

# MR-GUIDED FOCUSED ULTRASOUND SURGERY OF BREAST CANCER

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## Background

Among presently available modalities, MRI is considered to provide the closest images of breast cancer (BC) to pathological findings. MR-Guided Focused Ultrasound Surgery (MRgFUS) is a recently developed non-invasive thermal ablation system. MRgFUS system is composed of a treatment device (Exablate2000, InSightec Inc., Israel) to focus ultrasound beams to produce sharply localized high temperature spots and MR imaging system (GE Healthcare, U.S.A.) for accurate planning, real-time guidance and temperature measurement. It has been shown to be clinically effective in the palliative treatment of uterine fibroids to be increasingly utilized world-wide now and just recently that of metastatic bone tumor. Complete thermal ablation of BC has been successfully performed in one integrated institute dedicated for breast diseases in Japan.

## Purpose

The purposes of this lecture are to introduce two clinical studies (BC003<sup>1)</sup> in comparison with BC002<sup>2)</sup> performed without injection of contrast medium performed in Canada and BC004), and non-study commercial treatment of breast cancer in Japan.

## BC003<sup>1)</sup>

In BC003, Thirty BC patients were treated by MRgFUS followed by conventional surgery almost 2 weeks later. Immediate post-treatment contrast enhanced MR images (Fig. 1 & 2) were compared to the treatment outcome as evaluated by the pathological core lab. The areas and degrees of coagulation were measured by real-time target volume and temperature profile of MRI in comparison with pathology of the excised tissues. This study has demonstrated sufficient ability to safely, accurately and thoroughly coagulate a target volume up to 3.5 cm regions. The pathological data showed that the mean necrosis of the targeted breast tumors was  $98\% \pm 2\%$ , and that 50% of all evaluated patients had 100% necrosis of the ablated tumor. MRgFUS was also proven to be well tolerable procedure with low rates of adverse effects, although one severe skin burn was observed. Furthermore, this study showed that the use of contrast medium in MR imaging for treatment planning is crucial for a reliable and successful treatment outcome. The outcome of BC003 was superior to BC002<sup>2)</sup> which was designed to treat BC under MRI without contrast medium.

## BC004

This study is a follow-up study of BC patients with masses <1.5cm, locally treated by MRgFUS and radiation therapy (RT). The primary objective is to evaluate safety and effectiveness. The secondary objective is to evaluate local recurrence during a 5 year period following the MRgFUS treatment. Thirty-eight patients have been treated since April, 2006. No local recurrence and a few light-degree skin burns have been reported so far.

## Non-study Treatment

MRgFUS was performed for the patients most of whose tumors are larger than 1.5cm and also who did not want RT. Forty-seven BC patients have been treated with a small number of skin burns. However, four patients suffered from local recurrence at this moment.

## Conclusion

MRgFUS has a potential to be one of the safe and effective noninvasive treatment device of BC. The larger scale clinical studies and a sufficient follow-up time duration are essential for its prevalence. In the meantime, technological development of FUS device and MRI and their interface to make treatment more accurate and efficient will solve the present problems of this treatment in the near future.

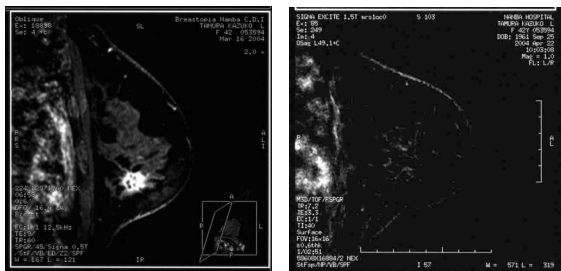


Fig. 1 (Left) Pre-treatment MRI

BC tumor is strongly enhanced and well demarcated.

Fig. 2 (Right) Post-treatment MRI taken immediately after MRgFUS.

Treated area is completely blacked out even after injection of contrast medium. The unenhanced area indicates the treated (ablated) extent.

## Reference

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