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Validation of a novel sham cervical manipulation procedure

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Abstract

Background Context—No clinical trial of spinal manipulation for chronic neck pain, either for single or multiple intervention session(s), has employed an effective sham-manipulation control group.

Purpose—Validate a practical sham cervical high velocity, low amplitude (HVLA) spinal manipulation.

Study design/Setting—Randomized, experimental validation study in an institutional clinical research laboratory

Patient Sample—Eligible subjects were males and females, 18–60 years of age with mechanical neck pain (as defined by the International Association for the Study of Pain Classification) of at least 3 months duration. Subjects with arm pain, any pathologic cause of neck pain or any contra-indication to spinal manipulation were excluded.

Outcome Measures—The primary outcome was the patient's self-report or "registration" of group allocation following treatment. Secondary outcomes were NRS-101 for neck pain, range of motion (by goniometer), tenderness (by pressure algometry).

Methods—Eligible subjects were randomly allocated to one of two groups: "real" or sham cervical manipulation (RM or SM). All subjects were given two procedures in sequence, either RM+SM or SM+SM. Immediately following the two procedures, subjects were asked to register any pain experienced during the procedures and to identify their treatment group allocation. Force-time profiles were recorded during all procedures. Secondary clinical outcome measures were obtained at baseline, 5 and 15 minutes after the intervention including range of motion, self-report of pain and local spinous process tenderness. Data for each variable were summarized and tested for normality in distribution. Summary statistics were obtained for each variable and statistically tested. Funding for this study was obtained from the National Institutes of Health (NCCAM: R21 AT004396-01A1) and the Canadian Institutes of Health Research (BMT91926). No conflicts of interest exist in this study.

Results—Sixty-seven subjects were randomized. Data from 64 subjects (32 per group) were available for analysis. There were no significant differences between the groups at baseline. One adverse event occurred in the "real" group which was a mild post- treatment pain reaction lasting < 24 hours. In the RM group, 50% of subjects incorrectly registered their treatment allocation; in

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the sham group, 53% did so. For the SM group, none of the procedures resulted in cavitation while in the RM group, 87% of procedures resulted in cavitation. There were no significant changes between groups on pain, tenderness or ROM. Force-time profiles of the RM and SM procedures demonstrated fidelity with significant differences between components as intended.

Conclusions—The novel sham procedure has been shown to be effective in masking subjects to group allocation and to be clinically inert with respect to common outcomes in the immediate post-treatment stage. Further research on serial applications and for multiple operators is warranted.

Keywords

cervical; manipulation; sham; clinical study; neck pain

INTRODUCTION

Neck pain is a very common problem, second only to low back pain in its frequency both within the general population [1–6] and in musculoskeletal practice [7–9]. Approximately 15% of females and 10% of men suffer with chronic neck pain at any one time [4–6]. Chronic neck pain produces a high level of morbidity by affecting occupational and avocational activities of daily living and by affecting quality of life [10–18].

A variety of conservative treatments are available for chronic mechanical neck pain. One commonly used treatment, spinal manipulation (SM), is recommended by several evidenced-based guidelines for patients without severe or progressive neurological deficits [19–26]. There is a wide range of terms often grouped under the heading of SM that currently show limited differences with respect to clinical effectiveness, but are mechanically distinct. One classification system of procedures provides four clusters based on mechanisms of treatment delivery and include: continuous passive motion, mobilization, high-velocity low-amplitude (HVLA) and mechanically assisted [27]. The differences in procedures rely upon cyclical repetition versus single impulse loading with user variability on frequency, force and postural displacement amplitudes. Mechanically assisted procedures couple use of segmented tables with moving sections that guide patient body segments in controlled cyclical ranges of motion or that drop under force control to assist in developing an impulse load during manual force applications. Other applications include hand held probes that direct a brief impulse to a target site.

Recently, Vernon et al. [28] identified clinical trials that had utilized control procedures. Twenty-one trials were identified, four of which employed some form of placebo or sham control [29–32]. None of the trials of manipulation for neck pain or for headache [28–32], employed an effective manual sham manipulation procedure. Sham/placebo/mimic procedures have been attempted, with limited success, for treatment in the lumbar spine [33–36].

Strong placebogenic effects have been hypothesized for manipulation [37–40] resulting from manual contact, personal attention and provider enthusiasm. Placebo or sham-controlled studies are necessary to determine whether results of treatment are related to the degree that the clinical outcomes are attributable to the intervention as an active factor rather than to non-specific effects. A valid sham manipulation procedure is critical for future studies in the efficacy of spinal manipulation through randomized clinical trials. We hypothesized that a novel sham cervical manipulation based on core elements of the patient experience during a procedure, would result in blinding of subjects so that their ability to accurately detect their group assignment would be no greater than chance.

