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ARTICLE

Spinal Intervention Efficacy on Correcting Cervical Vertebral Axes of Rotation and the Resulting Improvements in Pain, Disability and Psychsocial Measures

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Abstract

Objectives: Mean axes of rotation [MAR] of cervical joints are an effective measure of spine pathology. Khan Kinetic Treatment [KKT] is known to relieve symptoms, but its biomechanical effects have not been quantified. This study assesses KKT efficacy using MAR correction and its associated effects.

Methods: The intervention applies vibrations via stylus to a bony landmark of the spine. Using saggital plane cervical X-rays, pre-post intervention MARs were computed for 44 patients with chronic neck pain. The study was randomized, single blinded, and sham controlled for outcome measure comparisons. Mechanical input was assessed using a load cell and vertebral acceleration and the outcome measures were: 1. cervical MARs, 2. self-reported neck pain, 3. neck disability index scores, and 4. psycho-social assessments.

Results: 1. Average peak force on vertebrae during treatment was 10.3 N and the average peak acceleration was 2.19G, 2. KKT improved pain and neck disability scores significantly over shams, 3. KKT corrected 62 percent of abnormal MARs with significantly larger MAR vector magnitude differences [pre-post] at the C5-6 level than shams, 4. in patients without changes in MAR locations, KKT significantly improved neck disability scores above shams, 5. MAR correction was significantly related to improving both pain and neck disability across all subjects.

Conclusions: We present biomechanical evidence of spinal "re-alignment" and its ability to improve both pain and neck disability. Capacity to improve neck disability despite no change in MAR locations indicates that MAR correction, while effective, is not the sole mechanism behind the interventions success.

Keywords: Pain, axes of rotation, disability, spine, biomechanics, assessment

INTRODUCTION

Mean Axes of Rotation

Tools to validate new spinal treatments are scarce as patients with neck pain typically do not exhibit obvious abnormalities in plain neck radiographs (1–3). Noting the lack of effectiveness of neck range of motion [ROM] investigations, investigators began exploring the notion of the quality of motion of the cervical vertebrae, they reasoned that while ROM may be normal, abnormalities of the cervical spine might be revealed by abnormal motion patterns within individual joints (4). When a cervical vertebra moves from full flexion to full extension, its path appears to lie along an arc whose center lies somewhere below the moving vertebra. This center is called the mean axes of rotation [MAR] and its location can be determined using geometry (5). Further, ROM has been shown to be an unreliable measure of cervical joint pathology (4), and has a

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larger technical error than MARs (6). Normative MAR data of the cervical spine were provided by Penning (7,8). However, improvements on the technique occurred over time (9–11). Amevo et al. (11) developed accurate maps of the mean location and distribution of the instantaneous axes of rotation of the cervical motion segments based on normalized values. This study showed that the interobserver variation of construction of the normalized MAR was small as they differed by a maximum of 0.12 ± 0.14 mm in the X coordinate and 0.14 ± 0.16 mm in the Y coordinate (10). Further, the maximum relative variations [one standard deviation of the interobserver differences divided by the quantity being measured] found were 0.11 in the X coordinate and 0.10 in the Y coordinate (10). These MAR locations and distributions agreed with those described by Penning, and the new data offered the advantage of being able to be described statistically. Hypotheses concerning the normal or abnormal locations of MARs could now be tested. van Mameren et al. (6) showed that in contrast to cervical ROM, a given MAR can be reliably calculated within a small margin of technical error.

Abnormal MAR

The first exploration of abnormal cervical MARs was performed by Dimnet and colleagues (12). However, abnormal MARs was not investigated formally until Amevo et al. (13) studied 109 patients with post-traumatic neck pain. The MAR locations were subsequently compared with previously determined normative data (11). It emerged that 72 percent of the patients with neck pain exhibited at least one abnormally located cervical MAR. The relationship between axis location and pain was highly significant statistically [$P < 0.001$]. However, no relationship was reported between the cervical segmental level of an abnormally located MAR and the segment found to be symptomatic on the basis of provocation discography or cervical zygapophysial joint blocks (13). The difference between abnormal MARs and intrinsic abnormality locations suggests that MAR abnormalities were secondary to separate factors [e.g. muscle spasms]. In fact, it has been hypothesized that the location of any normal or abnormal cervical MARs are governed by the net effect of compression forces, shear forces, and moments acting on the moving segment (14).

Application of MAR

The MAR technique has currently been used for characterization of normals and the identification of abnormal MARs, but no articles using the technique to asses a spinal treatment could be found in the literature.

