Three-Dimensional Computerized Mobilization of the Cervical Spine for the Treatment of Chronic Neck Pain: A Pilot Study

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Abstract

Background. Manual therapies for chronic neck pain are imprecise, inconsistent, and brief due to therapist fatigue. A previous study showed that computerized mobilization of the cervical spine in the sagittal plane is a safe and potentially effective treatment of chronic neck pain.

Objective. To investigate the safety and efficacy of computerized mobilization of the cervical spine in a three-dimensional space for the treatment of chronic neck pain.

Design. Pilot, open trial.

Setting. Physical therapy outpatient department.

Participants. Nine patients with chronic neck pain.

Interventions. A computerized cradle capable of three-dimensional neck mobilizations was used. Treatment sessions lasted 20 minutes, biweekly, for six weeks.

Main Outcome Measures. Visual analog scale (VAS) for pain, cervical range of motion (CROM), neck disability index (NDI), joint position error (JPE), and muscle algometry.

Results. Comparing baseline at week one with week six (end of treatment), the VAS scores dropped by 2.9 points ($P < 0.01$). The six directions of movement studied by the CROM showed a combined increase of 11% ($P = 0.01$). The NDI decreased significantly from 16 to 10 ($P = 0.03$), and the JPE decreased significantly from 3.7° to 1.9° ($P = 0.047$). There was no change in the pressure pain threshold in any muscle tested. There were no significant adverse effects.

Conclusions. These preliminary results demonstrate that this novel, computerized, three-dimensional cervical mobilization device is probably safe. The data also suggest that this method is effective in alleviating neck pain and associated headache, and in increasing the CROM, although the sample size was small in this open trial.

Key Words. Neck Pain; Manual Therapy; Three-Dimensional Computerized Cervical Mobilization

Introduction

Chronic neck pain (NP) is the most prevalent pain syndrome after low back pain [1]. The etiology of NP is diverse. In many patients with chronic NP, the pathogenesis is uncertain [1,2].

The current solutions for NP are suboptimal, and their benefit is unclear [3,4]. Therefore, new research into the mechanism of NP syndromes and clinical trials evaluating

unexplored innovative therapeutic interventions are needed. In a previous trial, computerized mobilization of the cervical spine confined to the sagittal plane was shown to be safe and potentially effective [5]. The improvement observed in this trial was reflected in both objective physiological measures and reliable questionnaires.

Head and NP is associated with, and possibly caused by, substantial neck biomechanical abnormalities. These include reduced neck muscle endurance, contraction and shortening of the neck muscles (extensor, flexor, and side-bending muscles), reduced activation of the deep flexor muscles as evident on electromyography (EMG), reduced cervical range of motion (CROM), abnormal neck posture with forward neck position, disrupted head and neck position sense, and multiple active and latent trigger points [3–7]. The neck biomechanical abnormalities are associated with central sensitization as evidenced by reduced mechanical pain thresholds particularly in patients with whiplash injury [3,4]. Mobilization of the cervical spine and other manual therapy techniques can reverse central sensitization and change the pattern of cervical muscle activation [6,8]. Manual therapy applied to the cervical spine has been shown to elicit widespread hypoalgesia in both healthy volunteers and patient populations [7,9,10]. Several meta-analyses published on the effectiveness of manual therapy in chronic NP have shown promising yet conflicting results [11–13].

The researchers of this article believe that manual therapy interventions can result in a more efficacious outcome if several inherent disadvantages of these techniques can be overcome. These disadvantages include 1) inconsistency: therapists (and patients) 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 due to the therapist's fatigue (the head weighs about 7% of the body weight); 4) the angular and linear velocities and accelerations (with a change in course) are often too large, leading to vestibular activation or neck injury; and 5) utilization of high-velocity aggressive manipulation or mobilization leads 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 [14]. In order to eliminate the shortcomings of manual mobilization and to achieve superior results, while at the same time reduce the risk, a device capable of three-dimensional computerized neck mobilization has been investigated.