METHODS

The study was conducted in the Biomechanics and Elastography Laboratory of the Canadian Memorial Chiropractic College utilizing a randomized, single-blind, repeated measures experimental design with independent assessors. Subjects were recruited from the population of patients consulting for care of chronic mechanical neck pain (NP) at an outpatient teaching clinic and by local area advertisements.

Patient recruitment and random allocation

Table 1 lists the Inclusion/Exclusion criteria. For the purposes of this study, neck pain was defined as being; 1) located anywhere in the bilateral area from the posterior skull (nuchal ridge), inferiorly to the spine of the scapula, 2) determined clinically to be of mechanical origin following the criteria of the International Association for the Study of Pain (IASP) [42]. IASP criteria include specifying the affected cervical segment, aggravation of pain by selectively stressing that segment and no pain upon stressing adjacent segments.

Candidates were given an orientation to the experiment and provided written informed consent, approved by the institutional ethics board, prior to proceeding with any intake assessments. During consent, subjects were told they would receive one of two kinds of cervical spinal manipulation treatments and that there was no scientific evidence as to whether one is superior to the other. This was done in an effort to minimize participant expectation bias. The Research Clinician (RC) then performed a clinical screen for eligibility and a manual examination of the neck. The target segment for tenderness measurement and for manipulation was identified by palpation (See Table 1). On clearance for participation, the patient was randomly assigned to the intervention group. Randomization was accomplished prospectively using block allocation to ensure equal numbers in each group. The random allocation was concealed using sealed individual numbered envelopes sequestered from the assessors in the study.

Treatment Interventions

For purposes of this study, the conceptualization of the sham sought to provide a similar sensory experience for the subject as would be provided during treatment with HVLA. To achieve this, four sensory cues were mimicked: touch near the target region, positioning of the head and neck, movement and sound timed with treatment delivery. As described below, the touch and positioning are readily achieved manually. To achieve movement and sound, mimicking the events during application of force and frequently associated joint cavitations, a table drop-assist approach was taken. Drop segments for treatment tables are widely available and used with HVLA in isolation [43] or combined with continuous passive motion [44]. Reported as the third most common procedure type [43] by survey of practitioners, drop table mechanisms provide short interval movement associated with noise that involves the head-neck unit in the targeted region.

Each group was given treatment by a practising chiropractor, the RC, with 35 years of clinical experience, who was responsible for carrying out all interventions. Once the intervention procedure commenced, verbal communication with the participant was limited to positioning instructions. The spinal site targeted for the study intervention was the most locally tender/restricted level [45–47] determined during the screening evaluation. Following pre-positioning, the RC performed the assigned treatment, either a real (RM) or sham (SM) manipulation. Each of these treatments included two procedures: the real treatment consisted of one RM on the side of the lesion followed by one SM on the opposite side, separated by a 60-second rest period. The sham treatment consisted of an SM procedure on the side of the lesion, followed by a second SM to the opposite side, again,

after a 60-second rest interval. This dual treatment approach is consistent with the common practice where more than one procedure is often applied to the neck in treatment of neck pain [18] complaints while simultaneously making operator intent for the individual procedure more ambiguous to the subject.

The RM procedure was accomplished following the protocol described by Petersen and Bergmann [48]. With the patient supine the head lifted into mild flexion, rotated (≤ 40°) [49] to the side away from the lesion and allowed to rest on the RC's forearm (Figure 1) which, in turn, rested on the head piece. The head rest support consisted of a mechanical cam mechanism set to trip with 20 lb downward force, dropping the support a distance of 3/8 inch, with associated sound of impact. Local joint preload, in the direction of the intended treatment load, was applied by pressure over the target lesion site only, not by additional head motion. A combination of minimal (<10 degree) [49] rotary/cephalad axial motion to the head with manipulative impulse load to the lesion site was administered. Simultaneously, a downward pressure was given by the head- supporting arm onto the head-piece activating the cam-drop mechanism. The participant's head/neck was then returned to the neutral position. Joint cavitation within the cervical spine, commonly associated with RM, was expected to occur during this procedure [50–54].

