# Effects on balance skills and patient compliance of biofeedback training with inertial measurement units and exergaming in subacute stroke: a pilot randomized controlled trial

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**Summary**

**Stroke patients have reduced balance and postural control that limits their activities of daily living and participation in social life. Recently, many exergaming systems based on video-biofeedback have been developed for balance training in neurological conditions, however their efficacy remains to be proven. The aim of this study was to investigate the effects on balance skills and patient compliance of biofeedback training based on inertial measurement units and exergaming in subacute stroke.**
**The enrolled subjects were randomized into two groups: subjects allocated to the experimental group performed 10 sessions of biofeedback balance training using inertial sensors, whereas subjects allocated to the control group performed 10 sessions of conventional balance training. All subjects were assessed at T0 (pre-treatment), T1 (post-treatment) and T2 (1-month follow-up). The Berg Balance Scale, Rivermead Mobility Index and modified Barthel Index were used to assess balance, mobility and global disability, respectively. To assess the severity of the stroke and its effects on the patient we used the National Institutes of Health Stroke Scale and the Canadian Neurological Scale. Finally, a static force platform evaluating stabilometric parameters was used to assess balance skills. Fifteen subjects with subacute stroke (4F; age 57.80 ± 13.7) completed the experimental protocol. The analysis showed a significant improvement in balance skills and in the overall clinical outcomes in the experimental group compared with the control group; the experimental group also showed better compliance with the training.**
**The biofeedback system of the device used in this study probably enhances neuroplasticity mechanisms of postural and balance skills in subacute stroke patients.**

*KEY WORDS: biofeedback, participation, postural balance, rehabilitation, stroke, virtual reality.*

## Introduction

Stroke survivors often have a deficit in motor control which can contribute to impairment of balance, postural control and mobility (Chen et al., 2016). Moreover, balance impairment and increased fall risk are associated with lower quality of life (QoL) in stroke patients. If balance can be improved and maintained into the chronic phases of stroke, affected individuals are likely to benefit through improved QoL (Schmid et al., 2013). Nowadays, the rehabilitation of balance functions in stroke patients is based on the use of conventional physiotherapy exercises, as well as technologies such as biofeedback and virtual reality (immersive or non-immersive) (Iosa et al., 2012; Corbetta et al., 2015; Tieri et al., 2018). An extensive review regarding virtual reality and non-immersive virtual reality/exergaming was recently published by Tieri et al. (2018).
Conventional physical therapy for stroke recovery has shown positive effects on trunk control, balance and gait skills (Jung et al., 2014; Jung et al., 2016; Jeon and Hwang, 2018). Biofeedback has been used for many years in the rehabilitation of several medical disorders, providing patients with biological information that would otherwise be unknown. Biomechanical biofeedback involves measurement of the movement, postural control and forces produced by the body (Giggins et al., 2013). Post-stroke patients often suffer from impaired postural and balance control and some of them never regain the ability to stand.
The balance of those who do prove able to resume standing is typically characterized by increased sway during quiet stance and asymmetrical lower limb weight distribution (De Nunzio et al., 2014). Some studies have investigated the role of force plate biofeedback or inertial based sensing biofeedback in balance training in

stroke populations, but, while this is a promising field, there is still a lack of systematic reviews and randomized clinical trials examining the topic (Giggins et al., 2013).
Therapists, too, perceive many benefits of feedback-based technologies in rehabilitation, and see them as useful tools for a tailored approach, especially if they can adapt the technology to individual patients (Hamilton et al., 2018). Virtual reality, even the non-immersive type, has become generally accepted as a therapeutic tool for neurological patients that allows them to interact with simulation from the environment via multiple sensory channels (Yang et al., 2016). Virtual reality and exergaming have emerged as recent treatment approaches in stroke rehabilitation in clinical settings and they seem to be beneficial in improving upper limb functions and activities of daily living (ADL) when used as adjunct treatments to usual care, but there is still insufficient evidence about their effects on gait speed and balance (Morone et al., 2014; Laver et al., 2017).
The extra cost of applying virtual reality and exergaming to standard rehabilitation is lower when it is spread over many patients in a clinic, and adding extra virtual reality to standard rehabilitation could have some benefits (Corbetta et al., 2015). Unfortunately, high levels of motivation and adherence are often lacking during therapeutic exercise programs for balance impairments (Fitzgerald et al., 2010), but this kind of training is enjoyable and increases participation in rehabilitation treatment (Hung et al., 2014). The level of participation in rehabilitation treatment has been shown to be a positive prognostic factor for rehabilitation efficacy in stroke patients (Paolucci et al., 2012).
We designed a pilot randomized controlled trial to evaluate, in patients with subacute stroke, the efficacy of training involving the use of a combined biofeedback system (inertial motion sensors, force platform and exergaming-based feedback), *versus* conventional balance training, on postural and balance skills, ADL, sensorimotor functions and the level of training participation.

