Initial Results Using Khan Kinetic Treatment™ as a Low Back Pain Treatment Option

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ABSTRACT. *Objectives:* Demonstrate initial results using Khan Kinetic Treatment [KKT™] as a low back pain [LBP] treatment option.

Methods: A self-reported functional assessment, LBP questionnaire, and pain medication dose were used as the outcome measures for 48 matched subjects randomly split into two groups [treatment and control]. The treatment group underwent a treatment period consisting of several individual KKT™ treatments over a few weeks period, while the control group continued conventional treatment. A paired t-test analyzed the functional assessment scores and a two group by two LBP score [positive or non-positive] McNemar's test was used for the LBP questionnaires. Pain medication dose analysis consisted of a two group by two pain medication dose outcome [same or reduced] McNemar's test.

Results: Compared to a control group, the treatment group lowered both their self-recorded LBP scores [$P < 0.001$] and showed a strong positive trend to lower their pain medication dose [$P = 0.054$]. Only the range of motion assessment questionnaire [range of motion, overall activity, and recreation/work activities] detected changes in these measurements [$P = 0.046$, $P = 0.061$, $P = 0.052$, respectively].

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Conclusions: Although we await blinded and randomized placebo controlled trials, initial results suggest that KKT™ may be an effective treatment for LBP, may increase the range of motion, and may decrease the need for pain relieving medication. doi:10.1300/J094v15n03_12 *[Article copies available for a fee from The Haworth Document Delivery Service: 1-800-HAWORTH. E-mail address: <docdelivery@haworthpress.com> Website: <http://www.HaworthPress.com> © 2007 by The Haworth Press, Inc. All rights reserved.]*

KEYWORDS. Spine, Khan Kinetic Treatment™, pain, medical device, low back pain

INTRODUCTION

The Khan Kinetic Treatment [KKT™] manufactured by Datrend Systems Inc. [Richmond, British Columbia, Canada] is a medical device for the treatment of spine related abnormalities causing pain. The KKT™ is currently being sold, used, and further developed by Optima Health Solutions International Corporation [Optima]. The prototype design, research, development, and manufacturing operations conforms to the International Organization for Standardization standard 13485:2003 [#9309] and already has class two approval by the Medical Devices Bureau of Health Canada [#68884], a United States provisional patent [#60-556360], and electromagnetic compatibility approval of the European Community Council Directive 93/42/EEC [# 4131565] for a CE Mark in the European Union. The KKT™ is also being used in Germany. The device is still undergoing additional and more advanced clinical outcome studies in preparation for randomized placebo controlled clinical trials. The results summarized here are a consolidation of data recently acquired by utilizing the device in a clinical setting on chronic [longer than six weeks] low back pain [LBP] sufferers. Hence, these results are a prelude to additional placebo-controlled clinical outcome and high quality mechanistic studies in the near future.

Scope of the Problem

Low back pain is a common condition affecting a large percentage of the population. It is estimated that between 70 and 85 percent of the population will experience LBP at some point in their lives (1-3). Although the majority of these cases can be resolved within the first six weeks after treatment (2), the small minority that progress to become chronic draws a significant cost burden to our already taxed medical system (4,5). Not surprisingly, LBP is one of the most prevalent and costly health problems in Western society (1). Within British Columbia, Canada, LBP accounts for 25 percent of all workplace injuries and approximately 40 percent of compensation costs (6). Injury trends in North America have shown that disability from LBP dramatically increased between 1950 and 1980 (2,7) with disability rates increasing by 14 times the rate of population growth over this time period (7). These numbers are echoed in developing and industrialized countries across the globe. Low back pain incidence in rural North India is exacerbated by ignorance to report for early treatment and occupational obligations (8). Toroptsova et al. (9) from Moscow and Lau et al. (10) from Hong Kong state slightly lower [48.2 and 39 percent, respectively] life-time prevalence of LBP, but partly explain these results through differences in stature. Meanwhile, a study of adults from southern Brazil shows 4.2 percent prevalence of chronic LBP throughout its population (11). Lack of effective medical management is believed to be one of the primary causes of these numbers and their associated costs (2). The need for further understanding of these conditions is required to develop additional evidence-based treatment approaches to minimize the impact of LBP in society. The KKT™ takes into account the existing scientific knowledge base and was designed to accommodate to future clinically relevant biomechanical models in the treatment of LBP.

