UNIVERSITY OF LEEDS

This is a repository copy of A proof of concept study investigating the feasibility of combining iPAM robot assisted rehabilitation with functional electrical stimulation to deliver whole arm exercise in stroke survivors.

White Rose Research Online URL for this paper: http://eprints.whiterose.ac.uk/95824/

Version: Accepted Version

Article:

O'Connor, RJ, Jackson, A, Makower, SG et al. (2 more authors) (2015) A proof of concept study investigating the feasibility of combining iPAM robot assisted rehabilitation with functional electrical stimulation to deliver whole arm exercise in stroke survivors. Journal of Medical Engineering and Technology, 39 (7). pp. 411-418. ISSN 0309-1902

https://doi.org/10.3109/03091902.2015.1088094

Reuse

Unless indicated otherwise, fulltext items are protected by copyright with all rights reserved. The copyright exception in section 29 of the Copyright, Designs and Patents Act 1988 allows the making of a single copy solely for the purpose of non-commercial research or private study within the limits of fair dealing. The publisher or other rights-holder may allow further reproduction and re-use of this version - refer to the White Rose Research Online record for this item. Where records identify the publisher as the copyright holder, users can verify any specific terms of use on the publisher's website.

Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.



A proof of concept study investigating the feasibility of combining iPAM robot assisted rehabilitation with functional electrical stimulation to deliver whole arm exercise in stroke survivors

Rory J O'Connor MD FRCP,^{1 2 3} Andrew Jackson PhD,⁴ Sophie G Makower BA (Hons), Grad Dip Phys,³ Alastair Cozens MD FRCS,⁵ Martin Levesley PhD⁴

- Academic Department of Rehabilitation Medicine, Faculty of Medicine and Health, University of Leeds
- National Demonstration Centre in Rehabilitation, Leeds Teaching Hospitals NHS Trust
- Community Neurological Rehabilitation Service, Leeds Community Healthcare NHS Trust
- 4. School of Mechanical Engineering, University of Leeds
- 5. Department of Rehabilitation Medicine, Woodend Hospital, Aberdeen

Correspondence: Dr Rory O'Connor, Clinical Associate Professor and Lead Clinician in Rehabilitation Medicine, Academic Department of Rehabilitation Medicine, Faculty of Medicine and Health, University of Leeds, Level D, Martin Wing, Leeds General Infirmary, Leeds LS1 3EX, UK

Tel: + 44 (0) 113 3922531

Fax: + 44 (0) 113 3922559

Email: R.J.O'Connor@leeds.ac.uk

Keywords: Stroke, functional electrical stimulation, robots, rehabilitation, arm

Word count: 3,301

Abstract

Background: Rehabilitation robots can provide exercise for stroke survivors with weakness at the shoulder and elbow, but most do not facilitate hand movements.

Aim: To combine robotics and functional electrical stimulation to facilitate exercise in stroke survivors with upper limb impairment.

Methods: iPAM Mk II to assist active reaching in combination with an Odstock Pace stimulator to assist hand opening. The ABILHAND, Action Research Arm Test (ARAT) and the Stroke Impact Scale (SIS) were recorded at baseline and completion.

Results: Nine participants (8 males and 1 female; mean age 58 years) were recruited; mean time since stroke was 16 months (range 6-64). The ABILHAND at baseline was -2.73 improving to -1.45 at follow-up (p=0.038). The ARAT changed from 4.1 to 2.6 (p=0.180), and the SIS from 49 to 60 (p=0.019).

Discussion: This study demonstrates that it is possible to combine two technologies in stroke rehabilitation.

