The use of electrical stimulation for correction of dropped foot in subjects with upper motor neurone lesions.

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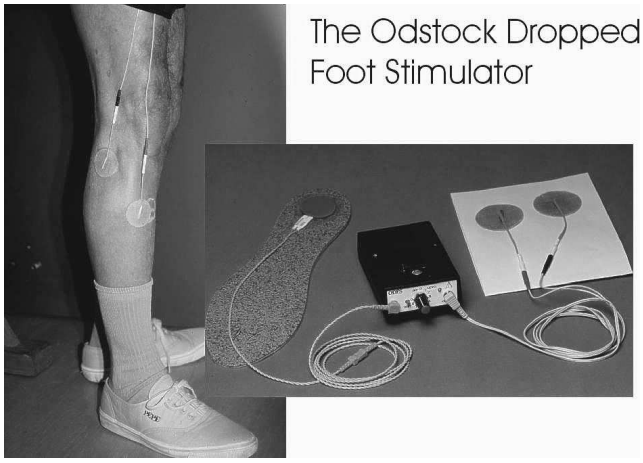


The concept of Functional Electrical Stimulation (FES) was put forward by Liberson[1, 2] in 1960 when he and his team produced the first electrical stimulation device for the correction of dropped foot due to an upper motor neurone lesion. His concept was that by applying electrical stimulation to paralysed muscles, functional movement could be produced, providing the user with a useful orthotic device. Liberson's device was a portable neuromuscular stimulator which produced pulses of between 20 and 250µs at a frequency of 30-100Hz and current amplitudes of up to 90mA. Stimulation was timed using a switch placed under the heel of the affected side. When weight was taken from the switch, stimulation was delivered to carbon rubber electrodes placed over the common peroneal nerve as it passes over the head of fibula, causing dorsiflexion. Liberson reported that the gait of hemiplegics was significantly improved by use of the device and that on several occasions users acquired the ability of voluntary dorsiflexion for short periods after its use. Since that time several groups have developed similar systems and the devices have received some clinical use, most notably in the former Yugoslavia. However, until recently, the technique has not been widely used in the UK and there has been a shortage of evidence to support its use.

There has not been much reported in the literature on the use of dropped foot stimulators with people with multiple sclerosis (PWMS) v. The first report is by Carnstam et al.[3] who reported increased active dorsiflexion strength and reduced calf tone after peroneal stimulation observed in one PWMS. Karsnia et al.[4] reported a retrospective study of 99 stimulator users, 43 of whom had MS. Twenty-five, mainly those with MS had stopped using the device because of a decline in their condition while 16, mainly CVA, had stopped due to improved mobility. Overall the device was well accepted. Crone et al.[5] demonstrated disynaptic reciprocal inhibition in 74 neurologicaly intact subjects by showing the H reflexes induced in the soleus muscle were inhibited by stimulation of the common peroneal nerve. The effect was greatly reduced in 39 patients who had spasticity except for 4 PWMS who were regular dropped foot stimulator users. This suggests that regular stimulation of the common peroneal nerve may help to preserve this reflex.

The Odstock Dropped Foot Stimulator (ODFS) is a single channel, foot switch triggered stimulator designed to elicit dorsiflexion and eversion of the foot by stimulation of the common peroneal nerve, (max. amplitude 100mA, 350µs pulse, 40 Hz). It is a development of the device first described by Liberson. Skin-surface electrodes are placed, typically, over the common peroneal nerve as it passes over the head of the fibula and the motor point of tibialis anterior. If greater knee flexion is required, the indifferent electrode can be placed over the common peroneal nerve as it passes through the

popliteal fossa, eliciting a withdrawal reflex. The rise and fall of the stimulation envelope can be adjusted to prevent a sudden contraction, which might induce a stretch reflex in the calf muscles. There is also a facility to add an extension to the stimulation envelope after heel strike which mimics the natural activity of the anterior tibialis muscle which contracts eccentrically lowering the foot to the ground. The Odstock 2 Channel Stimulator (O2CHS) is a version of the ODFS allowing the correction of bilateral dropped foot controlled by a single foot switch and the stimulation of other combinations of muscles.

