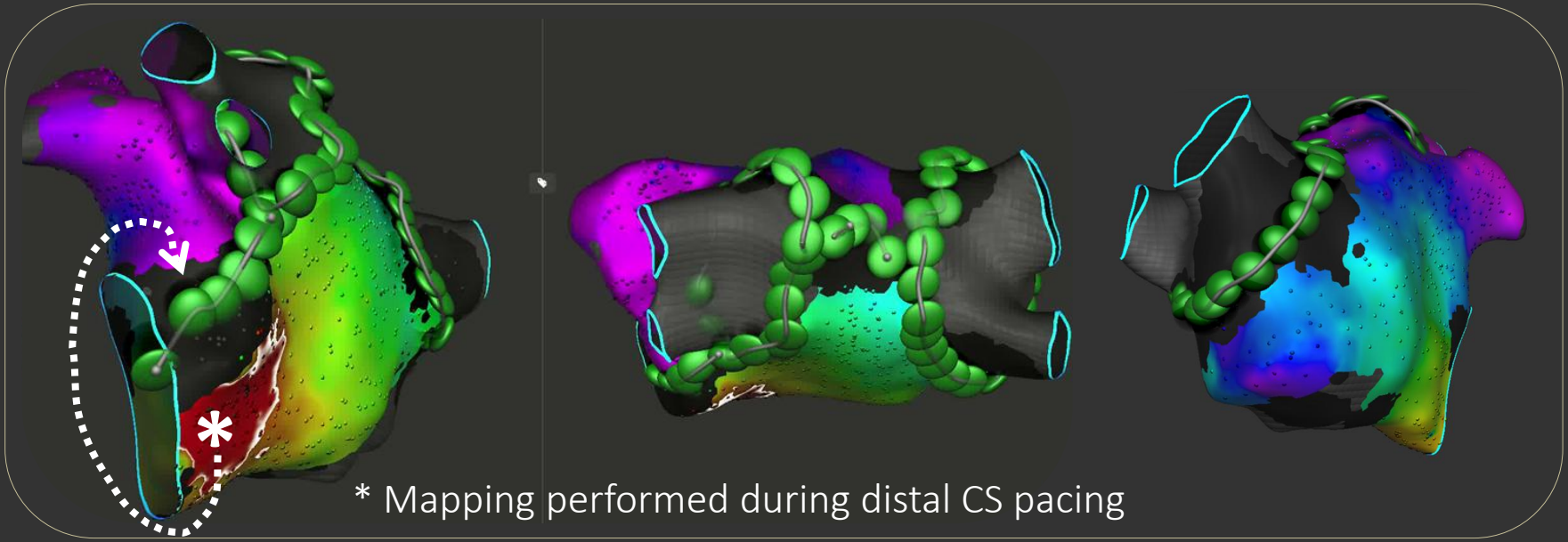




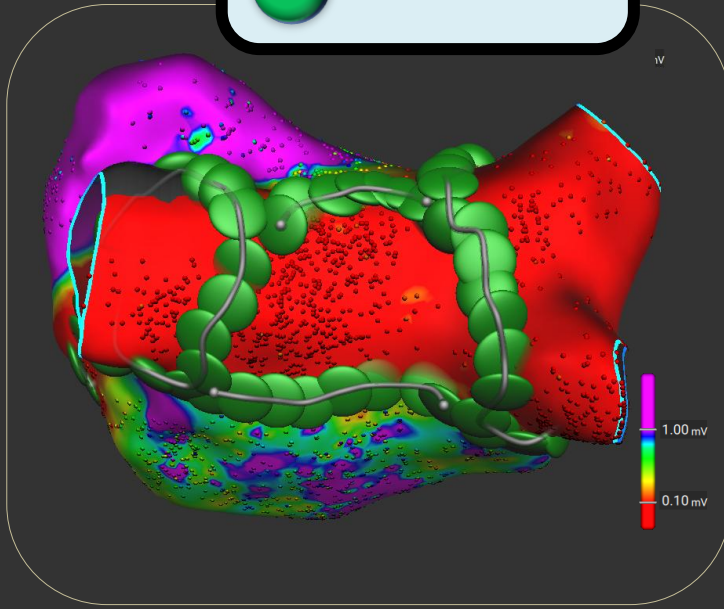
= RF Lesion

= PF Lesion

Post-PF/PF Ablation Mapping



* Mapping performed during distal CS pacing



FIH PF±RF Clinical Study Outcomes

Safety

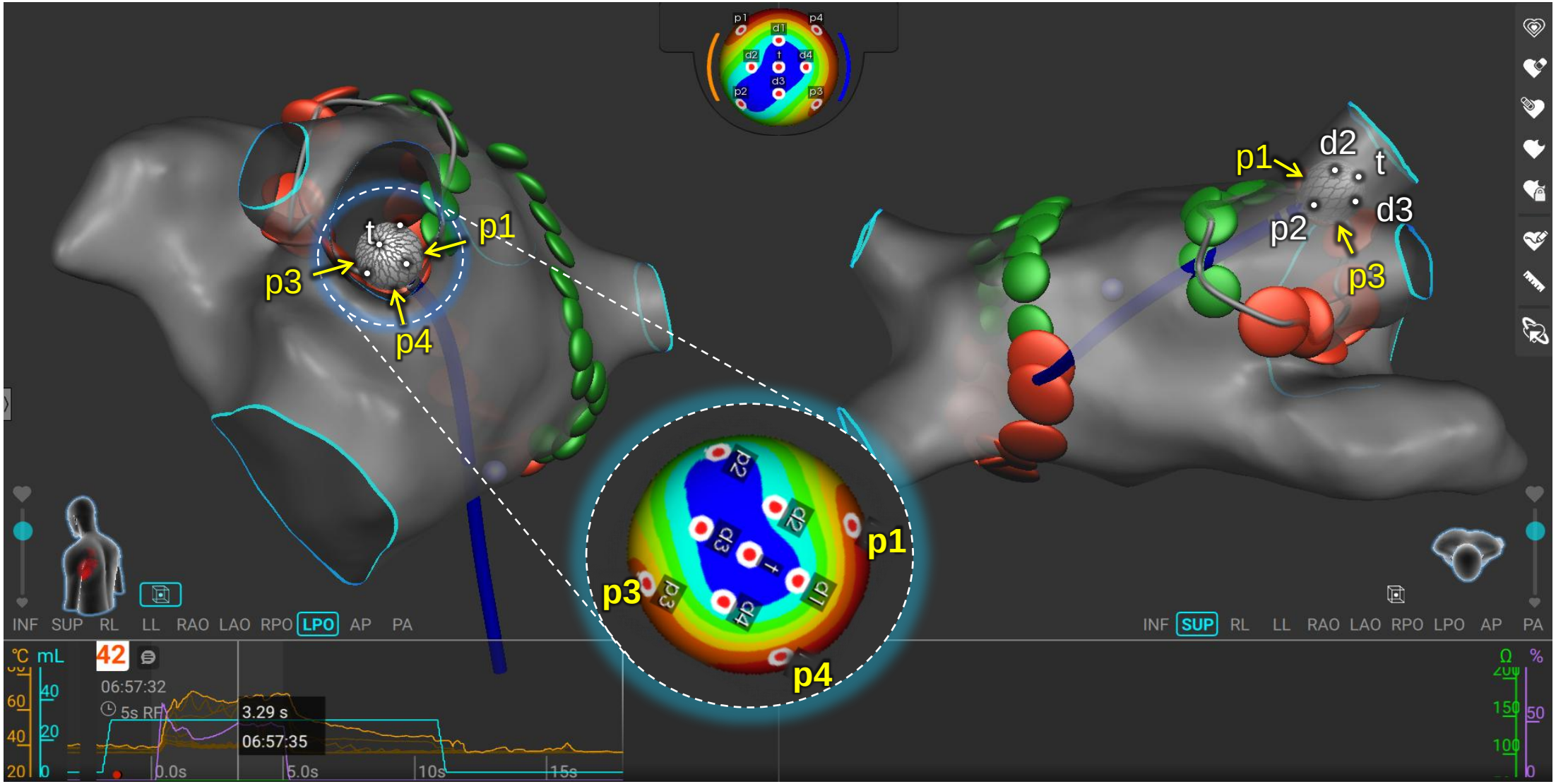
	Cohort (n=76 pts)
MAJOR COMPLICATIONS	
Stroke	0
Pericardial tamponade	0
Phrenic nerve paralysis	0
Pulmonary Vein Stenosis	0
CT scanning (3-mo), n=44	No Stenosis
Atrio-esophageal fistula	0
Death	0
Vascular – Major Complications *	1 / 76 (1.3%)
MINOR COMPLICATIONS	
Transient Ischemic Attack	0
Vascular – Minor Complications †	4 / 76 (5.3%)
Pericardial Effusion without tamponade	0
ESOPHAGEAL OBSERVATIONS (EGDs in 60 pts)	
Any Esophageal Abnormality	2 / 60 (3.3%)
Minor Erythema	2 / 60 (3.3%)
Moderate Erosion	0 / 60 (0%)
Ulceration	0 (0%)
Esophageal Abnormality (per Ablation Strategy)	
RF / PF	2 / 36 (5.6%)
PF / PF	0 / 24 (0%)

Brain MRIs

- (Rem: No strokes/TIAs)
- MRIs performed in 51 pts
  - Performed at 1.2±0.6 days
- Outcomes
  - DWI+/FLAIR-: 5 (9.8%)
  - DWI+/FLAIR+: 3 (5.9%)
- But, mean ACT:
  - MRI+ 266 ± 41 sec
  - MRI- 335 ± 67 sec

Why were there *any* esophageal lesions?

