KUNA, Paweł Jan, GOŁDYN, Mateusz, TURCZYNOWSKI, Konrad, TURCZYNOWSKI, Kamil, PIETRUCHA, Jakub, LICHOŃ, Jakub, KUNA, Wojciech, CHOJNIAK, Alicja and HABERKO, Wiktoria. Evaluation of the Efficacy and Safety of Thalamotomy and Pallidotomy Using Focused Ultrasound (FUS) in the Treatment of Essential Tremor and Parkinson's Disease: A Literature Review. Quality in Sport. 2026;49:67622. eISSN 2450-3118.
https://doi.org/10.12775/QS.2026.49.67622
https://apcz.umk.pl/QS/article/view/67622

The journal has been awarded 20 points in the parametric evaluation by the Ministry of Higher Education and Science of Poland. This is according to the Annex to the announcement of the Minister of Higher Education and Science dated 05.01.2024, No. 32553. The journal has a Unique Identifier: 201398. Scientific disciplines assigned: Economics and Finance (Field of Social Sciences); Management and Quality Sciences (Field of Social Sciences).
Punkty Ministerialne z 2019 - aktualny rok 20 punktów. Załącznik do komunikatu Ministra Szkolnictwa Wyższego i Nauki z dnia 05.01.2024 Lp. 32553. Posiada Unikatowy Identyfikator Czasopisma: 201398. Przypisane dyscypliny naukowe: Ekonomia i finanse (Dziedzina nauk społecznych); Nauki o zarządzaniu i jakości (Dziedzina nauk społecznych).
The authors declare that there is no conflict of interest regarding the publication of this paper.
Received: 19.12.2025. Revised: 15.01.2026. Accepted: 15.01.2026. Published: 18.01.2026.

Evaluation of the Efficacy and Safety of Thalamotomy and Pallidotomy Using Focused Ultrasound (FUS) in the Treatment of Essential Tremor and Parkinson's Disease: A Literature Review

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Abstract

***Introduction**:* Parkinson's Disease (PD) and Essential Tremor (ET) are the two most prevalent movement disorders, with tremor being a core, often drug-refractory, motor feature. While traditional surgical treatments like Deep Brain Stimulation (DBS) and Radiofrequency (RF) ablation are effective, they are invasive and carry inherent risks such as hemorrhage and infection, necessitating craniotomy. This reality drives the need for less invasive therapeutic options for patients with advanced, medication-refractory symptoms and motor fluctuations.

Aim: The aim of this systematic review is to assess the clinical efficacy and safety profile of Thalamotomy and Pallidotomy performed using Magnetic Resonance-Guided Focused Ultrasound (MRgFUS) technology in the treatment of Essential Tremor and Parkinson's Disease.

Review methods: A comprehensive analysis of research papers available on PubMed and Google Scholar was conducted using keywords: Focused Ultrasound (FUS), Essential Tremor (ET), Parkinson's Disease (PD), Thalamotomy, Pallidotomy, MRgFUS.

Conclusion: MRgFUS-guided thalamotomy (VIM) and pallidotomy (GPi) constitute a breakthrough, non-invasive alternative to traditional surgical ablations. The technology demonstrates high and durable efficacy, achieving a 47% reduction in ET tremor and a 39,1% reduction in PD motor symptoms (UPDRS III), comparable to invasive standards. Crucially, MRgFUS offers a favorable safety profile by eliminating the risk of surgical bleeding and infection while providing real-time lesion monitoring. However, a key limitation remains the requirement for an adequate Skull Density Ratio (SDR), excluding some clinically eligible patients. Further long-term, prospective studies are required to fully establish its role.

