Case Series

A sock for foot-drop: A preliminary study on two chronic stroke patients.

Background

Foot-drop is a common motor impairment seen amongst chronic stroke patients, characterised by a lack of active dorsiflexion (1). Plastic, metal or composite-based ankle foot orthoses (AFOs) are commonly used to manage foot-drop, as recommended by the Royal College of Physicians (2). Despite this recommendation, issues around comfort, usability and their restrictive nature during walking can limit their use (3). Orthoses based on Lycra ® or other similar materials (fabric orthoses) are being used clinically and may address these issues. However, despite positive results with similar products, primarily in a paediatric population (4-6), there are no reports on the efficacy of the application designed to correct foot-drop in an adult population with stroke. The principle behind the foot-drop application is to introduce a net dorsiflexion moment through elastic panels that are stiffer on the dorsal than the plantar aspect of a custom-fitted Lycra ® sock. In addition, there is a suggested benefit from increased proprioception due to the tight-fitting nature of the garment (7). We therefore aimed to investigate the effects of the dorsiflex sock (DS) in addressing foot-drop,

(DMOrthotics,Redruth,Cornwall,UK).

http://www.dmorthotics.com/products/dynamic-lycra-orthotics.php)

(Figure 1). by:

1. Collecting initial data on the efficacy of the DS on step symmetry, energy expenditure, speed, exercise capacity and walking ability.
2. Investigating users' perception of the DS.

Figure 1.

Case Descriptions and Methods

Following ethical approval from Xxxxxxx (Xxxxxxxxx) participants were recruited through the Xxxxxxxxxx network. Participant information sheets were given to local stroke club network co-ordinators and distributed at meetings and electronically. Potential participants contacted the chief investigator and were screened against inclusion and exclusion criteria (Table 1).

Table 1.

The majority of the screened volunteers were already using modalities for their foot-drop and hence were ineligible (see Table 1). A convenience sample of 2 who

met the criteria, and were willing to complete the study protocol, were recruited to participate in the study.

Participants

Participant 1 was an unemployed 56 year old gentleman with right hemiplegia. He could walk indoors with no walking aid, but used a four point stick at night for safety. Outdoors he was independent with a stick over short distances, although he lacked the confidence to do this, depending on the conditions. He lived alone and was receiving no other therapy. His foot-drop was primarily due to weakness in his dorsiflexors. He had no cognitive deficit but did have expressive dysphasia.

Participant 2 was an unemployed 48 year old gentleman with right hemiplegia. He was independently mobile both inside and out with a stick. He had been given a functional electrical stimulator but did not use it due to difficulties donning. He lived with his partner and was receiving no other therapy. His foot-drop was primarily due to increased tone in his plantarflexors. He had no cognitive or communication deficits.

Written informed consent for participation and publication was collected for both participants.

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Design

An A-B single case experimental design (SCED) (8) was used. Both phases (A and B) spanned 4 weeks, with participants visiting the Xxxxxxxxxx for testing twice weekly (V1-V16). This produced 8 baseline (A) and 8 intervention (B) data points, over a total of 8 weeks (Figure 2). Testing was on the same days each week and approximately the same time, no food or caffeine was allowed one hour prior to testing, and participants rested for two minutes prior to testing to allow heart rate to settle. Participants wore the same shoes at every visit.

Figure 2.

At V1 participants were measured for a custom DS, according to manufacturer guidelines, and the measurements sent to the manufacturer. The DS was provided at the end of V8, then donning/doffing and care guidelines were explained, according to the manufacturer's instructions. The participants were encouraged to take their DS home and use it between subsequent visits.

Outcome Measures

According to the World Health Organisation international classification of functioning, disability & health (ICF) model, measuring human function can be categorised as measures of: 'body functions and structures' and/or 'activities and participation'. 'Activities and participation' can be further categorised into measurements within a standardised environment (capacity qualifiers) and a person's own environment (performance qualifiers) (9). Outcome measurements that assess specific domains of these three ICF components (body functions & structures, capacity qualifiers and performance qualifiers) were chosen from the relevant lower limb orthotic evaluation core set, developed by Brehm et al. (10).

Body Functions & Structures (BFS)

Gait pattern: At each visit (V1-V16) participants first performed three self-paced 6 metre walks (with 1.5 metres at either end (11)). Mean values for step and stride regularity were calculated from vertical accelerations taken using a tri-axial lumbar-located accelerometer (Biometrics Ltd, Cwmfelinfach, Gwent, UK) (11). Step symmetry was then determined as a function of these (11).

Energy Expenditure: Heart rate was monitored whilst the participants then walked for 6 minutes over a pre-defined course to calculate the total heart beat index (THBI) (12). This is a measure of energy expenditure which is reliable in non-steady state conditions and is comparable to more established measures (12).

Capacity qualifiers (CQ)

Gait speed: Mean values over the three 6 metre walks (13) were calculated using a stopwatch.

6 minute walk distance (6MWD): The distance walked during 6 minutes was recorded. This is a recognised measure of sub-maximal functional exercise capacity (14).

Performance qualifiers (PQ)

Walking ability: Functional ambulation categories (FAC) distinguish walking ability by the amount of physical assistance required ranging from ‘0’ (non-functional, ambulatory) to ‘5’ (independent, ambulatory) (15). These were recorded at V1 and V16.

User perception: Participants completed the validated user opinion orthotic questionnaire by Tyson and Thornton (16) at the end of V16. Diaries which recorded donning/ doffing times, time worn and any effects/ issues participants encountered were completed once a week in the intervention (B) phase on a day the participants were not at the University (4). On V16 participants were asked specific questions on the logistical feasibility of the design and whether they would continue to use the DS. Although these measures are not within the core set of

measures proposed by Brehm et al. (10), inclusion was justified in this first study of a new product.

