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

Incisionless MR-Guided Focused Ultrasound Surgery
- Immediate reduction of hand tremor
- Incisionless
- Low to no risk of infection
- Little to no hospitalization
- Fast recovery

What is Neuravive MR-Guided 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 medication-refractory 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

<table>
<thead>
<tr>
<th>Patient Prep</th>
<th>Planning</th>
<th>Target Verification</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>During the treatment, the patient is awake and lies inside the MRI scanner. MR images are taken to plan the treatment.</td>
<td>Light doses of energy are applied to accurately pinpoint the target and assess tremor improvement and identify any potential side effects.</td>
<td>High energy is applied to create a small ablation, or burn and provide a therapeutic effect, reducing the hand tremor.</td>
</tr>
</tbody>
</table>
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

- MRI scanner
- Focused ultrasound helmet
- Treatment bed
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.

Clinical Evidence: Improvement in QOL

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

## Clinical Evidence: Temporary Side Effects During Treatment

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Number n=56</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heat or pressure discomfort</td>
<td>17</td>
<td>30%</td>
</tr>
<tr>
<td>Vertigo</td>
<td>12</td>
<td>21%</td>
</tr>
<tr>
<td>Nausea</td>
<td>11</td>
<td>20%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2</td>
<td>4%</td>
</tr>
<tr>
<td>Scalp tingling</td>
<td>4</td>
<td>7%</td>
</tr>
<tr>
<td>Back pain</td>
<td>5</td>
<td>9%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>3</td>
<td>5%</td>
</tr>
<tr>
<td>Pain, edema, bruising due to frame</td>
<td>17</td>
<td>30%</td>
</tr>
</tbody>
</table>
Clinical Evidence: Side Effects at 12 months

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paresthesias (tingling or numbness)</td>
<td>8</td>
<td>14%</td>
</tr>
<tr>
<td>Taste Disturbance</td>
<td>2</td>
<td>4%</td>
</tr>
<tr>
<td>Ataxia (objective) (lack of coordination when walking)</td>
<td>2</td>
<td>4%</td>
</tr>
<tr>
<td>Unsteadiness (subjective)</td>
<td>3</td>
<td>5%</td>
</tr>
<tr>
<td>Dysmetria (difficulty judging distance)</td>
<td>2</td>
<td>4%</td>
</tr>
<tr>
<td>Weakness</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Vertigo</td>
<td>1</td>
<td>2%</td>
</tr>
</tbody>
</table>
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
Thank You!

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For more information, please call 800-720-0692
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