Improving independence in the community for stroke survivors

The role of biomechanics visualisation in ankle-foot orthosis tuning

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Abstract— One of the key priorities for stroke survivors in their rehabilitation process is regaining their ability to walk. Evidence has shown that provision of ankle-foot orthoses (AFOs) can have a positive impact on walking. This paper discusses the role of gait analysis in the provision of AFOs for stroke survivors. A discussion of the shortcomings of gait analysis techniques is included, with a description of how these might be overcome during the AFO tuning process through the ongoing development of data visualisation software. The design of a randomised controlled trial in conjunction with a series of qualitative measures is described, which will be used to test the efficacy of the visualisation software.

Keywords- stroke; biomechanics; ankle-foot orthoses; gait analysis; visualisation; randomised controlled trial; rehabilitation

I. INTRODUCTION

Patient understanding of their treatment and effective communication with clinicians have both been identified as having a positive impact on their compliance [1] which leads to a better chance of improved treatment outcomes [2]. When providing rehabilitation to patients clinicians are expected to comprehend and communicate complex biomechanical concepts to patients to aid their understanding, help improve motivation and assist with goal setting. It is thought that when it comes to biomechanics those studying physiotherapy "are happier studying material that is interactive and widely illustrated with animations and drawings" [3] rather than equations, tables and graphs. This is supported by the findings of Macdonald et al. [4] who found that animated visuals can be used to explain complex biomechanical data to both clinicians and older adults.

Having identified a unique opportunity for using visual techniques as a means to allow biomechanics to have greater impact in healthcare in a general sense, it was clear that a logical step for this research would be to investigate how this general principle might be applied in a number of specific clinical scenarios. Barry Meadows WestMARC Southern General Hospital Glasgow, UK barry.meadows@ggc.sco t.nhs.uk Philip Rowe Bioengineering Department University of Strathclyde Glasgow, UK philip.rowe@strath.ac.uk



Figure 1. A rigid ankle-foot orthosis, courtesy of the Neurobiomechanics team, Southern General Hospital, Glasgow, UK

II. THE CLINICAL SCENARIO

Stroke is the most common cause of severe adult disability in the UK [5] and gait dysfunction is the most commonly reported post-stroke disability [6]. Michael et al. [7] found that stroke survivors exhibited low levels of ambulatory activity and also suffered from other health problems, such as profound cardiovascular and metabolic deconditioning. The remobilisation of stroke patients is considered to be important and has resulted in the development and launch of a best practice statement in NHS Scotland [8]. This publication is supported by evidence which suggests that AFO provision for stroke patients leads to improved walking and subsequently a better quality of life [9-11].

The provision of ankle-foot orthoses (AFOs) for stroke survivors was considered to be a relevant clinical scenario, as an AFO represents a biomechanical intervention which can improve kinetic and kinematic aspects of a patients' gait pattern [12]. The general process for providing a stroke survivor with a rigid AFO (Fig. 1) is as follows; referral by the physical therapy team, gait assessment, AFO casting, AFO fitting followed by AFO tuning. The importance of this final AFO tuning phase has been described in detail [13] with shank and thigh kinematics identified as being of particular importance in efforts to correct gait abnormalities. It was therefore decided that the AFO tuning phase represented an ideal specific clinical scenario where biomechanical data can not only be used to assist clinical decision making, but also measure the progress of the patient.

Gait analysis plays a key role in the provision of AFOs. It provides a basis on which clinicians can prescribe an AFO, assess the immediate effects of an AFO (and adjust the design accordingly) and also to measure the long-term effect on the patient.

III. SHORTCOMINGS OF GAIT ANALYIS

'Gait analysis' is a broad term and can be carried out in many different ways from the cheapest and most basic (observational analysis) through to the most expensive and complex (computerised 3D analysis). All gait analysis techniques have their relative shortcomings, so it is important to acknowledge these and attempt to improve them.

A. Computerised 3D Gait Analysis

Computerised 3D gait analysis offers an objective method for the measurement of gait in clinical rehabilitation settings. It does however rely on such a system being available, expertise to run the system, and experienced clinicians to interpret the findings. One study found that computerised 3D gait analysis results had a significant impact on clinical decision making (Lofterod et al., 2007) [14] although there are still a number of barriers to the widespread uptake of motion analysis. Baker [15] described many of these barriers and identified the interpretation of clinical gait data as being a significant problem. The same paper also highlights the need for allowing clinicians to choose between alternative options, or possibly to predict the outcomes of interventions.

