RF ablation guided by polarization sensitive optical coherence reflectometry

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October 18th 2015

Venice Arrhythmias

The Problem

Real-world results are not satisfying

- Poor success rate: 59% recurrence at 1 year follow-up.
- High rate of complications: 2.5% major adverse events

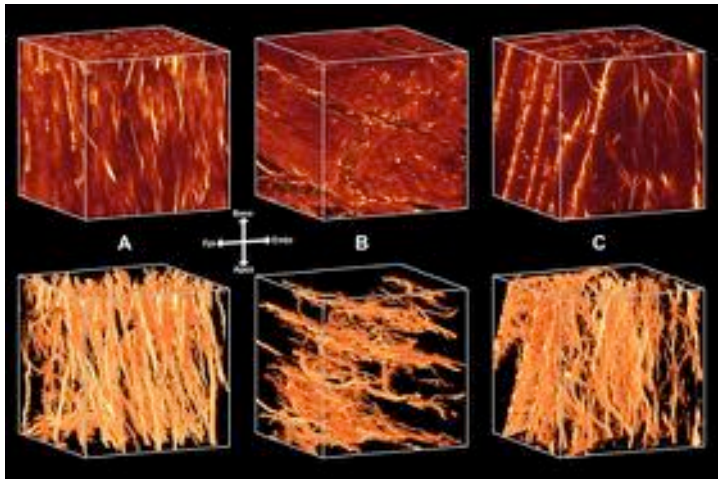
Improving *what* to ablate: Mapping

- Protocol for paroxysmal AF targets pulmonary vein isolation.
- The role of the atrial substrate is not fully understood.
- Theories with therapeutic implications include rotors, CFAE's, MRI-guided fibrosis …
- Proper execution of the ablation procedure is always required.

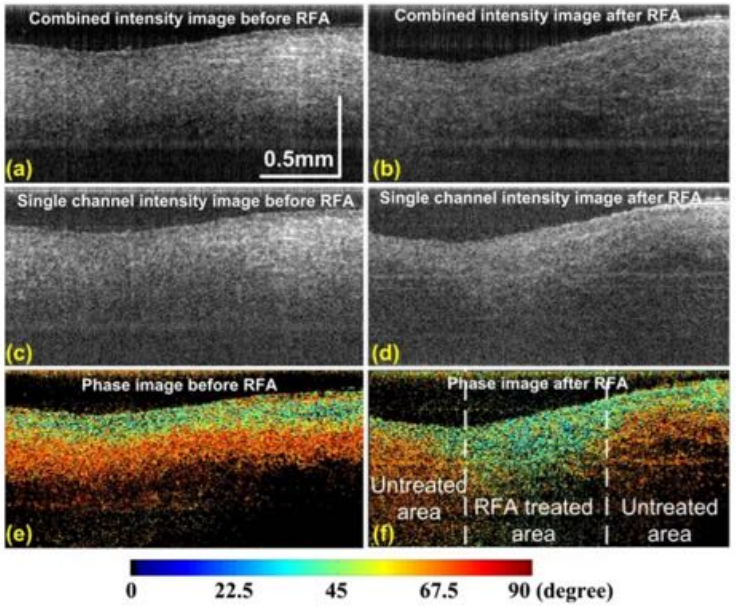
Improving *how* to ablate: New Ablation Techniques

- Goal: ensure safe long-term pulmonary vein isolation.
- End points: transmurality, continuity, controlled lesion creation.
- Simpler technique for more homogeneous results.

Optical Coherence Tomography for Lesion Assessment



Oriented Collagen in Cardiac Muscle



Fu X., Wang Z., Wang H. et al. Opt. Lett. 39 (17)

Coagulative necrosis detection

- Oriented collagen exhibits strong optical birefringence
- Key component of the extracellular matrix of muscular fibers
- Optical Coherence Tomography quantifies birefringence accurately
- Collagen coagulation happens at known temperature (69.8ºC)

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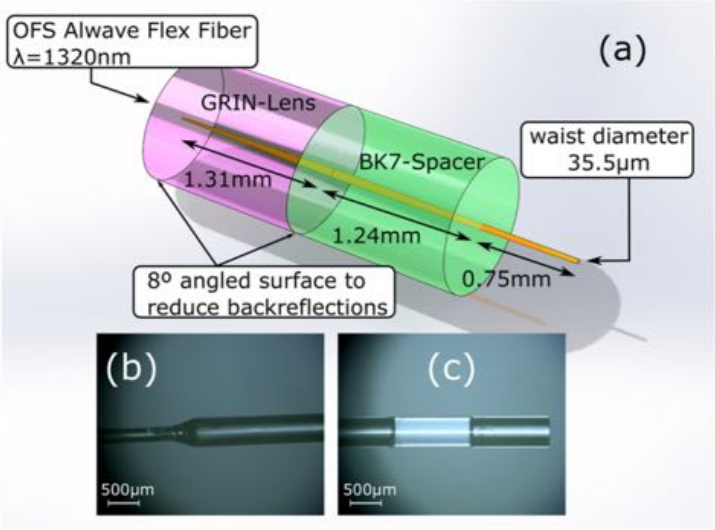
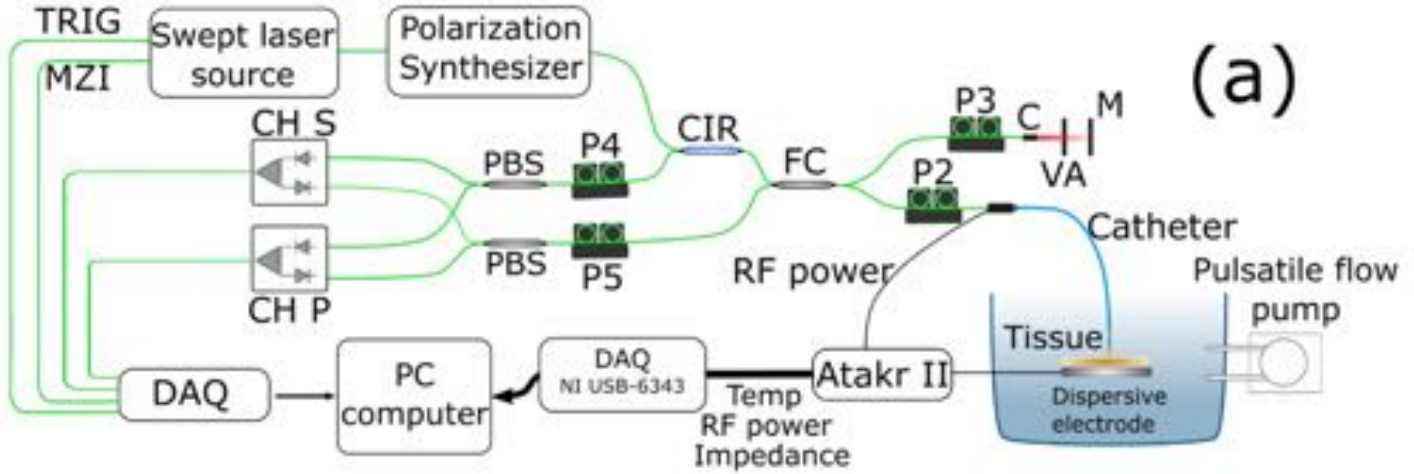
Polarization Sensitive Optical Coherence Reflectometry





