IMPLEMENTATION OF NOVEL FES BASED FOOT DROP FOR REHABILITATION OF PARALYSIS, SCLEROSIS AND OTHER AILMENTS

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ABSTRACT

This paper reviews the technological advances and clinical results obtained in the neuro-prosthetic management of foot drop. Functional electrical stimulation has been widely applied owing to its corrective abilities in patients suffering from a stroke, multiple sclerosis, or spinal cord injury among other pathologies. This review aims at identifying the progress made in this area over the last two decades, addressing two main questions: What is the status of neuro-prosthetic technology in terms of architecture, sensorization, and control algorithms?. What is the current evidence on its functional and clinical efficacy? The results reveal the importance of systems capable of self-adjustment and the need for closed-loop control systems to adequately modulate assistance in individual conditions. Other advanced strategies, such as combining variable and constant frequency pulses, could also play an important role in reducing fatigue and obtaining better therapeutic results. The field not only would benefit from a deeper understanding of the kinematic, kinetic and neuromuscular implications and effects of more promising assistance strategies, but also there is a clear lack of long-term clinical studies addressing the therapeutic potential of these systems. This review paper provides an overview of current system design and control architectures choices with regard to their clinical effectiveness. Shortcomings and recommendations for future directions are identified.

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DECLARATION

We as a team have done this project **"IMPLEMENTATION OF NOVEL FES BASED FOOT DROP FOR REHABILITATION OF PARALYSIS, SCLEROSIS AND OTHER AILMENTS**" as a part of our J – component for the subject BIT2024

Biomechanics and it is the original study conducted by us under the guidance Prof. Sharmila N

I further declare that this project work has not previously formed the basis for the award of any degree, diploma, associateship, fellowship, or other similar title of recognition.

1. INTRODUCTION

1.1 Problem Statement

Foot drop is highly distressing, and attention to the patient's psychological needs is very important. Pain should be managed. Optimizing glucose control in diabetic patients and managing vitamin deficiencies with supplements of vitamin B1, B6, or B12 can also be useful. When foot drop is not amenable to surgical treatment, an ankle-foot orthosis (AFO) is often used. If the foot drop is due to hemiplegia, peroneal nerve stimulation can be considered. Foot drop due to direct trauma to the dorsiflexors generally calls for surgical repair. When nerve insult is the cause of foot drop, treatment is directed at restoring nerve continuity, either by direct repair or by removal of the insult.

An AFO may be used for foot drop when surgery is not warranted or during surgical or neurologic recovery. The specific purpose of an AFO is to provide toe dorsiflexion during the swing phase, medial or lateral stability at the ankle during stance, and, if necessary, pushoff stimulation during the late stance phase. An AFO is helpful only if the foot can achieve plantigrade position when the patient is standing. Any equinus contracture precludes its successful use.

The most commonly used AFO in foot drop is constructed of polypropylene and inserts into a shoe. If it is trimmed to fit anterior to the malleoli, it provides rigid immobilization. This device is used when ankle instability or spasticity is problematic, as is the case in patients with upper motor neuron diseases or stroke.

If the AFO fits posterior to the malleoli (posterior leaf spring type), plantarflexion at heel strike is allowed, and pushoff returns the foot to neutral for the swing phase. This provides dorsiflexion assistance in instances of flaccid or mild spastic equinovarus deformity. A shoeclasp orthosis that attaches directly to the heel counter of the shoe also may be used.

A study by Menotti et al suggested that anterior AFOs are associated with lower energy costs of walking and higher levels of perceived comfort than posterior AFOs are and thus may allow people with foot drop to walk longer distances while expending less physical effort. (F, L, A, P, & A, 2014)

When foot drop is due to hemiplegia, peroneal nerve stimulation has potential advantages over an AFO, in that it provides active gait correction and can be tailored to individual patients. A short burst of electrical stimulation is applied to the common peroneal nerve between the popliteal fossa and the fibular head. This burst is controlled by a switch in the heel of the affected limb. The stimulator is activated when the foot is lifted and stopped when the foot contacts the ground. This achieves dorsiflexion and eversion during the swing phase of gait. In a study by Ring et al, the effects of a radiofrequency-controlled neuroprosthesis were compared with those of a standard AFO in 15 patients with foot drop caused by stroke or traumatic brain injury (H, I, L, & JM, 2009). Compared with the AFO, the neuroprosthesis yielded better balance control during walking and thus managed foot drop more effectively. The nerve stimulator can be either external or implanted and radiofrequency-activated. In a study of stroke patients with spastic hemiplegia, Chae et al found electrical stimulation to be useful in approximately 2% of the cases (18(1):41-7, 2008).This method may enhance gait speed and quality, and it can contribute to motor relearning.