The five purposes for using MARs to assess the interventions efficacy are: first, an abnormal MAR provides biomechanical evidence that agrees with the Yale University School of Medicine's spinal injury model (15). The model fits well to the interventions hypothesized mechanisms of success (16). Second, an abnormal MAR that is corrected confirms our hypotheses of the effects of vertebral linear displacement regarding the intervention as indicated in a previous review on spinal mechanisms of chronic pain (17). Third, utilizing readily available x-ray technology allows this technique to be used widely and at the clinic level. Fourth, this technique has been validated with both normal and pathological patient pools (6,8–11,13,14,18). Fifth, there is a potential to use a combination of MAR and traditional methods for differential diagnosis and treatment follow up in our clinics. The overall purpose of this study, however, was to characterize the mechanical input of the intervention, test its ability to correct cervical MAR in humans, and determine effects of the intervention and MAR correction on patients with chronic neck pain.

MATERIALS AND METHODS

Participants

Ethics approval was obtained from the Institutional Review Board Services [Aurora, Ontario, Canada]. Procedures were conducted according to the Helsinki Declaration (19), clearly explained to all subjects, and participants signed a consent form prior to participation. All information regarding the participants has been kept confidential.

A total of 56 subjects were recruited for the study; however, 10 withdrew, one moved away, and one died of an unrelated incident. Forty four subjects completed the study [22 treatment, 22 sham], 23 female [13 treatment, 10 sham], and 21 male [nine treatment, 12 sham]. These participants were between the ages of 18 and 66 years [40.7 ± 11.8] and had a recurrent history of varying levels of chronic neck pain [longer than six months] (20). Inclusion criterion was chronic neck pain of non-cancerous origins. Exclusion criteria were pain related to tumors, fractures, dislocations at any joint, infections, or destructive lesions. The prevalence of normal and abnormal MARs in 44 patients with chronic neck pain, at one or more spinal levels, was 24 percent and 76 percent, respectively [Table 1]. The groups [treatment versus sham] MAR abnormality, age, gender, pre-

Table 1. The Prevalence of Normal and Abnormal MARs Occurring in 44 Patients with Chronic Neck Pain, Showing the Proportions of Subjects Who had no Abnormal MARs and Those Who had Abnormal MARs at One or More Spinal Levels

MAR	Prevalence
Normal	24%
Abnormal	76%

MAR = mean axis of rotation, Prevalence = the total percentage of cases with none [normal] or at least one abnormal [abnormal] cervical region MAR in the given patient population.

pain levels, pre-neck disability levels, and psychosocial status did not differ significantly [$P > 0.05$], demonstrating that the groups were comparable.

Intervention

The Khan Kinetic Treatment [KKT], manufactured by StarFish Product Engineering Inc. [Victoria, British Columbia, Canada], is a spinal and upper cervical treatment device consisting of a controller mounted on top of an impulse delivery mechanism, or device head, which is mounted on a movable armature to a fixed stand [Figure 1, top]. For this investigation the device head generated waveforms [sinewave at 50–110 Hz] and the stylus located at the base of the device head mechanically transduced the waveforms through the skin and ultimately to the spine, as it is placed over a spinal bony landmark, causing minor vibration of the vertebrae and minor repetitive stretching/activation of the attached soft tissues [Figure 1, bottom]. The device head may be freely moved in three dimensions so that the stylus may be positioned accurately on the skin. The stylus amplitude is controlled by a touch screen setting which controls the amplitude of current that is supplied to the stylus actuator. As the device head is fixed in location, a collapsible rod provides a necessary element of safety to the patient. The rod has been designed to collapse under sufficient force that indicates a nonclinical incident [i.e., the patient moves out of position]. The position of the rod is being tracked by a Hall effect sensor. Thus, if the rod collapses, the device turns off within a few milliseconds.

The KKT is being used and further developed by Optima Health Solutions International Corporation [KKT International]. Device design, research, development, and manufacturing operations conform to the International Organization for Standardization standard 13485:2003 [No. 9309]. The KKT has class 2 approvals by the Medical Devices Bureau of Health Canada [No. 68884] and a 510 [k] from the Center for Devices and Radiological Health of the Food and Drug Administration [No. K060043].

Patients in both groups were required to undergo treatment, either actual or sham, two or three times per week for a period of four to six weeks with each treatment lasting about 10 minutes. A more detailed description of the device has been published previously (16).

