Biomechanical Impact of Interspinous Spacers on Sagittal Alignment in Patients with Lumbar Spinal Stenosis

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BACKGROUND

Degenerative Lumbar Spinal Stenosis (LSS) is characterized as the narrowing of the spinal canal and/or intervertebral foramina. Pain, numbness, cramping, and/or fatigue in the legs or buttocks with or without back pain are primary symptoms of LSS, which are relieved in flexion.[1] Surgical interventions are used to treat LSS once conservative treatment options are exhausted. However, decompression with or without fusion may result in loss of the normal lumbar lordosis curvature leading to the development of sagittal imbalance of the spine which is known a major cause of pain and disability.[2] Here, we report the biomechanical impact (if any) of a non-fusion interspinous spacer (or IDS) implanted in LSS patients.

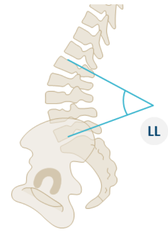
METHODS

Study	Multicenter, Prospective, Randomized Controlled Trial: Imaging Analysis
Device	Boston Scientific Indirect Decompression Systems (IDS) 
Patients	190 moderate LSS subjects implanted with IDS system
Outcome Measures	Comparison of Global Lordosis Angles of radiographs obtained at baseline (pre-procedure) and up to 5 years post-implantation

RESULTS

Baseline Characteristics (n = 190)

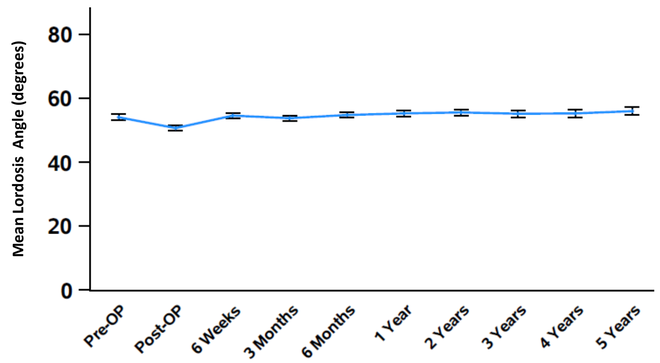
Gender - Males (%)	58% (110/190)
Age [Mean (SD)]	67 (9) years
Diagnosis	Lumbar Spinal Stenosis
Oswestry Disability Index (ODI) [Mean (SD)]	39 (13)
Back Pain Scores (VAS) [Mean (SD)]	55 (28)



Lumbar Lordosis (LL) Angle is measured from the superior end plate of L1 to the end plate of S1

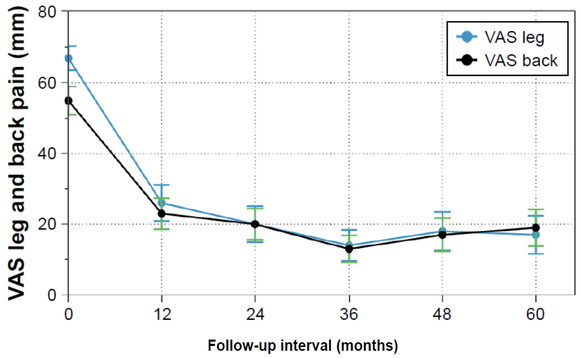
(Note: Normal Range of Lordosis Angle [40 - 60°])[3]

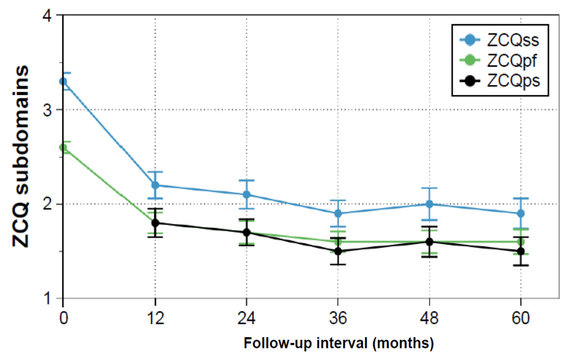
Global Lordosis Angle up to 5-years



Study Visit	Lordosis Angle (Mean Deg)
Pre-Op	54.1
Post-Op	50.7
6 Weeks	54.6
3 Months	53.8
6 Months	54.8
1 Year	55.3
2 Year	55.6
3 Year	55.2
4 Year	55.3
5 Year	56.1

Pain Scores and Functional Outcomes (up to 5-years)





At 5 years:

- **Significant reduction in pain (back and leg)**
- **Substantial and sustained reduction in all ZCQ sub-domains**

ZCQ = Zurich Claudication Questionnaire: symptom severity [ss]; physical function [pf]; patient satisfaction [ps]*

*Zurich Claudication Questionnaire is used to specifically measure treatment outcomes in patients with LSS

CONCLUSIONS

- **Sagittal Imbalance is a major cause of pain and disability in patients which may develop as a result of loss of lumbar lordosis.**
- **Results of this long-term evaluation (n = 190 subjects) out to 5-years post-implantation demonstrate that the use of non-fusion interspinous spacers or IDS can help maintain lordosis angle (sagittal alignment) while maintaining sustained pain relief and improved functional outcomes.**
- **Non-fusion interspinous spacers are a safe and effective way of treating patients with symptomatic LSS which do not appear to alter the sagittal alignment of the spine over time.**

REFERENCES

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3. Bernhardt M, Bridwell KH. Segmental analysis of the sagittal plane alignment of the normal thoracic and lumbar spines and thoracolumbar junction. *Spine* 1989; 14: 717-72.

DISCLOSURES

- This study is sponsored by Boston Scientific.
- Drs. Whang and Antony have consulting agreements with Boston Scientific.
- Lilly Chen and Roshini Jain are employees of Boston Scientific.

Indications

Indications for Use: The Superion™ Indirect Decompression System (IDS) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, having radiographic evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing . The Superion™ Interspinous Spacer is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, with or without back pain, who have undergone at least 6 months of non-operative treatment. The Superion Interspinous Spacer may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5. Contraindications, warnings, precautions, side effects. The Superion Indirect Decompression System (IDS) is contraindicated for patients who: have spinal anatomy that prevent implantation of the device or cause the device to be unstable in situ (i.e., degenerative spondylolisthesis greater than grade 1), Cauda equina syndrome, or prior decompression or fusion at the index level. Refer to the Instructions for Use provided on www.vertiflex.com for additional Indications for Use, contraindications information and potential adverse effects, warnings, and precautions prior to using this product. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

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