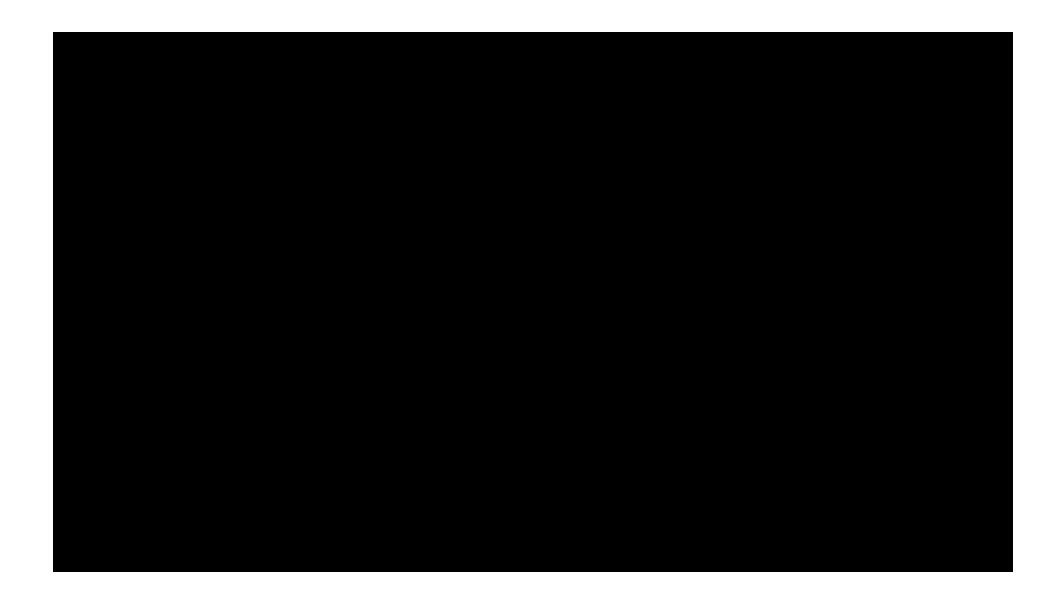
Advances in Treating Involuntary Tremors

MRI-guided Focused
Ultrasound for Essential Tremor

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Agenda



- Essential Tremor facts
- Essential Tremor treatment options
- What is Neuravive?
- How does it work?
- Who is a candidate for Neuravive?
- What can I expect from the Neuravive procedure?
- Clinical evidence
- Benefits of Neuravive
- In a patient's own words

Essential Tremor (ET) Facts



- The most common movement disorder affecting an estimated 10 million Americans.
- Usually affects the hands, but may also affect the voice, legs or torso.
- Daily activities such as eating and writing become difficult and may require care from family members.
- Exact cause unknown, but it runs in families about 50% of the time.
- The location in the brain that controls tremor is the Vim of the thalamus.



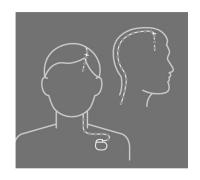






Essential Treatment Options







1ST LINE OF THERAPY

- Medications
- Only 40-50% of patients receive benefit from currently available medications such as Propranolol and Primidone

INVASIVE SURGERY

- Deep Brain Stimulation (DBS)
- Good tremor control, however requires 2 interventions with hardware implanted in brain and chest
- Risk of infection
- Lifetime of maintenance

FOCUSED ULTRASOUND SURGERY

- Immediate reduction of hand tremor
- Incisionless
- Low to no risk of infection
- Little to no hospitalization
- Fast recovery

Thanvi B, Lo N, Robinson T. Essential tremor-the most common movement disorder in older people. Age Ageing. 2006;35(4):344–349. Lyons KE, Pahwa R. Pharmacotherapy of essential tremor: an overview of existing and upcoming agents. CNS Drugs. 2008;22(12):1037–1045.

What is Neuravive MR-Guide Focused Ultrasound?



