EPD TECHNOLOGY
A NEW PARADIGM FOR INTRACARDIAC MAPPING

Larry A Chinitz MD FACC FHRS
Benjamin and Coyle Family
Professor of Medicine and Cardiac Electrophysiology
Director, Cardiac Electrophysiology
Clinical Director, Leon Charney Division of Cardiology
NYU Grossman School of Medicine
DISCLOSURES

• Speaker Honoraria / Consultant
  Medtronic, Biotronik, Biosense Webster, Abbott, Boston Scientific, Pfizer, Phillips

• Research Support
  Biosense Webster, Medtronic, Phillips
Challenges with Electroanatomic Mapping For RF ABLATION

- Accurate Real Time Acquisition of Cardiac Geometry; Eliminate need for preprocedural imaging
- Dynamic Imaging of Cardiac Motion; Eliminate problems with catheter movement related to mechanical systole, breathing or thoracic impedance shifts
- Localization of ANY Catheters or Wires in the Heart
- Characterization of Ablated tissue, Tissue Thickness, and Transmurality
- Electrophysiologic identification of voltages and potentials
- Arrhythmogenic indices
- Eliminate flouroscopy
Limitation of Current Technology

X-Ray imaging
- Simple with device tracking
- Difficult to interpret
- Radiation and contrast agent with no insight on tissue characteristics

3D mapping
- 3D, easy to interpret
- Minimum need for X-ray or contrast agent
- Inferred anatomy with no insight on tissue characteristics / Tx impact

ICE
- Real time without radiation or contrast
- Tissue characteristics with device tracking
- Additional venous sheath required

Remaining Challenges
- Complex workflows, long procedure times
- Up to 40% of AF Ablations must be redone (after 12 months)¹
- Difficult to further reduce X-ray exposure and contrast agent usage

Facilitating RFA via Dielectric-based Tissue & Lesion Imaging (TLI)
Radiofrequency Ablation 2020

Marked edema formation

Erroneous interpretation of Electrical Isolation Test

Unknown exact Wall Thickness

Relying solely on surrogate measurements

Suboptimal applied ablation parameters

Suboptimal execution of ablation plan

Using currently available RFA → too many gaps are still being left behind

![Bar chart showing durability (%) for different ablation studies and measurements.](chart.png)
Acute enhancement of necrotic radio-frequency ablation lesions in left atrium and pulmonary vein ostia in swine model with non-contrast-enhanced T1-weighted MRI
The potential of Tissue Imaging

Real-time

**Wall Thickness**

Optimal tailored applied RF ablation parameters

Real-time

**Tissue Pressure**

Affordable safe & effective RFA

Real-time

**Lesion Visualization**

Monitoring RFA process & immediate acute gap detection

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**Actionable tissue-based measurables**

Educated decision making

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Optimal execution of planned RFA Tx

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Improved immediate & long term outcome
Early evidence of clinical potential

**DURABLE-I**

(2016-2018, ClinicalTrials.gov identifier: NCT02878213)

(Wei Dielectric Unravelling of Radiofrequency ABLation Effectiveness)

- Single center
  (Meshalkin Institute, Novosibirsk)
- Non-randomized
- 36 consecutive PAF patients
- CARTO®3-guided conservative PVI using SMARTTOUCH® catheter
- Lesion dielectric characteristics recorded concomitantly
- PVI durability fully validated by both electrical and Adenosine tests
- Revisited, by the same operator, 1-month post-ablation...
- Long term 24-month follow up

- Patients with gaps – 27 (75%)
- Durability – 25%
- Gaps/patient – 2.64 ± 1.96
- Gaps – 61 (3.3% of ablation pairs)
- Dielectrics detected gaps in 18 out of 27 pts

- The rate of durable, contiguous and permanent PVI, could potentially reach 75% (3-fold increase of success rate)
- AF did not recur in any of the patients who had durable PVI at 1-month
Enhanced 3D anatomy
With detailed cardiac structures in one overview (PANO view)
Very Relevant to RF Ablation

All relevant structures in one unified view
See detailed anatomical variations to help in ablation planning
Reduced need to constantly manipulate or edit the image
NYU Experience
Anatomic Variability
NYU Experience
Anatomic Variability
LAT mapping and voltage mapping capabilities

Images courtesy of Prof. K-H. Kuck and Dr. T. Maurer, Asklepios Klinik St. Georg, Hamburg, Germany
NYU Experience
Right Atrial Flutter
NYU Experience
Right Atrial Flutter
NYU Experience
Atrial Flutter Ablation
Smart dielectric interrogation of tissue – Wall Thickness

