Tremor and Other Hyperkinetic Movements

Preliminary Experience with Simultaneous Bilateral Radiofrequency Vim Thalamotomy: Two Cases Including the First Participant in a Prospective Trial

CASE REPORTS

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ABSTRACT

Background: Simultaneous bilateral thalamotomy has historically been discouraged because of neurological risks.

Case Report: We report a retrospective index case and the first participant in an ongoing prospective trial undergoing simultaneous bilateral radiofrequency Vim thalamotomy. A stepwise intraoperative MRI protocol was used in the prospective case. At 6 months, CRST improved by 91.2% and 70.2%, respectively. Transient dysarthria and dysphagia resolved, no gait or balance disturbance was observed, and mild lingual paresthesia persisted in Case 2.

Discussion: These preliminary findings support continued prospective evaluation of a lesion-minimizing strategy.

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INTRODUCTION

Historically, bilateral thalamotomy has been discouraged due to high risks of permanent neurological complications. Reports from the 1960s on radiofrequency (RF) thalamotomy documented alarmingly high complication rates, with speech disturbances occurring in 23.8–36.0% [1–3]. While MRI-guided focused ultrasound (MRgFUS) has increased reports of staged bilateral thalamotomy with meaningful tremor reduction, a staged strategy remains the standard approach because it avoids complications related to simultaneous bilateral lesioning and allows assessment of adverse effects after unilateral treatment before proceeding with contralateral intervention [4–6]. However, long-term safety has not been clearly established to depend solely on the interval between procedures, and additional factors, such as accurate targeting and careful control of lesion volume, may also be involved. A simultaneous bilateral approach offers the distinct advantage of immediate functional restoration for bilateral disability. In this study, we investigated the feasibility and safety of same-session bilateral RF thalamotomy using stereotactic MRI targeting, physiological verification through macrostimulation, intraoperative MRI confirmation, and strict lesion-volume limitation.

PATIENTS AND STUDY DESIGN

This report includes two patients evaluated under separate ethics approvals: Case 1 under IRB No. 2021-0169 and Case 2 under IRB No. 2025-0015. Case 1 was retrospectively analyzed after same-session bilateral treatment had been selected through individualized shared decision-making for severe bilateral occupational disability. Case 2 was the first participant in an ongoing prospective, open-label interventional study (IRB No. 2025-0015, NCT07066358) evaluating simultaneous bilateral radiofrequency (RF) Vim thalamotomy for medication-refractory essential tremor. Inclusion criteria for the prospective study include age 20–70, MMSE ≥27 and MRI compatibility. Clinical outcomes—including Clinical Rating Scale for Tremor (CRST), Quality of Life in Essential Tremor Questionnaire (QUEST) and Scale for the Assessment and Rating of Ataxia (SARA)—are assessed at baseline and 1, 3, and 6 months postoperatively. Global cognitive function was assessed using the MMSE preoperatively and at 6 months postoperatively. In both cases, staged bilateral treatment and the potential risks of same-session bilateral lesioning were discussed, and the simultaneous approach was selected because unilateral treatment was considered insufficient to address the patients' substantial bilateral or midline disability. Both patients provided written informed consent. Safety was assessed by study investigators through neurological examinations. In Case 2, adverse events were evaluated on postoperative day 1, at 7–14 days, and at 1, 3, and 6 months, including speech, swallowing, sensorimotor function, coordination, gait, and balance. Adverse events were defined irrespective of causality and characterized by their functional impact and outcome. Events remaining at 6 months were considered persistent.

SURGICAL PROCEDURE

Procedures were performed under local anesthesia using a Leksell stereotactic frame. The ventral intermediate nucleus (Vim) was anatomically determined using stereotactic 3-T MRI and functionally verified by macrostimulation through the RF lesioning electrode at 130 Hz, with a pulse width of 100 μs and an intensity of 0.5–3.5 mA. Tremor suppression and sensory or capsular responses were assessed before coagulation; MER was not used. The coagulation temperature was fixed at 70°C, whereas coagulation duration and lesion number were adjusted according to the intraoperative clinical response. The Day 0 T1-hyperintense area was manually segmented by one investigator (EK) using MRIcroGL, and the calculated volume was used as a surrogate for the central thermocoagulated lesion rather than the broader T2/FLAIR abnormality, which includes transient edema. Early RF thalamotomy lesions have been shown to decrease in volume by approximately 90%, with the chronic lesion approximating the early necrotic core [7].

