PILOT: Effectiveness & Safety of Non-Surgical Spinal Decompression

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**ABSTRACT**

**OBJECTIVE:** Prospective, multicenter, 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 multidisciplinary protocol.

**METHODS:** 20 patients with chronic LBP based on a diagnosis of musculoskeletal or mechanical LBP, herniated disc 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 minutes each) for 6 weeks with 5 sessions the first week tapering to 1 session/week. Treatment multidisciplinary 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, 66.7% white, mean age 46.6, 77.8% employed) had mean pain score 6.4 on a 0 to 10 scale (0=no pain, 10=worst pain) prior to first DRX™ treatment that decreased to 0.8 after last DRX™ treatment. 88.9% of patients (16 out of 18) reported an 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 8.7. No patient required any invasive therapies (e.g., epidural injections, surgery).

**CONCLUSION:** Overall, patients’ pain improved after DRX™ treatment, requiring fewer analgesics, with better function. There were no safety issues identified with the multidisciplinary 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.