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Prenton, Sarah, Kenney, Laurence P., Stapleton, Claire, Cooper, Glen, Reeves, Mark L., Heller, Ben W., Sobuh, Mohammad, Barker, Anthony T., Healey, Jamie, Good, Timothy R., Thies, Sibylle B., Howard, David and Williamson, Tracey

Feasibility Study of a Take-Home Array-Based Functional Electrical Stimulation System With Automated Setup for Current Functional Electrical Stimulation Users With Foot-Drop

Original Citation

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

3 **Design:** A feasibility study.

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

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

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

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

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

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

26 *Word count: 290*

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

29 **Abbreviations:**

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

34

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

59 further developed and CE marked as ShefStim. This paper is the first feasibility (9) study of

60 ShefStim which combined a period of unsupervised use in conjunction with gait evaluation

61 at the start and end of the study period. The primary aim was to investigate whether

62 ShefStim could be used, unsupervised, by foot-drop FES users within the community

63 environment. In addition a number of other sub-aims were addressed. These were to

64 investigate:

65   1. The community-usage patterns and user-satisfaction with ShefStim.

66   2. The total setup (TS) time compared with their own FES system, as well as AS times

67   for ShefStim.

68   3. The effects of ShefStim on walking speed, ankle angles (at initial contact) and foot

69   clearance during swing, compared with participants' own FES system.

70 *Word count: 404*

71   **METHODS**

72 **ShefStim system**

73 A detailed description of the operating principles of the stimulator, and changes in order to

74 achieve CE marking, are given in the Heller *et al*. paper (1). The same fixed parameters

75 (monophasic waveform, charge-balanced, 40Hz, 160µs) were used but the system used in

76 Heller's study restrained the leg in a support during the AS process. This was deemed

77 impractical for a take-home device so instead users were requested to extend their leg and

78 rest their heel on the floor during home AS.

79 **Figure 1:**

80 The ShefStim consists of (Fig. 1): a leg-worn stimulator (Fig. 1. a.) housed in a modified knee

81 sleeve[i] (Fig. 1. b.); a flexible printed circuit board array of 64 electrodes (cathode electrodes)

82 (Fig. 1. c.), covered with a thin layer of high resistivity hydrogel (10-12) . Sweat ingress

83 changes the conductive properties of the hydrogel sheet so a replacement array fitted with

84 a new sheet of hydrogel is used each day (12); a conventional footswitch[ii]; a conventional

85 anode[iii] (Fig. 1.d.) and a foot sensor and remote control device housed in a bespoke foot-

86 pod[iv] (Fig. 1. e.). The foot sensor and remote control device detects foot orientation,

87 provides voice commands during AS and acts as a handheld remote unit post AS, allowing

88 the user to pause, and change intensity as required.

89 *Word count: 209*

90 **Donning the system**

91 To don ShefStim the following steps are required:

92 1. The footswitch (Fig. 1. f.) is placed under the heel, with the connecting cable

93 extending from the shoe.

94 2. The knee sleeve is donned aligning the stimulator pocket with the long axis of the

95 tibia

96 3. The stimulator is placed in the knee sleeve's stimulator pocket

97 4. The foot-pod, containing the foot sensor and remote control device is positioned

98 over the shoe locating it approximately centrally over the dorsum of the foot and

99 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.

122   *Word Count: 171*

123   **Participants**

124   Ethical Approval was granted from the University of Salford (REP10/113) and the integrated

125   research application system (10/H1003/107) for ten participants. Existing foot-drop FES

126   users within the North-West region were given information by clinicians. Interested

127   participants contacted the chief investigator. Inclusion/exclusion criteria are shown in Table

128   1.

129   **Table 1:**

130   *Word count: 46*

131   **Protocol**

132   At visit 1 participants attended the University of Salford gait laboratory and were provided

133   with standard shoes[v] for all conditions to avoid the potential impact of different footwear

134   on foot clearance (13). Participants walked approximately five metres along the gait

135   laboratory up to five times at a self-selected speed initially with no stimulation and then

136   with participant's own FES system (self-setup). Following visit 1 the knee sleeve, stimulator

137   and electrode arrays were prepared for that individual. Participants returned for visit 2

138   where fitting was completed, rising/falling ramps and extension configured, adjustments

139   made to AS settings if required (to ensure appropriate virtual electrode selection) and

140   ShefStim use taught. Following two weeks of unsupervised use of ShefStim at home (with a

141   home-visit after approximately one week to replenish arrays and answer any queries)

142   participants returned to the gait laboratory (visit 3) which duplicated visit 1 but using

143   ShefStim rather than their own FES system.

144 *Word count: 151*

145 **Measures**

146 **Estimate of usage** (between visits 2 and 3)

147 Usage data has been collected in previous foot-drop FES studies (14-18). ShefStim logs the

148 number of heel lifts per day which can be used as an estimate of usage.

149 *Word count: 29*

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

151 With one notable exception (1), setup time has been largely neglected in previous foot-drop

152 FES research . TS times, defined as time from first starting to don equipment to being

153 satisfied with the outcome and walking away (including AS time for ShefStim), were

154 recorded for participants' own FES (visit 1) and ShefStim (visit 3). Average AS time (time for

155 AS to complete) was logged by ShefStim.

156 *Word count: 65*

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

158 Problems encountered were recorded in a paper diary by each participant. User-reported

159 problems have been collected previously (15) but never during the period of use. Recorded

160 problems were collated and grouped into two categories (19): External and Setup. External

161 were classed as being independent of the stimulator design and so referred to the housing

162 of ShefStim (knee sleeve), issues with the standard wired footswitch or issues with charging.

