Drop foot treatment: Functional electrical stimulation

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Background: The gait pattern after stroke can be disturbed by foot drop. The conventional approach to the treatment of drop foot gait is a splint, the ankle-foot orthosis (AFO). An active approach is functional electrical stimulation (FES). Functional electrical stimulation (FES) refers to electrical stimulation of muscles in order to improve the impaired motor function. This is achieved by activating skeletal muscles with constant frequency trains of stimulations.

Objective: The objective of this paper is to compare the conventional treatment, the transcutaneous device and the implanted device of electrical stimulation to correct drop foot in stroke patients. Further, developments and improvements are discussed.

Results: FES is divided in surface and implanted electrodes system, both improve the gait pattern and reduce spasticity. AFO is a passive treatment, which also improves the gait pattern of the ankle joint. Drop foot treatment with FES results in a more natural gait pattern. Different groups of patients with different lifestyles will also have different opinions in what treatment they prefer. The implantable FES has some advantages in comparison with the transcutaneous FES, but the surgery needed for this is the biggest disadvantage.

Conclusion: FES is, in theory, a better technique for treating drop foot in stroke patients than AFO. It is however really the choice of the patient what the patient prefers. Transcutaneous FES yet remains the common approach of FES, since the disadvantages of surgery are too big. The new technology BION microstimulation looks very promising to overcome the risks of surgery and still have the advantages of implanted electrodes.

1 Introduction

Stroke is a major global health problem with huge disabling consequences. On January 1, 2007 there were approximately 191,000 stroke patients in the Netherlands. In 2007 the incidence of stroke is approximately 35,600 patients. Thus the total number of patients diagnosed with a stroke in 2007 is 226,600, the annual prevalence [1]. Impairment of the cognitive, perceptive, sensory and motor functions is caused by stroke. Initially, some 80% of all patients with stroke experience motor impairments of the contralateral limbs, i.e. hemiparesis [2].

Hemiparesis induces ankle-control disturbances and equinovarus deformity. This leads to a difficulty in walking. Beside motor weakness, poor motor control, and spasticity result in altered gait pattern, poor balance, and risk of falls during walking.[3] The gait pattern after stroke can be disturbed by foot drop [2]. Drop foot is known as a motor deficiency caused by total or partial central paralysis of the muscles innervated by the common peroneal nerve, or the anterior tibial muscle and the peroneal group. The two major complications of drop foot are slapping of the foot after heel strike (foot slap) and dragging of the toe during swing (toe drag).[4] Drop foot after stroke is thought to be caused by increased and inappropriate tone in the muscles of the leg, particularly the calf, and by poor active control of the anterior tibial muscle. The spasticity of the calf disturbs walking. [2] In stroke patients characteristically the muscles of extension of the leg, the soleus, the gastrocnemius and the quadriceps, are spastic and the muscles of flexion, the anterior tibials and the hamstrings, are weak.[5]

1.1 Treatment

A conventional approach to the treatment of drop foot gait is a splint. This is usually a custom fitted ankle-foot orthosis (AFO), which is a plastic support worn inside the shoe. An AFO for drop foot is used to
keep the ankle at 90 degrees and prevent the foot from dropping towards the ground, so the ankle joint is maintained in a neutral position. This treatment has limitations, being both uncomfortable and awkward to use.[4]

An active approach to the treatment of drop foot gait is functional electrical stimulation (FES). FES is the electrical stimulation of a muscle deprived of nervous control for providing muscular contraction and thereby producing a functionally useful movement. FES is a methodology that uses bursts of short electrical pulses. Surface or implanted electrodes can activate the motor nerves.[6]

Today, FES is mainly routinely applied for cardiac pacemakers, bladder voiding and pain suppression. In recent years few neuroprotheses for walking were introduced.[7] FES has been used to correct foot drop in hemiplegics, since the 1961. Liberson et al. introduced the method and proposed that electrical stimulation of the anterior tibial muscles can be coordinated with the gait cycle, and can improve gait quality in patients with a central foot drop [8]. That the FES system for the treatment of drop foot improves gait and effort of walking in stroke patients, is also reported by other researchers [9]. A study of Taylor et al. showed that electrical stimulation to correct drop foot improved the physiological cost index (PCI) and walking speed [9]. A clinical study of Burridge et al. has reported that the quality of life and range of motion are improved due to use of FES system [10]. In this study is also claimed that FES reduced spasticity without any muscle weakness or paralysis.

The aim of this paper is to compare the transcutaneous device and the implanted device with AFO, which are used to correct foot drop in stroke patients.

