# A Prospective Randomized Clinical Comparison of Catheter Ablation of Atrial Fibrillation Using the CENTAURI PEF System and Standard Radiofrequency Ablation

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# Random. Comparison Afib Abl. CENTAURI vs standard RFA

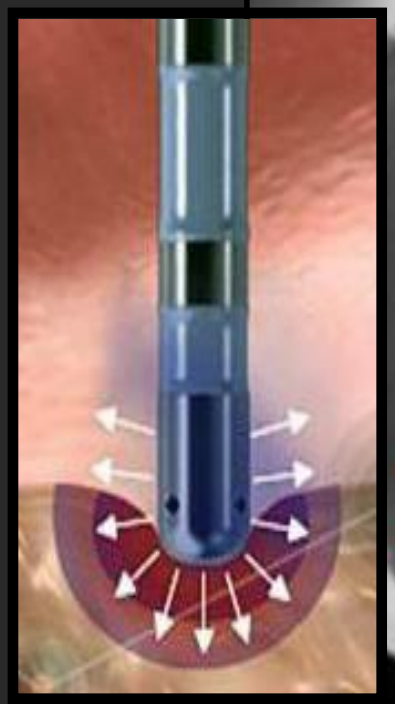
## Introduction

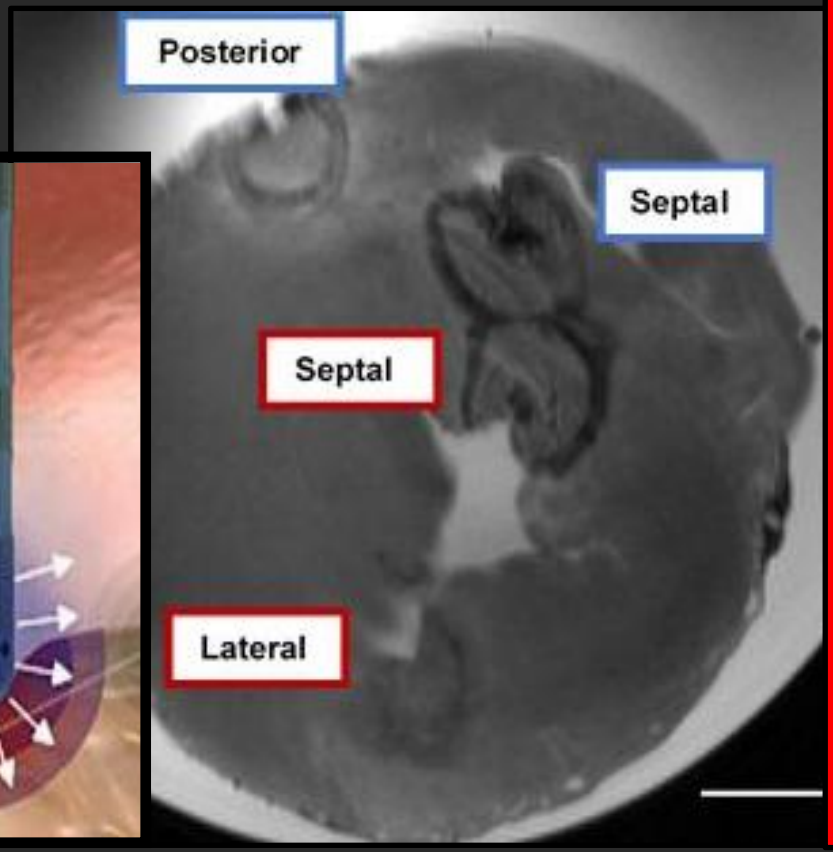
- Radiofrequency (RF) catheter ablation of atrial fibrillation (afib) has been the most effective method in the treatment of this arrhythmia in recent years
- The use of irreversible electroporation (puls field ablation, PFA) appears to be a promising method
- The aim of our study is to show the one-year results of a project comparing the efficacy and safety of the catheter ablation of the atrial fibrillation using point to point CENTAURI PEF System (CardioFocus Inc.) and standard 3D mapping guided RF ablation

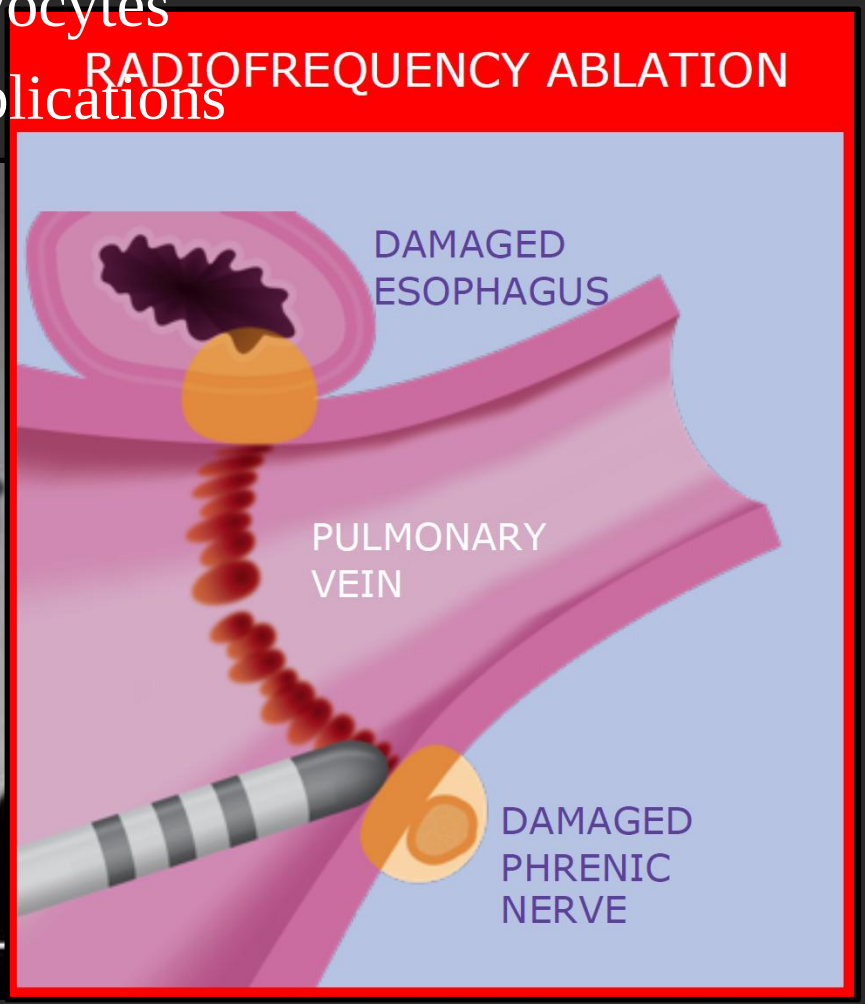
# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Introduction

- Radiofrequency ablation
  - Application of high frequency electric current
  - Thermal damage of the cardiomyocytes
  - Limited efficacy and risk of complications



