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Biomechanical Evaluation of a New Total Posterior-Element Replacement System

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Study Design. *In vitro* study to characterize the flexibility of a new total posterior-element system when instrumented to L4–L5 segments.

Objective. The goal of this *in vitro* study was to investigate whether an optimized version of the TOPS implant (Impliant Ltd., Ramat Poleg, Israel) is capable to restore the physiologic motion characteristic of a spinal segment after facetectomy.

Summary of Background Data. The TOPS implant is designed to replace the posterior elements of a functional spinal unit, to provide flexible restabilization and spinal alignment, while maintaining the intervertebral disc. The implant is composed of bilateral pedicle screws, connected with 2 crossbars in the transversal plane. The crossbars are joined together by an elastic element capable of transmitting tensile and compressive loads, as well as shear forces.

Methods. Six human cadaver specimens (L3–S1) (median age 61 years: minimum 47 and maximum 74 years) were used for this *in vitro* experiment. The specimens were loaded with pure moments of ±7.5 Nm in flexion/extension, lateral bending, and axial rotation. The following states were investigated: (1) intact; (2) after bilateral laminectomy, including facetectomy of the lower facet joints, of the upper vertebra L4; and (3) after device implantation. The range of motion (ROM), neutral zone, and intradiscal pressure were determined from a third cycle. In a second step, the ROM in axial rotation was determined as a function of different flexion/extension postures.

Results. In the neutral position, the laminectomy and facetectomy increased the median values of the ROM in flexion plus extension, lateral bending right plus left, and significantly in axial rotation left plus right from: 8.2°, 7.6°, 3.6° to 12.1°, 8.5°, and 8.5° (Wilcoxon signed rank test; $P < 0.05$). After fixation of the implant, the ROM was again reduced to 6.8°, 7.8°, and 3.8°. In a flexed posture, the ROM in axial rotation was slightly increased compared to the neutral position. With increasing extension, the axial rotation decreased linearly from 3.7° in neutral position to 2.3° in 4° extension in the segment L4–L5. The characteristic of the intradiscal pressure *versus* load with the implant was similar to that of the intact specimen.

Conclusion. The TOPS implant almost ideally restored the ROM in lateral bending and axial rotation compared to that of the intact specimen. In the sagittal plane, 85% of the intact ROM could be obtained. The ROM in axial rotation as a function of flexion and extension angle also mimics the biomechanical behavior of the posterior complex of a lumbar spine. This relationship between ROM and posture emphasizes the importance of a proper implantation.

Key words: biomechanics, facet joints, lumbar spine, posterior motion preserving implant, spine arthroplasty, posterior arthroplasty. **Spine 2006;31:2790–2796**

Lumbar fusion supported by rigid instrumentation is often used in the treatment of a wide variety of spinal disorders. However, there are numerous clinical studies reporting accelerated disc degeneration adjacent to fused and/or rigidly instrumented segments. While some of these studies found alterations in only a few cases, others reported disc degeneration in more than 40% of the patients.[1,2] Also, biomechanical studies are not in agreement.[3,4] Nonetheless, ideas of dynamic nonfusion systems became more and more popular in order to maintain the mobility of a motion segment and to prevent negative effects on adjacent segments.

The different ideas can be divided in anterior or posterior procedures.[5] The anterior systems have the goal to restore or maintain disc height and motion either by total disc replacement or by just replacing the nucleus to preserve the anulus.[6–8]

The posterior systems are of interest because in a spinal segment, not only the disc but also the facet joints may degenerate independently from each other. From a biomechanical point of view, it is not be desirable to sacrifice a moderately degenerated disc, therefore, surgeons prefer to maintain the disc. The attempt to preserve the disc by using only an internal fixator may lead to fatigue failure of the implant system, as seen in unsuccessful bony fusions stabilized with an internal fixator. However, this is pure speculation, since it could not be proven that a bony fusion has a strong unloading effect on the internal fixator.[9] Nevertheless, this argument has been used to develop semirigid fixators to reconstruct the posterior elements. In contrast to the Graf ligamentoplasty,[10–12] the Dynesys implant (Zimmer, Minneapolis, MN) combines the posterior tension band with the possibility for distraction of the segment. However, this im-