Abstract word count: 144

1.0 Introduction

Stroke is the commonest cause of acquired severe disability in adults of working age in developed countries. Approximately 150,000 people have a stroke each year in the UK and up to 85% of these people experience upper limb paresis at onset.[1] The amount of exercise therapy that people receive determines the speed and completeness of recovery in the arm.[2] However, conventional physical and occupational therapy is resource-limited. This is important because arm function contributes to personal independence and self-esteem. Independence in many activities of daily living requires efficient smooth reach-to-grasp movement. Temporal and spatial coordination between shoulder, elbow, wrist and finger movements are key to this process. In normal human movement there is relative invariance in the temporal coordination of reaching and hand opening, indicating that for most reach to grasp movements that the timing of hand opening is coordinated with the phase of the reaching movement to the target.

Sensory and motor impairments can cause loss of coordination between reaching and hand opening. This results in a reduction in accuracy and efficiency of reach to grasp movements. Although there are many factors contributing to this, for the purposes on this investigation we are focused on the motor impairments that affect the spatial and temporal aspects of efficient reach to grasp.

We have developed a novel robotic system, iPAM (intelligent Pneumatic Arm Movement), to assist patients in undertaking additional therapeutic exercise with minimal input from the therapist.[3] It assists the person to undertake active reaching iPAM-NMES Resubmission 27 05 2015 exercises and addresses weakness of shoulder, upper arm, and elbow and forearm movements. It supplements, but does not replace, therapists' input. However, one of the limitations of robotic devices in providing rehabilitation is the lack of assisted hand opening for those patients where not only reaching ability is impaired but also the ability to smoothly open the hand during a reach to grasp arm movement. Neuromuscular electrical stimulation (NMES) can provide a relatively simple way to provide assisted hand opening by electrically stimulating certain muscles of the forearm which are concerned with wrist and finger extension movement. NMES devices are commonly used in healthcare settings to address muscle weakness in conditions such as stroke.

The aim of this study is to investigate the feasibility of using iPAM with NMES within a laboratory setting to provide simultaneous hand opening exercises during assisted reaching exercises for stroke survivors who have moderate to severe arm weakness. The rationale for investigating a combined approach is that it more realistically mimics normal prehension rather than developing an intervention that involves undertaking NMES hand opening exercises separately from reaching exercises. This is in keeping with device development and concurs with the MRC guidance on the evaluation of complex health care interventions in the context of phase 1 clinical trials. While it is usually unacceptable to modify an intervention during the course of an RCT, an exploratory or feasibility trial can be developed to explicitly explore the nature of the intervention and build up safety data prior to a formal controlled clinical trial. Therefore the objectives of this feasibility study were: (a) to determine whether the robot and NMES combined therapy can provide the type of movement therapy that is deemed necessary by the physiotherapist; (b) to assess patient compliance/comfort, and usefulness to physiotherapists in terms of its flexibility in providing different arm/hand exercises; (c) to inform a future larger randomised clinical trial of the intervention dose, appropriate outcomes and practicality of using the equipment.

2.0 Methods

2.1 The iPAM Mk2 system

iPAM Mk2 is a dual robot system designed to mimic the manner in which a physiotherapist facilitates assisted upper-limb exercise [Figure 1]. Two identical robot arms, each consisting of three pneumatically powered revolute joints, attach to the patient's upper-limb via two custom designed orthoses.[4] A distal orthosis attaches to the forearm close to the wrist while a proximal orthosis attaches at the mid-point of the upper-arm. The ends of each robot can be exchanged to provide both left and right-sided operation. Each orthosis allows three passive rotational degrees of freedom (DoF) aligned through the centre of the limb, preventing unwanted torques being applied at the attachment points. Rotary sensors measure the rotation of the six active robot joints while two six-DoF force/torque transducers record the relative forces between the robot and the patient's limb.

The position of each robot orthosis can be controlled in Cartesian space. However, to ensure the robots coordinate with each other at all times, a novel control strategy was developed. Rather than control the end points of the robots individually, the control strategy coordinates the movement of the robots around a model of the human arm. This prevents excessive torques or forces being applied to the human limb due to misalignment of the robot end effectors. With each robot providing three active DoF, it is possible to control a total of six DoF of the human arm. This six DoF human arm model incorporates shoulder elevation/depression, shoulder protraction/retraction, shoulder abduction/adduction, shoulder flexion/extension, shoulder internal/external rotation and elbow flexion/extension. iPAM Mk2 does not iPAM-NMES Resubmission 27 05 2015 provide assisted forearm pronation/supination, wrist flexion/extension or hand grasping. Further details of the iPAM system can be found in [1,2].

