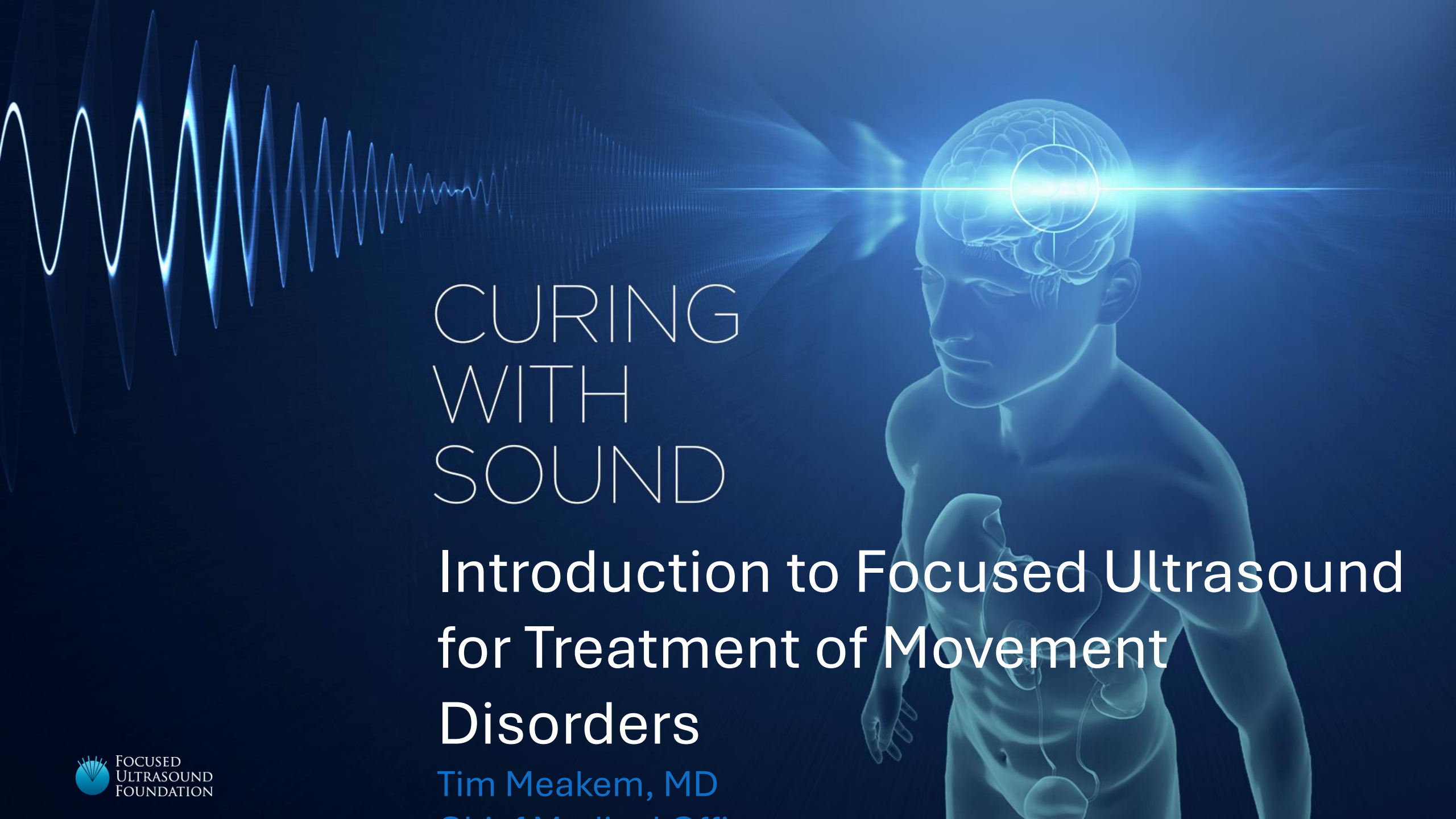


Introduction to Focused Ultrasound for Treatment of Movement Disorders

Tim Meakem, MD
Chief Medical Officer

FOCUSED ULTRASOUND FOUNDATION

Agenda

Thank You to the Parkinson and Movement Disorder Alliance!

Agenda

- Introduction to Focused Ultrasound
- Brief discussion of the Focused Ultrasound Foundation
- Research update
- Bobby Krause
- Questions

