Treatment Options for Scoliosis

Your spine consists of three primary sections:

- Cervical — Neck
- Thoracic — Upper back
- Lumbar — Lower back

Spinal Anatomy

Vertebral Bodies

Intervertebral Disc

Pedicles

Facet Joint

Bony structure that connects the vertebrae to facet joints
The left and right joints at a motion segment that join each vertebra together
Bodies of bone that make up the spinal column
Shock absorbing structure allowing for stability and motion of the spine
What is scoliosis?

Scoliosis is not a disease—it is a descriptive term. All spines have curves. Some curvature in the neck, upper trunk and lower trunk is normal. Humans need these spinal curves to help the upper body maintain proper balance and alignment over the pelvis. However, when there are abnormal side-to-side (lateral) curves in the spinal column, we refer to this as scoliosis.

Types of Scoliosis

Adolescent Idiopathic scoliosis (AIS)
- The most common type of scoliosis
- More common in girls

Early onset scoliosis
- Occurs before the age of 5
- Seen more commonly in boys

Congenital scoliosis
- Present at birth due to anatomic defects

Neuromuscular scoliosis
- Scoliosis caused by a neurological condition

Diagnosing AIS

- Physical Exam
  - Adam’s Forward Bend Test
  - Your doctor will look for signs of asymmetry—uneven shoulders, hips or prominent rib cage.

- X-Rays
  - Front and side x-rays of your spine allow your doctor to evaluate the severity of the curve.

- Cobb angle
  - The degree of tilt between the end vertebrae of the scoliotic curve. A Cobb angle of 10 degrees or greater is diagnosed as scoliosis.
Treatment Options

Considerations when determining treatment options:

• Spinal maturity
  Is the patient’s spine still growing and changing?
• Degree and extent of curvature
  How severe is the curve and how does it affect the patient's lifestyle?
• Location of curve
  According to the Scoliosis Research Society, thoracic (upper spine) curves are more likely to progress than thoracolumbar (middle spine) or lumbar (lower spine) curves.
• Potential for progression
  Patients who have large curves prior to their adolescent growth spurts are more likely to experience curve progression.

Non-Surgical Treatment Options

Observation
• Often recommended for patients who have less severe curves

Bracing
• Intended to halt progression of curve
• Often recommended for curves between 25 & 40 degrees in patients who are still growing

Studies show that the more the patient wears the brace, the better the chances are that it will successfully stop the curve from getting worse!

Surgical Treatment Options

Potential indications for surgery
• Cobb angle of greater than 40 to 45 degrees
• Rapid progression of curve

Goals of surgery
• Prevent progression of the curve
• Restore the spine’s natural balance
Surgical Treatment Options

Types of AIS surgery

- **Anterior fusion**
  - Best for lumbar curves
  - May involve fewer fused levels
  - May be associated with higher complication rates

- **Posterior fusion**
  - Best for thoracic curves
  - Most common procedure

- **Anterior/posterior fusion**
  - Patients with severe or very rigid curves may require both approaches. An "anterior release" allows for better manipulation and correction of the spine

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**Anterior Fusion**

- Incision made in the patient’s chest or abdomen to access the spine from the side
- Select intervertebral discs are removed to make the spine more flexible
- Bone grafting material is placed to help bone grow and "fuse" the spine in its corrected position
- Screws are placed into vertebral bodies and connected by a rod. The spine is straightened as much as possible and secured by the screws and rods.
- In the weeks and months after surgery, bone growth or "fusion" occurs to maintain correction

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**Posterior Fusion**

- Incision made in the patient’s back to access the spine
- CD HORIZON® screws are placed into the vertebral bodies and connected by 2 rods. The spine is straightened as much as possible and held in place by the screws and rods.
- Bone grafting material is placed to help bone grow and "fuse" the spine in its corrected position
- In the weeks and months after surgery, bone growth or "fusion" occurs to maintain correction
About Spinal Instrumentation

- CD Horizon® Spinal System is the first system to have clearance under the new FDA product category "Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis."
- CD HORIZON® SOLERA™ Spinal System features a lower profile screw.

CD HORIZON® Spinal System

Contraindications & Warnings
- The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
- The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature.
- Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurovascular injury.
- Pediatric patients may be at increased risk for device-related injury because of their smaller stature.
- Additional potential adverse events include proximal or distal junctional kyphosis and pancreatitis.