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In Vitro and In Vivo Proof of Concept

Preclinical prototype

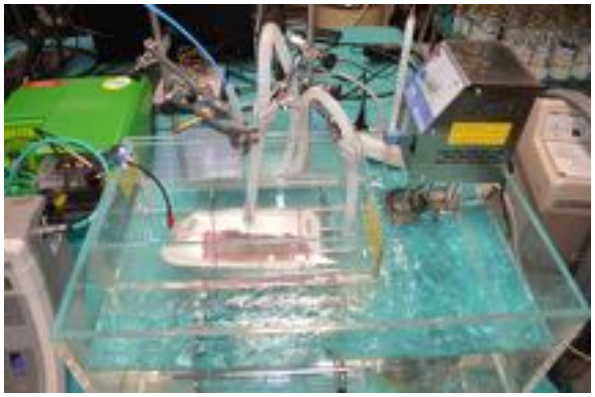
- Non-irrigated electrode
- Forward imaging only

In-vitro verification

- Thermalised bath
- Signal processing & stability

In-vivo endocardial ablation

- Percutaneous access with fluoroscopy
- Pig model (large-white)



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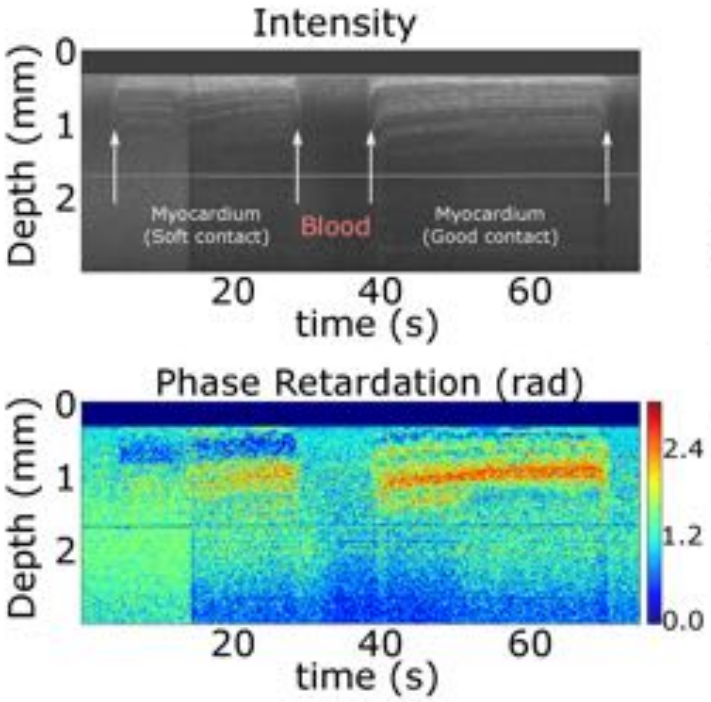
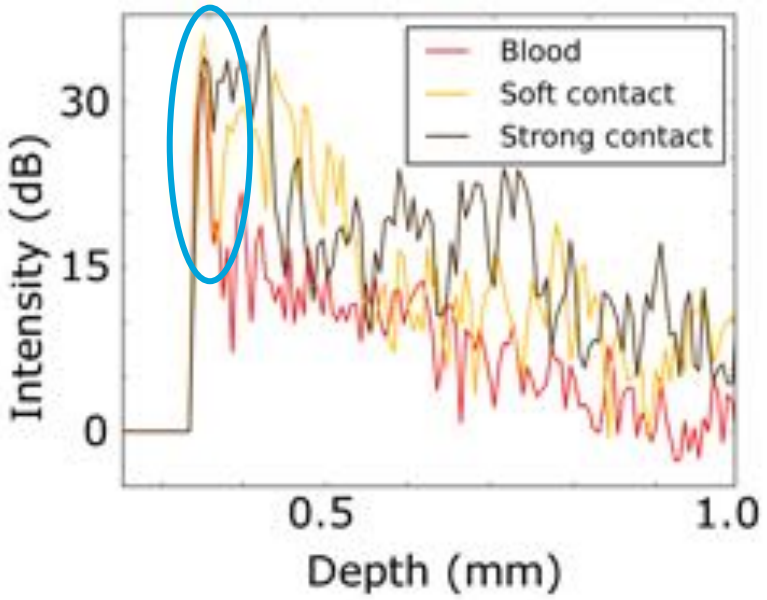
Quantitative Contact Information





- Clear contrast between blood and myocardium.
- Quantifiable soft & hard tissue contact.
- Determination of catheter-tissue distance better than 15µm.
- Presence of birefringence band consistent in all atrial walls.
- Robust with respect to wall angle up to ±30°

