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Chairman's Column

By Edward C. Benzel, M.D.

Chairman, Cleveland Clinic Spine Institute

WELLNESS – WHAT A CONCEPT! Like we do so many other things in life, we humans often deal with our own health via crisis management maneuvers. We wait for a clinical problem or malady to arise before addressing the root problem. We wait until we become hypertensive before we embark upon a weight-reduction and fitness program. We wait until we have a heart attack before we begin working on a smoking-cessation program.

Very few people die from the direct consequences of a spinal disorder. So it is even easier to rationalize a lackadaisical approach to prophylactic spine care than it is for the prophylactic management of cardiac and stroke risk factors. The 10 to 15 minutes per week required to maintain a healthy spine seems impossible to busy people. We go through life without regard for our spine until we have a spinal crisis. Then, we ask for the quick fix (i.e., pills, surgery or the like), while disregarding our own active involvement in the process. Even after recovering from an initial episode of incapacitating back pain, the absence of a life-threatening component of the problem diminishes an already deflated enthusiasm for preventive spine care.

Patient education is key

It is clear that the key to the successful management of spine health is patient education. The informed patient is much more likely to make appropriate health-related decisions and choose to act preemptively

regarding the care of his/her back. This individual is more likely to make time to exercise (both aerobic and back exercises), more likely to lose weight, and more likely to lift properly. The multidisciplinary approach to spine care taken by the Cleveland Clinic Spine Institute, the subject of a superb article on page 4, is centered on patient education.

Controversies in spine care

In this issue of *Spinal Column*, you also will find a discourse regarding a controversial surgical intervention, interspinous distraction for lumbar stenosis, used for a small subset of the spine disorders population. This article addresses the controversy that obligatorily exists regarding surgical management of most spine conditions.

We appreciate you taking a few minutes from your busy day to peruse this issue of *Spinal Column*. We hope you find it informative and useful.



Edward C. Benzel, M.D.

For more information about the Spine Institute, please contact Dr. Benzel at 216.445.5514 or our administrator, Kathy Huffman, at 216.445.8442.

To refer patients, call 216.445.2225 or 800.553.5056, ext. 42225.

Interspinous Process Spacers in the Treatment of Spinal Pathology: Arguments Against Their Use

By Isador H. Lieberman, M.D., MBA, FRCS(C)



Isador H. Lieberman, M.D.

Dr. Lieberman can be contacted at 216.445.2743 or at lieberi@ccf.org.

NEW MEDICAL DEVICES CALLED INTERSPINOUS PROCESS DISTRACTORS OR POSTERIOR DYNAMIC STABILIZERS HAVE RECENTLY DRAWN MUCH ATTENTION. These devices are intended to treat neurogenic claudication by distraction of the spinous processes, resisting lumbar spine extension, reducing pressure on the posterior annulus and indirectly enlarging the neural foramina.

Most of these devices are under FDA investigation, including the DIAM Spinal Stabilization System (Medtronic), Wallis Stabilization System (Spinal Concepts, Abbott Laboratories) and Interspinous U or Coflex (Paradigm Spine). However, the X STOP Interspinous Decompression System (St. Francis Medical Technologies) received FDA approval late last year. The X STOP device is in clinical use for the treatment of “back pain” and/or “spinal stenosis.”

Pros

Proponents of interspinous distraction devices claim they have many benefits, including an easy surgical technique, less invasive approach, the ability to provide for neural decompression, and easy reversibility to decompression or fusion procedures.

Cons

Detractors of the technology counter that:

- the devices do not directly address the underlying spinal pathology;
- microdecompression remains the gold standard for foraminal or central stenosis at a single or even multiple levels;
- most patients have multiple-level disease and elements of spinal instability;
- the devices force the already degenerative and flattened lumbar spine into further focal kyphosis;
- the devices do not support or protect lateral bending, axial rotation, or translation;
- the devices shift the instantaneous axis of rotation well anterior from its native position in the posterior third of the disc space; and
- the devices add significant implant costs to procedures that typically are not associated with any implant costs.

Literature sparse

A PubMed online literature search revealed very few articles describing clinical indications or outcome results for these devices. Only one randomized clinical trial with the X STOP device was found (Zucherman et al. *Spine*. 2005;30:1351-1358). This study limited patient inclusion to those with “leg, buttock or groin pain, with or without back pain, that was relieved by flexion.” Exclusion criteria were fixed motor deficit, cauda equina syndrome, previous lumbar surgery, and spondylolisthesis greater than grade 1. The control group consisted of patients managed nonoperatively, including treatment with epidural injection, NSAIDs and physical therapy.

