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**KHAN KINETIC TREATMENT™**

**HEALTH TECHNOLOGY ASSESSMENT SECTION  
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## **EXECUTIVE SUMMARY**

The Khan Kinetic Treatment™ (KKT) device is a medical device for the treatment of spine related abnormalities which causes pain. It is to be used in the aid of management of chronic pain due to non congenital defects more specifically, conditions of chronic pain arising from structural anomalies such as misalignments and muscle imbalances. The device can be used as part of a series of steps in the total care of the patient. The procedure can involve x-ray analysis that quantifies the lateral and rotational misalignment between the vertebrae. The treatment is then administered using the KKT device to deliver precise impulses at a required vector configuration. It is mainly used in chiropractic clinics.

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 is mounted on a movable armature to a fixed stand. The device head generates waveforms and the stylus located at the base of the device head mechanically transduces the waveforms through the skin and ultimately to the spine, causing minor vibration of the vertebrae and minor repetitive stretching/activation of the attached soft tissues.

It has a class II approval by the Medical Devices Bureau of Health Canada and a 510(k) from the US Food and Drug Administration (FDA). The FDA found that there was a substantial equivalence of the device to a legally marketed predicate device (The Atlas Orthogonal Percussion Instrument). There was no retrievable article related to adverse events.

In conclusion, there was limited evidence on the effectiveness of KKT for treatment of chronic low back pain and chronic neck pain. There was no retrievable evidence on the cost effectiveness of Khan Kinetic Treatment™.

Based on the above review, the routine use of Khan Kinetic Treatment™ for treatment of pain resulting from spine abnormalities is not recommended until more evidence from good quality clinical research is obtained.

# **KHAN KINETIC TREATMENT™**

## **1. INTRODUCTION**

The Khan Kinetic Treatment™ (KKT) device is a medical device for the treatment of spine related abnormalities which causes pain.<sup>1</sup> It is to be used in the aid of management of chronic pain due to non congenital defects more specifically, conditions of chronic pain arising from structural anomalies such as misalignments and muscle imbalances. The device can be used as part of a series of steps in the total care of the patient. The procedure can involve x-ray analysis that quantifies the lateral and rotational misalignment between the vertebrae. The treatment is then administered using the KKT device to deliver precise impulses at a required vector configuration. It is mainly used in chiropractic clinics.<sup>2</sup>

Traditionally, over the centuries, spinal manipulation or impulse (low amplitude high velocity) treatment has been performed using bare hands. As the number of treatment using this methodology increases, it is becoming evident that the variability of patient outcomes as a result of this type of treatment can be significant. These results may be due to the variability in the pressure applied by the hand associated with variations in practitioner hand anatomy, or the variability of the application itself.<sup>1</sup>

This device was developed to minimize potential harm by having a system that generates impulses as opposed to uncontrolled mechanical force generated by the individual clinician at present, who practice manual adjustments.<sup>2</sup>

The device is manufactured in Canada and currently being marketed in Canada, Germany, China, Taiwan and United Arab Emirates.<sup>3</sup> Khan Kinetic Treatment™ is being operated in selected hospital settings within Germany and Canada.<sup>4</sup>

This technology review was conducted following a request from the Director of Medical Practice Division, Ministry of Health.

## **2. OBJECTIVE**

The objective of this systematic review was to determine the safety, effectiveness and cost effectiveness of Khan Kinetic Treatment™.

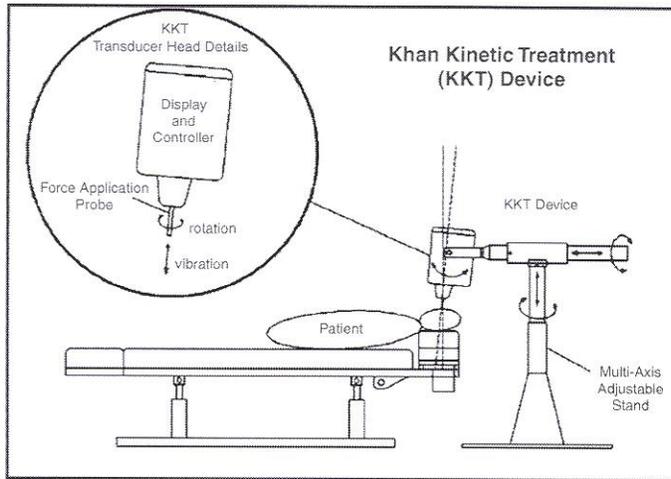
## **3. TECHNICAL FEATURES**

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 is mounted on a movable armature to a fixed stand. The device head generate waveforms and the stylus located at the base of the device head mechanically transduces the waveforms through the skin and ultimately to the spine, causing minor vibration of the vertebrae and

minor repetitive stretching/activation of the attached soft tissues. The device head may be freely moved in 3 dimensions so that the stylus may be positioned accurately on the skin. The stylus invokes multiple pain relieving mechanisms by delivering sinusoidal waveform of various frequencies (80 to 120 Hz) and amplitudes (maximum displacement = 5mm) both linearly and rotationally to the spinous or transverse processes of the spine through the skin.<sup>4</sup>

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 for example, 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. In addition, before treatment, the patient receives a thumb depressed "halt" switch which, when depressed, immediately stops the device from continuing treatment.<sup>4</sup>

At the beginning, digital radiographs of the spine are taken. Software receiving the patients' digital radiographs (Spinalytics) automatically calculates the 3- dimensional orientation (x, y, and z) of the atlas as compared with the occipital condyles and the axis. Clinical decisions for the treatment follow standard clinical protocol. Once the precise location and type (amplitude, frequency, duration of pulses, and number of pulses) of necessary treatment is 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 are electronically archived for each patient. After appropriately placing the patient on the treatment table, the device head is manipulated in 3 dimensions. To ensure the appropriate impulse vector, the controller has accelerometers to obtain precise stylus position feedback on the touch-screen display. When the correct impulse vector of the stylus is achieved, the device head is lowered so that the stylus makes skin contact and is then locked in position before treatment. Only then the device may begin when initiated by the clinician.