The purpose of the current trial is to provide evidence for the safety of the three-dimensional continuous computerized mobilizations and to gather preliminary information about the possible efficacy of this method in the treatment of patients with chronic NP.

Materials and Methods

A pilot, open, clinical trial was conducted during February–May 2011 in which patients with chronic NP were treated for 6 weeks at the physical therapy department of Hillel Yaffe Center, Hadera, Israel. The primary outcome measure was the safety of the computerized cervical mobilization. The secondary outcome measure was short-term efficacy as determined by the neck disability index (NDI).

Participants

Ten patients were recruited. One patient had a whiplash injury during the trial. Therefore, his data were not included in the final analysis. Nine patients (seven women and two men) with a mean age of 50.5 (±11.1) years completed the trial. Participants were eligible for inclusion if they were 18–65 years old and had NP for at least 6 months in 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 [15].

Subjects were excluded if they had evidence of myelopathy or radiculopathy based on physical examination, cervical spine computerized tomography/magnetic resonance imaging, and 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. The Israeli Ministry of Health Medical Research Ethics Committee gave ethical approval. Patients were allowed to continue treatment with analgesic drugs taken prior to recruitment. However, neither an increased dose nor the use of an additional active treatment for NP was permitted during the active treatment phase of the trial.

Investigational Instruments

NDI is a valid and reliable measure of pain and disability due to NP [16], and therefore served as the main questionnaire to evaluate efficacy. Pain was measured using the 10-cm visual analog scale (VAS), as part of the NDI questionnaire.

Pressure pain thresholds (PPT) were measured with a handheld pressure algometer, Wagner FPX (Greenwich, CT, USA), which had a probe size of 1 cm [2] and an application rate of 0.2 kg/s. The average of triplicate measures was 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 was measured with the CROM device, CROM Basic (Performance Attainment Associates, Lindstrom, MN, USA), a reliable and valid instrument for the measurement of CROM [17]. Duplicate measurements were performed for each movement (flexion, extension, right and left: rotation and lateral bending) as the patient was seated comfortably. The data were expressed as a percentile fraction of the normal value of CROM for healthy subjects

according to a specific movement, age, and gender [18], where 0% means normal values.

NDI, pain VAS, and PPT were recorded on the first, fourth, and sixth weeks of treatment. NDI and pain VAS were repeated 2 weeks after the completion of the study.

Joint position error (JPE) was measured with the CROM device in the first week and in the sixth week. The patient was seated comfortably in a dark room. He was blind-folded. The CROM device was mounted on the head. The neck was slowly flexed from 0° to 35° along the sagittal plane, left in this position for 3 seconds, and then brought back to 0°. The patient was asked to repeat the movement and reach the same final position. The same experiment was repeated with 35° extension and 25° lateral bending to the left and right in the coronal plane. Duplicate measures were taken for each movement. The JPE was calculated as the difference between the examiners guided final neck angle and the patient's final neck angle as measured by the CROM device.

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

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

Figure 1 Sketch of the Occiflex device. Patient is lying on treatment table (left) and therapist standing beside.

raised by 15°, while the occiput was at the same level as the C_7 posterior spinal process. This ensured that the initial neck angle at the sagittal plane was 0°. The knees were bent and supported by a cylindrical cushion to provide a comfortable body posture. The treatment lasted for 20 minutes and provided continuous mobilization in the sagittal, coronal, and horizontal planes. The initial mobilization started with a range of 0–20° in the sagittal plane, 0–10° in the horizontal plane, and 0–5° in the coronal plane. Mobilization comprised a sequence of movements that started with left coronal and horizontal mobilization, followed by pure sagittal mobilization, and ended with right horizontal and coronal mobilization. The physical therapist could increase or decrease the range of motion at each of the planes by 2–5° every treatment session. The physical therapist had to increase the range of movement of both the horizontal and coronal planes together, and keep the former twice as large as the latter.