Two-year follow-up results showed that 53 of 93 patients (57 percent) in the X STOP group experienced clinically significant improvement in their physical function score as opposed to only 12 of 81 patients (14.8 percent) in the nonoperative group. Seven patients in the operative group and 10 patients in the nonoperative group were lost to follow-up.

Study design questionable

When Zucherman and colleagues compared spinal stenosis literature results with the X STOP trial results, they not only found that the X STOP device appears as clinically effective as lumbar laminectomy but also that the control group did not experience the same level of clinical improvement as one would expect. These outcomes call into question the validity of the study design and statistical analysis. Regardless, it is clear that comparing the X STOP to historical antiquated data of lumbar laminectomy serves no purpose. Furthermore, it is intriguing that the nonoperative group did not achieve the expected level of improvement.

To truly determine whether an interspinous process distraction device serves any benefit in the treatment of neurogenic claudication, the trial must randomize against a less invasive microdecompression laminotomy technique. Until data such as that is available, the use of these devices should be limited to protocol-based studies.

X STOP Device for Lumbar Stenosis Worth Considering

By Robert F. McLain, M.D.

ALTHOUGH A NUMBER OF MEDICAL DEVICES ARE BEING DEVELOPED TO RELIEVE LEG AND BACK PAIN ASSOCIATED WITH LUMBAR SPINAL STENOSIS, only one has been approved by the FDA for this purpose – the X STOP Interspinous Process Decompression System (St. Francis Medical Technologies).

The small bullet-shaped implant is placed between the spinous processes, outside the spinal canal. This opens the space between the processes and forces the selected spinal segment into slight flexion. As a result, patients assume the posture that they naturally seek for pain relief and to improve walking tolerance (e.g., leaning forward on a shopping cart or walker). This position is maintained when the patient stands or walks because the vertebrae are held in alignment.

Select group chosen

Like any implant or surgical technique, the X STOP system is intended for a select group of patients. Prospective trials have focused on relief of neurogenic claudication, the leg pain caused by lumbar canal stenosis. The implant is indicated for treatment of moderate stenosis – the type commonly addressed with conservative therapy. It has not been recommended for treatment of severe stenosis – the type commonly addressed through laminotomy or laminectomy.

Studies have shown that patients with persistent neurogenic claudication respond poorly to nonsurgical care; only about a third of patients treated conservatively have significant improvement in pain or function. By comparison, patients treated with laminectomy and surgical decompression experience improvement in 60 percent to 70 percent of cases.

Low complication rate

The randomized, prospective, multicenter, controlled trial reported by Zucherman and colleagues in 2004 (*Eur Spine J.* 2004;13:22-31) and 2005 (*Spine.* 2005;30:1351-1358) clearly spelled out the inclusion criteria for the X STOP device, and outlined the solid study design. This study sought to demonstrate that the X STOP device provided superior results compared to nonoperative methods including physical therapy, anti-inflammatory medications, and epidural steroids. The authors were satisfied to show that the implant was comparable – not superior – to results of surgical decompression, but demonstrated a

clear advantage over conservative treatment. A full 57 percent of patients treated with the device achieved good to excellent results. At two-year follow-up, X STOP patients reported a 45 percent improvement in symptom severity, compared to 7 percent improvement in the conservatively treated patients, ($p < 0.001$). No dural tears or nerve injury, no epidural fibrosis or arachnoiditis, and no deep infections occurred in these patients, because the spinal canal is not entered during X STOP placement. Compare this with the 6 percent incidence of dural tears and 13 percent incidence of overall complications associated with decompressive surgery (Turner, JA et al. *Surgery for lumbar spinal stenosis. Spine* 1992;17:1-8.), and the appeal of the X STOP system becomes apparent.

Retreatment not needed

Only 6 percent of the implant patients in the X STOP FDA trial required further surgery due to treatment failure, but 30 percent of the nonoperative patients required surgical decompression during the first two years of follow-up. These findings reflect the fact that the X STOP device is placed under local anesthesia, reducing surgical risk and cost, as opposed to decompressive surgery, which must be performed under either spinal or general anesthesia.

Surgical decompression remains the gold standard and is my preferred approach for patients with severe canal stenosis, but X STOP represents a unique and effective tool to relieve leg pain in patients with moderate disease and persistent symptoms. For patients whose leg pain is no longer controlled by nonoperative measures, X STOP is a procedure worth considering.



