Objective: To investigate the feasibility of unsupervised community use of an array-based automated setup (AS) functional electrical stimulator (FES) for current foot-drop FES users.

Design: A feasibility study.

Setting: Participants' gait, total setup (TS) times and satisfaction were evaluated twice in the gait laboratory. Usage, AS times and problems encountered were recorded during a two week period of unsupervised use.

Participants: Participants (N=7) with diagnosis of uni-lateral foot-drop of central neurological origin (>6mo), who were regular users of a foot-drop FES system (>3mo).

Intervention: Array-based AS FES system for foot-drop (ShefStim).

Main Outcome Measures: Logged usage; TS times for both FES systems and logged AS times for ShefStim; diary recording of problems experienced; Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) questionnaire; walking speed; ankle angles at initial contact and foot clearance during swing.

Results: All participants were able to use ShefStim. TS took longer with ShefStim than participants' own FES systems and AS was longer than in a previous study of a similar system (1). Some problems were experienced but overall participants were as satisfied with ShefStim as their own FES systems. The increase in walking speed (N=7), relative to no stimulation, was comparable between both systems and appropriate ankle angles at initial contact (N=7) and foot clearance during swing (N=5) were greater with ShefStim.

Conclusions: This study demonstrates, for the first time, that an array-based AS FES system (ShefStim) for foot-drop can be successfully used unsupervised. Despite setup taking longer and some problems users are satisfied with it and it would appear as effective, if not better, at addressing the foot-drop impairment. Further product development of this unique system, followed by a larger-scale and longer-term study is required before firm conclusions about its efficacy can be reached.

Word count: 290

Key words: electric stimulation therapy; peroneal nerve; hemiplegia; gait disorders, neurologic; rehabilitation

Abbreviations:

Functional electrical stimulation=FES**;** Automated setup=AS; Odstock drop foot stimulator=ODFS; Inter-quartile range=IQR; Standard deviation=SD; Total setup=TS; Quebec User Evaluation of Satisfaction with assistive Technology=QUEST; Dorsiflexion=DF; Plantarflexion=PF

INTRODUCTION

The efficacy, and safety, of functional electrical stimulation (FES) as a treatment for foot-drop of central neurological origin is well established (2), however, usability issues have been noted (3, 4). In fact a survey of new and established users of the Odstock drop foot stimulator found that 44% of users reported difficulties in locating the correct electrode position (4), and this finding is of particular relevance to this study. Traditional single-channel surface foot-drop FES systems deliver current via a pair of electrodes, accurate placement of which is crucial to the correct functioning of the system. The optimal site for stimulation may vary from day-to-day and even throughout a day which further complicates the setup process (4). Interestingly, despite wide recognition of this issue (5), only one study specifically reported on the impact of user-defined electrode placement on functional outcomes (1), finding a poorer foot response when participants located electrodes themselves, compared with clinician setup.

In response to this issue, new designs of FES systems have been produced. These include electrodes integrated into cuffs (6, 7) and implantable systems (5, 8). Most recently, Heller *et al.* (1) reported on an array-based FES stimulator for foot-drop. The system uses the principle of a 'virtual electrode'. Stimulation is delivered via a 4x4 cluster of small electrodes, chosen from within an 8x8 array. The choice of which virtual electrode to use and at what level to stimulate is determined automatically during setup by an algorithm, which uses as its input the foot response to stimulation. This approach fully automates the setup process (both location and amplitude of stimulation) thus, potentially, reducing setup difficulty. Heller's study found that automated setup (AS) was comparably effective and quicker than user setup conventional FES. The system, originally studied by Heller, has been

further developed and CE marked as ShefStim. This paper is the first feasibility (9) study of ShefStim which combined a period of unsupervised use in conjunction with gait evaluation at the start and end of the study period. The primary aim was to investigate whether ShefStim could be used, unsupervised, by foot-drop FES users within the community environment. In addition a number of other sub-aims were addressed. These were to investigate:

1. The community-usage patterns and user-satisfaction with ShefStim.
2. The total setup (TS) time compared with their own FES system, as well as AS times for ShefStim.
3. The effects of ShefStim on walking speed, ankle angles (at initial contact) and foot clearance during swing, compared with participants' own FES system.

Word count: 404

METHODS

ShefStim system

A detailed description of the operating principles of the stimulator, and changes in order to achieve CE marking, are given in the Heller *et al*. paper (1). The same fixed parameters (monophasic waveform, charge-balanced, 40Hz, 160µs) were used but the system used in Heller's study restrained the leg in a support during the AS process. This was deemed impractical for a take-home device so instead users were requested to extend their leg and rest their heel on the floor during home AS.

Figure 1:

The ShefStim consists of (Fig. 1): a leg-worn stimulator (Fig. 1. a.) housed in a modified knee sleeve[i] (Fig. 1. b.); a flexible printed circuit board array of 64 electrodes (cathode electrodes) (Fig. 1. c.), covered with a thin layer of high resistivity hydrogel (10-12) . Sweat ingress changes the conductive properties of the hydrogel sheet so a replacement array fitted with a new sheet of hydrogel is used each day (12); a conventional footswitch[ii]; a conventional anode[iii] (Fig. 1.d.) and a foot sensor and remote control device housed in a bespoke foot-pod[iv] (Fig. 1. e.). The foot sensor and remote control device detects foot orientation, provides voice commands during AS and acts as a handheld remote unit post AS, allowing the user to pause, and change intensity as required.

Word count: 209

Donning the system

To don ShefStim the following steps are required:

1. The footswitch (Fig. 1. f.) is placed under the heel, with the connecting cable extending from the shoe.
2. The knee sleeve is donned aligning the stimulator pocket with the long axis of the tibia
3. The stimulator is placed in the knee sleeve's stimulator pocket
4. The foot-pod, containing the foot sensor and remote control device is positioned over the shoe locating it approximately centrally over the dorsum of the foot and attached with Velcro®

5. Electrode array placement: the centre of the third row of electrodes down from the top of the array is aligned with the head of the fibula and the inner edge parallel to the tibia.
6. The electrical connector for the array (Fig. 1. g.) is inserted into the array socket on the side of the stimulator and the array is secured with a Velcro® strap.
7. The self-adhesive anode is positioned over the tibialis anterior.
8. The footswitch connector (Fig. 1. h.) is inserted in the stimulator.

AS is then started.

Word count: 177

AS

For a more detailed description of the AS algorithm refer to Heller's study (1). The only difference between the algorithm used in Heller's study (1) and the ShefStim algorithm, relates to the cost function used in stage 3 of the setup process. The cost function enables many factors that are not directly comparable (e.g. the angle of dorsiflexion (DF) and the stimulation current) to be combined into one optimisation routine. In this case, for example, the angle of DF and the stimulation current are related and the benefits of increasing DF have to be balanced against the potential disadvantages of increasing current excessively. The cost function attributes each a cost score, the lower the cost the better, and the optimisation routine is used to find a minimum cost solution. Compared with the cost function described in Heller's study, the one used in ShefStim reduced the degree of eversion associated with zero cost from 10 to 5 degrees. This change was implemented following observation of excessive (>10 degrees) eversion in 19% of Heller's participants.

Word Count: 171

Participants

Ethical Approval was granted from the University of Salford (REP10/113) and the integrated research application system (10/H1003/107) for ten participants. Existing foot-drop FES users within the North-West region were given information by clinicians. Interested participants contacted the chief investigator. Inclusion/exclusion criteria are shown in Table 1.

Table 1:

Word count: 46

Protocol

At visit 1 participants attended the University of Salford gait laboratory and were provided with standard shoes[v] for all conditions to avoid the potential impact of different footwear on foot clearance (13). Participants walked approximately five metres along the gait laboratory up to five times at a self-selected speed initially with no stimulation and then with participant's own FES system (self-setup). Following visit 1 the knee sleeve, stimulator and electrode arrays were prepared for that individual. Participants returned for visit 2 where fitting was completed, rising/falling ramps and extension configured, adjustments made to AS settings if required (to ensure appropriate virtual electrode selection) and ShefStim use taught. Following two weeks of unsupervised use of ShefStim at home (with a home-visit after approximately one week to replenish arrays and answer any queries) participants returned to the gait laboratory (visit 3) which duplicated visit 1 but using ShefStim rather than their own FES system.

Word count: 151

Measures

Estimate of usage (between visits 2 and 3)

Usage data has been collected in previous foot-drop FES studies (14-18). ShefStim logs the number of heel lifts per day which can be used as an estimate of usage.

Word count: 29

TS (visits 1 and 3) and **AS time** (between visits 2 and 3).

With one notable exception (1), setup time has been largely neglected in previous foot-drop FES research . TS times, defined as time from first starting to don equipment to being satisfied with the outcome and walking away (including AS time for ShefStim), were recorded for participants' own FES (visit 1) and ShefStim (visit 3). Average AS time (time for AS to complete) was logged by ShefStim.

Word count: 65

Diary recording problems during community use (between visits 2 and 3).

Problems encountered were recorded in a paper diary by each participant. User-reported problems have been collected previously (15) but never during the period of use. Recorded problems were collated and grouped into two categories (19): External and Setup. External were classed as being independent of the stimulator design and so referred to the housing of ShefStim (knee sleeve), issues with the standard wired footswitch or issues with charging. Setup was defined as any problem related to setup or satisfaction with the foot response.

Word count: 81

User-satisfaction (visits 1 and 3)

User-satisfaction has previously been captured using purposive questionnaires (4, 15, 18). Given the risk of bias and lack of validation we sought an alternative. The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) device scale (20) is a validated user-satisfaction measure . Participants rated their satisfaction against eight single item criteria (dimensions, weight, ease of adjustment, safety and security, durability, ease of use, comfort, effectiveness) using a five-point Likert scale (1=not satisfied at all to 5= very satisfied: maximum score=40) for their own FES system and ShefStim. In addition, participants ranked their top three priorities from the eight criteria.