The maximal range of movement allowed in the trial was 0–40° in the sagittal plane, 0–20° in the horizontal plane, and 0–10° in the coronal plane. The angular velocity allowed was 0.5–2°/second. Changes in the angular velocity and the range of movement were based on the patient's response to treatment and the physical therapist's clinical judgments. 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.

Adverse Effects

Any negative unusual experience or problem, during or after the treatment session, was considered an adverse effect. All the adverse effects were meticulously recorded. Both the physical therapist and the principal investigator interviewed the patient. A structured interview form was used to record the severity, duration, and possible relationship of the adverse effect to the therapy. Clinical judgment was used to determine whether the NP or headache was caused or aggravated by the treatment. Adverse effects were rated as mild, moderate, or severe. The following definitions were used: *Mild* adverse effects require minimal therapeutic intervention. *Moderate* adverse effects require active treatment or further testing or evaluation to assess the extent of non-serious outcome. *Severe* adverse effects include any serious outcomes, resulting in life- or organ-threatening situation or death, and significant or permanent disability, requiring intervention to prevent permanent impairment or damage, or hospitalization.

Statistical Analysis

Significant changes over time were tested with regard to several outcome measures, and for various time points. Paired *t* tests and the Wilcoxon signed rank test were used to assess changes from baseline to one time point. The paired *t* test was applied for continuous end points, whereas the Wilcoxon signed rank test was used for discrete end points, (such as on a scale one, two, three . . . ten).

Table 1 Clinical data of the patients who completed the trial

	Sex/Age	Diagnosis of Neck Pain Syndrome	Neck Pain Duration (Years)	Pain (VAS) Week 1/6	Headache
1	M/30	Whiplash injury	2	8/4	TTH, cervicogenic
2	F/44	Whiplash injury	24	3/1	No headache
3	F/57	Idiopathic neck pain	20	6/3	TTH
4	F/48	Myofascial pain	4.5	5/6	Cervicogenic
5	F/53	Idiopathic neck pain	4	6/2	Migraine and TTH
6	F/40	Myofascial pain	0.7	5/0	No headache
7	M/64	Idiopathic neck pain	1	4/4	TTH
8	F/56	Myofascial pain	15	4/1	Migraine
9	F/63	Myofascial pain, Facet joint disorder	10	8/1	Cervicogenic

TTH = tension type headache; VAS = visual analog scale.

Mixed models were applied when the follow-up included more than two time points. These models are suitable for repeated measures as they enable to account for the correlation between observations within subject.

In all cases, when the *F* test indicated that at least one change occurred at some time point, pairwise comparisons were made to detect when these changes happened. The method of Tukey–Kramer was used to obtain the adjusted *P* value. All tests were two-sided.

Box-plots were used for the detection of outliers. In order to assess the influence of outliers, analyses were done with and without the outliers. In all cases, the main conclusions were unchanged, and only minor *P* value differences were obtained with and without the outliers.

F tests were performed on pairs of parameters: VAS of pain, CROM, JPE, and the PPT between the first, fourth, and sixth week. For the NDI and pain VAS, an additional comparison between the first and eighth week was performed. The level of significance chosen was 0.05. SAS software (SAS Institute Inc., Cary, NC, USA) was used for the analysis.

Results

Nine patients with chronic resistant NP completed the trial. Table 1 specifies the clinical relevant data. The average baseline pain was 5.4 (0–10 cm scale). The median duration of chronic NP prior to screening was 5 years.

Primary Outcome Measure—Safety Adverse Effects (Table 2)

No serious adverse effects were reported. There were 18 reported adverse effects in 120 therapeutic sessions (15%), 12 of them were considered to be treatment-related (10%). All of the adverse effects were mild and transient. Headache was the most frequent side effect,

followed by dizziness and scapular pain. Headache was considered to be treatment-related when it was reported during or shortly after a treatment session and when it had different characteristics compared with the patient's usual headache. One patient had a benign positional vertigo episode a couple of hours after the treatment. She was successfully treated with the Epley maneuver.

