

# The Importance of Biomechanics: Looking at the Treatment of Stenosis through a New Lens

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# Disclosures

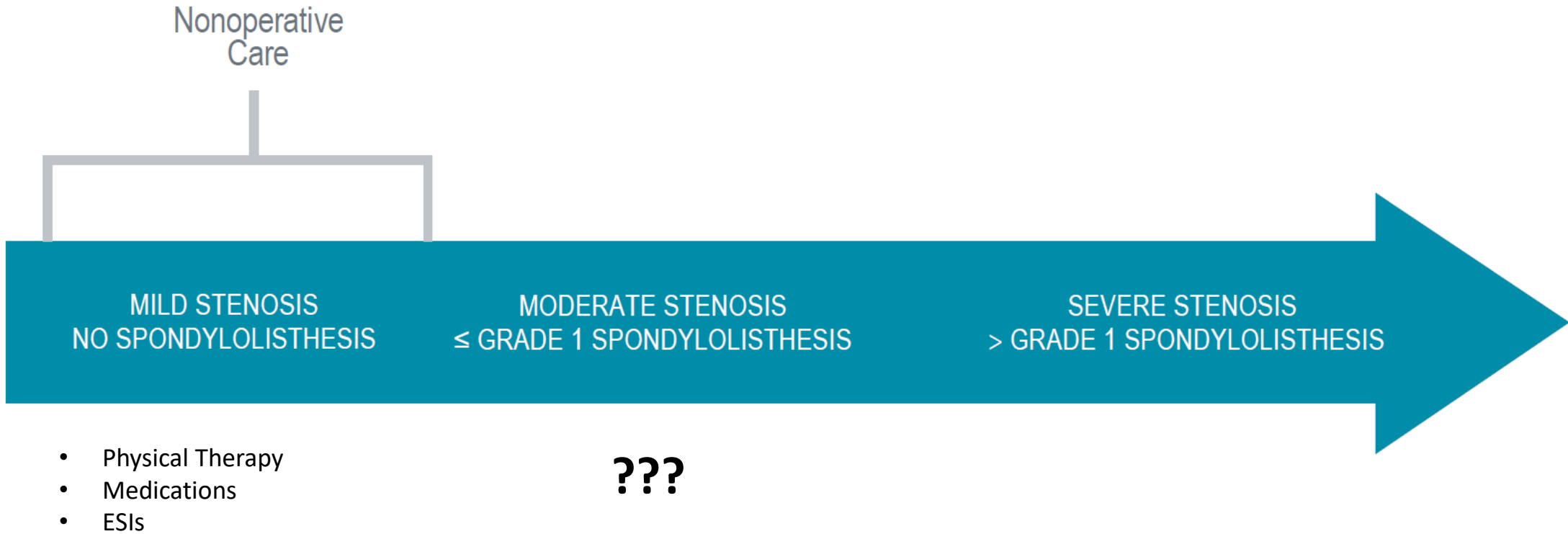


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Dr. Michael Esposito

Financial disclosure:

