This original study was headed by C. Norman Shealy, M.D., PhD, as lead researcher and was performed on the DRS system device. The DRS was the first vertical angle decompression system, awarded patent by the U.S. Patent and Trademark Office. The named inventors of this patented technology were Dr. Shealy and Carlos Becerra.
Carlos Becerra is the founder and CEO of North American Medical Corporation, a private U.S. company which manufactures the SPINA System™ line of devices. Dr. Shealy currently serves as Chairman of the Scientific Advisory Board for North American Medical where he continues to contribute to the advancement of this emerging technology.

Peer Review Network, Inc.

MTG Newsletter

October 1998/Vol. 5 No. 3

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SPECIAL REPORT
DRS SYSTEM

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 exceedlingly 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 that 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 vertebrae 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 disease 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 functional 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. Some patients appear to even be more disabled after treatment than before treatment. Surgery versus conservative trial 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

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use of high-dose opiods can 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 posterior 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 with a prolapsed nucleus pulposus. We reviewed studies on traditional traction that report less than 50% positive outcomes.

Although the use 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 of Intradiscal Pressures

The intervertebral disc and the two zygapophysial 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 hydrostatically as a viscous fluid changing shape in response to body position - in effect, acting like a joint.

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 this inner nucleus is received by diffusion. Compared to the disc, the zygapophysial joints hold only 10-15% of the load while standing but 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 orthopaedic 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 Ramos et al ("Effects of vertebral axial decompression and intradiscal pressure", Journal of Neurosurgery, 1994) have studied 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 flexion 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 demonstrated 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 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 that 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 stated: "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 at 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 research 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%) in the vertebrae above and below. It is estimated that the cycle of proline 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 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 grater 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 of 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 cannot 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 at Georgetown University on a scientifically statistical number of patients (initially evaluated by an orthopaedic surgeon for diagnosis confirmed by MRI) showed the subsiding of symptoms directly correlated with the progression of treatment; all patients had final evaluations at which time functional range of motion was restored and activities of daily living were resumed. All patients had complete relief of pain and MRI documented findings. The patients were instructed in biomechanics and modifications were made according to postural changes as outlined in the DRS System protocol.

One of the most important notations in 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 ie 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.

Claims Adjudication

* For the adjudication of claims, submissions should contain documentation validating diagnosis as given earlier in this article via neurological testing or MRI where appropriate.

* Number of DRS System treatments should be 20 or less. (More than 20 treatments should be rationalized in special documentation submitted with the claim.) Unlisted code in the nervous system - 64999.

* An initial exam of level 4 or 5 should be given to new patients. A level 2 exam may be acceptable weekly to re-evaluate patient progress and to make treatment adjustments. CPT Codes 99204, 99205 for initial visit; Codes 99212 (or for some patients 99213) for subsequent re-evaluations.

*Hot/cold packs, electrical stimulation and/or other physical therapy modalities may be included for those patients who are receiving treatment with the DRS System. Preventing muscle spasm which would delay treatment outcomes is the primary need for adjunct therapy. CPT Codes 97010, 64550, 97110, 97265, 97530, 90901, and/or 95831 et seq. may apply.

* Strengthening and stabilization may be introduced during any phase of the DRS System treatment, based on the decision of the treating physician. CPT Codes 97110, 97545, 97750, 99071, 99080 may apply.

* Counseling and/or risk factor reduction interventions following or during DRS System treatments. CPT Codes 99401 et seq. may apply.

* Treatment supplies. CPT Code 99070.

* Laboratory, radiological, MRI/CT scans as appropriate and medically indicated. Those patients with ruptured discs that are receiving IV Colchicine will need frequent special testing (CBC and Smac, renal functions). Special supplies eg 24 gauge Jelco needles, IV set-ups, normal saline solutions etc. will also be billed.