Word count: 97

Speed and ankle angles at initial contact (visits 1 and 3)

Increased walking speed indicates an improvement in overall walking performance (21) and is frequently used in FES research (22, 23). Measuring walking speed over five metres from a static starting position is a validated measure with neurological populations (24) and was calculated by averaging the velocity of a recorded waist marker (L3 vertebra) over the measurement space (13).

Foot-drop leads to abnormal joint alignment during stance (25) with a tendency for plantarflexion (PF) and inversion (21) which can reduce ankle stability. Sagittal and frontal plane ankle angles were captured at initial contact to measure this. The calibrated anatomical system technique (CAST)(26, 27) was used for shank marker placement. Foot marker placement was based on the shod-foot model by Pratt *et al*. (28).

Data for both speed and ankle angles was captured at 100Hz using a 16-camera 3D motion analysis system[vi]; a fourth-order low-pass Butterworth filter was used with a 6Hz cut-off frequency. Ankle angles at initial contact were analysed using Visual 3D[vii]

Word count: 152

Foot clearance during swing (visits 1 and 3)

Foot-drop is associated with an increased risk of tripping and falling due to a lack of foot clearance during swing phase (29). Foot clearance was obtained for seven different points on the shoe sole as described in Thies *et al* (13). Only three of the seven markers from Thies' study (13) (distal toe, medial and lateral forefoot) were investigated since these were deemed most relevant. Healthy gait consistently has a minimum clearance value during swing (13, 30). Hemiplegic gait, however, has an altered clearance trajectory and does not always produce a minimum value during swing, so an alternative and consistently definable point along the trajectory was chosen. Specifically, in this study it was calculated at the moment in time when the reference point on the shoe sole passed the contra-lateral medial malleolus. Data was processed using Matlab®[viii] code (13).

Word count: 133

Total methods word count: 1311 (not including sub-headings)

Data Analysis

As a feasibility study (9, 31), statistical analysis was limited to graphical representation of data and descriptive methods. Ratio data (AS log data, speed and ankle angles at initial contact) was analysed using mean and standard deviation (SD). Median was used for

skewed data (usage, TS times and toe clearance (32) , with inter-quartile range(IQR)) and ordinal data (QUEST (33)).

Word count: 56

RESULTS

Table 2:

Table 2 provides participant characteristics. Prior to data collection three participants were withdrawn (1, 6, 10). The withdrawal of participants 1 and 10 was due to unrelated medical issues. Subject 6 was withdrawn as it became clear, post recruitment, that he was not a regular user of FES for foot-drop. He had discontinued use following ankle instability problems and a number of falls. The average age of the remaining participants was 58 yrs. (SD 12.9) which is comparable to other foot-drop FES studies (1, 21, 34). Of the five men and two women, four had non-progressive and three had progressive neurological disorders, which is representative of the FES user population (16, 35). The FES systems used by participants varied but all use a single cathode and single anode, and so were classed as 'conventional'.

Word count: 126

Estimate of usage

All participants used ShefStim (Fig. 2) with an average of 1314 heel lifts (steps) per day. There was variability in the number of heel lifts from day-to-day for each participant (for example participant 8) and between participants (participants 5 and 7 versus participant 3). The number of days participants used ShefStim within the two week period also varied, with

participants 7 (6/15) and 9 (4/15) using it far less than participants 5 (14/15) or 2 (13/15) (Fig. 2)

Word count: 78

Figure 2:

TS and AS time

TS time for ShefStim took an average of exactly 14 min [range: 12 min 24 s -37 min 30 s] compared to 3 min 20 s [range: 40 s -8 min] for their own FES. The average AS time was 9 min [range: 7 min 34 s – 10 min 20 s].

Word count: 51

Diary recording problems during community use

Of the recorded problems 64% [48 problems] were related to setup with poor voice command clarity from the foot sensor and remote control device (e.g. participant 2, day 3 "remote voice garbled"), frequent pausing during and/or unacceptable AS specifically cited (e.g. participant 5, day 9 "pausing, why?" and participant 2, day 2 "2x setups as chaplin walk"). 36% [27 problems] were related to external issues, for example participant 8, day 6 "despite charging overnight controller battery was flat". The overall number of reported problems diminished towards the end of the testing period (Fig. 3).

Word count: 94

Figure 3:

User-satisfaction

Overall, on average, participants were as satisfied with ShefStim as with their own FES system (Fig. 4). They were more satisfied with their own FES in terms of: 'Ease of use', which was the criteria most frequently prioritised on QUEST, and 'safety and security'. ShefStim outscored participants' own FES with regards to 'effectiveness', the second most frequently cited priority, and 'ease of adjustment'. On the remaining four criteria the systems scored equally.

Word count: 72

Figure 4:

Speed

Both FES systems produced the same increase in walking speed [0.06 m/s] compared to no stimulation (Table 3).

Word count: 18

Table 3:

Ankle angles at initial contact

With no stimulation PF with inversion was seen (Table 3). Both ShefStim and conventional systems corrected this; however, ShefStim achieved this to a greater extent (Table 3).

Word count: 27

Foot clearance during swing

This outcome could not be determined for participants 5 and 7 who both exhibited short step lengths and a significant degree of external rotation of the leg during swing, therefore none of the reference points passed the contra-lateral malleolus during swing as was required by the algorithm. The distal toe marker showed the smallest overall clearance values and with ShefStim the clearance was greatest (Table 3). Table 3 shows that without FES, the median value of the medial marker was higher than the lateral; with participant's own FES they were approximately equal and with ShefStim the lateral was higher than the medial. This foot pose at mid-swing was consistent with the ankle angles at initial contact (see above).

Word count: 118

Total results word count: 584 (excluding sub-headings)

DISCUSSION

This study sought to investigate the feasibility of unsupervised use of ShefStim by FES users within the community environment. Usage results show ShefStim is a usable device because without exception, albeit with variation, all participants used ShefStim.

Previous studies have reported a number of different measures of usage (6, 14, 15, 17, 18). Only our results for steps (heel lifts) per day could be compared to previous, larger, studies (6, 15, 18), with our participants generally walking less. For example Stein *et al's* (6) participants took 1842 (+/- 198) steps per day when first starting to use the Walkaide system and van Swigchem *et al's* (18) took 5733 (SD 2516). Worthy of note was that van Swigchem *et al's* (18) participants were encouraged to wear the NESS L300 for the entire

298 day whereas participants in ours and Stein *et al's* were not guided in this way. Further, our
299 participants reported a number of problems associated with the pre-commercial nature of
300 the ShefStim system, which may have impacted on use on certain days (see Fig. 3). Further
301 studies should continue to report detailed FES usage to allow further exploration of the
302 population and allow comparison between systems and/or baseline.

303 Results did not fully meet the prediction made by Heller *et al* (1) that ShefStim would result
304 in shorter TS times. There are a number of possible reasons for this. Firstly, Heller used self-
305 report to assess setup time with participants' own FES systems, finding an average of 11
306 minutes. In our study participants were timed during setup in the lab and took an average of
307 3 minutes to setup their own FES systems. In the Heller study participants placed their
308 affected leg in a rigid brace, thereby removing the possibility of significant leg movement. In
309 our study, the participant's leg was not constrained during setup and leg movement
310 detected during the AS process led to pauses which lengthened the process, a problem
311 recorded by participants. Further, our ShefStim users relied on audio feedback from the
312 foot sensor and remote control device, which participants reported was sometimes difficult
313 to hear. Participants also sometimes reached the end of setup and decided that the
314 automatically chosen site was not acceptable, then ran the entire AS again. Although a 'skip-
315 site' function was available (1) to address this issue (alternative sites identified as suitable to
316 be selected manually) participants did not use it, hence further refinement of user training
317 material and/or the user interface is warranted.

318 The finding that, overall, participants were as satisfied with ShefStim as with their own FES
319 systems, is encouraging because unlike conventional foot-drop FES systems ShefStim has
320 not been subject to significant product design. The fact that problems diminished and 'ease

of use' was rated lower than participants own FES systems, however, suggests that two weeks was insufficient for participants to fully familiarise themselves with ShefStim. Alternatively it might be due to the cited problems with ShefStim itself. Our results cannot be compared to other studies as QUEST has not been used before in this field of research. Future studies should allow longer unsupervised periods of use and should use a validated measure such as QUEST.

Speed increase, for both ShefStim and conventional FES systems, compared to no FES was in keeping with previous studies (21) and classed as clinically meaningful (36). In Heller's study, in which subjects did not have time to accommodate to the automated setup, speed increase (relative to no FES) when using the automated setup system was smaller than with their own system (0.04 m/s vs 0.11m/s). In both studies foot response with AS was improved compared with participants' setup of their own stimulators. Although there is a risk of over-interpretation of the results, our findings may suggest that once users become accustomed to a new FES system, their walking speed is relatively insensitive to small differences in foot response. These findings are supported by the foot clearance results and indicate that the underlying operating principle of an array-based FES system with AS may be more effective at addressing foot-drop than conventional FES systems by reducing human error/influence over electrode placement. However, larger scale study is required to fully substantiate these initial findings.

Word count: 676

Study limitations

This was a feasibility study with a small sample size, self-referred participants and was not randomised (9, 31). As such, whilst encouraging, results should be viewed with caution. The outcome measures selected would appear appropriate but many have been largely unused in previous research in this field making comparison to previous studies challenging.

Further development of the electrode-skin interface is required (12) to negate the need for daily array replacement and improve future commercial viability. Further iterations of ShefStim need to also consider addressing the cited setup and external problems, such as voice command clarity, the impact of pausing on AS time, user training and charging, to facilitate further study and widespread implementation.

