Spine[redacted]® DECOMPRESSION SYSTEM

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DISCLAIMER

Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It is not subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

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DISCLOSURE

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EXECUTIVE SUMMARY

Introduction

Intervertebral disc pathology is one of the primary causes of back and neck pain. The discs are prone to degeneration and injury as they are compressed and twisted through daily activities. Damaged intervertebral discs seldom heal because they remain under constant pressure, even while a person is at rest. The most commonly used traction techniques are mechanical or motorized traction (where the traction is exerted by motorized pulley), and manual traction (in which the traction is exerted by the therapist, using his or her body weight to alter the force and direction of the pull). The Spine[redacted] Decompression System provides a program of treatment for relief from pain for those patients suffering with low back pain, neck pain or sciatica.

Objective / Aim

The objective of this technology review was to assess the safety, effectiveness and cost-effectiveness of Spine[redacted] Decompression System for treatment of low back pain, neck pain or sciatica.

Results and Conclusions

There was no retrievable evidence on the safety of Spine[redacted]® Decompression System for treatment of low back pain, neck pain or sciatica. However, it has received approval from United State Food & Drug Administration (USFDA).[2]

There was insufficient, poor level of evidence to show the effectiveness of the Spine[redacted]® Decompression System for the treatment of patients suffering from low back pain.

There was no retrievable evidence on the cost-effectiveness of Spine[redacted] Decompression System for treatment of low back pain, neck pain or sciatica. However, the company claimed that the cost for the full Spine[redacted] program is approximately $[redacted] (US dollar).[1]

Methods

Electronic databases were searched, which included PubMed, Medline, Journal @ Ovid full text via OVID, OVID EBM Reviews - Cochrane central register of controlled trials, OVID EBM Reviews - Cochrane database of systematic review, Ovid EBM Review – Health Technology Assessment, Horizon scanning databases - Centre, Birmingham,

Australia and New Zealand Horizon scanning (ANZHSN), FDA website, MHRA website and from non scientific database - Google search engine. Relevant articles were critically appraised and evidence graded using US / Canadian Preventive Services Task Force.

Spine® DECOMPRESSION SYSTEM

1.0 INTRODUCTION

Intervertebral disc pathology is one of the primary causes of back and neck pain. The discs are prone to degeneration and injury as they are compressed and twisted through daily activities. Damaged intervertebral discs seldom heal because they remain under constant pressure, even while a person is at rest. The most commonly used traction techniques are mechanical or motorized traction (where the traction is exerted by motorized pulley), and manual traction (in which the traction is exerted by the therapist, using his or her body weight to alter the force and direction of the pull). It is widely accepted that the ideal environment to improve disc pathology is to decompress, or reduce the intradiscal pressures of the damaged disc.[1]

The Spine® Decompression System provides a program of treatment for relief from pain for those patients suffering with low back pain, neck pain or sciatica. Each treatment session consists of a physician prescribed treatment period on the Spine and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain, neck pain or sciatica. It is claimed to relieve pain associated with herniated discs, bulging or protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.[2]

This technology review was conducted following a request from the Director of Medical Development Division, Ministry of Health Malaysia, following a proposal by an e-mail from one patient who suffers chronic back pain but claimed immediate resolution of symptoms after undergoing spinal decompression treatment with Spine Decompression System in Singapore.

2.0 OBJECTIVE /AIM

The objective of this technology review was to assess the safety, effectiveness and cost-effectiveness of Spine Decompression System for treatment of low back pain, neck pain or sciatica.

3.0 TECHNICAL FEATURES

The Spine Decompression System is designed to isolate and decompress lumbar or cervical discs through distraction and positioning of the spine. Under distraction the pressure exerted on the discs can be reduced dramatically. Reduced intradiscal pressure may help draw the gel like nucleus pulposis back into the center of the disc, thereby relieving pressure on a compressed nerve root. Additionally, reduced pressures may increase the diffusion of fluids and nutrients across the end plates back into the disc, to enhance the body's natural healing abilities.[1]

Spine[redacted] Decompression System

The Spine[redacted] Decompression System is patented technology (patent # 7201729). This technology has been claimed to eliminate the use of cumbersome nylon harnesses and outdated traction components. The patented pelvic restraint system provides a secure, comfortable and repeatable capture of the skeletal structure, eliminating the variability and inconvenience of pelvic harnesses. Once the pelvis is captured, the technician can accurately isolate the damaged spinal segment by adjusting the patented pelvic tilting section. Increased specificity combined with a more efficient capture results in lower force requirements than previous technologies (as little as 60%). The Spine[redacted] Decompression System's ability to achieve results using lower distractive forces greatly increases the scope of patient suitability, particularly with acute patients and the growing geriatric population. Extensive computerization and hospital grade components make the Spine[redacted] Decompression System the most sophisticated decompression device on the market.[1]

The Spine[redacted] protocol consists of 20-25 sessions that are 30 minutes each in duration. Spine[redacted] sessions are typically administered 3-5 times per week over a 4-6 week period. The procedure is performed with the patient fully clothed and has been described as safe, painless and extremely effective. In fact, it is not uncommon for patients to fall asleep during the procedure. Each session has a cumulative effect designed to significantly reduce pain and improve function as patient's progress through the Spine[redacted] program.[1]

For lumbar procedures, the patient is positioned supine on the Spine[redacted] system. The Patented Pelvic Restraints are adjusted to comfortably secure the patient's pelvis. The upper torso is secured to the fixed section of the table. The Patented Pelvic Tilt section electronically tilts the pelvis to target specific spinal segments. With precise computer controlled tension, the specific disc segment is gently distracted.[1]