Focused Ultrasound

- More than 1,000 beams safely pass through the skull and brain
- Only where they meet, the temperature rises to create a tiny burn in the Vim

MR Imaging

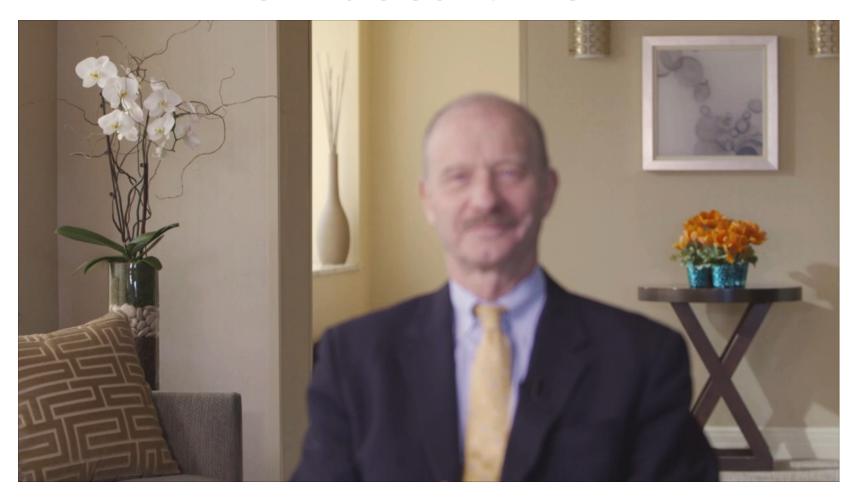
- Provides clear images of the treatment area for patient-specific planning
- Monitors temperatures in real-time for safety



The thalamus is about the size of a walnut. The ablation is about 5mm in size.



How does it work?



Who is a candidate for Neuravive?



- A confirmed diagnosis of medicationrefractory essential tremor.
- Men and women age 22 years or older.
- Patient is able to tolerate the procedure with or without some form of sedation (e.g., conscious sedation), communicate sensations during the procedure, fit in the MRI scanner and activate the Stop Sonication button.





What to expect during the Neuravive Treatment





Patient Prep

The patient's head is shaved so nothing interferes with the ultrasound beams. After local numbing medication is applied, a frame is secured to their head.



Planning

During the treatment, the patient is awake and lies inside the MRI scanner. MR images are taken to plan the treatment.



Target Verification

Light doses of energy are applied to accurately pinpoint the target and assess tremor improvement and identify any potential side effects.



Treatment

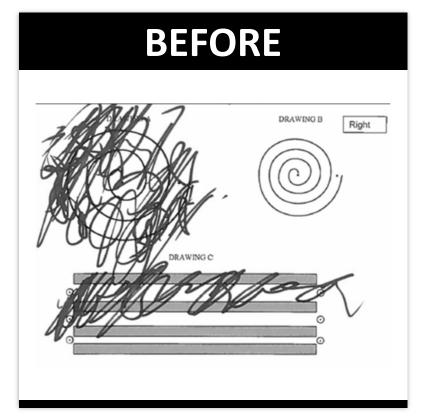
High energy is applied to create a small ablation, or burn and provide a therapeutic effect, reducing the hand tremor.

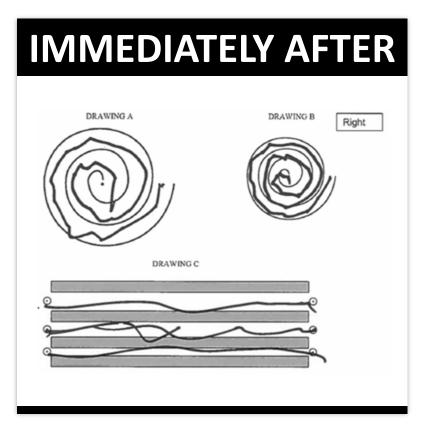


What results can be expected?