## Materials and methods

The study participants were recruited according to the following inclusion criteria: single ischemic stroke in the area of the middle cerebral artery with diagnosis confirmed by MRI or CT (hemorrhagic subjects were excluded because in such subjects an initial clinical improvement is due to reduction of edema), ability to walk safely with supervision, conserved cognitive and language functions (Mini-Mental State Examination score ≥ 23), age between 18 and 80 years. The exclusion criteria were: severe neglect (positive results on 3/4 of the tests administered for neglect), previous neurosurgery, bone fracture(s) or surgery of the limbs and/or spine resulting in limitation of strength or mobility.
All patients were informed of the study purposes and were asked to sign an informed consent form before being randomly assigned to one of the two groups: the experimental group (RIABLO) or the control group (CTRL). Randomization was carried out by means of a simple computer-generated random numbers system. Both groups underwent a total of 10 add-on therapy sessions. These consisted of balance training and were performed at a frequency of three per week; each training session lasted 20 minutes. The RIABLO group performed experimental training with biofeedback through inertial motion sensors. The CTRL group performed conventional balance training of the same intensity and duration as the training undertaken by the RIABLO group. All subjects were assessed at T0 (pre-treatment), T1 (post-treatment, 20 days from T0), and T2 (1 month after the end of treatment, 50 days from T0). To minimize variability, a single specialized blinded operator performed all the evaluations of all the patients.

### *RIABLO training*
The RIABLO™ (CoRehab, Trento, Italy) is an adaptive system, comprised of several inertial measurement units and a force platform connected wirelessly to a computer; it is designed to enhance standard rehabilitation programs by guiding the user's performance of prescribed physical exercises through a video interface. The inertial measurement units used each weigh 20 grams. They are based on the wireless Bluetooth™ communication protocol, and work at a sampling frequency of 50 Hz (Leardini et al., 2014). The inertial sensors are held in place by elastic bands. The three bands we used were placed on the chest (on the mammillary line), at mid-thigh level and at mid-tibial level (on the affected or the healthy side, depending on the exercise proposed). The training administered was designed to simulate ADL; six different exercises were chosen for our study:
1) latero-lateral load shift: this exercise reflects the most common actions performed during the day (e.g. walking, climbing stairs, walking sideways);
2) displacement of latero-lateral load on an oscillating platform: this exercise is similar to the previous one but the difficulty is increased by the oscillating platform (the exercise replicates, for example, walking on unstable surfaces such as the escalators of shopping centers);
3) antero-posterior load shift (as in, for example, rising on tiptoe to reach an object on a shelf);
4) displacement of antero-posterior load on the oscillating platform (as when moving on to the toes or heels on unstable surfaces);
5) displacement of latero-lateral load with knee flexion: this exercise is more difficult since it combines the latero-lateral load shift with the knee flexion movement (e.g.: squatting to retrieve an object low down);
6) lateral load displacement with knee flexion on the oscillating platform: this is the most difficult exercise of all, since the latero-lateral load displacement and knee flexion are performed on the oscillating platform.

### *CTRL training*
For the conventional training, the protocol we adopted was similar to the one used for the RIABLO training; the exercises performed are propaedeutic for the recovery of independence in ADL and based on the use of stable surfaces (i.e. steps) and unstable ones (i.e. oscillating tables and balls of different sizes); the protocol included the use of stabilization techniques and target achievement.

