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Low back pain can have many causes. It is exceedingly frequent and is experienced at some time by up to 80% of the population. The differential diagnosis of low back pain is broad and includes systemic diseases (e.g. metastatic cancer), primary spine disease (e.g. disc herniation, degenerative arthritis) and regional diseases (e.g. aortic dissection) that refer pain to the low back. Treatment is often flawed, frequently painful and can be exceedingly expensive.

As demonstrated in the literature, the causes of mechanical low back pain probably include degenerative disc disease, degenerative spondylosis with limitation of range of motion, facet arthropathy, relative lateral recess stenosis; pressure changes affecting the thecal and epidural space from disc bulging, subligamentous and/or extruded herniation and segmental instability. Any activity such as sitting, standing and/or lifting increases axial loading on the spine will exacerbate low back pain.

Anatomically, the spine consists of individual small bones called vertebrae that are stacked on top of one another to form a column. The cushion between each vertebra is called a disc. The problem with a disc is that it can pinch or irritate a nerve from the spinal cord resulting in pain that affects the legs (sciatica). Sciatica can be severe and disabling. If it persists longer than four weeks, worsens and there is no improvement, there is strong physiologic evidence of dysfunction of the spinal segment consisting of the intervertebral disc and its adjoining vertebrae. This condition needs to be confirmed at the corresponding level and side by findings on an imaging study (MRI) and warrants an appropriate physician consultation. Primary disc pain can occur with mechanical strain of the annulus allowing nuclear herniations through radial fissures as well as from inflammation following trauma. A healthy disc could become painful if diseases in other portions of the spine cause it to bear greater mechanical load and secondarily subject it to excessive strain. It is critical to realize that several mechanisms of causing pain may coexist and that similar disease processes give varying symptoms.

But, what type of therapy would be best in order to return the patient to a function level of activity without pain? Diagnostic/ treatment variations imply a lack of consensus about appropriate assessment and treatment and suggest that these treatments sometimes are inappropriate or suboptimal. Surgery versus conservative trail is the most obvious of such choices. However, surgery is not the only treatment that can lead to increased disability: Methods such as extended bedrest or extended use of high-dose opiods prolong symptoms and further debilitate patients. And although the existing literature has shortcomings, there is sufficient evidence for a number of conclusions about the efficacy and safety of current assessment and treatment methods.

The manipulative techniques used for mechanical low-back pain associated with facet syndrome or muscle strain have not been found to be as useful in the management of herniated or degenerated lumbar discs. Similarly, other modalities including ultrasound, electrical stimulation, short-wave therapy, acupuncture, steroids, anti-inflammatory agents and muscle relaxants can fall short of treating underlying problems associated with intervertebral disc lesions. None of these methods relieve the pain from neurocompression or from the stimuli associated wit a prolapsed nucleus pulposus. We reviewed studies on traditional traction that report less than 50% positive outcomes.

Although the uses of physical modalities in many forms are useful as adjunct therapy, in the treatment of disc pathology they are largely empirical. Nachemson et al have comprehensively outlined changes in intradiscal pressures through various activities. They found that certain spinal motions and positions lower intradiscal pressures so that exercise programs and preventive ergonomic advice are fashioned after these principles. Research implies that raised intradiscal pressures play a role in producing disc lesions and now it is shown that lowering intradiscal pressures in a controlled manner plays a role in treating low back pain. New advances centering on the use of decompression, reduction and stabilization produced several important studies on the effect of decompression on intradiscal pressure.

Effects on Intradiscal Pressures

The intervertebral disc and two zygapophysical joints above and below form a spinal segment with limited range of movement when isolated. Several spinal segments together, however, can produce large ranges of sagittal and coronal plane movement.

The disc provides the main strength and stiffness and consists of a thick annular wall which attaches through cartilaginous plates to the vertebral bodies while the inner nucleus pulposus behaves hydrostically as a viscous fluid changing shape in response to body position – in effect, acting like a join.

The nucleus receives axial loads and redistributes the load centripetally to the surrounding annulus, but aging reduces the vascularity of the outer annulus and cartilaginous plates to a few small vessels. The nucleus pulposus is held under tension within an envelope formed by the annulus and cartilage plates, but this envelope is not extensible and maintains turgor by the attraction of water to the proteoglycan macromolecules. Thus, nutrition to the inner nucleus is received by diffusion. Compared to the disc, the zygapophysical joints hold only 10-15% of the load while standing by much larger when flexed or lifting. In other words, they are the guiding and restricting segment during spinal motion and protect the disc from rotational and transitional strains. Thus, back pain may result when these fibrous capsules or synovial folds are irritated. The nucleus of the intervertebral disc is contained under pressure and this is a useful index of function.