Review of Low Back Pain Treatment Options

Traditionally, LBP has been treated using many different approaches. The more conservative approaches include applications of ice

and heat (12), bed rest of no more than two days (13), general exercise, and specific conditioning of back and abdominal muscles to help stabilize hypermobile lumbar regions (14-16), spinal manipulation to increase the range of motion for hypomobile lumbar regions (17-19), massage therapy (20-22), and transcutaneous electrical nerve stimulation (23-25).

More invasive treatment involves the use of medications such as over-the-counter analgesics, opiates, anticonvulsant agents, antidepressants (26-28), acupuncture (20,22,29), epidural, and facet joint corticosteriod injections (30), spinal nerve blocking techniques (31-33), and depending on the diagnosis, surgery may consist of procedures ranging from microdiscectomy and spinal fusion to a full laminectomy (34-36).

Despite the multitude of treatments and clinical studies, LBP still remains one of the most elusive ailments of our time and lacks available standardized guidelines for treatment that achieve acceptable results (13). In fact, within the framework of evidence-based medicine [high-quality blinded randomized trials] being conducted, the best treatment for chronic LBP remains cognitive intervention combined with physical exercises specific for stabilizing the lumbar spine (8,16,30,34). Therefore, the need for further high-quality studies of new approaches is required for the advancement of patient care in the area of LBP.

Prior Art Review

Traditionally, over the centuries, spinal manipulation or impulse [low amplitude high velocity] treatment has been performed using bare hands (37). As the number of investigations using this methodology increases, it is becoming evident that the variability of patient outcomes implementing this type of treatment can be significant (30,37). These results may be due to the variability in the pressure applied by the hand due to variations in practitioner hand anatomy (19), variability in patient anatomy (38,39), or the variability of the application itself (40).

Spinal impulse treatment devices trying to circumvent these problems have been experimented with (41-46). United States Patent Number 4,461,286 describes a percussive prototype operated by a trigger (41). The hand held device [HHD] would be positioned, both in location and direction by a practitioner. These are known to be important elements in delivering impulses (19); however, the linear force impulse delivered by a loaded spring would have a tendency to drift over time as the mechanical properties of the spring began to fail. It is also completely dependent on the reactive force holding the prototype in place. United States Patent Number 4,841,955 is also a HHD but uses solenoids as a means to improve accuracy and repeatability of the linear force impulse (42). These devices only deliver a single force impulse.

The HHD US Patent Number 4,549,535 delivered multiple linear force impulses [pulse width, frequency, and amplitude] (43). A square wave drove the device. Using a square wave presented several drawbacks. Most importantly, abrupt forces to sensitive areas of the body are often considered undesirable. In addition, a perfect square wave places excessive performance requirements on the electronic and mechanical systems that attempt to produce them. As a result, high frequency artifacts in the impact pin might occur.

United States Patent Number 5,618,315 also describes multiple linear force impulses as well as rotational forces. However, draw backs are again using square wave forms to drive the impact pin and the uncertainness of a HHD (44). In addition, there are no fail-safe mechanisms built into the device.

Other devices exist [US Patent 6,228,042 and 6,602,211], but neither incorporates feedback on device position (45,46).

Objectives and Hypotheses

The first objective of the study was to show initial results demonstrating that the KKT™ is an effective LBP treatment option by reducing levels of pain experienced and improving overall function.Our hypothesis of this objective was that the majority of the treatment group would display an improvement in the post-treatment period [several individual treatments over three to six weeks] on both a self-reported functional assessment and an LBP questionnaire when compared to a control group.