### *Assessment*
Evaluation scales for balance (Berg Balance Scale – BBS, Berg et al., 1989), mobility (Rivermead Mobility Index – RMI, Collen et al., 1991), global disability (Modified Barthel Index – BI, Shah et al., 1989), and severity

of the stroke and its effects on the patient (National Institutes of Health Stroke Scale – NIHSS, Lyden et al., 1994; Canadian Neurological Scale – CNS, Côté et al., 1989) were used.

*Postural assessment*

Stabilometric parameters were analyzed using a 320 cm by 75 cm (length x width) static force platform (Platform BPM 120, Physical Support Italia, Italy). The signals were amplified and acquired using dedicated software (Physical Gait Software Vv. 2.66, Physical Support Italia, Italy). In assessing static stability, patients stood barefoot in a natural and relaxed position with their arms by their sides and heels aligned, under two sensory conditions: eyes open and facing a target 1.5 m away (OE) and eyes closed (CE).

Feet were placed with the forefoot turned out at 30 degrees and the heels at a comfortable distance from each other. We chose 51.2 seconds as the testing time, as per the indications of the platform manufacturer and in accordance with other studies.

During the data collection, subjects were asked to "stand as still as possible" while looking straight ahead. We measured the length of the centre of pressure (CoP) trajectory (mm); this is an indicator of the overall CoP path during the acquisition on the platform (Tamburella et al., 2014).

***Statistical analysis***

All statistical analyses were performed using STATISTICA 8.0 Software (StatSoft Inc., USA). Two-way ANOVA with repeated measures was used for statistical analyses, choosing TIME of evaluation (T0 *vs* T1 *vs* T2) and GROUP (RIABLO *vs* CTRL) as variables and considering significant all results with a *p* value < 0.05, both for the TIME & GROUP effects and the TIME × GROUP interaction. Bonferroni adjusted multiple comparisons were performed as post-hoc analyses. The Wilcoxon paired t-test was used to evaluate post-treatment compliance.

## Results

We enrolled 15 patients (4F; average age 57.80 ± 13.7, ranging from 36 to 78 years): 9 were randomly assigned to the RIABLO group and 6 to the CTRL group.

At the pre-treatment evaluation (T0) the patients in the two groups did not differ significantly in terms of demographic characteristics, time from stroke and mean scores on the administered scales (p>0.05) (Table I).

The RIABLO group showed a significant improvement in balance skills compared with the CTRL group (BBS: $F_{2,26}$=5.73; p=0.008), recording improvements in balance functions from T0 to T1 (p<0.0001) and T2 (p<0.0001). Moreover, significant regression of signs and symptoms (NIHSS: $F_{2,26}$=3.66; p=0.03) in the RIABLO group *versus* the CTRL group was recorded both from T0 to T1 (p<0.001) from T0 to T2 (p<0.0001) (Fig. 1). Stabilometric tests showed a significant reduction of COP trajectory in both the OE (COP-OE: $F_{2,26}$=18.07; p=0.0001; Post-hoc: T1 p=0.01, T2 p=0.01), and CE (COP-CE: $F_{2,26}$=11.66; p=0.0002; Post-hoc: T1 p=0.08, T2 p=0.04) conditions. Assessment of post-treatment compliance using the Pittsburgh Rehabilitation Participation Scale showed that the level of participation in the rehabilitation program was greater in the RIABLO group (Z=2.20, p=0.02). Table II shows the results related to the effect of TIME.

## Discussion

The improvement in balance skills (BBS and stabilometry assessment) observed in the experimental group potentially indicates efficacy of the biofeedback training with inertial motion sensors in a virtual reality system. The biofeedback system of the device used in this study probably enhances neuroplasticity mechanisms of postural and balance skills in subacute stroke patients, promoting and facilitating a rebalancing through sensory stimuli.

A recent study supported the effectiveness of audio-visual biofeedback in balance recovery in stroke patients, demonstrating a reduction in COP sway patterns (De Nunzio et al., 2014).

Indeed, virtual reality rehabilitation approaches to postural control have been used to enhance functional recovery, which, in turn, may reduce the risk of falling (Cho et al., 2012).

