



Hand tremor reduction for patients with Essential tremor

The results from the research shows that VILIM ball device can effectively reduce hand tremors. There are many ways to prove such an effect. One of the most popular ones is an Archimedes spiral drawing. Smooth spiral drawing means that a person does not have any hand tremor symptoms. Wobbly, uneven and noisy spiral drawing can mean that the person do have hand tremor in action state. Such an approach was used in one of our studies. The results were positive – VILIM ball device makes spiral drawings smoother. In other words, the device reduces hand shakiness. Image below illustrates findings from this particular study. The efficacy is self explanatory.



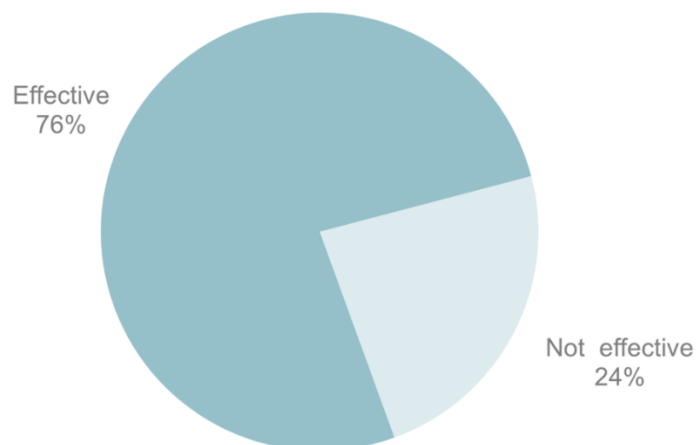
Clinical investigations

Currently there are at least 2 published clinical studies regarding the VILIM ball device. Efficacy study No. 1 was a prospective, single-center, randomized, controlled study designed to evaluate device efficacy. 17 subjects with diagnosed Essential tremor were randomly selected. VILIM ball therapy was performed for each patient on dominant hand. Collected data was filtered to evaluate the range of 4-12 Hz which is hand tremor frequency with diagnosed essential tremor. The results: 13 of 17 patients witnessed reduction in hand tremor after the therapy ($\alpha = 0.0352$).

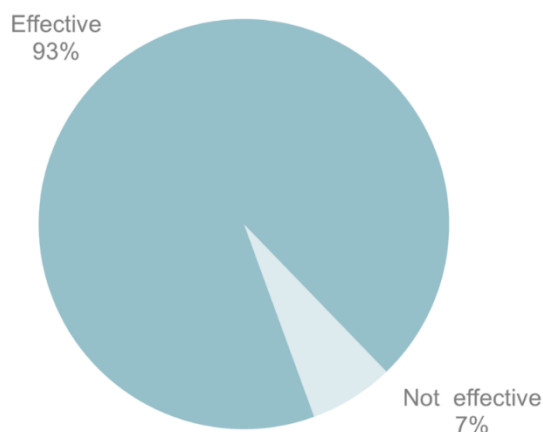
Study concluded an average of 56 % reduction. To remove the possible “placebo” effect another group of patients (N =

15) performed same procedure with fake device (sham group). It was concluded that fake device was not effective in comparison to VILIM ball.

EFFICACY STUDY NO. 1 (ET)



EFFICACY STUDY NO. 2 (ET)



Detailed information regarding this study is presented in a publication “Local vibrational therapy for essential tremor reduction: a clinical study”*.

**Abramavičius, Silvijus; Venšlauskas, Mantas; Vaitkus, Antanas; Gudžūnas, Vaidotas; Laucius, Ovidijus; Stankevičius, Edgaras. Local vibrational therapy for essential tremor reduction: a clinical study // Medicina. Basel : MDPI AG. ISSN 1010-660X. eISSN 1648-9144. 2020, vol. 56, iss. 10, art. no. 552, p. 1-9. DOI: [10.3390/medicina56100552](https://doi.org/10.3390/medicina56100552).*

The second VILIM ball efficacy study was a cross-sectional study performed on patients with Essential and Parkinsonian tremors. In total 50 patients with the mean age of 66.9 were included

(30 in the essential tremor and 20 Parkinsonian tremor). The primary efficacy outcome was the Patient-Reported Outcome based on a non-validated patient telephone questionnaire. The secondary outcome was the occurrence of adverse events. 46 patients reported improvement in tremor symptoms and function. 4 patients (2 PD and 2 ET) reported lack of effect in terms of symptoms and function. The patients used the VILIM ball for 7.63 months. 38 patients were able to report the duration of improved function which was 90.79 minutes. 4 more patients refused to participate in the study because of no improvement in tremor during the two-week initial testing phase. No adverse events were reported by the patients in this study.

