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Early Feasibility Study for Cardiac Radiosurgery: Evaluation of Novel 3-D Treatment PlanningSoftware and Safety Data on First Three Patients

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Objectives: Cardiac radiosurgery

to treat ventricular tachycardia is being evaluated in an IDE approved Early Feasibility Study. Our objective was

to evaluate proprietary 3-D software for contouring of myocardial ventricular targets and review three-month

safety data on the first three patients. Methods: A cardiac electrophysiologist contoured ablation targets in the left

ventricle using proprietary cardiac treatment planning software. The target data was imported into the

radiosurgical treatment planning software and the radiosurgical team created the treatment plans with a target dose

of 25 Gy. A margin was placed on the targets and critical structures to allow for cardiac motion (assessed in a

cardiac, four-dimensional CT). Plans were judged deliverable based on efficacy (assessed through target

coverage) and safety (assessed through dose to critical structures). The radiosurgical team delivered the treatment

plans with a robotic radiosurgical system. Stereotactic x-ray images of a cardiac pacing lead placed temporarily in

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the right ventricle were used to align the patient in the radiosurgical system. This lead was also used for tracking

respiratory motion of the heart. Results: The proprietary 3-D contouring software was used adjunctively by the

electrophysiologist. In all treated subjects, the proprietary software enabled the initial definition of the target based

on a 3-D rendering of the cardiac surface. All three treatments were developed and delivered as planned, with

treatment volume 153.2+/-49.7cc, treatment time 89.3+/-2.5min. Conclusion: In this first FDA approved Early

Feasibility Study for the treatment of ventricular tachycardia with stereotactic radiosurgery, three patients

completed three-month follow-up as of June 9, 2018. There have been no deaths and no unanticipated serious or

non-serious adverse events, with close clinical follow up and imaging. Efficacy at three months cannot be

adequately assessed, and will be evaluated in the future.