MRgHIFU safety issue: Multi-layer protection against tissue-to-air interface heating

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Introduction. MRgHIFU is a hybrid technology which aims to offer efficient and safe thermal ablation of targeted tumors or other pathological tissues, while preserving healthy surrounding structures unaltered. Theoretically MRgHIFU has no limitation regarding lesion size [1]. The main challenge is to avoid near and far field heating [2]. We demonstrate here that reflection at tissue-to-air exit interfaces may cause severe problems (e.g. skin or bowel burns) and we evaluate the effectiveness of a home-made multi-layer protection against tissue-to-air interface heating.

Figure 1. Drawing and picture of the multi-layer protection made from ultrasonic coupling gel (Aquasonic® 100).

Ex vivo rabbit thighs were heated by MRgHIFU with and without a multi-layer protective material against tissue-to-air interface heating (see Fig1). The same volumetric sonication pattern consisting of 5 x 2 points (4 mm gap) was performed with automatic feedback control of T°. The protective material was created by superposing two different layers of ultrasonic coupling gel (see Fig1). A first layer (Fig1.label1), applied topically, directly onto the distal region of the skin in the HIFU beam pathway (Fig1.label1), consisted of commercially available ultrasonic coupling gel in untreated form, where special care was taken to remove any residual air bubbles. A second layer (Fig1.label3), which is applied directly onto the first homogeneous gel layer, is composed of the same ultrasonic coupling gel, but in this case it has been whipped in order to introduce a large number of small air bubbles, resulting in infra-millimeter sized air bubbles randomly dispersed and suspended within the gel. This structure is expected to scatter the acoustic waves and hence completely trap the residual acoustic energy propagating at the exit window. The intrinsic acoustic attenuation of each layer was determined from transmitted energy measurements using the radiation force technique. A home-made absorber (RTV 60 silicone, MG chemicals, Surrey, B.C, Canada) of 18 cm diameter and 6 cm thickness was placed in front of the HIFU transducer and attached to a high precision balance (Ohaus Adventurer™ Pro, Leicester, UK)). An immobilized gel layer of known thickness (denoted here as x) was interposed between the HIFU transducer and the silicone absorber. Its attenuation coefficient was calculated from the following equation:

$$\mu(Np / MHz / mm) = \frac{1}{2 \cdot f(MHz) \cdot x(mm)} \ln \left( \frac{I(x)}{I_0} \right)$$

where I(x) is the acoustic intensity measured by the balance when the gel layer is inserted between the transducer and the silicone absorber, I0 is the acoustic intensity measured without the gel layer, for identical sonication parameters. Three measurements were repeated and averaged for each gel, for two levels of acoustic power (22.5W and 40W).

Results. The attenuation coefficient of the two different gel layers, calculated as an average over the radiation force measurement data set, was found to be 9.5x10^-3 ± 3.9x10^-3 cm^-1 and 0.17 ± 2.04x10^-3 cm^-1 respectively, i.e. a ratio of 18 between the two layers. Fig2. (a-c) corresponds to a reference experiment without protective material, demonstrating that very strong heating occurs at the tissue-to-air exit interface when no protection is used. Fig2. (d-i) displays the GRE/EPI T2* magnitude images in transverse and sagittal plane with overlaid PRFS T* maps and T2* maps obtained during HIFU thermal ablation where the multi-layer protection was applied to the skin-to-air exit interface of the rabbit thigh. PRFS derived T* variation are displayed at the end of the sonication. The T* isotherms follow the transparent layer interface, delineating a non heated area in the first non absorber layer (+) and widely spread heating in the foam (*). A zone covered by lethal TD is obtained around the foci, with symmetric thermal build-up and without significant T° enhancement related to acoustic reflection at the interface. In each of the protective layers, the T° remained far below the thermal dose accumulation regime. A global T° elevation of 23.5°C at the focus, a maximum T° elevation of 3°C in the homogeneous gel and 4.5°C in the foamed were found. Visual inspection of the skin of the ex vivo piece showed no sign of thermal coagulation.

Discussion. Behind the focal point, a large part of the HIFU beam has not been absorbed and therefore continues its propagation through the tissue towards the skin. As a result of the HIFU wave interaction with tissue/air (e.g. skin) interface, reflection and localized heating may occur, which can be uncomfortable for the patient and, if severe, could cause injury. By placing the multi-layer gel on the patient’s skin so as to substantially cover the exit region, the beam will freely exit from the tissue, propagate in the non-foamed layer, before finally entering the foamed layer where multiple reflections will scatter the residual beam. If significant local heating occurs in the foamed layer when dissipating the wave energy, the tissue would still be protected from passive heat flow due to the first layer of gel (practically transparent and hence unheated by the beam), provided a sufficient thickness of the first layer.

The method investigated here was demonstrated to be a low cost, flexible, readily available and effective solution to avoid far field heating at the exit acoustic window (e.g. skin burns at the opposite side to the transducer). This protection is perfectly MR compatible in contrast to metal-charged silicones (RTV 60 silicone, MG Chemicals, Canada). Made from commercialized biocompatible ultrasonic coupling gel directly available in any clinical department, it ensures that no side effects, such as allergies or inflammatory skin reactions, result from its use.
