RHYTHM AI

# STAR Mapping™

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# Disclosures

RHYTHM AI

- Founder and shareholder - RHYTHM AI Ltd
- Research grants and speaker fees:
  - Abbott, Medtronic, Boston Scientific, Biosense Webster
- STAR Mapping has not been cleared by any regulatory authority in the world and is not available for clinical use

# Background

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- 3D mapping systems present ↑ data to clinicians
- Interpretation challenging even after years experience/training
- Irregular/non-sustained  rhythms even more complex
- Develop technology aid clinicians - democratises heart rhythm management:
  - No manipulation of data
  - Independent of theories of heart rhythm mechanism
  - Presents data in as raw a form as possible
- STAR Matlab tested on Carto, Ensite/Precision, Rhythmia
- STAR Apollo – PC version  for use with Ensite/Precision under review by FDA

# STAR Mapping

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- Summarises AF activation during 30 second recordings
- Presents:
  - Activation patterns
  - Sites of localised activation
- Ignores:
  - low voltage/scar
  - Infrequent phenomena
  - Recordings that are too short or catheter unstable/poor contact
- Errors of timing/interpretation overwhelmed by repeating patterns

# STAR Mapping - process

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- Any proprietary 3D mapping system and suitable multipolar catheter
- Create geometry
- Isolate PV’s
- Acquire 10-15, 30s acquisitions of data with stable catheter
- Transfer data to STAR PC

Ensite or Carto image in here

# STAR maps

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- 3D geometry from case with:
- Location of recordings/electrodes
- dominant activation patterns (purple arrow)
- Repetitive sites of local activation (red spheres)
- Recording and electrode number, other characteristics available with mouse click

