

## Preliminary Results of a Phase I/II Clinical Trial for Coneless, Frameless MLC-based Radiosurgical Thalamotomies for Essential and Parkinsonian Tremor

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## Abstract

**Objectives:** Radiosurgery (SRS) has been used with success to manage tremor in select patients with medically refractory tremor. Because of high doses, small target, and required precision, Gamma Knife has been the traditional platform. Our first objective was to develop and evaluate a safe, effective, and precise alternative on the linear accelerator without frame or cone based delivery. We present here the initial clinical results.

**Methods:** Patients' pre-treatment tremor is evaluated with FTM score and PROMIS index. Patients are imaged on a Phillips 3T Magnetom Prisma MRI with additional optional Siemens 7T Magnetom MR imaging, to generate MPRAGE, diffusion-weighted tractographic, and resting-state fMRI sequences. VIM is identified via thalamic parcellation and stereotactic reference location. Patients were immobilized in a Qfix Encompass rigid thermoplastic mask. The VIM was targeted to 130Gy dmax. SRS was delivered on a Varian Edge linac with high-definition multi-leaf collimator (HDMLC) and intrafraction optical surface monitoring (OSMS) to ensure patient stationariness. Treatment is delivered with fixed-MLC position and pre-determined beam modulation (Virtual Cone), resulting in spherical dose distribution equivalent to 4mm Gamma Knife shot. Post-treatment imaging and FTM/PROMIS scores were compared to pre-treatment baselines at scheduled intervals.

**Results:** Of the 20 patients enrolled, 15 had been treated at time of submission. 2 withdrew and three were pending treatment. Of the 15 treated patients, >6mo follow-up was available for 11. In patients with 6 month or greater follow-up, clinically meaningful tremor reduction was observed in 10. Median tremor reduction according to FTM was 59%. Two patients experienced attributable grade 1 side effects. No patients have experienced grade 2 or higher side effects.

**Conclusions:** We completed enrollment of a phase I/II pilot trial evaluating feasibility and safety of MLC-based coneless, frameless radiosurgery for tremor. Data continue to mature, however early results indicate the safety and efficacy of this dosimetrically identical approach to be congruent to the historical results of Gamma Knife.

### Open Access

#### Abstract

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