# Therapeutic MRI-guided High Intensity Focused Ultrasound Ablation of Uterine Fibroids with Volumetric Heating Technique: Early Clinical Experience in South Korea

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## Introduction:

A recent development in the treatment of uterine fibroids is the use of magnetic resonance guided high intensity focused ultrasound (MR-HIFU), which has been tested in several clinical trials and has been approved for clinical use in several countries[1-3] In a traditional MR-HIFU treatment, a single focal point is iteratively sonicated at a time until the desired volume is ablated, with each sonication followed by a cooling period. The efficiency of this point-by-point method of ablation remains limited since a relatively large part of the energy deposited is lost via heat diffusion out of the small targeted region without being utilized for ablation.

Recently, as an alternative sonication method in MR-HIFU treatment, Köhler[4] et al demonstrated the applicability and usefulness of the volumetric sonication method under volumetric MRI thermometry in-vivo on a large animal model by comparing the resulting non-perfused volume of each sonication to the lethal thermal dose volume calculated on-line from MRI temperature maps. This method efficiently utilizes the inherent heat diffusion by electronically switching the focal point between a number of predetermined locations situated at outwards-moving concentric circles with diameters of upto 16 mm. The aim of this study was to describe our early experience using this volumetric sonication method with feedback control under volumetric MRI thermometry for the ablation of uterine fibroids.

## Materials and Methods:

**Therapy:** Full treatment was performed by stepping through several treatment cell ablations with cooling times between each sonication using a Philips Healthcare clinical HIFU platform integrated into a 1.5 T Philips Achieva MR scanner. Before starting therapy, test sonications with low energy were performed within the planned target area, typically 20–50 W at 1.2 or 1.45MHz. Based on low power test sonications, each HIFU volumetric cell ablation power was set to achieve a tissue heating of 60 – 75ºC, and correspondingly an appropriate thermal dose. Ablation was performed with volumetric techniques utilizing feedback control[5]. During each sonication, the transducer applies heat in a continuous manner to adjacent points within the planned large volumetric treatment cell. These treatment cells of diameter 4, 8, 12 or 16 mm are placed within a target treatment area to make up the planned treatment volume (PTV). Volumetric temperature imaging was achieved simultaneously to sonication using three coronal slices perpendicular to the beam-axis centered on the focal-region and one sagital slice aligned along the HIFU propagation direction. Two additional coronal slices were positioned to monitor potential excessive near-field (i.e. on the skin) and far-field tissue heating introduced by volumetric sonication. All 6 slices were acquired every 3 seconds with slice thickness of 7 mm with an in-plane pixel size of 2.5 x 2.5 $mm^2$. Thermal dose maps were also calculated online using the Sapareto-Dewey equation[6] with units given in equivalent minutes at 43°C. The MR sequence used for temperature mapping is an RF-spoiled segmented Echo Planar Imaging sequence (*EPI-factor = 11, repetition time TR = 37ms, echo time TE = 19.5ms, 121-binomial water selective excitation*).

**Post-Therapy:** Immediately following the treatment, 3D turbo spin echo (T1w TSE) sequence, the post-treatment non-contrast and contrast MR imaging were acquired before and after intravenous injection of 10mL gadotetrate meglumine for adult (BW >50kg).

**Results:** In compliance with the local ethics committee and regulatory authorities, 40 patients were screened between August and October, 2009, and 15% (6/40) of the patients passed the screening. One patient withdrew her consent just before the treatment. Finally, 12.5% (5/40) of these women underwent treatment. 61.8% (21/34) of the remaining 34 patients were women who did not meet all of the inclusion and exclusion criteria, and 38.2% (13/34) were screening failures that occurred after review of the MRI images because of bowel interposition between fibroid and abdominal wall, too deep location of fibroid, or lack of contrast enhancement indicating prior degenerative change.

Patients had a mean age of 45 ± 3.7 years and a body mass index of 23.4 ± 3.4 $kg/m^2$. All treatments were conducted in an outpatient setting with minimal discomfort for subjects and no major or unanticipated complications. There were only minor complications during, immediately and at 1 month follow-up after HIFU treatment: Only moderate pain and mild abdominal cramping were reported. The sonication time - the time from the first to the last sonication - ranged from 67 to 175 minutes. Four out of five patients had a mean symptom severity score (SSS) of 57.2 ± 11.4 at baseline, which decreased to 25.2 ± 16.6 at 1 month. Fifth patient SSS score was not considered here since 1 month follow-up was not yet completed. Figure 1 shows 3D T2W planning image (coronal) with different sizes of planned treatment circles and T1-weighted contrast enhanced coronal image with fat saturation of same fibroid obtained immediately after MR-HIFU treatment.

**Discussion:** Volumetric treatment allows for complete and uniform cell coverage, and the delivery of optimal thermal dose significantly minimizes the risk of overtreatment. In this study, the physician will have the option of using 4, 8, 12, and 16 mm cell sizes with and without thermal feedback. Our preliminary experience suggests that volumetric ablation with multiplane thermometry can provide the clinician with a rapid and accurate online control of the temperature evolution within the target area and the surrounding tissues for increased safety, thus providing a clinical end point for this noninvasive therapy. Since the patient population was very limited in this study, further multi-site studies are ongoing with larger patient populations to provide evidence for safety and technical effectiveness of this MR-HIFU method.

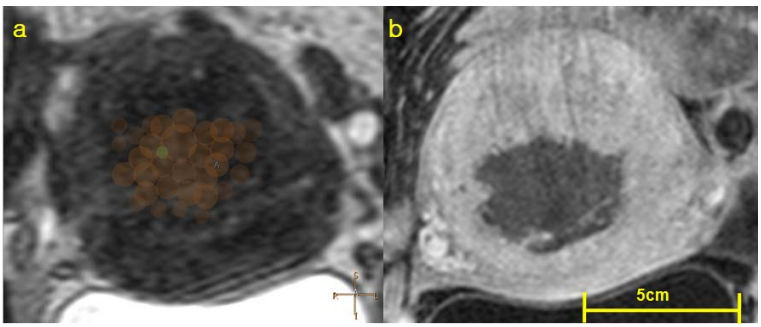


Figure:1: Different sizes of treatment planning circles overlaid on a T2w coronal image before HIFU therapy sonications and T1w contrast enhanced image of uterine fibroid immediately after HIFU treatment

**References** [1] Tempany CM et al. Radiology 226:897–905,2003. [2] Stewart EA et al. Fertil Steril 85:22–29, 2006. [3] Hesley GK et al. Mayo ClinProc 81:936–942, 2006. [4] Köhler MO et al. Med. Phys. 36, 3521-3535 August 2009. [5] Enholm J et al. IEEE Trans. Biomed. eng, In press. [6] Sapareto SA et al. Int. J. Radiat. Oncol., Biol., Phys. **10**, 787–800,1984.