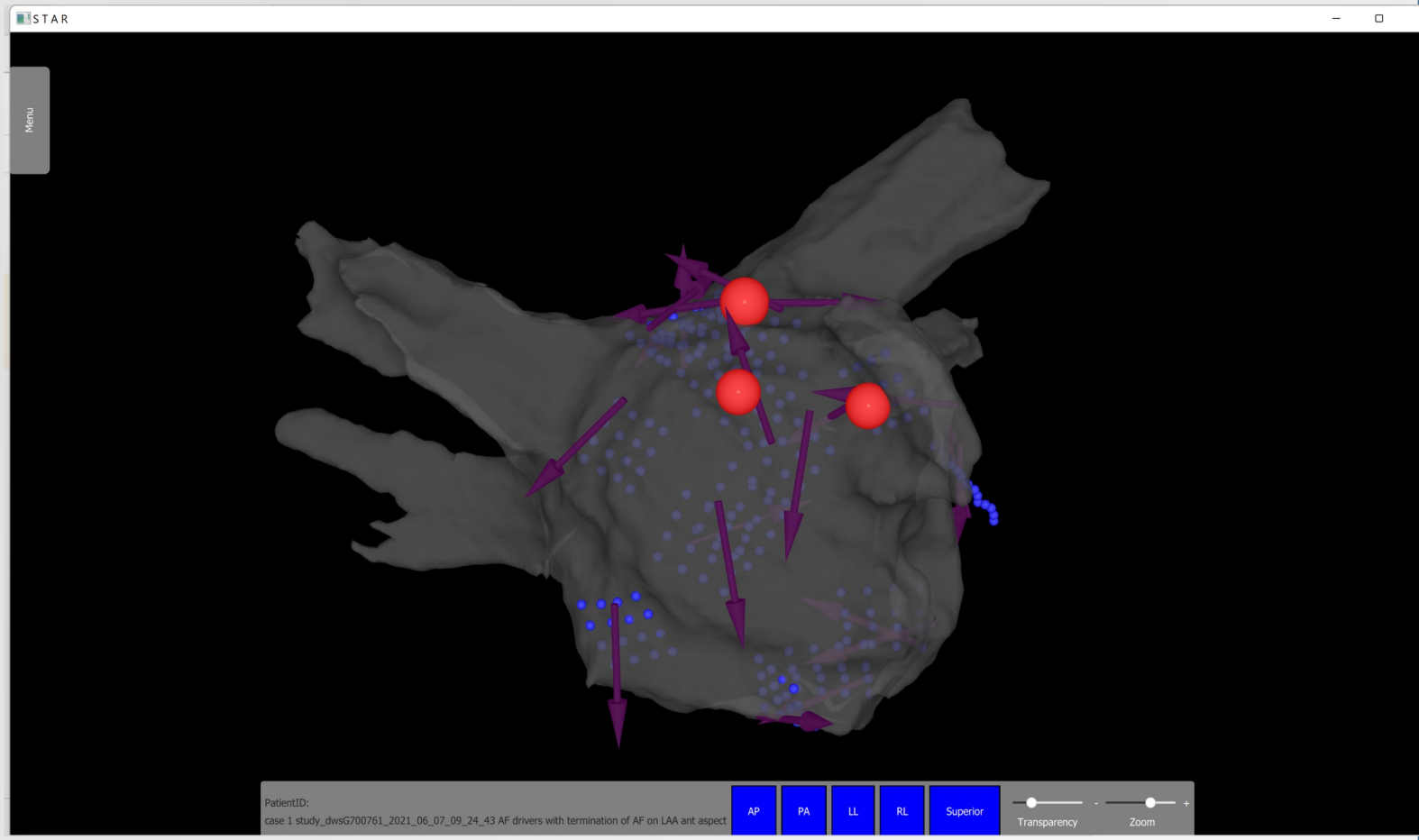


Image shown is STAR Apollo Ensite/Precision version of STAR

# Validation – STAR-Matlab

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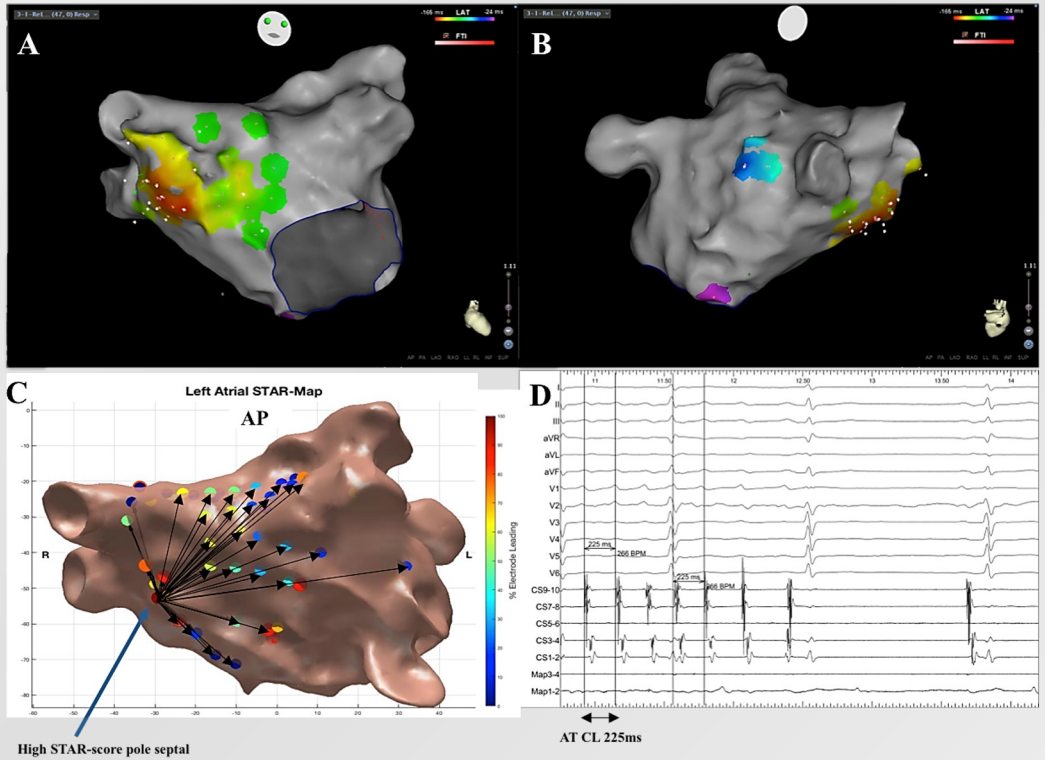
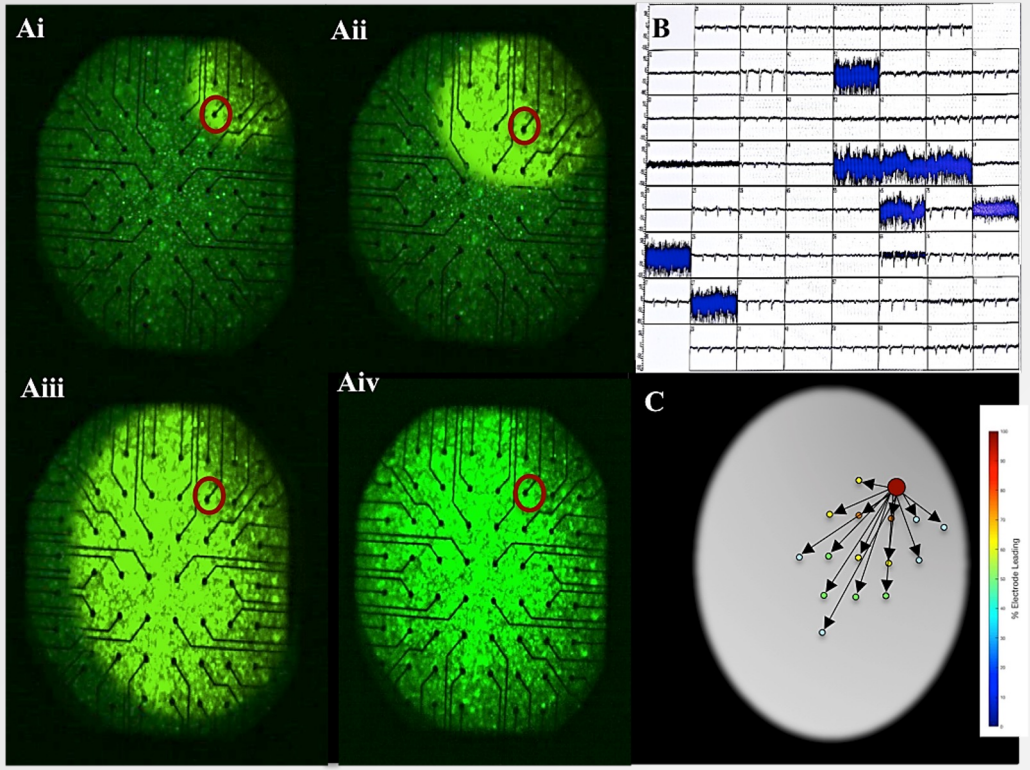
- Identification of known arrhythmia mechanisms by blinded observers and comparison with optimal mapping



