Treatment of lumbar spinal stenosis with a total posterior arthroplasty prosthesis: implant description, surgical technique, and a prospective report on 29 patients

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Object. Total disc replacement is an alternative to lumbar fusion, but patients with spinal stenosis, spondylolisthesis, and facet arthropathy are often excluded from this procedure because increased adjacent-segment motion can exacerbate dorsal spondylotic changes. In such cases of degenerative spondylolisthesis with stenosis, decompression and fusion remain the gold standard of treatment. To avoid attendant loss of motion at the treated segment, the TOPS system is a novel total posterior arthroplasty prosthesis that allows for an alternative dynamic, multiaxial, three-column stabilization and motion preservation. The purpose of this study is to report preliminary surgical data and clinical outcomes in patients treated with the TOPS lumbar total posterior arthroplasty system.

Methods. Twenty-nine patients were enrolled in a nonrandomized, multicenter, prospective pilot study outside the US. All patients had spinal stenosis and/or spondylolisthesis at L4–5 due to facet arthropathy. Radiographs and scores on outcome measures including the visual analog scale (VAS) for pain, Oswestry Disability Index (ODI), Short Form-36, and Zurich Claudication Questionnaire were prospectively recorded before surgery and at 6-week, 3-month, 6-month, and 1-year intervals after surgery. Prior to instrumentation, a bilateral total facetectomy and laminectomy at L4–5 or L3–4 was performed via a standard midline posterior approach. After decompression, the TOPS screws were inserted into four pedicles to achieve maximal purchase with triangulating bicortical trajectories. An appropriately sized TOPS arthroplasty implant was then applied.

The mean surgical time was 3.1 hours, and patients’ clinical status improved significantly following treatment with the TOPS device. The mean ODI score decreased compared with baseline by 41% at 1 year, and the 100-mm VAS score declined by 76 mm over the same time period. Radiographic analysis showed that lumbar motion was maintained, disc height was preserved, and no evidence of screw loosening was found. No device malfunctions or migrations and no device-related adverse events were reported during the study.

Conclusions. The TOPS total posterior arthroplasty system represents a novel, dynamic, posterior arthroplasty device that provides multiaxial stability in flexion, extension, rotation, and lateral bending after total facetectomy and neural decompression. The surgical data indicate that it can be safely applied via a traditional approach with low surgical morbidity and excellent 1-year functional and radiographic outcomes in patients with degenerative spondylolisthesis accompanied by stenosis and back pain.

Key Words • spondylolisthesis • spinal stenosis • motion preservation • dynamic stabilization • surgical outcome • prospective study

The pathophysiological mechanisms of low-back pain continue to be poorly understood and are difficult to study. Whereas pain resulting from neurological compression has been traditionally treated with great success by using dorsal decompressive procedures, successful treatment of mechanical or discogenic lumbar pain has proven far more problematic. For many patients whose symptoms remain refractory to conservative or less aggressive modalities, spinal fusion continues to be the mainstay of surgical treatment for the relief of axial back pain.1,2

Unfortunately, clinical outcomes have been variable and inconsistent with regard to the efficacy of spinal fusion in relieving lumbago as quantified using standardized measures such as the ODI, VAS, and Short Form-36.1 To
compound the problem, accelerated degeneration of the segment adjacent to the fused level has been demonstrated in biomechanical laboratory investigations, short- and long-term radiological studies, and numerous retrospective clinical surgical series. Although the exact incidence and cause of adjacent-segment disease remains controversial and poorly defined, it is clear that this is one of the most dreaded long-term clinical sequelae after successful fusion. From published biomechanical and radiographic analyses, there appears to be an immediate alteration of load-sharing after rigid segmental fusion, with an increase in mobility, shear, strain, and pressure at the intervertebral disc, uncovertebral joints, and facet complex of the adjacent segment(s). With this in mind, many have postulated that preservation of motion and/or load-sharing at the original diseased level would help to mitigate or reduce the overall incidence of adjacent-segment disease, thereby reducing the need for subsequent surgical treatment of the adjacent segments.