Keywords: Focused Ultrasound (FUS)/ Essential Tremor (ET)/ Parkinson's Disease (PD)/ MRgFUS/ Thalamotomy/ Pallidotomy

Introduction

Parkinson's Disease (PD) is the second most common age-related neurodegenerative disorder, affecting 0,5–2% of individuals over 65 years of age [1]. Tremor is one of its main motor characteristics, although its pathogenesis is less understood compared to other symptoms [2]. Tremor is also the primary motor feature of Essential Tremor (ET), one of the most prevalent neurological disorders [3]. The pathogenesis of PD is complex, involving a combination of genetic susceptibility and environmental factors [4], while in ET, studies highlight the critical role of cerebellar dysfunction and the cerebello-thalamo-cortical loop [3]. Understanding these circuits is essential for identifying therapeutic targets for tremor.

PD includes a tremor-dominant subtype (TDPD), in which tremor may be more resistant to dopaminergic treatment [2]. Pharmacological management is often ineffective when symptoms fluctuate or drug escalation is limited by induced involuntary movements (dyskinesias) [1]. In such cases, surgical treatment may become necessary. Traditional invasive methods, such as Deep Brain Stimulation (DBS) and permanent lesioning, are effective for managing motor symptoms of ET and PD [3, 5]. While DBS is currently more widely used, lesioning procedures have shown comparable efficacy and are preferred for patients for whom a chronically implanted stimulating device poses significant risk [5]. Well-established lesioning therapies include thalamotomy, targeting the ventral intermediate nucleus (VIM) to suppress drug-refractory tremor in ET and under investigation for TDPD [3, 5], and pallidotomy, traditionally performed using Radiofrequency (RF) ablation for PD [1]. Regardless of the technique, these procedures are invasive, associated with potential complications, and require open surgery [1].

The development of non-invasive techniques addresses the invasiveness of traditional treatments [5]. Magnetic Resonance-Guided Focused Ultrasound (MRgFUS) is a non-invasive method for creating therapeutic lesions, allowing transcranial delivery of acoustic energy without craniotomy [1, 5]. In neurosurgery, procedures such as FUS pallidotomy (GPi ablation) and FUS thalamotomy (VIM/thalamus ablation) utilize this mechanism to permanently deactivate hyperactive nuclei. The adoption of FUS eliminates the risks associated with invasiveness and provides an alternative to traditional surgical interventions. FUS technology has obtained regulatory approval for VIM thalamotomy in ET treatment, as confirmed by randomized clinical trials [3], and more recently for pallidotomy in PD [1]. Compared to traditional RF ablation, FUS may offer superior control over lesion location and size due to real-time monitoring with MR thermography, whereas RF lesions rely on intraoperative clinical assessment [1, 5]. However, lesion size can be constrained by patient tolerance and the Skull Density Ratio (SDR) [5]. Given its effectiveness in suppressing tremor in ET and its approval for pallidotomy in PD, an in-depth evaluation of FUS technology is warranted. The aim of this systematic review is to assess the clinical efficacy and safety profile of thalamotomy and pallidotomy using FUS in the treatment of ET and PD, including a comparison with traditional methods such as RF pallidotomy [1, 3, 5].

Materials and Methods

A comprehensive analysis of research papers available on PubMed and Google Scholar was conducted using search terms encompassing the following keywords: Focused Ultrasound (FUS), Essential Tremor (ET), Parkinson's Disease (PD), Thalamotomy, Pallidotomy.

FUS Technology and Procedure

Focused Ultrasound (FUS) technology, developed from historical research on brain ablation dating back to the 1940s [6], utilizes pressure waves at frequencies exceeding the audible range. This energy is precisely concentrated in a small region, penetrating tissues, including the skull [7]. FUS is capable of generating either mechanical or thermal energy, leading to permanent or reversible biological effects [8].