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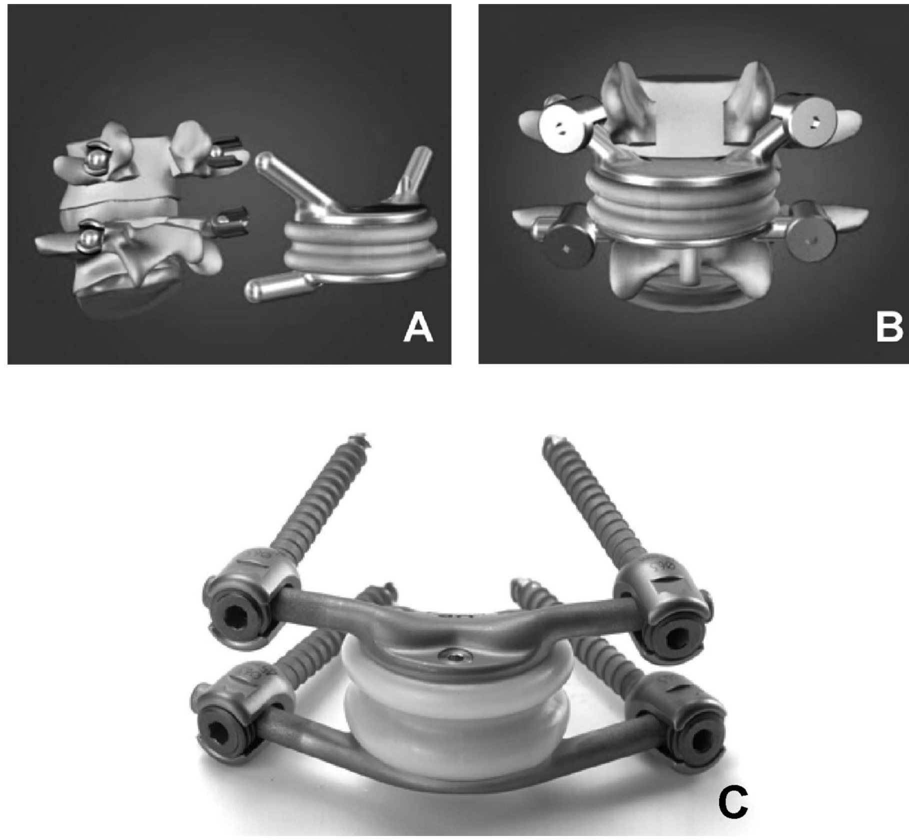

Figure 1. Schematic diagrams (**A**, **B**) and posterior view (**C**) of the TOPS implant, which is fixed with regular polyaxial transpedicular screws to the spinal segment.

plant provides more stiffness than originally desired, and the indications are not clear yet.[13–17]

Another alternative may be to replace just the small facet joints or the complete posterior complex. There are miniature implants in development, which replace only the facet joint surfaces, however, to our knowledge, they are not yet in clinical use.

The TOPS system (Impliant Ltd., Ramat Poleg, Israel), a mobile spinal implant for total posterior arthroplasty, addresses a full range of posterior pathologies, including facet arthrosis, spinal stenosis, and spondylolisthesis. The TOPS device is designed to stabilize, but not fuse, the affected vertebral level and to alleviate pain resulting from these common degenerative posterior indications. The TOPS device is a unitary implant comprised of 2 titanium plates with an interlocking flexible articulating core, surrounded by a polyurethane elastomer cover; its metal arms connect horizontally to the pedicles *via* 4 polyaxial pedicle screws. The device is implanted after a standard decompression by removal of the lamina and the medial facets, and provides mobility in flexion, extension, and lateral bending while stabilizing in axial rotation and shear directions.

The aim of the study was to investigate whether this implant TOPS is suitable for posterior stabilization of the lumbar spine and whether the implant is capable of restoring the physiologic motion of the intact segment. Additionally, the characteristics of stability with TOPS implant during axial rotation in different flexion/extension angle positions were analyzed.