163 Setup was defined as any problem related to setup or satisfaction with the foot response.

164 *Word count: 81*

165 **User-satisfaction** (visits 1 and 3)

166 User-satisfaction has previously been captured using purposive questionnaires (4, 15, 18).

167 Given the risk of bias and lack of validation we sought an alternative. The Quebec User

168 Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) device scale (20) is a

169 validated user-satisfaction measure . Participants rated their satisfaction against eight single

170 item criteria (dimensions, weight, ease of adjustment, safety and security, durability, ease of

171 use, comfort, effectiveness) using a five-point Likert scale (1=not satisfied at all to 5= very

172 satisfied: maximum score=40) for their own FES system and ShefStim. In addition,

173 participants ranked their top three priorities from the eight criteria.

174 *Word count: 97*

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

176 Increased walking speed indicates an improvement in overall walking performance (21) and

177 is frequently used in FES research (22, 23). Measuring walking speed over five metres from a

178 static starting position is a validated measure with neurological populations (24) and was

179 calculated by averaging the velocity of a recorded waist marker (L3 vertebra) over the

180 measurement space (13).

181 Foot-drop leads to abnormal joint alignment during stance (25) with a tendency for

182 plantarflexion (PF) and inversion (21) which can reduce ankle stability. Sagittal and frontal

183 plane ankle angles were captured at initial contact to measure this. The calibrated

184 anatomical system technique (CAST)(26, 27) was used for shank marker placement. Foot

185 marker placement was based on the shod-foot model by Pratt *et al*. (28).

186 Data for both speed and ankle angles was captured at 100Hz using a 16-camera 3D motion

187 analysis system[vi]; a fourth-order low-pass Butterworth filter was used with a 6Hz cut-off

188 frequency. Ankle angles at initial contact were analysed using Visual 3D[vii]

189 *Word count: 152*

190 **Foot clearance during swing** (visits 1 and 3)

191 Foot-drop is associated with an increased risk of tripping and falling due to a lack of foot

192 clearance during swing phase (29). Foot clearance was obtained for seven different points

193 on the shoe sole as described in Thies *et al* (13). Only three of the seven markers from Thies'

194 study (13) (distal toe, medial and lateral forefoot) were investigated since these were

195 deemed most relevant. Healthy gait consistently has a minimum clearance value during

196 swing (13, 30). Hemiplegic gait, however, has an altered clearance trajectory and does not

197 always produce a minimum value during swing, so an alternative and consistently definable

198 point along the trajectory was chosen. Specifically, in this study it was calculated at the

199 moment in time when the reference point on the shoe sole passed the contra-lateral medial

200 malleolus. Data was processed using Matlab®[viii] code (13).

201 *Word count: 133*

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

203 **Data Analysis**

204 As a feasibility study (9, 31), statistical analysis was limited to graphical representation of

205 data and descriptive methods. Ratio data (AS log data, speed and ankle angles at initial

206 contact) was analysed using mean and standard deviation (SD). Median was used for

9

207   skewed data (usage, TS times and toe clearance (32) , with inter-quartile range(IQR)) and

208   ordinal data (QUEST (33)).

209   *Word count: 56*

210   **RESULTS**

211   **Table 2:**

212   Table 2 provides participant characteristics. Prior to data collection three participants were

213   withdrawn (1, 6, 10). The withdrawal of participants 1 and 10 was due to unrelated medical

214   issues. Subject 6 was withdrawn as it became clear, post recruitment, that he was not a

215   regular user of FES for foot-drop. He had discontinued use following ankle instability

216   problems and a number of falls. The average age of the remaining participants was 58 yrs.

217   (SD 12.9) which is comparable to other foot-drop FES studies (1, 21, 34). Of the five men and

218   two women, four had non-progressive and three had progressive neurological disorders,

219   which is representative of the FES user population (16, 35). The FES systems used by

220   participants varied but all use a single cathode and single anode, and so were classed as

221   'conventional'.

222   *Word count: 126*

223   **Estimate of usage**

224   All participants used ShefStim (Fig. 2) with an average of 1314 heel lifts (steps) per day.

225   There was variability in the number of heel lifts from day-to-day for each participant (for

226   example participant 8) and between participants (participants 5 and 7 versus participant 3).

227   The number of days participants used ShefStim within the two week period also varied, with

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

229   (Fig. 2)

230   *Word count: 78*

231

232   **Figure 2:**

233

234   **TS and AS time**

235   TS time for ShefStim took an average of exactly 14 min [range: 12 min 24 s -37 min 30 s]

236   compared to 3 min 20 s [range: 40 s -8 min] for their own FES. The average AS time was 9

237   min [range: 7 min 34 s – 10 min 20 s].

238   *Word count: 51*

239

240   **Diary recording problems during community use**

241   Of the recorded problems 64% [48 problems] were related to setup with poor voice

242   command clarity from the foot sensor and remote control device (e.g. participant 2, day 3

243   "remote voice garbled"), frequent pausing during and/or unacceptable AS specifically cited

244   (e.g. participant 5, day 9 "pausing, why?" and participant 2, day 2 "2x setups as chaplin

245   walk"). 36% [27 problems] were related to external issues, for example participant 8, day 6

246   "despite charging overnight controller battery was flat". The overall number of reported

247   problems diminished towards the end of the testing period (Fig. 3).

