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A review of the design and clinical evaluation of the ShefStim array-based functional electrical stimulation system.

Laurence P. Kenney*[1]. Ben W. Heller[2], Anthony T. Barker [3], Mark L. Reeves[3], Jamie Healey[3], Timothy R. Good[3],Glen Cooper[1,4], Ning Sha[1], Sarah Prenton[1,5], Anmin Liu[1], David Howard[1]

[1]Centre for Health Sciences Research, University of Salford, Salford M6 6PU, U.K.

[2] Centre for Sports Engineering Research, Sheffield Hallam University, Sheffield S1 1WB,U.K.

[3] Department of Medical Physics and Clinical Engineering, Royal Hallamshire Hospital, Sheffield S10 2JF U.K.

[4] School of Mechanical, Aerospace and Civil Engineering, University of Manchester, Manchester, M13 9PL, U.K.

[5] Division of Health and Rehabilitation, University of Huddersfield, Huddersfield HD1 3DH, U/K.

* Corresponding author: email - l.p.j.kenney@salford.ac.uk; tel 0161295 2289

Abstract: Functional electrical stimulation has been shown to be a safe and effective means of correcting foot drop of central neurological origin. Current surface-based devices typically consist of a single channel stimulator, a sensor for determining gait phase and a cuff, within which is housed the anode and cathode. The cuff-mounted electrode design reduces the likelihood of large errors in electrode placement, but the user is still fully responsible for selecting the correct stimulation level each time the system is donned. Researchers have investigated different approaches to automating aspects of setup and/or use, including recent promising work based on iterative learning techniques. This paper reports on the design and clinical evaluation of an electrode array-based FES system for the correction of drop foot, ShefStim. The paper reviews the design process from proof of concept lab-based study, through modelling of the array geometry and interface layer to array search algorithm development. Finally, the paper summarises two clinical studies involving patients with drop foot. The results suggest that the ShefStim system with automated setup produces results which are comparable with clinician setup of conventional systems. Further, the final study demonstrated that patients can use the system without clinical supervision. When used unsupervised, setup time was 14 minutes (9 minutes for automated search plus 5 minutes for donning the equipment), although this figure could be reduced significantly with relatively minor changes to the design.

1. INTRODUCTION

Functional electrical stimulation has been shown to be a safe and effective means of correcting foot drop of central neurological origin [1-3]. Surface-based devices typically stimulate via a cathode placed over the common peroneal nerve immediately distal to where it bifurcates into the deep and superficial branches, and an anode placed over tibialis anterior. Appropriate levels of stimulation delivered via accurately placed electrodes should result in suitably weighted recruitment of the two nerve branches, leading to a useful and safe foot response during the swing phase of walking (dorsiflexion with a small degree of eversion). However, in certain individuals even very small electrode positioning errors can lead to a poor foot response. Indeed, a 1999 survey of users of drop foot stimulators reported over 40% of respondents finding electrode positioning problematic [4]. Some current systems such as the WalkAide (Innovative Neurotronics Inc., Austin, Texas, USA) embed electrodes in a cuff, worn below the knee (the reader is referred to [5] for a recent review of current systems). Such an approach greatly reduces the likelihood of large errors in electrode placement, but the user is still fully responsible for selecting the correct stimulation level each time the system is donned. Interestingly, despite improvements in both stimulator designs and patient education, two recent studies demonstrated that when patients set up their stimulators without clinician support, the resultant foot response is often less than optimal[6, 7].

One approach to the challenge of stimulator setup is to implant the electrodes on the nerve(s), thereby removing the electrode placement problem from the user [8, 9]. However, an invasive approach carries risks and the implantable devices and surgical costs remain relatively expensive. As a result, a number of groups have been investigating the possibility of automating the surface-based drop foot setup process through a two-channel stimulation approach to software steering of the foot [10-12], or electrode array-based approaches [13-18]. Both approaches feature a ‘setup space’ which can be automatically searched, either through replacing single electrode(s) with one or two arrays of discrete electrodes, or by allowing modulation of pulse waveform. Both

approaches also use measurement of foot orientation, usually derived from foot-worn inertial sensors, to guide the search.

Elsaify proposed an automatic array element search algorithm, but using array elements with separate gel layers (a matrix of small single electrodes) [14]. More recently, Valtin [17] demonstrated an array search algorithm that takes roughly two minutes using two flexible PCB electrode arrays (one over the nerve and one over Tibialis Anterior), each interfaced with a continuous, high-resistivity hydrogel layer. However, in contrast to the work presented here, only preliminary results with a healthy subject were presented. In the most recent work, Seel reported on a system using a foot-mounted inertial sensor to adjust the steering based on realtime measurements of the foot orientation[11]. The system uses only two electrodes and, in laboratory studies with stroke participants, demonstrates convergence on a suitable foot response within one or two strides. However, studies of the system outside of the laboratory setting have yet to be published.

In this paper we expand on a recent conference paper [19] to report on the design, development and demonstration of a system for automated setup of drop foot FES (ShefStim). The paper extends the conference paper by presenting the model used to define the initial electrode array geometry design (section 2) and provides discussion of the merits and limitations of ShefStim compared with alternative systems. The ShefStim design concept was proposed by Heller in 2003 [20]. For this study the Department of Medical Physics at Sheffield Teaching Hospitals initially developed a 'proof-of-concept' multi-electrode stimulator, which could simultaneously stimulate any manually-selected subset out of a conveniently sized, 8 by 8 rectangular array of metal electrodes. The subset of activated electrodes is termed a virtual electrode (VE). In order to develop this concept into a clinically usable system for automated setup a series of design problems needed to be solved. The first problem was the electrode array design; the second problem was the development of an array search algorithm. The remaining part of the paper summarises the results from two studies of the ShefStim involving people with drop foot of central neurological origin.

2. DESIGN OF THE ELECTRODE ARRAY

For clinical applications a moderately electrically conductive hydrogel interface between the electrodes and skin provides the benefits of hydration of, and adhesion to, the skin. However, in array applications a continuous hydrogel layer also introduces the issue of spatial selectivity loss due to transverse currents in the hydrogel. Spatial selectivity is defined as the ability to activate discrete groups of nerve fibres in a localised region without stimulating nerve fibres in neighbouring regions.

In order to achieve a satisfactory degree of spatial selectivity, it was necessary to identify an appropriate electrode geometry and interface layer properties. Two finite-element models were therefore developed to investigate the effects of electrode geometry and hydrogel layer properties on spatial selectivity, characterised in our model by the activation area (see below). Model 1 was developed to explore the effects of hydrogel resistivity and electrode size on activation area under a single cathode electrode and; Model 2 extended Model 1 through the addition of electrodes surrounding the cathode, to allow investigation of activation area under a multi-electrode array. The results of the second model, together with practical constraints imposed by the stimulator, led to the array geometry and interface layer properties used in part 3 of this paper.

Model 1

Figure 1 shows the 3D finite-element model, developed using ANSYS Multiphysics (Version 10.0, Ansys, Inc, Canonsburg, PA, USA) to predict the effects of electrode geometry and hydrogel properties on electric field distribution in the underlying tissue [21]. The model represents a cathode, an anode, a hydrogel layer, skin, fat and muscle. The skin, fat and muscle were modelled as flat, extended layers, whose thicknesses were based on their anatomical dimensions. As bone has much higher resistivity than the other media, it was assumed to be non-conductive volume underlying the muscle, and hence was represented as the lower boundary of the model. Structures of smaller dimension, such as hair follicles or blood vessels, were not explicitly modelled, as their influence on stimulation at the depth of the motor nerve branchescould be considered negligible.

Appropriate electrical conductivity properties were assigned to the elements, based on values from Duck [22] (Table 1). Although the skin's capacitance cannot normally be neglected, the skin in the model was assumed to be hydrated due to intimate contact with the hydrogel layer. Hence capacitive effects were not included in this model.

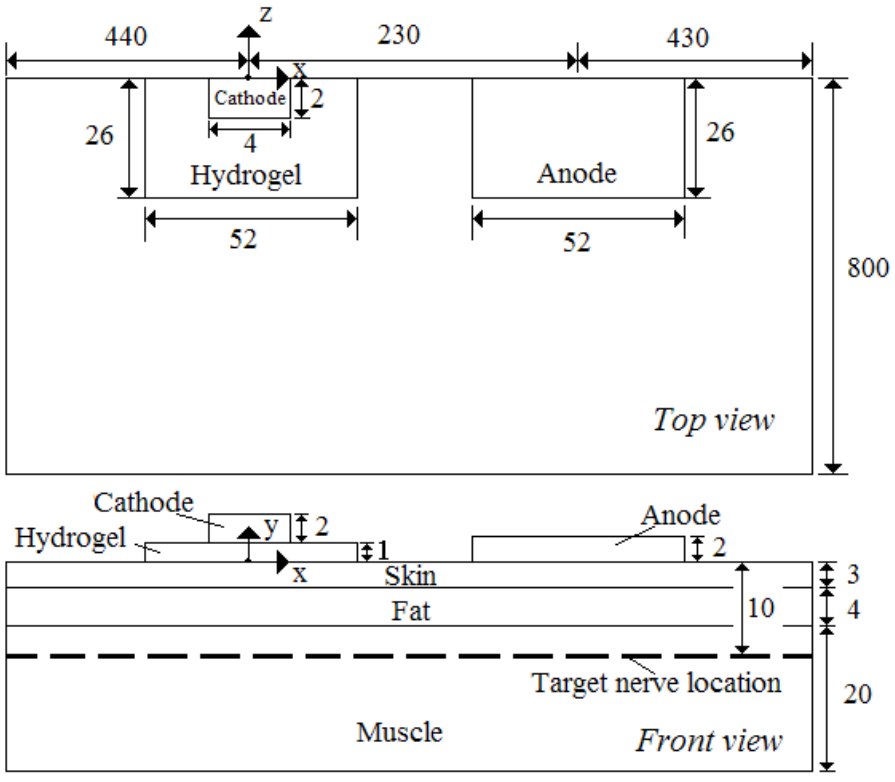

Figure 1: Schematic of the geometry of the selectivity FE model (not to scale) (dimensions in mm)

Table 1: Model parameters

Biological tissues and materials	Resistivity (Ωm)
Bone	7×10^{4}
Muscle	2 in X and Z directions
	4 in Y direction
Fat	62.5
Skin (hydrated)	833
Hydrogel	Model variable
Cathode and Anode	1.5×10^{-8}

The calculation of whether a point in the model was deemed to be stimulated was based on the stimulation function [23]. To explore spatial selectivity we first defined a stimulus pool to be a volume over which the value of the stimulation function exceeds a threshold at which action potentials in a nerve fibre are generated. The maximum stimulation function always appears in the stimulus pool centre, just underneath the cathode, and the

amplitude of the stimulation function decreases from the centre to the edge of the stimulus pool. Although the value of the maximum stimulation function varies between models, it can always be scaled to the same value by changing the input current, and this scaling does not change the shape or size of the stimulus pool. Contours may be defined which connect points in the model with identical stimulation function values (expressed as a percentage of the maximum) and the 50% contour was selected to represent the boundary of the stimulus pool for the results presented here. The 50% contour choice was somewhat arbitrary, but avoided problems which would be associated with choice of a contour near 100% or 0% of maximum stimulation function (all contours converge to a point at 100% of maximum stimulation function and contours enclose infinitely large areas at 0%) As the electrical properties of the tissue were uniform, the current density distribution was symmetric along the plane normal to the skin surface and along the centres of the cathode and the anode. This symmetry allowed a study to be performed on a half model. To represent the location of the nerve, we defined a plane representing the anatomical depth of the target nerve (10mm). The intersection of the stimulus pool with the plane defined an area; the smaller the area, the more focused is the stimulation and thus the better the spatial selectivity. Therefore, the area of the stimulus contour associated with 50% of maximal stimulation was used as the metric of spatial selectivity.

