

Peer review file

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Reviewer A

You presented a valuable review about interspinous process devices for the treatment of lumbar spinal stenosis. This is a really good review of the features of each interspinous process devices and the studies to date. However, there are some issues with the paper that could use some improvements. Please find attached file.

The authors presented a valuable review about interspinous process devices for the treatment of lumbar spinal stenosis. This is a really good review of the features of each interspinous process devices and the studies to date. However, there are some issues with the paper that could use some improvements.

Principles of treatment

Comment 1: Line 140: The authors mentioned, “, and providing distraction of posterior elements.⁴”. Number “4” in citation should be changed to superscript.

Reply 1: This has been changed accordingly.

Changes in text: The sentence now reads, “The principle behind surgically treating LCS is decompression of central canal and foramen by preventing lordosis, and providing distraction of posterior elements (4).” The citations have been changed according to the requirements of the journal submission checklist. All other citations have been amended as well.

Comment 2: Line143-145: The authors mentioned, “Radiological studies demonstrated that extension or rotation of the lumbar spine reduces sagittal diameters and cross-sectional areas of the spinal canal by up to 15%”. The authors cited two different references.

Chung SS et al.⁶) studied the MR images while supine with their spine in neutral, flexed, extended, and right and left rotational positions, and described, “ extension or rotation decreased the sagittal diameters and cross-sectional areas of the dural sac and spinal canal and increased the thickness of the ligamentum flavum”. Inufusa A et al.⁷) used

cadaveric spines in flexion and in extension, and described, “the cryomicrotome sections showed the cross-sectional area of the foramen to be 12% greater for the flexion group and 15% smaller for the extension group than the cross-sectional area of the neutral group”.

This sentence by the authors is misleading because it mixes up studies using MR images with cadaver studies. The authors should change the sentence to differentiate those two different studies.

Reply 2: The sentence has been rectified accordingly.

Changes in text: The sentence now reads, “An MRI study demonstrated that extension or rotation of the lumbar spine reduces sagittal diameters and cross-sectional areas of the spinal canal and increased the thickness of ligamentum flavum (6). This was consistent with a cadaveric study that reported a 15% reduction in cross sectional area of the spinal canal whne in extension (7).”

Comment 3: Line 150-154: The authors mentioned, “Treating NC with IDD achieves indirect decompression without jeopardizing spinal stability at the instrumented level. IDD not only restricts extension, but also preserved some degree of flexion at the instrumented level. By doing so, ligamentum flavum is stretched and its thickness reduced. Eventually, diameter of spinal canal is enlarged whilst allowing flexion to relieve the compression of nerve roots.6,7”

The citation 6 and 7 are not appropriate articles to explain the mechanism of IDD. The authors should cite as more appropriate articles to explain the mechanisms to improve NC by using IDD.

Reply 3: The citation has been amended accordingly

Changes in text: Citation 4 and 8 has been used instead. The sentence now reads, “Treating NC with IDD achieves indirect decompression without jeopardizing spinal stability at the instrumented level. IDD not only restricts extension, but also preserves some degree of flexion at the instrumented level. By doing so, ligamentum flavum is stretched and its thickness reduced. Eventually, diameter of spinal canal is enlarged whilst allowing flexion to relieve the compression of nerve roots (4, 8).”

Comment 4: Line 158-162: The authors mentioned, “ISS not only maintain decompression of neural structures following open decompression, but also achieve

some form of dynamic stabilization. Posterior element stabilization would be indicated if observed grade I spondylolisthesis is observed on pre-operative XR or if the spine was found to be unstable intraoperatively.”

The authors should demonstrate appropriate citations.

Reply 4: A new citation has been added

Changes in text: the sentence now reads, “Posterior element stabilization would be indicated if observed grade 1 spondylolisthesis is observed on pre-operative XR or if the spine was found to be unstable intraoperatively (10).” Due to the addition of this citation, the citation numbers following this addition has been changed accordingly.

Biomechanical analysis

Comment 5: Line 293-294: The authors mentioned, “Aperius IDD had no significant increase in DSCSA at the operated level (mean: increase: 3mm², p=0.42)” .

Erase the colon after the word “mean” (“mean increase” is correct).

Reply 5: This has now been rectified.

Changes in text: It now reads, “Aperius IDD had no significant increase in DSCSA at the operated level (mean increase: 3mm², p=0.42),”

Comment 6: Line 341: The authors mentioned, “left-right twisting (1.8° vs 1.8°, p= - 0.998)”.

