Focused Ultrasound: State of the Field and Potential for Treating Desmoid Tumors

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Chief Scientific Officer
Focused Ultrasound Foundation
Focused ultrasound

Early stage, noninvasive, therapeutic technology

Alternative or complement to surgery, radiation therapy, drug delivery

*Potential* to transform treatment

Improved outcomes, decreased cost
Desmoid tumor

Slide courtesy of P. Ghanouni, Stanford University
Desmoid tumor

Slide courtesy of P. Ghanouni, Stanford University
Desmoid tumor

Slide courtesy of P. Ghanouni, Stanford University
Pancreatic Cancer

Baseline
Post treatment
22 Months
Pancreatic cancer – Abscopal effect

Baseline

2 Days

10 Months

Baseline

16 mm

8 mm
Essential tremor

Awake, no anesthesia
No incisions
No burr holes
No electrodes
No infection
No blood clots
No brain damage
The Principle
Multiple intersecting beams of ultrasound

- Focused accurately (submillimeter)
- Target in body
- Individual beams pass harmlessly through adjacent tissue
- Profound effect at point of convergence
Adjacent tissue sparing

Liver

Brain
Effects at the focal point

Platform technology
18+ Biomechanisms

Drug Delivery
Destroy Tissue
Immuno Modulation
BBB Opening

Variety of effects, variety of disorders
Focused ultrasound devices
Focused ultrasound manufacturers
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<th>Global development landscape</th>
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<td>Deep vein thrombosis</td>
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<td>Malignant obstructive jaundice</td>
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<td>Esophageal cancer</td>
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Desmoid Tumors – Unmet Clinical Need

Standard treatment options

• Surgical resection
• Radiation therapy
• Chemotherapy
• Novel systemic treatments (targeted therapies)

Side effects

• Surgical morbidity
• Radiation burns, secondary malignancy, fibrosis, chronic edema
• Chemotherapy toxicity

**Clinical need**

• Decrease morbidity associated with treating soft tissue tumors
• Primary, recurrent, or palliative treatment

Slide courtesy of P. Ghanouni, Stanford University
Summary of treatment results

- 41 patients: 28 women, 13 men
- 69 treatments
  - Treatments repeated in 16 (39%) patients to target residual viable tumor

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<th>Range</th>
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<td>Patient age</td>
<td>36 years</td>
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<td>4–66 years</td>
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<td>Follow-up</td>
<td>12.7 months</td>
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<td>1–47 months</td>
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<td>Non-Perfused Volume Ratio*</td>
<td>60%</td>
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<td>15–100%</td>
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Tumor volume, median

- Total, Pre-FUS: 98 mL, 4–1060 mL
- Total, Post-FUS: 48 mL, 0–840 mL
- Viable, Post-FUS: 16 mL, 0–840 mL

*relative to total tumor volume

On per patient basis, MRgFUS results in an average of 60% reduction in viable tumor volume

Slide courtesy of P. Ghanouni, Stanford University
Durable clinical benefit

- Durable clinical benefit of the MRgFUS treatments defined as:
  - reduction in tumor size of >50% since the most recent treatment and
  - reduction in worst and average pain scores of at least two points,
  - both maintained for a period of at least 6 months after treatment.

- Overall pain relief
  - Max: $6.9 \pm 2.8 \rightarrow 3.3 \pm 3$ (p < 0.0001)
  - Avg: $3.9 \pm 2.3 \rightarrow 1.3 \pm 1.7$ (p < 0.0001)

- Durable clinical benefit
  - Observed in 13 of 23 patients (56%)
  - These 13 had median reduction of viable tumor volume of 99% (IQR 12%)
  - Average follow up of 19 months since most recent treatment

- Common theme in those without local control
  - proximity to nerve, for example in popliteal fossa
  - large tumor size
  - proximity to skin
  - scar from prior surgery

Slide courtesy of P. Ghanouni, Stanford University
Durable clinical benefit of the MRgFUS treatments based on

- Change in SF-36 scores

<table>
<thead>
<tr>
<th>SF-36 Category</th>
<th>Pre FUS</th>
<th>Post FUS</th>
<th>Change, per patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>69</td>
<td>78</td>
<td>11</td>
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<tr>
<td>Role limitations due to physical health</td>
<td>38</td>
<td>68</td>
<td>36</td>
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<tr>
<td>Role limitations due to emotional problems</td>
<td>63</td>
<td>94</td>
<td>22</td>
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<tr>
<td>Energy/fatigue</td>
<td>44</td>
<td>58</td>
<td>13</td>
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<tr>
<td>Emotional well-being</td>
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<td>Social functioning</td>
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<td>Pain</td>
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<tr>
<td>General health</td>
<td>59</td>
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</tbody>
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Slide courtesy of P. Ghanouni, Stanford University
Clinical successes

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Process is complicated and inefficient

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- Pre-clinical proof of concept
- Regulatory approval
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Complex ecosystem

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- Industry
- Venture capital, private equity
- Payers; public and private
- Patient advocacy organizations
- Treatment facilities
- Physicians, numerous specialties
- Patients
- Academic research sites
- Disease specific foundations
- Medical societies
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Impediments

Awareness: patients and physicians

Robust evidence; safety, efficacy, cost

Regulatory approvals

Insurance reimbursement

Inertia: physicians resistance to change

Turf battles: medical specialists, manufactureres

Cultural Issues: patient centricity, urgency, collaboration

Purchasing value proposition
Unique medical research, education, advocacy organization

- Founded 2006, Charlottesville, Va: Global impact
- Tax exempt
- Entrepreneurial, high impact, market driven, action and results oriented

Catalyst to accelerate the development and adoption of FUS
Create Evidence: Research

Organize, conduct and fund research

- Clinical, preclinical, technical
- Focus: Brain, cancer immunotherapy
- Largest non-governmental funding source

Convene the Community

Organize meetings, symposia, workshops

- Exchange knowledge and ideas
- Foster collaborations and partnerships
- Stimulate innovation

Workshops

Symposia
Sessions will highlight image-guided focused ultrasound to treat cancer and benign tumors, including:

- Brain, breast, liver, pancreas, kidney, prostate, bone, soft tissue, and thyroid
- Key biological mechanisms for treatment: immuno-oncology, drug delivery

More info: https://symposium.fusfoundation.org/
Positioning

Private philanthropy

Academic research sites

Disease specific foundations

Media

Venture capital, private equity

Payers; public and private

Patient advocacy organizations

Treatment facilities

Physicians, numerous specialties

Patient

Industry

Medical societies

Focused Ultrasound Foundation

FDA

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Focused Ultrasound Foundation

FDA
Adoption
Adoption: without Foundation
Impact

- **Investment**
- **Activities**
Saving Time = Saving Lives