248   *Word count: 94*

249

250   **Figure 3:**

251

252 **User-satisfaction**

253 Overall, on average, participants were as satisfied with ShefStim as with their own FES

254 system (Fig. 4). They were more satisfied with their own FES in terms of: 'Ease of use', which

255 was the criteria most frequently prioritised on QUEST, and 'safety and security'. ShefStim

256 outscored participants' own FES with regards to 'effectiveness', the second most frequently

257 cited priority, and 'ease of adjustment'. On the remaining four criteria the systems scored

258 equally.

259 *Word count: 72*

260 **Figure 4:**
261

262 **Speed**

263 Both FES systems produced the same increase in walking speed [0.06 m/s] compared to no

264 stimulation (Table 3).

265 *Word count: 18*

266

267 **Table 3:**

268

269 **Ankle angles at initial contact**

270 With no stimulation PF with inversion was seen (Table 3). Both ShefStim and conventional

271 systems corrected this; however, ShefStim achieved this to a greater extent (Table 3).

272 *Word count: 27*

273

274 **Foot clearance during swing**

275   This outcome could not be determined for participants 5 and 7 who both exhibited short

276   step lengths and a significant degree of external rotation of the leg during swing, therefore

277   none of the reference points passed the contra-lateral malleolus during swing as was

278   required by the algorithm. The distal toe marker showed the smallest overall clearance

279   values and with ShefStim the clearance was greatest (Table 3). Table 3 shows that without

280   FES, the median value of the medial marker was higher than the lateral; with participant's

281   own FES they were approximately equal and with ShefStim the lateral was higher than the

282   medial. This foot pose at mid-swing was consistent with the ankle angles at initial contact

283   (see above).

284   *Word count: 118*

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

286

287

288   **DISCUSSION**

289   This study sought to investigate the feasibility of unsupervised use of ShefStim by FES users

290   within the community environment. Usage results show ShefStim is a usable device because

291   without exception, albeit with variation, all participants used ShefStim.

292   Previous studies have reported a number of different measures of usage (6, 14, 15, 17, 18).

293   Only our results for steps (heel lifts) per day could be compared to previous, larger, studies

294   (6, 15, 18), with our participants generally walking less. For example Stein *et al's* (6)

295   participants took 1842 (+/- 198) steps per day when first starting to use the Walkaide

296   system and van Swigchem *et al's* (18) took 5733 (SD 2516). Worthy of note was that van

297   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

14

321   of use' was rated lower than participants own FES systems, however, suggests that two

322   weeks was insufficient for participants to fully familiarise themselves with ShefStim.

323   Alternatively it might be due to the cited problems with ShefStim itself. Our results cannot

324   be compared to other studies as QUEST has not been used before in this field of research.

325   Future studies should allow longer unsupervised periods of use and should use a validated

326   measure such as QUEST.

327   Speed increase, for both ShefStim and conventional FES systems, compared to no FES was in

328   keeping with previous studies (21) and classed as clinically meaningful (36). In Heller's study,

329   in which subjects did not have time to accommodate to the automated setup, speed

330   increase (relative to no FES) when using the automated setup system was smaller than with

331   their own system (0.04 m/s vs 0.11m/s). In both studies foot response with AS was

332   improved compared with participants' setup of their own stimulators. Although there is a

333   risk of over-interpretation of the results, our findings may suggest that once users become

334   accustomed to a new FES system, their walking speed is relatively insensitive to small

335   differences in foot response. These findings are supported by the foot clearance results and

336   indicate that the underlying operating principle of an array-based FES system with AS may

337   be more effective at addressing foot-drop than conventional FES systems by reducing

338   human error/influence over electrode placement. However, larger scale study is required to

339   fully substantiate these initial findings.

340   *Word count: 676*

341   **Study limitations**

342   This was a feasibility study with a small sample size, self-referred participants and was not

343   randomised (9, 31). As such, whilst encouraging, results should be viewed with caution. The

344   outcome measures selected would appear appropriate but many have been largely unused

345   in previous research in this field making comparison to previous studies challenging.

346   Further development of the electrode-skin interface is required (12) to negate the need for

347   daily array replacement and improve future commercial viability. Further iterations of

348   ShefStim need to also consider addressing the cited setup and external problems, such as

349   voice command clarity, the impact of pausing on AS time, user training and charging, to

350   facilitate further study and widespread implementation.

351   *Word count: 110*

352

353   **CONCLUSION**

354   This is the first study of ShefStim and one of very few investigating foot-drop FES both

355   within the lab and during unsupervised use (37, 38). Ultimately this study demonstrates, for

356   the first time, an array-based AS FES system (ShefStim) for foot-drop can be successfully

357   used unsupervised. Despite longer and more problematic setup in the population studied,

358   users were satisfied with it and it would appear to have comparable, if not better, effects on

359   gait than conventional foot-drop FES systems.

360   Further product development and a larger-scale, longer-term study is required before firm

361   conclusions about the efficacy and effectiveness of ShefStim, compared to conventional FES,

362   can be reached.

363   *Word count: 104*

364   *Total word count: 3245*

365   **References**

366

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484 eng.

485

486

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.

1 **Objective:** To investigate the feasibility of unsupervised community use of an array-based

2 automated setup (AS) functional electrical stimulator (FES) for current foot-drop FES users.