The SM procedure differed from the RM by eliminating the joint preload and thrust component, following the preliminary work of Vernon et al. [37]. It consisted of the same degree of head rotation and manual support to the head and neck as in the RM with light touching of the skin by the back of the RC's hand over the target segment, but no thrusting force applied through that site. A rapid application of motion was created only through the drop action of the head-piece cam mechanism with associated sharp sound.

Immediately following the intervention, the participant was asked by the Project Manager to 1) identify their group assignment using the question "Did you receive a real chiropractic treatment to your neck (YES/NO)?", and, 2) indicate if there was any new pain or exacerbation of pre-treatment pain during the procedure. The term "treatment" was used to avoid technical jargon associated with manipulation that might cue subjects previously experienced with these procedures and because of its generalizability to any therapeutic encounter. Approximately twenty-four hours after completion of the testing, the participant was contacted again to determine if any late adverse events had occurred. At that time, they were also informed of their group allocation.

Outcome Measures

The primary outcome measure used to evaluate the study hypothesis was the rate of successful identification of group allocation through registering the subject's response at de-briefing after the procedure was administered. The proportion of subjects who correctly characterized the procedure was compared with the proportion incorrectly identifying their group allocation.

Local tenderness of the spinous process of the target vertebra, neck range of motion (ROM) and NRS-101[41] pain scale obtained at baseline 5 and 15 minutes post-treatment served to evaluate for objective symptomatic change. An electronic pressure algometer was constructed from a uniaxial load cell (Futek, 10 Thomas, Irvine, CA, 92618 USA), sampling force levels at 50 Hz, and a probe ending in a 0.79 cm^2 flat rubber tip. Tenderness was determined by a single application of the probe to the spinous process of the lesioned cervical segment from the posterior direction. The patient was seated with the head held by the assessor in slight flexion. The probe pressure was increased at 1 kg force per second until the participant signalled onset of tenderness by pressing an event marker. Range of motion was measured in seated position using a CROM [55–57] device for range in all three

cardinal planes. The presence of audible or palpable cavitation of cervical joints arising during the administration of the procedure was recorded by the RC.

Force-time profiles were monitored during administration of each procedure. The loads passing through the neck during the manipulation procedures were estimated using inverse statics [49]. A treatment table (Leader Health Technologies 900 Z– series, Port Orchard, WA) was modified with a cam-drop headpiece isolated on its own support separate from the upper torso support system which was instrumented by a force plate (AMTI OR6 Series, Watertown, MA) capable of sensing reaction forces and moments in three planes. The lower body was also supported by an independent platform. The separate support infrastructure to the table pieces permitted isolation of the force plate from redundant loads that would confound the measurements. Using anthropometric measures from the subject (height, weight, treatment site) inverse dynamic calculations provided estimates of the loads passing through the neck at the target site. Samples were obtained at 1000 Hz over the 5 second window during which the treatment manoeuvres were performed and post-processed with the anthropometric data.

Data Analysis

According to Bang et al. [58] the ideal assumption in typical clinical trials is that 50% of subjects in both control and treatment groups would correctly identify their group allocation at de-briefing, a rate equal to chance alone. We employed the assumptions from Bang et al. [58], the data from Vernon et al. [37] and clinical judgment to derive a sample size estimate of 68 subjects (alpha = 0.05, beta = 0.80, PO = 0.73, P1 = 0.50, PHI = 0.02). A difference in proportions test was applied to test this primary outcome.

The tenderness scores, NRS-101 and ROM, were assessed for normality in distribution and analyzed in separate repeated-measures ANCOVA's . Post-hoc means testing was performed using appropriate parametric or non-parametric procedures. In order to develop hypotheses for future studies, a secondary analysis of the pain scores was conducted to determine the proportion of subjects in each group who achieved pain reduction at or above a minimally clinically important difference (MCID) of 20% [59]. Once the number of subjects achieving this MCID was determined, the proportion of those subjects who correctly identified their group assignment was determined. Chi Square analysis of these data was performed. Peak values from force-time profiles of the treatment procedures were compared by Student-t test, adjusted for multiple measures, to physically characterize the effective difference between sham and real procedures.

RESULTS

A total of 67 subjects were recruited. The demographic and clinical baseline measures are shown in Table 2. No group differences were observed in the data prior to intervention. The mean age of participants was 38 with a mean duration of neck pain lasting 40 months. In the SM group, one subject aborted the test for unrelated health reasons and failed to return to complete the study. Two protocol violations (one per group) occurred when the cam-drop mechanism failed to engage during the treatment procedure. In both instances, the data was eliminated from final analysis.

