

Personalized, 3-Dimensional, Computerized Mobilization of the Cervical Spine for the Treatment of Chronic Neck Pain - A Pilot Study

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Abstract

Background: Previous studies have shown that computerized mobilization of the cervical spine (CMCS) is safe and potentially effective treatment for chronic neck pain (CNP).

Objective: The investigation of safety, clinical outcome, and changes of specific physiological parameters, in CNP patients, treated with individualized, 3-dimensional CMCS.

Participants: Nine patients with CNP.

Interventions: A cradle capable of CMCS was utilized. Each participant underwent individualized treatment sessions, lasting 20 min each, carried out biweekly over 6 weeks.

Main Outcome Measurements: Pain visual analog scale (VAS), Neck disability index (NDI), pressure pain thresholds (PPT), cervical range of motion (CROM), joint position error (JPE), forward neck tilt (FNT), and flexion relaxation ratio (FRR).

Results: Minor side effects encountered during the study. Comparing baseline measurements with measurements after treatment completion: VAS scores dropped by 2.3 points ($p=0.04$). NDI improved, but this improvement was not significant ($p=0.086$). CROM increased, on the average, by 11% but this increase was insignificant ($p=0.061$). JPE decreased from 2.88° to 1.14° ($p<0.01$). PPT increased from 1.27 kg/cm^2 to 2.44 kg/cm^2 ($p=0.043$). FNT insignificantly decreased from 20.36 cm to 19.02 cm ($p=0.104$). Left-sided FRR significantly increased ($p=0.017$).

Conclusions: This study provides preliminary evidence that suggest that personalized, 3-dimensional, CMCS is a safe treatment. This novel treatment may positively change cervical neuromuscular control, and the processing of proprioceptive and nociceptive information.

Keywords: Chronic neck pain; Magnetic resonance imaging; Computerized tomography; Cervical spine

Abbreviations: CROM: Cervical Range of Motion; CMCS: Computerized Mobilization of the Cervical Spine; CT: Computerized Tomography; EMG: Electromyography; FNT: Forward Neck Tilt; FRR: Flexion Relaxation Ratio; JPE: Joint Position Error; MRI: Magnetic Resonance Imaging; NDI: Neck Disability Index; CNP: Chronic Neck Pain; PPT: Pressure Pain Threshold; TTH: Tension-Type Headache; VAS: Visual Analogue Scale (pain)

Introduction

Chronic neck pain (CNP) is the most prevalent pain syndrome after low back pain [1]. The pathogenesis of CNP is not yet fully understood [1,2]. Manual therapy is potentially a promising avenue for the management of CNP; yet, as several meta-analyses indicate, the efficacy of manual approaches has yet to be conclusively supported

[2-4]. In a previous pilot trial, we showed that computerized mobilization of the cervical spine confined to the sagittal plane is a safe and potentially effective treatment of CNP. Specifically, the treatment yielded improvements in objective physiological measures, as well as in patients' self-reports of their condition, as reflected in reliable questionnaires [5,6]. In a second pilot trial we showed that a 6-week treatment course of biweekly computerized mobilization with a sequence of movements in the sagittal, coronal and horizontal planes is followed by significant reduction of CNP, improvement in neck range of motion, and reduction in joint position error [7].

Whereas our first two trials employed limited neck mobilization in one or several consecutive planes, the purpose of the current trial is to apply natural, combined, mid-range movements (combined rotation and translation in the sagittal, coronal and horizontal planes). The intervention is personalized for the patient through a two-stage process: 1) the "teach" phase, which entails recording the course of movement of the patient's head and neck as the neck is mobilized by the physical therapist; and 2) the treatment phase, in which the

recording in the first phase is used as a template for a precise, continuous, computerized neck mobilization that maintains six degrees of freedom.