Nachemson et al ("The lumbar spine: An orthopedic challenge, Spine 1975; "Intravital dynamic pressure measurement of lumbar discs," and "Intervertebral disc pressure during traction," Scand, Journal Rehab. Medicine Supplement, 1 and 9) and Ramous et al ("Effects of vertebral axial decompression and intradiscal pressure," Journal of Neurosurgery, 1994) have studies intradiscal pressures and have concluded that the ability of the disc to withstand compressive forces depends on both the integrity of the envelope and the turgor within; that movements such as felion and lateral bending increase intradiscal pressure while resting pressures are lowest in supine and prone positions, lower in standing than sitting and very low in activities of lumbar extension and rotation. Exercise programs and ergonomic techniques emphasize the maintenance of a lordosis to maintain decreased disc pressures. Since decreasing pressures helps prevent injury, then a controlled decrease in pressure can directly treat injury.

One of the best studies on intradiscal pressure was conducted by the Department of Neurosurgery and Radiology, Rio Grande Regional Hospital and the Health Sciences center, University of Texas. Intradiscal pressure measurement was performed by connecting a cannula inserted into the patients L4-5 disc space to a pressure transducer. The patient was placed in a prone position on a vertebral axial decompression therapeutic table and the tensionometer on the table was attached. Changes in pressure were recorded at resting state and while controlled tension was applied by the equipment. Intradiscal pressure deomonstrated an inverse relationship to the tension applied and tension in the upper range was observed to decompress the nucleus pulposus significantly, to below –100 mm Hg. The results of this study indicated that it was possible to lower pressure in the nucleus pulposus of herniated lumbar discs to levels significantly below 0 mm Hg when distraction tension was applied according to the protocol described for the decompression therapy.

In an outcome study of 778 patients, Gose et al (Vertebral axial decompression therapy for pain associated with herniated or degenerated discs or facet syndrome: An outcome study, Neurological Research, April 1998) found that decompression therapy was a primary treatment modality for low back pain associated with lumbar disc herniation at single or multiple levels, degenerative disc disease, facet arthropathy, and decreased spine mobility; that pain, activity, and mobility scores were all greatly improved after therapy. They demonstrated a success rate ranging from 68% for facet syndrome to 72% for multiple herniated discs and 73% for patients with a single herniated disc. The average successful outcome for all diagnoses was 71%. The authors have concluded that for patients with low back pain decompression therapy should be considered a front line treatment for degenerative spondylosis, facet syndrome, disc disease and nonsurgical lumbar radiculopathy.

DRS System

C. Norman Shealy, M.D., Ph.D., has developed a medical device that lowers intradiscal pressures, is non-invasive and has high patient compliance – the DRS System. Dr. Shealy, a board-certified neurosurgeon who began his career at Harvard University School of Medicine, is a nationally recognized author and is the founder of the Shealy Institute in Springfield, Missouri. Dr. Shealy has dedicated his life to the elimination of pain through non-invasive, cost effective treatments and the Shealy Institute is one of the most respected pain management facilities in the world. Focusing on treatment of complex and often perplexing medical problems, the institute has been instrumental in the successful rehabilitation of more than 70% of its patients, who are now once again leading productive lives. In a tribute to Dr. Shealy and the American Academy of Pain Management, an Institute affiliate, The Congressional Record state: "The American Academy of Pain Management is the largest society of learned clinicians in the United States concerned with pain management. Because of dedicated organizations such as the American Academy of Pain Management, our ability to reduce pain and suffering is improving." The American Academy of Pain Management operates an outcomes measurement system called the National Pain Data Bank which is designed to measure the efficacy of pain treatments. The average cost of successful pain treatment at the Shealy Institute is cited less than half the national average.

Dr. Shealy is a firm believer in treating the disease, not just the symptoms. Phase One of the Shealy Pain program involves using the DRS System to relieve pain quickly and effectively. This is followed by Phase Two – early mobilization and strengthening

– and finishing with Phase Three dealing with education and prevention of reoccurrence and further injury.

