

## Real World Evidence of Cala TAPS Therapy Further Supports Long-Term Safety and Efficacy of its Treatment for Essential Tremor

*The retrospective post-market surveillance study, published in Tremor and Other Hyperkinetic Movements, found that long-term usage of Cala TAPS therapy resulted in tremor reduction and was preferred by two out of three patients over medication or surgery*

SAN MATEO, CA — September, 27, 2022 — [Cala](#), the bioelectronic medicine leader setting a new standard of patient care for chronic disease, announced today publication of long-term real world evidence in [Tremor and Other Hyperkinetic Movements](#) (TOHM). These data further validate that Cala TAPS (Transcutaneous Afferent Patterned Stimulation) therapy, delivered by the Cala Trio device, effectively reduces tremor with no loss of effect over time and improves patient quality of life for those living with essential tremor (ET). The real-world evidence provides the largest patient set with the longest usage period, up to two years, of any evaluation of a non-invasive treatment for ET.

The retrospective post-market surveillance study, titled “Real-World Evidence of Transcutaneous Afferent Patterned Stimulation for Essential Tremor,” evaluated the real-world effectiveness of Cala TAPS therapy based on a total 321 users who had completed at least 90 days of therapy and met the criteria for analysis between August 2019 through June 2021.

Key findings include:

- TAPS reduced tremor power by 71% (geometric mean), confirming previous findings from the PROSPECT clinical study<sup>1</sup>. More than half of patients experiencing reduction of tremor power by at least 50%.<sup>2</sup>
- No loss of effect was observed with use for longer than a year, with no significant reduction in patients’ tremor power improvement ratio between the first 90 days and beyond a year.
- Patients completing multiple sessions in a single day experienced no loss of effect when completing multiple sessions in a single day.
- Patients were instructed by their prescribing physician to use therapy as needed. Patients used therapy an average of 5 to 6 times per week.

These real-world patients were invited to complete a voluntary survey, which showed<sup>3</sup>:

- Most patients reported improvement in at least one important activity of daily living: eating (74%), drinking (65%), or writing (64%).
- Of the patients who were on tremor medication prior to starting Cala TAPS therapy, 24% reduced their tremor medication and 14% discontinued medication use.

This real-world evidence follows a publication in the [Journal of Health Economics and Outcomes Research](#) (JHEOR) in August 2022, which found that patients with ET had a significantly higher number of comorbidities (such as hypertension, pain disorders, and diabetes), a higher prevalence of psychiatric disorders (such as depression and anxiety) and higher total healthcare costs than non-ET patients (\$17,560 vs \$13,237).<sup>4</sup>

“Historically, patients with ET have had limited treatment options,” said Dr. Salima Brillman, lead author and a movement disorder neurologist at the Parkinson’s Disease and Movement Disorder Center of Silicon Valley. “The evidence, coupled with self-reported quality of life improvement and patient preference for TAPS, reinforce that TAPS is a valuable treatment option for patients with ET. It’s exciting to see advancements for individualized care within the movement disorder space for this patient population.”

“The fact that patients prefer Cala TAPS therapy over standard management options, with some able to reduce or discontinue medications, validates that our solution is transforming the standard of care for patients with essential tremor,” said Renee Ryan, CEO of Cala. “We are proud of this real-world outcome and remain dedicated to improving patients’ quality of life and expanding access and affordability for Cala TAPS therapy.”

The publication was authored by experts from the Parkinson’s Disease and Movement Disorders of Silicon Valley, Edward Fines Jr. VA Hospital, Temple VA Medical Center, Valley Parkinson Clinic, Houston Methodist Neurological Institute, Pacific Neuroscience Institute, Pacific Movement Disorders

<sup>1</sup> Isaacson et al. Tremor Other Hyperkinet Mov (N Y). 2020;10:29. doi:10.5334/tohm.59

<sup>2</sup> Based on the 216 patients who had tremor measurements for analysis.

<sup>3</sup> Based on the 69 patients who had completed the voluntary survey.

<sup>4</sup> Dai D, et al. JHEOR. 2022;9(2):37-46. DOI: 10.36469/jheor.2022.37307

Center, and Swedish Neuroscience Institute. Data was derived from the healthcare provider-completed prescription form, device logs automatically generated during therapy home use, and a voluntary survey sent to patients after 90 days of therapy use.

### **About Cala Health**

Cala is a bioelectronic medicine company transforming the standard of care for chronic disease. The company developed a unique therapeutic approach, Transcutaneous Afferent Patterned Stimulation (TAPS), to target the source of tremor and deliver individualized relief as needed. Cala TAPS therapy, delivered by the Cala Trio device, is the only FDA-cleared, clinically validated bioelectronic therapy for hand tremor relief for patients with essential tremor. New approaches are in development for applying TAPS to Parkinson's disease, as well as for other applications in neurology, psychiatry, cardiology, and autoimmune disorders. Founded in 2014, the company is headquartered in the San Francisco Bay Area and backed by leading investors in both healthcare and technology.

Indication: The Cala Trio device is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. It has been available in the US since 2019.

Caution: Federal law restricts this device to sale by or on the order of a physician. Prior to use, refer to the product labeling for complete product instructions for use, contraindications, warnings, and precautions at <https://calatrio.com/Safety>.

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