# Clinical data – STAR Matlab simultaneous mapping with basket

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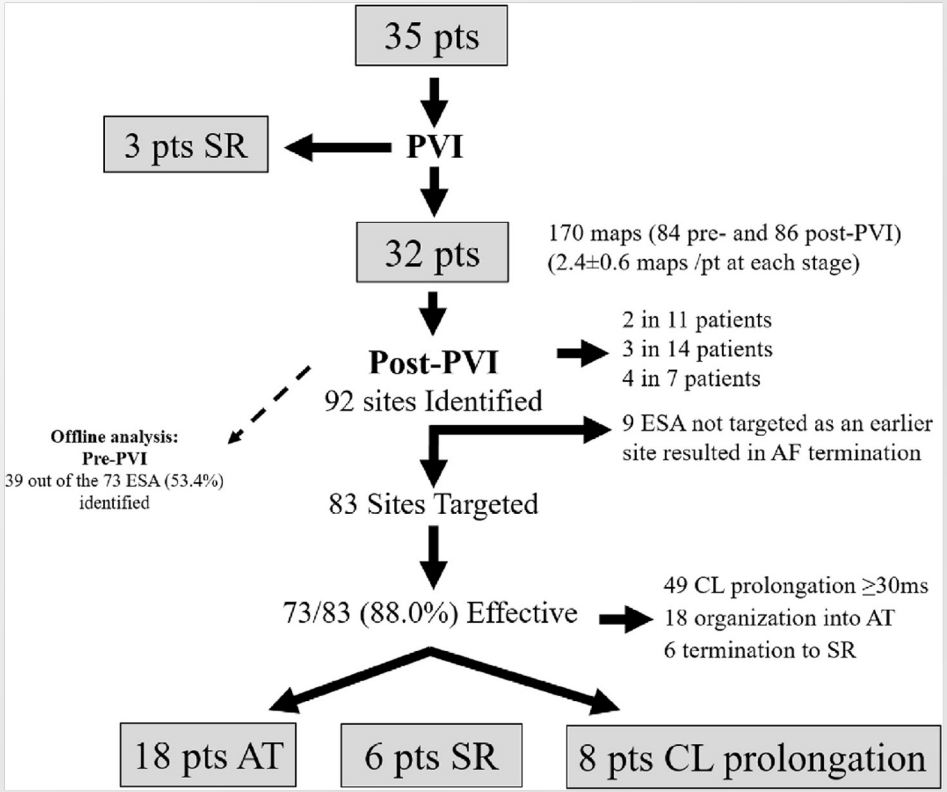
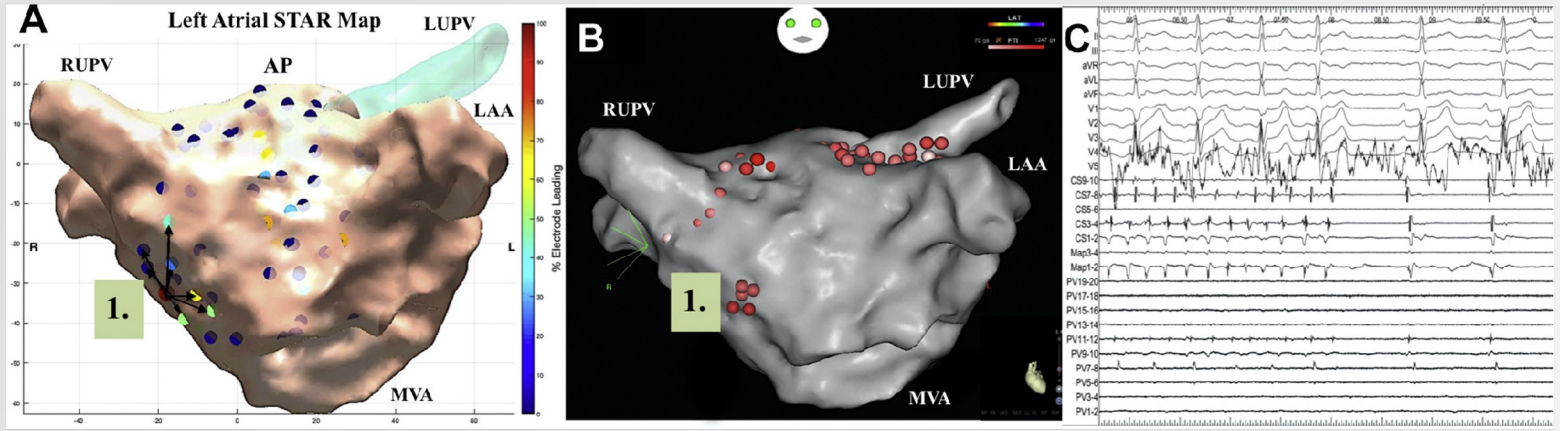
- Identification of known arrhythmia mechanisms by blinded observers and comparison with optimal mapping