Materials and Methods

The TOPS implant (total posterior-element system) developed by Impliant Ltd. (Ramat Poleg, Israel) is comprised of titanium alloy endplates with an interlocking polycarbonate urethane boot. Inside the device, there is a titanium-polycarbonate urethane articulating construct that is attached to the respective upper and lower endplates (Figure 1). The flexible boot and the internal mechanism allow relative movement between the endplates so that the device can impart axial rotation, lateral bending, extension, and flexion at the implanted segment of the spine. While enabling motion, the internal construct and the boot mechanically constrain each other to restrict motion and stabilize the segment. In this *in vitro* study, TOPS implants were available in 2 heights, normal and low profile. They are designed to bridge the segment L4–L5 because that level will probably be the most common level where this implant will be applied.

Six fresh frozen human cadaver lumbar spine specimens L3–S1, with a median age of 61 years (range 47–74) were tested. The specimens were freshly dissected, sealed in triple plastic bags, frozen, and stored at −28°C until testing. Radiographs were taken before preparation to exclude spinal diseases, damage, and severe degeneration. Furthermore, the degree of degeneration was determined on the basis of radiography, and only specimens with slight or median degeneration (grades 1 and 2) were used.[18]

The specimens were thawed to 4°C 10–12 hours before starting the preparation process. All soft tissue was removed, leaving all ligaments, joint capsules, and bony structures intact.

The cranial (L3) and caudal (S1) vertebral bodies of each specimen were embedded half in polymethylmethacrylate

(Technovit 3040; Heraeus Kulzer GmbH, Wehrheim/Ts, Germany).

The middle disc was aligned horizontally. Screws for the motion analysis system were fixed in the vertebrae L4 and L5, and an intradiscal pressure sensor (FMSPEZ50; Mammendorfer Institut für Physik und Medizin GmbH, Mammendorf, Germany) was implanted in the disc L4–L5 under fluoroscope control.

Before the implantation of the TOPS, a bilateral laminectomy, including facetectomy of the lower facet joints, of the upper vertebra (L4) was carried out.

The experiment itself was performed at room temperature. Before implantation, the TOPS implant was warmed up in a 37°C water bath of saline solution (0.9%), to create a realistic implantation situation comparable with the human body. It was implanted and tested as quickly as possible.

For positioning the implant, 4 polyaxial pedicle screws were fixed in the pedicles of L4 and L5. The implant was fixed with set screws in these pedicle screws with a tightening torque of 13 Nm.

The flexibility tests were carried out in a specially designed spine tester (Figure 2).[19] In this apparatus, the caudal end of the spinal specimens was rigidly fixed to a frame, while the cranial vertebra was mounted to a gimbal. This gimbal was integrated into a 3-dimensional slide system enabling unconstrained movements in all 6 degrees of freedom.

With integrated motors in the gimbal, 3.5 cycles with pure bending moments of ±7.5 Nm were applied in the 3 main anatomic planes. The motor speed was 1°/s in lateral bending and flexion/extension and 0.5°/s in axial rotation. A 6-component load cell (FTS 1500/40; Schunk, Lauffen/Neckar, Germany), mounted between the specimen and the gimbal, recorded continuously the applied moments and forces. During loading, the specimens were allowed to move unconstrained in the 5 uncontrolled degrees of freedom.

The specimens were first tested in the intact state, in the defect state, and after implantation of the TOPS implant.

The intersegmental motion of the segment L4–L5 was measured with an ultrasound-based system for 3-dimensional motion analysis (WinBiomechanics; Zebris, Isny, Germany). The system consists of special triple markers based on miniature ultrasound transmitters and sensors. The measuring sensor mounts on a tripod detecting the travel time of the ultrasonic signals and transmitting the results to the basic unit. After flexibility tests, the specimens were sealed in triple plastic bags and frozen again at −28°C.

About 4 weeks later, the specimens were defrosted, and the implant was fixed again to test axial rotation in different flexion/extension angle positions.

This time, each specimen was first tested in the unloaded neutral position with the implant in place (0°). Starting from this neutral position, the specimens were then moved with the Cardan joint in defined flexion (2°) and extension (−1°, −2°, −3°, and −4°) positions. The other testing parameters were the same as in the first part of this study.

The third cycle was used to determine all the measurements of range of motion (ROM) and neutral zone.