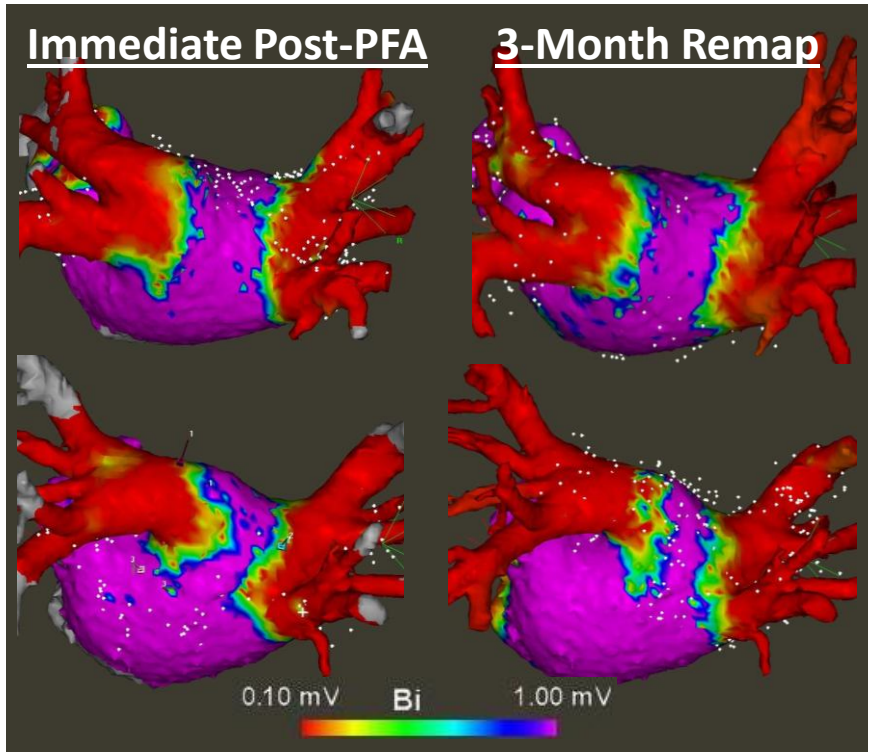
Posterior Heating During *Anterior* RFA

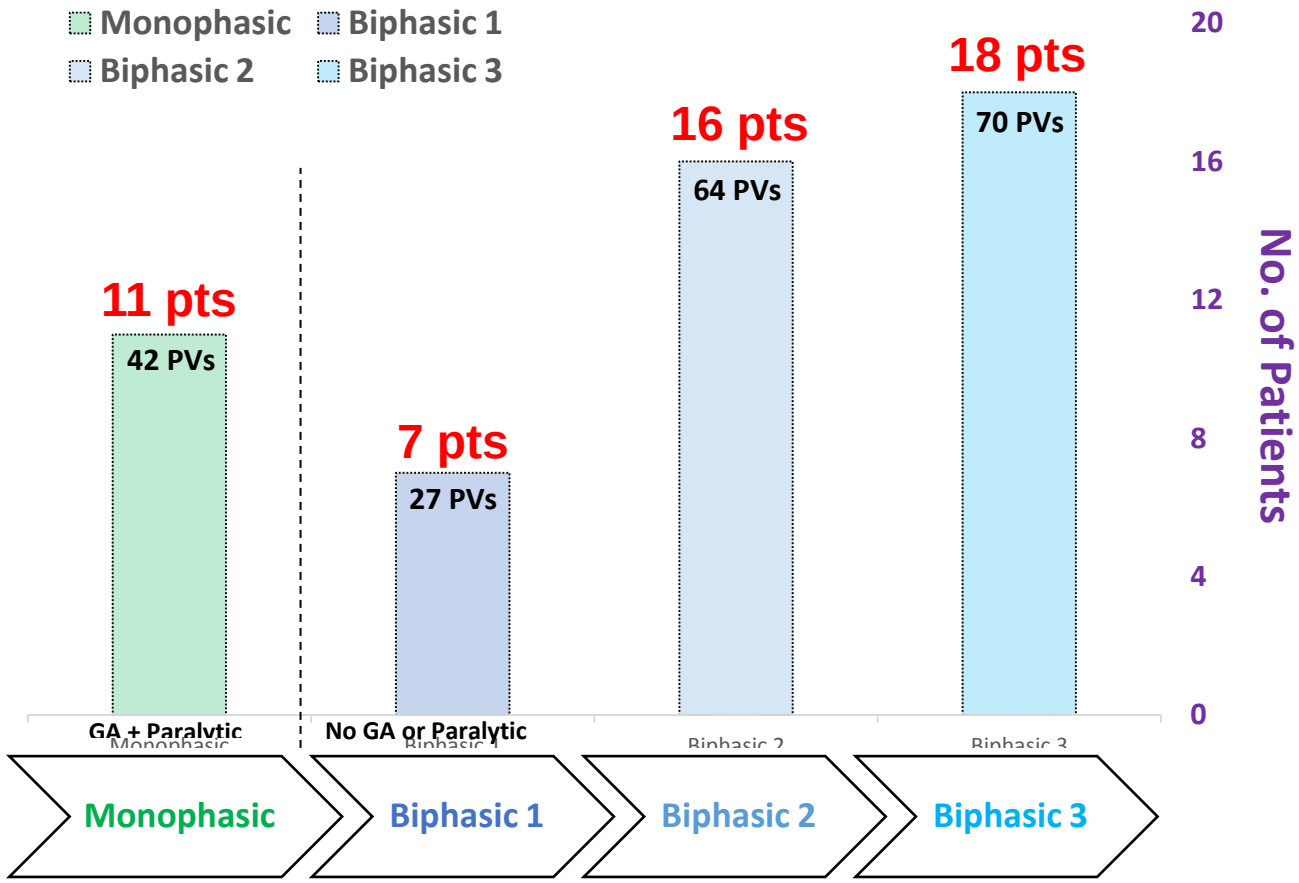


IMPULSE & PEFCAT

3-Month Remapping Outcomes