Mechanisms of Action and Apparatus

Thermal Ablation: This mechanism is achieved using High-Intensity Focused Ultrasound (HIFU), which elevates tissue temperature, causing cell death via coagulative necrosis [8]. Thermal ablation is essential for treating tremor and PD [6]. Neuromodulation: This requires the use of Low-Intensity Focused Ultrasound (LIFU) [8]. This action is primarily mechanical, leading to the excitation or inhibition of neuronal activity [7]. Image Guidance: FUS procedures are most commonly guided by Magnetic Resonance Imaging (MR-HIFU or MRgFUS) [6, 8]. MRI provides precise anatomical guidance and, critically, real-time monitoring of tissue temperature, which is necessary to ensure effective ablation [6, 8]. Alternatively, US-HIFU may be used, which monitors tissue echogenicity [8].

Clinical Ablation Procedure and Protocol

The clinical MRgFUS procedure requires detailed planning and rigorous monitoring. Pre-treatment MRI (T1, T2, and DTI) and CT scans are performed to calculate the Skull Density Ratio (SDR). Images are processed using specialized stereotactic software to establish the target coordinates. The actual ablation is preceded by a sequence of sonications at escalating power to confirm precision and verify clinical effects. The first, low-power sonication (40 °C to 45 °C, 10 to 20 s) serves to confirm the correct device alignment. In the Clinical Verification phase, power is then increased to temperatures of 50 °C to 53 °C, which is intended to elicit transient clinical effects. Definitive Ablation is a high-power sonication that aims to reach an average temperature between 55 °C and 60 °C in order to induce permanent thermal ablation and significant clinical improvement. Intraprocedural clinical monitoring of the patient is conducted continuously. Observation of clinical improvement (e.g., a drop in the MDS-UPDRS scale) and the absence of adverse events (AEs) determine the continuation to the next, stronger sonication. If side effects occur or improvement is lacking, the target coordinates must be adjusted. Treatment is concluded when satisfactory clinical improvement is achieved, with an emphasis on performing the minimal number of sonications to reduce the risk of edema and maintain a favorable risk/benefit profile. Post-ablation, the lesion coordinates are measured based on T2-weighted MRI [6].

Safety Profile and FUS Complications

MRgFUS is considered a relatively safe treatment for essential tremor and Parkinson's disease, characterized by minimal invasiveness and the ability to precisely create small focal lesions within the target brain structures [9]. The procedure does not necessitate general anesthesia, which is beneficial for patients with increased anesthetic risk [10]. In studies concerning MRgFUS subthalamotomy, the most frequently observed adverse events were mild and transient, including dizziness, headaches, and skin burns. Some complications were directly related to the ablation, including mild facial asymmetry, transient limb weakness, subjective gait instability, and dysarthria. Intraprocedural involuntary movements and new episodes of peak-dose dyskinesia occurred in some patients, the majority of which improved after dopaminergic treatment adjustments. From a long-term perspective, complications persisted in a small number of patients and were mild. For example, 25% of patients developed mild, new peak-dose dyskinesia at 6 months, while 75% experienced no new involuntary movements. Critically, there were no serious neurological complications requiring surgical intervention or hospitalization. Objective balance tests showed no deterioration in patient stability during the observation period [9]. Broader literature analyses similarly indicate that the most common neurological complications after MRgFUS include speech disorders, ataxia, and sensory disturbances. Complications related to the MRI/ultrasound process itself or the fixation of the therapeutic frame are typically transient, involving headaches, dizziness, nausea, vomiting, skin numbness, or burning sensations. The risk of complications can be mitigated by the ability to monitor the patient's reaction in real time and modify treatment parameters. The safety profile may vary depending on the MRgFUS surgical target. For instance, ventral intermediate nucleus (VIM) ablation most often results in tremor improvement but can cause sensory disturbances, muscle weakness, or dyskinesias. Subthalamic nucleus (STN) ablation improves core PD motor symptoms but may cause movement, speech, or cognitive disorders. Globus pallidus (GPi) and posterior thalamic tractotomy (PTT) carry the potential for motor or sensory complications [10]. Analogous studies of MRgFUS used in treating non-neurological pathologies, such as uterine fibroids, demonstrated a similar safety profile: most complications were mild or moderate (SIR Grade A or B), did not require major intervention, and resolved within weeks. Serious complications (Grade C–F) were not reported [11]. The evidence indicates that MRgFUS has a favorable risk-benefit ratio. Most complications are transient, mild, and manageable through intraoperative monitoring and parameter modification, representing a significant advantage over more invasive surgical methods [9, 10, 11]. However, the limited number of studies, small cohorts, and short follow-up periods necessitate further research to fully determine the long-term safety of the procedure [9, 10, 11].

