

# MR Guided Focused Ultrasound (MRgFUS) for Treatment of Lower Back Pain

Viola Rieke, Eugene Ozhinsky, Matthew Bucknor, Vinil Shah,  
Carol Stillson, Teri Moore, Colin Yee, Ellen Liebenberg,  
Roland Krug

## HIGHLIGHTS

The goal of this research is to establish MRgFUS as a new non-invasive treatment option for lower back pain with a focus on the sacroiliac (SI) joint. The FDA required a preclinical study in a chronic swine model which was funded through the Focused Ultrasound Foundation. Here we present our results demonstrating the safety and effectiveness of MRgFUS ablation in the SI joint. We are currently seeking FDA approval for a clinical trial in patients with back pain.

## INTRODUCTION

There is evidence that MRgFUS might be a very safe and effective minimally invasive technique to treat facet and sacroiliac joint pain caused by arthritis and other degenerative changes. In contrast to radiofrequency neurotomy, MRgFUS is non-invasive, eliminates the risk of bleeding or infection, is radiation free, and can be repeated if necessary. However, due to safety concerns it has not yet been approved by the FDA. Here, we longitudinally evaluated the safety and effectiveness of MRgFUS ablation of the SI joint in a swine model.

## METHODS

Seven animals were treated with InSightec's ExAblate 2000 (in-table) system at 3T using three levels of energy (n=3 with 700J, n=3 with 1000J, n=1 with 1500J; duration=20secs at 1.35 MHz). Sonications were planned in oblique coronal slices (Fig. 1a) around the foramina targeting the lateral branches of the nerve roots. The left side of the animal was treated (Fig. 1a-c), the right side served as control. After post-treatment MR imaging (Fig.1d-e), the animals were recovered from anesthesia, assessed for pain, behavior, ambulation, and gait, followed for 5 weeks, and euthanized after a follow-up MR imaging session. The sacrum was removed (Fig. 1f) for histopathological analysis using H&E and Neurofilament 200 staining (Fig. 1g).

## RESULTS

Temperature rise was clearly seen on MR temperature mapping showing contiguous lesions along the lateral sacral branches. The ablated region was well estimated by thermal dose measurements (Fig. 1b). Treatment effects were clearly seen on baseline and follow-up MRI (Fig. 1d-e). The lesion extent depended on the applied energy. Animal assessment showed no signs of pain or impairment. H&E images clearly shows the ablated area within the targeted region. Neurofilament demonstrated the ablated nerves (Fig. 1g).

## CONCLUSIONS

This study in a chronic swine model demonstrated safety and effectiveness of MRgFUS sacroiliac joint ablation. Histological results showed treatment effectiveness through successful nerve ablation.