Rem: 100% Acute Isolation

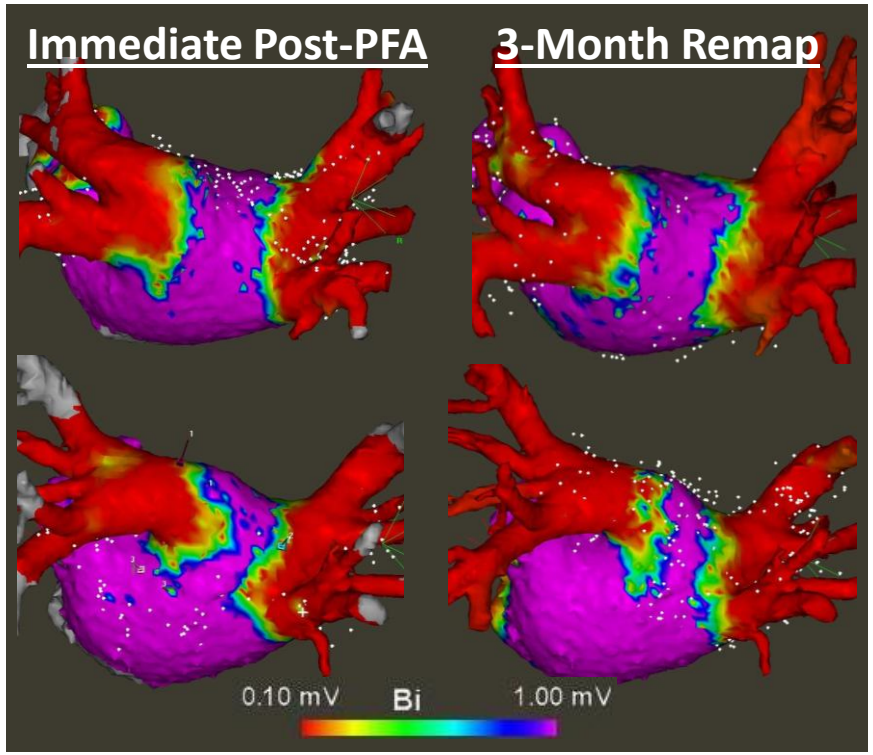


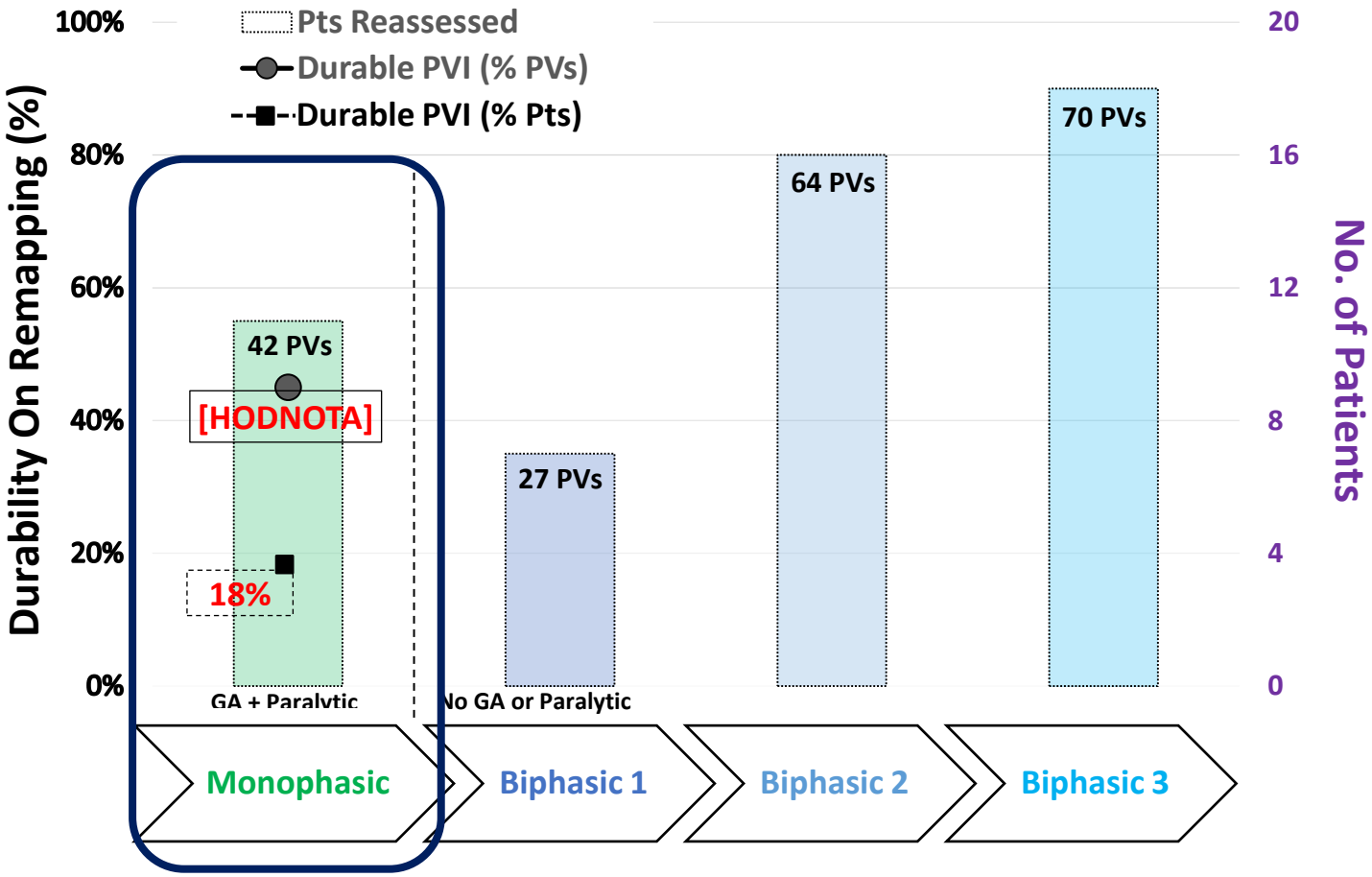


IMPULSE & PEFCAT

3-Month Remapping Outcomes