These results prove that the VILIM ball therapy is effective and can reduce hand tremor symptoms. Further researches will be dedicated for the optimization of the device effectiveness.



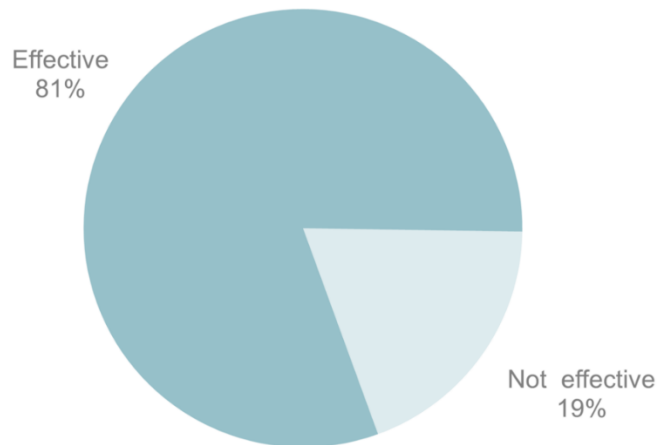
Post-market studies

A survey questionnaire is periodically sent to all customers who bought the device and kept it for 2 weeks to 2 years. This activity aims to gather real-world evidence about how the device performs when presented to the customer. By processing survey results we get an idea of the device efficacy level and how it changes during short to long periods.

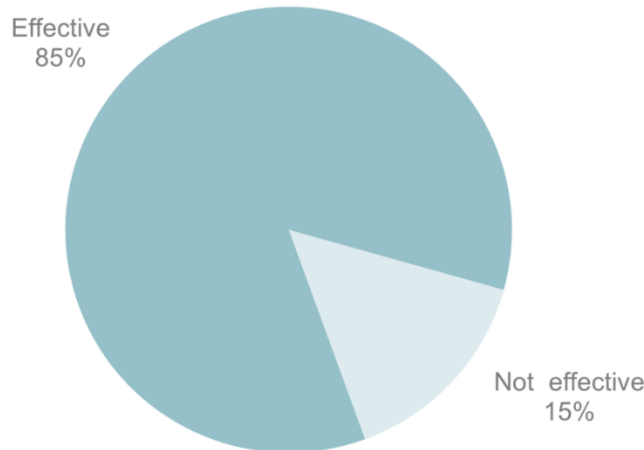
In the year 2023, we surveyed 35 customers with a mean age of 67 years and an average VILIM ball usage time of 1.88 months. Most of the respondents were patients with Essential tremor (ET), however, 25.7% of customers were patients with Parkinson's disease (PD). Improvement in symptoms was noticed by 80.8% of ET patients. The average improvement time was 69.2

minutes. It was concluded that there were no significant differences between the results of questionnaire and the results of clinical studies. However, more real-world data is needed to make strong conclusions. Aggregated data from all studies and post-market surveillance suggests that the device is effective for ~84.9% of ET patients.

POST MARKET SURVEILLANCE (ET)



ALL STUDIES (ET)



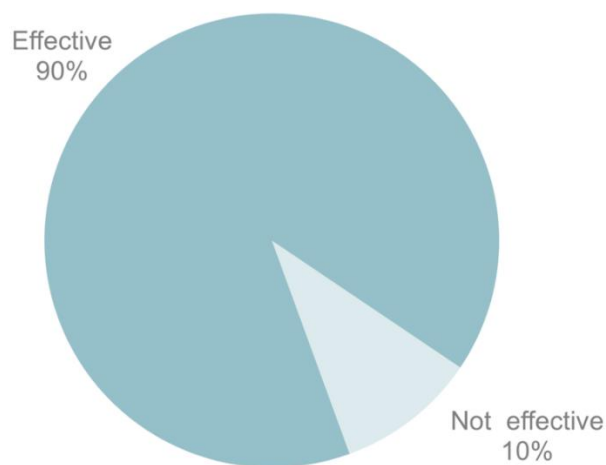
Studies on Parkinsonian tremors

High off-label use detected in the post-market surveillance reflects the need to investigate the device's effect on other tremors, especially Parkinsonian. Communication about the intended use of labeling, marketing, or informational channels is sufficient. However, during non-formal communication with customers, it was noted that customers who use device off-label are typically aware that the device is meant solely for Essential Tremor. However, available solutions, mainly for Parkinson's disease, are not effective. Patients tend to seek help on other fronts.