Word count: 110

CONCLUSION

This is the first study of ShefStim and one of very few investigating foot-drop FES both within the lab and during unsupervised use (37, 38). Ultimately this study demonstrates, for the first time, an array-based AS FES system (ShefStim) for foot-drop can be successfully used unsupervised. Despite longer and more problematic setup in the population studied, users were satisfied with it and it would appear to have comparable, if not better, effects on gait than conventional foot-drop FES systems.

Further product development and a larger-scale, longer-term study is required before firm conclusions about the efficacy and effectiveness of ShefStim, compared to conventional FES, can be reached.

Word count: 104

Total word count: 3245

References

1. Heller BW, Clarke AJ, Good TR, Healey TJ, Nair S, Pratt EJ, et al. Automated setup of functional electrical stimulation for drop foot using a novel 64 channel prototype stimulator and electrode array: Results from a gait-lab based study. Med Eng Phys. 2013 May 3. PubMed PMID: 22559959. Epub 2012/05/09. Eng.
2. NICE. Functional electrical stimulation for drop foot of central neurological origin. National Institute for Clinical Excellence, 2009 Contract No.: Interventional procedure guidance 278.
3. Wilkie KM, Shiels JE, Bulley C, Salisbury LG. "Functional electrical stimulation (FES) impacted on important aspects of my life"-A qualitative exploration of chronic stroke patients' and carers' perceptions of FES in the management of dropped foot. Physiother Theory Prac. 2012 Jan;28(1):1-9. PubMed PMID: BCI:BCI201200024459.
4. Taylor PN, Burridge JH, Dunkerley AL, Lamb A, Wood DE, Norton JA, et al. Patients' perceptions of the Odstock Dropped Foot Stimulator (ODFS). Clin Rehabil. 1999 Oct;13(5):439-46. PubMed PMID: 10498351. Epub 1999/09/25. eng.
5. Kottink AI, Hermens HJ, Nene AV, Tenniglo MJ, van der Aa HE, Buschman HP, et al. A randomized controlled trial of an implantable 2-channel peroneal nerve stimulator on walking speed and activity in poststroke hemiplegia. Arch Phys Med Rehabil. 2007 Aug;88(8):971-8. PubMed PMID: 17678657. eng.
6. Stein RB, Everaert DG, Thompson AK, Chong SL, Whittaker M, Robertson J, et al. Long-Term Therapeutic and Orthotic Effects of a Foot Drop Stimulator on Walking Performance in Progressive and Nonprogressive Neurological Disorders. Neurorehabil Neural Repair. 2010 Feb;24(2):152-67. PubMed PMID: WOS:000274015500005.
7. Laufer Y, Ring H, Sprecher E, Hausdorff JM. Gait in individuals with chronic hemiparesis: one-year follow-up of the effects of a neuroprosthesis that ameliorates foot drop. J Neurolog Phys Ther: JNPT. 2009;33(2):104-10. PubMed PMID: 19556919. Language: English. Language Code: eng. Date Created: 20090626. Date Completed: 20091208. Update Code: 20111122. Publication Type: Journal Article.
8. Weber DJ, Stein RB, Chan KM, Loeb G, Richmond F, Rolf R, et al. BIONic WalkAide for correcting foot drop. IEEE Transactions On Neural Systems And Rehabilitation Engineering: A Publication Of The IEEE Engineering In Medicine And Biology Society. 2005;13(2):242-6. PubMed PMID: 16003906. Language: English. Language Code: eng. Date Revised: 20061115. Date Created: 20050711. Date Completed: 20050801. Update Code: 20111122. Publication Type: Journal Article.
9. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Med Res Methodol. 2010;10:67-73. PubMed PMID: 52844644.
10. Sha N, Kenney LP, Heller BW, Barker AT, Howard D, Moatamedi M. A finite element model to identify electrode influence on current distribution in the skin. Artif Organs. 2008 Aug;32(8):639-43. PubMed PMID: 18782136. eng.
11. Sha N, Kenney LP, Heller BW, Barker AT, Howard D, Wang W. The effect of the impedance of a thin hydrogel electrode on sensation during functional electrical stimulation. Med Eng Phys. 2008 Jul;30(6):739-46. PubMed PMID: 17942361. eng.
12. Cooper G, Barker AT, Heller BW, Good T, Kenney LPJ, Howard D. The use of hydrogel as an electrode-skin interface for electrode array FES applications. Med Eng Phys. 2011 Oct;33(8):967-72. PubMed PMID: WOS:000295107800010.
13. Thies SB, Kenney LPJ, Howard D, Nester C, Ormerod M, Newton R, et al. Biomechanics for inclusive urban design: Effects of tactile paving on older adults' gait when crossing the street. J Biomech. 2011;44(8):1599-604.

14. Granat MH, Maxwell DJ, Ferguson ACB, Lees KR, Barbenet JC. Peroneal stimulator: Evaluation for the correction of spastic drop foot in hemiplegia. Arch Phys Med Rehabil. 1996;77(1):19-24.
15. Stein RB, Chong S, Everaert DG, Rolf R, Thompson AK, Whittaker M, et al. A multicenter trial of a footdrop stimulator controlled by a tilt sensor. Neurorehabil Neural Repair. 2006 Sep;20(3):371-9. PubMed PMID: 16885423. Epub 2006/08/04. eng.
16. Taylor P, Burridge J, Dunkerley A, Wood D, Norton J, Singleton C, et al. Clinical Audit of 5 years Provision of the Odstock Dropped Foot Stimulator. Artif Organs. 1999;23(5):440-2.
17. Kottink AI, Hermens HJ, Nene AV, Tenniglo MJ, van der Aa HE, Buschman HP, et al. A Randomized Controlled Trial of an Implantable 2-Channel Peroneal Nerve Stimulator on Walking Speed and Activity in Poststroke Hemiplegia. Arch Phys Med Rehabil. 2007;88(8):971-8.
18. van Swigchem R, Vloothuis J, den Boer J, Weerdesteyn V, Geurts ACH. Is transcutaneous peroneal stimulation beneficial to patients with chronic stroke using an ankle-foot orthosis? A within-subject study of pateints' satisfaction, walking speed and physical activity level. J Rehabil Med. 2010 Feb;42(2):117-21. PubMed PMID: WOS:000275650700003.
19. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. Nurs Ed Today. 2004;24(2):105-12.
20. Demers L, Monette M, Lapierre Y, Arnold DL, Wolfson C. Reliability, validity, and applicability of the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) for adults with multiple sclerosis. Disabil Rehabil. 2002;24:21-30.
21. Voigt M, Sinkjaer T. Kinematic and kinetic analysis of the walking pattern in hemiplegic patients with foot-drop using a peroneal nerve stimulator. Clin Biomech. 2000;15:340-51.
22. Kottink AIR, Oostendorp LJM, Buurke JH, Nene AV, Hermens HJ, Ijzerman MJ. The Orthotic Effect of Functional Electrical Stimulation on the Improvement of Walking in Stroke Patients with a Dropped Foot: A Systematic Review. Artif Organs. 2004;28(6):577-86. PubMed PMID: 13154253.
23. Roche A, Laighin G, Coote S. Surface-applied functional electrical stimulation for orthotic and therapeutic treatment of drop-foot after stroke -- a systematic review. Phys Ther Rev. 2009;14(2):63-80. PubMed PMID: 2010314708. Language: English. Entry Date: 20090821. Revision Date: 20091218. Publication Type: journal article.
24. Graham JE, Ostir GV, Kuo Y-F, Fisher SR, Ottenbacher KJ. Relationship Between Test Methodology and Mean Velocity in Timed Walk Tests: A Review. Arch Physl Med Rehabil. 2008;89(5):865-72.
25. Burridge JH, Elessi K, Pickering RM, Taylor PN. Walking on an Uneven Surface: The Effect of Common Peroneal Stimulation on Gait Parameters and Relationship Between Perceived and Measured Benefits in a Sample of Participants With a Drop-Foot. Neuromodulat : J Internat Neuromodulat Soc. 2007;10(1):59-67. PubMed PMID: 23634177.
26. Cappozzo A, Catani F, Della Croce U, Laeardini A. Position and orientation in space of bones during movement: anatomical frame definition and determination. Clin Biomech. 1995;10(4):171-8.
27. Whittle M, Levine D, Richards J. Methods of gait analysis. In: Levine D, editor. Whittle's Gait Analysis. 5th ed. Edinburgh: Churchill Livingstone; 2012. p. 83-112.
28. Pratt EJ, Reeves ML, van der Meulen JM, Heller BW, Good TR. The development, preliminary validation and clinical utility of a shoe model to quantify foot and footwear kinematics in 3-D. Gait Posture. 2012;36(3):434-8.
29. Everaert DG, Stein RB, Abrams GM, Dromerick AW, Francisco GE, Hafner BJ, et al. Effect of a Foot-Drop Stimulator and Ankle–Foot Orthosis on Walking Performance After Stroke: A Multicenter Randomized Controlled Trial. Neurorehabil Neural Repair. 2013 April 4, 2013.
30. Thies SB, Jones RK, Kenney LPJ, Howard D, Baker R. Effects of ramp negotiation, paving type and shoe sole geometry on toe clearance in young adults. J Biomech. 2011;44(15):2679-84.
31. Medical Research Council. A framework for development and evaluation of RCTs for complex interventions to improve health. 2000.

