

Safety and Effectiveness of Sacroiliac Joint Palliation in Swine using MRgFUS

Six-month Progress Report

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The overall objective of this research project is to assess the safety and effectiveness of sacroiliac (SI) joint palliation in 9 farm pigs. We hypothesized that MRgFUS is a safe and effective tool for palliative treatment of lower back pain by denervation near the sacroiliac (SI) joints. In order to test our hypothesis, we have proposed 2 Specific Aims:

AIM 1: To determine the safety of MRgFUS palliation of the SI joint in 9 swine. To this end, 9 swine will be treated and followed longitudinally over a period of 5 (8 animals) or 12 (1 animal) weeks to assess recovery after treatment. All animals will be imaged pre-sonication, directly post-sonication and after 5 or 12 weeks post-sonication.

Aim II: To determine the effectiveness of MRgFUS palliation of the SI joint in 9 swine. It is generally assumed that higher sonication energies result in more effective denervation of the joint. However, higher energies also result in higher risks for damage of surrounding tissues. Thus, the trade-off between safety and effectiveness needs to be established as a function of sonication energy in the same animals of Aim 1. MR and CT imaging as well as histology will be used to assess effectiveness as well as damage similar to Aim 1.

PROGRESS TO DATE

We have successfully obtained IACUC approval for this study and have started the project. To date, three animals have been treated and two more are currently scheduled. We have treated two animals using 700 Joule and 35 Watt with a sonication duration of 20 seconds and one animal with 1000 Joule and 50 Watt in 20 seconds. On each animal, seven sonication were performed on S1, 6 sonication on S2, and 3-4 sonication on S3 (see Figure 1). We have observed clear indications of HIFU treatment on T2-weighted MR images (edema) as well as delayed contrast enhanced (DCE) MR images (Figure 2). We have dissected the SI joints for histology (Figure 3). Histology is currently under way and will be performed in a batch process of 4 joints in order to reduce costs. After treatment, we have assessed pain, behavior, ambulation, and gait which did not demonstrate any signs of impairment so far. Furthermore, our lameness score was 0 in all treated cases (score 0 means that all animals stood up immediately from a lying position and moved freely in the pen with balanced weight on all four limbs. No changes in animal behavior was observed so far).

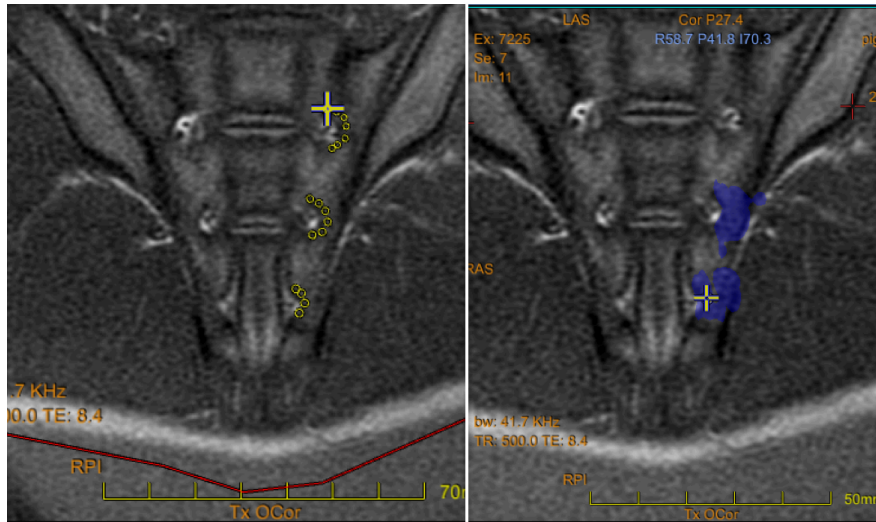


Figure 1:

Shown are the coronal planning images with the indicated sonication spots (left image) and the treatment area shown for S2 and S3 (right image).

