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CASE STUDY

An evaluation of the effects of a dynamic lycra® orthosis on arm function in a late stage patient with acquired brain injury

MARTIN J. WATSON[1], PIPPA CROSBY[2], & MARTIN MATTHEWS[3]

[1]*School of Allied Health Professions, Faculty of Health, University of East Anglia, Norwich, UK,* [2]*Occupational Therapy Department, and* [3]*Orthotics Department, Norfolk and Norwich University Hospital, Norwich, UK*

Abstract

Primary objective: The aim of this study was to assess the effect of a dynamic lycra® orthosis in the management of upper limb paresis in a late stage stroke patient.
Research design: A single case experiment, adopting a 3-phase ABA withdrawal design (without follow-up), ∼6-weeks per phase, intervention being delivered in the middle/B phase.
Method and procedures: Assessment of arm function was carried out on a weekly basis for the 18-weeks, using a battery of upper limb tests. The subject was prescribed a tailor-made lycra® orthosis which was worn daily during the middle phase of the trial.
Main outcomes and results: Orthosis wear appeared to result in improvements in active range of movement, self-rated function and one component of a writing test, with some suggestion of a carryover effect when treatment was withdrawn. No intervention-related changes were seen in a dressing test. Ambiguous results were seen in a further writing test and a peg board manipulation assessment. Irrespective of intervention, the subject made positive changes in scores in the majority of assessments used, throughout the 18-week period.
Conclusions: The findings suggest that a lycra® orthosis may have some beneficial effects on upper limb function late after brain injury. Results were however equivocal, suggesting (a) that effect mechanisms may be quite complex and (b) that future evaluations may require careful construction.

Keywords: *Arm, brain, brain injuries, case report, cerebrovascular accident, hemiplegia, movement, orthotics, physiotherapy, recovery of function, rehabilitation, stroke, treatment efficacy, treatment outcome, upper extremity*

Introduction

The extent to which an individual can continue to demonstrate recovery following brain injury has long been a topic of contention. This is a significant issue in particular for physiotherapists, who may be working to help subjects achieve further improvements in their physical performance, many months—and sometimes years—following the original brain lesion.

Seminal work and statements in the 1980s led to the (then) commonly held view that most (motor) recovery in brain injured adults, following stroke and severe head injury, has occurred by somewhere between 3–6 months following the original insult [1–3]. By the end of the 1980s this view was being challenged and it is now accepted that, for some individuals, the capacity for change will remain after this time. Following stroke it is now recognized that further functional changes can sometimes occur many months later [4–6]. Following severe brain injury, further motor recovery can sometimes occur up to several years later [7].

The underlying profile of motor recovery (the 'recovery curve') following acquired brain injury still remains to be absolutely ascertained [7]. A few
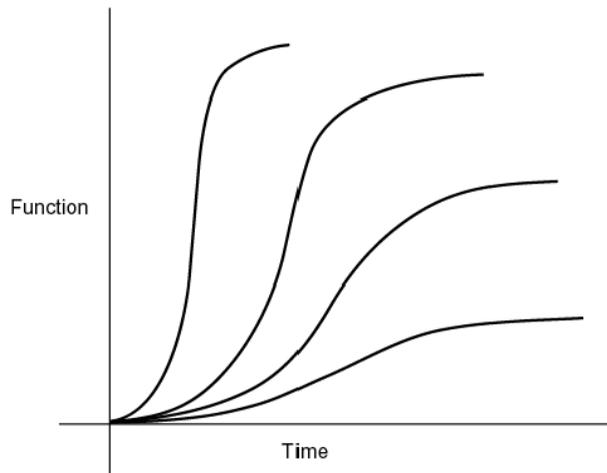
Figure 1. S-shaped recovery curves, plotting functional recovery against time. The underlying model is one where some subjects achieve faster and more complete recoveries than others but where all subjects eventually reach a plateau.

studies have plotted the recovery of specific motor tasks (e.g. gait, manual manipulation) and ascertained the likely shape of the curve [8–11]. The resulting profile, which probably matches that which is implicitly held by the majority of clinicians, is commonly referred to as a logistic function or s-shaped curve [12] (see Figure 1).