Several physiological parameters deviate from the normal range in patients with CNP. These parameters include reduced neck muscle endurance (as compared with that of healthy patients), over-contraction and shortening of the neck muscles associated with multiple active and latent trigger points, reduced activation of the deep flexor muscles, reduced cervical range of motion (CROM), abnormal forward neck posture, and disrupted head and neck position sense [6-9]. These abnormal physiological parameters, are associated with a state of central sensitization as reflected in low mechanical pain thresholds [9,10]. The aim of the current trial is to gather preliminary data, with respect to the effects of individualized, 3-dimensional, computerized neck mobilization, on several physiological parameters, that deviate from the normal range in CNP patients. It is also the goal of this trial to obtain preliminary safety data following this novel treatment.

Materials and Methods

We conducted an open pilot trial, in which patients with CNP were treated for 6 weeks at the physical therapy department of the Hillel Yaffe Medical Center, Hadera, Israel (Institutional review board approval: 0086-11-HYMC); Ethical approval was also granted by the Israeli Ministry of Health Medical Research Ethics Committee. The trial was registered in the NIH ClinicalTrials.gov database (ClinicalTrials.gov Identifier: NCT01518530)

Participants

We screened consecutive twenty three patients with CNP, who had been referred to the Hillel Yaffe medical center, by their primary physicians, and recruited ten patients (seven women, three men), with a mean age of 47 (\pm 11.1) years. One patient was lost to follow up subsequent to his initial screening. All recruited nine patients completed the trial. Participants were eligible for inclusion if they were 18-65 years of age and had been suffering, for at least 6 months, from CNP that was attributed to whiplash injury, facet joint disorder, muscle sprain, or from CNP associated with myofascial trigger points, according to the IASP classification of chronic pain [11].

Patients were excluded if they showed evidence of cervical myelopathy or radiculopathy, evaluated through physical examination, cervical spine CT/MRI (computerized tomography/magnetic resonance imaging), and electromyography (EMG) of the upper extremity muscles. We also excluded patients with cerebrovascular disease, significant osteoporosis, or underlying malignant disease. In addition to the patients with CNP we recruited ten healthy volunteers as a control group for the measurements of flexion relaxation ratio. Participants provided informed written consent.

Computerized mobilization

Computerized mobilization treatment was performed with the Occiflex device (Figure 1) [6,7]. This device was developed to optimize neck mobilization. It consists of an adjustable therapeutic bed and a cradle, capable of any movement in three-dimensional space with six degrees of freedom (Figure 1). The device can record any head-and-neck mobilization that the therapist performs on the patient. After a "teach" phase, in which the device records a series of individualized mobilizations for the patient, the device performs treatment

automatically, for 20 min, by carrying out multiple precise repetitions of the recorded mobilization, utilizing slower angular speed of up to 2°/s (treatment phase). During the treatment phase the patient's head is not restrained, and he or she can sit up at any time. The patient holds a safety brake that when activated leads to immediate cessation of treatment.

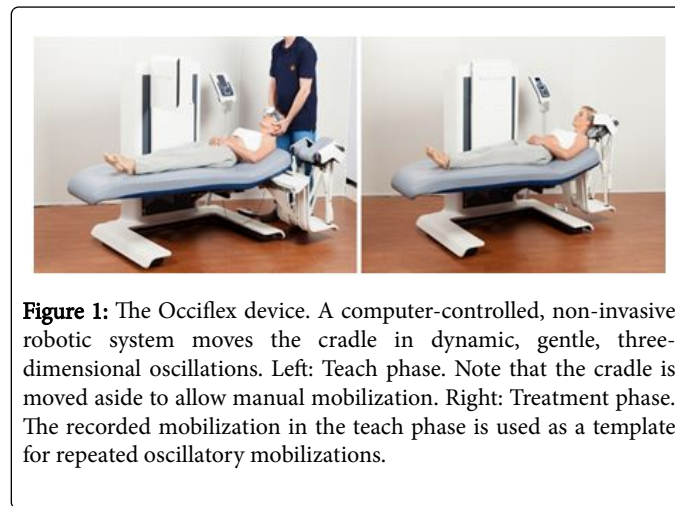


Figure 1: The Occiflex device. A computer-controlled, non-invasive robotic system moves the cradle in dynamic, gentle, three-dimensional oscillations. Left: Teach phase. Note that the cradle is moved aside to allow manual mobilization. Right: Treatment phase. The recorded mobilization in the teach phase is used as a template for repeated oscillatory mobilizations.