Moreover, through task-specific intense exercise, virtual reality and videogame-based systems produce a boost effect on motor learning pathways, potentiating motor activity/motor skills through the augmented feedback and knowledge of performance and results (Franklin et al., 2012; Morone et al., 2014; Sharma et al., 2016). It has been reported that task-oriented training can result in improvements in balance ability, movement and task performance in stroke patients (Yoo et al., 2015).

The significant reduction in signs and symptoms shown,

**Table I - Demographic characteristics of the enrolled patients.**

| | GROUP | | |
|---|---|---|---|
| | RIABLO (n=9) | CTRL (n=6) | p-value/chi-square |
| Age (mean±SD) | 52.56±13.92 | 65.66±9.64 | p=0.07$^{ns}$ |
| Gender (%Female) | 33.3% | 16.6% | $\chi$ 2=0.51$^{ns}$ |
| Time from onset, days (mean±SD) | 42.66±31.94 | 82±67.76 | p=0.15$^{ns}$ |
| Side of lesion (% left) | 55.55% | 83.33% | $\chi$ 2=0.29$^{ns}$ |

Abbreviations: RIABLO= Experimental group; CTRL= Control group; ns=not significant; SD= standard deviation.

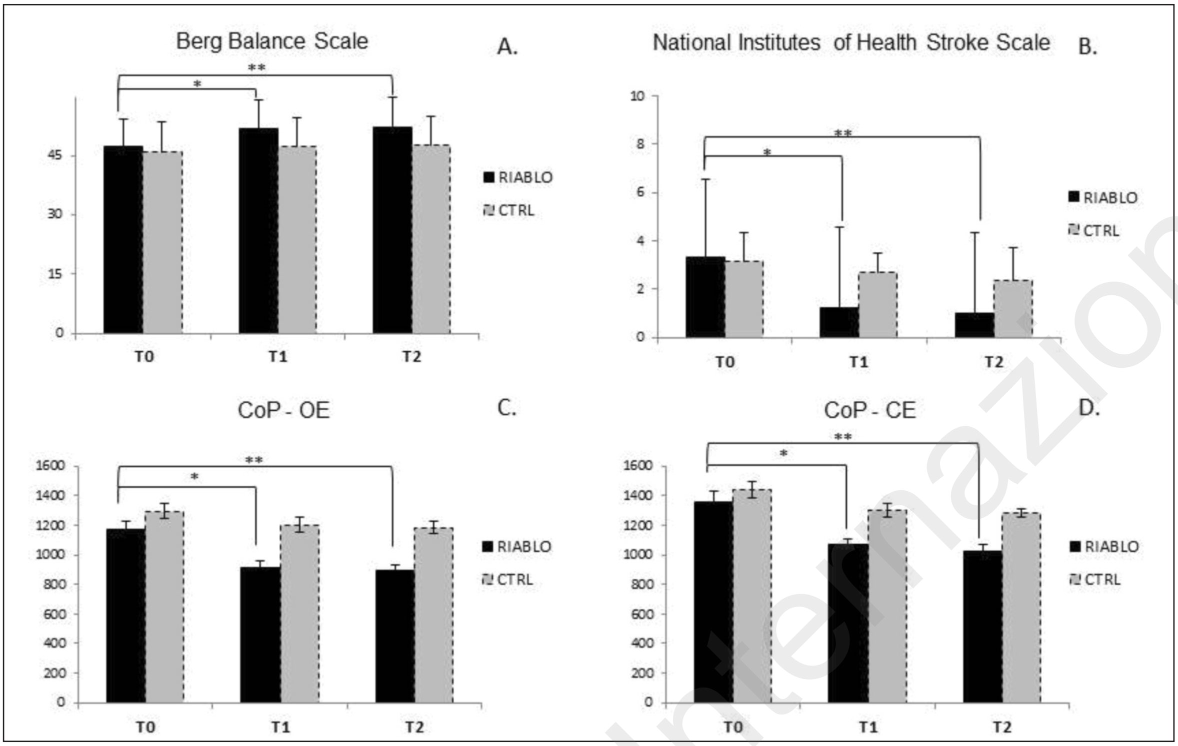


Figure 1 - Effects of training on clinical (A., B.) and postural (C., D.) assessment in the experimental group *versus* the control group.

in the present study, by the NHISS results, could be an effect of augmented motor feedback during task-oriented exercises. In addition, knowledge of performance and results could have generated increased motivation and participation in the exergaming-based training as opposed to the conventional therapy.