Figure 1 about here

At the beginning of a treatment session, when the patient's arm is being attached to the system, the iPAM controller requests sufficient force from the pneumatic actuators to offset the weight of the robot arms and orthoses. This state is known as the passive warm-standby mode. At the same time the inherent back drivability of the pressure regulating valves means the end points of the robots can be freely moved around by the patient and physiotherapist to allow easy attachment of the orthoses. Once attached, a calibration process is undertaken to match the patient's arm with the human arm model used by the control system. Custom measurement tools are used to record the relative position of the distal and proximal orthoses to the patient's elbow and shoulder respectively and the location of the patient's shoulder relative to the base of the proximal robot arm. A virtual "3D" model of the arm is presented to the physiotherapist to assess the success of the calibration procedure. Once calibration has been confirmed, the physiotherapist must decide on the type of exercise the patient will undertake, these can either be recorded manually (fixed tasks) or automatically generated based on a clinical assessment of the patient (automated tasks). The latter allows targeted and varied exercise practice based on a particular treatment strategy within a safe workspace defined by the physiotherapist. Each exercise consists of up to eight component trajectories, each leading to a virtual target that the patient should attempt to reach. A virtual environment is displayed to the patient on an LCD display incorporating a "3D" representation of their arm, the target location and movement prompts to aid the patient. iPAM will assist the patient **iPAM-NMES** Resubmission 27 05 2015 to reach the target. The level of assistance is determined by the exercise program or can be set manually by the physiotherapist. At the end of each exercise, feedback is provided to the patient. This includes the number of targets achieved during the attempt along with encouraging text messages and movement prompts e.g. "sit-up straight". Once a prescription has commenced, a patient will typically undertake between 30 and 50 exercises without the need for further physiotherapist intervention. Depending on the category of exercise, iPAM will automatically adjust parameters, such as increasing the movement range or reducing the assistance provided by the system, as the patient progresses.

2.2 Neuromuscular Electrical Stimulation System

The NMES system used in this study is a commercially available Odstock PACE neuromuscular electrical stimulator. It is a CE-marked medical device made by Odstock Medical Limited (Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ. http://www.odstockmedical.com/products/odfs-pac-kit). The electrodes used in the study were ACUPAD silver carbon TENS electrode (SLS5050) 5cm x 5cm square (Nidd Valley Medical Ltd, Unit 22 Claro Court Business Park, Claro Road, Harrogate, HG1 4BA. http://www.niddvalley.co.uk).

Electrodes were placed over the extensor aspect of the forearm on the side affected by the stroke. The active electrode was placed over the motor points of extensor carpi radialis brevis and longus and extensor digitorum communis muscles. The indifferent electrode was placed over the motor points of extensor pollicis longus and abductor pollicis longus.

2.3 Equipment Interface

In order to allow the Odstock PACE stimulator to be triggered by iPAM changes to the system hardware of iPAM Mk2 were required. An existing digital output from the chassis was used to trigger the NMES. The 3.4v signal from the digital line is used to turn on a solid-state relay (SSR). The output line of the SSR was then connected to a 2.5mm audio jack socket on the iPAM base unit. A connection lead was made to connect the external trigger input of the NMES stimulator to the iPAM base unit. When the digital line is set to high, it allows current to flow through the external trigger circuit. When the digital line is then set to low, the SSR turns off and the external trigger appears off. The Odstock PACE is set to operate on the falling edge of the external trigger. An image of the Odstock PACE connected to iPAM is shown in Figure 2.