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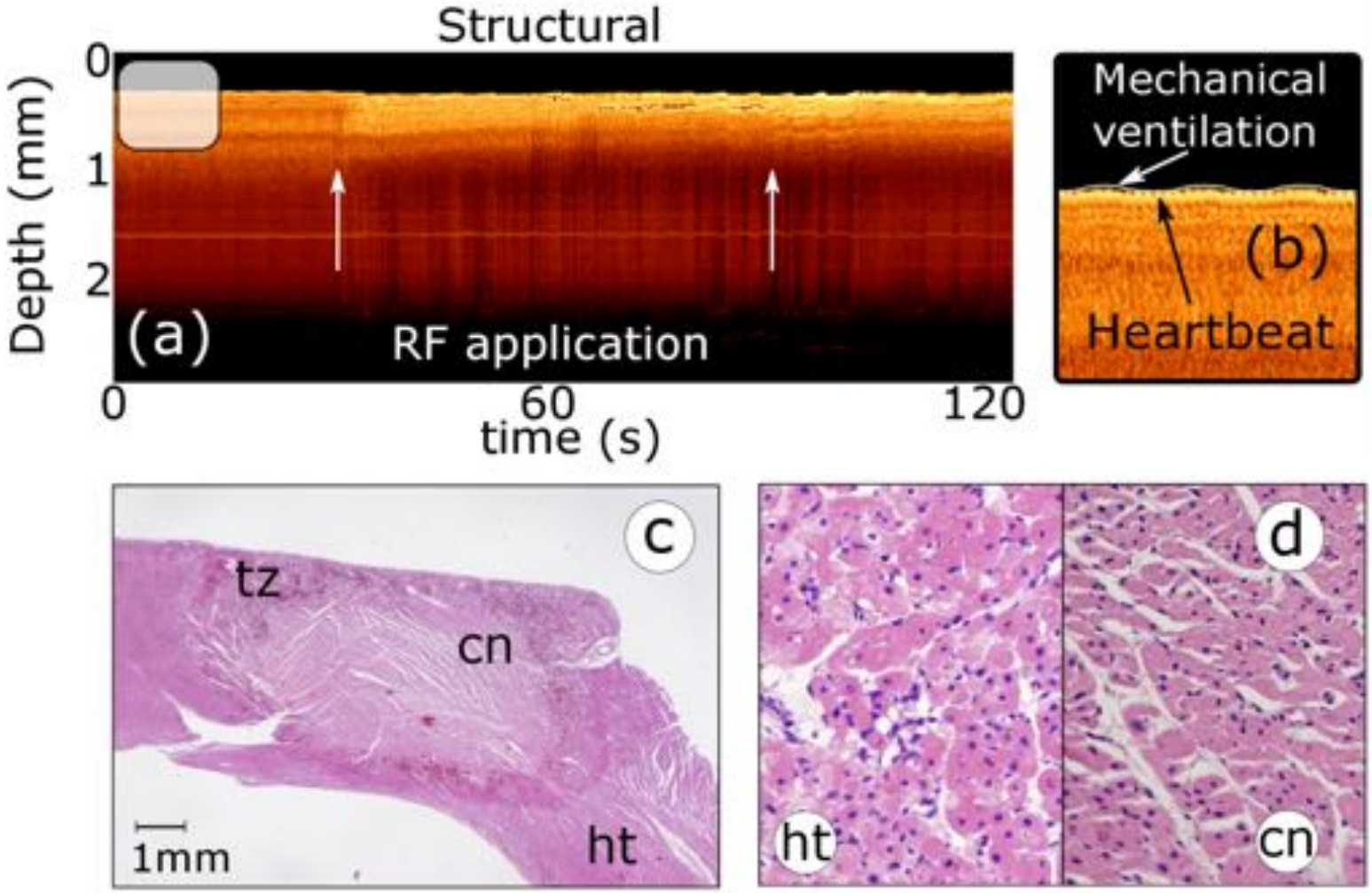
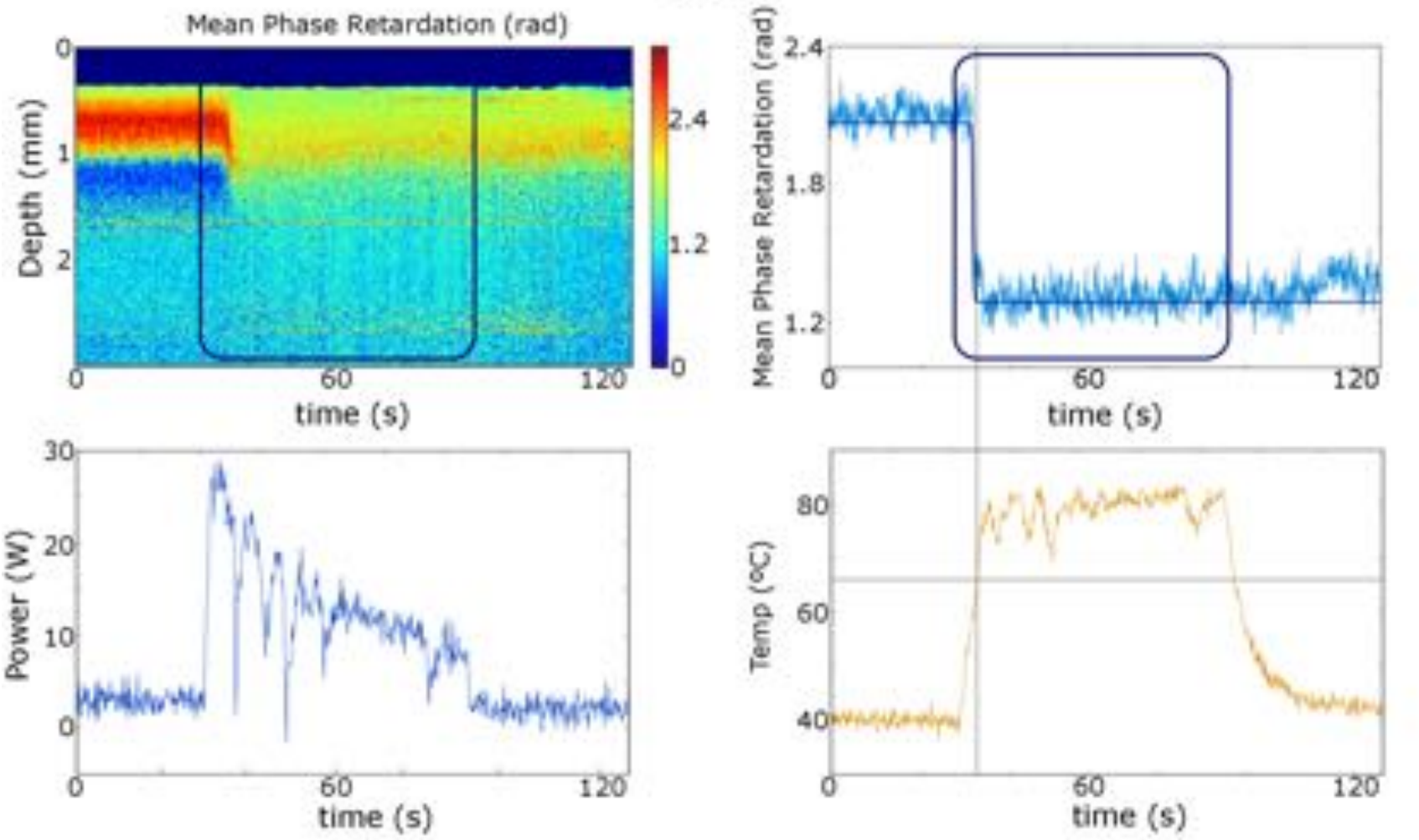
Catheter Stability