STEPWISE SAFETY PROTOCOL

While Case 1 underwent simultaneous ablation without intraoperative imaging, Case 2 utilized a "stepwise safety protocol" incorporating iMRI. Immediately after completion of the first thalamotomy and before contralateral lesioning, iMRI was performed to assess radiographically apparent acute hemorrhage and potential target displacement, including brain shift due to cerebrospinal fluid leakage. With the stereotactic frame maintained in place, the contralateral target was revalidated on iMRI and subsequently confirmed by macrostimulation through the RF electrode. Contralateral lesioning proceeded only after confirming no radiographically apparent acute hemorrhage and no clinically relevant target displacement. If acute hemorrhage was detected on iMRI, the procedure was terminated; if brain shift was identified, the contralateral coordinates were recalculated.

CASE 1: RETROSPECTIVE INDEX CASE

A 70-year-old right-handed male presented with severe, medication-refractory ET (Baseline Total CRST: 57; QUEST: 70). The patient's livelihood was at immediate risk; he worked as a server at a busy Chinese restaurant, a role that demanded the steady use of both hands to carry heavy trays of food and pour liquids (Video 1). Although staged bilateral treatment was discussed, restoring function in only one hand would not have allowed him to perform his essential duties while awaiting contralateral treatment. Given the urgent occupational need, his refusal of DBS, and the financial burden of multiple hospitalizations, he chose a simultaneous bilateral approach after discussion of the potential neurological risks. We employed an asymmetric ablation strategy to balance bilateral functional recovery with speech safety. The left (dominant) Vim received two lesions (70°C, 40 s each), and the right (non-dominant) Vim received a single, smaller lesion (70°C, 20 s). The lesion volume (Day 0 T1-high intensity area) was strictly controlled at 30 mm^3 (left) and 17 mm^3 (right) (Figure 1A). Because bilateral upper-limb tremor improved immediately after surgery, interference with his work-related tasks resolved, allowing him to return to work shortly thereafter. Although he experienced mild, transient dysarthria and decreased appetite, these resolved within one month. Postoperative Susceptibility-weighted imaging (SWI) at 3 months demonstrated low-intensity areas at both targets (Figure 1B). At the 6-month assessment, his Total CRST was 5 (91.2% reduction) and QUEST was 3 (95.7% reduction), with a SARA score of 0, indicating marked functional improvement (Table 1). His MMSE score was 30/30 both preoperatively and at 6 months postoperatively. No gait or balance disturbance was observed from the immediate postoperative period through the final assessment. Video 2 shows tremor severity in Case 1 immediately after surgery and at 3 months postoperatively.



Video 1 Case 1: Preoperative clinical status.



Video 2 Case 1: Clinical status immediately after surgery and at 3 months postoperatively.

CASE 2: PROSPECTIVE TRIAL CASE

A 62-year-old right-handed male (Baseline Total CRST: 57) was enrolled in our prospective trial. Notably, his primary concern was tongue tremor, which caused significant social embarrassment and functional impairment, even more than his bilateral hand tremor (Video 3). Because midline symptoms typically require bilateral intervention for effective suppression, the patient strongly requested a simultaneous bilateral approach to achieve immediate relief. We first targeted the left Vim. After two RF lesions (70°C for 40 and 30 s), iMRI was performed, confirming accurate lesion placement and the absence of hemorrhage or clinically relevant brain shift (Figure 1C, D). With these objective safety confirmations and the absence of neurological deficits, we proceeded to the contralateral right Vim during the same session, performing a single lesion (70°C, 30 s). Day 0 MRI confirmed asymmetric volumes of 44 mm^3 (left) and 24 mm^3 (right) (Figure 1E). Postoperatively, the perioral and tongue tremor and bilateral upper-limb tremor disappeared immediately. He developed dysgeusia and very mild dysarthria in the early postoperative period. The dysarthria improved within approximately 1 week, whereas dysgeusia persisted and resolved by around 4 months. Dysphagia newly emerged at 1 month postoperatively but had resolved by the 6-month assessment. Postoperative SWI at 3 months demonstrated low-intensity areas at both targets (Figure 1F). At 6 months, his Total CRST was 17 (70.2% reduction), QUEST was 17 (76.7% reduction), and SARA score was 1. His MMSE score remained 30/30 from baseline to the 6-month assessment. Mild lingual paresthesia was present at 6 months. No gait or balance disturbance was observed from the immediate postoperative period through the final assessment (Table 1). Video 4 shows his clinical status immediately after surgery and at 3 and 6 months postoperatively.