# Clinical data - STAR Matlab – sequential mapping vs basket

- Pentarray acquisitions compared with basket acquisitions

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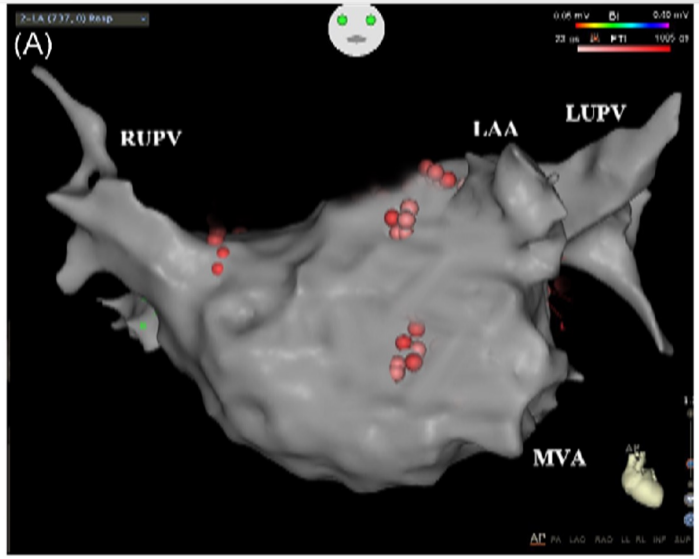