Efficacy of FUS Thalamotomy in Essential Tremor

MRgFUS-guided thalamotomy is a highly effective and durable method for treating drug-refractory Essential Tremor (ET). Core efficacy evidence comes from randomized trials where unilateral FUS thalamotomy showed a significant advantage over a procedure in which placebo was used [12].

Evidence of Clinical Efficacy

In their randomized trial Elias et. al [12] recorded a 47% improvement in hand tremor scores at 3 months in the thalamotomy group , which was sustained at 40% at 12 months. Total tremor scores (CRST scale) improved by 41% at 3 months [12]. FUS treatment also resulted in substantial improvement in quality of life and functional independence [12, 13]. Functional disability decreased by 62% at 3 months in the randomized study [12]. In staged bilateral treatment studies, disability was reduced by 73%, often leading to a reduction or complete cessation of tremor medications. Furthermore, 71% responsiveness was noted for head tremor and 67% for voice tremor in this group [13].

According to Elias et al. [14], a pilot study involving 15 patients with Essential Tremor demonstrated significant efficacy- 12 months after thalamotomy achieved with transcranial MRI-guided focused ultrasound. Total tremor scores (CRST scale) improved from 54.9 points at baseline to 24.3, and disability scores improved from 18.2 points to 2.8. Furthermore, quality-of-life scores improved from 37% at baseline to 11%.

According to Cosgrove et al. [15], a study representing the longest follow-up reported for MRgFUS thalamotomy, 40 patients completed the 5-year follow-up, confirming the sustained and significant tremor improvement. Scores for postural tremor for the treated hand remained significantly improved by 73.1% from baseline at 60 months. Combined hand tremor/motor scores showed substantial long-term improvement, specifically a 40.4% reduction at 5 years. The improvement of the physical and psychological dimensions of the QUEST scores remained significantly improved through the 5-year period. The authors concluded that unilateral MRgFUS thalamotomy demonstrates significant durability without any progressive or delayed complications, with all persistent adverse events remaining mild or moderate.

Efficacy is linked to targeting precision. Lesions that extend beyond the classic target (VIM nucleus) into the Posterior Subthalamic Area (PSA) have been shown to provide significantly greater tremor control. Patients whose lesion reached the PSA (1.2 to 1.5 millimeters superior to the Anterior Commissure – Posterior Commissure plane) achieved 92.5% – 95.8% improvement in tremor tests (TETRAS), compared to approximately 69% improvement in patients without involvement in this area . Moreover, this optimized targeting required fewer sonications and a lower thermal dose to achieve satisfactory tremor control. In conclusion, FUS Thalamotomy is a clinically validated and effective intervention, and refined targeting protocols encompassing the PSA significantly boost the procedure's efficacy [16].