Erase the minus in the critical p-value (“p = 0.998” is correct).

Reply 6: This has now been rectified.

Changes in text: It now reads, “left-right twisting (1.8o vs 1.8o, p=0.998).”

Comment 7: Line 345: The authors mentioned, “left-right twisting (2.8° vs 3.7°, p= - 0.996)”.

Erase the minus in the critical p-value (“p = 0.996” is correct).

Reply 7: This has now been rectified.

Changes in text: It now reads, “left-right twisting (2.8o vs 3.7o, p=0.996).”

Comparing IPD and other management

Comment 8: Line 456-457: The authors mentioned, “Quantitative analysis was performed to consolidate comparative results between IDD and open decompression...”.

In this paragraph, you are comparing IPD and other management, so I think “Quantitative analysis was performed to consolidate comparative results between IPD and open decompression...” is correct.

Reply 8: This has now been rectified.

Changes in text: It now reads, “Quantitative analysis was performed to consolidate comparative results between IPD and open decompression”

Table 1

Comment 9: What is the number described after brand names? If they are citation numbers, the authors should fix them to appropriate citation numbers, (5) to (10), for example.

Reply 9: This has now been rectified.

Changes in text: The correct citation numbers have now been inserted.

Figure 1

Comment 10: In figure legend, the authors presented the case applied two interspinous spacers between L3/4 and L4/5. In line 3, the authors mentioned, “after insertion of a interspinous spacers”, but it should be fixed to “after insertion of two interspinous spacers”. And they presented the brand of interspinous spacer and manufacturer as “Lobster, Techlamed, ITA”. The authors did not show this brand in Table 1. Which group is “Lobster” classified, IDD or ISS?

Reply 10: This has now been amended accordingly.

Changes in text: The sentence now reads, “Preoperative (top row) and postoperative (bottom row) CT sagittal images of a 64 year old male, demonstrating increased interspinous space, and greater foraminal space after insertion of two interspinous distraction devices (Lobster, Techlamed, ITA).”

Figure 2

Comment 11: In figure legend, the authors numbered the chart A), 2), 3), 4), but should

be fixed to A), B), C), D) or 1), 2), 3), 4).

Reply 11: This has now been rectified.

Changes in text: The sentence now reads, “A) Introducer inserted through percutaneous approach, B) The probe is inserted through outer sheath and between L3/4 spinous processes, C) ISS device deployed, D) ISS device expanded to achieve distraction of spinous processes.”

Reviewer B

Comment: I would like to thank the authors for this well-written manuscript that's of interest to the readership.

However, the included studies are significantly limited. The most important limitation - that the authors also acknowledged in the discussion- is that the cohorts included in the studies are heterogeneous in baseline characteristics and indications for surgery.

I'm afraid that this totally limits their conclusions including that miniopen IDD has greater quality of life... etc.

Reply: The author acknowledges the limitations of the study in the discussion due to the heterogeneity of individual studies. However, this is one of the known limitation of systematic review as a study design, where only the best available evidence is used and synthesised into a consolidated message.

Changes in text: No change was made in response to this comment.

Reviewer C

This is a good comprehensive review of the literature of this technology and spinal pathology management. The authors recognize the limitations of the data. This is important review should add to the field of knowledge.

Reviewer D

Comment: Overall very well written and excellent review. I would like to see a

discussion on the role of IS fractures and location of IDD devices, e.g. anterior placement at spinolaminar junction vs mid SP and how that may impact the frequency of SP fracture. Also should include Spinal Simplicity Minuteman in the discussion.

Reply: The influence of IDD device placement on spinous process fractures is an area that has not been published in the literature. This may be a topic that would be of benefit to further research on. The discussion on Spinal simplicity Minuteman has been added.

Changes in text: The discussion on Spinal Simplicity Minuteman reads, “Another area of development is the approval for use of the minimally invasive, interspinous-interlaminar fusion device (Minuteman, Spinal Simplicity, USA) (70). This supplemental fixation device provides fixation and stabilisation of spinal segments with the aim of bony fusion. The Minuteman is designed to attach to the spinous processes of non-cervical spine with its bilateral locking plates and bone graft material placed within the device. Its minimally invasive approach reduces significant soft tissue dissection and eliminates the need for neural monitoring. Whilst clinical results of this device have not been published in the literature, this is a device that may become an alternative to traditional pedicle screw fixation constructs.”