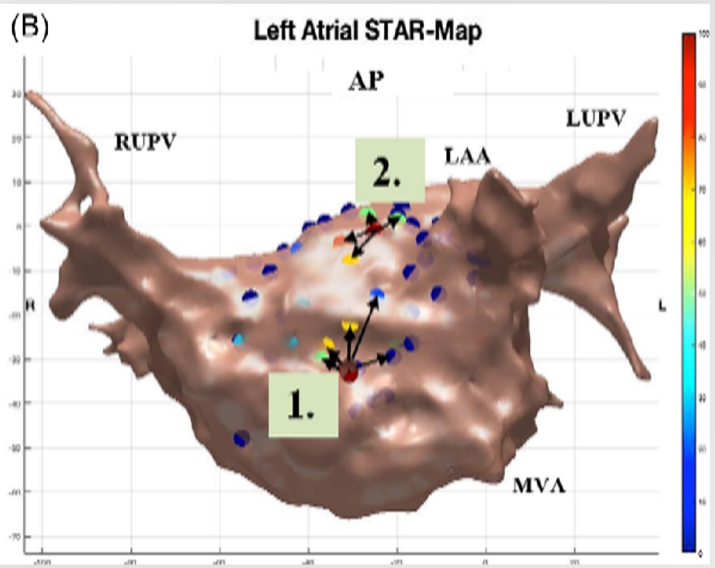


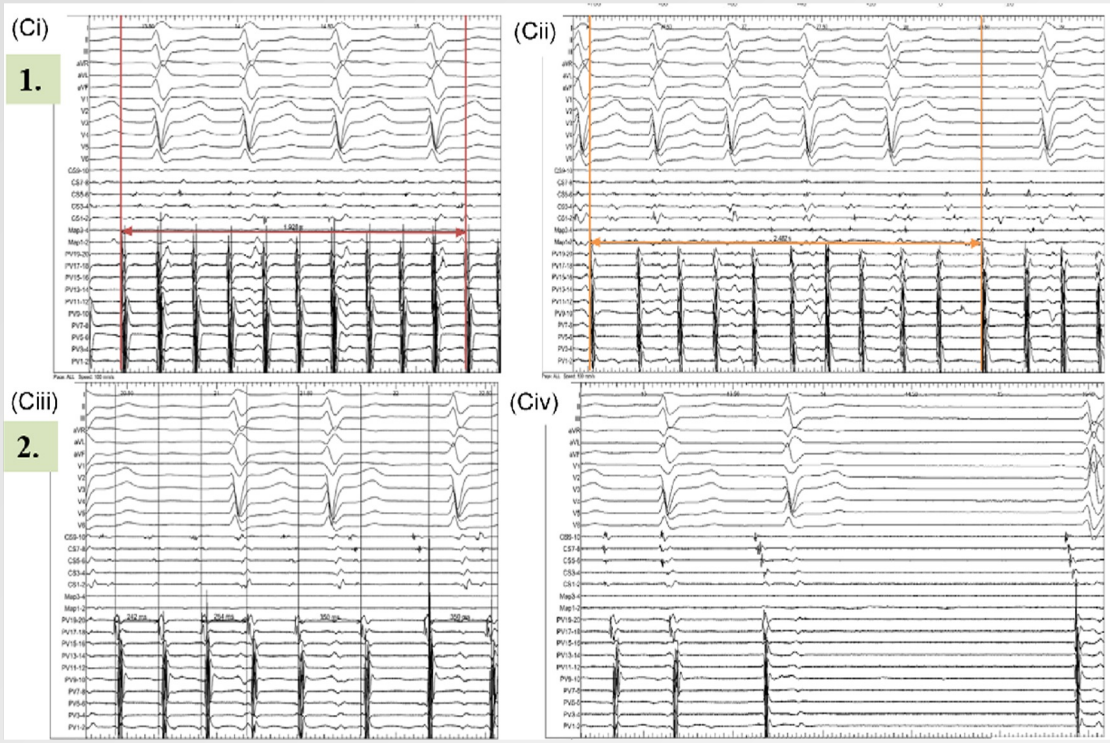

# Clinical data STAR Matlab – long term outcomes vs conventional approaches

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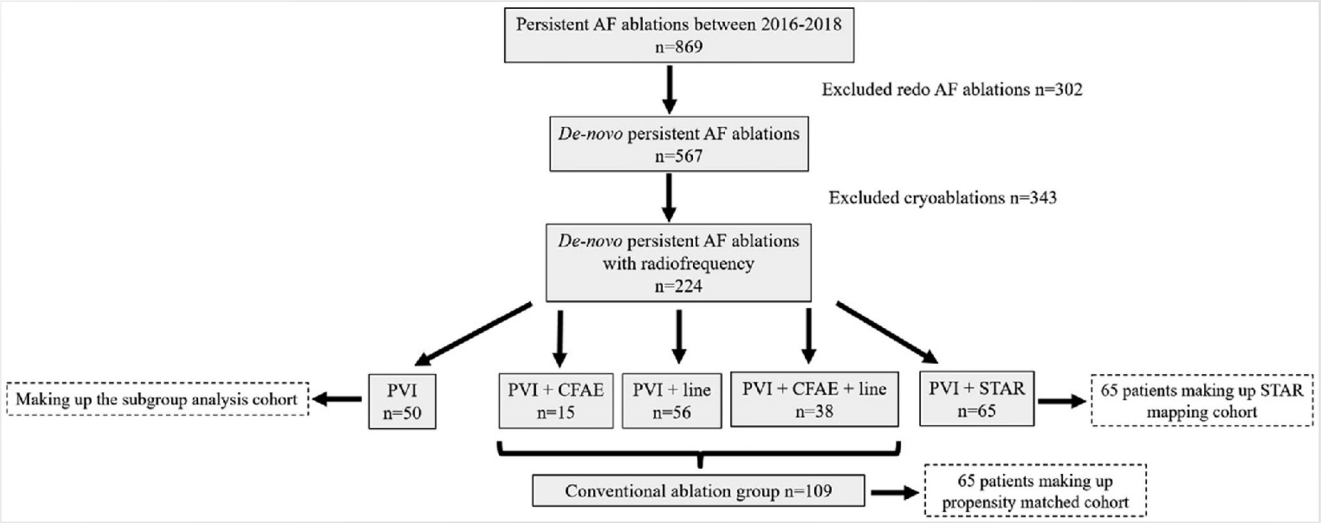
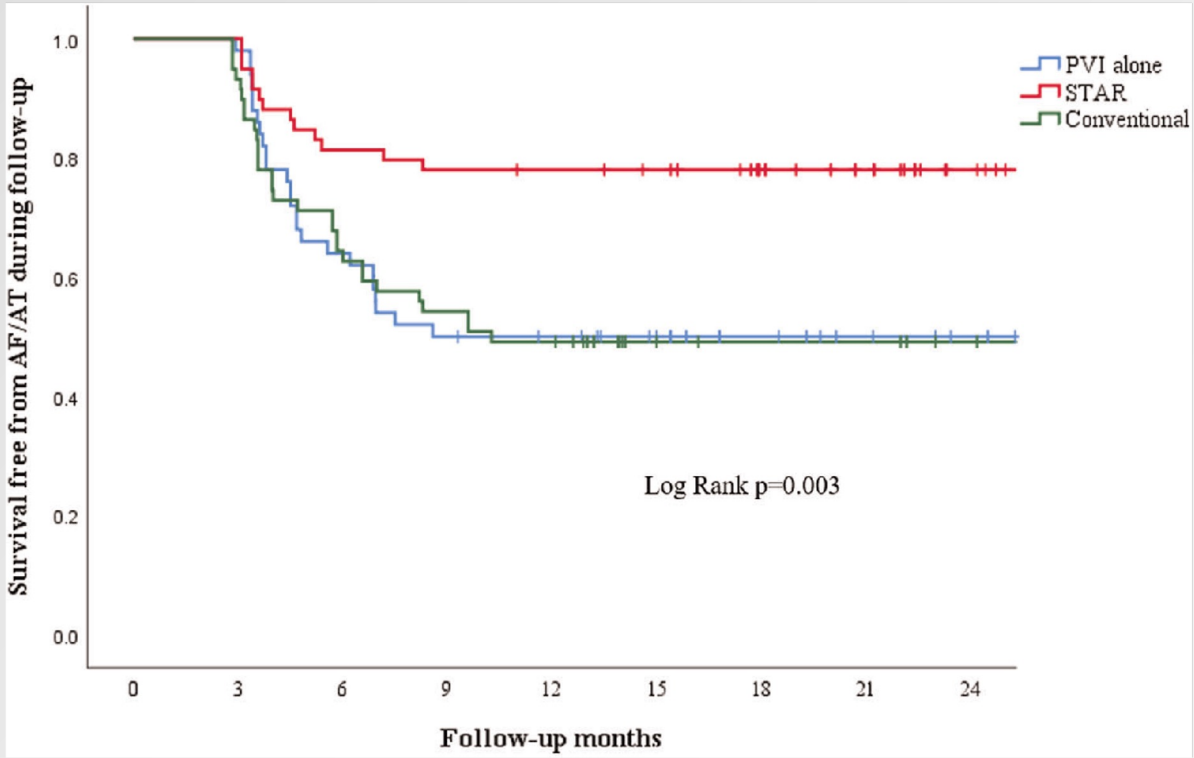
- Case cohort analysis – STAR guided vs conventional