The mobilization used in this trial was a slow oscillatory osteokinematic, mid-range mobilization, avoiding the end of the available neck range of movement. The determination of the specific chosen course of movement was based on three principles: A) Stretching muscles that had active trigger points. B) Mobilization of facet joints if prior information indicated their involvement in the etiology of CNP. C) Extending limited neck range of movement following the baseline CROM examination. During the "teach" and treatment phases 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°, yet the occiput was at the same level as the C7 posterior spinal process, so 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 maximal range of movement allowed in the trial was 0°-80° in the sagittal plane, 0°-70° in the horizontal plane, and 0°-60° in the coronal plane. The angular velocity allowed was 0°-2°/s. Changes in the course and range of movement were based on the patient's response to treatment and the physical therapist's clinical judgment. Each patient underwent the therapeutic procedure once biweekly for 6 weeks.

Outcome measurements

We collected the following primary outcome measurements, by a blind observer, before, during and after the treatment course: pressure pain thresholds (PPT), cervical range of motion (CROM), joint position error (JPE), flexion relaxation ratio (FRR), and forward neck tilt (FNT). In addition, we recorded the neck disability index (NDI), pain visual analog score (VAS), and safety, as reflected in the occurrence of adverse effects. In what follows, measurements obtained at week 1 of treatment are referred to as "baseline" measurements; these measurements were taken before commencement of the treatment procedure. Other measurements taken during the course of treatment were collected immediately before the computerized mobilization procedure. Each patient underwent two follow-up examinations, carried out 2 and 6 weeks, respectively, after completion of the 6 weeks of treatment. The outcome measurements were collected

by a blind observer who was completely unaware of the timing of the measurement (i.e. the stage of the study for any individual patient). With respect to the flexion relation ratio (FRR), the observer did not know whether he examined a patient with CNP or a control group volunteer.

Adverse effects

Any negative unusual experience or problem, during or after the treatment session, was considered an adverse effect. All adverse effects were meticulously recorded. Each participant was interviewed both by the physical therapist who carried out the treatment and by the principal investigator. We used a structured interview form to record the severity, duration and possible relationship of the adverse effect to the therapy. Clinical judgment was used to determine whether CNP or headache was caused or aggravated by the treatment.

NDI

NDI is a valid and reliable questionnaire of pain and disability associated with CNP [12]. Disability measurements were obtained in weeks 1, 4 and 6 during the treatment phase, as well as in weeks 8 and 12 (the second and sixth weeks post-treatment).

VAS

Participants indicated their pain levels on a 10-cm Visual Analog Scale (VAS): 0=no pain; 10=the worst pain imaginable. VAS measurements were obtained in weeks 1, 4 and 6 during the treatment phase, as well as in weeks 8 and 12 (the second and sixth weeks post-treatment).

PPT

To measure PPT, we used a hand-held pressure algometer that has a digital force gauge (Wagner FPX[™]-25, Greenwich CT) [13], with a probe size of 1 cm². We utilized the device with an application rate of 0.2 kg/s. We calculated the averages of triplicate measurements; each measurement was taken bilaterally at the following muscles: mid-trapezius (midpoint of the line between the lateral part of the Acromion and the C7 posterior spinal process); levator scapulae at the superior-medial border of the scapula; and over the splenius capitis insertion, posterior to the mastoid process and below the skull lateral superior nuchal line. Participants were asked to report when the sensation changed from pressure to pressure and pain. PPT was measured at weeks 1, 4, and 6 of treatment.

CROM

CROM was measured using a CROM device that combines inclinometers and magnets (CROM Basic, Performance Attainment Associates, Lindstrom, MN) [14]; this instrument has been shown to be reliable and valid for the measurement of CROM [15]. Duplicate measurements were obtained and averaged for each of the following movements as the patient was seated comfortably: flexion, extension, right and left rotation, and right and left lateral bending.

The data were expressed as percentile fractions of normal measurement values for the corresponding movements in healthy subjects of the same age and gender as the participant [16] (a score of 0% corresponds to normal values for age and gender). CROM was measured at weeks 1, 4 and 6 of treatment.

