# Circumferential pressure treatment reduces post-stroke spasticity: a pilot randomized controlled trial

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#### Abstract

**Introduction.** Circumferential pressure is used to promote the inhibition of the spastic muscle. The purpose of this study was to evaluate the immediate effect of circumferential pressure applied by Johnstone pressure splint on the tonus level, reflex excitability, and electromyographic activity of plantar flexor and dorsiflexor muscles in post-stroke patients.

**Methods.** An experimental single-blinded study with random allocation of patients to a control group (conventional inhibition techniques) or experimental group (conventional inhibition techniques along with circumferential pressure) was performed. All patients received one 25-minute therapeutic session. The muscle tonus according to the Modified Ashworth Scale, soleus H-reflex, and electromyographic signals during the sit-to-stand movement of plantar flexor-dorsiflexor muscles were evaluated before and after treatment.

**Results.** Overall, 30 stroke survivors (20 men, 10 women; age:  $60.3 \pm 5.7$  years; evolution time:  $27.8 \pm 14.7$  months) were studied. The muscle tone decreased in both groups, but the experimental group exhibited a greater reduction. The experimental group presented a significant increase in the H-wave duration and maximal H/maximal M wave ratio of the H-reflex as compared with the control group. No significant difference was observed in muscular electrical activity.

**Conclusions.** One session of combined therapy contributes to a reduction in the tone of plantar flexor muscles and the reflex activity, without altering the muscle activity.

Key words: rehabilitation, splints, muscle spasticity, H-reflex, ankle

## Introduction

Spasticity is one of the main complications of stroke, with a prevalence of 20–42.6% at 12 months after stroke [1, 2]. In the paretic lower limb (PLL), the prevalence and incidence reach 40–600 and 30–485 per 100,000 individuals, respectively [3, 4], compromising the plantar flexor muscles in 66% of patients [5]. Spasticity determines neural and biomechanical muscular changes that involve hyperexcitability of the stretch reflexes, muscular hypertonia, pathological co-contraction, muscular weakness, stiffness, fibrosis, and atrophy, as well as alterations of postural control and coordination; this results in altered mobility and functionality of patients [6–8].

The Hoffmann's reflex (H-reflex) is one of the neurophysiological measures to evaluate post-stroke spasticity [9]. In stroke subjects, the H-wave presents a decreased latency and an increased amplitude owing to the reflex hyperexcitability [10, 11]. Additionally, it has been shown that spasticity alters the recruitment order of muscle groups during the execution of functional activities, e.g., the sit-to-stand (STS) movement and the gait pattern [12]. The STS task is commonly performed every day and it is considered as a prerequisite for locomotion, which is related to functional independence [13]. There is some evidence that suggests pathological co-activation or earlier activation of plantar flexor muscles and low-amplitude muscle activation of the tibialis anterior in PLL during the STS movement [12, 14].

Inhibition techniques (IT), like sustained stretch and movement patterns [15, 16], which are part of the Bobath approach [17], have been widely used by the physical therapist during conventional treatment to decrease the muscle tone and improve motor performance. Pollock et al. [18] and Kollen et al. [19] analysed previous studies of patients after stroke to compare the effectiveness of different therapeutic approaches. They found that not a single approach, namely, the Bobath treatment, proprioceptive neuromuscular facilitation, a motor relearning program, or the eclectic therapeutic approach, was more effective than the other ones.

Circumferential pressure (CP) applied through the Johnstone pressure splint (JPS) combined with IT has been used for sensory re-education and inhibition of excitability of spastic muscles in post-stroke patients [20–25]. However, the effectiveness of CP in post-stroke spasticity has scarcely been studied, and the results are controversial. Poole et al. [26] did not find any significant difference (p > 0.05) between standard occupational therapy alone and combined with CP in the motor function of the upper limb according to Fugl-Meyer assessment. On the other hand, Robichaud et al. [27] reported a decreased (55%) amplitude in the H-wave after applying CP. Similar studies carried out in children with cerebral palsy have shown that CP combined with Bobath approach decreases the muscle tone, increases the joint range of motion, and improves the motor function [20, 28, 29].