In a study of 197 patients who had sustained a stroke approximately 3 months previously, Kluding et al compared use of an AFO with use of a foot-drop stimulator (FDS) for treatment of foot drop (PM, et al., 2013;).They concluded that whereas both approaches resulted in significant improvement in gait speed and functional outcomes, user satisfaction was higher with the FDS; they also stressed that initial therapy can provide long-term benefit.

Van Swigchem et al studied the potential benefits of peroneal functional electrical stimulation (FES) versus an AFO in regard to the patient's ability to avoid an obstacle. They concluded that FES was superior and that this finding was particularly relevant to people with low strength in the lower leg muscle.

Chou et al found that application of FES to the upper limbs as well was useful for abnormal arm swing in hemiplegic patients with foot drop.

Bethoux et al carried out a 12-month follow-up analysis of a multicenter unblinded randomized controlled study that compared FES with AFOs over a period of 6 months. At 12 months, there were no statistically significant differences between the FES group and the AFO group with respect to either primary endpoints (10-Meter Walk Test and device-related serious adverse event rate) or secondary endpoints (6-Minute Walk Test, GaitRite Functional Ambulation Profile, and Modified Emory Functional Ambulation Profile).

Miller et al compared two different FES devices, the Odstock Dropped Foot Stimulator (ODFS) and the Walkaide (WA), in terms of their effect on energy cost and speed of walking. The ODFS yielded a significant increase in walking speed over what was achieved without FES, and the WA yielded a near-significant increase. Neither walking speed nor eenrgy cost differed significantly between the two FES systems.

1.2 Methodology

Studies investigating a mixed neurological sample were included where data for patients could be extracted separately. Studies included all types of FES devices for foot drop. Studies investigating other interventions in addition to FES were included where the other intervention was a comparator group. Studies reporting on device development were excluded. To be eligible for inclusion studies had to report on a minimum of one measure of gait speed using either short or long walking tests with and without the device, at a minimum of one time point. Gait speed is described in meters per second (m/s) and measured by walking over a short distance (e.g.10 meters, 25 feet) or a longer distance (e.g. 2 or 6 Minute Walk) FES electrodes can be used.

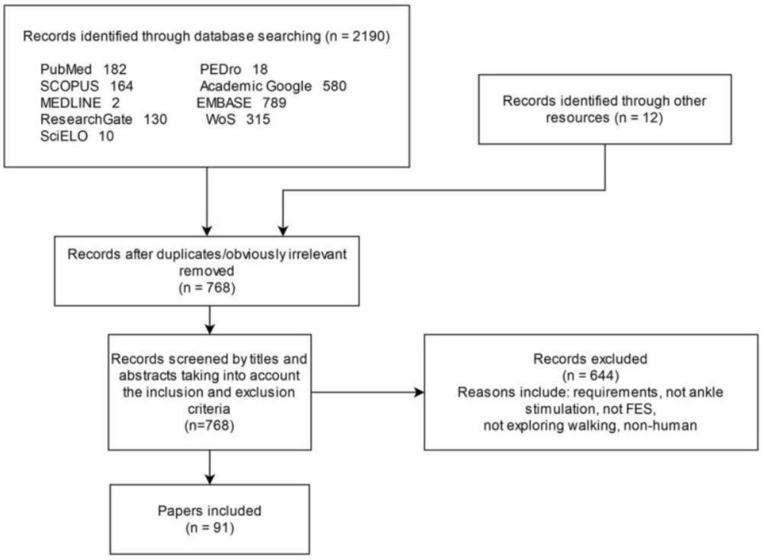
FES and AFO devices were used by set of patients for different tasks

Following Databases were used CINHAIL, EBSCO and Medline was observed via OVID.
Data Extraction was performed using articles on participants (e.g. age, gender, 164 MS type), methods (e.g. study design) interventions (FES type, description of control 165 intervention) and outcomes (e.g. assessment time points and outcome measures) 166 and results using an a priori developed data extraction form.

