Application of robots at patients with paresis of the upper limb as a consequence of central motor neuron lesion for supporting physiotherapy during rehabilitation

PhD Thesis Summary

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Introduction

Many patients who require rehabilitation as a consequence of neurological impairments have paresis due to upper motor neuron lesion. Beside the paresis itself other symptoms also occur as part of the upper motor neuron syndrome. Among them spasticity is very important, because it often causes secondary impairments (contracture, pressure ulcer) and it can significantly decrease the patient's functional performance and the level of self-care. The most frequent cause of spastic paresis is stroke, but it can occur due the traumatic brain injury, anoxia, brain tumour, multiple sclerosis, perinatal brain damage and some other reasons. Stroke is especially important because of its high incidence and also because a significant number of the patients have permanent disability post-stroke. In the developed countries stroke is the leading cause of serious, permanent disability in adults. Patients with traumatic brain injury also have frequently spastic paresis of the upper extremity. Although their number is lower than that of the stroke-patients, they are younger (their mean age is 30), and thus the outcome of their rehabilitation has significant social-economic aspects.

The leading impairment in these patients is usually the spastic hemiparesis. The rehabilitation of these patients is a challenging task for the team including the physiotherapist: they should deal not only with strengthening of the paretic muscles, but also with decreasing spasticity, inhibition of pathological reflexes, improvement of coordination and proprioception. Due to their brain damage, the cooperation of these patients is usually limited, making the physiotherapist's work more complicated. Also concomitant diseases can restrict the patient's loading capacity. Several methods have been used for the movement therapy of patients with spastic hemiparesis, nevertheless there is no evidence if any of them were superior to the others.

Spasticity is velocity- and acceleration dependent and for this reason it can be useful to execute the exercises with a slow and constant velocity and acceleration during the physiotherapy of these patients. The monotony of such exercises is advantageous for decreasing spasticity, but it is physically and mentally exhausting for the therapist. Thus for moving the spastic paretic extremity with a slow and constant velocity, and with a high repetition number of exercises, the use of robots could be highly advantageous. In these cases – also during passive, active assisted and active resisted movements – a robot can give useful support to the physiotherapist.

Robots are flexibly re-programmable devices executing tasks that require complex movements. In contrast to the traditional machines they are able to execute not only pre-determined tasks, but the end-user can change their programme and determine their actual task. Programming of robots is carried out in a user-friendly way: the robots can be taught, the types with built-in artificial intelligence are suitable for decision making. Modern manufacturing industry uses the highest number of robots, but for the past few years they have been applied in medicine, as well. Indeed, during the last 10-15 years several projects started which aimed to involve the robots to the rehabilitation of patients post-stroke. There are two trends of research and development: supporting self-care and physiotherapy. There is a third field as well: the assessment of motor impairments. This task does not require special robots, as the therapeutic robots can be used for this purpose. Robots of the therapeutic group form different subgroups according as they are used for the treatment of the upper or the lower extremity.

Clinical trials with therapeutic robots have usually involved 3-20 patients. The American MIT-Manus is the only exception, in the trials with this robot some hundreds of patients have already been included. Nevertheless, clinical trials on this field are only on the stage of gaining the initial experiences. The overall aim is not to replace the physiotherapist, but to find those applications where the robots can contribute to a better outcome of rehabilitation giving a new method to the hand of the therapist. The robots that are under development all over the world are different both technically and in their modes of operation. Up to now in the clinical trials only stroke-patients have been included. The research groups have no experiences with disabled people as a consequence of traumatic brain injury. There are very few long-term follow up results. While most clinical trials have identified improvement in the scores of motor impairment of the upper limb, corresponding improvement in functional scales have not been found, or they did not investigate it at all. In summary that has been gained with the use of robots for upper limb physiotherapy can be summed up as follows: these robots are safe and reliable, the patients attitude is positive and the physiotherapists' early reserved attitude have changed. It will be the task of the next years to identify the exact place of the robots in rehabilitation (at which patient, in what stage and operational mode should be used the robots).