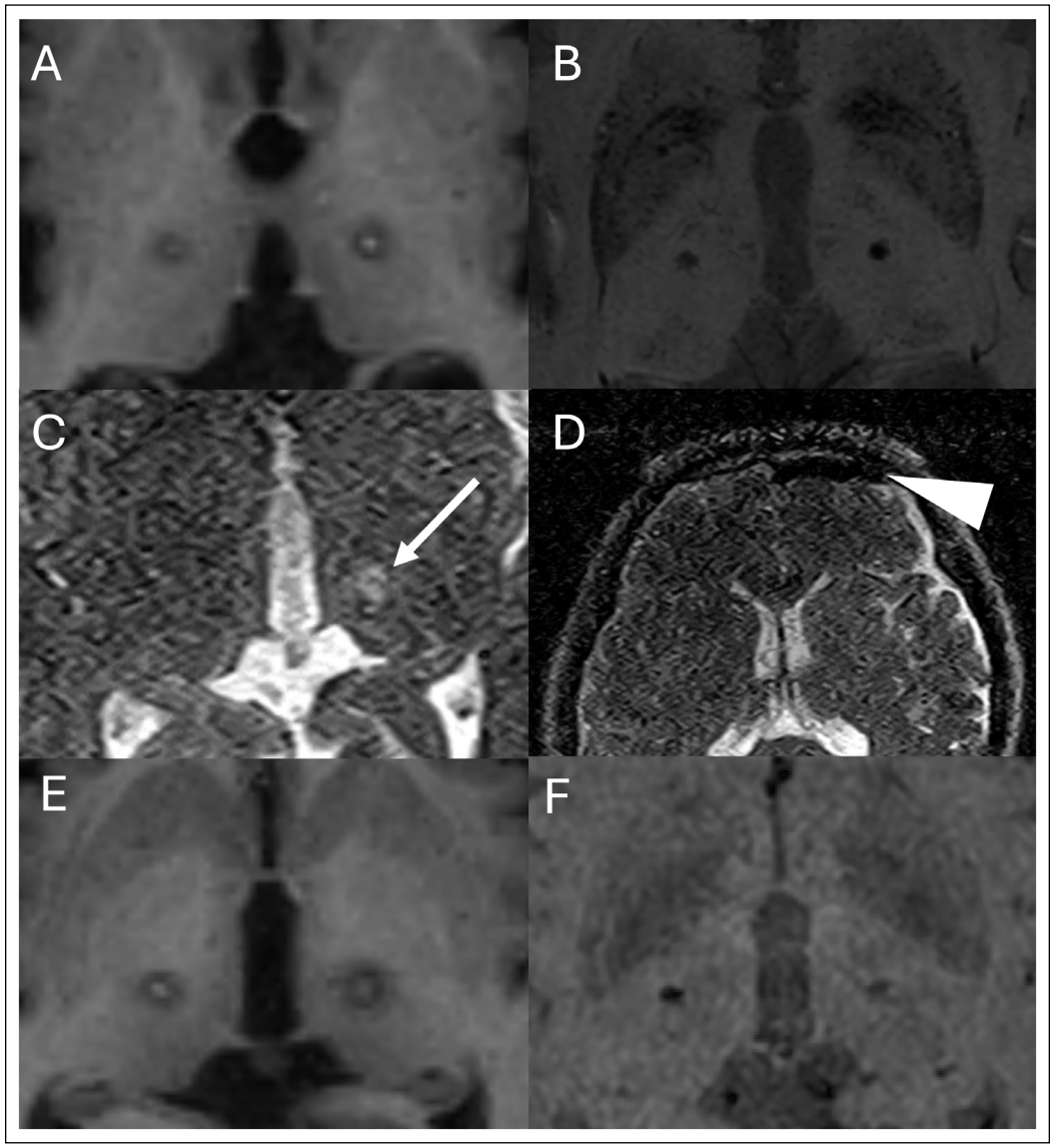
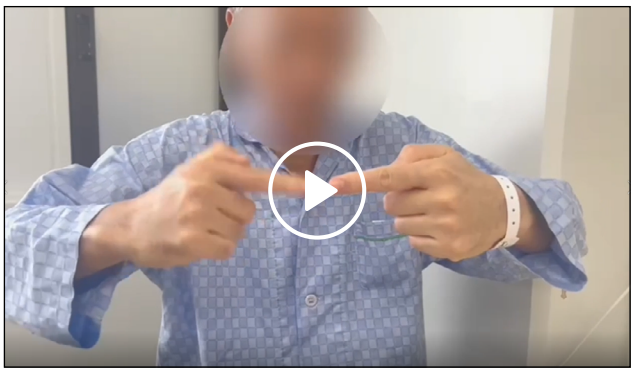