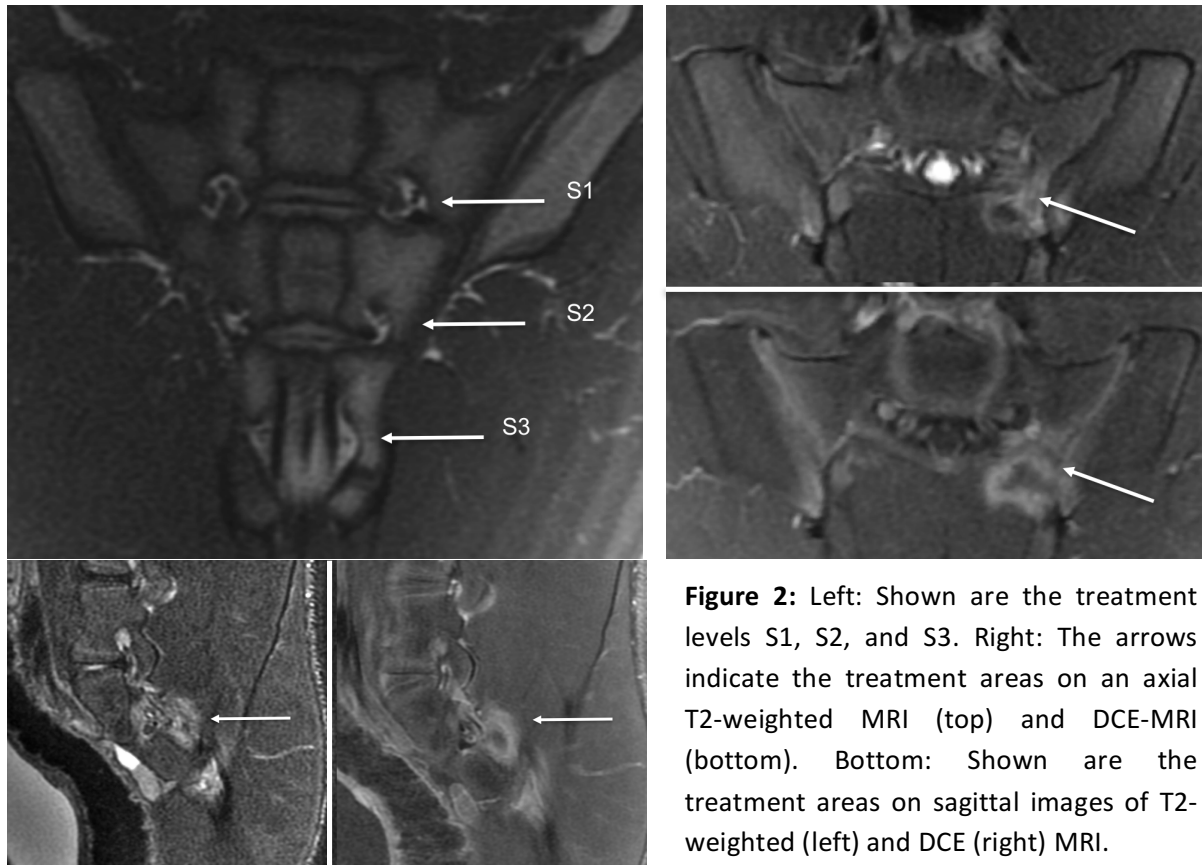


Figure 2: Left: Shown are the treatment levels S1, S2, and S3. Right: The arrows indicate the treatment areas on an axial T2-weighted MRI (top) and DCE-MRI (bottom). Bottom: Shown are the treatment areas on sagittal images of T2-weighted (left) and DCE (right) MRI.

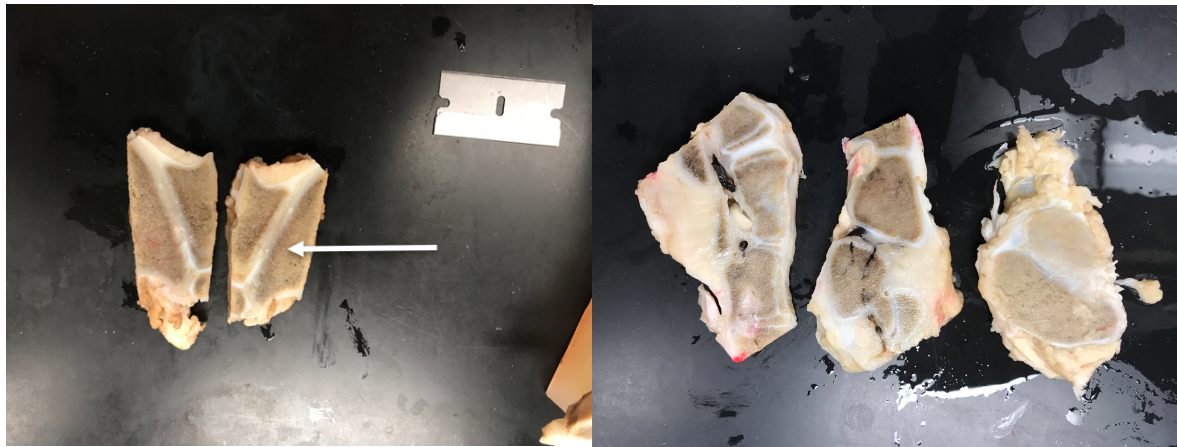


Figure 3: Shown are cuts for histology through the SI joint. Left: the SI joint is shown by the arrow. Right: Additionally, cuts through the lower spinal lumbar levels are shown.