In this profile, recovery (usually after an initial delay) is relatively steep. At some stage an inflection point is approached at which the rate of recovery begins to reduce, eventually reaching a plateau. For some subjects the plateau will be reached before full recovery has been achieved, the full extent and rate of recovery varying between individuals (see Figure 1). One additional feature of the s-shaped curve is that plateaux are not technically 'flat'; change potentially continues towards infinity but occurs in such smaller increments that at some point it is negligible.

The implications of the s-shaped curve for recovery are fairly obvious. First, it would presumably be useful to ascertain the point at which the recovery plateau is being approached. As stated above, recent research shows that this may sometimes not occur until many months or years following the initial brain injury. Secondly, if the model is 'correct', then however late the potential for recovery remains, there will be a point at which payoff between therapy input and further motor gain becomes increasingly negligible.

There are suggestions of instances where patients achieve a fresh 'burst' of renewed progress at a much later stage. This would suggest that the s-shaped curve may not necessarily be the true or only model of recovery; sometimes subjects may achieve a plateau but then later demonstrate further step-wise incremental change(s) in performance.

This implies a discontinuous phase phenomenon rather than a curvilinear model. The literature suggests that this can sometimes be achieved through innovative interventions and renewed 'pulses' of therapy [9, 13–15]. It has recently been suggested that therapists should not be complacent regarding the chronic brain-damaged patient's capacities for further change [7, 15, 16]. Such authors have encouraged practitioners to *reconsider* the notion of the recovery plateau; adaptation to therapeutic exercise they suggest can sometimes be overcome by the introduction of novel treatment strategies and/or changes in and reintroductions of therapeutic regimen.

A number of novel therapeutic strategies have recently become available for physical therapy. Recent reports have suggested that pharmacotherapy used in conjunction with physical treatment may mediate further/later changes in physical performance [17, 18]. A relatively new therapeutic application is the use of treadmill training, with or without body weight support (BWS) for gait re-education [19, 20]. For rehabilitation of the upper limb, constraint-induced movement therapy, which is essentially a 'forced use' paradigm, is showing promising results with some subjects [21]. A further relatively new approach in the physical treatment of some of the movement problems resulting from brain lesions is the utilization of dynamic lycra® orthoses. The beneficial effects of these tailor-made elasticated garments have been documented following stroke [22] and cerebral palsy [23–25]. There is as yet no definitive explanation as to their effect mechanism, however the following suggestions have been made [26]:

- Beneficial stretching and patterning effect: the garment delivers a low-load prolonged stretch on shortened soft tissues, as well as encouraging the limb to adopt improved functional positioning;
- Provision of elastic dampening effect: for subjects with involuntary movement problems, an external dampening effect;
- Provision of external support—'exoskeleton': for subjects with weakness, an external supporting effect;
- Motivational effect of novel intervention strategy;
- Prevention of 'learned non-use'; and
- Enhanced sensory feedback: the suggestion that skin tension and contact may enhance sensory and proprioceptive input.

This report describes a single case experiment involving a subject who was at a relatively late stage following a stroke. The study's aim was to evaluate the therapeutic effect of a dynamic lycra® orthosis to treat functional problems affecting the subject's hemiparetic upper limb. The overall intention was

to identify if the late stage provision of this relatively novel intervention could be of benefit in enabling the subject to make further functional changes at the stage when recovery was considered to have reached a plateau.

Subject

The subject was a male, aged 70 years at the time of the evaluation. He had sustained a left-sided cerebro-vascular accident (CVA) ~ 8.5 years previously. His most recent period of physiotherapy had been 2-years previously, when it had been judged that he would not benefit from further input. His persisting functional deficits were due to his unresolved right-sided hemiplegia, which resulted in the primary problem of limited use of his right arm.

