# Computerized Mobilization of the Cervical Spine for the Treatment of Chronic Neck Pain

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Background: Manual therapies for chronic neck pain (NP) are imprecise, inconsistent, and brief because of therapist fatigue.

Objective: Investigate the safety and efficacy of computerized mobilization of the cervical spine in the sagittal plane for the treatment of chronic NP.

Design: Pilot open trial.

Setting: Physical therapy outpatient department.

Participants: Ten patients with chronic NP.

Interventions: A computerized cradle capable of 3-dimensional neck mobilization was utilized. However, in the present trial the cradle was only utilized in the sagittal plane. Treatment sessions lasted 20 minutes, biweekly, for 6 weeks.

Main Outcome Measures: Numerical rating scale for pain, Neck Disability Index questionnaire, muscle algometry, cervical range of motion (CROM), surface electromyography, and 36-item Short Form Health Survey questionnaire.

Results: Treatment was not associated with any significant adverse effects. Pain scores reduced by  $2 \pm 0.5$  numerical rating scale points. CROM showed significant improvement at the end of the study (P < 0.05). Neck Disability Index showed marked improvement by the fourth week, end of study, and 2 weeks after treatment (P < 0.05); headache subscale showed marked reduction.

Conclusions: These preliminary results demonstrate the safety of a novel computerized mobilization of the cervical spine. In addition, the data suggest that this method is effective in increasing CROM and in alleviating NP and associated headache.

Key Words: neck pain, manual therapy, computerized cervical mobilization

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hronic neck pain (NP) is the most prevalent pain syndrome after lower back pain. The etiology of NP is diverse. In many patients with chronic NP the pathogenesis is not clear.1,2

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The current solutions for NP are suboptimal. Martin and colleagues examined the health expenditures and selfreported health status among US patients. They found that spine-related expenditures have increased substantially from 1997 to 2005, without evidence of corresponding improvement in self-assessed health status.<sup>3</sup> Measures of mental health and work, social and physical limitations worsened over time among people with spine problems.<sup>3,4</sup> Analgesics such as nonsteriodal anti-inflammatory drug, medications for neuropathic pain, invasive procedures, and physical therapy are often utilized; yet, they produce limited short-lasting effects and their benefit is not clear.<sup>5</sup> Therefore, new research into the basic mechanism of NP syndromes and clinical trials evaluating unexplored therapeutic interventions are necessary.

Headache and NP are associated with significant neck biomechanical abnormalities such as abnormal neck posture with forward neck tilting, shortening of the neck extensor muscles, 6 multiple active and latent trigger points, 6,7 reduced cervical range of motion (CROM), reduced neck muscle endurance,8 overcontraction of the neck extensor muscles, and reduced activation of the deep flexor muscles as evident on surface electromyography (sEMG). 9-11 Current research suggests that after injury NP is related to central sensitization as evident by reduced mechanical pain thresholds. 12,13 Mobilization of the cervical spine and other manual therapy techniques can reverse central sensitization manifested with both muscle dysfunction and sensory hypersensitivity and consequently change the pattern of cervical muscle activation. <sup>14,15</sup> Spinal manual therapy applied to the cervical spine has been shown to elicit widespread hypoalgesia in both healthy volunteers and patient populations. 15-17 Several meta-analyses published on the effectiveness of manual therapy in chronic NP have shown promising yet conflicting results. <sup>18–20</sup>

Critical evaluation of the literature shows that current clinical research is inconclusive because of the heterogeneity of manual therapeutic interventions, the choice of different study populations, and poor quality methodology. In addition, current manual therapy interventions have several common inherent disadvantages: (1) Inconsistency: therapists cannot repeat treatment with precision over time; (2) the lack of reliability between practitioners on subsequent therapeutic sessions; (3) the therapeutic session is very short because of the therapist's fatigue (the head weighs about 7% of the body weight); (4) the angular and linear velocities and acceleration during mobilization are often too fast, leading to vestibular activation or neck injury (mobilization involves both rotational and linear translation of the head and neck); (5) utilization of high-velocity, aggressive manipulation or mobilization can lead to overcontraction of neck muscles. increased NP, or serious adverse effects such as dissection of the vertebral arteries, dural tear, nerve injury, disc herniation, hematoma, and bone fracture.<sup>2</sup>

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To increase the efficacy of neck mobilization, and at the same time reduce the risk, we have been investigating a device capable of 3-dimensional computerized neck mobilization. The purpose of the current trial is to establish the safety of continuous computerized mobilization and gather information about the possible efficacy of this method in the treatment of patients with NP.

