Cardiovascular Center
OLV Aalst

Pulsed Field Ablation

Experience with the Biosense multi-electrode IRE catheter

Tom De Potter, MD
OLV Hospital, Aalst, Belgium

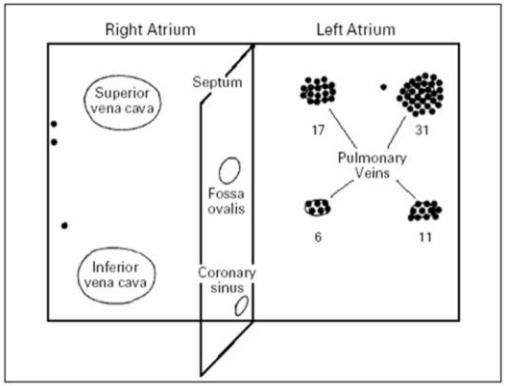
Disclosures relevant to presentation

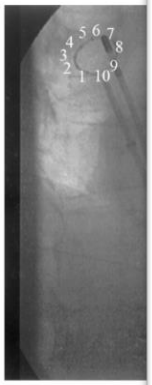
- Travel support: Abbott, Biotronik, Boston Scientific, CardioFocus, J&J
- Consultancy activity: Adagio Medical, Boston Scientific, CardioFocus, J&J
- Grant support to Cardiac Research Institute Aalst: Boston Scientific, J&J
- Investigator for the J&J InspIRE trial

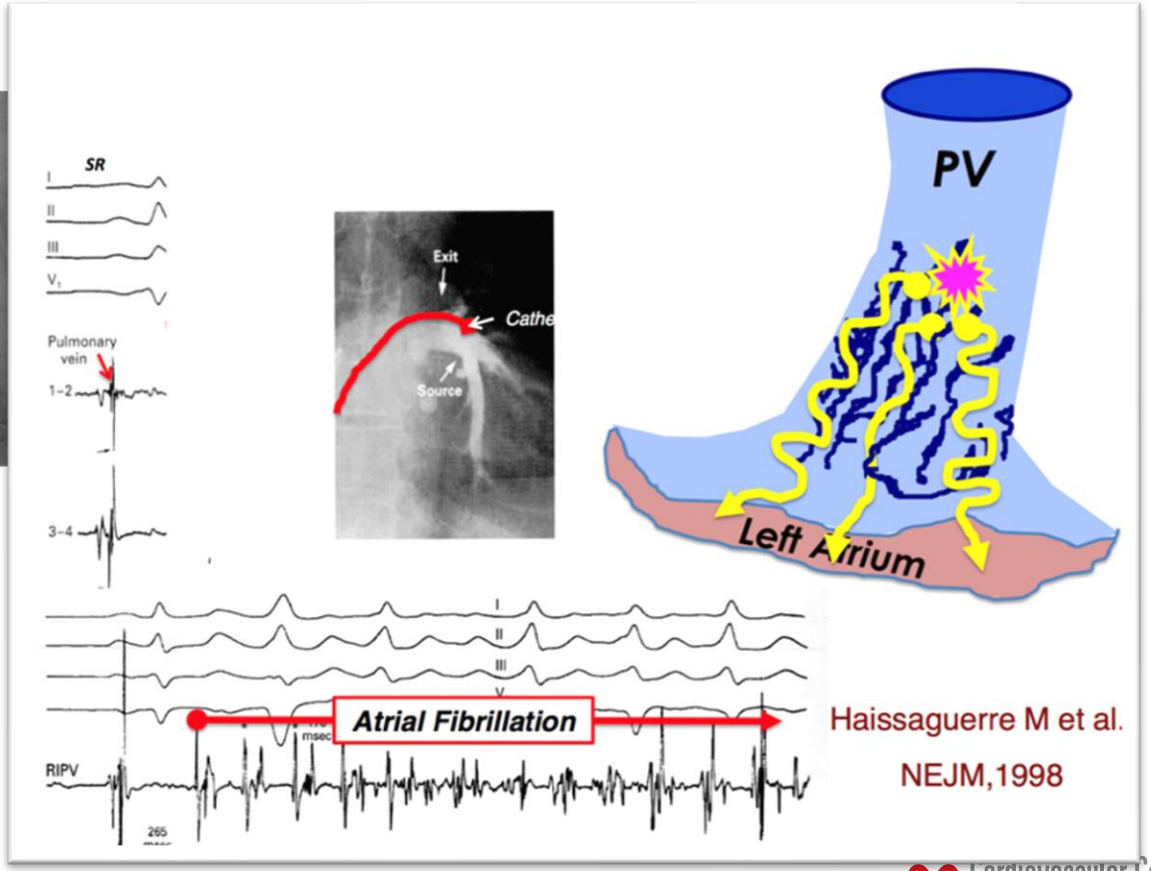
- All fees invoiced to CRI Aalst
- No personal disclosures to report

