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CLINICIAN PROFICIENCY IN DELIVERING MANUAL TREATMENT FOR NECK PAIN WITHIN SPECIFIED FORCE RANGES

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Abstract

Background Context—Neck pain is a common musculoskeletal complaint responsive to manual therapies. Doctors of chiropractic commonly use manual cervical distraction, a mobilization procedure, to treat neck pain patients. However, it is unknown if clinicians can consistently apply standardized cervical traction forces, a critical step toward identifying an optimal therapeutic dose.

Purpose—The purpose of this study was to assess clinicians' proficiency in delivering manually applied traction forces within specified ranges to neck pain patients.

Study Design/Setting—Observational study nested within a randomized clinical trial.

Sample—Two research clinicians provided study interventions to 48 participants with neck pain.

Outcome Measures—Clinician proficiency in delivering cervical traction forces within three specified ranges (low force <20 newtons (N); medium force 21–50N; and high force 51–100N).

Methods—This study was funded by a grant from the National Center for Complementary and Alternative Medicine, National Institutes of Health (Grant # 1 U19AT004663-01), and conducted in a facility funded by National Center for Research Resources, National Institutes of Health (Grant # C06 RR15433-01), and approved by an Institutional Review Board for the protection of human subjects. Senior author receives approximately \$400–600 travel reimbursements per year for giving research presentations at certification seminars. The table manufacturer (Haven Innovations) sold the treatment table at a discounted price (\$5000 discount) for research purposes. Participants were randomly allocated to three force-based treatment groups. Participants received five manual cervical distraction treatments over two weeks while lying prone on a treatment table instrumented with force sensors. Two clinicians delivered manual traction forces by treatment group. Clinicians treated participants first without real-time visual feedback displaying traction force and then with visual feedback. Peak traction force data were extracted and descriptively analyzed. None of the authors have any conflict of interest relative to this study.

Results—Clinicians delivered manual cervical distraction treatments within the prescribed traction force ranges 75% of the time without visual feedback and 97% of the time with visual feedback.

Conclusions—This study demonstrates that doctors of chiropractic can successfully deliver prescribed traction forces while treating neck pain patients enabling the capability to conduct force-based dose-response clinical studies.

This trial was registered with [ClinicalTrials.gov](https://clinicaltrials.gov) NCT01765751

Keywords

BIOMECHANICS; DOSE; TRACTION FORCES; CLINICIAN TRAINING; MOBILIZATION; CHIROPRACTIC; MANUAL THERAPY; NECK PAIN

INTRODUCTION

Musculoskeletal conditions are common causes of pain and disability [1,2] with neck pain representing a prevalent musculoskeletal complaint and costly societal burden [3–9]. Doctors of chiropractic treat neck pain patients as the second most common condition seen after low back pain [10]. Manual therapists deliver several types of spinal manipulation and mobilization therapies for the treatment of spine related pain[11] [12]. Spinal manipulative therapy includes manually delivered high-velocity low-amplitude (HVLA-SM) procedures, while mobilization therapies involve low-velocity movements including distraction procedures [10]. The *Bone and Joint Decade Task Force on Neck Pain* and recent systematic reviews noted that non-invasive manual therapy procedures involving mobilization are effective for the management of neck pain [13,14]. One such mobilization procedure is manual cervical distraction, or flexion-distraction [15]. While several published case reports and case series show the utility of manual cervical distraction for patients with neck pain [16–19], no randomized clinical studies have demonstrated the effectiveness of this type of spinal mobilization for persons with neck pain.

One issue in conducting clinical trials of manual therapies is the standardization of intervention delivery, such as treatment dose [14]. A recent study suggests that the biomechanical forces applied by clinicians during mobilization treatments may have a dose-response effect on clinical outcomes, such as pain or stiffness [20]. However, a systematic review reported that inter-clinician reliability of forces applied during spinal mobilization procedures was poor-to-moderate while intra-clinician reliability was good [21]. Because force application varies for these procedures, there is a need for innovative methods to train and validate the forces clinicians apply during mobilization treatments.