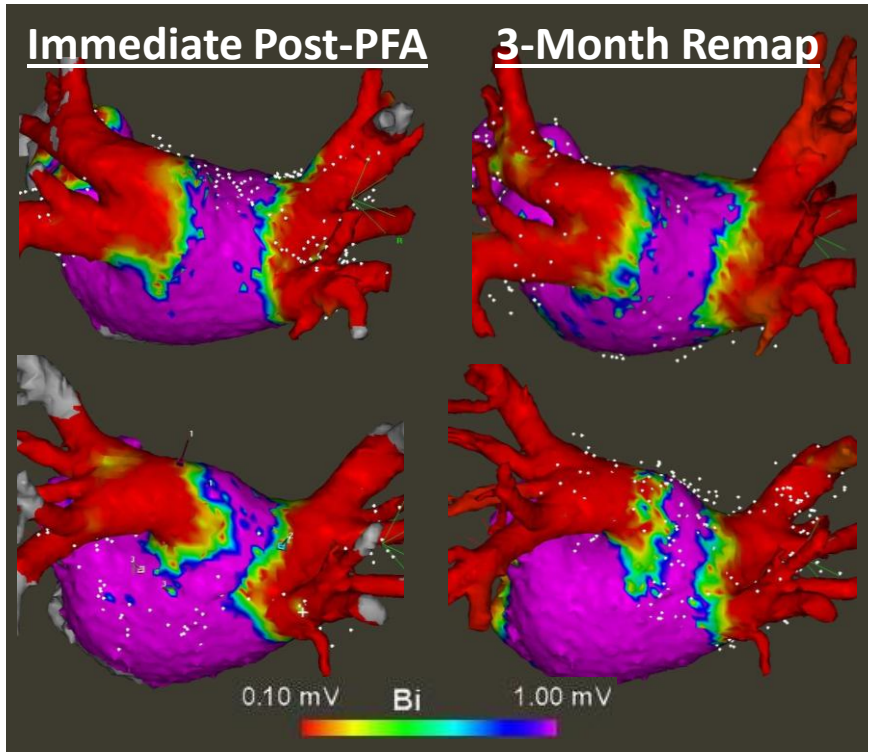
Rem: 100% Acute Isolation

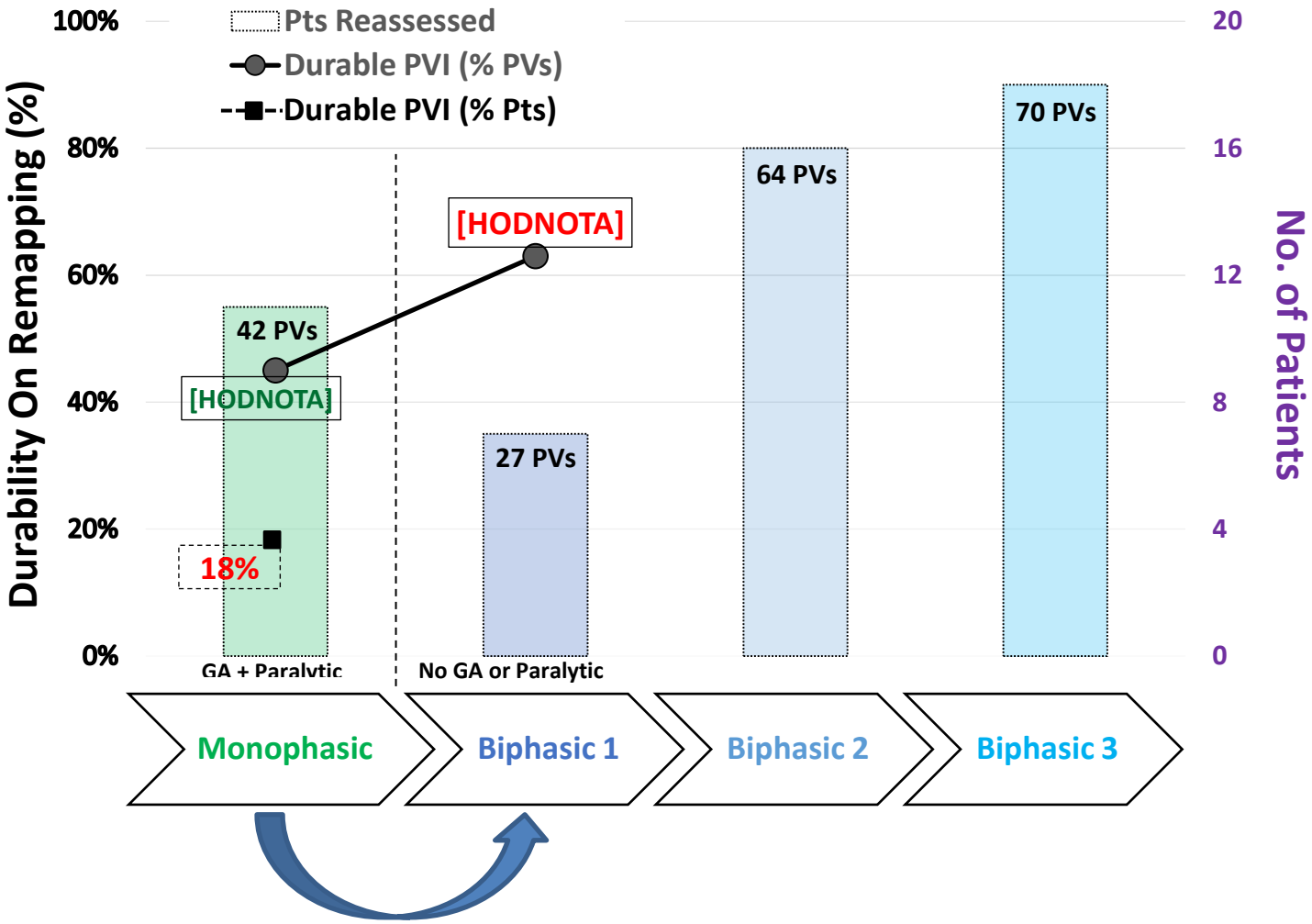




IMPULSE & PEFCAT

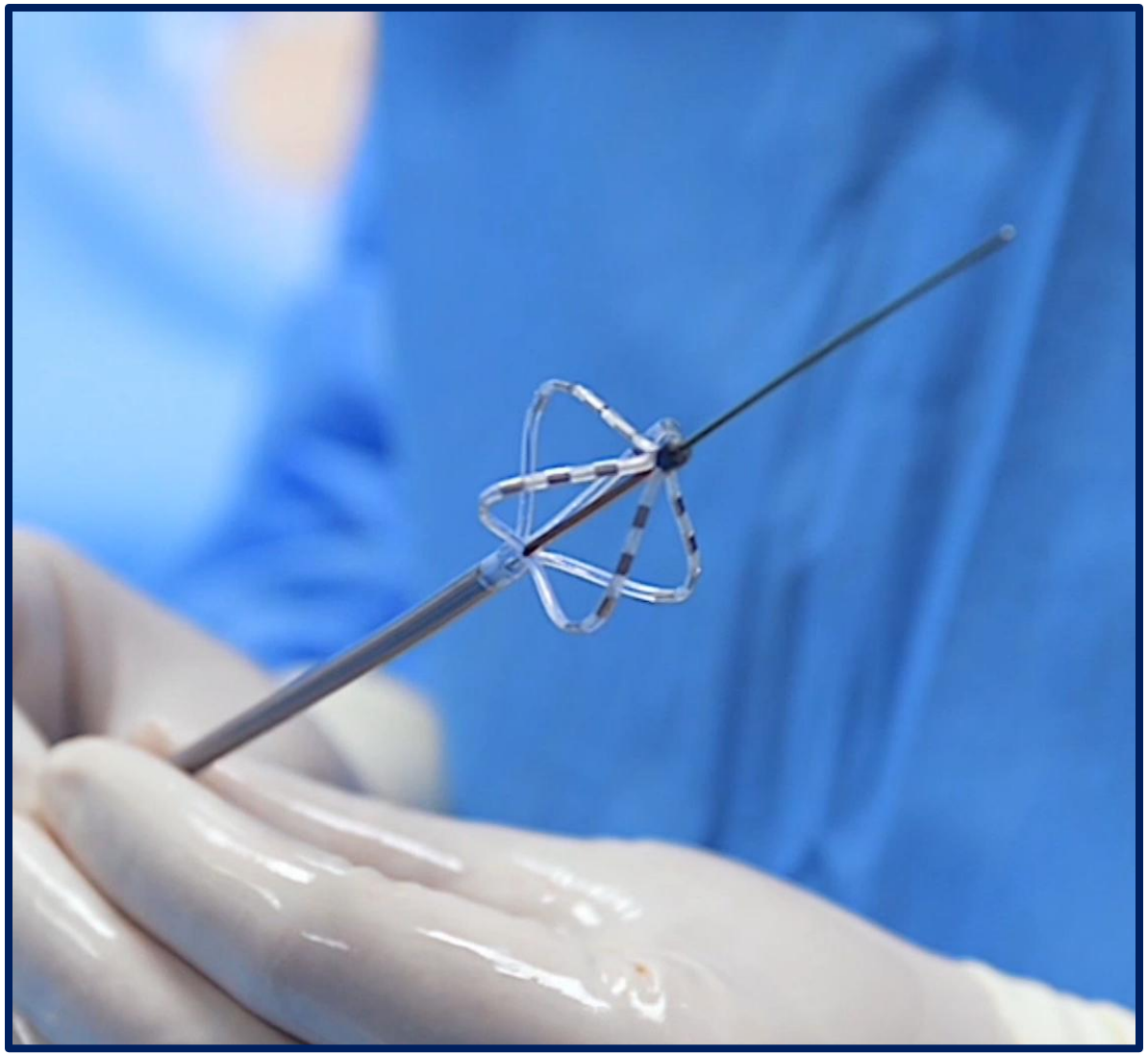