There are critical methodological differences in the prior studies (heterogeneous samples and variable time of CP use), and no study has investigated the effects of combined therapy (CP and therapeutic exercise) on hypertonia, reflex excitability, and muscle activity, evaluated as a whole. It is crucial to understand whether CP leads to positive results in spasticity. The purpose of the present study was to assess the effect of CP along with one session of conventional IT treatment on the muscle tone, H-reflex, and electromyographic (EMG) activity in post-stroke subjects.

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#### Research design

A parallel-group randomized controlled trial was conducted with post-stroke patients, who were randomly allocated to 2 intervention groups (1:1 ratio). All therapeutic approaches were applied by an unblinded examiner, and all measurements were performed by a blinded one.

The independent variables were intervention group (control group and CP group) and time of measurement (before and after treatment).

The dependent variables were muscle tone; amplitude (mV), latency (ms), duration (ms), and maximal H/maximal M wave (Hmax/Mmax) ratio of the H-reflex; root mean square amplitude expressed as a percentage of sub-maximal isometric voluntary contraction; and median frequency (Hz) of the EMG signal.

## Participants

The participants were informed about the experimental procedures. A total of 30 individuals (20 men) who had experienced a haemorrhagic or ischemic stroke were enrolled in this study. Their mean  $\pm$  standard deviation of age, mass, height, and body mass index were  $60.3 \pm 5.7$  years,  $70.2 \pm 9.2$  kg,  $1.62 \pm 0.1$  m, and  $26.5 \pm 2.7$  kg/m<sup>2</sup>, respectively.

The inclusion criteria were as follows: age of 50–70 years, post-stroke time between 6 months to 4 years, spasticity level of 1–3 according to the Modified Ashworth Scale (MAS), Barthel Index score  $\geq$  60, independent gait pattern with or without ambulation aids, and the ability to perform the STS movement independently. The exclusion criteria involved altered cognitive ability according to the Short Portable Mental Status Questionnaire, botulinum toxin injection within 6 months before the study, diabetic polyneuropathy, lower limb pain or hyperalgesia, peripheral vascular disease, fractures or musculoskeletal lesions, and consumption of muscle relaxant drugs. The participants were recruited from March to December 2016 at 2 local medical centres and were community-dwelling people from Bucaramanga, Colombia.

The sample size was calculated by using the StataCorp 2013 software and was based on the standard deviation of 2.5, 1.4, and 0.9 for latency, amplitude, and duration of H-wave, respectively, with an alpha level of 0.05 and power of 0.80.

#### Instruments

The muscle tone was evaluated with MAS. The H-reflex variables were determined with a Nicolet Compass Meridian System (Nicolet Biomedical Co., Fitchburg, WI, USA). The device is provided with a bipolar disk-type bar electrode (9 mm diameter and 30 mm spacing) and a stainless-steel ground electrode. Surface EMG signals from the tibialis anterior, soleus, and medial and lateral gastrocnemius muscles were recorded by using the DataLOG MWX8 device, equipped with 8 analogue and 4 digital channels, a surface EMG sensor (Biometrics Ltd., Newport, UK). A 100-Kg-output force plate (FP3; Biometrics Ltd.) served to synchronize the STS movement with the EMG signal.

A foot single chamber air-type JPS (length: 38 cm, top width: 20 cm, bottom width: 42 cm) (NC13013-F; North Coast Medical Inc., Morgan Hill, CA, USA) was used in this study. A hand pump pressure gauge (NC13025) was utilized to apply and monitor the splint pressure.

#### Procedure

The participants were randomly assigned (computerized random numbers) to the control group or the CP group by using a website tool (http://www.randomization.com). All interventions and tests were performed on PLL. The measurements were conducted before and immediately after treatment in the same sequence and were obtained by the same blinded examiner.

During a home visit, a physical therapist assessed the functional disability of the participants using the Barthel Index. On a different day, the subjects visited the laboratory, where the anthropometry data, patellar-ankle jerk, and pathological reflexes were evaluated. The individuals wore T-shirts and shorts and rested in lying position for 10 minutes to acclimate; meanwhile, the required arrangements for H-reflex and EMG recordings were set up.

