

Original Article

## Effect of extracorporeal shock wave therapy on spastic equinus foot in children with unilateral cerebral palsy



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### المخلص

**أهداف البحث:** تهدف الدراسة لمعرفة تأثير العلاج بالموجات التصادمية الشعاعية خارج الجسم على التحكم الحركي الانتقائي، التنشج، الوظيفة الحركية الإجمالية والتوازن لدى الأطفال المصابين بالشلل الدماغي احادي الجانب.

**طرق البحث:** تم إجراء هذه الدراسة العشوائية الضابطة على ٣٤ طفلاً أعمارهم ٧ إلى ٩ أعوام، مصابين بالشلل الدماغي احادي الجانب. الذين تم تقسيمهم عشوائياً للمجموعة الضابطة أو مجموعة الدراسة. تلقت المجموعتان تمارين تقليدية لمدة ١٢ أسبوعاً. تلقت مجموعة الدراسة موجات تصادمية (جلسة واحدة / أسبوع) على عضلات الساق (١٥٠٠ صدمة، تردد ٤ هرتز، طاقة ٠.٣٠ مللي جول / مم<sup>٢</sup>). تم تقييم جميع الأطفال قبل بدء العلاج وبعد ١٢ أسبوعاً باستخدام مقياس أشورث المعدل، جهاز بيوركس دينامومتر ٤ متساوي الحركة، مقياس الوظيفة الحركية الإجمالية ٨٨-، ذو ابعاد "د" للوقوف و "أي" للمشي، ومقياس التحكم الحركي الانتقائي تروست، واختبار الوقوف على قدم واحدة.

**النتائج:** أظهرت النتائج تحسناً ملحوظاً في عزم الدوران المنحرف، وزوايا عتبة عزم الدوران، والوظيفة الحركية الإجمالية، والتحكم الحركي الانتقائي والتوازن في مجموعة الدراسة بالمقارنة بالمجموعة الضابطة.

**الاستنتاجات:** قد يكون العلاج بالموجات التصادمية أداة قيمة إلى حد كبير للحد من التنشج، تحسين القدرة على عزل الحركة والتحكم فيها، وبالتالي، تحسين التوازن والوظيفة الحركية الإجمالية لدى الأطفال المصابين بالشلل الدماغي احادي الجانب.

**الكلمات المفتاحية:** الشلل الدماغي؛ العلاج بالموجات التصادمية الشعاعية خارج الجسم؛ التنشج؛ التحكم الحركي الانتقائي.

### Abstract

**Objectives:** This study aims to investigate the effects of radial extracorporeal shock wave therapy on selective motor control, spasticity, gross motor function, and balance in children with unilateral cerebral palsy.

**Methods:** This randomised controlled study recruited 34 children aged 7–9 with spastic unilateral cerebral palsy. They were randomly allocated to either the control or study group. Both groups undertook traditional exercises for 12 weeks. The study group received shock waves (one session/week) on the calf muscle (1500 shocks, frequency of 4 Hz, energy of 0.030 mJ/mm<sup>2</sup>). All children were evaluated at baseline and after 12 weeks using the Modified Ashworth Scale, a Biodex System 4 isokinetic dynamometer, dimensions D (standing) and E (walking) of the Gross Motor Function Measure – 88, the Trost Selective Motor Control test, and the single leg standing test.

**Results:** Mixed analysis of variance and Mann–Whitney results showed significant improvement in eccentric peak torque, torque threshold angles, gross motor function, selective motor control, and balance in the study group compared with the control group ( $p < 0.05$ ).

**Conclusions:** Shock wave therapy may be a valuable instrument for reducing spasticity, improving the ability to isolate and control movement, and consequently,

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improving balance and gross motor function in children with unilateral cerebral palsy.

**Keywords:** Cerebral palsy; Extracorporeal shock wave therapy; Selective motor control; Spasticity; Wave therapy

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## Introduction

Cerebral palsy (CP) is a cluster of long-lasting developmental postural and movement disorders that produce performance restrictions caused by disturbances during foetal or infant brain development.<sup>1</sup> Unilateral CP (UCP) is regarded as one of the most common types of CP. Spasticity is considered the main motor disorder in most children with CP. Muscle deformities usually occur owing to a discrepancy between the agonists and antagonists, leading to gait problems.<sup>2–4</sup> Selective voluntary motor control (SVMC) is considered the foundation of exercise performance as it allows for the isolation of targeted muscular action through movement patterns. In CP, dysfunction of the corticospinal tract decreases the ability to regulate the speed, power, and timing of muscular action, which leads to abnormal movement patterns. Subsequently, deficient SVMC significantly impedes the motor abilities of children with CP. The primary challenge CP cases face is difficulty in maintaining balance through movement control.<sup>5–7</sup>

Equine foot is one of the most common deformities in patients with UCP. Equine foot in children has many causes, including spasticity, altered motor control, muscle contractures, contractures of the ankle joint, and muscle weakness.<sup>8</sup> Equine foot due to weakness substantially affects the gait of children with mild hemiparesis. Dorsiflexor muscle weakness leads to inefficient foot clearance, which may result in a staggering gait and falls.<sup>9</sup>

Various methods have been reported for the treatment of equinus foot. These include nonoperative treatment (casting, orthotics, biofeedback devices, botulinum toxin type A, and pharmacological methods) and operative treatment (tendon transfers and tenotomy). However, many of these methods do not have significant benefits; alternatively, the benefits are questionable or associated with adverse effects and complications.<sup>10–12</sup>