Figure 2 about here

In order to incorporate the triggering of the NMES within the iPAM system, it was necessary to make several changes to the low-level control software. So that the NMES triggers appropriately during each exercise, i.e. the patient's hand will open realistically in a reach-and-grasp movement, a strategy was developed to trigger the NMES at a particular point during the active exercises. For each exercise, the

iPAM-NMES Resubmission

system determines a component, which is the movement from one virtual target to the next. During the arm movement, one would expect the hand to open at a particular point in that component. The point at which hand opening would be initiated in a reach-and-grasp movement is the active radius. The active radius percentage is the percentage of the distance between starting a movement and when the hand would begin to open, and the overall distance between the start point and the final target. For the purposes of this treatment, as the hand opening is triggered by NMES, we have termed the point at which NMES should trigger hand opening as the NMES active radius. The system determines, for each component, the straight-line distance between the previous (or start hand position in the case of the first component) and the current target and then calculates an NMES active radius based on this distance and the NMES radius percentage value as these will vary depending on the overall distance the patient's hand travels. If needed, the NMES radius percentage parameter can be altered by the physiotherapist using the clinician interface.

During exercises, iPAM monitors the distance between the patient's hand and the current target. When the patient gets within the NMES active radius of the target, the NMES triggers by setting the digital line for the NMES to high and then low again. As the purpose of iPAM therapy is to enhance upper limb movement, therapies concentrated on overall movements of the upper limb. Due to the velocity at which these exercises were intended to be performed, it was not possible to trigger the NMES on every component, as we found the extensor muscles of the forearm were refractory to stimulation when stimulated too quickly in succession. Instead, the

NMES was set to trigger on only odd numbered components. Changes were made to the patient interface to include an indicator to show when the hand should open during the movement. The patient interface during active exercises is shown in figure 3.

Figure 3 about here

2.4 Participant recruitment

Participants were recruited through NHS stroke services within Leeds. The study was approved by Leeds West Research Ethics Committee (12/YH/0263) and the Medicines and Healthcare Regulatory Agency (Cl/2012/0025). The main recruitment criteria were that patients should have difficulty with arm reaching movements and suitable hand characteristics for NMES. The main exclusion criteria were inability to give informed consent, or any medical issues which would affect their safe participation with the combined therapy. The plan of the phase 1 study was to recruit up to 10 patients and undertake up to 10 treatment sessions each. While improvements in patient movement and function would be considered a successful outcome of the trial, the main aim was to determine the potential of iPAM – NMES as a combined therapy with up to10 patients.

2.5 Research intervention

These exploratory trials took place at The Charterhouse Rehabilitation Technologies Laboratory, a purpose-built laboratory for rehabilitation technology research, at the University of Leeds. It is situated on the ground floor allowing convenient access. The laboratory was partitioned as required for each session to allow separate areas for clinical assessment, iPAM exercise and break periods. All sessions were run by the iPAM research physiotherapist.

In order to ensure that the participant's impairment was amenable to NMES, written, informed Stage 1 Consent was obtained. Participants were then clinically assessed and NMES was applied to the forearm to stimulate hand opening and settings adjusted as required to obtain comfortable, adequate hand opening with the arm at rest while seated at a table and when performing reaching movements with facilitation by the research physiotherapist. If the research physiotherapist considered that the NMES effectively opened the participants' hand, and the participant wished to continue, he or she was then invited to sign Stage 2 of the written informed consent and proceed to completing the full set of outcome assessments and agree a rehabilitation prescription.

2.6 Outcome assessments

Participants consenting to Stage 2 completed three outcome measures:

 ABILHAND is a self-reported questionnaire which evaluates perceived performance in actual daily life activities.[5] The 23 items are simple daily life activities that the patients are asked to estimate the difficulty in performing them as impossible, any difficulty or easy. This questionnaire takes approximately 10 -15 minutes to complete. Item responses are entered onto an online database which uses Rasch analysis to derive an interval level score.