Many patients show immediate tremor improvement in their dominant hand.



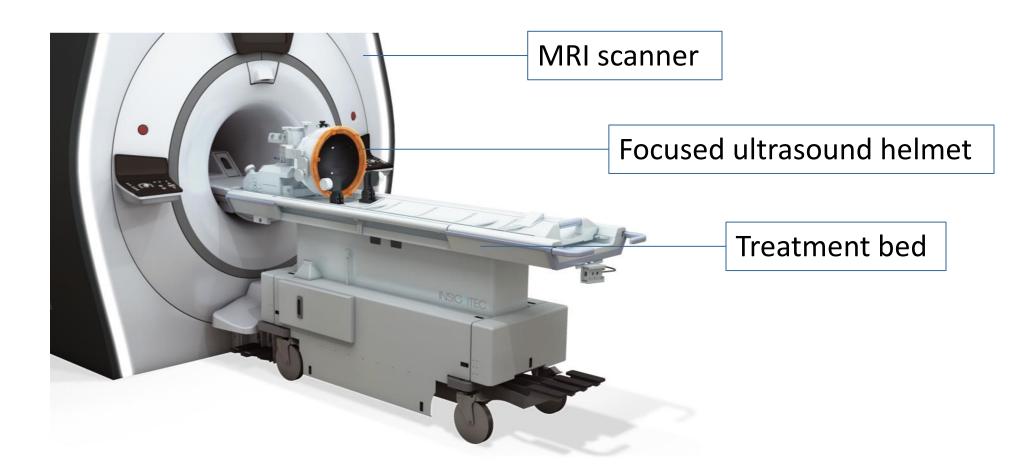


This may not be representative of all treatment outcomes.



The Exablate Neuro System

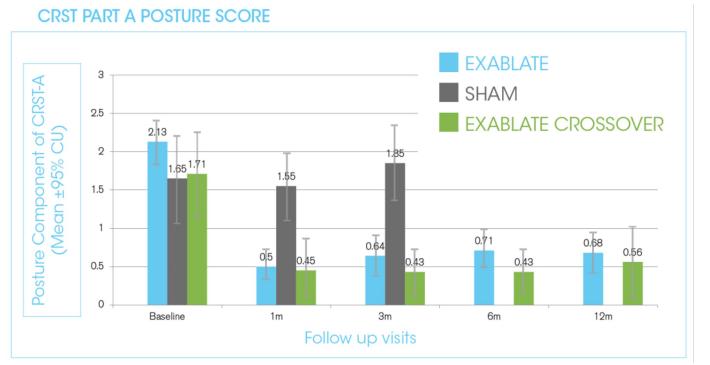




Clinical Evidence: Reduction in Tremor



In a multicenter clinical trial, results showed a 69.5% reduction in tremor amplitude at 3 months, which was maintained at 24 months.





ORIGINAL ARTICLE

A Randomized Trial of Focused Ultrasound Thalamotomy for Essential Tremor

W. Jeffrey Elias, M.D., Nir Lipsman, M.D., Ph.D., William G. Ondo, M.D., Ghanouni, M.D., Ph.D., Young G. Kim, M.D., Ph.D., Wonhee Lee, M.D., Ph.D. Michael Schwartz, M.D., Kullervo Hynynen, Ph.D., Andres M. Lozano, M.D., linit B. Shah, M.D., Diane Huss, D.P.T., N.C.S., Robert F. Dallapiazza, M.D., Ph.D. Ryder Gwinn, M.D., Jennifer Witt, M.D., Susie Ro, M.D., Howard M. Eisenberg, M.D., Ph.D., Paul S. Fishman, M.D., Ph.D., Dheeraj Gandhi, M.D., M.B., B.S., Casey H. Halpern, M.D.,

