Biomechanical study of dynamic changes in L4–L5 foramen surface area in flexion and extension after implantation of four interspinous process devices

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A R T I C L E   I N F O
Article history:
Received 30 October 2012
Accepted 19 November 2014

Keywords:
Interspinous process device
Lumbar spinal stenosis
Biomechanics

A B S T R A C T
Background: Lumbar spinal stenosis is a major public health issue. Interspinous devices implanted using minimally invasive techniques may constitute an alternative to the reference standard of bony decompression with or without intervertebral fusion. However, their indications remain unclear, due to a paucity of clinical and biomechanical data. Our objective was to evaluate the effects of four interspinous process devices implanted at L4–L5 on the intervertebral foramen surface areas at the treated and adjacent levels, in flexion and in extension.

Materials and method: Six fresh frozen human cadaver lumbar spines (L2–sacrum) were tested on a dedicated spinal loading frame, in flexion and extension, from 0 to 10 Nm, after preparation and marking of the L3–L4, L4–L5, and L5–S1 foramina. Stereoscopic 3D images were acquired at baseline then after implantation at L4–L5 of each of the four devices (Inspace®, Synthes; X-Stop®, Medtronic; Wallis®, Zimmer; and Diam®, Medtronic). The surface areas of the three foramina of interest were computed.

Results: All four devices significantly opened the L4–L5 foramen in extension. The effects in flexion separated the devices into two categories. With the two devices characterized by fixation in the spinous processes (Wallis® and Diam®), the L4–L5 foramen opened only in extension; whereas with the other two devices (X-Stop® and Inspace®), the L4–L5 foramen opened not only in extension, but also in flexion and in the neutral position. None of the devices implanted at L4–L5 modified the size of the L3–L4 foramen. X-Stop® and Diam® closed the L5–S1 foramen in extension, whereas the other two devices had no effect at this level.

Conclusion: Our results demonstrate that interspinous process devices modify the surface area of the interspinous foramina in vitro. Clinical studies are needed to clarify patient selection criteria for interspinous process device implantation.

Level of evidence: Level IV. Investigating an orthopaedic device.

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1. Introduction

Lumbar spinal stenosis is the most common degenerative disease of the spine in individuals older than 65 years and the leading reason for spinal surgery in this age group in the US [1–3]. The reference standard surgical procedure is open decompression of the narrowed segment, often combined with intervertebral fusion to stabilise the spine at the treated site. Although Kovacs et al. reported evidence that open surgery was superior over conservative treatment, other studies showed high rates of peri-operative and post-operative complications in the short- and long-terms [4–7]. Interspinous process devices (IPDs) are claimed by their manufacturers to constitute valid therapeutic alternatives to conventional surgery [8,9]. The underlying rationale is that the local kyphosis induced by these devices may open up the spinal canal and intervertebral foramina while also stabilising the spine in extension. Implantation of IPDs using minimally invasive techniques may decrease both the complication rate and the overall treatment costs.

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http://dx.doi.org/10.1016/j.otsr.2014.11.016
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compared to conventional open surgery \cite{10, 11}. Nevertheless, the paucity of biomechanical and clinical data on the effects of IPDs mandates caution regarding the indications of these devices, which remain unclear \cite{10, 12}. To date, no studies have compared IPDs with and without fixation to the spinous process.

The objective of this biomechanical study was to evaluate and to compare the effects of four IPDs implanted at L4–L5 on the surface areas of the intervertebral foramina at L3–L4, L4–L5, and L5–S1, in flexion and in extension.

2. Material and method

2.1. The four interspinous process devices (IPDs)

We studied four IPDs, two with and two without fixation to the spinous processes (Fig. 1). Inspace\textsuperscript{®} (Synthes, West Chester, PA, USA) is a cylindrical polyetheretherketone implant equipped with two titanium wings to ensure stability. X-Stop\textsuperscript{®} (Medtronic, Minneapolis, MN, USA) is made of titanium and also has two stabilising wings. Both devices are implanted into the interspinous space, after simple division of the interspinous ligament, and neither is attached to the spinous processes.