Whereas patients with degenerative spondylolisthesis and stenosis treated with decompression alone have traditionally experienced good relief of their neurological symptoms, long-term clinical Class II studies have since demonstrated that patients treated with decompression and fusion had statistically improved outcomes for central axial back pain symptoms. Therefore, decompression combined with fusion remains the gold standard of treatment and, accordingly, can often result in a loss of global spinal motion and in accelerated degeneration of the adjacent lumbar levels. The total posterior arthroplasty system called TOPS (Impliant, Inc.) is a dynamic facet arthroplasty prosthesis that is designed specifically for the purpose of restoring segmental stability while preserving near-anatomical motion characteristics after surgical decompression of a diseased, stenotic lumbar spinal segment. By using the TOPS prosthesis in lieu of arthrodesis and/or rigid pedicle screw instrumentation after decompression, our goal was to gain experience with this novel means of treating patients suffering from spondylolisthesis and to achieve validated clinical low-back pain and neurological outcome scores that were at least equivalent to those of traditional posterior lumbar decompressive and fusion procedures.

Implant Characteristics

The TOPS system is a unitary device (Fig. 1) composed of a titanium construct with an interlocking PCU articulating core. The design allows relative movement between the titanium plates to enable axial rotation, lateral bending, extension, and flexion. The normal human ROM in these axes varies with age, strength, flexibility, and general physical state. Most studies indicate that individuals can achieve ROMs of $\pm 1.5^\circ$ of axial rotation, $\pm 5^\circ$ of lateral bending, $2^\circ$ of extension, and $8^\circ$ of flexion. The implant is designed to allow these ROMs while also blocking excessive posterior and anterior sagittal translation. The TOPS system uses cannulated standard pedicle screws blasted with hydroxyapatite for fixation to the vertebrae (Fig. 2). Because the internal configuration of the PCU bumpers ultimately acts to limit motion, the TOPS system has an inherent dampening property that serves to dissipate energy that is passed through it during standard load-sharing of the active spinal motion segment. Furthermore, because the PCU elements also have some shock-absorption properties in the vertical axis, the axial load transmitted through the crossbars to the central core of the device is somewhat dampened as well. Unlike existing posterior dynamic motion devices such as the Graf ligament and the Dynesys prosthesis, which are not linked across the midline, the central core of the TOPS device is directly attached to all four pedicles, thereby effectively stabilizing rotation and lateral bending, which are normally coupled and restricted by the native lumbar facets. These features not only preserve almost full spinal motion but also serve to decrease significantly the load transfer to the adjacent levels and also to decrease stresses at the implant–bone interface, thereby minimizing the risk of screw pullout and construct failure before osteointegration of the pedicle screws.

Finite Element Analysis

As part of the overall development program on early designs of the TOPS system, a finite element analysis was performed on the implant by using ANSYS computation-
al software. The original model developed for this theoretical stress analysis was a half-section representation of the device. The model was chosen because the device itself and the loading conditions on it were found to be symmetrical around the central plane. This hemimodel analysis allowed for faster computation without loss of precision. The results of this assessment show the principal stresses acting on the model as a result of the applied loading. The principal stress generated in the device during maximum anticipated loading is well below the yield stress for the titanium alloy from which it is fabricated17 (Fig. 3).

Biomechanical in Vitro Motion Segment Analysis

The TOPS system was implanted in and tested on six fresh cadaveric lumbar segments to evaluate its capability of restoring motion to the intact spinal segment and to evaluate its effects on motion to the adjacent spinal segment after stabilization. Functional mobility and intradiscal pressures of the L4–5 functional spinal unit motion segment in flexion, extension, lateral bending, and rotation was assessed sequentially, as follows: 1) at the initial intact state; 2) after bilateral laminectomy and functional total facetectomy; and 3) after dynamic stabilization with the facet prosthesis. The test results showed that, compared with the intact segment, the TOPS implant was able to significantly restore normal motion behavior to the treated functional spinal unit in left and right lateral bending (Fig. 4A) and left and right axial rotation (Fig. 4B) after facet removal. In flexion and extension (Fig. 4C), the ROM was 55% of that seen in an intact segment, which is higher than that reported previously in biomechanical studies of similar implants like the Dynesys system.26 Of particular note, there was no significant increase in mobility at the adjacent segment after prosthesis implantation, compared with the intact state. This finding, however, has to be interpreted carefully, because it might be due to the loading condition with pure moments. Additionally, pressure measurements obtained from the L4–5 disc demonstrated that the implant significantly reduced intradiscal forces but still allowed the disc to participate in near-normal load-sharing. Nevertheless, the absolute values cannot be directly compared with in vivo conditions because no known preload could be simulated. Additionally, the hydrostatic pressure can only be determined accurately in a nondegenerated disc.