Extracorporeal shock waves are sound pressure waves with a higher power level applied from outside the body. They are frequently used in the medical treatment of various problems.<sup>13</sup> Radial extracorporeal shock wave therapy (rESWT) is an effective and safe physical therapy modality for reducing spasticity caused by upper motor neuron lesions in many conditions. However, its effectiveness in CP has not been fully investigated. Shock wave therapy results in a long-term reduction in the hypertonicity of calf muscles in children with CP and young adults.<sup>14,15</sup>

Non-invasive treatments such as rESWT may be a promising alternative in the management of equinus foot in children with UCP and may produce improvement in SMC

and functional movements such as gait. Further, to the best of the authors' knowledge, only a few studies have applied clinical assessments to determine the consequences of spasticity management in CP, and none used a biomechanical assessment. Thus, this study aimed to investigate the effects of rESWT on ankle plantar flexor spasticity, as well as selective motor control, balance, and gross motor function (GMF) in unilateral CP. Our main hypothesis was that rESWT could be an effective tool for reducing ankle plantar flexor spasticity in patients with unilateral CP.

## Materials and Methods

### Study design

The study was a prospective, single-blinded, randomised clinical trial. Neither the participants nor the assessors were privy to the former's group assignments. Measurements were assessed pre-treatment, at Week 0, and post-treatment, at the end of the twelfth week.

### Subjects

Children with UCP who presented at King Fahd Hospital, the Hospital of Medical Rehabilitation, and the Comprehensive Rehabilitation Center in Almadinah Almunawwarah, KSA, were recruited to participate in the current study. Inclusion criteria were as follows: (1) children aged 7–9; (2) children who could walk independently or with assistive devices; (3) those with motor dysfunction graded as a 1 or 2 according to the Gross Motor Function Classification System; (4) those who scored 1 or 1<sup>+</sup> on the Modified Ashworth Scale (MAS); (5) children with dynamic contracture of the ankle while walking (Table 1). The exclusion criteria were as follows: (1) patients who received a botulinum toxin type A injection in the gastrocnemius muscle or serial casting for the management of ankle contracture in the past six months; (2) children with structural contracture of the ankle; (3) those who underwent an operative procedure to the lower extremity in the previous year; (4) those experiencing pain in the lower limbs.

Sample size calculations were performed, with peak eccentric torque (PET) as a primary outcome measure, using G\*Power software (latest ver. 3.1.9.7; Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). The calculations were based on an effect size of 0.184 (partial eta squared was determined to be 0.113, based on a pilot study performed by the principal investigator), an alpha level of .05, and a desired power of 80%. Further, the estimated desired total sample size for the study was 34 patients. A total of 45 participants were included in the study to compensate for the portion of participants expected to drop out before completing the study. Initially, 45 patients were selected for inclusion in the study. However, six did not meet the selection criteria, and five did not attend the post-programme evaluation.

### Randomisation

The study participants were randomised after the baseline measurements were taken. Randomisation was done as follows. Envelopes with cards labelled either 'study group' or 'control group' were prepared, and each participant was

asked to choose a sealed envelope to determine their group assignment.

### Assessment

Biomechanical measurements of ankle plantar flexor spasticity were taken using the Biodex<sup>®</sup> System Pro 4. The MAS was used to assess ankle plantar flexor spasticity clinically. This scale has been reported to have good validity and reliability.<sup>16</sup> The Gross Motor Function Measure – 88 (GMFM-88) has also been found to have excellent validity and reliability<sup>17–19</sup>; therefore, it was selected for use in the current study to determine GMF. Owing to its good inter-rater reliability, the Trost Selective Motor Control (TSMC) test was employed to assess the ability of each child to complete isolated movement of the ankle.<sup>20</sup> The single leg standing test (SLS) test was used to assess static balance, as its reliability in children with CP has previously been confirmed.<sup>21</sup>

The evaluation was performed as follows: evaluation of spasticity, followed by application of the GMFM-88 and SVMC, concluding with balance assessment using the Biodex<sup>®</sup> System Pro 4. Each child was stabilised using a dynamometer. The subject's knee joint was positioned at 30° flexion using a Velcro<sup>®</sup> strap. The ankle attachment was assembled, ensuring accurate alignment between the anatomical and mechanical axes. The participants were asked to relax during the assessment to eliminate voluntary contraction of the plantar flexors. From a neurophysiological perspective, dampening voluntary muscular activity is important during the assessment of spasticity. This is because any active contraction can negatively affect the reliability of the results by increasing muscle tone, consequently increasing the force produced by the tested muscle.<sup>22</sup>

During the tests, passive ankle joint movement, induced by an isokinetic dynamometer, from 30° of plantar flexion to 20° of dorsiflexion, was performed at velocities of 60°/s and 180°/s. The reference point was 30° of ankle plantar flexion (0°). Three trials were conducted at each velocity, and the mean of the trials was determined. PET—which represents the highest amount of eccentric torque generated during passive motion—and the torque threshold angle (TTA) were used to assess spasticity because of their reliability and validity. A direct relationship exists between PET and spasticity, while there is a reverse relationship between TTA and spasticity.<sup>23</sup>

For clinical assessment of spasticity, the MAS was used to determine the degree of ankle plantar flexor spasticity. A therapist applied passive dorsiflexion of the ankle on the affected side and graded the amount of spasticity according to the MAS. Only the GMFM-88 standing dimension (dimension D) and gait and climbing (dimension E) were included.<sup>17</sup> The minimum and maximum scores of the D and E dimensions of the GMFM-88 were 39 and 72, respectively. The ability to perform isolated ankle dorsiflexion was assessed using the TSMC protocol. During the test, grades 0, 1, and 2 signified the inability of the subject to isolate movement, their ability to isolate the movement partially, and their ability to isolate the movement completely, respectively. For clinical assessment of balance using the single leg standing test (SLST), each subject was asked to stand on the affected leg with their eyes open for as long as possible. The duration was recorded using a digital

stopwatch. The time started once the foot was flexed off the ground. The test was deemed to be completed once the foot touched the ground again, if upper limb movement occurred, if there was a need to place a hand down on the adjacent seat for steadying purposes, or if balance was lost. The test was terminated after a maximum period of 60 s. The mean scores of the three trials were calculated, and the test was performed without orthosis.

