

PŘEDBĚŽNÉ ZKUŠENOSTI JEDNOHO CENTRA S MULTIABLAČNÍM SYSTÉMEM Affera SPHERE-PVI (MEDTRONIC SPHERE 360™)

Škoda J., Reddy V.* , Petrů J., Funasako T., Šedivá L.,
Janotka M., Hála P., Chovanec M., Neužil P.

Kardiologické odd. Nemocnice Na Homolce

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Medtronic Sphere-360™ ablační katetr PFA „single-shot“



ESC

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CLINICAL RESEARCH

First-in-human clinical series of a novel conformable large-lattice pulsed field ablation catheter for pulmonary vein isolation

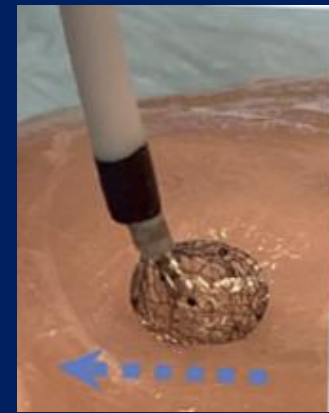
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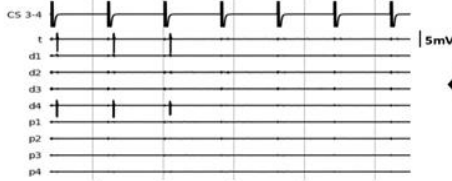
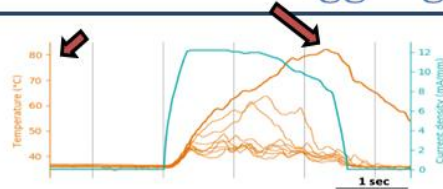
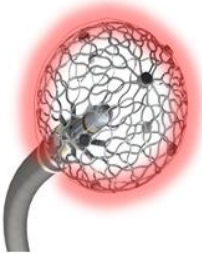
Úvod: Affera RF/PF

Mřížkový Fokální katetr Sphere-9™

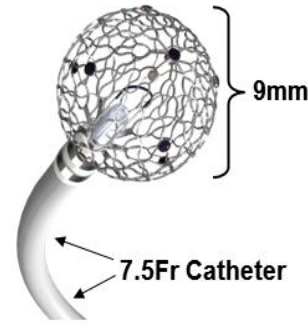
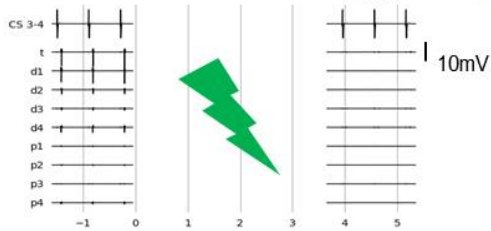
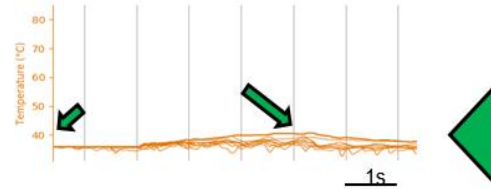
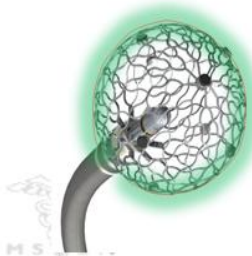