32. Begg R, Best R, Dell'Oro L, Taylor S. Minimum foot clearance during walking: Strategies for the minimisation of trip-related falls. Gait Posture. 2007;25(2):191-8.
33. Esnouf JE, Taylor PN, Mann GE, Barrett CL. Impact on activities of daily living using a functional electrical stimulation device to improve dropped foot in people with multiple sclerosis, measured by the Canadian Occupational Performance Measure. Mult Scler. 2010 Sep;16(9):1141-7. PubMed PMID: 20601398. Epub 2010/07/06. eng.
34. van Swigchem R, van Duijnhoven HJR, den Boer J, Geurts AC, Weerdesteyn V. Effect of Peroneal Electrical Stimulation Versus an Ankle-Foot Orthosis on Obstacle Avoidance Ability in People With Stroke-Related Foot Drop. Phys Ther. 2012 Mar;92(3):398-406. PubMed PMID: WOS:000300940500004.
35. Taylor PN, editor How long do Dropped foot stimulator users continue to use FES and how much does it cost? An eleven and six year clinical audit. IFESS; 2010; Vienna, Austria.
36. Perera S, Mody SH, Woodman RC, Studensk SA. Meaningful Change and Responsiveness in Common Physical Performance Measures in Older Adults. J Am Geriatrics Soc. 2006;54(5):743-9. PubMed PMID: 20620658.
37. Barrett C, Taylor P. The effects of the odstock drop foot stimulator on perceived quality of life for people with stroke and multiple sclerosis. Neuromodulat : J Internat Neuromodulat Soc. 2010 Jan;13(1):58-64. PubMed PMID: 21992766. Epub 2010/01/01. eng.
38. Barrett CL, Mann GE, Taylor PN, Strike P. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. Mult Scler. 2009 Apr;15(4):493-504. PubMed PMID: 19282417. Epub 2009/03/14. eng.

Suppliers

[i] Adidas knee support, Adidas, Herzogenaurach, Germany.

[ii] Odstock Medical Ltd, Salisbury, UK

[iii] 5x5 PALS ®Platinum Neurostimulation electrode, Axelgaard Manufacturing co.Ltd, San Diego, USA.

[iv] Adapted from an I-pod holder, Signalex, Birmingham, UK.

[v] Hotter Comfort Concept shoes, Skelmersdale, UK. (for men) and Clarks Un Betty from Unstructured Autumn /Winter 2011 range, Street, UK. (for women)

[vi] Qualisys, Stockholm, Sweden.

[vii] C-Motion, Maryland, USA.

[viii] Matlab®, Mathworks, Cambridge, UK.

Figure legends

Figure 1: ShefStim system (medial view of leg during AS)

Figure 2: Logged heel lifts (N=7): Blank cells=0 heel lifts; the length of bar represents the number of heel lifts. The median number overall of steps per day was 1314.

Figure 3: Recorded problems over two week unsupervised community use (N=7).

Figure 4: Median QUEST results. Black= own FES system; Grey= ShefStim (n=7). Both systems scored a total of 32 out of 40.

Objective: To investigate the feasibility of unsupervised community use of an array-based automated setup (AS) functional electrical stimulator (FES) for current foot-drop FES users.

Design: A feasibility study.

Setting: Participants' gait, total setup (TS) times and satisfaction were evaluated twice in the gait laboratory. Usage, AS times and problems encountered were recorded during a two week period of unsupervised use.

Participants: Participants (N=7) with diagnosis of uni-lateral foot-drop of central neurological origin (>6mo), who were regular users of a foot-drop FES system (>3mo).

Intervention: Array-based AS FES system for foot-drop (ShefStim).

Main Outcome Measures: Logged usage; TS times for both FES systems and logged AS times for ShefStim; diary recording of problems experienced; Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) questionnaire; walking speed; ankle angles at initial contact and foot clearance during swing.

Results: All participants were able to use ShefStim. TS took longer with ShefStim than participants' own FES systems and AS was longer than in a previous study of a similar system (1). Some problems were experienced but overall participants were as satisfied with ShefStim as their own FES systems. The increase in walking speed (N=7), relative to no stimulation, was comparable between both systems and appropriate ankle angles at initial contact (N=7) and foot clearance during swing (N=5) were greater with ShefStim.

Conclusions: This study demonstrates, for the first time, that an array-based AS FES system (ShefStim) for foot-drop can be successfully used unsupervised. Despite setup taking longer and some problems users are satisfied with it and it would appear as effective, if not better, at addressing the foot-drop impairment. Further product development of this unique system, followed by a larger-scale and longer-term study is required before firm conclusions about its efficacy can be reached.

Word count: 290

Key words: electric stimulation therapy; peroneal nerve; hemiplegia; gait disorders, neurologic; rehabilitation

Abbreviations:

Functional electrical stimulation=FES**;** Automated setup=AS; Odstock drop foot stimulator=ODFS; Inter-quartile range=IQR; Standard deviation=SD; Total setup=TS; Quebec User Evaluation of Satisfaction with assistive Technology=QUEST; Dorsiflexion=DF; Plantarflexion=PF

INTRODUCTION

The efficacy, and safety, of functional electrical stimulation (FES) as a treatment for foot-drop of central neurological origin is well established (2), however, usability issues have been noted (3, 4). In fact a survey of new and established users of the Odstock drop foot stimulator found that 44% of users reported difficulties in locating the correct electrode position (4), and this finding is of particular relevance to this study. Traditional single-channel surface foot-drop FES systems deliver current via a pair of electrodes, accurate placement of which is crucial to the correct functioning of the system. The optimal site for stimulation may vary from day-to-day and even throughout a day which further complicates the setup process (4). Interestingly, despite wide recognition of this issue (5), only one study specifically reported on the impact of user-defined electrode placement on functional outcomes (1), finding a poorer foot response when participants located electrodes themselves, compared with clinician setup.

In response to this issue, new designs of FES systems have been produced. These include electrodes integrated into cuffs (6, 7) and implantable systems (5, 8). Most recently, Heller *et al.* (1) reported on an array-based FES stimulator for foot-drop. The system uses the principle of a 'virtual electrode'. Stimulation is delivered via a 4x4 cluster of small electrodes, chosen from within an 8x8 array. The choice of which virtual electrode to use and at what level to stimulate is determined automatically during setup by an algorithm, which uses as its input the foot response to stimulation. This approach fully automates the setup process (both location and amplitude of stimulation) thus, potentially, reducing setup difficulty. Heller's study found that automated setup (AS) was comparably effective and quicker than user setup conventional FES. The system, originally studied by Heller, has been

further developed and CE marked as ShefStim. This paper is the first feasibility (9) study of ShefStim which combined a period of unsupervised use in conjunction with gait evaluation at the start and end of the study period. The primary aim was to investigate whether ShefStim could be used, unsupervised, by foot-drop FES users within the community environment. In addition a number of other sub-aims were addressed. These were to investigate:

1. The community-usage patterns and user-satisfaction with ShefStim.
2. The total setup (TS) time compared with their own FES system, as well as AS times for ShefStim.
3. The effects of ShefStim on walking speed, ankle angles (at initial contact) and foot clearance during swing, compared with participants' own FES system.

Word count: 404

METHODS

ShefStim system

A detailed description of the operating principles of the stimulator, and changes in order to achieve CE marking, are given in the Heller *et al*. paper (1). The same fixed parameters (monophasic waveform, charge-balanced, 40Hz, 160µs) were used but the system used in Heller's study restrained the leg in a support during the AS process. This was deemed impractical for a take-home device so instead users were requested to extend their leg and rest their heel on the floor during home AS.

Figure 1:

The ShefStim consists of (Fig. 1): a leg-worn stimulator (Fig. 1. a.) housed in a modified knee sleeve[i] (Fig. 1. b.); a flexible printed circuit board array of 64 electrodes (cathode electrodes) (Fig. 1. c.), covered with a thin layer of high resistivity hydrogel (10-12) . Sweat ingress changes the conductive properties of the hydrogel sheet so a replacement array fitted with a new sheet of hydrogel is used each day (12); a conventional footswitch[ii]; a conventional anode[iii] (Fig. 1.d.) and a foot sensor and remote control device housed in a bespoke foot-pod[iv] (Fig. 1. e.). The foot sensor and remote control device detects foot orientation, provides voice commands during AS and acts as a handheld remote unit post AS, allowing the user to pause, and change intensity as required.

Word count: 209

Donning the system

To don ShefStim the following steps are required:

1. The footswitch (Fig. 1. f.) is placed under the heel, with the connecting cable extending from the shoe.
2. The knee sleeve is donned aligning the stimulator pocket with the long axis of the tibia
3. The stimulator is placed in the knee sleeve's stimulator pocket
4. The foot-pod, containing the foot sensor and remote control device is positioned over the shoe locating it approximately centrally over the dorsum of the foot and attached with Velcro®

5. Electrode array placement: the centre of the third row of electrodes down from the top of the array is aligned with the head of the fibula and the inner edge parallel to the tibia.
6. The electrical connector for the array (Fig. 1. g.) is inserted into the array socket on the side of the stimulator and the array is secured with a Velcro® strap.
7. The self-adhesive anode is positioned over the tibialis anterior.
8. The footswitch connector (Fig. 1. h.) is inserted in the stimulator.

AS is then started.

Word count: 177

AS

For a more detailed description of the AS algorithm refer to Heller's study (1). The only difference between the algorithm used in Heller's study (1) and the ShefStim algorithm, relates to the cost function used in stage 3 of the setup process. The cost function enables many factors that are not directly comparable (e.g. the angle of dorsiflexion (DF) and the stimulation current) to be combined into one optimisation routine. In this case, for example, the angle of DF and the stimulation current are related and the benefits of increasing DF have to be balanced against the potential disadvantages of increasing current excessively. The cost function attributes each a cost score, the lower the cost the better, and the optimisation routine is used to find a minimum cost solution. Compared with the cost function described in Heller's study, the one used in ShefStim reduced the degree of eversion associated with zero cost from 10 to 5 degrees. This change was implemented following observation of excessive (>10 degrees) eversion in 19% of Heller's participants.

Word Count: 171

Participants

Ethical Approval was granted from the University of Salford (REP10/113) and the integrated research application system (10/H1003/107) for ten participants. Existing foot-drop FES users within the North-West region were given information by clinicians. Interested participants contacted the chief investigator. Inclusion/exclusion criteria are shown in Table 1.