Robert F. McLain, M.D.

Dr. McLain can be reached at 216.444.2744 or at mclainr@ccf.org.

Making the Right Choices for Spine Health

By Daniel Mazanec, M.D.; Judith Scheman, Ph.D.; and Paula Lidestri, M.D.



Daniel Mazanec, M.D.



Judith Scheman, Ph.D.



Paula Lidestri, M.D.

Dr. Mazanec can be reached at 216.444.6191 or mazaned@ccf.org

Dr. Scheman at 216.444.2875 or schemaj@ccf.org

Dr. Lidestri at 216.445.2241 or lidestp@ccf.org.

BACK PAIN IS THE MOST PREVALENT MEDICAL DISORDER IN INDUSTRIALIZED SOCIETIES. Eighty percent of individuals in the general United States population will have at least one episode of low back pain during their lifetime, and about 50 percent of adults currently have back discomfort. Low back pain alone disables at least 5.4 million Americans and is the leading cause of work-related disability. Additionally, back pain is the most common reason for functional impairment in persons younger than 40 years old.

Back pain also has a significant impact on society. Total health care expenditures for persons suffering from back pain in the United States are in excess of \$90 billion, and more than one-quarter of that cost is devoted to treatment. Individuals with back pain incur 60 percent higher health care expenses than individuals without back pain. Fortunately, most episodes of acute back pain resolve within a few weeks, although recurrence is common. Yet, for 5 to 10 percent of people, pain persists longer than six months, with increasing risk of prolonged disability. This group of patients consumes 85 percent of the money spent on spine care.

The etiology of back pain is often ambiguous and frequently multifactorial. Nevertheless, back pain is often viewed in unidimensional terms and approached in an incomplete, piecemeal fashion. Furthermore, treatment is typically focused on evaluation and management of current symptoms, with little attention paid to spine health maintenance and prevention of future episodes. Lastly, the important psychosocial issues involved in long-standing back pain are frequently ignored.

Interdisciplinary approach

It is unlikely that a single intervention – medication, therapy, injections or surgery – will be effective in treating back pain, particularly in persons with chronic spinal pain. For these patients, an interdisciplinary approach is more likely to garner success. Many patients with chronic back pain also pursue alternative treatments, such as spinal distraction (decompression, automated traction), prolotherapy, acupuncture and herbal supplements. Unfortunately, the value of many of these therapies is dubious or unproven, and they are provided by therapists with uncertain credentials.

Multiple modifiable risk factors for neck and back disease have been identified, including cigarette smoking; stress, tension, and a number of other psychological factors; deconditioning and poor posture; obesity; and poor lifting techniques or improper body mechanics. Smoking increases the risk of back pain through several mechanisms, including increased intradiscal pressure due to increased cough; nicotine-induced vasoconstriction of the already marginal blood supply to the disc; and the replacement of oxygen in the blood with carbon monoxide, resulting in accelerated degenerative disc disease.

Stress and tension typically cause chronic muscle contraction, resulting in tight, aching and burning muscles; muscular fatigue and pain are caused by the secondary mechanisms involved in poor posture. Chronic stress may also contribute to pain magnification by altering CNS pain perception (central sensitization). Similarly, poor posture and tense muscle causes chronic muscle strain, fatigue and pain. Obesity increases demands on musculoskeletal structures and may inhibit participation in aerobic exercise, vital to preservation of spine health.

Disability from pain can compound risk factors. Pain that leads to disability can lead to depression, a sedentary life style as well as the choice of ineffective and harmful coping mechanisms, including smoking and overeating. As the pain increases, so can the disability. Although it starts to sound like a vicious circle, in fact, it is a downward spiral with each iteration worsening. Unless the pain and disability spiral is interrupted, it becomes self-perpetuating and ultimately often leads to profound loss of function.

Help patients avoid catastrophizing

Another factor associated with increased pain and suffering is catastrophizing, which is often unintentionally fueled by the physician. When information about benign results, such as bulging discs on an MRI, are not shared appropriately with a patient, the patient can use the information to catastrophize about his or her condition. If the patient believes that a medical result is significant, he or she may modify their activity in unhealthy ways and may become depressed. Depression, in turn, leads to increased perception of pain.