Honarbakhsh et al JCE 2020

# STAR Apollo™ Mapping System

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- First ‘commercial’ version of STAR Mapping
- Received FDA 510k clearance in December 2022
- Indication for use:
  - STAR Apollo™ Mapping System assists users in manual annotation of 3D anatomical and electrical maps of human atria using data from multipolar, intracardiac, atrial, electrograms during atrial fibrillation
  - The clinical significance of utilizing the STAR Apollo Mapping System, to help identify areas with intracardiac atrial electrograms, of atrial arrhythmias, such as atrial fibrillation, has not been established by clinical investigations

# External clinician validation STAR Apollo

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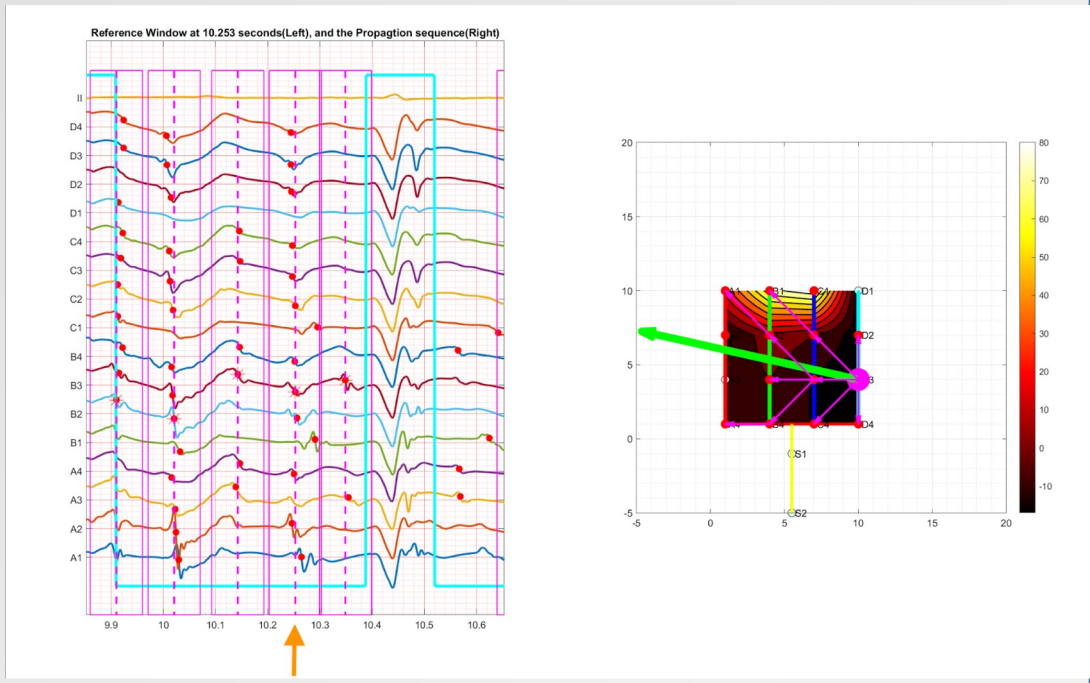
- 5 independent clinicians asked to review:
  - Allocation of electrogram timing-
    - N=31980, 164 mistimed, 518 not timed
  - Identification of:
    - earliest electrode n=500 (87%±9.92)
    - activation direction n=500 (89.2%±10.55)
  - R wave blanking accuracy
    - N=1005, 3 mistimed, 2 not blanked
  - STAR maps of cases they recorded for clinical utility and credibility
    - Score 4.99/5 across all parameters



