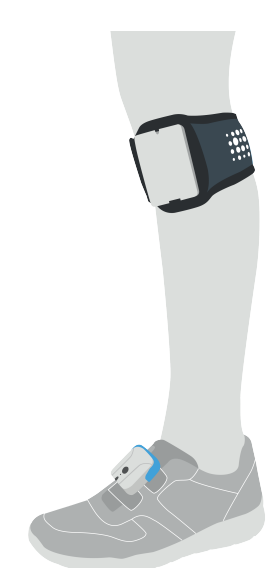


## CLINICAL EVIDENCE

Fesia products – Summary of the evidence

November 2020

FESIA  
WALK

**10** Publications

**37** Patients included

A **single-blind randomized study** with **16 post-acute patients** held in **Belgrade (Serbia)** showed that:

- Fesial Walk combined with conventional rehabilitation is **more effective on walking speed, mobility of the lower extremity, balance disability and activities of daily living** compared to a conventional rehabilitation program only.
- Fesial Walk is **effective both in acute and chronic stroke patients** with stroke related foot drop.

(Dujović, et al., 2017)

A **usability study** carried out with **10 patients** in a clinical environment in **Pamplona (Spain)** showed that:

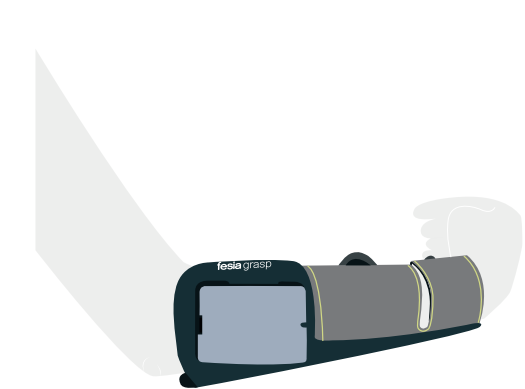
- It is **feasible to include surface multi-field technology** while keeping the **device simple and intuitive for successful integration** in common neurorehabilitation programs.
- All the participants were **very satisfied** with the **Fesial Walk device in terms of usability**.

(Imatz-Ojanguren, et al., 2019.)

ONGOING: A **clinical trial** with **30 stroke patients** at the Ubarmin Clinic in **Pamplona (Spain)**.

**Use case**

JM. an **84-year-old male patient** has a **severe polyneuropathy** caused by a paraneoplastic syndrome, which produced an **absence of motor capacity in the muscles below the knee**. After 6 weeks of **treatment with Fesial Walk**, JM. can **activate his muscles voluntarily**, has increased his **walking speed by 30%** and has **stopped using his walking stick**. *Fesia Clinic, San Sebastian, Spain.*

FESIA  
GRASP

**16** Publications

**47** Patients included

**Studies** carried out in **Belgrade (Serbia)** with **stroke patients** showed that:

- Multi-field electrodes provide the **desired level of selectivity** and can be used for **generating a functional grasp both in the clinical and home environments**. *(Malešević, et al., 2012.)*
- **Combining the performance of multi-field electrodes** (increased selectivity and facilitated positioning) with **surface-distributed low-frequency asynchronous stimulation** (decreased fatigue), as **Fesial Grasp** does, **improves FES applications**. *(Maneski, et al., 2013.)*
- The use of multi-field electrodes resulted in **fully functional and reproducible palmar and lateral grasps similar to healthy-like grasps**. *(Popović-Maneski, et al., 2013.)*

A **doctoral thesis** developed by Dr. Imatz-Ojanguren with **stroke patients** in **Pamplona (Spain)** showed that:

- **Asynchronous stimulation** (used in **Fesial Grasp**) resulted in **lower perceived deep discomfort** than synchronous stimulation and affected its efficacy. *(Imatz-Ojanguren, et al., 2013.)*

ONGOING: A **clinical study** with **15 patients** with **acquired brain injury** in **Mondragon (Spain)**.

**Use case**

PL. a **69-year-old female patient** suffered an **ischemic stroke** a year ago, which produced **severe hemiplegia, with serious impairment of the hand function**. After 10 1-hour sessions of treatment with **Fesial Grasp**, PL. can **move her fingers selectively**, has increased her **grasping strength by 21%** and is beginning to **use her upper limb in daily living activities**, such as drinking from a glass. *Fesia Clinic, San Sebastian, Spain.*

# CLINICAL EVIDENCE

Fesia products – Summary of the evidence

November 2020

## FES for the treatment of foot drop

# > 70

Clinical Trials

Some of the **effects** that have been observed are:

- 38,7% increase in **gait speed** (Sabut, et al., 2010)
- Improvement in **neurophysiological indicators**. (Sabut, et al., 2010)
- Increased **dorsal flexion and swing phase time**. (Nolan, et al., 2015)
- 56,5% increase in dorsiflexor **muscles strength**. (Sabut, et al., 2011)
- 38,3% decrease in plantar flexor **muscles spasticity**. (Sabut, et al., 2011)
- Decreased **joint pain**. (Street, et al., 2018)
- **Biomechanical improvements** in the least affected leg and in arm swing angle. (Danino, et al., 2013. Chou, et al., 2014)

"Current evidence on the safety and efficacy (in terms of improving gait) of FES for drop foot of central neurological origin appears adequate to support the use of this procedure."

**NICE** National Institute for Health and Care Excellence

"FES can have a positive orthotic effect, particularly for gait speed and physiological cost index, in patients who were in the chronic stage of stroke recovery."

Chest Heart & Stroke Scotland

## FES for upper limb rehabilitation

# > 40

Clinical Trials

Some of the **effects** that have been observed are:

- Improvement of **motor function** (differences up to 27,2 points in Fulg-Meyer Assessment) and **use of the paretic arm**. (Cerda, et al., 2017)
- Activities of **daily living** (measured with the Barthel Index). (Nakipoglu Yuzer, et al., 2017)
- **Functionality** (differences up to 48% in the Box and Block test). (Marquez-Chin, et al., 2017)
- Range of motion in **flexion and extension movements of wrist and fingers**. (Yildizgören, et al., 2014)
- 56% decrease in wrist and finger flexor **muscles spasticity**. (Ring, et al., 2005)
- Joint **pain reduction**. (Malhotra, et al., 2013)

**Combinable with:**

Mirror therapy

Botulinum toxin

Action observation + Brain computer Interface

Task-oriented therapy

Bilateral arm training

Virtual reality

"FES targeted at the wrist and forearm muscles should be considered to reduce motor impairment and improve function" [Evidence Level: Early-Level A; Late-Level A].

**Canadian Stroke Best Practices**

"There is strong evidence that FES treatment improves upper extremity function" [Evidence Level: 1a]

HEART & STROKE FOUNDATION  
**Canadian Partnership for Stroke Recovery**