2 Functional Electrical Stimulation

As mentioned above, functional electrical stimulation (FES) refers to electrical stimulation of muscles in order to improve the impaired motor function. This is achieved by activating skeletal muscles with constant frequency trains of stimulations. When stimulation pulses are applied to motor nerves, action potentials are generated. Once these action potentials reach the muscle they cause muscle contraction. To achieve a continuous muscle contraction (tetanization) the FES system has to induce at least 20 action potentials per second, otherwise the muscle would not generate a steady output force and would only twitch. The action potential can only be propagated when the motor nerves of the targeted muscle are intact. In principle, monophasic and biphasic current or voltage pulses can be used to stimulate the motor nerves. The majority of FES systems uses the biphasic current pulses, since monophasic pulses can possibly cause skin burns and tissue damage due to the galvanic processes. [6, 7]

The motor nerves can be stimulated using either surface electrodes, transcutaneous, or implanted electrodes. The transcutaneous stimulation is carried out with electrodes that are attached on the skin, superiorly of the nerve bundles. The percutaneous stimulation is performed with implanted electrodes attached to the nerves or to the muscles close to the nerves [7]. Functional electrical stimulation-assisted walking implicates stimulating the relevant leg muscles in a coordinated manner to perform the walking motion. The main nerve to be stimulated is the peroneal nerve. The lower-limb muscle groups that are activated include the hip extensors and flexors, the knee extensors and flexors, the ankle plantar flexors and the ankle dorsiflexors [11, 12]. Figure 1 is the gait pattern.

2.1 Methodology

A conventional foot drop stimulator has a heel sensor, placed in the shoe, which is connected to the stimulator with wires, or in the case of a newer stimulator, radio frequency communication between foot sensor and stimulator. The sensor can detect and measure the pressure exerted by the heel on the ground as well as the tilt of the leg. At the end of stance phase the lower leg is tilted back and the tilt sensor turns on a train of stimuli. The stimuli stop when the leg tilts forward just after the foot strikes the ground. Software is used to compute the threshold for turning on stimulation for optimum results. Stimulation time and other time parameters are to be set manually or automatically.[13] FES is
not appropriate for all stroke patients with a dropped foot. The patient has to be able to stand and walk either alone or with minimal assistance, and the muscles that raise the foot should not be denervated. And above all the patient has to be well motivated.[14]

2.2 Effects of FES
The therapeutic effects of FES can be divided into two effects: orthotic effect and carry over effect. The orthotic effect is the effect that immediately works on the gait while the FES is used. The carry over effect refers to continuation of the improvement in motor strength and motor control even after the cessation of treatment by FES. The therapeutic effect may derive from many factors such as plasticity of both the peripheral and the central nervous system. Muscles activated by either electrical or voluntary means, undergo changes in the property of their fibers [15]. The mechanism behind the carry over effect of FES is not understood yet [16].

3 Ankle Foot Orthosis
An ankle foot orthosis (AFO) is frequently prescribed for patients with a paretic dorsiflexion muscles to improve the ambulation and prevent stumbling during walking. The orthosis lifts the foot during swing and early stance phase of gait cycle in order to prevent the toes from touching the ground and facilitate heel loading. The orthosis is commonly a plastic mold which can be fitted in the patients shoe. The simplest AFO prevent any dorsiflexion and lock the foot in a 90 angle degree with the ankle. Although there are more complicated orthosis that do allow some dorsiflexion and thus allow a more natural looking gait pattern.

In contradiction to the FES, AFO is a passive treatment that does not utilize the patients muscle for the dorsiflexion of the foot. Therefore patient using the AFO cannot exercise the muscles. This could reduce the muscle tone after prolonged use[17] and result in a dependence of the orthosis, but not much research has been done on this subject. However, a immediate reduction of the muscle activity of the ankle dorsiflexors has been reported [18]. Furthermore, research has been done by Sherk et al about structural bone differences between the non-affected and the affected leg after a long time use of the orthosis. The research concluded that there was a slightly reduction in bone strength of the tibia bone[19].

3.1 AFO versus FES
When comparing AFO to FES a number of advantages and disadvantages can be noted. These can be divided in a physiological and user preferences. FES has been reported to allow for a more symmetrical and natural looking gait pattern, ranges of motion of the ankle knee and hip where almost normalized[20]. The same research also reports that the obstacle avoidance score with FES where much better in comparison to AFO which may be the result of the more natural gait pattern. But no differences where found when a comparison was made for walking speed [20, 21], stride length [21] and function ambulation[22]. However, the most important factor when selecting a treatment is the user preference. The user preference depends on the user characteristic such as age and severity of the paralysis. But some general preferences can be noted. C. Bulley et al [23] did a user experience research on the differences between AFO and FES. The most important outcomes are summarized in the following paragraph.