Data from all 170 3 short walking tests (10MWT, 25 foot walk test (25ftWT), 6 meter walkway test 171 (6MWT)) were combined and presented as the primary outcome measure

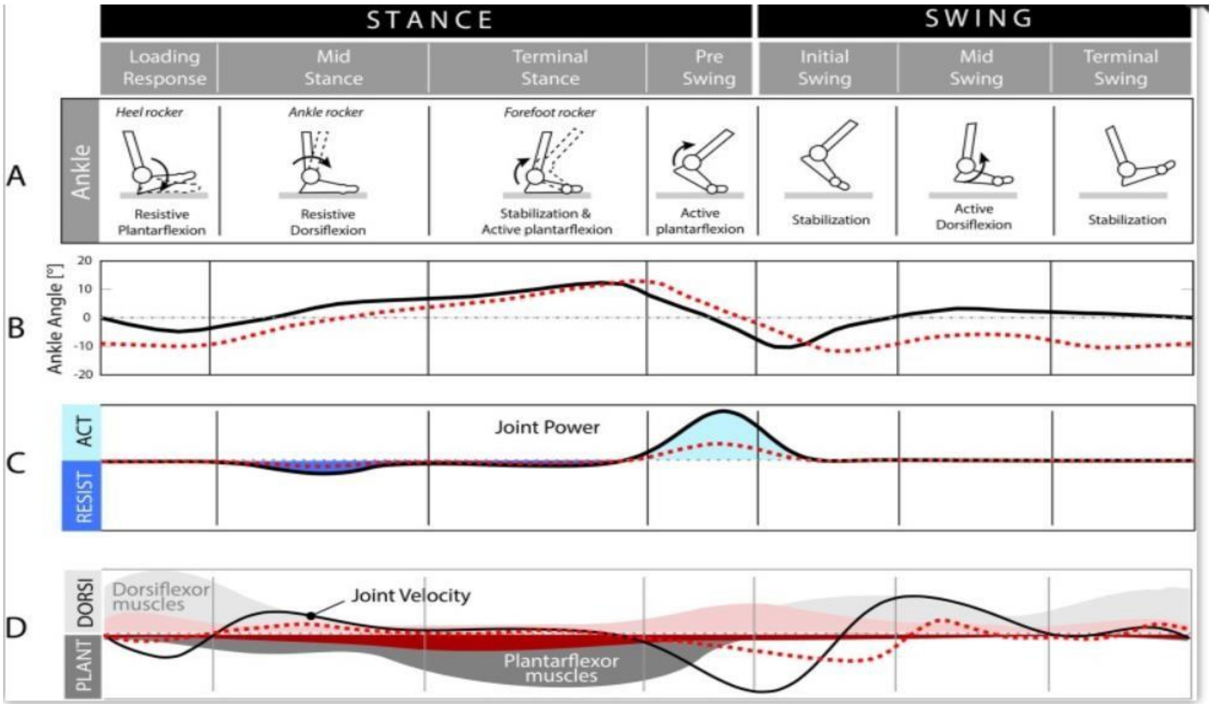
The other Data from longer walking tests for 3 mins etc, were presented as secondary outcome measure.

We carried out a search on the following databases: PubMed, PEDro, SCOPUS, Academic Google, MEDLINE, EMBASE, ResearchGate, WoS, and SciELO were consulted. The search keywords were "FES system," "drop foot," "foot drop," "ankle," "gait," "efficiency," "neuroprosthesis," and "clinical results.