Understanding safe activity

Patients often fail to distinguish between activities that may cause increased pain but no further injury vs. those that may actually cause further damage or harm. Therefore, they may needlessly limit their home and work activities based primarily on whether or not the activity causes pain. For some, the erroneous emphasis on rest may lead to excessive inactivity and fuel fear of re-injury, which may actually prolong pain and increase disability. Additionally, many patients frequently do not appreciate the well-documented benefit of exercise on improvement of chronic back pain and function

Spine wellness: the interdisciplinary approach

An interdisciplinary approach to spinal wellness begins with education of the patient about the risk factors for back pain as well as the generally benign nature of most back pain. With the participation of the appropriate members of the interdisciplinary team, the informed patient is better able to make the best choices in the prevention of chronic back pain and disability. Such preventive treatment services might include a smoking-cessation program, a weight-reduction program, fitness training, biofeedback,

yoga, stress-reduction program, cognitive behavioral therapy, physical therapy, occupational therapy, and a bone health program. This approach proactively encourages physical and mental fitness in addition to risk-reduction activities.

Using a risk-reduction approach similar to that employed in other medical conditions, an interdisciplinary approach to spinal health also requires addressing each of the risk factors in a comprehensive setting. Because back pain and injuries represent the No.1 cause of work-related disability, programs to promote spinal health in the workplace are especially important. Strategies should include matching the physical capabilities of the individual to the demands of the job as well as education in proper lifting mechanics.

A significant amount of data exists showing that the interdisciplinary approach is efficacious in reducing pain and suffering as well as health care costs. To further reduce the enormous personal and societal burden of back disorders in terms of dollars and disability, insurers and health care professionals need to accept and embrace the interdisciplinary team approach to back pain.

Interdisciplinary Team for Spine Health

Medical spine physician specialist
Spine pain medicine specialist
Clinical psychologist / pain specialist
Physical therapist
Occupational therapist

Spine Wellness Services

Acupuncture
Manipulation / manual medicine
Pain and stress reduction / biofeedback / cognitive behavioral therapy
Smoking cessation
Weight management/nutrition
Fitness / aerobic training
Bone health
Yoga
Massotherapy

New Director of Spine Research Laboratory

The appointment of Lars G. Gilbertson, Ph.D., as Director of the Spine Research Laboratory, Cleveland Clinic Spine Institute, underscores the continued growth in this area.

Dr. Gilbertson, who also has a joint appointment in the Department of Biomedical Engineering, Lerner Research Institute, comes to Cleveland Clinic from the University of Pittsburgh, where he was Co-Director of Spinal Research, Department of Orthopaedic Surgery.

He received bachelor and masters degrees from the University of Vermont in mechanical engineering and biomedical engineering, respectively, and his doctoral degree in biomedical engineering from the University of Iowa. Dr. Gilbertson also completed a two-year post-doctoral fellowship (NIH National Research Service Award) at the Iowa Center on Aging.

Dr. Gilbertson is actively engaged in various bioengineering studies of the human spine, including robotics-assisted measurement of in vitro lumbar spinal kinetics, virtual reality-assisted measurement of in vivo cervical spine kinematics, and tissue engineering approaches to the treatment of intervertebral disc degeneration.

Dr. Gilbertson is a two-time recipient of the international Volvo Award for Outstanding Research in the Lumbar Spine—the highest societal award from the International Society for the Study of the Lumbar Spine (ISSLS).

Dr. Gilbertson has authored more than 30 scientific articles, six book chapters and nearly 100 abstracts. He can be reached at 216.445.5911 or gilberl2@ccf.org.



Lars Gilbertson, Ph.D.

Expanded Services in Northeastern Ohio

Medical and surgical specialists from the Cleveland Clinic Spine Institute now see patients at our Willoughby Hills Family Health Center. They are available in Willoughby on Tuesdays, Wednesdays and Thursdays (at main campus on other days). Patients may call 440.943.2500 for appointments in Willoughby Hills.

The following physicians see patients in Willoughby Hills and main campus:



Augusto Hsia Jr., M.D.

Augusto Hsia Jr., M.D.

Telephone: 216.445.3450

E-mail: hsiaa@ccf.org

Medical Degree: Saint Louis University College of Medicine, Banguio City, Philippines

Training: Fellowship – Stony Brook University Hospital, NY; Fellowship – Cleveland Clinic; Internship – Medical Center Manila, Philippines; Residency – New York University Medical Center

Clinical Interests: Medical spine



Ajit Krishnaney, M.D.

Ajit Krishnaney, M.D.