toggling Between RF & PF Energy

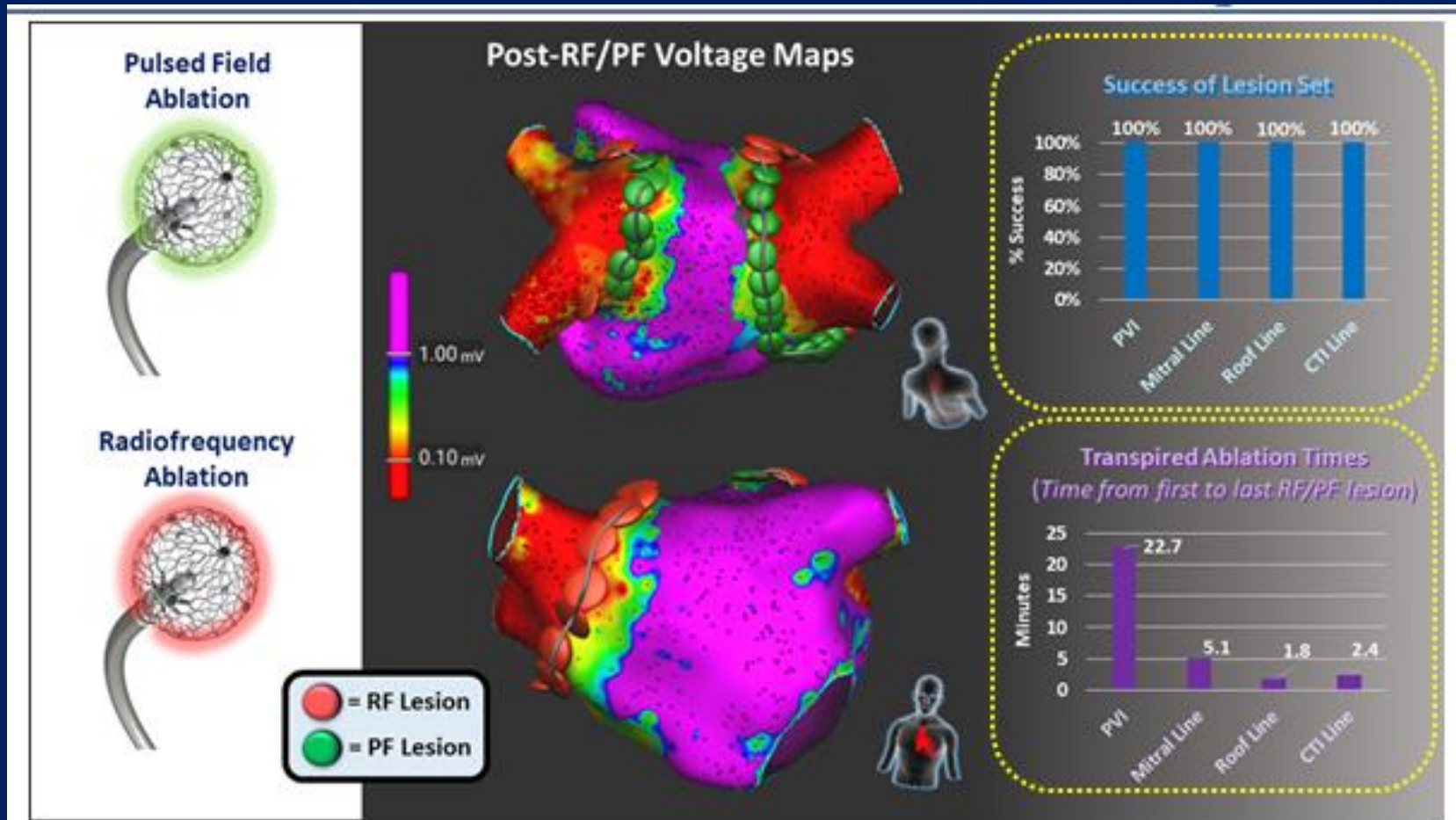
RF Ablation



PF Ablation



Úvod: FIH-Studie Affera RF/PF Mřížkový katetr Sphere-9™

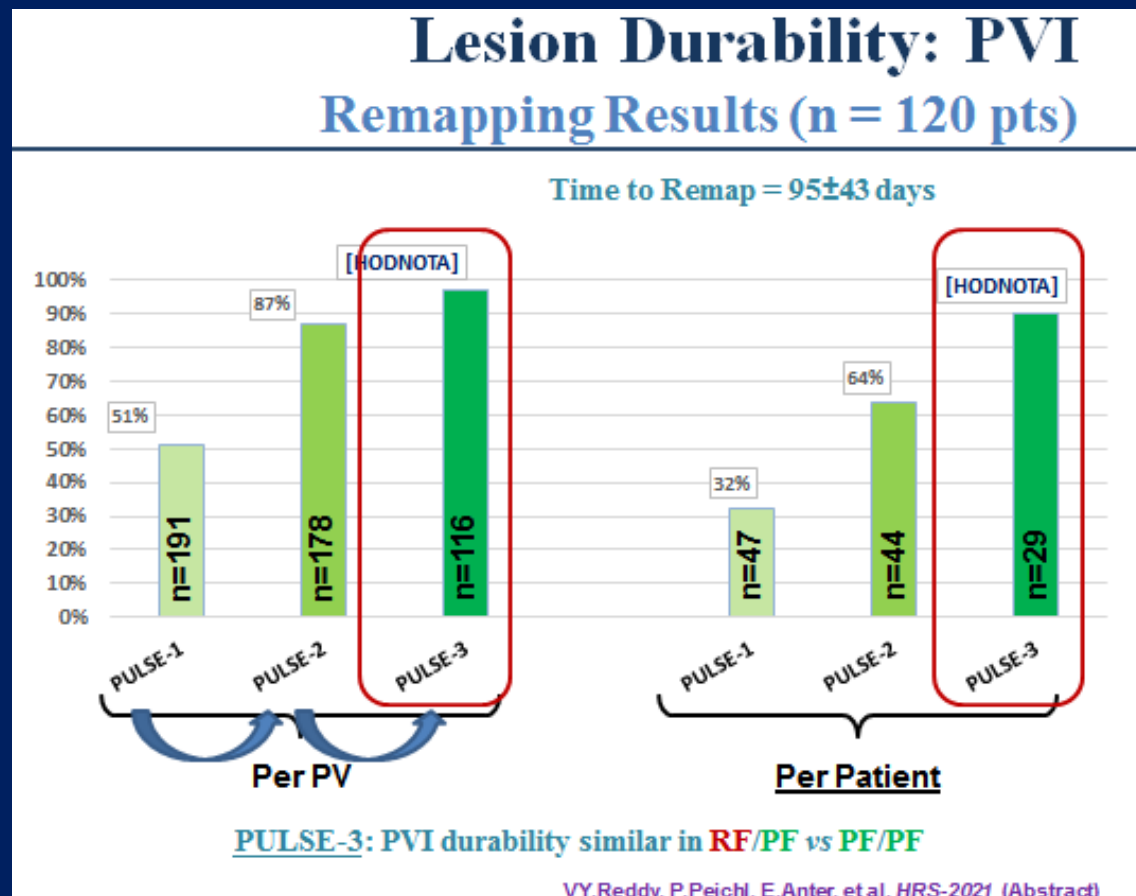
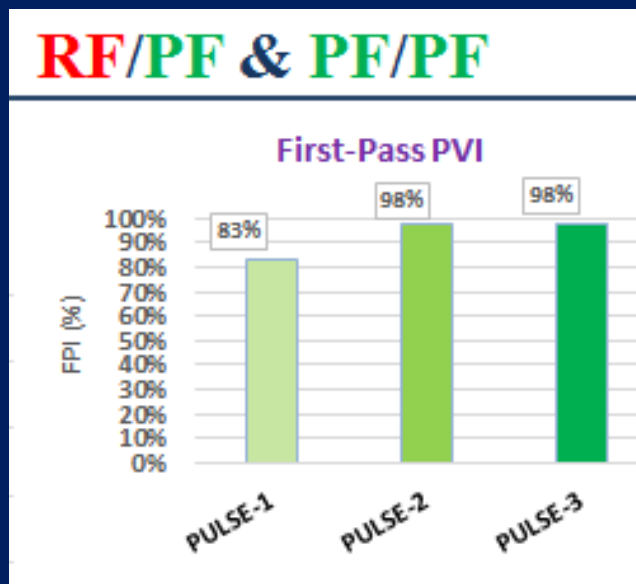