Table 1:

Word count: 46

Protocol

At visit 1 participants attended the University of Salford gait laboratory and were provided with standard shoes[v] for all conditions to avoid the potential impact of different footwear on foot clearance (13). Participants walked approximately five metres along the gait laboratory up to five times at a self-selected speed initially with no stimulation and then with participant's own FES system (self-setup). Following visit 1 the knee sleeve, stimulator and electrode arrays were prepared for that individual. Participants returned for visit 2 where fitting was completed, rising/falling ramps and extension configured, adjustments made to AS settings if required (to ensure appropriate virtual electrode selection) and ShefStim use taught. Following two weeks of unsupervised use of ShefStim at home (with a home-visit after approximately one week to replenish arrays and answer any queries) participants returned to the gait laboratory (visit 3) which duplicated visit 1 but using ShefStim rather than their own FES system.

Word count: 151

Measures

Estimate of usage (between visits 2 and 3)

Usage data has been collected in previous foot-drop FES studies (14-18). ShefStim logs the number of heel lifts per day which can be used as an estimate of usage.

Word count: 29

TS (visits 1 and 3) and **AS time** (between visits 2 and 3).

With one notable exception (1), setup time has been largely neglected in previous foot-drop FES research . TS times, defined as time from first starting to don equipment to being satisfied with the outcome and walking away (including AS time for ShefStim), were recorded for participants' own FES (visit 1) and ShefStim (visit 3). Average AS time (time for AS to complete) was logged by ShefStim.

Word count: 65

Diary recording problems during community use (between visits 2 and 3).

Problems encountered were recorded in a paper diary by each participant. User-reported problems have been collected previously (15) but never during the period of use. Recorded problems were collated and grouped into two categories (19): External and Setup. External were classed as being independent of the stimulator design and so referred to the housing of ShefStim (knee sleeve), issues with the standard wired footswitch or issues with charging. Setup was defined as any problem related to setup or satisfaction with the foot response.

Word count: 81

User-satisfaction (visits 1 and 3)

User-satisfaction has previously been captured using purposive questionnaires (4, 15, 18). Given the risk of bias and lack of validation we sought an alternative. The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) device scale (20) is a validated user-satisfaction measure . Participants rated their satisfaction against eight single item criteria (dimensions, weight, ease of adjustment, safety and security, durability, ease of use, comfort, effectiveness) using a five-point Likert scale (1=not satisfied at all to 5= very satisfied: maximum score=40) for their own FES system and ShefStim. In addition, participants ranked their top three priorities from the eight criteria.

Word count: 97

Speed and ankle angles at initial contact (visits 1 and 3)

Increased walking speed indicates an improvement in overall walking performance (21) and is frequently used in FES research (22, 23). Measuring walking speed over five metres from a static starting position is a validated measure with neurological populations (24) and was calculated by averaging the velocity of a recorded waist marker (L3 vertebra) over the measurement space (13).

Foot-drop leads to abnormal joint alignment during stance (25) with a tendency for plantarflexion (PF) and inversion (21) which can reduce ankle stability. Sagittal and frontal plane ankle angles were captured at initial contact to measure this. The calibrated anatomical system technique (CAST)(26, 27) was used for shank marker placement. Foot marker placement was based on the shod-foot model by Pratt *et al*. (28).

Data for both speed and ankle angles was captured at 100Hz using a 16-camera 3D motion analysis system[vi]; a fourth-order low-pass Butterworth filter was used with a 6Hz cut-off frequency. Ankle angles at initial contact were analysed using Visual 3D[vii]

Word count: 152

Foot clearance during swing (visits 1 and 3)

Foot-drop is associated with an increased risk of tripping and falling due to a lack of foot clearance during swing phase (29). Foot clearance was obtained for seven different points on the shoe sole as described in Thies *et al* (13). Only three of the seven markers from Thies' study (13) (distal toe, medial and lateral forefoot) were investigated since these were deemed most relevant. Healthy gait consistently has a minimum clearance value during swing (13, 30). Hemiplegic gait, however, has an altered clearance trajectory and does not always produce a minimum value during swing, so an alternative and consistently definable point along the trajectory was chosen. Specifically, in this study it was calculated at the moment in time when the reference point on the shoe sole passed the contra-lateral medial malleolus. Data was processed using Matlab®[viii] code (13).

Word count: 133

Total methods word count: 1311 (not including sub-headings)

Data Analysis

As a feasibility study (9, 31), statistical analysis was limited to graphical representation of data and descriptive methods. Ratio data (AS log data, speed and ankle angles at initial contact) was analysed using mean and standard deviation (SD). Median was used for

skewed data (usage, TS times and toe clearance (32) , with inter-quartile range(IQR)) and ordinal data (QUEST (33)).

Word count: 56

RESULTS

Table 2:

Table 2 provides participant characteristics. Prior to data collection three participants were withdrawn (1, 6, 10). The withdrawal of participants 1 and 10 was due to unrelated medical issues. Subject 6 was withdrawn as it became clear, post recruitment, that he was not a regular user of FES for foot-drop. He had discontinued use following ankle instability problems and a number of falls. The average age of the remaining participants was 58 yrs. (SD 12.9) which is comparable to other foot-drop FES studies (1, 21, 34). Of the five men and two women, four had non-progressive and three had progressive neurological disorders, which is representative of the FES user population (16, 35). The FES systems used by participants varied but all use a single cathode and single anode, and so were classed as 'conventional'.

Word count: 126

Estimate of usage

All participants used ShefStim (Fig. 2) with an average of 1314 heel lifts (steps) per day. There was variability in the number of heel lifts from day-to-day for each participant (for example participant 8) and between participants (participants 5 and 7 versus participant 3). The number of days participants used ShefStim within the two week period also varied, with

participants 7 (6/15) and 9 (4/15) using it far less than participants 5 (14/15) or 2 (13/15) (Fig. 2)

Word count: 78

Figure 2:

TS and AS time

TS time for ShefStim took an average of exactly 14 min [range: 12 min 24 s -37 min 30 s] compared to 3 min 20 s [range: 40 s -8 min] for their own FES. The average AS time was 9 min [range: 7 min 34 s – 10 min 20 s].

Word count: 51

Diary recording problems during community use

Of the recorded problems 64% [48 problems] were related to setup with poor voice command clarity from the foot sensor and remote control device (e.g. participant 2, day 3 "remote voice garbled"), frequent pausing during and/or unacceptable AS specifically cited (e.g. participant 5, day 9 "pausing, why?" and participant 2, day 2 "2x setups as chaplin walk"). 36% [27 problems] were related to external issues, for example participant 8, day 6 "despite charging overnight controller battery was flat". The overall number of reported problems diminished towards the end of the testing period (Fig. 3).

Word count: 94

Figure 3:

User-satisfaction

Overall, on average, participants were as satisfied with ShefStim as with their own FES system (Fig. 4). They were more satisfied with their own FES in terms of: 'Ease of use', which was the criteria most frequently prioritised on QUEST, and 'safety and security'. ShefStim outscored participants' own FES with regards to 'effectiveness', the second most frequently cited priority, and 'ease of adjustment'. On the remaining four criteria the systems scored equally.

Word count: 72

Figure 4:

Speed

Both FES systems produced the same increase in walking speed [0.06 m/s] compared to no stimulation (Table 3).

Word count: 18

Table 3:

Ankle angles at initial contact

With no stimulation PF with inversion was seen (Table 3). Both ShefStim and conventional systems corrected this; however, ShefStim achieved this to a greater extent (Table 3).

Word count: 27

Foot clearance during swing

This outcome could not be determined for participants 5 and 7 who both exhibited short step lengths and a significant degree of external rotation of the leg during swing, therefore none of the reference points passed the contra-lateral malleolus during swing as was required by the algorithm. The distal toe marker showed the smallest overall clearance values and with ShefStim the clearance was greatest (Table 3). Table 3 shows that without FES, the median value of the medial marker was higher than the lateral; with participant's own FES they were approximately equal and with ShefStim the lateral was higher than the medial. This foot pose at mid-swing was consistent with the ankle angles at initial contact (see above).

Word count: 118

Total results word count: 584 (excluding sub-headings)

DISCUSSION

This study sought to investigate the feasibility of unsupervised use of ShefStim by FES users within the community environment. Usage results show ShefStim is a usable device because without exception, albeit with variation, all participants used ShefStim.

Previous studies have reported a number of different measures of usage (6, 14, 15, 17, 18). Only our results for steps (heel lifts) per day could be compared to previous, larger, studies (6, 15, 18), with our participants generally walking less. For example Stein *et al's* (6) participants took 1842 (+/- 198) steps per day when first starting to use the Walkaide system and van Swigchem *et al's* (18) took 5733 (SD 2516). Worthy of note was that van Swigchem *et al's* (18) participants were encouraged to wear the NESS L300 for the entire

298 day whereas participants in ours and Stein *et al's* were not guided in this way. Further, our
299 participants reported a number of problems associated with the pre-commercial nature of
300 the ShefStim system, which may have impacted on use on certain days (see Fig. 3). Further
301 studies should continue to report detailed FES usage to allow further exploration of the
302 population and allow comparison between systems and/or baseline.

303 Results did not fully meet the prediction made by Heller *et al* (1) that ShefStim would result
304 in shorter TS times. There are a number of possible reasons for this. Firstly, Heller used self-
305 report to assess setup time with participants' own FES systems, finding an average of 11
306 minutes. In our study participants were timed during setup in the lab and took an average of
307 3 minutes to setup their own FES systems. In the Heller study participants placed their
308 affected leg in a rigid brace, thereby removing the possibility of significant leg movement. In
309 our study, the participant's leg was not constrained during setup and leg movement
310 detected during the AS process led to pauses which lengthened the process, a problem
311 recorded by participants. Further, our ShefStim users relied on audio feedback from the
312 foot sensor and remote control device, which participants reported was sometimes difficult
313 to hear. Participants also sometimes reached the end of setup and decided that the
314 automatically chosen site was not acceptable, then ran the entire AS again. Although a 'skip-
315 site' function was available (1) to address this issue (alternative sites identified as suitable to
316 be selected manually) participants did not use it, hence further refinement of user training
317 material and/or the user interface is warranted.

