

INSIGHTEC

Women's Health



MR GUIDED FOCUSED ULTRASOUND (MRgFUS)

A non-invasive solution for
treating uterine fibroids &
adenomyosis

MRgFUS - THE FUTURE OF NON-INVASIVE THERAPIES

INSIGHTEC, the global leader in Magnetic Resonance guided Focused Ultrasound (MRgFUS) has developed ExAblate, a therapy platform that is transforming medicine. MRgFUS presents a non-invasive alternative for deep tissue procedures that combines two proven technologies - focused ultrasound and magnetic resonance imaging (MRI) with real-time feedback. The procedure spares non-targeted tissue and does not leave superficial scars. CE approved applications of MRgFUS in Europe in the field of

Women's Health include uterine fibroids and adenomyosis.

MRgFUS enables the physician to offer a uterine preserving, minimal pain alternative for treatment of uterine fibroids and adenomyosis. MRgFUS is performed on an outpatient basis and requires at most conscious sedation, with return to normal activity in one day. Equally important, MRgFUS is characterized by a low rate of adverse events.



The MRgFUS treatment modality will expand a hospital or clinic's services by attracting new patients and in so doing, transform the site into a center of excellence.. INSIGHTEC is proud to play an integral role in facilitating site development and success.

MRgFUS PROVIDES UNIVERSAL VALUE



PHYSICIAN & CLINICAL VALUE

- No incision
- Conscious sedation
- Anatomic results evident immediately following procedure
- Minimal complications and adverse events

PATIENT VALUE

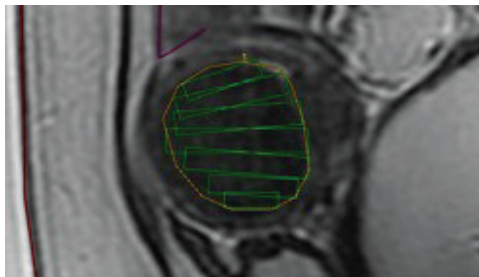
- Uterine preserving
- No incision or superficial scarring
- Return to work and normal activity within one day
- Minimal pain or discomfort

ECONOMIC VALUE

- Outpatient procedure
- Expands hospital services
- Diversifies use of MR suite

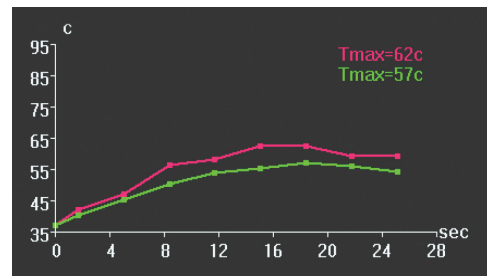
CLOSED-LOOP THERAPY VIA REAL-TIME FEEDBACK

Closed loop therapy enables physicians to visualize in real-time, the treated tissue volume and its thermal response.



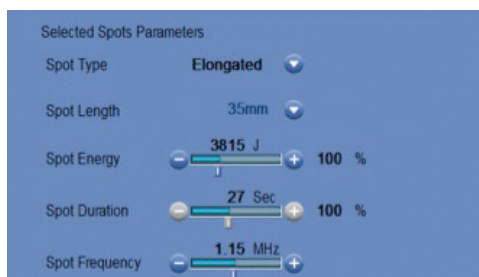
1. PLANNING

Beam path superimposed on MR image to guide treatment and avoid non-targeted tissue



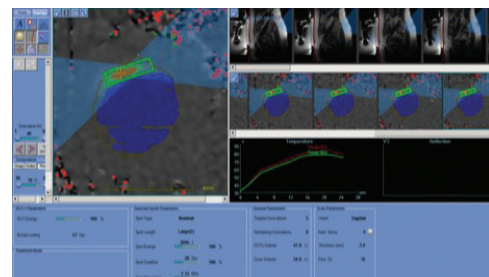
2. THERMOMETRY

MR thermal tracking for real-time treatment monitoring



4. ADJUSTMENT

Parameters adjusted as necessary to ensure safe and effective response

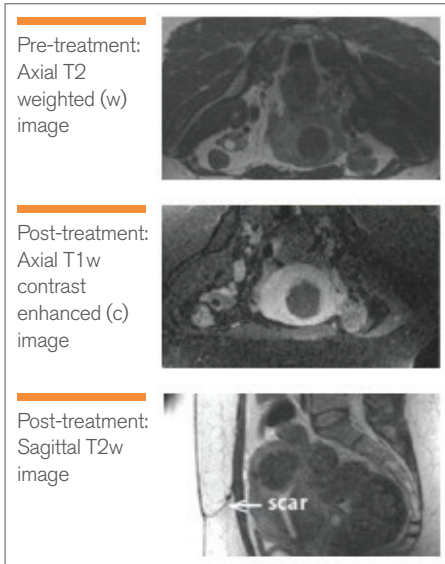


3. EVALUATION

Thermal data analyzed to determine cumulative thermal impact on tissue

Disclaimer: The above figures are not representative of future treatments.