Aims

1. Assessment of the features and the limitations of the exercises used in the upper limb physiotherapy of patients with spastic hemiparesis.
2. Development of a robot mediated rehabilitation system for supporting the work of the therapist in the upper limb physiotherapy of patients with spastic hemiparesis in order to overcome limitations and make physiotherapy more effective.
3. Testing the robotic therapy system in a pilot study, and if necessary improving the system according to the experiences.
4. Assessment of the safety and the usefulness of the robotic therapy system in a controlled trial.
5. Preparation of the medical documents for gaining the medical certificate.
6. Introducing the system to the routine clinical practice as a therapeutic device based on advanced technology.
7. Preparation of the improvement of the system for making suitable for several therapy modes (passive, active assisted, active resisted).

Achieving these aims requires strong medical-engineering cooperation. All steps include medical tasks, first of all determining the user's requirements, continuous feed back to the engineers during the development, planning the clinical trials, the ethics process, data procession and interpretation.

Methods

The work started with the assessment of the exercises used in the upper limb physiotherapy of patients with spastic hemiparesis. A multimedia catalogue was edited including 45 exercises. The catalogue involves the description of the exercises both in Hungarian and in English, photos of the starting and the end position and a short video recording. The catalogue is available for everyone on the Internet.

The collected exercises were analyzed: they were recorded by a 3 dimensional motion analyzer system and force-torque measurements were also executed. The main parameters of the exercises were established, and using these data the engineer partners developed a programme for the simulation of the layout optimization of the desired robotic rehabilitation system.

The REHAROB Therapeutic System (involving two industrial robots, a frame, a coach and the operating panel) was developed according to the user’s requirements determined by us. It was an objective that the system should be built first of all commercially available elements. According to the result of a tender two ABB industrial robots were selected. The robots can be attached to the patient’s upper- and forearm through instrumented orthoses. The low level controller is original, the high level controller was developed by engineers of the Budapest University of Technology and Economics.

The REHAROB Therapeutic System is operating as follows: after placing the patient in the coach and attaching the robots, the physiotherapist teaches in a series of exercises to the robots by moving the patient’s upper limb together with the robotic arms. The robots learn these exercises. As a next step, the physiotherapist edits a complex therapy programme from the exercises that had been previously taught in: she determines the order of the exercises and the repetition number. If necessary, she can decrease the velocity of them during the play back phase. Then the robots play back the edited therapy programme. The system executes passive exercises, but it is able to make complex series of exercises in the whole range of motion of the shoulder-girdle and the elbow. The forearm orthesis fixes the wrist and the fingers. The user interface is “physiotherapist friendly”, and the operation does not require experience in robotics.

The aim of the initial trial of REHAROB was to prove that the desired robotic therapeutic system is operational and safe, and also to gain experience during the operation of the system. Four healthy volunteers and eight patients with spastic hemiparesis were included. All subjects received 30-minute-long robot mediated therapeutic sessions on 20 consecutive workdays. According to our suggestions based on the experiences of the first clinical trial, the engineer partners have modified some parts of the system.

The second clinical trial was executed with the modified system. The aim of this trial was to investigate if supplementation of the traditional physiotherapy with this kind of robot mediated therapy would be useful for the patients with spastic hemiparesis. 30 hemiparetic patients were included and randomly divided to robotic and control group (15 subjects in both). Members of both groups received the same amount of traditional therapy. Members of the experimental group received 30-minute-long robot mediated sessions each day, in addition. The therapy programme included 20 consecutive workdays in both groups. The clinical status of the patients was assessed before the 1st event, after the 10th and the 20th sessions. The assessments were made by a blinded physiotherapist. The following parameters were measured: Rivermead arm score, modified Ashworth score of the shoulder adductors and elbow flexors, active range of movement of shoulder and elbow flexion, Fugl-Meyer score – shoulder and elbow subsection, Functional Independence Measure – self-care, Barthel index.