- Speaker/advisory- Boston Scientific

# Treating LSS- Care Continuum



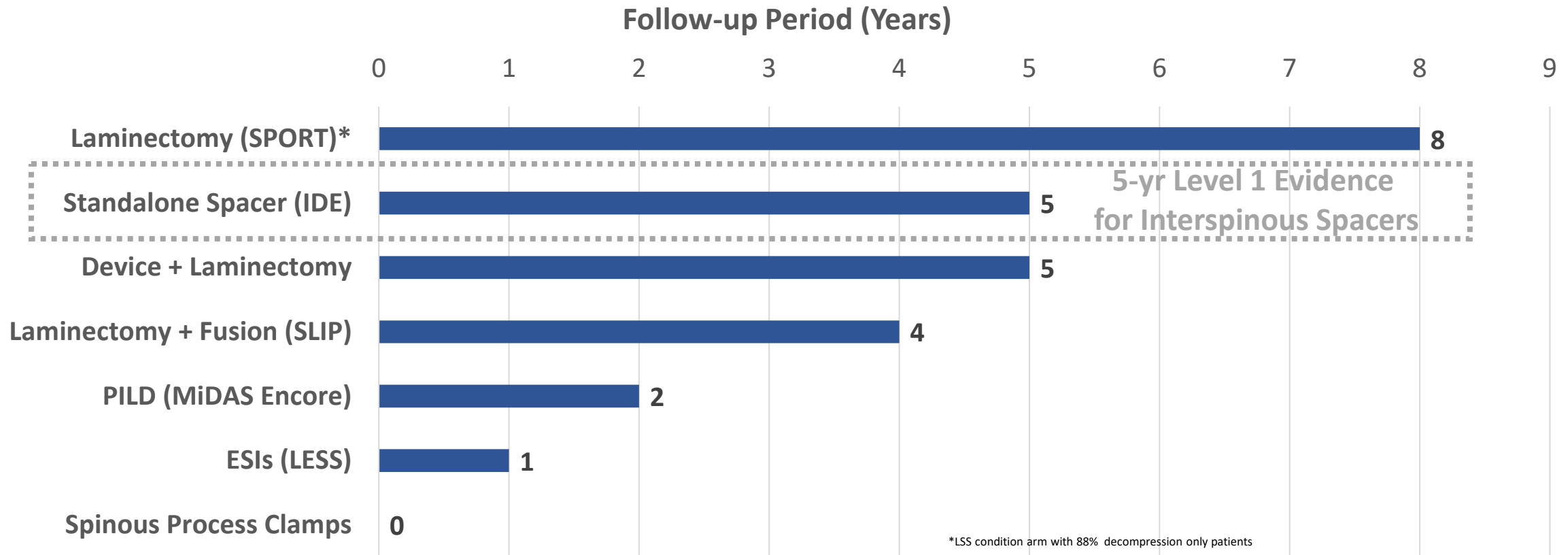
#### References:

- Nunley PD, Shami AN, Blumenthal SL, Orndorff D, Block JE, Geisler FH. Interspinous Process Decompression: Expanding Treatment Options for Lumbar Spinal Stenosis. Biomed Res Int. 2016;2016:3267307.

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# Looking at the Clinical Evidence:

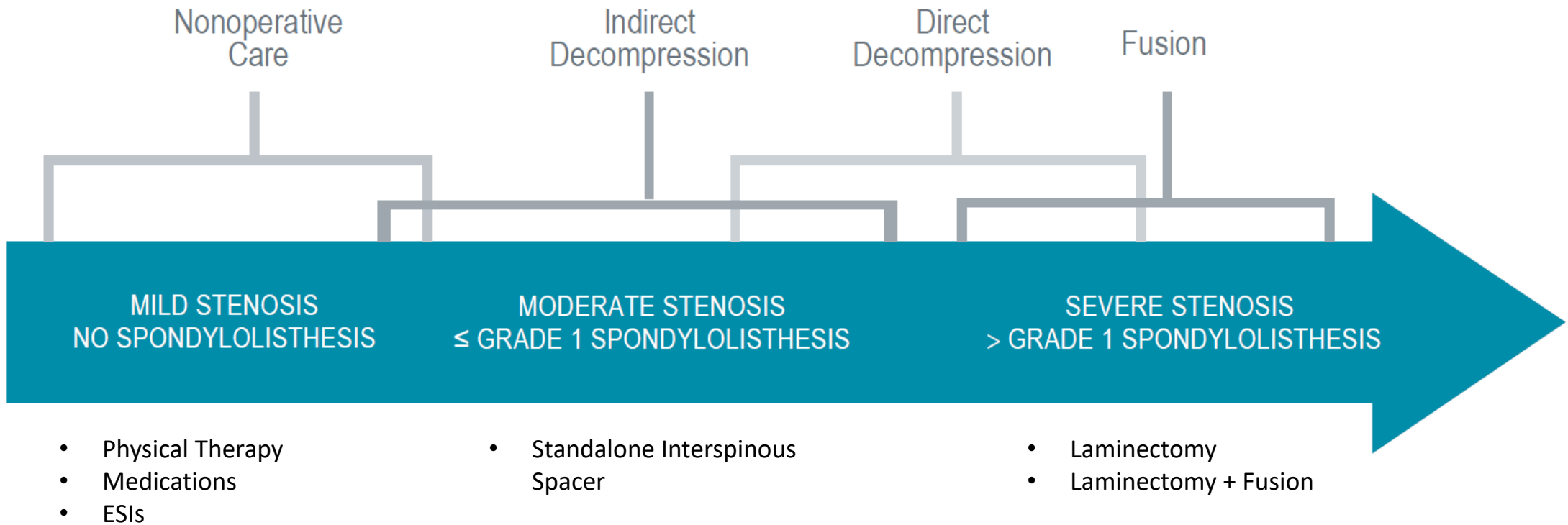
Key Completed RCTs for LSS Treatment on ClinicalTrials.gov