- 2. Action Research Arm Test (ARAT) is a measure of grasp, grip, pinch and gross voluntary movements of the affected arm.[6] It is a validated and widely used outcome in stroke research. This test takes approximately 20 minutes to complete. The participants' arm movements will be captured on digital camera during ARAT tasks for review of the qualitative aspects of arm and hand movement during reaching and grasping tasks. The test is scored out of 57.
- 3. Stroke Impact Scale (SIS) is a stroke specific questionnaire that measures the impact of stroke on participants, and it has been widely used as the outcome measure in randomised controlled trails and more specifically in robot rehabilitation studies.[7] It is a reliable and valid scale for assessing overall outcome of people with stroke. This questionnaire takes approximately 15-20 minutes to complete. It is scored out of 295, but is transformed to a 0 100 scale.

Outcome measures were completed with support from the research therapist as required to assist participants with communication or writing impairments. A single set of outcomes was recorded during visits to the research laboratory before commencing any experimental treatment and a further set was recorded on conclusion of the intervention. On conclusion of their involvement in the study, participants also completed a user satisfaction questionnaire adapted from instruments used in previous user-centred design projects in our Department. Participants were encouraged to provide free comments and suggestions for improvement.

2.7 iPAM – NMES treatment sessions

At each session, a brief clinical assessment was done to ensure it was appropriate to conduct the session and to guide the appropriate rehabilitation prescription. At the first session the required measurements were done for iPAM set-up. Participants completed up to 60 repetitions over 45 minutes at each session. At all sessions NMES was set up and appropriate muscle contraction obtained away from iPAM and then the usual iPAM set-up procedure was followed with a set of standardized iPAM exercises with NMES in situ but turned off. NMES was then manually triggered by the research physiotherapist for a few initial exercises followed by NMES set to automatically trigger as required for optimum hand opening and participant comfort.

3.0 Results

3.1 Recruitment

Twenty potential participants were provided with information in the study by staff from the NHS stroke rehabilitation teams in Leeds, of whom 13 made contact with the study physiotherapist. Ten participants met the inclusion criteria to take part in this exploratory study. Following recruitment, one participant no longer wished to participate and withdrew from the study. The demographics of the remaining nine participants are outlined in Table 1.

Table 1 about here

Two participants (NMES 07 and NMES 08) received no iPAM-NMES treatment due to recurrent malfunctions with the technology which were not resolved until after the treatment period of the study had completed. The other participants received between one and ten sessions of treatment before the treatment period of the study finished.

3.2 Outcome measures

The two participants who did not receive any treatments did not complete the follow up standard clinical outcome measures or the iPAM patient feedback questionnaire. Their baseline scores are included in the outcomes presented along with the baseline and follow-up scores of the other participants.

iPAM-NMES Resubmission

ABILHAND Scores

Scores for ABILHAND (Table 2) indicate an improvement with iPAM-NMES treatment with the score increasing from -2.730 logits to -1.448 logits (p = 0.038).

Table 2 about here

ARAT Scores

ARAT scores for the participants' unaffected upper limb were all 57 (the ceiling score). The mean score of the affected upper limbs was 4.1 before treatment and 3.0 after treatment (p = 0.182)

Table 3 about here

SIS Scores

The mean Stroke Recovery Score at baseline was 49 which improved to 60 at follow-up (p = 0.019).

Table 4 about here

3.3 Patient feedback questionnaire

iPAM-NMES Resubmission

The participants' feedback on the technology was positive (Table 5). Participants endorsed comments reflecting that they found iPAM-NMES acceptable and useful in their rehabilitation. Apart from several participants commenting on the time to set-up and failures of the technology, unstructured comments were also positive.

Table 5 about here

3.4 Adverse events

There was one serious adverse event and one adverse event. Thirteen days after receiving two treatment sessions, a participant fell at home sustaining a fractured hip. Following surgery and a recovery period, he resumed his participation in the trial eight weeks after the fall and completed the study treatment. It was not felt that this event was directly related to the study. Another participant noted during his first treatment session that his arm felt tight having completed 63 repetitions of the exercise programme. This resolved and did not recur during subsequent sessions.