- Feasibility of measuring thickness of RA and LA wall confirmed in Research setup
- Excellent correlation of KODEX-EPD measurement and CT-based measurement demonstrated
- Wall thickness measurement may support definition of optimal lesion sets to

Early-clinical: N=20 PAF patients, CT vs. Dielectric-sensing
Smart dielectric interrogation of electrode-tissue interface – Tissue Pressure

All Electrodes are both Transmitters and Receivers

*TAP irrigated ablation catheter
Dielectric-based Gap Detection

In-vitro

Non-transmural 3.5 mm gap

2 mm physical gap (skipped ablation)

Pre-clinical

Transmurality

Closing the Gap
Research: Real-time therapy assessment
Feasibility of RF lesion transmurality / contiguity

Left PVI line (Hamburg 4.7.2017) using ThermoCool® catheter

- Pink spheres = design line
- Green spheres = transmural ablations
- Green lines = contiguity
- Red lines = gap
Electroporation and its Relevance for Cardiac Catheter Ablation

Fred H.M. Wittkampf, PHD, René van Es, PHD, Kars Neven, MD, PHD

Irreversible electroporation can be used as a nonthermal energy source to ablate tissue. Cardiac catheter ablation by irreversible electroporation may be a safe and effective alternative for thermal ablation techniques such as radiofrequency or cryoablation. Total applied current, not delivered power (watts), energy (joules), or voltage, is the parameter that most directly relates to the local voltage gradient that causes electroporation. Electroporation can be achieved with various modalities: direct current, alternating current, pulsed direct current, or any combination of these. Experimental cardiac and noncardiac studies have demonstrated tissue specificity with survival of arteries and nerves in large lesions. In addition, porcine data suggest that application inside a pulmonary vein does not lead to pulmonary vein stenosis and that the esophagus is remarkably insensitive to electroporation. Therefore, irreversible electroporation is a very promising technique for cardiac catheter ablation and especially for electrical pulmonary vein isolation.

(J Am Coll Cardiol EP 2018;4:977–86) © 2018 by the American College of Cardiology Foundation
PFA Spares Vessels and Nerves
Ablation of Atrial Fibrillation With Pulsed Electric Fields

An Ultra-Rapid, Tissue-Selective Modality for Cardiac Ablation

Vivek Y. Reddy, MD, Jacob Koruth, MD, Pierre Jais, MD, Jan Petru, MD, Ferdinand Timko, MD, Ivo Skalsky, MD, Robert Hebele, MD, Louis Labrousse, MD, Laurent Barandon, MD, Stepan Kralovec, Moritoshi Funosako, MD, Boochi Babu Mannuva, MD, Lucie Sediva, MD, Petr Neuzil, MD, PhD

ABSTRACT

OBJECTIVES The authors report the first acute clinical experience of atrial fibrillation ablation with PEF—both epicardial box lesions during cardiac surgery, and catheter-based PV isolation.

BACKGROUND Standard energy sources rely on time-dependent conductive heating/cooling and ablate all tissue types indiscriminately. Pulsed electric field (PEF) energy ablates nonthermally by creating nanoscale pores in cell membranes. Potential advantages for atrial fibrillation ablation include: 1) cardiomyocytes have among the lowest sensitivity of any tissue to PEF—allowing tissue selectivity, thereby minimizing ablation of nontarget collateral tissue; 2) PEF is delivered rapidly over a few seconds; and 3) the absence of coagulative necrosis obviates the risk of pulmonary vein (PV) stenosis.

METHODS PEF ablation was performed using a custom over-the-wire endocardial catheter for percutaneous transseptal PV isolation, and a linear catheter for encircling the PVs and posterior left atrium during concomitant cardiac surgery. Endocardial voltage maps were created pre- and post-ablation. Continuous and categorical data are summarized and presented as mean ± SD and frequencies.

RESULTS At 2 centers, 22 patients underwent ablation under general anesthesia: 15 endocardial and 7 epicardial. Catheter PV isolation was successful in all 57 PVs in 15 patients (100%) using 3.26 ± 0.5 lesions/PV; procedure time...
KODEX-EPD

- Dielectric imaging is an exciting new imaging approach with the potential to address several limitations of existing cardiac mapping tools.
- True accurate tissue sensing (Non Contact) representing the structural characteristics of the myocardium, valves, and vessels.
- Thickness, Scar, Ablated tissue, Transmurality, Gaps
- Visualization of all intracardiac catheters in 3D
- Contact Sensing with Any Catheter