Improving upper limb functions in stroke patients: a clinical study of the efficiency of robot-mediated therapy

Ph.D. Thesis

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Introduction

Industrial robot as defined by ISO 8373:2012 standard:

„An automatically controlled, reprogrammable, multi-purpose manipulator programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications."

In the process of rehabilitation one way to assist patients is to use (personal) assistive robots, while a solution for enhancing personal performance can be with the use of therapeutic training robots. These devices are most commonly used during the rehabilitation process of stroke patients. Clinical studies have also been performed in the case of patients with traumatic brain-injuries, spinal-cord injuries, cerebral paresis and other neuromotor disorders.

Stroke is a leading cause of long-term disability among adult people in developed countries. Therefore, the possibilities and methods that can enhance the self-supporting ability of these patients, alleviate their pains and reduce the cost of therapy and nursing have been placed in the centre of attention.

Robot-mediated therapies are highly useful in the early phase in the case of intensive, task-specific, goal-oriented and repetitive exercises. Another advantage of using robots is that they can guarantee an infinite number of

repetitions without becoming exhausted, in opposition to the limited abilities of a physiotherapist.

The Reharob Therapeutic System, which is a passive shoulder-elbow training device, was developed in our country under the fifth framework programme of the EU. Previously two clinical studies had been performed with the device. The first one was conducted in 2003, with the aim of gaining experience. On the basis of this trial the system has been improved. The second clinical study occurred in 2005 with a control group. The results showed that stroke-patients taking part in robot-mediated therapies achieved significantly higher Fugl-Meyer and Modified Ashworth scores than the members of the control group.

Objectives:

Objectives of the technical development:

- To supplement Reharob, which originally was only a passive shoulder-elbow training device, with distal modules enabling the improvement of wrist-hand functions.
- To ensure active and active-assistive movements beside passive ones.
- The robot should be suitable for helping patients practice the activities of daily living (ADL).

Clinical aims:

- To gain experience about the further-improved system.
- To prove the safeness of robot-mediated physiotherapy.
- To examine whether the paretic upper limbs of chronic stroke patients are capable of showing further improvement after an intensive four-week long ADL training with the help of robot-mediated physiotherapy.

Methods:

Review of the applied technology:

Reharob was developed by engineers from the Budapest University of Technology and Economics' Department of Manufacturing Science and Engineering and the Department of Mechanical Engineering. The robot was mainly constructed from elements available on the market. Two industrial robotic arms produced by the ABB Company are attached to the upper arm and forearm of the patient with two instrumented orthoses. The following tools were installed between the orthosis and the robot: two torque meters, a safety releasing mechanism, a handle for the therapist, and a tool to detach the robotic arm. The stand includes the processing

units of the robots, the control panel and the touch-screen computer. The custom-developed programme runs on Microsoft Windows, which sends an error message if necessary, and stores the movements of the robotic arms.

The following new technical developments had been added to the robot before the clinical study took place:

- Creation of a new software component capable of processing the data of the force sensors in order to ensure active physical exercise.
- Development of objects equipped with force sensors (for detecting grip) to enable ADL training.
- A new elbow orthosis was created to help the movement of the shoulders, the elbows and the wrists. A set of various sizes was also created which secures the three middle fingers to enable their movement.
- In order to help physiotherapists, the movements of the active training for each patient can be saved and reloaded to the robot’s memory in the processing unit.
- Installation of speakers and a screen in order to inform patients.

- Development of a six-axis force sensor and of a safety releasing mechanism in order to ensure a more reliable functioning of the device.
- The translation of certain components of the processing programme into the modern C# language and the renewal of the graphic user interface.

The development occurred with the constant cooperation of physicians and engineers. The author's task was to inform the engineering staff about the users' needs, to select the exercises to be performed by the robot, to give continuous feedback during the developmental phase and to test the final system.

Patients and methods:

Twenty chronic stroke patients took part in the clinical study. The average age of the patients was 60.35 years. Thirteen of the patients suffered right hemipareses and seven of them had left hemipareses. The average time elapsed since the stroke occurred was 31.95 months. Sixteen of them went through ischemic strokes, while four of them were affected by haemorrhagic strokes.

Review of the applied interventions

The following assessment scales were used in the clinical study:

Motoric scales: Fugl-Meyer Assessment – Upper Extremity (FM), Modified Ashworth Scale (MAS), British Medical Research Council Muscular Strength Scale (MRC)

Functional scales: Action Research Arm Test (ARAT), Functional Independence Measure (FIM), Barthel Index (B1)

The assessment scales were recorded by an independent physiotherapist, who did not participate in the physiotherapy.

The clinical study's procedure:

- Pre-screening of patients (P1): since it was a self-controlled study, the pre-screening was necessary in order to prove that there was no spontaneous improvement in the patients' condition. Common and anamnestic data, medical and neurological status, as well as assessment scales were recorded.
- Selecting patients (S1): was performed one month after P1, by using the same assessment scales. In case there was no significant change in the patient's condition, the person was chosen for selection.

- Therapeutic sessions (T1-T20): robot-mediated therapy (twenty sessions within six weeks). After sessions T10 and T20 the patients' status was assessed. (S1 was usually directly followed by T1, if for some reason the first therapeutic session did not take place on the same day as the selection, T1 took place within two days of S1, which was previously laid down in the research plan).
- Follow-up (F1): took place three months after the last therapeutic session and it consisted of a conversation and an additional status assessment.