To explore the combined effect of hydrogel resistivity and electrode size on selectivity, a series of simulations were run with square electrodes from infinitely small (a point) to 16mm×16mm with a range of interface layers. The first simulation considered the no interface layer case; subsequent simulations varied the 1mm thick hydrogel layer resistivity from 20Ωm to 1000Ωm. The results are shown in Figure 1.

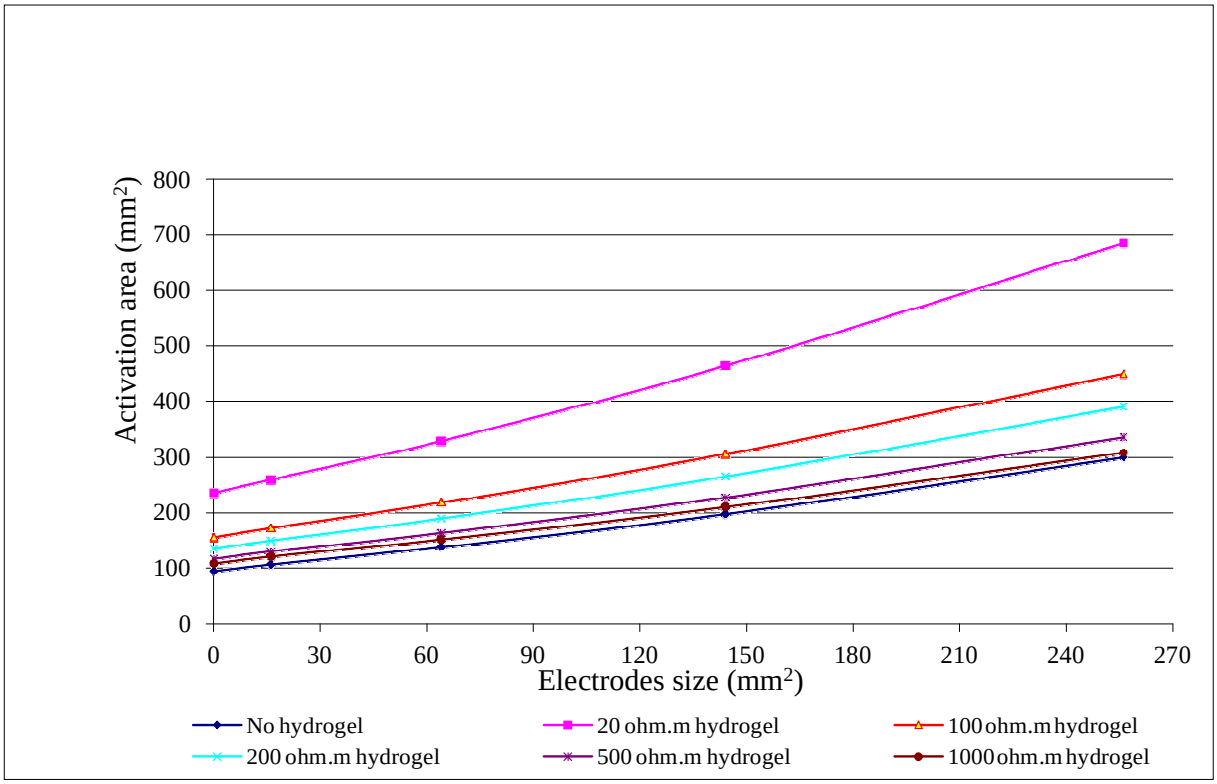

Figure 2: The effects of electrode size on activation area for a range of hydrogel resistivities.

Figure 1 shows that there is a minimum limit to activation area of approximately 100mm^2 at 10mm depth, and that spatial selectivity becomes poorer (activation area increases) with increasing size of electrode and decreasing resistivity. When the resistivity reaches 500Ωm or greater, the spatial selectivity is similar to that of the model without the hydrogel sheet.

Model 2

Model 1 had shown that the introduction of a 1 mm hydrogel interface layer did not significantly degrade selectivity providing the hydrogel resistivity was at least 500Ωm. However, the model did not account for the presence of neighbouring electrodes which would surround an electrode in the array. The presence of these electrodes will lead to a decrease in selectivity compared with the single electrode condition, as current can flow from activated electrodes across inter-electrode gaps and into adjacent non-activated electrodes. These effects would be modulated by the size of the inter-electrode gap and hydrogel properties. Therefore, Model 1 was used as the basis for a new model (Model 2) to enable the electrode array design to be finalised.

It was assumed that the magnitude of reduction in selectivity due to current passing across the inter-electrode gaps would be dominated by electrodes immediately surrounding any given electrode in the array. Hence, Model 1 was extended to include eight more electrodes surrounding the original cathode electrode (Figure 2)[1]. The interface between the electrode array and the skin was a sheet of hydrogel. The initial geometry of Model 2 was informed by previous pilot experimental work carried out as part of a Master's research project, demonstrating the viability of using a 70mm x70mm electrode array consisting of 64 electrodes (arranged in an 8x8 format)[24].

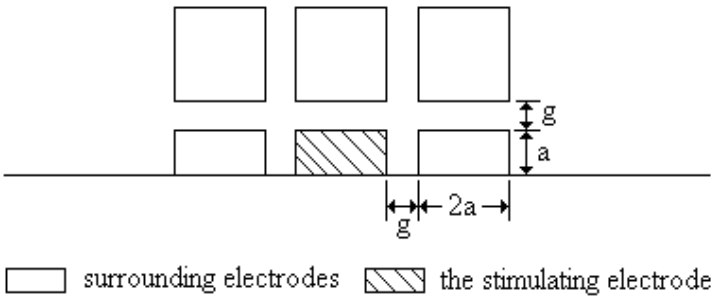

Figure 3: Model 2. The electrode gap (g) is the edge-to-edge distance between any two neighbouring electrodes in the array; 2a is the dimension of each square electrode

As the feasibility work suggested maintaining an overall array size of approximately 70mm x 70mm , we fixed the centre-to-centre spacing of electrodes in the model to be 9mm (2a + g =9, see Figure 2). Five different gap sizes were modelled (Table 1) and for each of these, four commercial hydrogel sheets were modelled (Table 2). The set of hydrogel properties were informed not only by the results of Model 1, but also by earlier experimental work [25, 26] which provided further evidence to support the use of a thin, high-resistivity hydrogel layer between the electrode and skin.

Table 2: Electrode gap and size evaluated in the FE model, and resultant overall electrode array size

Electrode gap (mm)	Electrode size (mm)	Electrode array size (mm)
1	8×8	71×71
2	7×7	70×70
3	6×6	69×69
4	5×5	68×68
5	4×4	67×67

Table 3: Hydrogel materials represented in the model. Note that the different sheet thicknesses modelled were chosen to represent the sheet thicknesses provided by the manufacturers.

Hydrogel (abbreviation)	Approx thickness (mm)	Resisitivity at 1.67kHz (Ωm)

[1] Note, as per Model 1, a half model was developed to take advantage of symmetry.

AG703, Axelgaard manufacture Co., Ltd. Fallbrook, CA. USA (Hydrogel 703)	0.9	55
AG803, Axelgaard manufacture Co., Ltd. Fallbrook, CA. USA (Hydrogel 803)	0.9	206
SRBZAB-05SB, Sekisui Plastics, Co., Ltd. Tokyo, Japan (Hydrogel ST)	0.5	1363
AG, AG3AM03M-P10W05, Sekisui Plastics, Co., Ltd. Tokyo, Japan (Hydrogel AG)	0.3	25185

In order to quantify the effects of the surrounding electrodes on selectivity, two versions of each model were run. In the first version, the surrounding electrodes were not represented and in the second, the surrounding electrodes were represented. The selectivity loss resulting from the introduction of surrounding electrodes was quantified by a selectivity loss ratio, defined in equation 1.

$$Selectivity\_loss\_ratio = \frac{A_2 - A_1}{A_1} \times 100\% \qquad (1)$$

Where, A_1 is the activation area of the model without surrounding electrode and A_2 is the activation area of the model with surrounding electrode

Figure 3 shows the selectivity loss ratio due to the surrounding electrodes calculated for each combination of hydrogel interface layer and inter-electrode gap.