At de-briefing, 50% of those subjects who were in the RM treatment group correctly reported that they had received a real treatment. In the SM group, 47% correctly stated they had received a sham treatment. There was no statistical difference between the subject perceptions by group (X^2=0.06, df = 1, p=0.80).

In the SM group, 9% of subjects of subjects indicated that the intervention was slightly painful while 12% of the RM reported similarly (p=0.69). Only 1 subject, who was a member of the RM group, had slight mild pain lasting to the 24-hour follow-up which then resolved uneventfully. Cavitation was obtained during the procedure from 87% of the RM and in none of the SM subjects. Measures of tenderness obtained by pressure pain threshold remained unchanged for both the sham and treatment groups from baseline to 15 minutes post-treatment. Pain scores from the NRS-101, on the other hand, showed a trend (p= 0.049), decreasing for both groups over time.

Pain change scores (Table 4) between time points were calculated. The analysis of the proportion of subjects whose NRS-101 change scores exceeded the 20% threshold showedno difference between groups (38% in RM vs 28% in SM). When the factor of group registration for the sub-sets of subjects achieving at least 20% change in pain was examined, it appeared that 83% of RM ‘pain improvers’ (10/12) guessed that they had received the “real” treatment, while, in the SM group, only 22% (2/9) correctly guessed their group allocation.

Cervical ROM remained unchanged across all three times of measurement regardless of group ($F = 0.4$, $p = 0.96$).

Force-time histories were compared for each component of treatment force applied during all SM and RM procedures. Results were centered on the force magnitude and the value of force for each directional component (transverse, axial or antero-posterior) determined at that point. The cam-drop mechanism threshold (20 Lb), activated in both RM and SM procedures, accounted for essentially all of the antero-posterior force, as would be expected. Statistical comparisons were conducted on the remaining components taken as the effective treatment forces (Table 5). All components of the mean sham procedures ranged between 10% and 50% ($0.055 < p < 0.001$) of the real manipulations. Only the procedures delivered by the operator’s left hand failed to be significantly different between SM and RM, only trending with a $p<0.055$.

Discussion

To our knowledge, this is the first study to demonstrate the validity of a sham cervical manipulation procedure. The critical features of this procedure can be divided into two categories: intrinsic and extrinsic. The intrinsic features include: systematic accounting for multiple sensations that the subject may experience during treatment including auditory, movement and skin surface loading cues as well as the consistent application of procedural forces that are quantitatively different between groups. The extrinsic feature is that the sham manoeuvre was performed twice, once on each side in the SM group (double placebo manoeuvre). Both features are believed to act in concert to influence the subject’s ability to identify treatment allocation.

Machado et al. [60] described the ideal attributes of a placebo treatment as having two components: inertness, meaning no known or substantiated therapeutic mechanism; and, mimicry of the index treatment. An inert placebo which mimics the index treatment in all aspects, including the replication of any common side effects is termed “indistinguishable”. When side effects are absent, the placebo is said to have “structural equivalence”, where, at minimum, the registration of group allocation is no better than chance. When these criteria are applied to the sham treatment in this study, the lack of change in measures of pressure pain threshold, spontaneous pain by NRS101 (Table 2) and range of motion after a single treatment application suggest that the sham procedure is clinically inert. More patients reporting improvement in pain following treatment were in the RM group (38% vs 28% in

the sham group); however, this study was not designed for nor did it have sufficient power for this comparison.

With regard to masking of group registration, the results are consistent with Machado et al.'s qualification of a "structurally equivalent" [60] placebo. This is especially noteworthy given that almost all participants had had prior experience with cervical manipulation, with many having current treatment. The use of a "double" administration of treatment that paired sham with real or sham with sham in a dual maneuver mimics the common occurrence in practice where more than one procedure may be applied to the neck. At the same time it holds a potential advantage of increasing the ambiguity in the subject's experience as to which element the operator intends to be therapeutic. While the sensory input to the subject was comparable with respect to manual touch, head positioning, movement and sudden noise the force-time history of the applied loads demonstrate clearly the successful dampening of loads (Table 4) to a range of 10% to 50% of the treatment loads. The sole larger force in the antero-posterior direction matches the force necessary to trip the cam-drop mechanism and is independent of the treatment forces.

An obvious advantage of our procedure is that it is a manual sham maneuver making it a desirable comparison to other manual methods. Previous randomized clinical trials of manipulation have employed other forms of placebo or sham control [28–32]. Two studies employed a de-tuned therapy instrument [31, 32] whereas Sloop et al. [29] employed a manipulation under anamnestic valium administration, attempting to avoid all sensory cues. Only Vernon et al.'s trial [30] for manipulation and tension-type headache attempted a manual sham manipulation procedure [37], but this was in conjunction with a placebo version of a medication, creating a double-placebo condition that did not permit the identification of the separate effect of the manual sham.