3-Month Remapping Outcomes

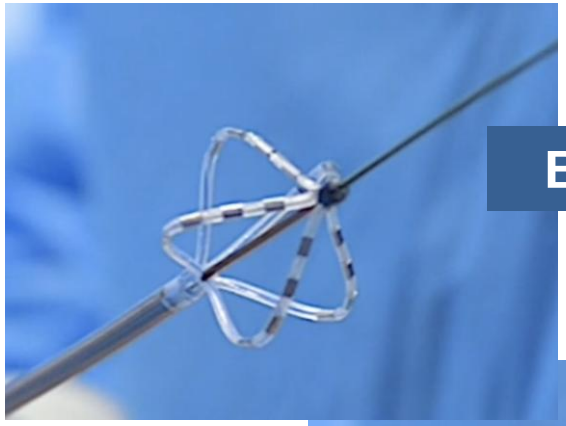




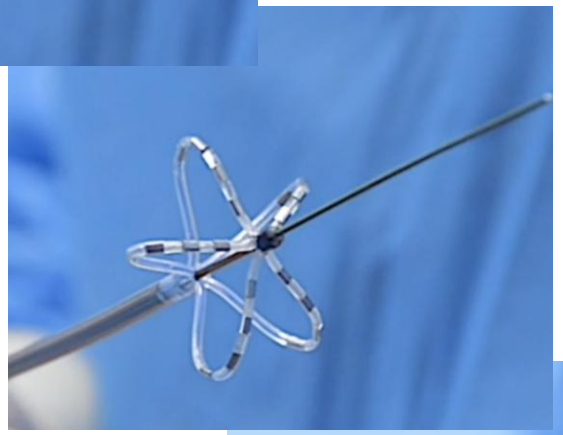
PFA Ablation Catheter

Deployment into Various Poses