Results

In the first clinical trial:

1. The robots executed their tasks according to the conception, subjects received altogether 240 sessions, that equals 120-hour-long robot mediated therapy. During the operation there was no dangerous situation or significant malfunction.
2. According to the experiences some parts of the system required modification. Emergency stops occurred sometimes without real reason, but after them the therapy could be continued in some minutes. After checking the cause of the emergency stop the physiotherapist could re-start the robots. (In these cases the robots continued working from the beginning of the exercise which was in process at the moment of the sudden stop.) We presented our critical notices and suggestions to the engineering partners, who modified some parts of the system using our suggestions as follows:
   - it was very tiring to push the three-state-enabling button permanently even for healthy subjects – solution: the modified button can be pushed not by the thumb, but it can be grasped by the whole hand;
   - the safety release device opened several times without real reason, when closing it the therapist’s finger could get hurt – solution: the lower part of the device connects to the upper part with bigger cogs, when closing it the therapist can grasp the device far form the connecting surface;
   - the instrumented orthosis was too long, it hindered the therapist during the teaching in phase, it was difficult to move the patients arm with the safeballs – solution: skipping one of the quick changers and merging the function of the two force-torque sensors the orthosis became shorter, instead of the safeballs the physiotherapist can grasp any part of the orthosis during the teaching in process;
   - high force resistance was experienced during programming – solution: a new kinematic constrained-based algorithm was implemented;
   - the physiotherapist had to remember the programmed exercises – solution: a three-dimensional simulation module was added to the user interface to allow visualization of the programmed exercises;

- exercises of the previous sessions cannot be played back, they should be taught in again – solution: special safety functions, checking and calibrating methods were developed to ensure safe utilization of exercises already saved in previous sessions (this option has not been used yet, because not only the system, but the also the patient should be exactly in the same status);

3. The status of the patients was assessed several times during the trial. The most considerable changes were found in spasticity: the mean modified Ashworth score of shoulder adductors decreased from 1,25 to 1,125 (with 10%), that of the elbow flexors decreased from 1,75 to 1,375 (with 21,4%) between the 1st and the 20th sessions. The Rivermead arm score increased in 7 cases of 8. The range of the changes was between 1 to 5 points. The mean Functional Independence Measure (FIM) score was 106,875 at the beginning and 113,5 at the end of the trial (the increase is 6,2%). Considering the self-care part of FIM (where the upper extremities have distinguished role) the increase is 8,46%. The Barthel index increased from 87,5 to 96,25. Since patients received traditional therapy as well, the improvement in their clinical status cannot be fully attributed to the robot mediated therapy.
4. At the end of the trial the patients filled in a questionnaire: 2 patients out of 8 experienced inconveniences: one of them complained that the orthosis was uncomfortable, another found the technical setting too long. These notices were taken into consideration when modifying the system. Nevertheless, all patients declared that they would participate at a similar trial.

In the second clinical trial:

1. Almost all assessed parameters improved in both groups. (Except for the shoulder-girdle anteflexion, which did not show significant improvement in any groups.) The modified Ashworth score of shoulder adductors and elbow flexors showed statistically significant improvement only in the robotic group.
2. The other five scores improved significantly in both groups. Comparison of the changes in these scores between the two groups showed that the improvement of the shoulder – elbow subsection of Fugl-Meyer score was significantly higher in the robotic group. As for the other four parameters the difference was statistically non-significant between the two groups.

3. Subjects received altogether 150 hours of robot mediated therapy. No adverse events occurred.
4. At the end of the trial the patients filled in a questionnaire. They did not experience any inconveniences during the robot mediated therapy. All subjects declared that they would participate at a similar trial.