An observation noted on secondary analysis, is the tendency of subjects, when their clinical findings improve to a minimum clinically important difference of 20%, to identify their group allocation as being RM, regardless of their actual group assignment. This happened in 83% and 23% of the subset of subjects who achieved a minimum clinically important improvement in the real and sham treatment groups, respectively. This may provide a means in future studies to begin understanding those who are sometimes called placebo responders [35–38, 40, 59].

The most important limitation of this study is that the findings apply only to a single treatment over a 24-hour investigative interval. It is not known if these procedures can sustain similar levels of blinding and, in the case of the sham manipulation procedure, the same levels of inertness over a series of treatments over intervals of many days. This is a critical topic for future research. Future studies should also address subject's baseline clinical expectations as well as the reason(s) they give for their post- intervention group registration.

Conclusions

The double-treatment method of pairing real-sham and sham-sham procedures using carefully selected physical components that systematically account for patient experience during manipulation provides an effective and inert sham/placebo for manual manipulation of the cervical spine.

Acknowledgments

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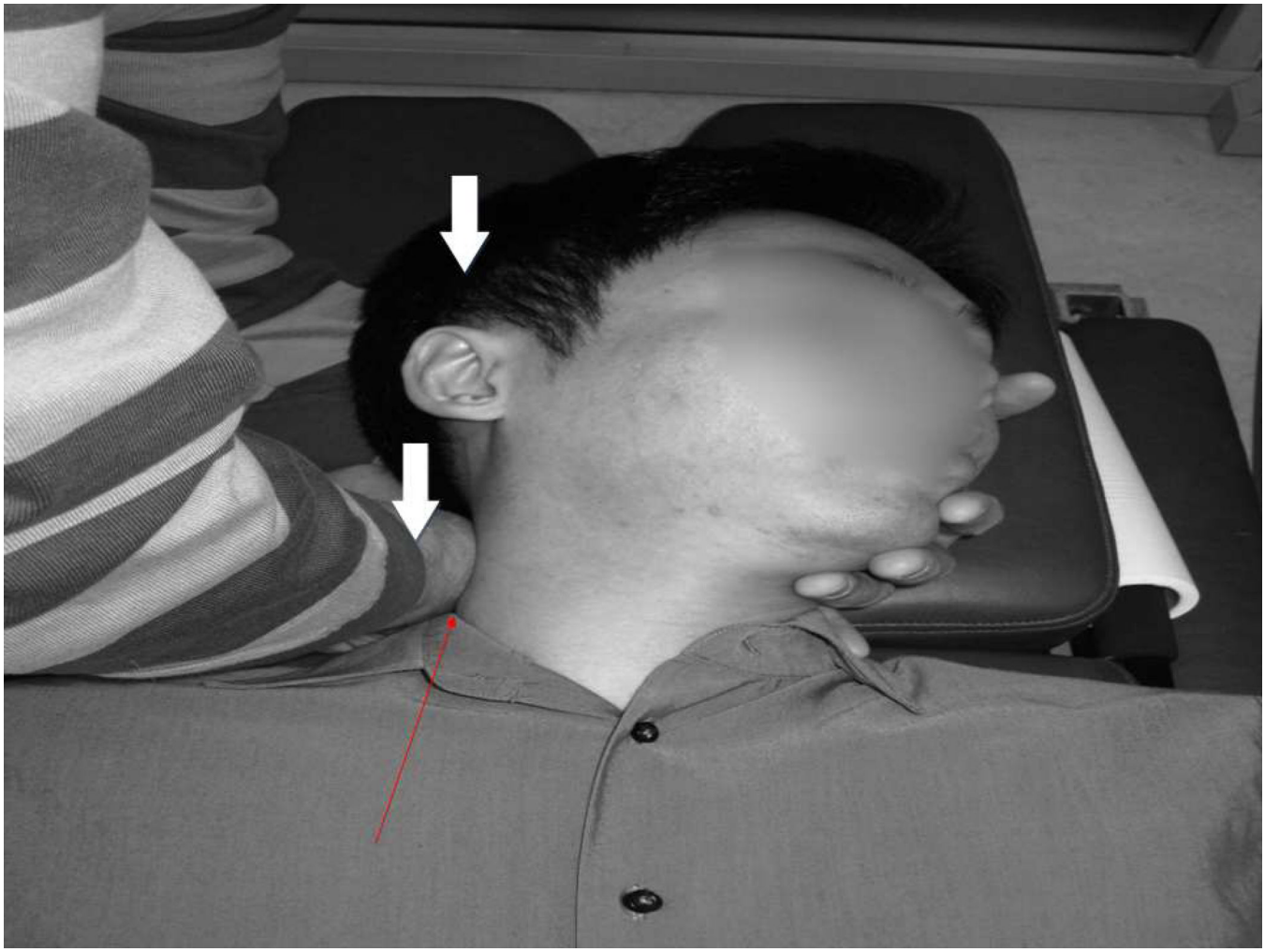
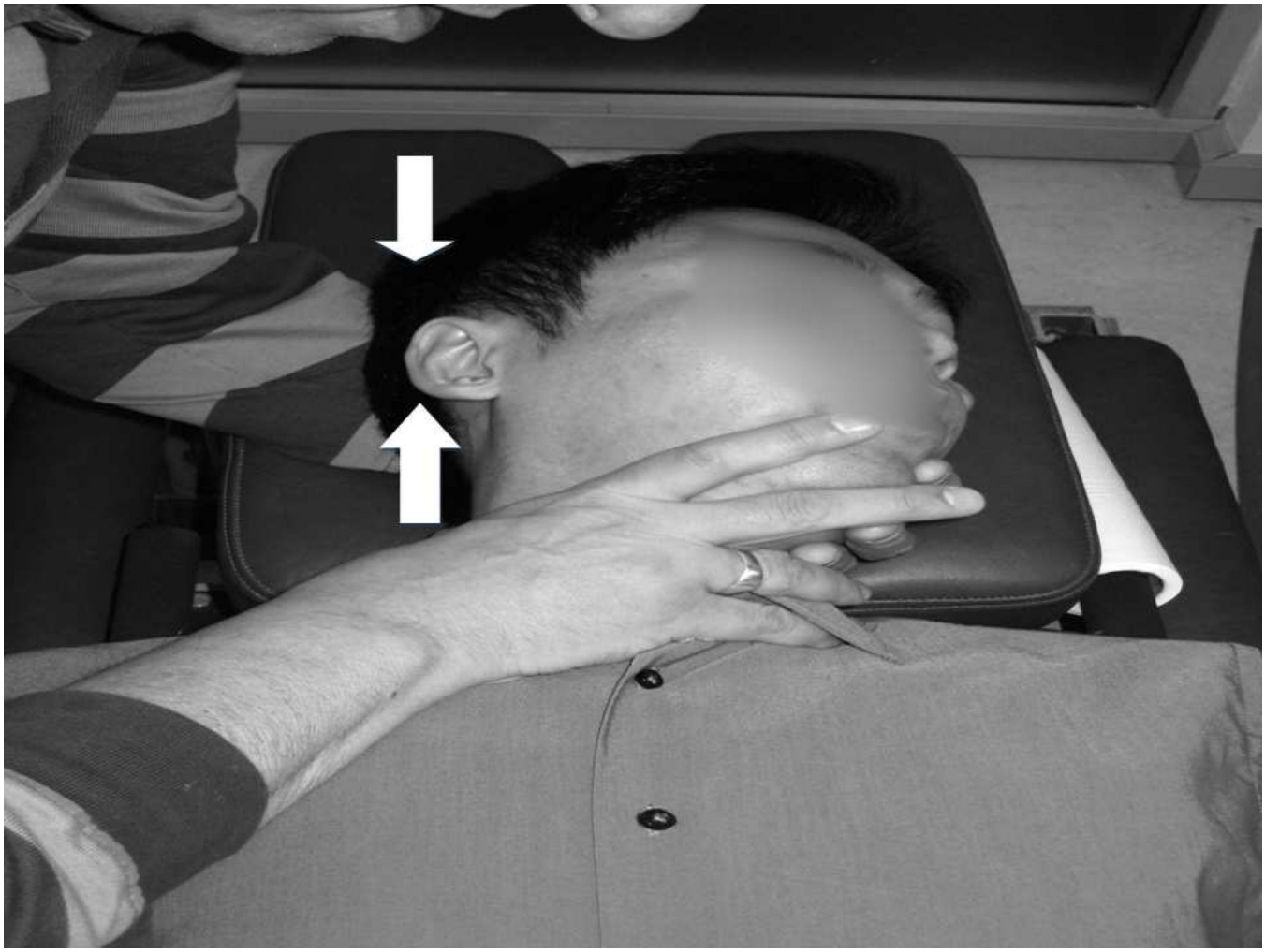


Figure 1.
Head and operator arm orientations for the SM. Wide arrows show the direction of the downward force to trip the cam mechanism. The thin arrow shows the skin contact between the arm and patient's neck.