Method

Design

The proposed methodology for this investigation was a single case experimental design (SCED). SCED represents a suitable method for exploratory treatment evaluation in instances where the individual and/or the intervention is relatively unique. The methodology provides a means by which individual interventions can be documented in great detail. This provides opportunities to identify specific strengths and weaknesses of the treatment in individual cases. SCED may also be the method of choice in instances where the investigator has a limited number of suitable subjects to enter into a study. The methodology has gained widespread acceptance as an alternative means of evaluating rehabilitative interventions [27–29].

Evaluation of the intervention may vary from case-to-case; however a likely model is the ABA design. In this, an initial 'baseline' (A_1) phase is used to identify the extent of the problem. This involves the repeated measurement of the subject's motor performance, over a period of days or weeks, using standardized assessment tools. This establishes the baseline performance level. Then, in the 'intervention' (B) phase, lasting a similar period of time, performance measurement continues whilst the intervention is delivered. This enables the extent of the treatment effect to be identified. Finally, a second 'baseline' (A_2) phase occurs, wherein monitoring continues following withdrawal of the treatment. This latter phase allows the investigator to confirm any effect occurring during the intervention phase, as well as identifying any treatment carryover.

Procedure

The subject was recruited to the study via contact in the clinic. He was one of a small number of subjects involved in a trial of upper limb lycra® orthoses. The premise of the study was the evaluation of lycra® gloves as a late stage intervention in the treatment of chronic non-progressive neurological disorders affecting upper limb function. Subjects were those whose physiotherapy had ceased and who were felt to have achieved a plateau in their upper limb recovery. Subjects were asked to attend on an approximately weekly basis for 18-weeks for assessment of upper limb function. During the middle (~ 6-week) phase of this 3-phase evaluation, the lycra® glove was prescribed and worn on a daily basis. The subject was informed that the initial phase (pre-glove) was a procedural requirement of the study. The subject was also informed that the glove, when prescribed, could not be guaranteed to lead to any functional changes, but that the final post-glove phase would enable the researchers to better identify if any change had occurred. The subject was not informed of the results of any of the tests which were administered during the trial, neutral feedback being provided throughout. Patient consent was obtained and the trial obtained ethical approval from the appropriate local ethics committee.

Orthotic prescription

The upper limb lycra® orthosis was prepared for the subject according to pre-determined orthotic criteria (DM Orthotics, Tescan Units, Pool Industrial Estate, Redruth, Cornwall TR15 3RX, UK). Measurement and fitting was carried out by a specialist orthotist. The patient and carer were instructed in garment care and don/doff technique. The garment was a full length orthosis, covering the upper arm and extending to include all five digits as far as approximately the distal inter-phalangeal joints. Two identical garments were provided to facilitate washing and hygiene care.

Outcome measures

One premise of a SCED approach to intervention investigation is that outcome measures are selected which are specific to the subject; i.e. the clinician/researcher aims to select those measurement tools which best evaluate each specific individual's (movement) problems. Appropriate measurement tools are chosen from those available to the clinician or else appropriate objective measures are devised which best fits the subject's needs. Following consideration

of the subject's main upper limb problems, the following outcome measures were chosen:

(1) *The peg-board test.* This is a commonly used evaluation of upper limb function which requires the subject to move a number of wooden pegs between two rows of holes [10].

(2) *Two of the upper limb components of the Motor Assessment Scale* [30]. This test assesses aspects of motor function following stroke, including a number of standardized measures of upper limb performance. The two components which were chosen were (a) time taken to draw 10 lines and (b) time taken to draw 10 dots.

(3) *The jacket test.* This test involves timing how long it takes the subject to don and fasten a loose-fitting 3-button long-sleeved jacket. A standardized operational procedure for this test had previously been devised by the first author.

(4) *Active range of movement at the affected shoulder.* The subject was asked to elevate his arm (elevation through flexion at the shoulder) as far as he was comfortably able, at which point an orthogonal digital photograph was taken following a standardized procedure. The angle of arm elevation, in degrees, was later measured from this image using a validated digital system [31, 32].