SCAR IN BEAM PATH ¹



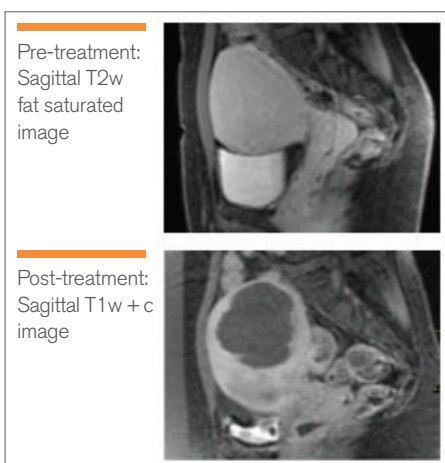
PATIENT INFORMATION

43 year old female presented with menorrhagia, blood clots and irregularities in her menstrual cycle attributed to a 50 cc fibroid. A scar was observed in the energy beam path.

OUTCOME

- 90% NPV was achieved in 55 minutes with no adverse effects.
- Aperture control along with transducer position in close proximity to the skin enabled safe and effective treatment through the scar tissue.

PROXIMITY TO BOWEL AND SACRUM ¹



PATIENT INFORMATION

48 year old female presented with menorrhagia and a bulging belly attributed to a 240 cc fibroid.

OUTCOME

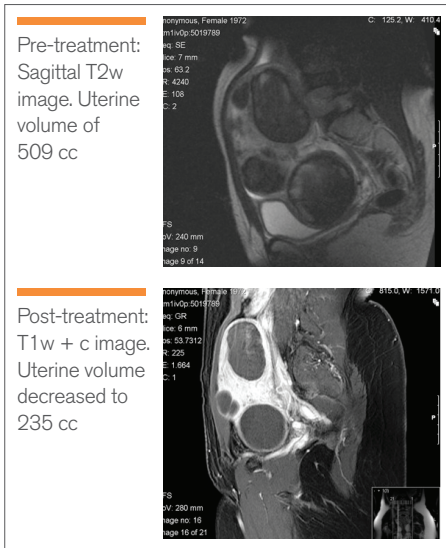
- 91% NPV was achieved in 180 minutes with no adverse effects.
- Beam shaping enabled treatment of the superior aspect of the fibroid which was in close proximity to the bowel.

¹ Courtesy of Sheba Hospital, Tel Aviv, Israel

Disclaimer: The above case may not be representative of all treatment outcomes.

CASE REVIEW

FERTILITY PRESERVATION ²



PATIENT INFORMATION

39 year old female presented with menorrhagia and urinary frequency including nocturia attributed to 5 hyper-intense fibroids: one fundal posterior intra-mural fibroid of 5 cm, three anterior intramural fibroids and a low anterior wall fibroid of 4.5 cm. First pregnancy resulted in a premature delivery at 28 weeks of a 1170 g female infant. Pretreatment Uterine Fibroid Symptoms Quality of Life (UFS-QOL) score was 65.

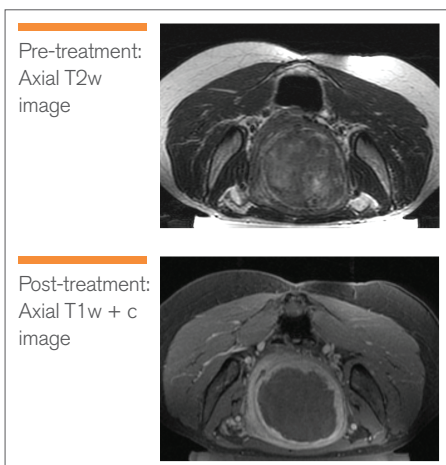
OUTCOME

- 90% NPV of total fibroid volume achieved.

DURABILITY

- 6 months post-procedure UFS-QOL score decreased to 24.
- 2nd pregnancy 4 months post-treatment resulted in a vaginal delivery at 41+6 weeks of a 3580 g female infant.
- 6 months post-delivery UFS-QOL score continued to decrease to 22.

HYPER-INTENSE FIBROID ³



PATIENT INFORMATION

28 year old female presented with menorrhagia, blood clots and discomfort in her lower abdomen attributed to a 200 cc hyper-intense fibroid.

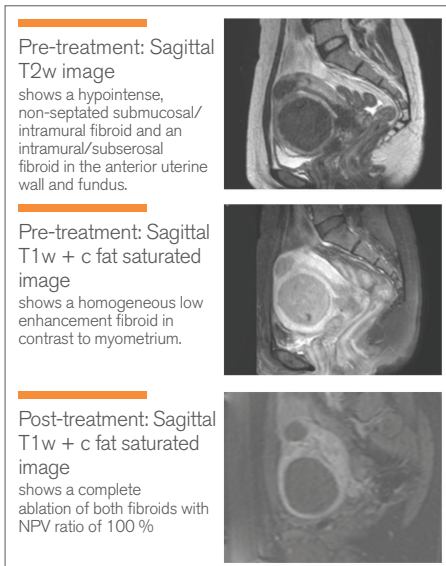
OUTCOME

- 80% NPV was achieved with no adverse effects.
- Increased energy density and position of the transducer in close proximity to the skin enabled effective treatment of the hyper-intense fibroid.