Figure 2 summarises when measures were collected.

Data Analysis

Graphical interpretation and visual inspection was performed on all BFS and CQ data (17). The autocorrelation coefficient, 'the extent to which scores at one point in a series are predictive of scores at other points in the same series'(18) (p652), was calculated for the baseline (A) data points using the method described by Bengali and Ottenbacher (18). In the absence of significant autocorrelation (<p=0.05), which would bias any calculations based on averages, the quasi-experimental 2 SD method was applied (19). This involves calculating a 2 SD 'band' based on baseline (A) data points which is then projected onto the intervention (B) phase. If 2 successive intervention (B) phase data points sit outside of the band it is said to show a significant ($p<0.05$) improvement (19).

PQ measures were recorded and summarised.

Findings

BFS and CQ measures

Visual inspection of THBI, walking speed and 6MWD (Figures 3 and 4) showed an improvement trend for Participant 1 over the course of testing (V1-16). Conversely step symmetry demonstrated a declining trend for Participant 1. Neither of these trends appeared to be affected in any way by the introduction of the DS (Figures 3 and 4). Significant baseline autocorrelation (18), even with first difference transformation (19), was found in all measures apart from 6MWD. Participant 1's improvement in this measure was classed as significant ($p<0.05$) using the 2SD method (17). Participant 2 showed no change in any measure (Figures 3 and 4).

Figure 3.

Figure 4.

PQ measures

Walking ability: According to the descriptions by Mehrholz et al. (15) at V1 the FAC for Participant 1 was 4 (ambulatory, independent, level surface only), and for Participant 2 was 5 (ambulatory, independent). These scores were unchanged at V16.

User perception: With regard to the questionnaire (16) Participant 1 reported the DS resulting in '*little*' or '*much*' improvement in all the areas of gait asked about. Overall he reported his walking being '*much better'* (16). The only impact

Participant 2 reported was *'a little improvement'* in the ability to lift his toes, but overall he felt his walking was 'Better'(16). Both felt the DS was '*easy*' to don/doff, '*comfortable*' and were *'not concerned'* by its appearance (16).

Diary entries showed that donning/doffing was consistently independent for both participants and times remained consistent throughout (Participant 1 reporting 2-3 minutes to don/doff; Participant 2 reporting 10-15 seconds to don and 5-10 seconds to doff). This was not consistent with what was observed, with both underestimating how long it took. Participants wore the DS all day after their first week, where the manufacturer recommended a gradual increase in use. Regarding effects of the device, Participant 1 consistently wrote that his affected leg felt "very very limp" without the DS on and he wrote he felt "better with it on". Participant 2 had less to report, but noted that with the DS, "his toes were not catching when walking".

Questioning around the logistics of the study design indicated that for Participant 1 two visits per week were all they could manage, but that he enjoyed his involvement as "it got him out of the house", whereas Participant 2 could have come more frequently. Both stated they would carry on using the DS.

Outcomes

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This study set out to preliminarily investigate the efficacy and users' perceptions of the DS.

The single quasi-statistical change in the 6MWD seen for Participant 1 cannot be confidently attributed to the effects of the DS. There was no change in any other BFS or CQ measures and the change in the 6MWD is confounded by the continually improving trend observed for Participant 1 (Figures 3 and 4) (20). When taken together, this suggests it is more likely that the observed change was due to the repeated bouts of exercise during the walking tests at V1-16, rather than the wearing of the DS. The DS had no impact on any measured aspect of Participant 2's walking.

In terms of PQ measures, walking ability (FAC) was not affected by the DS. In contrast to the objective findings both participants' perceptions of the impact of the DS on their gait were positive. This could be due to the inclusion/exclusion criteria (Table 1) which notably required repeated dedicated testing over 8 weeks during the day and the absence of other foot-drop modalities (Table 1). This restricted eligibility to those without daytime commitments and who were not having health care input. The combination of these factors may well have resulted in a self

referred convenience sample whose views were positively influenced by the fact that their foot-drop was being addressed.

The A-B design is the basic single case experimental design and has well established limitations (8, 17). As the DS could have a carryover effect, recruitment numbers were unknown (and were ultimately small), and compliance could not be predicted, alternatives such as A-B-A or multiple baseline design (8, 21) were not deemed appropriate. In addition the participants were rather homogenous being male, right sided hemiplegic and functioning at a relatively high level which limits the generalisability of the findings.

However the design and measures chosen aimed to capture the breadth of impact of the DS, and are indicative of measures used in studies that informed the Royal College of Physicians guidelines (2). In contrast to our findings thermoplastic AFOs have been reported to have a significant impact on a range of measures including speed, symmetry, exercise capacity and walking performance (2, 3, 22).

Conclusion

Despite positive views of the DS from both participants, and the recognised limitations, this preliminary study found no clear evidence to demonstrate that the DS, with its current design, was effective in improving walking for two community

dwelling, chronic stroke patients with foot-drop. It should be viewed with caution as an alternative to AFOs, until further research becomes available. To strengthen the external validity of these findings further research should include a greater variety of participants in terms of side of hemiplegia, age, gender and FAC to represent the heterogeneous stroke population. Comparison to an AFO, or placebo, either using a SCED or group design would strengthen internal validity. Measures should continue to refer to Brehm et al. (10) core set recommendations, however BFS might be best served by using 3D gait analysis, which would record the effect of the DS on kinematics, including toe clearance, a measure of trip risk, during swing (23).

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Declaration of Conflicting Interests

The authors declare that there is no conflict of interest with this work

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