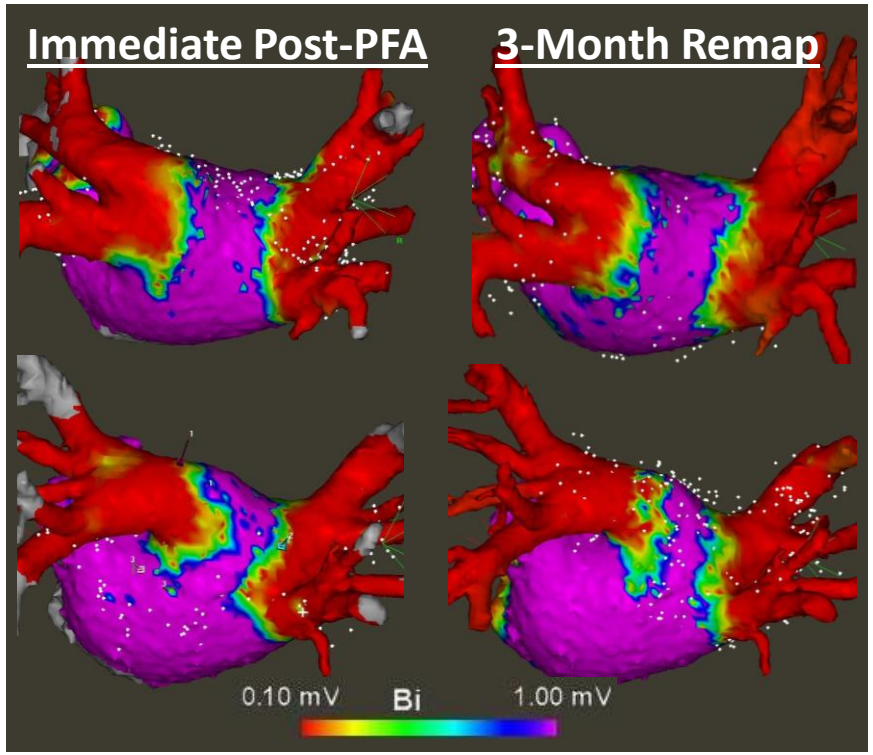
Basket Pose

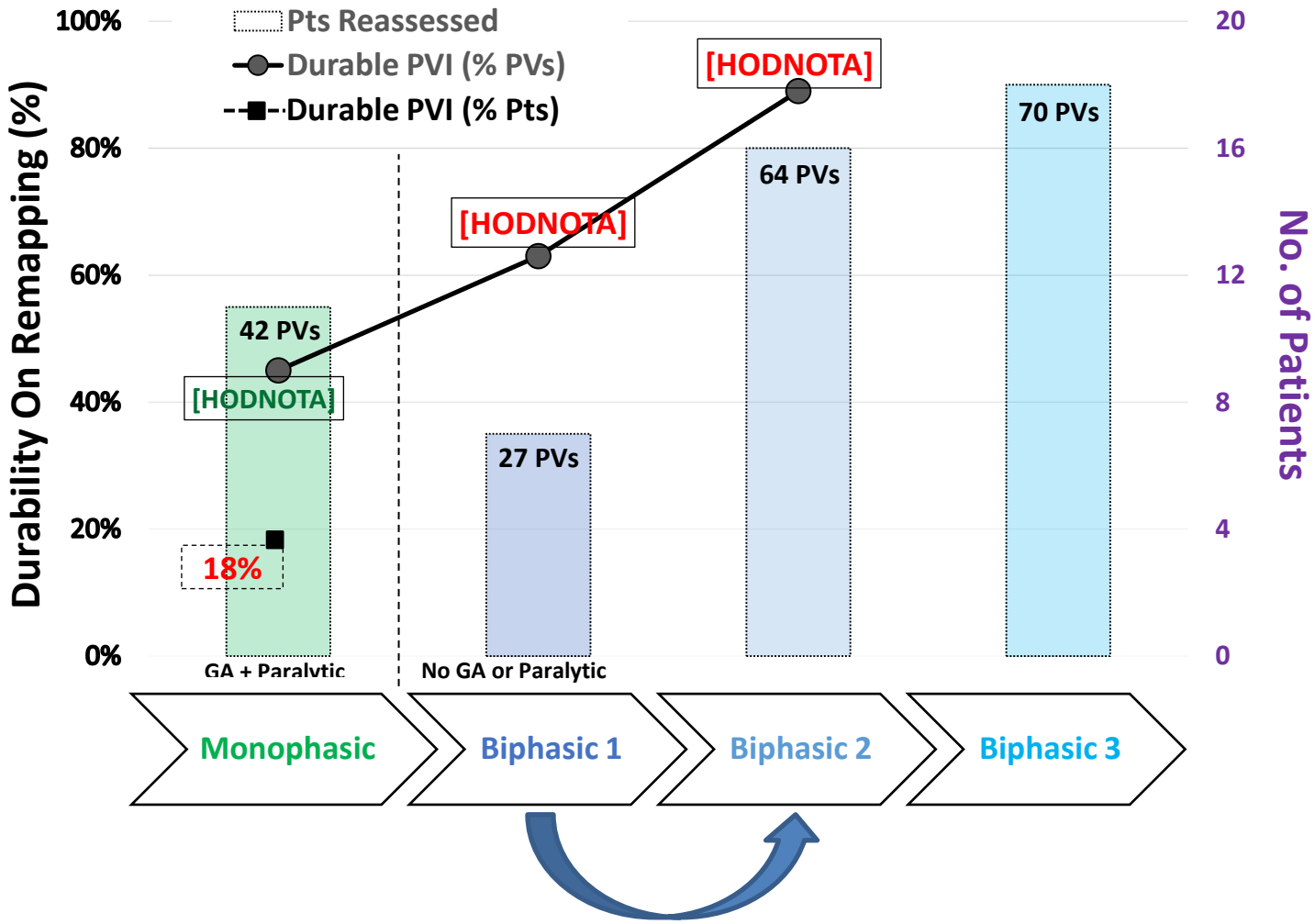


Flower Pose

IMPULSE & PEFCAT

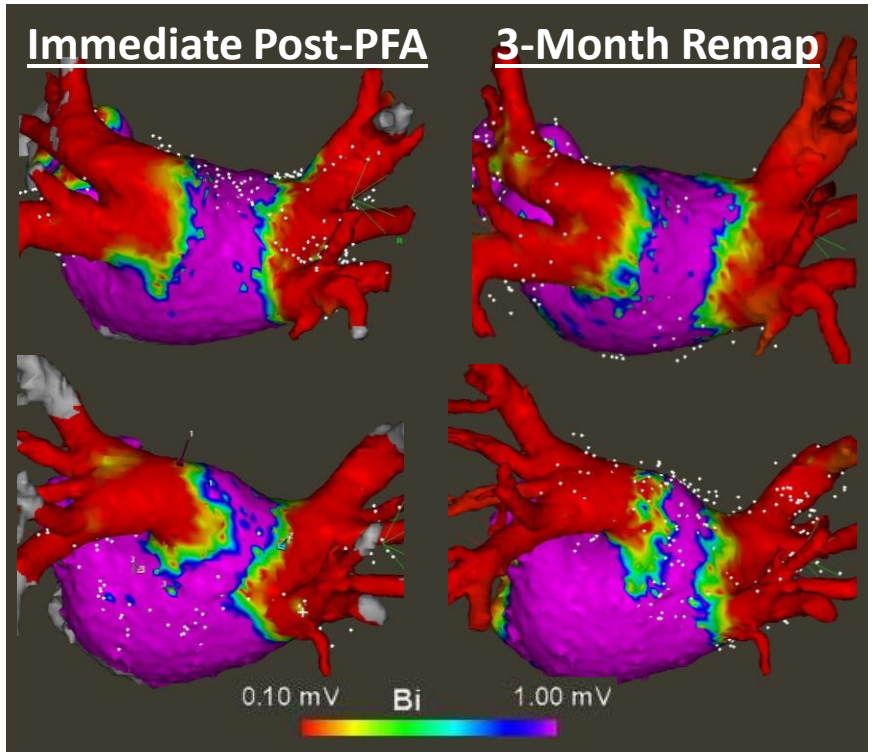