McGinley et al. [16] described in detail the reliability of 3D gait analysis techniques and concluded that clinically acceptable errors are possible but are not always accomplished, particularly when measuring hip and knee rotation in the transverse plane. Marker placement was cited as a significant source of error. Schache et al.[17] investigated hip rotation in the transverse plane and attempted to minimise inaccuracies caused by soft tissue artefact at the thigh. They concluded that due to a lack of a true 'gold standard' for measuring hip rotation in this plane, clinicians must remain cautious when using this data.

B. Observational Gait Analysis

While new scoring tools have been developed to assist with observational gait analysis [18], it has generally been shown to be ineffective and unreliable. Watelain et al. [19] found that when observational gait analysis was inconsistent across clinical disciplines, and was therefore unreliable. Williams et al. [20] found that accuracy of observational gait analysis was low and there was considerable variability in the observations made by the different clinicians. The same study found that while experienced clinicians generally gave more accurate observations, experience did not always guarantee accuracy of observation. Similarly the findings of another study also suggested that, due to significant inter-disciplinary differences in how gait data is analysed, there is a need for a common gait analysis language for use that can be understood by all clinicians [21].

Clinicians need the best possible information and data on how individual stroke survivors walk such that they can make the correct clinical decisions. On one hand they have a highly sophisticated technology which (although expensive and time consuming) collects objective and accurate data, however fails communicate it effectively. On the other hand they have observational techniques (freely available and quick to administer) which have been shown to be unreliable.

The mindset adopted by this study is that the barriers to 3D gait analysis can be overcome, particularly those surrounding the problem of interpreting clinical gait data. It is hypothesised that by designing and building a series of visualisations to help interpret gait data, and arranging them in a software package, will lead to improved patient outcomes. The efficacy of this software package will then be tested in a randomised controlled trial.

IV. VISUALISATIONS

The main aim of the visualisations under development is to communicate to patient and clinicians how the patient walks. Patients and clinicians will have different requirements of the visualisations; the former is likely to be concerned with their rehabilitation progress, while the latter will be interested in data and information that will allow them to make the best possible clinical decision. The requirements of both groups have been captured qualitatively through a series of informal meetings with clinical experts and observation of current standard care delivery.

The gait cycle is complex as it relies on the combination of numerous interrelated spatio-temporal, kinematic and kinetic parameters to describe how a person walks. The gait cycle's complexity is such that despite over 30 years of research effort "no unifying concept has emerged to explain the motion of the body during gait" [22]. One key aim of this study is to break down the complexities of the gait cycle and make it more accessible and understandable to both clinicians and patients. While full 3D motion analysis will be used, only selected parameters relevant to AFO tuning will be shown to the clinicians to allow them to make their decisions. Previous work suggests that gait velocity alone is not an effective indicator of gait abnormality, and that some measure of symmetry should also be used [23]. The authors assume that two main components of gait that will be easily understandable by patients are velocity (speed) and symmetry. It is therefore proposed that all specific gait parameters involved can be then described in terms of their contribution to those two key components (Fig. 2).

It is intended that during analysis sessions selected gait parameters will be described by clinicians to patients, according to the patient's unique difficulties identified during that session. This will be done using visual explanations of both the concept which underpins the parameter in conjunction with visual representations of their actual performance and progress with regards to that parameter.

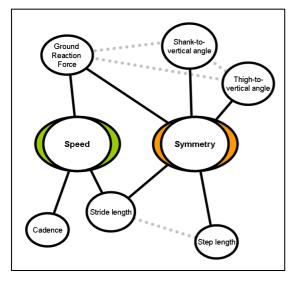


Figure 2. The interrealtionships between the main parameters for AFO tuning and their relation to the key components of gait; speed and symmetry

Achievable targets can then be set for each of the specific parameters by the clinician which, if reached, will contribute to improvements in the two key gait components; speed and symmetry. This approach of providing a structured simplification of a complex problem to patients may well be useful for other gait-related clinical decision-making scenarios.

V. THE RANDOMISED CONTROLLED TRIAL

A trial has been designed in conjunction with NHS Greater Glasgow and Clyde Health Board. The aim of the trial design is to test what effect using visualisations has on the clinical scenario of AFO tuning from the point-of-view of the stroke survivors patients and clinicians.

A single-blind randomised controlled trial (RCT) design was selected for the study, with patients blinded as to the intervention they will be given however blinding of the clinicians involved will not be possible. A sample of 70 patients will be recruited, with 35 in each arm of the study.

