Technology and Disability 25 (2013) 177–187
DOI 10.3233/TAD-130374
IOS Press

Effects of a dynamic hand orthosis for functional use of the impaired upper limb in sub-acute stroke patients: A multiple single case experimental design study

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Abstract.
OBJECTIVE: To investigate the usability and the effects of a dynamic spring-loaded orthosis, adjunct to therapy-as-usual (TAU), on functional use of the impaired hand in moderately/severely impaired sub-acute stroke patients.
DESIGN: Single case experiment (A-B-A'-design).
SUBJECTS: Eight sub-acute stroke patients.
METHODS: The orthosis was used for six weeks, five days/week, 45'/day, and adjunct to TAU. Outcome measures: Action Research Arm Test (ARAT), ABILHAND, Intrinsic Motivation Inventory (IMI).
RESULTS: At group level, patients improved on ARAT ($p = 0.001$) and ABILHAND ($p = 0.005$). After detrending for baseline trends (caused by e.g. spontaneous recovery and/or TAU), such improvement was only found for ARAT ($p = 0.009$). At individual level, three patients whose baseline ARAT changed little (0–3 points), had improved at follow-up, and four remained constant regarding detrended ARAT results. In four patients mean detrended ABILHAND results were higher during follow-up relative to baseline ($p \leqslant 0.036$). Average IMI sub-scores were between 5.4 and 6.6 (of 7), except for 'pressure/tension' (2.1).
CONCLUSION: Patients, who, in the early sub-acute phase after stroke, display only little/modest improvement on their capacity to perform activities or their perceived level of daily performance, seem to benefit most from training with a dynamic arm orthosis. Patients perceived a high intrinsic motivation and sense of self-regulation.

Keywords: Stroke, rehabilitation, upper extremity, orthotic devices, single case experimental design, motor skills

1. Introduction

In The Netherlands, in 2010 the incidence of stroke was 33,862 [16]. Thirty to 66% of the stroke survivors suffer from a severe upper limb paresis, and face long-term impaired arm function [11,30]. Only 5–20% of stroke survivors regain arm-hand function in the first weeks post-stroke and are able to re-use the impaired hand in daily life activities [27,28]. These patients experience mild limitations in daily occupations and are able to control finger and wrist extension [18,39]. Approximately 20% of the stroke survivors suffer from a moderate paresis [37]. These persons will never regain hand dominance. However, they have the potential to regain dexterity and may be able to use their arm in basic functional tasks.

An important focus of stroke rehabilitation is to improve arm-hand skill performance to maximize functional motor ability [24]. Well-known treatment approaches to improve arm-hand performance after stroke are constraint-induced movement therapy

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ISSN 1055-4181/13/$27.50

(CIMT) [42], mental practice [3,38], task-oriented training [33], and technology-supported rehabilitation [2,31]. Although these approaches have been proven successful, most approaches have been evaluated in patients who are able to execute functional grasp-and-release tasks with their impaired arm and hand without assistance, i.e. in patients with voluntary wrist and finger extension in the paretic arm and hand [20]. For patients who suffer from a moderate or severe paresis, it is often difficult to participate in task-oriented interventions, as they lack the capacity for voluntary movement in their paretic hand.

Technology-assisted training, featuring robotics, electrical stimulation, gaming devices and/or assistive orthoses, can be used in conjunction with training of everyday tasks [10,31,32]. Mehrholz et al. [26] indicated in a systematic review that motor strength of the paretic arm and motor function are more likely to improve when patients after stroke train with electromechanical devices and allow stroke patients to practice intensively by themselves [12,19,31]. These electromechanical training systems of arm and hand performance after stroke may be roughly divided into passive (stabilising the arm and hand), active systems (actuators moving the arm and/or hand) and interactive systems, the latter of which react to patients' inputs to provide an optimal assistance strategy [29]. Most of these systems are equipped with high-end electronics, mechanical features and software. However, elaborating on the (dis)advantages of these devices is beyond the scope of this article. The orthosis as has been tested in the present study is a passive, mechanical device.

In neurorehabilitation in general, and more specifically in (chronic) stroke patients, effects of treatment regimes featuring orthoses are not unequivocal. At the impairment level, minor effects of stretching on muscle spasticity [21,22,35], strength, range of movement and grip have been reported [5,6]. Modest improvements at activity and participation level are reported in a study by Butler [5], who used a dynamic spring-loaded hand orthosis (Saeboflex, Saebo Inc, Charlotte, NC) in one patient suffering from a chronic stroke. Such orthoses aim to assist persons who are not able to make a functional grasp with their paretic arm and hand themselves. The creation of a functional grasp by means of spring-loading finger extension enables patients to execute task-oriented grasp and release exercises and practice intensively using repetitive movements. This dynamic orthosis can be used in goal-directed activities and lowers the threshold for patients to participate in a greater variety of evidence-based treatment programs like group therapy and CIMT. From the perspective of (therapy) efficiency and patient satisfaction, the use of such orthosis may be beneficial, because less individual therapy assistance is needed.

To date, most clinical studies reporting effects of dynamic spring-loaded hand orthoses have been performed in chronic stroke patients. So far, only Davenport et al. [7] reported results, at patients' capacity level, in sub-acute stroke patients. A clinical assumption is that the benefits of such an orthosis may be larger in sub-acute stroke patients, because learned non-use [41] and secondary complications like contractures may be prevented. However, this has not yet been investigated systematically.

Besides evaluation of the effects of the use of a dynamic spring-loaded hand orthosis, it is essential to investigate whether patients are motivated to train with the orthosis. The level of motivation is an important beneficial factor in pursuing goals and activities [15] and in maintaining a high degree of training practice compliance. Therefore, information about user experience (i.e. usability), perceived competences and motivational aspects (like values and beliefs related to functional arm-hand training combined with the orthosis from the patients' perspective) should be gathered.

