

DRS System Clinical Trial

Clinical Trial Study of a Non-Invasive Decompression System in the Treatment of Lumbosacral Radiculopathies

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Introduction:

Low back pain will affect millions of Americans in some form. From strains to ruptured discs, this has become a dilemma on how to treat effectively. The strains should resolve themselves within 2-4 weeks and the significant disc herniations may require surgery. The debate looms on how to treat the majority of these people whose back conditions do not resolve, may or may not have radicular symptoms, and may or may not be a surgical candidate.

Professional scientific journals (*The Spine, Physical Therapy, The Journal of Musculoskeletal Medicine, New England Journal of Medicine, etc.*) month after month produce articles on treatment protocols that will create a ray of hope in dealing with these conditions. There are monthly newsletters (*The Back Letter, Spine Letter, etc.*) which are just devoted to this segment of the anatomy. The frustration initiates the difficulty in accurately diagnosing the symptoms (20, 21).

The literature has shown that between 85-88% of the problems go undiagnosed (11,26). The conditions that can be diagnosed are spinal tumors, ankylosing spondylitis, arthritis, stenosis, infection, herniated disc, spinal stenosis, and spondylolisthesis. People seek treatment for their low back pain because it has interfered with their ADL's (work, home) as well as sleep. (8) Therefore, diagnosis is based on patient symptoms with minimal data from objective tests. These patients need to be actively involved in their treatment plan so the patient feels more confident with the outcome. (8) Lumbosacral injuries are a mechanical dysfunction as a result of degeneration, postural compensations, and biomechanical forces. "Mechanical low back pain syndrome therefore is referred to as ' nonspecific ' low back pain."(12) There is much controversy as to what anatomical structures that are involved in the elicitation of symptoms(19). The spine is a chain of bones flexibly connected by interweaving discs forming a continuous flexible column which is the central axis of the body in locomotion(22). This structure supports the weight of the head and trunk and there are considerable forces generated by the muscles that directly or indirectly attach to it. Erect posture increases the load on the lumbar spine predisposing it to injury.

The articular processes (zygapophyses) are paired superior and inferior from the vertebral arch from the junction of the pedicles and laminae. The superior articular processes jut upward and face dorsally and often laterally while the inferior processes project downward, forward, and medially. Therefore, the articular surfaces of adjacent vertebrae form the synovial joints, and while permitting movement, are primarily

concerned in guiding and restricting the range of movement between the vertebrae. The angle at which these joints are formed determines the planes and degrees of movement. The spinous and transverse processes vary in shape, size, and direction in the various spinal regions and provide a lever system for the muscular attachments. Intervertebral discs function to absorb the mechanical stresses sustained by the vertebral column. The discs assume a different morphology based on the degree of movement in the spinal segments. The plasticity of the spinal segments lies in its multi-segmental composition interlinked by the ligaments and muscles allowing for structural changes while maintaining its rigidity(23).

The discs in the lumbar region are thicker in the front and thinner in the rear which determines the convexity of the curve. The intervertebral disc at L4-5 is relatively large in the front and thick due to its large loading properties and is strongly bound to the ilium and sacrum. The L5-S1 stable relationship is created by a wedge shaped disc, zygoapophyseal joints, and iliolumbar ligaments. Blood supply to the disc periphery is from adjacent vessels and from diffusion through the spongy bone of the adjacent surfaces of the vertebrae(21). The annulus fibrosus (outer layer) consists of a narrow outer zone of collagen fibers and a wider inner zone of fibrocartilage. In the posterior of the annulus, the fibers lie in parallel and run obliquely between two vertebrae to assist in resisting torsion(21,23). The nucleus pulposus lies nearer the posterior portion of the disc. Make-up of the nucleus is soft, gelatinous, and mucoid material. Over time, the mucoid material is replaced by fibrocartilage. With these changes, the water binding capacity is reduced in conjunction with its elasticity properties. There is a consensus that the lumbar disc is involved in the production of symptoms. The disruption of this pressure gradient system is believed to exert pressure on pain sensitive tissues.

In the second decade, degenerated changes within the disc are liable to occur. As a result of these changes coupled with compression and motion, internal and external derangement of the discal tissue is liable to occur. This can produce secondary muscle spasm and guarding of the surrounding joints. Kulak, et al., in studies of disc behavior with pure axial pressure, finds that the aqueous nucleus structure pressure is transferred to the periphery. The ability of the disc to resist this pressure and prevent injury is dependent on the angle of the fibers. This allows the annulus fibers to become taut during torsion. With degenerative changes, the inner annulus fibers lengthen placing almost all of the load on the outer fibers resulting in damage. Another factor affecting the disc is the length of time the load is lifted. The cross bridging protective factor of the disc can be maintained for approximately 4.5 seconds before there is a breakdown(24).

The nutritional component of the disc for healing is based on multiple factors. First is mechanical to reduce the stress load to allow for growth and repair. Second is to promote through changes in discal pressure gradients to allow osmolarity to occur for increased protein and mucopolysaccharide transport for growth and repair.