Reddy V, Peichl P, Rackauskas G, Anter E, Kautzner J, Neuzil P et al:
Circulation Arrhythmia and Electrophysiology. 2020;13:e008718

Úvod: Studie Affera RF/PF

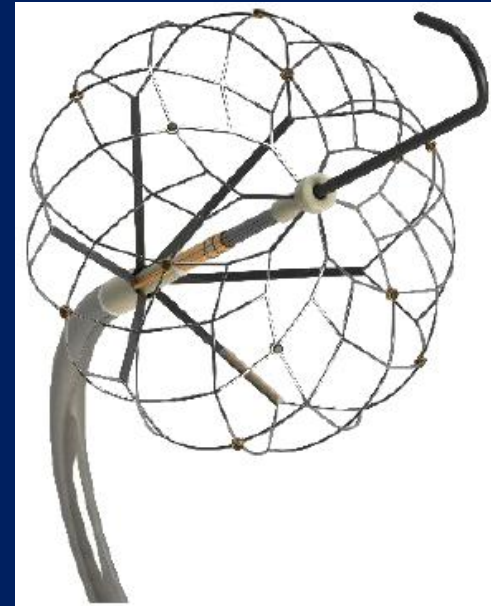
Mřížkový katetr Sphere-9™

akutní IPV a 3M remapování



Medtronic Sphere-360™ ablační katetr PFA „single-shot“

- mřížový „lattice-tip“ katetr aktivně expandibilní do 34mm pro 8.5F řid.sheath
- vodič 0.032", irigační lumen
- nitinol-PFA pole se 6 monopolárními elektrosegmenty pro sekvenční PFA 3-5s
- elektromagnetické senzory – EA mapování 3D
- EGM elektrody, bez povrchových termosenzorů (x Sphere-9 pro RF titraci)