The procedure of the robot-mediated physiotherapy:

The participants attended a fifty-minute-long robot-mediated physiotherapy for twenty consecutive working days. Before the training started, the patients were placed on and secured to a treatment chair, following which the orthoses were attached to the patients. Each session consisted of a fifteen-minute-long passive warm-up, followed by five ADL tasks, each lasting for seven minutes. The ADL tasks were the following:

- lifting a mug to one's mouth by its handle
- zipping up and unzipping a waistcoat
- lifting up and laying down a phone

- wiping the mouth with a sponge
- opening and closing a cupboard door

Applied statistics:

The statistical analysis was conducted by using version 13 of the Statistica programme produced by StatSoft Inc. In order to prove that there was no spontaneous improvement in the condition of the chronic stroke patients, the results of the P1 and S1 status assessments were compared with one-sample t-test. In order to determine the efficiency of the robot-mediated therapy, the data of the S1, T20 and F1 status assessments were compared by using one-way analysis of variance (ANOVA).

The clinical survey was approved by The Scientific and Research Ethical Committee of the Medical Research Council and the Office of Health Authorisation and Administrative Procedures. The authorisation number is: 10128/2012/OTIG.

The patients signed a declaration of consent after receiving information about the study.

Results:

Technical results:

The patients altogether received 20 x 20 x 50 minutes = 20,000 minutes (333.33 hours) of robot-mediated

physiotherapy. No undesirable events took place during this time period.

However some technical problems emerged in the course of the therapy:

- An engineer's assistance had to be requested in order to turn on and off (calibrate) the robotic device, due to a battery breakdown.
- Sometimes the force meters had to be recalibrated during the therapeutic sessions.
- When one of the wrists of the robotic arm reached the end position, the given string of exercises was interrupted. Consequently, an engineer's help was needed to reposition the robotic arm and also to teach the robot the given set of exercises.
- Some objects broke and/or their force sensors failed.

Results of the motoric scales:

Within the motoric scales, visible improvement could be observed in the FM values, which showed improvement in the case of eighteen patients out of twenty. The improvement was significant ($p<0.05$) when using one-way analysis of variance for the comparison of the S1-T20 values. The MRC value did not show notable improvement in the case of shoulder abduction, elbow

flexion and extension, and wrist dorsal and volar flexion. The modified Ashworth values of shoulder adductors and elbow and wrist flexors did not show any change.

Results of the functional scales:

Among the functional scales, significant improvement could be seen in the case of ARAT. The results of thirteen patients improved, in five cases the values remained constant, and in the case of two patients the study could not be performed, due to their insufficient hand functions. The change in the ARAT scale, comparing the beginning and the end results, showed a significant improvement ($p<0.05$) when analysed with the use of ANOVA.

Regarding FIM, positive change occurred in the case of six out of twenty patients, which also means a significant improvement when comparing T1-T20 values evaluated by statistical tests.

The scores of Barthel Index improved in the case of two patients. However, this change was not significant at the end of the therapy, when examined by the method of analysis of variance compared to the onset value.

The comparison of the results of the status assessment of S1 and the follow-up was performed by using ANOVA. It showed significant improvement in the case of FM, ARAT and FIM scales.

Results of the patient satisfaction questionnaires:

The data extracted from the patient satisfaction questionnaires revealed that the patients were pleased to take part in the robot-mediated physiotherapy. Most of them found the length of the sessions sufficient, they either did not find them overly exhausting, or found them tiring only to an extent which was still tolerable. Only one patient went through an unpleasant experience (his arm got stuck, and it was difficult for him to get off the experiment chair).

Conclusions:

1. The literature review presented hereby provides the most up-to-date and complete image of the presently used therapeutic robots that enable the training of the upper limb and also the improvement of motor functions.
2. With my professional help, I assisted the engineering process, thanks to which Reharob Therapeutic System, which originally could only be used for passive exercises, became suitable for training the whole of the upper limb and also for performing active-assisted exercises.
3. I took part in specifying the ADL set of movements, which enable the movement of any joint of the upper limb into any direction.

4. Based on the clinical survey we established that the robot-mediated physiotherapy that exercises the whole of the upper limb, and which was used only by our team in Hungary, is safe to use.
5. We observed that the robot-mediated therapy motivated the patients, who were pleased to have participated in the therapeutic programme and stated that they would willingly take part in a similar survey in the future.
6. I proved that even a year after the stroke took place, the robotic therapy may be suitable for improving the upper limb functions of patients who are in a good functional condition.

Publications related to the dissertation:

1. **Péter O**, Fazekas G, Zsiga K, Dénes Z. (2011) Robot-mediated upper limb physiotherapy: review and recommendations for future clinical trials. Int J Rehabil Res, 34: 196-202. **IF:1,083**

2. **Peter O**, Tavaszi I, Toth A, Fazekas G. (2017) Exercising daily living activities in robot-mediated therapy. J Phys Ther Sci, 29: 854-858.

3. Zsiga K, Edelmayer G, Rumeau P, **Péter O**, Tóth A, Fazekas G. (2013) Home care robot for socially supporting the elderly: focus group studies in three European countries to screen user attitudes and requirements. Int J Rehabil Res, 36: 375-378. **IF: 1,144**

4. Zsiga K, Tóth A, Pilissy T, **Péter O**, Dénes Z, Fazekas G. (2017) Evaluation of a companion robot based on field tests with single older adults in their homes. Assist Technol. 2017; 19(6): 1-8. **IF: 1.037**

Other publications:

1. Dénes Z, Fazekas G, Zsiga K, **Péter O.** (2012) Rehabilitációs ismeretek kórházi orvosok és szigorlók körében. Orv Hetil, 153: 954-961.