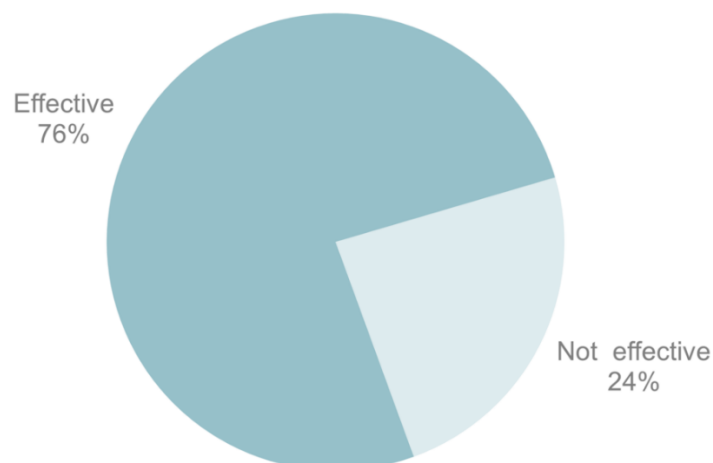
That includes VILIM ball. Various clinical studies regarding the VILIM ball therapy effect on Parkinsonian tremors are on-the-way.

Efficacy study no. 2 included 20 patients with Parkinson's Disease. 18 of them concluded reduction in tremor symptoms after therapy with the VILIM ball. Currently Dr. Dieter Volc, Specialist in Neurology and Psychiatry, is performing an internal study focused on VILIM ball therapeutic effect on Parkinsonian tremor patients. Even though the conclusions are not yet public, latest recorded data concluded tremor reduction for 19 of 25 PD patients.

EFFICACY STUDY NO. 2 (PD)



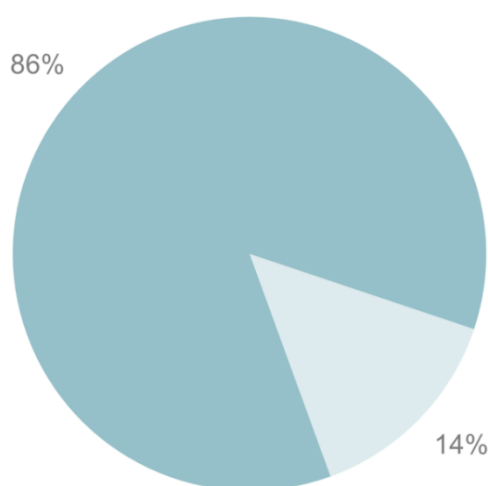
DR. DIETER VOLC STUDY (PD)



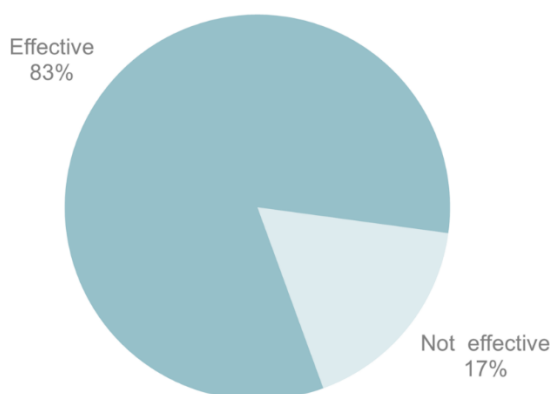
Post market surveillance data (Q3 2023) showed that the device was effective for 84.6% of PD patients. Another PD related study, that is currently being peer reviewed concluded average of ~40% tremor power reduction for Parkinson's disease patients when combining VILIM ball with physiotherapy.

Currently, the VILIM ball device holds certification solely for Essential Tremor (ET) patients. Nevertheless, the available information strongly indicates that Parkinson's Disease (PD) patients can also experience benefits from personalized mechanical vibration therapy. Based on aggregated data, VILIM ball demonstrates efficacy for 83% of PD patients. Consequently, Team VILIMED aims to pursue approval for extending the use of VILIM ball to PD patients in the near future.

POST MARKET SURVEILLANCE (PD)



ALL STUDIES (PD)



Other studies

According to other similar study, the vibrational therapy could reduce hand tremor and stiffness for Parkinson's disease by 25% and 24%, respectively. ([Haas, 2006](#)). Also, [King et al. \(2009\)](#) have found that vibrational therapy could significantly decrease rigidity, and tremor. Results of their initial investigation provide support for vibration therapy as a non-pharmacological treatment alternative.

A group of researchers performed study on combination of the whole body vibration therapy and exercises. It was observed that this kind of therapy gives short term benefit for human motor system, posture and daily activities ([Edmonston, 2016](#)).

Heiko ([2009](#)) and others have found that the whole body vibration therapy significantly reduces hand tremor and stiffness as well as step length and walking speed.

Certification

Vilimed has implemented the EN ISO 13485 quality management system standard for the medical device industry and was granted the CE0197 Class 2a mark for the VILIM ball device. The quality certificates were granted by the notified body TÜV Rheinland.