The second objective of this study was to show initial results demonstrating that the treatment group reduced total dosage of pain medications being used during the post-treatment period. Our hypothesis of this objective was that in the post-treatment period, the treatment group would reduce the total amount of pain medication when compared to a control group.

The basis for these hypotheses was from the results of numerous case study reviews as the prototype is currently being used for the treatment of LBP.

MATERIALS AND METHODS

Ethics

Ethics approval was obtained from a formal research ethics review committee [Institutional Review Board Services, Aurora, Ontario] for the procedures outlined in this paper. The procedures were also conducted according to the Helsinki Declaration (47) and clearly explained to all subjects prior to participation. Subjects were asked to sign a consent form agreeing to full participation in the research protocol. They were also informed that they could withdraw from the study at any time without repercussions. All information regarding the subjects has been kept confidential.

Experimental Design

This was an initial results study that examined the ability of the treatment to cause changes in patient outcome. The design was a non-blinded, control-matched, randomly assigned clinical outcome study of a current LBP treatment option. All subjects that signed the consent form were first matched to the best of our ability regarding sex, age, and diagnosis. We randomly split the matched pairs into two groups: treatment and control. Although all subjects eventually underwent KKT™ treatment, the treatment group underwent the treatment period as soon as possible after signing the consent form. The control group agreed to continue with their current conventional treatment [undocumented] until the treatment match finished the treatment period. At that time both the control match and treatment subject underwent data acquisition for a second time.

Subjects

Subjects between the ages of 18 and 77 and having recurrent history of varying levels of disabling LBP were recruited for this study. A summary of the demographics, diagnoses, mechanism of injury and current medications are shown in Table 1.

Summary of Khan Kinetic Treatment™ and Protocol

The KKT™ is a spinal and upper cervical treatment device consisting of a controller mounted on top of an impulse delivery mechanism, or device head, which in turn is mounted on a movable armature to a fixed stand [See Figure 1]. The device head may be freely moved in three dimensions. At the base of the device head there is a stylus used to deliver the sinusoidal wave forms of various frequencies and intensities both linearly and rotationally. Since the device head is fixed in location, a collapsible rod provides the necessary element of safety to the patient. The rod has been designed to collapse under sufficient force that indicates a non-clinical incident. 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. In addition, prior to treatment, the subject receives a thumb depressed "kill" switch which, when depressed, immediately stops the device from continuing treatment.

Although we reserve the right to apply the device anywhere along the spine, we have found the best results are achieved at all spinal levels when we apply the wave forms to the transverse process of the atlas, as we did in this study.

Software receiving the patients' intake digital radiographs automatically calculates critical angles necessary to make clinical decisions. For obvious reasons following standard medical clinical protocols, clinical decisions were also based on physical examination, diagnosis, current medications, and clinical experience. Once the precise location and type [amplitude,

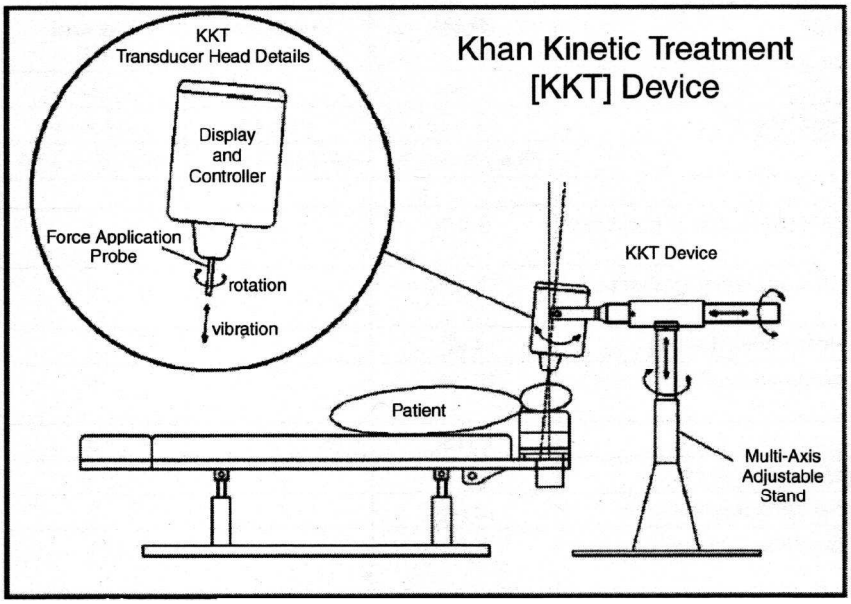
TABLE 1. Demographics, Diagnosis, Mechanism of Injury, and Medication Summary for All Subjects