#### Treatment protocol

The therapeutical sessions for both intervention groups lasted for 25 minutes and were performed by another physical therapist, who had been previously trained in the approaches. The duration of the session had been recommended by Johnstone and the PRO-Active approach to Neurorehabilitation (PANat) [25] as enough for achieving therapeutic effects without complications resulting from the pressure of the splint. In both groups, all the subjects received one session of the conventional IT with a dynamic emphasis on the ankle in the following postures: supine, bridging, sitting, intermediate between sitting and standing, and modified plantigrade.

The sustained stretching (3 sets, 1 minute each for stretching and resting) was performed in the supine position with the knee extended for stretching the gastrocnemius and knee flexed at  $45^{\circ}$  for stretching the soleus muscle. In the hook-lying position, with approximately 60° hip flexion and 90° knee flexion, the subject performed the bridging position, which involves extending the hips and elevating the pelvis (3 sets, 5 repetitions each).

In the sitting position, with both feet flat on the floor, upper extremities were held steady in front, shoulders flexed, elbows extended, and hands clasped together. The therapist instructed the participant to move the trunk forward and backward (3 sets, 5 repetitions each, maintaining the maximal flexion position for 10 seconds; 30-second rest intervals between sets were allowed). In the intermediate position between sitting and standing, the therapist guided the patient to lift the buttocks off the chair, encouraging more weight shift toward the paretic leg, holding the position for 10 seconds (5 repetitions with 30-second rest intervals between them). In the last posture, modified plantigrade, holding the paretic leg in a step position and the upper extremities on a tabletop hand support, the participants were asked to move the pelvis forward and then to the initial position (3 sets, 5 repetitions each). The physical therapist provided verbal commands and visual cues, and monitored all the movement patterns.

In the CP group, the patient's limb was covered with a thin cotton sleeve for protecting skin while the air splint was in use. The inflation pressure of the splint was 40 mm Hg at rest and it was checked by a manometer. The CP applied by JPS is a deep, constant pressure exerted by the device encompassing the whole circumference of a limb. CP provides a constant stimulus to the agonist and antagonist musculature during the therapeutic exercise.

#### Muscle tone assessment

The tone of the plantar flexor muscles was evaluated in the supine lying position, in accordance with the protocol described by Ansari et al. [30]. The examiner graded the resistance felt with a single score of MAS [31].

#### H-reflex measurement

The H-reflex of the PLL soleus muscle was tested with the patient in the sitting position, with the arms resting on the thighs, with 30° flexion of knees and 30° plantar flexion of the ankle. The participant was instructed to sit barefoot and keep both feet flat, supported on a wooden base. The Nicolet unit set-up was as follows: sensitivity/gain of 1 mV/division, sweep speed of 10 ms/division, bandwidth of 2–10 kHz.

The H-reflex response was elicited by an electrical impulse applied to the tibial nerve, and the current output was adjustable in the range of 0–200 V. The stimulation electrode delivered 1-ms percutaneous electrical stimuli. The active disc recording electrode was placed 2 cm below the myotendinous junction of the gastrocnemius and soleus muscles, and the ground electrode on the anterior middle third of the calf; the stimulator was put on the medial aspect of the knee crease. The inter-stimulus interval length was 15 seconds to minimize the effect of homosynaptic depression [32].

## Electromyography recording

EMG signals were recorded from the tibialis anterior, soleus, medial gastrocnemius, and lateral gastrocnemius muscles during the STS movement with an electrode placed in accordance with the Surface Electromyography for the Non-Invasive Assessment of Muscles (SENIAM) guidelines [33]. Initially, the sub-maximal isometric voluntary contraction was registered in the sitting position; these data were used for normalizing the signal obtained during STS. Data were obtained during 3 valid trials of STS (1-minute rest after each trial), which were averaged and used in the analysis. For the STS movement, the subjects were asked to sit on a chair with the knee in 90° flexion and ankle at a neutral position on some reference marks on the floor. The upper limbs were crossed in front (cradled position), with 1/3 of the femur resting on the seat [14]. The individuals were instructed to perform the movement at a reasonable speed without using the upper limbs.