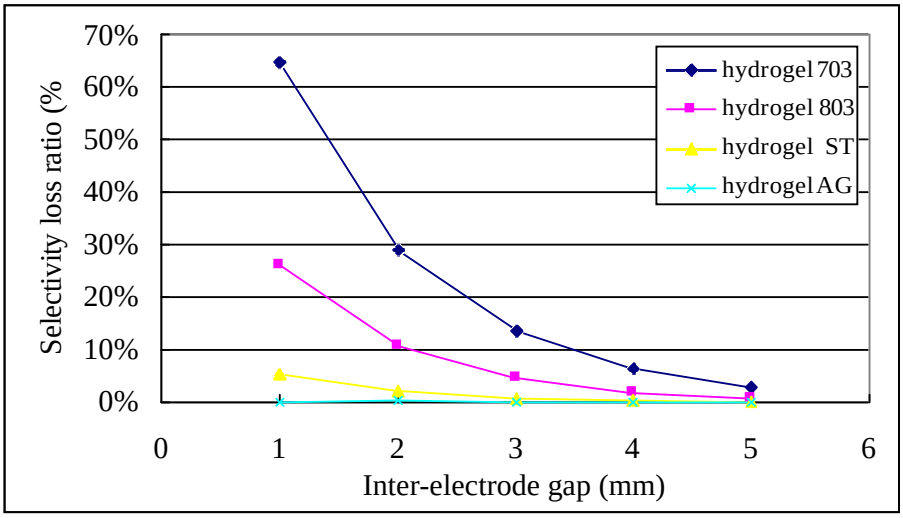

Figure 3: Selectivity loss ratios with different hydrogels

The results suggested that for hydrogels ST and AG an electrode gap between 1mm and 5mm will result in an acceptably low selectivity loss (defined as less than 10%) in the presence of the surrounding electrodes. From a manufacturing perspective, an inter-electrode gap of less than 2mm would make it very difficult to route the tracks between electrodes, so a 2mm inter-electrode gap was chosen. A final practical test demonstrated that our stimulator (200V drive voltage) could not drive the specified 8mA per channel when using the more resistive of the two most promising materials (hydrogel AG) and hence hydrogel ST was selected.

3. FEASIBILITY STUDY OF ELECTRODE ARRAY SEARCH STRATEGY

Section 3 described the design of an 8 x 8 electrode array interfaced to the skin via a thin high-resistivity hydrogel layer. The next design problem was the development of a quick, reliable method of searching the set of all possible stimulation electrodes to find the optimal virtual electrode. In this section we report on two

methods for searching the array used to identify appropriate virtual electrodes and their associated stimulation levels, which extended the work of Elsaify et al. [14]. In the first part of the work, we apply a slowly ramped stimulation through each virtual electrode while continuously monitoring the orientation of the foot relative to the leg. These data allow identification of electrode sets that, when appropriately stimulated, result in acceptable foot movement. The ramped stimulation results were used to investigate whether it is possible to reduce the search space through prediction of the location of the best subset of these electrodes based only on the response of the foot to short bursts of stimulation (twitch stimulation). We investigated use of a cost function to rank the response to short bursts of stimulation and examine whether this ranking may be used to isolate smaller groups of electrodes that contain one or all of the best subset of electrodes identified in the slow ramped stimulation search.

For brevity, here we only report on the search for appropriate single VEs. Additional work to identify suitable pairs of VEs is reported elsewhere [27]. Ethical approval for the study was granted by the University of Salford's Research Governance and Ethics committee (RGE06/102). Twelve healthy subjects were recruited from within the University and a full set of results were obtained for ten (9 male) subjects (median 30 years)[2].

The stimulation system consisted of a constant current portable 64 channel stimulator designed and built by the Medical Engineering section of Sheffield Teaching Hospitals NHS Foundation Trust (size: 155 mm × 95 mm × 33 mm), an.8×8 electrode array, described in section 2 and a 50x50 mm square conventional hydrogel electrode (PALS® Platinum electrode, Axelgaard Manufacturing Co. Ltd.), The charge-balanced asymmetrical biphasic stimulus pulses were software controllable via a graphical user interface, with the pulse width fixed at 300 μs, and the frequency at 35 Hz. Stimulation intensity through each electrode was software controlled and measured by an analogue to digital converter built-in to the stimulator itself. During the experiment, groups of 2×2 electrodes were activated simultaneously (the minimum number required to elicit adequate contractions, providing a total current of up to 32 mA), and act as a virtual electrode.

A 5-camera Qualisys motion capture system (Proreflex, Qualisys AB, Sweden) was used to record foot movement at 100Hz and the motion data were transferred to and simultaneously analysed in Visual3D (Visual3D™, C-Motion Inc, USA). Hence the foot movement was captured, and ankle angles in sagittal, coronal and transverse planes were displayed in real-time. Synchronisation between the stimulator and the motion capture system was achieved using a data acquisition device via the stimulator control program. An electrically-isolated button was included to allow the user to stop stimulation at any stage in the experiment.

The experiment started with measurement of the neutral foot orientation for the subject while standing upright. He/she was then asked to sit in a chair and their right lower leg was strapped in the brackets to keep the shank in a consistent pose throughout. The stimulator and electrodes were then donned. The subject was then asked to maintain their sitting posture and relax the foot in a natural (dropped) position throughout the experiments. As the analysis of data did not dictate the order in which the tests were conducted, the foot twitch experiment was conducted first to reduce fatigue. However, here they are explained in reverse order for clarity.

Prior to beginning the slow ramped stimulation experiment a user-defined maximal current was identified. We assumed that sensation would be most acute over bony prominences and hence at the start of the experiment increased stimulation over these sites until a user-defined maximum was reached and the value noted. Next, current through each VE in turn was ramped from zero to the user-defined maximal current over 10 seconds. The twitch stimulation part of the experiment involved six different bursts of stimulation (1 and 4 pulses/burst, at 3 different levels of stimulation (16, 24 and 32mA) being applied in turn through each of the 49 VEs. Ankle angles together with time-synchronised current data for each of the different electrodes were recorded for both experiments.

The target for foot orientation was defined as dorsiflexion at or above neutral, and inversion/eversion within -1SD of the previously reported healthy subject mean foot orientation at heel strike [28]. All VEs which, when stimulated over the 10 second period, resulted in the foot reaching the target foot orientation were identified and the set of electrodes satisfying these criteria were labelled Set A.

When sitting relaxed in the chair the subject's foot was typically plantarflexed and inverted, compared with its neutral position. Hence, it was assumed that a twitch response that moved the foot towards dorsiflexion and eversion was desirable. A cost function was defined which used the maximum value of dorsiflexion and inversion angles observed during the twitch response

[2] Two subjects could only tolerate 12.8 mA and 16 mA respectively, which was insufficient to produce target dorsiflexion when applied through any of the virtual electrodes electrodes during the slowly ramped stimulation

$$Cost = -2 \cdot Dorsi + Inver$$

Where $Dorsi$ is the peak dorsiflexion angle (in degrees) measured during stimulation relative to the relaxed position. Dorsiflexion is positive and plantarflexion is negative. $Inver$ is the peak inversion angle (in degrees) measured during stimulation relative to the relaxed position. Inversion is positive and eversion is negative. A weighting factor of 2 was applied to the dorsiflexion angle to reflect its relative importance compared to inversion/eversion.

This cost function was used to rank the foot responses to each of the different twitch stimulation bursts applied to each of the VEs. The cost function, which was applied to the positive peak value of dorsiflexion and inversion, maximizes dorsiflexion and minimizes inversion. The VE with the lowest cost was ranked 1st and each of the remaining 48 VEs were then assigned a rank based on their cost. To identify how well the cost function could be used to predict membership of Set A (the set of VEs which, when stimulated resulted in the foot reaching the target foot orientation) two metrics were derived. First, how far down the ranking it was necessary to go to include all of the members of Set A, defined as Rank_all ; second, how far down the ranking it was necessary to go to include any member of Set A, defined as Rank_any.

In 9 out of the 10 subjects to complete the slow ramped stimulation study, at least 1 VE was identified which, when stimulated, produced the target foot response. The maximum number of acceptable VEs found for any individual subject was 4 (out of 49) and the minimum was 0.

The results of the twitch stimulation analysis for the 9 subjects are shown in Table 4. Note that stimulation at 16mA produced no or minimal response.

Table 4: Rank_any and Rank_all for different twitch stimuli

	1 pulse @ 32mA	4 pulses @32mA	1 pulse @ 24mA	4 pulses @ 24mA
Rank_all Median (range)	5 (1-33)	4 (1-41)	11 (2-40)	8 (2-41)
Rank_any Median (range)	2 (1-19)	3 (1-15)	6 (1-15)	4 (1-29)

Although there was significant inter-subject variability, the results showed that in most cases by using a cost function to rank responses to twitch stimulation it was possible to identify a much smaller set of electrodes containing one, or all of Set A. For example, using a 4 pulse burst of stimulation at 32mA, a suitable electrode was identified in all cases within the first 15 of the responses ranked according to the slow ramped stimulation results. The data suggested therefore there could be advantage to using a twitch stimulation consisting of multiple pulses at high currents and a two stage search strategy was worth further investigation.

4. FIRST LAB-BASED DEMONSTRATION OF SHEFSTIM

Further development work on both the stimulator and the search algorithm was carried out over the period 2009-11 resulting in the first demonstration of an array-based FES system with automated setup for the correction of drop foot. The study is reported in detail elsewhere [6], so in this paper, we focus on the improvements made to the stimulator hardware and implementation of the search algorithm, and provide an overview of the laboratory-based study involving subjects with drop foot.

4.1 Stimulator

Further stimulator development led to a new design weighing 200 g with a volume of 211cc (130 mm x 65 mm × 25 mm). During automated setup the stimulator was controlled via an isolated serial link by a program running on an external computer, the participant's leg was held in a brace, with the knee extended and foot movement was measured using an electromagnetic position and orientation sensor (Patriot, Polhemus Inc,

Vermont) (Figure 4). For walking trials the setup parameters were downloaded and the stimulator disconnected from the computer, enabling it to function as a standalone drop foot stimulator being triggered using a foot switch.

4.2 Search algorithm

The work described in section 4 had been based on the use of a 2 x 2 VE. Following further pilot work it was found that a 4 x 4 VE still provided satisfactory resolution over foot response, but reduced sensation compared to a 2x2 arrangement and increased robustness to tissue movement during gait. The move to a 4 x 4 VE also served to reduce the array search space by a factor of ~2, compared with the original approach (25 VEs to be searched rather than 49).

As described in section 4, we had already demonstrated the potential to use the response of the foot to short bursts of stimulation as a means of homing in on promising VEs. However, further work was needed to develop a clinically usable search algorithm. In the final system a three phase search strategy was implemented.