4.0 Discussion

This pilot study is the first to combine an upper limb robotic rehabilitation device with a commercially available upper limb functional electrical stimulation system. The study demonstrated that the combination was safe, well tolerated and resulted in modest improvements in upper limb function. Participants found the combination of therapies engaging and enjoyed the exercise sessions even when their movement was not optimally therapeutic e.g. when only partial or minimal hand opening was achieved.

To achieve hand opening during a simple iPAM movement requires several technical adjustments, but the set-up time is reasonable, and it can then work effectively and consistently without requiring further adjustment. But facilitating optimum hand opening in conjunction with a variety of iPAM movements by means of manual adjustments significantly limits the therapeutic practicalities of the combination of treatments. Either a more sophisticated method of matching the NMES action with the iPAM movements needs to be developed or it needs to be accepted that the full variety of iPAM movements cannot be used when in conjunction with NMES.

The degree of hand opening is affected not just by the patient's level of impairment or the level of intensity of the NMES but on the participant's muscle tone while exercising. Muscle tone in the upper limb changes with effort, fatigue, emotion and the degree of voluntary activity in the limb and trunk at any given moment in a particular context. This observation, commonly made and adjusted for, during conventional therapy has to be accommodated in a therapeutically appropriate way iPAM-NMES Resubmission 27 05 2015 during the use of any rehabilitation technology. A therapeutic decision has to be made during the delivery of combination therapy whether to prioritise the exercise for the session as hand opening or a reaching movement from the shoulder and elbow as the settings required for each may conflict. This decision has to be taken to balance the optimal therapeutic movement and the disruption to therapy and therapist time needed to make these adjustments.

This study is limited by the small number of participants and the relatively small quantity of treatment each participant received. In addition, there was substantial variability amongst the participants in terms of since stroke, severity of impairments and the amount of treatment received. Therefore, it was not possible to perform any subgroup analyses to suggest whether the treatment was any more beneficial in the first year after stroke compared to the second and subsequent years nor whether there was the response related to the amount of treatment.

Furthermore, as we only collected one set of baseline measures before treatment commenced, it was not possible to determine if participants' disabilities were changing due to natural recovery. While the improvements in patient movement and function were gratifying outcomes, the main aim of the trial was to determine the potential of iPAM – NMES as a combined therapy and so the trial was not powered to detect a difference greater than would be noted due to natural recovery following stroke. The generally accepted definition of chronic stroke is persistence of disability six months after stroke [8] and although the amount of improvement more than six months after stroke would necessarily be limited, there is a possibility that the iPAM-NMES Resubmission 27 05 2015 changes seen were due to natural recovery. An alternative view is that there is potential for further recovery and iPAM – NMES is a useful strategy to unlock this potential.

These points need to be considered when implementing this treatment into routine clinical rehabilitation. There is no reason to believe that the treatment would not work for other central nervous conditions that cause upper limb impairment such as hemiplegic traumatic brain injury or tetraplegic spinal cord injury. Widening the indications for this treatment will improve cost effectiveness for centres purchasing the device. Extra time from a qualified therapist will be required for patients who are commencing this treatment, but once set up patients will continue to exercise independently for the remaining time. This frees the skilled therapist to do more sophisticated tasks for patients requiring individualised assessments or treatments.

The literature on arm recovery after stroke, indeed recovery of any activity after any neurological injury, strongly suggests that recovery of function is directly related to the amount of practise.[2] Despite the low number of treatments received by participants in this study, small, but important, improvements were noted in their level of functioning, indicating that further recovery may be possible for stroke survivors months, and sometimes years, after a stroke. This may be because participants in this study actively assisted in their exercises, which is known to promote recovery, probably through physiological muscle activation and afferent proprioceptive input enhancing the training effect of the exercise. [9, 10]

iPAM-NMES Resubmission

27 05 2015

Conclusion

The objectives of this study were to determine if a combination therapy of robotic and electrical stimulation was feasible and acceptable to patients and therapists. These objectives were met and this is the first study to report that a combination of robotic upper limb therapy with functional electrical stimulation can be used in a group of chronic stroke survivors with persisting upper limb impairments. Based on the findings in this report, future work is planned to explore the possibilities of further combinations, including in lower limb rehabilitation, and to optimise the characteristics of robotic and stimulation parameters.