JPE

JPE was measured with the CROM device. The patient was seated comfortably in a dark room and blindfolded. The CROM device was mounted on the patient's head. The examiner slowly flexed the patient's neck from 0° to 35° in the sagittal plane, left the neck in this posture for 3 s, and then brought it back to 0°. The patient was asked to repeat the movement and reach the same final posture. The JPE was calculated as the difference between the final neck angle obtained with the guidance of the examiner and the patient's final neck angle as measured by the CROM device. A similar procedure was used to evaluate 35° extension, 25° lateral bending to the left, and 25° lateral bending to the right in the coronal plane. Triplicate measurements were obtained and averaged for each movement. JPE was measured at weeks 1 and 6 of treatment.

FNT

FNT was measured with the CROM Deluxe head forward unit for postural measurements (CROM Basic, Performance Attainment Associates, Lindstrom, MN). The patient was instructed to assume and maintain his or her preferred upright position. The head forward arm was attached to the CROM mainframe, and the vertebra locator was held on the C7 vertebra. When the vial on the vertebra locator was level, the reading on the head forward arm was the number of centimeters between the bridge of the patient's nose and C7. FNT was measured at weeks 1 and 6 of treatment.

FRR

FRR is a measure of neuromuscular control. It reflects a reduction in activity of neck extensor muscles that occurs in full forward neck flexion as compared with extensor muscles increased activity during neck extension. In healthy control subjects the cervical extensor muscles exhibit a consistent and reproducible flexion-relaxation phenomenon. FRR is significantly lower in patients with CNP than in control subjects, suggesting that this measure may be a useful marker of altered neuromuscular function [17].

Procedure: FRR was measured using the following method: After carefully abrading the skin and applying an isopropyl alcohol swab, we applied pairs of electrodes (FlexComp Infinity, Thought Technology, Montreal, QC, Canada) to the right and left cervical extensor muscles with a center-to-center distance of 2 cm, aligned parallel to the direction of the muscle fibers of the semispinalis capitis. The electrode pairs were approximately 2 cm from the C4 posterior spinous process. Each participant was requested to sit upright in a straight-backed chair with lumbar and mid-thoracic support, but with no support to the upper thoracic and cervical regions. The participant was asked to bend his or her head forward with the aim of approximating the chin to the upper chest, and then to maintain this position until asked to return to the neutral position. The FRR procedure comprised three different phases of movement: flexion, relaxation, and re-extension. Each phase lasted 3 sec. A verbal recorded command was provided to signify each movement phase. Preliminary practice was carried out before actual data collection in order to train the participant on the proper speed of movement for each phase.

A total of three trials were performed at each testing session. Each patient underwent the FRR study on week 1 and on week 6 of treatment. An age-matched control group of ten volunteers who did not have CNP underwent the same experimental FRR study. Electromyography data analysis: Bipolar surface EMG (sEMG) signals were detected bilaterally from the mid-neck extensor muscles, with

pairs of electrodes. The signals were amplified and digitized using sEMG sensors (FlexComp Infiniti, Thought Technology) with a bandwidth of 10 to 500 Hz, sampled at 2048 Hz. Signals were analyzed using customized software (BioGraph Infiniti, Thought Technology). Artifacts were rejected, and the raw EMG signal was rectified. The root mean square of the filtered signal was used for analysis. Specifically, we used the BioGraph Infiniti software to calculate the root mean square of the maximal extent of activity for 1 s during the forward flexion phase, the fully flexed phase, and the re-extension movement. The FRR was calculated by dividing the maximal activity measured during the re-extension phase by the activity measured during the relaxation phase. For each subject, the mean of the measurements obtained in the three trials was used to determine the FRR values for the left and right extensor muscles.

Statistical analysis

We sought to identify significant changes over time in several outcome measurements, taken at different time points. When change was assessed only from baseline to one time point, we used paired t-tests or the Wilcoxon signed rank test. The former was used for continuous measurements, whereas the latter was used for discrete measurements (such as ratings on a 10-point scale). Mixed models were used for measurements taken at more than two time points.