Surface Ag/AgCl electrodes were applied for recording the EMG signals (20 mm inter-electrode spacing). Skin impedance was reduced by slight abrasion and cleaning with alcohol. EMG signals were amplified through a surface EMG amplifier (SX230FW), with a 20–460 Hz bandpass filter (band pass: 30 Hz to 1 KHz; gain: 1000; noise: < 5  $\mu$ V; common mode rejection ratio: 60 Hz (dB)). A sampling rate of 1000 Hz per channel, a sensitivity of 3 V, and an output excitation of 4600 mV were taken into account.

The EMG record was synchronized with a force plate located under the chair support to detect the phases of the STS movement: pre-extension (from the beginning position to the take-off of movement) and extension (from the take-off to the standing position). The force plate (100-Kg output) had a sampling rate of 500 Hz, sensitivity of 3 mV, and an output excitation of 2000 mV. Data analysis was performed by using the MATLAB software (R2008a).

#### Statistics

The statistical analysis was performed with the Stata-Corp 2013 software. The distribution of data was analysed with the Shapiro-Wilk normality, skewness, and kurtosis tests. Univariate analysis was conducted for variables recorded from each treatment group. Intra-group differences were evaluated with the paired Student's *t*-test or the Wilcoxon test, depending on the distributions of the variables. Differences between the intervention groups were defined with an analysis of covariance (ANCOVA), with the post-treatment measurements as dependent variables adjusted by the pre-treatment ones. The significance value was set up at p = 0.05.

## **Ethical approval**

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the Ethics Committee of the University of Santander in Colombia (protocol No.: 12458). The study was registered in the Brazilian Registry of Clinical Trials (ID No.: RBR-7zmz3y).

## Informed consent

Informed consent has been obtained from all individuals included in this study.

## Results

A total of 84 potential participants were assessed for eligibility; 44 of them did not meet the inclusion criteria, 1 subject declined to participate, and 5 could not be enrolled for other reasons (place of residence far from Bucaramanga). A total of 34 participants were randomly assigned to either of the intervention groups (17 to the control group and 17 to the CP group). Overall, 2 participants in each group were excluded because pre-treatment H-reflex measurements could not be obtained. Finally, 30 participants were enrolled in the study (Figure 1). The sociodemographic, anthropometric, and clinical (Table 1) variables were not significantly different (p > 0.05) between the 2 groups.

Overall, 33% and 60% of individuals in the control group and the CP group, respectively, showed a 1-point decrease on MAS for the plantar flexor muscle tone (p = 0.02). Also, the CP group within-group analysis revealed a significant increase in the H-wave latency (p = 0.04) and a significant decrease in the H-wave duration (p = 0.03) and the Hmax/Mmax ratio (p = 0.02). The control group exhibited a significant increase in the M-wave duration (p = 0.01) (Table 2). In the between-group analysis, ANCOVA demonstrated a higher effect of the combined treatment in the CP group for the H-wave duration ( $\beta = -1.29$ ; p = 0.009) and the Hmax/Mmax ratio log ( $\beta = -0.46$ ; p = 0.04), after adjusting the post-treatment measurement against the pre-treatment one (Table 3). ANCOVA showed no significant differences in the EMG signal (Tables 4 and 5) between the intervention groups (p > 0.05). These results remained the same after adjusting for the control variables, age, sex, type of stroke, the time course of the disease, body mass index, medial calf skinfold, and functionality.

