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Effect of postural insoles on gait pattern in individuals with hemiparesis: A randomized controlled clinical trial

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ABSTRACT

Introduction: Recovering the ability to walk is an important goal of physical therapy for patients who have survived cerebrovascular accident (stroke). Orthotics can provide a reduction in plantar flexion of the ankle, leading to greater stability in the stance phase of the gait cycle. Postural insoles can be used to reorganize the tone of muscle chains, which exerts an influence on postural control through correction reflexes. The aim of the present study was to perform kinematic and spatiotemporal analyses of gait in stroke survivors with hemiparesis during postural insole usage.

Material and Methods: Twenty stroke victims were randomly divided into two groups: 12 in the experimental group, who used insoles with corrective elements specifically designed for equinovarus foot, and eight in the control group, who used placebo insoles with no corrective elements. Both groups were also submitted to conventional physical therapy. The subjects were analyzed immediately following insole placement and after three months of insole usage. The SMART-D 140® system (BTS Engineering) with eight cameras sensitive to infrared light and the 32-channel SMART-D INTEGRATED WORKSTATION® were used for the three-dimensional gait evaluation.

Results: Significant improvements were found in kinematic range of movement in the ankle and knee as well as gains in ankle dorsiflexion and knee flexion in the experimental group in comparison to the control group after three months of using the insoles.

Conclusion: Postural insoles offer significant benefits to stroke survivors regarding the kinematics of gait, as evidenced by gains in ankle dorsiflexion and knee flexion after three months of usage in combination with conventional physical therapy.

1. Background

The ability to walk following cerebrovascular accident (stroke) is often hindered due to muscle weakness, spasticity, impaired sensory-motor control and/or the loss of cognitive function. Most patients with hemiparesis exhibit motor dysfunction, which leads to an abnormal gait pattern (De Wit et al., 2004). Gait coordination problems persist in stroke victims despite physical therapy, including altered coordination of the trunk, pelvis, knee and ankle, leading to reductions in endurance and walking velocity (Hollands et al., 2012).

A number of therapeutic methods are described in the literature for the motor recovery of limb function and improvements in muscle strength and range of motion as well as a reduction in spasticity in patients with hemiparesis (Rezende et al., 2009; Díez, 2004; Spaich and Tabernig, 2002; Lima et al., 2008). Equinovarus foot, which is very common among stroke survivors, moves the weight bearing from the heel to lateral plantar surface of the foot, which can cause a loss of balance and diminished security

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regarding one's stride. An ankle-foot orthosis (AFO) is often prescribed to facilitate ankle control for patients with equine foot and/or varus foot (Lucareli et al., 2007) and can help reduce energy expenditure during the task of walking (Bregman et al., 2012).

Recovering the ability to walk properly is a major goal of physical therapy for stroke survivors. According to Gök et al. (2003) gait velocity, cadence (number of steps per minute) and step length are generally diminished in individuals with hemiparesis, which has encouraged the use of devices that favor the improvement of these gait variables, such as an AFO. Such devices offer greater mediolateral stability of the ankle in the stance phase and facilitate the swing phase of the gait cycle. However, some authors state that an AFO can encourage and prolong one's dependence on mechanical devices, which could lead to increasingly underused muscles, especially ankle dorsiflexors, with a consequent delay in the recovery of function (Erel et al., 2011).

Different types of braces may be prescribed for stroke victims, such as an AFO, which assists in alignment and gait quality and reduces plantar flexion of the ankle during the initial contact with the ground, leading to greater stability during the stance phase of the gait cycle (Lucareli et al., 2007; Haydar et al., 2003; Esquenazi et al., 2009). Postural insoles have also been employed for similar purposes and are used to reorganize the tone of muscle chains. A postural insole acts on muscle proprioception and leads to a change in ascending chains as a result of a proprioceptive stimulus (Gagey and Weber, 2000). Postural insoles correct the distribution of plantar loads in contact with a hard surface, favoring a better distribution of body mass in the plantar region and providing better alignment of the knees, hips, pelvis and spinal column (Almeida et al., 2009). According to Bricot (1999) these effects occur due to the fact that postural insoles reorganize the tone of muscle chains and affect body posture through corrective reflexes.

Kinematic analysis has been used for the evaluation of normal and pathological human gait by allowing the evaluation of spatiotemporal characteristics, such as step length, cadence, stride duration and velocity. Spatiotemporal gait variables describe the quantitative aspects of the movement pattern (Iwabe et al., 2008). According to Leung and Moseley (2003) changes in stride length and duration of the swing phase and double support phase of the gait cycle are related to a reduction in symmetry and gait velocity, leading to a relatively shorter step length, greater time in the stance phase and less time in the swing phase of the affected lower limb, which causes a specific gait pattern seen in patients with hemiparesis.