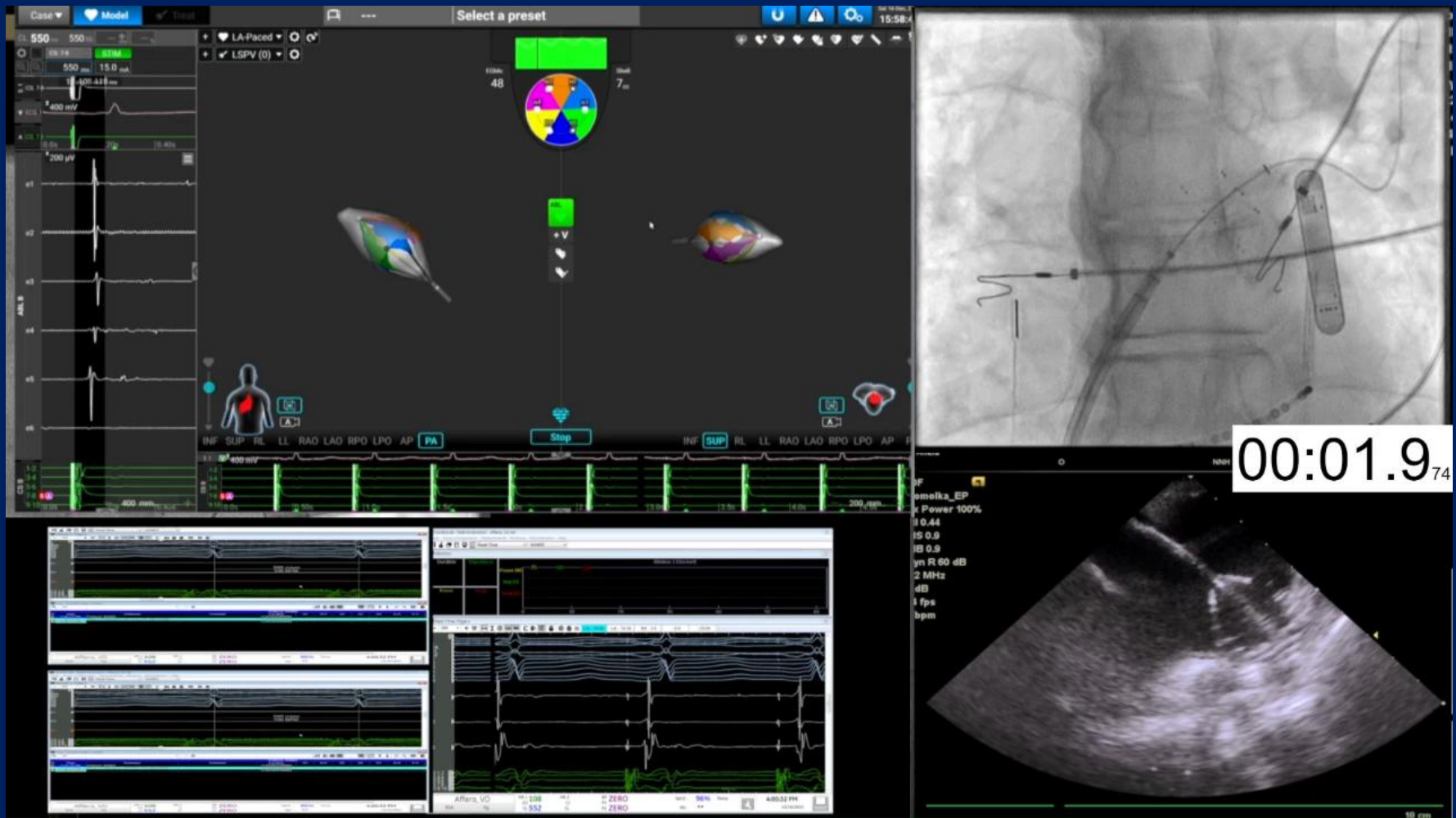
Medtronic Sphere-360™ ablační katetr

FIH: Prospektivní studie proveditelnosti a bezpečnosti

- 3 centra NNH (53pts), IKEM, Litva, celkem 85pts
- parox.FiS, recid, rezist. 1xAAD
- incl. x excl. kritéria (PLAX < 55mm, EFLK > 40%, NYHA I-II, BMI < 40)
- EA mapování Sphere-360 abl.kat.
- cíl: 2+2x aplikace 5s á IPV, 1.3-2.0 kV
- nad rámec IPV...Sphere-9 (linie, fokus)
- Celk. anest, ICE, jícen nemonitorován
- po výkonu MRI mozku, GSK (24-72h)
- 3M remapování, ev. reablace konv/Sph9
- TTM 1xt + sympt, Hekg 6,12M,
- endpointy: PVI, recid.nad 30s, 1R-FUP