The aims of the present study have been to investigate a) the effects of a dynamic spring-loaded orthosis, adjunct to therapy-as-usual, on the functional use of the impaired upper limb in moderately to severely impaired sub-acute stroke patients, and b) patients' motivation regarding the use of a dynamic orthosis. The following research questions were posed:

1) Does a six-week, upper limb-based rehabilitation regime, assisted with a dynamic spring-loaded hand orthosis, improve arm-hand capacity and perceived daily activity performance beyond effects of spontaneous recovery and therapy-as-usual in patients with moderate to severe upper extremity paresis in the sub-acute phase after stroke?
2) How do moderately to severely impaired stroke patients rate user experience with regard to a dynamic spring-loaded hand orthosis during a six-week arm-hand training regime?

2. Methods

2.1. Study design

This study featured a single case experimental design (A-B-A' design) [4], involving multiple single

cases. During the baseline phase (A), intervention phase (B) and follow-up phase (A'), three, two and five measurements were performed respectively, each interspaced by approximately two weeks, thus producing a time series, per measure, for each patient. Meta-analyses, on the pooled single case data, have also been performed.

2.2. Subjects

The current investigation was a sub-study in a large longitudinal clinical project called AMUSE (Activity Monitoring of Upper extremity use in Stroke patients during and after rEhabilitation), clinimetrically quantifying progress in arm-hand use at the patients' level of function, activity and participation. Patients suffering from a first-ever stroke, who were admitted to Adelante Rehabilitation Centre in Hoensbroek, The Netherlands, were asked to participate.

Additional inclusion criteria were:

1) post-stroke time less than three months;
2) problems during the performance of daily activities due to a moderately to severely impaired upper limb;
3) no severe cognitive or communication problems;
4) clinically diagnosed with a paresis of the arm and hand, i.e.: Active range of motion (AROM) shoulder: 15°–20° (elevation/abduction); AROM elbow: 15°–20° flexion; Active finger flexion: $^1/_4$ active interphalangeal flexion during passive wrist extension $>15°$ starting with full extension of the fingers; Passive range of motion: optimal wrist extension of 35° (with a minimum of 15°) with metacarpophalangeal, proximal interphalangeal, and distal interphalangeal joints in extension.

Exclusion criteria were:

1) serious problems regarding vision or hearing;
2) severe arm edema;
3) severe shoulder pain;
4) insufficient understanding of the Dutch language.

All procedures and protocols of the AMUSE project were approved by the Medical Ethics Committee of the Maastricht University Medical Centre in Maastricht, the Netherlands. Written informed consent was obtained from all subjects prior to their participation.

2.3. Apparatus

A dynamic spring-loaded hand orthosis (Saeboflex, Saebo Inc, Charlotte, NC), assisting wrist extension muscles, and counterbalancing excessive activity of the wrist and finger flexors, was used. This orthosis allows subjects to use active wrist flexion to grasp objects. The orthosis is designed to position a non-functional hand in a biomechanically more optimal position, thus facilitating grasp and release activities. Using a fixed wrist extension angle (35°) and a variably loadable 'finger and thumb spring-loaded system' the optimal position of the hand is maintained and finger extension is supported after the grasp movement has ended. The orthosis is fitted and checked by a certified therapist, one criterion being the patient's ability to grasp a 3.5 inch soft foam ball.

2.4. Intervention

During the baseline phase, the intervention phase and the follow-up phase, stroke patients received a conventional protocolized rehabilitation program (therapy-as-usual), enabling them to optimize their arm-hand use in daily activities. During the intervention phase, this protocolized rehabilitation program was used in conjunction with a dynamic spring-loaded hand orthosis (Saeboflex). Key elements of the program are: 1) the patient is the main stakeholder and acquires knowledge about his possibilities and limitations regarding upper limb training; 2) the optimal integration of the paretic upper limb in daily occupations to improve arm and hand function; 3) the patients are enabled to maintain optimal care for their arm and hand.

Before the start of the program, the patient's self perceived problems related to self-care, productivity and leisure are identified and inventoried. In dialogue with the occupational therapist, a minimum set of three of these problems are translated into meaningful and attainable performance goals (individual goal setting). These goals should be directly related to home-based daily activities. Given their functional possibilities, patients will then undergo a personalised arm-hand training regime, within a training group of stroke survivors with a moderately to severely impaired arm and hand. As all group members experience and observe similar impairments among the other group members, group-wise training is an excellent (motivational) training tool [43]. During the execution of group tasks and individual tasks, each patient learns how to integrate his paretic arm and hand during manual activities in daily life situations. Special attention is given to 'active fixation' tasks, 'gross motor grip and displacement' tasks and simple bimanual daily life activities.

In a first session, the dynamic spring-loaded orthosis is fitted by a certified therapist. Subsequently, the

participant will undergo the arm-hand training regime while wearing the orthosis. Patients start with training on a personal goal for 5 minutes, followed by 45 minutes of training with the dynamic orthosis, picking up and moving 3.5 inch soft foam balls. Immediately after this session the participant works for 15 minutes towards personal goals again. This training regime is followed for six weeks, five days per week, divided in three days during in the rehabilitation setting and two days at home. Participants work with a personal log and a self-administered home exercise program (including the use of the orthosis) during the weekends.

A therapist is present during training to help with pre-training adjustments like arranging exercises and matching materials or configuring the dynamic orthosis to the patient's performance level. Within the first week of the program, the patient will learn to work with the orthosis, how the orthosis can be fitted properly without professional assistance and how to manage some exercises during the weekend, according to the homework assignment scheme.

2.5. Measures used

2.5.1. Utrecht Arm/hand Test

The Utrecht-Arm/hand-Test (UAT) is a simple bedside test measuring arm-hand motor impairment after stroke. Evaluation criteria are comparable to stages of motor recovery after stroke. The ordinal scale represents eight stages, ranging from 0 (non-functional arm) to 7 ('clumsy hand') [17]. In the present study the UAT is used for classification at baseline.