References:

- ClinicalTrials.gov # [NCT00692276](#), [NCT00534235](#), [NCT00000411](#), [NCT00109213](#), [NCT02093520](#), [NCT01238536](#)

# Treating LSS- Care Continuum



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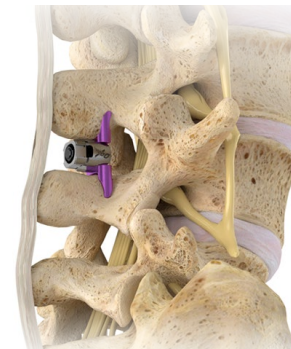
# Non-fusion Interspinous Spacers for the Treatment of LSS



Canal and foraminal space for nerves increase in **FLEXION**



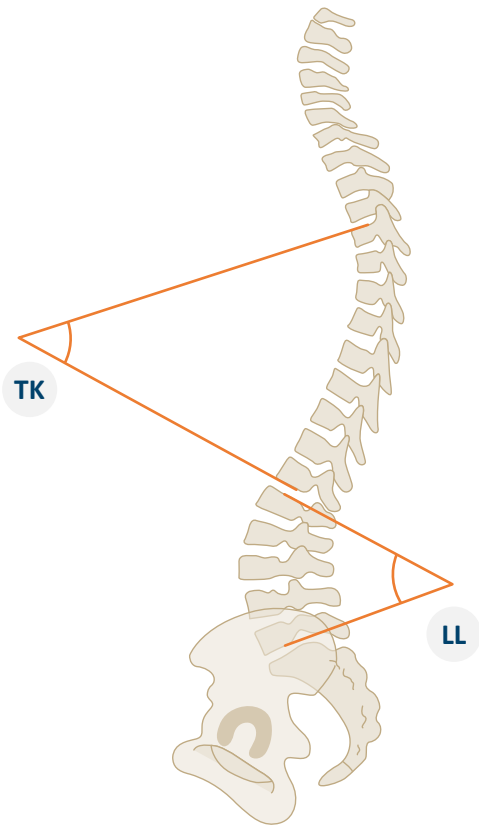
Canal and foraminal space for nerves decrease in **EXTENSION**



The non-fusion interspinous spacers **restrict EXTENSION**

Non-fusion Interspinous Spacers are FDA approved to treat moderate LSS

# Sagittal Imbalance & Lumbar Lordosis



**Sagittal balance** is an energy efficient way of balancing the head over the pelvis

- Harmonious alignment of the cervical lordosis, thoracic kyphosis (TK), lumbar lordosis (LL), and pelvic anatomy
- Normal Lumbar Lordosis Angles (L1 to S1) are between 40° and 60°

**Sagittal Imbalance** is a major cause of pain and disability in patients and is often caused by loss of lumbar lordosis due to:

- Spinal Pathologies (e.g., DDD)
- Instrumentational Spinal Surgery (e.g., Spinal Fusion Surgery)

**Spinal Fusion Surgery** may lead to loss of lumbar lordosis when there is:

- Pseudarthrosis (failed bony fusion)
- Adjacent-Segment Disease (post-fusion)

Changes to the lumbar lordosis will impact the overall alignment and further sagittal balance