By provision of dorsiflexion and eversion, the foot clears the ground in the swing phase more easily. This reduces the effort of gait, reducing compensatory activities such as hip hitching and circumduction. Reduction in effort will lead to a reduction of associated reactions and result in a general lowering of tone. Contraction of the tibialis anterior muscle and the hamstrings via the withdraw reflex may, by reciprocal inhibition, reduce antagonist activity leading to a more normal modulation of tone in gait. Repeated use of the stimulator may then lead to a pattern of "normal" walking being relearned centrally and long term potentiation of the required pattern of synapses may lead to a reinforcement of this pattern of walking. However, a more immediate benefit from the orthotic use of the device is that walking is easier and safer and therefore confidence will improve leading to an extension of mobility range and an overall improvement in quality of life.

The ODFS was the subject of a randomised controlled trial in which 32 stroke patients who had had a stroke for in excess of 6 months were allocated to a treatment group or a control group. The treatment group used the device and also received 12 sessions of physiotherapy in the first month, while the control group who received the same contact time only received physiotherapy[6, 7, 8]. After three months of use the treatment group showed a statistically significant increase in walking speed of 16% and a reduction in the Physiological Cost Index (PCI) of 29% when the stimulator was used while no changes were seen in the control group. No significant 'carryover' effect was seen although a trend was present. Users of the ODFS showed a continuing reduction in quadriceps spasticity measured using the Wartenberg Pendulum Drop Test, which was only seen in the control group while physiotherapy continued. The treatment group also showed a reduction in the Hospital Anxiety and Depression index suggesting an improvement in quality of life. Cost benefit analysis showed that use of the device gave a QALY (quality adjusted life years) gain over the control group of 0.042, indicating that the use of the device met the requirements for a treatment within the NHS. The trial results together with case series data from subjects who had multiple sclerosis were presented to the South and West Regional Health Authority Development and Evaluation Committee[9]. After examining this and evidence from other groups, the committee recommended the ODFS for use in the UK's National Health Service for patients with upper motor neurone lesions.

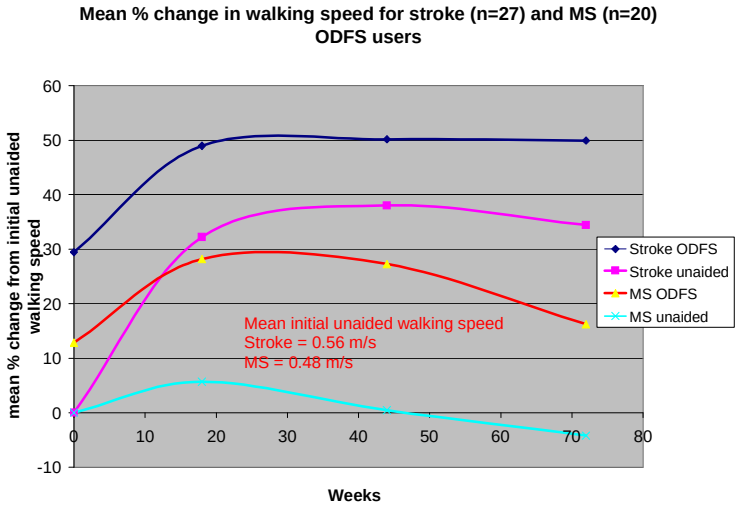
Following the trial and some publicity in a national newspaper, there was some considerable demand for treatment and it was therefore decided to set up a clinical service. As previously mentioned the idea of FES is not new and it was our opinion that the reason for its poor take up into clinical practice was for several reasons. Firstly, initial devices had been unreliable with poor technical back up. Secondly, the clinical techniques for its successful application have been poorly documented and practitioners received no training in its use. Thirdly, it was plain from our clinical experience that regular follow up was required to ensure continued effective use of the device. The first problem we hoped we had solved by using new technology and careful design based on considerable clinical experience. The second problem was tackled by writing a detailed clinical manual and by running a regular two day training courses for clinicians that wished to use the device.

