

# Optical Contact and Lesion Assessment (OCALA) During Atrial Mapping

## A First-in-Human Proof of Concept Study



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### BACKGROUND

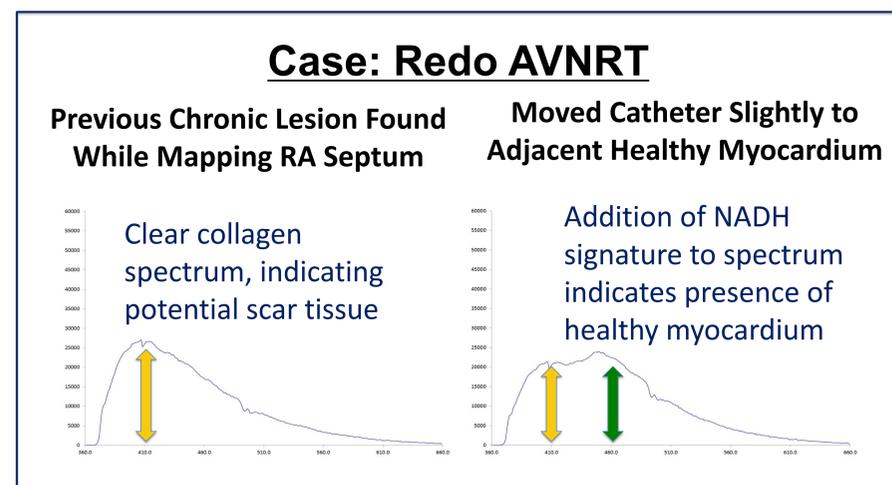
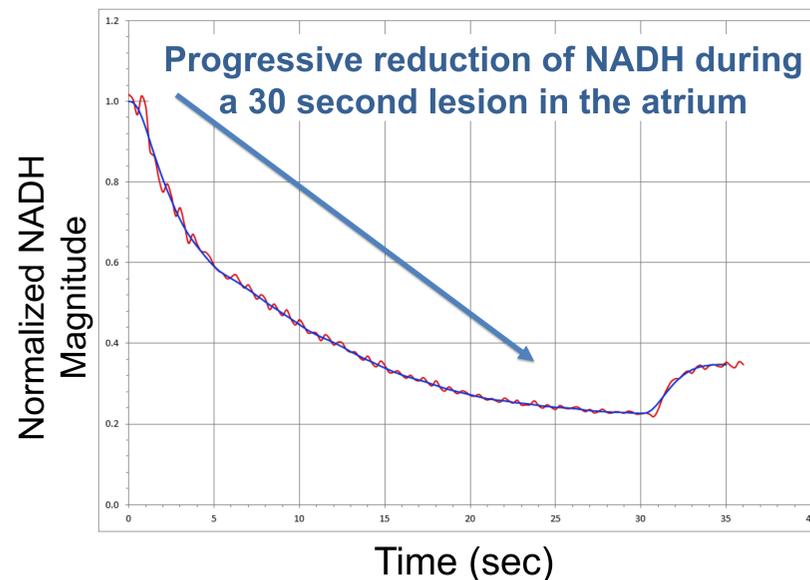
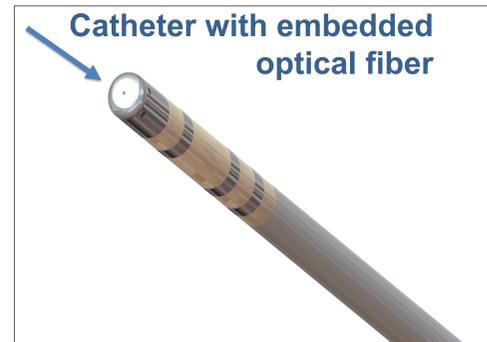
Real time *in vivo* visualization of tissue ablation has not been clinically possible. Pre-clinical data has revealed a relationship between lesion formation and reduction of endogenous fluorescence of mitochondrial NADH – indicating cell death.

### OBJECTIVE

In a first-in-human trial, we used a proof of concept catheter able to detect NADH to identify both tissue contact and tissue destruction.

### METHODS

- OCALA was a single-center study in 11 pts undergoing atrial ablation (with IRB & Regulatory approval).
- An off-the-shelf irrigated-tip catheter (Celsius Thermocool, Biosense-Webster) was modified with a quartz fiber through which a 355nm laser could illuminate tissue, and a spectrometer could analyze the resulting myocardial fluorescence.
- Imaging was only possible with this first-generation catheter in a near-perpendicular orientation to tissue, as it is only forward-looking. RF ablation was performed under x-ray/electroanatomic guidance.
- The spectral content of the fluoresced light (450-470 nm) was recorded from the initiation of tissue contact until the end of ablation.



### RESULTS

- In 11 patients, 189 lesions were made. Of these, 25 (RA-19, LA-6) were “imaged” for contact and lesion progression.
- We successfully demonstrated the ability to assess tissue contact in all 25 recordings by detecting NADH fluorescence from the viable tissue immediately under the catheter tip.
- Optical assessment of electrode tissue contact was verified successfully by ultrasound imaging in all patients.
- The mean RF power for the 25 applications was 29W (range 20-40W) and mean duration was 24.7 seconds (range 6-54 seconds.)
- The mean reduction in NADH spectral content average was 53.3 +/- 15% (range 28-90%).
- There were no complications.

### CONCLUSION

This is the first successful *in vivo* real-time optical detection of catheter contact and tissue injury during RF catheter ablation.

Future studies will require a dedicated catheter with the capacity for optical interrogation regardless of catheter orientation relative to the tissue.