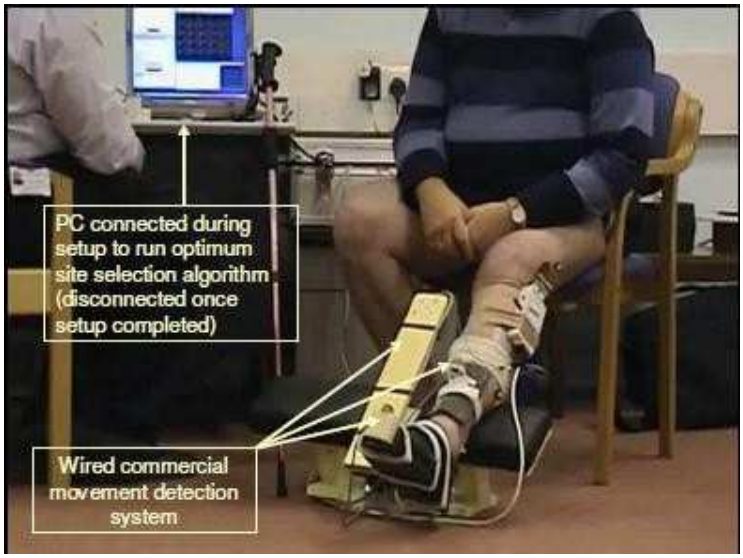

Figure 4: Setup of ShefStim

In phase one the level of stimulation at which the foot first responds is determined. Short bursts of stimulation are applied to each of the 25 virtual electrodes, a process taking about 2.5 seconds. The amplitude is automatically titrated until the threshold for repeatable foot movement, irrespective of direction, is determined. This threshold amplitude is used as the base for searches in subsequent phases. In phase two (twitch response), the algorithm searches for candidate stimulation sites, using twitches rather than tetanic contractions to speed-up search time and reduce sensation. Four pulses of stimulation are applied to each electrode in turn. The foot response is monitored for short periods after each stimulation, if there is a detectable response it is added to the list of candidate sites. Again the current is automatically adjusted until between 4 and 12 sites are found or the maximum current limit is reached. These sites are ranked in order of sensitivity using a cost function based on the angular displacement. The first two stages therefore allowed for rapid identification of the most sensitive VEs.

In phase three (tetanic testing), up to 8 of the sites identified in phase two were tested in rank order with an increasing stimulation intensity. Stimulation began at the level identified in phase two and incremented in steps until one of the following conditions were met: either plantarflexion was corrected to neutral dorsiflexion; or current reaching twice the starting value; or 150% of starting value with no movement detected; or motion saturation was detected. The algorithm included safeguards if unexpected movements occurred, enabling the system to temporarily wait if a leg spasm was detected or to pause the search process if repeated non-stimulated leg movement was detected. Once all the candidate sites were assessed, they were given a score based on a three-part cost function, designed to penalise solutions resulting in plantarflexion, excessive inversion or eversion, and high current If at any point during this phase the user found a site uncomfortable the clinician was able to skip that site. Once the tetanic testing phase was complete the first-ranked site was activated and, after initial testing of the site while sitting, the user then walked using the stimulator: If the foot response or stimulation sensation was not satisfactory it could be manually changed to an alternative site the ranking list.

Finally, stimulus pulse width could be adjusted by the user, if necessary, to fine-tune the magnitude of foot response.

4.3 Laboratory-based clinical study

Ten participants with drop foot due to stroke (ages 53–71 years) and 11 due to MS (ages 40–80 years) were recruited to test the system. Each participant walked twice over 10 m under each of four conditions; a). using their own stimulator setup by themselves; b) using their own stimulator set up by a clinician, c). using ShefStim with automated setup, and d). no stimulation. Outcome measures were walking speed, foot angle at initial contact and the Borg Rating of Perceived Exertion. As described in Heller et al [6], the results showed that when setup using ShefStim subjects' walking speed, dorsiflexion and frontal plane ankle angle at initial contact were all broadly comparable with clinician setup and, apart from walking speed, better than patient setup. The study demonstrated for the first time that fully automated setup of an array stimulator is feasible in a population with drop foot of central origin.

5. FIRST TAKE-HOME STUDY OF SHEFSTIM

A final iteration of the stimulator design resulted in the CE- marked ShefStim system shown below.

Figure 5: ShefStim stimulator (left) being used by a subject during setup (right)

The ShefStim stimulator measures 142mm x 50mm x 14mm (volume 99cc) and weighs 125 g (including batteries). In contrast to the earlier versions of the system, it includes a combined foot angle sensor and remote control device, and setup does not involve holding the leg in a brace (Figure 5). The remote control device is placed on the foot during set up and wirelessly provides triaxial accelerometer inputs to the search algorithm described in the previous section. Users are provided with an attachment, based on an iPod holder, which could be slipped onto the shoe prior to setup. Guidance is provided to the users on the correct mounting of the remote control on the shoe and the importance of aligning the ShefStim box with the long axis of the leg. Once setup is completed, the foot angle sensor device serves as a remote control with which the user can pause stimulation, adjust intensity or receive audible error messages. Stimulation timing during gait is controlled using a conventional footswitch, located under the heel of the shoe. Integrating the foot angle sensor into the system enabled the stimulator to carry out the automated setup routine without requiring input from any external sensors or connection to a PC, making it suitable for use in the home environment.

In the final clinical study seven subjects with drop foot (3 subjects with MS, 3 with stroke and 1 with traumatic brain injury) used ShefStim over a 2 week period. The reader is referred to [7] for the experimental protocol and full results. Log data showed that all subjects were able to setup the stimulator outside of the laboratory environment without technical support. Automated setup time averaged 9 minutes, plus 5 minutes to don the equipment. Despite the challenges associated with unsupervised use, including the need for users to correctly align the ShefStim, placed in a pocket of a leg-mounted sleeve, and the remote on their shoe, speed and foot response with ShefStim, evaluated in a gait laboratory at the end of the 2 week period showed results comparable with the previous study by Heller [6]. The study demonstrated, for the first time, that array-based automated setup FES system for foot-drop can be successfully used without technical support outside of the laboratory environment.

6. DISCUSSION AND CONCLUSIONS

The work presented in this paper describes the evolution of the ShefStim design from initial concept in 2003 to evaluation of the CE-marked system by people with stroke in their own homes. A number of issues are worth discussing before conclusions are drawn on the revisions needed to be made to the design.

In section 2 we introduced two models used for the identification of electrode array geometry. The activation area is similar in concept to the measure used by Kuhn et al [29], who based their measure of selectivity on an activation volume. As our model assumes the nerve depth to be known (at 10mm in this case), the cross-sectional area of the stimulation pool at 10mm is the measure of the selectivity of stimulation. The larger this area is, the less selective the array stimulation is (i.e. the worse the ability to selectively stimulate neural structures). There are a number of limitations with the model, including the prismatic geometry and assumptions regarding the nerve depth, which undoubtedly varies significantly between subjects. Further, in contrast to Kuhn et al. [29], we did not experimentally validate the model. However, the array geometry and hydrogel properties derived using the model proved to be similar to the array design successfully used in the final take-home study.

Although the ShefStim stimulator has been CE marked, there remain a small number of barriers to clinical uptake. By far the most significant of these is that sweat ingress to the hydrogel electrode interface layer leads to a significant drop in its resistivity and an inevitable decay in focality and stimulation efficiency with wear time [30].These effects limit use of a given array to around one day of continuous wear. In the final study of ShefStim [7] we were able to provide participants with sufficient arrays to use a fresh hydrogel layer each day. However, the cost of such an approach is high and not a realistic solution in clinical practice. To address this we are exploring alternative solutions, including the use of dry electrodes (see, for example [31]). Other minor product development issues remain, including the development of an improved garment to house the stimulator on the leg and minor improvements to the firmware, all of which may be easily resolved. We believe that these improvements would lead to a significant reduction in setup time, as recorded in our final (unsupervised) study [7].

In conclusion, this paper has described the complete design, development and evaluation of an array-based FES system with automated setup for the correction of drop foot. The results demonstrate that an array-based stimulator with automated setup is a viable alternative to a conventional surface stimulator, or an implanted stimulator, for the correction of drop foot. Longer term clinical exploitation of ShefStim is dependent on identifying an acceptable alternative to the high-resistivity hydrogel electrode-skin interface layer.

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A review of the design and clinical evaluation of the ShefStim array-based functional electrical stimulation system.

Laurence P. Kenney*[1]. Ben W. Heller[2], Anthony T. Barker [3], Mark L. Reeves[3], Jamie Healey[3], Timothy R. Good[3],Glen Cooper[1,4], Ning Sha[1], Sarah Prenton[1,5], Anmin Liu[1], David Howard[1]

[1]Centre for Health Sciences Research, University of Salford, Salford M6 6PU, U.K.

[2] Centre for Sports Engineering Research, Sheffield Hallam University, Sheffield S1 1WB,U.K.

[3] Department of Medical Physics and Clinical Engineering, Royal Hallamshire Hospital, Sheffield S10 2JF U.K.

[4] School of Mechanical, Aerospace and Civil Engineering, University of Manchester, Manchester, M13 9PL, U.K.

[5] Division of Health and Rehabilitation, University of Huddersfield, Huddersfield HD1 3DH, U/K.

* Corresponding author: email - l.p.j.kenney@salford.ac.uk; tel 0161295 2289

Abstract: Functional electrical stimulation has been shown to be a safe and effective means of correcting foot drop of central neurological origin. Current surface-based devices typically consist of a single channel stimulator, a sensor for determining gait phase and a cuff, within which is housed the anode and cathode. The cuff-mounted electrode design reduces the likelihood of large errors in electrode placement, but the user is still fully responsible for selecting the correct stimulation level each time the system is donned. ~~Over recent years r~~Researchers have investigated different approaches to automating aspects of setup and/or use, including recent promising work based on iterative learning techniques. This paper reports on the design and clinical evaluation of an electrode array-based FES system for the correction of drop foot, ShefStim. The paper reviews the design process from proof of concept lab-based study, through modelling of the array geometry and interface layer to array search algorithm development. Finally, the paper summarises two clinical studies involving patients with drop foot. The results suggest that the ShefStim system with automated setup produces results which are comparable with clinician setup of conventional systems. Further, the final study demonstrated that patients can use the system without clinical supervision. ~~Although w~~When used unsupervised, setup time was ~~found to be~~ 14 minutes (~~relatively long (~~9 minutes for automated search plus 5 minutes for donning the equipment), although this figure ~~cannot be directly compared with other systems, which have reported setup time from purely lab-based~~could be reduced ~~studies~~significantly with relatively minor changes to the design.~~.~~

1. INTRODUCTION

Functional electrical stimulation has been shown to be a safe and effective means of correcting foot drop of central neurological origin ~~[1]~~[1-3]. Surface-based devices typically stimulate via a cathode placed over the common peroneal nerve ~~close~~ immediately distal to where it bifurcates into the deep and superficial branches, and an anode placed over tibialis anterior. Appropriate levels of stimulation delivered via accurately placed electrodes should result in suitably weighted recruitment of the two nerve branches, leading to a useful and safe foot response during the swing phase of walking (dorsiflexion with a small degree of eversion). However, in certain individuals even very small electrode positioning errors can lead to a poor foot response. Indeed, a 1999 survey of users of drop foot stimulators ~~over~~ reported over 40% of respondents ~~reported~~ finding electrode positioning problematic [4] ~~[2]~~. ~~Modern~~ Some current systems ~~(the reader is referred to~~ [5] ~~for a recent review paper),~~ such as the WalkAide (Innovative Neurotronics Inc., Austin, Texas, USA) embed electrodes in a cuff, worn below the knee (the reader is referred to [5] for a recent review of current systems). ~~,~~ Such an approach ~~which~~ greatly reduces the likelihood of large errors in electrode placement, but the user is still fully responsible for selecting the correct stimulation level each time the system is donned. ~~The reader is referred to a recent review of drop foot stimulator technologies for an overview of commercial and other systems~~ [5]. Interestingly, despite improvements in both stimulator designs and patient education, two recent studies demonstrated that when patients set up their stimulators without clinician support, the resultant foot response is often less than optimal ~~[3,4]~~[6, 7].