Experimental Design and Outcome Measures

This study characterized the KKT's mechanical input to the spine using bovine tissue and examined its ability to cause changes in human cervical MAR and related its effects on changes to patient outcome measures when compared to a sham control group over the same period of four to six weeks. Standardized outcome measures included: 1. self-reported levels of neck pain that range from "none" to "worst" on a scale from 0 to 10 (21), 2. a neck disability index test (22,23), and 3. independent measures of depression, anxiety, and stress [DASS 42] (24). The study design was single blinded, sham-controlled, and randomly assigned. Subjects were required, via informed consent, to inform the intake clinician of any other form of therapy prior to the start of the study or should they begin participating in any other means of therapy during the study. Subjects understood that either may disqualify them from continuing with the study. Once enrolled in the study we randomly split participants, who were blinded to group allocation, into two groups: treatment and sham, using the complete randomization technique [i.e. no stratified groups]. The sham treatment consisted of applying KKT at reduced amplitude on the soft tissues of the trapezius muscle rather than on a bony landmark of the transverse process of the atlas typically used during actual treatment. The mechanics of the stylus input in both sham and actual treatment were quantified using intact bovine tail in a clinical emulation set-up, three-dimensional acceleration [Analog Devices, MA, USA], and a 100 lb. load cell [Honeywell, NJ, USA; Figure 2]. The imparted mechanics set-up mirrors the KKT treatment, where mechanical vibrations are transmitted to the spinal system via the devices stylus tip. The load cell and accelerometers were attached directly to vertebrae in order to achieve accurate measurements.

The treating clinician could not be blinded to the treatment since they were required to administer it. However, subject contact with the treating clinician was standardized between the two groups and reduced to only necessary discussion. Questionnaires were administered by separate staff in the waiting room of the clinic.

X-Rays: To determine the MAR, lateral radiographs of the cervical spine in flexion and extension were analyzed. In obtaining cervical imaging [C0-7],

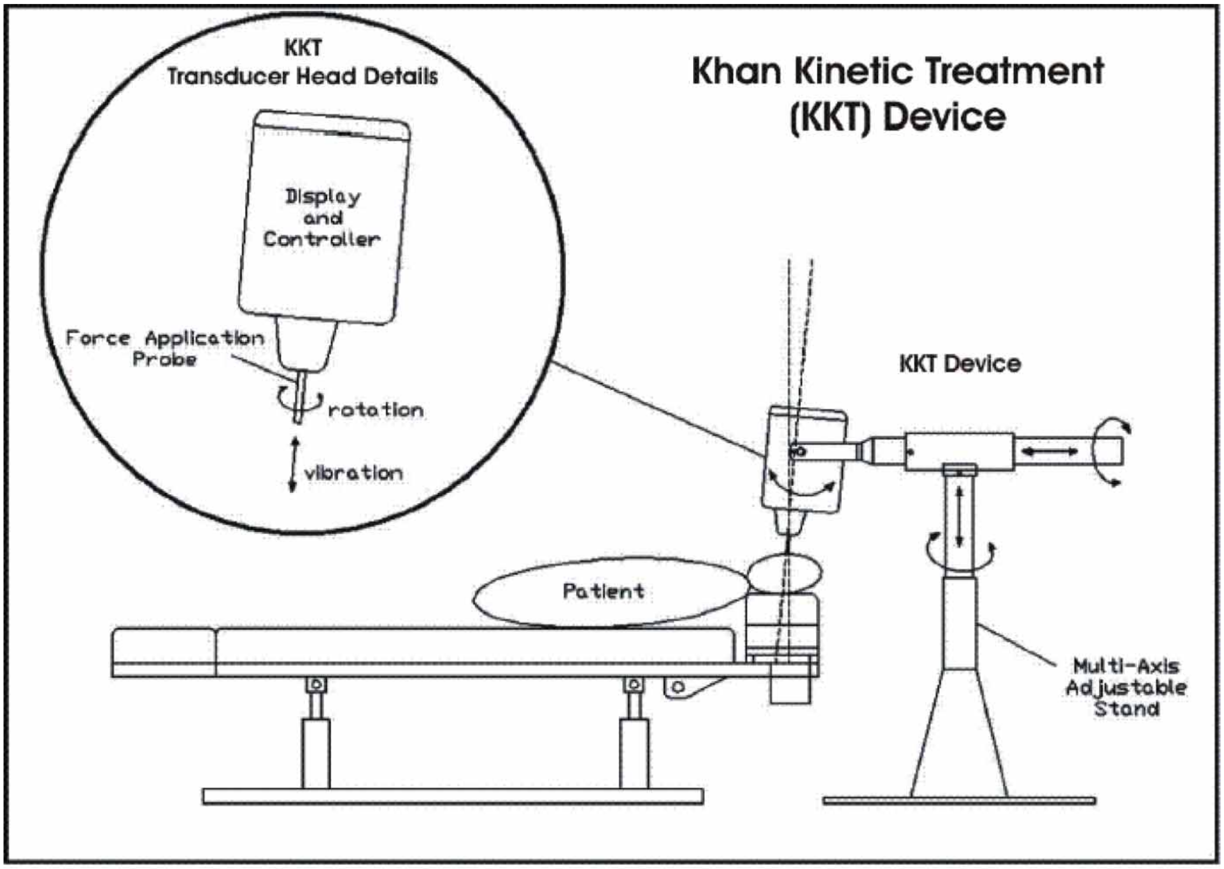

Figure 1. KKT prototype set-up.