2.5.2. Action Research Arm Test

The Action Research Arm Test (ARAT) is a capacity test [23] regarding upper extremity activity. It consists of four subtests comprising 16 grasp movements and three reaching movements to be performed by the patient. Items are scored on a 4-point scale, its sum score ranging from 0 to 57. The test is valid [13], reliable [25] and sensitive to change [8] in patients with stroke. The ARAT is suitable for the evaluation of arm-hand activity changes in clinical trials [36].

2.5.3. ABILHAND

The ABILHAND is a clinical assessment tool evaluating perceived everyday performance of the impaired hand related to real life tasks [1,23] using a set of 23 bimanual activities [40]. The test is administered as a semi-structured interview, using a 3-level ordinal rating scale: impossible (0), difficult (1), and easy (2) to perform. Activities not performed in the last three months are not scored. To compare inter- or intra-individual manual ability, the ordinal scores are converted to an interval scale and consequently to a linear measure of manual ability, based on a Rasch analysis [1]. The ABILHAND is valid, responsive and clinically useful [40].

2.5.4. Intrinsic Motivation Inventory

The Intrinsic Motivation Inventory (IMI) assesses participants' subjective experience related to a target activity. It has been used in several experiments related to intrinsic motivation and self-regulation [9,14]. The 7-point Likert scale instrument was administered at the end of the follow-up phase to assess participants' interest/enjoyment, perceived competence, effort, value/usefulness, pressure/tension felt, and perceived choice while training with the dynamic spring-loaded hand orthosis [9]. Its reliability was found to be good [34].

2.6. Data analysis

Baseline data stability and any trends regarding the ARAT and ABILHAND, i.e. the average change between consecutive measurement dates, were calculated. Subsequently, three approaches were used to analyse the ARAT and ABILHAND data. Firstly, to ascertain whether patients improved over time irrespective of training, differences between mean baseline data, mean training phase data and mean follow-up data were analysed using a Friedman two-way analysis of variance by ranks. Multiple comparison involved Wilcoxon signed ranks tests. Secondly, data were linearly detrended for baseline trends per subject, using a least squares method, to (partially) compensate for improvements caused by e.g. spontaneous recovery and/or conventional therapy received. An example of linear detrending of the ARAT time series of one subject is shown in Fig. 1.

The residuals, i.e. the detrended (and thereby rendered mutually independent) data, were subsequently analysed for the whole group using a Kruskal-Wallis test, and, where applicable, followed by multiple comparison involving Mann-Whitney U-tests. Thirdly, the linear detrended time series (i.e. series of residuals) of each individual patient was analysed separately, i.e. per subject the residual baseline measurement results were compared to the residual follow-up measurement results using Mann-Whitney U-tests. The aforementioned procedures were applied to both the ARAT and

Table 1
Patient characteristics at entrance in the study

Patient	Gender	Age (year)	UAT	Post-stroke time (weeks)	Dominant side	Impaired side
1	F	72	1	7	R	R
2	M	75	0	7	R	R
3	M	54	5	19	R	L
4	M	59	1	17	R	R
5	F	50	1	6	L	R
6	F	27	0	13	R	R
7	F	64	2	4	R	R
8(*)	M	51	1	8	R	L
9	M	35	3	5	R	L
10(*)	M	62	1	7	R	R
Mean (sd) of all 10 participants		54.9 (15.1)			9.8 (5.8)	
Mean (sd) of remaining 8 participants		54.5 (16.9)			9.3 (5.2)	

F = female; M = male; UAT = Utrecht Arm/hand Test; R = right; L = left; sd = standard deviation; (*) = 2 participants who withdrew from the study during the baseline measurement phase.

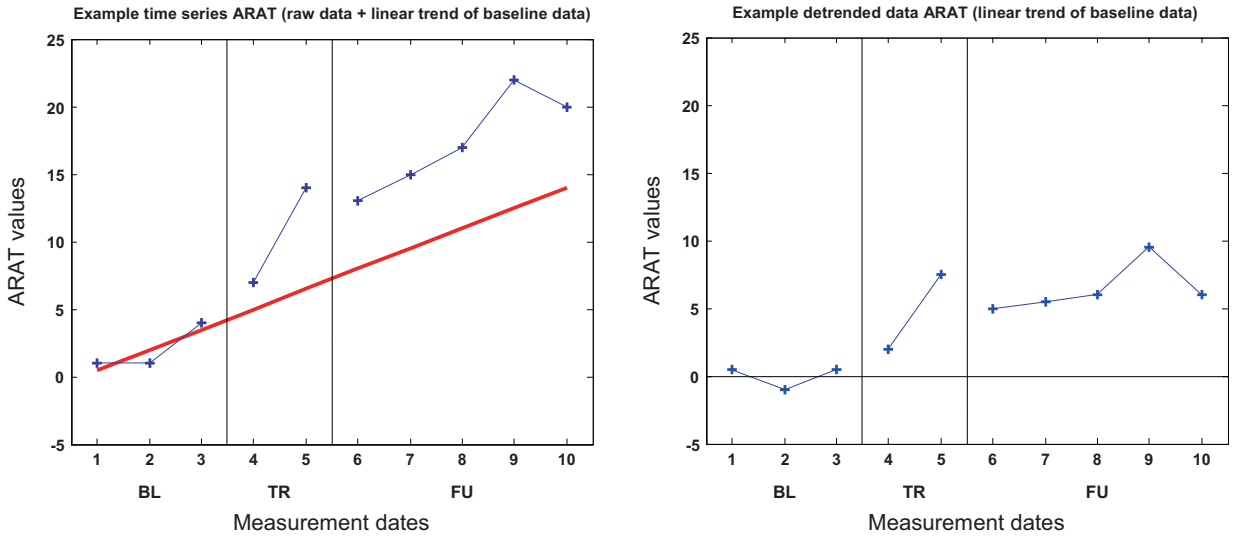

Fig. 1. Example of linear detrending of the ARAT time series of 1 subject. ARAT = Action Research Arm Test; BL = Baseline; TR = Training; FU = Follow-up.

