

Quality assurance of volumetric feedback MR-guided HIFU ablation technique in human uterine fibroids

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Introduction: Recent studies have shown the capability of Magnetic Resonance guided High Intensity Focused Ultrasound (MR- HIFU) in thermal ablation of uterine fibroids [1, 2]. Volumetric techniques with automated thermal feedback have been developed in order to thermally ablate a larger volume during a single sonication to reduce treatment times while avoiding under or over heating of the target area [3-5]. The present study demonstrates the *in vivo* spatial targeting accuracy and thermal dose volume accuracy of the Philips Sonalleve MR-HIFU platform using the volumetric feedback technique [4, 5] as assessed from data acquired during a clinical trial.

Materials and methods: 33 patients with symptomatic uterine fibroids (N=38) were enrolled in a clinical trial (NCT00897897) assessing the safety and efficacy of the Philips Sonalleve MR-HIFU system for uterine fibroid treatment. Over the treatment sessions, there were a total of 621 successful sonifications of which 471 were volumetric feedback sonifications. Low-power test sonifications used to fine-tune the transducer position (N=94) and non-feedback treatment sonifications with predefined sonication times (N=56) were excluded from the analysis. There were altogether 356 and 115 volumetric feedback sonifications applied at the nominal frequencies of 1.2 MHz and 1.45 MHz, respectively. The spatial targeting accuracy of the ablations was determined along three orthogonal directions as the distance between the center of the intended volume of ablation and the center of the realized ablation volume. The center of the ablated volume was determined from thermal dose images as the center-of-mass location of the dose exceeding 240 equivalent minutes at 43°C (EM). The accuracy of the thermal dose volume size was assessed from the dimensions of the thermal dose ellipsoid, *i.e.* diameter and length, at the 240 EM threshold as compared to the intended cell size. The accuracies of targeting and applied thermal dose volume were assessed for the different cell sizes (diameter: 4, 8, 12 and 16 mm) and the different frequencies (nominal frequency: 1.2 MHz and 1.45 MHz).

Results: The targeting accuracy of the ablations was observed to be -0.04 ± 1.2 mm, 0.35 ± 1.5 mm and -0.52 ± 3.4 mm (N=471) in the left-right (LR), feet-head (FH) and anterior-posterior (AP) directions, respectively. The absolute targeting accuracy was similar for all cell sizes at both frequencies in the FH and LR directions (mean offset range, -0.4 – 0.6 mm). The targeting accuracy in the AP direction was also similar to this for all cell sizes at both frequencies (mean offset range, -0.4 – 0.4 mm) except for the 8 and 16 mm ablations at 1.2MHz where the ablated volume had an average offset of -1.7 mm and -3.2 mm, respectively. At both frequencies, the average diameter of the thermal dose volumes matched the cell size with an accuracy of 0.2 – 1.5 mm for the 4, 8 and 12 mm cells while deviating on average by 2.1 – 3.2 mm for the 16 mm cells (Figure 1). The average thermal dose length of the differently sized volumetric ablations was approximately 2 – 2.5 times the cell diameter as expected from acoustic and thermal simulations.

Discussion: As suggested by the results, the targeting accuracy and the accuracy with which the ablated volume diameter corresponded to the cell diameter were excellent at both frequencies tested for the 4 – 12 mm cells when taking into account that the resolution of the MR thermometry and the thermal dose images was $2.5 \times 2.5 \times 7.0$ mm. The obtained subvoxel accuracy is clearly sufficient for the intended use of uterine fibroid ablation since the typical fibroid size is 3–15 cm in diameter. The mean AP offset of the ablated volume for the 16 mm cells at 1.2MHz was found to be slightly larger than the thermometry resolution; however, the -3.2 mm offset remains quite acceptable clinically and can be corrected. The slightly reduced AP targeting accuracy for the 16 mm cells is likely a combination of heterogeneous heat diffusion having a larger effect on the ablation volume offset for larger heated volumes and the small amount of samples (N = 30 at 1.2MHz, N=2 at 1.45MHz). Qualitatively, there was no evident frequency dependency of the targeting accuracy. The thermal dose volume accuracy, as assessed by comparing the thermal dose diameter to the cell diameter, was stable but increased slightly as the cell size increased, which is to be expected due to partial volume effects [5]. The accuracy of even the larger cells, nevertheless, remained within the resolution of the thermal dose images. The reader should note that the number of 4 and 16 mm cells is small (4 mm, N= 9 at 1.2MHz, N=3 at 1.45MHz). More data using 4 and 16 mm cells are being collected in currently ongoing trials. To conclude, the spatial targeting and thermal dose volume accuracies of volumetric feedback sonifications with the Philips Sonalleve MR-HIFU platform can be considered clinically acceptable for the treatment of uterine fibroids.