(5) *The patient specific functional scale* [33]. This is a validated measure in which the patient subjectively identifies his main functional problem(s). The magnitude of the identified problem(s) is then quantified using a visual analogue scale (VAS) of 0–10 (0 = 'unable to perform activity', 10 = 'able to perform activity at same level as before injury or problem'). Because this tool loses validity if used too frequently during an intervention evaluation, testing was only carried out on the four occasions of phase end and/or start (i.e. assessments 1, 7, 13 and 18).

For all measurements, the same order of assessment administration was maintained. Appropriate gaps of ~5-minutes were maintained between tests in an attempt to limit fatigue. To maintain neutrality of testing procedure, in all instances of testing the subject was not informed of his scores in that or previous test sessions.

Finally, the subject was also asked to keep a record of the amount of time that the garment had been worn daily during the intervention (B) phase of the trial.

Analysis

The proposed analysis was to graphically plot the weekly performance values of all outcome measures. The intention was to compare the data trends within and between the study's three phases,

using visual analysis. This is one of the accepted means by which single system designs can be analysed [27, 34].

Results

Reaching and manipulation: The Peg-board test

Results from the peg-board test suggested an overall trend for improvement (i.e. a decrease in time taken to carry out the test) across all 18 weeks of the trial (see Figure 2). Mean time to complete the test decreased by 32.58% between the 1st and 18th week. However, though improvement over time occurred, a specific intervention effect due to introduction of the orthosis in the middle phase was difficult to discern; indeed the garment may actually have slowed the overall recovery trend. This can be seen from the reduced gradient of the phase trend line in the intervention period, as well as which the level of performance also appears to fall back (i.e. times to perform the test are somewhat slower) at this time.

Manual dexterity: The Handwriting test, line-drawing component

Results from the line-drawing component of the handwriting test suggested an overall improvement in performance over the 18-weeks, with a progressive reduction in time taken to complete the test (a 31.38% change between the 1st and 18th test). All three phase trends (see Figure 3) suggest improvement, though there is also a strong suggestion of a levelling out and plateauing as the end of the trial is approached. The phase trend during the intervention (middle) period shows a less steep gradient,
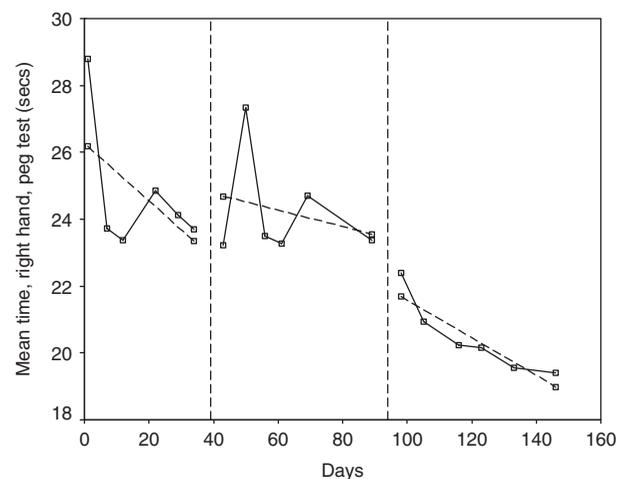
Figure 2. Performance on the peg board test for the affected upper limb, across the three phases of the study. Dotted lines within each phase represent phase trends. Decreasing score (*y*-axis) represents improvement.
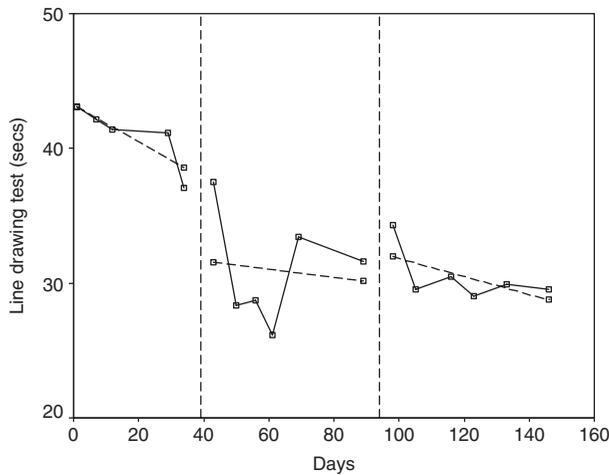
Figure 3. Performance on the line drawing component of the handwriting test, across the three phases of the study. Dotted lines within each phase represent phase trends. Decreasing score (*y*-axis) represents improvement.
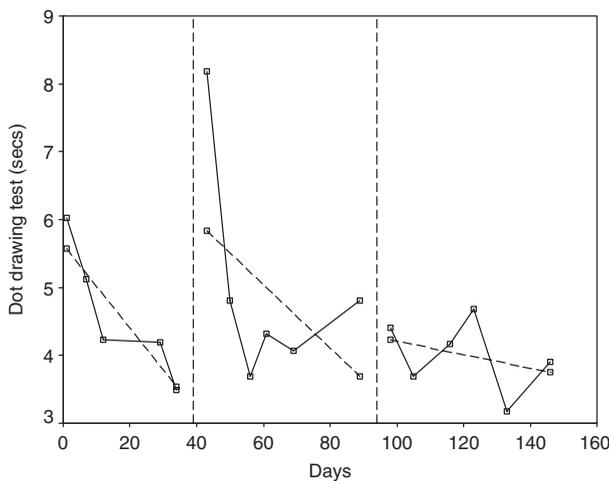

