Lumbar Spinal Stenosis

Symptoms & Diagnosis, Treatment Options, and the X-STOP® IPD® System

Pri-Med West
Exhibit Hall Theater

Thursday, May 15, 2008
12:15pm – 1:15pm

OVERVIEW

Lumbar spinal stenosis (LSS) is the most common reason for spine surgery in people over the age of 65 in the United States.[1] This program will cover the clinical issues around LSS: clinical presentation, diagnosis, and treatments. The various treatment options for the symptoms of LSS that will be presented include: non-operative care, surgical intervention, and the new minimally invasive procedure the X-STOP® IPD® Spacer.

OBJECTIVES

At the conclusion of this presentation, participants will gain knowledge of the following:

- The symptoms and clinical presentation of lumbar spinal stenosis (LSS)
- The medical information needed to properly diagnose LSS
- Various LSS treatment options, including non-surgical management, surgical management, and minimally invasive procedures, including the X-STOP® IPD® Spacer
- Indications for the X-STOP® IPD® Spacer
- Clinical outcomes of the X-STOP® IPD® Spacer

SPEAKERS

*Consultant for Medtronic

A. Nick Shamie, MD* – Chief, Wadsworth Spine Service; Assistant Professor of Orthopaedic Surgery and Neurosurgery, UCLA School of Medicine

Dr. Nick Shamie is a Board Certified Spine Surgeon who has served on the UCLA School of Medicine faculty since joining the Department of Orthopaedic Surgery in 2000. Dr. Shamie earned his B.S. in Biological Sciences at UC Irvine and his M.D. at the Northwestern University. After receiving his medical degree, he did a general surgery internship at Los Angeles County and USC Medical Center followed by a residency in orthopaedic surgery at St. Mary's Medical Center. Dr. Shamie also did fellowship training at UCLA in Bone Research and Spinal Surgery and is involved in graduate and medical education. Dr. Shamie actively participates in both basic science and clinical research in the field of spine surgery and is a recipient of the UCI School of Medicine Award for Excellence in Research.

Lee Trevino – Legendary Golf Pro & X-STOP® Spacer Patient

An entirely self-taught golfer, Lee Trevino is one of the most decorated professional golfers and is celebrated for his humor and showmanship on the fairway. He joined the PGA tour in 1969 and in his 22 years on the tour won several major tournaments, including the U.S. Open, the British Open and the PGA championship. As part of the Senior Tour, beginning in 1989, he added 29 more titles to his storied career. Trevino's career unfortunately hit a set back in 1975 when he was struck by lightning, leading to back problems and several spine surgeries. He also developed debilitating lumbar spinal stenosis and in 2005 he had the X-STOP® Spacer implanted to help treat his symptoms.

Program sponsored by Kyphon (now Medtronic)

Visit us at Booth #643

This educational event is not approved for CME credit.

1. Ciol – *J Am Geriatr Soc* 1996

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Indications for Use: The X-STOP® Interspinous Process Decompression (IPD®) System is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with X-Ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing). The X-STOP is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of non-operative treatment. The X-STOP may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

Contraindications: The device is contraindicated in patients with: an allergy to titanium or titanium alloy; spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as: significant instability of the lumbar spine, e.g. isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4), an ankylosed segment at the affected level(s), acute fracture of the spinous process or pars interarticularis and significant scoliosis (Cobb angle greater than 25 degrees); cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction; diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or some comparable study) in the spine or hip that is more than 2.5 SD below the mean of adult normals in the presence of one or more fragility fractures; and active systemic infection or infection localized to the site of implantation.

Warnings: The X-STOP implant must be placed in the concavity between the spinous processes. Posterior positioning of the implant may result in dislodgement. If correct placement of the implant cannot be achieved due to variant anatomy, the surgeon should consider aborting the procedure because incorrect placement may result in device dislodgement, particularly if the patient experiences a traumatic event.

Precautions: Radiological evidence of stenosis must be correlated with the patient's symptoms before the diagnosis can be confirmed; if the spinous processes at the affected level are not distracted in flexion, the X-STOP system may not be indicated; the safety and effectiveness of the X-STOP device has not been studied in patients with the following conditions: axial back pain without leg, buttock or groin pain, symptomatic lumbar spinal stenosis at more than 2 levels, prior lumbar spine surgery, significant peripheral neuropathy, acute denervation secondary to radiculopathy, Paget's disease, vertebral metastases, morbid obesity, pregnancy, a fixed motor deficit, angina, active rheumatoid arthritis, peripheral vascular disease and advanced diabetes or any other systemic disease that may affect the patient's ability to walk; surgeons should not implant the X-STOP implant until receiving adequate training regarding surgical technique because inadequate training may result in poor patient outcomes and/or increased rates of adverse events; and a stress fracture of the spinous process may occur if strenuous physical activity is resumed too soon postoperatively.

Potential Adverse Events: The following potential adverse events may occur as a result of interspinous process decompression with the X-STOP system; some of these adverse events were reported in the Pivotal Clinical Trial. X-STOP system related: implant dislodgement/migration; implant not positioned correctly; fracture of the spinous process; additional surgery, which could include removal of the X-STOP implant; foreign body reaction; mechanical failure of the device; failure of the device/procedure to improve symptoms and/or function. Surgery Related: reactions to anesthesia; myocardial infarction; infection; blood vessel damage/bleeding; deep vein thrombosis; hematoma; pneumonia; neurological system compromise; stroke; nerve injury or spinal cord damage; paralysis; thrombus formation; wound dehiscence or delayed healing; pain/discomfort at the operative site; and death.

Note: Medication or additional surgery may be necessary to correct some of these potential adverse events.

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