318 The finding that, overall, participants were as satisfied with ShefStim as with their own FES
319 systems, is encouraging because unlike conventional foot-drop FES systems ShefStim has
320 not been subject to significant product design. The fact that problems diminished and 'ease

of use' was rated lower than participants own FES systems, however, suggests that two weeks was insufficient for participants to fully familiarise themselves with ShefStim. Alternatively it might be due to the cited problems with ShefStim itself. Our results cannot be compared to other studies as QUEST has not been used before in this field of research. Future studies should allow longer unsupervised periods of use and should use a validated measure such as QUEST.

Speed increase, for both ShefStim and conventional FES systems, compared to no FES was in keeping with previous studies (21) and classed as clinically meaningful (36). In Heller's study, in which subjects did not have time to accommodate to the automated setup, speed increase (relative to no FES) when using the automated setup system was smaller than with their own system (0.04 m/s vs 0.11m/s). In both studies foot response with AS was improved compared with participants' setup of their own stimulators. Although there is a risk of over-interpretation of the results, our findings may suggest that once users become accustomed to a new FES system, their walking speed is relatively insensitive to small differences in foot response. These findings are supported by the foot clearance results and indicate that the underlying operating principle of an array-based FES system with AS may be more effective at addressing foot-drop than conventional FES systems by reducing human error/influence over electrode placement. However, larger scale study is required to fully substantiate these initial findings.

Word count: 676

Study limitations

This was a feasibility study with a small sample size, self-referred participants and was not randomised (9, 31). As such, whilst encouraging, results should be viewed with caution. The outcome measures selected would appear appropriate but many have been largely unused in previous research in this field making comparison to previous studies challenging.

Further development of the electrode-skin interface is required (12) to negate the need for daily array replacement and improve future commercial viability. Further iterations of ShefStim need to also consider addressing the cited setup and external problems, such as voice command clarity, the impact of pausing on AS time, user training and charging, to facilitate further study and widespread implementation.

Word count: 110

CONCLUSION

This is the first study of ShefStim and one of very few investigating foot-drop FES both within the lab and during unsupervised use (37, 38). Ultimately this study demonstrates, for the first time, an array-based AS FES system (ShefStim) for foot-drop can be successfully used unsupervised. Despite longer and more problematic setup in the population studied, users were satisfied with it and it would appear to have comparable, if not better, effects on gait than conventional foot-drop FES systems.

Further product development and a larger-scale, longer-term study is required before firm conclusions about the efficacy and effectiveness of ShefStim, compared to conventional FES, can be reached.

Word count: 104

Total word count: 3245

References

1. Heller BW, Clarke AJ, Good TR, Healey TJ, Nair S, Pratt EJ, et al. Automated setup of functional electrical stimulation for drop foot using a novel 64 channel prototype stimulator and electrode array: Results from a gait-lab based study. Med Eng Phys. 2013 May 3. PubMed PMID: 22559959. Epub 2012/05/09. Eng.
2. NICE. Functional electrical stimulation for drop foot of central neurological origin. National Institute for Clinical Excellence, 2009 Contract No.: Interventional procedure guidance 278.
3. Wilkie KM, Shiels JE, Bulley C, Salisbury LG. "Functional electrical stimulation (FES) impacted on important aspects of my life"-A qualitative exploration of chronic stroke patients' and carers' perceptions of FES in the management of dropped foot. Physiother Theory Prac. 2012 Jan;28(1):1-9. PubMed PMID: BCI:BCI201200024459.
4. Taylor PN, Burridge JH, Dunkerley AL, Lamb A, Wood DE, Norton JA, et al. Patients' perceptions of the Odstock Dropped Foot Stimulator (ODFS). Clin Rehabil. 1999 Oct;13(5):439-46. PubMed PMID: 10498351. Epub 1999/09/25. eng.
5. Kottink AI, Hermens HJ, Nene AV, Tenniglo MJ, van der Aa HE, Buschman HP, et al. A randomized controlled trial of an implantable 2-channel peroneal nerve stimulator on walking speed and activity in poststroke hemiplegia. Arch Phys Med Rehabil. 2007 Aug;88(8):971-8. PubMed PMID: 17678657. eng.
6. Stein RB, Everaert DG, Thompson AK, Chong SL, Whittaker M, Robertson J, et al. Long-Term Therapeutic and Orthotic Effects of a Foot Drop Stimulator on Walking Performance in Progressive and Nonprogressive Neurological Disorders. Neurorehabil Neural Repair. 2010 Feb;24(2):152-67. PubMed PMID: WOS:000274015500005.
7. Laufer Y, Ring H, Sprecher E, Hausdorff JM. Gait in individuals with chronic hemiparesis: one-year follow-up of the effects of a neuroprosthesis that ameliorates foot drop. J Neurolog Phys Ther: JNPT. 2009;33(2):104-10. PubMed PMID: 19556919. Language: English. Language Code: eng. Date Created: 20090626. Date Completed: 20091208. Update Code: 20111122. Publication Type: Journal Article.
8. Weber DJ, Stein RB, Chan KM, Loeb G, Richmond F, Rolf R, et al. BIONic WalkAide for correcting foot drop. IEEE Transactions On Neural Systems And Rehabilitation Engineering: A Publication Of The IEEE Engineering In Medicine And Biology Society. 2005;13(2):242-6. PubMed PMID: 16003906. Language: English. Language Code: eng. Date Revised: 20061115. Date Created: 20050711. Date Completed: 20050801. Update Code: 20111122. Publication Type: Journal Article.
9. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Med Res Methodol. 2010;10:67-73. PubMed PMID: 52844644.
10. Sha N, Kenney LP, Heller BW, Barker AT, Howard D, Moatamedi M. A finite element model to identify electrode influence on current distribution in the skin. Artif Organs. 2008 Aug;32(8):639-43. PubMed PMID: 18782136. eng.
11. Sha N, Kenney LP, Heller BW, Barker AT, Howard D, Wang W. The effect of the impedance of a thin hydrogel electrode on sensation during functional electrical stimulation. Med Eng Phys. 2008 Jul;30(6):739-46. PubMed PMID: 17942361. eng.
12. Cooper G, Barker AT, Heller BW, Good T, Kenney LPJ, Howard D. The use of hydrogel as an electrode-skin interface for electrode array FES applications. Med Eng Phys. 2011 Oct;33(8):967-72. PubMed PMID: WOS:000295107800010.
13. Thies SB, Kenney LPJ, Howard D, Nester C, Ormerod M, Newton R, et al. Biomechanics for inclusive urban design: Effects of tactile paving on older adults' gait when crossing the street. J Biomech. 2011;44(8):1599-604.

14. Granat MH, Maxwell DJ, Ferguson ACB, Lees KR, Barbenet JC. Peroneal stimulator: Evaluation for the correction of spastic drop foot in hemiplegia. Arch Phys Med Rehabil. 1996;77(1):19-24.
15. Stein RB, Chong S, Everaert DG, Rolf R, Thompson AK, Whittaker M, et al. A multicenter trial of a footdrop stimulator controlled by a tilt sensor. Neurorehabil Neural Repair. 2006 Sep;20(3):371-9. PubMed PMID: 16885423. Epub 2006/08/04. eng.
16. Taylor P, Burridge J, Dunkerley A, Wood D, Norton J, Singleton C, et al. Clinical Audit of 5 years Provision of the Odstock Dropped Foot Stimulator. Artif Organs. 1999;23(5):440-2.
17. Kottink AI, Hermens HJ, Nene AV, Tenniglo MJ, van der Aa HE, Buschman HP, et al. A Randomized Controlled Trial of an Implantable 2-Channel Peroneal Nerve Stimulator on Walking Speed and Activity in Poststroke Hemiplegia. Arch Phys Med Rehabil. 2007;88(8):971-8.
18. van Swigchem R, Vloothuis J, den Boer J, Weerdesteyn V, Geurts ACH. Is transcutaneous peroneal stimulation beneficial to patients with chronic stroke using an ankle-foot orthosis? A within-subject study of patients' satisfaction, walking speed and physical activity level. J Rehabil Med. 2010 Feb;42(2):117-21. PubMed PMID: WOS:000275650700003.
19. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. Nurs Ed Today. 2004;24(2):105-12.
20. Demers L, Monette M, Lapierre Y, Arnold DL, Wolfson C. Reliability, validity, and applicability of the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) for adults with multiple sclerosis. Disabil Rehabil. 2002;24:21-30.
21. Voigt M, Sinkjaer T. Kinematic and kinetic analysis of the walking pattern in hemiplegic patients with foot-drop using a peroneal nerve stimulator. Clin Biomech. 2000;15:340-51.
22. Kottink AIR, Oostendorp LJM, Buurke JH, Nene AV, Hermens HJ, Ijzerman MJ. The Orthotic Effect of Functional Electrical Stimulation on the Improvement of Walking in Stroke Patients with a Dropped Foot: A Systematic Review. Artif Organs. 2004;28(6):577-86. PubMed PMID: 13154253.
23. Roche A, Laighin G, Coote S. Surface-applied functional electrical stimulation for orthotic and therapeutic treatment of drop-foot after stroke -- a systematic review. Phys Ther Rev. 2009;14(2):63-80. PubMed PMID: 2010314708. Language: English. Entry Date: 20090821. Revision Date: 20091218. Publication Type: journal article.
24. Graham JE, Ostir GV, Kuo Y-F, Fisher SR, Ottenbacher KJ. Relationship Between Test Methodology and Mean Velocity in Timed Walk Tests: A Review. Arch Physl Med Rehabil. 2008;89(5):865-72.
25. Burridge JH, Elessi K, Pickering RM, Taylor PN. Walking on an Uneven Surface: The Effect of Common Peroneal Stimulation on Gait Parameters and Relationship Between Perceived and Measured Benefits in a Sample of Participants With a Drop-Foot. Neuromodulat :J Internat Neuromodulat Soc. 2007;10(1):59-67. PubMed PMID: 23634177.
26. Cappozzo A, Catani F, Della Croce U, Laeardini A. Position and orientation in space of bones during movement: anatomical frame definition and determination. Clin Biomech. 1995;10(4):171-8.
27. Whittle M, Levine D, Richards J. Methods of gait analysis. In: Levine D, editor. Whittle's Gait Analysis. 5th ed. Edinburgh: Churchill Livingstone; 2012. p. 83-112.
28. Pratt EJ, Reeves ML, van der Meulen JM, Heller BW, Good TR. The development, preliminary validation and clinical utility of a shoe model to quantify foot and footwear kinematics in 3-D. Gait Posture. 2012;36(3):434-8.
29. Everaert DG, Stein RB, Abrams GM, Dromerick AW, Francisco GE, Hafner BJ, et al. Effect of a Foot-Drop Stimulator and Ankle–Foot Orthosis on Walking Performance After Stroke: A Multicenter Randomized Controlled Trial. Neurorehabil Neural Repair. 2013 April 4, 2013.
30. Thies SB, Jones RK, Kenney LPJ, Howard D, Baker R. Effects of ramp negotiation, paving type and shoe sole geometry on toe clearance in young adults. J Biomech. 2011;44(15):2679-84.
31. Medical Research Council. A framework for development and evaluation of RCTs for complex interventions to improve health. 2000.

