

Review Article

Magnetic Resonance-Guided Focused Ultrasound Thalamotomy for Medication-Refractory Essential Tremor

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Abstract

Background: Essential tremor is among the most common adult movement disorders. A substantial minority of patients become refractory to first-line pharmacotherapy. Magnetic resonance-guided focused ultrasound (MRgFUS) thalamotomy offers an incisionless alternative to deep brain stimulation and radiofrequency thalamotomy.

Objective: To synthesise published evidence on unilateral and staged bilateral MRgFUS thalamotomy for medication-refractory essential tremor.

Methods: Narrative review of pilot and pivotal trials, long-term follow-up studies, comparative literature, and mechanistic imaging studies.

Findings: The pivotal sham-controlled trial showed 47% tremor/motor improvement at three months versus 0.1% with sham. Benefit persisted through five years. Numbness and gait disturbance are common adverse events. Skull density ratio constrains candidacy in some patients. Staged bilateral treatment adds benefit with additional risk.

Conclusions: MRgFUS thalamotomy is a durable, well-tolerated option for carefully selected patients, complementing rather than replacing deep brain stimulation and radiofrequency approaches.

Keywords: Essential tremor; Focused ultrasound; Thalamotomy; Ventral intermediate nucleus; Movement disorder surgery

Abstract

Background: Essential tremor (ET) is among the most common adult movement disorders, and a substantial minority of patients become refractory to first-line pharmacotherapy. Magnetic resonance-guided focused ultrasound (MRgFUS) thalamotomy of the ventral intermediate nucleus offers an incisionless alternative to deep brain stimulation (DBS) and radiofrequency thalamotomy. **Objective:** To synthesise the published evidence on unilateral and staged bilateral MRgFUS thalamotomy for medication-refractory ET. **Methods:** Narrative review of pilot and pivotal trials, long-term follow-up studies, comparative and health-technology-assessment literature, and mechanistic/imaging studies. **Findings:** The pivotal sham-controlled trial showed 47% tremor/motor improvement at three months versus 0.1% with sham; benefit persisted through three and five years in extension cohorts, though numbness/paraesthesia and gait disturbance are common. Skull density ratio constrains candidacy in a meaningful minority. Staged bilateral treatment adds benefit with additional risk. **Conclusions:** MRgFUS thalamotomy is a durable, well-tolerated option for carefully selected medication-refractory patients, complementing rather than replacing DBS and radiofrequency approaches.

Keywords: essential tremor; focused ultrasound; thalamotomy; ventral intermediate nucleus; movement disorder surgery

Introduction

Essential tremor is a chronic, often progressive action tremor syndrome and one of the most prevalent movement disorders in adults, with a pooled worldwide prevalence of roughly 1.3% overall and nearly 6% beyond age 65 [1]. The current consensus classification of the International Parkinson and Movement Disorder Society situates essential tremor within a two-axis framework

combining clinical phenotype and aetiology, distinguishing it from dystonic, cerebellar, and other tremor syndromes that may mimic it and that respond differently to surgical intervention [2]. First-line pharmacotherapy, principally propranolol and primidone, is codified in American Academy of Neurology guidance, but a meaningful fraction of patients either fail to respond adequately or cannot tolerate escalating doses, leaving disabling hand, head, or voice tremor unaddressed by medical therapy alone [3].

For these medication-refractory patients, stereotactic options targeting the ventral intermediate nucleus (Vim) of the thalamus have long included radiofrequency thalamotomy and deep brain stimulation (DBS). Radiofrequency thalamotomy produces a durable lesion via a stereotactically placed electrode and heat, but requires a burr hole and carries a recognised haemorrhage risk along the electrode track. DBS avoids a destructive lesion, offering adjustable, reversible stimulation, but requires implanted hardware and carries infection and hardware-related risks over a patient's lifetime. MRgFUS thalamotomy adds a third, incisionless option: transcranial delivery of converging ultrasound beams creates a discrete thermal lesion in the Vim under real-time MR thermometry, without a burr hole, implanted hardware, or general anaesthesia, while retaining the irreversibility of a destructive lesion. Proof-of-concept work demonstrated feasibility [4], followed by an open-label pilot establishing substantial early benefit [5] and, ultimately, a sham-controlled pivotal trial that led to United States regulatory approval in 2016 [6,7].