3 **Design:** A feasibility study.

4 **Setting:** Participants' gait, total setup (TS) times and satisfaction were evaluated twice in the

5 gait laboratory. Usage, AS times and problems encountered were recorded during a two

6 week period of unsupervised use.

7 **Participants:** Participants (N=7) with diagnosis of uni-lateral foot-drop of central

8 neurological origin (>6mo), who were regular users of a foot-drop FES system (>3mo).

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

10 **Main Outcome Measures:** Logged usage; TS times for both FES systems and logged AS times

11 for ShefStim; diary recording of problems experienced; Quebec User Evaluation of

12 Satisfaction with assistive Technology (QUEST 2.0) questionnaire; walking speed; ankle

13 angles at initial contact and foot clearance during swing.

14 **Results:** All participants were able to use ShefStim. TS took longer with ShefStim than

15 participants' own FES systems and AS was longer than in a previous study of a similar system

16 (1). Some problems were experienced but overall participants were as satisfied with

17 ShefStim as their own FES systems. The increase in walking speed (N=7), relative to no

18 stimulation, was comparable between both systems and appropriate ankle angles at initial

19 contact (N=7) and foot clearance during swing (N=5) were greater with ShefStim.

20 **Conclusions:** This study demonstrates, for the first time, that an array-based AS FES system

21 (ShefStim) for foot-drop can be successfully used unsupervised. Despite setup taking longer

22 and some problems users are satisfied with it and it would appear as effective, if not better,

23 at addressing the foot-drop impairment. Further product development of this unique

24 system, followed by a larger-scale and longer-term study is required before firm conclusions

25 about its efficacy can be reached.

26 *Word count: 290*

29 **Abbreviations:**

30 Functional electrical stimulation=FES**;** Automated setup=AS; Odstock drop foot

31 stimulator=ODFS; Inter-quartile range=IQR; Standard deviation=SD; Total setup=TS; Quebec

32 User Evaluation of Satisfaction with assistive Technology=QUEST; Dorsiflexion=DF;

33 Plantarflexion=PF

34

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

2

59 further developed and CE marked as ShefStim. This paper is the first feasibility (9) study of

60 ShefStim which combined a period of unsupervised use in conjunction with gait evaluation

61 at the start and end of the study period. The primary aim was to investigate whether

62 ShefStim could be used, unsupervised, by foot-drop FES users within the community

63 environment. In addition a number of other sub-aims were addressed. These were to

64 investigate:

65   1. The community-usage patterns and user-satisfaction with ShefStim.

66   2. The total setup (TS) time compared with their own FES system, as well as AS times

67   for ShefStim.

68   3. The effects of ShefStim on walking speed, ankle angles (at initial contact) and foot

69   clearance during swing, compared with participants' own FES system.

70 *Word count: 404*

71 **METHODS**

72 **ShefStim system**

73 A detailed description of the operating principles of the stimulator, and changes in order to

74 achieve CE marking, are given in the Heller *et al*. paper (1). The same fixed parameters

75 (monophasic waveform, charge-balanced, 40Hz, 160μs) were used but the system used in

76 Heller's study restrained the leg in a support during the AS process. This was deemed

77 impractical for a take-home device so instead users were requested to extend their leg and

78 rest their heel on the floor during home AS.

79 **Figure 1:**

80 The ShefStim consists of (Fig. 1): a leg-worn stimulator (Fig. 1. a.) housed in a modified knee

81 sleeve[i] (Fig. 1. b.); a flexible printed circuit board array of 64 electrodes (cathode electrodes)

82 (Fig. 1. c.), covered with a thin layer of high resistivity hydrogel (10-12) . Sweat ingress

83 changes the conductive properties of the hydrogel sheet so a replacement array fitted with

84 a new sheet of hydrogel is used each day (12); a conventional footswitch[ii]; a conventional

85 anode[iii] (Fig. 1.d.) and a foot sensor and remote control device housed in a bespoke foot-

86 pod[iv] (Fig. 1. e.). The foot sensor and remote control device detects foot orientation,

87 provides voice commands during AS and acts as a handheld remote unit post AS, allowing

88 the user to pause, and change intensity as required.

89 *Word count: 209*

90 **Donning the system**

91 To don ShefStim the following steps are required:

92   1. The footswitch (Fig. 1. f.) is placed under the heel, with the connecting cable

93   extending from the shoe.

94   2. The knee sleeve is donned aligning the stimulator pocket with the long axis of the

95   tibia

96   3. The stimulator is placed in the knee sleeve's stimulator pocket

97   4. The foot-pod, containing the foot sensor and remote control device is positioned

98   over the shoe locating it approximately centrally over the dorsum of the foot and

99   attached with Velcro®

100   5. Electrode array placement: the centre of the third row of electrodes down from the

101   top of the array is aligned with the head of the fibula and the inner edge parallel to

102   the tibia.

103   6. The electrical connector for the array (Fig. 1. g.) is inserted into the array socket on

104   the side of the stimulator and the array is secured with a Velcro® strap.

105   7. The self-adhesive anode is positioned over the tibialis anterior.

106   8. The footswitch connector (Fig. 1. h.) is inserted in the stimulator.