2.BACKGROUND

Most of the neurological impairments affecting gait, such as a cerebrovascular accident (CVA) or stroke, spinal cord injuries (SCIs), multiple sclerosis (MS), cerebral palsy (CP), and brain injuries (BIs), occur at significant incidence rates globally . Foot drop (FD) is a common gait impairment derived from these pathologies, which consists of a paralysis or significant weakness of the ankle dorsiflexor muscles. It is characterized by the inability to achieve an adequate dorsiflexion, as shown in Fig. 1b, to obtain a sufficient distance with the ground during the swing phase of gait . As a result, it can lead to inefficient gait compensations increase falls, greater energy expenditure, and reduced endurance . It is also characterized by an uncontrolled plantarflexion, which leads to foot slap. As a result of muscle weakness and/or spasticity, individuals with FD may also become unable to support their own weight . It is therefore vital to identify appropriate strategies of intervention to overcome foot drop symptoms and improve gait . Conventional treatment involves the use of an ankle-foot orthosis (AFO), which keeps the ankle joint in a neutral position . However, techniques based on robotic and/or electrical stimulation assistance are being developed and represent promising alternatives.



Biomechanics of the ankle in the gait cycle, musculature and nerves. The graphs represent the biomechanics of the ankle of a healthy subject (black continuous line) versus the biomechanics of a subject

with foot drop (red segmented line). An example of muscle activity in foot drop

To choose the most appropriate FD treatment, it is important to take into consideration its causes and severity of the as well as the pre- and post-operative conditions of the patient. Figure 1 depicts profiles of gait biomechanics in intact humans compared to an example of a patient with FD. An inspection of gait biomechanics is relevant to establish the joint and muscular alterations that are to be reestablished or compensated. On the other hand, it is necessary to pay attention to the central or peripheral origin of the pathology, since treatment choice may vary depending on whether the first or second motor neurons are affected .

Neuromuscular electrical stimulation consists of the application of an electrical current through electrodes placed above the motor point to achieve a muscle contraction. It is achieved when the stimulation applied exceeds the motor threshold. The most common techniques to compensate FD are *functional electrical stimulation* (FES), which sequentially activates paralyzed muscles through electrical stimulation to restore the functional movement and is clinically advantageous in gait restoration, or *transcutaneous electrical nerve stimulation* (TENS), which is a non-invasive technique that is usually used as analgesic treatment . These two techniques have different effects on FD, but in both of them the second motor neuron must be intact and the electrical excitability in the peripheral nerves and muscle tissues must be preserved . FES is usually applied to increase dorsiflexion force, with a reduction in the muscular tone and a stiffness of the gastrocnemius. TENS is effective in reducing pain and increasing presynaptic inhibition, resulting in reduced spasticity, muscle tone, and stiffness. Functionally, FES has demonstrated significant effect on the spatiotemporal parameters of the gait, whereas TENS has not reported positive results yet.

The first neuroprosthesis based on FES was developed in 1961 by Liberson et al. . It was controlled by a foot switch that activated a peroneal nerve stimulation during the swing phase . Since then, numerous systems have been developed to stimulate the tibialis anterior (TA) or common peroneal nerve (CPN) during the swing phase to ensure an adequate dorsiflexion, allowing the necessary foot clearance . Subsequently, many other systems have been designed and developed that share a common architecture integrating a wearable sensor set and stimulation hardware embedding a control algorithm . Enabling daily and unsupervised use of this type of systems is crucial for its success. These implies that systems need to be easy to place, adjust and use. In addition, they must be able to properly assist and adapt the electrical stimulation according to the muscle response that is time-varying, non-linear and coupled. Ideally, the use of a non-invasive neuroprosthesis must target both compensatory (gait facilitation) and rehabilitative effects. In other words, on the one hand, the use of a neuroprosthesis must improve the biomechanics of gait and facilitate this activity. On the other hand, a long-term rehabilitation must be intended to promote recovery towards a more physiologically autonomous gait without neuroprosthetic assistance.