Dr. Shealy's has shown that nutrition in the avascular disc depends on diffusion of collagen precursors, nutrients and oxygen through direct channels in the annulus (30%) and the hyaline end plate (70%) n the vertebrae above and below. It is estimated that the cycle of praline uptake and renewal in the normal disc takes approximately 500 days. This inherently slow cycle is additionally compromised in herniated or degenerative discs. By lowering the intradiscal pressures, the DRS System greatly facilitates this process and accelerates healing in the disc segment. Maximum clinical improvement occurs when treatment is delivered directly to the affected disc. With the DRS System, the treating physician can make adjustments in the angle of distraction, positioning of the spine and amounts of force necessary to unload through distraction and positioning to create the effect of decompression at the specific intervertebral lumbar disc level. The FDA concluded that the DRS achieves its effects through decompression, that is, unloading die to distraction and positioning of the intervertebral discs and facet joints of the lumbar spine. Regular application of the DRS treatments results in remodeling of shortened structures by applying end-range movement to the spine in a controlled manner. Mobilization of the hypomobile joint is used to restore motion. Limitations of the patient's motion depend on the irritability of the disorder. Decompressing the disc space through positioning of the patient promotes tissue healing as evidenced through MRI documented reductions in the size and extent of herniations.

Inclusion/Exclusion Criteria

Inclusion criteria should include: Unrelenting or increasing pain over one week duration not responding to conservative care; pain over one month duration from causes other than herniation; patient at least 18 years old or case by case consideration under age 18 as there still may be growth plate activity; and documented herniated and degenerative disc disease or facet syndrome by MRI.

Exclusion criteria includes pregnancy; lumbar fusion less than 6 months old; metastatic cancer; severe osteoarthritis or osteoporosis with over 45% bone loss; compression fracture within one year; aortic aneurysms recently diagnosed or greater than 5cm; hemiplegia, paraplegia or cognitive dysfunction and uncontrolled concurrent medical disorder.

Smoking, previous surgery and chronic use of narcotic or steroid medications, obesity and large amounts of daily caffeine can have negative influences on the treatment.

Treatment frequency is based on diagnosis. For example, a patient with a herniated disc will on average be treated daily for two weeks, then 3x week for two weeks with re-evaluation weekly. For a degenerated disc, 3x/week for five weeks and re-evaluation on the first and third week. Patients with facet arthropathy may report a sudden pop sensation as facets unlock followed by relief symptoms. Treatments are tapered off following this occurrence.

Motrin, Vitamin B complex, Vitamin C, mechanical massage or diathermy are given before sessions for cases of degenerated discs and facet arthropathy and therapeutic TENS for use during waking hours especially if the patient cannon tolerate anti-inflammatory drugs.

No additional benefit has been shown for treatment times over 45 minutes; inconsistent results are shown with treatment less than for 45 minutes. Patients have follow-up exams every week to monitor progress and make adjustments to treatment. Joint mobilization occurs at the therapeutic force of one-half the patient's weight plus ten to twenty five pounds. This window of treatment is altered by factors such as small body frame (less weight), large frame (more weight), acute injury (less weight), etc.

The DRS System is FDA approved and the outcomes of a recently completed clinical study with orthopedists affiliated with Georgetown University and George Washington University on a scientifically statistical number of patients (initially evaluated by an orthopedic surgeons for diagnosis confirmed by MRI) showed the subsiding of symptoms directly correlated with the progression of treatment; all patients had final evaluation at which time function range of motion was restored and activities of daily living were resumed; all patients had complete relief of pain. The patients were instructed in biomechanics and modifications were made according to postural changes as outlined in the DRS System protocol. All patients who were surgical candidates also had MRI documented findings.

One of the most important notations is the studies and reviews of the literature (also discussed in an earlier study by Shealy, LeRoy et al) was that **conventional spinal traction was less effective and biomechanically insufficient for optimal therapeutic outcome i.e. regular traction does not produce decompression, that is, unloading due to distraction and positioning of the intervertebral discs and facet joints of the lumbar spine. The DRS System is not regular spinal traction and does not utilize the conventional traction table. It is also not physical therapy although the protocol does contain elements of physical medicine. It is not to be confused with standard traction that is often used by physical therapists and/or chiropractors.**