### Treatment program

#### Both groups

Mats, rolls, wedges, balls, stools, sitting chairs, wobble boards, standing bars, and sticks were used in the physical therapy programme. The programme was delivered by four well-trained physical therapists with ten years of experience in paediatric rehabilitation. Stretching, strengthening exercises, neurodevelopmental technique, and balance, proprioceptive, and gait training were offered to both the study and control groups for 12 weeks (one-hour sessions at a frequency of three days per week).

#### Study group

The subjects in the study group received rESWT. An rESWT pneumatic device, Shock Med<sup>®</sup>, was used during one weekly session (for 12 weeks). The handpiece of the device was placed on the belly of the calf muscle to treat plantar flexion spasticity after applying the gel. The treatment parameters were 1500 shocks at a pressure of 1.5 bar, an energy flux density of 0.030 mJ/mm<sup>2</sup>, and a frequency of 4 Hz. Each session provided seven minutes of treatment (Figure 1).

### Statistical analysis

SPSS version 16 windows (Charles R Flint, New York, USA) was used for statistical analysis. To test the normality of the data, we used the Kolmogorov–Smirnov and Shapiro–Wilk tests to analyse normally distributed data and non-parametric tests to analyse the data that were not normally distributed. A mixed analysis of variance was used to test differences between or within groups for PET, TTA, GMFM, and SLST. MAS scores, the selective motor control baseline, and the subjects' post-programme characteristics were analysed using the Mann–Whitney U test; within-group changes were analysed with the Wilcoxon signed-rank test. Alpha=0.05 to assess significance.

### Results

No statistically significant differences were found between the study and control groups' mean baseline demographics (age, height, and weight;  $p = 0.441, 0.806, \text{ and } 0.518$ , respectively) (Table 1). Additionally, the groups were homogenous in terms of sex, affected side, and orthosis.

#### Peak eccentric torque

##### Plantar flexors at 60°/s

Regarding the PET of the ankle plantar flexors at 60°/s, no significant interaction was found between intervention type (traditional or shock wave) and time, Wilks' Lambda

( $\Delta$ ) = 0.996,  $F(1, 32) = 0.113$ ,  $p = 0.739$ , partial eta squared ( $\eta_p^2$ ) = 0.004. A significant main effect for time was found, ( $\Delta$ ) = 0.682,  $F(1, 32) = 14.893$ ,  $p = 0.001$ , ( $\eta_p^2$ ) = 0.318, with both groups showing a decrease in the mean values of peak torque of the ankle plantar flexors at (60°/sec) pre- and post-intervention (Table 2 and Figure 2). A significant main effect was found between groups,  $F(1, 32) = 7.534$ ,  $p = 0.010$ ,  $\eta_p^2 = 0.191$ . This suggests a significant difference in the mean values of peak torque of the ankle plantar flexor between the control and study groups in favour of the study group.

#### Plantar flexors at 180°/s

Regarding the peak torque of the ankle plantar flexors at 180°/s, no significant interaction was found between intervention type (traditional or shock wave) and time, ( $\Delta$ ) = 0.962,  $F(1, 32) = 1.237$ ,  $p = 0.268$ ,  $\eta_p^2 = 0.038$ . A significant main effect for time was found, ( $\Delta$ ) = 0.383,  $F(1, 32) = 51.54$ ,  $p = 0.000$ ,  $\eta_p^2 = 0.617$ , with both groups showing a decrease in the mean values of peak torque of the ankle plantar flexors at 180°/s pre- and post-intervention (Table 2 and Figure 3). Further, there was a significant main effect between the groups,  $F(1, 32) = 5.138$ ,  $p = 0.030$ ,  $\eta_p^2 = 0.138$ . This suggests a significant difference in the mean values of peak torque of the ankle

plantar flexor between the control and study groups in favour of the study group.

#### Torque threshold angles at 60°/s

Regarding the TTA of the ankle plantar flexors at 60°/s, no significant interaction was found between intervention type (traditional or shock wave) and time, ( $\Delta$ ) = 0.971,  $F(1, 32) = 0.956$ ,  $p = 0.336$ ,  $\eta_p^2 = 0.029$ . A significant main effect for time was found, ( $\Delta$ ) = 0.521,  $F(1, 32) = 29.392$ ,  $p = 0.000$ ,  $\eta_p^2 = 0.479$ , with both groups showing an increase in the mean values of the TTA of the ankle plantar flexors at 60°/s pre- and post-intervention (Table 2 and Figure 4). Further, there was a significant main effect between the groups,  $F(1, 32) = 8.296$ ,  $p = 0.007$ ,  $\eta_p^2 = 0.206$ . This suggests a significant difference in the mean values of the TTA of the ankle plantar flexors between the control and study groups in favour of the study group.