In light of the common biomechanical abnormalities in patients with NP and headache<sup>6-8</sup> and their cooccurrence, it is also our goal to describe the effects of computerized mobilization on the severity of headache. In addition to the use of accepted research instruments such as the Neck Disability Index (NDI), we would like to establish that this treatment is associated with physical relaxation, based on reduced skin conductance and reduced pulse. Furthermore, it is our objective to use sEMG to show that the treatment induces muscle relaxation during neck mobilization and reduced muscle fatigue after mobilization.

#### **MATERIALS AND METHODS**

We conducted a pilot, open, clinical trial from July to September 2009, in which patients with chronic NP were treated for 6 weeks at the physical therapy department, Bnai Zion Medical Center, Haifa, Israel. The primary endpoint was safety of computerized mobilization. The secondary endpoint was short-term efficacy based on the NDI.

## **Participants**

Twelve patients were recruited. Two patients dropped out after the first week, for reasons not related to the trial. Ten patients (8 women, 2 men) with a mean age of 50.5 ( $\pm$  13.5) years completed the trial. Participants were eligible for inclusion if they were 18 to 65 years old and had NP of at least 6 months duration, which was attributed to whiplash injury, facet joint disorder, muscle sprain, or NP associated with myofascial trigger points, according to the International Headache Society classification.<sup>2</sup>

Participants were excluded if they had evidence of myelopathy or radiculopathy on the basis of physical examination, cervical spine computerized tomography/magnetic resonance imaging, and electromyography (EMG) of the upper-extremity muscles. They were also excluded if they had cerebrovascular disease, significant osteoporosis, or an underlying malignant disease. Participants provided informed written consent. Ethical approval was given by the Israeli Ministry of Health Medical Research Ethics Committee (ref. number HT-4480, approved on October 7, 2008).

#### **Investigational Instruments**

Pain was reported using numerical rating scale (NRS). Overall disability was also assessed, using a 0 to 10 NRS, where 0 denoted no disability and 10 denoted complete inability to function. Pain and overall disability were reported biweekly for 9 weeks. Reports were made a week before the beginning of the treatment, during the treatment (6 wk), and 2 weeks after trial completion.

NDI is a valid and reliable measure of pain and disability due to NP<sup>23</sup> and served as the main questionnaire to evaluate efficacy. The Hebrew version of the 36-item Shortform Health Survey (SF-36) was used as a survey of the patient's health perception.  $^{24}$ 

# Pressure Pain Thresholds (PPT)

A hand-held pressure algometer Wagner FPX-25 (Greenwich, CT) with a probe size of 1 cm<sup>2</sup> and application

rate of 0.2 kg/s was used to measure PPTs. Triplicate measures were taken bilaterally at the following muscles: mid-trapezius, levator scapulae insertion at the superior-medial border of the scapula, and over the splenius capitis posterior to the mastoid process. Participants were asked to report when the sensation changed from pressure to pressure and pain.

## CROM

CROM was measured with the CROM device CROM Basic (Lindstrom, MN), a reliable and valid instrument for the measurement of CROM.<sup>25</sup> Duplicate measurements were obtained for each movement as the patient was seated comfortably.