Lesion Assessment



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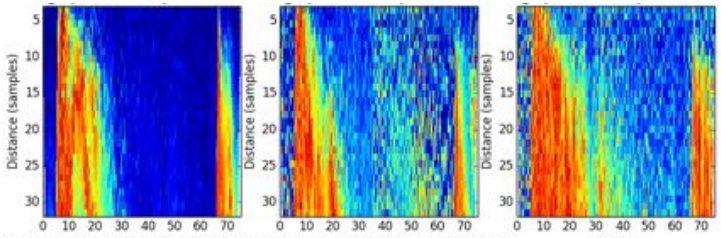
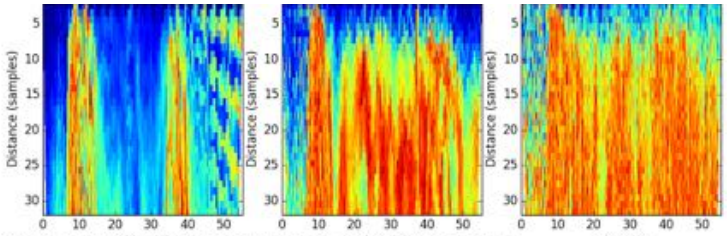
Model of Deep Lesions

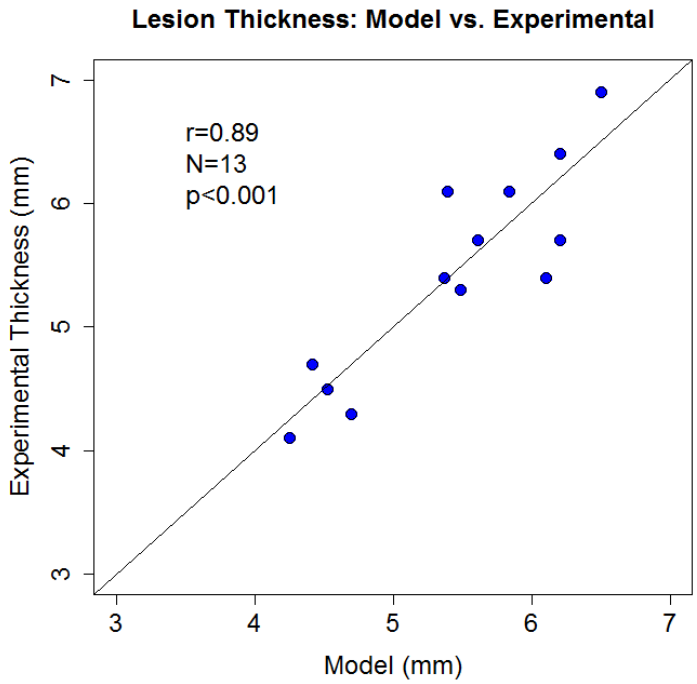
Self Correlation Analysis



Lesion 1: shallow



Lesion 2: deep



- Study in ventricular walls much thicker than imaging depth.
- Good depth prediction based on optical parameters only.
- Ongoing work: extend to in vivo, improve signal processing and modeling to increase predictive value.

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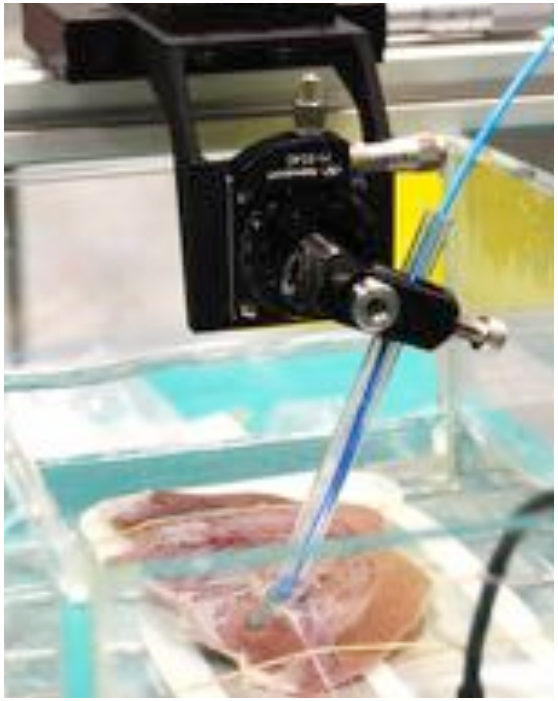
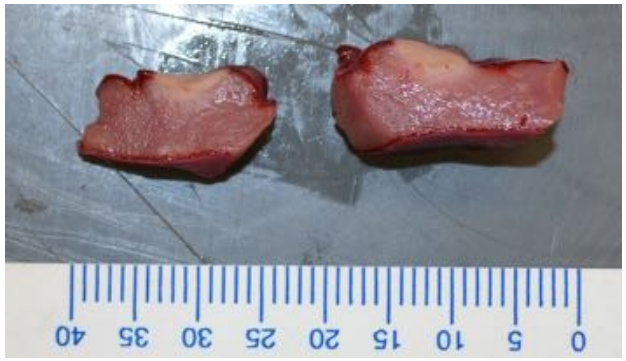
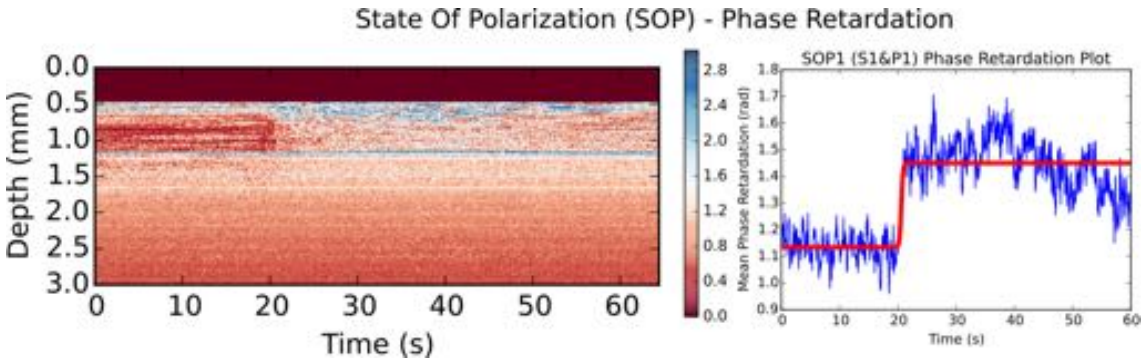
Robust with Respect to Angle