## Discussion

In this study, both treatments decreased the muscle tone; notwithstanding, this change in the resistance to passive movement was more frequent in subjects who received conventional IT combined with CP than in those treated with



Figure 1. The study flowchart

Variable	Control group (n = 15)	Circumferential pres- sure group ( <i>n</i> = 15)	Total ( <i>n</i> = 30)	p
Type of stroke <sup>a</sup>				1.00
Ischemic	12 (80)	12 (80)	24 (80)	
Haemorrhagic	3 (20)	3 (20)	6 (20)	
Hemiplegic side <sup>a</sup>				0.68
Right	10 (66.7)	12 (80)	22 (73.3)	
Left	5 (33.3)	3 (20)	8 (26.7)	
Modified Ashworth Scale <sup>a</sup>				
Mild (1+)	7 (46.7)	6 (40)	13 (43.3)	
Moderate (2 or 3)	8 (53.3)	9 (60)	17 (56.7)	
Tendon jerk hyperreflexiaª	15 (100)	15 (100)	30 (100)	1.00
Clonus (+)	9 (60)	7 (46.7)	16 (53.3)	0.71
Babinsky (+)	10 (66.7)	13 (86.7)	23 (76.7)	0.39
Time after stroke (months) <sup>b</sup>	26.6 ± 14.8	29.1 ± 15.1	27.8 ± 14.7	0.65
Barthel Index <sup>b</sup>	83.3 ± 8.3	83.6 ± 13.6	83.5 ± 11.1	0.93

Table 1. Clinical characteristics of the participant
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<sup>a</sup> Data shown as *n* (%); *p*-value evaluated by Fisher's exact test

<sup>b</sup> Data shown as mean ± *SD*; *p*-value evaluated by paired Student's *t*-test

H-wave variable	Control group (n = 15)			Circumferential pressure group ( $n = 15$ )		
	Before	After	р	Before	After	p
Latency <sup>a</sup>	33.3 ± 2.2	33.7 ± 2.5	0.35	33.8 ± 2	34.2 ± 2.4	0.04°
Amplitude	1.77 [1.97]	1.04 [1.27]	0.06	3.36 [2.81]	1.10 [2.59]	0.08
Duration <sup>a</sup>	7.7 ± 1.4	8.1 ± 1.8	0.28	7.4 ± 1.6	6.6 ± 1.2	0.03°
Hmax/Mmax <sup>b</sup>	0.54 [0.60]	0.48 [0.46]	0.60	0.71 [0.37]	0.35 [0.56]	0.02°

#### Table 2. Variables of H-reflex measured before and after treatment

<sup>a</sup> Data shown as mean ± SD

<sup>b</sup> Data shown as median [interquartile range]

 $^{\circ}$   $\rho$  < 0.05 within each group: paired Student's t-test and Wilcoxon sum rank test for normal and non-normal data, respectively

Table 3. Differences in H-reflex latency, amplitude, and duration (ANCOVA with the control group as reference)

H-wave variable	β coefficient	95% CI	p
Latency	-0.007	-0.97 to 0.950	0.980
Amplitudeª	0.100	-0.53 to 0.730	0.740
Duration	-1.290	-2.25 to -0.340	0.009 <sup>b</sup>
Hmax/Mmax <sup>a</sup>	-0.460	-0.92 to -0.002	0.040 <sup>b</sup>

<sup>a</sup> Log-transformed variables

 $^{\rm b} p < 0.05$ 

Table 4. Differences in the root mean square amplitude <sup>a</sup> of plantar
flexor and dorsal flexor muscles during the sit-to-stand movement
(ANCOVA with the control group as reference)

Variable	β oefficient	95% CI	р
Pre-extension			
Tibialis anterior <sup>a</sup>	-0.03	-0.35 to 0.29	0.84
Gastrocnemius medialª	0.27	-0.33 to 0.88	0.36
Gastrocnemius lateral <sup>a</sup>	0.36	-0.22 to 0.95	0.21
Soleusª	0.30	-0.30 to 0.90	0.31
Extension			
Tibialis anterior <sup>a</sup>	-0.03	-0.38 to 0.31	0.83
Gastrocnemius medialª	-0.0008	-0.30 to 0.30	0.99
Gastrocnemius lateral <sup>a</sup>	0.18	-0.30 to 0.66	0.44
Soleusª	0.19	-0.09 to 0.47	0.17

<sup>a</sup> Log-transformed variables

conventional IT only (60% vs. 33.3%). Although MAS is a subjective clinical tool, it was carefully standardized [7, 34, 35]; besides, the evaluation of the H-reflex, a highly reproducible and objective measurement, was included [36].