#### Torque threshold angles at 180°/s

Regarding the TTA of the ankle plantar flexors at 180°/s, a significant interaction was found between intervention type (traditional or shock wave) and time, ( $\Delta$ ) = 0.809,  $F(1, 32) = 7.562$ ,  $p = 0.01$ ,  $\eta_p^2 = 0.191$ . A significant main effect for time was found, ( $\Delta$ ) = 0.428,  $F(1, 32) = 42.681$ ,  $p < 0$

**Table 1: Participant demographics.**

Variable	Control group (n = 17)	Study group (n = 17)	t/ $\chi^2$	p
Sex (male/female)	9/8	10/7	0.119	0.729
Age (years)	7.9172 ± 0.4577	7.794 ± 0.4621	0.7805	0.441
Height (cm)	125.52 ± 5.395	126.04 ± 6.774	0.2476	0.806
Weight (kg)	25.3 ± 5.62	24.161 ± 4.490	0.6534	0.518
Affected side (Rt/Lt)	10(58.823%)/7(41.176%)	9(52.941%)/8(47.058%)	0.119	0.729
GMFCS (1/2)	11/6	10/7	0.724	0.124
Orthotics (AFO/KAFO/MS)	6/7/4	5/7/5	0.202	0.903

AFOs: Ankle-foot orthosis; KAFO: Knee-ankle-foot orthosis; MS: Medical shoes; GMFM-d: Gross Motor Functional Measure Dimension D; GMFM-e: Gross Motor Function Measure Dimension E;  $\chi^2$ : Chi-squared value; t: t-test.



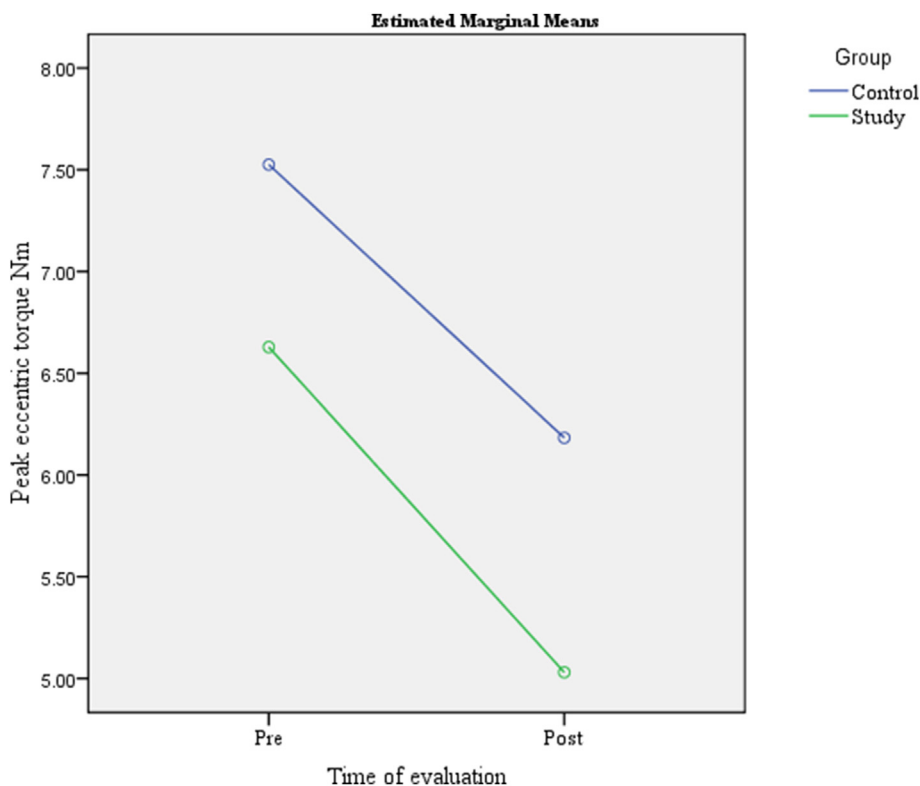
**Figure 1:** Shock wave application to spastic plantar flexors to treat hemiplegic cerebral palsy.

**Table 2: Variables of control and study groups (mean and standard deviation).**

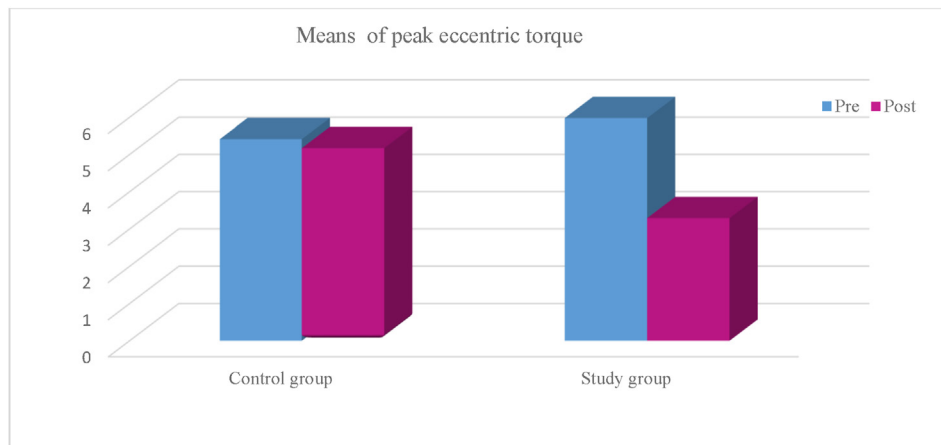
Variable	Mean $\pm$ SD		<i>F</i> (1,32)	<i>P</i> -value
	Pre	Post		
<i>Peak eccentric torque at 60°/s</i>				
Control group	7.53 $\pm$ 1.87	6.18 $\pm$ 1.35	7.53	0.01
Study group	6.63 $\pm$ 1.14	5.03 $\pm$ 1.52		
<i>Peak eccentric torque at 180°/s</i>				
Control group	5.41 $\pm$ 1.09	5.17 $\pm$ 0.92	5.14	0.03
Study group	5.98 $\pm$ 1.07	3.29 $\pm$ 1.35		
<i>Torque threshold at 60°/s</i>				
Control group	11.88 $\pm$ 2.83	14.79 $\pm$ 1.79	8.25	0.01
Study group	12.98 $\pm$ 3.33	17.18 $\pm$ 2.18		
<i>Torque threshold at 180°/s</i>				
Control group	8.80 $\pm$ 2.37	11.35 $\pm$ 2.33	6.27	0.02
Study group	8.60 $\pm$ 2.56	14.87 $\pm$ 3.57		
<i>GMFM-88 dimension D</i>				
Control group	28.86 $\pm$ 3.95	34.96 $\pm$ 1.83	4.98	0.03
Study group	29.55 $\pm$ 1.581	37.229 $\pm$ 1.67		
<i>GMFM-88 dimension E</i>				
Control group	42.86 $\pm$ 3.95	50.78 $\pm$ 4.19	20.81	0.00
Study group	42.96 $\pm$ 2.29	58.56 $\pm$ 3.58		
<i>Single leg standing test (s)</i>				
Control group	2.17 $\pm$ 0.52	5.17 $\pm$ 0.88	26.66	0.00
Study group	2.46 $\pm$ 0.37	6.54 $\pm$ 0.49		