107   AS is then started.

108   *Word count: 177*

109   **AS**

110   For a more detailed description of the AS algorithm refer to Heller's study (1). The only

111   difference between the algorithm used in Heller's study (1) and the ShefStim algorithm,

112   relates to the cost function used in stage 3 of the setup process. The cost function enables

113   many factors that are not directly comparable (e.g. the angle of dorsiflexion (DF) and the

114   stimulation current) to be combined into one optimisation routine. In this case, for example,

115   the angle of DF and the stimulation current are related and the benefits of increasing DF

116   have to be balanced against the potential disadvantages of increasing current excessively.

117   The cost function attributes each a cost score, the lower the cost the better, and the

118   optimisation routine is used to find a minimum cost solution. Compared with the cost

119   function described in Heller's study, the one used in ShefStim reduced the degree of

120   eversion associated with zero cost from 10 to 5 degrees. This change was implemented

121   following observation of excessive (>10 degrees) eversion in 19% of Heller's participants.

122   *Word Count: 171*

123   **Participants**

124   Ethical Approval was granted from the University of Salford (REP10/113) and the integrated

125   research application system (10/H1003/107) for ten participants. Existing foot-drop FES

126   users within the North-West region were given information by clinicians. Interested

127   participants contacted the chief investigator. Inclusion/exclusion criteria are shown in Table

128   1.

129   **Table 1:**

130   *Word count: 46*

131   **Protocol**

132   At visit 1 participants attended the University of Salford gait laboratory and were provided

133   with standard shoes[v] for all conditions to avoid the potential impact of different footwear

134   on foot clearance (13). Participants walked approximately five metres along the gait

135   laboratory up to five times at a self-selected speed initially with no stimulation and then

136   with participant's own FES system (self-setup). Following visit 1 the knee sleeve, stimulator

137   and electrode arrays were prepared for that individual. Participants returned for visit 2

138   where fitting was completed, rising/falling ramps and extension configured, adjustments

139   made to AS settings if required (to ensure appropriate virtual electrode selection) and

140   ShefStim use taught. Following two weeks of unsupervised use of ShefStim at home (with a

141   home-visit after approximately one week to replenish arrays and answer any queries)

142   participants returned to the gait laboratory (visit 3) which duplicated visit 1 but using

143   ShefStim rather than their own FES system.

144   *Word count: 151*

145   **Measures**

146   **Estimate of usage** (between visits 2 and 3)

147   Usage data has been collected in previous foot-drop FES studies (14-18). ShefStim logs the

148   number of heel lifts per day which can be used as an estimate of usage.

149   *Word count: 29*

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

151   With one notable exception (1), setup time has been largely neglected in previous foot-drop

152   FES research . TS times, defined as time from first starting to don equipment to being

153   satisfied with the outcome and walking away (including AS time for ShefStim), were

154   recorded for participants' own FES (visit 1) and ShefStim (visit 3). Average AS time (time for

155   AS to complete) was logged by ShefStim.

156   *Word count: 65*

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

158   Problems encountered were recorded in a paper diary by each participant. User-reported

159   problems have been collected previously (15) but never during the period of use. Recorded

160   problems were collated and grouped into two categories (19): External and Setup. External

161   were classed as being independent of the stimulator design and so referred to the housing

162   of ShefStim (knee sleeve), issues with the standard wired footswitch or issues with charging.

163   Setup was defined as any problem related to setup or satisfaction with the foot response.

164   *Word count: 81*

165   **User-satisfaction** (visits 1 and 3)

166   User-satisfaction has previously been captured using purposive questionnaires (4, 15, 18).

167   Given the risk of bias and lack of validation we sought an alternative. The Quebec User

168   Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) device scale (20) is a

169   validated user-satisfaction measure . Participants rated their satisfaction against eight single

170   item criteria (dimensions, weight, ease of adjustment, safety and security, durability, ease of

171   use, comfort, effectiveness) using a five-point Likert scale (1=not satisfied at all to 5= very

172   satisfied: maximum score=40) for their own FES system and ShefStim. In addition,

173   participants ranked their top three priorities from the eight criteria.

174   *Word count: 97*

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

176   Increased walking speed indicates an improvement in overall walking performance (21) and

177   is frequently used in FES research (22, 23). Measuring walking speed over five metres from a

178   static starting position is a validated measure with neurological populations (24) and was

179   calculated by averaging the velocity of a recorded waist marker (L3 vertebra) over the

180   measurement space (13).

181   Foot-drop leads to abnormal joint alignment during stance (25) with a tendency for

182   plantarflexion (PF) and inversion (21) which can reduce ankle stability. Sagittal and frontal

183   plane ankle angles were captured at initial contact to measure this. The calibrated

184   anatomical system technique (CAST)(26, 27) was used for shank marker placement. Foot

185   marker placement was based on the shod-foot model by Pratt *et al*. (28).

186 Data for both speed and ankle angles was captured at 100Hz using a 16-camera 3D motion

187 analysis system[vi]; a fourth-order low-pass Butterworth filter was used with a 6Hz cut-off

188 frequency. Ankle angles at initial contact were analysed using Visual 3D[vii]

189 *Word count: 152*

190 **Foot clearance during swing** (visits 1 and 3)

191 Foot-drop is associated with an increased risk of tripping and falling due to a lack of foot

192 clearance during swing phase (29). Foot clearance was obtained for seven different points

193 on the shoe sole as described in Thies *et al* (13). Only three of the seven markers from Thies'

194 study (13) (distal toe, medial and lateral forefoot) were investigated since these were

195 deemed most relevant. Healthy gait consistently has a minimum clearance value during

196 swing (13, 30). Hemiplegic gait, however, has an altered clearance trajectory and does not

197 always produce a minimum value during swing, so an alternative and consistently definable

198 point along the trajectory was chosen. Specifically, in this study it was calculated at the

199 moment in time when the reference point on the shoe sole passed the contra-lateral medial

200 malleolus. Data was processed using Matlab®[viii] code (13).