# Stability of activation patterns

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- Sequential acquisitions at identical locations - Activation patterns appear stable and consistent

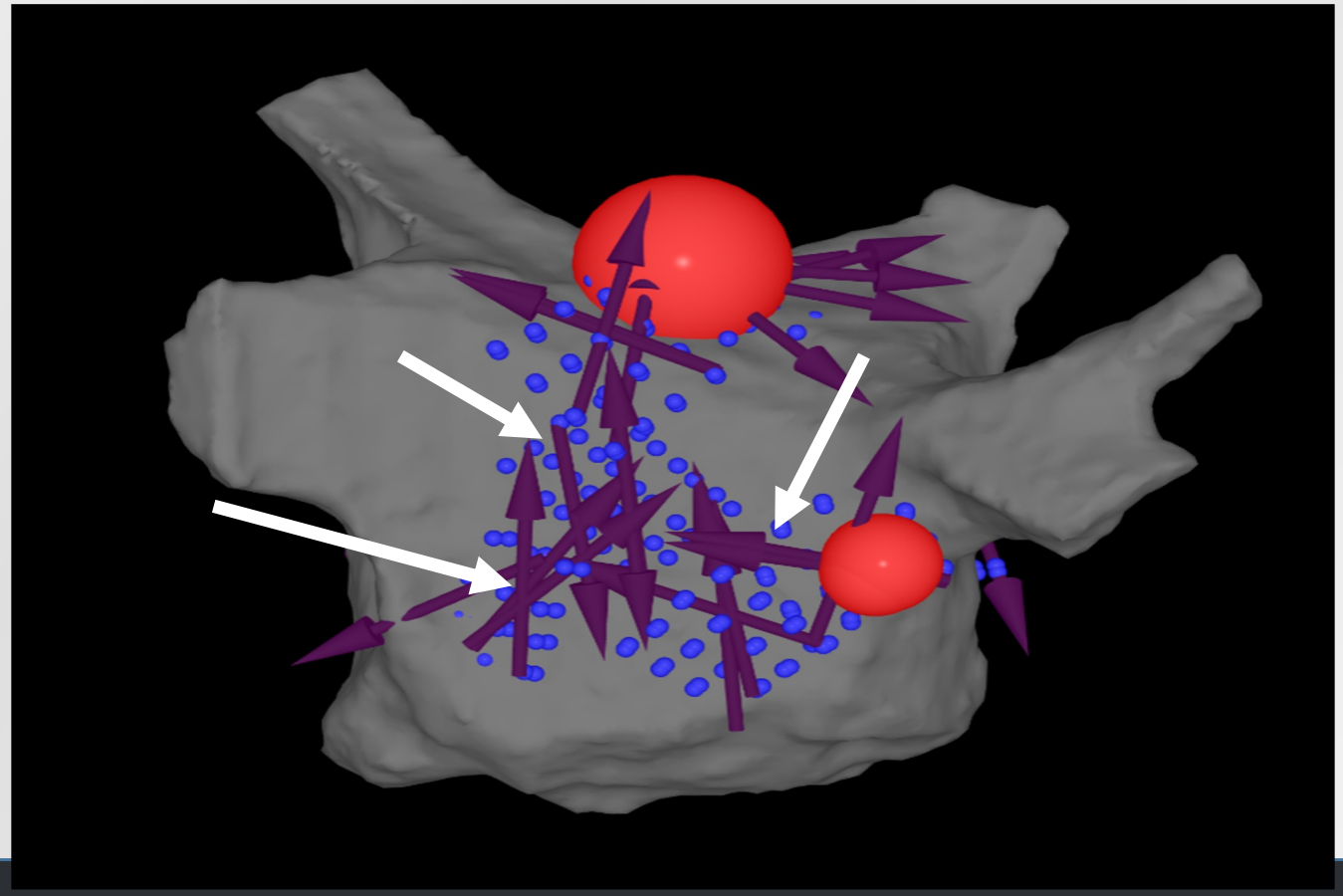

Image shown is STAR Apollo Ensite/Precision version of STAR

# Early sites of activation

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- Highly repetitive with activation emerging from that region on separate activations

