Magnetic Resonance Imaging-guided Focused Ultrasound ablation procedure of facet joint of patient with MRI non-conditional pacemaker

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Introduction

Magnetic Resonance Imaging-guided Focused Ultrasound (MRgFUS) is a minimally-invasive thermal treatment modality that utilizes a phased-array ultrasound transducer embedded inside the MRgFUS patient table integrated with the MRI scanner. During MRgFUS treatment, ultrasound energy is selectively focused within target tissues causing localized thermal ablation.

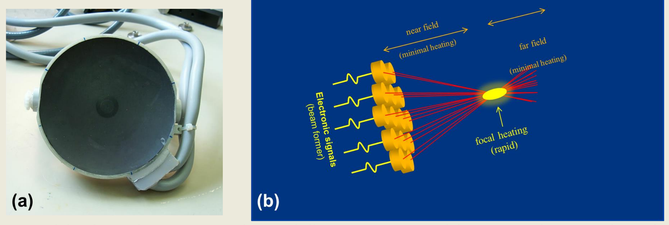

Figure 1: (a) Phased array transducer delivers energy and heats up tissue *only* at focal spot. This 1MHz transducer has five degrees mechanical of motion (3 translational, 2 angular) and (b) Schematic of electronically steering used to adjust the focal spot location and angle

MRI is used for treatment planning, guidance of the US beam, real-time MR-thermometry and for treatment assessment [1]. MRgFUS systems have been successfully used to treat a variety of conditions, such as symptomatic uterine fibroids [1-2], essential tremor [3], and facet joint pain [4]. Facet joint treatments in our practice employ the ExAblate 2100 MRgFUS system (Insightec, Haifa, Israel) integrated with a 60 cm bore 1.5T MR scanner (Signa Excite, General Electric, Waukesha , WI). Facet joint MRgFUS is a relatively new treatment for facet joint pain[4], this procedure has the advantage of not requiring skin incision, and employs MRI for treatment planning and monitoring of the ablation in the real-time.

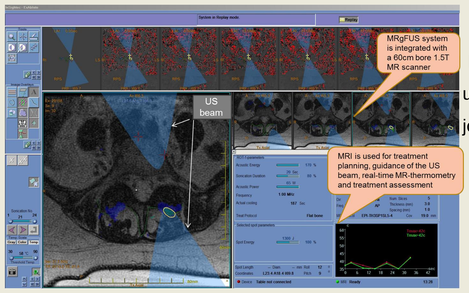

Figure 2: ExAblate 2100 system user interface for lumbar facet joint treatment

However, the use of MRI can pose significant safety challenges for patients with cardiac implantable electronic devices (CIEDs), such as pacemakers or defibrillators, potentially excluding them from treatment. Presently, there has only been one other case report of MRgFUS treatment, of essential tremor, in a patient with implanted MRI-conditional pacemaker [5].

Purpose: This study describes an MRgFUS ablation of lumbar facet joints in a patient with implanted MRI *non-conditional* pacemaker.

Disclosures: MRgFUS use for facet joint treatment is an off-label use in the United States.

Methods

Clinical Presentation

- 80 year old male with history of chronic axial lower back pain.
- The patient's past medical history was significant for coronary artery disease, hypertension, and symptomatic sinus bradycardia (50 bpm and 2:1 block), which led to placement of a dual chamber transvenous pacemaker system in 2015 (Assurity DR 2240 pulse generator, Model 1642T right atrial lead, Model 1646T right ventricular lead, all ***MRI non-conditional***, St Jude Medical, Memphis, TN). The patient was not pacemaker-dependent.
- Prior to the MRgFUS treatment, a risk-benefit analysis was carried out given the MRI non-conditional CIED system, and the decision was made to proceed with treatment. The risk-benefit analysis was performed in accordance with our established CIED/MRI practice procedure, which has been used to safely scan over 3000 patients for diagnostic indications [6]. This practice involves a coordinated team of radiologists, cardiologists, MRI physicists, cardiology pacing nurses, and MRI technologists.
- Listed below are our **institutions established** CIED/MRI practice procedures which had to be modified to account for the specific requirements of the MRgFUS treatment. Where the procedure remained the same ***"Yes"*** is indicated and where it needed to be altered ***"No"*** is indicated.
  - Cardiology pacing nurse present for entire procedure. Programs the pacemaker to DOO* mode of 80 bpm prior to treatment — Yes
    *(dual chamber, absence of sensing with no response to sensed input)
  - Patient positioned on MR table outside of the scanner room and subsequently transferred into scanner room where the table is docked to MR scanner — NO

  → this was not possible for this MRgFUS Procedure for 2 reasons:

  1. Following completion of pre-treatment quality assurance (QA) testing of MRgFUS system the table needs to remain docked to the MR scanner (undocking would necessitate repeating the QA)
  2. Prior to start of the treatment (with the patient positioned on the table) the FUS transducer has to be registered within coordinates of the MR scanner which requires automatic execution of MR sequences with the whole body SAR of 1.73 W/kg, exceeding our practice safety limit of 1.5W/kg