These models are suitable for repeated measurements, as they can account for within-subject correlations. F-tests were performed for the following parameters: VAS, disability (NDI), PPT, CROM, and JPE. In all cases, when an F-test indicated that at least one change had occurred over the course of treatment, we carried out pairwise comparisons across all measurement points to detect at which point the change had occurred. When multiple comparisons were used, the reported p-values are adjusted p-values, obtained using Tukey-Kramer's method. The level of significance chosen was 0.05.

Specifically, for each parameter, we compared measurements in week 1 with measurements in week 4 and with measurements in week

6. For the VAS and disability indices we carried out an additional comparison between the measurements obtained in week 1 and those obtained in week 8 and week 12 (i.e., the second and fourth week post-treatment). SAS software was used for the analysis. 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, exclusion or inclusion of outliers had only minor influence on the significance of the results and did not affect the main conclusions.

Results

All nine participants completed the trial. Table 1 specifies the clinically-relevant data for each patient. Table 2 provides a summary of the results.

Participants	Sex/age	Diagnosis of neck pain syndrome
1	M/38	Idiopathic neck pain
2	M/47	Myofascial pain
3	F/59	Idiopathic neck pain
4	F/46	Myofascial pain
5	M/54	Whiplash injury
6	F/52	Left facet joint disorder
7	F/62	Myofascial pain syndrome
8	F/38	Myofascial pain
9	F/27	Myofascial pain, Facet joint disorder

Table 1: List of the patients who completed the trial.

Parameter/Time	Week 1	Week 4	Week 6	Week 8	Week 12	p value
VAS	5.12 ± 2.17*	4.06 ± 2.57*	2.83 ± 2.03*	3 ± 1.47	2.88 ± 2.03*	p<0.05
NDI (0-50)	15.4 ± 6	13.5 ± 8.03	11.4 ± 7.2	9.4 ± 4.3	11.8 ± 9	ns
FNT (cm)	20.36 ± 1.14		19.02 ± 1.66			ns
CROM average per specific movement (%)	-10 ± 9	-4.6 ± 7.8	1 ± 7.35			p=0.063
JPE average (°)	2.88° ± 0.73		1.14° ± 0.34*			p=0.05
PPT average Kg/cm ²	1.27 ± 0.4	1.82 ± 0.84	2.44 ± 0.5*			p=0.043
FRR-control	Right -4.04 ± 2.5 Left -4.5 ± 2.8					
FRR-patients	Right -3.01 ± 1.3 Left -2.65 ± 0.58		Right -4.3 ± 2 Left -3.9 ± 1.3*			p<0.05**

CROM: Cervical Range of Motion; FNT: Forward Neck Tilt; FRR: Flexion Relaxation Ratio; PE: Joint Position Error; NDI: Neck Disability Index; PPT: Pressure Pain Threshold; VAS: Visual Analogue Scale (pain); *Significant change in comparison to week 1 baseline measurement, p<0.05; **Comparison of the patient- group means FRR on the left side, before versus after treatment

Table 2: Summary of results.

Adverse Effects

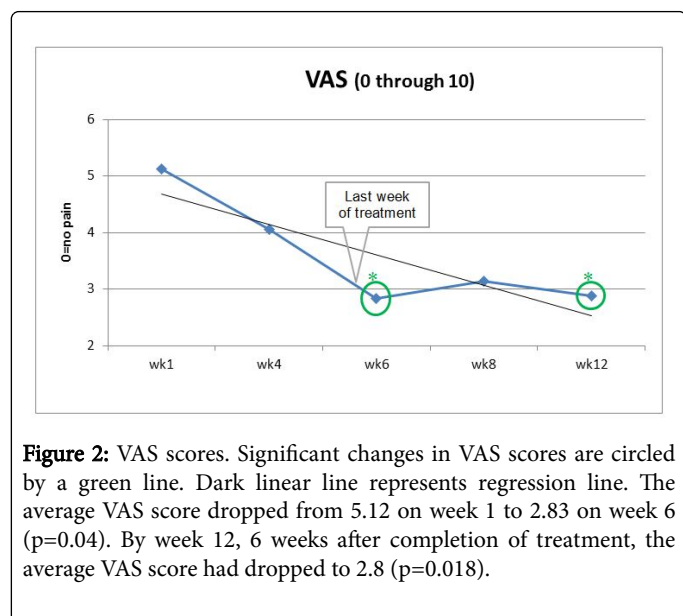
No serious adverse effects were reported. There were 23 reported adverse effects in 108 therapeutic sessions; 15 of them were considered to be treatment-related. All the adverse effects were mild and transient. Four patients complained about mild headache during or shortly after the treatment. Four patients developed mild, short-lasting scapular, thoracic or shoulder pain. Three patients in four separate episodes reported dizziness but not vertigo. Five patients reported exacerbation of their neck pain in nine treatment sessions. However, in only one patient did neck pain seem to be directly related to the treatment.

