

# Real-World Evidence Supports use of Transcutaneous Afferent Patterned Stimulation for Tremor Control in Veterans Affairs Essential Tremor Patients



Kalea Colletta, DO<sup>1</sup>, Sally Borucki, MD<sup>2</sup>, Denson Fujikawa, MD<sup>3</sup>, Charles Handforth, MD<sup>3</sup>, Allan Phan, MD<sup>3</sup>, Annie Killoran, MD<sup>4</sup>, Alex Li<sup>5</sup>, Kathryn Rosenbluth<sup>5</sup>

<sup>1</sup>Edward Hines Jr. VAMedical Center, Department of Neurology, Hines, IL, USA <sup>2</sup>Temple VA Medical Center, Department of Neurology, Temple, TX, USA <sup>3</sup>Department of Veterans Affairs Parkinson's Disease Research, Education, and Clinical Center, Los Angeles, CA, USA <sup>4</sup>Iowa City Veterans Affairs Health Care System, Iowa City, IA, USA <sup>5</sup>Cala Health, Burlingame, CA, USA

## Background & Objective

Essential tremor (ET) is one of the most common movement disorders in adults but has limited treatment options. Transcutaneous afferent patterned stimulation (TAPS) of the median and radial nerves at the wrist at a frequency tuned to an individual's tremor has been shown in controlled clinical studies and post-market real world studies to be a safe and effective on-demand prescription therapy for reducing ET upper limb tremor symptoms.<sup>1-3</sup>

**This post-market analysis evaluated TAPS therapy for symptomatic tremor relief of ET in a cohort of Veteran Affairs (VA) patients.**

## Methods & Data

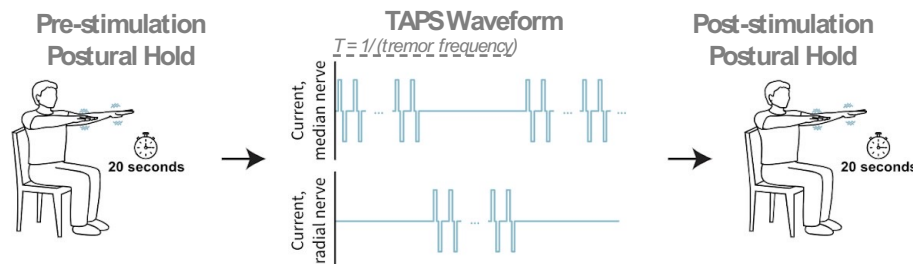
The therapeutic device (Cala Health, Burlingame, CA, USA) consisted of a stimulator and detachable band containing working and ground electrodes positioned to deliver TAPS to the median and radial nerves (Figure 1). Users were given instruction on device setup, including calibrating stimulation to their tremor frequency and setting stimulation intensity to a comfortable but non-painful level (Figure 2). On-demand TAPS therapy sessions were 40-minutes long, with users advised to use the therapy as needed. Device data included timestamps for all therapy sessions and pre- and post-stimulation postural hold accelerometry data for a subset of sessions (Figure 2).

**Study Population:** Prescriptions were primarily from neurologists (45%) and movement disorder specialists (38%). Fifty-eight VA patients (age 71 ± 10 years; mean ± 1 SD) who used the device for at least 30 days were included in this study. **Device log data indicated these users completed 5.5 ± 4.3 (mean ± 1 SD) sessions per week.**



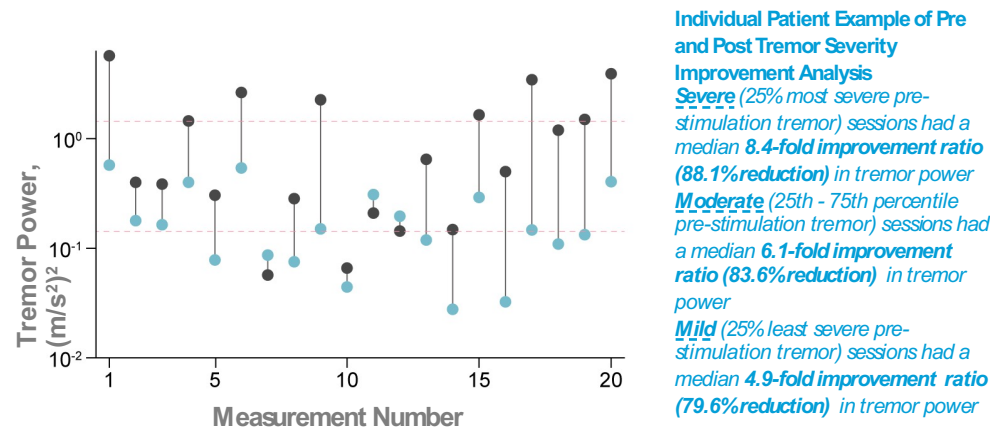
Figure 1 Wrist-worn TAPS device, including stimulator, two working electrodes (median and radial nerves), and one ground electrode.