.001,  $\eta_p^2 = 0.572$ , with both groups showing an increase in the mean values of the TTA of the ankle plantar flexors at 180°/s pre- and post-intervention (Table 2). Further, there was a significant main effect between the groups,

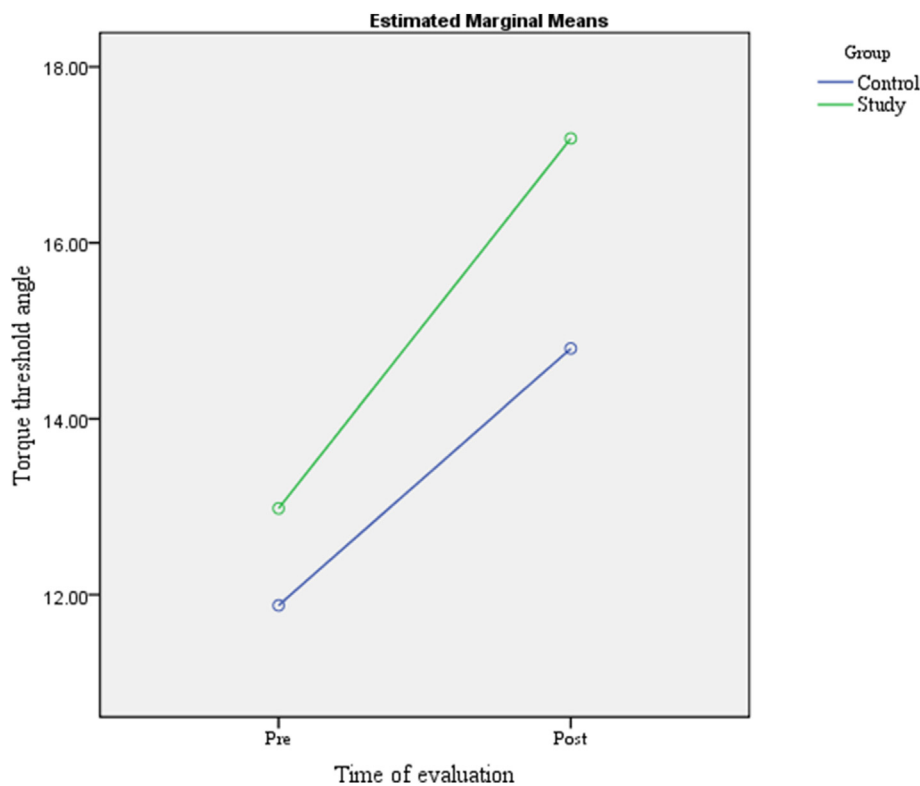
$F(1, 32) = 6.272$ ,  $p = 0.018$ ,  $\eta_p^2 = 0.164$ . This suggests a significant difference in the mean values of peak torque of the ankle plantar flexor between the study and control groups in favour of the study group.



**Figure 2:** Peak eccentric torque of the ankle plantar flexors at 60°/s.



**Figure 3:** Peak eccentric torque of the ankle plantar flexors at 180°/s in control and study groups.



**Figure 4:** Torque threshold angles of the ankle plantar flexors at 60°/s.

#### GMFM-88 (dimension D)

Regarding GMFM-88 dimension D, no significant interaction was found between intervention type (traditional or shock wave) and time, ( $\Delta$ ) = 0.934,  $F(1, 32) = 2.279$ ,  $p = 0.14$ . There was a significant main effect for time, ( $\Delta$ ) = 0.156,  $F(1, 32) = 1.730$ ,  $p < 0.012$ ,  $\eta_p^2 = 0.844$ , with both groups showing an increase in the mean values of GMFM-88-dimension D in both groups pre- and post-intervention (Table 2 and Figure 5). Further, there was a significant main effect between the two groups,

$F(1, 32) = 4.982$ ,  $p = 0.033$ ,  $\eta_p^2 = 0.135$ . This suggests a significant difference in the mean values of the GMFM-88 dimension D scores between the groups in favour of the study group.

