

Evaluation of the impact of body mass and abdominal fat on MR-guided Focused Ultrasound Surgery for uterine fibroids

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Introduction: MR-guided Focused Ultrasound Surgery (MRgFUS) is a noninvasive treatment option for women with symptomatic uterine fibroids.^{1,2} The focused ultrasound beam, or sonication, passes through the anterior abdominal wall and can potentially be distorted by intervening fat layers, which may lead to focal aberrations and potentially cause thermal damage.^{3,4} In addition when the fat layer is thick, the focal plane must be located further from the transducer, leading to a decrease in the gain of the transducer and increase in the power level required to reach the therapeutic temperature. Increased central adiposity is associated with more bioavailable estrogen, which can stimulate uterine fibroid growth. In recent years, the Body Mass Index (BMI) of the U.S. population has been increasing. Thus, it is important to evaluate whether patients with higher BMI and thick abdominal wall fat can benefit from MRgFUS without adverse effects. We have noted in several patients treated at our institution, areas of abnormal enhancement with Gadolinium in the anterior abdominal wall fat immediately post-treatment (Fig. 1). The purpose of this study is to determine whether BMI and the anterior abdominal fat thickness affects MRgFUS treatment patterns.

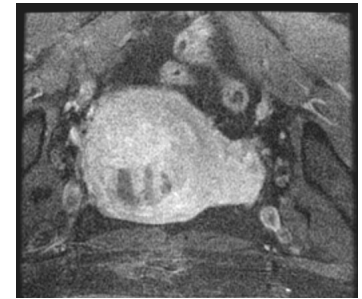


Figure 1. Post-treatment axial prone image with Gadolinium showing abnormal enhancement in anterior abdominal fat.

Methods: We are conducting a Phase III clinical trial of the Ex-Ablate 2000 system (Insightec, Inc.) for treatment of symptomatic uterine fibroids. Multiplanar T2WIs are obtained at time of treatment. Abdominal fat thickness was measured from the skin surface to the anterior surface of the rectus sheath, in the path of the FUS beam during treatment (Fig. 2). The parameters selected of the MRgFUS treatment included: treatment plane depth, rate of sonications, and the percentage of the number of sonications reaching a focal temperature greater than 55°C (%N>55°C). Treatment plane depth was calculated by the distance between the treatment pad and the center of the sonications. The rate of sonications delivered was calculated by the total number of sonications/treatment time (minutes) from first to last sonication. %N>55°C was calculated by the number of sonications reaching a temperature greater than 55°C/ total number of sonications x 100. Statistical methods used were correlation coefficient and independent samples t-test.

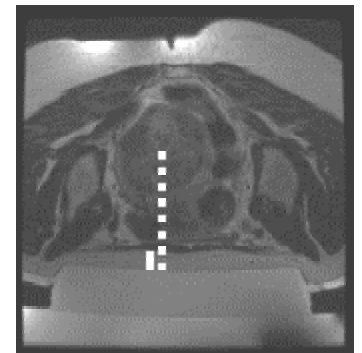


Figure 2. T2W axial prone image measuring anterior abdominal fat thickness (solid line) and treatment plane depth (dashed line).

Results: A total of 62 patients (ages 35-58 years) with 74 fibroids treated formed our study population (9 patients with 2 fibroids, 1 with 3 fibroids). Seven of 74 fibroids treated had abnormal enhancement with Gadolinium in the fat. We found that higher %N>55°C was associated with abnormal enhancement in fat compared to treatments without abnormalities (mean= 73.4, 47.5; p=0.01). BMI and abdominal fat thickness did not affect the rate of sonications delivered (r=0.10, r=0.13) or the %N>55°C (r=-0.20, r=-0.17). BMI, abdominal fat thickness, rate of sonications, and treatment plane depth were not statistically different in the 2 groups.

Conclusions: Abnormal enhancement in the fat after MRgFUS was seen in 7/74 (9%) fibroids. Higher %N>55°C was associated with these abnormalities, which were all resolved by 6 months post-treatment, except in 2 patients. No correlation with BMI and abdominal fat thickness was seen in treatments with MR enhancement abnormalities. Although the patients with MR enhancement abnormalities were asymptomatic, the association with %N>55°C suggests that further correlations such as temperature range, thermal dose, power level, and repeated thermal doses causing energy deposition, should be performed to prevent such abnormalities from occurring.

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2. Stewart, et al. Am J Obstet Gynecol 189(1): 48-54 (2003)
3. Fan et al. J Acoust Soc Am 91(3): 1727-36 (1992)
4. Hinkleman et al. J Acoust Soc Am 104(6): 3635-49 (1998)