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

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 (69.8°C)

Polarization Sensitive Optical Coherence Reflectometry
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)
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°
Catheter Stability
Lesion Assessment
Model of Deep Lesions

- 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.
Robust with Respect to Angle

90°

70°
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).
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
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.

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.
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
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.