Usual and Customary Charge Data

Regular CPT codes billed on the 1500 forms should be reimbursed according to individual code data and percentiles subject to patient contract. For the unlisted code used for the DRS System device, a national data survey plus a calculation of the RVUs, taking into account all three components of the RVU indicator, resulted in the following: 13.95 RVUs for an average (1.0 geographical local factor) of $153 per 45 minute session - global (technical/professional components).

Determination

The Medical Technology Assessment Group recommends coverage of the DRS System device. This device is FDA approved and not considered investigational; clinical trials and outcome studies have been published in the literature showing high percentage treatment results for the diagnoses listed. It is a superior version of some of the other types of decompression devices on the market and has produced similar or superior clinical outcomes due especially to the product's design and the treatment protocol. It is also non-invasive and is cost-effective for the treatment of the diagnoses listed. The cost per patient can be in the range of $2,500 - $5,000 as compared to surgical procedures costing more than $30,000 (surgicenter facility fees plus procedure costs). A CPT code application process is currently being initiated.

CRANIAL MOLDING HELMETS

From January 1992 to December 1994, the Division of Neurosurgery, New York University, School of Medicine, reviewed 52 consecutive cases of patients presenting with deformational problems; deformities of the face, skull and jaw. All infants were initially positioned on their back/side. In 52 patients, 61% had plagiocephaly or brachycephaly.

All skull radiographs demonstrated patent sutures. Follow-up clinical exam and photography demonstrated significant improvement of cranial

form in all patients with recommended frequent head turning (73%), helmet wearing (23%), and surgery (4%). All the affected infants in this study had been managed according to the "positioning" and only 27% later had to be referred to the use of helmets or surgery.

Similar studies in Switzerland, Bowman Gray School of Medicine, Winston-Salem, North Carolina, Children's Hospital of Pittsburgh, Pa., and the University of Buffalo, New York, School of Medicine, found the same results: Positioning is the recommended first-line treatment followed by the helmet use and then surgery if positioning did not produce the desired results.

If after a trial of 4-6 months, there is no change using positioning, then helmet use may be indicated. Positioning must be done per protocol and then re-evaluated for use of the helmet. It should be noted that due to a child's growth, more than one helmet may be necessary.

LASIK AND MYOPIA

The medical necessity of keratorefractive surgery is in a state of flux in the United States at this time. Some insurance companies cover all keratorefractive procedures, while others cover no keratorefractive procedures. Either of these policies can be considered internally consistent.

While some companies will cover Radial Keratotomy (RK) and/or Photorefractive Keratectomy (PRK), they do not cover Laser Assisted In Situ Keratomilleusis (LASIK).This approach limits the surgeon's ability to choose the keratorefractive procedure he considers best for the patient.

Keratorefractive surgery is rarely "medically mandatory". One does not lose vision if one does not undergo LASIK. However, myopia is not normal and LASIK is the preferred surgical option for the management of myopia.

CHIROPRACTIC/ACUPUNCTURE

Guidelines for Outside Review

The following guidelines were designed to assist the claims adjudicators in identifying claims in need of review by an outside consultant:

* Claims submitted for any patient under 12 years of age for chiropractic or acupuncture treatments should be reviewed prior to payment.

* Claims submitted by a chiropractor or acupuncturist for more than one member of the same family should be sent for medical review prior to payment.

* Claims should be reviewed after 38 visits for the original diagnosis. Claims should also be submitted for review when any changes or additions to the original diagnoses are made.

The carrier also has the option of placing a dollar amount on both chiropractic and acupuncture claims which would take precedent over the 38 treatment guidelines listed above.

For this option modalities and other actual patient care (ie herbs, nutritional supplements, physical therapy, etc) should be included as well as any special testing performed by the treating provider. Referral to a specialist for outside testing, X-Ray, and lab fees should be excluded when determining the total dollars.

Claims submitted for review should include treating provider's notes, as well as the 1500 forms of the provider. The 1500 forms provide a more definitive way of detecting changes or additions to the diagnoses. Results of any testing should also be included.

The MTG Newsletter is happy to receive suggestions for topics to be included in future editions of the NEWSLETTER. Please fax topic requests/ideas to (708)771-2331.