This review synthesises the published evidence on MRgFUS thalamotomy for medication-refractory essential tremor: the pivotal trial and its long-term extensions, comparative and health-technology-assessment data relative to DBS and radiofrequency thalamotomy, the

adverse-event profile and the practical constraint imposed by skull density ratio, the evidence for staged bilateral treatment, and the emerging literature on recurrence and retreatment. It is a narrative synthesis of the literature, not a report of the authors' own surgical series.

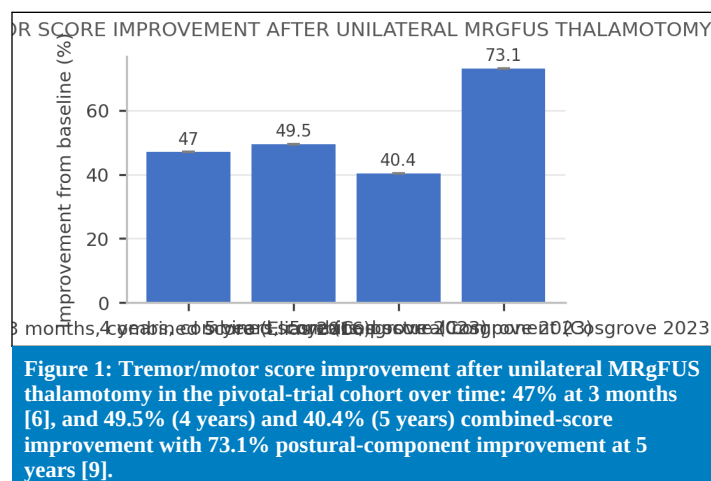
Epidemiology and Rationale for Thalamotomy

Essential tremor's high prevalence and tendency to progress in amplitude and anatomical distribution over decades mean that a sizeable absolute number of patients eventually exhaust pharmacological options or cannot tolerate them [1]. Accurate phenotypic classification matters because the diagnostic label determines candidacy and expected response: the current consensus statement separates essential tremor, essential tremor plus (with soft additional neurological signs), and tremor attributable to other aetiologies, and thalamotomy trials have generally required a confirmed essential tremor phenotype with a defined minimum severity and duration of medication resistance [2]. The AAN guideline formalises first- and second-line pharmacotherapy and implicitly defines the "medication-refractory" population from which surgical candidates are drawn, whether for Vim DBS, radiofrequency thalamotomy, or MRgFUS [3]. This population is precisely the one enrolled in the pivotal MRgFUS trials described below.

Pivotal Trial Evidence

The first transcranial MRgFUS thalamotomy series in humans established feasibility and early benefit in a small proof-of-concept cohort of four patients, using incremental sonications to confirm the target before creating a permanent lesion [4]. A larger open-label pilot of fifteen patients confirmed substantial tremor and motor score improvement within days of a unilateral procedure [5], setting the stage for a definitive, double-blind, sham-controlled trial in seventy-six patients allocated 3:1 to active treatment or a simulated procedure

replicating the noise, positioning, and duration of active sonication without therapeutic energy. At three months, the active-treatment group improved 47% on the primary hand tremor/motor score versus essentially no change (0.1%) with sham, a robust between-group difference, with quality-of-life and disability measures improving concordantly [6]. This trial directly supported US FDA approval of the Exablate Neuro system for unilateral Vim thalamotomy in July 2016, prompting subsequent exploration of bilateral and retreatment strategies discussed later in this review [7].



Long-Term Durability

Durability has been a central question since approval. Three-year follow-up of the pivotal-trial cohort found sustained improvement, with paraesthesia and gait disturbance the most frequent persistent complaints [8]. Five-year data on the same cohort showed the postural tremor component improved roughly 73% at both four and five years, and the combined tremor/motor score remained approximately 40% improved relative to baseline, with disability improvement sustained and no new severe adverse events [9]. A meta-analysis pooling twenty-one studies and 395 patients corroborated this trajectory, with an initial 61.5% improvement in hand tremor score at three months attenuating only modestly

by three years [10]. Independent replication, including a Chinese cohort followed for two years, has reproduced comparable benefit [11]. Not all durability data are reassuring: a double-lesion strategy followed for 4.5 years proposed a framework for distinguishing genuine loss of lesion efficacy from disease progression [12], and a case-control imaging analysis found more caudal lesion extension below the anterior commissure-posterior commissure line, rather than lesion size or peak temperature, distinguished patients who remained tremor-free from those who recurred [13].