The intradiscal pressure indicates how much load is transferred through the anterior column. For the quantitative evaluation of intradiscal pressure, only nondegenerated discs can

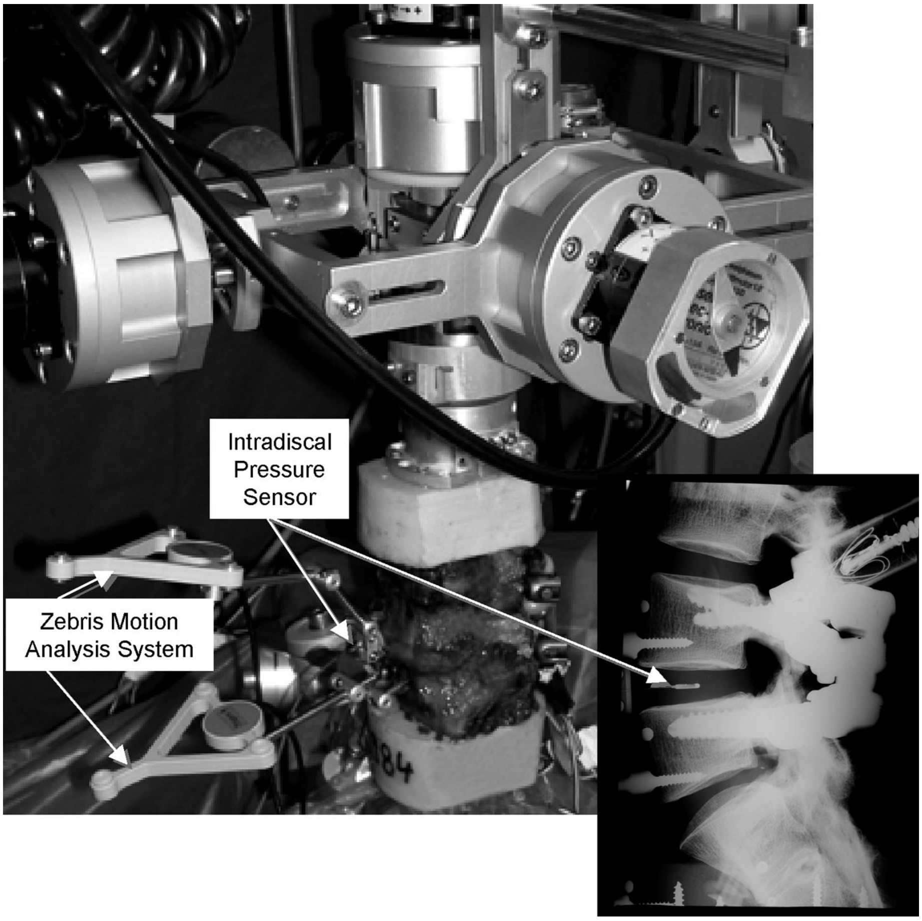

Figure 2. Setup of the experiment in the spine simulator with implanted specimen instrumented with the Zebris motion analysis system (Isny, Germany) and pressure transducer placed in the center of the disc L4–5 (also see radiograph).

be used. Curves of healthy discs, which represent the pressure *versus* the applied moment, have a butterfly-shape characteristic for flexion/extension and lateral bending, and v-shape for axial rotation.

Each pressure curve starts with the unloaded specimen at 0 Nm. The pressure value of a healthy or only slightly degenerated disc in this unload position is usually around 0.1 MPa.

In the current test, specimens with slightly degenerated discs were used. For this reason, a quantitative evaluation of intradiscal pressure was not possible, and values could only be presented exemplarily.

For statistical evaluation, the Wilcoxon signed rank test was used to test within the group. Since the tests were explorative, a correction for multiple comparisons was not carried out.

Results

The load-displacement hysteresis curves from the flexibility test showed an increase of the ROM in the defect situation, which could be restored to similar values with the implant in the 3 principle motion planes (Figure 3). In flexion/extension, the ROM increased compared to the intact state about 30%, in axial rotation it even increased significantly ($P < 0.05$), more than double the values, whereas in lateral bending, the removal of the posterior complex had only a minor influence (Figure 4). The neutral zone was mainly affected in flexion/extension. With mounted TOPS implant, the ROM and neutral zone in neutral position could almost be restored to normal values in lateral bending and allowed approximately 85% of intact ROM in the sagittal plane.

