Surgical Treatment for Lumbar Spinal Stenosis – Dynamic Interspinous Distraction Interlaminar Stabilization Implant - Coflex

John C Chiu, MD, FRCS (US), DSc
Chief, Neurospine Surgery
California Spine Institute
Thousand Oaks, California, USA
President AAMISMS
Introduction:

Lumbar Spinal Stenosis (LSS):

- **1.5 m** people *diagnosed with LSS each* year in the USA and growing due to aging boomers
- It is one of the most common *indications for spinal surgeries* in patients over 55 years old
- **Degenerative LSS caused by** hypertrophic ligamentum flavum, facet hypertrophy and disc protrusion, are *common* in an *aging population*
Introduction:

- **Lumbar stenosis** - descriptive term denoting **narrowing** of the **spinal canal** as result of degenerative aging spine – with central and lateral stenosis

- **LSS leading to intermittent neurogenic claudication (INC)** includes pain, numbness, and weakness that are worse with ambulation and improve on rest and spinal flexion

- **MRI scanning is single imaging modality of choice** to delineate the severity of neural compression

- Segmental instability in some cases- **spondylolisthesis**
Introduction:

- **Non-operative treatment** includes **physical therapy** spinal flexion exercises, **aerobic conditioning**, administration of non-steroid **anti-inflammatory drugs**, and epidural steroid injections.

- The natural history of the disease is associated with **deterioration of symptoms**.

- When **conservative treatment**, at least 6 months **fails**.

- Many types of lumbar decompressive spinal surgery and **fixation** have been developed.
Classification of LSS:

- **Etiological** Classification
  1. Congenital or Developmental (e.g. short pedicle)
  2. Acquired stenosis (or due to degenerative spinal stenosis)

- **Anatomical** Classification
  1. Used to identify specific area of narrowing
  2. Particularly useful as a guide for surgical decompression
  3. The anatomy of spinal canal at each vertebral segments can be divided into three transverse level (are the pedicle levels, the intermediate – foraminal and the disc level and five different sagital zones

Anatomical grid to evaluate spinal stenosis
Classification by Pathophysiology:

- **Central spinal stenosis** commonly occurs at the disc and upper pedicle level as the result of facet joint hypertrophy and the hypertrophic ligamentum flavum
- **Lateral spinal stenosis** affects the lateral recess zone and intervertebral foramen
- **Stenosis rarely occurs** at the pedicle level except extruded disc and congenitally short pedicles
- **Stenosis of the intervertebral foramen** is most common at the disc level, usually in the inferior portion of the foramen, especially when it involves the superior aspect of the foramen at the intermediate level where the exit nerve root passes laterally
- **Lateral recess stenosis** occurs as the result of degenerative changes effecting the nerve root canal at the disc level and superior aspect of the pedicle level
- **Lateral recess stenosis** at the inferior aspect of the pedicle level is uncommon
Coflex Design Rationale Implant for Treatment of LSS:

- The Coflex system/procedure, is a **minimally invasive dynamic interlaminar distraction/stabilization system**, designed for treatment of LSS
- **Functionally dynamic** - Preserving spinal motion by being compressible in extension, absorbing axial force shock, maintaining sagittal balance and lordosis, and maintaining physiological adjacent segmental kinematics
- **Allowing flexion and increased rotational stability**
- It **maintains neural foraminal height** and **off loads facet joint** and posterior annulus with reduction of stress on facet joints
Minimally Invasive Surgical Treatment for LSS with Coflex Implant and Lumbar Microdecompression
Surgical Indications:

- Age **50 or older**
- **Significant** intermittent neurogenic claudication (**INC**)
- Evidence of LSS with x-ray, **MRI scan** and/or CT scan
- Not responding to at least six months of **conservative treatment** - Failed
- **Spinal flexion** gives **relief**
- Often “**grocery cart syndrome**” for relief of low back and leg pain
Surgical Indications:

Symptomatic lumbar post fusion disc herniation

- Lumbar post fusion Junctional Disc Herniation Syndrome (JDHS) or Adjacent Segment Disease (ASD)
- JDHS - large L3-4 disc herniation into right lateral recess and neural foramen of 8mm in size
Surgical Procedure/Technique

Pre-op Prep Anesthesia – Patient Positioning

- **Local anesthesia** and monitored **IV conscious sedation or general anesthesia**
- 2 grams Ancef and 8 mg dexamethasone IV pre-op
- **Surface EEG monitoring** (BIS)
- **IOM - EEG, EMG** to prevent undue neural trauma
- **Patient positioning**: is usually positioned on a set of bolsters in a **prone** position
- A **head-holder** with a mirror is used to **support** and to stabilize the patients head
Surgical Procedure/Technique

Lumbar spinal decompression

- Lumbar midline approach
- Preservation of supraspinous ligament
- Muscle and fascia are sharply dissected lateral to the supraspinous ligament
- Paraspinal muscles are stripped off the laminae
- Interspinous ligament is sacrificed
- Any bony overgrowth of the spinous process is resected to prepare for the implant
- Lumbar decompressive laminectomy to relieve neural compression
- By excision of hypertrophic ligamentum flavum, partial facetectomy, and decompressive neuroforaminotomy with a curved Kerrison ronguer
Surgical Procedure/Technique

Measuring and Inserting of COFLEX Implant

Insertion of Coflex down to facet joint level, 3mm posterior to dura

Measuring the space

Crimping the wings and inserting implant
Surgical Procedure/Technique

**Coflex – F:** if needed for stabilization/fixation with screw and sleeves
Surgical Procedure/Technique

One Level or More COFLEX Implantation

1 Level

2 Level
Surgical Procedure/Technique

Wound Closure

- In the usual manner
- Muscle, fascia and the **supraspinous ligament** can be re-sutured and closed in one layer over the spinous processes
LSS for Spinal Instability Coflex – F can Combine with other Lumbar Decompression/Fusion Techniques
Surgical Procedure/Technique