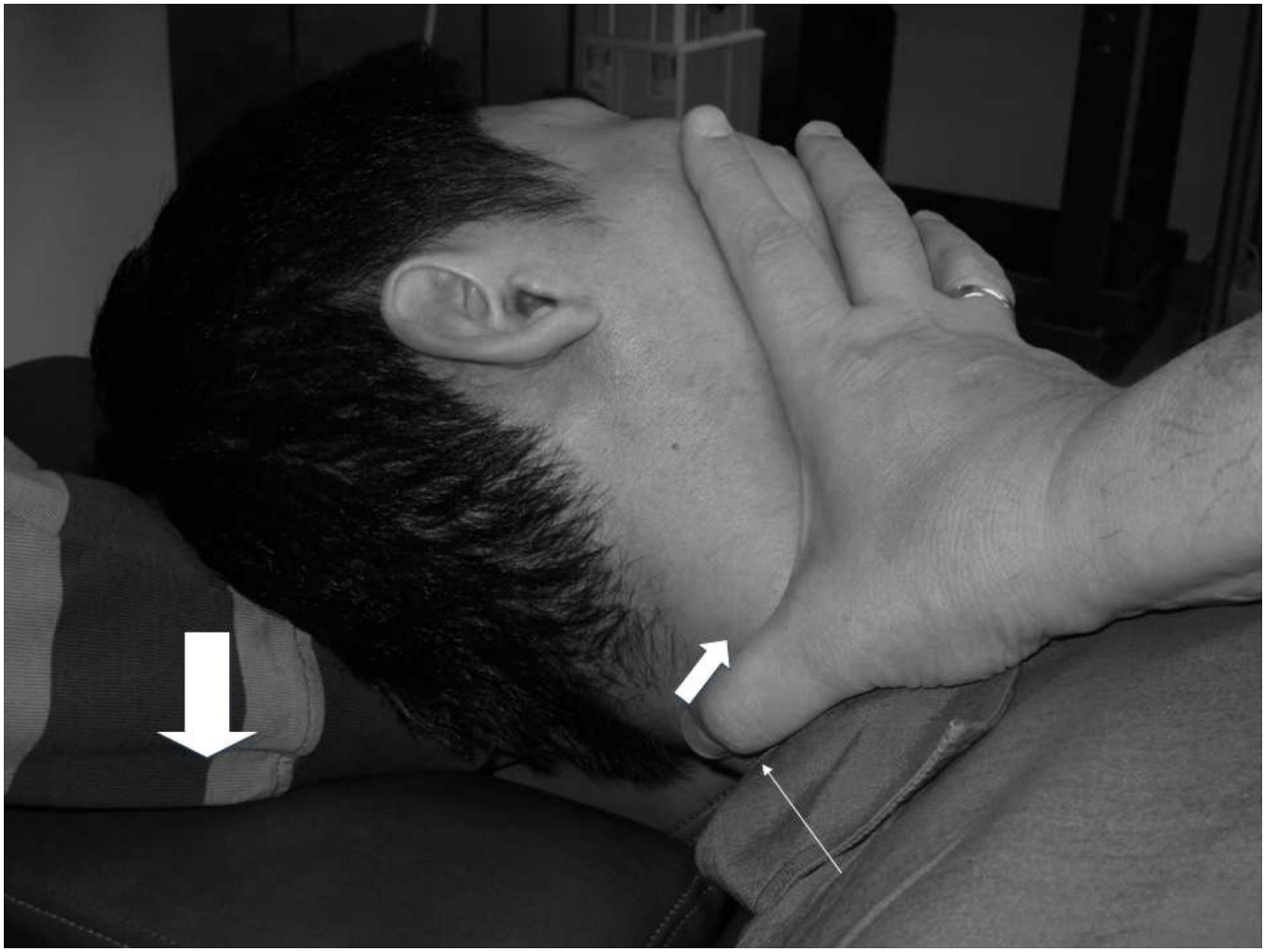


Figure 2.
RM configuration; the wide arrow shows the force to trip the cam and the thinner arrow gives one component of the intended treatment force.
RM configuration; the wide arrow as in 2a; the manual contact with the operator's thumb (thin arrow) and direction of second intended component (thinnest arrow) are shown (head is over-rotated to show thumb contact).

