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Original article

# 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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ABSTRACT

*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 N·m, 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.


## 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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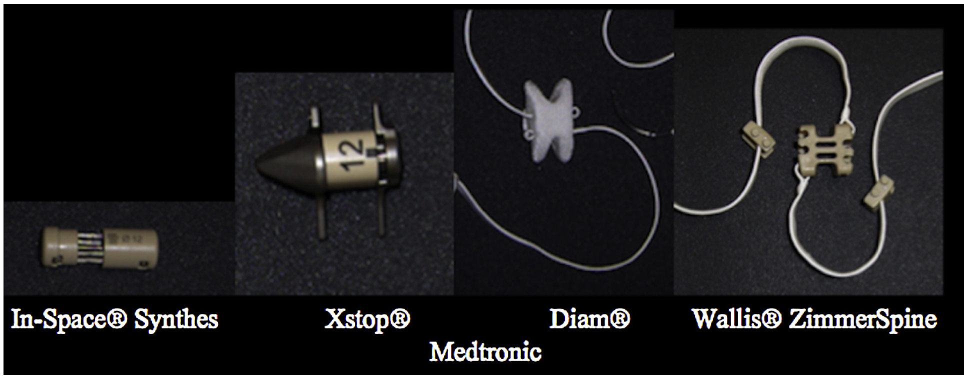


**Fig. 1.** The four commercially available interspinous process devices tested.

compared to conventional open surgery [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 [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® (Synthes, West Chester, PA, USA) is a cylindrical polyetheretherketone implant equipped with two titanium wings to ensure stability. X-Stop® (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 interspinous processes.

Wallis® (Zimmer Spine, Warsaw, IN, USA) and Diam® (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).

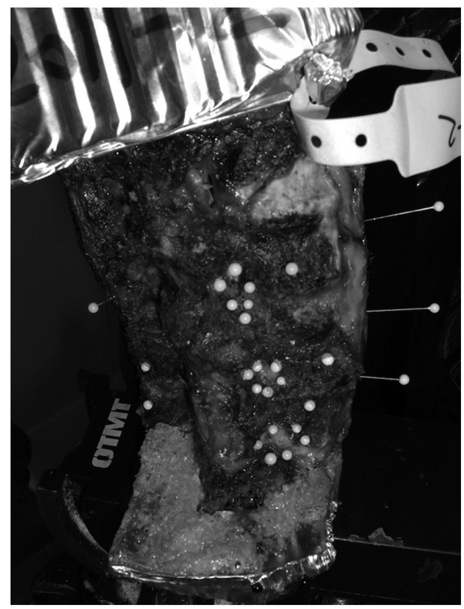

**Fig. 2.** Six markers were placed around each of the three foramina of interest, namely, L3–L4, L4–L5, and L5–S1. The stereoscopic cameras record the changes in spatial position of these markers, in flexion and in extension, thereby enabling measurement of the changes in foraminal surface area.

### 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® 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.