ABILHAND data. Linear detrending of the data was performed using MATLAB software (The MathWorks Inc, Natick, MA). All data were statistically analysed using IBM SPSS software version 19 (IBM Inc, Houston, TX). Patients' experience is reported descriptively.

3. Results

3.1. Error analysis

Ten patients entered the study. However, two patients (P8 and P10) withdrew from the study very early during the baseline measurement phase because of shoulder pain or autonomic dysregulation problems in the arm. No further data were missed during data acquisition. No adverse effects of the training were found. Patients' characteristics at entrance in the study are presented in Table 1.

3.2. Baseline data stability

In Table 2 baseline data as well as the average change, i.e. any improvement or deterioration, across the baseline phase that may have been due to spontaneous recovery and/or conventional therapy received,

Table 2
Baseline data for the ARAT and the ABILHAND of each subject

Patient	Baseline ARAT				Baseline ABILHAND			
	T1	T2	T3	Average change (u./meas.)	T1	T2	T3	Average change (u./meas.)
1	1	1	4	1.5	−1.85	−0.75	−0.72	0.565
2	0	0	14	7.0	−4.04	−2.85	−2.12	0.960
3	28	30	28	0.0	0.69	0.39	0.26	−0.215
4	1	3	4	1.5	−1.49	−0.73	−0.13	0.680
5	0	0	4	2.0	−1.75	−1.45	−0.40	0.675
6	0	3	14	7.0	−1.64	−0.63	−0.46	0.590
7	7	9	8	0.5	0.54	0.94	−1.77	−1.155
9	19	23	30	5.5	−1.83	−0.97	−1.60	0.115

ARAT = Action Research Arm Test; T = measurement date; u. = units; meas. = measurement.

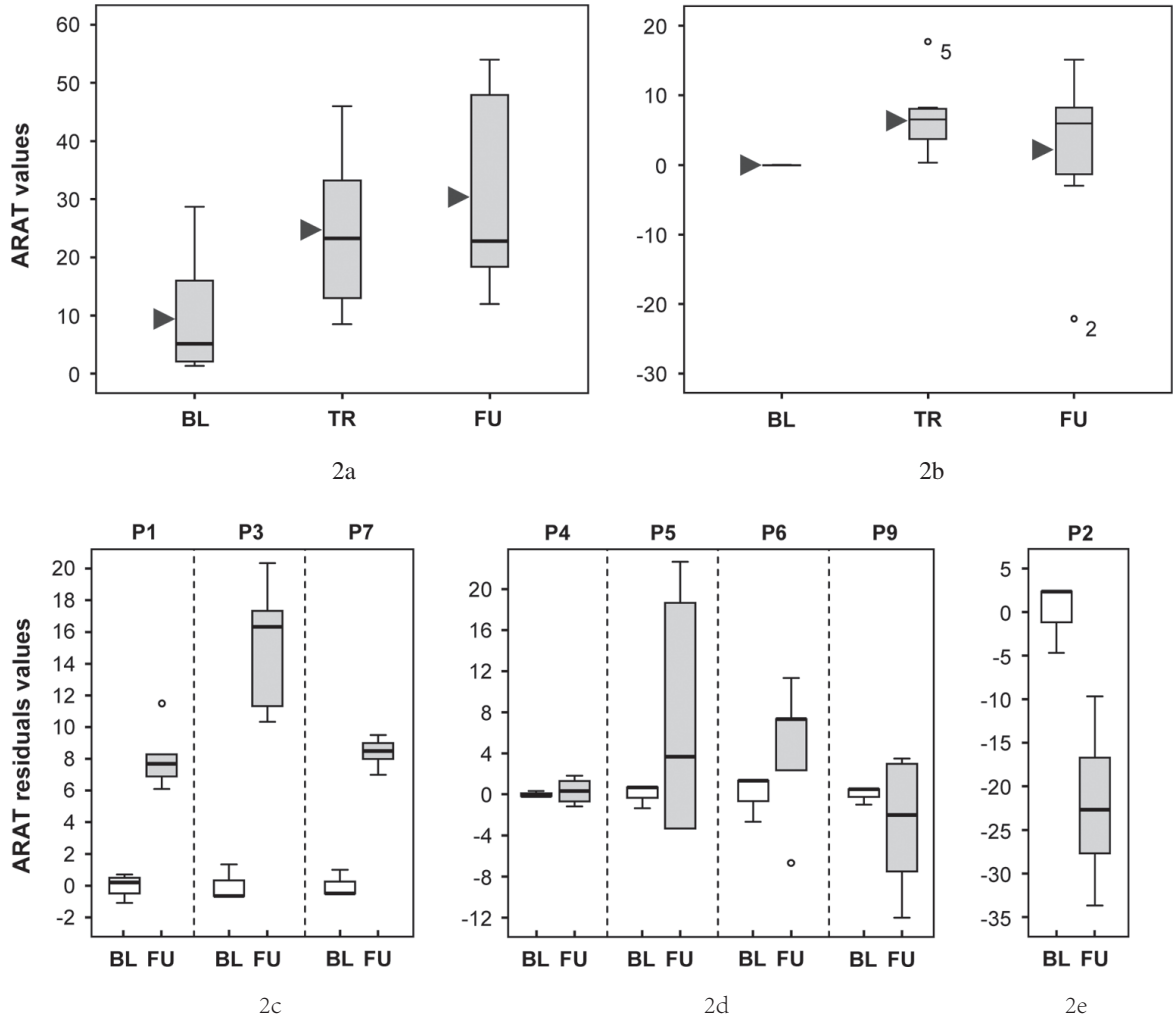

Fig. 2. Boxplots of ARAT results. ARAT group results (2a), within-subject averaged residuals for all 3 phases (2b) and within-subject residuals for all subjects for the baseline phase and the follow-up phase (2c-e) are depicted. ARAT = Action Research Arm Test; BL = Baseline; TR = Training; FU = Follow-up; Circles = outlier value; 2 and 5 = patient number; P = patient number; Arrows in Figs 2a and 2b indicate mean value. (a): overall: $p = 0.001$; BL-TR: $p = 0.012$; BL-FU: $p = 0.012$; (b): overall: $p = 0.009$; BL-TR: $p = 0.001$; BL-FU: $p = 0.105$; (c–e): P1, P3, P7: $p = 0.036$; P4, P5, P6, P9: N.S; P2: $p = 0.036$.