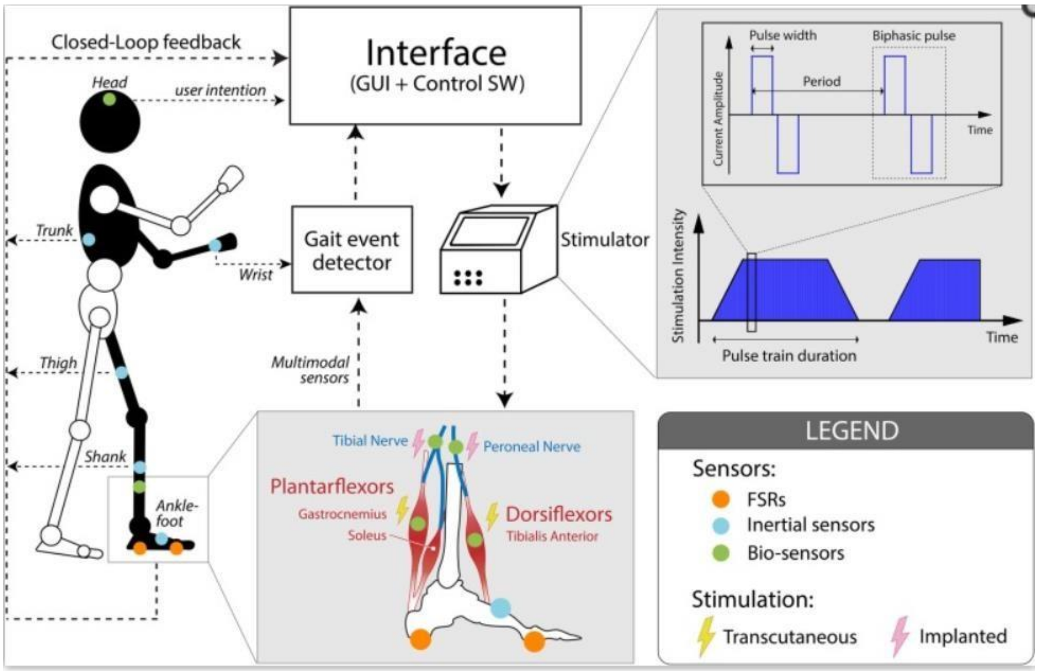
As far as the compensatory effect is concerned, an FES-based neuroprosthesis for FD correction must be able to achieve a sufficient distance between the floor and foot during the swing phase through a correct dorsiflexion of the ankle, as well as reduce the foot slap produced during the load response phase owing to uncontrolled plantar flexion . However, it is important to note that it FES assistance of the dorsiflexors alone also can decrease the knee flexion and ankle plantar flexion at the toe-off. As a result, the propulsive force generated during a pre-swing has also been shown to decrease . A possible solution to this may be plantar flexion assistance with FES during the pre-swing, which improves the knee flexion during the swing and enhances the propulsive force during the push-off . Moreover, the stimulation time can be prolonged after contact with the ground to avoid a sudden plantar flexion .

Although non-invasive neuroprosthetic technologies for human walking continue to advance and their functional benefits for neurologically injured subjects have been demonstrated, technological barriers remain regarding the wider and sustainable adoption of such systems by patients. Although several reviews have been released to date , none of them provided a thorough analysis of the rehabilitation potential of the existing solutions. This perspective is in our opinion necessary to analyze the viability of the different advances in the face of real use in clinical and daily life settings. (Gil-Castillo J, 2020)

2. WORK DONE

2.1 Rough design of proposed solution

the basic fundamentals required for the design and use of a neuroprosthesis whose architecture is reflected in Figure below. Specifically, the methods found for (a) establishing an optimal electric current technique that allows a minimally aggressive effective assistance to be applied to the foot drop, (b) detecting gait events and using that information to control the timing of the applied stimulation , and (c) controlling the supply of electric stimulation during gait to adjust the applied electric stimulation to achieve the desired effect in an effective and optimal manner are detailed.



Architecture of a FD neuroprosthesis. This figure shows the sensors that have been used in the last two decades, as well as their location on the body. It also details the stimulation parameters and where

FES uses electrical pulse trains on the muscle or peripheral nervous system to trigger a controlled tetanic muscle contraction . The shape of the individual pulses that make up the electric pulse trains has an effect on the muscle response. They are usually rectangular as they are the most efficient in generating muscle contractions, aiming at a reduction of the habituation effect. Pulse trains must provide an equal distribution of charges within the tissue to avoid an electrochemical imbalance, which produces its damage. This is generally achieved by applying one pulse during the positive phase and another during the negative phase, symmetrical or not [4]. In this way, such pulses can be distinguished as monophasic (positive phase only) and biphasic (both positive and negative phases) . Monophasic pulses create charge imbalances because of a unidirectional current flow. By contrast, biphasic pulses allow the application and removal of electrical charges to and from the tissue, and thus the majority of neuroprostheses use biphasic pulses .