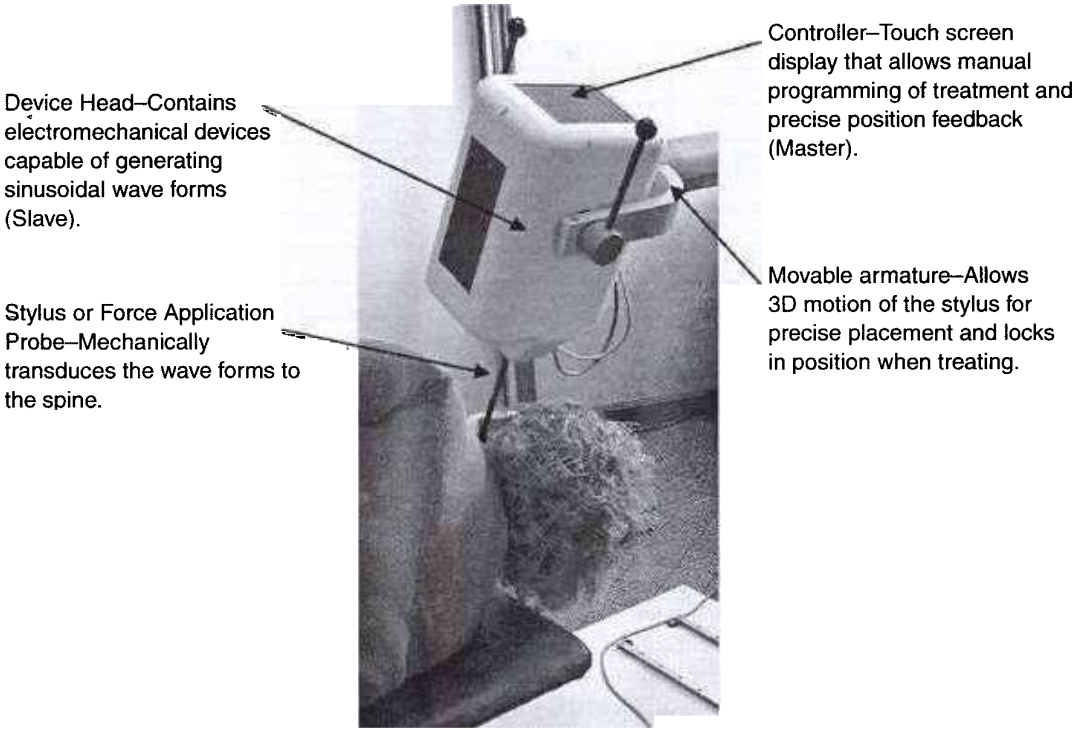
Demographics	Total	Treatment [N]	Control [N]	P-Value
N	48	24	24	N/A
Age [mean ± SD years]	43 ± 15	41 ± 14	44 ± 15	0.138
Gender	M = 28; F = 20	M = 14; F = 10	M = 14; F = 10	N/A
Diagnosis				
Lumbar [L4-S1] disk bulge or herniation only	5 [10]	4	1	0.143
As above with associated ligament strain	12 [25]	4	8	0.077
DJD and Osteoarthritis [L4-S1]	4 [8]	2	2	1.000
DJD with associated ligament strain [L4-S1]	12 [25]	7	5	0.462
Scoliosis	6 [13]	3	3	1.000
Ligament strain only [L4-S1]	5 [10]	2	3	1.000
Healed lumbar vertebrae fractures	2 [4]	1	1	1.000
Osteoporosis with associated Scoliosis and DJD	1 [2]	0	1	1.000
Sacroiliac ligament strain	1 [2]	1	0	1.000
Mechanism of Injury				
Motor vehicle accident	15 [31]	8	7	0.999
Falls [unspecified]	8 [17]	3	5	0.444
Falls [skiing related]	4 [8]	4	0	0.029
Sports collisions	5 [10]	4	1	0.143
Trauma [unspecified]	5 [10]	2	3	1.000
Insidious [degenerative over time]	8 [17]	1	6	0.015
Repetitive strain injury	1 [2]	0	1	1.000
Unknown	2 [4]	1	1	1.000
Medication				
Non-steroidal anti-inflammatory drugs	8 [17]	5	3	0.444
As above in combination with muscle relaxants	26 [54]	13	13	1.000
As above in combination with anti-depressants	10 [21]	5	5	1.000
Not currently taking medication for LBP	4 [8]	1	3	0.400