Secondary Outcome Measures—Efficacy

Six patients reported marked improvement; two patients reported some improvement and one patient did not improve. Five out of seven patients with concomitant headache reported that their headache improved during the trial and at 2 weeks after treatment completion.

Table 2 Side effects

No.	Sex/Age	Side Effect*	Mild/ Moderate	Related to Tx
1	M/30	Headache(1),	Mild	Yes
		scapular pain (1)	Mild	Yes
2	F/44	Nausea (1)	Mild	Yes
3	F/57	Neck pain (1)	Mild	No
		Dizziness (2)	Mild	Yes
		Vertigo (BPV) (1)	Moderate	Yes
4	F/48	Left scapular pain (1)	Mild	Yes
		Left ear pain (1)	Mild	Yes
		Neck pain (1)	Mild	No
5	F/53	No side effects		
6	F/40	Headache (1)	Mild	No
7	M/64	Headache (2)	Mild	Yes
		Headache (1)	Mild	No
8	F/56	Headache (1)	Mild	No
		Dizziness (2)	Mild	Yes
9	F/63	No side effects		

* number in brackets – number of episodes.
BPV = benign positional vertigo.

VAS (0 > 10, from NDI)

Statistical significance
(wk 1 vs wk 4, 6 and 8):
$P>0.0005$
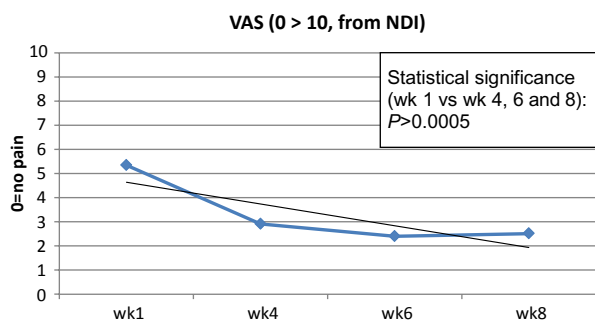
Figure 2 Average pain visual analog scale (VAS). Black straight line represents regression line. NDI = neck disability index.

Pain VAS Score (Figure 2)

There was a significant reduction of pain along time, F (3, 24) = 5.76 ($P = 0.0041$). The significant estimated mean reductions were from baseline (week 1, average VAS = 5.4) and over the following 4, 6, and 8 weeks: 2.43 (0.81*, $P = 0.03$)**; 2.94 (0.81, $P = 0.007$); and 2.83 (0.81. $P = 0.01$), respectively. The single asterisk refers to the number in bracket that denotes standard error, while the two asterisks mean that when multiple comparisons were used, the reported P values are adjusted P values (using the Tukey–Kramer's method).

CROM (Figure 3)

There was a significant increase of CROM along time, F (2, 16) = 6.04 ($P = 0.0111$). A marginal significant increase in CROM was observed at week four of treatment compared with baseline (–5%) to +3% (0.03, $P = 0.07$). This trend increased on the sixth week to +6% (0.03, $P = 0.01$).

The most notable changes occurred in the left lateral flexion movement F (2, 16) = 3.98 ($P = 0.0396$), which increased from 8% above the normal range in week one to 25% at week six ($P = 0.05$).

Using Box-plots, we detected one outlier in the right lateral flexion results. After performing the mixed procedure without the outlier, there is a significant CROM increase, $F(2, 15) = 3.59$ ($P = 0.0531$). Thus, right lateral flexion increased from a baseline of –5% to +2% in the fourth week of treatment ($P = 0.047$).