Pain (VAS) Scores and Disability Indices

Four patients reported marked improvement in pain over the course of treatment, and three patients reported some improvement. One patient reported less pain but increased disability (reflected in NDI), and one patient had decreased disability but slightly increased pain.

Disability Average NDI scores, decreased from 15.42 ± 6 at week 1 to 9.42 ± 4.3 at week 8, ($p=0.086$). It also decreased on other time points, yet this decrease was insignificant. Decreased average scores of particular questionnaire items such as work, recreation, reading and pain intensity decreased significantly on certain time points. For example, the ability to work was 1.89 at week 1 vs. 1.00 at week 4, $p=0.03$; 0.78 at week 6, $p<0.01$; 0.5 at week 8, $p<0.01$; and 0.89 at week 12, $p=0.012$).

VAS scores (Figure 2), VAS scores (measured on a 0-10 cm scale) decreased significantly over time ($p<0.05$). Specifically, the average VAS score dropped from 5.12 ± 2.17 on week 1 to 2.83 ± 2 on week 6 ($p=0.04$). At week 8, the average VAS score was still marginally lower than that at baseline ($VAS=3.00 \pm 2$, $p=0.069$). By week 12, 6 weeks after completion of treatment, the average VAS score had dropped to 2.8 ± 2 ($p=0.018$).



PPT

PPT increased significantly over time ($p=0.05$). In particular, mean PPT (average PPT at all sites of all the patients) was significantly higher at week 6 (2.44 ± 0.5 kg/cm²) than at baseline 1.27 ± 0.4 kg/cm² ($p=0.043$).

The most significant change was noted in the left levator scapulae muscle, when comparing the baseline measurement (2.24 ± 0.7 kg/cm²) with that obtained in week 6 (3.51 ± 1 kg/cm², $p=0.005$).

CROM

CROM values increased, on the average per movement, across all three planes (sagittal, coronal, and horizontal). However, this increase was statistically insignificant ($p=0.063$); average CROM value at baseline: $-10 \pm 9\%$ of the normal range for age and gender; average CROM value at week 6: $+1 \pm 7.3\%$, ($p=0.061$).

The only significant change for a specific plane occurred in the flexion movement which increased from -14% at week 1 to -1% at week 6 ($p=0.01$).

JPE

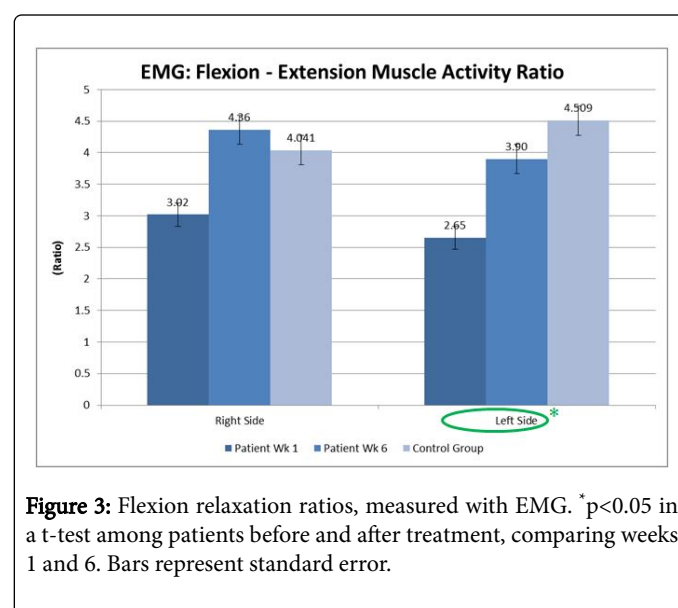
For all four movements, the JPE measurement at week 6 was significantly lower than that at week 1 (on average, we observed JPE values of $2.88^\circ \pm 0.73$ at week 1 and $1.14^\circ \pm 0.34$ at week 6, $p<0.01$). The most notable reduction was observed for flexion (3.72° at week 1 and 0.88° at week 6, $p=0.05$).