32. Begg R, Best R, Dell'Oro L, Taylor S. Minimum foot clearance during walking: Strategies for the minimisation of trip-related falls. Gait Posture. 2007;25(2):191-8.
33. Esnouf JE, Taylor PN, Mann GE, Barrett CL. Impact on activities of daily living using a functional electrical stimulation device to improve dropped foot in people with multiple sclerosis, measured by the Canadian Occupational Performance Measure. Mult Scler. 2010 Sep;16(9):1141-7. PubMed PMID: 20601398. Epub 2010/07/06. eng.
34. van Swigchem R, van Duijnhoven HJR, den Boer J, Geurts AC, Weerdesteyn V. Effect of Peroneal Electrical Stimulation Versus an Ankle-Foot Orthosis on Obstacle Avoidance Ability in People With Stroke-Related Foot Drop. Phys Ther. 2012 Mar;92(3):398-406. PubMed PMID: WOS:000300940500004.
35. Taylor PN, editor How long do Dropped foot stimulator users continue to use FES and how much does it cost? An eleven and six year clinical audit. IFESS; 2010; Vienna, Austria.
36. Perera S, Mody SH, Woodman RC, Studensk SA. Meaningful Change and Responsiveness in Common Physical Performance Measures in Older Adults. J Am Geriatrics Soc. 2006;54(5):743-9. PubMed PMID: 20620658.
37. Barrett C, Taylor P. The effects of the odstock drop foot stimulator on perceived quality of life for people with stroke and multiple sclerosis. Neuromodulat : J Internat Neuromodulat Society. 2010 Jan;13(1):58-64. PubMed PMID: 21992766. Epub 2010/01/01. eng.
38. Barrett CL, Mann GE, Taylor PN, Strike P. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. Mult Scler. 2009 Apr;15(4):493-504. PubMed PMID: 19282417. Epub 2009/03/14. eng.

Suppliers

[i] Adidas knee support, Adidas, Herzogenaurach, Germany.

[ii] Odstock Medical Ltd, Salisbury, UK

[iii] 5x5 PALS ®Platinum Neurostimulation electrode, Axelgaard Manufacturing co.Ltd, San Diego, USA.

[iv] Adapted from an I-pod holder, Signalex, Birmingham, UK.

[v] Hotter Comfort Concept shoes, Skelmersdale, UK. (for men) and Clarks Un Betty from Unstructured Autumn /Winter 2011 range, Street, UK. (for women)

[vi] Qualisys, Stockholm, Sweden.

[vii] C-Motion, Maryland, USA.

[viii] Matlab®, Mathworks, Cambridge, UK.

Figure legends

Figure 1: ShefStim system (medial view of leg during AS)

Figure 2: Logged heel lifts (N=7): Blank cells=0 heel lifts; the length of bar represents the number of heel lifts. The median number overall of steps per day was 1314.

Figure 3: Recorded problems over two week unsupervised community use (N=7).

Figure 4: Median QUEST results. Black= own FES system; Grey= ShefStim (n=7). Both systems scored a total of 32 out of 40.

Figure 1

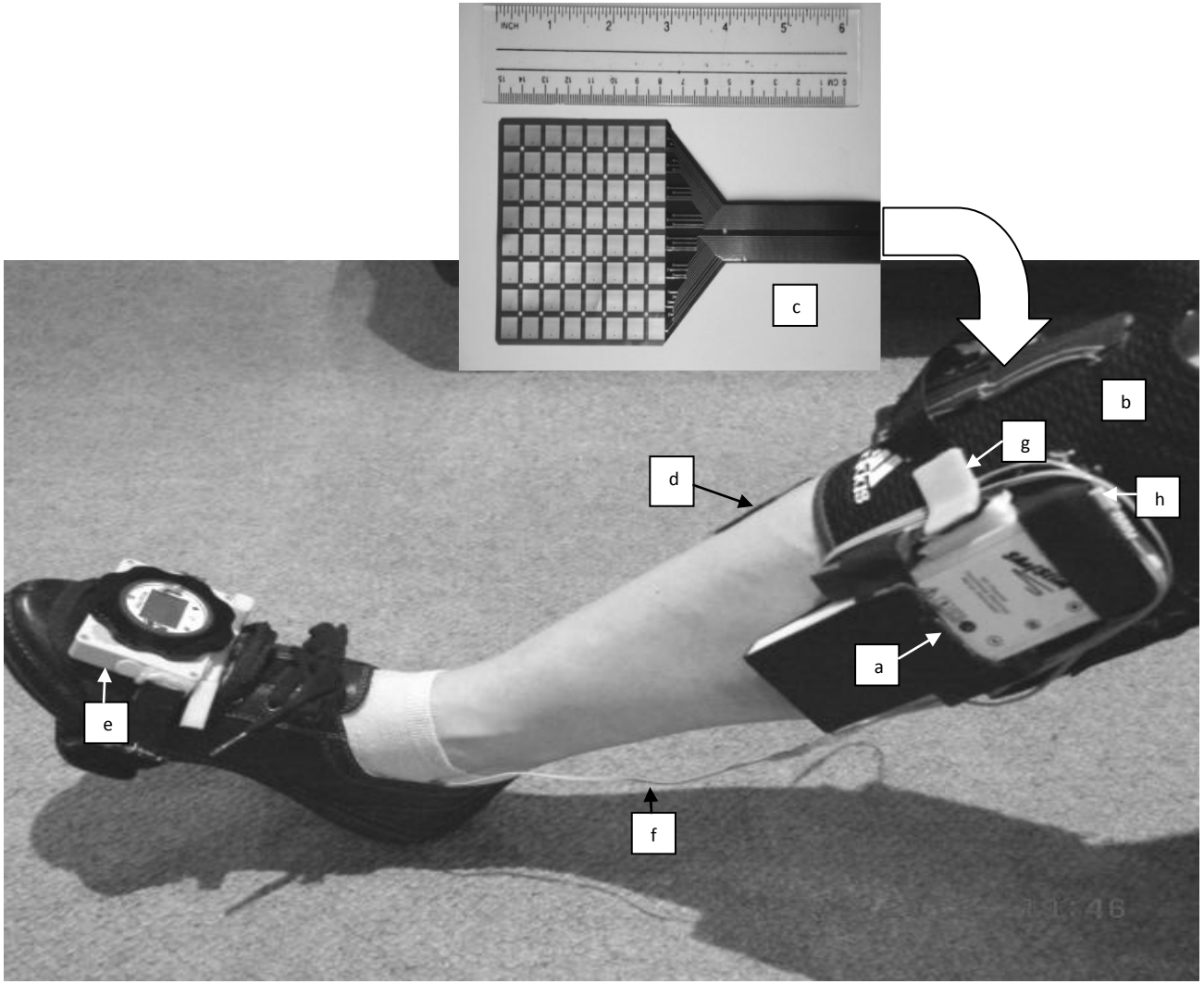
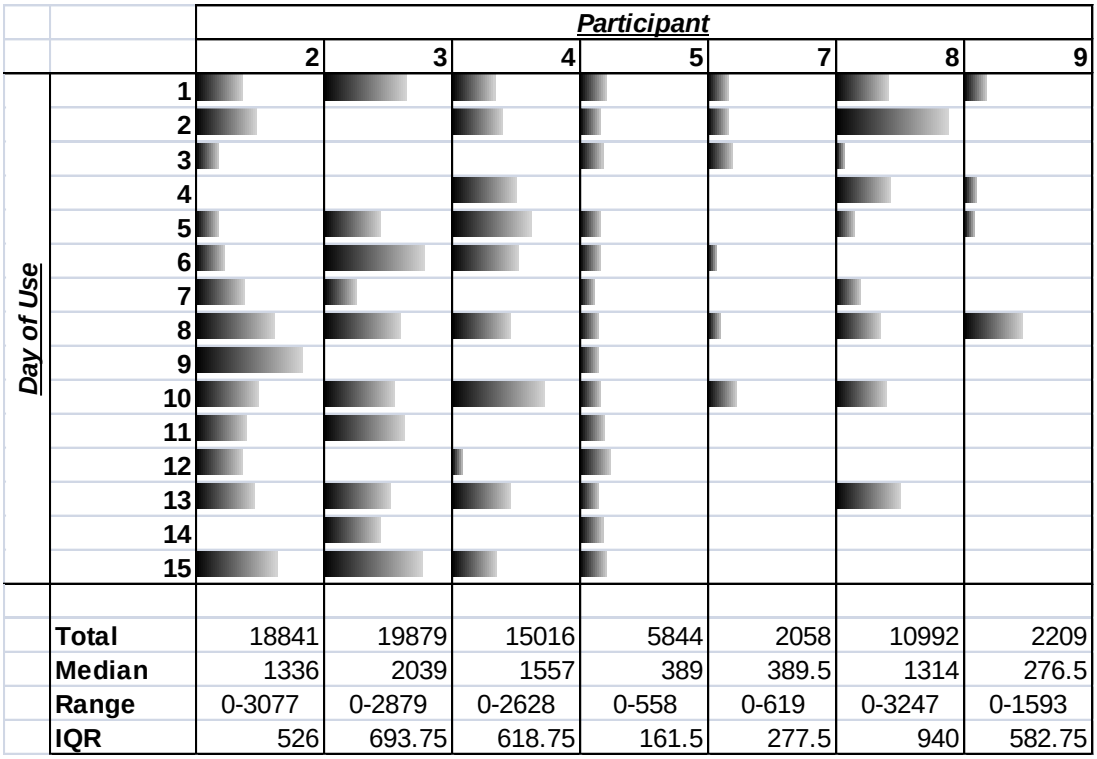


