Transfer of scientific concepts to clinical practice: recent robot-assisted training studies

Andreas Waldner, MD[a, b]
Christopher Tomelleri, MSc[a]
Stefan Hesse, MD, PhD[c]

[a] Neurological Rehabilitation Department, Villa Melitta Private Rehabilitation Clinic, Bolzano, Italy
[b] South Tyrol Neurorehabilitation Research Department, Bolzano, Italy
[c] Medical Park Berlin Humboldtmühle, Charité University of Medicine, Department of Neurological Rehabilitation, Berlin, Germany

Corresponding author: Andreas Waldner
CDC Villa Melitta
Via Col di Lana 6
39100 Bolzano, Italy
E-mail: waldner.andreas@villamelitta.it

Summary

Restoration of motor function is a priority of post-stroke rehabilitation, the aim being to facilitate the patient's reintegration into society. Innovative technologies for neurological rehabilitation must be easy to use and offer patients real benefits, and the treatments they provide must be efficacious and efficient. All these aspects must be carefully evaluated in their development. To achieve restoration of motor function after stroke, task-specific repetitive robot-assisted training of the upper and the lower extremity is currently the most promising approach. The results of clinical trials of robotic devices for upper limb (MIT-Manus, MIME, NeReBot, BiManuTrack, ARMin, ARMOR) and lower limb (LokoHelp, GangTrainer GT1, Haptic Walker, G-EO-Systems, Lokomat) training are here presented with the aim of highlighting the possible gains in motor function due to robotic therapy. Patients who receive robot-assisted training in combination with physiotherapy after stroke are more likely to achieve better motor function than patients trained without these devices, or only with these devices.

KEY WORDS: neurorehabilitation, robotics, stair climbing

Introduction

The annual incidence of stroke in industrialised countries is approximately 180 per 100,000 inhabitants (1). Three months after a stroke, a third of surviving patients are still wheelchair-dependent, while gait velocity and endurance are significantly reduced in approximately 80% of those who are ambulatory (2). Restoration of motor function is a priority of post-stroke rehabilitation, the aim being to facilitate the patient's reintegration into society (3). To achieve this goal, task-specific repetitive robot-assisted training of the upper and the lower extremity is currently the most promising approach. The main aim of conventional physiotherapy after a stroke is instead to reduce the elevated muscle tone and to practise gait preparatory tasks while sitting or standing. As a result of this, the number of steps actually taken in a single session of conventional physiotherapy may rarely exceed fifty to eighty (4).
To increase the number of steps per training session, gait machines, either applying an exoskeleton (5) or an end-effector principle (6,7), have been developed.
Traditionally, the activity of commercially available gait machines has been limited to the repetitive exercise of walking on the floor. Now, however, newer end effector-based walking robots (8) are appearing which have fully programmable trajectories and also enable harness-secured and partially body weight-supported patients to gain repetitive stair-climbing practice (both climbing and descending stairs).
With regard to the upper extremity, 30% of stroke survivors experience a severe upper limb paresis without volitional distal activity (9). Their prognosis for regaining functional hand activity six months after the stroke is very poor (10). Additional Bobath therapy does not improve outcome (11) and these patients do not meet the criteria to enter active training programmes (12). Most available robots (13-16) work on shoulder-elbow movement, but there are also robotic arm trainers that work on more distal arm movements (17).
This review of the literature to date looks at the most important results of clinical studies using the most common robotic systems for rehabilitation of the upper and the lower extremities.

Upper extremity robotic systems

Robotic systems for the upper extremity can be divided into end effector-based systems and exoskeletons.

End effector-based systems

The MIT-Manus (14) is considered the pioneer of robotic devices for the upper extremity. A clinical trial to test the safety and efficacy of this device (13) is currently in progress and its results are expected in early 2010. In this study, 128 participants (96% males, mean age 65 years) presenting upper extremity impairment more than six months after a stroke (ischaemic in 85% of cases) were randomly assigned to robot-assisted therapy (49 patients), intensive comparison therapy (50 patients), or usual care (28 patients). Robot-assisted therapy and intensive comparison therapy each consisted of three

one-hour treatment sessions per week for 12 weeks. The primary outcome in this study was the Fugl-Meyer (Fugl-Meyer 0-66) assessment at 12 weeks relative to baseline (the mean Fugl-Meyer score at entry was 18.9), while Wolf Motor Function Test and Stroke Impact Scale scores were among the secondary outcomes. Fifty-eight per cent of strokes occurred in the anterior circulation and 20% of the participants reported a stroke in addition to their index stroke. The average time from the index stroke to enrolment was 56 months (range: 6 months to 24 years).