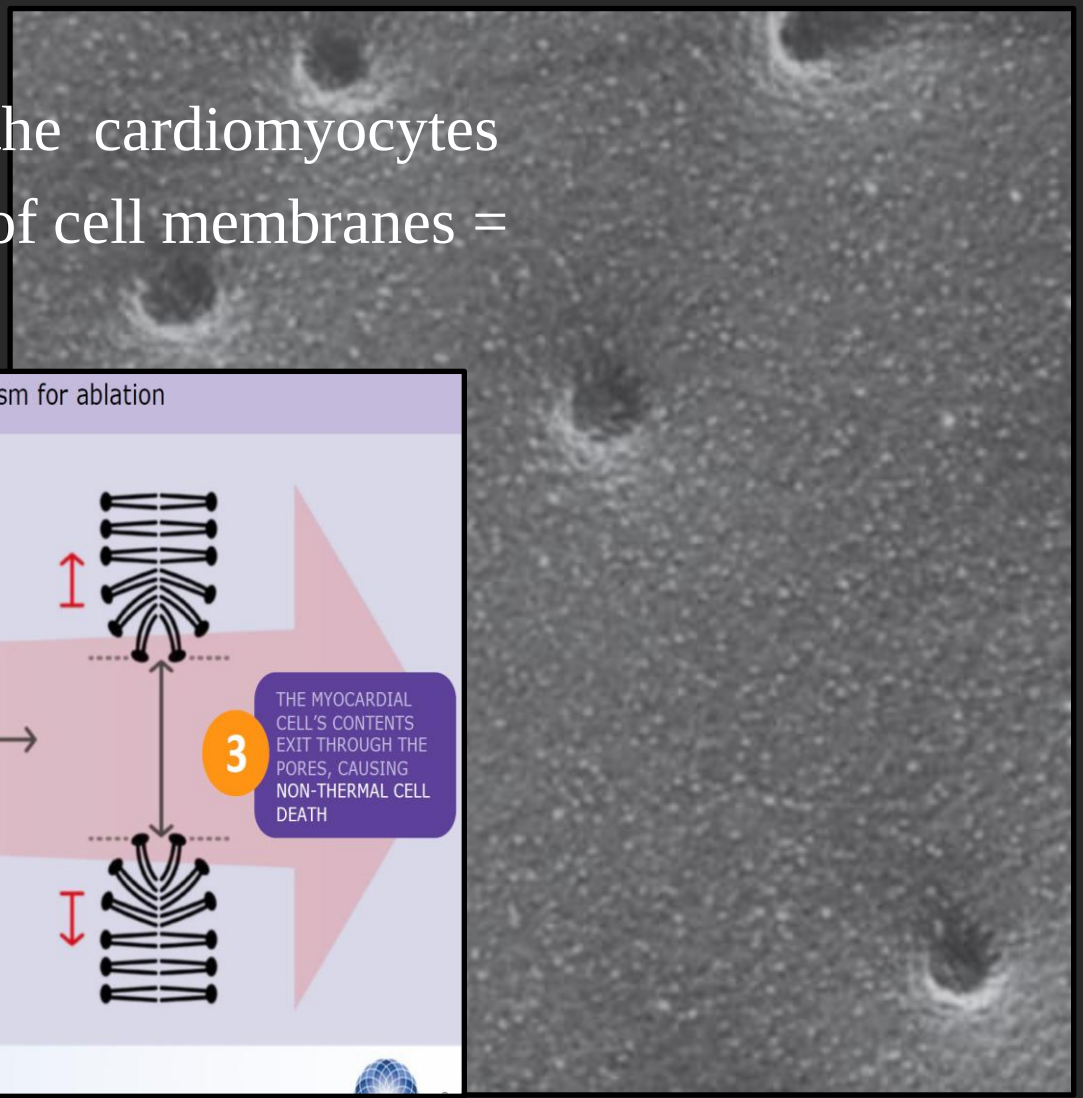


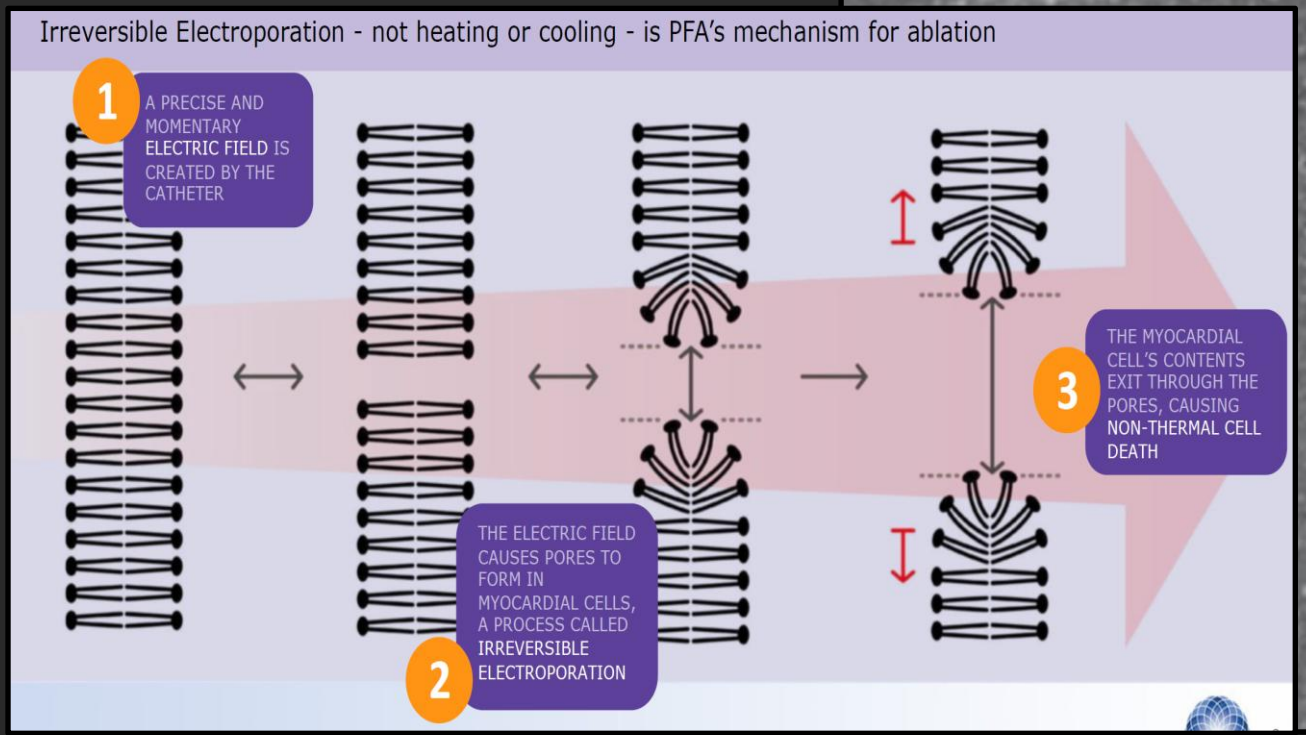



# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Introduction

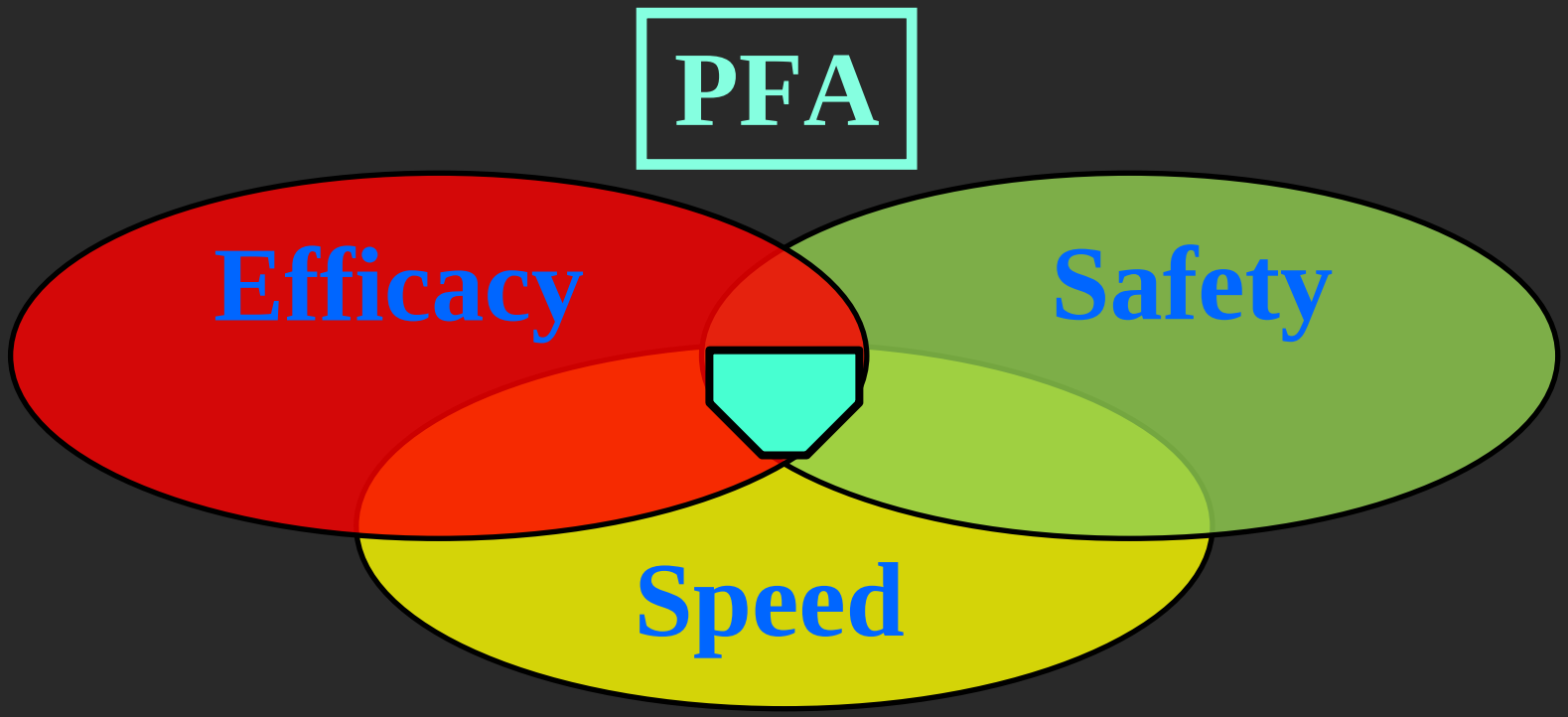
- Irreversible electroporation
  - Application of high voltage pulses of electrical current
  - Non thermal damage of the cardiomyocytes
  - Formation of nano pore of cell membranes = apoptosis or necrosis