# **EMG Recordings**

Bipolar sEMG signals were detected from the midtrapezius muscles bilaterally with pairs of electrodes Flex-Comp Infiniti (Montreal, QC, Canada). The electrodes were positioned over the trapezius muscles at the midpoint of the line between C7 and the Acromion after skin preparation. The signals were amplified and digitalized using sEMG sensors FlexComp Infiniti, with a bandwidth of 10 to 500 Hz, sampled at 2048 Hz. Signals were analyzed using customized software BioGraph Infiniti. Artifacts were rejected, the raw EMG signal rectified, and the root mean square of the filtered signal chosen for analysis. Two separate recordings were taken: (1) Baseline "resting" EMG signals were recorded continuously during the 20 minutes of treatment. The initial 2 minutes were compared with the last 2 minutes of treatment in terms of the root mean square of the signal both before and after internal mean normalization of the data. A comparison of the data from the first, second, fourth, and sixth week was performed for each patient. A comparison was also made for the total of 40 recordings obtained from all the participants comparing the initial 2 minutes of mobilization with the last 2 minutes; (2) A 1minute maximal contraction of the Trapezius was performed before and after the completion of the trial. The patients were instructed to shrug their shoulders with maximal force. They were verbally encouraged to maintain maximal force during contraction. The mean of the root mean square EMG signal over the entire period of time and the mean frequency were obtained. Heart rate was recorded with the electrocardiography Flex sensor FlexComp Infiniti and the data were amplified and digitalized using BioGraph Infiniti.

Skin conductance (SC) was recorded with SC Flex electrodes FlexComp Infiniti attached to the index and ring fingers of the left hand. The data were recorded continuously during the treatment and measured in Microsiemens (µS) units. The typical signal measured was at the range of 0.1 to  $3.5 \mu S$ .

NDI, SF-36, EMG, electrocardiography, SC, and PPT were recorded in the first, fourth, and sixth weeks of treatment. NDI and pain NRS were repeated 2 weeks after the completion of the study.

Computerized mobilization was performed using the Occiflex device (Headway Ltd. Misgav Venture Accelerator, Israel). This device is capable of a combined 3-dimensional mobilization of the head and neck with 6 degrees of freedom (Fig. 1). The device is attached to a cushioned cradle, which provides support to the cervical lordosis. The head is not restrained and the patient can sit up at any time. The device allows the mobilization of the neck as close as possible to the physiological axis at the coronal, sagittal, and horizontal planes.

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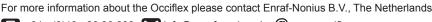






FIGURE 1. A, The Occiflex device separated from the treatment table; B, patient on the treatment table, with her head supported by the cradle.

# **Therapeutic Procedure**

The Occiflex device was attached to a treatment table. The patient lay supine in a quiet room. The upper part of the body from below the lower margin of the scapula was raised by 15 degrees; yet, the occiput was at the same level as that of the C7 posterior spinal process and so the initial neck angle at the sagittal plane was 0 degree. The knees were bent and supported by a cylindrical cushion to provide a comfortable body posture. The treatment lasted for 20 minutes and constituted continuous mobilization in the sagittal plane. The initial mobilization started with a range of 0 to 20 degrees, limited to the sagittal plane. The physical therapist could increase the maximal flexion angle by 5 degrees every week to a maximal range of 0 to 40 degrees according to the patient's response. The angular velocity allowed was 0.5 to 2 degrees/s. The patient held a safety brake that, when activated, led to an immediate cessation of treatment. The therapeutic procedure was performed biweekly for 6 weeks.

Statistical analysis was performed with multiple comparisons of data using repeated measures of analysis of variance and paired-sample t tests, with a level of significance of  $P \le 0.05$ . The Bonferroni correction method was applied whenever multiple comparisons were made.

# **RESULTS**

Ten patients completed the trial. Table 1 specifies the clinical relevant data. The average baseline pain score among all participants was  $6 \pm 1.6$  (0 to 10 scale). The median duration of chronic NP before screening was 6.5

# Primary Endpoint—Safety

# **Adverse Effects**

No serious adverse effects were reported. There were 11 reported adverse effects in 120 therapeutic sessions (9%). All of the adverse effects were mild and transient. Six of the 11

TABLE 1. Baseline Clinical Features of the Patients in the Study

Patient Sex/Age	Diagnosis	Duration of Pain Syndrome (y)	Pain NRS (1-10) on Admission	Associated Headache
F/55	After whiplash	6	3	Cervicogenic
F/47	Idiopatĥic	10	7	ТТЙ
F/58	After whiplash	1.5	5	TTH
F/35	Myofascial (FMS)	1	7.5	TTH
M/24	Myofascial	5	7	Cervicogenic
F/47	Myofascial	7	7.5	TTĤ
M/64	Facet joint disorder	0.6	5	No headache
F/54	Myofascial (FMS)	20	6	TTH
F/64	After whiplash, discopathy (no radiculopathy)	15	8	TTH
F/57	Myofascial	41	4	TTH and migraine

Cervicogenic indicates cervicogenic headache; FMS, fibromyalgia; NRS, Numerical Rating Scale; TTH, tension-type headache.