The ROM in axial rotation was strongly dependent on the posture of the specimen. The implant allowed normal motion in the neutral position but allowed more motion in flexion and restricted motion with increasing extension from 3.8° in neutral position to 2.3° in extension (Figure 5). The neutral zone seemed not to be influenced. Unfortunately, data are not available for all 6 specimens. With the first 2 specimens, we only tested in 2° steps (only 2°, 0°, −2°, and −4), then we decided to test with each 1° step in extension. This resulted in a maximum of n = 4 for −1° and −3°. The second reason was that 1 of the 6 specimens could not be extended more than 2° without exceeding 7.5 Nm. Therefore, we decided to stop at 2° with this 1 specimen.

The course of intradiscal pressure was also influenced by the removal of the posterior complex and could be restored with the TOPS to similar values like that in the intact segment, as shown exemplarily for 1 of the specimens (Figure 6). The intradiscal pressure measurements require nondegenerated discs, however, even the best specimens used in this study showed a mild degeneration of grade 1. Therefore, the pressure curve in lateral bending was not ideal, and no clear difference between the intact state and the defect situation could be shown.

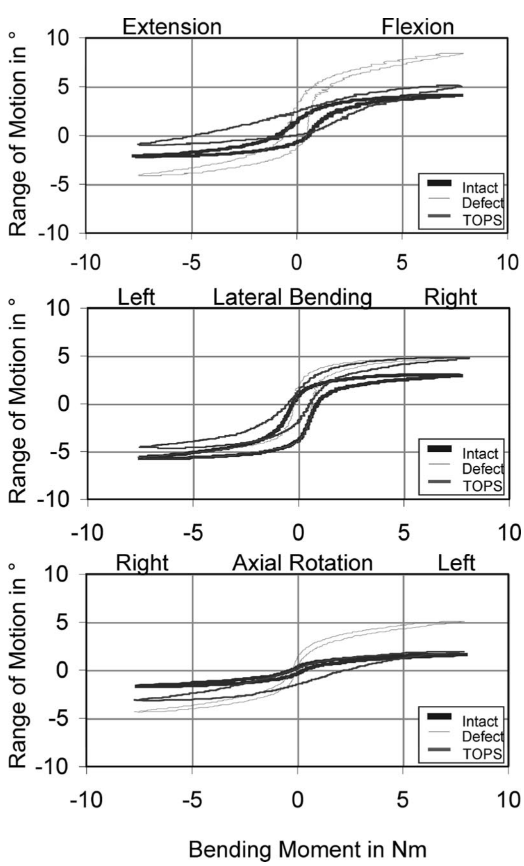

Figure 3. Exemplary load-displacement hysteresis curves in the 3 motion planes. The conditions intact, defect, and with TOPS implant were tested.

Discussion

The implant developed by Impliant Ltd. is designed to replace the posterior elements of a functional spinal unit, and to provide flexible restabilization and spinal alignment, while preserving the intervertebral disc.

The purpose of this *in vitro* study was to investigate whether the TOPS implant is capable of restoring the motion of the intact segment L4–L5 after a laminectomy and facetectomy of the inferior facets of L4.

It was shown that the TOPS implant almost ideally restored the ROM in lateral bending and axial rotation, and allowed 85% of the intact ROM in flexion plus extension when compared to that of the intact specimen.

The ROM in axial rotation additionally was quantified as a function of the flexion and extension angle. This analysis showed that the implant allows a larger axial rotation in flexion but increasingly restricts it with increasing extension, which also mimics the biomechanical behavior of the posterior complex of a lumbar spine, as experienced in many previous *in vitro* studies from our group.