N = number of subjects in group, N/A = not applicable, SD = standard deviation, M = male, F = female, DJD = degenerative joint disease, LBP = low back pain

frequency, duration of pulses, and number of pulses] of necessary treatment has been determined, the "treatment" parameters are saved for a particular patient and either sent to the KKT™ from a desktop computer or directly programmed into the KKT™ using its touch-screen software located on the device head. Either way, the data is electronically archived. The clinician then sets up the patient on the treatment table and orients the device for treatment. After placing the patient, the device head may be manipulated three-dimensionally to ensure the appropriate placement of the impulse stylus. The device head is locked in position prior to treatment. Only then may the device begin treatment when initiated by the clinician.

FIGURE 1. Khan Kinetic Treatment™ prototype set-up





This approach removes all forms of human error from the active treatment protocol.

Data Acquisition

The self-assessed LBP questionnaire used in this study was consistent with the standard format of the Pain Outcomes Questionnaire developed by the American Academy of Pain Management (48). Both the treatment and matched control subjects described their LBP on an ordinal scale ranging from 0 to 10 at intake of initial assessment before the treatment period began. For the treatment group, the treatment period consisted of six to 12 individual KKT™ treatments conducted over a period of three to six weeks. The control group was allowed to continue with current conventional treatment [undocumented]. At the end of the treatment period for the treatment subjects, the self-assessed LBP score was again recorded by each matched subject [treatment and control].

Three functional self-assessment measures consisted of 1. a general mobility or range of motion score [0 to 100], 2. an overall activity level score [0 to 100], and 3. a recreation/work activity level score [0 to 100]. These functional assessments were recorded for both groups. Scoring 100 on any of these tests meant that, despite the self-assessed LBP score, the subjects have full function in the areas indicated, and a score of 0 meant that the self-assessed LBP has incapacitated the subject to complete bed rest.

Medication types were recorded and grouped into several categories: analgesics and non-steroidal anti-inflammatory drugs [NSAIDs], anti-convulsants [muscle relaxants], and anti-depressants. The doses were noted by the subject pre- and post-treatment period for both groups and collectively grouped into two categories: same or decreased.

Data Analysis

Descriptive statistics [frequencies, means, and standard deviations] have been reported so that comparisons of similar data throughout the literature can be made.

Since a reliability and validity study of implementing ordinal scales in the assessment of self-reported pain has already been established (48), we will not address these issues here. A two-way paired t-test was performed to determine whether or not the severity of the initial self-reported low back pain scores [iLBP] differed between the treatment and control groups prior to study commencement. A two-group [treatment versus control] by two LBP outcome [positive or non-positive] McNemar's chi-square test was used to analyze the matched pairs self-reported LBP scores before and after the KKT™ treatment period.