subjects were seated comfortably, fit with the cervical ROM device [Performance Attainment Associates, St Paul, MN], and performed full cervical flexion and full cervical extension while maintaining both an erect torso and head alignment in the sagittal plane. Position was monitored using the cervical ROM device. The ROM in flexion-extension was not measured since calculation of the MAR does not depend on it.

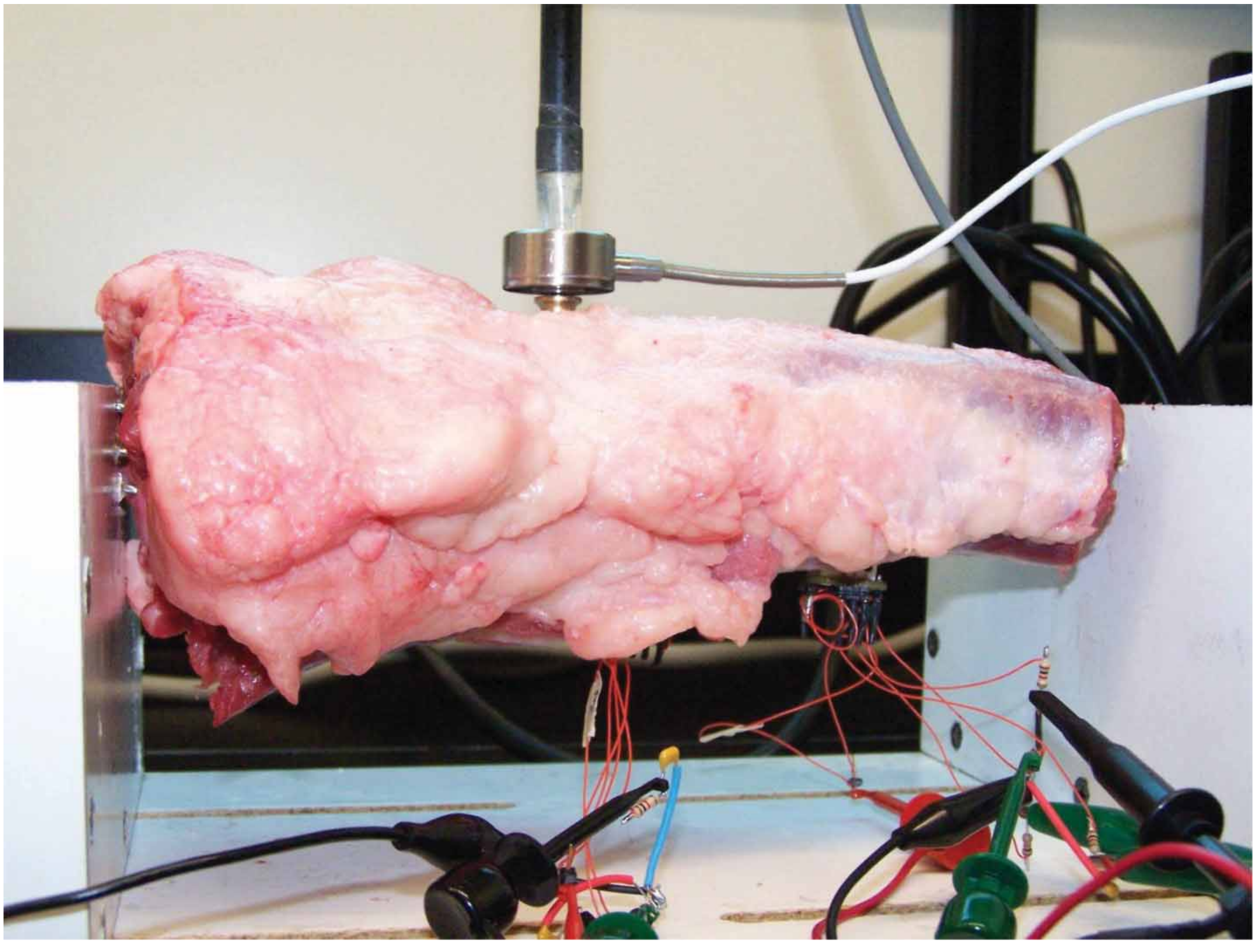

FIGURE 2. Imparted mechanics set-up. 100 lb load cell is attached to cleaned section of central vertebrae [five in total] and aligned with stylus of device. Three-dimensional accelerometer on central vertebrae [bottom] measures stylus effects on *in situ* vertebrae.