# Non-fusion Interspinous Spacer 5-year RCT Data: Radiographic Analysis of Patients

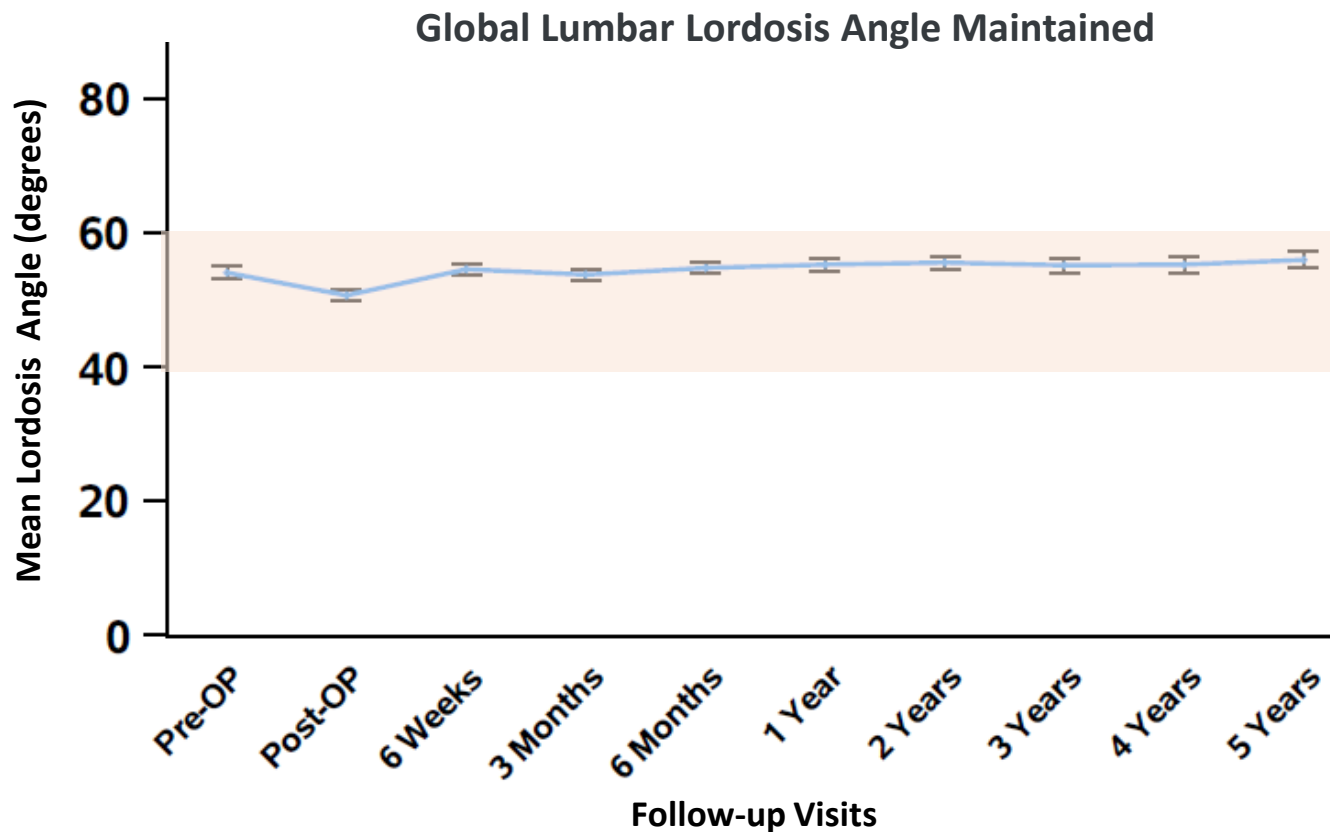
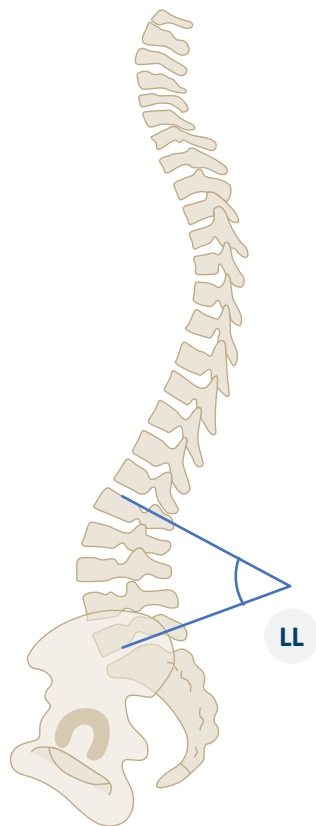


