

Breast cancer

Caution-Investigational Device
Limited by United States Law to
Investigational Use.

IDE

Clinical Studies:

- Protocol Submitted to FDA for an Extended Phase II trial, with excision (up to 200 patients).
- Study in collaboration with ACRIN
- Planned - Phase III (Pivotal) study, MRgFUS treatment of Breast Cancer without excision.

Potential Value of MRgFUS with ExAblate

- Totally non-invasive
- Continuous MR guidance
- No general anesthesia, surgery, surgical scar or need for breast reconstruction
- Low rate of complications

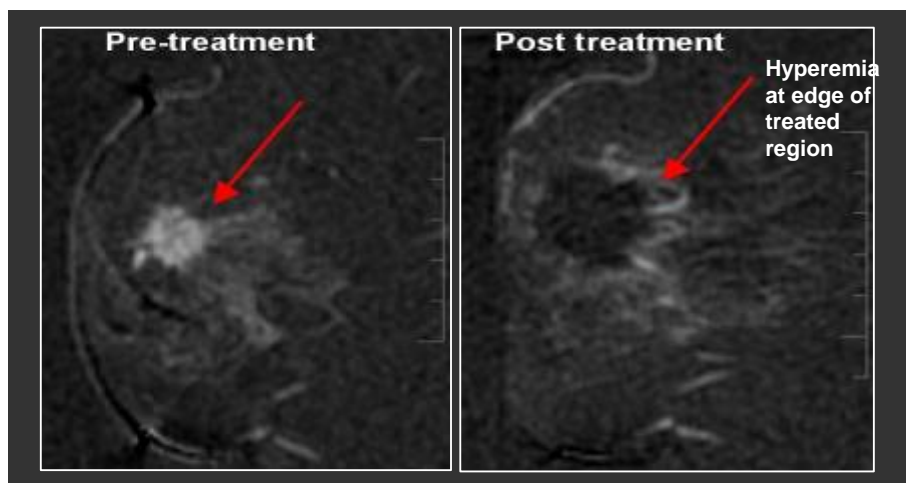


Breast cancer phase II results*

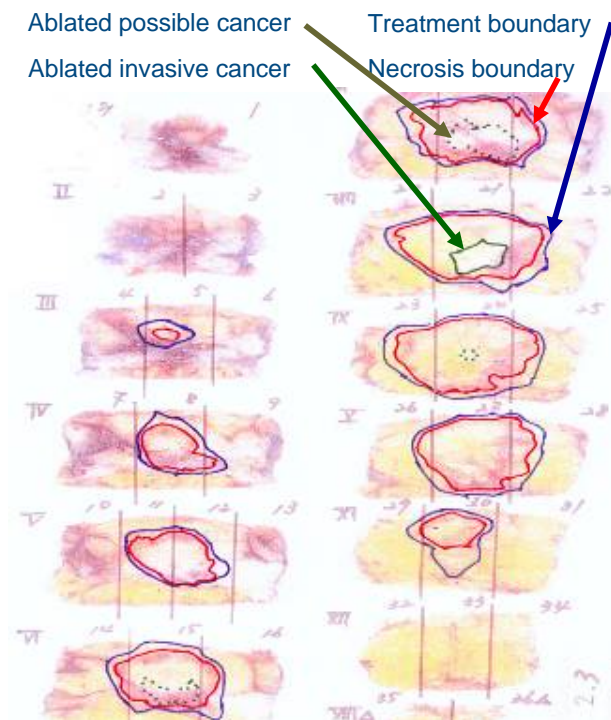
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- Evaluation of safety and efficacy
- Total 195 patients treated



T1w contrast enhanced subtracted images



Post-treatment pathologic results

* **Published paper:** Furusawa H, Namba K, Thomasen S, Akiyama F, Bendet A, Tanaka C, Yasuda Y, Nakahara H. *Magnetic Resonance- Guided Focused Ultrasound Surgery of Breast Cancer: Reliability and Effectiveness*, J Am Coll Surg, 2006, 203(1):54-63

Clinical case example – excisionless study

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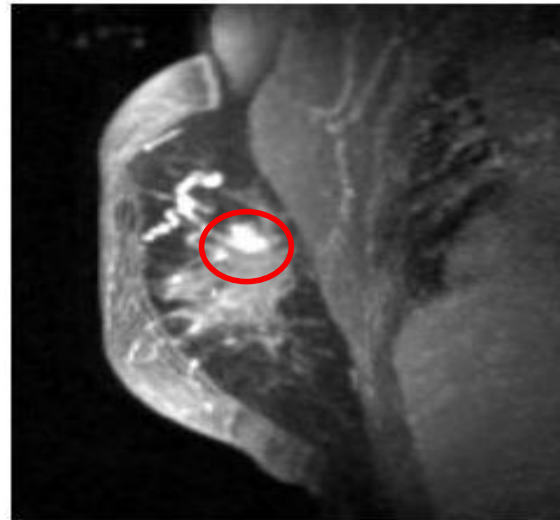
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Excisionless study objective:

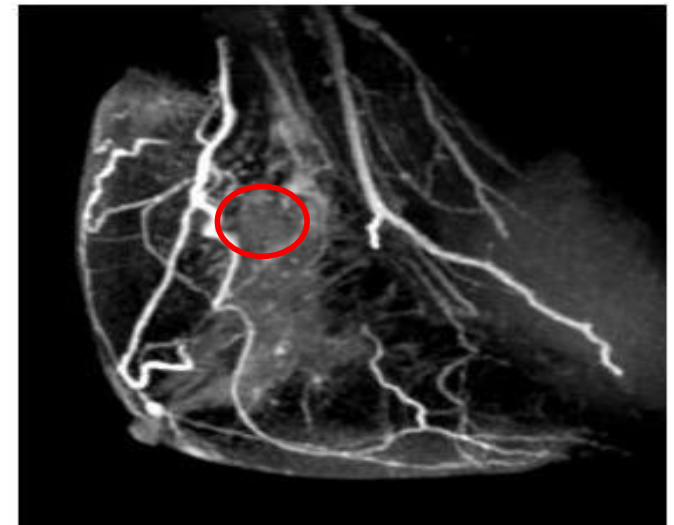
Evaluate long term local recurrence of up to 1.5 cm MRgFUS treated breast carcinoma and evaluate safety of the procedure

Status:

41 patients treated,
Max follow follow-up 39 months
Average follow-up 20 months
No recurrence
No complications



Pre treatment T1w+CE MIP image



2 weeks post treatment T1w CE MIP image

Courtesy of Breastopia Namba Medical Center, Miyazaki, Japan