Load on the Pedicle Screws

To evaluate the potential length of time that the TOPS prosthesis could maintain its pedicular fixation to the lumbar spinal segment, an assessment of the stress at the screw–bone interface was conducted. Because there is no
established standard torque or strain value for lumbar pedicle screw pullout in the published literature, it was decided to compare the TOPS device with the Dynesys system (Zimmer Spine), which has a low incidence of fixation failure in long-term clinical series. Strain gauges were applied to the same four screws for each device so that the mechanical stress and resulting strains transferred to them could be measured while the spine simulator manipulated the spine segments (Fig. 5). Results from this testing demonstrated that the load transmission to the pedicle screws was 36% less at the screw–bone interface in the pedicle screws of the TOPS compared with the Dynesys systems during flexion and extension, and 46% less during lateral bending. As clinical results of the Dynesys implant have indicated, at a 6 to 8% screw loosening rate at 2 to 3 years of follow up, it would be expected that the TOPS system will fare as well as if not better than the Dynesys after long-term clinical implantation.

**Patients and Methods**

**Patient Population**

Twenty-nine patients in whom a diagnosis of moderate to severe lumbar spinal stenosis was made were enrolled in a prospective clinical trial in which the TOPS system was used (Class II). The sites included in this study are Sao Paulo, Brazil; Istanbul, Turkey; Zreifin, Israel, and Antwerp, Belgium. As shown in Table 1, the mean age of the enrolled patients was 64.2 years (range 52–72 years). Inclusion criteria for this population encompassed patients requiring single-level spinal decompression and fusion surgery between L-2 and L-5. Neuroimaging analysis in which CT scanning, magnetic resonance imaging, myel-
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ography, or plain x-ray films were used was performed to diagnose and better characterize the exact location of lumbar spinal stenosis. Specifically, these studies were used to confirm the presence of any of the following: thecal sac and/or cauda equina compression, nerve root impingement by either osseous or nonosseous elements, or hypertrophic facets with canal encroachment. All patients displayed both low-back and sciatic pain, with or without claudication. Secondary inclusion criteria for this study encompassed but did not require the following: degenerative spondylolisthesis up to Meyerding Grade II, advanced facet arthrosis, and radiological segmental instability (based on dynamic flexion–extension radiographic analysis).

Standard anteroposterior, lateral, flexion, and extension radiographs were obtained preoperatively and at 3 weeks, 6 weeks, and 6 months. Sagittal angulation was measured on the lateral radiographs from L-1 to S-1 using the Cobb method. Flexion, extension, and total ROM were measured. The radiographs were examined by two independent observers for evidence of hardware failure, loosening of the construct, or signs of spinal instability. Clinical outcomes were assessed using the VAS, ODI, and ZCQ scores, with tests administered preoperatively and at 6-week, 3-month, 6-month, and 1-year intervals after surgery.

Surgical Technique

The patient was placed prone on the operative frame with a padding configuration of either a four-poster or double-roll type to recreate simultaneously the lumbar lordosis and to ensure that the abdomen was free and uncompressed. A vertical incision was made down to the level of the lumbodorsal fascia. Subperiosteal dissection was then continued with the use of Bovie cautery and periosteal elevators to produce gradual tension on and to elevate the dorsal musculoligamentous complex off the spinous processes, lamina, and facets of the target motion segment. Compared with classic spinal intertransverse fusion, exposure and retraction of the musculature for TOPS placement need only be extended to the lateral aspect of the facet complex. Additionally, particular care was taken to preserve the capsule and muscular attachments surrounding the superior facet complex.