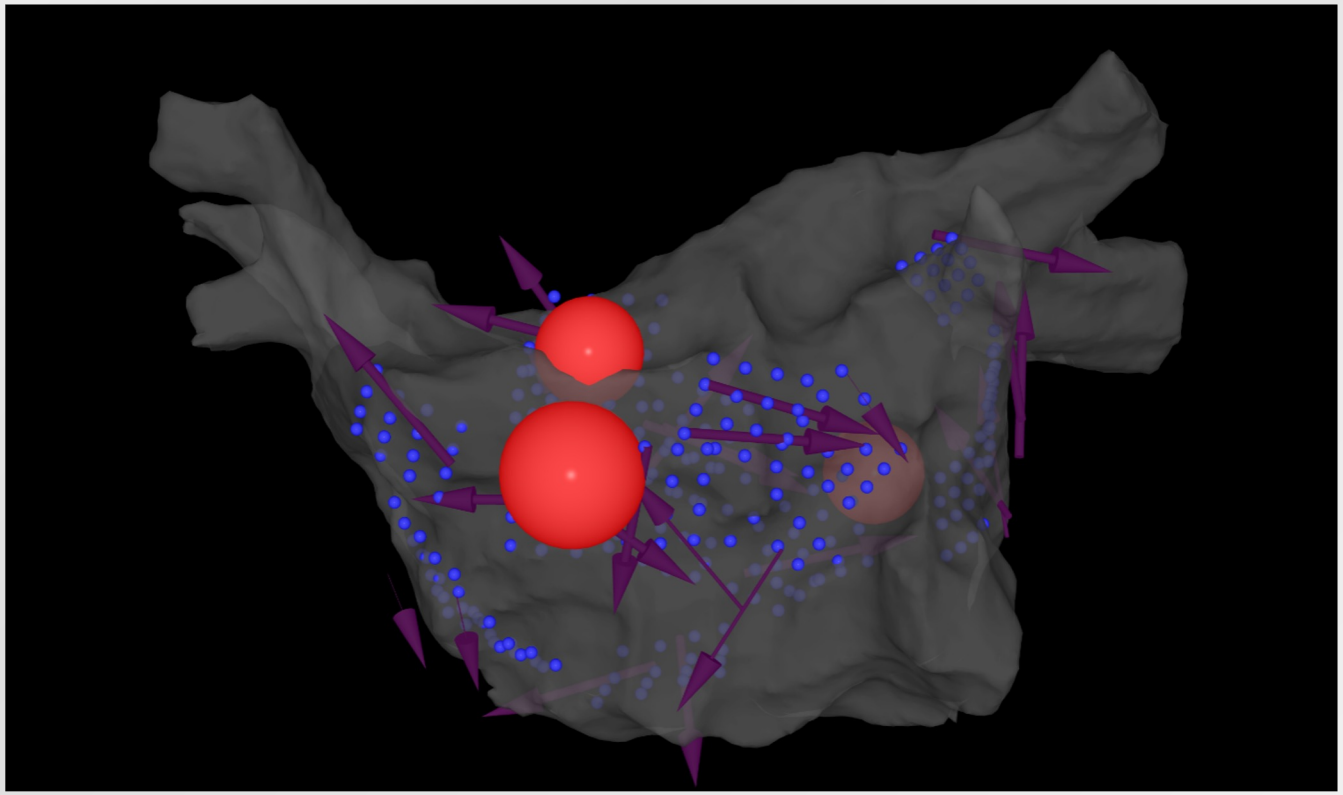

Image shown is STAR Apollo Ensite/Precision version of STAR

# Limitations

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- No multicentre randomized studies
- Yet to understand the clinical impact of this technology
- Physician driven therapy
- Not revealing any new universal mechanism for AF
- Clinician interpretation of the data likely to evolve and may improve over time

# STAR Mapping - conclusions

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- STAR Mapping endeavours to present a summary of activation data
- Physicians may then use these to assist in understanding the mechanism of that patients AF
- The system makes no assumptions of arrhythmia mechanism and does not prescribe any standardised treatment recommendations
- Future developments aim to use clinical outcomes to allow the system to more accurately emphasise relevant phenomena
- STAR Mapping has not been cleared by any regulatory authority in the world and is not available for clinical use