Interbody Fusion and T-LIF (Transforaminal)

Rampart interbody (PEEK) fusion system
Surgical Procedure/Technique

Spinal Facet Fusion

- Facet screw fixation
- Bony fusion after denuding and decorticating facet joints

Capture™ Facet Fixation System

Viper Facet Screw Fixation
Surgical Procedure/Technique:

Biologic morcelized bone graft – OptiMesh® Implant as Intervertebral/Disc Spacer/Fusion
Surgical Procedure/Technique:

- DIAM® Interspinous Implant
- Wallis® Device
- X-stop® spacer
- Superion® Interspinous Spacer System
Case Illustrations:

LUMBAR STENOSIS TREATED WITH LUMBAR DECOMPRESSION AND COFLEX IMPLANTS
Case Illustration I

LUMBAR STENOSIS TREATED WITH LUMBAR DECOMPRESSION AND ONE COFLEX IMPLANT

Severe lumbar stenosis

- 73 yo with severe rapid progressive (in 6 mos.) neurogenic claudication, leaning on grocery cart syndrome
- Successfully treated with microdecompressive discectomy and interspinous spacer Coflex-f with facet fusion
- Able to stand and walk unassisted and straight
Case Illustration II

LUMBAR STENOSIS TREATED WITH LUMBAR DECOMPRESSION AND ONE COFLEX IMPLANT

1 level lumbar stenosis caused by:
- Disc herniation
- Anterior offset of L4 over L5 hypertrophy of the ligamentum flavum
- Neuro-foraminal stenosis

Successfully treated with MISS microdecompression Coflex-F interspinous spacer/fixation & lumbar facet fusion with relief of neurogenic claudication & correction of stooped posture

77 yo male with severe L4-5 lumbar stenosis, stooped posture & neurogenic claudication relieved by Coflex-F fixation & lumbar facet fusion
Case Illustration III

LUMBAR STENOSIS TREATED WITH LUMBAR DECOMPRESSION AND TWO COFLEX IMPLANTS

- 81 y o female with progressive severe neurogenic claudication secondary to L3 & L4 LSS relieved by Lumbar decompression, Coflex fixation & lumbar facet fusion with relief of neurogenic claudication & correction of stooped posture.
Case Illustration IV

LUMBAR STENOSIS TREATED WITH LUMBAR DECOMPRESSION AND THREE COFLEX IMPLANTS

- 3 level lumbar stenosis caused by:
  - Disc herniation
  - Anterior offset of L4 over L5 hypertrophy of the ligamentum flavum
  - Neuro-foraminal stenosis
- Successfully treated with MISS microdecompression Coflex-F interspinous spacer/fixation & lumbar facet fusion with relief of neurogenic claudication & correction of stooped posture

59 year old office manager with severe L2-3, L3-4 & L4-5 lumbar stenosis, stooped posture & neurogenic claudication relieved by MISS, Coflex-F fixation & lumbar facet fusion
Post Operative Care:

- **Ambulatory within one hour** and discharged subsequently
- May shower the following day
- Usually patient **has relief of neurogenic claudication** immediately after surgery with improved
- Ice pack is helpful
- Mild **analgesics** and muscle relaxant are required at times
- **Progressive spine exercise** second post operative day on
- Responds to postoperative treatment with **significant improvement** of VAS, ODI, and patient satisfaction score
Discussion and Comment:

- The author’s personal experience with this out patient Coflex system for treatment of LSS has been positive.
- **The Coflex procedure combined with lumbar decompression provides excellent symptomatic relief of INC, low back and pain, symptoms related to LSS, and improves mobility with much less trauma.**
- **With the following additional advantages for Coflex:**
  - Less traumatic and minimal blood loss
  - **Preserves spinal motion**
  - Small incision
  - Economic savings due to earlier return to work
  - Local anesthesia/IV sedation usually
  - Early post – op exercise
  - Multiple levels can be performed at one sitting
  - Can be performed for high risk patients including morbid obesity, emphysema, and cardiac conditions with much less risk
  - Intra-operative neurophysiological/EMG monitoring, and direct visualized endoscopic significantly reduces the chance for inadvertent injury of neural structure
  - Shorter hospital stay
Discussion and Comment:

• Other Types of Lumbar Stenosis Decompression Surgeries being utilized:

1. Decompressive Lumbar Stenosis:
   • **Minimally Invasive Lumbar Decompression**

2. **Traditional wide decompressive** lumbar laminectomy with and without instrument fixation/fusion – traumatic open surgery

3. **Static lumbar stabilization** systems
   • X-Stop
   • Vertiflex
   • Facet Screw/fixation/fusion

4. **Dynamic stabilization**
   • Coflex/Coflex-F
   • DIAM dynamic stabilization
   • WALLIS Interspinous Device

5. Others
Conclusion:

- **Coflex** procedure combined with lumbar microdecompression provides excellent relief of LSS symptoms and INC.
- It is a **safe, effective and less traumatic** spinal surgery with a dynamic distraction/stabilization implant.
- It avoids the more traumatic open spinal surgery and is a treatment option for treating moderate to severe degenerative LSS.
- It is a **smart way to treat symptomatic LSS**.
Hope you enjoyed this presentation!

Thank you for your attention!

John C. Chiu, M.D., FRSC (US), D.Sc.
California Spine Institute