Cardiovascular Center OLV Aalst

THE CLINICAL PROBLEM



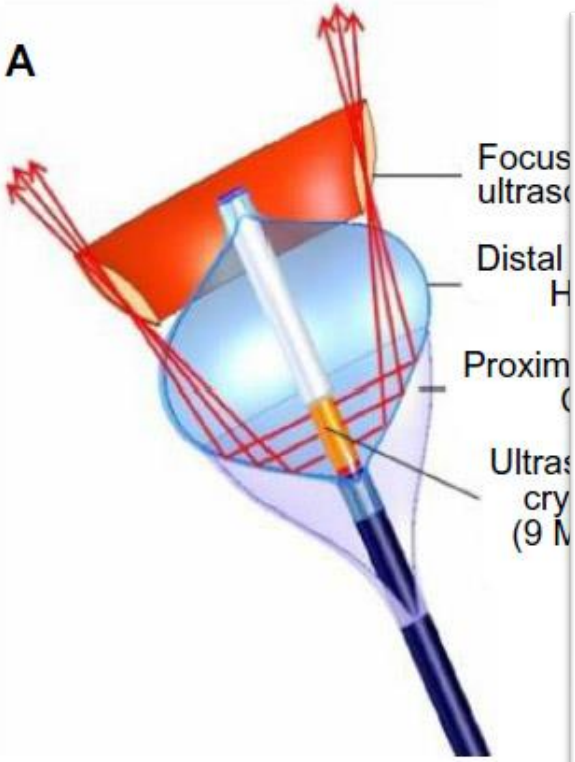


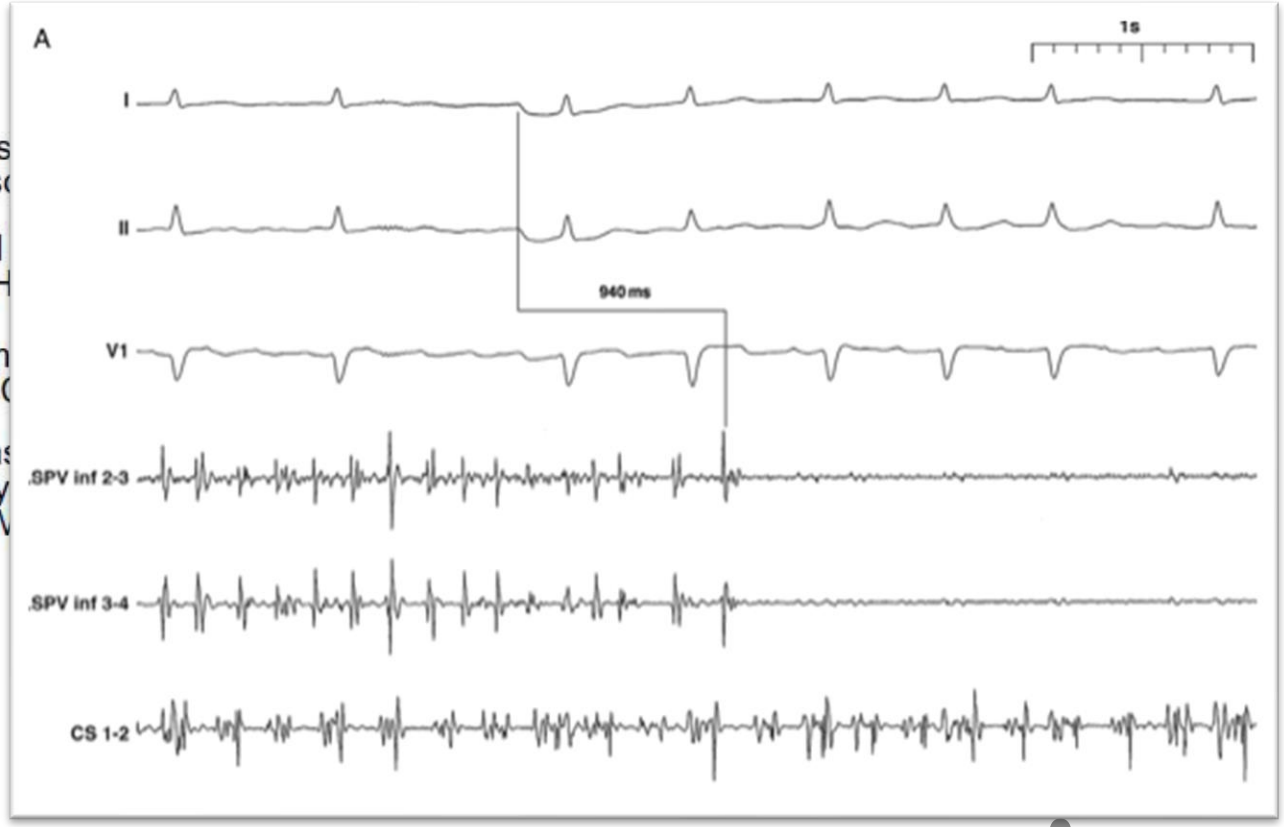


Cardiovascular Center OLV Aalst


user: eptracer
PAS: Trace22
EP TRACER 1.2
HR 46 RR 1302
Stim Ready
Cont No Sync
2 1000 2
OUT1 QUADd
OUT2 CARTO
0:55 On On On
55:38

HIFU - A TRUE SINGLE SHOT ABLATION





Source: Schmidt B. et al. Europace 2009. 11:1281-128

Cardiovascular Center OLV Aalst

SINGLE SHOT DISADVANTAGES

- Mostly single purpose (PVI only)
- Usually no mapping
- Usually no power titration / regional adjustment