Table 1

Inclusion / Exclusion Criteria

Inclusion:

- male or female 18–60 years of age
- chronic pain ≥8 weeks duration
- NRS-101 pain scale range 30 to 65
- a specified cervical segment where pain is aggravated by selectively stressing that segment with no pain upon stressing adjacent segments (IASP [41]).

Exclusion:

- Medical history
  - prior history of stroke or TIA or current symptoms including:
    - dizziness or vertigo
    - tinnitus
    - visual, sensory or motor disturbances
    - new pattern headache complaint
  - upper respiratory infection within 4 weeks
  - regional injury or disease
    - recent whiplash injury (within 12 months)
    - cervical fracture/dislocation
    - discopathy with radicular symptoms
    - severe degenerative joint disease
    - connective tissue disorders
    - primary fibromyalgia
    - metabolic or metaplastic bone disease
    - cervical spine surgery
  - uncontrolled high blood pressure or vascular disease;
  - current use of anticoagulant therapy
- Examination findings
  - Pain provocation testing > 7/10
  - radicular arm pain
  - hypermobility of multiple peripheral joints

Table 2

Baseline Characteristics – Sham and Real groups

VARIABLE	SHAM	REAL	TOTAL
Number enrolled	34	33	67
Session Success	97% (1 drop out;1 protocol violation)	97% (1 protocol violation)	
Number analyzed	32	32	64
M/F	12/20	18/14	30/34
Age	38.8 (11.3)	38.3 (9.9)	p = 0.46
Height (in; M/F)	68.6(3.8)/63.3(2.3)	69.8(3.4)/62.4(4.6)	p = 0.27
Weight (lbs; M/F)	179.2(19.5)/158(3.2)	185(39.1)/142.9(31.2)	p = 0.90
Duration (Months)	31.4 (43.6)	48.9 (82.6)	p = 0.16
NRS	49.5 (17.6)	44.4 (15.3)	p = 0.09
Tenderness	58.8 (31.4)	65.7 (32.4)	p = 0.19

Table 3

Intervention and post-intervention outcomes

	SM Group (Correct/Incorrect)	RM Group (Correct/Incorrect)	Significance
Treatment Registration	15/17	16/16	p=0.80
Procedure painful	3/32 mild	4/32 mild	p = 0.689
Reaction at follow-up	0/32	1/32 mild	
Cavitation (procedure 1/procedure 2)	0%/0%	87%/0%	Not tested
Pressure Pain Threshold (Kilopascals) **Baseline** **5 min post** **15 min post**	405.4 (216.5) 404 (227.5) 418.5(278.5)	456.4(226.1) 408.8(211.6) 408.8(211.6)	p= 0.166
NRS-101 Pain Score **Baseline** **5 min post** **15 min post**	50.4(17.5) 45.7(20.1) 43.4 (20.9)	44.3(15.5) 37.2 (16.7) 36.1 (17.4)	For Time only (both groups), P = 0.049

Table 4

Change in pain pressure threshold and NRS101 pain scores.

	Pressure Pain Threshold						NRS101					
	Sham			Rea Manipulation			Sham			Real Manipulation		
	Correct	Incorrect	P	Correct	Incorrect	P	Correct	Incorrect	P	Correct	Incorrect	P
N	15	17		16	16		15	17		16	16	
5 min- Baseline	4.7 (4.1)	−4.6 (3.1)	0.08	−4.8 (4.1)	−8.8 (3.6)	0.47	−4.3 (1.7)	−5.0 (2.9)	0.85	−12.2 (4.7)	−1.9 (1.9)	0.05
15 min- Baseline	0.6 (5.4)	2.9 (6.6)	0.79	−2.5 (4.6)	−6.9 (3.4)	5.5	−5.5 (2.3)	−8.2 (3.2)	0.49	−14.7 (5.1)	−1.6 (1.5)	0.02

Table 5

Peak force components of Sham and Real maneuvers defined in terms of percent of subject body weight. Negative signs denote direction opposite positive values.

	Sham Maneuver		Real Maneuver		
	mean	**sd**	**mean**	**sd**	**P**
Left Transverse	−0.1	3.5	2.5	3.7	0.01
Right Transverse	0.4	3.1	−3.8	5.2	0.0006
Left Axial	−1.2	3.1	2.4	9.4	0.055
Right Axial	−1.2	3.6	7.3	8.4	0.0001