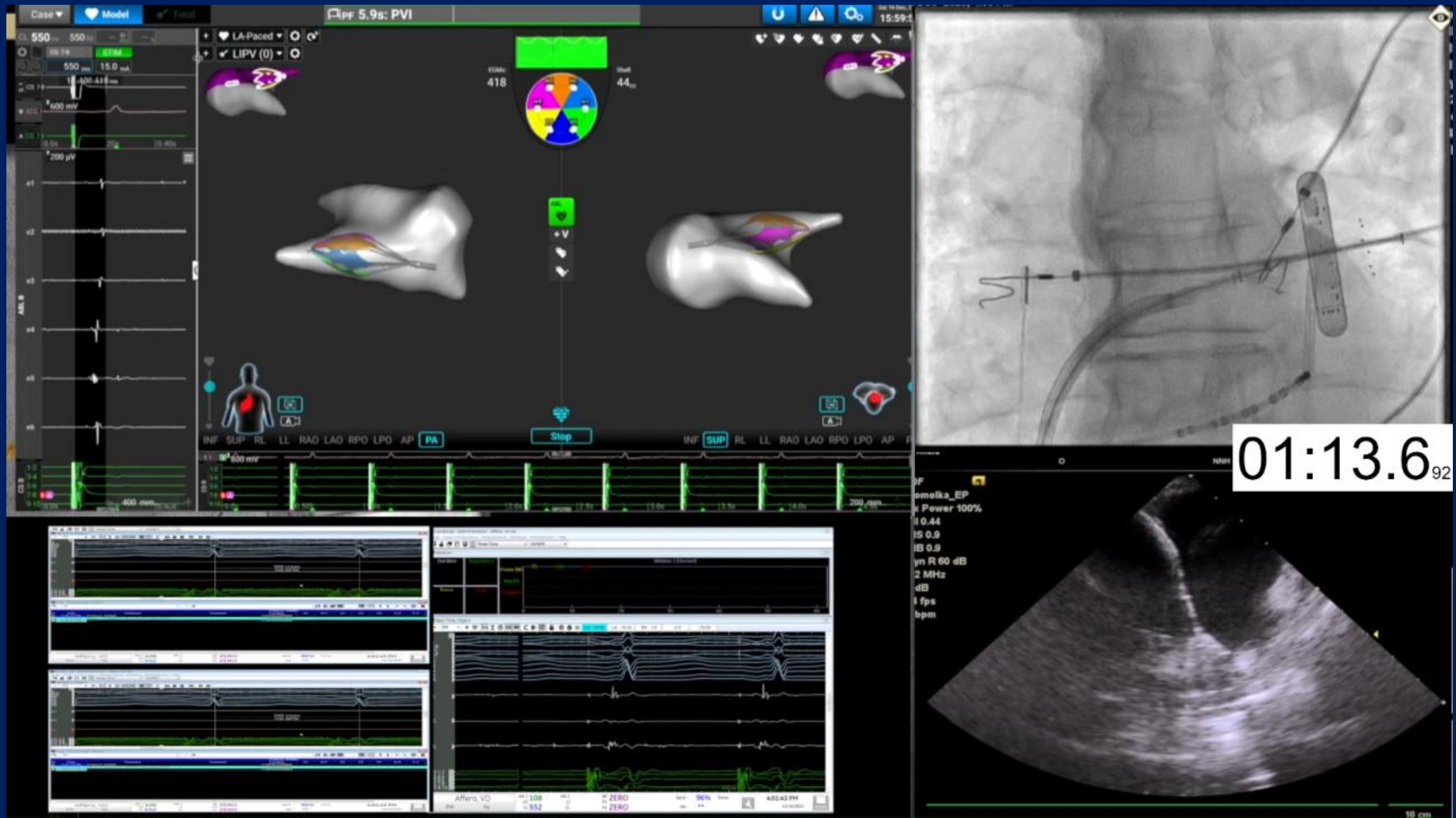


Medtronic Sphere-360™ ablační katetr (FIH)



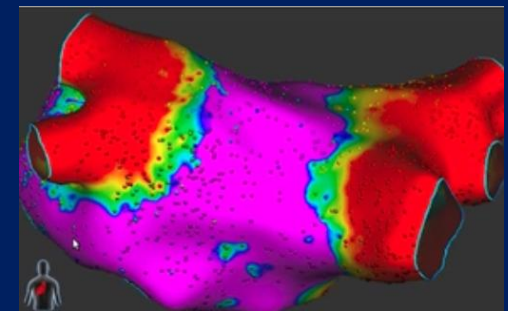
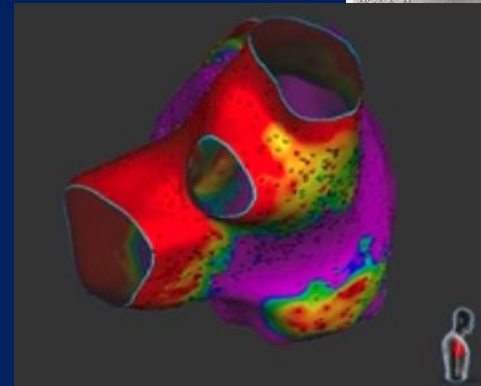
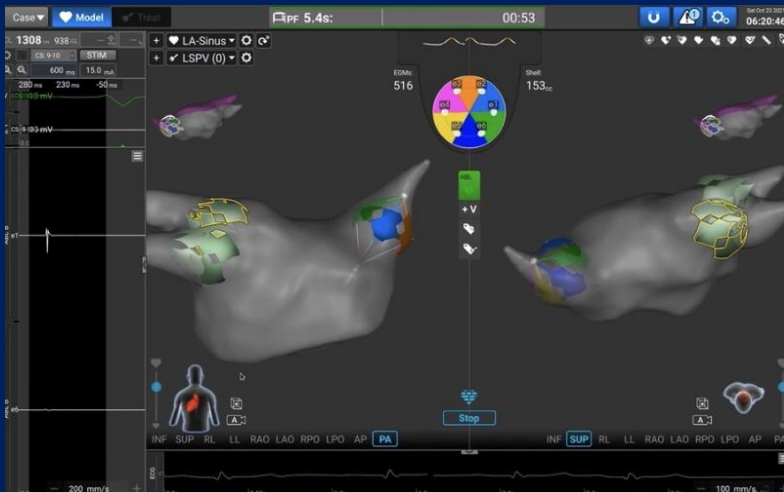
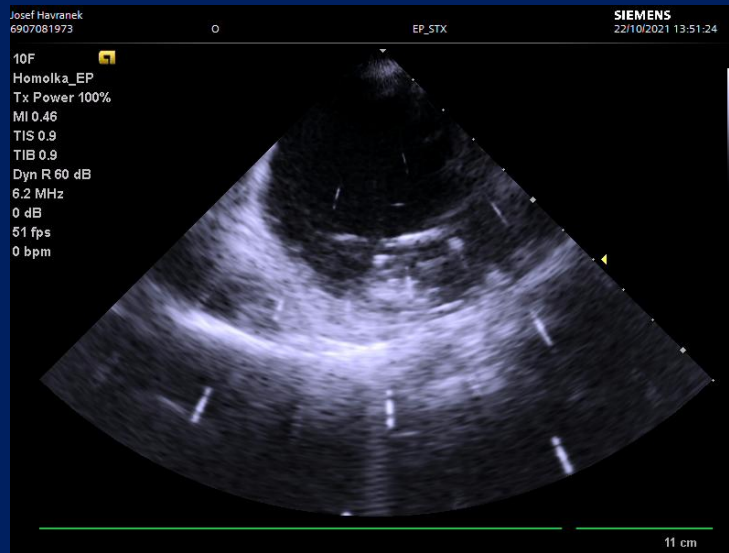
First-in-Human Clinical Experience Of A Novel Conformable 'Single-Shot' Pulsed Field Ablation Catheter For Pulmonary Vein Isolation. V.Reddy, G.Rackauscas, J.Kautzner, P.Neuzil, HRS 2022