Cutting spinal structures due to the defect model with laminectomy and facetectomy may have an additional destabilizing effect on the adjacent segments. A previous study on polysegmental and monosegmental specimens showed that shortening the tested specimens increases the ROM in the segment of interest, suggesting that ligament that spans several segments may be cut and have

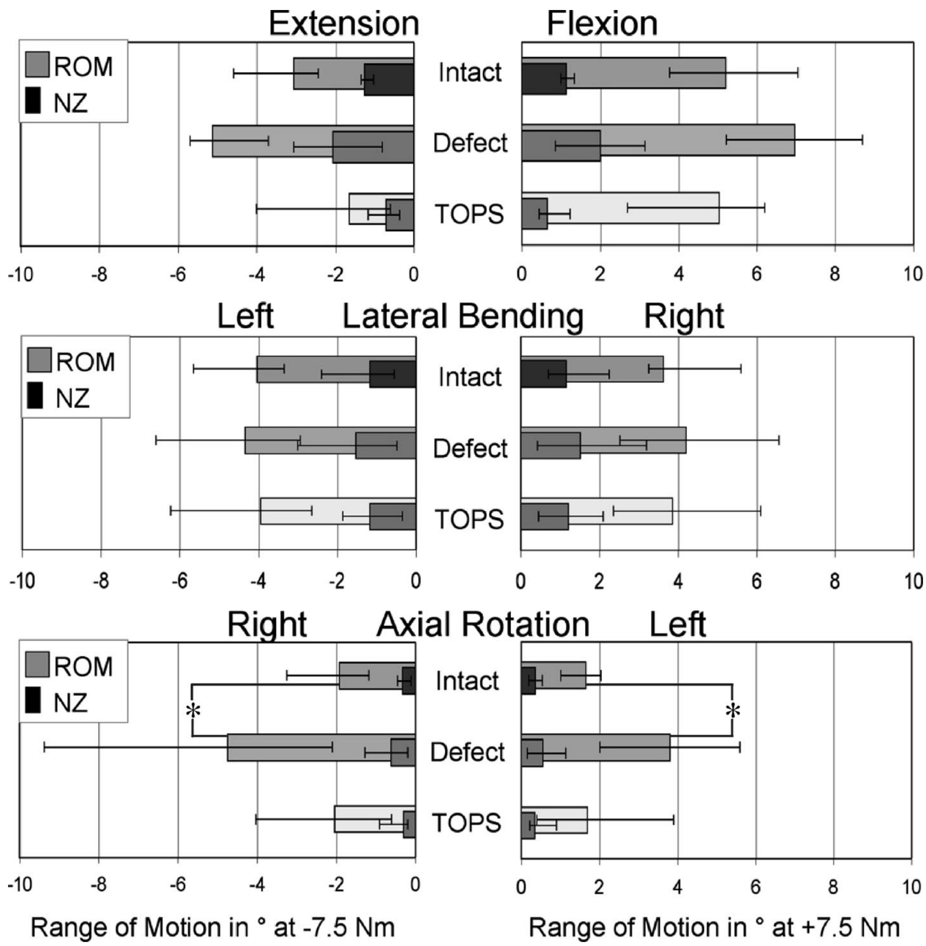

Figure 4. Median and ranges of ROM and neutral zone (NZ) in flexion/extension, lateral bending right/left, and axial rotation left/right for pure moments of ±7.5 Nm (* $P < 0.05$).

an influence on shorter segments.[20] However, this defect created here did not influence the ROM in the adjacent segment. This could be shown in preliminary studies, which were carried out to characterize and optimize the implant. In these preliminary studies, the same setup was used, however, additionally, the ROM in the adjacent segments was determined.

The intradiscal pressure data showed that the implant allows the disc to bear a part of the load, close to the natural biomechanics of the disc. However, the absolute values cannot be directly compared to the *in vivo* conditions, since there was no preload simulated in this test. Additionally, the hydrostatic pressure can only be determined accurately in nondegenerated discs. Therefore, these results should be interpreted with caution.

This test was performed with pure moments without additional preload. Although this might not represent perfectly the physiologic condition, it follows internationally accepted recommendations, which suggest that these kinds of *in vitro* tests should be performed in a standardized way.[21,22] A comparison of *in vivo* and *in*