# Irreversible electroporation in the treatment of cardiac arrhythmias

**Introduction**



# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Introduction

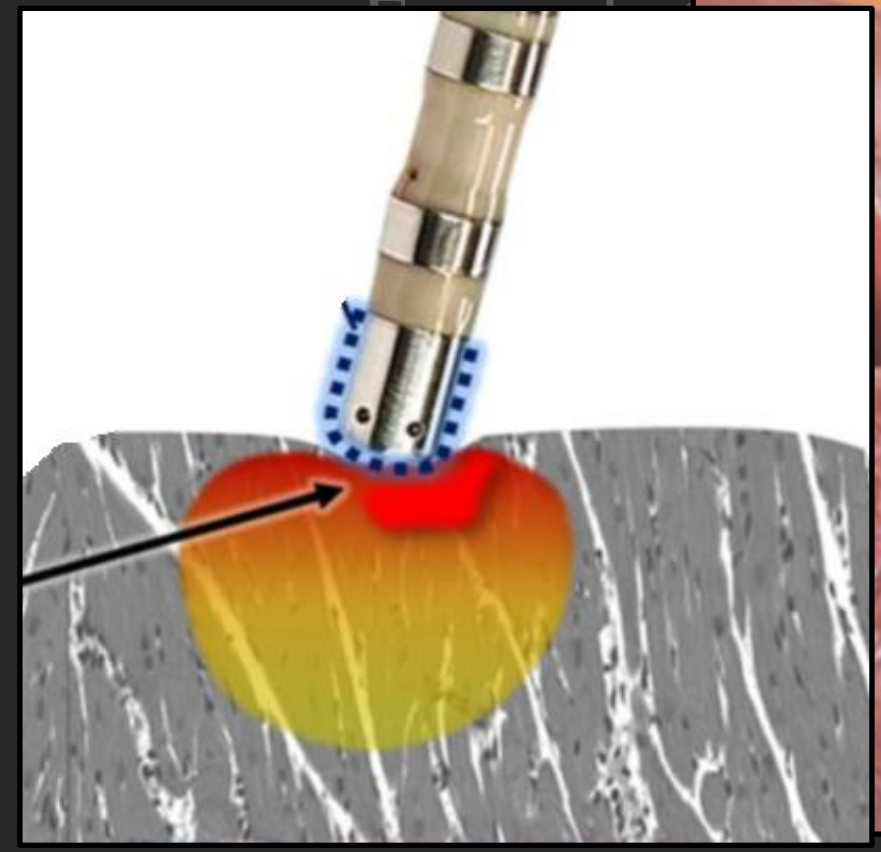
- PFA systems in the clinical practice
  - Farapuls (Boston Scientific)
  - Centauri PEF (Galvanize EP)
  - Affera (Medtronic)
  - Varipuls (Biosense Webster)

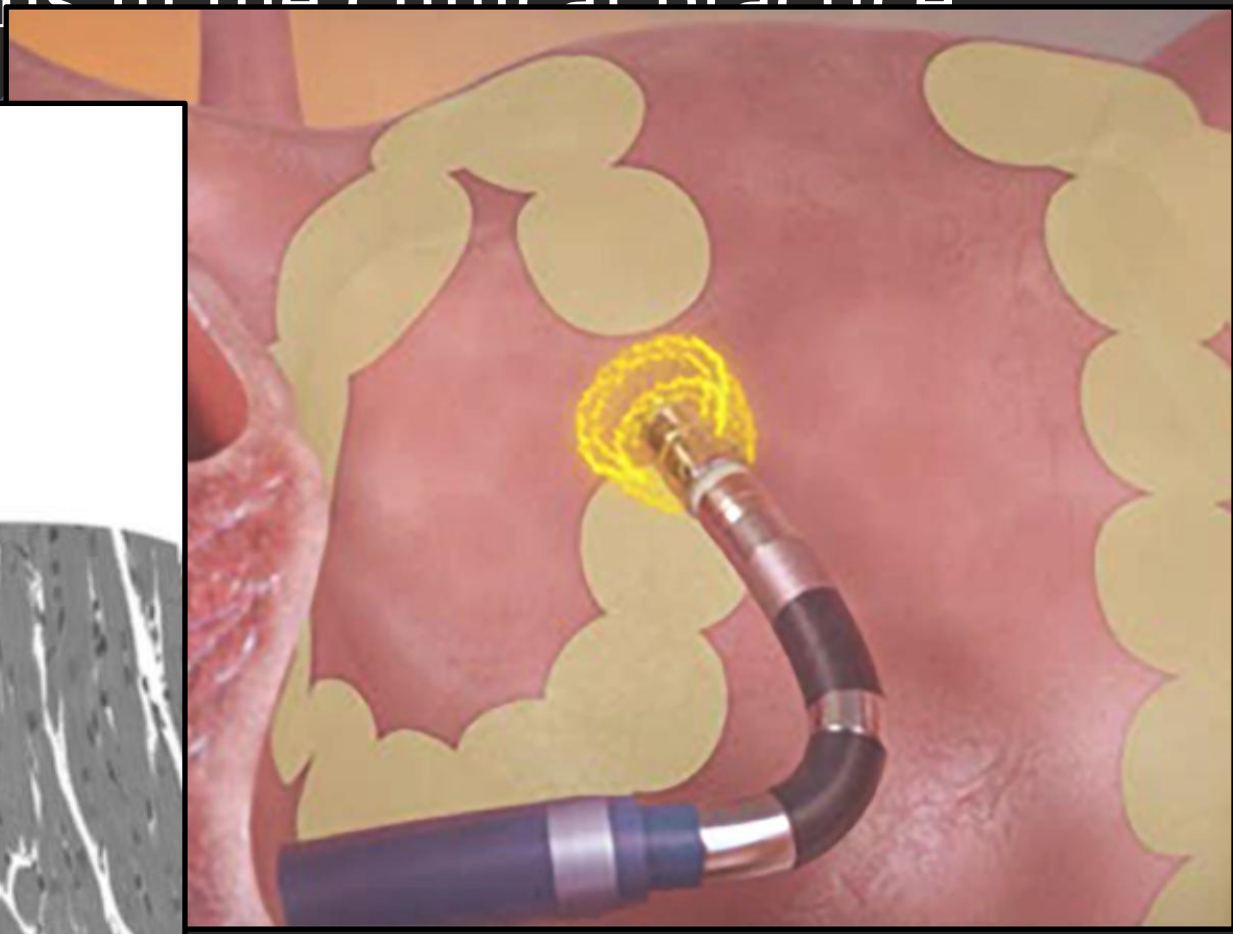
Random. Comparison Afib Abl. CENTAURI vs standard RFA

**Point to point aplication of the PFA using standard contact force irrigati catheter with support of the 3D electroanatomical mapping system (EnSite or Carto)**

