

Safety Using Novel Multi-Array Catheters and Phased Radiofrequency Energy in Left Atrial Ablation for Chronic Atrial Fibrillation

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PROTOCOL

INTRODUCTION

Widespread adoption of radiofrequency catheter ablation (RFCA) of chronic atrial fibrillation (CAF) has been limited by technical challenges, procedural risk and low efficacy. This U.S. pilot study was designed to evaluate the safety of multi-array mapping and ablation catheters combined with low power phased radiofrequency energy for RFCA of CAF.

SCREENING CRITERIA

- Symptomatic CAF lasting greater than seven (7) days but less than four (4) years with at least one failed DC cardioversion within the previous two years
- Age between 18 and 70
- Failure of at least one class I or III rhythm control AAD
- LAD \leq 55 mm
- LVEF \geq 40%
- No previous left sided AF ablation
- No history of stroke or TIA
- No structural heart disease including:
 - PFO closure
 - Hypertrophic cardiomyopathy
 - Pulmonary hypertension
 - Recent MI or ongoing myocardial ischemia

ENDPOINTS

ACUTE SUCCESS: antral isolation of all PVs, elimination of complex fractionated atrial electrograms (CFAEs) and restoration of sinus rhythm at the end of the procedure

CHRONIC SUCCESS – Absence of AF or AT assessed with a continuous 48 hour Holter monitor at six months post procedure

TECHNOLOGY

MULTI-ELECTRODE ABLATION CATHETERS

- **Pulmonary Vein Ablation Catheter [PVAC]:** adjustable, helical, 10-electrode catheter for mapping and antral ablation around PV
- **Multi-Array Septal Catheter [MASC]:** 3-arm, 12 electrode catheter for mapping & ablating septal CFAEs
- **Multi-Array Ablation Catheter [MAAC]:** 4-arm, 8 electrode catheter for mapping & ablating LA free wall CFAEs



PVAC



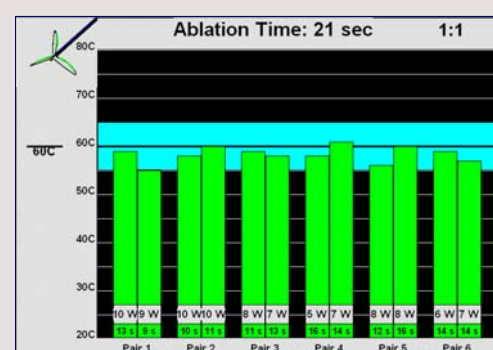
MASC



MAAC

MULTI-CHANNEL RF GENERATOR

- **Selective RF Energy Delivery:** User defines target temperature, ablation time, energy mode and electrode pairs to be ablated
- **Temperature Controlled and Power Limited:** Electrodes have individual thermocouples & RF circuit
- **Control Lesion Depth:** Bipolar:Unipolar energy modes allow for depths between 3mm & 7mm



METHODS and RESULTS

METHODS

- Suggested lesion set
 - Antral isolation of all PVs [PVAC]
 - CFAE ablation on septum [MASC]
 - CFAE ablation LA roof, floor and LAA ridge [MAAC]
- AADs discontinued before 3 months
- Second procedure for recurrent AF encouraged (reset follow up)
- 48 hour Holter-success if no AF or AT >30 seconds
- Safety measurement with CT/MRI, symptom severity surveys and recording of all adverse events

RESULTS

- **PROCEDURE**
 - 31 procedures completed in 20 patients
 - First use for all 12 operators
 - Age 57 ± 8 years
 - Follow Up 158 ± 30 days
 - 11/20 (55%) required two ablations
- **SAFETY:**
 - No Severe Adverse Events (SAE's)
 - Procedure and follow up AEs
 - TIA 6 days status post ablation
 - Groin hematoma (2)
 - Throat pain from TEE (1)
 - Generalized muscular skeletal pain (3)
- **EFFICACY**
 - 30/31 (97%) procedures with acute success
 - 8/11 (73%) with chronic success off AADs

CONCLUSIONS

First use experience with anatomically specific multi-array catheters in conjunction with phased radiofrequency energy for ablation of chronic atrial fibrillation demonstrated an acceptable safety and efficacy profile allowing for advancement to a pivotal clinical trial.