Pilot: Effectiveness & Safety of Non-Surgical Spinal Decompression

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OBJECTIVE

OBJECTIVE: Prospective, multi-center, phase II, non-randomized, clinical study to evaluate the effectiveness and safety of the Axiom Worldwide DRX9000™ for active treatment of chronic LBP utilizing a standardized clinical research multimodal protocol.

METHODS: 20 patients with chronic LBP based on a diagnosis of musculoskeletal or mechanical LBP, herniated discs, bulging or protruding discs, degenerative disc, pain from failed back surgery more than 6 months previously, posterior facet syndrome or sciatica underwent a series of 20 DRX™ treatments (28 mins each) for 6 weeks with 5 sessions the first week tapering to 1 session/wk. Treatment multimodal protocol included ice after DRX™ sessions, lumbar stretching exercises, and adjunct analgesics as required. Assessments of pain, analgesic use, functionality, satisfaction, activities of daily living and safety were collected through examinations, questionnaires and patient diaries.

RESULTS: 18 evaluable subjects (33.3% female, 83.3% white, mean age 46.6, 77.8% employed) had a change in mean pain score per week of 6.4 (n=18) on a 0 to 10 scale (0=no pain 10=worst pain) at baseline that decreased to 0.8 (n=17) at week 6. Patients reported a mean 88.9% (16 out of 18) improvement in back pain, and better function as measured by activities of daily living. On a 0 to 10 scale (0=Not satisfied 10=Very satisfied) patients rated the DRX9000™ an 8.1. No patient required any invasive therapies (e.g., epidural injections, surgery).

CONCLUSION: Overall, patients’ pain improved immediately after DRX™ treatment, requiring fewer analgesics, with better function. There were no safety issues identified with the multimodal treatment routine. Non-treatment or control groups were not included making efficacy outcome versus placebo or spontaneous recovery difficult to determine. Randomized double-blinded or comparative long-term outcome trials are needed to further prove the efficacy of the DRX9000™ non-surgical spinal decompression system for the routine treatment of chronic LBP.

DISCLOSURE: This study was funded by Axiom Worldwide.

BACKGROUND

- Paucity of literature on benefits of non-surgical spinal decompression over other non-surgical treatments
- Previous studies are poorly designed
- Results are descriptive in nature
- Efficacy versus placebo or spontaneous recovery difficult to determine
- Over 1,200 DRX9000™ in use today

MATERIALS & METHODS

METHODS
- Prospective, multi-center, phase II, non-randomized clinical trial
- 3 free-standing clinics (2 MDs and 1 DC)
- Diagnosis: Low back pain > 12 weeks
- Outcome measures assessed:
  - Daily Pain Diary
  - Verbal Rating Scale (VRS)
  - Oswestry Pain Questionnaire
  - Adverse Events
  - Satisfaction Survey

TREATMENT PROTOCOL
- DRX9000™ sessions
  - 28 minute sessions for 6 weeks
  - Total of 20 treatments
    - 5 sessions week 1 & 2
    - 3 sessions week 3 & 4
    - 2 sessions week 5 & 6
- Additional Therapy
  - Ice therapy post DRX™
  - Back exercises after week 2

RESULTS

DEMOGRAPHICS

<table>
<thead>
<tr>
<th>Total Number of Subjects = 18</th>
</tr>
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<tbody>
<tr>
<td>Male 66.7%</td>
</tr>
<tr>
<td>LBP Symptom Duration (mean) 526 weeks</td>
</tr>
<tr>
<td>Employed 77.8%</td>
</tr>
<tr>
<td>Retired 16.6%</td>
</tr>
<tr>
<td>Other 5.6%</td>
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</table>

SUMMARY OF LOW BACK PAIN

<table>
<thead>
<tr>
<th>DIAGNOSIS</th>
<th>LOCATION</th>
</tr>
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<tbody>
<tr>
<td>Bulging/Protruding Disc 15</td>
<td>L1-L2</td>
</tr>
<tr>
<td>Degenerative Disc 8</td>
<td>L2-L3</td>
</tr>
<tr>
<td>Herniated Disc 6</td>
<td>L3-L4</td>
</tr>
<tr>
<td>Posterior Facet Syndrome 2</td>
<td>L4-L5</td>
</tr>
<tr>
<td>Failed Back Surgery 1</td>
<td>L5-S1</td>
</tr>
</tbody>
</table>
RESULTS

FAILED THERAPY PRIOR TO DRX9000™

<table>
<thead>
<tr>
<th>Procedure</th>
<th>#</th>
<th>Procedure</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiropractic</td>
<td>16</td>
<td>TENS</td>
<td>5</td>
</tr>
<tr>
<td>Muscle Stimulation</td>
<td>10</td>
<td>Acupuncture</td>
<td>3</td>
</tr>
<tr>
<td>Ice Therapy</td>
<td>9</td>
<td>Lumbar support</td>
<td>3</td>
</tr>
<tr>
<td>Massage Therapy</td>
<td>9</td>
<td>Epidural Injections</td>
<td>3</td>
</tr>
<tr>
<td>Exercise</td>
<td>6</td>
<td>Facet Injections</td>
<td>1</td>
</tr>
<tr>
<td>Heat</td>
<td>5</td>
<td>Ultrasound</td>
<td>1</td>
</tr>
<tr>
<td>Physical Therapy</td>
<td>5</td>
<td>Other Decompressive Therapy</td>
<td>1</td>
</tr>
</tbody>
</table>

CHANGE IN PAIN SCORE BY TREATMENT WEEK

CHANGE IN OSWESTRY SCORE

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Related to device</th>
<th>Adverse Event</th>
<th>Related to device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck Pain</td>
<td>Possibly</td>
<td>Shoulder Pain</td>
<td>No</td>
</tr>
<tr>
<td>Head Cold (2)</td>
<td>No</td>
<td>LBP/flu-like symptoms</td>
<td>No</td>
</tr>
<tr>
<td>Sinus headache (2)</td>
<td>No</td>
<td>Vertigo</td>
<td>No</td>
</tr>
<tr>
<td>Sinus infection</td>
<td>No</td>
<td>Adrenal Insufficiency</td>
<td>No</td>
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</tbody>
</table>

SATISFACTION SURVEY

<table>
<thead>
<tr>
<th>Satisfaction by Week</th>
<th>Would you recommend DRX9000™ to anyone else?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 3</td>
<td>Week 6</td>
</tr>
<tr>
<td>7.6</td>
<td>8.1</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>88.9%</td>
<td>11.1%</td>
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DISCLAIMER:
This study was funded by Axiom Worldwide LLC.

CONCLUSION

- A 6-week course of 20 DRX9000™ treatments significantly reduced the severity of chronic LBP in 89% (16 of 18) of treated patients from 6.4 to 3.1 after 2 weeks and to only 0.8 (scale 0-10) after completion of treatment.
- Oswestry Disability scores improved from 23.7 to only 5.5 at end of therapy
- Adjunctive pain medication consumption was decreased by DRX9000™ treatments
- No significant adverse events or safety issues resulted from DRX9000™ treatments
- The DRX9000™ shows great promise in treating chronic LBP arising from multiple causes
- Comparative outcome trials utilizing a set of standardized and validated multiple outcome variables, as was utilized in this study, are being planned to document the value of DRX9000™ non-surgical spinal decompression system in routine treatment of chronic LBP