201 *Word count: 133*

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

203 **Data Analysis**

204 As a feasibility study (9, 31), statistical analysis was limited to graphical representation of

205 data and descriptive methods. Ratio data (AS log data, speed and ankle angles at initial

206 contact) was analysed using mean and standard deviation (SD). Median was used for

207   skewed data (usage, TS times and toe clearance (32) , with inter-quartile range(IQR)) and

208   ordinal data (QUEST (33)).

209   *Word count: 56*

210   **RESULTS**

211   **Table 2:**

212   Table 2 provides participant characteristics. Prior to data collection three participants were

213   withdrawn (1, 6, 10). The withdrawal of participants 1 and 10 was due to unrelated medical

214   issues. Subject 6 was withdrawn as it became clear, post recruitment, that he was not a

215   regular user of FES for foot-drop. He had discontinued use following ankle instability

216   problems and a number of falls. The average age of the remaining participants was 58 yrs.

217   (SD 12.9) which is comparable to other foot-drop FES studies (1, 21, 34). Of the five men and

218   two women, four had non-progressive and three had progressive neurological disorders,

219   which is representative of the FES user population (16, 35). The FES systems used by

220   participants varied but all use a single cathode and single anode, and so were classed as

221   'conventional'.

222   *Word count: 126*

223   **Estimate of usage**

224   All participants used ShefStim (Fig. 2) with an average of 1314 heel lifts (steps) per day.

225   There was variability in the number of heel lifts from day-to-day for each participant (for

226   example participant 8) and between participants (participants 5 and 7 versus participant 3).

227   The number of days participants used ShefStim within the two week period also varied, with

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

229   (Fig. 2)

230   *Word count: 78*

231

232   **Figure 2:**

233

234   **TS and AS time**

235   TS time for ShefStim took an average of exactly 14 min [range: 12 min 24 s -37 min 30 s]

236   compared to 3 min 20 s [range: 40 s -8 min] for their own FES. The average AS time was 9

237   min [range: 7 min 34 s – 10 min 20 s].

238   *Word count: 51*

239

240   **Diary recording problems during community use**

241   Of the recorded problems 64% [48 problems] were related to setup with poor voice

242   command clarity from the foot sensor and remote control device (e.g. participant 2, day 3

243   "remote voice garbled"), frequent pausing during and/or unacceptable AS specifically cited

244   (e.g. participant 5, day 9 "pausing, why?" and participant 2, day 2 "2x setups as chaplin

245   walk"). 36% [27 problems] were related to external issues, for example participant 8, day 6

246   "despite charging overnight controller battery was flat". The overall number of reported

247   problems diminished towards the end of the testing period (Fig. 3).

248   *Word count: 94*

249

250   **Figure 3:**

251

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

275   This outcome could not be determined for participants 5 and 7 who both exhibited short

276   step lengths and a significant degree of external rotation of the leg during swing, therefore

277   none of the reference points passed the contra-lateral malleolus during swing as was

278   required by the algorithm. The distal toe marker showed the smallest overall clearance

279   values and with ShefStim the clearance was greatest (Table 3). Table 3 shows that without

280   FES, the median value of the medial marker was higher than the lateral; with participant's

281   own FES they were approximately equal and with ShefStim the lateral was higher than the

282   medial. This foot pose at mid-swing was consistent with the ankle angles at initial contact

283   (see above).

284   *Word count: 118*

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

286

287

288   **DISCUSSION**

289   This study sought to investigate the feasibility of unsupervised use of ShefStim by FES users

290   within the community environment. Usage results show ShefStim is a usable device because

291   without exception, albeit with variation, all participants used ShefStim.

292   Previous studies have reported a number of different measures of usage (6, 14, 15, 17, 18).

293   Only our results for steps (heel lifts) per day could be compared to previous, larger, studies

294   (6, 15, 18), with our participants generally walking less. For example Stein *et al's* (6)

295   participants took 1842 (+/- 198) steps per day when first starting to use the Walkaide

296   system and van Swigchem *et al's* (18) took 5733 (SD 2516). Worthy of note was that van

297   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

321 of use' was rated lower than participants own FES systems, however, suggests that two

322 weeks was insufficient for participants to fully familiarise themselves with ShefStim.

323 Alternatively it might be due to the cited problems with ShefStim itself. Our results cannot

324 be compared to other studies as QUEST has not been used before in this field of research.

325 Future studies should allow longer unsupervised periods of use and should use a validated

326 measure such as QUEST.

327 Speed increase, for both ShefStim and conventional FES systems, compared to no FES was in

328 keeping with previous studies (21) and classed as clinically meaningful (36). In Heller's study,

329 in which subjects did not have time to accommodate to the automated setup, speed

330 increase (relative to no FES) when using the automated setup system was smaller than with

331 their own system (0.04 m/s vs 0.11m/s). In both studies foot response with AS was

332 improved compared with participants' setup of their own stimulators. Although there is a

333 risk of over-interpretation of the results, our findings may suggest that once users become

334 accustomed to a new FES system, their walking speed is relatively insensitive to small

335 differences in foot response. These findings are supported by the foot clearance results and

336 indicate that the underlying operating principle of an array-based FES system with AS may

337 be more effective at addressing foot-drop than conventional FES systems by reducing

338 human error/influence over electrode placement. However, larger scale study is required to

339 fully substantiate these initial findings.