MAR Computation: Using data from control subjects, Amevo et al. (11) computed standard errors plus a technical error that can be used to determine a two-dimensional ellipsoid of "normal" [within the ellipsoid] and statistically "abnormal" [external to ellipsoid]. We use this definition when classifying subject MAR data [Figure 3]. A detailed description of how to perform MAR computation is provided in supplemental material. To gain additional detail from MAR locations, the hypotenuse of each was calculated using Pythagoreans theorem [pre and post for both groups] forming the MAR vector magnitude. Further, the difference between the pre and post MAR vector magnitude was also determined [Figure 4].

Statistical Justification of Group Size

Based on previously existing published data for each outcome, statistical power calculations were run using JMP IN [version 7.1] software, a statistical power curve was used to justify the number of subjects in each group [treatment versus sham]. The number of subjects chosen was based on a *minimum* desired power level of 60 percent. Based on an alpha level = 0.05, to detect a 50 percent shift in the mean response, N = 16 [eight per group] was required to achieve 60 percent power on the 11-point pain scale, and N = 20 [10 per group] to achieve 60 percent power on

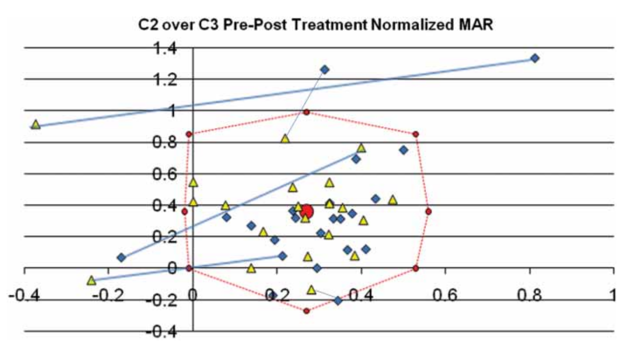

FIGURE 3. A scatter plot of normalized MARs for the cervical motion both pre [diamond] and post [triangle] treatment [treatment group only]. Abnormal MARs are tracked with a line connecting pre and post treatment MARs. The dotted line represents the 95 percent confidence interval from the normal segment MAR mean [circle] plus the technical error inherent to the technique at that segment level.

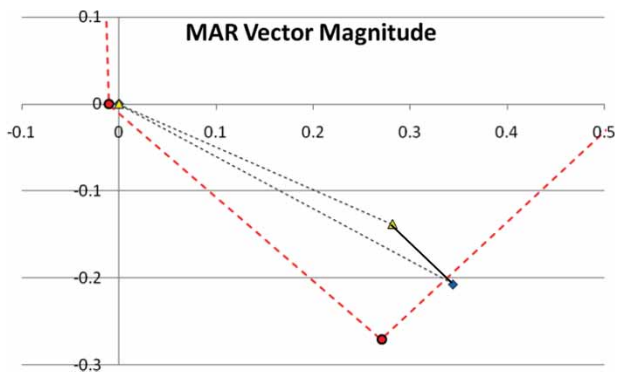

FIGURE 4. MAR vector magnitude example. First, the hypotenuse [dashed line] is calculated for the pre-treatment MAR [diamond] and the post-treatment MAR [triangle], and then the difference between them is calculated [solid line]. The MAR vector magnitude differences were subject to statistical analysis.

the Neck Disability Index scores. Since, N = 44 [22 per group] in this study we demonstrate that the number of subjects more than double the number of subjects recommended by statistical power analysis.

Statistical Methods

A Shapiro–Wilk test statistic and a normal probability plot were used to test the normality assumption for all data sets. If a non-normal distribution was discovered, a non-parametric test [Kruskal–Wallis chi-square test] was used to compare median scores between groups for that particular data set. A two-tailed t-test was used to compare mean responses between groups for all normally distributed continuous data. Fisher's exact test was used to compare proportions between groups when the expected cell counts were less than five. Chi-square tests were used to compare proportions between groups when the expected cell counts were greater than five. A Pearson correlation matrix was used to determine if there was a linear relationship between important factors.

RESULTS

Imparted Mechanics

While the force applied to the central vertebrae of the five segments in situ bovine tail was only 25 percent smaller in the sham group, the resulting z-axis acceleration was 40 percent reduced [Table 2].