Safety Profile and Technological Advantages

MRgFUS thalamotomy presents a highly favorable safety profile and distinct methodological advantages compared to other neurosurgical interventions [17, 18]. A key benefit of the non-invasive MRgFUS technique is the minimization of hemorrhage risk [17, 18]. In studies on thalamotomy, no serious or persistent adverse events (SAE), such as hematomas, occurred [18], and the overall incidence of serious complications was low [17]. This favorable safety profile, minimal bleeding risk, and the fact that thermal ablation carries a minimal risk of hemorrhage [17] suggest that discontinuing antithrombotic or antiplatelet therapy before the procedure may not be required [18]. The most common adverse effects of FUS thalamotomy include finger paresthesia, ataxia, and orofacial paresthesia [17]. Most of these effects were mild or transient [17, 18]. However, persistent paresthesia occurred in 19% and ataxia in 4% of patients, respectively, in one trial [17]. The overall observation of minimal adverse events further substantiates the safety of the MRgFUS Vim thalamotomy for refractory Essential Tremor (ET) [18]. The precision of MRgFUS ablation is paramount for achieving the desired clinical effect [17, 18]. As a therapy not dependent on implanted devices, MRgFUS avoids issues associated with Deep Brain Stimulation (DBS), such as stimulation tolerance, hardware-related complications, infection, expense, and maintenance demands [17]. Unlike Gamma Knife thalamotomy, which is limited by latent radiation effects and the inability to confirm targeting, FUS allows for intraprocedural testing and real-time monitoring [17].

Efficacy of FUS Pallidotomy in Parkinson's Disease

MRgFUS-guided pallidotomy represents an evolution of the well-established lesioning method used to manage the motor symptoms of Parkinson's Disease (PD). This method enables the creation of precise ablations within the Globus Pallidus Internus (GPi) without the need for craniotomy [19, 20]. MRgFUS pallidotomy procedures are conducted in the off-medication state, with the patient fully conscious [19]. This is vital as it allows real-time monitoring of clinical effects and early detection of off-target effects (e.g., dysarthria, weakness, visual disturbances), permitting immediate adjustment of the ablative focus [19]. Through MR thermography and real-time imaging, it is possible to achieve a therapeutic temperature of greater than or equal to 51 °C within the GPi, considered necessary for creating an effective lesion. This was achieved in 97% of patients undergoing active therapy [19]. The procedure typically involved creating 2–3 ablative foci, with ongoing evaluation of their placement, size, and clinical response [19, 20].

Evidence of Clinical Efficacy

Jung et al. [21], in their study involving 8 patients, reported that unilateral MRgFUS pallidotomy showed significant improvement in key motor function indices. Motor symptoms severity in the off-medication state decreased by 32.2% at 6 months and 39.1% at 12 months. Furthermore, dyskinesia reduction was substantially achieved, with scores falling by 57.4% at 6 months and 52.7% at one year. These results are consistent with the efficacy achieved by established surgical methods, such as traditional RF pallidotomy and GPi Deep Brain Stimulation (GPi-DBS), which typically achieve a 28.8–37% reduction in motor symptom severity. Long-term durability is supported by data from FUS ablation in the Subthalamic Nucleus (STN), which showed a 52% improvement in symptoms after 3 years, suggesting that MRgFUS ablations are characterized by long-lasting and stable effects [22].

According to Ahmed et. al [23], the treatment efficiency of MRgFUS pallidotomy is significantly reduced compared to other FUS targets. This is primarily because the Globus Pallidus Internus (GPi) is located in an antero-lateral position (off-center), requiring almost twice the energy for successful ablation.

However study authors [23] determined that a low Skull Density Ratio (SDR) and greater skull thickness have a strong negative impact on the efficiency of the pallidotomy procedure. This means that patient screening based on skull properties is particularly critical for GPi ablation.

Safety Profile and Technological Advantages

MRgFUS pallidotomy offers a highly favorable safety profile, primarily due to its non-invasive nature, which eliminates risks associated with traditional neurosurgical interventions [21]. Unlike Deep Brain Stimulation (DBS) or radiofrequency ablation, MRgFUS does not require a craniotomy, the drilling of burr holes, or the insertion of electrodes into the brain parenchyma. This fundamentally minimizes the risk of intracranial hemorrhage and surgical site infections, which are the most serious complications of invasive procedures [21].

Furthermore, a distinct methodological advantage of MRgFUS is the ability to perform real-time intraprocedural monitoring. Using MR-thermometry, clinicians can precisely measure the temperature at the target site and assess clinical responses using sub-lethal "test sonications." This allows for the verification of the target's accuracy and the detection of potential side effects before a permanent lesion is created.