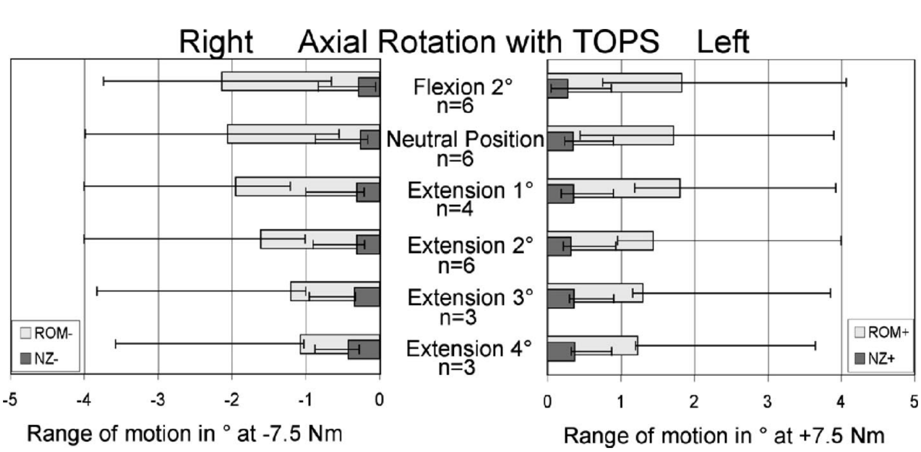

Figure 5. Median and ranges for the ROM and neutral zone (NZ) in axial rotation with different flexion/extension angles in the instrumented segment L4–L5 with the TOPS implant.

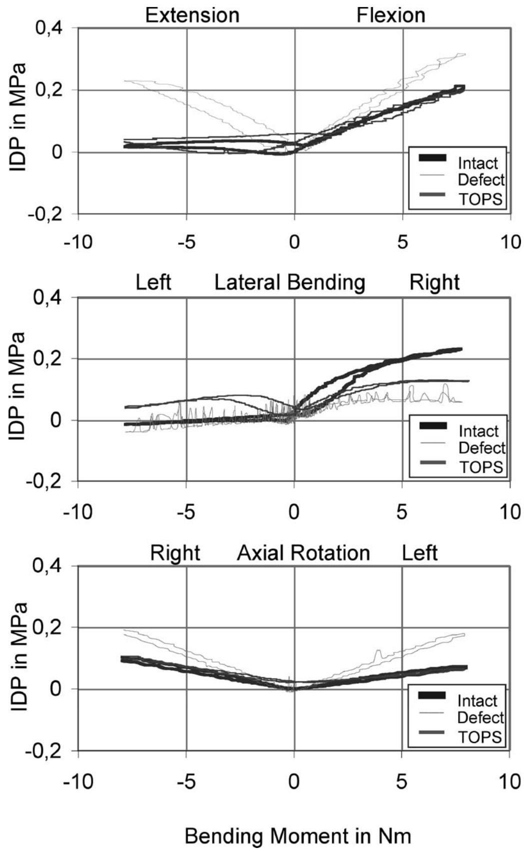

Figure 6. Characteristic intradiscal pressure (IDP) curves loaded with pure moments in the 3 principle motion planes.

vitro data obtained under these loading conditions proved that applying pure moments is a good compromise when performing *in vitro* experiments if the intervertebral discs are intact.[23]

Due to the complex nature of the posterior column, clinical studies must be performed to correlate long-term *in vivo* results with the observed *in vitro* findings. However, early clinical outcomes indicate that the TOPS system affords segmental motion. Moreover, radiographic analysis in an 8-patient series with follow-up ranging from 3 months to 1 year shows no loss in disc height, no screw loosening, and no change in spondylolisthesis.

The goal of the TOPS implant is to replace the posterior complex, including the facet joints and the lamina, and to provide segmental stability and motion in the presence of the native disc. With this goal in mind, this implant can currently only be compared with the Dynesys, which follows similar goals.

Both implants show similar motion characteristics in extension and axial rotation. However, in flexion and particularly in lateral bending, the Dynesys restricts motion strongly,[15] which is also expressed in the intradiscal pressure.[14] In contrast, the TOPS system allows at least 85% of the ROM in sagittal plane and mimics the flexibility in lateral bending ideally. This is also expressed in the almost physiologic loading of the disc. In axial rotation, it mimics the biomechanical behavior of the posterior complex of a lumbar spine, however, this emphasizes the importance of a proper implantation.

■ Key Points

- *In vitro* study to characterize the flexibility of a new total posterior-element system instrumented to L4–L5 segments.
- The TOPS implant almost ideally restored ROM and loading in the disc.
- The TOPS mimics the biomechanical behavior of the posterior complex of a lumbar spine.

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