One approach to the challenge of stimulator setup is to implant the electrodes on the nerve(s), thereby removing the electrode placement problem from the user ~~[5,6]~~[8, 9]. However, an invasive approach carries risks and the implantable devices and surgical costs remain relatively expensive. As a result, a number of groups have been investigating the possibility of automating the surface-based drop foot setup process through ~~using~~ a two-channel stimulation approach to software steering of the foot [10-12]~~[7,8]~~, or electrode array-based approaches

[9-12][13-18]. Both approaches aim to de-skill the physical electrode placement and setup process, which in turn may lead to improved, and more consistent foot responses. Both approaches relyfeature on a methoda for 'opening up the search setup space' which can be automatically searched, either through replacing single electrode(s) with one or two arrays of discrete electrodes, or by allowing modulation of manipulating pulse waveform. Both approaches also use feedback omeasurement ofn foot poseorientation, usually derived from foot-worn inertial sensors, to guide the search.

The replaces an electrode array replaces the single stimulating electrode used with conventional surface FES. Each electrode in the array can be independently activated and used to deliver stimulation to localized areas. Simultaneous activation of several neighbouring electrodes can be used to form a virtual stimulating electrode or virtual electrode (VE). Such an approach opens up the potential of software selection of the size, shape and position of the virtual electrode without physical re-location of the electrode array and hence the automation of the (virtual) electrode positioning process Elsaify proposed an automatic array element search algorithm, but using array elements with separate gel layers (a matrix of small single electrodes) were used [14]. More recently, Valtin [17] demonstrated an array search algorithm that takes roughly two minutes, using two flexible PCB electrode arrays (one over the nerve and one over Tibialis Anterior), each interfaced with a continuous, high-resistivity hydrogel layer. However, in contrast to the work presented here, only preliminary results with a healthy subject were presented. In the most recent work, Seel reported on a system using a foot-mounted inertial sensor to adjust the steering based on realtime measurements of the foot orientation[11]. The system uses only two electrodes and, in laboratory studies with stroke participants, demonstrates convergence on a suitable foot response within one or two strides. However, studies of the system outside of the laboratory setting have yet to be published.

In this paper we expand on a recent conference paper [13][19] to report on the design, development and demonstration of a system for automated setup of drop foot FES (ShefStim). The paper extends the work presented in the conference paper by presenting the model used to define the initial a detailed description of the electrode array geometry design problem (section 2) and provides discussion of the merits and limitations of ShefStim compared with alternative systems. by xxx.

Following a review of the design and development process, results from world first demonstrations of an array-based system for drop foot in clinical groups, first in the laboratory and then unsupervised in community settings, are summarised. Finally, the plans for future work are discussed.The ShefStim design concept was proposed by Heller in 2003 [14][20]. In this approach an electrode array replaces the single stimulating electrode used with conventional surface FES. Each electrode in the array can be independently activated and used to deliver stimulation to localized areas. Simultaneous activation of several neighbouring electrodes can be used to form a virtual stimulating electrode or virtual electrode (VE). Such an approach opens up the potential of software selection of the size, shape and position of the virtual electrode without physical re-location of the electrode array and hence the automation of the (virtual) electrode positioning process.

For this study Tthe Departmentt. of Medical Physics at Sheffield Teaching Hospitals initially developed a 'proof-of-concept' multi-electrode stimulator, which. This device could simultaneously stimulate any manually-selected subset out of a conveniently sized, 8 by 8 rectangular array of metal electrodes. The subset of activated electrodes is termed a virtual electrode (VE). In order to develop this concept into a clinically usable system for automated setup a series of design problems needed to be solved. These are addressed in turn, below.The first problem was the electrode array design; the second problem was the development of an array search algorithm. The remaining part of the paper summarises the results from two studies of the ShefStim involving people with drop foot of central neurological origin.

2. SHEFSTIM DESIGN CONCEPT

The ShefStim design concept was proposed by Heller in 2003 [14]. In this approach an electrode array replaces the single stimulating electrode used with conventional surface FES. Each electrode in the array can be independently activated and used to deliver stimulation to localized areas. Simultaneous activation of several neighbouring electrodes can be used to form a virtual stimulating electrode or virtual electrode (VE). Such an approach opens up the potential of software selection of the size, shape and position of the virtual electrode without physical re-location of the electrode array and hence the automation of the (virtual) electrode positioning process.

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~~usable system for automated setup a series of design problems needed to be solved. These are addressed in turn, below.~~

~~3~~2. DESIGN OF THE ELECTRODE ARRAY

For clinical applications a moderately electrically conductive hydrogel interface between the electrodes and skin provides ~~increased comfort,~~the benefits of hydration of, and adhesion to, the skin. However, in array applications a continuous hydrogel layer also introduces the issue of spatial selectivity loss due to transverse currents in the hydrogel. Spatial selectivity is defined as the ability to activate discrete groups of nerve fibres in a localised region without stimulating nerve fibres in neighbouringregions.

In order to achieve a satisfactory degree of spatial selectivity, it was necessary to identify an appropriate electrode geometry and interface layer properties. Two finite- element models were therefore developed to investigate the effects of electrode geometry and hydrogel layer properties on spatial selectivity, characterised in our model by the activation area (see below). ~~:~~ Model 1 was developed to explore the effects of hydrogel resistivity and electrode size on ~~spatial selectivity~~activation area under a single cathode electrode and; Model 2 extended Model 1 through the addition of ~~a number of~~ electrodes surrounding the cathode, to allow investigation of ~~spatial selectivity~~activation area under a multi-electrode array. The results of the second model, together with practical constraints imposed by the stimulator, led to the array geometry and interface layer properties used in part ~~4~~3 of this paper.

Model 1

Figure 1 shows ~~A~~the 3D finite ~~-~~element model, ~~was~~ developed using ANSYS Multiphysics (Version 10.0, Ansys, Inc, Canonsburg, PA, USA) to predict the effects of electrode geometry and hydrogel properties on electric field distribution in the underlying tissue ~~[15]~~[21]. The model represent~~sed~~ a cathode, an anode, a hydrogel layer, skin, fat and muscle. The skin, fat and muscle were modelled as flat, extended layers, whose thicknesses were based on their anatomical dimensions. As bone has much higher resistivity than the other media, it was assumed to be non-conductive volume underlying the muscle, and hence was represented as the lower boundary of the model. Structures of smaller dimension, such as hair follicles or blood vessels, were not explicitly modelled, as their influence on stimulation at the depth of the motor nerve branches could be considered negligible.

Appropriate electrical conductivity properties were assigned to the elements, based on values from Duck [22] (Table 1). ~~Time was not represented, as the electrical properties were assumed to be dominated by resistance.~~ Although the skin's capacitance cannot normally be neglected, the skin in the model was assumed to be hydrated due to intimate contact with the hydrogel layer. Hence capacitive effects were not included in this model.

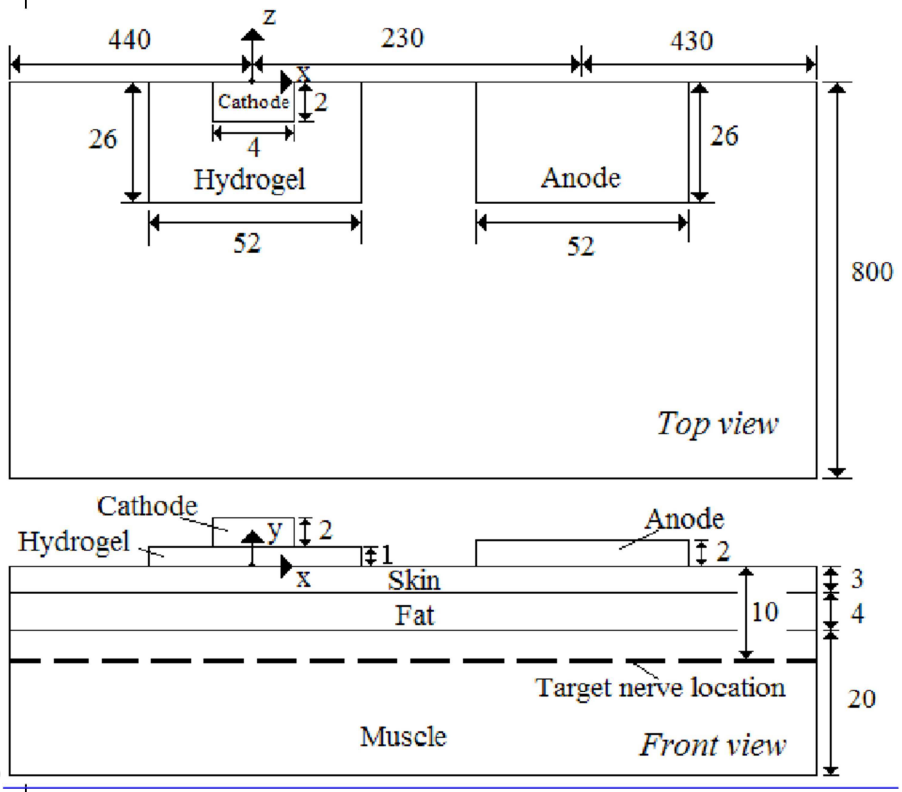

Figure 1: Schematic of the geometry of the selectivity FE model (not to scale) (dimensions in mm)

Table 1: Model parameters

Biological tissues and materials	Resistivity (Ωm)
Bone	7×10^{4}
Muscle	2 in X and Z directions
	4 in Y direction
Fat	62.5
Skin (hydrated)	833
Hydrogel	Model variable
Cathode and Anode	1.5×10^{-8}