A very recent study (14) was conducted with the aim of testing the performance of linear regression models in estimating clinical scores for the upper extremity from systematic robot-based metrics. Twenty kinematic and kinetic metrics were derived from movement data recorded, using the MIT-Manus device, from 111 chronic stroke patients. Multiple linear regression models were developed to calculate Fugl-Meyer, motor status, motor power, and Modified Ashworth Scale scores from these robot-based metrics. The best performance-complexity trade-off was achieved by the motor status score model based on eight kinematic macro-metrics. Models that included kinematic micro-metrics did not achieve significantly higher performances. The performances of the Modified Ashworth Scale models were consistently low.

Another shoulder-elbow robotic device is the Mirror Image Movement Enabler (MIME) (15), which applies forces to the paretic limb during unilateral and bilateral movements in three dimensions. A randomised controlled clinical trial of the MIME in shoulder and elbow neurorehabilitation was carried out in subacute stroke patients; data on its use in bilateral training mode were also gathered. Robot-assisted treatment (bilateral, unilateral, and combined bilateral and unilateral) was compared with conventional therapy. In line with the findings of a previous study in chronic stroke, combined unilateral and bilateral robotic training showed advantages compared with conventional therapy, producing larger improvements on a motor impairment scale and a measure of abnormal synergies. However, gains in all treatment groups were equivalent at the six-month follow up. Combined unilateral and bilateral training yielded functional gains that were similar to the gains from equivalent doses of unilateral-only robotic training, although the combined group had more hypertonia and less movement out of synergy at baseline.

A simpler end effector-based robot is the NeReBot (16), which passively moves the paretic arm in three dimensions. A clinical trial of this device was conducted in 20 patients with post-stroke hemiparesis or hemiplegia submitted to standard post-stroke multidisciplinary rehabilitation and randomly assigned to exposure to the robotic device either without or with four weeks' preliminary sensorimotor robotic training (about 4 hours/week). This training consisted of peripheral manipulation of the shoulder and elbow of the impaired limb, correlated with visual stimuli. On discharge from hospital, impairment and disability had declined in all the patients, but the robot training group recorded higher gains in the areas of motor impairment and functional recovery, which were maintained at three months. No adverse events resulted from robot-assisted therapy in either group.

The BiManuTrack (17) is another end effector-based robot for the upper extremity; the difference is that this device works on more distal arm movements, practising bilateral prosupination and flexion/extension of the wrist. In a clinical trial, 44 patients with severe arm paresis (Fugl-Meyer Motor Score lower than 18) four to eight weeks after stroke were randomly assigned to six weeks of robot-assisted therapy or six weeks of electrical stimulation: one 20-minute session per workday, each session consisting of 800 repetitions with the robot or 60-80 wrist extensions, respectively. The primary outcome measure was the blindly assessed Fugl-Meyer, and the secondary measures were upper limb muscle power [Medical Research Council (MRC) sum, 0 to 45] and muscle tone (Ashworth score sum, 0 to 25), assessed at the beginning and end of treatment and at the three-month follow up. With the exception of a higher Barthel Index score at baseline recorded in the robot-assisted therapy group (found to have no influence), the groups were homogenous. The Fugl-Meyer and MRC sum scores improved over time in both groups but the improvement was significantly greater in the robot-assisted therapy group. The Fugl-Meyer score at the end of the study and at the three-month follow up was 15 points and 13 points higher in the robot-assisted therapy group than in the control group, while the MRC sum score was 15 points higher at both time points compared with the electrical stimulation control group. Muscle tone remained unchanged, and no side effects were reported.

The possibility of combining robotics with transcranial direct stimulation (tDCS) is an interesting new option in this field. The findings of the pilot study in which this technique was combined with BiManuTrack (18) suggest that central stimulation may enhance the effect of conventional physical therapies after stroke. The use of tDCS with robot-assisted arm training was examined in a pilot study in 10 patients who had suffered an ischaemic stroke 4-8 weeks before the study onset and who had no history of epilepsy. Eight had a cortical lesion and two had subcortical lesions: all had severe arm paresis and, coincidentally, five had severe aphasia. Over six weeks, they received thirty 20-minute sessions of robot-assisted arm training. During the first seven minutes, tDCS (1.5mA) was applied, with the anode placed over the lesioned hemisphere and the cathode above the contralateral orbit. Arm and language impairment were assessed using the Fugl-Meyer and the Aachener Aphasia Test, respectively. No major side effects occurred. The arm function of three patients (two with a subcortical lesion) improved significantly, their Fugl-Meyer scores increasing from 6 to 28, 10 to 49 and 11 to 48. The remaining seven patients, all with cortical lesions, showed little change in their arm function, their Fugl-Meyer scores failing to increase by more than five points. Unexpectedly, aphasia improved in four patients.

Exoskeleton systems

Exoskeleton systems are an alternative to end effector-based systems, and the first results of clinical studies conducted using exoskeletons are now becoming available. Compared to end effector-based robots, exoskeleton robots provide improved guidance of the human limb and are able to train task-oriented movements with a large range of motions.

In a recent study, the feasibility of using the ARMin ro-