Apart from the shape, pulse trains are described through the following five parameters, all them having an influence on the stimulation effects: the amplitude or intensity of the pulses, the frequency or repetition rate of the pulses, the duration of a single pulse, the duration of a pulse train, and the stimulation pattern or disposition of the pulses within a stimulation train . The first two parameters are the primary parameters that are modulated to control the movements and are related to the intensity of the contraction and fatigue . By modulating the amplitude of the pulses that compose a train of pulses, different wave profiles can be obtained. This is usually trapezoidal with a ramp up and down, the adjustment of which influences the strength and comfort of the stimulation and avoids a sudden response . In terms of frequency, the most commonly used are between 20 and 50 Hz . The width of the pulses has a direct effect on the intensity of the contraction and therefore in the fatigue . Moreover, in relation to stimulation pattern, pulse trains can be classified into two types according to the inter-pulse intervals: constant frequency trains (CFTs) and variable frequency trains (VFTs). CFTs is often used and consists of stimulation pulses separated by constant inter-pulse intervals. In VFTs, the inter-pulse intervals are not constant

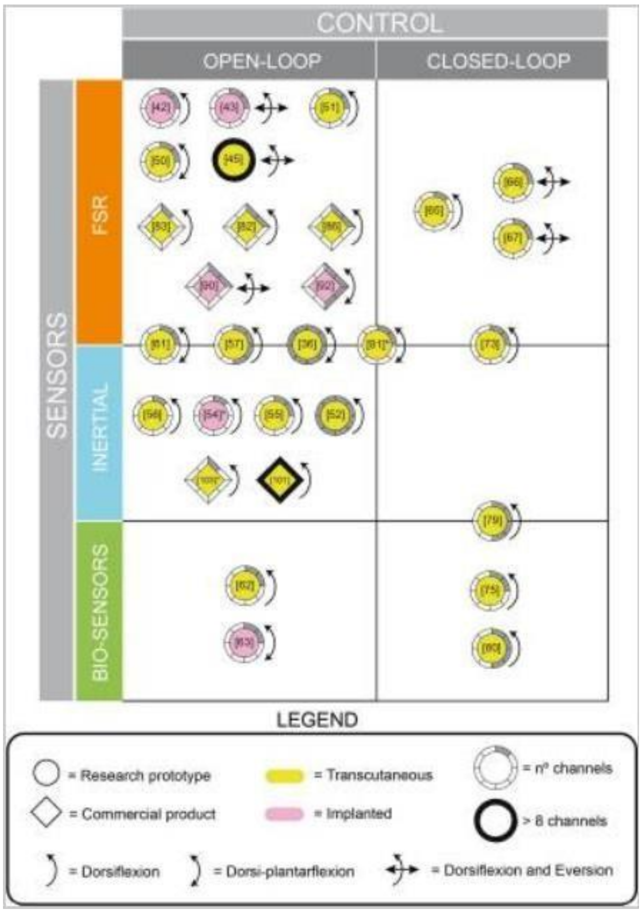
Mentioned below are some of the FES based system which are in commercial as well as inresearch and development.