340 *Word count: 676*

341 **Study limitations**

342   This was a feasibility study with a small sample size, self-referred participants and was not

343   randomised (9, 31). As such, whilst encouraging, results should be viewed with caution. The

344   outcome measures selected would appear appropriate but many have been largely unused

345   in previous research in this field making comparison to previous studies challenging.

346   Further development of the electrode-skin interface is required (12) to negate the need for

347   daily array replacement and improve future commercial viability. Further iterations of

348   ShefStim need to also consider addressing the cited setup and external problems, such as

349   voice command clarity, the impact of pausing on AS time, user training and charging, to

350   facilitate further study and widespread implementation.

351   *Word count: 110*

352

353   **CONCLUSION**

354   This is the first study of ShefStim and one of very few investigating foot-drop FES both

355   within the lab and during unsupervised use (37, 38). Ultimately this study demonstrates, for

356   the first time, an array-based AS FES system (ShefStim) for foot-drop can be successfully

357   used unsupervised. Despite longer and more problematic setup in the population studied,

358   users were satisfied with it and it would appear to have comparable, if not better, effects on

359   gait than conventional foot-drop FES systems.

360   Further product development and a larger-scale, longer-term study is required before firm

361   conclusions about the efficacy and effectiveness of ShefStim, compared to conventional FES,

362   can be reached.

363   *Word count: 104*

364   *Total word count: 3245*

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Suppliers

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.
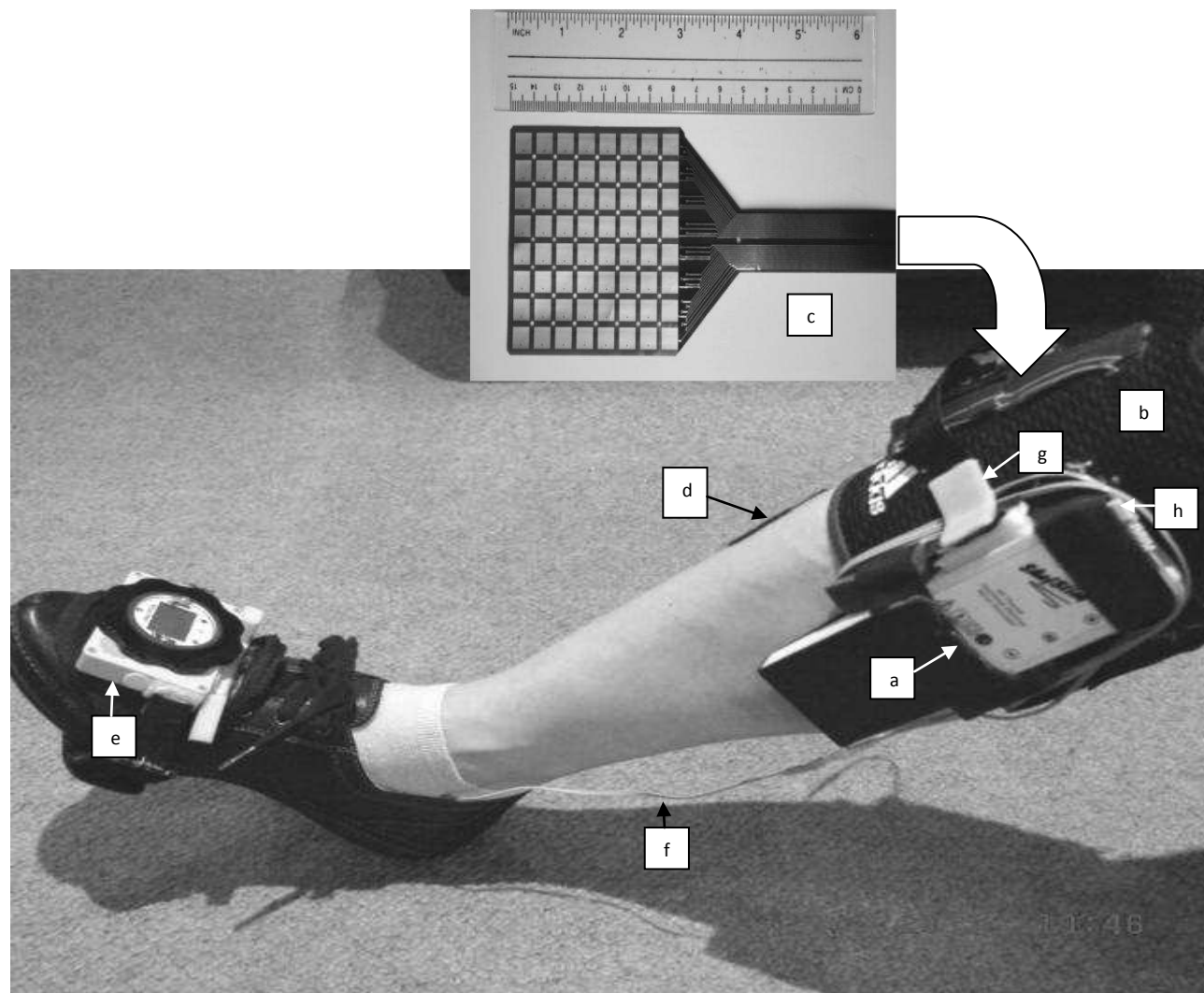
Figure 1