Early stage

MRI 40 years ago

- Unknown
- Revolutionized diagnoses

Focused ultrasound today

- Unknown; "Medicine's Best Kept Secret”
- Revolutionize therapy

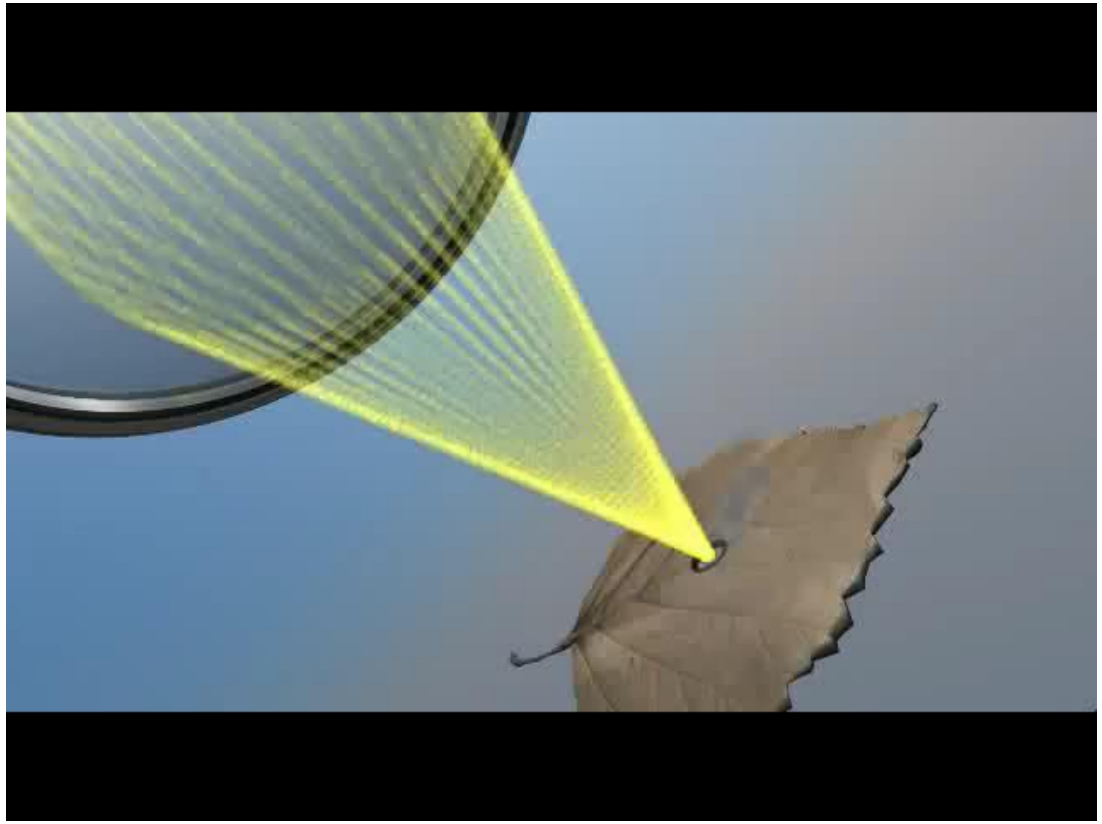
Multi-billion dollar industry

Infancy, real today

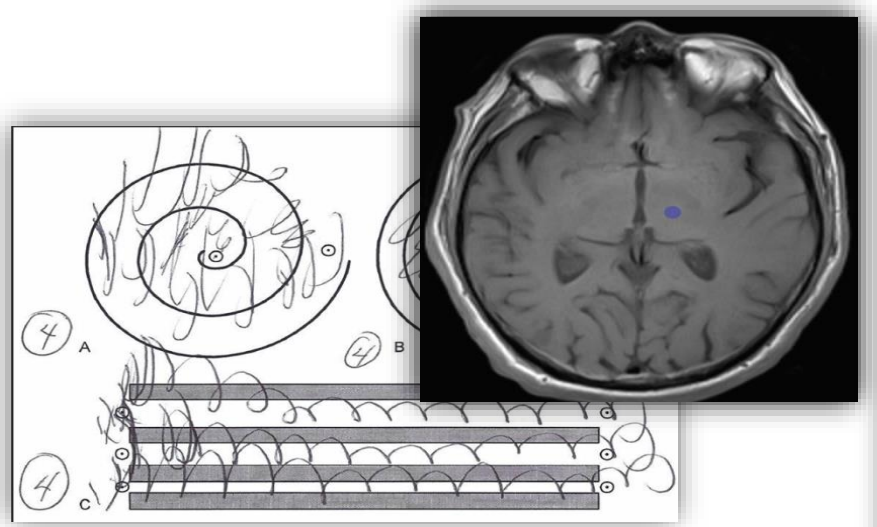
The principle

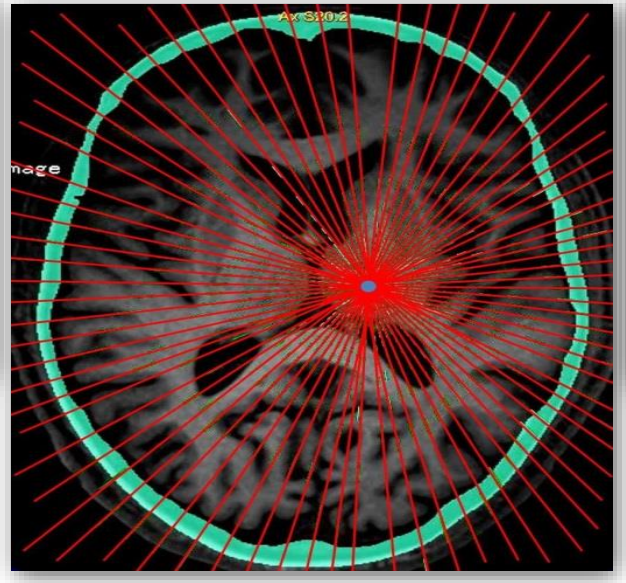
Multiple intersecting beams of ultrasound

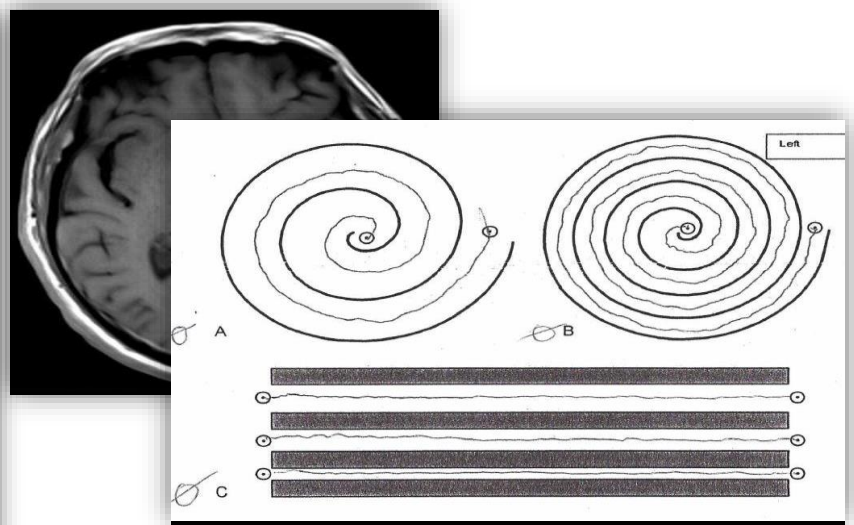
- Focused accurately (submillimeter)
- Target in body
- Individual beams pass harmlessly through adjacent tissue
- Profound effect at point of convergence



Essential tremor







Awake, no anesthesia
No incisions
No burr holes
No electrodes
No infection
No blood clots
No brain damage

Noninvasive therapeutic technology

Outpatient

No incisions, less pain

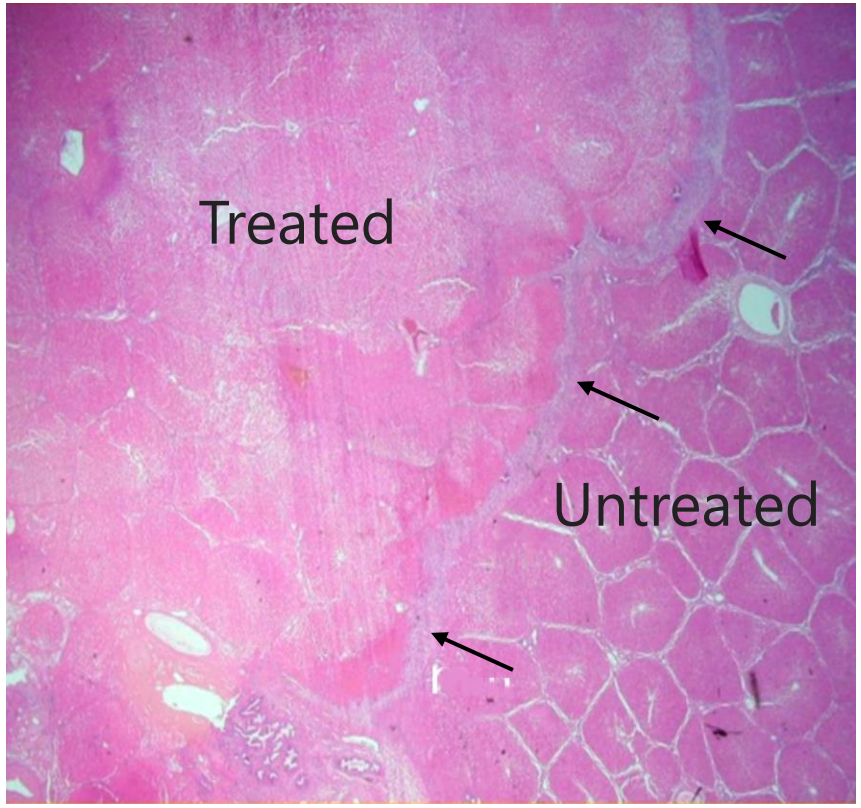
Decreased complications: infection, hemorrhage, tissue damage