Mean Axes of Rotation

The four conditions of pre- and post-treatment abnormal/normal MAR, for both subject groups [Table 3], at each spinal level from C2-3 to C6-7, suggests two observable trends: 1. KKT corrected over double the percent of abnormal MARs to within the normal region [62 percent] compared to the sham group [30 percent] with significantly [P = 0.028] larger MAR vector magnitude differences [pre-post] at the C5-6 level than shams, 2. Two percent of normal MARs were found to be abnormal after treatment and eight percent in the sham group.

TABLE 2. Quantifying Imparted Mechanics Using *In situ* Bovine Tail and Direct Stylus Contact with the Central Vertebrae [Five in Total] of the Specimen

Intensity	Force on vertabrae [peak-N]	SD	Z-axis acceleration of vertebrae [peak-G]	SD
0.2	7.8	1.9	1.30	0.20
0.5	10.3	1.9	2.19	0.62

An intensity of 0.2 was used for the human sham group but was applied to the fleshy portion of the trapezius muscle. Results here therefore represent the maximum the stylus was capable of applying to C1 in humans. The actual treatment in humans was applied at an intensity of 0.5 and so the results here represent its mechanical input. Intensity = clinician parameter on device that sends more or less current to the actuator, Force on Vertabrae = averaged peak force of vibration over 100 cycles, acceleration of vertebrae = averaged peak, acceleration [g] over 100 cycles, SD = standard deviation.

The reported MAR correction, lack of change, and deviation from normal to abnormal [Table 4], each relate to improvements in neck disability and pain categories. When a MAR is corrected from abnormal to normal there is a significant trend to improve both pain [P = 0.024] and neck disability [P < 0.001] across all subjects that experienced a corrected MAR regardless of group. Further, in patients that did not experience MAR correction, KKT was able to improve neck disability beyond that of sham despite no changes in MAR location [P = 0.044].

Neck Pain, Disability, and Psycho-social Measures

KKT improved pain [P = 0.011] and neck disability scores [P = 0.009] significantly compared to sham controls. While no significant differences existed between the sham and treatment groups concerning psycho-social measures, the correlation matrix revealed that there was a significant linear trend between C4-5 and C5-6 MAR vector magnitude differences [pre-post] and differences [improvements] in both depression [C4-5: r = 0.582, P = 0.007, C5-6: r = 0.582, P = 0.007] and anxiety [C4-5: r = 0.537, P = 0.015, C5-6: r = 0.537, P = 0.015] across the treatment group. When the percentage improvements represented by the difference between pre and post pain scores are expressed as a percentage and rounded to the nearest 10 we see that larger percentage differences are present in the treatment group [Tables 5].

TABLE 3. The Distribution of Pre-abnormal and Pre-normal Mean Axis of Rotations Across Groups and Spinal Levels

	sig Pre-ab to Post-norm	sig Pre-ab to Post-ab		
Coordinates	N	N	Totals	% Pre-ab
C2–C3	3 [0]	1 [7]	4 [7]	31 [35]
C3–C4	1 [2]	0 [1]	1 [3]	8 [15]
C4–C5	0 [2]	0 [1]	0 [3]	0 [15]
C5–C6	2 [0]	1 [2]	3 [2]	23 [10]
C6–C7	2 [2]	3 [3]	5 [5]	38 [25]
Totals	8 [6]	5 [14]	13 [20]	
%	62 [30]%	38 [70]%		
Coordinates	sig Pre-norm to post-ab	sig Pre-norm to Post-norm	Totals	% Pre-norm
	N	N		
C2–C3	1 [1]	16 [13]	17 [14]	20 [18]
C3–C4	0 [1]	21 [17]	21 [18]	25 [23]
C4–C5	1 [2]	21 [16]	22 [18]	27 [23]
C5–C6	0 [0]	19 [19]	19 [19]	23 [24]
C6–C7	0 [2]	4 [7]	4 [9]	12 [5]
Totals	2 [6]	81 [72]	83 [78]	
%	2 [8]	98 [92]		

The outcome of four key pre and post MAR measures because of the intervention period over both groups [treatment [sham]] of patients with chronic neck pain. MAR = mean axis of rotation, N = number of MARs under that condition that are associated with that spinal level for each group, Treatment [Sham] = treatment group number of MARs given without brackets, Sham group numbers given in brackets, Coordinates = MAR coordinate spinal level. sig Pre-ab to Post-norm = before the treatment began the spinal segment MAR was statistically abnormal but after the treatment period its location became statistically normal. sig Pre-ab to Post-ab = before: the spinal segment MAR remained statistically abnormal throughout testing. sig Pre-norm to Post-ab = before treatment began the spinal segment MAR was statistically normalbut after treatment its location became statistically abnormal. sig Pre-norm to Post-norm = the spinal segment MAR remained statistically normal throughout testing. Totals = sum of either column or row for each group. %: Using the row and column totals and grand totals the percentage of each condition for each group is calculated.