As patients are recruited to the trial they will be randomly allocated to one of two study arms, with each arm having its own multidisciplinary team (MDT). Each of these MDTs will be made up of a physiotherapist, orthotist and bioengineer. The only difference in the treatment given to the two patient groups is that patients in Group A will be shown visualisations of their gait patterns and progress throughout the trial. MDT-A will also be able to use the gait data and visualisation software to aid their clinical decision making during the AFO tuning session. MDT-B will use the 'standard' approach to AFO tuning (observational gait analysis). All clinical decision making will be carried out by the physiotherapists and orthotists, while the bioengineer will play a purely technical role collecting data and presenting to the clinicians when it is required. As shown in Fig.3, all patients recruited to the trial will attend a total of four measurement sessions:

1. Baseline 3D gait measurements

2. AFO tuning (using either visualisation or observation techniques)

- 3. 3 month follow-up 3D gait measures
- 4. 6 month follow-up 3D gait measures

A. Quantitative Outcome Measures

Gait velocity has been selected as the primary outcome measure as it has been shown that a significant improvements are related to better function and quality of life [24]. This measure also fits well with the objectives of stroke survivors, as walking function is their most frequently stated goal [6]. Secondary outcomes measures will include; step length, stride length, gait symmetry, ground reaction force magnitude and alignment, joint (ankle/knee/hip) kinematics, segment (shank and thigh) kinematics, joint (ankle/knee/hip) kinetics, Euroqol Questionnaire, Modified Ashworth Scale and the Abbreviated Rivermead Mobility Index.

B. Qualitative Measures

The overall aim of this study is to increase people's confidence and independence through improving their ability to walk. While the quantitative clinical measures used in this study will measure the efficacy of the intervention, they are not appropriate for measuring independence and confidence of those receiving treatment. In order to investigate such effects of the trial, a series of qualitative measures will be used throughout, in parallel with the quantitative clinical measures.

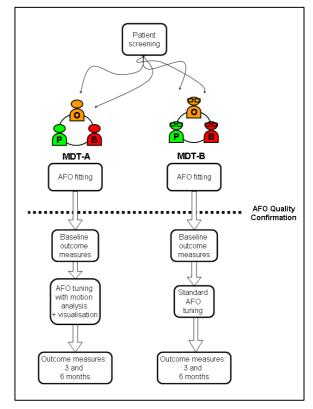


Figure 3. Flowchart of RCT design

This approach has been shown to both support trial design as well as improve understanding of the effects of complex interventions [25].

As mentioned previously, during the design of the trial informal meetings with clinical experts and observation of current standard care delivery were used to establish a comprehensive understanding of AFO provision for stroke survivors. In order to build on these findings, focus groups with clinicians and patients will be used to find out which visuals are most effective. The focus groups will then be followed up by a series of short pilot studies where both groups are able to get some 'hands on' experience of the software and give feedback to the research team. Once the visualization software is ready to be included in the RCT, the following qualitative measures will be taken.

1) Before

Before the trial all four clinicians will be given short (30 minute) structured interviews before the RCT begins. These interviews will focus on how confident they feel about biomechanics, what they look for during observational gait analysis (are there differences between disciplines?), and establish if there are any interdisciplinary differences of opinion on AFO fitting and tuning. All patients will be required to participate in short (15 minute) structured interviews after recruitment. The main focus of the questions will be on their expectations of the AFO process.

2) During

During the trial video footage will be captured during all four measurement sessions. The footage will be analysed with a focus on how the software is used during the different measurement sessions, and to test for any differences in how the patients and clinicians interact between the two arms of the study.

3) After

After the trial detailed structured interviews with all four participating clinicians will be conducted, lasting 45 minutes. Topics to be covered in these interviews will include; evidence of enhanced understanding of biomechanics, team working, perceived benefits/drawbacks of using software and confidence in their clinical decision making. Short interviews with all patients will be conducted after their final measurement session lasting 30 minutes. Topics to be covered in these interviews will include; patient-clinician communication, understanding of treatment, motivation levels, goals achieved and impact of visualisations.

By combining these quantitative and qualitative measures this study should produce a comprehensive evaluation of the efficacy of biomechanical data visualisation for improving the confidence and independence of stroke patients.

VI. CONCLUSIONS

It has been shown that it is important for stroke survivors to regain the ability to walk as it increases their independence, confidence and ability to reengage themselves with their community. 3D gait analysis has the ability to assist clinicians in their decision making when providing AFOs, however a number of barriers to its use have been identified. Through the careful design of a series of visualisations to aid the interpretation of clinical gait data, it is anticipated that AFO tuning can be enhanced. A combination of quantitative clinical measures and qualitative methods will be used to robustly test this hypothesis.

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