Figure 4. Performance on the dot drawing component of the handwriting test, across the three phases of the study. Dotted lines within each phase represent phase trends. Decreasing score (*y*-axis) represents improvement.

suggesting improvement actually slowed, though the overall level of performance actually improved (i.e. times overall were better); the best performance at any time is also seen during this phase.

Manual dexterity: The Handwriting test, dot-drawing component

Results from the dot-drawing component of the handwriting test also suggested overall improvement in performance over 18-weeks, though to a lesser extent (and less clearly) than other results (a 35.16% change between the first and last assessment) (see Figure 4). A fairly steep trend for improvement seen in the first phase appeared actually to be interrupted
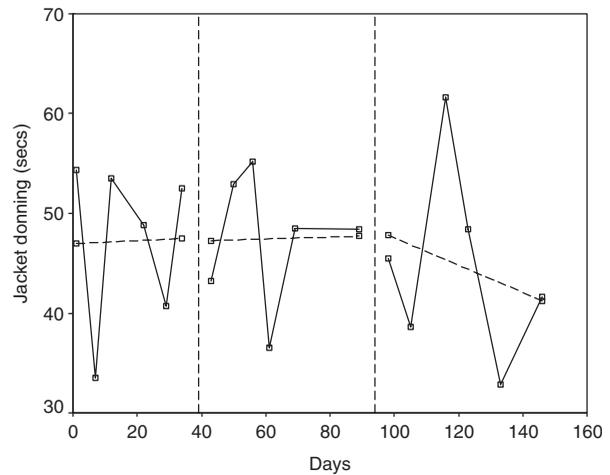

Figure 5. Performance on the jacket donning test, across the three phases of the study. Dotted lines within each phase represent phase trends. Decreasing score (*y*-axis) represents improvement.

by the introduction of the intervention; i.e. though the phase trend in the middle appears equally steep, data are perhaps suggestive of a poorer overall level of performance. This was undoubtedly compounded by a very poor result on the first occasion of testing in the middle phase (and this poor result may be the only reason why the overall phase trend here is able to suggest continuing improvement). As with Figure 3, there is a suggestion of levelling out of performance as one approaches and enters the third phase.

Dressing: The Jacket test

Results from the timed jacket test were somewhat ambiguous (Figure 5). Overall there appeared to be slight improvement across all 18 weeks, time taken having decreased between the 1st and 18th test (a 23.47% change overall). Performance appeared very variable during each of the three phases of the trial, with phase trends suggesting a fairly flat level of performance in the first two phases. A particularly poor performance on the 3rd assessment of the second baseline (A_2) phase meant that results here appeared worse overall than they might otherwise have done (the subject identified that he was having particular problems with buttoning on that day of testing); otherwise this phase is suggestive of the most improvement. Overall, it was difficult to discern a specific effect due to introduction of the intervention in the middle phase.