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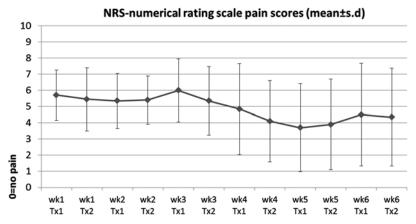


FIGURE 2. Numerical Rating Scale (NRS) pain score (mean ± SD) among 10 subjects with chronic neck pain during 6 weeks of Occiflex therapy. Tx indicates treatment; wk, week of treatment.

adverse effects were thought to be related to the treatment, including pressure and discomfort of the auricles (1 patient), paresthesia of the neck (1), discomfort in the neck area (2), new-onset mild headache (1), and right-hand pain (1).

Overall, 6 patients reported marked improvement, 2 patients reported some improvement, and 2 patients did not improve. Six of 9 patients with concomitant headache reported that their headache subsided 2 weeks after completion of treatment.

# Secondary Endpoints—Efficacy

#### Pain Score

Data were collected before treatment biweekly for 6 weeks of treatment. We compared the reports obtained during the first half of the treatment (weeks 1 to 3) with those obtained during the second half of treatment (weeks 4 to 6; Fig. 2). The results indicate that pain significantly decreased by an average of 2 NRS points (t(9))2.518, P < 0.05).

#### **Overall Disability**

Overall disability was assessed with a 0 to 10 NRS. It showed a significant improvement of 2 NRS points as early as the third week (P = 0.034).

#### **CROM**

An improvement in the CROM was realized in the fourth week of treatment (Fig. 3). A comparison of the sum of the average 6 movements in the first versus the sixth week was significant (from 301.3  $\pm$  13.7 degrees to 336.7  $\pm$  9.7 degrees; P = 0.034). The most notable changes occurred in the neck extension movement, which changed from  $47.8 \pm 16$  degrees (first week) to  $59.3 \pm 10$  degrees (sixth week; P = 0.049) and rotation to the left side, which changed from 59.8  $\pm$  6.1 degrees (first week) to 68.3  $\pm$  9.1 degrees (sixth week; P = 0.037). However, applying the Bonferroni correction method requires a significance level of 0.008 (0.05/6), which was not obtained for the 6 separated movements. Thus, none of the changes observed in the separated movements are statistically significant.

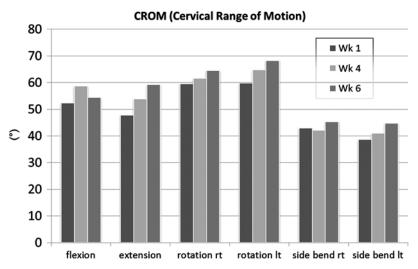


FIGURE 3. Histogram of the 6 different movements of the cervical spine. Values averaged for the 10 patients in degrees of motion.

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#### Algometry

A comparison in time of the average sum of PPT, obtained from the trapezius, levator scapulae, and splenius capitis muscles bilaterally, was made. PPT increased from the first week (M =  $2.97 \pm 0.7 \, kg/cm^2$ ) to the sixth week of treatment (M =  $3.5 \pm 0.71 \, kg/cm^2$ ). This increase was found to be insignificant (t(9) = 2.03, P = 0.073).

### **SF-36**

We found that 6 of 8 subscales in this questionnaire showed a nonsignificant trend of improvement during the treatment (reported current health, limits in daily activities, emotional limitations, social activities, body pain, and interference with normal work).

### NDI

A statistical t test revealed that a significant improvement was reached at the fourth week of treatment  $(t(9) = 2.756, P \le 0.05)$ ; improved significance was noted in the sixth week (t(9) = 3.339, P < 0.01) and remained significant 2 weeks after study completion (t(9) = 2.279,P < 0.05). A continued improvement was noted in 4 of 10 NDI subscales, including the headache subscale (Fig. 4). The NDI headache subscale dropped from  $3.8 \pm 1.6$  in the first week to  $2.8 \pm 1.68$  in the fourth week. It further decreased to  $2.5 \pm 1.35$  2 weeks after the completion of the study (P < 0.02). However, because 10 separate NDI subscale comparisons were made, the level of significance, according to the Bonferroni correction method, for each NDI subscale should be 0.005, which was not attained.