Wallis\textsuperscript{®} (Zimmer Spine, Warsaw, IN, USA) and Diam\textsuperscript{®} (Medtronic) IPDs attach to the infra- and supra-jacent spinous processes via two polyester bands. Implantation of these devices requires preparation of the interspinous space with division of the interspinous ligament and removal of any spinous process overgrowth. The supra-spinous ligament is left intact.

2.2. Source and preparation of the cadaver specimens

We studied six fresh frozen human lumbar spines (L2 to sacrum) from individuals who had donated their body to accredited research centres, in compliance with French law. Mean age of the six individuals was 82.5 years (range, 78–90 years). Radiographs were obtained to rule out disc or bone pathology, such as vertebral crush fractures, spondylolisthesis, or junction abnormalities.

The specimens were thawed for 12 hours then cleared of soft tissues except the capsules, ligaments, and discs. The sacrum of each specimen was clamped in a vice via a resin block, in order to leave the L5–S1 disc free. A loading rod was anchored into the body of L2 for load application. The L3–L4, L4–L5, and L5–S1 foramina on the right side were prepared to allow the placement of six white markers delineating the contour of each foramen (Fig. 2).

2.3. The test bench

We used the Tinius Olsen 10 kN traction-compression machine equipped with a 500 N load cell. Three-dimensional stereoscopic films were recorded using two digital, high-definition cameras (Fig. 3).

2.4. Experimental protocol

Each of the four IPDs was tested on each of the six spinal specimens. The loading cycle started at 0 N then increased from 0 to 50 N in compression then from 0 to 50 N in traction at near-zero speed (15 mm/min). The camera field of view embraces all the markers placed around the three foramina (L3–L4, L4–L5, and L5–S1). A reference sight was used to calibrate the cameras. The differences in the size of the four IPDs precluded testing in random order (Table 1). Loading without any IPD was performed to obtain paired series of data with and without each IPD. The entire loading cycles were recorded. The films were then analysed using DEFTAC 3D\textsuperscript{®} software to compute marker displacements by assigning spatial coordinates to each marker over time (Fig. 4). The software allowed computation of the surface area of each foramen, first according to time then according to the moment applied.
3. Results

3.1. L4–L5 foramen

Tables 2 and 3 report the changes in L4–L5 foraminal surface area in flexion and in extension. The two IPDs not attached to the spinous processes, i.e., Inspace® and X-Stop®, distracted the foramen at 0 N·m, as well as in flexion at 5 N·m. X-Stop® significantly increased the foraminal surface area, an effect not seen with either Wallis® or Diam®. These last two IPDs, which were attached to the spinous processes, had no effect at rest and induced statistically significant closure of the foramen in flexion at 5 N·m. During loading in extension, all four IPDs significantly opened up the foramen at 10 N·m. No significant differences were found across the four IPDs. Fig. 5 shows the typical pattern of change in the L4–L5 foraminal surface area after implantation of the Wallis® IPD.

3.2. L3–L4 and L5–S1 foramina

None of the four IPDs significantly changed the L3–L4 foramen surface in flexion or in extension (Table 4). In flexion, none of the IPDs changed the surface area of the L5–S1 foramen (Table 5). In extension, in contrast, Diam® and X-Stop® closed the L5–S1 foramen at 5 N·m. Foraminal opening showed no significant differences across the four IPDs (Table 4).

4. Discussion

We report the first 3D stereoscopy kinematic study of changes in foraminal surface area after IPD implantation. Our main finding is that the IPDs induced significant in vitro changes in the surface area of the foramen where the device was implanted (L4–L5). All four IPDs tested significantly opened the L4–L5 foramen during loading in extension, with no significant differences in this effect across the four implants.