**Figure 2 Postural hold for TAPS calibration and tremor severity measurement.** The device prompted users to perform a postural hold for TAPS calibration, and before and after a subset of therapy sessions (first forty, and every seventh thereafter). A triaxial accelerometer on the device measured tremor motion during this postural hold. Tremor severity was quantified using tremor power, computed from the accelerometry data.



## Tremor Power Improvement

Figure 3. Individual Patient Example of Therapy Remote Monitoring Measurements



Sample pre-stimulation (grey) and corresponding post-stimulation (blue) measurements for a sample ("above average-responder") VA patient are shown above (Figure 3). Note, only sessions with completed pre- and post-stimulation measurements are illustrated. Therapy efficacy was quantified using the **improvement ratio**, defined as pre-stimulation power divided by post-stimulation power (% reduction = % reduction in pre to post tremor power). While tremor power varies from session to session, TAPS therapy reduced pre-stimulation tremor power consistently for this patient with larger improvements observed for more severe sessions.

## Figure 4. Tremor Power Improvement

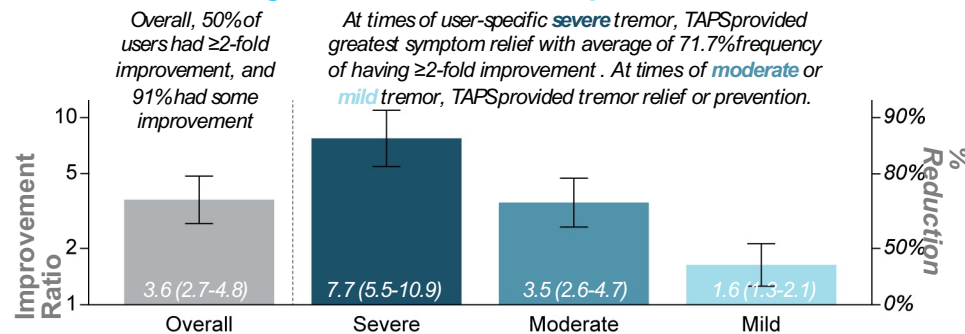
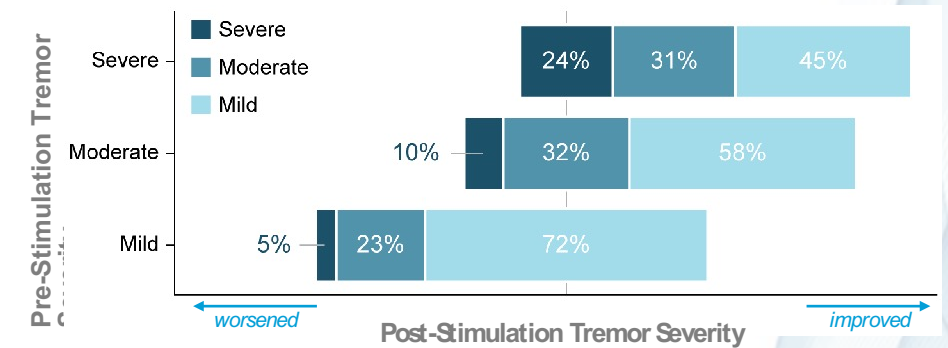


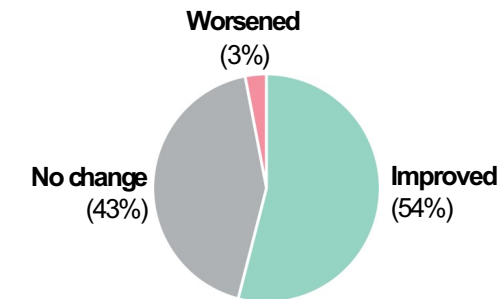
Figure 4 is a detailed analysis of tremor power improvement in subset of twenty-four VA users who fully completed ≥10 sessions (i.e., pre- and post-stimulation) of motion data capture. Overall, 50% of users had ≥2-fold improvement in tremor with TAPS, and 91% had some improvement. Degree of improvement increased with baseline tremor severity (all values and error bars represent mean ± 1 standard error of log-transformed values).

## Tremor Severity Changes



TAPS therapy, when used during times of severe tremor, provided significant tremor relief, with 76% of sessions improving to user-specific moderate or mild ranges (above, top row). TAPS therapy when used during times of mild tremor maintained that mild tremor in 72% of sessions, suggesting TAPS can also be used prophylactically.

## Patient Reported Outcomes



Users were asked to self-rate post-TAPS improvement for a subset of therapy sessions. Out of all self-rated sessions for the (N=859), 54% sessions were rated as improved (left).

## Conclusions

**These data are consistent with findings from prior clinical and post-market studies,<sup>1,3</sup> and suggest that TAPS therapy provides meaningful tremor reduction in cases of more severe tremor.**

### References

- Isaacson Set al. (2020) *TOHM 2020*; <http://doi.org/10.5334/tohm.59>
- Pahwa Ret al. (2019) *Neuromodulation*; <https://doi.org/10.1111/ner.12930>
- Rajagopal A et al. (2020) *Value in Health*

**Disclosures:** AL and KR are current employees of Cala Health.