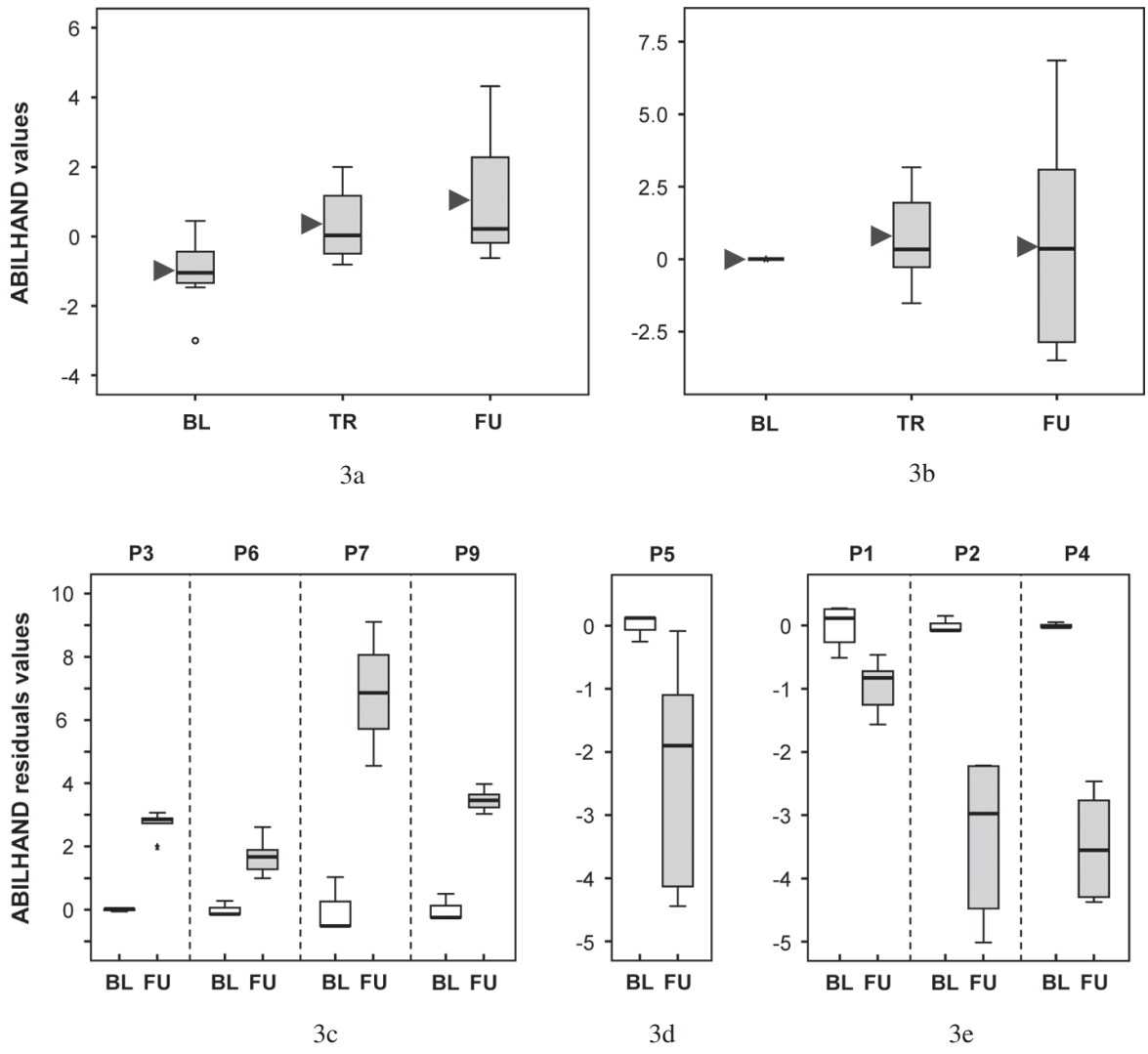

Fig. 3. Boxplots of ABILHAND results. ABILHAND group results (3a), within-subject averaged residuals for all 3 phases (3b) and within-subject residuals for all subjects for the baseline phase and the follow-up phase (3c-e) are depicted. BL = Baseline; TR = Training; FU = Follow-up; asterisk = extreme value; P = patient number; Arrows in Fig. 3a and 3b indicate mean value. (a): overall: $p = 0.005$; BL-TR: $p = 0.017$; BL-FU: $p = 0.012$; (b): overall: $p =$ NS; BL-TR: $p =$ NS; BL-FU: $p =$ NS; (c–e): P3, P6, P7, P9: $p = 0.036$; P5: N.S ; P1, P2, P4: $p = 0.036$.

for the ARAT and the ABILHAND of each subject are presented.

Small improvements on the ARAT during baseline are foremost observed in P3, P7, P1 and P4. For the ABILHAND this primarily holds for P7, P3 and P9. Largest improvements during baseline were found in P2 and P6 (ARAT) and P2 (ABILHAND).

3.3. ARAT results

3.3.1. General improvement over time

Overall, patients improved over time on the ARAT ($p = 0.001$). Furthermore, ARAT group results were higher both during the training phase and during follow-up, relative to baseline data ($p = 0.012$). Boxplots of ARAT results are presented in Fig. 2a.

3.3.2. Improvement over time, corrected for baseline trends

Representing data of the whole group ($n = 8$), boxplots of the within-subject averaged ARAT time series data for all three phases, i.e. baseline, training and follow-up phase, linearly detrended for the baseline trends, are presented in Fig. 2b.