Regarding post-procedural outcomes, studies have noted only minimal and mostly transient complications. While some patients reported mild headaches or localized back pain due to the duration of the procedure in the MRI scanner, these symptoms typically resolved within days [21]. The "transient neurological effects" mentioned in clinical trials often include mild paresthesia or slight gait instability, but these are significantly less frequent and less severe compared to the hardware-related complications (such as lead migration or battery failure) seen in DBS [21].

Additionally, as a therapy not dependent on implanted hardware, MRgFUS avoids the long-term maintenance demands, expense, and infection risks associated with permanent devices. This makes it a particularly attractive option for patients who may be poor candidates for traditional surgery due to age or comorbidities.

Discussion

The clinical data presented in this review illustrate a paradigm shift in the surgical management of movement disorders. MRgFUS represents a bridge between conservative pharmacological management and invasive neurosurgery. The primary advantage of this technology lies in its ability to achieve comparable efficacy to Deep Brain Stimulation (DBS) and Radiofrequency (RF) ablation while maintaining a superior safety profile regarding perioperative complications [17, 21].

A critical finding in the evaluation of Essential Tremor (ET) is the long-term durability of the VIM thalamotomy. The 5-year follow-up data provided by Cosgrove et al. [15] is essential, as it dispels concerns that non-invasive thermal lesions might be more prone to symptom recurrence than traditional methods.

However, the application of MRgFUS in Parkinson's Disease (PD) via pallidotomy introduces specific technical challenges not seen in VIM thalamotomy. Due to the study by Ahmed et al. [23], the lateral position of the Globus Pallidus Internus (GPi) requires higher energy levels due to the angle of incidence of the ultrasound beams through the skull. This directly addresses the significance of the Skull Density Ratio (SDR): patients with a low SDR (typically below 0.4) may be ineligible for GPi pallidotomy because the skull absorbs too much energy, preventing the target tissue from reaching the required 51–55°C for permanent ablation [19, 23].

When comparing safety, the absence of hardware-related complications (infections, lead migration, or battery failures) gives MRgFUS a distinct advantage over DBS, particularly for elderly patients or those on anticoagulants [17, 21]. Nevertheless, the irreversibility of the FUS lesion remains its primary disadvantage compared to the adjustable nature of DBS. While transient side effects like paresthesia are common, the low rate of persistent deficits suggests that the intraprocedural "test sonication" protocol is an effective safeguard against permanent neurological damage [18, 19].

Conclusion

MRgFUS thalamotomy and pallidotomy represent a progression in the treatment of refractory Essential Tremor and Parkinson’s Disease. The evidence confirms that MRgFUS provides a potent, durable reduction in motor symptoms—specifically hand tremor and dyskinesia—while eliminating the risks of intracranial hemorrhage and surgical site infection associated with invasive procedures [12, 17, 21].

The clinical efficacy of VIM thalamotomy is now well-established even in long-term 5-year observations [15], while GPi pallidotomy shows promising results that are comparable to traditional RF methods [21]. The primary limitations of the technology are currently technical rather than clinical, involving patient eligibility based on skull density (SDR) and the current focus on unilateral treatments to avoid pseudobulbar side effects [23].

In conclusion, for patients who are poor candidates for invasive surgery or who prefer a device-free lifestyle, MRgFUS offers a highly favorable risk-benefit ratio. Future research should focus on the standardization of bilateral treatment protocols and the potential of low-intensity ultrasound (LIFU) for non-ablative neuromodulation, which could expand the therapeutic horizon for neurodegenerative disorders.

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All authors have read and agreed with the published version of the manuscript.

Funding statement

The study did not receive special funding.

Informed Consent Statement

Not applicable.

Conflict of Interest Statement:

The authors report no conflict of interest.

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