Table 1: Major prospective trials and cohorts of unilateral MRgFUS thalamotomy for essential tremor reviewed here [4,5,6,8,9,10,11].				
Study	Design	N	Follow-up	Key outcome
Lipsman 2013	Proof-of-concept	4	Acute	Feasibility of transcranial lesioning
Elias 2013	Open-label pilot	15	Short-term	Substantial early tremor/motor improvement
Elias 2016	Sham-controlled RCT	76	3 months	47% improvement vs 0.1% sham (P<0.001)
Halpern 2019	Trial extension	Not stated	3 years	Benefit sustained; paraesthesia, gait AEs
Cosgrove 2023	Trial extension	40 of 75	5 years	73% postural, 40.4% combined score improvement
Miller 2022	Meta-analysis	395 (21 studies)	Up to 36 months	61.5% at 3 months, attenuated but sustained
Wu 2021	Independent cohort	48	2 years	Comparable durable improvement in Chinese cohort

Comparison with Deep Brain Stimulation and Radiofrequency Thalamotomy

A formal health-technology assessment concluded that

MRgFUS produces high-quality evidence of benefit over sham, with comparative effectiveness against DBS and radiofrequency thalamotomy graded as low-to-very-low certainty because head-to-head trials remain scarce; the non-invasive nature of MRgFUS was highlighted as a distinct safety advantage, offset by the irreversibility of the lesion compared with adjustable DBS [14]. A more recent systematic review and meta-analysis synthesising the accumulated efficacy and adverse-event literature reached a broadly concordant conclusion, reaffirming MRgFUS as an effective option for appropriately selected patients while emphasising that comparative superiority over established alternatives has not been rigorously established [15]. In practice, patient preference, candidacy factors such as skull density ratio, and the reversibility afforded by DBS all inform selection among these three thalamic procedures rather than a single evidence-based hierarchy.

Adverse Events and Skull Density Ratio

Pooled analysis of the pivotal-trial cohorts identified paraesthesia/numbness and gait disturbance as the dominant persistent neurological adverse events after unilateral MRgFUS thalamotomy, generally mild-to-moderate in severity [16]. Baseline tremor severity and procedural sonication parameters have been shown to predict post-procedural imbalance, offering a route toward pre-operative risk stratification [17]. A practical and frequently underappreciated constraint on candidacy is skull density ratio (SDR), a measure of skull composition that governs how efficiently transcranial ultrasound energy reaches the target; multicentre data show that patients with SDR below 0.45, and even below 0.40, can still be treated safely and often effectively, though treatment efficiency and the probability of achieving a therapeutic lesion are reduced [18]. Because a substantial proportion of tremor patients present with skull scores or SDR below common thresholds, this factor meaningfully

limits candidacy in unselected populations rather than representing a rare edge case [19]. Imaging and connectivity studies help explain both benefit and risk: resting-state network reorganisation of the cerebello-thalamo-cortical circuit tracks clinical improvement [20], and multicentre lesion mapping has defined a Vim/cerebellothalamic-tract "sweet spot" associated with maximal tremor control alongside adjacent "sour spots" associated with speech, gait, or sensory side effects, offering a template for refining targeting to reduce adverse events without sacrificing efficacy [21].