DISCUSSION

The purpose of this study was to characterize the mechanical input of the intervention using bovine tissue, test KKT's ability to correct human cervical MAR, and determine effects of the intervention and MAR correction on patients with chronic neck pain.

Imparted Mechanics

It is important to note that while the bovine vertebral acceleration was reduced by 40 percent in the sham

TABLE 4. Pain [>20 Percent, ≤20 Percent and Worse] and Neck Disability Improvement [Improved, Same and Worse] as a Function of MAR [Correction to Normal, Tending to Normal, No Change or Moving to an Abnormal Position] Showing the Trends of Pain and Neck Disability as MAR Locations vary in Each Group

Pain % improvement	Sig Pre-ab to Post-norm[a] N	MAR-tended to normal N	MAR-no change N	Sig Pre-norm to Post-ab N
>20	6 [2]	1 [0]	5 [1]	2 [0]
<= 20	2 [4]	0 [3]	8 [5]	0 [5]
Worse	0 [0]	0 [0]	1 [4]	0 [1]
Neck disability improvement				
Improved	6 [6]	0 [1]	*10 [2]	1 [2]
Same	1 [0]	0 [2]	2 [5]	0 [3]
Worse	1 [0]	1 [0]	2 [3]	1 [1]

MAR = mean axis of rotation, N = number of MARs under that condition that are associated with changes in pain and disability. Treatment [Sham] = treatment numbers given without brackets; Sham group numbers given in brackets. [a]MAR correction significantly related to pain improvements [P = 0.024] and neck disability improvements [P < 0.001]. *Significantly greater than shams [P = 0.044].

TABLE 5. Subject Pain Scores [0–10] both Before and After Several Weeks of the Intervention Period and Their Associated Percent Pain Changes [100-0/Worse]

Pain score	Pre-treatment N	Post-treatment N	% Reduction in pain	N
10	0 [0]	0 [0]	100	1 [1]
9	3 [0]	0 [1]	90	0 [0]
8	6 [4]	3 [4]	80	3 [0]
7	1[6]	1 [1]	70	2 [1]
6	3 [3]	2 [5]	60	0 [0]
5	0 [5]	3 [6]	50	5 [0]
4	2 [2]	3 [2]	40	2 [0]
3	3 [0]	1 [0]	30	0 [0]
2	3 [1]	3 [2]	20	2 [2]
1	1 [1]	5 [0]	10	3 [4]
0	0 [0]	1 [1]	0	3 [9]
			Worse	1 [5]

The percentage is the difference between pre and post pain scores expressed as a percentage and rounded to the nearest 10. N = number of subjects under that condition that are associated with the level of pain/changes in pain, Treatment [Sham] = treatment numbers given without brackets, Sham group numbers given in brackets, % Reduction in Pain = represents the difference between pre and post pain scores expressed as a percentage and rounded to the nearest 10.

condition, utilizing the reduced current to the actuator, the stylus was applied directly to the central vertebrae [five in total] of the bovine tail during the imparted mechanics measurements. However, during the human sham condition the stylus was applied to the central location of the muscle belly of the trapezius muscle. While transfer of load from the center of the trapezius muscle to the spine has not been delineated in humans, given that muscles act like mechanical low pass filters (25,26), it is likely that little to no load reached the spine. The sham subject would have still felt similar tactile sensations [vibration] to the skin over the trapezius muscle as the actual treatment group making this a sham condition.

Abnormal Cervical MARs

This study reported evidence that individualized and regular KKT treatment over a several week period is capable of correcting about 62 percent of abnormal cervical MARs, should one exist prior to treatment. This MAR recovery rate is over double that of the sham group but was not found to be significant statistically. While we believed the sham condition did not load the spine this insignificant finding may have been due to the fact that the sham condition actually did load the spine causing it to have a mild treatment effect; hence increasing the number of corrected MARs in the sham group. Motion at the C5-6 region, indicated by significantly larger MAR magnitude differences [pre-post] in the treatment group, is the area that compensates the majority of the motion in the cervical spine despite what level the abnormal MAR was corrected. Interestingly, Gertzbien et al. (27) discovered that there was a relationship between vector magnitudes of MARs and level of disc degeneration in cadaveric specimen. The research group showed that with increasing disc degeneration, MAR vector magnitude decreases. Therefore, correcting abnormal MARs tends to counter act the mechanical detriments that disc degeneration has on spine joint function at least at the C5-6 level. Further, one of the most common areas to herniate a disc traumatically is the C5-6 region of the cervical spine. Like the L4-5 region of the lumbar spine, these injuries are typically found in areas with the greatest ROM with respect to neighboring joints. While the cervical spine is related to mechanical linkages of the Kutzbach–Gruebler's equation for three-dimensional motion, it is clearly more complex and requires further study of this motion to gain full understanding of this finding.