Figure 1 Postoperative and intraoperative MRI findings. (A) Immediate postoperative T1-weighted MRI of Case 1 demonstrating bilateral thalamic lesions. **(B)** Susceptibility-weighted imaging (SWI) of Case 1 at 3 months postoperatively, showing low-intensity areas corresponding to the lesion sites. **(C)** Intraoperative MRI of Case 2; the white arrow indicates the radiofrequency coagulation lesion, confirming accurate lesion placement and the absence of acute hemorrhage. **(D)** Intraoperative MRI of Case 2; the white arrowhead indicates intracranial air related to cerebrospinal fluid leakage. No asymmetry of the lateral ventricles is observed, indicating the absence of clinically relevant brain shift. **(E)** Immediate postoperative T1-weighted MRI of Case 2 demonstrating bilateral thalamic lesions. **(F)** SWI of Case 2 at 3 months postoperatively, demonstrating low-intensity areas corresponding to the bilateral lesion sites.



Video 3 Case 2: Preoperative clinical status.

DISCUSSION

Across prior studies of staged bilateral lesioning (RF/MRgFUS), neurological adverse events are generally mild yet not uncommon, and importantly, may emerge in the subacute to delayed postoperative period [4–6, 8]. In a staged bilateral RF thalamotomy series in essential tremor (n = 17), we reported prolonged adverse events in 9 patients after the second procedure, including dysarthria in 5, unsteady gait in 3, and dysphagia in 1, all of which were mild [8]. Crucially, 35% of the adverse events first manifested at approximately one month postoperatively;

		PRE	1 WEEK	1 MONTH	3 MONTHS	6 MONTHS
CRST	Case 1	57	0	3	5	5
	Case 2	57	9	11	13	17
QUEST	Case 1	70				3
	Case 2	73	5	9	14	17
SARA	Case 1	2	0	0	0	0
	Case 2	2	0	0	1	1
Adverse events	Case 1		dysarthria, decreased appetite	none	none	none
	Case 2		dysgeusia, dysarthria	dysgeusia, dysphagia	dysgeusia, dysphagia	lingual paresthesia

Table 1 Clinical outcomes and postoperative adverse events.
CRST, Clinical Rating Scale for Tremor; QUEST, Quality of Life in Essential Tremor Questionnaire; SARA, Scale for the Assessment and Rating of Ataxia.