Table 2: Key adverse-event and skull-density-ratio (SDR) findings relevant to patient selection [16,18,19,17].		
Source	Focus	Key finding
Fishman 2018	Pooled neurological AE profile	Paraesthesia/numbness and gait disturbance dominant, mostly mild-moderate
D'Souza 2019	SDR and outcome	SDR <0.40 still treatable; ~50% substantial improvement vs ~68% if SDR >=0.45
Tsai 2021	SDR distribution	19-50% of tremor patients fall below common SDR treatment thresholds
Jha 2024	Predictors of imbalance	Baseline tremor severity and sonication parameters predict post-procedural imbalance

Bilateral and Staged Treatment

Because unilateral thalamotomy leaves contralateral tremor untreated, staged bilateral MRgFUS has been explored for patients with bilaterally disabling tremor. A prospective staged-bilateral trial found that second-side lesioning added meaningful further tremor control but at the cost of higher rates of persistent dysarthria and gait imbalance than after the first side [22]. An open-label trial supporting regulatory authorisation of staged bilateral treatment in patients previously treated unilaterally found the tremor/motor score improved 66% at three months after the second procedure, with numbness/tingling the most common adverse event and transient dysarthria also

observed [23]. Independent real-world cohorts have corroborated this efficacy and safety profile [24], and direct comparison of bilateral MRgFUS outcomes against bilateral DBS with probabilistic lesion/electrode mapping has begun to clarify how the two bilateral strategies compare on tremor control and speech/gait side effects [25]. A cautionary correspondence nonetheless emphasises that adverse-event rates after the second side remain incompletely characterised outside single-centre series, arguing for continued vigilance as bilateral MRgFUS is adopted more widely [26].

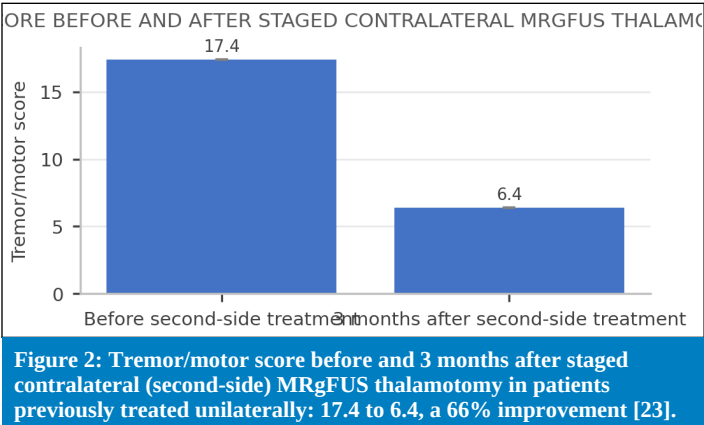


Figure 2: Tremor/motor score before and 3 months after staged contralateral (second-side) MRgFUS thalamotomy in patients previously treated unilaterally: 17.4 to 6.4, a 66% improvement [23].

Recurrence, Retreatment and Patient Selection

When tremor recurs after an initially successful unilateral procedure, both re-lesioning and staged bilateral DBS have been reported as salvage strategies. A repeat ipsilateral MRgFUS procedure has been documented, though pre-existing lesion changes complicated thermometry and re-targeting during the second treatment [27]. An alternative approach places a DBS lead within, or adjacent to, the prior MRgFUS lesion bed, favouring the reversibility and adjustability of stimulation over further irreversible lesioning, particularly when tremor has progressed bilaterally [28]. Collectively, this body of evidence argues for individualised patient selection informed by tremor phenotype [2], medication-refractory status [3], skull density ratio [18,19],

laterality and bilateral disability, and patient preference regarding the reversibility trade-off between lesioning and neuromodulation.

Conclusion

Since the first proof-of-concept lesions [4], MRgFUS thalamotomy has matured from an experimental procedure into a regulator-approved, evidence-based option for medication-refractory essential tremor, anchored by a rigorous sham-controlled pivotal trial [6] and corroborated by long-term follow-up extending to five years [9] and independent replication cohorts [11,10]. Paraesthesia and gait disturbance are the principal adverse events, skull density ratio meaningfully constrains candidacy in a non-trivial subset of patients, and staged bilateral treatment extends benefit to patients with bilateral disability at the cost of additional risk. Comparative evidence against deep brain stimulation and radiofrequency thalamotomy remains lower-certainty than the sham-controlled efficacy data, leaving procedure choice guided by candidacy, reversibility preference, and local expertise. Continued long-term follow-up, refined lesion-location targeting, and structured comparative trials should further clarify where MRgFUS thalamotomy fits within the broader armamentarium for medication-refractory essential tremor.

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