One-way paired t-tests were used to analyze the three functional activity measures and to show that pre-treatment measures did not differ between the groups. Although data ranging from 0 to 10/100 could be considered ordinal data, the t-test robustness in distributional violations is considered a valid test in this case.

A two-group [treatment and control] by two-pain medication dose outcome [same or reduced] McNemar's chi-squared test was used to analyze the reported changes in medication doses. Also, a two-group [treatment and control] by three pain medication types [NSAIDS, NSAIDS plus muscle relaxants, and NSAIDS, muscle relaxants, and antidepressants] chi-squared test was used to analyze differences in medication types between groups.

RESULTS

Forty-eight subjects, 20 female and 28 male, were recruited. These subjects were between the ages of 18 and 77 [43.4 ± 15.4 years] and had a recurrent history of varying levels of disabling LBP. A summary of the clinical outcome variables before and after the treatment period for both groups are shown in Table 2.

Low Back Pain Outcome

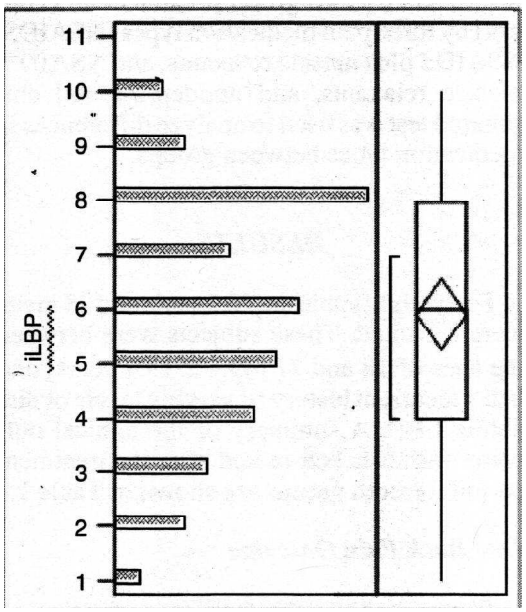
Figure 2 shows the frequency distribution and quantile box plot of the initial LBP scores from all subjects. The Shapiro-Wilk Test showed that the distribution of this data was normal [P = 0.072]. A two-tailed paired t-test determined that the severity of the self-reported LBP scores prior to KKT™ treatment did not differ between the treatment and control groups [P = 0.353, see Figure 3].

TABLE 2. Clinical Outcome Variables Before and After Treatment Period for Both Groups [Treatment and Control]

Clinical outcome variable	Before		After	
	Treatment [mean ± SD]	Control [mean ± SD]	Treatment [mean ± SD]	Control [mean ± SD]
LBP	5.5 ± 2.1	6.2 ± 2.4	2.2 ± 1.9	5.4 ± 2.8
Overall range of motion	56.9 ± 33.7	57.9 ± 31.0	74.1 ± 33.6	57.9 ± 31.0
Overall activity level	54.0 ± 34.3	51.9 ± 30.8	68.5 ± 35.5	51.9 ± 30.8
Overall work activity	53.8 ± 34.1	45.6 ± 33.0	66.7 ± 38.3	46.5 ± 33.7
Clinical outcome variable	Before		After	
	Treatment	Control	Treatment N same/reduced	Control N same/reduced
Medication dose	Not recorded	Not recorded	10/10	16/4

SD = standard deviation, LBP = low back pain, N = number of subjects

FIGURE 2. Quantile box and frequency distribution for the initial low back pain scores for all subjects [N = 48]