Acknowledgements

We would like to thank the participants and clinicians who referred patients to this study. We would like to thank the Leeds Teaching Hospitals Research Capability Fund for providing financial assistance to the research physiotherapist to complete the study.

The research reported in this publication was funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

21

5.0 References

- Department of Health, *National Stroke Strategy*. 2007, Department of Health: London.
- Adkins, D.L., et al., *Motor training induces experience-specific patterns of plasticity across motor cortex and spinal cord.* J Appl Physiol (1985), 2006.
 101(6): p. 1776-82.
- Jackson, A.E., et al., *Development of the iPAM MkII system and description of a randomized control trial with acute stroke patients.* IEEE Int Conf Rehabil Robot, 2013. 2013: p. 6650407.
- Jackson, A.E., et al., *Effector force requirements to enable robotic systems to provide assisted exercise in people with upper limb impairment after stroke.*IEEE Int Conf Rehabil Robot, 2011. 2011: p. 5975391.
- 5. Penta, M., et al., *The ABILHAND questionnaire as a measure of manual ability in chronic stroke patients: Rasch-based validation and relationship to upper limb impairment.* Stroke, 2001. **32**(7): p. 1627-34.
- Platz, T., et al., Reliability and validity of arm function assessment with standardized guidelines for the Fugl-Meyer Test, Action Research Arm Test and Box and Block Test: a multicentre study. Clin Rehabil, 2005. 19(4): p. 404-11.

- Lin, K.C., et al., *Psychometric comparisons of the Stroke Impact Scale 3.0 and Stroke-Specific Quality of Life Scale.* Qual Life Res, 2010. 19(3): p. 435-43.
- 8. Kwakkel, G., et al., *Effects of augmented exercise therapy time after stroke: a meta-analysis.* Stroke, 2004. **35**(11): p. 2529-39.
- Dietz, V., K. Fouad, and C.M. Bastiaanse, *Neuronal coordination of arm and leg movements during human locomotion.* European Journal of Neuroscience, 2001. 14(11): p. 1906-14.
- Dietz, V., *Do human bipeds use quadrupedal coordination?* Trends in Neuroscience, 2002. 25(9): p. 462-7.

Patient id	Sex	Age	Month since stroke	Affected side	Number of iPAM–NMES sessions received
NMES 01	Male	56	8 months	Left	10
NMES 02	Male	50	8 months	Right	10
NMES 03	Male	65	31 months	Right	9
NMES 04	Male	28	7 months	Right	6
NMES 05	Male	55	12 months	Right	2
NMES 06	Male	64	8 months	Right	5
NMES 07	Female	79	17 months	Left	Attended 2 sessions but no treatment given due to technical problems
NMES 08	Male	68	46 months	Left	2 sessions booked but cancelled
NMES 09	Male	55	6 months	Left	1

Table 1 Demographics of participants

Table 2 ABILHAND scores

Detient		Baseline)	Follow up			
Patient	Score	Patient Measure (logits)	Standard Error (logits)	Score	Patient Measure (logits)	Standard Error (logits)	
NMES 01	0	-6.078	1.687	5	-2.839	0.519	
NMES 02	6	-2.603	0.487	8	-2.179	0.445	
NMES 03	12	-1.448	0.402	11	-1.647	.407	
NMES 04	2	-3.847	0.714	14	-1.187	0.383	
NMES 05	23	0.160	0.368	25	0.263	0.359	
NMES 06	0	-6.072	1.688	10	-1.644	0.431	
NMES 07	4	-3.129	0.558	-	-	-	
NMES 08	27	1.046	0.405	-	-	-	
NMES 09	6	-2.603	0.487	16	-0.905	.373	