**Objective:** To evaluate the biomechanical impact of non-fusion interspinous spacers on the sagittal alignment of moderate LSS patients, using Lumbar Lordosis measurements.

<b>Study</b>	Multicenter, Prospective, Randomized Controlled trial: Imaging analysis
<b>Study Device</b>	Non-fusion interspinous spacer
<b>Subjects</b>	190 moderate LSS subjects implanted with non-fusion interspinous spacer

<b>Gender - Males (%)</b>	58% (110/190)
<b>Age [Mean (SD)]</b>	67 (9) years
<b>Diagnosis</b>	Lumbar Spinal Stenosis
<b>Oswestry Disability Index (ODI) [Mean (SD)]</b>	39 (13)
<b>Back Pain Scores (VAS) [Mean (SD)]</b>	55 (28)

# Sagittal Balance Maintained



Study Visit	Lordosis Angle (Mean Deg)	N
Pre-Op	54.1	186
Post-Op	50.7	173
6 Weeks	54.6	177
3 Months	53.8	166
6 Months	54.6	172
1 Year	55.3	162
2 Year	55.6	149
3 Year	55.2	123
4 Year	55.3	107
5 Year	56.1	101

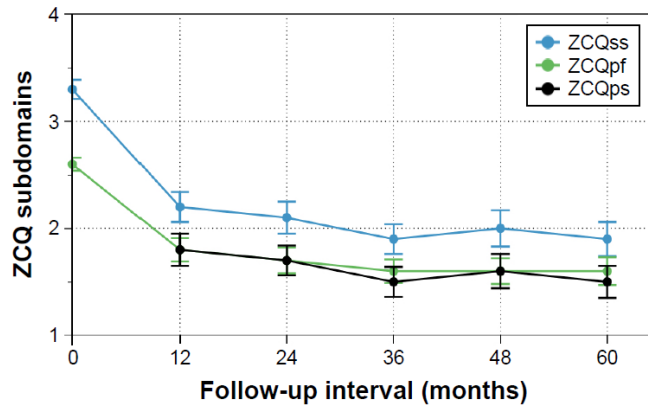
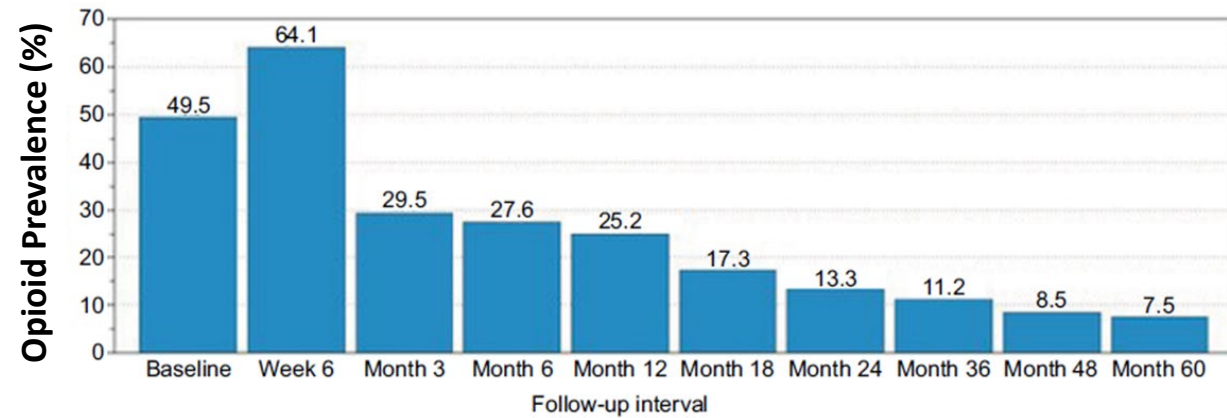
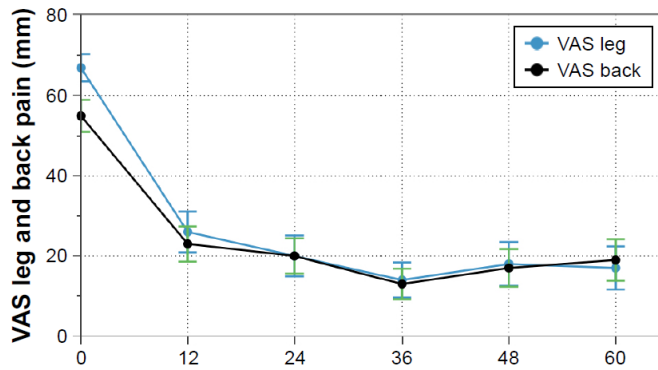
Normal LL : 40-60°