#### GMFM-88 (dimension E)

Regarding the GMFM-88 scale dimension E, there was a significant interaction between time and intervention type (traditional or shock wave), ( $\Delta$ ) = 0.622,  $F(1, 32) = 19.458$ ,  $p < 0.001$ . A significant main effect for time

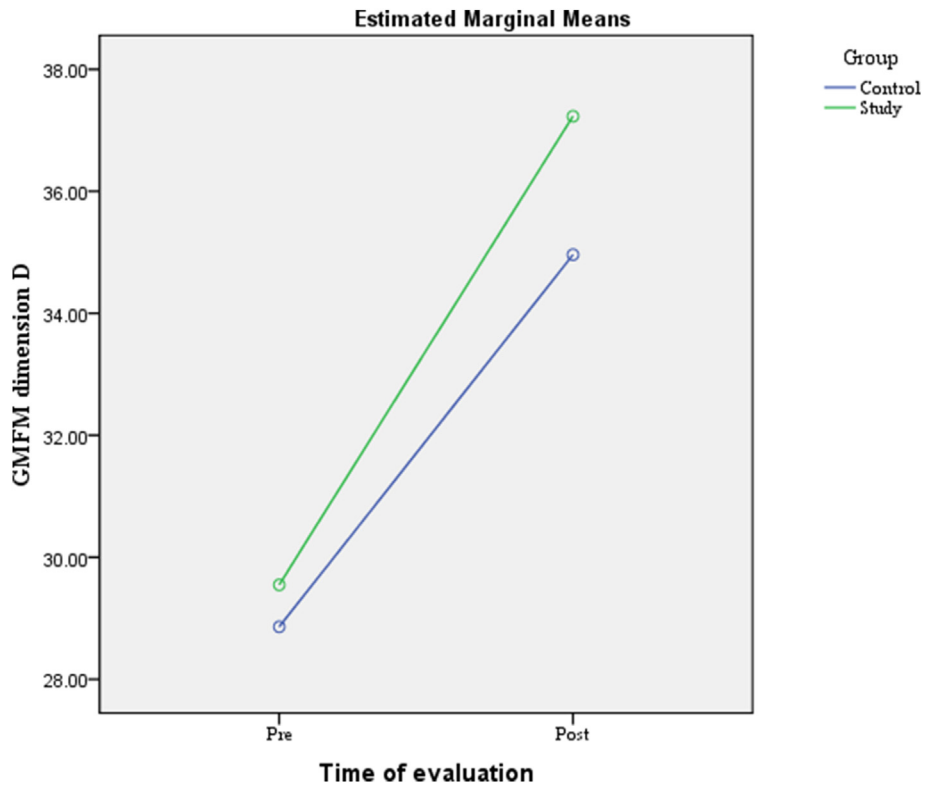


Figure 5: GMFM (D – standing) scores for both groups.

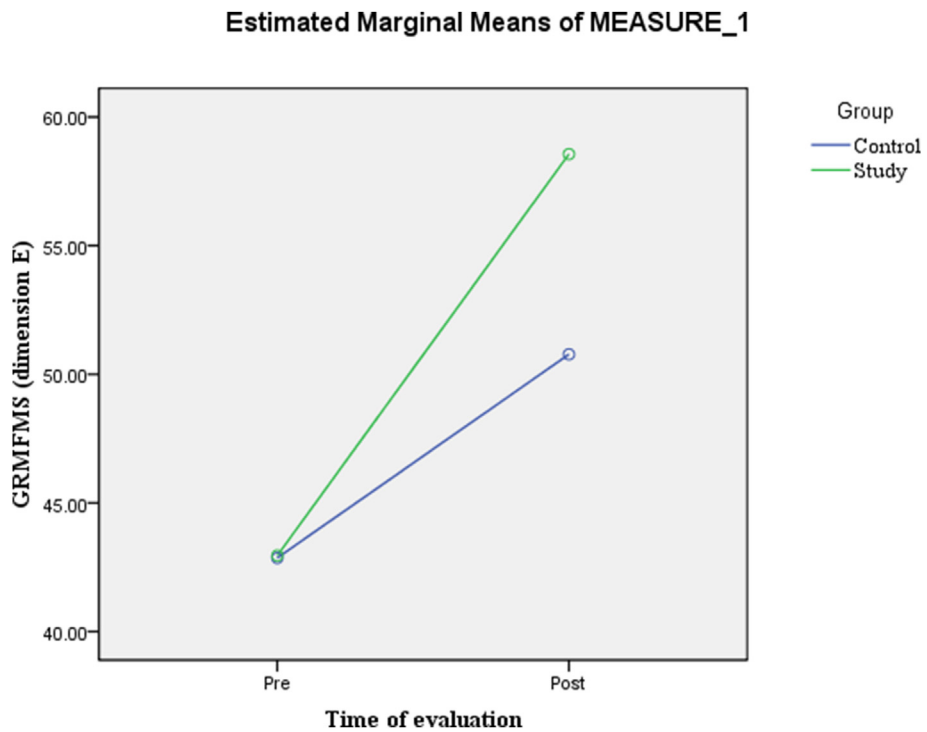


Figure 6: Interaction between group and time regarding GMFM (E – walking) scores.