**Úvod**

- PFA systems in the clinical practice

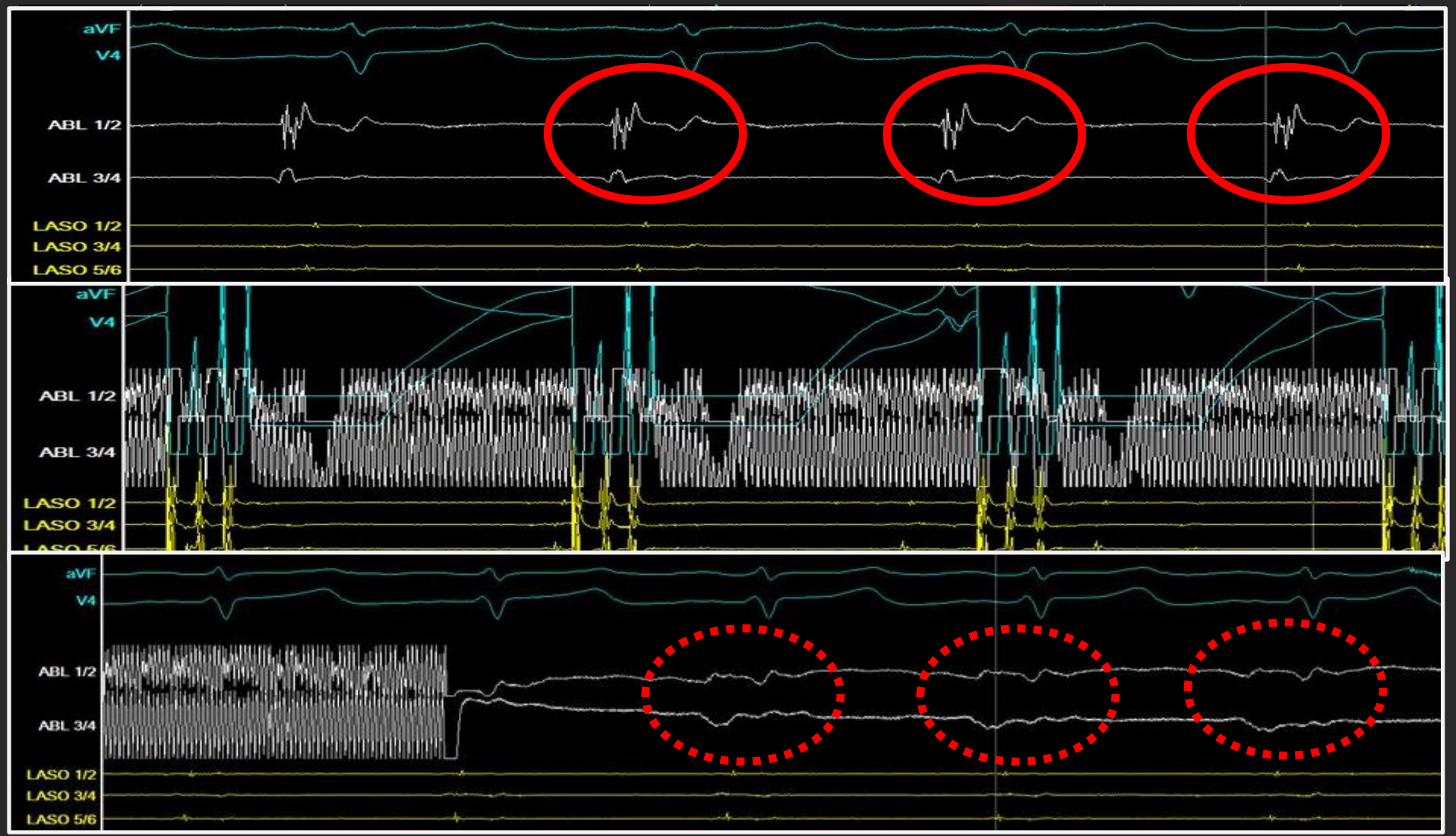




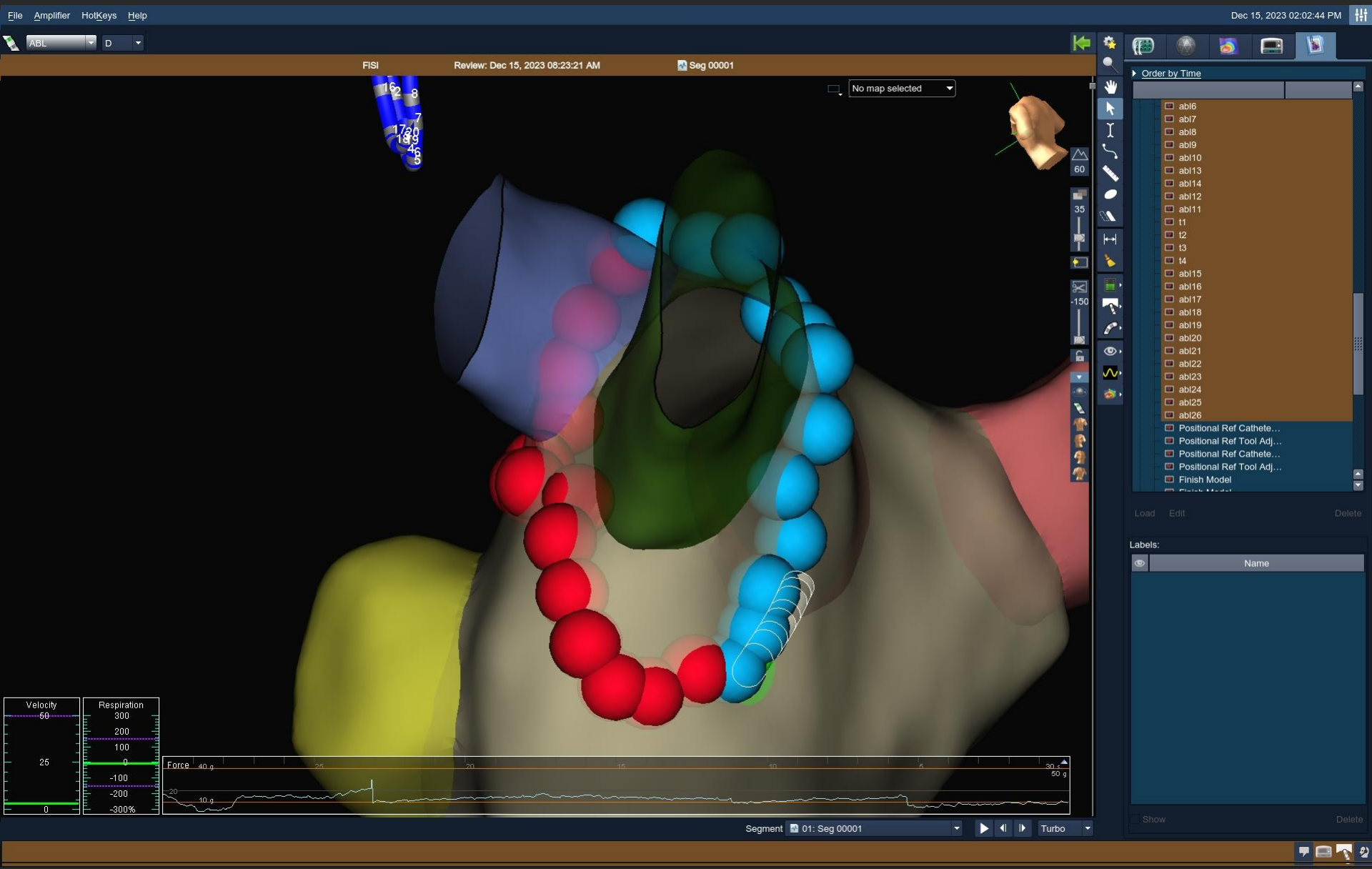
# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Introduction