Discussion

Several projects aim to improve the outcome of rehabilitation of patients with hemiparesis due to central motor neuron lesion. Among several new methods (constraint-induced movement therapy, functional electric stimulation, EMG-biofeedback, exercises in virtual reality) robot mediated physiotherapy is one of the research trends. Although it has not been cleared yet, where will be the place of the physiotherapeutic robots in the rehabilitation programmes, it is sure, that the aim is not to replace the physiotherapist, but to make her work more effective. Though scientists dealing with the development of upper limb therapeutic robots follow different trends, we can say, they want to climb the same hill on different ways. The important role of the high repetition number is a general feature of the robotic projects. It is a difference in the approach that some researchers emphasize the importance of the interactive, robot assisted exercises, the improvement of the attention and the coordination.

In the scope of the REHAROB-project of the 5th Framework Programme of the European Commission a robotic physiotherapy system was developed. Our starting point was as follows: regarding that spasticity is velocity and acceleration dependent, exercises executed with a slow and constant velocity can be beneficial for patients with spastic paresis. It is difficult for the physiotherapist to execute such exercises in high repetition number. Decreasing spasticity can help to improve motor performance, use better residual muscle-strength and prevent secondary impairments. The different trends of robot-development do not contradict, rather supplement one another: the patient who has not yet been suitable for interactive therapy, can be suitable for treatment with the REHAROB Therapeutic System.

Two clinical trials have been performed with this system. The objective of the 1st one ("REHAROB Clinical Trial") was to prove, that the desired robotic therapy would be executable and safe. We also aimed to gain experiences during the operation of the system. The main result of this study was, that during a 120-hour-long robot mediated therapy the system worked reliably, and there was no dangerous situation. We have identified some inconveniences: the safety release mechanism sometimes opened without real reason; when closing this device the therapist's hand could get hurt; it was tiring to push the button of the patient enabling device for half an hour. On the basis of these experiences the engineer partners modified some parts of the system. The changes in the status of the patients were followed and we found that the assessed parameters improved in the majority of the patients. As our patients received traditional physiotherapy as well, this improvement cannot be fully attributed to the robot mediated therapy.

The next trial was performed with the system after having been modified according to the experiences the first clinical trial. 30 hemiparetic patients due to upper motor neuron lesion were included in the second trial. They were randomly divided to two groups. Members of both groups received 30-minute-long Bobath therapy sessions each day. In addition members of the experimental group also received a 30-minute-long passive robot mediated therapy. There were no significant difference between the two groups in age, gender, side of the paresis. The time since onset of the brain lesion (stroke or traumatic brain injury) was the only significant difference: it was 9,5 months in the control group (minimum 5 weeks, maximum 44 months) and 23,2 months in the robotic group (minimum 6 weeks, maximum 87 months). In the inclusion criteria we did not specify the minimal and maximal time since onset of the brain lesion, as our aim was to gain experiences with a wide group of patients. The significant difference arose from the randomization. Members of the control group were closer in time to the onset, therefore the difference in this parameter could give better chance to the control subjects for the improvement. In spite of this, the majority of the assessed parameters improved in a higher degree in the experimental group.

The modified Ashworth scores decreased in a statistically significant degree only in the robotic group. Five parameters improved significantly in both groups. Considering these variables the changes between the two groups were compared. The shoulder-elbow subsection of the Fugl-Meyer scale improved in a significantly higher degree in the robotic group. The other scales, measuring the impairment, also improved better in the experimental group, but the difference proved to be non-significant (probably the relatively low number of patients could play a role in it, as well.)

Regarding the functional scales we found that the control subjects started from a lower score and reached the same (Barthel) or a bit higher (FIM) level, than the members of the robotic group. In case of the controls the time since the onset of the brain lesion was shorter and for this reason they could reach higher improvement in the daily living activities.