Enabling Technologies

- Viewing the spine during surgery
- Neuromonitoring
Viewing the Spine

O-Arm® Imaging System
- Allows for intraoperative 3-dimensional imaging of the spine

Navigation
- Image-guidance

Neuromonitoring

Spinal Cord Nerve Monitoring
- Electrical impulses are given in the legs and then read in the brain. Slowing of signals can indicate compromise to the spinal cord.

The NIM- ECLIPSE™ System allows physicians to monitor neural pathways which may help reduce the risk of neurological problems after surgery.

Risks of Surgery

- Potential risks associated with surgery
  - Excessive blood loss
  - Spinal cord or other neurological injury
  - Infection
  - Failure or malfunction of instrumentation
  - Anesthesia complications
Sample Case

Case #1

Pre-Op
- AIS Case
- Lenke 2 curve (double thoracic)

Post-Op
Questions?

Lumbar Spinal Stenosis:
Symptoms and Treatment

By
Glenn Trent

Agenda

• Introduction
• Anatomy of the Spine – Helpful Terms
• Clinical Presentation
• Symptoms of Lumbar Spinal Stenosis
• Treatment Options
  – Non-Operative & Surgical Treatment
  – A New Alternative
Lumbar Spinal Stenosis (LSS)

- 8 - 11% Incidence of LSS in the U.S.¹
- LSS is the most common reason for spine surgery in older people²
- More than 125,000 laminectomy procedures were performed for LSS in 2003³
- Financial impact and lost work hours reaches billions of dollars each year in the U.S.⁴

4. Knowledge Enterprises, Inc.

Anatomy of the Spine

Understanding your spine: Helpful Terms

- Vertebra
- Disc
- Spinous Process
- Lumbar Spine (L1-L5)
- Interspinous space
Lumbar Vertebra

- Vertebrae provide support for your head and body
- Discs act as "shock absorbers"
- Vertebra protects spinal cord
- Nerves have space and are not pinched
- As we age, ligaments and bone can thicken
- Narrowing is called "stenosis"
- Narrowing impinges on nerves in spinal canal and nerve roots exiting to the legs
- Result - pain & numbness in back and legs

Anatomy of the Spine

Understanding your spine: Helpful Terms

- Extension – occurs when standing
- Flexion – Occurs when sitting or bending forward

Symptoms of Lumbar Spinal Stenosis

- Standing provokes symptoms
- Pain/weakness in the legs
- Patients lean forward while walking to relieve symptoms
- Sitting or bending forward relieves symptoms
Symptoms of Lumbar Spinal Stenosis

Classic Presentation:
• Dull or aching back pain spreading to your legs
• Numbness and “pins and needles” in your legs, calves or buttocks
• Weakness, or a loss of balance
• A decreased endurance for physical activities

Burden of Lumbar Spinal Stenosis

Lack of activity may lead to:
• Obesity
• General physical deterioration
• Depression/other psychological problems
• Worsening of co-morbidities

Treatment Options
Lumbar Spinal Stenosis Treatment Options

Spinal Stenosis Symptoms: Continuum of Care

Mild
Moderate
Severe

Non Operative Care
- Epidural injections
- Physical therapy
- NSAIDs & other drugs
- Lifestyle modification
- Exercise & weight reduction

Surgical Care
- Laminectomy
- Laminectomy with Fusion
- Micro Endoscopic Decompressive Laminectomy
- Laminotomy-facetectomy

Lumbar Spinal Stenosis Treatment Options

Standard of Care: Mild to Moderate Symptoms

Non-operative care
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
  - Reduce swelling and pain, and analgesics to relieve pain
- Epidural Steroid Injection
  - Reduce swelling and treat acute pain that radiates to hips or down the legs
  - May be temporary
  - Typically limited to 3 injections every six months
- Physical Therapy, Exercise & Weight Reduction
  - To help stabilize the spine
  - Build endurance
  - Self-limiting activities of daily living

Lumbar Spinal Stenosis Treatment Options

Standard of Care: More Severe Symptoms

Laminectomy
- Referred to as "unroofing" the spine
- Removal of parts of the vertebra, including:
  - Lamina (bone)
  - Attached ligaments
  - Facets (bone)
- Goal: relieve pressure on spinal cord and nerves by increasing area around spinal canal and neural foramen
- Most common surgery for stenosis, may require a fusion
  1. General anesthesia
  2. In-patient procedure
  3. OR time: 1.5 – 4.5 hours
  4. Average length of hospital stay: 4 days