To satisfy the need for follow up the following clinical model has been adopted. Patients are first seen at an assessment clinic. Subjects are suitable for treatment if they have a dropped foot due to an upper motor neurone lesion and are able to walk at least a few metres with appropriate aids or assistance. The following are contraindications; fixed contractures of the ankle, poorly controlled epilepsy (there is some anecdotal evidence of symptoms being exacerbated by electrical stimulation) and poor skin condition in the area of the electrodes. The effect of the stimulation is not known in pregnancy and pacemaker users are assessed by a cardiologist to ensure the ODFS doses not interfere with the pacemaker. The stimulator is tried and if gait can be improved, the patient is recommended for treatment.

The ODFS is fitted over two clinic sessions on consecutive days. On the first day the user is taught how to apply the device while on the second day their ability to do so is assessed and further training given if necessary. If appropriate, carers are also instructed in its use. If the patient has severe calf spasticity it has been found useful to use an exercise stimulator for a period of about an hour a day for one month. By using a stimulator with a slow rising edge ramp,

calf spasticity can be reduced and range of motion increased. A recent pilot study has shown that botulinum toxin may also be beneficial in such cases[10]. Use of the stimulator is increased gradually over 2 to 3 weeks until it can be used all day. Follow up is made at 6 weeks, 18 weeks, 45 weeks and 72 weeks from first use and then yearly for as long as the device is used. If users experience problems they are encouraged to contact the clinic so advice can be given, equipment repaired or extra clinic sessions arranged if necessary.

Following the establishment of a clinical service, it was decided to continue recording the main outcome measures of walking speed and PCI that had been recorded in the RCT. While increased walking speed was not highlighted as a significant reason for continued use of the ODFS, it has been shown by Wade[11] et al. to be representative of overall gait function. An audit of these parameters over the first 18 weeks of use confirmed the results of the original RCT and also showed a significant carryover effect, i.e. an improvement in walking ability when not using the stimulator, in a group of 111 stroke subjects[12]. Overall, users walked 27% faster when they used the device with a carryover effect of 14%. In a subgroup of 27 ODFS users walking speed both with and without the device was observed to improve over the first 18 weeks and thereafter remain unchanged. As the ODFS users were an average of 5.4(sd ±10.7) years post stroke this supports the hypothesis that the carryover observed was due to use of the stimulator rather than natural recovery following the stroke. In a group of 78 MS subjects, users walked 20% faster when using the device[13]. Although no overall carryover effect was observed, one third showed an improvement in unaided walking speed of more then 10%. In a subgroup of 20 MS users, this improved walking speed with the device was shown to also peaks at 18 weeks with no significant change from initial values after that time. 18 MS users of the bilateral dropped foot stimulator showed a 48% increase in walking speed at 18 weeks but again no significant carryover effect although a strong trend was observed.



A questionnaire survey indicated that the most common reasons for using the ODFS were that it reduced the effort of walking, reduced tripping and improved confidence[14]. Overall, compliance was 92% at 18 weeks and 86% at 1 year. However, if MS users are looked at separately, out of 134 who started using FES between January 1999 and December 2001, 9 stopped its use within 1 year, a compliance of 93%. In the year 2000 the device was recommended by the Royal College of Physicians in their publication "National clinical guidelines on stroke"[15].

Future developments

While the ODFS has been shown to improve gait by correction of dropped foot, problems often remain with movement of other joints, in particular the knee and hip. The O2CHS can be used to add a second channel of stimulation. Hip extension in the stance phase can be improved by stimulation of the gluteus maximus while hip abduction can be improved by stimulation of the gluteus medius. Knee flexion can be improved by stimulation of the hamstrings at terminal stance and initial swing while the same muscle can be used to control knee hyperextension at initial floor contact. The calf muscles can be

stimulated to improve push off and triceps can be stimulated to improve arm swing and therefore balance while walking in patients with significant associated reaction in the upper limb[16].

Preliminary investigations suggest that the ODFS may be applied in cases of Parkinson's Syndrome to help initiate gait and prevent freezing[17].

Conclusion

It has been demonstrated by RCT that the ODFS can improve the mobility of people who have a dropped foot following stroke. A clinical service has been successfully set up and these techniques successfully transferred to other centres. Audit of these services has confirmed the RCT results and further indicated that mobility can be improved in people with multiple sclerosis. A RCT with this group is now underway. Use of the bilateral system in MS can delay final dependence on a wheel chair, providing a means of access where a chair can not be used. Compliance of both devices is high suggesting that they are well accepted and provide a useful benefit to their users.

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