Overall, two percent of MARs moved from normal to abnormal in the treatment group and eight percent moved from normal to abnormal in the sham. Moving in this opposite direction [normal to abnormal] is undesirable and could be considered an adverse event. While no statistical significance of the proportions between the groups existed for this "adverse event" the trend indicated that the treatment had a protective effect when compared to the sham proportion [four-fold decrease]. These findings promote use of the treatment as a means to correct abnormal MARs and shows that KKT treatment at the C1 level does affect motion and pathology at the lower levels of the spine, particularly at the C5-6 region, while improving MAR locations at other levels.

Interestingly, neck disability improved significantly in the treatment group in patients of either group that experienced no changes in MAR locations [Table 4, $P < 0.001$]. It is important to note that this is a separate finding from improvement in symptoms in patients that experienced MAR correction. There was an analysis of two different data sets [pre-abnormal to post-normal and MAR – no change] that assessed two different outcomes. The first [pre-abnormal to post-normal] assessed the symptoms of neck disability and pain as they relate only to subjects across both groups that experienced MAR correction. Whereas the second case [MAR-No Change] assessed only the effects of the intervention in patients across both groups that did not experience MAR correction. Hence, these are two different scenarios with two different outcomes. The interpretation is that MAR correction is a mechanism of symptom relief [first case] and that the KKT has other mechanisms of efficacy in addition to MAR correction that seem to effect neck disability only [second case]. These mechanisms have been previously published (16) but we provide a short summary here. First, KKT applies a linear displacement to the vertebrae of the spine as many manual therapy approaches recommend mobilization interventions especially if patients lack spine mobility and present with no sign of contraindications (28,29). Second, as a result of dysfunction the spinal muscle firing patterns change significantly (30) and gamma motor neuron sensitivity increases (31). This enhanced sensitivity may act to create load asymmetries on the spine. As the vertebrae are moved during the treatment, they stretch the muscles attached to them and as has been found previously in animal models, we note that the vibratory aspect results in decreases to gamma motor neuron input mediated by Renshaw cells activated during the vibration (32). Said another way, KKT treatment may relax the paraspinal muscles increasing function of the spine as a result.

Neck Pain and Disability

This study presented evidence showing that the treatment improves both chronic neck pain and neck disability significantly when compared to a sham group that protects against placebo effects. The relationships to pain found here agree with a previous neck pain study (16).

In contrast to Desmoulin et al. (16), this study showed the treatment also improves neck disability index scores compared to a sham group. However, the functional assessments used in the previous study did not follow any standard seen in the literature. Therefore, using validated methods (21) has substantially increased our ability to measure this improvement.

Psycho-Social Measures

Expectedly, pain and neck disability scores were strongly correlated to each other [$r = 0.600$, $P = <0.001$], but unexpectedly, all psycho-social measures [stress, anxiety, and depression] both prior to and after treatment were not correlated to either pain or disability [$P > 0.05$]. However, the MAR vector magnitude differences [pre-post] at the C4-5 and C5-6 level correlated with differences [improvements] in both depression [C4-5: $r = 0.582$, $P = 0.007$, C5-6: $r = 0.582$, $P = 0.007$] and anxiety [C4-5: $r = 0.537$, $P = 0.015$, C5-6: $r = 0.537$, $P = 0.015$] across the treatment group. This suggests that a pure biomechanical phenomenon resulting in an unknown physiological change due to KKT treatment causing MAR changes was responsible for the psycho-social response.

Such somato-psychological responses as opposed to psycho-somatic presentations test the traditional distinction between physical and mental disorders and are a constant source of debate (33). However, many researchers now believe that as long as clinical psychological disorders, such as depression, anxiety or otherwise, are not prevalent then it is likely any changes in quality of life seen in psycho-social measures are a consequence of changes in pain rather than vise-versa (34,35).

CONCLUSION

MAR correction was significantly related to improving both pain and neck disability across all subjects. KKT's linear displacement of cervical vertebrae and ability to correct a large portion of abnormal MARs and a significant larger change in MAR vector magnitude differences pre-post treatment at the C5-6 segment level shows biomechanical evidence for spinal "realignment" that results in significant improvements in pain and disability when compared to sham groups. In patients without changes in MAR locations, KKT significantly improved neck disability scores above the sham group that indicates that MAR correction, while effective, is not the sole mechanism behind the interventions success. We presume this is due to one or more of the devices previously published theories on treatment mechanisms.

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