Rapid recovery

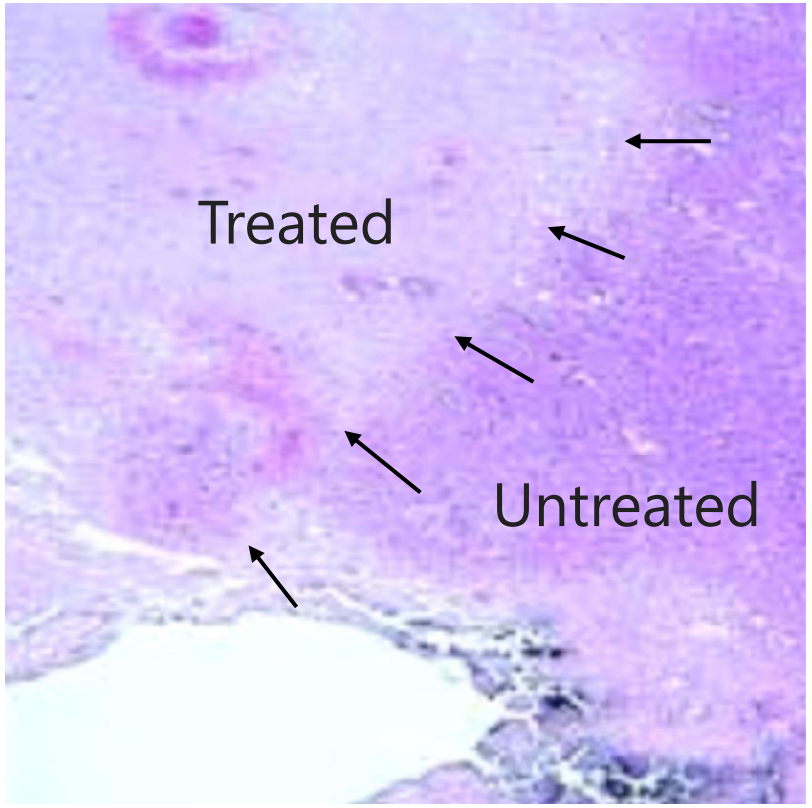
Improved outcomes, lower cost

Adjacent tissue Sparing

Liver



Brain



Biomechanisms

Tissue Destruction

Thermal ablation
coagulative cell death

Histotripsy
mechanical cell disruption

Microvascular occlusion
ischemic cell death

Sonodynamic therapy activation of cytotoxic drugs, apoptotic cell death

Gene therapy
activation of apoptotic cell death

Radiation Sensitization

Hyperthermic tumor preconditioning

Increased tumor oxygenation
oxygen microbubbles
vasodilation

Therapeutic Delivery

Carrier mediated
nanoparticles, liposomes, microbubbles, stem cells

Increased vascular permeability
blood-brain barrier opening

Increased cell membrane permeability
sonoporation

Increased blood flow
vasodilation

Increased drug diffusion tumor stroma disruption

Neuromodulation

Stimulation and inhibition

Peripheral and central nervous system

Immunomodulation

Cell disruption
exposure of tumor antigens
release of cytokines

Immune cell trafficking