  - transducer calibration scans were performed on the QA phantom — NO
  - the patient was walked slowly into the MR scanner room and was guided into the feet-first supine position with his back located above the transducer, the table was then slowly advanced to isocenter — NO
  - the cardiology nurse continually monitored electrocardiography, pulse oximetry, and blood pressure — Yes
  - all MRI was performed in the *Normal scan* mode — Yes
  - Physics assisted the MRI technologist in adjusting *sequence parameters* to limit whole-body SAR to 1.5 W/kg (as verified by real-time SAR monitor) — Yes

Results

Pre-planning sequences acquired in axial, sagittal and coronal planes with SAR of <1.2 W/kg for each sequence (Table 1). This was achieved with adequate image quality

Procedure time was 2½ hours with 22 individual sonications (treatment doses 40-60 W)

Treatment was monitored in axial plane using real-time MR thermometry with 6s temporal resolution (SAR < 0.01 W/kg)

- **Vendor recommendation is to use First-level controlled mode for MR thermometry, which was not possible in this case. Upon testing using multiple sonications in a phantom, the quality of MR thermometry acquired in the N*ormal mode* was comparable to that of *1st level mode***
- *Post-treatment T2-weighted sequence* with fat suppression was acquired to assess treatment effects (edema) around treated joints (SAR <1.12W/kg). This was achieved with adequate image quality

Results

Table 1: Details of MR sequences and image acquisition that were used during the MR guided focused ultrasound ablation procedure and the corresponding whole-body SAR values for each image sequence

Sequence	Purpose	Whole Body SAR (W/kg)
Single-shot fast spin echo pulse sequence (TE/TR, 126/2108msec; ETL, 16; FA,90°; NEX,1; slice, 6mm; skip, 1.5mm; FOV, 440mm; BW, 31KHz; Matrix, 256 x 224 mm²)	Calibration –Transducer localization in MRI coordinates – PERFORMED USING QA PHANTOM	1.73
3D-Localization T2 (TE/TR, 1.42/4.98msec; ETL, 1; FA,30°; NEX,1; slice, 7mm; skip, 12mm; FOV, 440mm; BW, 244Hz/px; Matrix, 256 x 224 mm²)	Anatomical reference images of treatment areas for MRgFUS treatment planning	0.26
Fast spin echo sequence - Axial T2 (TE/TR, 81/3400msec; ETL, 10; FA,90°; NEX,1; slice, 3mm; skip, 3mm; FOV, 160mm; BW, 122Hz/px; Matrix, 256 x 192mm²)	Pre-ablation planning images	1.13
Fast spin echo sequence - Sagittal T2 (TE/TR, 81/4200msec; ETL, 12; FA,90°; NEX,1; slice, 3mm; skip, 4mm; FOV, 200mm; BW, 81.4Hz/px; Matrix, 256 x 224 mm²)	Pre-ablation planning images	0.95
Fast spin echo sequence -Coronal T2 (TE/TR, 1.42/4.98msec; ETL, 1; FA,30°; NEX,1; slice, 3mm; skip, 3mm; FOV, 440mm; BW, 244Hz/px; Matrix, 256 x 224 mm²)	Pre-ablation planning images	0.94
Echo Planar Imaging- Gradient Echo (phase-sensitive gradient-recalled echo sequences) - Axial (TE/TR, 18/250msec; ETL, 1; FA,35°; NEX,2; slice, 3mm; skip, 1mm; 5 slices; BW, 62kHz)	Thermal mapping of the treatment zone	0.01
Fast spin echo sequence with fat suppression - Axial T2 (TE/TR, 40/4701msec; ETL, 15; FA,90°; NEX,1; slice, 3mm; skip, 3mm; FOV, 160mm; BW, 122Hz/px; Matrix, 320 x 192 mm²)	Post Procedure evaluation	1.12

Discussion

- We report a first case of MRgFUS ablation of lumbar facet joints in a patient with refractory low back pain and MRI non-conditional pacemaker.
- More than 1.8 million people in the United States have pacemakers or implantable cardioverter defibrillators [7]. Facet joint degenerative changes and pain often occur in older demographics, including those with confounding cardiac morbidities, including a substantial number with CIEDs.
- Therefore, an appropriate risk-benefit analysis for such cases is of paramount importance. CIEDs from multiple manufacturers have been specifically engineered and are labeled as MRI-conditional.
- The key to this MRgFUS case was the successful integration of the existing CIED / MRI practice to this interventional procedure.
- In this present case study, the patient maintained stable vital signs and cardiac function throughout the procedure and there were no changes in pacemaker function or in pacing threshold post MRgFUS facet joint ablation.

Conclusions

This study reports a successful MRgFUS lumbar facet joint ablation in a patient with an MRI non-conditional pacemaker. By careful use of our MRI CIED protocol [6], we demonstrated that the MRgFUS ablation treatment of facet joints can be performed, and going forward can be offered to patients with CIEDs on a case-by-case basis.

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