Medtronic Sphere-360™ ablační katetr (FIH)



First-in-Human Clinical Experience Of A Novel Conformable 'Single-Shot' Pulsed Field Ablation Catheter For Pulmonary Vein Isolation. V.Reddy, G.Rackauscas, J.Kautzner, P.Neuzil, HRS 2022

Medtronic Sphere-PVI™ ablační katetr (FIH)



First-in-Human Clinical Experience Of A Novel Conformable 'Single-Shot' Pulsed Field Ablation Catheter For Pulmonary Vein Isolation. V.Reddy, G.Rackauscas, J.Kautzner, P.Neuzil, HRS 2022

Medtronic Sphere-360™ ablační katetr

FIH-Prospektivní studie proveditelnosti a bezpečnosti

Soubor a procedurální výsledky NNH 2021-2023

	53 pacientů, 21ž, parox.FiS
věk při zařazení	59.5 ± 8.8
BMI , AA terapie (n), AK-antikoag.(n)	29.9 ± 3.5, AA: 0.7 (0-3), AK: 53/53
LA-PLAX (mm), EFLK (%)	41.5 ± 3.2mm, 63.2 ± 4.0%
Akutně izolováno PV	212/212 (100%) PV
Celk.čas aplikací (s) , počet aplikací (n)	83 ± 21s /IPV, 18 ± 5x /IPV
Čas abl. katetru v LA = Dwell-time (min)	18.4 ± 10.3 min
Doba výkonu-IPV (min-max), skia	62 ± 16 min (16-80), 4.6 ± 2.9 min, 4 x 0m
Jiné výkony	4x CTI (RF), 1x roof (RF), 2x box (PF)
MRI mozku (24-72h)	5/30 asympt nálezy 1x přechodná diplopie-vertigo
GSK (24-72h)	9/9 bez patol. nálezu

Medtronic Sphere-360™ ablační katetr

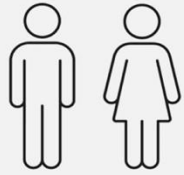
FIH-Prospektivní studie proveditelnosti a bezpečnosti

FUP v NNH 2021-2023, n=(24+29) pac.

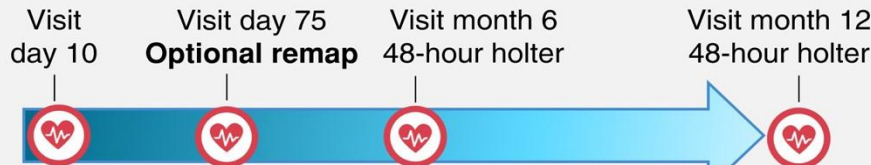
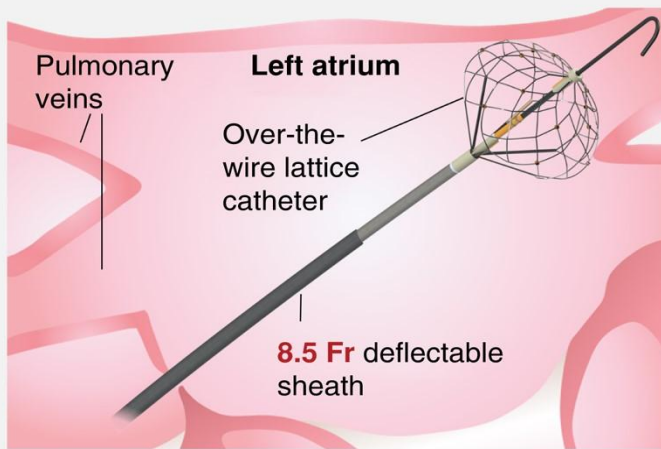
kompletní FUP: 34/34 pac.	<u>Skupina 1.-24.pac.</u>	<u>Skupina 25.-53.pac.</u> rekonfigurace PFA generátoru
3M remap (n)	n=19/24	n=22/29
3M remapování nálezy	<u>rekonexe</u> : 13/97 (13.4%) PV 8/19 (42%) pac. <u>redo</u> : LCPV 2x, LSPV 5x, LIPV 2x, RIPV 2x, LMPV 2x	rekonexe 0/88 PV = 0/22 pac.
3M FUP	7 pac. recid FiS/AT (5xFiS/2xAT), redo IPV a 1x mitrální linie+CS, EAT LAA	dokum. recid/palp. : 0/12 pac.
6M FUP	1x parox.FiS po redo, 1x AT po rozsáhlém redo 1x AT/FiS (remapa OK), 1X parox. FiS (remapa OK),	dokum. recid/palp. : 0/12 pac.
12M FUP	1x AT (remapa nebyla, první recidiva) 1x parox FiS (remapa OK, první recidiva)	dokum. recid/palp. : 0/12 pac., AAD: (5/12)