# Measures of Relaxation

Treatment induced a state of relaxation in all participants on the basis of the subject's report and physiological measures: heart rate dropped by  $8.4 \pm 7$  beats/s in the first week and by  $4.8 \pm 4.1$  beats/s in the sixth week. SC decreased by an average of  $0.56 \pm 0.4 \,\mu\text{S}$  during the first treatment and  $0.68 \pm 0.3 \,\mu\text{S}$  during the 11th treatment.

#### **EMG**

Baseline sEMG of the trapezius muscles during mobilization showed a nonsignificant decreased root mean square of the voltage between the initial 2 minutes and the last 2 minutes (3  $\pm$  1  $\mu$ V, average of 40 recordings).

Maximal activation of the trapezius muscles for 1 minute performed at the beginning of the trial and after the last treatment session showed a nonsignificant increased average root mean square of the voltage. The mean frequency of the EMG signal (right and left, analyzed over the entire 1 minute) was  $67 \pm 10.5$  Hz before treatment and  $72.5 \pm 9.7 \,\text{Hz}$  after treatment (P < 0.002).

#### DISCUSSION

This pilot proof-of-concept open trial was intended to find out whether computerized, precise neck mobilization, performed biweekly for 6 weeks, as a possible therapy for chronic NP is safe. Our observations support the safety of this intervention when the mobilization is confined to the sagittal plane, the angular velocity < 2 degrees/s and the CROM is < 40 degrees. Minor side effects related to the treatment appeared in only 6 of 120 sessions.

We recruited patients with treatment-resistant chronic NP. Significant improvement was noted in 8 patients as early as the third week. Several measures indicate that the therapy was efficacious despite the small sample size. Pain scores and overall disability reduced by 2 NRS points. NDI showed marked improvement, which remained significant 2 weeks after the completion of the study. Several physiological measures support the improvement reflected in the various self-report measures. The total CROM improved significantly during the trial. Yet, the separate change of the range of each movement was not significant. Nevertheless, of note is the fact that the change appeared in the horizontal and coronal plane, where mobilization was not performed. This could be because of central motor reorganization as pain signals from the periphery decrease<sup>26</sup> or could stem from zygapophysial joint mobilization or splenius capitis muscle stretching (mobilization in the

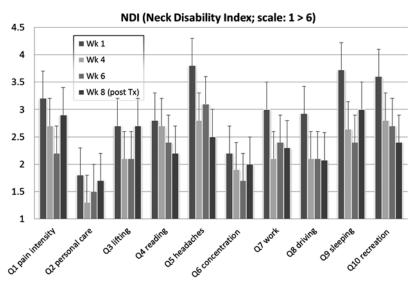
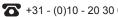
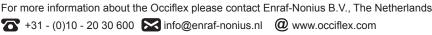


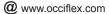
FIGURE 4. Histogram of the different neck disability index (NDI) questionnaire subscales (mean+SD). For this figure the subscale results are not multiplied. Q indicates question number; Wk, week of treatment.

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sagittal plane would stretch this muscle, which could antagonize rotation).<sup>27</sup>

Algometry showed an increase in the average sum of PPT of about 0.5 kg/cm<sup>2</sup>. This change was insignificant (P = 0.073) but it was observed in all muscular locations tested and suggests that our intervention could potentially have an effect on central sensitization.<sup>13</sup>

Nine of the 10 patients in our study reported headache as part of their baseline symptoms. The present study showed a consistent reduction of headache severity reflected by the NDI headache subscale. Two of the 9 patients had clinical features suggestive of cervicogenic headache. This type of unilateral cephalgia is related to neck pathology by definition<sup>20</sup>; it is associated with muscle dysfunction and limitation of CROM particularly in the sagittal plane 10 and it responds to manual therapy.<sup>28</sup>