Enhanced immunotherapeutic delivery and activation

Hyperthermia
release of tumor necrosis molecules

Other

Clot lysis

Chemosensitization

Vasoconstriction and vasodilation

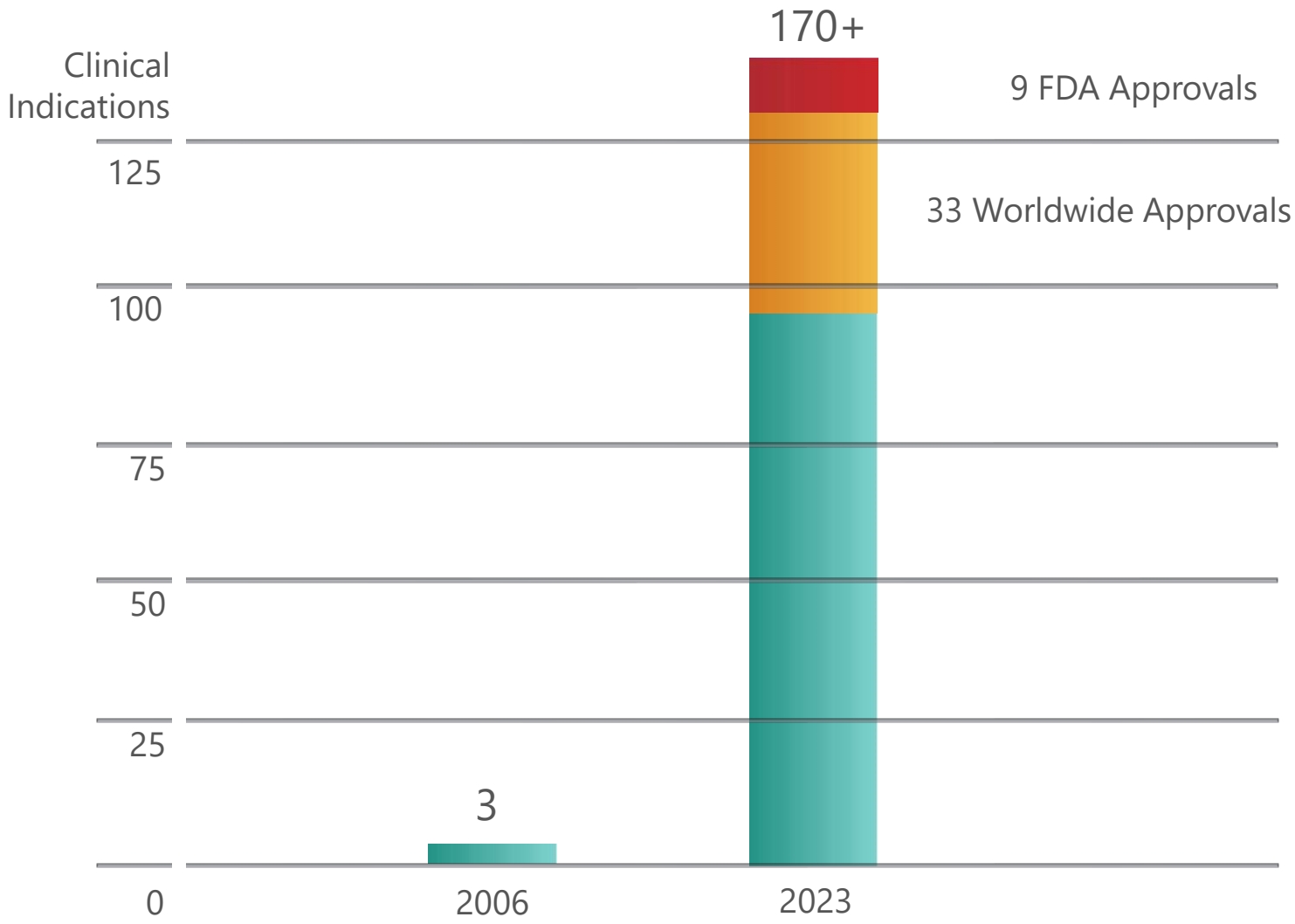
Vascular occlusion

Cancer biomarker enhancement

Stem cell homing

Tumor boundary delineation

Global development landscape



Focused ultrasound devices

Agenda

- Introduction to Focused Ultrasound
- **FUS Foundation**
- Review of the current research status
- Bobby Krause
- Questions

Impact

Urgent need: widespread availability of focused ultrasound

- Saving time = Saving lives

Delay results in unnecessary death, disability and suffering

- Countless individuals

Impediments

Awareness: patients and physicians

Robust evidence; safety, efficacy, cost

Regulatory approvals

Insurance reimbursement

Inertia: physicians resistance to change

Turf battles: medical specialists, manufacturers

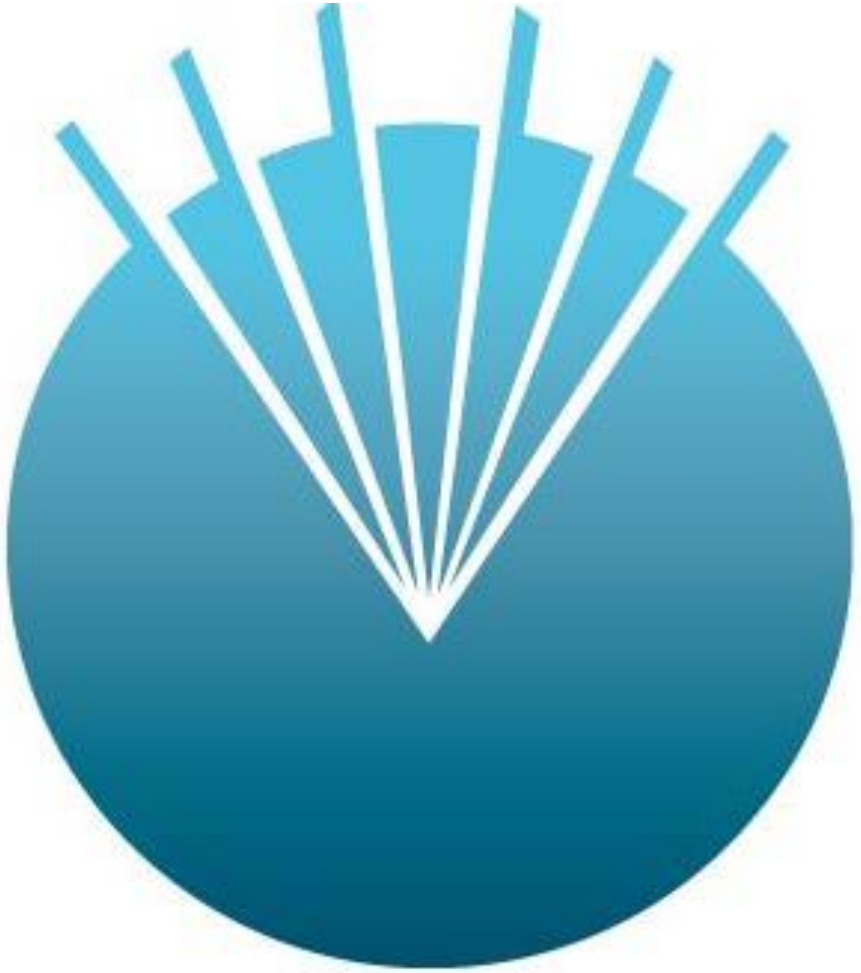
Cultural Issues: patient centricity, urgency, collaboration