Affera Sphere-360™ ablační katetr

FIH-Prospektivní studie proveditelnosti a bezpečnosti



First-in-human clinical trial
Symptomatic drug-refractory paroxysmal atrial fibrillation
N = 85



Weekly TTMs 8 weeks post 90-day blanking period, monthly, and symptomatic TTMs thereafter

0%

Primary safety event rate

100%

12M freedom from atrial arrhythmia with pulse 3

100%

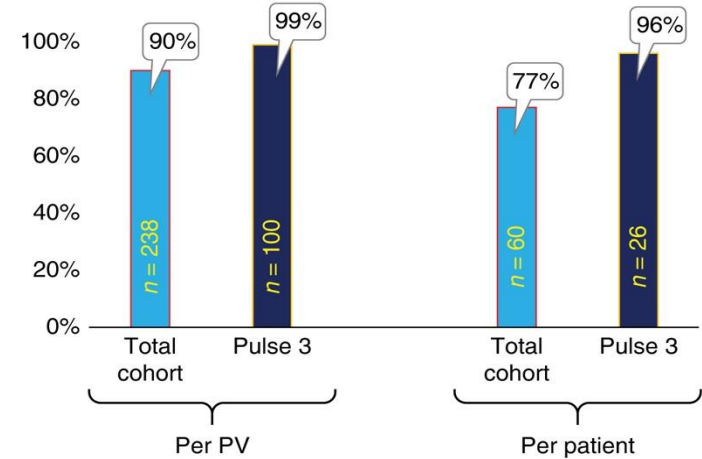
Acute efficacy

81.8%

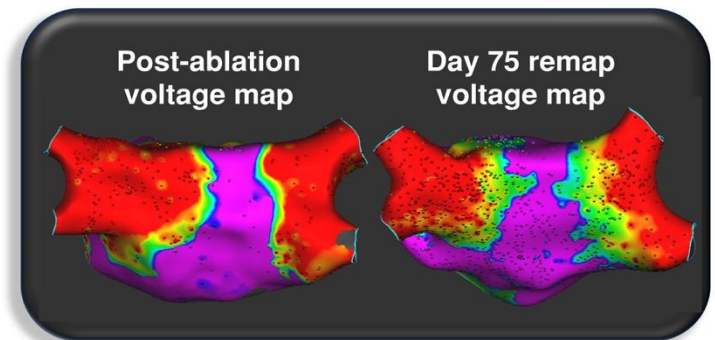
12M freedom from atrial arrhythmia in total cohort