The calculation of whether a point in the model was deemed to be stimulated was based on the stimulation function ~~[16]~~[23]. To explore spatial selectivity we first defined a stimulus pool to be a volume over which the value of the stimulation function exceeds a threshold at which action potentials in a nerve fibre are generated. The maximum~~al~~ stimulation function always appears in the stimulus pool centre, just underneath the cathode, and the amplitude of the stimulation function decreases from the centre to the edge of the stimulus pool. Although the value of the maximum stimulation function varies between models, it can always be scaled to the same value by changing the input current, and this scaling does not change the shape or size of the stimulus pool. Contours may be defined which connect points in the model with identical stimulation function values (expressed as a percentage of the maximum) and the 50% contour was selected to represent the boundary of the stimulus pool for the results presented here. The 50% contour choice was somewhat arbitrary, but avoided problems which would be associated with choice of a contour near 100% or 0% of maximum stimulation function (all contours converge to a point at 100% of maximum stimulation function and contours enclose infinitely large areas at 0%) ~~For brevity in the results presented in this paper we consider only a stimulus pool representing 50% of the maximum stimulation function (readers are referred to [17] for more details).~~ As the electrical properties of the tissue were uniform, the current density distribution was symmetric along the plane normal to the skin surface and along the centres of the cathode and the anode. This symmetry allowed a study to be performed on a half model. To represent the location of the nerve, we defined a plane representing the anatomical depth of the target nerve (10mm). The intersection of the stimulus pool with the plane defined an area; the smaller the area, the more focused is the stimulation and thus the better the spatial selectivity. Therefore, the area of the stimulus contour associated with 50% of maximal stimulation was used as the metric of spatial selectivity.

To explore the combined effect of hydrogel resistivity and electrode size on selectivity, a series of simulations were run with square electrodes from infinitely small (a point) to 16mm×16mm with a range of interface layers. The first simulation considered the no interface layer case; subsequent simulations varied the 1mm thick hydrogel layer resistivity from 20Ωm to 1000Ωm. The results are shown in ~~f~~Figure 1.

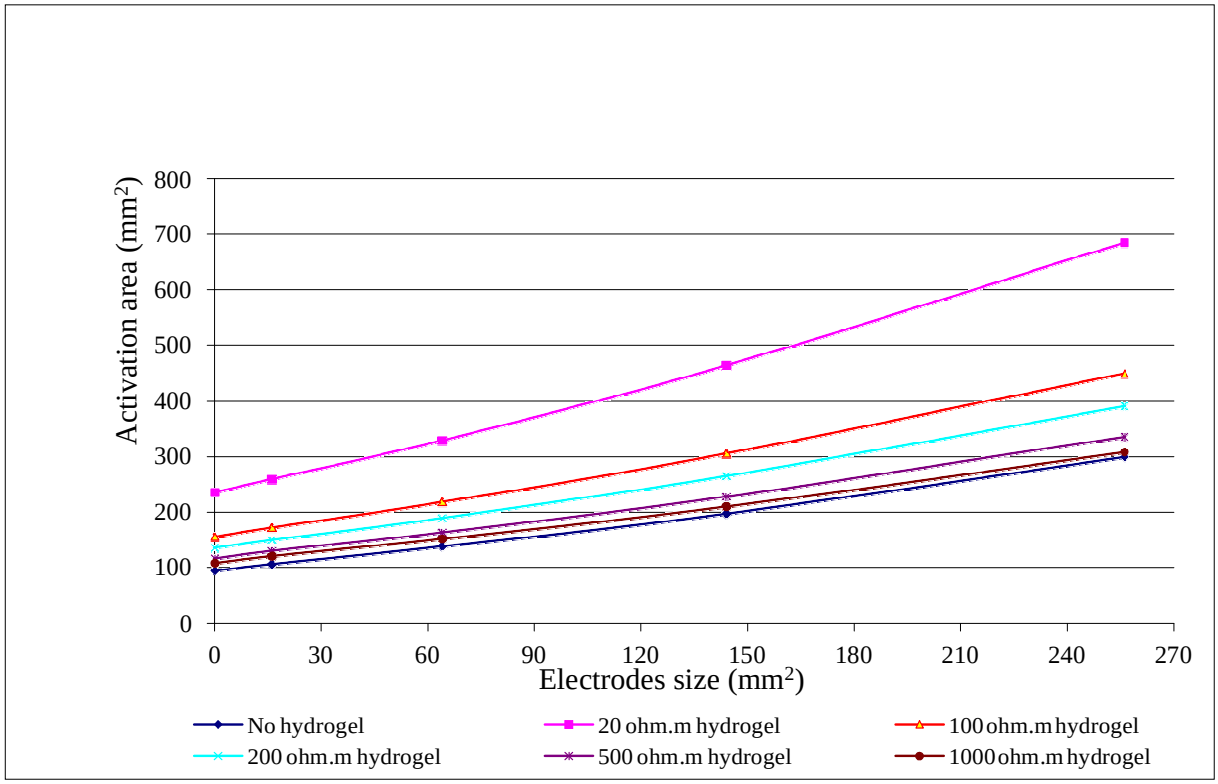

Figure ~~2~~2~~1~~: The effects of electrode size on ~~spatial~~ activation area~~selectivity~~ for a range of hydrogel resistivities.

Figure 1 shows that there is a minimum limit to activation area of approximately 100mm^2 at 10mm depth, and that spatial selectivity becomes poorer (~~selectivity coefficient~~activation area increases) with increasing size of electrode and decreasing resistivity. When the resistivity reaches 500Ωm or ~~more~~greater, the spatial selectivity is similar to that of the model without the hydrogel sheet.

Model 2

Model 1 had shown that the introduction of a 1 mm hydrogel interface layer did not significantly degrade selectivity providing the hydrogel resistivity was at least 500Ωm. However, the model did not account for the presence of neighbouring electrodes which would surround an electrode in the array. The presence of these electrodes ~~may~~ will lead to a decrease in selectivity compared with the single electrode condition, as current can flow from activated electrodes across inter-electrode gaps and into adjacent non-activated electrodes. These effects would be modulated by the size of the inter-electrode gap and hydrogel properties. Therefore, Model 1 was used as the basis for a new model (Model 2) to enable the electrode array design to be finalised.

It was assumed that the magnitude of reduction in selectivity due to current passing across the inter-electrode gaps would be dominated by electrodes immediately surrounding any given electrode in the array. Hence, Model 1 was extended to include eight more electrodes surrounding the original cathode electrode (Ffigure 2)[1]. The interface between the electrode array and the skin was a sheet of hydrogel. The initial geometry of Model 2 ~~were~~ was informed by previous pilot experimental work carried out as part of a Master's research project, demonstrating the viability of using a 70mm x70mm electrode array consisting of 64 electrodes (arranged in an 8x8 format)[24].

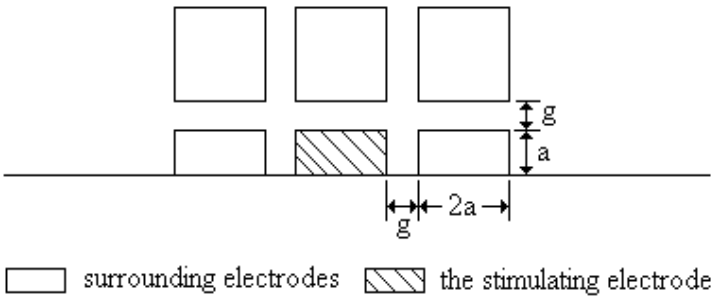

Figure ~~33~~2: Model 2. The electrode gap (g) is the edge-to-edge distance between any two neighbouring electrodes in the array; 2a is the dimension of each square electrode

As the feasibility work suggested maintaining an overall array size of approximately 70mm x 70mm , we fixed the centre-to-centre spacing of electrodes in the model to be 9mm (2a + g =9, see fFigure 2). Five different gap sizes were modelled (Ttable 1) and for each of these, four commercial hydrogel sheets were modelled (tTable 2). The set of hydrogel properties were informed not only by the results of Model 1, but also by earlier experimental work ~~[18,19]~~ [25, 26] which provided further evidence to support the use of a thin, high-resistivity hydrogel layer between the electrode and skin.

Table ~~22~~1: Electrode gap and size evaluated in the FE model, and resultant overall electrode arraysize

Electrode gap (mm)	Electrode size (mm)	Electrode array size (mm)
1	8×8	71×71
2	7×7	70×70
3	6×6	69×69
4	5×5	68×68
5	4×4	67×67

[1] Note, as per Model 1, a half model was developed to take advantage of symmetry.

Table 3~~3~~2: Hydrogel materials represented in the model. Note that the different sheet thicknesses modelled were chosen to represent the sheet thicknesses provided by the manufacturers.

Hydrogel (abbreviation)	Approx thickness (mm)	Resisitivity at 1.67kHz (Ωm)
AG703, Axelgaard manufacture Co., Ltd. Fallbrook, CA. USA (Hydrogel 703)	0.9	55
AG803, Axelgaard manufacture Co., Ltd. Fallbrook, CA. USA (Hydrogel 803)	0.9	206
SRBZAB-05SB, Sekisui Plastics, Co., Ltd. Tokyo, Japan (Hydrogel ST)	0.5	1363
AG, AG3AM03M-P10W05, Sekisui Plastics, Co., Ltd. Tokyo, Japan (Hydrogel AG)	0.3	25185

In order to quantify the effects of the surrounding electrodes on selectivity, two versions of each model were run. In the first version, the surrounding electrodes were not represented and in the second, the surrounding electrodes were represented. The selectivity loss resulting from the introduction of surrounding electrodes was quantified by a selectivity loss ratio, defined in equation 1.

$$Selectivity\_loss\_ratio = \frac{A_2 - A_1}{A_1} \times 100\% \qquad (1)$$

Where, A_1 is the ~~selectivity coefficient~~activation area of the model without surrounding electrode and A_2 is the ~~selectivity coefficient~~activation area of the model with surrounding electrode

Figure 3 shows the selectivity loss ratio due to the surrounding electrodes calculated for each combination of hydrogel interface layer and inter-electrode gap.