Device Head – Contains electromechanical devices capable of generating wave forms (Slave).

Stylus or Force Application Probe – Mechanically transduces the wave forms to the spine.



Controller – Touch screen display that allows programming of treatment and precise position feedback (Master).

Movable armature – Allows 3D motion of the stylus for precise placement and locks in position when treating.

## **4. Methodology**

### **4.1. Searching**

Electronic databases were searched, which included PubMed, Ovid Full Text, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Review-Cochrane database of systematic reviews, HTA Databases, FDA website and Google for published reports. Additional articles were identified from reviewing the bibliographies of retrieved articles.

The search strategy used the terms, which are either used singly or in various combinations: Khan kinetic Treatment, “Khan Kinetic Treatment”, chiropractor, safe\*, cost\*.

### **4.2. Selection**

All published articles related to safety, effectiveness and cost effectiveness of Khan Kinetic Treatment were included. Critical appraisal of relevant literature was performed and evidence graded according to US/Canadian Preventive Services Task Force (Appendix 1)

## **5. RESULTS AND DISCUSSION**

The search strategies yielded limited published articles related to effectiveness of Khan Kinetic Treatment for chronic neck pain and chronic low back pain. Only two randomized controlled trials were retrieved.

### **5.1. SAFETY**

It has a class II approval by the Medical Devices Bureau of Health Canada and a 510(k) from the US Food and Drug Administration (FDA). The FDA found that there was a substantial equivalence of the device to a legally marketed predicate device (The Atlas Orthogonal Percussion Instrument).<sup>2,4</sup> There was no retrievable article related to adverse events.

### **5.2. EFFECTIVENESS**

Two studies were retrieved on the effectiveness of KTT for treatment of chronic low back pain and chronic neck pain. However, both studies have low methodological qualities.

The use of KTT as low back pain (LBP) treatment option was demonstrated by Desmoulin GT, Yasin NI and Chen DW. They randomly allocated 48 subjects with chronic low back pain into treatment and control groups. A self-reported functional assessment (range of motion, overall activity, and recreation/work activities), LBP questionnaire and pain medication dose reduction were used as an outcome measure. The treatment group underwent 6 to 12 individual KKT treatments conducted over a period of three to six weeks. The control group continued with the conventional therapy. However, the conventional therapy was not documented. They found that the treatment group had a

significantly lower self-reported LBP scores post-treatment period compared to control subjects ( $p < 0.001$ ). They also found that the treatment group had a positive trend to reduce the dose of their medications when compared with the control group ( $p = 0.054$ ). As for the functional assessment outcome, only range of motion assessment scores were significantly different when compared to the same measurements in the control group ( $p = 0.046$ ).<sup>1 level II-I</sup>

Another study involving 44 patients was also conducted by Desmoulin GT, Yasin NI and Chen D using KKT for treatment of chronic neck pain. Patients were randomly allocated into treatment and control groups. The treatment group underwent 6 to 12 individual KKT treatments lasting 6 to 12 minutes conducted over a period of three to six weeks. The control group continued with the conventional therapy. They noted that the treatment group had significantly lower self-reported neck pain scores post-treatment period when compared with control patients ( $p = 0.012$ ). The study also showed that the treatment group had significantly reduced the dose of their medications when compared with the control group ( $p = 0.048$ ). However, they noted that none of the functional assessment scores were significantly different when compared with the control group [range of motion ( $p = 0.233$ ), overall activity ( $p = 0.311$ ), and recreation/work activities ( $p = 0.472$ )].<sup>4 level II-I</sup>

### **5.3. COST EFFECTIVENESS**

There was no retrievable evidence on the cost effectiveness of Khan Kinetic Treatment™.

## **6. CONCLUSION**

### **6.1. SAFETY**

There was limited evidence to show the safety of Khan Kinetic Treatment™.

### **6.2. EFFECTIVENESS**

There was limited evidence to show the effectiveness of Khan Kinetic Treatment™ for treatment of chronic low back pain and chronic neck pain.

### **6.3. COST EFFECTIVENESS**

There was no retrievable evidence on the cost effectiveness of Khan Kinetic Treatment™.

## **7. RECOMMENDATION**

Based on the above review, the routine use of Khan Kinetic Treatment™ for treatment of pain resulting from spine abnormalities is not recommended until more evidence from good quality clinical research is obtained.

## **8. REFERENCES**

1. Desmolin GT, Yasin NI and Chen DW. Initial results using Khan Kinetic Treatment™ as a Low Back Pain Treatment Option. Journal of Musculoskeletal pain. 2007; 15(3):91-102
2. 510(k) Summary. Khan kinetic Treatment Device (KKT-MI). Available at <http://www.fda.com>
3. Khan Kinetic Treatment KKT-The ultimate spine treatment. Available at <http://www.khankinetic.com/index.htm>
4. Desmolin GT, Yasin NI and Chen DW. Spinal Mechanisms of pain control. Clin J Pain. 2007; 23(7):576-585

## **9. APPENDIX**

### **9.1 Appendix 1**

#### **DESIGNATION OF LEVELS OF EVIDENCE**

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-I Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

**SOURCE:** *US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)*