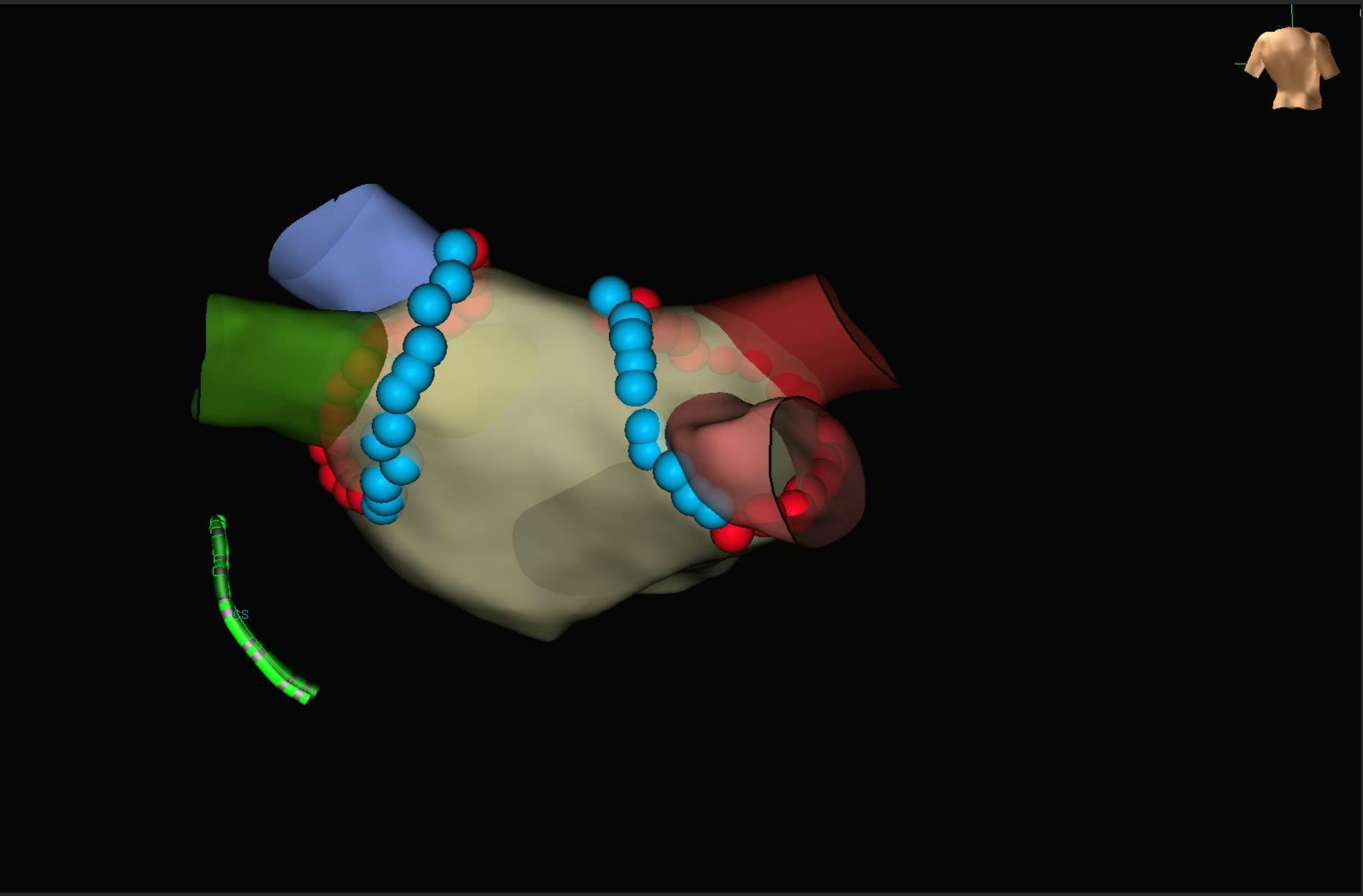
**Centauri PEF**
**Intracardiac potentials**



# Random. Comparison Afib Abl. CENTAURI vs standard RFA



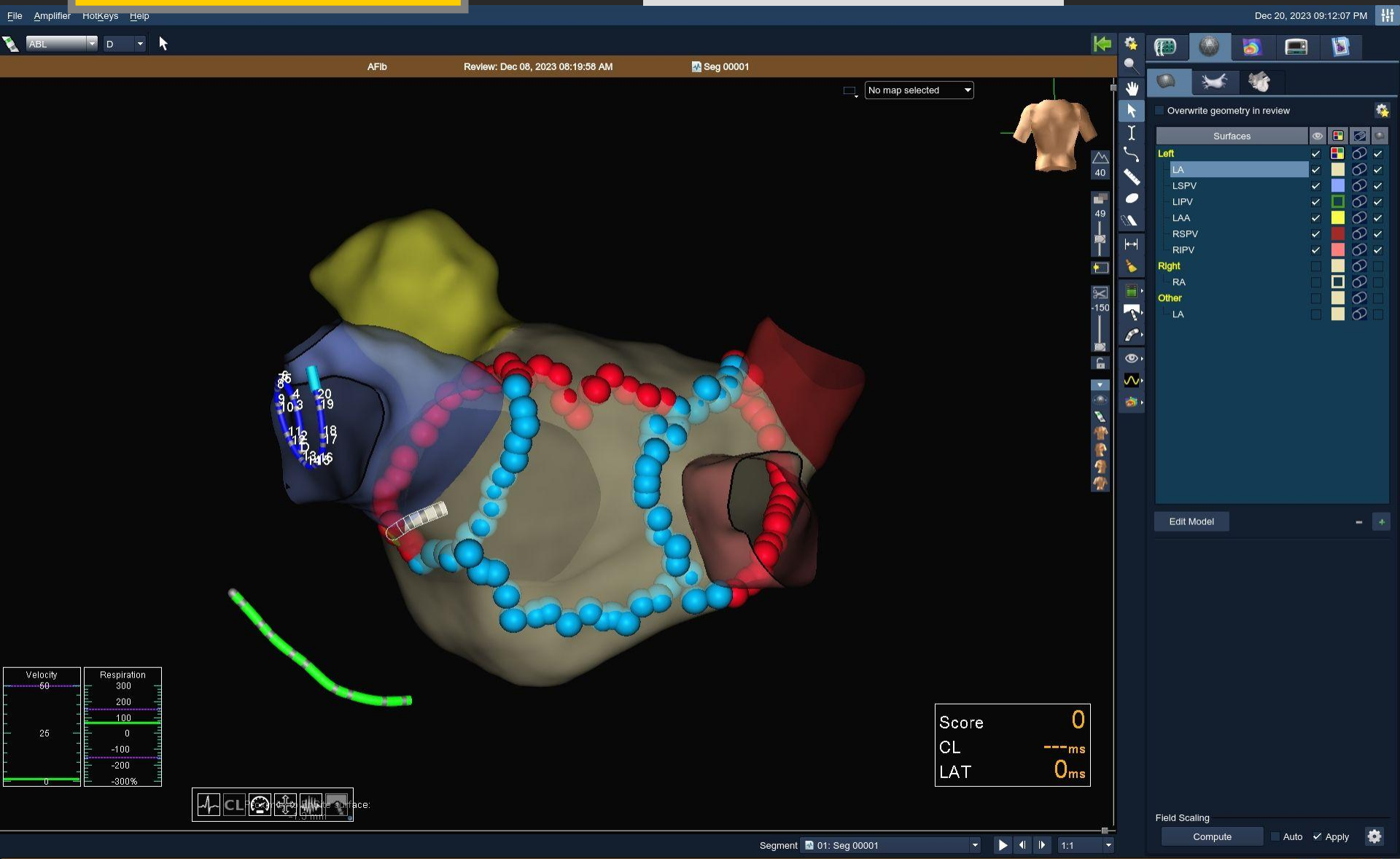
# Random. Comparison Afib Abl. CENTAURI vs standard RFA



# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Introduction

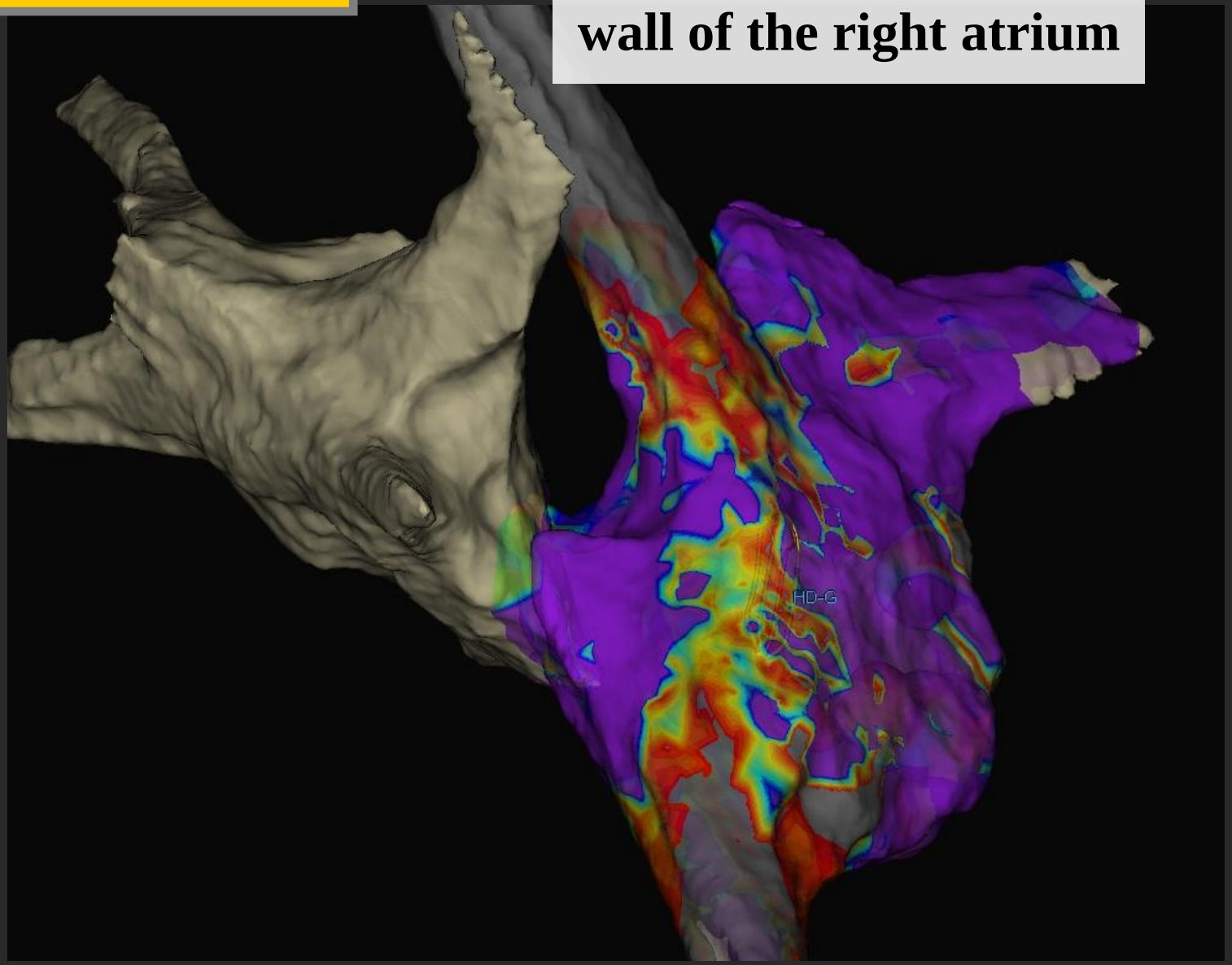
## Box lesion



# Random. Comparison Afib Abl. CENTAURI, FARAPULSE, RFA

## Introduction

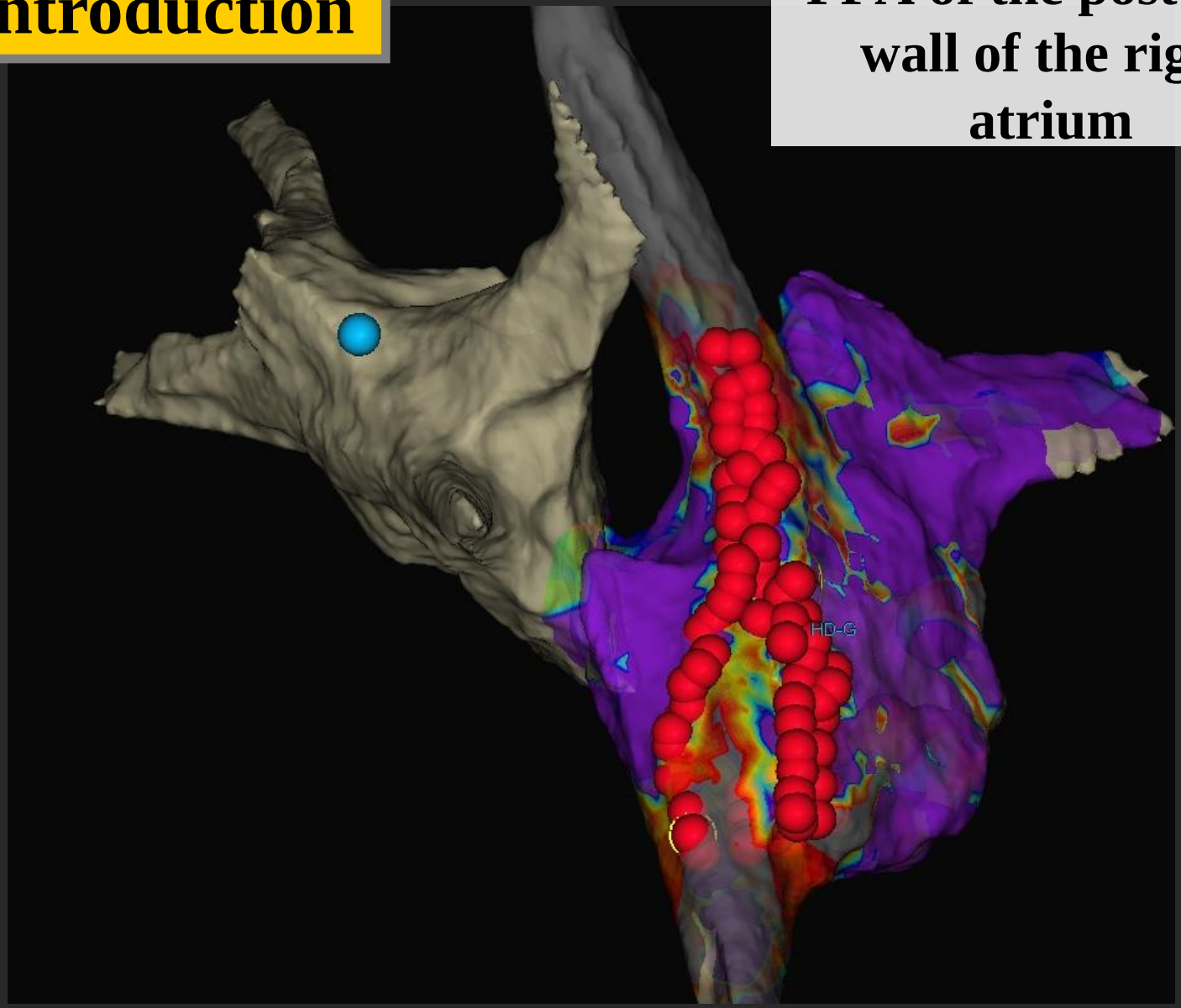
**PFA of the posterior wall of the right atrium**



# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Introduction

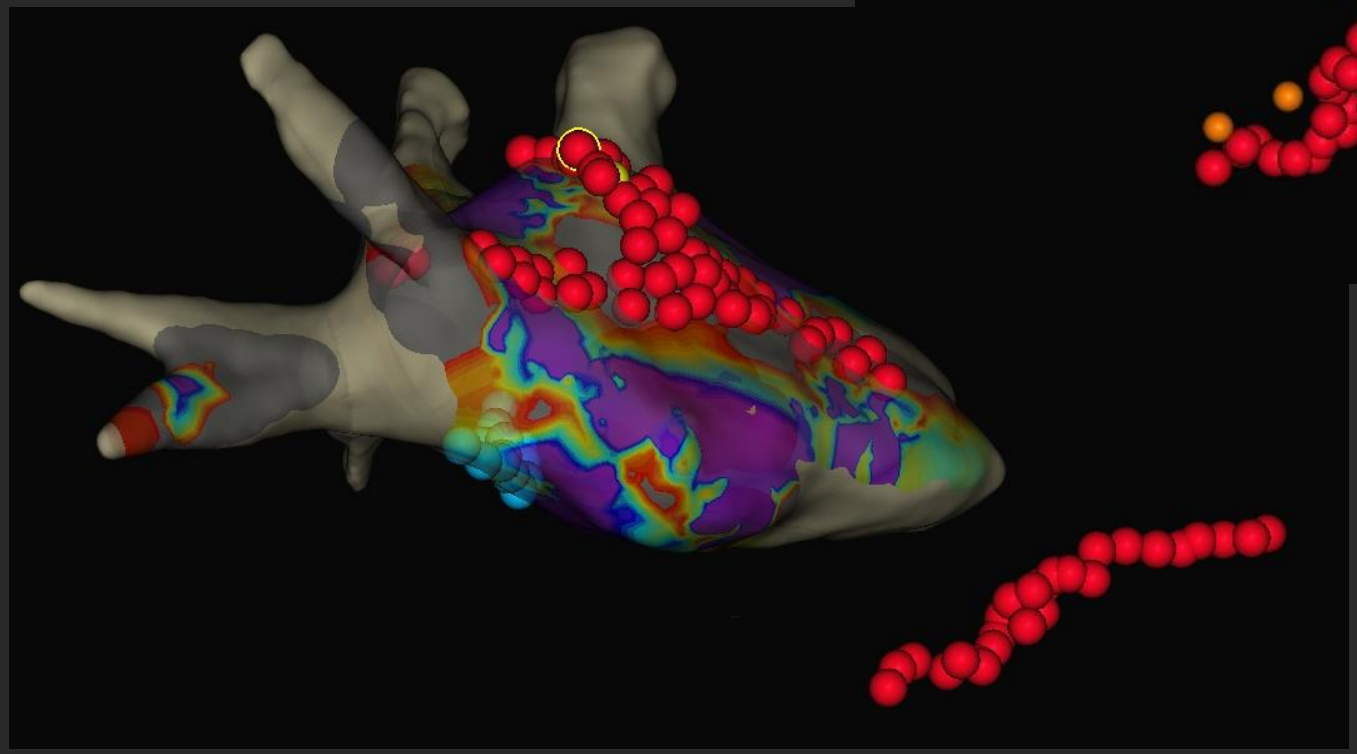
**PFA of the posterior wall of the right atrium**