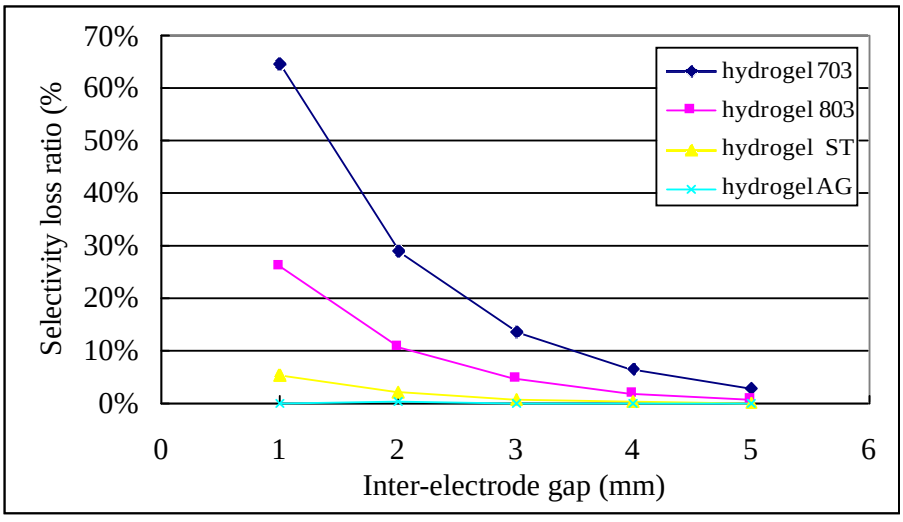

Figure 3: Selectivity loss ratios with different hydrogels

The results suggested that for hydrogels ST and AG an electrode gap between 1mm and 5mm will result in an acceptably low selectivity loss (defined as less than 10%) in the presence of the surrounding electrodes. From a manufacturing perspective, an inter-electrode gap of less than 2mm would make it very difficult to route the tracks between electrodes, so a 2mm inter-electrode gap was chosen. A final practical test demonstrated that our

stimulator (200V drive voltage) could not drive the specified 8mA per channel when using the more resistive of the two most promising materials (hydrogel AG) and hence hydrogel ST was selected.

~~4~~3. FEASIBILITY STUDY OF ELECTRODE ARRAY SEARCH STRATEGY

Section 3 described the design of an 8 x 8 electrode array interfaced to the skin via a thin high-resistivity hydrogel layer. The next design problem was the development of a quick, reliable method of searching the set of all possible stimulation electrodes to find the optimal virtual electrode. ~~Prior to this work, Elsaify et al [10] had already shown promising results using foot twitch response, the response of the muscle to a single stimulation pulse, in their search of an electrode array.~~ In this section we report on two methods for searching the array used to identify appropriate virtual electrodes and their associated stimulation levels, which extended the work of Elsaify et al. ~~[10]~~ [14]. In the first part of the work, we apply a slowly ramped stimulation through each virtual electrode while continuously monitoring the orientation of the foot relative to the leg. These data allow identification of electrode sets that, when appropriately stimulated, result in acceptable foot movement. The ramped stimulation results were used to investigate whether it is possible to reduce the search space through prediction of the location of the best subset of these electrodes based only on the response of the foot to short bursts of stimulation (twitch stimulation). We investigated use of a cost function to rank the response to short bursts of stimulation and examine whether this ranking may be used to isolate smaller groups of electrodes that contain one or all of the best subset of electrodes identified in the slow ramped stimulation search.

For brevity, here we only report on the search for appropriate single VEs. Additional work to identify suitable pairs of VEs is reported elsewhere ~~[17]~~[27]. Ethical approval for the study was granted by the University of Salford's Research Governance and Ethics committee (RGE06/102). Twelve healthy subjects were recruited from within the University and a full set of results were obtained for ten (9 male) subjects (median 30 years)[2].

The stimulation system consisted of a constant current portable 64 channel stimulator designed and built by the Medical Engineering section of Sheffield Teaching Hospitals NHS Foundation Trust (size: 155 mm × 95 mm × 33 mm), an.8×8 electrode array, described in section ~~3~~2 and a 50x50 mm square conventional hydrogel electrode (PALS® Platinum electrode, Axelgaard Manufacturing Co. Ltd.), The charge-balanced asymmetrical biphasic stimulus pulses were software controllable via a graphical user interface, with the pulse width fixed at 300 μs, and the frequency at 35 Hz. Stimulation intensity through each electrode was software controlled and measured by an analogue to digital converter built-in to the stimulator itself. During the experiment, groups of 2×2 electrodes were activated simultaneously (the minimum number required to elicit adequate contractions, providing a total current of up to 32 mA), and act as a virtual electrode.

A 5-camera Qualisys motion capture system (Proreflex, Qualisys AB, Sweden) was used to record foot movement at 100Hz and the motion data were transferred to and simultaneously analysed in Visual3D (Visual3D™, C-Motion Inc, USA). Hence the foot movement was captured, and ankle angles in sagittal, coronal and transverse planes were displayed in real-time. Synchronisation between the stimulator and the motion capture system was achieved using a data acquisition device via the stimulator control program. An electrically-isolated button was included to allow the user to stop stimulation at any stage in the experiment.

The experiment started with measurement of the neutral foot orientation for the subject while standing upright. He/she was then asked to sit in a chair and their right lower leg was strapped in the brackets to keep the shank in a consistent pose throughout. The stimulator and electrodes were then donned. The subject was then asked to maintain their sitting posture and relax the foot in a natural~~ly relaxed~~ (dropped) position throughout the experiments. As the analysis of data did not dictate the order in which the tests were conducted, the foot twitch experiment was conducted first to reduce fatigue. However, here they are explained in reverse order for clarity.

Prior to beginning the slow ramped stimulation experiment a user-defined maximal current was identified. We assumed that sensation would be most acute over bony prominences and hence at the start of the experiment increased stimulation over these sites until a user-defined maximum was reached and the value noted. Next, current through each VE in turn was ramped from zero to the user-defined maximal current over 10 seconds. The twitch stimulation part of the experiment involved six different bursts of stimulation (1 and 4 pulses/burst, at 3 different levels of stimulation (16, 24 and 32mA) being applied in turn through each of the 49 VEs. Ankle angles together with time-synchronised current data for each of the different electrodes were recorded for both experiments.

The target for foot orientation was defined as dorsiflexion at or above neutral, and inversion/eversion within -1SD of the previously reported healthy subject mean foot orientation at heel strike ~~[20]~~[28]. All VEs which,

[2] Two subjects could only tolerate 12.8 mA and 16 mA respectively, which was insufficient to produce target dorsiflexion when applied through any of the virtual electrodes electrodes during the slowly ramped stimulation

when stimulated over the 10 second period, resulted in the foot reaching the target foot orientation were identified and the set of electrodes satisfying these criteria were labelled Set A.

~~As can be seen from figure 4, w~~When sitting relaxed in the chair the subject's foot was typically plantarflexed and inverted, compared with its neutral position. Hence, it was assumed that a twitch response that moved the foot towards dorsiflexion and eversion was desirable. A cost function was defined which used the maximum value of dorsiflexion and inversion angles observed during the twitch response

$$Cost = -2 \cdot Dorsi + Inver$$

Where *Dorsi* is the peak dorsiflexion angle (in degrees) measured during stimulation relative to the relaxed position. Dorsiflexion is positive and plantarflexion is negative. *Inver* is the peak inversion angle (in degrees) measured during stimulation relative to the relaxed position. Inversion is positive and eversion is negative. A weighting factor of 2 was applied to the dorsiflexion angle to reflect its relative importance compared to inversion/eversion.

This cost function was used to rank the foot responses to each of the different twitch stimulation bursts applied to each of the VEs. The cost function, which was applied to the positive peak value of dorsiflexion and inversion, maximizes dorsiflexion and minimizes inversion. The VE with the lowest cost – was ranked 1st and each of the remaining 48 VEs were then assigned a rank based on their cost. To identify how well the cost function could be used to predict membership of Set A (the set of VEs which, when stimulated resulted in the foot reaching the target foot orientation) two metrics were derived. First, how far down the ranking it was necessary to go to include all of the members of Set A, defined as Rank_all ; second, how far down the ranking it was necessary to go to include any member of Set A, defined as Rank_any.

In 9 out of the 10 subjects to complete the slow ramped stimulation study, at least 1 VE was identified which, when stimulated, produced the target foot response. The maximum number of acceptable VEs found for any individual subject was 4 (out of 49) and the minimum was 0.

The results of the twitch stimulation analysis for the 9 subjects are shown in tTable ~~3~~4. Note that stimulation at 16mA produced no or minimal response.

Table ~~4~~3: Rank_any and Rank_all for different twitch stimuli

	1 pulse @ 32mA	4 pulses @32mA	1 pulse @ 24mA	4 pulses @ 24mA
Rank_all Median (range)	5 (1-33)	4 (1-41)	11 (2-40)	8 (2-41)
Rank_any Median (range)	2 (1-19)	3 (1-15)	6 (1-15)	4 (1-29)

Although there was significant inter-subject variability, the results showed that in most cases by using a cost function to rank responses to twitch stimulation it was possible to identify a much smaller set of electrodes containing one, or all of Set A. For example, using a 4 pulse burst of stimulation at 32mA, a suitable electrode was identified in all cases within the first 15 of the responses ranked according to the slow ramped stimulation results. The data suggested therefore there could be advantage to using a twitch stimulation consisting of multiple pulses at high currents and a two stage search strategy was worth further investigation.

~~4~~5. FIRST LAB-BASED DEMONSTRATION OF SHEFSTIM

Further development work on both the stimulator and the search algorithm was carried out over the period 2009-11 resulting in the first demonstration of an array-based FES system with automated setup for the correction of drop foot. The study is reported in detail elsewhere – [6]~~[21]~~, so in this paper, we focus on the improvements

made to the stimulator hardware and implementation of the search algorithm, and provide an overview of the laboratory-based study involving subjects with drop foot.

~~5.1~~4.1 Stimulator

Further stimulator development led to a new design weighing 200 g with a volume of 211cc (130 mm x 65 mm × 25 mm). During automated setup the stimulator was controlled via an isolated serial link by a program running on an external computer, the participant's leg was held in a brace, with the knee extended and foot movement was measured using an electromagnetic position and orientation sensor (Patriot, Polhemus Inc, Vermont) (~~figure~~ Figure 4). For walking trials the setup parameters were downloaded and the stimulator disconnected from the computer, enabling it to function as a standalone drop foot stimulator being triggered using a foot switch.

~~5.2~~4.2 ~~–~~ ~~———~~Search algorithm

The work described in section 4 had been based on the use of a 2 x 2 VE. Following further pilot work it was found that a 4 x 4 VE still provided satisfactory resolution over foot response, but reduced sensation compared to a 2x2 arrangement and increased robustness to tissue movement during gait. The move to a 4 x 4 VE also served to reduce the array search space by a factor of ~2, compared with the original approach. ~~-~~(25 VEs to be searched rather than 49).