Active range of movement at the affected shoulder (arm elevation test)

Results from goniometric measurement appeared to show an overall improvement across the period of the trial (see Figure 6). There was a modest 8.70%
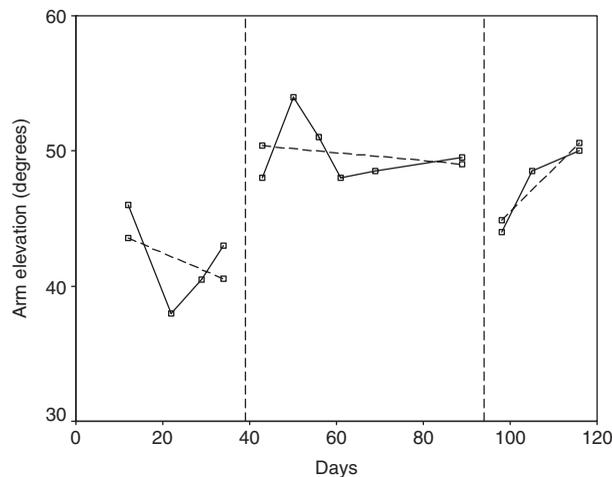
Figure 6. Performance on the arm elevation test for the affected upper limb, across the three phases of the study. Dotted lines within each phase represent phase trends. Increasing score (*y*-axis) represents improvement.
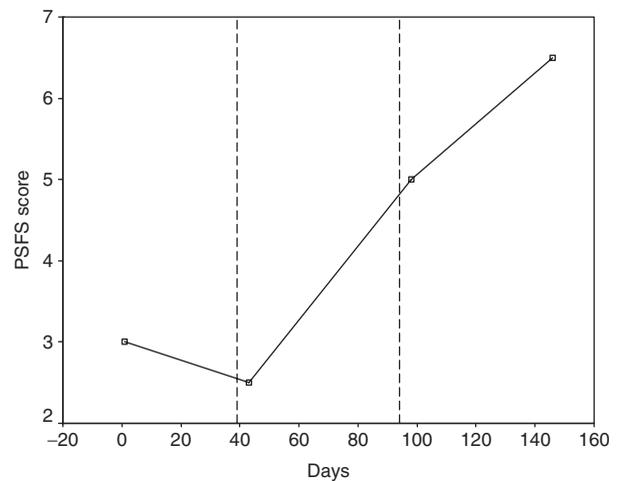

Figure 7. Change in subjective perceived difficulty on a patient-specified task, as measured on a visual analogue scale (Patient Specific Functional Scale). Increasing score (*y*-axis) indicates improvement.

improvement in active range of movement between the first and last occasions of testing. The relatively small changes in active shoulder flexion achieved during the trial needs to be interpreted with some caution considering the repeatability of goniometric measurement when carried out this way. Nonetheless, Figure 6 also appears to show an improvement linked to introduction of the intervention, which is then maintained (after an initial fallback) in the third phase once the intervention is withdrawn. Unfortunately the photographic equipment used for this testing failed on several occasions, leading to some missing data.

Patient specific functional scale

On initial assessment, the subject identified his main upper limb problem as '... being able to reach upwards and outwards (with my arm); being afraid to take something once I've reached up; it's frustrating'. He was asked to score this on the VAS. He was then reminded of his stated problem on three other appropriate occasions (i.e. starts of phases B and A_2 and final assessment at end of phase A_2) and asked to score its magnitude again. His previous scores were not revealed. Resulting VAS scores are shown in Figure 7. This appears to demonstrate an overall improvement over time, which was related to the introduction of the intervention; i.e. improvement occurs across the intervention (B) phase and is sustained into the A_2 phase.