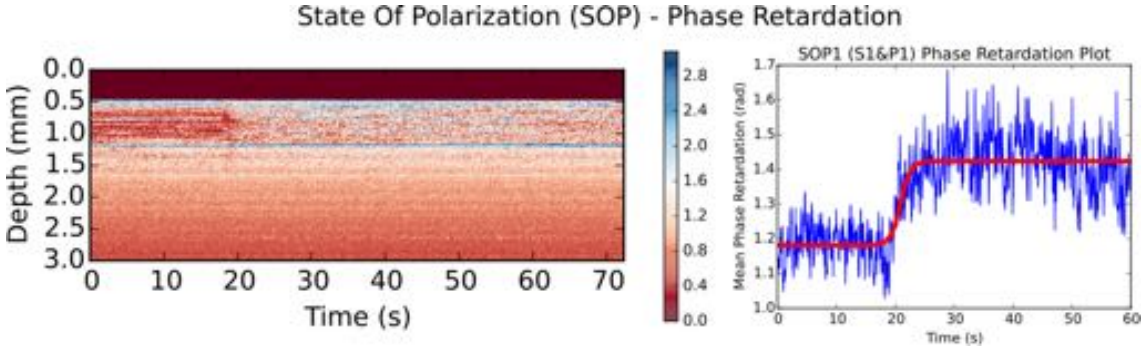




90°



70°



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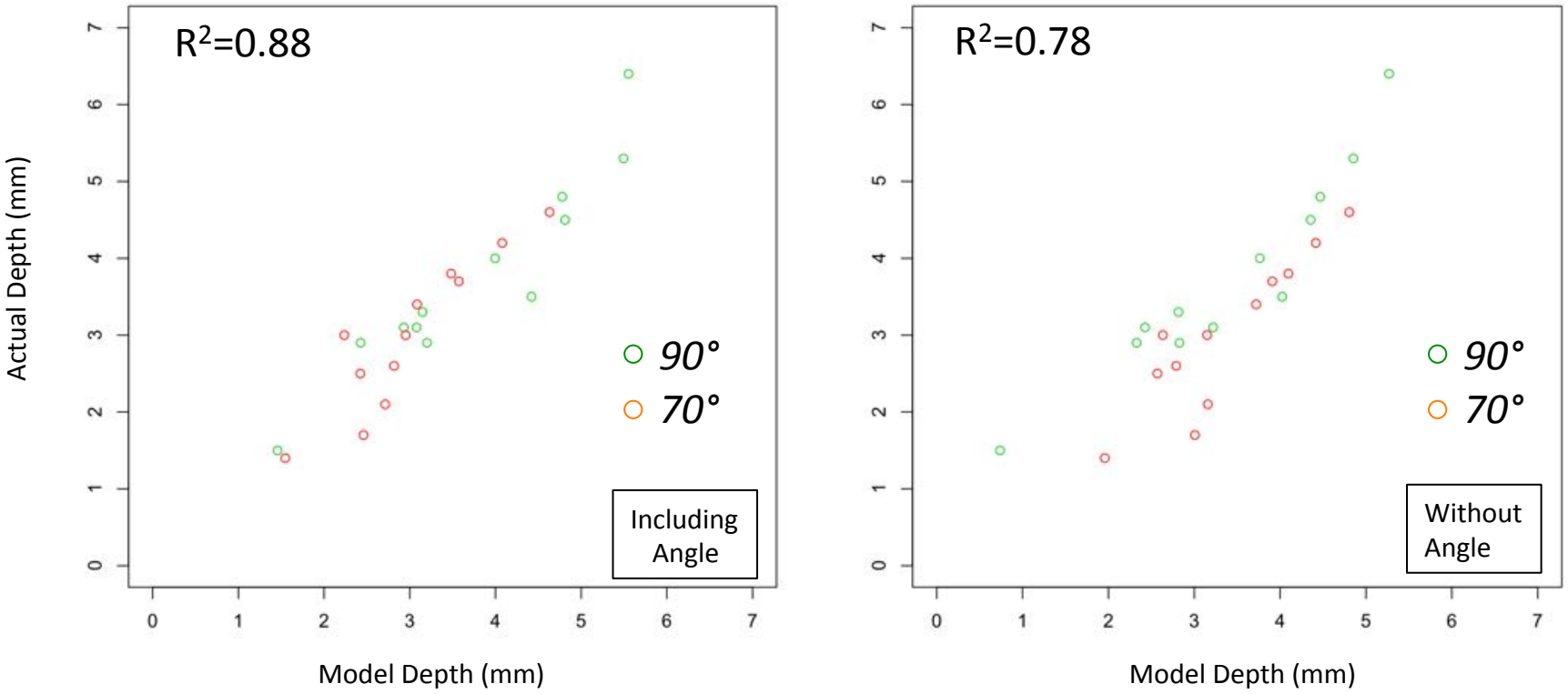
Lesion size: predictive value



Optical parameters alone can predict 78% of variance in lesion depth
Adding angle as a predictor results in a 10% higher predictive value ($p<0.01$)