As described in section 4, we had already demonstrated the potential to use the response of the foot to short bursts of stimulation as a means of homing in on promising VEs. However, further work was needed to develop a clinically usable search algorithm. In the final system a three phase search strategy was implemented.

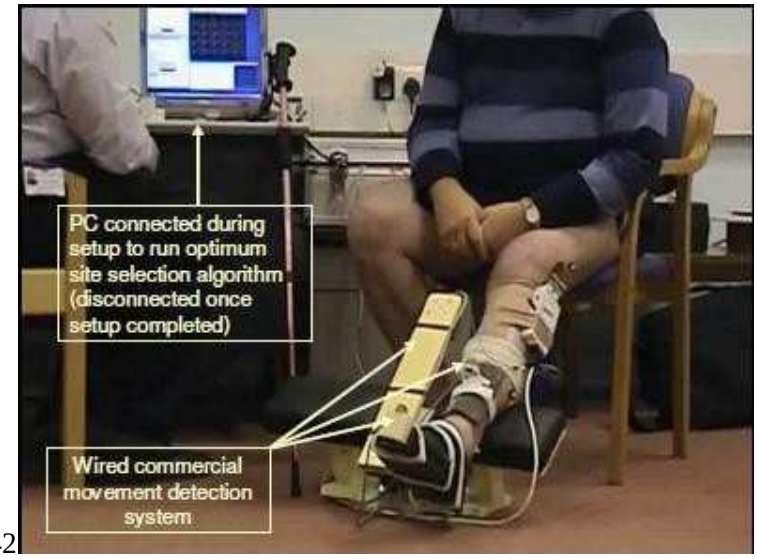

Figure 4: Setup of ShefStim

In phase one the level of stimulation at which the foot first responds is determined. Short bursts of stimulation are applied to each of the 25 virtual electrodes, a process taking about 2~~1~~.5 seconds. The amplitude is automatically titrated until the threshold for repeatable foot movement, irrespective of direction, is determined. This threshold amplitude is used as the base for searches in subsequent phases. In phase two (twitch response), the algorithm searches for candidate stimulation sites, using twitches rather than tetanic contractions to speed-up search time and reduce sensation. Four pulses of stimulation are applied to each electrode in turn. The foot response is monitored for short periods after each stimulation, if there is a detectable response it is added to the list of candidate sites. Again the current is automatically adjusted until between 4 and 12 sites are found or the maximum current limit is reached. These sites are ranked in order of sensitivity using a cost function based on the angular displacement. The first two stages therefore allowed for rapid identification of the most sensitive VEs.

In phase three (tetanic testing), up to 8 of the sites identified in phase two were tested in rank order with an increasing stimulation intensity. Stimulation began at the level identified in phase two and incremented in steps until one of the following conditions were met: either plantarflexion was corrected to neutral dorsiflexion~~zero dorsiflexion~~; or current reaching twice the starting value; or 150% of starting value with no movement detected; or motion saturation was detected. The algorithm included safeguards if unexpected movements occurred,

enabling the system to temporarily wait if a leg spasm was detected or to pause the search process if repeated non-stimulated leg movement was detected. Once all the candidate sites were assessed, they were given a score based on a three-part cost function, designed to penalise solutions resulting in plantarflexion, excessive inversion or eversion, and high current [21] If at any point during this phase the user found a site uncomfortable the clinician was able to skip that site. Once the tetanic testing phase was complete the ~~. The user then stood and the~~ first-ranked site was activated and, after initial testing of the site while sitting, the user then walked using the stimulator: If the foot response or stimulation sensation was not satisfactory it could be manually changed to an alternative site ~~if the response was not satisfactory it could be manually changed to an alternative from~~ the ranking list. Finally, ~~overall~~ stimulus pulse width could be adjusted by the user, if necessary, to fine-tune the magnitude of foot response.

~~5.3~~4.3 ~~L~~aboratory-based clinical study

Ten participants with drop foot due to stroke (ages 53–71 years) and 11 due to MS (ages 40–80 years) were recruited to test the system. Each participant walked twice over 10 m under each of four conditions; a) ~~1~~. using their own stimulator setup by themselves; b ~~2~~) using their own stimulator set up by a clinician, c) ~~3~~. using ShefStim with automated setup, and d) ~~4~~. no stimulation. Outcome measures were walking speed, foot angle at initial contact and the Borg Rating of Perceived Exertion. As described in Heller et al [21][6], the results showed that when setup using ShefStim subjects' walking speed, dorsiflexion and frontal plane ankle angle at initial contact were all broadly comparable with clinician setup and, apart from walking speed, better than patient setup. The study demonstrated for the first time that fully automated setup of an array stimulator is feasible in a population with drop foot of central origin.

~~6~~5. FIRST TAKE-HOME STUDY OF SHEFSTIM

A final iteration of the stimulator design resulted in the CE- marked ShefStim system shown below.

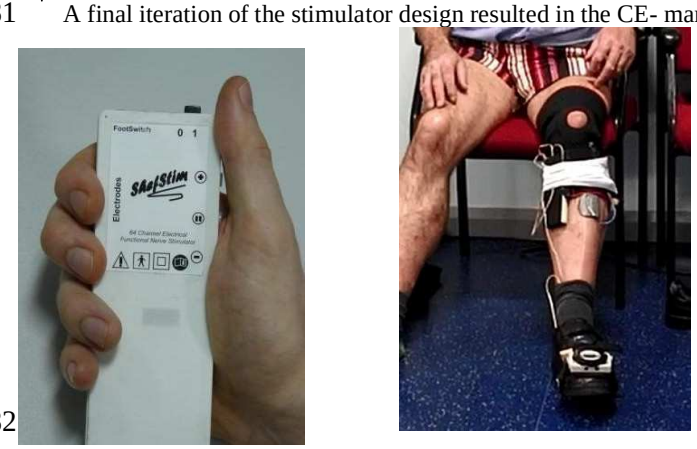

Figure 5: ShefStim stimulator (left) being used by a subject during setup (right)

The ShefStim stimulator measures 142mm x 50mm x 14mm (volume 99cc) and weighs 125 g (including batteries). In contrast to the earlier versions of the system, it includes a combined foot angle sensor and remote control device, and setup does not involve holding the leg in a brace (F~~f~~igure 5). The remote control device is placed on the foot during set up and wirelessly provides triaxial accelerometer inputs to the search algorithm described in the previous section. Users are provided with an attachment, based on an iPod holder, which could be slipped onto the shoe prior to setup. Guidance is provided to the users on the correct mounting of the remote control on the shoe and the importance of aligning the ShefStim box with the long axis of the leg. Once setup is completed, the foot angle sensor device serves as a remote control with which the user can pause stimulation, adjust intensity or receive audible error messages. Stimulation timing during gait is controlled using a conventional footswitch, located under the heel of the shoe. Integrating the foot angle sensor into the system enabled the stimulator to carry out the automated setup routine without requiring input from any external sensors or connection to a PC, making it suitable for use in the home environment.

In the final clinical study seven subjects with drop foot (3 subjects with MS, 3 with stroke and 1 with traumatic brain injury) used ShefStim over a 2 week period. The reader is referred to ~~[22]~~[7] for the experimental protocol

and full results. Log data showed that all subjects were able to setup the stimulator outside of the laboratory environment without technical support. Automated setup time – averaged 9 minutes, plus 5 minutes to don the equipment. Despite the challenges associated with unsupervised use, including the need for users to correctly align the ShefStim, placed in a pocket of a leg-mounted sleeve, and the remote on their shoe, ~~S~~speed and foot response with ~~and without~~ ShefStim, ~~were~~ evaluated in a gait laboratory at the end of the 2 week period ~~and~~ showed results ~~were~~ comparable with the previous study by Heller ~~[21]~~[6]. ~~In addition, t~~The study demonstrated, for the first time, that array-based automated setup FES system for foot-drop can be successfully used without technical support outside of the laboratory environment.

~~7~~6. DISCUSSION AND CONCLUSIONS

The work presented in this paper describes the evolution of the ShefStim design from initial concept in 2003 to evaluation of the CE-marked system by people with stroke in their own homes. A number of issues are worth discussing before conclusions are drawn on the revisions needed to be made to the design.

In section 2 we introduced two models used for the identification of electrode array geometry. The activation area is similar in concept to the measure used by Kuhn et al [29], who based their measure of selectivity on an activation volume. As our model assumes the nerve depth to be known (at 10mm in this case), the cross-sectional area of the stimulation pool at 10mm is the measure of the selectivity of stimulation. The larger this area is, the less selective the array stimulation is (i.e. the worse the ability to selectively stimulate neural structures).~~).~~ ~~There~~ There are a number of limitations with the model, including the prismatic geometry and assumptions regarding the nerve depth, which undoubtedly varies significantly between subjects. Further, in contrast to Kuhn et al. [29], we did not experimentally validate the model. However, the array geometry and hydrogel properties derived using the model proved to be similar to the array design successfully used in the final take-home study.~~Our model was not as detailed as the Kuhn model; for example, the model geometry was a greatly simplified representation of the true anatomy, and we did not investigate the effects of modelled nerve depth on selectivity.~~

Although the ShefStim stimulator has been CE marked, there remain a small number of barriers to clinical uptake. By far the most significant of these is that sweat ingress to the hydrogel electrode interface layer leads to a significant drop in its resistivity and an inevitable decay in focality and stimulation efficiency with wear time ~~[23]~~[30].These effects limit use of a given array to around one day of continuous wear. In the final study of ShefStim ~~[22]~~[7] we were able to provide participants with sufficient arrays to use a fresh hydrogel layer each day. However, the cost of such an approach is high and not a realistic solution in clinical practice. To address this we are exploring alternative solutions, including the use of dry electrodes (see, for example ~~[24]~~[31]). Other minor product development issues remain, including the development of an improved garment to house the stimulator on the leg and minor improvements to the firmware, all of which may be easily resolved. We believe that these improvements would lead to a significant reduction in setup time, as recorded in our final (unsupervised) study [7].

In conclusion, this paper has described the complete design, development and evaluation of an array-based FES system with automated setup for the correction of drop foot. The results demonstrate that an array-based stimulator with automated setup ~~i~~as a viable alternative to a conventional surface stimulator, or an implanted stimulator, for the correction of drop foot. Longer term clinical exploitation of ShefStim is dependent on identifying an acceptable alternative to the high –resistivity hydrogel electrode-skin interface layer.

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