Fatal End of a Safety Algorithm for Pulmonary Vein Isolation With Use of High-Intensity Focused Ultrasound

Kars Neven, MD; Boris Schmidt, MD; Andreas Metzner, MD; Kiyoshi Otomo, MD; Dieter Nuyens, MD, PhD; Tom De Potter, MD; K.R. Julian Chun, MD; Feifan Ouyang, MD; Karl-Heinz Kuck, MD

(*Circ Arrhythm Electrophysiol.* 2010;3:260-265.)

Cardiovascular Center OLV Aalst

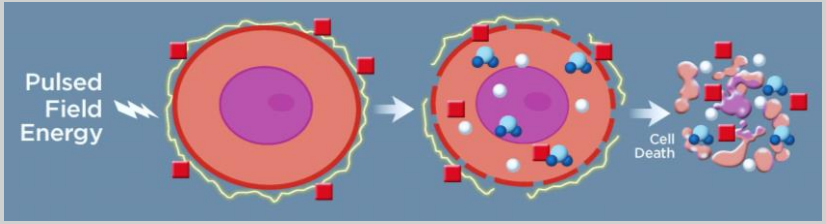
PULSED FIELD ABLATION (PFA) TECHNOLOGY

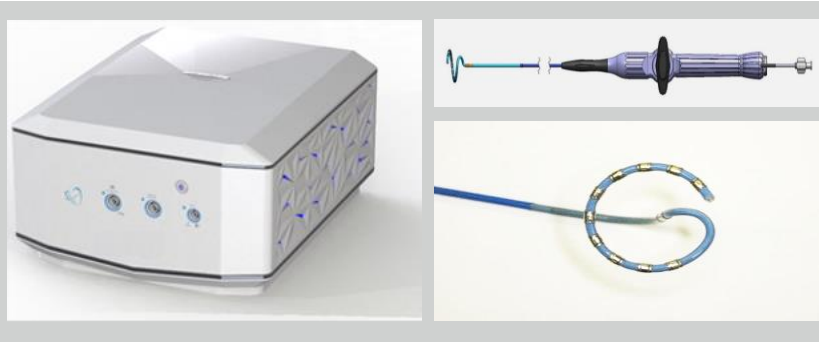
VARIPULSE & TRUPULSE: A novel PFA system developed for catheter ablation to treat atrial fibrillation (AF)