N = number, iLBP = initial low back pain

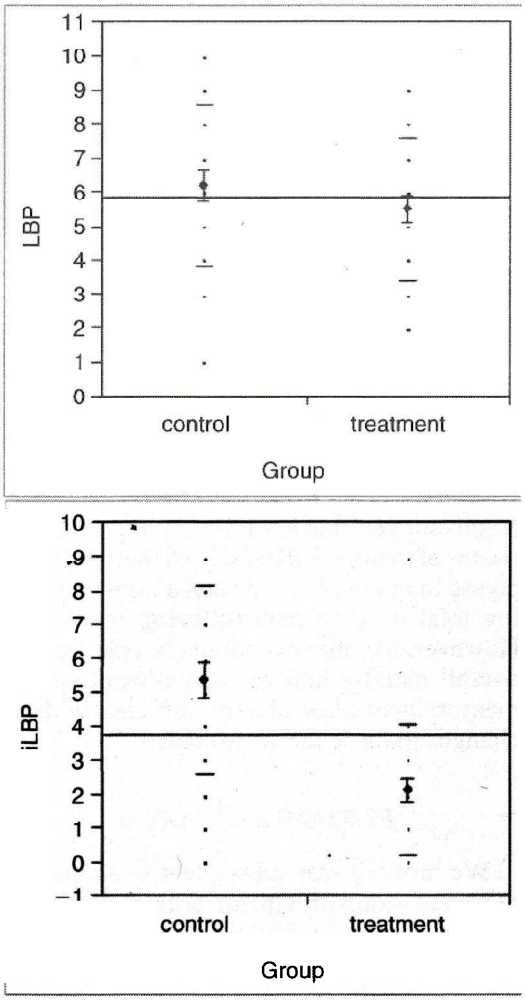
However, after the treatment period for the treatment group was complete, the self-reported LBP scores were again collected from both groups and a two group by two LBP outcome [positive or non-positive] McNemar's chi-squared test was performed. Figure 3 shows the mean, standard error, and standard deviation for all subjects [N = 48] in the two groups after the treatment period. Table 3 shows the software 2 × 2 input table that was used to conduct the test. The treatment group had significantly lower self-reported LBP scores post-treatment period when compared to control subjects [$P < 0.001$].

One subject reported an increase in LBP post-treatment period. Both the subject reporting an increase in LBP and their matched control subject were included in the McNemar's chi-squared test [Table 3]. Hence, the total sample number located at the bottom right corner of Table 3 equals 24 pairs, which include all 48 matched subjects. However, a Fischer's exact test was also computed. The 2 group [treatment or control] × 2 LBP outcome [same or increased] table showed that the Fisher's Exact test was non-significant [$P = 0.296$].

Functional Assessment Outcome

Self-reported functional assessment scores were also compared. Three two-tailed paired t-tests were performed to see whether or not the groups differed from one another prior to the initiation of treatment. The tests show that none of the functional assessment scores [range of motion, overall activity, and a recreation/work activities] of either group were significantly different [$P = 0.914$, $P = 0.833$, and $P = 0.524$,

FIGURE 3. Mean [bold dot], ± standard error of the mean [solid vertical bar ending with short horizontal hatch marks for each group], and ± standard deviation [upper and lower limit wider horizontal hatch marks for each group] of scatter plot data from initial low back pain scores [top] and post treatment period low back pain scores [bottom] from the two groups [N = 48; 24 subjects each].



N = number, LBP = initial low back pain, fLBP = post-treatment period low back pain

respectively] a-priori. Although repeating these tests post-treatment period showed a trend of improvement, only range of motion assessment scores were significantly different when compared to the same measurements in the control group [P = 0.046, P = 0.061, and P = 0.052, respectively].

Pain Medication Dose Outcome

Ninety-two percent of subjects were taking some form of medication to treat their LBP. However, a chi-squared test showed that neither group was significantly different from each other [P = 0.286] prior to treatment. Additionally, there was no significant difference between the groups and the types of medication they were taking to treat their LBP [P = 0.523]. However, a two group by two pain medication dose outcome [same or reduced] McNemar's chi-squared test showed that the treatment group had a strong positive trend to reduced the dose of their medications when compared to the control group [P = 0.054, see Table 4] post-treatment period. The N value for this test was reduced to 40 subjects in total, 20 from each group. Four subjects [three control and one treatment] were currently not on any medication to treat their LBP. Hence, these subjects, along with their matched subjects, were removed from the McNemar's chi-squared test.