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ABSTRACT

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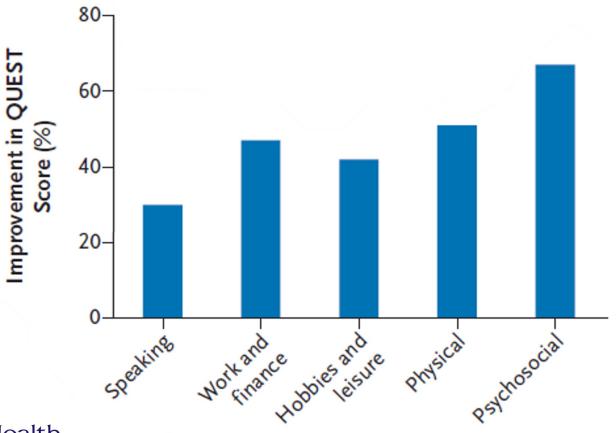
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Clinical Evidence: Improvement in QOL Boulder Community Health



QUEST Scores representing Quality of Life (QoL) significantly improved 47.4% at 12 months.





Domain



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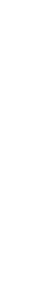
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Clinical Evidence: Temporary Side Effects During Treatment



Adverse Events	Number n=56	%
Heat or pressure discomfort	17	30%
Vertigo	12	21%
Nausea	11	20%
Vomiting	2	4%
Scalp tingling	4	7%
Back pain	5	9%
Anxiety	3	5%
Pain, edema, bruising due to frame	17	30%



The NEW ENGLAND JOURNAL of MEDICINE

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BACKGROUND

Uncontrolled pilot studies have suggested the efficacy of focused ultrasound thalamotomy with magnetic resonance imaging (MRI) guidance for the treatment of essendal tremor.

ME

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Clinical Evidence: Side Effects at 12 months



Adverse Events	Number n=56	%
Paresthesias (tingling or numbness)	8	14%
Taste Disturbance	2	4%
Ataxia (objective) (lack of coordination when walking)	2	4%
Unsteadiness (subjective)	3	5%
Dysmetria (difficulty judging distance)	2	4%
Weakness	1	2%
Vertigo	1	2%



A Randomized Trial of Focused Ultrasound

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Neuravive Treatment for Essential Tremor

Benefits

- The first & only focused ultrasound treatment for ET approved by FDA
- Results
 immediately
 following
 treatment



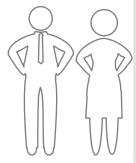
Safety Benefits

- Incision-free
- No implants
- No radiation
- Low risk of infection

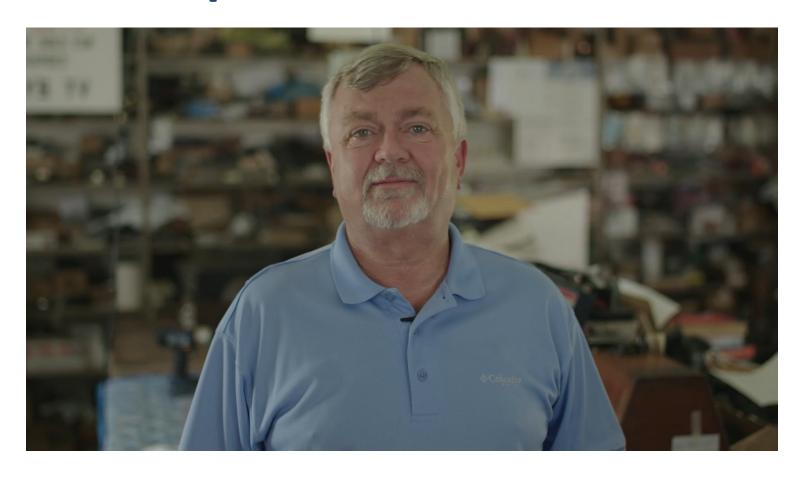


Patient Benefits

- Outpatient/short hospitalization
- Short recovery
- Return to normal life within days



In a patient's own words







Thank You!

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For more information, please call 800-720-0692 Insightec educators are standing by.



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