The lumbosacral musculature are also involved with this type of injury. There are postural compensatory patterns assumed to restrict movement and allow the physiological healing sequence to take place. Stabilization of the spine is dependent upon the strength of the flexors and extensors. EMG studies have shown the role of specific back muscles

under endurance conditions(5). What occurs in these muscles in patients with low back pain has clinically yet to be determined. Research has shown that there is a definite discrepancy in back muscle function between healthy and those individuals with low back pain(9,10). Therefore the type of exercise prescribed are very important to reduce the load and shearing forces in the lumbar spine. This philosophy is supported by Sullivan and Jantzen in their study showing the biomechanical importance of back support mechanism(15). Callaghan, Gunning, and McGill show that appropriate extension exercises do not create excessive loads and shearing forces within the contractile and non-contractile structures of the lumbar spine(14). The neurological impairment of these injuries may have a direct correlation to this muscular impairment.

Within the literature, there is much discrepancy in the most effective means of rehabilitating this condition. AHCPR after reviewing the literature on the treatment of back injuries stated that 80% of these injuries resolved themselves in 4 weeks. These individuals must be carefully screened for any serious underlying disorders that may effect the outcome of their rehabilitation potential(6). What do you do with the other 20% if you follow these guidelines? The patient that is referred for physical therapy for the treatment of low back pain is based on severity. Those patients with radicular symptoms below the knee in either both or one leg were most likely to be referred to a physical therapist, depending on who the initial practitioner was(4). The chiropractor was less likely to refer this type of patient as opposed to the primary care physician or orthopedist. Patients with radicular symptoms uni or bilaterally below the knee, will most likely be more functionally impaired, warranting greater utilization of rehabilitation services. The literature has also stated that 3 days of rest followed by gradual resumption of exercise is an acceptable mode of treatment. Hashemi, et al, showed in their study that the best way to reduce low back disability costs is with an early comprehensive intervention program(2). There are also many other treatment protocols which have an affect on this condition(16,17,18). Which modalities and exercise regime will bare the tests of investigation.

In this health care environment, the treatment and rehabilitation of low back problems pose two interrelated dilemmas. One is to produce positive outcomes, the other is to manage treatment in a cost effective manner. Despite advances in medical technology, patients with similar conditions and treatment regimes attain far different results.

The DRS has documented the creation of significant segmental spinal distraction decompression(1). This creates a negative pressure gradient which is conducive for promoting discal changes(25). As discussed earlier, the aqueous nucleus pulposa, with its water, protein,, mucopolysaccharide content, are subject to positive osmotic tissue changes. This should reduce pressure on the tissues around the vertebral structures and therefore reduce pain. These structures are to include the lumbar disc, posterior longitudinal ligament, and extermal rim of the vertebral body. The DRS is the only system that has been shown to create separation within the lumbar vertebrae. The literature has not shown traction to produce similar results. "There really haven't been randomized clinical trials to prove if traction works"(7). Studies have been done documenting the effects of mechanical traction to the lumbar spine. The numerous factors in treating low back conditions such as diagnosis, type of traction and technique, and physical therapy

treatment techniques have prevented definitive conclusions on the effectiveness of lumbar traction(13).

This case study evolved out of this need for a cost effective conservative treatment regimen producing functional outcomes. This program uses the latest technology of the Decompression Reduction Stabilization System (DRS) along with a proven multi-discipline physical therapy regime.

Procedure:

The patients in this study will have radicular symptoms into a lower extremity. All patients received a medical evaluation to rule out organic problems and specific entities (such as tumors, infections, ankylosis, spondylitis, spinal stenosis, or disc herniation). "The task confronting the examining physician is to integrate the symptoms, physical findings, and diagnostic test results into a logical diagnosis and treatment plan suitable for each patient"(3). That evaluation is accompanied by a physical therapy evaluation looking for specific movement patterns and whether those movements reproduce or diminish the symptoms which occurred within 72 hours of the physicians evaluation. The physical therapy evaluation included a patient education program of therapeutic exercises and biomechanics for their ADL's based on ilium rotations, muscle length/tension relationships, movement patterns, and neural tissue tension signs. The patients continued treatment for a maximum of six weeks or until they were able to resume normal function whichever came first. Functional ability was evaluated by the patient.

Results:

Twenty seven men and twenty three women all diagnosed with a lumbosacral radiculopathy received physical therapy and DRS. The average age of the participants is 49.61 years with a range of 23-77 years of age. They had a back condition for an average of 2.6 years with the shortest being three months and the longest 15 years. It took an average of 57.13 days to initiate treatment and the average length of treatment was 7.08 sessions. Of the patients being treated, 86% resumed their normal activities of daily living. Neural tissue tension signs were either diminished or significantly less rated by the patients (1-2 on the pain rating scale) along with functional range of motion. There were twenty different physician diagnosis' with 10 different radicular sites. All patients are currently working with two receiving further medical evaluation, 3 did not return after the first session, and 2 not returning after the third session. There were 22 different job professions with light to moderate physical requirements.

Discussion:

The purpose of this clinical trial study was to determine if we could get patients with lumbosacral radicular symptoms back to normal function in a cost effective manner. As substantiated by the literature, the programs were individualized based on clinical findings. The patient played an active role in their rehabilitation program and all treatments were administered on a one to one basis by a physical therapist. This developed a rapport between therapist and patient which help deal with the psychosocial aspects of this condition. This study was intended to determine the effectiveness of the DRS System and

use its proven results as an adjunct to the rehabilitation process. As with many other studies conducted in the treatment of low back problems, we evolved another treatment regime. A specific analysis variable was not used at this time because using the patient as the evaluator of their functional capacity was the most stringent. Another study is in the process with a control and experimental group to investigate further the effectiveness of the DRS System.

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