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Summary

- Real-time ability to assess contact *in vivo*.
- Depth-resolved molecular imaging in the atrial wall.
- Direct lesion assessment demonstrated *in vivo.*
- Robust with respect to small angle variation.
- Able to predict lesion size *in vitro.*
- Potential for improved outcomes:
  contact, transmurality & continuity
- Potential for improved safety:
  avoiding overtreatment; thin wall and pop detection

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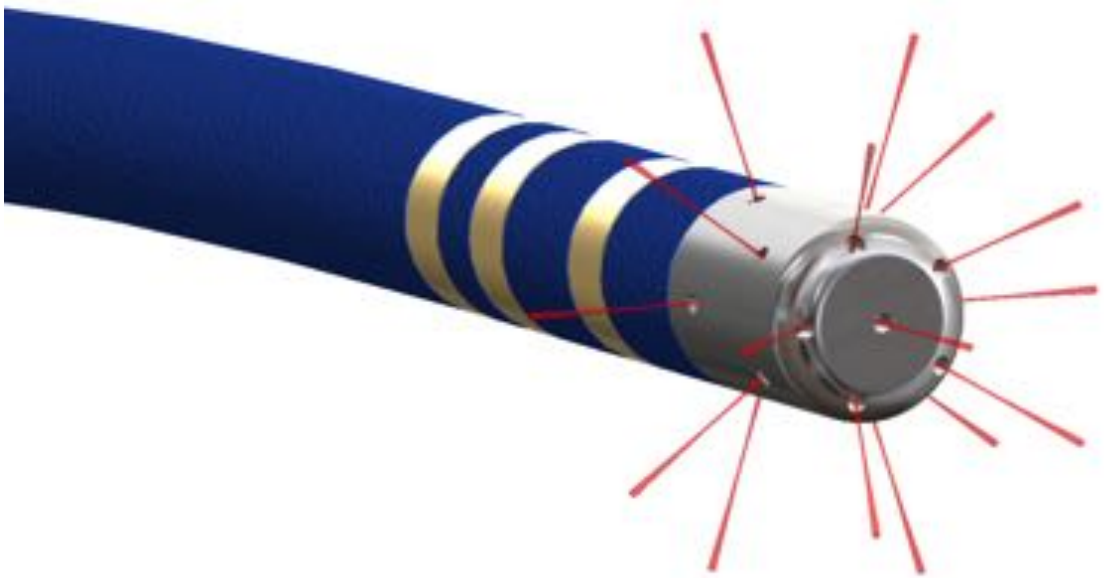
Outlook



- Develop 15 beam irrigated catheter for clinical use
- Improve and validate lesion model *in vivo*
- Validate creation of continuous lesions *in vivo*
- Clinical studies with optically guided RF Ablation
- Analyse ability of catheter to detect local fibrosis

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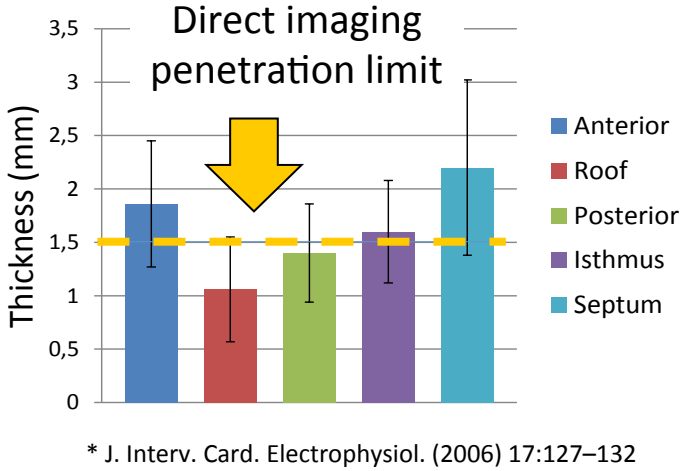
Imaging Depth & Wall Thickness

Adequate depth for patient safety

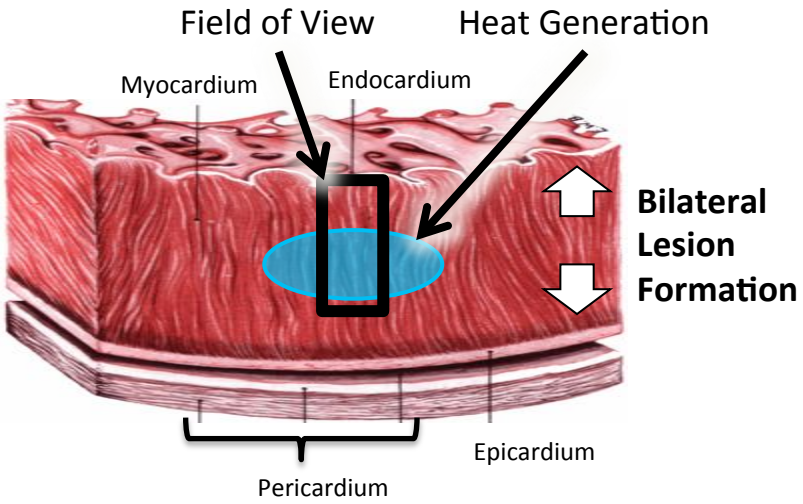
- Maximum imaging depth is ~1.5mm.
- Atrial walls are thinner than this in average, except for anterior and septum areas.
- Roof walls, which are most vulnerable, can be fully imaged with complete lesion control.
- Posterior walls, with irregular thickness and close to aesophagus, are also within reach.
- Key info to prevent atrioaesophageal fistula and tamponade available.



* J. Interv. Card. Electrophysiol. (2006) 17:127–132

Sufficient information to ensure transmurality in thick walls

- Even in septum 75% of average wall visible.
- Bilateral lesion growth: thermal model can extend imaging with good reliability.