3-month remapping: PV durability

PVI durability

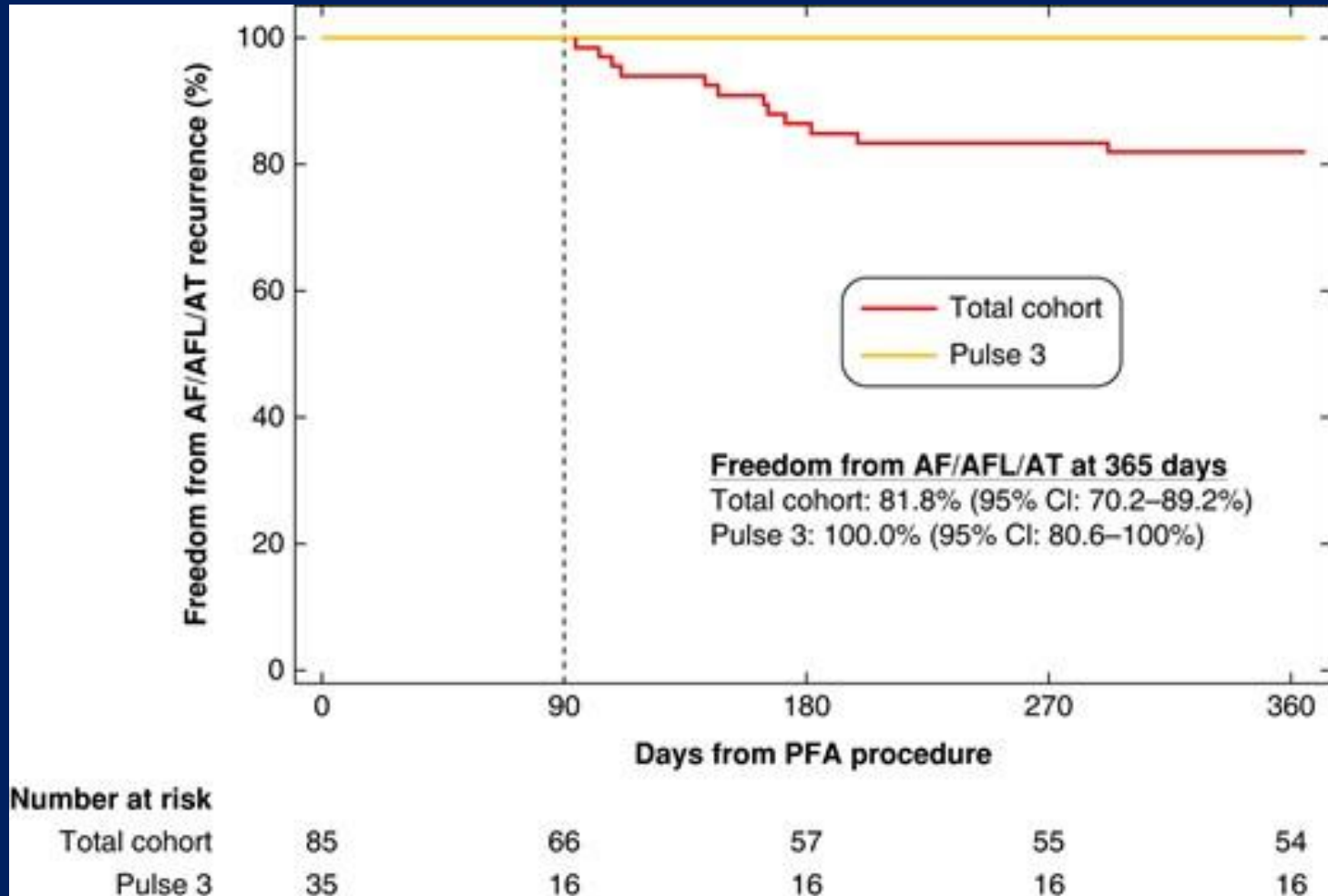


3-month remapping: Voltage maps



Affera Sphere-360™ ablační katetr

FIH-Prospektivní studie proveditelnosti a bezpečnosti



Affera Sphere-360™ ablační katetr

FIH-Prospektivní studie proveditelnosti a bezpečnosti

	Adverse event	Number of adverse events (n = 85)
SAEs included in the primary safety endpoint	Total subjects with primary safety event	0
	Death	0
	Myocardial infarction	0
	Persistent phrenic nerve palsy	0
	Transient ischaemic attack (TIA)	0
	Stroke/cerebrovascular accident (CVA)	0
	Thromboembolism	0
	Major vascular access complications/bleeding	0
	Heart block	0
	Gastroparesis	0
	Severe pericarditis	0
	Hospitalization (initial and prolonged) due to cardiovascular of pulmonary AE ^a	0
	Cardiac tamponade/perforation ^b	0
	Pulmonary vein stenosis ^c	0
	Atrio-esophageal fistula ^c	0
Serious procedure-related adverse events	Diplopia and vertigo ^d	1 (1.2)

Affera Sphere-360™ ablační katetr

FIH-Prospektivní studie proveditelnosti a bezpečnosti

Safety assessments	Total cohort (n = 85)
.....	
Oesophageal observations	
Patients with assessment	18 (21)
Minor erythema ^a	1 (6)
Injury to mucosa ^a	1 (6)
Post-anaesthesia intubation irritation ^b	1 (6)
Thermal injuries	0 (0)
Brain MRI findings	
Patients with assessment	40 (47)
Acute ischaemia with FLAIR hyperintensity ^c	4 (10)
Acute ischaemia without FLAIR hyperintensity ^c	3 (8)

Závěr

Předběžné výsledky našeho centra ve shodě s publikovanými výsledky multicentrické prospektivní FIH studie katetrizační ablace paroxysmální fibrilace síní s využitím single shot mapovacího PF katetru Medtronic 360™ velmi dobrou efektivitu a bezpečnostní profil zejm. po rekonfiguraci PFA generátoru ve finální části patientského souboru.

Dedikovaný 3D mapovací systém umožňuje krátké procedurální (10min kumulativní PF čas, 18min dwell LA čas), a skiaskopické časy výkonu (pod 5min, 4x zero Fluoro), hodnoty dosažené v rámci FIH s potenciálem další redukce.