Telephone: 216.445.3777

E-mail: krishna@ccf.org

Medical Degree: University of Wisconsin Medical School, Madison

Training: Fellowship, internship and residency – Cleveland Clinic

Clinical Interests: Surgical spine

Cleveland Clinic Spine Institute Locations

Cleveland Clinic

9500 Euclid Avenue
Cleveland, OH 44195
216.444.BACK

Euclid Hospital

18901 Lake Shore Blvd.
Euclid, OH 44119
216.692.8222

Lutheran Hospital

1730 West 25th Street
Cleveland, OH 44113
216.363.2410

**Beachwood Family Health
and Surgery Center**

26900 Cedar Road
Beachwood, OH 44112
216.839.3000

Solon Family Health Center

29800 Bainbridge Road
Solon, OH 44139
440.519.6800

**Strongsville Family Health
and Surgery Center**

16761 SouthPark Center
Strongsville, OH 44136
440.878.2500

Westlake Family Health Center

30033 Clemens Road
Westlake, OH 44145
440.899.5555

**Willoughby Hills
Family Health Center**

2570 SOM Center Road
Willoughby Hills, OH 44094
440.943.2500



Outcomes Data Available

The latest outcomes data from the Cleveland Clinic Spine Institute are available. Our outcomes booklet also offers summary reviews of medical and surgical trends and approaches. Charts, graphs and data illustrate the scope and volume of procedures performed in our department each year. To view outcomes booklets for the Spine Institute as well as many other Cleveland Clinic medical and surgical disciplines, visit clevelandclinic.org/quality.

Cleveland Clinic Spine Institute Clinical Trials

Prospective outcomes evaluation of decompression with or without instrumented fusion for lumbar stenosis with degenerative grade I spondylolisthesis

Edward Benzel, M.D.
216.445.5514

Prospective, randomized clinical investigation of the Cervitech, Inc., Porous Coated Motion Artificial Disc for stabilization of the cervical spine in patients with DDD and neurological symptoms at one level (C3-C4 or C7-T1)

Richard Schlenk, M.D.
216.445.4318

Isador Lieberman, M.D.
216.445.2743

The precision of pain reduction in the treatment of facet joint syndrome monitored by CERSR technology

Daniel Mazanec, M.D.
216.444.6191

Lumbar spine instability study: the role of flexion/extension radiographs

Russell DeMicco, D.O.
216.444.0229

Aspiration of marrow progenitor cells from the vertebral body during pedicle screw fixation: comparison to iliac crest

Robert McLain, M.D.
216.444.2744

Anterior cervical fusion augmented with autologous marrow: a controlled, prospective, randomized trial

Robert McLain, M.D.
216.444.2744

Prospective randomized trial of two anterior interbody cages: Osteonics SAC and Sulzer Spinetech BAK

Robert McLain, M.D.
216.444.2744

Pilot study assessing the use of Cortoss, a synthetic cortical bone void filler in kyphoplasty

Isador Lieberman, M.D.
216.445.2743

Application of seating support for patients with coccygodynia

Gaurav Kapur, M.D.
216.445.7378

Comparison of femoral ring allograft with supplemental translaminar facet screw fixation versus stand-alone anterior lumbar interbody fusion cages

Douglas Orr, M.D.
216.363.2410

Allograft bone augmented with autogenous bone marrow aspirate for lumbar interbody fusion-pilot study

Isador Lieberman, M.D.
216.445.2743



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Institute, call **216.444.2225**

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CLEVELAND CLINIC SPINE INSTITUTE



Cleveland Clinic is ranked third in the nation in *U.S. News & World Report's*
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Upcoming Symposia

Call the Cleveland Clinic Continuing Education Department at 216.444.5696 or 800.762.8173, or log onto clevelandclinicmeded.com for seminar details.

September 8-9
Innovative Spine Care Conference for RNs
InterContinental Hotel & Conference Center
Cleveland, OH

Contact Martha Tobin at 216.445.3449 or 800.223.2273, ext. 53449,
or at tobinm@ccf.org

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Co-Editor:
Edward C. Benzel, M.D.
Chairman, Cleveland Clinic Spine Institute

Co-Editor:
Daniel J. Mazanec, M.D., F.A.C.P.
Vice Chairman, Cleveland Clinic
Spine Institute
Head, Section of Spine Medicine

Marketing Program Manager:
Ellie Palmer

Managing Editor:
Laura R. Greenwald

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Stephanie Di Biase