Purchasing value proposition

The solution: overcome impediments

Obscure: No model, example or formula

Obligated to invent



Focused Ultrasound Foundation

Unique medical research, education, advocacy organization

Founded 2006, tax exempt

Entrepreneurial, high impact, market driven, action and results oriented

Charlottesville, VA based: global influence

Top 10 Medical Research Organization

Social entrepreneurship model

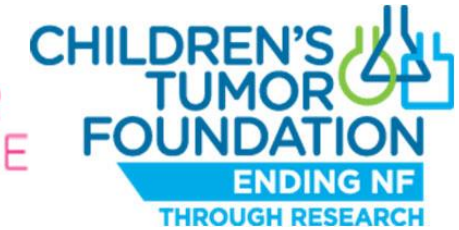
Mission

Accelerate development and adoption of focused ultrasound

Global standard of care

Media placements

Partner organizations



Funding

Annual Budget: $15 million, >60% research

Committed donors

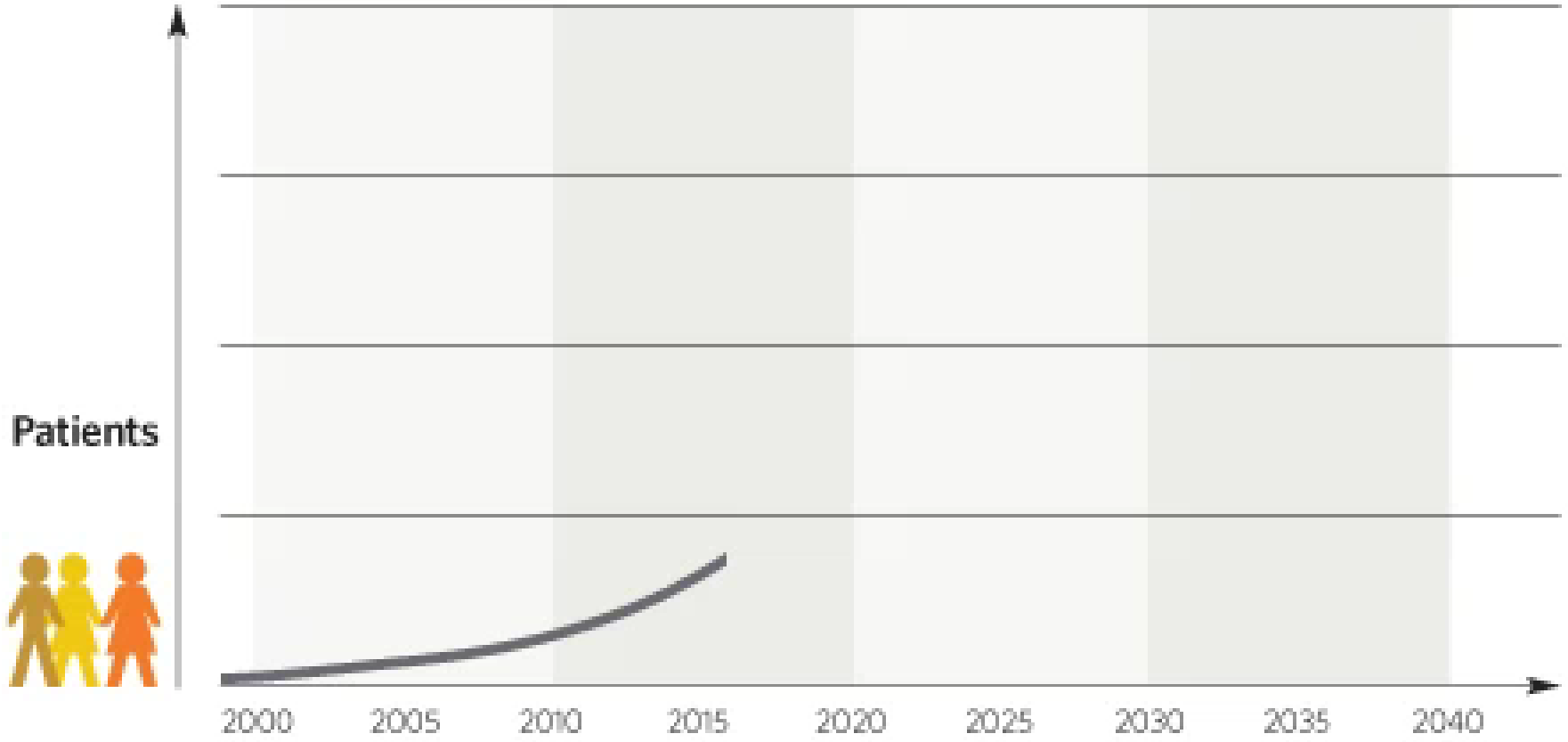
If any of you want to contribute, see our website **https://www.fusfoundation.org/**

-donations can be directed to only Parkinson's disease research

Impact

Focused Ultrasound Foundation

Adoption: with Foundation



Saving Time = Saving Lives

FOCUSED ULTRASOUND FOUNDATION

Agenda

- Introduction to Focused Ultrasound
- FUS Foundation
- **Review of the current research status**
- Bobby Krause
- Questions

Essential Tremor (ET): FDA Approved

- **A Randomized Trial of Focused Ultrasound Thalamotomy for Essential Tremor.** Elias WJ, Lipsman N, Ondo WG, Ghanouni P, Kim YG, Lee W, Schwartz M, Hynynen K, Lozano AM, Shah BB, Huss D, Dallapiazza RF, Gwinn R, Witt J, Ro S, Eisenberg HM, Fishman PS, Gandhi D, Halpern CH, Chuang R, Butts Pauly K, Tierney TS, Hayes MT, Cosgrove GR, Yamaguchi T, Abe K, Taira T, Chang JW. N Engl J Med. 2016 Aug 25;375(8):730-9. doi: 10.1056/NEJMoa1600159. PMID: 27557301
  - 76 patients
  - Randomized, blinded evaluators. 3:1 Sham, crossover at 3 months
  - Evaluated on Clinical Rating Score for Tremor (32 point scale, higher = worse)
- Results
  - 8.3 reduction in tremor score vs sham (47% improvement, p<.0001) at 3 months
  - This was preserved at 12 months, 7.2 improvement (40% improvement, p<.0001).
  - QOL and Disability Measurement also improved (p<.0001 for both)
- Adverse Effects
  - Gait disturbance in 36% at 3 months, went to 9% at 12 months
    - (ataxia, subjective weakness)
  - Paresthesias/numbness in 38% at 3 months, went to 14% at 12 months
    - (Face, hand or fingers)
- Medicare approval for all 50 states
- Staged (9 month) Bilateral treatment is also approved

Current PD FDA approvals: Tremor

Tremor Dominant Parkinson's Disease

- Target = VIM (Ventral intermediate nucleus), same as for essential tremor
  - Bond et al. Safety and Efficacy of Focused Ultrasound Thalamotomy for Patients With Medication-Refractory, Tremor-Dominant Parkinson Disease: A Randomized Clinical Trial. JAMA Neurol. 2017 Dec 1;74(12):1412-1418. doi:10.1001/jamaneurol.2017.3098.PMID: 29084313
- 62% improvement in tremor scores at 3 months (27 patients)
- Persistent side effects (1 year)
  - Orofacial paresthesia (4)
  - Finger paresthesia (1)
  - Ataxia (clumsy voluntary movements)(1)
- Medicare reimbursement (unilateral) in AK, AL, AZ, CA, CT, GA, HI, IA, ID, IL, IN, KS, KY, MA, ME, MI, MN, MO, MT, NC, ND, NE, NH, NV, NY, OH, OR, RI, SC, SD, TN, UT, VA, VT, WA, WI, WV, WY (38 states)

American Association of Neurology Schiff_Poster 130324 (2024)

Safety of magnetic resonance-guided focused ultrasound thalamotomy for essential tremor: real-world experience

Gilat Schiff[1], Amit Sokolov[1], Neha Dhawan[2], Giulia Frazzetta[3], Katie Gant[4]

[1]Treatment Interventions Affairs, Insightec, Tirat Carmel, Israel. [2]Treatment Interventions Affairs, Insightec, Michigan, USA. [3]Treatment Interventions Affairs, Insightec, Milan, Italy. [4]Medical Affairs, Insightec, Miami, USA.

Background

Magnetic resonance-guided focused ultrasound (MRgFUS) is a precise, incisionless method for thermal ablation of targets in the brain. It combines a 1024-channel phased-array transducer and MR imaging in a closed-loop procedure. Stepwise energy titration with real-time thermal and clinical feedback allows for precise control and adjustment before definitive treatment. In the United States, MRgFUS thalamotomy is currently indicated for treatment of essential tremor (unilateral and staged, bilateral), and tremor-dominant Parkinson's disease (unilateral procedure). Unilateral MRgFUS pallidotomy is indicated for motor complications of Parkinson's [1]. Additional indications are approved in other regions. The number of MRgFUS procedures performed each year has been growing since its introduction in 2016 (Figure 1). In the US, MRgFUS has surpassed DBS as a treatment option for functional intervention of essential tremor (Figure 2).

In a pivotal, randomized clinical trial (RCT) involving patients with essential tremor, unilateral MRgFUS thalamotomy produced immediate and significant tremor relief [2], and improvement was sustained for at least 5 years [3,4]. The procedure was generally well tolerated. Adverse events (AEs) were mainly transient and mild. However, safety findings from RCTs, which adhere to strict patient monitoring procedures, may not be representative of real-world clinical practice.