An overall improvement was found for the ARAT results (Kruskal-Wallis test, $p = 0.009$). Multiple com-

parison revealed that ARAT residuals were higher in the training phase, relative to those recorded in the baseline phase ($p < 0.001$), whereas no statistical differences were found between the ARAT residuals of the follow-up phase, relative to those recorded in the baseline phase ($p = 0.105$).

3.3.3. Single case time series

To ascertain how each subject's ARAT score changed over time, boxplots of ARAT time series residuals for the baseline and follow-up phase are presented in Fig. 2c through 2e.

In three patients (P1, P3 and P7) mean (and median) ARAT residuals were higher in the follow-up phase relative to the baseline phase ($p \leqslant 0.036$). In four patients (P4, P5, P6 and P9) no statistically significant improvement in ARAT scores was observed. In one patient (P2) a decrease in mean (and median) ARAT residuals was observed between the baseline phase and follow-up phase ($p = 0.036$).

3.4. ABILHAND results

3.4.1. General improvement over time

Overall, patients improved over time on the ABILHAND ($p = 0.005$). Multiple comparison revealed that ABILHAND results were higher both at follow-up and during the training phase, relative to baseline data ($p = 0.017$ and $p = 0.012$ respectively). Boxplots of ABILHAND results are presented in Fig. 3a.

3.4.2. Improvement over time, corrected for baseline trends

Boxplots of the within-subject averaged ABILHAND time series data for all three phases, linearly detrended for baseline trends, are presented in Fig. 3b. No significant differences in ABILHAND residuals values were found between any of the three phases.

3.4.3. Single case time series

To ascertain how each subject's ABILHAND score changed over time, boxplots of ABILHAND time series residuals for the baseline and follow-up phase are presented in Fig. 3c through 3e.

In four patients (P3, P6, P7 and P9) mean (and median) ABILHAND residuals were higher in the follow-up phase relative to the baseline phase ($p \leqslant 0.036$). In one patient (P5) no statistically significant improvement in ABILHAND scores was observed ($p = 0.071$). In three patients (P1, P2 and P4) a decrease in mean (and median) ABILHAND residuals was observed between the baseline and follow-up phase ($p \leqslant 0.036$).

Table 3
Overview of IMI scores

IMI item	Mean (sd)
Interest/Enjoyment	5.4 (0.53)
Perceived competence	5.9 (0.46)
Effort/Importance	6.3 (0.53)
Pressure/Tension	2.1 (0.26)
Value/Usefulness	6.6 (0.21)
Relatedness	6.3 (0.38)

Likert scale: 1–7. IMI = Intrinsic Motivation Inventory; sd = standard deviation.

3.5. IMI results

In Table 3 mean IMI results per participant are displayed.

4. Discussion

The aims of this study have been to investigate a) the effects of a dynamic spring-loaded hand orthosis, adjunct to therapy-as-usual (TAU), on the functional use of the affected upper limb in moderately to severely impaired sub-acute stroke patients, and b) the patients' motivation regarding the usage of a dynamic orthosis.

In general, patients improved considerably on their ability to use their affected arm during and after training, i.e. they improved on both ARAT (measuring patient's capacity) and ABILHAND (measuring patient's perception regarding his actual real life task performance), between baseline phase, training phase and follow up phase. However, as patients were in the sub-acute phase after stroke, this improvement might have (partly) been due to several factors, i.e.; a) spontaneous recovery, b) TAU patients received, c) the use of the dynamic orthosis, or d) a combination of these factors. After removal of the baseline trends, the ARAT group results showed that during the training phase patients improved on their capacity to perform activities. At follow-up, this improved capacity was still clearly present in three patients, indicating that they had benefitted more permanently from the additional dynamic spring-loaded hand orthosis training. These patients improved their dexterity, i.e. gross motor grip function combined with active shoulder movements (abduction and forward flexion). Two additional patients improved on their capacity to perform activities, although results failed to attain statistical significance, whereas in another 2 patients no change was observed. In one patient ARAT improvement, induced during the training phase, had declined post-training, suggesting that, regarding his capacity to perform activities, he did not

benefit from the additional orthosis training. In contrast to the results of the ARAT, after correction of the ABILHAND data for spontaneous recovery and TAU no significant additional (group) effect of the dynamic orthosis training was found. However, when assessing the time series of each individual, four patients clearly improved as to their perceived real life task performance post-training, relative to their baseline performance. The four other patients did not improve in this area, but seem to have slightly performed worse at follow-up.

In general, data from both the patients' capacity to perform activities using the affected arm-hand and the patients' perceived real life task performance indicate that those patients who show little progress during baseline, i.e. little improvement at an early stage post-stroke, benefitted more from the adjunct training featuring a dynamic hand orthosis. This seems to both hold for patients with an initially low or intermediate functional capacity (low or intermediate ARAT ($<$ 30)). In contrast, for those patients who, during the baseline phase clearly improve (e.g. P2), benefit from the adjunct training with the dynamic hand orthosis seems to be less. In literature, little is reported about the possible added value of dynamic hand orthoses in sub-acute stroke patients. As one of the few, Davenport et al. [7] in an exploratory study, reported proof-of-concept of using a dynamic spring-loaded orthosis adjunct to TAU. In contrast to our findings, they concluded that patients with a lower baseline ARAT made less change at the end of their intervention. However, in their study effects of TAU and spontaneous recovery were not taken into account, thereby obscuring (and overestimating) any effect of dynamic hand orthoses used.

As to user experience, also encompassing elements of motivation and usability, as measured with the IMI, patients rated the use of the dynamic spring-loaded arm orthosis very favourably at the end of the study. All patients were highly motivated to use the orthosis during training sessions. They felt confident using the orthosis and working with it in an intensive training program, whereas perceived pressure or tension to achieve certain goals or marks was relatively low. Even patients who did not benefit as much as expected from the adjunct orthosis training, anecdotally, reported a higher level of acceptance because they felt *"... having done everything that could be done during this period of training"*.