- TRUPULSE: Multi-channel PFA generator
- VARIPULSE: 10-electrode circular PFA catheter
- Fully integrated with CARTO 3D electroanatomical mapping system

<u>Preclinical data</u> demonstrated the feasibility of PFA using this system[1-3]

- Ablates tissue by irreversible electroporation-mediated cell death
- Effective, transmural, and durable ablation of cardiac tissue and PV isolation
- No collateral damage to adjacent structures





Objective: To report on initial (acute) **<u>clinical experience</u>** with the novel PFA system

AF, atrial fibrillation; IRE, irreversible electroporation; PFA, pulsed field ablation; PV, pulmonary vein.

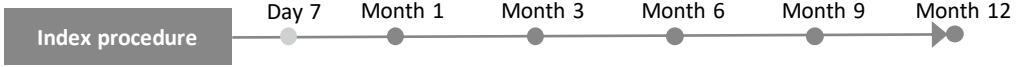
1. Hsu J, et al. Presented at the EHRA 2021 Online Congress. 2. Grimaldi M, et al. Presented at the HRS 2021 Annual Meeting.
3. Yavin H, et al. JACC. Clinical electrophysiology vol. 6,8 (2020): 973-985. doi:10.1016/j.jacep.2020.04.023

Cardiovascular Center OLV Aalst

INSPIRE TRIAL – ESC 2021 ABSTRACT

ONGOING PROSPECTIVE, NON-RANDOMIZED, MULTICENTER STUDY (NCT04524364)

ENROLLMENT: UP TO 550 SUBJECTS*



Stringent Arrhythmia Monitoring

1) Remote monitoring weekly 3-6M, then monthly/symptomatic 6-12M
2) 24-hr Holter at 3, 6, and 12M
3) 12-lead ECG at 1, 3, 6, and 12M

Key Eligibility Criteria

- 18–75 years of age
- Drug-refractory Paroxysmal AF (PAF)
  - Failed at least 1 AAD (class I–IV) as evidence by recurrent symptomatic AF, or
  - Unable to tolerate/contraindicated to AAD
- Selected for AF ablation procedure by PVI

Index Procedure

- PVI performed and confirmed via entrance block in targeted PVs post-adenosine/isoproterenol challenge

Primary Safety

Safety: primary adverse events (PAEs)

- Within 7 days post-procedure: cardiac tamponade/perforation, myocardial infarction, stroke, systemic embolism, transient ischemic attack, permanent phrenic nerve paralysis, pulmonary edema, pericarditis, and any major vascular access complications
- Device or procedure related death, atrio-esophageal fistula, or PV stenosis occurring beyond 7 days were also considered PAEs

- **Endoscopy performed for subset of subjects within 72hrs of procedure**

AAD, anti-arrhythmic drug; AF, atrial fibrillation; PAE, primary adverse event; PAF, paroxysmal atrial fibrillation; PV, pulmonary vein; PVI, pulmonary vein isolation.

*Final sample size will be determined using a Bayesian adaptive design.