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

Figure 2

	Participant						
	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.
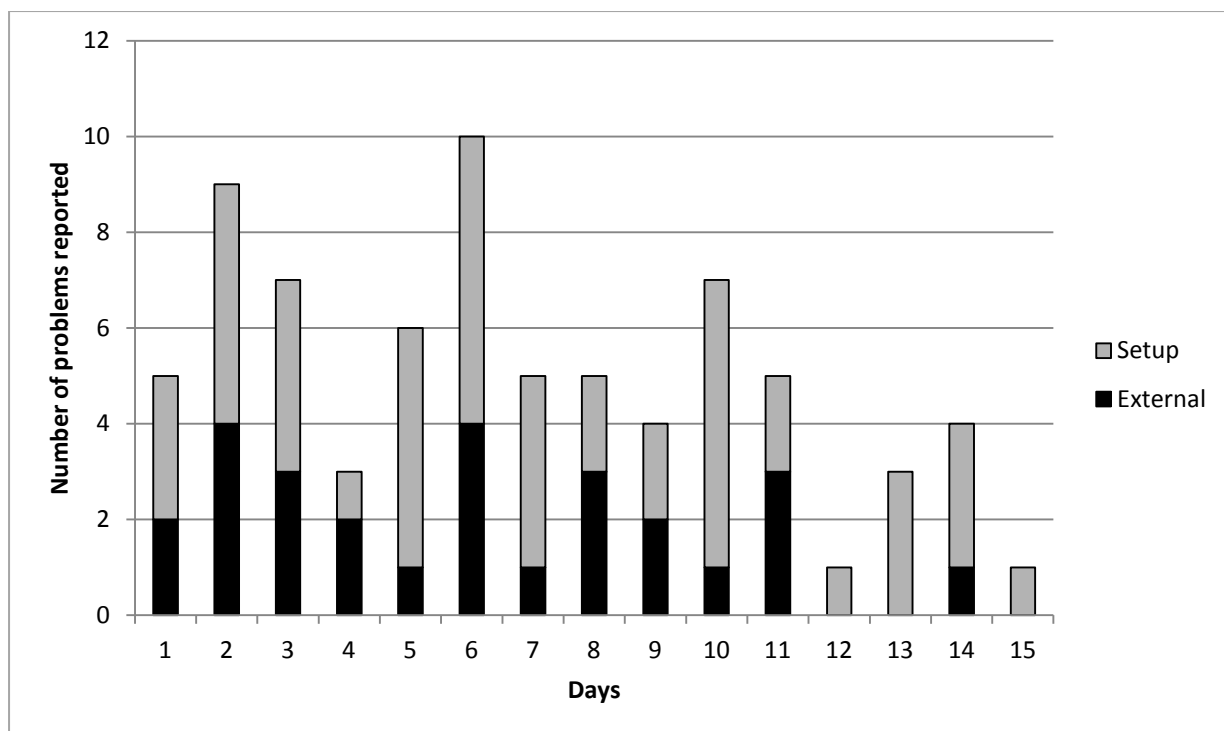
Figure 3

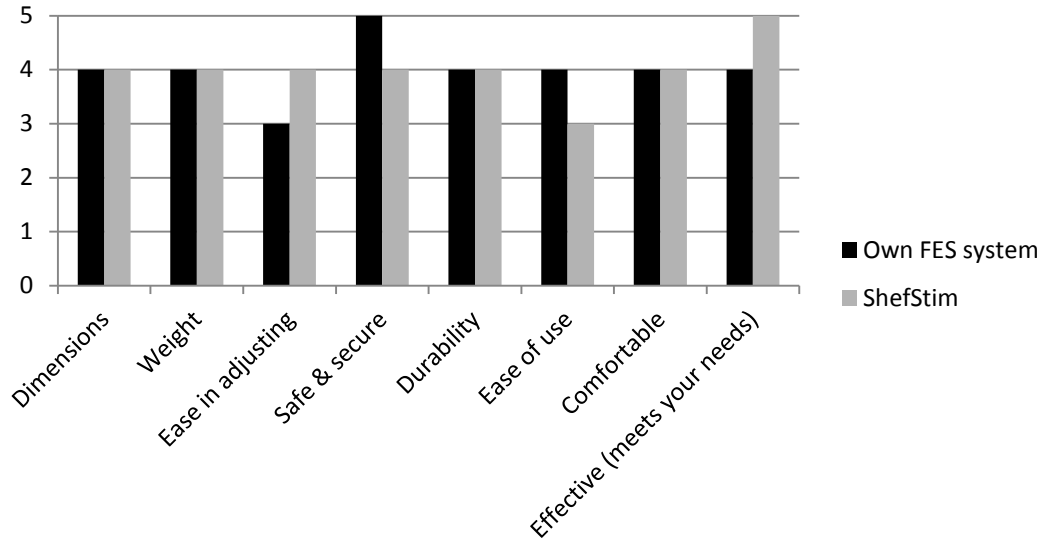**Figure 3:** Recorded problems over two week unsupervised community use (N=7).

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

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

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)>