## Estimated Marginal Means of MEASURE\_1

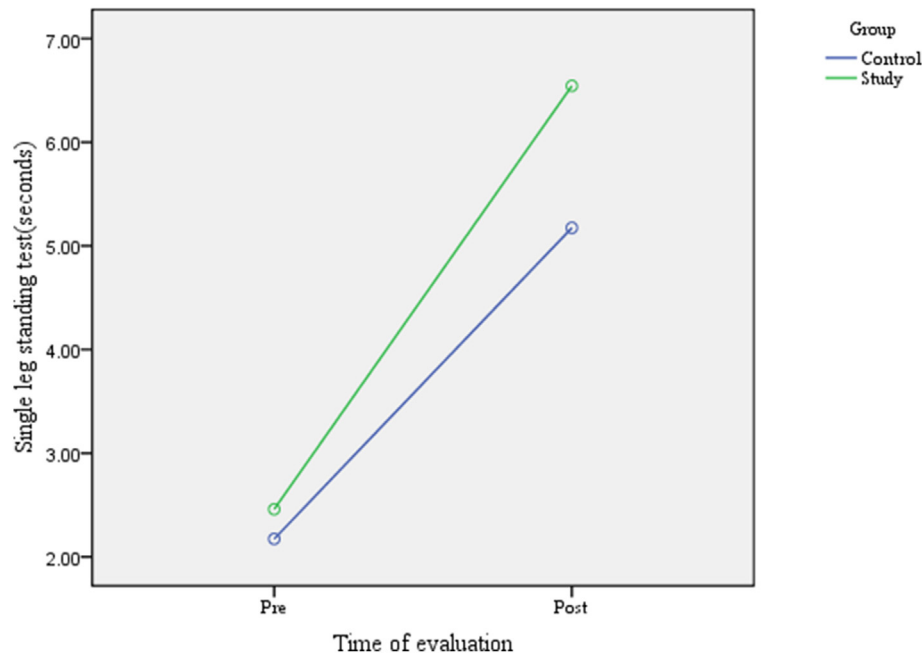


Figure 7: Single leg standing test scores for both groups.

Table 3: Median of MAS and SMC pre- and post-treatment.

	Median (range)		z	p
	Control group (n = 17)	Study group (n = 17)		
<b>Modified Ashworth Scale</b>				
Pre	1 <sup>+</sup> (1-1 <sup>+</sup> )	1 <sup>+</sup> (1-1 <sup>+</sup> )	0.797	0.426
Post	1 (1-1 <sup>+</sup> )	1 (1-1 <sup>+</sup> )	2.659	0.008
z	2.449	3.742		
p	0.014	<0.001		
<b>Selective voluntary motor control</b>				
Pre	0.4943 (0-2)	0.6250 (0-2)	1.567	0.117
Post	1.0573 (0-2)	1.7394 (0-2)	2.566	0.010
z	2.911	3.574		
p	0.004	<0.001		

was found, ( $\Lambda$ ) = 0.150,  $F(1, 32) = 1.819$ ,  $p < 0.001$ ,  $\eta_p^2 = 0.850$ , with both groups showing an increase in the mean values of the GMFM-88 scale dimension E scores pre- and post-intervention (Table 2 and Figure 6). Further, there was a significant main effect between the groups,  $F(1, 32) = 20.808$ ,  $p < 0.001$ ,  $\eta_p^2 = 0.394$ . This suggests a significant difference in the mean values of the GMFM-88 scale dimension E scores between the control and study groups in favour of the study group.

#### Single leg standing test

Regarding the SLST, a significant interaction was found between intervention type (traditional or shock wave) and time, ( $\Lambda$ ) = 0.636,  $F(1, 32) = 18.342$ ,  $p < 0.001$ . A significant

main effect for time was found, ( $\Lambda$ ) = 0.039,  $F(1, 32) = 7852$ ,  $p < 0.001$ ,  $\eta_p^2 = 0.961$ , with both groups showing an increase in the mean values representing single-limb stance pre- and post-intervention (Table 2 and Figure 7). Further, there was a significant main effect between the groups was found,  $F(1, 32) = 26.656$ ,  $p < 0.001$ ,  $\eta_p^2 = 0.454$ . This suggests a significant difference in the mean values of the SLST scores between the groups in favour of the study group.

#### Modified Ashworth Scale

A significant difference was found between the MAS scores of the study group and the control group ( $U = 76$ ,  $p = 0.008$ ), suggesting that rECSW treatment was more effective (Table 3).



### Selective voluntary motor control

A significant difference was found between SVMC in the study group and the control group ( $U = 7.000$ ,  $p = 0.010$ ), suggesting that rECSW treatment was more effective (Table 3).

## Discussion

The current study evaluated the impact of rESWT on plantar flexor spasticity, balance, SVMC, and GMF in children with UCP. The results showed that ankle plantar flexor spasticity significantly decreased after the application of rESWT. This was accompanied by a subsequent improvement in selective motor control, balance, and GMF.

The study was conducted on children aged 7–9, an age when cognitive abilities are sufficiently mature to enable the child to understand commands. Children at this age also show defects in agility and balance tasks.<sup>24</sup>

The reduced spasticity found in the current study is in agreement with the results Manganotti and Amelio obtained<sup>24</sup> when they used one session of rESWT to stimulate the wrist flexor muscle with  $0.030 \text{ mJ/mm}^2$  and 1500 shocks and the finger flexor muscle with  $0.030 \text{ mJ/mm}^2$  and 800 shocks. They reported a significant reduction in spasticity.<sup>25</sup>

Further, Yoo et al.<sup>26</sup> stimulated the elbow flexors and forearm pronator muscles over three sessions with  $0.069 \text{ mJ/mm}^2$ , 1000 shocks, and 4 Hz. They reported reduced spasticity that lasted up to one month post-treatment. Similarly, Bae et al. reported a considerable decrease in spasticity following the application of rESWT to stimulate the elbow flexors over three sessions using  $0.12 \text{ mJ/mm}^2$ , 1200 shocks, and 4 Hz.<sup>27</sup>