This study has shown that rehabilitation treatment involving biofeedback from the RIABLO™ device, which uses inertial motion sensors and a platform with baro sensors, and provides feedback through serious game, is effective in improving the motor skills of balance, while promoting greater motivation and participation in the therapeutic exercise, as shown by the scores on the clinical scales and instrumental tests. The present findings with this combined approach support the usefulness of biofeedback and exergaming-based feedback in the recovery of sub-acute stroke. Other technologies have been proposed for improving balance in patients with stroke.

No significant differences in terms of balance were found between robotic intervention and conventional therapy in a recent systematic review (Swinnen et al., 2014). The Authors reported that robotic treatment can lead to improvements in balance in stroke patients; however, it is not clear whether the improvements are greater than those associated with other gait rehabilitation methods.

On the other hand, balance training performed with a robotic walker showed positive results in patients with stroke (Morone et al., 2016).

Balance is a complex task and, with regard to the proposed technologies, many factors should be taken into account, including cognitive load, compliance, and active participation versus biomechanical constraints forcing passive movements (these constraints could be greater in robotic treatment) (Morone et al., 2016). This is the first study on the efficacy of the Riablo™ system in patients with mild stroke and, more generally, in patients with neurological impairments. In further research, it will be interesting to study its efficacy in patients affected by moderate stroke or other pathologies in which balance is impaired, such as cerebellar ataxia and/or Parkinson's disease.

Finally, with regard to the limitations of the present study, multidimensional assessment with gait and dynamic balance evaluation, as well as a larger sample size, might have been useful to confirm our preliminary results.

Finally, a sample of stroke patients showing more severe disability is needed in order to generalize results to the entire subacute stroke population.

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**Table II -Time x Group interaction.**

| GROUP | | RIABLO | | | CTRL | | | *p* value | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | T0 | T1 | T2 | T0 | T1 | T2 | TIME x GROUP | T1 | T2 |
| BBS | Mean±SD | 47.3±7.01 | 52±7.26 | 52.3±7.34 | 45.8±7.90 | 473±7.36 | 47.6±7.44 | p=0.008 | p>0.0001 | p>0.0001 |
| CNS | Mean±SD | 8.6±1.45 | 10±1.67 | 10.5±1.45 | 7.9±1.31 | 8.9±1.49 | 9±1.48 | p=0.328 | | |
| BI | Mean±SD | 90±9.09 | 95.2±8.58 | 95.7±8.40 | 87.8±6.17 | 90.6±5.53 | 91±5.29 | p=0.209 | | |
| RMI | Mean±SD | 10.8±2.57 | 12.7±2.72 | 13±2.73 | 9.6±2.58 | 10.3±2.65 | 10.5±2.73 | p=0.059 | | |
| NIHSS | Mean±SD | 3.3±2 | 1.2±0.97 | 1±0.86 | 3.2±1.16 | 2.7±0.81 | 2.3±1.36 | p=0.039 | p=0.0004 | p=0.0001 |
| COP OE | Mean±SD | 1175.5±158.00 | 912.2±128.35 | 889.9±127.06 | 1296±129.08 | 1204.4±121.06 | 1182.9±103.12 | p<0.0001 | p<0.0001 | p<0.0001 |
| COP CE | Mean±SD | 1355.3±203.42 | 1067.3±125.88 | 1026.1±114.16 | 1441.2±145.61 | 1302.9±107.09 | 1285.0±74.78 | p=0.0002 | p<0.0001 | p<0.0001 |

Abbreviations: BBS=Berg Balance Scale; CNS=Canadian Neurological Scales; BI=Barthel Index; RMI=Rivermead Mobility Index; NIHSS=National Institutes of Health Stroke Scale; COP=center of pressure.

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