Though manual therapies are used to treat a wide variety of musculoskeletal conditions, few clinical trials have quantified the forces delivered to patients. Little is known regarding the question of force as dose for manual therapy procedures including spinal mobilization procedures for neck pain patients. A recent force-based dose randomized controlled trial reported higher posterior-to- anterior mobilization forces resulted in better clinical outcomes for neck pain patients suggesting that force as dose plays an important role and underscores the importance of conducting force dose response studies for manual therapies [20].

However, to design such studies, technologies and training methods must be developed to reliably quantify forces and certify proficiency in delivering prescribed forces.

In this study, we evaluated clinicians in their proficiency to deliver manual distraction procedures for prescribed force ranges on neck pain patients undergoing manual cervical distraction in a force-based dose-response randomized clinical trial. We developed and used bioengineering technology that provides force-related audio and graphical feedback to train and certify clinicians to deliver manual cervical distraction within prescribed force ranges and measured their ability to perform force prescribed treatment first without any feedback and then with real-time visual force feedback [22].

METHODS

This project was part of a larger developmental/translational center grant designed to study chiropractic interventions for cervical spine disorders. We conducted a prospective, observational study nested within a pilot randomized clinical trial of chiropractic clinicians' proficiency in delivering 3 traction force range doses of manual cervical distraction. The results of the clinical trial will be reported elsewhere. The institutional review board affiliated with the authors' institution approved this study. The neck pain patients who participated in the trial provided written informed consent.

Participants

Two doctors of chiropractic delivered all study treatments. The clinicians (1 male and 1 female) had extensive clinical experience (31 years and 28 years, respectively) in chiropractic private-practice, research, and technique instruction. One clinician had over 5 years of experience treating patients with the manual cervical distraction technique while the other clinician had not utilized the technique in clinical settings before this study. The research clinicians underwent 7-weeks of training in the clinical trial protocol that included certification in the delivery of the force-based manual cervical distraction procedure[22]. The clinicians were trained to deliver manual cervical distraction within prescribed force ranges using bioengineering technology that provided audio feedback and subsequently enhanced with visual feedback on the applied traction force.

Trial participants were adults 18–70 years old, who had mechanical neck pain or neck-related upper extremity pain of at least 4 weeks duration. Eligible participants rated their neck pain scores from 3 to 7 on an 11-point numerical rating scale. All participants were naïve to manual cervical distraction. They were randomly allocated to one of three groups defined by traction force ranges: 1) a low force range of <20 newtons (N); 2) a medium force range of 20N to 50N; and 3) a high force range of 51N to 100N.

Intervention

Manual cervical distraction was performed while the participant rested prone on a chiropractic table (Figure 1). The clinician grasped the posterior aspect of the neck with a broad contact (contact hand) between the thumb and index finger. The clinician's hand contact gently applied superior traction over a specific vertebral level while the opposite hand ensured simultaneous, controlled movement of the table headpiece (Figure 2). The

procedure created a slow rhythmic (1–2 second) distractive movement, isolated near the manual contact point (Figure 2). The amount of distractive force did not exceed patient tolerance. Although manual cervical distraction offers several treatment options, only neutral distraction, the most common procedure, was used. Participants received five manual cervical distraction treatments over a two-week period delivered within 1 of 3 traction force ranges defined by their assigned treatment group. Dosing was limited to 3 sets of 5 repetitions with a hand contact over C5 and 3 sets of 5 repetitions with a hand contact on the occiput. Clinician proficiency was established as 12 of 15 repetitions (80%) delivered within the target traction force range at each contact point.