DISCUSSION

Our first objective was to determine whether KKT™ is an effective LBP treatment option. The preliminary results of the self-recorded LBP scores suggested that when the current prototype of KKT™ is utilized, as outlined in the Methods section, it is a potentially effective treatment alternative for LBP sufferers. Although we hold promise in these introductory results, we cannot differentiate between those subjects truly helped by the device and those experiencing a placebo effect. Hence, we will require a larger placebo-controlled or sham blinded trial to fully explain these early findings.

While range of motion assessments differed significantly, the introductory results of the other two self-reported functional assessment questions [range of motion, overall activity, and recreation/work activities] did not significantly differ when compared to the control group. These types of questions were chosen for their ease of data collection and the fact that they were already in use by the clinic who recruited subjects for the study. This allowed for

TABLE 3. Two-Group by Two LBP Scores Pre- and Post-Treatment Used for McNemar's Chi-Square Analysis

KKT™ Response	Control		
Treatment	Decreased LBP Present	Decreased LBP Absent	Total [N]
Decreased LBP Present	5	15	20
Decreased LBP Absent	0	4	4
Total [N]	5	19	24

KKT = Khan Kinetic Treatment, LBP = low back pain, N = number matched pairs

TABLE 4. Two-Group by Two Medication Dose Outcome Table Used for McNemar's Analysis

KKT™ Response	Control		
Treatment	Reduced Dose Present	Reduced Dose Absent	Total [N]
Reduced Dose Present	2	8	10
Reduced Dose Absent	2	8	10
Total [N]	4	16	20

KKT = Khan Kinetic Treatment, N = number of matched pairs

recruitment of subjects who had already recently undergone an intake examination. Unfortunately, the format of these questions does not follow any standard seen in literature. This may be a contributing factor as to why we did not detect changes in overall activity and recreation/work activity measurements. Hence, future studies ought to include a more detailed evaluation of vitality and impairments in completing activities of daily living using current standardized questionnaires in reference to KKT™ treatment.

Our second objective was to show initial results demonstrating that the treatment would reduce their dosage of pain medications post-treatment period when compared to a control group. Preliminary results show that although a strong trend exists, we did not significantly detect a reduction in the treatment group's use of pain medication when compared to a control group.

Although these initial results will require further explanation with blinded sham-controlled and mechanistic studies, results of the combination of both decreased levels of perceived LBP, increases in range of motion, and a strong trend for decreasing pain medication have been encouraging, despite differences in LBP etiology.

CONCLUSION

When compared to a control group, initial results suggest that KKT™ may be an effective means of treating LBP and contributes to the increase in range of motion and a trend of reducing total dose in pain relieving medication. However, the unconventional but pre-existing overall activity and recreation/work activity measurement tools did not sufficiently detect changes in these measurements.

FUTURE RESEARCH

We propose that subsequent work consists of a three group [treatment, normal, and sham] randomized sham-controlled, repeated measures design. The sham treatment would consist of using the device at decreased amplitude on the soft tissues of the trapezius muscle rather than on a landmark of the transverse process of the atlas. Data would be collected pre-treatment, post-treatment, and on follow-up, both in local and global dimensions. The design would include double blinding and more standardized approaches to patient outcomes. For example, bio-electronic recording systems, goniometric range of motion measurements, visual acuity, heart rate, and blood pressure could all be pos-

sible objective measures. This future study would detect whether or not the effects are reproducible and maintained after a three-week non-treatment period. If we find that the treatment effects are not maintained after this three-week non-treatment period, we will propose further studies to include a parallel active versus sham controlled design.

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