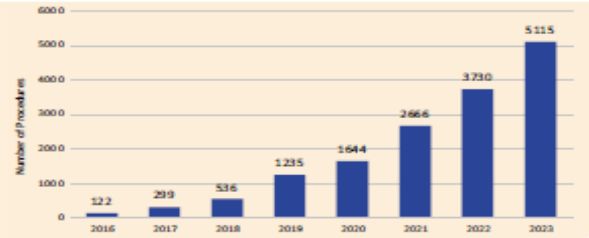


Figure 1. Adoption of MRgFUS has been increasing steadily since its introduction in 2016.

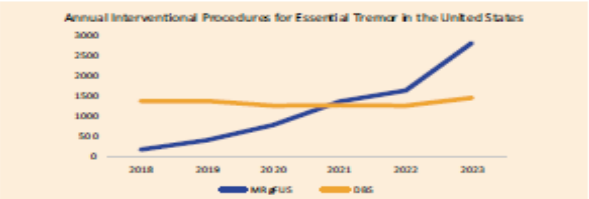


Figure 2. In the US, MRgFUS has surpassed DBS as a treatment option for functional intervention of essential tremor. DBS, deep brain stimulation.

Objective

To assess the safety of MRgFUS thalamotomy in patients with essential tremor in real-world clinical practice.

Design/Methods

Safety findings from real-world sources (published literature, post-marketing surveillance data, customer survey data, registry data) were collated and compared with safety findings from the pivotal trial of MRgFUS thalamotomy in patients with essential tremor.

Results

Pivotal trial

The pivotal trial enrolled patients with moderate-to-severe essential tremor that was refractory to at least two trials of medical therapy [2].

Patients were randomized 3:1 to receive MRgFUS thalamotomy (n = 56) or a sham procedure (n = 20). After 3 months, patients in the sham procedure group could cross over to active treatment.

Mean age was 71.0 ± 8.3 years and mean disease duration was 16.8 ± 12.3 years.

At 3 months, the mean tremor/motor score for the treated hand, measured by the composite clinical rating scale for tremor (CRST) Part A+B, was reduced by 47% in the MRgFUS thalamotomy group versus 0.14% in the sham procedure group ($p < 0.001$).

Intraprocedural sensations and events were brief and resolved by the end of the procedure (Table 1).

Approximately one-third of patients in each group had transient symptoms attributable to placement of the MRgFUS frame (Table 1).

Table 1. Treatment-related events at the time of MRgFUS procedure in a pivotal randomized controlled trial of patients with essential tremor [2].

Adverse event	MRgFUS thalamotomy (n = 56)	Sham (n = 20)
Intraprocedural sensations and events		
Head discomfort	30%	
Vertigo	21%	
Nausea	20%	10%
Vomiting	4%	
Scalp tingling	7%	5%
Back pain	9%	5%
Anxiety	5%	10%
Pin-site pain, edema, or bruising attributable to placement of the MRgFUS frame	30%	35%

The most frequently reported non-transient (> 72 hours) thalamotomy-related AEs were paresthesias/numbness and gait disturbance, which diminished over time (Table 2).

No new AEs related to or probably related to MRgFUS thalamotomy developed during long-term follow-up from 12 months to 5 years (Table 2).

Table 2. Non-transient (> 72 hours) MRgFUS thalamotomy-related adverse events in a pivotal randomized controlled trial and during long-term follow-up of patients with essential tremor [2-4].

Adverse event*		1 week (n = 56)	3 months (n = 56)	1 year (n = 56)	3 years (n = 52)§	5 years (n = 40)§
Paresthesia or numbness, any region		30%	25%	14%	21%	20%
Gait disturbance	Ataxia†	18%	4%	4%	2%	5%
	'Unbalanced'‡	14%	13%	5%	12%	15%
	'Unsteady'‡				4%	5%
Taste disturbance		5%	4%	4%	2%	5%
Dysmetria, limb		13%	9%	4%	2%	5%
Weakness		4%	4%	2%	4%	5%
Dysarthria / Dysphagia		4%	4%	0%	2%	0%
Headache		7%	4%	0%	-	3%
Fatigue		5%	2%	0%	2%	-

* Patients may have had more than 1 adverse event.

§ Data were unified for the treatment arm (n = 56) and crossover arm (n = 21) which included 19 sham crossover patients and two patients assigned to treatment who underwent a repeat procedure. Percentages of AEs are based on the number of patients observed at 3-year (n = 52) and 5-year (n = 40) follow-up, not on the total number of procedures performed (n = 77).

† Noted objectively on examination.

‡ Reported subjectively by patient or examiner.

All thalamotomy-related AEs recorded during 5 years of follow-up were classified by study investigators as mild (71%) or moderate (29%); none was deemed serious.

Literature review

A literature search was conducted using the search terms 'Insightec OR Exablate', 'focused ultrasound AND thalamotomy', and 'focused ultrasound AND essential tremor' to identify relevant articles of MRgFUS thalamotomy for essential tremor to compare with the pivotal RCT.

Inclusion criteria: peer reviewed articles from 2019 onwards with a cohort of ≥ 10 patients.

Exclusion criteria: articles with no safety results; expert opinion articles; articles with selective data.

A total of 248 articles were identified; 152 were screened and 7 met the selection criteria [5-11].

Main challenges in comparing data with the pivotal RCT were different metrics: follow-up duration, symptom name, symptom severity.

The optimal time point for comparison (most available data) was 3 months post-procedure.

Similar to the pivotal RCT, comparable studies indicated mild transitory procedure-related AEs (e.g., headache, nausea/vomiting, floating sensation) and mild-to-moderate gait disturbances and paresthesias/numbness (Table 3).

Table 3. Adverse events reported with MRgFUS thalamotomy in a pivotal randomized controlled trial [2], in comparable clinical studies (literature review) [5-11] and during post-marketing safety surveillance.

Adverse event	Pivotal study (n = 56)*	Literature review (n = 35-445)*	Post-marketing surveillance	
			2017-2021 (n = 6380 procedures)	2022 (n = 3730 procedures)
Ataxia	4%	14%	0.75%	0.03%
Gait disturbance	13%	13%		
Unbalanced		10%	0.4%	0.1%
Paresthesia/numbness	25%	13%	0.6%	0.1%
Dysmetria	9%	12%	< 0.1%	-
Dysarthria	4%	3%	0.2%	0.08%
Dysgeusia	4%	4%	0.1%	0.03%
Weakness	4%	0%	0.4%	0.2%
Headache	4%	-	0%	
Dystonia	-	-	0.05%	0%
Dizziness	-	-	0.05%	0.03%
Face swelling	-	-	0.06%	0%
Others	-	-	0.09%	0%

* Point of comparison was 3 months post-procedure.

Safety events reported during post-marketing surveillance

All safety events reported with real world MRgFUS thalamotomy procedures performed globally from 2017-2021 and 2022 were investigated and summarized.

Main challenges in comparing data with the pivotal RCT were that AEs were categorized subjectively by the physician (severity and duration not standardized).