Instrumentation

A Cox flexion-distraction chiropractic treatment table (Model 7, Haven Innovation, Grand Haven, MI) was equipped with a moveable headpiece for long axis horizontal, flexion, lateral flexion, and/or rotational movement of the head and neck while the trunk and legs of the patient rest on fixed table sections (Figure 1). We incorporated three-dimensional force plates (Model # 2850-06, Bertec Inc., Columbus, OH, USA) into the table that were connected to a desktop computer by means of amplifiers (Model 6800, Bertec Inc., Columbus, OH) and 16 bit analog-to-digital converters (Model PCIM-DAS 1602/16, MicroDAQ Ltd., Contoocook, NH). Manually applied traction force was obtained as a function of time using the force plates. A 3-D force sensor (Model Py6-100, Bertec Inc., Columbus, OH) was also placed under the table headpiece. This sensor under the head piece provides data on posterior-to-anterior forces used by the clinicians.

We independently tested the force measures against a 3-D force sensor (Model Mini45, ATI Industrial Automation, Apex, NC) in both normal and shear directions and found good agreement (less than 3% difference) [23]. We determined the traction force by measuring the shear gathered from the two force plates generated by friction from the patient's body as well as the ankle. During MCD, traction forces are delivered at a rate of approximately 0.5 Hz. The force plates had a natural frequency of 400Hz resulting in no detrimental effects on measurements. Motion Monitor Software (Version 7, Innovative Sports Training Inc., Chicago, IL, USA) collected data at a sampling rate of 100Hz from the force transducers and displayed the information graphically as a function of time. Shear forces from both the trunk and ankle sensors are added to obtain the total traction force in real time using the software.

Following a study treatment, the computer stored the force data in graphical format as a function of time (Figure 3). The saved data was exported into a Microsoft Excel spreadsheet (Version 2010, Microsoft Corp., Redmond, WA). A custom written MatLab (Version 7, Mathworks Inc., Natick, MA) program extracted the 15 peak forces for each hand contact point corresponding to the mobilization cycles. The average peak force was computed.

Visual Force Feedback Technology

Clinicians trained on manual cervical distraction delivery using an audio- and visual feedback technology. This technology was not employed for treatment delivery with study participants during the first half of the clinical trial, so as to replicate the current standard of practice in clinical settings. However, the clinicians identified the difficulty encountered

with delivering manual cervical distraction within the prescribed ranges when relying only on their estimation of muscular effort and tactile sense during the monthly re-certification process. The use of audio-feedback, while useful during the pre-trial training period, was not feasible in the clinical trial as the audio feedback would have unmasked the participant and the biomechanical technician who was collecting research data to the intervention group. Thus, our team developed a real-time visual force feedback technology to address these challenges. This procedure was implemented with participants randomized during the second half of the trial. This quality control measure also allowed us to compare the proficiency of our clinicians to deliver treatment first without and then with real-time visual feedback.

Visual force feedback was accomplished through the biofeedback feature of the Motion Monitor software. Visual feedback corresponding to the applied manual traction force was displayed in real-time during treatment by the movement of a cursor sliding along a color coded scale and visible to the clinician. The cursor moved across a horizontal line with three color regions corresponding to the three prescribed traction force ranges. The patient while lying face down during the study intervention and could not see the visual display of forces applied. The display monitors were kept in the visual range of the clinician, but outside of the range of the biomechanics technician. Thus, the biomechanics technician and the participant remained blinded to the treatment allocation.

RESULTS

We randomly allocated 48 participants into this study. Table 1 describes baseline participant characteristics. Most participants were middle-aged, white females. Nearly all of the participants had received chiropractic care in the past, with approximately one-third of participants receiving chiropractic care in the past month or more recently. No participant had previously received manual cervical distraction to the cervical spine.

Each session consisted of delivering treatment to the C5 vertebra and the occiput level for a total of 480 expected observations. The two study clinicians delivered a total of 449 manual cervical distraction treatments to study participants on distinct visits over a 10-month timeframe, with missing data (n=31) due to missed appointments (n=20) and technical difficulties (n=11). The clinicians provided 231 treatments without the visual feedback technology between February-June 2013 and delivered 218 treatments with the visual feedback technology between June-October 2013.