Seven patients in our study had NP and concomitant tension-type headache (TTH). TTH and NP have several common features. Central to both conditions is muscle dysfunction, the emergence of trigger points, reduced PPT over both cephalic and extracephalic locations, limited CROM, and generalized neck and shoulder muscular hyperalgesia.<sup>2</sup> Some of these changes are associated with structural abnormalities in extensor neck muscles seen in magnetic resonance imaging.35,36 The relation between headache and NP is probably bidirectional. TTH is not only associated with neck muscle dysfunction but chronic NP is associated with reduced PPT in the trigeminal area.<sup>37</sup> Research in recent years showed that physical therapy is an effective therapy for some patient groups with TTH<sup>30,38</sup> and that several predictors of response to treatment can be characterized.3

What are the possible mechanisms underlying the therapeutic effect of neck mobilization in the sagittal plane? Chronic NP is associated with reduced deep cervical flexor muscle activity, increased activity of the superficial cervical flexor muscles, and lack of flexion induced extensor muscle relaxation. <sup>11,40</sup> This altered pattern of muscle activation leads to forward head posture and forward neck tilting.<sup>41</sup> Abnormal neck posture can be further maintained in patients with chronic NP because of disrupted head and neck position sense. 42 Forward neck tilting increases the head gravity lever with an increase in the extensor muscles' force, which is required to stabilize the head.<sup>27</sup> The increased load of several extensor muscle groups sets the ground for a state of muscle fatigue, muscle hyperalgesia, and muscular trigger points. <sup>9,12,13</sup> Computerized mobilization provides an extremely slow, precise, and consistent mobilization, which could circumvent the patient's fear of neck movement. Continuous lengthening of the extensor neck muscles performed in a precise and slow manner for a prolonged period of time could change the status quo, reverse the constant contraction, reduce peripheral sensitization, reduce the number of trigger points, and increase mechanical PPT. Stretching when applied to a previously fatigued muscle of chronic neck patients further depresses the maximum force-generating capacity of these muscles and reduces muscle spindle-evoked reflexes.<sup>43-45</sup>

It is plausible that by reducing the magnitude and threshold of spindle muscle-evoked reflexes the activation of extensor neck muscles in response to passive lengthening would be reduced. Indeed, such changes would modify neural control and lead to an altered state of balance between cervical muscles.

Several reports show that even 1 session of manual therapy that includes muscle stretching or mobilization could increase pain thresholds and change motor behavior

at a distance from the stretched muscle. 45 Sterling et al15 showed the immediate effect of spinal manual therapy on the thresholds and pain ratings of the nociceptive flexion reflex in whiplash injury patients. Thus, at a basic physiological level, stretching and mobilization modify spinal hypersensitivity in patients with chronic pain and also in healthy people. However, the exact mechanism of this effect is not known. Sterling et al<sup>15</sup> and Vicenzino et al<sup>16</sup> found that manual treatment is associated with sympathetic excitation; Sterling ascribed the effects of the treatment to the activation of central mechanisms and the sympathetic discharge. In contradistinction, our preliminary trial shows different results. We observed indices of relaxation and reduced sympathetic activity, as evident by decreased skin conductance and reduced pulse. It is possible that manual techniques, utilized by several authors, are either painful or accentuate the patient's stress with concomitant sympathetic discharge as an epiphenomenon. Painful interventions can activate stress-induced analgesia or diffuse inhibitory noxious control mechanisms. 46,4

Our data showed only minimal reduction of the mean of the root mean square EMG signal over the entire treatment session and no consistent results when a comparison of the first week with the fourth and sixth weeks was performed. A comparison of the maximal contraction of the Trapezius muscle before the treatment session in the first week of the trial and after the completion of the trial showed that the mean frequency of the EMG signal increased significantly. This could suggest that stretching performed in the current trial reduced Trapezius muscle fatigue. 48,4

Our study has several limitations: (1) it is a pilot noncontrolled proof-of-concept trial; (2) neither the physical therapist nor the patients were blinded; (3) the number of patients recruited was small; (4) mobilization was limited to the sagittal plane, and the CROM was limited to 40 degrees; (5) the follow-up period was only 2 weeks.

Thus, our conclusions should be accepted with caution, but the results support previous studies in the area of mobilization and NP and give further impetus to continued research. Clearly, a larger controlled trial of computerized mobilization in a 3-dimensional space is warranted. This would allow us to better define the safety and efficacy of this novel approach.

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