FNT

FNT decreased from 20.36 ± 1.14 cm to 19.02 ± 1.66 cm; however, this small change was insignificant ($p=0.104$).

FRR

At week 1, FRR (Figure 3) in the patient group was lower than that in the control group (patient group: 3.015 on the right side and 2.65 ± 0.58 on the left side; control group: 4.041 ± 2.5 on the right side and 4.509 on the left side).



These differences were not statistically significant. However following treatment, FRR in the patient group significantly increased on the left side (to 3.9 at week 6, $p<0.05$), approaching the values obtained in the control group.

Discussion

This open pilot trial was intended to explore the safety and the physiological effects of treatment consisting of personalized, computerized, neck mobilization in patients with CNP. In addition to evaluating patients' self-reported indices of pain and disability, we measured the following five parameters before, during and after the treatment course: mechanical pain thresholds, CROM, FNT, JPE, FRR.

We extend the treatment method described in our previous pilot trials by using the Occiflex device in a two-stage procedure consisting of a "teach" phase, in which natural, three-dimensional head and neck mobilization is tailored to the patient; and a treatment phase, in which the patient undergoes repetitive oscillatory movements, recorded in the "teach" phase.

In spite of the fact that in the current trial a combined, 3-dimensional mobilization of the cervical spine was performed, as opposed to our previous trials, we observed only mild adverse treatment-related effects in 12% of the therapeutic sessions. Over time, we identified two distinct groups of side effects: 1) side effects related to over-pressure of the cradle on the scalp or discomfort associated with the posture of the patient in relation to the treatment table; these effects included mild headache, and scapular pain; 2) side effects related to the actual mobilization/movement of the head/neck, such as dizziness and neck pain. Changing the body posture and the position of the head during mobilization might prevent the first type of adverse effect, whereas reducing the velocity and the range of mobilization might prevent the second type.

In three of the five physiological parameters we evaluated, patients' scores differed significantly between baseline measurements and measurements following completion of treatment. Specifically, mechanical pain thresholds at week 6 were nearly double those at week 1. JPE significantly increased, and FRR significantly increased on the left side following treatment. We also observed a statistically insignificant decrease in FNT and increased CROM.

Participants further showed a positive clinical response to treatment, reporting significant reduction of pain (VAS measurements). Reported pain levels continued to be significantly lower than baseline values even 6 weeks after the completion of treatment, suggesting that this short intervention may have long-lasting effects.

To our knowledge, this is the first trial in which CNP patients have shown a significant increase in FRR following treatment. In this trial, the FRR change was observed unilaterally on the left side.

Cervical FRR was initially reported by Meyer et al. [18] and has since been shown to be reproducible [17]. Pialasse et al. observed that positioning the subject in a trunk-forward inclination facilitates the evaluation of FRR, owing to the influence of the gravitational vector [19]. The authors observed asymmetric occurrence of FRR in 18% of their experimental group (comprising 19 participants in total). They explained the unilateral appearance of FRR as a product of methodological inconsistency or as a signature of an abnormal clinical condition [19].

Kumar et al. used sEMG recordings to evaluate the neuromotor control of cervical muscles (trapezius, splenius capitis and sternocleidomastoid) [20]. The authors were able to distinguish patients with CNP from normal control subjects on the basis of EMG frequency domain analysis. When examining neck extension, they observed that in 6 out of 10 frequency bands, activity of the left

trapezius muscle differed between patients and controls, whereas that of the right muscle did not. Kumar et al. noted that such asymmetry of muscle activity has been identified as a cause of pain development [20]. Thus, it is possible that asymmetry of extensor muscle function is a typical feature of patients with chronic neck pain.