Video 4 Case 2: Clinical status immediately after surgery and at 3 and 6 months postoperatively.

even in patients without abnormalities on intraoperative test stimulation, new symptoms could appear after a delay of several days to weeks [8]. A similar time course was reported in the multicenter staged bilateral MRgFUS trial by Kaplitt et al. (n = 51; mean inter-procedural interval 2.2 years) [5]. Although 85% of adverse events were mild, dysarthria occurred in 15 patients, ataxia in 12, and gait disturbance in 5 [5]. Dysarthria and ataxia frequently worsened or newly appeared within one month after treatment, and dysphagia worsened significantly from baseline at one month in 9 patients [5]. Furthermore, Iorio-Morin et al. reported that 70% of patients experienced mild adverse events, and highlighted delayed onset: in two patients, dysphagia was absent at 2 hours and at 1 month but was first reported at 3 months, and one patient similarly developed dysarthria at 3 months [6]. Simultaneous bilateral MRgFUS thalamotomy has also been reported; in a Russian single-center experience, tremor severity was reduced by 57.5–69.7% with no neurological complications observed at 6 months [9]. Taken together, these reports indicate that certain neurological adverse events are time-dependent. Intraoperative neurological assessment and iMRI can identify immediate procedural concerns but cannot exclude subtle or delayed neurological adverse events emerging during postoperative follow-up. Although staging permits the second procedure to be withheld if clinically meaningful adverse effects emerge after the first lesion, unilateral thalamotomy itself is not risk-free, and adverse effects such as ataxia or gait instability may occur after the first-side procedure. Thus, staging provides an additional decision point but does not guarantee preservation of neurological function after the initial lesion. Even when bilateral interventions are separated by a prolonged interval, neurological complications may still occur, indicating that the interprocedural interval alone does not determine safety. Based on our clinical experience, we hypothesize that persistent adverse effects after bilateral thalamotomy may be more closely related to the location and cumulative volume of the permanent bilateral lesions. The present trial therefore prioritizes small, asymmetric lesions; the key trade-off is whether lesion minimization can reduce persistent adverse effects while maintaining durable tremor control.

RF ablation permits direct physiological verification through macrostimulation using the lesioning electrode, together with adjustable parameters for lesion creation. Tremor suppression and sensory or capsular responses can therefore be assessed immediately before coagulation. RF also allows lesion formation to be controlled by adjusting temperature, duration, and lesion number, enabling specific tailoring of lesion geometry and laterality. Ohye et al. have reported that effective tremor control can be achieved

with relatively small lesions confined to the physiologically defined Vim (approximately 40–60 mm³) [10]. Consistent with this concept, lesion volumes in our cases were within or below this range, thereby using relatively small lesion volumes for bilateral procedures. In this context, limiting coagulation to one or two lesions per target, as in the present cases, is a rational strategy to minimize hemorrhagic risk. In addition, intraoperative MRI provides immediate confirmation of the absence of hemorrhage after the first-side lesion and offers an objective basis to abort contralateral treatment if any safety concern arises.

This study is limited by its sample size of two and a 6-month follow-up period and therefore cannot determine the incidence of uncommon or delayed adverse events. Mild lingual paresthesia remained present in Case 2 at the final 6-month assessment and was therefore considered persistent at that time. Extended long-term observation is essential to evaluate its eventual outcome, the durability of tremor control, and the risk of other late-onset adverse events. In conclusion, simultaneous bilateral RF Vim thalamotomy was technically feasible and produced marked tremor improvement without gait or balance disturbance in these two patients. The stepwise iMRI-guided protocol used in the prospective case warrants continued evaluation in the ongoing clinical trial.

DATA ACCESSIBILITY STATEMENT

The trial was registered at ClinicalTrials.gov (Clinical Trial Registration: NCT07066358).

The data supporting the findings of this study are available upon request. The data are not publicly available due to restrictions that could compromise the privacy of the study participants.

ETHICS AND CONSENT

Case 1 was retrospectively reviewed under approval from the Institutional Review Board of Tokyo Women's Medical University (No. 2021-0169). Case 2 was enrolled in a prospective interventional study approved by the certified review board of Tokyo Women's Medical University (No. 2025-0015; NCT07066358). Both patients provided written informed consent.

COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHOR CONTRIBUTIONS

Conception: SH. Execution: EK, KK, YK, MM and SH.
Writing of the first draft: EK.
Organization: KY, KM, TT and SH.
Review and critique: SH.

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