Therefore, only the CP group showed an inhibition of the H-reflex, represented in the increased latency and the decreased Hmax/Mmax ratio, which, in turn, denotes a slowing down of the reflex activation. The Hmax/Mmax ratio reflects the percentage of motor neurons in a given pool that can be activated by the reflex afferents [11, 32]; the decrease could be attributed to the stimulation of the cutaneous mechanoreceptors and Ia and Ib afferent fibres in the spastic muscle. This stimulation results in activation of GABA receptors, and therefore of the pre-synaptic inhibitory mechanism. Table 5. Differences in the median frequency of plantar flexor and dorsal flexor muscles during the sit-to-stand movement (ANCOVA with the control group as reference)

Variable	β coefficient	95% CI	p
Pre-extension			
Tibialis anterior	-2.970	-8.45 to 2.50	0.27
Gastrocnemius medial	-2.840	-17.34 to 11.65	0.69
Gastrocnemius lateral <sup>a</sup>	-0.003	–0.15 to 0.15	0.96
Soleus	0.870	-14.39 to 16.13	0.90
Extension			
Tibialis anterior	3.520	-6.19 to 13.24	0.46
Gastrocnemius medial <sup>a</sup>	0.010	-0.14 to 0.17	0.86
Gastrocnemius lateral <sup>a</sup>	0.007	-0.11 to 0.12	0.90
Soleus	-0.250	-15.86 to 15.35	0.97

<sup>a</sup> Log-transformed variables

Another possible mechanism could be initiated by the stimulation of the A $\beta$  fibres that activate the type II sensory fibres, therefore decreasing the excitability of alpha motoneurons in the plantar flexor muscles [21, 24, 37–39].

Robichaud et al. [27] observed a 55% decrease in the H-reflex amplitude when post-stroke patients were using JPS (p < 0.008). Agostinucci [40] did not report any change in the H-reflex attributable to JPS in healthy individuals. In both studies, CP was applied for a short time (5 minutes), a period shorter than the one used in the present study, established in accordance with the Johnstone and PANat guide-lines [25].

The inhibitory effect of CP over the muscle tone and reflex activity could be ascribed to the activation of cutaneous and muscle mechanoreceptors and the resultant enhancement of IT effects [20, 27, 29]. Also, the decreased duration of the H-reflex caused by CP suggests better synchrony in the triggering of reflex-activated muscle fibres of the plantar flexor muscles [41–43]; possibly, this is due to a higher effect on the type II fibres, which could be activated through the sustained stimulation of cutaneous and muscle mechanoreceptors [21, 22, 24].

The EMG activity during the STS movement did not present any differences between the 2 therapeutic approaches. It seems that individuals with stroke use different muscle activation strategies during STS because a substantial intersubject variability in the paretic leg was evidenced.

## Limitations

The comparison of these results with other studies was difficult since there are few reports on CP effect in the literature, and the available studies refer to other populations and variables. On the other hand, our study has some limitations that are important to mention. The recruitment curve was not included because the equipment used to measure the H-reflex does not allow it. Additionally, we involved patients with a Barthel Index score  $\geq$  60; in this way, our results are not applicable to patients with severe functional dependence. Moreover, the study covered only one therapy session, which has to be interpreted with caution.

# Conclusions

Our results suggest that IT along with CP during a 25-minute physical therapy session have mainly biomechanical and neural effects, as evidenced by the decreasing muscle tone and reflex activity. The CP applied by JPS exerts a constant stimulus and provides support for extremity stabilization during therapeutic exercise. However, future studies are required to assess the criteria for CP prescription and use in the management of spasticity of different clinical aetiology, particularly concerning the length of treatment and the pressure of the splint.

## **Disclosure statement**

No author has any financial interest or received any financial benefit from this research.

## **Conflict of interest**

The authors state no conflict of interest.

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