In our patients, FRR values on the left side were smaller than those among participants in the control group. FRR increased bilaterally following treatment, but the increase was significant only on the left side. A plausible explanation for this asymmetric finding is pain-induced reflex inhibition of the left Para spinal extensor muscles upon extension, or decreased relaxation during full flexion. According to our data, the latter explanation is preferred.

Continuous asymmetric contraction of extensor muscles could be of major importance in the evolution of CNP. Such contraction can increase pain and decrease CROM. It might also be the basis of atrophy and fatty infiltration of extensor muscles, phenomena that impair these muscles' stabilizing effects [21]. In light of the anatomical connection between the sub occipital muscles and the dura mater, reduced function of these muscles, caused by over-contraction and fatty infiltration, could lead to improper position and tension of the dura during cranio-cervical movements [22]. Such tension, in turn, could be the underlying cause of upper CNP exacerbation or headache.

Continuous contraction of sub occipital and extensor muscles might also be a source of elevated JPE in patients with CNP. JPE reflects the accuracy of the head and neck position sense, which, coupled with vestibular information, facilitates accurate activation of the neck muscle and maintenance of optimal head posture [23].

Elevated JPE is associated with over-activation of antagonistic and synergistic neck muscles, which may be reflected in decreased FRR of extensor muscles [24]. Accordingly, disrupted sensory motor integration and elevated JPE have been observed in patients with upper neck pain but not in patients with lower neck pain [25].

Both the current trial and our previous trial showed that JPE decreased in patients who underwent computerized neck mobilization treatment. This reduction may reflect a better sensory-motor integration, improvements in head posture, and a different status quo of neck muscles. Indeed, the small decrease we observed in FNT following treatment implies a possible improvement in neck posture, which might be the consequence of a reduction in JPE and an increase in extensor muscle FRR.

Moreover, since a smaller FNT value corresponds to a shorter head gravity lever, a decrease in FNT reduces the extensor muscle force required to stabilize the head [26]. Accordingly, extensor muscle fatigue may decrease, or extensor muscle endurance may increase [27].

The changes in neck posture, the increase in CROM, the increase in FRR, and the reduction in JPE that we have observed may be associated with reduced afferent pain signals and consequently with diminished central sensitization. In our view, the fact that patients' mechanical pain thresholds nearly doubled following the treatment reflects a reduction in central sensitization.

The results of the present trial are of more significance and applicability than those of our previous trials, since we employed an intervention that was based on combined three-dimensional, physiological neck movements.

Limitations

1. The study is a non-controlled, pilot trial. Therefore, we cannot rule out the argument that reductions in pain are a consequence of a placebo effect, and that these reductions are the source of the observed improvements in the physiological parameters.
2. We employed a blind observer, yet the patients were not blinded.
3. The number of patients recruited was small.
4. The follow-up period was only 6 weeks after the end of treatment. In light of these limitations, our findings should be interpreted with caution.

Conclusion

Significant physiological changes following computerized mobilization, a novel therapy, may underlie the reduction in pain and disability in patients with CNP.

In order to establish the efficacy of this therapeutic method, a controlled trial is warranted.

List of manufacturers and other nondrug products used directly in the study

1. Algometer (Wagner FPX™-25, Greenwich CT): performs pain diagnostic testing with a digital force gauge [13].
2. Cervical range of motion device (CROM Basic, Performance Attainment Associates, Lindstrom, MN): combines inclinometers and magnets to measure cervical range of motion [14].
3. Monitoring system for flexion-relaxation ratio (FlexComp Infiniti with BioGraph Infiniti software, Thought Technology, Montreal, QC, Canada).

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Declarations

Ethical Approval

The current trial was approved by the Hillel Yaffe ethical committee.

Funding

The research is funded by Headway Ltd. The Occiflex device has a CE-mark. Submission for FDA clearance is expected by the end of 2017.

Ethical issues

The corresponding author established Headway Ltd., the company that developed the Occiflex device. He is a shareholder in Headway Ltd.

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