4.1. Considerations and future research

Despite the seemingly wide variance between subjects, across measures used, the baseline-corrected time series of the individual patients showed similarities between categories of patients, i.e. patients with low initial progress as to arm-hand performance seem to benefit more form the adjunct training provided. Future research should further focus on patient characteristics that may identify these patients as early as possible.

Research into specific training adjunct to TAU in sub-acute stroke patients is always methodologically challenging, because of the (speed of the) natural or therapy-induced recovery processes that take place, and the limited time window within the sub-acute stage in which valid data on this topic may be acquired. In our investigation we tried to model this recovery, in order to identify the unique contribution of the adjunct therapy. However, our linear model most certainly has led to a) an increasing degree of overestimation of (in our case) spontaneous recovery and TAU effects in the long term post-training, and b) a concurrent increase in within-subject data variance, resulting in underestimation of any effects of the adjunct training. The latter may have been the case especially in P2. In general, for all patients, an S-shaped model or at least a model 'levelling off over time' may have better fitted the reality of spontaneous recovery. However, gathering enough data to adequately fit such a model would have necessitated a much longer baseline phase, which, in turn, would inevitably have compromised the sub-acuteness of the patients' status during the ensuing intervention phase. Future research should focus on optimizing this model to better contrast spontaneous recovery with intermediate and long-term effects of (adjunct) therapy.

Conflict of interest

The authors declare that they have no competing interests.

References

[1] Ashford S., Slade M., Malaprade F. and Turner-Stokes L., Evaluation of functional outcome measures for the hemiparetic upper limb: A systematic review, *J Rehabil Med* **40** (2008), 787-95.

[2] Balasubramanian S., Klein J. and Burdet E., Robot-assisted rehabilitation of hand function, *Curr Opin Neurol* **23** (2010), 661-70.