Cardiovascular Center OLV Aalst

BASELINE CHARACTERISTICS

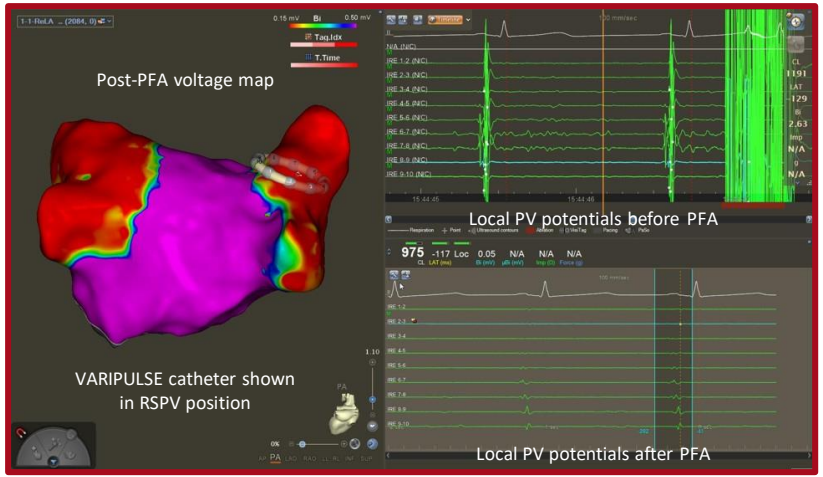
Characteristics	Subgroup (n=40)
Age (years), mean ± SD	58.4±10.9
Male, n (%)	23 (57.5%)
Body mass index (kg/m^2), mean ± SD	27.4 ± 4.3
Left ventricular ejection fraction (%), mean ± SD	57.9 ± 4.7
Left atrial diameter (mm), mean ± SD	38.0 ± 5.1
CHA_2DS_2-VASc score, mean ± SD	1.8 ± 1.5
Medical History[a]	
Symptomatic atrial fibrillation duration (months), mean (range)	79.4 (0.3, 400.1)
Arrhythmias other than AF[b]	
Atrial flutter (typical right)	2 (5.0%)
Myocardial infarction	3 (7.5%)
Hypertension	21 (52.5%)
Percutaneous coronary intervention	5 (12.5%)
Coronary disease	4 (10.0%)
Thromboembolic events[b]	2 (5.0%)
Congestive heart failure	5 (12.5%)
Type II diabetes	4 (10.0%)
Obstructive sleep apnea	1 (2.5%)
Previously failed AADs	
Class I AAD	21 (52.5%)
Class II AAD	16 (40.0%)
Class III AAD	2 (5.0%)

[a]Table values are reported as n (%) unless otherwise indicated. [b]Multiple selections per patient permitted. [c]1 of 2 cases of hyperthyroidism ongoing; the other was resolved.

AAD, anti-arrhythmic drug AF, atrial fibrillation; NYHA, New York Heart Association; SD, standard deviation.

Cardiovascular Center OLV Aalst

Procedural Characteristics and Acute Results



Acute procedural effectiveness[b]	Subgroup (n=40)
Acute PVI success[c]	**40 (100.0%)**
Instances of PV reconnection with provocative adenosine testing, m/n (%)[d]	6/151 (4.0%)

Procedural Characteristics[a]	Subgroup (n=40)
General anesthesia	34/40 (85.0%)
Total procedure time (min)	82.4 ± 20.0
Total LA mapping time (min)	10.1 ± 8.4
Total PFA catheter LA dwell time (min)	46.2 ± 16.6
Total fluoroscopy time (min)	9.8 ± 6.8

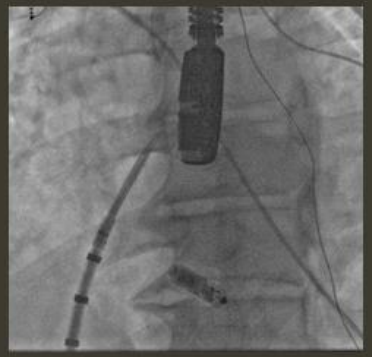
Safety	Subgroup (n=40)
Primary AE	**0/40 (0%)**
Esophageal thermal lesions	**0/40 (0%)**
Serious AE (NOT related to device/procedure)	
Gonarthritis	1/40 (2.5%)
Anterior interventricular branch narrowing	1/40 (2.5%)

[a]Table values reported as mean ± SD unless otherwise indicated. [b]Table values reported as n (%) unless otherwise indicated. [c]Confirmation of entrance block in all clinically relevant targeted PVs after adenosine/isoproterenol challenge. [d]Number of targeted PVs that were reconnected as a proportion of veins targeted. Veins that did not go undergo adenosine isoproterenol challenge were excluded from analysis

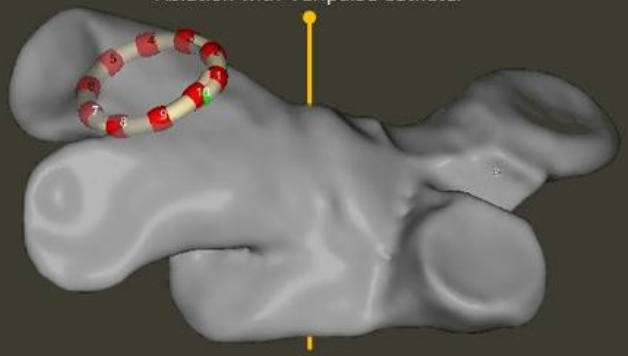
AE, adverse event; AF, atrial fibrillation; LA, left atrium; PAE, primary adverse event; PFA, pulsed field ablation; PV, pulmonary vein; PVI, pulmonary vein isolation