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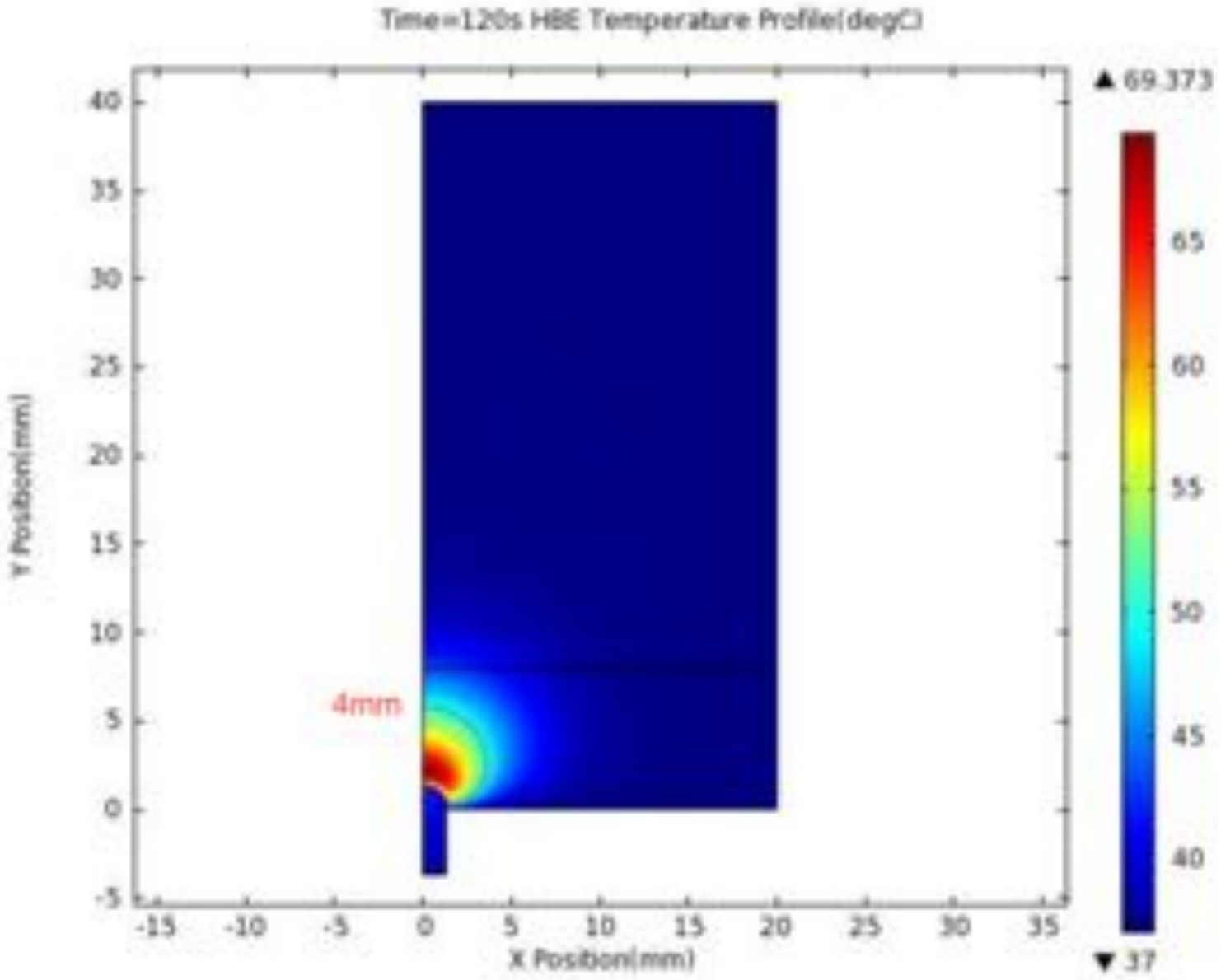