Patient		Bas	Follow up		
Falleni	Hemiplegia	Right	Left	Right	Left
NMES 01	Left	57	0	57	0
NMES 02	Right	6	57	6	57
NMES 03	Right	0	57	0	57
NMES 04	Right	2	57	0	57
NMES 05	Right	18	57	15	57
NMES 06	Right	0	57	0	57
NMES 07	Left	57	0	-	-
NMES 08	Left	57	11	-	-
NMES 09	Left	57	0	57	0

Table 3 Action Research Arm Test scores

Table 4 Stroke Impact Scale scores

Patient		Baseline	Follow-up			
	Score	Stroke Recovery 0-100	Score	Stroke Recovery 0-100		
NMES 01	173	50	178	75		
NMES 02	147	50	165	50		
NMES 03	187	48	181	57		
NMES 04	136	63	146	64		
NMES 05	221	42	233	60		
NMES 06	162	40	188	75		
NMES 07	165	65	-	-		
NMES 08	211	65	-	-		
NMES 09	171	20	189	42		

Table 5 Patient Feedback Questionnaire

Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
I was reassured by the robot's appearance	3	2	2		
I was intimidated using the robot				2	5
The robot's sound distracted me			1	3	3
The robot's sound irritated me			1	3	3
The robot's sound was intimidating			1	3	3
The robot was easy to attach to my upper arm.	3	3	1		
The robot was easy to attach to my lower arm	3	3		1	
My hand was supported while in the robot	5	1		1	
The robot was comfortable (at rest) when attached to my upper arm	4	3			
The robot was comfortable (at rest) when attached to my lower arm	4	3			
The robot was comfortable (while exercising) when attached to my upper arm	4	2			1
The robot was comfortable (while exercising) when attached to my lower arm	4	2	1		
Releasing my upper arm from the robot was easy	5	1	1		
Releasing my lower arm from the robot was easy	3	2	2		
My arm felt secure while using the robot	4	2	1		
I felt safe while using the robot	6	1			
The chair was comfortable	4	2			1

The harness was comfortable	3	2	2		
Releasing my hand from the robot was easy.	1	4			
I felt the robot system encouraged me to exercise my arm	5	1	1		
I understood how to use the robot system	4	3			
The computer screen instructions were understandable	3	2		1	1
The exercise tasks were fun	3	1	3		
The exercise tasks were motivating	3	1	2	1	
The exercise tasks were varied	2	2	1	2	
The exercise tasks were boring	1		2	1	2
The exercise tasks were frustrating		1	1	1	3
Using iPAM with FES was comfortable	2	5			
The Odstock PACE helped my hand to join in the iPAM arm exercise	1	5		1	
The smoothness of my arm and hand movements was good.	1	4	2		
iPAM and Odstock PACE work well together.	1	3	1	1	1
iPAM and Odstock PACE took too long to set up.		1	2	2	2
I would consider using iPAM and Odstock PACE combined for my future rehab	6	1			
I would be willing to take part in future research sessions about and iPAM and Odstock PACE combined	5	1			1



Figure 1 The iPAM Mk2 dual robot rehabilitation system

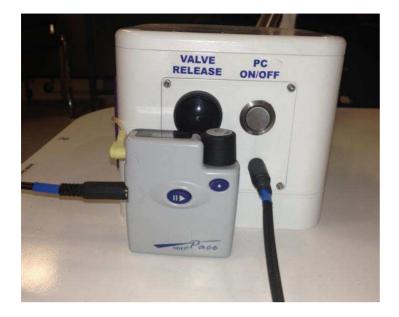


Figure 2 Odstock PACE connected to iPAM via the external trigger input

Figure 3 The Patient Interface during an active exercise with NMES active