Global lordosis angle remains stable following non-fusion interspinous spacer up to 5 years

# Durable Outcomes with No Changes to Lordosis Angle



## Improved Pain Scores, Functional Outcomes & Opioid Usage (up to 5 years)



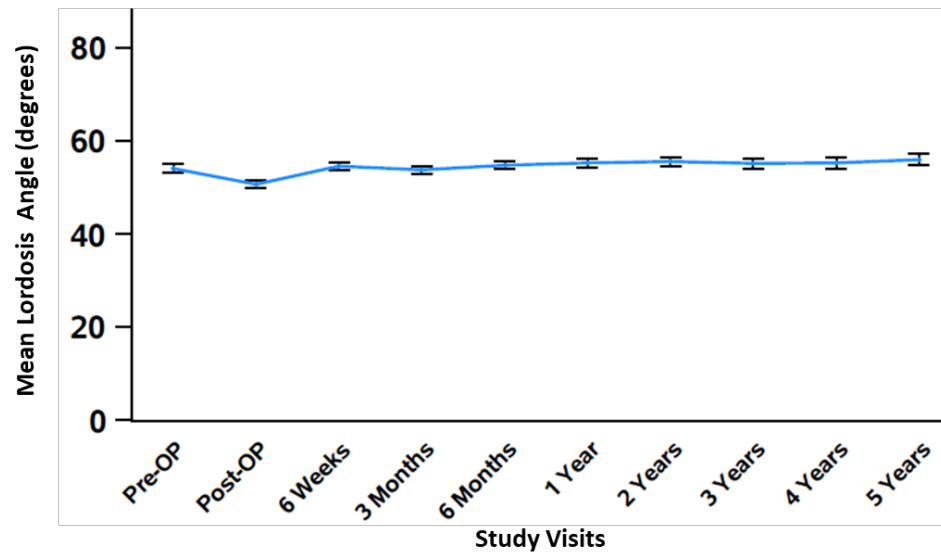
**66%**  
BACK PAIN  
Improvement<sup>1\*</sup>

**75%**  
LEG PAIN  
Improvement<sup>1\*</sup>

**85%**  
ELIMINATED  
Opioid use<sup>2+</sup>

**90%**  
PATIENT  
Satisfaction<sup>1\*</sup>

\*Study completers at 5 years when compared to baseline scores  
+decrease in the proportion of patients using opioids compared to baseline at 5 years



- **Sagittal Imbalance is a major cause of pain and disability** in patients and is often caused by loss of lumbar lordosis
- **Non-fusion interspinous spacers maintain lordosis angle** (sagittal alignment).
  - In contrast, fusion procedures might alter sagittal alignment by decreasing the lordosis angle.
- **Non-fusion interspinous spacers function as an extension blocker to treat all forms of LSS**

**66%**

BACK PAIN  
Improvement<sup>1\*</sup>

**75%**

LEG PAIN  
Improvement<sup>1\*</sup>

**85%**

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