Cardiovascular Center OLV Aalst

WORKFLOW EXAMPLE



Ablation with Varipulse Catheter



Summary

Skin to skin time	23 min
Access time	6 min
Map time	1 min
Ablation time	11 min
Validation time	5 min
Fluoro time	3.58 min
Fluoro Dose	0.85 mGy

Femoral puncture 15u47

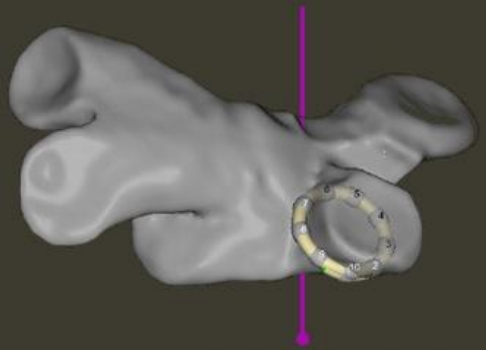
Transseptal puncture 15u51

Insertion of Catheter 15u53

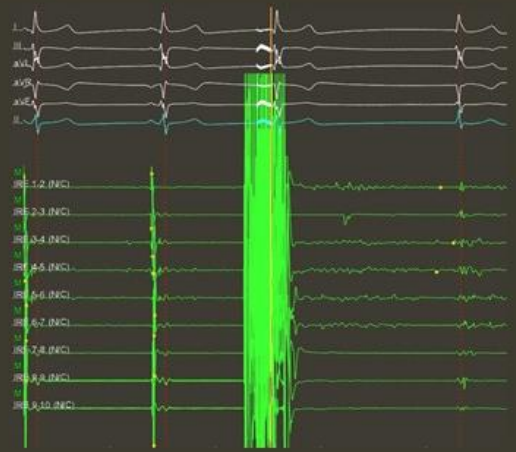
Start ablation 15u54

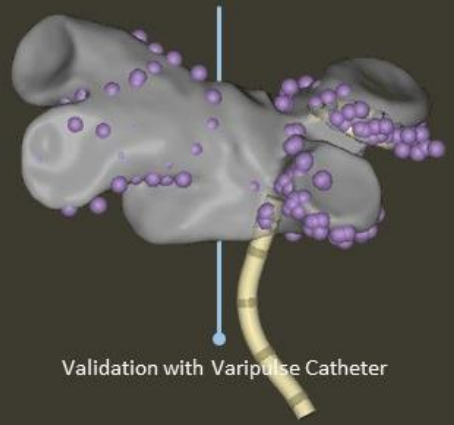
End ablation 16u05

End procedure 16u10

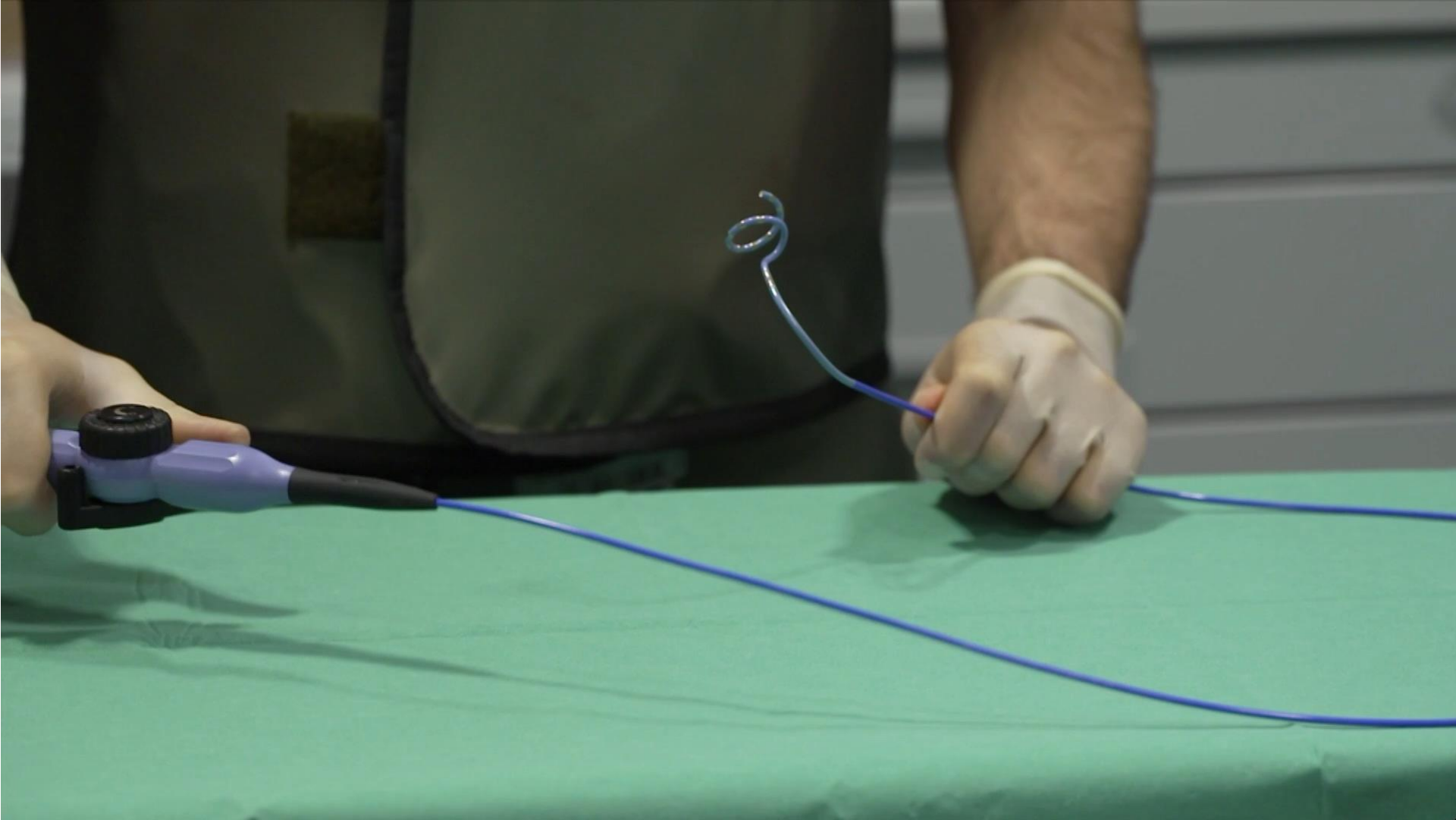


FAM (with Varipulse Catheter)





Validation with Varipulse Catheter



CONCLUSION

- Initial results support safety and acute effectiveness of a novel integrated PFA system
- Findings agree with prior safety and efficacy observations from preclinical trials [1-3]
- Very high safety + efficacy simplified workflows achievable
- The pivotal phase of the InspIRE study is ongoing (12-m safety and efficacy)

PAF, paroxysmal atrial fibrillation; PFA, pulsed field ablation; PVI, pulmonary vein isolation.

1. Hsu J, et al. Presented at the EHRA 2021 Online Congress.
2. Grimaldi M, et al. Presented at the HRS 2021 Annual Meeting.
3. Yavin H, et al. JACC. Clinical electrophysiology vol. 6,8 (2020): 973-985. doi:10.1016/j.jacep.2020.04.023

Cardiovascular Center OLV Aalst

THANK YOU

EP staff
Peter Geelen, MD, PhD
Peter Peytchev, MD

Fellows
Davide Fabbricattore, MD
Chiara Valeriano, MD

Technical staff
Ilse Degend, RN
Isabelle Devulder, RN
Nathalie Haleydt, RN
Steffi Heremans, RN
Kathleen Rooselaers, RN
Ayla Verbeurgt, RN
David Verhelst, RN

Biomedical engineering
Dimitri Buytaert, PhD

Biosense clinical support
Louis Verdonckt

Biosense R&D
Assaf Govari, PhD

Cardiovascular Center
OLV Aalst