Table 2 depicts the proficiency of study clinicians in delivering the cervical traction forces without the aid of the visual feedback technology. The two clinicians delivered similar mean traction forces for each force range [mean (SD): low range 11.57 N (6.85) vs. 14.43 N (6.05); medium range 35.83 N (17.54) vs. 35.43 N (13.42); high range 65.48 N (18.21) vs. 63.26 N (17.52)]. However, study clinicians delivered only 174/231 (75%) of the study treatments within the targeted traction force range without visual feedback. The clinicians experienced the most difficulty delivering the traction forces in the medium range (20N-50N), with only 63% of these treatments occurring within the assigned treatment group range.

Table 3 depicts the proficiency of study clinicians in delivering the cervical traction forces while utilizing visual feedback technology. With visual feedback the majority of study treatments were delivered within the targeted force range (212/218; 97%). The clinicians delivered mean traction forces at ranges nearer to the maximum targeted force range for each group, but with a slightly wider inter-rater range [mean (SD): low range 17.58 N (1.24) vs. 18.58 N (0.95); medium range 40.89 N (7.96) vs. 45.91 N (2.46); high range 70.93 N (10.62) vs. 78.96 N (4.12)].

DISCUSSION

This innovative study evaluated the proficiency of chiropractic clinicians in delivering manual cervical distraction, a form of spinal mobilization, within prescribed traction force ranges using a real-time, visual force-feedback technology. Our results demonstrated that the research clinicians delivered 97% of study treatments within the prescribed ranges with visual feedback whereas, without visual feedback, only 75% of the treatments were delivered within the prescribed traction force ranges. Further, the delivered forces were more consistent when using the visual feedback technology as evidenced by less variability.

Gorgos and colleagues conducted a recent systematic review of intra- and inter-clinician reliability of delivering standardized treatment during spinal mobilization [21]. Their findings showed that inter-clinician reliability was poor-to-moderate (ICC 0.04 to 0.70) while intra-clinician reliability was good (ICC 0.75 to 0.99). The wide variation in clinician force application indicates a need for innovative methods to improve training consistency and to validate the forces applied during mobilization treatments, especially in clinical trials [21].

Our present study has validated the usefulness of such a technology. Real-time, visual feedback of traction forces provided a clear advantage to clinicians delivering manually-applied treatments to the cervical spine within the context of a randomized clinical trial. Real-time visual feedback enhanced the clinicians' proficiency to 97% and decreased their exclusive reliance on perceived differences in tactile sensation and muscular exertion during treatment delivery.

The results from this study provide a firm foundation for undertaking force-based dose response clinical trials of spinal mobilization treatments for neck pain patients. Force-based dose response studies could lead to information to develop optimum treatment parameters for different types of neck pain patients. A recent study by Snodgrass et al. evaluated the force-based dose response of a single intervention, posterior-to-anterior mobilization, on clinical outcomes of neck pain patients [20]. Improvement in pain and decreased cervical spine stiffness was reported in the group receiving the high force intervention compared to the low force intervention.

This visual force-feedback technology may also demonstrate its usefulness when translated to educational and field settings where it has potential as an effective training aid and as an objective measure of traction force delivered to patients in clinical settings. Previous investigations have demonstrated the utility of feedback to train students in delivering high

velocity low amplitude spinal manipulations to lumbar, thoracic, and cervical spine [24–30]. However, few studies have considered how to provide similar training to manual therapists and students using spinal mobilization techniques. Snodgrass et al. reported on the use of real-time feedback to train students to deliver posterior-to-anterior mobilization forces similar to those applied by expert physiotherapists [31]. We observed similar findings to Snodgrass et al. regarding higher accuracy in clinician delivery of mobilization forces using real time feedback [31]. However, our study differed in that: 1) we used experienced clinicians to deliver three prescribed force ranges; 2) our clinicians delivered distraction forces rather than posterior-to-anterior forces; 3) our clinicians delivered forces on neck pain patients rather than asymptomatic student volunteers; and 4) our study involved the application of forces at C5 and occiput contacts rather than a single (C7) contact point.

