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Measuring functional recovery of hemiparetic subjects during gentle robot therapy

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ABSTRACT

This paper presents a pilot, proof-of-concept study of robot arm therapy (RT) with a treatment protocol specifically designed for severe hemiparetic patients and integrated with a suitable performance measurement protocol. The robot is a planar haptic manipulandum, with low inertia, low friction and impedance control. The task is reaching, with targets arranged in the horizontal plane, in such a way to induce full extension of the arm. Targets are represented haptically, by means of an attractive force field applied by the manipulandum, and visually, by means of circles on a computer screen. The force field is smoothly activated until it reaches a preset intensity that is maintained until the target is reached. Such level of assistance is selected initially as the minimum level that allows each patient to fulfill the task. In each training session, two blocks of trials are alternated (with open and closed eyes, respectively). In the course of training, the level of assistance is reduced as performance improves. Functional recovery is evaluated by processing the kinematic measurements in order to express in quantitative terms the smoothness of the targeting movements. In particular, we defined four performance indicators or outcome measures: (1) the mean speed of the movements; (2) the number of sub-movements in which reaching is decomposed, (3) the remaining error after the first sub-movement, (4) the relative time of the first sub-movement with respect to the total reaching time. For these indicators we identified a measurement scale from the performance of a population of normal subjects performing the same task. The statistical analysis of the responses shows that the proposed protocol is capable to induce significant improvements in all the patients and the performance indicators are sufficiently stable to be chosen as candidates of future adaptive RT protocols in which the training and measurement protocols are designed in an integrated way.

1. Introduction

Although the application of robot technologies to the rehabilitation of neurological patients is more than a decade old [1] and since then many robot systems for rehabilitation have been proposed, the number of clinical studies is still limited, as documented in a recent systematic review [2]. Furthermore, there is not yet a consensus on the critical features that must characterize protocols of robot therapy (RT) and the measurement schemes for evaluating functional recovery in terms of motor performance.

With regards to the assessment of motor recovery after stroke, a number of clinical scales have been proposed. The most quoted one is the Fugl–Meyer (FM) scale [3,4]. As all clinical scales, based on human judgment, it is prone to subjective bias and is characterized by floor and ceiling effects, considering the wide variability of clinical conditions

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even for subjects with a well diagnosed pathology like stroke-determined hemiplegia. Moreover, it cannot be used "on-line" in order to adaptively modify a training protocol on the basis of performance. Nevertheless, the FM scale as well as other scales that focus on different aspects of the motor disability, such as muscle spasticity [5], is appropriate for an initial characterization of the population of patients and for defining inclusion/exclusion criteria in clinical studies.

With regards to the design of rational protocols of RT, a working hypothesis that we assumed in this study is that RT and PT (human physiotherapy) should complement each other. A natural meeting point between PT and RT relates to the very nature of haptic interaction between patient and therapist, in which force and energy must flow bi-directionally in an ordered and "informative" way. Accordingly, haptic interaction between patient and therapist must not be invasive and unidirectional, imposing movements in a passive way, but, rather, should aim at exploiting the innate plasticity of the neural system, present also in chronic, adult patients [6]: in other words, RT should be *gentle* in such a way to stimulate sensorimotor learning by means of a *minimal degree of intervention*. This general concept allows to identify, in the large class of robots that have been used in the biomedical field, the basic features that must characterize an ideal neuro-rehabilitation robot: it must be truly haptic, back-drivable, with very small inertia and friction.

In contrast with PT, RT allows to integrate in the rehabilitation protocol a performance measurement protocol that allows making available, in an automatic way, an evaluation of the efficacy of the treatment. Here we report a pilot clinical study, in which chronic hemiparetic patients are treated with a protocol of RT, based on a reaching tasks and a highly compliant robot manipulandum [7]. The rehabilitation protocol is minimally assistive, in the sense that the forces provided by the robot are adapted to the specific patient and are kept to a minimum value; moreover, this value is reduced over training in an adaptive way. The type of assistance provided by the robot is instrumental for allowing the patients to initiate the reaching movements but in no way imposes the trajectory, the reaching time, and the speed profile. In this framework, the emergence of features that are typical of normal reaching movements (approximately straight paths and bell-shaped velocity peaks [8]) would suggest that the patients have recovered their ability to generate coherent active patterns and, at the same time, have reduced the hypertonus and have improved their perception of the paretic limb. Therefore, we also designed a performance measurement protocol which aimed at making explicit the "distance" of the motion patterns of the patients from the motion patterns of a reference population of normal subjects, taken as the standard. The measurement protocol focuses on four performance indicators or outcome measures, that characterize complementary aspects of the reaching movements analysed in this rehabilitation protocol: (1) the mean speed of the movements; (2) the number of sub-movements in which reaching is decomposed, (3) the remaining error after the first sub-movement, (4) the relative time of the first sub-movement with respect to the total reaching time. The experimental protocol was designed in such a way to satisfy two constraints:

(1) the reference population of normal subjects could solve the task with a single movement, a null error at the end of the fist movement, and a stable mean speed; and
(2) the population of patients was unable to solve the task without robot assistance at the beginning of the training.

Thus, the measurement protocol has a clearly identified measurement scale and measurement range. The level of robot assistance was selected, different for each patient, as the minimum level that allowed the patient to solve the task. Moreover, this level was progressively decreased, in steps, as performance increased. With regards to the uncertainty of the measurements of each patient's performance, we should take into account that since the measurement protocol is integrated in the rehabilitation protocol, the measurand is actually modified by the underlying learning process, thus making repeated measurements somehow dependent on each other. However, learning is unlikely to progress in a linear way and thus we can assume that the effects of learning are relevant in inter-session fashion (the training protocol was characterized by one session per week) but can be neglected intra-session (each session lasted about 1 h). In summary, the reliability of the measurements and the influence of the training protocol on functional recovery were evaluated at the same time by means of an analysis of variance of the measurements (type A uncertainty), with the simplifying assumption (intended to reduce type B uncertainty) that learning occurs inter-session, not intra-session.

With respect to the previously quoted systematic review of the effect of robot-aided therapy on recovery of the hemiparetic arm after stroke [2], our study is mainly aimed at severely affected stroke patients, for which only an "active-assisted protocol" is appropriate. The novelty of our approach was to design a "gentle" interaction scheme that exploits the compliant features of the robot in order to allow the patients to be trained in two conditions, namely with or without vision: in the latter condition the role of the proprioceptive channel in the recovery of active motor patterns is greatly enhanced.

Research in this field is relatively young and few controlled clinical trials have been conducted. Therefore, the factors that might affect the outcome of robot-aided therapy and bias current research findings are still unclear. The present article presents a proof-of-concept study with regards to the feasibility of the gentle, proprioceptive-enhanced robot therapy approach.

2. Materials and methods

2.1. Subjects

Ten hemiparetic subjects (3 males, 7 females, age 53 ± 13 years) participated in this study. Subjects were recruited among those followed as outpatients of the ART