Pain palliation in patients with bone metastasis using MR-guided focused ultrasound with conformal bone system: A preliminary report

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<u>Title:</u> Pain palliation in patients with bone metastasis using MR-guided focused ultrasound with conformal bone system: A preliminary report

<u>Introduction:</u> MR-guided Focused Ultrasound (MRgFUS) with conformal bone system (CBS) integrates new features that were developed for the bone application. The system to be used in this study utilizes new software, a conformal transducer and patient interface that increases coupling by using a cooled porous membrane that in turn enhances safety. However, there has been no report about the safety and effectiveness of the CBS for pain palliation in patients with bone metastasis. The goal of this prospective, non-randomized, single-arm study is to evaluate the safety and effectiveness of this treatment using this ExAblate CBS in the treatment of pain resulting from metastatic bone tumors.

Methods: This study was performed as part of a clinical trial titled "Study to Evaluate the safety and Initial Effectiveness of ExAblate MR Guided Focused Ultrasound Surgery in the Treatment of Pain Resulting from Metastatic Bone Tumors with the ExAblate 2100 Conformal System: Feasibility Study". Five patients with painful bone metastases underwent the MRgFUS with CBS procedure in one institution. Treatment safety was evaluated by assessing the device-related complications. Effectiveness of pain

palliation was evaluated using the visual analog pain score.

Results: Six procedures were performed in five patients. Mean follow up time was 3.3months. One patient reported complete response in pain relief. Average VAS score was reduced from 5.8 prior to treatment to 0.8 at 3 months post treatment. One patient had second degree skin burn.



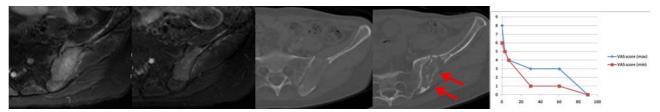


Fig 1. A patient with breast cancer. (A) MRI on pretreatment. (B) MRI on 90 days after treatment. The size of the enhancing mass has been decreased, especially right to left diameter. (C) CT on pretreatment. The lesion shows totally osteolytic. (D) There was new bone formation(arrows) after 90 days. (E) VAS score on 90 days after treatment was 0. After treatment, her hip joint rotation became free and the average walking distance per day was 4 km. There was no complication.



Fig 2. A patient with renal cell cancer. (A) MRI on pretreatment shows hypervascular metastasis on humerus from RCC. (B) MRI on immediate after treatment shows linear nonperfused area (arrow) on the lateroposterior aspect of the mass. (C, D) One day after treatment, there were 2nd skin burns on the opposite side of the transducer. During the treatment, the temperature didn't go up to the therapeutic level with the usual energy and we used higher energy.

<u>Conclusion:</u> MRgFUS with CBS is effective for pain palliation in patients with bone metastasis. Regarding safety issues, there were two suspected adverse event. Further study is needed to resolve this complication.

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