Figure 1: ShefStim (medial view of leg during AS)

Figure 2



	2	3	4	5	7	8	9
Total	18841	19879	15016	5844	2058	10992	2209
Median	1336	2039	1557	389	389.5	1314	276.5
Range	0-3077	0-2879	0-2628	0-558	0-619	0-3247	0-1593
IQR	526	693.75	618.75	161.5	277.5	940	582.75

Figure 2: Logged heel lifts (N=7): Blank cells=0 heel lifts; the length of bar represents the number of heel lifts. The median number overall of steps per day was 1314.

Figure 3

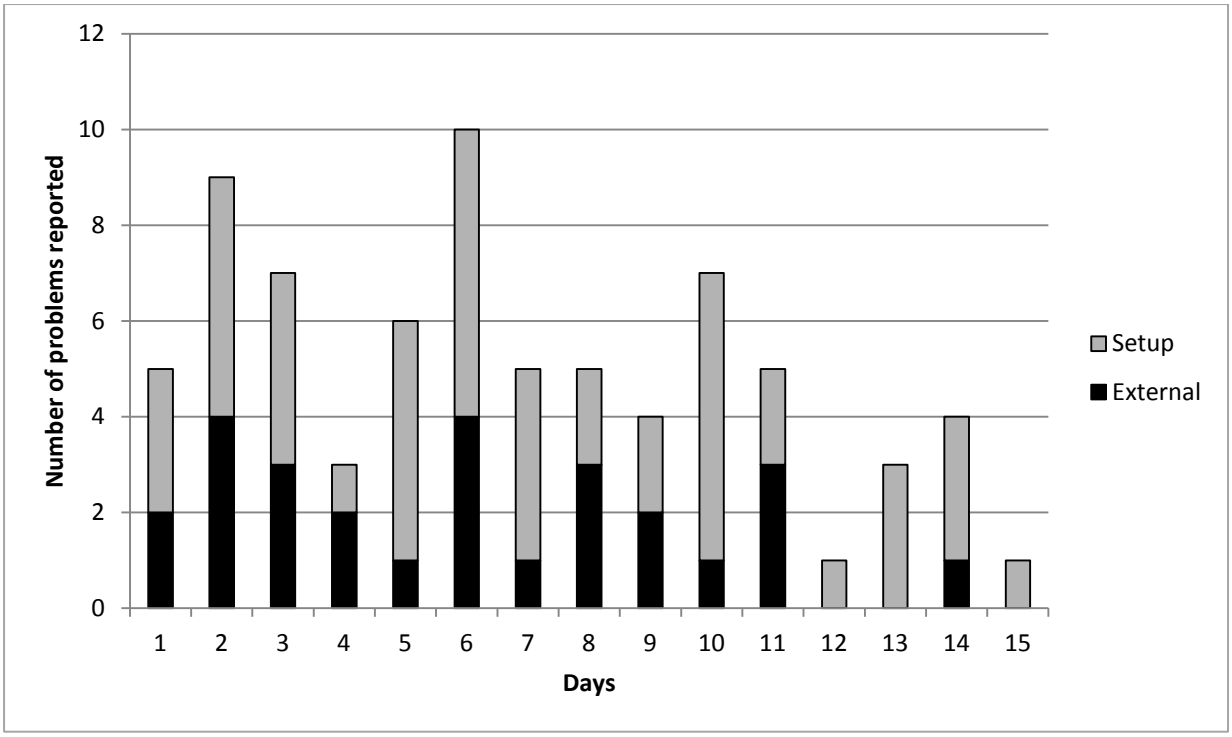


Figure 3: Recorded problems over two week unsupervised community use (N=7).

Figure 4

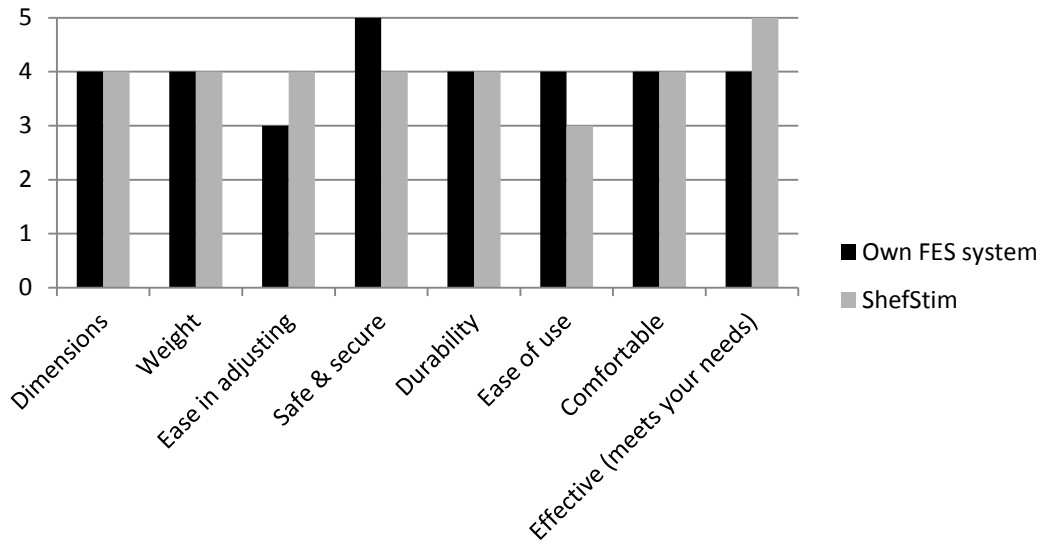


Figure 4: Median QUEST results. Black= own FES system; Grey= ShefStim (n=7). Both systems scored a total of 32 out of 40

Table 1: Inclusion/Exclusion criteria

Inclusion	Exclusion
• Unilateral foot-drop caused by disorder of central neurological origin diagnosed at least 6 months prior to the study	• Using alternative method to treat foot-drop (orthosis, physiotherapy, botulinum toxin)
• Regular user of a foot-drop FES system, for at least 3 months	• Unable to setup ShefStim, even with assistance
• 18 years of age or over	• Contraindications to FES use
	• Unable to consent (<25 mini mental state examination)
	• Unable to meet protocol/ timetable of study
	• Unable to walk 5m without physical assistance

Table 2

Table 2: Participant demographics. CVA= Cerebro-Vascular Accident/ Stroke; TBI=Traumatic Brain Injury; MS= Multiple Sclerosis; SPWS=Single Point Walking Stick; QBWS= Quad Base Walking Stick

Participant	Age at time of recruitment	Gender	Diagnosis	Side Affected	Assistive device used	Own FES system details
1	58	M	CVA	Right	SPWS	ODFS III® (Odstock Medical Ltd, Salisbury, UK)
2	69	M	CVA	Left	SPWS	ODFS Pace® (Odstock Medical Ltd, Salisbury, UK)
3	58	F	MS	Right	SPWS	WalkAide® (Innovative Neurotronics, Austin, USA)
4	41	M	TBI	Left	None	ODFS Pace® (Odstock Medical Ltd, Salisbury, UK)
5	79	M	CVA	Right	QBWS	ODFS III® (Odstock Medical Ltd, Salisbury, UK)
6	63	M	CVA	Right	SPWS	ODFS Pace® (Odstock Medical Ltd, Salisbury, UK)
7	49	F	MS	Right	SPWS	ODFS Pace® (Odstock Medical Ltd, Salisbury, UK)
8	62	M	CVA	Left	None	ODFS Pace® (Odstock Medical Ltd, Salisbury, UK)
9	51	M	MS	Right	None	ODFS Pace® (Odstock Medical Ltd, Salisbury, UK)
10	26	M	CVA	Left	None	ODFS Pace® (Odstock Medical Ltd, Salisbury, UK)

Table 3: Average speed, ankle angles at initial contact (with SD) and foot clearance during swing (with IQR). =,<,> show the comparison relative to the participant's own FES system.

	No FES	**Own FES system**	**ShefStim**
Speed (m/s)	0.72 (0.52)	0.78 (0.51)	0.78 (0.53)=
DF (°)	-3.95 (5.89)	1.96 (5.73)	4.22 (4.64)>
Inv (°)	9.24 (6.12)	1.65 (10.21)	-1.56 (7.73)<
Foot clearance: Distal toe (cm)	1.08 (0.62)	1.58 (0.47)	1.82 (0.89)>
Foot clearance: Medial (cm)	2.71 (1.06)	2.50 (1.12)	2.32 (0.83)<
Foot clearance: Lateral (cm)	1.19 (0.99)	2.38 (0.88)	2.97 (1.82)>