Lumbar Spinal Stenosis Treatment Options

**Spinal Stenosis Symptoms: Continuum of Care**

**Non Operative Care**
- Epidural injections
- Physical therapy
- NSAIDs & other drugs
- Lifestyle modification

**Surgical Care**
- Laminectomy
- Laminectomy with Fusion
- Micro Endoscopic Decompressive Laminectomy
- Laminotomy-facetectomy

X-STOP® Spacer

X-STOP® Spacer for Lumbar Spinal Stenosis

The X-STOP® Spacer

- X-STOP Spacer is implanted, separating the spinous processes and relieving pinched nerves
- Designed to remain safely and permanently in place
- The first Interspinous Spacer approved by FDA to treat the symptoms of LSS
The X-STOP® Spacer

- Minimally invasive procedure
- Rapidly alleviates pain
- Typically doesn’t require the removal of bone or tissue
- Can be done under local anesthesia
- Low rate of complications\(^1,2\)
- Not attached to bone or ligaments

\(^1\) Zucherman – Spine 2005
\(^2\) X-STOP® IPD® System Instructions For Use (IFU)

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The X-STOP® Spacer

- Spacer only limits extension
- Wings prevent side-to-side and upward migration
- Preserves your supraspinous ligament, which prevents backward migration
- Preserves anatomy
- Treats LSS symptoms, not “anatomy”

\(\) Supraspinous ligament
\(\) Spinous process

\(\) Siddiqui – Spine 2006

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X-STOP® Superior to Non-operative Care

Patients with Clinically Significant Improvement
(Indicated Population, 24-month follow-up)

\begin{center}
\begin{tabular}{lccc}
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 & \textbf{X-STOP (n = 73)} & \textbf{Control (n = 66)} \\
\hline
\textbf{Symptom Severity} & 64\% & 6\% \\
\textbf{Physical Function} & 66\% & 12\% \\
\textbf{Patient Satisfaction} & 72\% & 25\% \\
\textbf{ZCQ Success} & 95\% & 6\% \\
\textbf{Overall Treatment Success} (all 3 criteria) & 54\% & 6\% \\
\hline
\end{tabular}
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Differences between X-STOP and Control groups statistically significant (\(p < 0.001\)) at all follow-up intervals.

\textit{SOURCE: X-STOP® IPD® System Summary of Safety and Effectiveness (SSE); Includes all study sites.}
The X-STOP Spacer

Compared to traditional LSS surgery, X-STOP benefits include:
• Can be done under local anesthesia
• Can be done as an outpatient procedure
• No removal of the lamina (vertebral bone) or ligaments that protect and stabilize the spine
• Potential of a shorter recovery

Are you a candidate?

The X-STOP Spacer is indicated for:
• People aged 50 or older
• Pain or weakness in the legs
• Confirmed diagnosis of lumbar spinal stenosis
• Moderately impaired physical function
• Experience symptom relief in flexion (sitting)
• Completed 6 months of non-operative treatment
• Operative treatment indicated at one or two lumbar levels (but no more than 2 levels)

Questions & Answers
X-STOP® IPD® System
Instructions For Use (IFU)

Indication for Use
The X STOP Interspinous Process Decompression (IPD) System ("X STOP") 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 nonoperative 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 X STOP 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 anteriorly displaced segment at the affected level(s);
  – acute fracture of the spinous process or pars interarticularis;
  – 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;
• 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, the surgeon must consider aborting the procedure to prevent potential device dislodgement, particularly if the patient experiences a traumatic event.
• 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 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; heritable osteoporosis from familial or metabolic cause; significant scoliosis; advanced diabetes or any other systemic disease that may affect the patient’s ability to walk.
• Surgeons should not implant the X STOP until receiving adequate training regarding surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events.
• A stress fracture of the spinous process may occur if strenuous physical activity is resumed too soon postoperatively.
• The X STOP is supplied sterile; however, the instruments are supplied non-sterile and must be properly cleaned and sterilized prior to surgery.
X-STOP® IPD® System
Instructions For Use (IFU)

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; paralyisis; 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.

Scoliosis
Before and After
Dr. Trent
2014
Thank You