3.2 User preferences
Users mostly prefer AFO over FES because of the easy day-to-day use of the orthosis. The orthosis can be put on and used without any training, it is reliable. It can also be put on in case of an emergency and during air travel. The negative effect of using an AFO is that the orthosis is always on, even when sitting. This is not the case with FES, because the muscle is only stimulated when required. The users reported that the orthosis is uncomfortable, inflexible, cumbersome and it is difficult to find the appropriate shoes. For FES the participants of the research reported that the biggest advance of FES is the ability to exercise the muscle and thus increase the muscle tone. They also noted that they experienced a more natural looking gait pattern and less tripping during walking which are consisted with the previous present research. FES was also found to be lightweight and the users where less aware of having a disability. When walking, the users felt where less conscious of using the stimulator. It must be noted that the research only included the transcutaneous FES because to user experienced FES to be more difficult to put on, not reliable in water rich environments and to cause skin irritation. These disadvantages do not apply to the implanted FES.
3.3 Further practice

The user preferences are clear when comparing FES with AFO treatment, but the biomechanical differences in the long term use are not. More research is required in this area. Also, not much research can be found on the cost/effectiveness comparison of the both treatment. It could also prove an important factor in deciding which treatment should be prescribed.

4 Transcutaneous FES

Non-invasive functional electrical stimulation uses surface electrodes to apply the stimuli on the nerves. The utility of non-invasive FES has already been studied several times on patients who suffered stroke. Here, walking speed, effort of walking and spasticity were assessed where most of the studies are in favour of non-invasive FES [2]. According to previous studies, FES has a positive effect on the overall walking ability and in the participation in life skills of chronic stroke patients with hemiplegia [14, 24–26]. The stimuli given via surface electrodes reduces muscle tonicity via the reduction of the stretching reflex, causing lower spasticity and allowing a larger range of motion and preventing soft tissue stiffness and contractions [2]. With this the stimuli restore the motor functions.

Non-invasive FES therapy for foot drop is described as the placement of surface electrodes on the the common peroneal nerve on the motor point of the tibialis anterior muscle (ankle dorsiflexor). The system stimulates its target when it is needed in the gait cycle. So it is used as an orthosis during walking, where the stimulations are triggered by heel rise on the affected side and continues until heel strike occurs[2, 9]. In these studies, FES therapy is very often combined with conventional therapy (neurodevelopmental facilitation techniques, physiotherapy or/and occupational therapy) in order to compare this treatment with the conventional therapy only[2, 9, 24].

4.1 EMG-triggered FES

Heel-triggering is the common trigger mechanism in FES, but there is another way of triggering. To detect the intention of activating muscles, EMG electrodes can be used. The EMG signal temporally precedes the generation in a muscle [27]. Research is being done to investigate the possibility to use this in patients with an incomplete spinal cord injuries (iSCI). The detection can be performed by two kinds of classifiers. A threshold classifier that detects an activation signal by comparing the running mean of the EMG with a certain threshold and a pattern recognition classifier that compared the time-history of the EMG signal with a specified template of activity to generate the trigger whenever the cross-correlation coefficient exceeds a discrimination threshold [27]. The pattern recognition classifier generally outperformed the threshold-based classifier, particularly with respect to minimizing False Positive triggers. There are some limits though. A patient has to be able to perform a proper EMG signal.

4.2 Improvements

The non-invasive version of FES has the big advantage of avoiding surgery, but it has some downsides as well. Firstly, the surface electrodes have to be placed on the skin each time the FES is applied. This takes around 10 minutes, so it is time consuming and it has to be done in the right way [28]. This requires training of both patients and care giving personnel[29]. A significant percentage of the patients using the skin surface electrodes get skin irritations. For this group of patients along with the group having trouble placing the electrodes properly, make a group patients where treatment with implantable electrodes should be considered. This overcomes several problems with skin reaction and electrode placement.

Secondly, peroneal FES for foot-drop correction is becoming an accepted and effective orthotic device due to technological advances and commercially available systems. However, FES of the dorsiflexors does not improve all gait deficits associated with hemiplegic gait[30]. Therefore theories about simultaneously stimulating other nerves to improve the gait were born. Springer et al. investigated the use of a dual-channel FES system, to simultaneously stimulate the common peroneal nerve and the hamstrings to achieve ankle dorsiflexion, but a decreased knee hyperextension and an increased hip extension during the stance phase as well [30].