[3] Barclay-Goddard R. E., Stevenson T. J., Poluha W. and Thalman L., Mental practice for treating upper extremity deficits in individuals with hemiparesis after stroke, *Cochrane Database Syst Rev* (2011), CD005950.
[4] Barlow D. H., Nock M. K. and Hersen M., *Single Case Experimental Designs: Strategies for studying behavioral change*. Allyn and Bacon, Boston, MA, 2009.
[5] Butler A., Blanton S., Rowe V. and Wolf S., Attempting to improve function and quality of life using the FTM Protocol: Case report, *J Neurol Phys Ther* **30** (2006), 148-56.
[6] Davenport S., Recovery with grasp? A report on a preliminary study investigating the short and medium term effects of the SaeboFlex (FTM System) on chronic post stroke patients with residual upper limb deficit, *Synapse* **Spring** (2005), 12-15.
[7] Davenport S., Brogden S. and Cairns M. Clinical considerations from a study exploring the role of the SaeboFlex dynamic hand orthosis as an adjunct to therapy with acute and sub-acute stroke patients; 2008; Harrogate, UK.
[8] de Weerdt W. J. G. and Harrison M. A., Measuring recovery of arm-hand function in stroke patients: A comparison of the Brunnstrom Fugl-Meyer-test and the Action-Research-Arm test, *Phys Canada* **37** (1985), 65-70.
[9] Deci E. L., Eghrari H., Patrick B. C. and Leone D. R., Facilitating internalization: The self-determination theory perspective, *J Pers* **62** (1994), 119-42.
[10] Hayward K., Barker R. and Brauer S., Interventions to promote upper limb recovery in stroke survivors with severe paresis: A systematic review, *Disabil Rehabil* **32** (2010), 1973-86.
[11] Heller A., Wade D. T., Wood V. A., Sunderland A., Hewer R. L. and Ward E., Arm function after stroke: Measurement and recovery over the first three months, *J Neurol Neurosurg Psychiatry* **50** (1987), 714-9.
[12] Hsieh Y. W., Wu C. Y., Liao W. W., Lin K. C., Wu K. Y. and Lee C. Y., Effects of treatment intensity in upper limb robot-assisted therapy for chronic stroke: A pilot randomized controlled trial, *Neurorehabil Neural Repair* **25** (2011), 503-11.
[13] Hsueh I. P. and Hsieh C. L., Responsiveness of two upper extremity function instruments for stroke inpatients receiving rehabilitation, *Clin Rehabil* **16** (2002), 617-24.
[14] Johnson M. J., Loureiro R. C. V. and Harwin W. S., Collaborative tele-rehabilitation and robot-mediated therapy for stroke rehabilitation at home or clinic, *Intel Serv Robotics* **1** (2008), 109-121.
[15] Jones F., Partridge C. and Reid F., The Stroke Self-Efficacy Questionnaire: Measuring individual confidence in functional performance after stroke, *J Clin Nurs* **17** (2008), 244-52.
[16] Kiwa_Prismant_Ziekenhuisstatistiek_Diagnosen. 2010. Landelijke Medische Registratie [Dutch National Medical Registration database]. http://cognosserver.prismant.nl/cognos7/cgi-bin/ppdscgi.cgi?DC=Q&E=/Prisma-Landelijke-LMR/Landelijke+LMR-informatie+-+Diagnosen.
[17] Kruitwagen-van Reenen E. T., Post M. W., Mulder-Bouwens K. and Visser-Meily J. M., A simple bedside test for upper extremity impairment after stroke: Validation of the Utrecht Arm/Hand Test, *Disabil Rehabil* **31** (2009), 1338-43.
[18] Kwakkel G., Kollen B. and Lindeman E., Understanding the pattern of functional recovery after stroke: Facts and theories, *Restor Neurol Neurosci* **22** (2004), 281-99.
[19] Kwakkel G., Kollen B. J. and Krebs H. I., Effects of robot-assisted therapy on upper limb recovery after stroke: A systematic review, *Neurorehabil Neural Repair* **22** (2008), 111-21.
[20] Langhorne P., Bernhardt J. and Kwakkel G., Stroke rehabilitation, *Lancet* **377** (2011), 1693-702.
[21] Lannin N. A. and Ada L., Neurorehabilitation splinting: Theory and principles of clinical use, *NeuroRehabilitation* **28** (2011), 21-8.
[22] Lannin N. A., Cusick A., McCluskey A. and Herbert R. D., Effects of splinting on wrist contracture after stroke: A randomized controlled trial, *Stroke* **38** (2007), 111-6.
[23] Lemmens R. J., Timmermans A. A., Janssen-Potten Y. J., Smeets R. J. and Seelen H. A., Valid and reliable instruments for arm-hand assessment at ICF activity level in persons with hemiplegia: A systematic review, *BMC Neurol* **12** (2012), 21.
[24] Levin M. F., Kleim J. A. and Wolf S. L., What do motor "recovery" and "compensation" mean in patients following stroke? *Neurorehabil Neural Repair* **23** (2009), 313-9.
[25] Lyle R. C., A performance test for assessment of upper-limb-function in physical rehabilitation treatment and research, *Int J Rehabil Res* **4** (1981), 483-492.
[26] Mehrholz J., Hadrich A., Platz T., Kugler J. and Pohl M., Electromechanical and robot-assisted arm training for improving generic activities of daily living, arm function, and arm muscle strength after stroke, *Cochrane Database Syst Rev* **6** (2012), CD006876.
[27] Nakayama H., Jorgensen H. S., Raaschou H. O. and Olsen T. S., Recovery of upper extremity function in stroke patients: The Copenhagen Stroke Study, *Arch Phys Med Rehabil* **75** (1994), 394-8.
[28] Nijland R. H., van Wegen E. E., Harmeling-van der Wel B. C. and Kwakkel G., Presence of finger extension and shoulder abduction within 72 hours after stroke predicts functional recovery: Early prediction of functional outcome after stroke: The EPOS cohort study, *Stroke* **41** (2010), 745-50.
[29] Riener R., Robot-aided rehabilitation of neural function in the upper extremities, *Acta Neurochir Suppl* **97** (2007), 465-71.
[30] Sunderland A., Tinson D., Bradley L. and Hewer R. L., Arm function after stroke. An evaluation of grip strength as a measure of recovery and a prognostic indicator, *J Neurol Neurosurg Psychiatry* **52** (1989), 1267-72.
[31] Timmermans A. A., Seelen H. A., Geers R. P., Saini P. K., Winter S., te Vrugt J. and Kingma H., Sensor-based arm skill training in chronic stroke patients: Results on treatment outcome, patient motivation, and system usability, *IEEE Trans Neural Syst Rehabil Eng* **18** (2010), 284-92.
[32] Timmermans A. A., Seelen H. A., Willmann R. D. and Kingma H., Technology-assisted training of arm-hand skills in stroke: Concepts on reacquisition of motor control and therapist guidelines for rehabilitation technology design, *J Neuroeng Rehabil* **6** (2009), 1.
[33] Timmermans A. A., Spooren A. I., Kingma H. and Seelen H. A., Influence of task-oriented training content on skilled arm-hand performance in stroke: A systematic review, *Neurorehabil Neural Repair* **24** (2010), 858-70.
[34] Tsigilis N. and Theodosiou A., Temporal stability of the intrinsic motivation inventory, *Percept Mot Skills* **97** (2003), 271-80.
[35] Tyson S. F. and Kent R. M., Orthotic devices after stroke and other non-progressive brain lesions, *Cochrane Database Syst Rev* (2009), CD003694.
[36] van der Lee J. H., Roorda L. D., Beckerman H., Lankhorst G. J. and Bouter L. M., Improving the Action Research Arm test: A unidimensional hierarchical scale, *Clin Rehabil* **16** (2002), 646-53.
[37] van Kuijk A. A., Pasman J. W., Hendricks H. T., Zwarts M. J. and Geurts A. C., Predicting hand motor recovery in severe

stroke: The role of motor evoked potentials in relation to early clinical assessment, *Neurorehabil Neural Repair* **23** (2009), 45-51.

[38] Verbunt J. A., Seelen H. A., Ramos F. P., Michielsen B. H., Wetzelaer W. L. and Moennekens M., Mental practice-based rehabilitation training to improve arm function and daily activity performance in stroke patients: A randomized clinical trial, *BMC Neurol* **8** (2008), 7.

[39] Verheyden G., Nieuwboer A., De Wit L., Thijs V., Dobbelaere J., Devos H., Severijns D., Vanbeveren S. and De Weerdt W., Time course of trunk, arm, leg, and functional recovery after ischemic stroke, *Neurorehabil Neural Repair* **22** (2008), 173-9.

[40] Wang T. N., Lin K. C., Wu C. Y., Chung C. Y., Pei Y. C. and Teng Y. K., Validity, responsiveness, and clinically important difference of the ABILHAND questionnaire in patients with stroke, *Arch Phys Med Rehabil* **92** (2011), 1086-91.

[41] Wolf S. L., Winstein C. J., Miller J. P., Taub E., Uswatte G., Morris D., Giuliani C., Light K. E. and Nichols-Larsen D., Effect of constraint-induced movement therapy on upper extremity function 3 to 9 months after stroke: The EXCITE randomized clinical trial, *Jama* **296** (2006), 2095-104.

[42] Wolf S. L., Winstein C. J., Miller J. P., Thompson P. A., Taub E., Uswatte G., Morris D., Blanton S., Nichols-Larsen D. and Clark P. C., Retention of upper limb function in stroke survivors who have received constraint-induced movement therapy: The EXCITE randomised trial, *Lancet Neurol* **7** (2008), 33-40.

[43] Wulf G., Shea C. and Lewthwaite R., Motor skill learning and performance: A review of influential factors, *Med Educ* **44** (2010), 75-84.