For cervical procedures, the cervical unit is first electronically tilted to the angle required to target specific segments of the cervical spine. The patient is then placed on the table with their head positioned in the cervical cradle unit. The patented Cervical Restraints are designed to comfortably capture the base of the patient's skull for controlled distraction.[1]

Spine[redacted] Decompression System offers the most advanced decompression system which included:

i. Advanced computer controls to overcome reflex contraction
ii. Focused distraction
iii. Lower force requirements
iv. Wider patient suitability
v. Pepeatables sessions
vi. 2-minute setup time
vii. FDA cleared and patent protected
viii. Smart design
ix. Easy to operate
x. Automated patient reporting
xi. Solid reliability with upgradeable technology
xii. Built-in audio / video entertainment
xiii. Post purchase support
xiv. On-site office training
xv. Expert clinical support
xvi. Full marketing support
xvii. Case acceptance training
xviii. Ongoing coaching and consulting
xix. Flexible patient financing

4.0 METHODOLOGY

4.1. Searching

Electronic databases were searched, which included PubMed, Medline, Journal @ Ovid full text via OVID, OVID EBM Reviews - Cochrane central register of controlled trials, OVID EBM Reviews - Cochrane database of systematic review, Ovid EBM Review – Health Technology Assessment, Horizon scanning databases - Centre, Birmingham, Australia and New Zealand Horizon scanning (ANZHSN), FDA website, MHRA website and from non scientific database - Google search engine.

The following keywords were used either singly or in combinations: Spinal Decompression System, Spinal Decompression Therapy, Non Surgical Spinal Decompression Therapy, and Spinal Decompression. Additionally, keyword searches were performed using brand names of specific manufacturers. Additional material was gathered from the research sections of manufacturer websites and hand searches.

4.2. Selection

All published articles related to safety, effectiveness and cost-effectiveness of the Spine[redacted] Decompression System for treatment of low back pain, neck pain or sciatica were included.

5.0 RESULTS AND DISCUSSION

The search strategies yielded an article on the United State Food & Drug Administration (USFDA) related to Spine[redacted] Decompression System. However, there was no retrievable evidence on the effectiveness and cost-effectiveness of Spine[redacted] Decompression System from scientific databases.

5.1 Safety

USFDA has cleared SpineMED® Decompression System for both lumbar and cervical decompression (510(k) k051013). The SpineMED S200B/C system has been evaluated and has passed all mechanical and electrical safety according to CSA International. Standards that were investigated are: IEC 60601-1, UL 60601-1 and CAN/CSA C22.2No.601.1-M90 certified.[2] There was also no evidence in adverse events on the use of this device for treatment of low back pain, neck pain or sciatica.

5.2. Effectiveness

There was no retrievable evidence to show the effectiveness of the SpineMED® Decompression System for the treatment of patients suffering from low back pain, neck pain or sciatica. The document provided by the manufacturer were mainly claims from users and hospitals that provide such services where patients received some satisfaction from the treatment such as pain reduction, reduction in use of pain medications; normalization of range of motion, reflex, and gait; and recovery of sensory or motor loss.[1]

However, the document also included a cross-sectional study conducted on Spinal Decompression by Gionis T.A and Groteke E. The study included 229 patients with the following inclusion criteria; pain due to herniated and bulging lumbar discs that is more than 4 weeks old or persistent pain from degenerated discs not responding to 4 weeks of conservative therapy. Of the 229 patient selected, only 10 patients did not complete the treatment protocol. Reasons for non-completion included transportation issues, family emergencies, scheduling conflicts, lack of motivation, and transient discomfort. The study involved 79 female and 140 male patients, with age ranging from 24 to 74 years. From the study, the authors found that 86% of the 219 patients who had completed therapy reported immediate resolution of symptoms, and 84% of those remained pain-free for 90 days post-treatment. Physical examination findings revealed improvement in 92% of the 219 patients who completed the therapy.[3 Level III]

5.3. Cost-Effectiveness

There was no retrievable evidence on the cost-effectiveness of Spine[redacted] Decompression System for treatment of low back pain, neck pain or sciatica. However, the company claimed that the cost for the full Spine[redacted] program is approximately $[redacted] (US dollar).[1]

6.0 CONCLUSION

6.1. Safety

There was no retrievable evidence on the safety of SpineMED® Decompression System for treatment of low back pain, neck pain or sciatica. However, it has received approval from United State Food & Drug Administration (USFDA).[2]

6.2. Effectiveness

There was insufficient and poor level of evidence to show the effectiveness of the Spine[redacted] Decompression System for the treatment of patients suffering from low back pain.

6.3. Cost-Effectiveness

There was no retrievable evidence on the cost-effectiveness of Spine[redacted] Decompression System for treatment of low back pain, neck pain or sciatica. However, the company claimed that the cost for the full Spine[redacted] program is approximately [redacted] (US dollar).[1]

7.0 REFERENCES

1. Spine[redacted] decompression system CERT healthscience, LLC. Available at http://www.spinemed.com/.

2. CERT Health Science 510(K) Submittal Spin[redacted]™ Therapeutic Table Model S200B/C. Available at http://www.fda.gov/cdrh/industry/support/index.html.

3. Gionis T.A and Groteke E. Spinal Decompression. Available at http://www.therunningdoctor.com/report.pdf

9.0 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)