² Courtesy of Imperial College, St. Mary's Hospital, London, UK. Zaher et al. Uncomplicated term vaginal delivery following magnetic resonance-guided focused ultrasound surgery for uterine fibroids. Biomed Imaging Interv J, 2010

³ Courtesy of the Center of Obstetrics Gynecology and Perinatology, Moscow, Russia

HYPO-INTENSE FIBROID ⁴



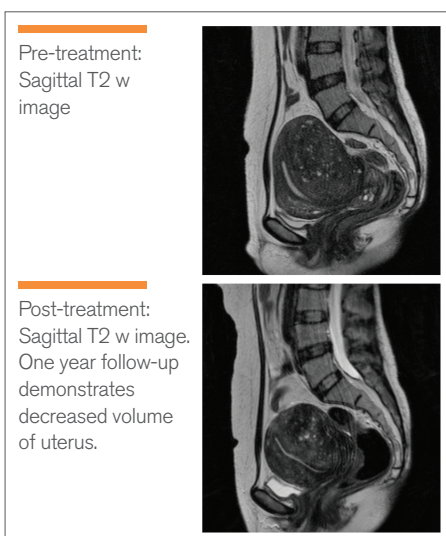
PATIENT INFORMATION

47 year old female presented with hypermenorrhoea attributed to two 98 cc fibroids; a hypo-intense, non-septated submucosal/intramural fibroid and an intramural/subserosal fibroid in the anterior uterine wall and fundus.

OUTCOME

- 100% NPV was achieved on both fibroids with no adverse effects.

ADENOMYOSIS ⁵



PATIENT INFORMATION

47 year old pre-menopausal female presented with symptomatic focal adenomyosis. Her enlarged uterus measured 510 cc. Pretreatment Uterine Fibroid Symptoms Quality of Life (UFS-QOL) score was 53. Pain score on a 0-10 scale was 10.

OUTCOME

All results evaluated at 6 months and remained constant at one year evaluation.

- 37% shrinkage of uterine volume.
- UFS-QOL score decreased to 28.
- Pain score decreased to 5.

⁴ Courtesy of Helios-Amper Klinikum Dachau, Germany. Mindjuk et al. MRI predictors of clinical success in MR-guided focused ultrasound (MRgFUS) treatments of uterine fibroids: results from a single centre. European Radiology, 2014.

⁵ Courtesy of CHA Bundang Medical Center, CHA University, Bundang-gu, Sungnam-si, Gyunggi-do Republic of Korea. Yoon et al. Successful use of magnetic resonance-guided focused ultrasound surgery to relieve symptoms in a patient with symptomatic focal adenomyosis. Fertility and Sterility, 2008.

Disclaimer: The above case may not be representative of all treatment outcomes.

A GROWING PORTFOLIO OF CLINICAL INDICATIONS

Women's Health

2002
2004
2009
2013

Uterine Fibroids approved in Europe (2002), US (2004), Japan (2009) and China (2013)

2010
2011

Adenomyosis approved in Europe (2010) and Korea (2011)

Oncology

2007
2012

Pain Palliation of Metastatic Bone Tumors approved in Europe (2007) and US (2012)

2013

Metastatic and Primary Malignant Bone Tumors approved in Europe

Benign Bone Tumors approved in Europe

Facet Rhizotomy approved in Europe

Neurosurgery

2012

Essential Tremor approved in Europe

Tremor Dominant Parkinson's Disease approved in Europe

Neuropathic Pain approved in Europe

Future Applications

2015+

Oncology

Prostate
Liver
Pancreas
Breast

Neurosurgery

Obsessive Compulsive Disorder
Brain tumors

INSIGHTEC

ABOUT INSIGHTEC

INSIGHTEC is the global leader in MRgFUS. The company, founded in 1999, develops and distributes ExAblate, a non-invasive therapy platform that is transforming medicine. INSIGHTEC is continuously expanding its applications ranging from functional neurosurgery to oncology and gynecology. MRgFUS is embraced by world renowned physicians in more than 120 medical facilities who applaud both its clinical and economic value.

The company has received numerous innovation awards, among others from the Wall Street Journal and TIME magazine. INSIGHTEC is privately held by GE Healthcare, Elbit Imaging, York Capital Management, GEOC Hengtong Investment Limited Partnership and MediTech Advisors.

For more information please visit:
www.insightec.com

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Device name: ExAblate
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