AEs were reported in 3.2% of 6380 real-world procedures performed in 2017-2021, and in 0.6% of 3730 real-world procedures performed in 2022 (Table 3).

AEs were mainly gait disturbances and paresthesias/numbness (Table 3).

Customer survey data

Customers of the MRgFUS system (ExAblate Neuro) receive an annual survey requesting feedback on the company's (Insightec) support, product usability, safety, and reliability.

Survey question 6 asks "Have you encountered any unexpected adverse events during or after the treatment? Yes/No. If yes, please elaborate".

In surveys conducted in 2018-2022, responding customers rated the safety of MRgFUS thalamotomy as good/fair (6-33%) or very good/excellent (67-100%) (Table 4).

All AEs encountered with MRgFUS thalamotomy (Table 4) were within the known safety profile [1].

Table 4. Customer survey feedback on MRgFUS thalamotomy.

	2018	2019	2020	2022
Sent	11 (in users' meeting)	55	108	49
Answered	11	12 (22%)	35 (32%)	38
Safety perception				
Poor	0%	0%	0%	0%
Good / Fair	0%	33%	18%	6%
Very good / Excellent	100%	67%	83%	94%
Encountered adverse events				
No	64%	50%	71%	79%
Yes	36%	50%	29%	21%
Details	Gait: 1 Pain: 1 Transient paresthesia: 1 Face swelling: 1	Imbalance: 1 Ataxia: 1 Numbness at lip: 1 Face swelling: 1 Heat spread: 1 Off target ablation: 1	Gait: 3 Ataxia: 2 Pins penetration: 1 Off target ablation: 1 Low temp effect: 1	Numbness: 2 Gait: 1 Asterixis: 1 Clumsiness: 1 Slurred speech: 1 Altered taste: 1 Ballistic movement: 1 Stroke like symptoms: 1

Registry study

By 2019, 248 patients were enrolled into a Global Registry: ExAblate Neuro MR Guided Focused Ultrasound (MRgFUS) of Neurological Disorders [NCT03100474].

The registry collects only serious AEs.

No serious AEs were reported.

Conclusions

Unilateral MRgFUS thalamotomy for essential tremor in the real-world setting is safe and well tolerated.

Incidence rates of thalamotomy-related AEs during routine clinical use are not higher than in the pivotal RCT.

As the number of MRgFUS thalamotomy procedures performed each year increases, no new safety signals have emerged.

Evidence supports the use of MRgFUS thalamotomy in patients with essential tremor in everyday clinical practice.

Acknowledgements

Medical writing support was provided by Content Ed Net (Miami, FL, USA) with funding from Insightec (Miami, FL, USA).

References

1. ExAblate® Model 4000 Type 1. Information for Prescribers. https://www.accessdata.fda.gov/cdrh_docs/pdf15/p150038c.pdf
2. Elias WJ, et al. A randomized trial of focused ultrasound thalamotomy for essential tremor. N Engl J Med. 2016;375(8):730-739.
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5. Boutet A, et al. Focused ultrasound thalamotomy location determines clinical benefits in patients with essential tremor. Brain. 2018;141(12):3405-3414.
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8. Fukutome K, et al. What factors impact the clinical outcome of magnetic resonance imaging-guided focused ultrasound thalamotomy for essential tremor? J Neurosurg. 2020;134(5):1618-1623.
9. Ito H, et al. Two-year follow-up results of magnetic resonance imaging-guided focused ultrasound unilateral thalamotomy for medication-refractory essential tremor. Intern Med. 2020;59(20):2481-2483.
10. Abe K, et al. Focused ultrasound thalamotomy for refractory essential tremor: a Japanese multicenter single-arm study. Neurosurgery. 2021;88(4):751-757.
11. Giordano M, et al. Comparison between deep brain stimulation and magnetic resonance-guided focused ultrasound in the treatment of essential tremor: a systematic review and pooled analysis of functional outcomes. J Neurol Neurosurg Psychiatry. 2020;91(12):1270-1278.

Key Point

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Headache	4%	-	0%	
Dystonia	-	-	0.05%	0%
Dizziness	-	-	0.05%	0.03%
Face swelling	-	-	0.06%	0%
Others	-	-	0.09%	0%

* Point of comparison was 3 months post-procedure.