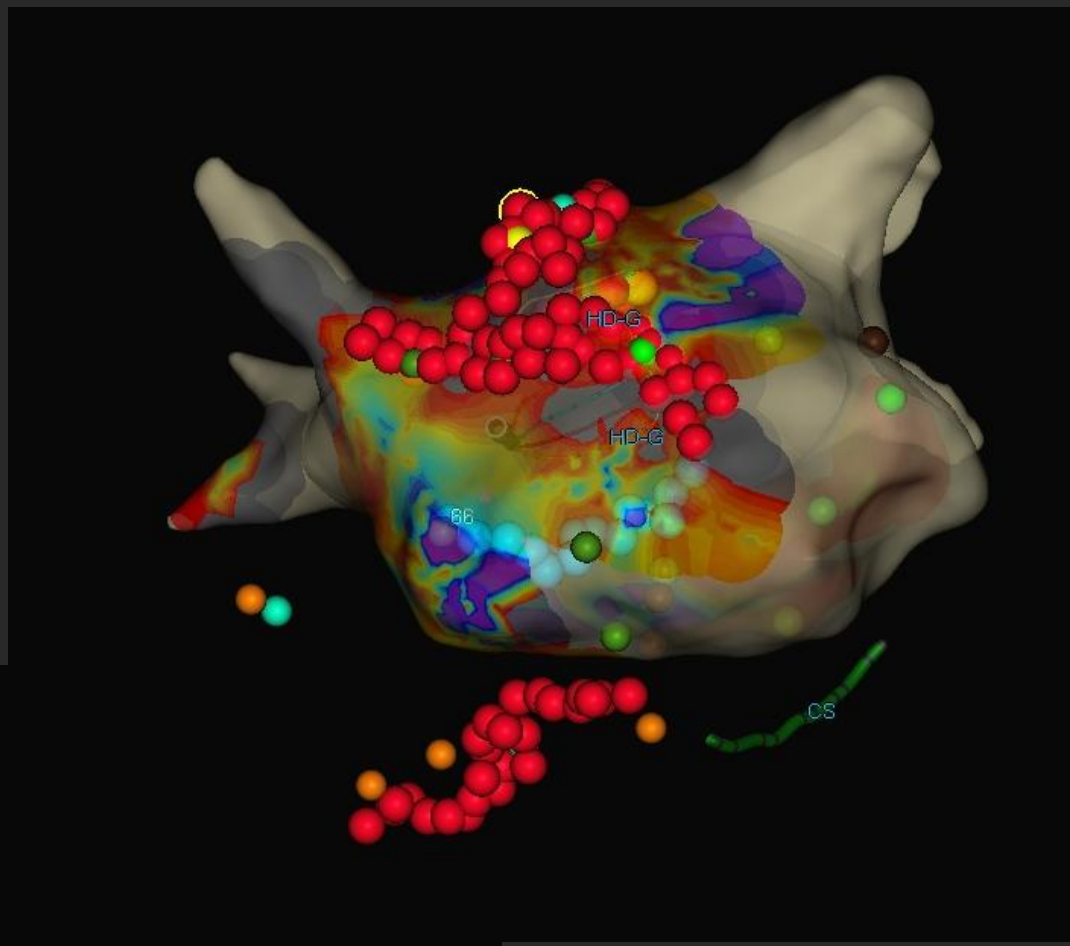


# Random. Comparison Afib

## Introduction

**PFA of the anterior wall and roof of the LA**





# Introduction

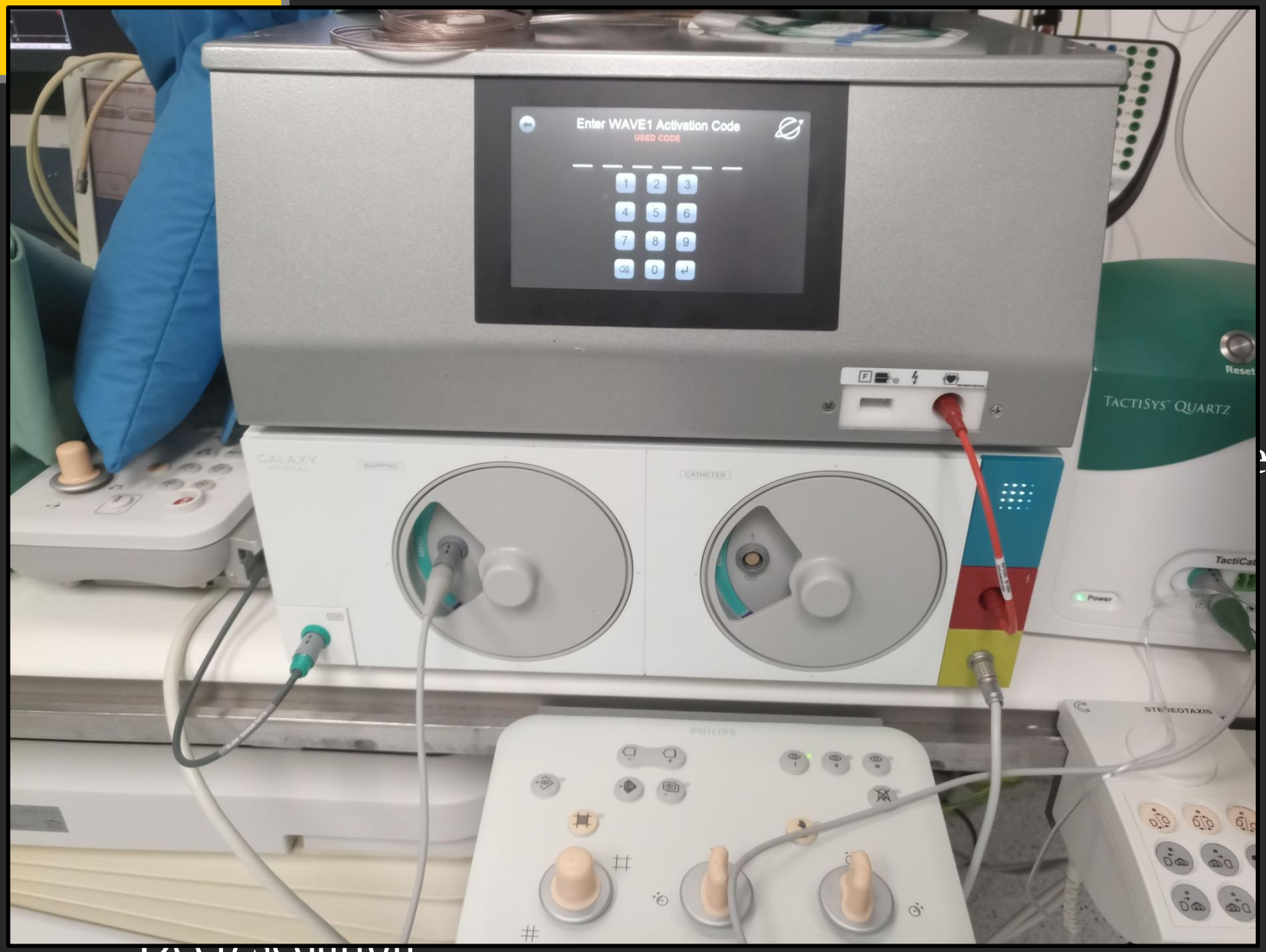
- The aim of my presentation is to show the one-year outcomes of a randomized comparison of efficacy and safety of catheter ablation for AF using
  - Standard 3D mapping and ablation with contact force (CF) catheter using PFA generated by the Centauri PEF system
  - Standard radiofrequency ablation with the same approach

# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Methods

- Patients referred for ablation of paroxysmal and persistent AF were enrolled in the study
- All pts were mapped and ablated in the same manner
- The EnSite Precision 3D mapping system (Abbott) for left atrial mapping, Tacticath CF ablation catheter (Abbott) for standard point-to-point RF ablation
- The basis was pulmonary veins isolation
- Cardioversion in  the case of persistent afib
- Voltage remapping
- Atrial wall fibrosis - adjuvant linear lesions across the scar were created according to St Anns protocol

# Random. Comparison Afib Abl. CENTAURI vs standard RFA




Deep sedation

# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Methods

- The following parameters were statistically compared
  - Procedure parameters
    - total time, ablation time, ipsilateral pulmonary vein isolation time, X-ray dose, acute effect, first pass effect
  - Complications
    - acute, medium and long-term
  - Follow up
    - 3, 6 and 12months follow up

# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Results

### Basic parameters all afib

- 5.3.2023 – 1.11.2024 a total of 164 patients underwent catheter ablation for afib
  - 95 with paroxysmal afib
  - 69 with persistent afib
  - 106 pts PFA group
  - 58 pts RFA group
  - The baseline characteristics both groups were similar

| Basic parameters | PFA (n=106) | RFA (n=58) |
|---|---|---|
| Age (years) | 61 ± 14.5 | 66 ± 13.1 |
| Sex (women in %) | 26 | 28 |
| BMI (kgm-2) | 29.9 ± 5.5 | 30.1 ± 5.3 |
| LV EF (%) | 58.0 (56.0–65.0) | 55.0 (57.8–65) |
| Size LS (mm) | 44 ± 6 | 46 ± 6 |
| Structural heart disease | 22 (21%) | 11 (20 %) |
| ICHS | 8 (8 %) | 5 (9%) |
| Valve disease | 2 (2 %) | (0 %) |
| DCMP | 8 (8 %) | 0 (4%) |
| HCMP | 1 (1 %) | 0 (6 %) |
| Hypertension | 60 (56 %) | 40 (70 %) |
| Diabetes mellitus | 13 (13 %) | 10 (17 %) |
| AA medication | 89 (84%) | 51 (89%) |
| Anticoagulaiton | 98 (93%) | 55 (95%) |

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## Basic parameters paroxyzmal afib

| Basic parameters | PFA (n=69) | RFA (n=26) |
|---|---|---|
| Age (years) | 60 ± 14.5 | 66 ± 13.1 |
| Sex (women) | 24 (35 %) | 6 (23 %) |
| BMI (kgm-2) | 29 ± 5 | 29 ± 5 |
| LV EF (%) | 61 (56 – 65) | 57 (54–60) |
| Size LS (mm) | 42 ± 6 | 46 ± 5 |
| Structural heart disease | 9 (13%) | 4 (17%) |
| ICHS | 2 (3%) | 0 |
| Valve disease | 2 (3%) | 0 |
| DCMP | 1 (2%) | 1 (4%) |
| HCMP | 0 | 3 (13%) |
| Hypertension | 37 (54%) | 18 (71%) |
| Diabetes mellitus | 9 (13%) | 3 (13%) |
| AA medication | 56 (81%) | 25 (96%) |
| Anticoagulaiton | 65 (93%) | 25 (96%) |

## Basic parameters persistent afib

| Basic parameters | PFA (n=37) | RFA (n=32) |
|---|---|---|
| Age (years) | 63 ± 14.5 | 67 ± 13.1 |
| Sex (women in %) | 4 (11 %) | 10 (31%) |
| BMI (kgm-2) | 31 ± 5.5 | 30 ± 5.3 |
| LV EF (%) | 52 (48–56) | 54 (50–60) |
| Size LS (mm) | 48 ± 6,00 | 46 ± 5,40 |
| Structural heart disease | 13 (36%) | 7 (23%) |
| ICHS | 6 (17%) | 5 (17%) |
| Valve disease | 0 | 0 |
| DCMP | 7 (19%) | 1 (3%) |
| HCMP | 1 (3%) | 0 |
| Hypertension | 22 (61%) | 22 (70%) |
| Diabetes mellitus | 5 (14%) | 6 (20%) |
| AA medication | 33 (89%) | 26 (83%) |
| Anticoagulaiton | 35 (95%) | 30 (94%) |

# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Results

## Periprocedural parameters

- Some parameters were significantly different in the PEF group
  - Shorter procedure time
  - Shorter ablation time
  - Shorter ipsilateral vein isolation time
  - Higher probability of pulmonary vein isolation on first pass
  - Longer duration of anesthesia

# Results

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## Periprocedural parameters all afib

| Periprocedural parameters | PFA (n=106) | RFA (n=58) |
|---|---|---|
| Time of procedure (min) | 110 | 159 |
| Time of anaesthesia (min) | 120 | 0 |
| X-ray time (min) | 4.9 | 8,5 |
| X-ray dose (mGycm2) | 2540 | 2700 |
| Isolation success LPV | 106 (100%) | 58 (100%) |
| Time of isolation LPV (min) | 16.9 | 28.4 |
| Number of PFA/RFA applications LPV | 29 | 42 |
| Application time of PFA/RFA LPV (sec) | 128 | 1210 |
| First pass effect LPV | 104 (99%) | 49 (85%) |
| Isolation success RPV | 106 (100%) | 58 (100%) |
| Time of isolation RPV (min) | 18 | 30 |
| Number of PFA/RFA applications RPV | 34 | 52 |
| Application time of PFA/RFA RPV (sec) | 141 | 1420 |
| First pass effect RPV | 100 (95%) | 47 (81%) |

# Results

## Periprocedural parameters paroxyzmal afib

| Periprocedural parameters | PFA (n=69) | RFA (n=26) |
|---|---|---|
| Time of procedure (min) | 103 | 161 |
| Time of anaesthesia (min) | 112 | 0 |
| X-ray time (min) | 4.4 | 9.1 |
| X-ray dose (mGycm2) | 2130 | 2960 |
| Isolation success LPV | 69 (100%) | 26 (100%) |
| Time of isolation LPV (min) | 16.6 | 28.8 |
| Number of PFA/RFA applications LPV | 27 | 40 |
| Application time of PFA/RFA LPV (sec) | 116 | 1450 |
| First pass effect LPV | 68 (98%) | 21 (81%) |
| Isolation success RPV | 69 (100%) | 26 (100%) |
| Time of isolation RPV (min) | 18 | 31 |
| Number of PFA/RFA applications RPV | 33 | 54 |
| Application time of PFA/RFA RPV (sec) | 118 | 1680 |
| First pass effect RPV | 66 (95%) | 21 (81%) |

# Results

## Periprocedural parameters persistent afib

| Periprocedural parameters | PFA (n=37) | RFA (n=32) |
|---|---|---|
| Time of procedure (min) | 122 | 158 |
| Time of anaesthesia (min) | 130 | 0 |
| X-ray time (min) | 5.7 | 8.0 |
| X-ray dose (mGycm2) | 3330 | 2490 |
| Isolation success LPV | 37 (100%) | 32 (100%) |
| Time of isolation LPV (min) | 17.4 | 27.9 |
| Number of PFA/RFA applications LPV | 32 | 44 |
| Application time of PFA/RFA LPV (sec) | 149 | 979 |
| First pass effect LPV | 37 (100%) | 29 (90%) |
| Isolation success RPV | 37 (100%) | 32 (100%) |
| Time of isolation RPV (min) | 20.0 | 28.9 |
| Number of PFA/RFA applications RPV | 36 | 50 |
| Application time of PFA/RFA RPV (sec) | 172 | 1167 |
| First pass effect RPV | 35 (94%) | 26 (81%) |

# Results

# mparison Afib Abl. CENTAURI vs standard RFA

## Follow up 6 months all afib

| | No of pts | Recurrence | AF | Other arrh. |
|---|---|---|---|---|
| **PFA** | 47 | 12 (26%) | 10 (83%) | 2 (17%) |
| **RFA** | 35 | 5 (15%) | 4 (80%) | 1 (20%) |

## Follow up 12 months all afib

| Paroxysmal AF | Number | Recurrence | AF | Other arrh. |
|---|---|---|---|---|
| **PFA** | 29 | 8 (28%) | 7 (88%) | 1 (12%) |
| **RFA** | 10 | 4 (40%) | 2 (50%) | 2 (50%) |

# Random. Comparison Afib Abl. CENTAURI vs standard RFA

**Results**

**Follow up**

- Assessment of long-term efficacy is limited by the relatively small sample size of available follow-up data

# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Results

## Complications

- No severe acute or subacute complications were recorded in both groups
- Centauri group – 3 pts (2,8%) had groin complications
- RFA group - 2 (3,4%) had groin complications

# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Conclusion

- Centauri PEF system is non-inferior compared to the standard RFA
- In some parameters is significantly better
  - Shorter procedure time
  - Shorter ablation time
  - Shorter ipsilateral vein isolation time
  - Higher probability of pulmonary vein isolation on first pass
  - Longer duration of anesthesia
- Follow up seems to be comparable
  - This is limited by small number of pts with longterm follow up

# Random. Comparison Afib Abl. CENTAURI vs standard RFA

## Conclusion

- Centauri PEF system is universal and flexible ablation system
- „dream of the electrophysiologist“ – precise, powerful, fast
- Could be used in many EP scenarios
  - For atria and ventricles
  - With or without 3D mapping
  - Endocardially or epicardially
- Long term efficacy need further studies
- Centauri PEF system needs further development

# Thank you for your attention

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