Besides dorsiflexor muscles, the plantar flexors is the other group of muscles that affect the movement of the ankle joint. Plantar flexor spasticity is a common impairment of hemiplegia that can cause abnormalities in gait movement. A proof of concept, for stimulating both the dorsiflexors and plantar flexors during gait for adults with stroke and improving push off, knee flexion during the swing phase and walking speed has
now been given by two studies [31, 32]. It should be taken into account that plantar flexion stimulation was only effective in half of the patients tested. This suggests that patient selection is very important in this case, as well as the application [31]. Nevertheless, the results are positive and the interventions even resulted in an improved gait pattern 3 months after the interventions were stopped [24].

5 Surgical implanted electrodes

To eliminate the disadvantages of the surface electrodes, implanted electrodes are developed. The implanted nerve electrodes require placing at open surgery. This has the advantages that during the open surgery direct identification of the anatomy is possible [33] and stimulation tests can be applied to check the ankle dorsiflexion. [34] The implanting stimulating electrodes near the motor points of individual muscles can achieve greater muscle selectivity[35]. Because the electrodes are implanted the stimulation is selective of as many muscles as are necessary and deep stimulation of the muscles is possible in addition to surface electrodes. The implanted electrodes stimulate the selective muscles, this is also a problem with surface electrodes because small difference in surface electrode placement create large difference in response, it is difficult to establish a balanced response of the foot. [34, 36]

Figure 2. Surgical implanted electrodes

Studies have showed that the stimulation of implanted electrodes improve walking. Kottink et al. measured a walking speed (23%) with patient with a nerve stimulator compared to control group (3%) that used conventional treatment, ankle-foot orthosis (AFO). [37] Shimada et al. showed that the mean percentage increase in walking speed with stimulation was 30.1% [34]. Also FES use has been shown to improve mobility en reduce spasticity.[35] On the other hand, an open surgery makes scars whereby repeat surgery is more difficult. The electrode can not be corrected, because the electrode is implanted. [38] Infection and electrode breaking is possible. Although the failure rate of electrodes were in the study of Shimada et al. very low, 0% at 1 year after implantation and 5% at 3 years after implantation [34]. Undergoing a surgery is not acceptable to many people who are reluctant to undergo surgery for a problem that is bothersome but not life-threatening. [35]

5.1 Developments

Several implantable systems have been developed in the past.

When an implanted electrode during surgery is misplaced, correcting of the implanted electrode is difficult. A solution in 2002 is developed, a two channel implantable drop foot stimulator, that stimulate two branches of the common peroneal nerve separately. Hereby a precisely balanced dorsal flexion and eversion of the foot can be achieved. First the stimulation occurs via small bipolar electrodes which are placed subepineural, but now automatic balancing based on quantitative evaluation of foot movements by sensor measurements may be possible.[36, 38]

In 2004 Weber et al. combined two techniques, the WalkAide2 and BION technology. The BION technology uses BION microstimulator that is a potential alternative to a completely implantable FES system. BIONs (BiOnic Neurons) are small enough to be injected into muscle with a 12 Gauge catheter, no surgery is necessary. The WalkAide2, is a stimulator that uses a tilt sensor to control the timing of stimulation during walking, is effective in correcting foot drop. Surface electrodes has some remaining limitations, for example uncomfortable sensations, skin irritation or unselective activation of the muscles. The use of implanted electrodes instead of surface stimulation will eliminate the limitations. That is the reason that WalkAide2
and BION technology are combined. Weber et al. showed that this combination is an alternative to surface stimulation and provides selective control of muscle activation.[35]

BION technology is in the first clinical phase 1, so more research is necessary. A small incision is needed for implanted the BIONics at the place of insertion with local anesthesia. A whole surgery is not necessary.[39]

Later a system is developed with a 4-channel implantable drop foot stimulator, ActiGait. The use of a 4-channel stimulator enables fine control of the inversion and eversion components of dorsiflexion. Buridge et al. demonstrated that the effect of the ActiGait on measured walking speed is similar to that reported with surface systems. Also Buridge et al. asked for the users’ perspective, the ActiGait appeared to be easier to use than a surface system.[28]

Another problem is that each individual has a different gait disorder, that is the reason that Halloran et al. developed a system that allows the intensity of stimulation to be modulated throughout gait using pulse-width modulation. An interface allows the clinician to graphically adapt the stimulation pulse-width profile applied to the user during the stimulation cycle.[40]

So, in the recent years FES has developed. First a single-channel implanted systems is developed to provide greater muscle recruitment selectivity and to remove the necessity to apply electrodes daily. Later, more -channels are developed to allow greater control over dorsiflexion. And the BIONic technology allows that surgery is not necessary anymore, because BION are small enough to be injected.