The aim of the present study was to perform kinematic and spatiotemporal analyses of gait in stroke survivors with hemiparesis during three months of postural insole usage in comparison to a group without the use of these insoles.

2. Materials and methods

A randomized, controlled, clinical trial was conducted at the Human Movement Analysis Laboratory of Nove de Julho University (Sao Paulo, Brazil). This study received approval from the human research ethics committee of the institution (process number: 34312/2012) and was conducted in accordance with the guidelines regulating research involving human subjects established in October 1996 by the Brazilian National Board of Health. All participants were informed about the study and signed the free and informed consent form, agreeing to participate in this research.

The sample size was calculated based on gait velocity reported in a study by Sungkarat et al. (2011) involving the use of insoles to influence functionality in patients with hemiparesis. For $\alpha = 0.05$ and $\beta = 0.20$ (80%), with an effect size of 23.5 m/s and a standard deviation of 13.6 m/s, a minimum of 10 individuals was determined for each group. To compensate for possible drop-outs, 15% more volunteers were recruited, totaling 12 patients per group.

Twenty-six patients were recruited, but two did not meet the eligibility criteria. Thus, twenty-four strokes survivors with hemiparesis were recruited from the rehabilitation clinics of the university and randomly allocated to two groups: 12 in the experimental group, who used an insole with corrective elements specifically designed for equinovarus foot on paretic limb and an insole without corrective elements on the non-paretic limb, and 12 in the control group, who used placebo insoles without corrective elements. Both groups were also submitted to conventional physical therapy. Four dropouts from the control group occurred during the data processing, totaling eight patients in this group, for which intention-to-treat analysis was employed. The inclusion criteria were a diagnosis of ischemic or hemorrhagic stroke, six months to five years since the occurrence of stroke, muscle hypertonia, spastic hemiparesis, independent gait without the need for a gait-assistance device, such as an AFO, and adequate comprehension and cooperation to perform the activities proposed. The exclusion criteria were treatment with botulinum toxin and/or neurolytic block in the previous six months and excessive joint stiffness due to spasticity. The allocation to the different groups and the order of the evaluations were determined randomly with the use of sealed, opaque envelopes to ensure the reliability of the study. All participants were blinded to the allocation of the different groups (see Fig. 1).

The participants were submitted to evaluations immediately following the placement of the insoles and after three months of insole use. The stipulated three months of insole use was based on the mean time for the insole to promote sensory and mechanical stimuli in the stride of the patients. During the evaluations, gait was analyzed under three conditions: 1) barefoot, 2) with habitual shoes and 3) with habitual shoes and insoles (postural or placebo). Throughout the period of insole usage, the participants were instructed to continue conventional physical therapy, such as muscle stretching and strengthening as well as gait and balance training at the physical therapy clinic of the university, while using the insoles at all times. The elements of the postural insoles were a pronating heel wedge measuring 6 mm, a pronating band and metatarsal-phalangeal inlay for the stabilization of the different segments of the foot in the neutral position (see Fig. 2).

Three-dimensional gait analysis was performed using the SMART-D 140® system (BTS Engineering, Milan, Italy; sampling rate: 100 Hz) with eight cameras sensitive to infrared light and the 32-channel SMART-D INTEGRATED WORKSTATION®. The kinematic data were collected using a force plate (Kistler, model 9286BA), which recorded displacement from the center of pressure and the time of contact between the foot and surface of the force plate. After the collection of anthropometric measures (height, weight, tibia length, distance between femoral condyles or diameter of the knee, distance between malleoli or diameter of the ankle, distance between the anterior iliac spines and thickness of the pelvis), passive markers were placed at points of reference directly on the skin, as described by Davis et al. (1991), for the evaluation of the kinematics of each body segment. Markers were placed over C7, sacrum and bilaterally on the anterior iliac spines, greater trochanter, femoral epicondyle, femoral wand, tibial head, tibial wand, lateral malleolus, lateral aspect of the foot at the fifth metatarsal head and the heel (only for static offset measurements). After placement of the markers, the participants completed two or more practice trials across the plate walkway to become familiarized with the experimental procedure. After familiarization, at least six trials were performed. The participants were instructed to walk barefoot at a self-selected pace along the walkway (10 m in length). Average values of three consistent trials were analyzed. The

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