3-Month Remapping Outcomes

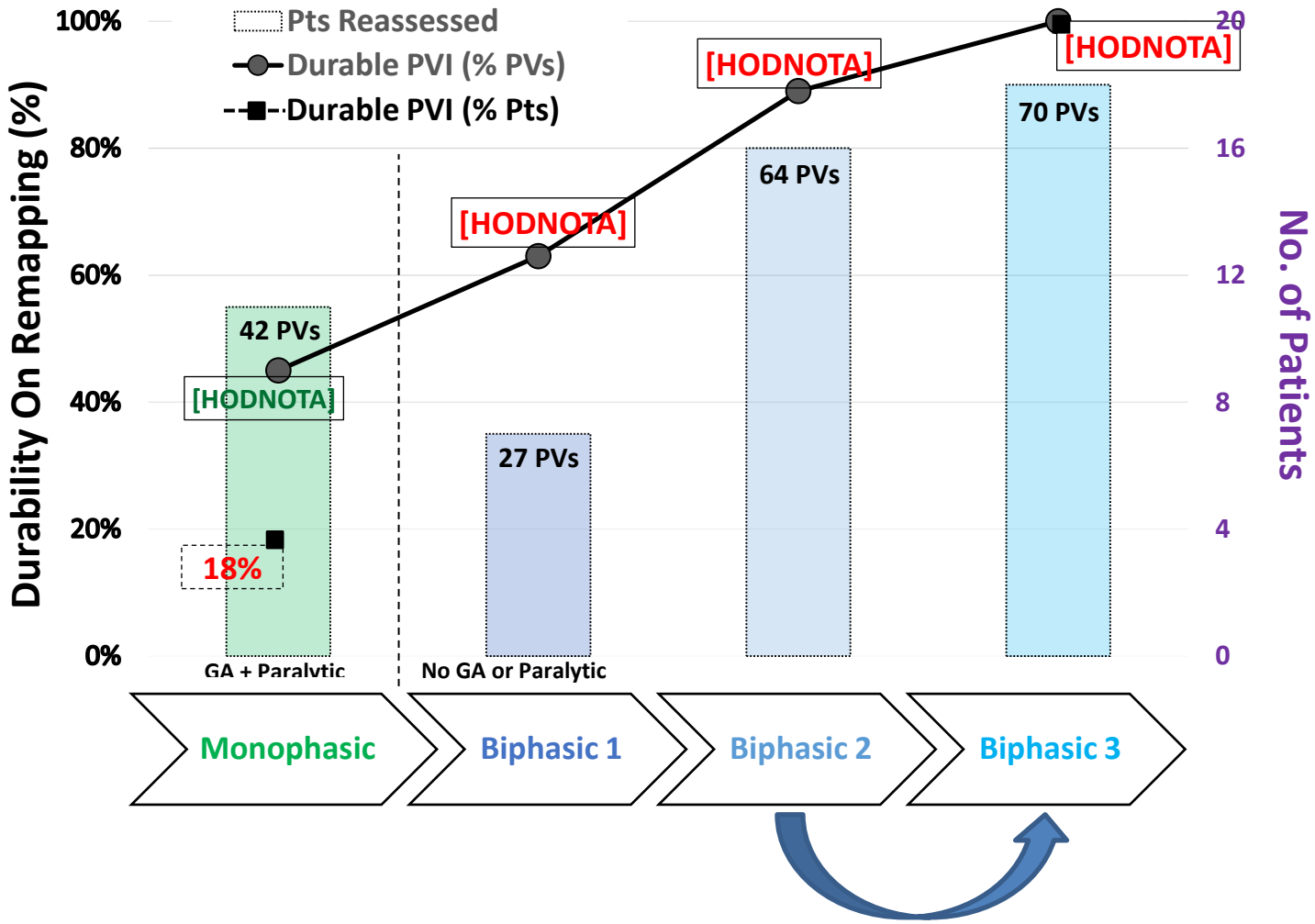




IMPULSE & PEFCAT

3-Month Remapping Outcomes





IMPULSE & PEFCAT

3-Month Remapping Outcomes