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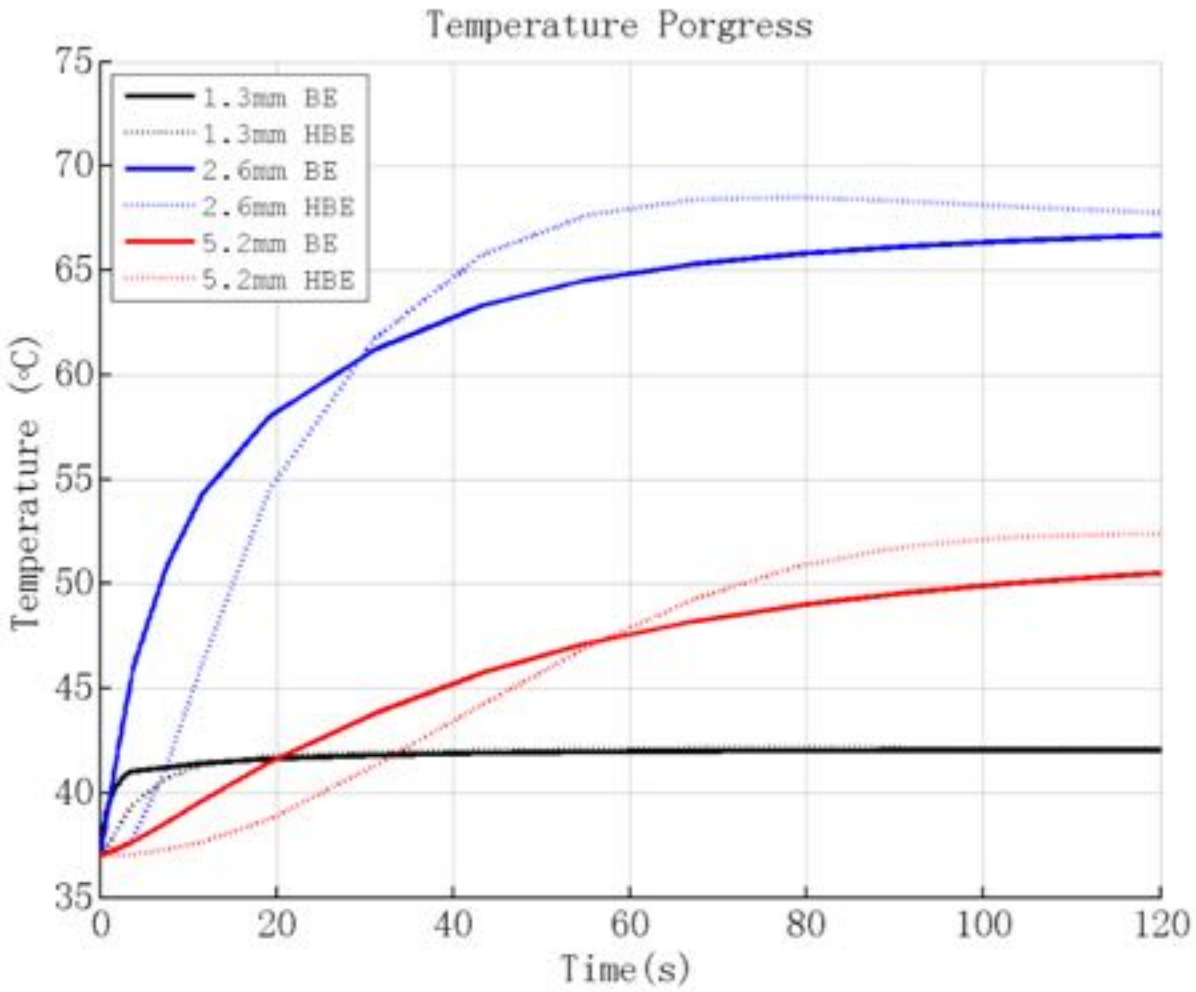
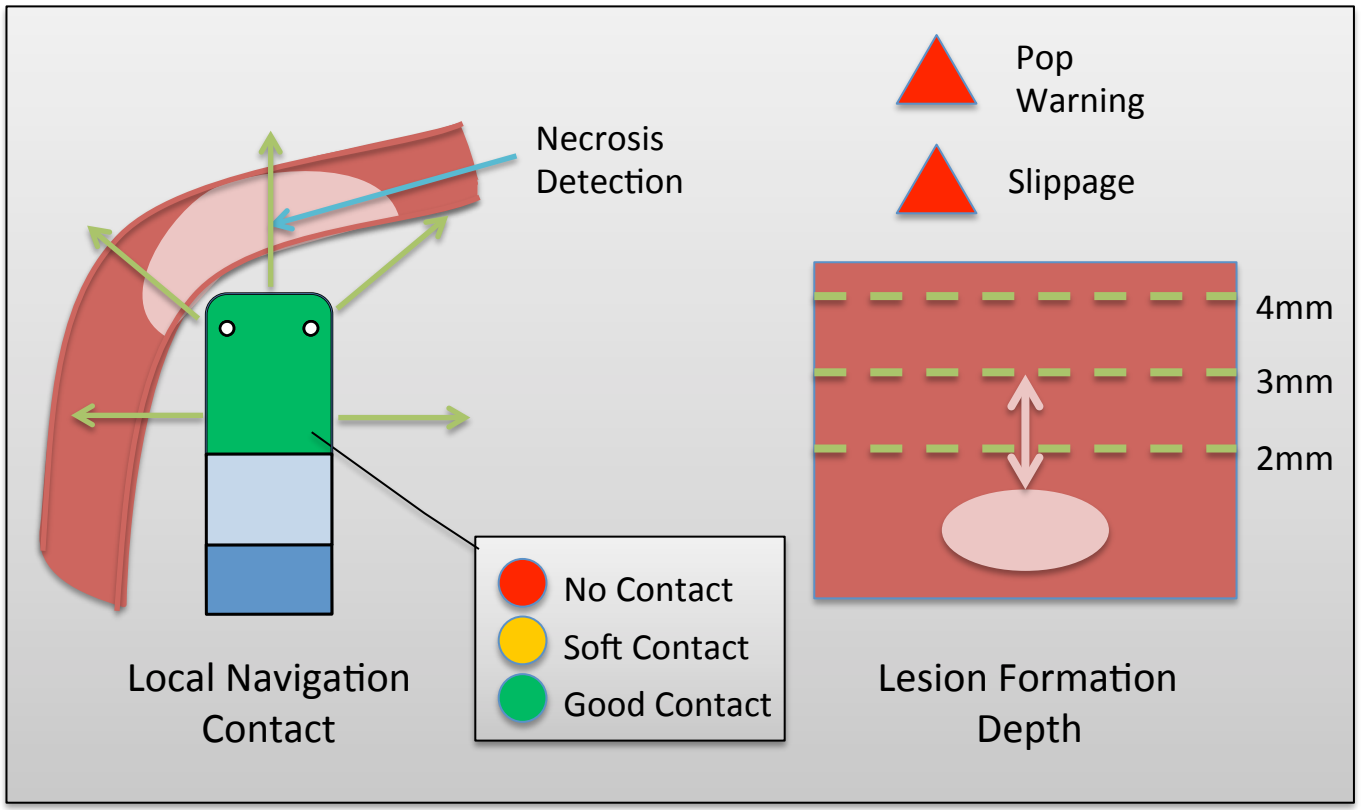


Full view of local environment



- Realtime 3D cath environment: walls, blood, thin regions, …
- Display of previous necroses
- Contact assessment

- Warning for pop & slippage
- Live estimation of ablation depth.
- Targetted lesion size

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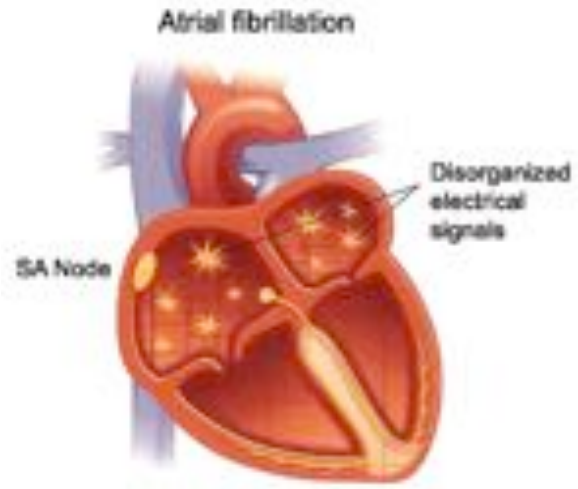
Atrial Fibrillation: Unmet Clinical Need



A life-threatening disease

- Increased risk of death and stroke.
- Lower exercise capacity, palpitations, fainting.
- Cognitive decline, higher risk of dementia.

A global epidemic

- AF affects 2% of population, 10% after 60.
- Number of patients driven by life-style diseases, like obesity, and an aging population: ~10M patients 2025 US.
- >$1B/yr. market for paroxysmal AF alone.

Insufficient therapy options

- Drugs are not effective for many patients, with >50% refractory after 1 year.
- Anti-arrhythmic therapies imply serious risks and side-effects.
- Catheter ablation suffers from recurrence, long interventions and patient safety problems.

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