

A home based trial of the ShefStim electrode array stimulator with automated setup to assist foot-drop



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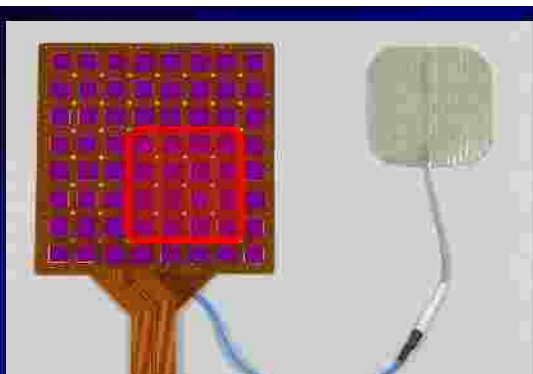
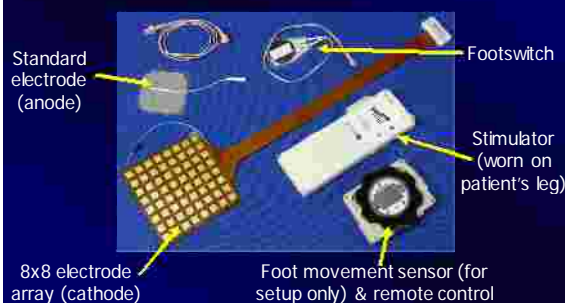
Introduction

- FES is an effective method of correcting foot-drop
- However, finding the electrode position is a problem for some FES patients
 - Causes poor foot movement
 - Increases stimulation intensity required to achieve adequate movement
 - Setting up FES can be time consuming

A Potential Solution

- Replace a conventional electrode with a larger array of small electrodes
 - Covers larger area while retaining selectivity
 - Able to select a combination of electrodes
 - Virtual Electrodes
 - The virtual electrode position is controlled automatically by the stimulator
 - By measuring foot movement during setup an algorithm can optimise stimulation position & intensity

ShefStim – a 64 channel stimulator



ShefStim: Automatic Setup Process

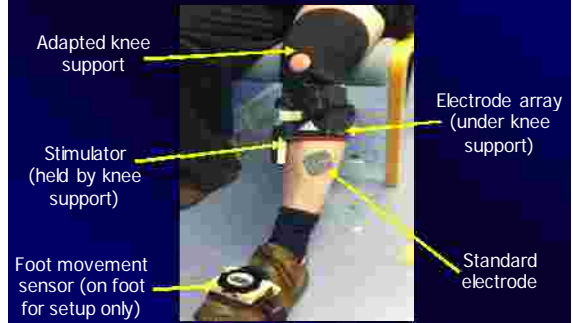
ShefStim Home Trial: Aims

- General: Explore unsupervised use of an automated array stimulator in the home environment
- Specific: Compare walking speed, foot orientation and floor clearance between:
 - No FES
 - Participant's own FES system
 - ShefStim

Method

- Visit 1: Gait analysis to assess walking with:
 - No FES
 - Participant's own FES
- Visit 2: ShefStim setup to individual's requirements & user training provided
 - Setup: algorithm parameters, ramp & extension
- Visit 3: After 2 weeks home use of ShefStim return for gait analysis with:
 - No FES
 - ShefStim

Method

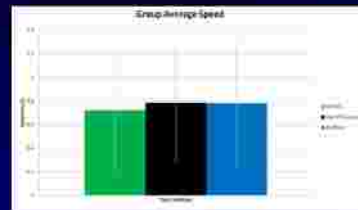


Results

- 7 participants completed the 2 week trial
 - All existing FES users with unilateral foot-drop
 - 3 CVA, 3 MS, 1 Brain Injury
 - Total of 10 recruited
 - 2 unable to participate due to unconnected health problems & 1 due to poor foot movement with all FES systems used
- ShefStim was used regularly by the participants during the trial
 - Median of 1314 heel lifts per day

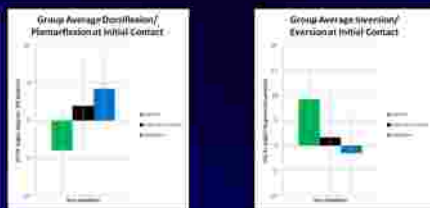
Walking Speed

- ShefStim & participant's FES provided same average speed increase relative to no FES (+8.3%)



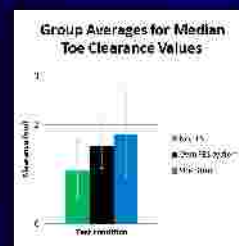
Foot Orientation (at initial contact)

- Both ShefStim & participant's own FES corrected plantarflexion & inversion
- ShefStim achieved more DF and eversion



Toe Clearance (at mid-swing)

- ShefStim also showed the greatest average toe clearance
- Participant's own FES also showed increased toe clearance compared to No FES but less than ShefStim



Discussion

- One aim was to help reduce setup time
 - Average ShefStim automatic setup time = 9 minutes
 - Limited benefit to many patients
- This mostly due to communication problems between the wireless foot movement sensor & stimulator
- Changing the communication modules in the system will resolve this issue
- Further time saving can be achieved by refining the algorithm

Discussion

- Walking speed increase was on average the same with both ShefStim & own FES
- Suggests walking speed relatively insensitive to the difference in foot movement between the FES setups
 - A lab based trial found a short period walking with the unfamiliar ShefStim was slower than walking with own FES
 - This home based trial shows this was not an issue once participants had become familiar with ShefStim

Discussion

- Foot orientation was improved with ShefStim compared to participant's own FES (& substantially compared to no FES)
- Average toe clearance also increased when using ShefStim
- Indicates that an array based FES system may be more effective at correcting foot-drop than standard FES

Conclusions

- Trial demonstrates an electrode array stimulator can be used independently in the home environment
- Participants were satisfied with ShefStim and their overall foot response and floor clearance was improved
- For patients with difficulties setting up standard FES, array based FES systems may be a more effective alternative

Acknowledgements

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