5.2 Improvements

With the developments discussed above, new improvements are needed to optimize these developments.

With the ActiGait some problems were with the timing of the stimulation. The initial cost of the ActiGait, including implantation is likely to be higher than a surface system, but running costs would be reduced. Future trails should include a cost-effectiveness component.[28]

With the implanted electrodes a stimulator is needed, most of the cases a surface sensor is used. An implantable sensor could solve the problem associated with the use of surface sensors. However, implantable heel switches or force sensors do not exist (yet), which is why it has been suggested that afferent neural signals, such as those recorded from sural or calcaneal sensory nerves in the ankle, can be used as a sensory feedback signal in an implanted system.[41]

Another improvement could be the use of a more-channel implanted system that can be injected like the BIONics, so a surgery is not necessary and a greater control of the muscles can be achieved.

6 Discussion

The aim of this paper was to compare the transcutaneous FES system with the implanted version of FES, which are both used to correct foot drop in stroke patients. This study also tried to investigate the results in comparison with the ankle foot orthosis.

The long term effects of both FES and AFO are still unclear. FES is said to allow a carry-over or therapeutic effect[24, 42]. This effect states that the gait cycle is improved even when the stimulator is off in comparison to pre-treatment. It is said that this could be the result in of motor relearning and strengthening of the muscles due to the ability to exercise the muscle. If such effect is indeed present, it could become an important argument in using FES above the orthosis. However, it has not yet been proven that this carry-over effect is an effect of the FES itself. The long term said effect of using an AFO is less beneficial. Due to the passive nature of the treatment, the muscles are not used during walking. This could result in a reduction of muscle tone[17] and even bone degeneration[19]. When a comparison in made between the long term effects of FES and AFO, the functional electrical stimulation inclines to be the victor. However, more research is need in either of the long term effects.

To the best of our knowledge, no numbers are known to indicate which of the two FES systems achieve a better result in treating the drop foot in stroke patients. There are some guesses, as mentioned earlier, about a difference in carry over effects, but this remains unclear. Because of the costs and invasive nature of the implanted FES electrodes, it is hard to study the direct relation between achievements of the two systems, but a long follow-up study should give more insight in this. However, there are some upsides and downsides known about each FES system, which are stated in table 6.

The bottom line of this is, whether or not the patient is willing to undergo surgery for something that is not life-threatening but is rather troublesome. So far, the invasive FES has no advantages that are big enough to overrule the disadvantages of surgery. The non-invasive FES therefore stays the common approach within the field of FES in the treatment of drop foot using. New developments are rising to overcome this disadvantage of surgery. The BION microstimulator has great potential to overcome this, because it has the
advantages of the invasive FES but without the need of surgery. It is however still in clinical research phase 2, so a lot of research has yet to be done, but it looks very promising.

The user preferences should also be taken into account when a treatment comparison is made. There are a lot of differences in the patient characteristics. For example, the more senior members of the patient group will prefer the AFO above a FES treatment because the disadvantages of surgery or the attachment of the transcutaneous electrodes are greater when compared to the ease of use of the orthosis. But then again, a young adult with a far larger life expectancy will prefer the transcutaneous or even the implanted FES because of the greater need of participating in daily living activities. The previous mentioned general user preferences incline to the advantages of the FES treatment, however, the participants of the summarised article [23] favoured the AFO. The preference of user is a important factor in the treatment prescription.

Not much research has been done on the cost efficiency comparison of the treatments. The cost for the fabrication of a simple AFO is much less then a complicated surgery and the production of the electrodes, software and control unit.

From all this it can be concluded that FES, in theory, is a better technique for treating drop foot in stroke patients than AFO. Because of its active nature, it also gets better results. It is really the choice of the patient what treatment he gets, where its lifestyle is a big factor in deciding this. Transcutaneous FES yet remains the common approach of FES, since the disadvantages of surgery are too big. Especially when improvements are made in the field of EMG-triggering, the transcutaneous FES is more and more improving. The new technology BION microstimulation looks very promising to overcome the risks of surgery and still have the advantages of implanted electrodes.

References


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<td>Other parts of the leg can be stimulated more easily</td>
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<td>Less pain sensation</td>
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Table 1: The up and downsides of transcutaneous and implanted FES