NDI (Figure 4)

This comprised 10 questions with a total score from 0 to 50. There was a significant decrease in NDI score along time, F (3, 24) = 4.09 ($P = 0.0177$).
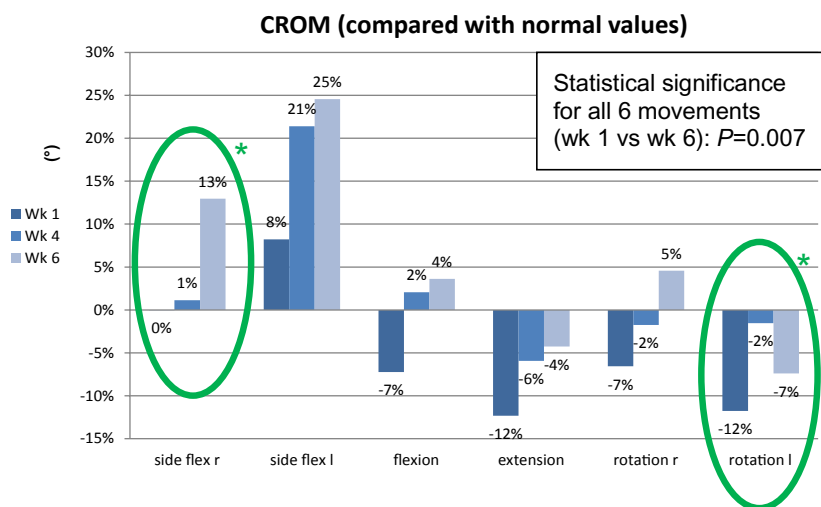
The significant estimated mean reductions were from baseline (week 1, average = 15.8) and at weeks four and six of treatment, 5.8 (0.19, $P = 0.03$) and 5.8 (0.19, $P = 0.029$), respectively.

Although there was not a significant difference between the sixth and eighth weeks, the change from baseline to week six was significant. The noted reduction from baseline to week eight was found to be marginally significant, 4.7 (0.19, $P = 0.098$).

The multiple NDI separate questions except for one (lifting) showed an improvement from the beginning to the end of the trial. However, a statistically significant reduction was noted for driving, comparing baseline (18.9) to weeks four, six, and eight (8.9, $P = 0.03$; 8.9, $P = 0.078$; and 7.8, $P = 0.03$, respectively), and the sleeping subscale (baseline = 30; 15, $P = 0.03$; 11.3, $P = 0.03$; and 13.8, $P = 0.03$).

JPE

A comparison of the JPE was made between the first and sixth weeks (Figure 5). The overall reduction of JPE, for all four movements, was significant, showing improvement from baseline (3.7°) to 1.9° ($P = 0.047$). The most notable reduction observed was for the right lateral bending, with a drop from baseline (4.3°) to 0.6° ($P = 0.016$).

CROM (compared with normal values)

