SUMMARY OF STUDY

Symptoms Prior to Treatment
- Radiating pain into the buttocks and legs
- Burning sensation down both legs into the feet and the right inguinal region.

Activities Making Symptoms Worse
- Walking and standing for more than 15 minutes
- Disrupted sleep
- Difficulty moving from a sitting to a standing position

MRI showed
- Disc protrusions at all lumber levels
- Degenerative changes throughout lumbar spine
- Decreased Disc Space

7 Week Protocol
- 22 Treatments

Post Treatment
- Pain went from a 10 on a scale of 1-10 down to a 1
- No longer felt the burning sensation in the buttocks or legs
- Decrease in the frequency of burning in the right inguinal region
- Improvement in muscular strength

MRI revealed
- Decreased herniation size
- Increased disc height at multiple lumbar levels

Research Proves Spinal Decompression Can Lead to an Increase in Disc Height And an up to 90% Reduction in Pain

Individual results may vary. These statements have not been evaluated by the FDA. All spinal decompression devices currently registered with the FDA have received their 510K clearance by claiming their device is substantially similar to predicate traction devices.
Pain with a Non-surgical Decompression System (DRX9000™)

CASE REPORT: Management of Low-back Pain

A 69-year-old man, patient A, presented at an out-patient facility in October 2007. He complained of having experienced LBP during the past year. Patient A said the pain had progressively worsened over the past two months. Patient A also reported radiating pain into the buttocks and legs, as well as a burning sensation down both legs to the feet and the right inguinal region. Patient A was 68 inches tall and weighed 192 pounds. His medical history revealed a history of spine surgery, diabetes, hypertension and lumbar surgery 13 years previously. Activities that exacerbated Patient A’s condition included walking and standing for more than 15 minutes. The pain disrupted his sleep and he had difficulty moving to a standing position. Magnetic resonance imaging (MRI) of the lumbar spine performed on 4 October 2007 showed disc protrusions at all lumbar levels with narrowing of the intervertebral spaces. The size of Patient A’s herniated disc and height of his disc space at first visit are shown in Table 1. Patient A underwent 22 treatments on the DRX9000 over a seven-week period. The initial parameters were a maximum decompression force of 80 pounds, with a minimum force of 40 pounds; the final treatment parameters were a maximum of 125 pounds and a minimum of 62 pounds. The decompressive force was raised in increments of five pounds at the discretion of the physician. The angle of treatment force – which allows the physician to make adjustments to treat the affected lumbar region – ranged from 10° to 20°. Adjunctive treatment included electric stimulation, as well as instruction on therapeutic exercise and home care. At initial treatment, Patient A reported pain ‘10’ on a scale of 0 to 10, at the end of the treatment protocol.

Presentation of Case

Table 1: Pre- and Post-treatment Magnetic Resonance Imaging Measurements

<table>
<thead>
<tr>
<th>Age</th>
<th>Height (in)</th>
<th>Weight (lb)</th>
<th>Lumbar Levels</th>
<th>Size of Herniated Disc (mm)</th>
<th>Height of Disc Space (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>69</td>
<td>68</td>
<td>192</td>
<td>L1-L5</td>
<td>4.0 (right)</td>
<td>4.1 (centre)</td>
</tr>
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</tbody>
</table>

Discussion

Spinal decompression systems such as the DRX9000 have become more prominent in clinical practice for the treatment of LBP. These systems were developed to provide a non-invasive intervention for the treatment of LBP, with the goal of expanding the intervertebral space and reducing disc protrusion. As described by Richmond et al. in 2007, “the DRX9000 True Non-surgical Spinal Decompression System” applies spinal distraction forces by using a sensitive computerised feedback mechanism to provide relief of LBP and symptoms associated with herniated discs, bulging or protruding inter-vertebral discs, degenerative disc disease, posterior facet syndrome and sciatica. The DRX9000 uses a split-plate design to reduce friction between the patient and the device. The patient lays supine in a chest and shoulder support system controls the upper body and a knee rest is utilized to eliminate pelvic rotation. The apparatus has built-in air bladders, disc-angle-pull adjusters and harnesses and can increase the decompression force in a stepwise manner in the latter part of the therapy. The DRX9000 uses a motor pulley to deliver mechanised segmental distraction, which can be defined in a static or an oscillatory fashion. In a pre-selected duration of lumbar spinal diseases determines the best pull-angle settings. A recent review of clinical trials evaluating spinal decompression systems concluded that currently available data are too limited to determine whether spinal decompression provides greater benefit over other non-surgical treatments. Since then, review, two new studies have demonstrated the safety and efficacy of the DRX9000. The first study was retrospective and analysed the treatment of 94 patients.6 At presentation, patients reported a mean pain rating of 6.05 on a scale of 0 to 10; this decreased significantly to 0.89 at the end of treatment. Analgesic use and physical function were also improved at the end of treatment. No adverse events were noted. The authors acknowledged that the clinical outcomes noted in the study necessitated further investigation.

The second study was a prospective, multicentre, non-randomised phase II pilot study to evaluate the efficacy of the DRX9000.5 At presentation, patients reported a mean pain rating of 6.13 on a scale of 0 to 10; this decreased to 0.81 at the end of treatment. Fifteen patients of the 20 DRX9000 treatments over the course of six weeks, with five sessions in each week for the two weeks. Two patients were removed from the study after the start of treatment because they did not meet the study inclusion criteria. Four patients withdrew from the treatment included ice, stretching exercises and analgesics as required. Pain, analgesic use, functionality, patient satisfaction and safety were evaluated throughout the study. Average daily pain was reduced from 6.4 to 3.1 after two weeks of treatment and continued to decrease to 0.8 at completion. This represents a >50% reduction in pain after two weeks of DRX9000 treatment. Sixteen patients (88.9%) reported better function as measured by activities of daily living. On a satisfaction scale of 0 to 10, patients gave the DRX9000 an average score of 8.5. Adjunctive pain medication use was decreased with treatment and no significant adverse events or safety issues were reported. Diagnostic imaging is currently being utilised to evaluate physical changes within the intervertebral disc after treatment with the DRX9000. The use of imaging findings may be beneficial for explaining the clinical improvement in pain and function often observed. Preliminary data from a retrospective review of patients with chronic musculoskeletal, mechanical or discogenic LBP who underwent a six-week course of non-invasive spinal decompression using the DRX9000 showed a decrease in chronic LBP compared with an increase in disc height. A recently published case study of a 33-year-old male with persistent LBP along with sciatica reported effectiveness of the DRX9000 that the DRX9000 has on the intervertebral disc. Post-DRX9000 MRI measurements showed an increase in intradiscal signal on T2-weighted images at L2–3, L4–5, L5–S1.

Conclusions

Evidence-based data show that the promising effects of DRX9000 on the intervertebral disc and the improvement of LBP continue to accumulate. This case report further builds on previous findings that have demonstrated improvements in disc morphology after treatment with the DRX9000. Patient A experienced pain relief, reduced disc height and disc space enlargement with treatment. To further test the efficacy of the DRX9000 on clinical and radiographic measures in patients with chronic LBP, additional prospective clinical studies are needed.

References