We also obtained other findings of interest. The biomechanical effects at the implanted and adjacent levels varied according to the type of IPD. IPDs can be categorised into two types depending on attachment to the spinous processes: unattached IPDs act as distractors, whereas attached IPDs stabilise the implanted level. Inspace® and X-Stop® predominantly induced posterior distraction of the interspinous processes, thereby opening up the L4–L5 foramen not only in the neutral position, but also in flexion. With Wallis® and Diam®, there was no significant effect in the neutral position (without loading) and foraminal opening was visible only in extension. Inspace® and X-Stop® are forcefully introduced into the interspinous space after simple division of the interspinous ligament, thereby probably inducing local kyphosis as soon as they are implanted, with foraminal opening as a result. Implantation of the Wallis® and Diam® IPDs, in contrast, requires prior ligament division and spinous process debulking. Consequently, they have no effect at rest but prevent foraminal closure during extension.

Our study provides the first stereoscopy-based kinematic data on the foramina adjacent to IPD implantation. IPD implantation at L4–L5 had no effect on the supra-jacent L3–L4 foramen in flexion or in extension. At the infra-jacent L5–S1 level, in contrast, all four IPDs tended to close the foramen in extension. With X-Stop® and Diam®, foraminal closure was significant starting at 5 N·m in extension, with mean decreases of 3.7 ± 6.5% and 1.7 ± 1.1%, respectively.

Studies involving computed tomography (CT) and positional magnetic resonance imaging (MRI) previously demonstrated that X-Stop® opened up the foramen in extension at the implanted level [13–15]. Sobottke et al. also reported increased in CT-measured foraminal surface area with the Wallis® and Diam® IPDs [16]. No previous studies of Inspace® effects on the foramina have been
Table 2
Relative increase in foraminal surface area as a percentage (mean ± S.D.) in flexion at L4–L5 at 0, 5, and 10 N·m.

<table>
<thead>
<tr>
<th>Flexion</th>
<th>Relative % gain (0 N·m)</th>
<th>P-value</th>
<th>Relative % gain (5 N·m)</th>
<th>P-value</th>
<th>Relative % gain (10 N·m)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspace®</td>
<td>5.0 (6.4)</td>
<td>NS</td>
<td>2.9 (4.5)</td>
<td>NS</td>
<td>1.10 (1.80)</td>
<td>NS</td>
</tr>
<tr>
<td>X-Stop®</td>
<td>+7.2 (4.4)</td>
<td>0.04</td>
<td>+0.5 (0.4)</td>
<td>0.04</td>
<td>-0.50 (1.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Diam®</td>
<td>1.9 (1.8)</td>
<td>NS</td>
<td>-1.9 (2.4)</td>
<td>0.04</td>
<td>-1.50 (2.50)</td>
<td>NS</td>
</tr>
<tr>
<td>Wallis®</td>
<td>0.3 (3.1)</td>
<td>NS</td>
<td>-2.4 (1.9)</td>
<td>0.04</td>
<td>-2.10 (1.20)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

NS: not statistically significant.

Table 3
Relative increase in foraminal surface area as a percentage (mean ± S.D.) in extension at L4–L5 at 0, 5, and 10 N·m.

<table>
<thead>
<tr>
<th>Extension</th>
<th>Relative % gain (0 N·m)</th>
<th>P-value</th>
<th>Relative % gain (5 N·m)</th>
<th>P-value</th>
<th>Relative % gain (10 N·m)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspace®</td>
<td>3.4 (4.7)</td>
<td>NS</td>
<td>+9.7 (11.8)</td>
<td>0.02</td>
<td>+ 9.8 (12.30)</td>
<td>0.02</td>
</tr>
<tr>
<td>X-Stop®</td>
<td>+6.8 (4.2)</td>
<td>0.04</td>
<td>+0.2 (1.8)</td>
<td>0.04</td>
<td>+10.20 (5.40)</td>
<td>0.04</td>
</tr>
<tr>
<td>Diam®</td>
<td>1.6 (1.4)</td>
<td>0.04</td>
<td>1.6 (2.1)</td>
<td>NS</td>
<td>+1.50 (2.30)</td>
<td>0.02</td>
</tr>
<tr>
<td>Wallis®</td>
<td>1.3 (4.9)</td>
<td>NS</td>
<td>+2.9 (3.1)</td>
<td>0.04</td>
<td>+3.20 (3.40)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

NS: not statistically significant.