Wear of the garment

The intervention phase of the trial lasted 48 days. (The period between the 5th and 6th assessment during this phase was longer than 1 week due to the

occurrence of a holiday break, though wear of the garment continued during the time.) The median time per day which the garment was worn was 12 hours with a range of 15.5 hours (minimum 0 hours, maximum 15.5 hours). There was just 1 day on which the subject chose not to wear the garment, this being due to ill-health.

Discussion

This study aimed to evaluate what if any changes in arm function occurred, coincident with daily wear of a lycra® orthosis in the middle phase of a 3 × 6 week period of weekly monitoring. Results from the study were somewhat equivocal; of six tests of arm function, three appeared to show a treatment effect, these being:

- Ability to elevate the arm as measured by goniometer (Figure 6);
- Ability to draw lines as part of a handwriting test (Figure 3); and
- Subjective opinion of arm function, as measured on a visual analogue scale (Patient Specific Functional Scale) (Figure 7).

In two of these three instances, there also appeared to be some evidence of a carryover effect when treatment was withdrawn; i.e. in Figures 6 and 7 the improvement in function achieved within the treatment phase appears to be more or less maintained into the second baseline (A_2) phase. Conversely, Figure 3 appears to show that, once the intervention was withdrawn, performance as measured by the line drawing test returned to the pre-intervention trend.

For the timed jacket donning test it was difficult to infer any change in performance in relation to intervention (Figure 5). Data from this measurement tool appear to show a varying level of performance across all three phases of the trial. It is conceivable that performance began to improve only once the intervention was withdrawn, though ability is so variable across the 18 weeks it is difficult to reach any firm conclusion from visual inspection of these data. It may be that this assessment was testing a specific aspect of function which it was unreasonable to expect the orthosis to have any effect on. It was noted for example that the subject had difficulty carrying out this test throughout the trial.

In two tests of arm function, introduction of the intervention appeared to have a deleterious effect on performance. Results from the peg board test (Figure 2) and the dot drawing test (Figure 4) both appear to show that when daily wear of the garment was introduced, performance actually appeared to get worse. (The graphs require cautious interpretation as, though trend lines for the intervention phases of both appear to show continuing improvement, the overall level of performance falls back.) It is interesting to note that decline in performance in both tests is perhaps particularly noticeable at the first two or three assessments of the intervention phase. This is not entirely surprising when one considers that the subject was probably getting accustomed to garment wear at this time.

What potentially complicates the interpretation of many of these results is that introduction of the intervention in the middle phase appears to be set against an overall trend for improvement across the whole of the 18 weeks. Hence, in Figures 2, 3, 4 and 6, there appears to be a trend for improvement throughout the whole of the trial, which can at best be described as being 'interrupted' by the intervention. This is perhaps particularly noticeable in Figures 2 and 3. For the five objective tests of arm function, there was a measurable improvement in arm function between the first and last assessments, ranging from a modest 8.70% for active arm elevation to 35.16% for the dot component of the drawing test (a mean improvement overall of 26.26% across the five tests).

This finding raises some speculation regarding the nature and influence of repeated weekly testing of the subject. It may be that he was 'simply' learning how to perform the tests, rather than the tests detecting any improvements in functional ability during the trial. This is a recognized potential problem when using a single case experimental design methodology [27, 34, 35]. Wilson et al. [36] have recently explored the nature of multiple testing in assessments of cognitive performance in brain injured subjects, albeit on a more frequent daily than weekly basis. Their findings were that some tests are more susceptible to confounding effects of practice than others and that researchers need to be aware of this when selecting their measurement tools. Against this it should be recognized that in this particular investigation, testing was no more than weekly in frequency, with each test being quite brief. Hence, the proportion of time spent performing the tests in any 1 week or overall was exceedingly small.