Our findings are close to those of the literature: the clinical trials executed with the upper limb robot mediated therapy systems show, that the scales, which measure impairments – first of all the Fugl-Meyer scale – often improve in the robotic group in a significantly higher degree, than in the controls. Nevertheless, this result usually does not appear in the functional scales. The reason for this according to some experts is as follows: the majority of the upper limb physiotherapeutic robots deal only with the shoulder-elbow motions, while in the daily living activities the wrist and hand movements play a bigger role.

Patients filled in a questionnaire after the end of both studies. They found the robot mediated therapy with interest. During the first trial some patients complained of the inconveniences caused by the orthosis. After the modification it did not occurred again. All patients stated that they would participate at a similar treatment again. Moreover, some of the former patients inquired when they could receive robot mediated therapy again.

Considering that the trials were executed with a new medical device, we think it an important result, that adverse or serious adverse event did not occur. The REHAROB Therapeutic System operated reliably, according to the requirements.

We could present a relatively low number of patients, because it is difficult to organize such trial with seriously disabled patients and the costs are high. Nevertheless, results suggest that supplementation of the traditional physiotherapy of patients with hemiparesis with robot mediated one – when passive exercises of the shoulder and elbow are executed on a well-determined trajectory with a slow and constant velocity in high repetition number – can improve the outcome of the rehabilitation. We plan further investigation on this topic on a higher number of the patients.

The development of the upper limb therapeutic robots has not been resulted in a product used in the everyday clinical practice, neither in the countries, which are on the top of research and development. The MIT-Manus robot is the closest to this level. It has been commercialized, but at present it is used only for research. The other robotic therapy system, which is not far from the everyday clinical use, is REHAROB. Its medical certificating is in process.

The role of the therapeutic robots has not been settled yet: they can support the physiotherapist’s work first of all when performing exercises in a high repetition number. These devices require some time to reach an acceptable cost-benefit ratio. Nevertheless all new technical devices have to go through this pioneering period before exceeding the level when they can produce enough at a reasonable price. Nowadays the therapeutic robots are on their pioneering way, but there is real chance, that in the next decade the robots can get into the devices of rehabilitation.

Conslusions

The listed issues are results of medical-engineering cooperation. The medical part was the author’s task:

1. Collecting the frequently executed exercises in the upper limb physiotherapy of patients with spastic hemiparesis, forming a multimedia catalogue of these exercises and making available it for anyone on the Internet.
2. Assessment of the features of the collected exercises, determining the user’s requirements for the engineering partners for planning the robotic physiotherapy system.
3. Development of the REHAROB Therapeutic System (the medical tasks in this work). This is the first robot mediated physiotherapy system developed in Hungary and the first one in the world aiming first of all the decrease of spasticity and working in the whole range of motion of the shoulder girdle and the elbow.
4. The first clinical trial performed with the system proved, that the carried out robot mediated therapy is executable, safe, and the patients’ attitude is positive.
5. According to the experiences of the first clinical trial I evaluated the operation of the system from medical aspect, and recommended modification of certain parts of it.
6. I proved with a clinical trial, that robot mediated therapy exceeding the continuous passive movement (CPM), based on complex series of passive exercises decreases spasticity and contribute to the decrease of the impairments in patients with spastic hemiparesis.
7. I proved with a controlled clinical trial that supplementation of the traditional physiotherapy with this kind of robot mediated therapy can improve the outcome of rehabilitation.
8. I prepared the medical documentation for the medical certification process of the first robot mediated therapeutic system developed in Hungary on the basis of the clinical trials. The medical certification will make it possible to use the REHAROB Therapeutic System not only in trials, but also in the everyday clinical work.
9. I organized the medical-engineering research programme of the National Institute for Medical Rehabilitation on the basis of the REHAROB-project. This programme deals with the application of high technology in rehabilitation. Beside the original robotic

field we deal with assessment of the status of patients post-stroke or with Parkinson's disease using three dimensional motion analysis, dynamic EMG and force-torque measurements. This programme was established on the basis of the REHAROB-project, but it exceeded its time and field, it became a continuous base for research.

List of publications related to the topics of the thesis

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