The mechanism behind reduced spasticity can be explained by the effect of rESWT on the secretion of nitric oxide,<sup>28</sup> the induction of mechanical vibration that acts on intrinsic muscular components and fibrosis, a reduction in spinal cord excitability, stimulation of the Golgi tendon organ, and muscle stiffness induced by the passivity of the muscles.<sup>29</sup> Nitric oxide secretion due to rESWT facilitates the formation of neuromuscular junctions. It plays a significant role in memory, central nervous system-related neural transmission, and impeded neuromuscular transmission with a subsequent decrease in spasticity. Therefore, nitric oxide plays a crucial role in the mechanisms responsible for spasticity breakdown.<sup>30–32</sup>

Quantitative and objective assessments of spasticity are critical for determining functional loss, treatment outcomes, and prognoses. Spasticity can be evaluated clinically, neurophysiologically, and biomechanically.<sup>33</sup> Clinical assessment of spasticity, which is regularly used in studies on the subject, is often inadequate owing to the subjectivity of the researchers, low statistical reliability, and the fact that alterations in spasticity cannot be sensitively detected given the large differences between the grades.<sup>32</sup> To the best of our knowledge, the current trial is the first clinical study to biomechanically assess the effects of rESWT on spasticity in children with CP. In the current study, a biomechanical assessment was performed to avoid the limitations of a clinical evaluation and assess spasticity

accurately. PET and TTA are important dimensions in this type of assessment.<sup>30</sup> The current clinical trial also quantitatively estimated reduced spasticity after the application of shockwaves by incorporating the two dimensions of PET and TTA at velocities of  $60^\circ/\text{s}$  and  $180^\circ/\text{s}$ , respectively.

Moreover, in the current study, we evaluated two of the main aspects objectively considered indicators of spasticity: PET and TTA. PET values at the angular speeds of  $60^\circ/\text{s}$  and  $180^\circ/\text{s}$  significantly decreased, while TTA values significantly increased compared to pre-intervention. PET reflects intrinsic ankle stiffness at slow velocities, as well as whole spasticity, which impacts intrinsic and stretch stiffness at fast speeds. The other aspect, TTA, reflects the stretch reflex in spasticity instead of intrinsic hypertonia.<sup>33,34</sup> The significant increase in TTA observed after the treatment programme at all the selected velocities is because the effect of the shockwaves on intrinsic stiffness was greater than their effect on the stretch reflex.

At a functional level, the improved GMF and balance observed could be explained by the modulation and reduction of spasticity, as demonstrated by the MAS score, with a synchronous increase in the plantar contact area and range of motion (ROM).<sup>35</sup> This explanation is supported by the results Park et al. obtained<sup>36</sup> when exploring the effect of shockwaves on the spasticity of gastrocnemius muscles in children with spastic CP. They reported positive findings in terms of MAS scores and ankle passive ROM.

Positive outcomes related to GMF were also obtained when different treatment protocols were adopted. Mirea et al.<sup>37</sup> evaluated the effects of shockwaves on upper and lower limb spasticity in children with CP. They found a considerable decrease in MAS spasticity levels in the group treated with rESWT, which led to an increase in the GMFM-66 scores.<sup>37</sup> The authors concluded that rESWT, applied over three sessions, using 500 shocks/min,  $0.15 \text{ mJ/mm}^2$ , and 10 Hz, decreased the levels of hypertonicity and pain in children, accompanied by a concurrent improvement in their gross motor control.<sup>37</sup>

The impaired pathophysiological mechanisms of SVMC remain unclear. It is partly unknown whether the lack of selective control is due to the absence of suppression and the release of primitive flexor/extensor patterns, insufficient connections to the corticospinal tract, or both.<sup>38</sup> The improvement in the selective motor control test scores obtained in the current trial could be explained by the reduction in spasticity.<sup>39</sup>

The present study showed that rESW positively impacted participants' balance. This finding is similar to the results of Amelio et al.'s<sup>40</sup> clinical trial; those scholars reported reduced muscle tension in the plantar flexor muscle to explain improved balance. Additionally, Lee et al.<sup>41</sup> evaluated dynamic postural adjustment in patients with low back pain. They reported a greater improvement in dynamic balance when ESWT therapy, rather than conservative physical therapy, was added to the exercise programme.

We did not investigate the long-term effects of rESW. Additionally, the interaction of multiple treatments in the two groups should be considered. Future studies that explore

the efficacy of rESWT in relation to spasticity should be conducted with a larger sample size. The effectiveness of this treatment approach in achieving long-term benefits also needs to be determined.

## Conclusion

The current study found a positive influence of rESW on spasticity and an improvement in the motor skills of children with CP, leading to advances in the quality of their movements.

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## Conflict of interest

The authors have no conflict of interest to declare.

## Ethical approval

The Ethics Committee of the College of Medical Rehabilitation Sciences, Taibah University, approved this study (CMR-PT-2020-07; approval date: 5-7-2020). The study was registered at [clinicaltrials.gov](https://clinicaltrials.gov) (clinical trial registration number: NCT04835753). The principles of the Declaration of Helsinki for human experimentation were followed.

## Consent

Prior to the commencement of the research activities, parents and guardians of the participating children were informed about the objectives of the study. Each signed informed consent for participation and publication of the data for research purposes.

## Authors contributions

Study conceptualisation, design, and data analysis were performed by HAE and AMA. HAE and AHA collected the data, and HAE, AMA, and OAK interpreted the data. Further, HAE, AMA, and OAK addressed organisation procedures, visualisation, and supervision and prepared the initial version of the manuscript. The final version of the manuscript was reviewed and approved by HAE, AMA, OAK, and WMR. A similarity check was conducted by all the authors using iThenticate software. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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