Fig. 5. Changes in foraminal surface area at L4–L5 in flexion/extension with and without the Wallis® interspinous process device.

Table 4
Relative increase in foraminal surface area as a percentage (mean ± S.D.) in flexion and extension at L3–L4 at 0, 5, and 10 N·m.

<table>
<thead>
<tr>
<th>Relative % gain in foraminal surface area</th>
<th>Flexion</th>
<th>Extension</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 N·m</td>
<td>5 N·m</td>
</tr>
<tr>
<td>Inspace®</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>X-Stop®</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Diam®</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Wallis®</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS: not statistically significant.

Table 5
Relative increase in foraminal surface area as a percentage (mean ± S.D.) in flexion and extension at L5–S1 at 0, 5, and 10 N·m.

<table>
<thead>
<tr>
<th>Relative % gain in foraminal surface area</th>
<th>Flexion</th>
<th>Extension</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 N·m</td>
<td>5 N·m</td>
</tr>
<tr>
<td>Inspace®</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>X-Stop®</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Diam®</td>
<td>-2.2 (2.2)</td>
<td>NS</td>
</tr>
<tr>
<td>Wallis®</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS: not statistically significant.
published. Regarding effects on the adjacent levels, Richards et al. found no significant change in L2–L3 or L4–L5 foraminal surface areas measured using positional MRI after X-Stop® implantation at L3–L4 [14]. This discrepancy is probably ascribable to the specific features of the L5–S1 level, which is the next lower level compared to the infra-jacent level in the study by Richards et al. Although we did not obtain accurate radiographic measurements of disc space narrowing, we suggest that the advanced age of our study donors was associated with restricted mobility of the L5–S1 level and therefore with greater sensitivity to changes induced by an L4–L5 IPD. Although small, the deleterious effect measured in our study mandates careful attention to the L5–S1 level during pre-operative planning. Finally, regarding the characterization of the two implant types, a biomechanical cadaver study by Wilke et al. previously indicated that fixation of the Wallis® and Diam® IPDs to the spinous processes induced a stronger stabilising effect in extension compared to X-Stop® [16,17].

One of the strengths of our study is the use of an innovative measurement system that is not only extremely simple to operate, but also highly accurate, with an estimated measurement error of 0.01 mm², i.e., less than with CT or MRI measurement. Furthermore, the dynamic nature of our evaluation is an advantage over the previous positional radiological studies.

Our study has several limitations. We performed in vitro measurements of cadaver specimens of lumbar spine segments after excision of all the muscles, which act as spinal stabilisers in vivo. Therefore, our data provide only indications about in vivo biomechanical behaviour, as is the case for all biomechanical studies. Furthermore, the advanced mean age of the donors does not reflect the mean age of the patients who might benefit from IPD implantation. Also, we did not measure the degree of kyphosis induced by the IPDs, which might vary across devices and would be a parameter of interest to further characterise the two IPD categories.

We see two main methodological limitations to our study: the small sample size limits the statistical power of the analysis, and the differences in IPD size precluded randomisation of the order of IPD implantation. Although the biomechanical effects documented in vitro seem indisputable, no information is available on whether the foraminal size increase correlates linearly with the clinical benefits. Thus, we do not know the foraminal opening cut-off above which an improvement in the clinical symptoms can be expected. Thus, our biomechanical study must be completed by a clinical study to confirm the efficacy of IPD implantation and to determine the best criteria for selecting patients likely to benefit from this procedure.

5. Conclusion

Our study demonstrates that IPD implantation modifies the size of the intervertebral foramina in vitro and that this effect varies across IPD types. In extension, all IPDs tested increase the foraminal surface area at the implanted level. In flexion, in contrast, differences were seen across IPDs. Thus, some types of IPD may constitute an alternative to decompression/fusion surgery. Our work also suggests that IPD implantation may have deleterious effects on the L5–S1 foramen and therefore mandates a detailed pre-operative analysis of the level infra-jacent to the implanted level. This in vitro evaluation should be completed by an in vivo study.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References