Statistical significance
for all 6 movements
(wk 1 vs wk 6): P=0.007

Figure 3 Cervical range of motion (CROM). *These parameters are statistically significant ($P < 0.05$).
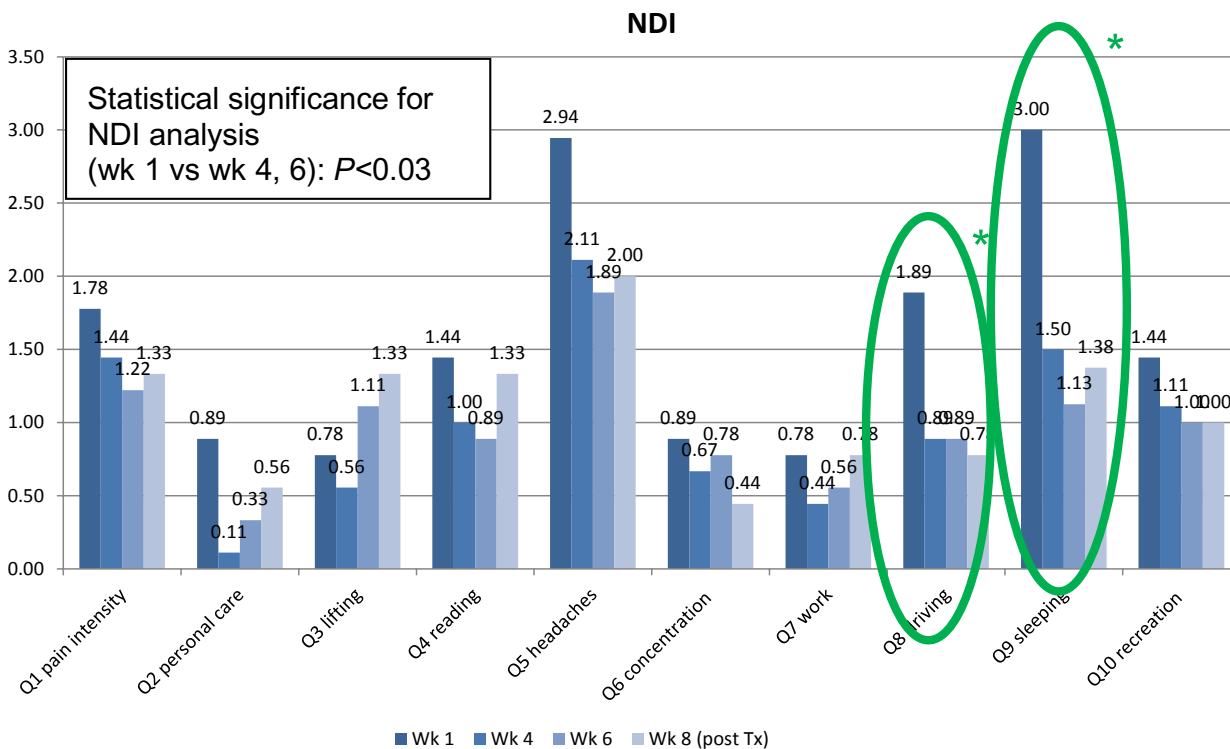
**Figure 4** Neck disability index (NDI). *These parameters are statistically significant ($P < 0.05$).

Algometry

A comparison of the average sum of the PPT was performed, obtained from the trapezius, levator scapulae, and splenius capitis muscles bilaterally. There was no significant change in any point of time.

Discussion

This proof of concept pilot open trial was intended to find out whether three-dimensional computerized, precise neck mobilization is safe as a possible therapy for chronic NP when performed biweekly for 6 weeks. The preliminary observations support the safety of this intervention. Minor side effects related to the treatment appeared in 12 of 120 sessions. The most common side effects were headache and dizziness. Headache may have been the result of mild pressure on the scalp-sensitive areas by the cradle, or else referred as head pain secondary to mobilization of the neck. The headache was mild, transient, and occurred in four patients. Dizziness occurred in two patients. In one patient, a true vertigo episode occurred probably due to
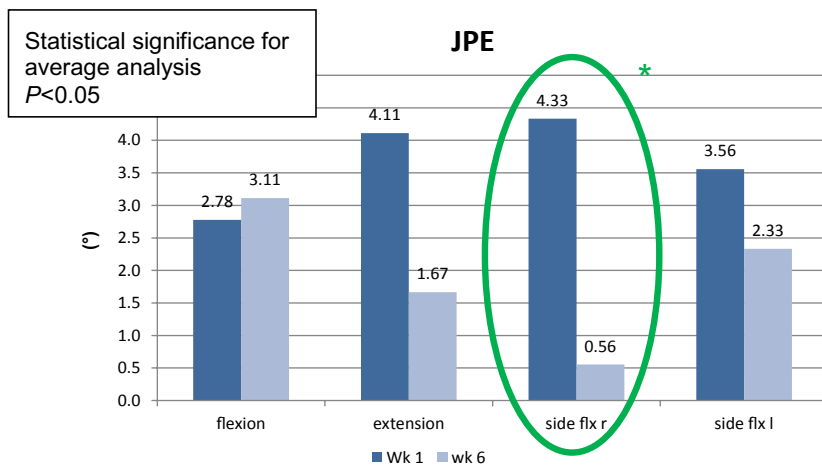
Figure 5 Joint position error (JPE) (absolute values). *These parameters are statistically significant ($P < 0.05$).

benign positional vertigo. Dizziness was more common in this trial, as compared with a previous trial [5], as three-dimensional space mobilizations can more effectively trigger vestibular semicircular canal activation. As a result, it can be suggested that avoiding excessive pressure on the scalp by the cradle, excluding patients with dizziness and vertigo, and limiting the angular velocities applied by the Occiflex device could reduce these minor side effects.