One is thus left to question why improvement was seen to be occurring throughout the trial, rather than only during the intervention phase. It would be tempting to label this as evidence of a placebo effect, identifying that change was occurring 'simply' because of trial participation and irrespective of the introduction of a specific intervention. Mengshoel [37] is one of a number of authors who have warned against the abuse of the concept of 'placebo', particularly with respect to physiotherapeutic interventions. Patient expectation and information can make a considerable contribution to a 'treatment' effect and it may be this which was (inadvertently) occurring during this investigation. The patient in this trial was someone who had previous positive experiences of physiotherapy. He had also possibly placed great store in being involved in an intervention study which might bestow further benefits. It is conceivable, therefore, that there may have been significant psychological, cognitive and endogenous effects as a result of involvement.

One further possibility is that the subject entered the study demonstrating an element of 'learned disuse' of his affected arm, which was then partially reversed as a result of trial participation. After several years of impaired function and despite the fact that earlier therapy had been to some extent beneficial, the patient was likely to have settled into a behavioural pattern of 'making do'; i.e. reliance on the sound upper limb to manage daily activities. Initial participation in the trial may then have served to draw his attention once more to his affected limb. Even after many months (and possibly in this case several years) of reduced limb activity, involvement in the trial may thus have reminded him of the possibilities for increased/renewed use of his affected arm, with beneficial results. One might also speculate that there was also a variant of the 'forced use' treatment paradigm occurring here. During the initial baseline phase, the subject was possibly beginning to use his affected limb more, reflected in improvements seen in some of the functional assessments. Introduction of the lycra® orthosis in the intervention phase may then have served as a 'restrictive' element, actually making the subject have to work harder to use his arm. Withdrawal of

the garment at the end of the intervention phase then freed the subject to make further gains in the third phase. Such an effect could be akin to certain kinds of athletics training wherein subjects attempt to make further gains in performance by introducing period(s) of extra loading. This effect is perhaps best seen in Figures 2 and 4. This offers interesting speculation regarding potential additional mechanism(s) of operation for this type of orthosis.

All of the above issues serve to highlight the difficulties inherent in evaluating interventions like this, particularly where a single case experimental approach is being used. The assessor (the first author) attempted to maintain neutrality throughout the trial, though of course the potential for bias through this obvious lack of blinding cannot be overlooked. A more suitable assessment strategy may have been to use a third party, acting as a blinded assessor, as well as evaluating performance by means of some form of observational assessment of upper limb use. By introducing a form of assessment which the subject was not overtly aware of, the possible confounding effects of test learning and placebo might also have been partly negated. Conversely though, it is difficult to blind the subject to the fact that he/she is participating in a trial or is being exposed to an intervention, unless a further intervention phase, utilizing a sham orthosis, is also used. The use of a smaller number of (perhaps) more pertinent assessments might also have negated the (possibly) spurious achievement of positive results; it is recognized that the greater the number of assessments which are used to evaluate an intervention, the higher the likelihood of a significant result [38]. A further means by which the study might have been made more robust could have been to extend the initial baseline phase beyond 6 weeks. As improvements in function appeared to occur almost immediately, possibly as a result of test practice and/or study participation, it might have been more appropriate to continue baseline monitoring until these changes had levelled out. In this way the possible effects of the (later) introduction of the orthotic intervention could then be more robustly ascertained. Finally, though improvements occurred during this study, the extent to which these were sustained is unknown. Whilst late-stage interventions are known to effect further change post-stroke, it has been suggested that these gains are not always maintained and that patients later fall back to pre-intervention levels [4, 39]. This study would therefore have benefited from further later-stage follow-up evaluations.

Conclusion

This study set out to evaluate if further late stage improvements in arm function could be brought about through the use of a lycra® orthosis. Guardedly positive results were achieved with respect to some of the assessment results, suggesting that even after several years further improvements in arm function can still be achieved. The picture was somewhat complicated as some improvements occurred irrespective of introduction of intervention. Additionally, there was some suggestion that the manner in which the intervention was taking effect was more complex than initially anticipated. Overall there was evidence that renewed intervention can lead to further change in performance late after initial brain damage. What was less clear was the extent to which the specific intervention under scrutiny was entirely responsible for the changes seen. The lasting effect of these later stage changes was not ascertained.

Acknowledgements

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