Foot drop FES systems

Devices	Sensors	Transcutaneous/Implanted	# of Channels	Assistance	Muscles/nerves
Open-loop systems: Research prototypes					
Haugland et al. [42]	FSRs	Implanted	2	Dorsiflexion	Peroneal nerve
Kottink et al. [43, 44]	FSRs	Implanted	2	Dorsiflexion, eversion	Peroneal nerve
ShefStim [45–49]	FSRs	Transcutaneous	64	Dorsiflexion, eversion	Multiple muscles
Perumal et al. [50]	FSRs	Transcutaneous	2	Dorsiflexion and	Flexor-extensor muscles
Closed-loop systems: Research prototypes					
Chen et al. [65]	FSRs	Transcutaneous	1	Dorsiflexion	Tibialis anterior muscle
DeltaStim [66]	FSRs	Transcutaneous	2	Dorsiflexion and eversion	Peroneal and anterior tibial nerves
APeroStim [67–72]	FSRs	Transcutaneous	2	Dorsiflexion, eversion and inversion	Tibialis muscle and fibularis longus
Duo-STIM [73, 74]	FSRs + Inertials	Transcutaneous	2	Dorsiflexion	Unspecified
Li et al. [75–78]	EMG	Transcutaneous	2	Dorsiflexion	Tibialis or medial gastrocnemius muscles
RehaMove Pro [79]	Inertial + EMG	Transcutaneous	4	Dorsiflexion	Unspecified
Nahrstaedt et al. [80]	Electrodes to measure bioimpedance	Transcutaneous	4	Dorsiflexion	Dorsiflexors muscles

Combined systems					
O'Keeffe et al. [13]	FSRs, Inertials, EMG and electrogoniometers	Unspecified	2	Dorsiflexion	Unspecified
Melo et al. [81]	FSRs + Inertials	Transcutaneous	2[a]	Dorsiflexion and plantarflexion	Flexor-extensor muscles
Open-loop systems: Commercial prototypes					
MyGait [82]	FSRs	Transcutaneous	2	Dorsiflexion	Peroneal nerve
Odstock [83–85]	FSRs	Transcutaneous	1	Dorsiflexion	Unspecified
NESS L300 [86–89]	FSRs	Transcutaneous	2	Dorsiflexion	Tibialis anterior and peroneal nerve
STIMuSTEP [90, 91]	FSRs	Implanted	2	Dorsiflexion, eversion	Peroneal nerve

In the figure given below will the figure showcasing the positioning of electrodes which are in use in the market and some in research.



3. RESULTS AND DISCUSSION

The process flow invloved literature review from CINHAIL, EBSCO and Medline was observed via OVID.
The mean age of participants ranged from 46.513 to 56.35 years and time since diagnoses ranged from 8.635 218 up to 17.725 219 years. Between 25 to 77 % of participants recruited in the studies were 220 female. Disability was only reported in 6 studies and ranged from Extended Disability Status Score 3.532 to 5.926.

FES was preferred over AFO by most of the patients, FES users reported less physical tension had longer distance walking abilities. AFO on the other hand enabled users to put in less effort when it came to stability and balance. 78% supported FES based devices over AFO.

Much practical work could not be done by us in this current scenario due to COVID-19 constraints and our research was limited to exploring existing articles and possible coming with a prospective design consideration to overcome the issue of FES based treatment for rehabilitation.

4. CONCLSUION

During the last two decades a variety of FD systems have been developed for clinical application, some of them reaching commercial exploitation. Although improvements in terms of the architecture of FES assistance and the application of strategies for obtaining optimal results have been achieved, several limitations need to be addressed for their widespread application in gait compensation, and as alternative therapeutic methods. Muscle fatigue, which results from continuous FES application, still needs to be managed in a sustainable manner. Stimulation strategies should focus on assistance as needed, as well as on closed-loop controllers that are able to dynamically cope with individual user characteristics and typical variations in spatio-temporal features of an individual gait. Moreover it seems highly relevant to include in future studies the kinetic evaluation with the assessment of the effects of FD systems on humans.

By taking all this design into consideration we are looking to create an affordable neuroprostheses which can be bought by the middle class people. The average price available

\FUTURE WORK PROSPECT

The shortcoming of our work are very definitive and these were due to the temporary constraints of time and circumstances. In the future we expect to be provided with better circumstance and if so will be able to progress with the work.

We can equip ourselves with more knowledge in the field of designing and simulation and bring about more to the project in terms of design and simulation accuracy. If this seems to a hectic endeavour along with equipping ourselves, we can seek help from trained personnel who will be able to help us move forward with the hardware implementation. They would be given a chance to form an integral part of our project work and thus making it sure that future developments in this project will consider all the designs to be scaled and well calculated.

Real-time data collection was restricted due to unforeseen circumstances. Hence once these restrictions are lifted we will be able to make proper progress in that aspect as well. This will enable for a better collection of gait related information other than based on previous literature.

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