Patients were recruited with treatment-resistant chronic NP. Significant improvement was noted in six patients and mild improvement was noted in two patients as early as the fourth week. Although the results are preliminary, several measures indicate that this therapeutic intervention was effective. The pain score dropped by 2.9 VAS points. CROM improved significantly during the trial. This consistent CROM improvement was noted for all six directions of movements. The average improvement of any one of the six examined directions of movement was 11%. NDI showed marked improvement as early as the fourth week. Several physiological measures support the improvement reflected in the VAS pain reports and the NDI.

JPE was significantly smaller at the end of the trial. JPE reflects the accuracy of the head and neck position sense. Position sense coupled with vestibular information allows an accurate activation of neck muscle and maintenance of optimal head posture [19]. Disrupted sensory motor integration and a larger JPE were found in patients with upper NP as opposed to lower NP [20]. Increased JPE is associated with inaccurate overactivation of antagonistic and synergistic neck muscles [21]. Thus, the reduction of JPE seen in these patients could lead to better sensory-motor integration, improved head posture, and a different status quo of neck muscles. Indeed, in a previous trial, results suggested that computerized mobilization in the sagittal plane reduced trapezius muscle fatigue [5].

Seven of the nine patients in this current study reported headache as part of their baseline symptoms. A consistent reduction of headache severity reflected in the NDI headache subscale was observed. This fact suggests shared pathophysiological mechanisms for both headache and NP.

What are the biomechanical abnormalities, observed in patients with chronic NP, that are relevant to the therapeutic effect of computerized neck mobilization? 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 [22,23]. This altered pattern of muscle activation leads to forward head posture and forward neck tilting [24]. Abnormal neck posture can be further maintained in patients with chronic NP due to disrupted head and neck position sense [25]. Forward neck tilting increases the head gravity lever with an increase of the extensor muscles' force, required to stabilize the head [26]. Different mechanisms might explain the effects of mobilization: Stretching when applied to overcontracted fatigued muscle, of chronic neck patients, depresses the maximum force-generating capacity of these muscles and reduces muscle spindle-evoked reflexes [27–29]. Thus, neck mobilization possibly increases the activation of the longus colli muscle and reduces the activation of the sternocleidomastoid muscle [30]. Consequently, a change in neck posture and reduced neck extensor muscle strain could evolve. Mobilization of chronic NP patients elicits pain which of its own accord could activate diffuse noxious inhibitory control supraspinal mechanisms that reduce pain [31]. In addition, computerized mobilization provides a slow, precise, and consistent mobilization that may well circumvent the patient's fear of neck movement. The above putative mechanisms underlying the effects of mobilization could change the neck biomechanical status quo, reduce the number of active and latent trigger points, and reduce referred neck and head pain [32]. This study has several limitations: 1) It is a non-controlled proof of concept pilot trial. 2) Neither the physical therapist nor the patients were blinded, thus there is a possibility of a significant placebo effect. 3) The number of patients recruited was small. 4) Mobilization was performed as a sequence of movements in space rather than a true combined natural neck movement with six degrees of freedom. 5) The follow-up period was only 2 weeks after the end of treatment. Therefore, these preliminary conclusions should be accepted with caution, but the results concur with previous studies of mobilization in the treatment of NP [11–13]. A larger controlled trial of computerized mobilization in a three-dimensional space is warranted to establish efficacy of this novel approach. This future trial should be performed with a natural combination of three-dimensional movements rather than a series of separate movements, tailored for the individual patient.

Acknowledgment

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