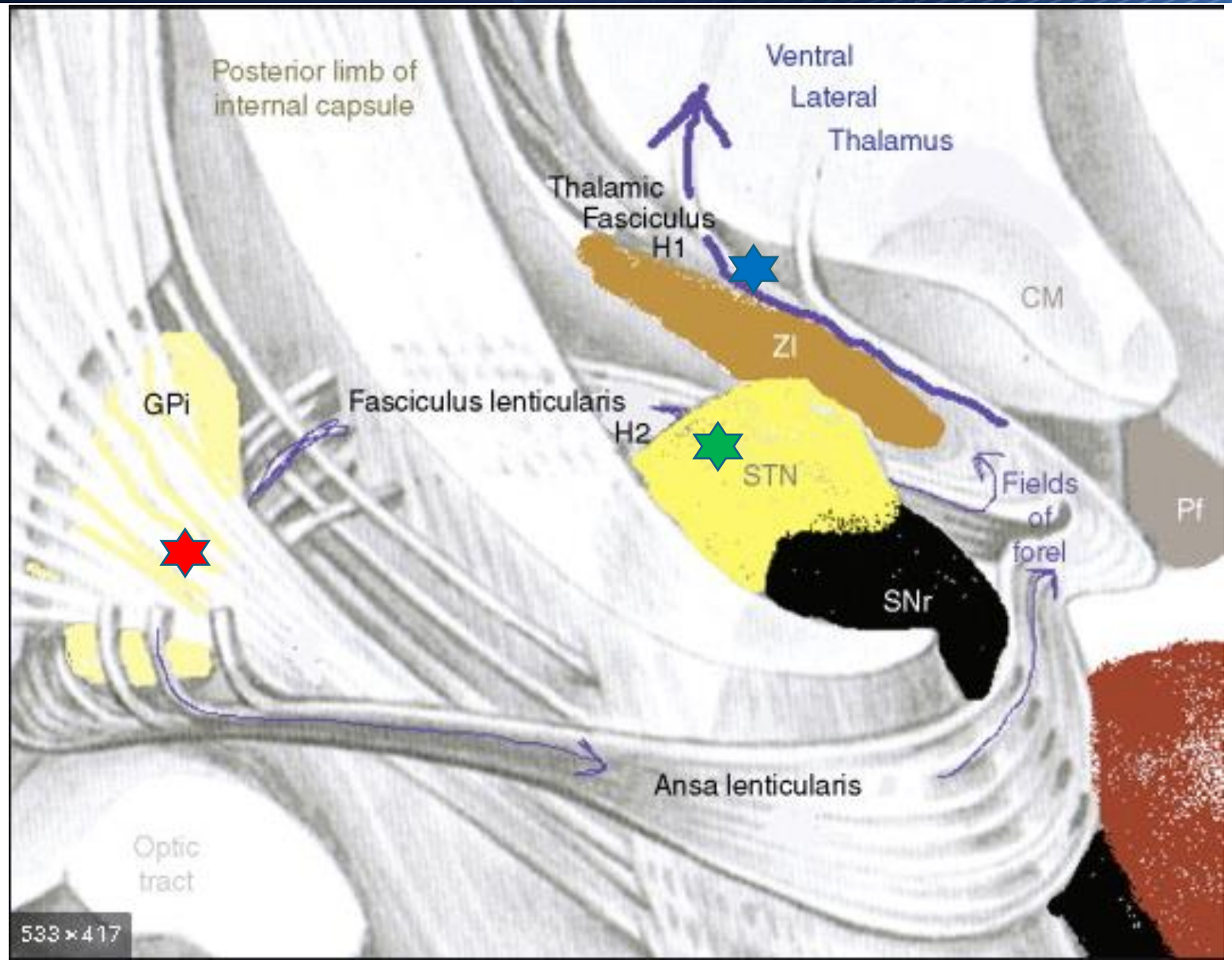
FOCUSED ULTRASOUND FOUNDATION

Current PD FDA Approvals: Dyskinesia

PD: Motor Fluctuations and Dyskinesia (also includes rigidity and bradykinesia)

- Target = GPi (Internal portion of the Globus Pallidus)
  - Krishna V, Fishman PS, Eisenberg HM, Kaplitt M, Baltuch G, Chang JW, Chang WC, Martinez Fernandez R, Del Alamo M, Halpern CH, Ghanouni P, Eleopra R, Cosgrove R, Guridi J, Gwinn R, Khemani P, Lozano AM, McDannold N, Fasano A, Constantinescu M, Schlesinger I, Dalvi A, Elias WJ. **Trial of Globus Pallidus Focused Ultrasound Ablation in Parkinson's Disease**. N Engl J Med. 2023 Feb 23;388(8):683-693. doi: 10.1056/NEJMoa2202721.
- 69% had a response at 3 months (94 patients)
  - Response = drop PD assessment by 3 points
- Pallidotomy related side effects at 3 months
  - Dysarthria (trouble speaking due to weak muscles, 1 moderate)
  - Visual disturbance (1 moderate)
  - Facial weakness (1 moderate)
- Medicare insurance coverage is in process (unilateral)
  - Anthem BC/CS coverage in US: CA, CO, CT, DC, GA, GA, IA, IN, KY, LA, ME, MI, MO, NH, NJ, NV, OH, TN, TX, VA, WA, WI

Clinical Trials for PD dyskinesia: Anatomy



With gratitude to Dr. Howard Eisenberg, UMD who shared this slide

Clinical Trials: Pallido-thalamic tractotomy

- Target PTT (Pallido-thalamic tractotomy)
  - 51 consecutive patient experience (Switzerland study)
    - Gallay MN, Moser D, Rossi F, Magara AE, Strasser M, Bühler R, Kowalski M, Pourtehrani P, Dragalina C, Federau C and Jeanmonod D (2020) **MRgFUS Pallidothalamic Tractotomy for Chronic Therapy-Resistant Parkinson's Disease in 51 Consecutive Patients: Single Center Experience.** Front. Surg. 6:76. doi: 10.3389/fsurg.2019.00076
    - Pop: tremor dominant PD (9), Akineto-rigid (5), mixed (37)
  - Results
    - UPDRS-III improved 54% from baseline and was preserved at 12 months ($p<.001$)
  - Adverse events at 12 months
    - Speech difficulties (6)
    - Hypophonia (3)
- Bilateral Parkinson's disease treatments (NCT04728295) {Mostly US study}
  - PTT, 50 patients, enrollment complete, no publication yet, no FDA action
  - 6 month interval between sides

Clinical Trials

- Couple of things to note
  - The symptoms did not completely resolve
  - What happens with the ongoing progression of disease?

Next steps for movement disorders

- Bilateral treatment
  - Is same technique for both sides safe?
  - What staging is needed, if at all?
- What size lesion is optimal?
  - Decrease risks effectiveness, but less side effects
- What is the optimal targeting technique
  - Traditional coordinates
  - MRI Tractography

Clinical Trials: underlying cause of PD

- FUSF article about 2 major releases https://www.fusfoundation.org/press-releases/two-landmark-studies-advance-focused-ultrasound-treatment-for-parkinson-s-disease
  - Dr. Obeso's group in Spain
  - Dr. Lipsman's group in Canada

Which is best for me?

Not a question of right vs wrong, but more of a decision for you to make

- DBS
  - This is an invasive procedure: this involves surgical incisions into the brain
  - Attractive for those who are very conservative
    - Patients who want to be able to reverse it all. You can have surgery to remove it all.
  - Both sides can be done at once
  - Not as good for those who do not want multiple MD visits or surgeries/interventions
- Focused Ultrasound
  - This is a non-invasive procedure: this does not involve surgical incisions into the brain
  - Well-suited for patient who wants it treated and you "get back to life"
    - Trade off is that this is not reversible. If bad result, you live with that too.
  - For bilateral disease, it takes two treatments, separated by 9 months,
  - Good in that it does not have multiple MD visits or surgeries/interventions

What to do if you are interested in FUS treatment?

- Remember: no issue in learning what is available
  - Even if you decide it is not for you
- If your movement disorder is predominantly tremor
    - Get evaluated by a FUS MD, to see what they can offer for you
    - **https://insightec.com/treatment-centers/**
  - Insurance Coverage
    - **Medicare Coverage (ET):** Covered in all 50 states (Medicare Advantage, need to check)
    - **Medicare Coverage (PD):** AK, AL, AZ, CA, CT, GA, HI, IA, ID, IL, IN, KS, KY, MA, ME, MI, MN, MO, MT, NC, ND, NE, NH, NV, NY, OH, OR, RI, SC, SD, TN, UT, VA, VT, WA, WI, WV, WY (38 states)
- If you have motor fluctuations, dyskinesia, bradykinesia or rigidity
  - If you have the capacity to cash pay, contact a treatment center (dyskinesia group)
  - Subscribe to the newsletter, and wait for Medicare payment to happen
- There is still a lot happening in this area, so the free newsletter is a good idea.
  - This can be found at the bottom left of our website (or **https://www.fusfoundation.org/newsletter-signup**).

To understand the details

- John Dutton is a FUS PD patient who had FUS done for tremor and made a film about it.
  - Worth the time to watch
- **https://www.youtube.com/watch?v=-WfDH94XQrk**

Agenda

- Introduction to Focused Ultrasound
- FUS Foundation
- Review of the current research status
  - Clinical trials
- **Bobby Krause**
- Questions

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Newsletter:

https://www.fusfoundation.org/newsletter-signup

Treatment site locations:

https://insightec.com/treatment-centers/

Focused Ultrasound Foundation