Limitations

This study was limited to measuring two clinicians and two hand contact locations (C5 and occiput). Other measurable components such as grip tension and anteriorly oriented manual pressure occur in manual cervical distraction delivery. Anterior oriented pressure was measured but was not included in the training component for this study and grip tension was not measured. Participants sometimes reported differences in perceived forces when receiving procedures by different clinicians within identical force ranges. These perceptual differences are likely due to several components such as differences in anterior oriented and grip pressure and could represent a dosing component of the procedure. Other factors such as hand size and flexibility in comparison with neck size, and degree of coordinated movement may also play a role in patient perceived forces.

Conclusions

This study demonstrates that with visual feedback clinicians can successfully deliver prescribed traction forces while treating neck pain patients enabling the capability to conduct force-based dose-response clinical studies.

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Figure 1.
Manual cervical distraction table with force plates and force sensor

Figure 2.
Doctor delivering manual cervical distraction in prone position showing clinician hand contacts

Figure 3.
A typical cyclical traction force application during manual cervical distraction

Table 1

Demographic characteristics of the neck pain participants (N=48)

Characteristics	Results
Age (years), mean (SD)	46.8 (12.5)
Female, n (%)	31 (65)
Race, white, n (%)	44 (92)
Body mass index, mean (SD)	29.5 (6.4)
Employment, full-time or part-time paid work, n (%)	34 (71)
Chiropractic care, any previous, n (%)	43 (90)
Chiropractic care, at least monthly, n (%)	14 (29)

Table 2

Clinician proficiency in delivering cervical traction forces without visual feedback

Clinician	Targeted force range	Number of treatments delivered	Mean traction force (N)	Standard Deviation	Minimum traction force (N)	Maximum traction force (N)	Number of treatments delivered outside targeted force range
Clinician A	Low	42	11.57	6.85	0.18	24.75	4
	Medium	23	35.83	17.54	8.61	69.57	12
	High	32	65.48	18.21	30.84	98.34	7
Clinician B	Low	40	14.43	6.05	5.63	26.64	10
	Medium	42	35.43	13.42	7.70	60.13	12
	High	52	63.26	17.52	30.63	98.81	12
Combined	Low	82	12.97	6.59	0.18	26.64	14
	Medium	65	35.57	14.87	7.70	69.57	24
	High	84	64.10	17.71	30.63	98.81	19
Totals		231					57

N, newtons

NOTE: Targeted force ranges: 1) low force range <20N, 2) medium force range 20–50N, 3) high force range 51–100N

Table 3

Clinician proficiency in delivering cervical traction force delivery with visual feedback

Clinician	Targeted force range	Number of treatments delivered	Mean traction force (N)	Standard Deviation	Minimum traction force (N)	Maximum traction force (N)	Number of treatments delivered outside targeted force range
Clinician A	Low	38	17.58	1.24	13.22	19.60	0
	Medium	28	40.89	7.96	16.59	48.65	2
	High	32	70.93	10.62	48.27	85.29	1
Clinician B	Low	40	18.58	0.95	16.95	21.38	3
	Medium	46	45.91	2.46	35.49	49.24	0
	High	34	86.51	4.12	66.42	92.21	0
Combined	Low	78	18.09	1.2	13.22	21.38	3
	Medium	74	44.01	5.76	16.59	49.24	2
	High	66	78.96	11.14	48.27	92.21	1
Totals		218					6

N, newtons

NOTE: Targeted force ranges: 1) low force range <20N, 2) medium force range 20–50N, 3) high force range 51–100N