Decompression was then completed via bilateral laminectomy and functional total facetectomy techniques. Depending on the exact pathological features of the individual case, the degree of bone, synovium, and ligamentum flavum resection varied accordingly (Fig. 6A). Because the TOPS system serves functionally to replace the motion restraint of the native facet complex, a functional decoupling of both facet complexes was required. This was achieved by aggressive resection through the joint itself and/or by removing the inferior articulating processes from the superior vertebrae. A trial of the template was used to confirm adequacy of bone decompression for subsequent prosthesis implantation (Fig. 6B). Once the necessary degree of bone resection was achieved, adequate neural decompression was confirmed with a Woodson elevator bilaterally over the thecal sac, the exiting nerve roots, and the traversing nerve roots.

The pedicle screw entry points were then identified and prepared. Particular attention was paid to obtaining a more

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TABLE 1

Demographic data in 29 patients with spondylolisthesis who were treated with dynamic stabilization*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value (%)</th>
</tr>
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<tbody>
<tr>
<td>sex</td>
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</tr>
<tr>
<td>male</td>
<td>12 (41.4)</td>
</tr>
<tr>
<td>female</td>
<td>17 (58.6)</td>
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<tr>
<td>age in yrs</td>
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<tr>
<td>mean ± SD</td>
<td>64.2 ± 6.10</td>
</tr>
<tr>
<td>range</td>
<td>52–72 BMI</td>
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<tr>
<td>mean ± SD</td>
<td>28.8 ± 4.94</td>
</tr>
<tr>
<td>range</td>
<td>18.1–39.2</td>
</tr>
<tr>
<td>% w/ spondylolisthesis†</td>
<td></td>
</tr>
<tr>
<td>Grade 0</td>
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</tr>
<tr>
<td>Grade I</td>
<td>44.8</td>
</tr>
<tr>
<td>Grade II</td>
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</tbody>
</table>

* BMI = body mass index; SD = standard deviation.
lateral-to-medial vector of pedicle cannulation to achieve maximal triangulation of the final screws. A unique pendulum-type guide was used to ensure that the trajectory of pedicle cannulation would remain within the acceptable range of angles that can be tolerated by the geometry of the four arms of the device (Fig. 6C). Triangulating screw trajectories and the largest anatomically acceptable screw diameters were used to maximize the pullout strength of each individual pedicle screw. The pedicles were then instrumented with the standard cannulated tulip-head polyaxial screws that are provided in the TOPS system. Slotted screw extension sleeves are available to facilitate final attachment of the implant when access to the screw heads is difficult (Fig. 6D). A two-part alignment gauge (Fig. 6E) was used to adjust the dorsal height of all four pedicle screws so that they could properly accept the TOPS device.

At this point, an appropriately sized TOPS device was prepared for implantation. A small amount of sterile saline was injected through a small port in the bottom of the implant to serve as a lubricant. The device was then loaded on a specialized holder (Fig. 6F) and inserted into the tulip heads of the polyaxial screws. Once in place, each of the four crossbar arms was then secured using a standard locking setscrew and countertorqued to its final tightness (Fig. 6G). If used, the extension sleeves were then removed from the polyaxial screw heads to complete the surgical procedure, but only after final biplanar fluoroscopic confirmation of the positions of the device and screws (Fig. 7). The wounds were then closed in a standard layered fashion. A lumbar corset or semirigid brace was used in the early perioperative period for support and comfort of the patient.

Results

As of the date of publication, the patients enrolled were at various stages of follow up, ranging from 6 weeks to 1 year (Table 2). Of the 29 patients enrolled, 28 were treated at L4–5 and one was treated at L3–4. Fifteen of the 29 patients had degenerative spondylolisthesis of Grade I or II (Meyerding classification; see Table 1). The mean surgical duration was 3.1 hours, with a standard deviation of 0.89 hours. The mean blood loss was approximately 200 ml. The mean 100-mm VAS leg score was 88 mm at baseline, 21 mm at 6 weeks, 19 mm at 3 months, 18 mm at 6 months, and 12 mm at 1 year (Fig. 8A). The mean preoperative ODI score was 57%. The ODI scores were 20 and 16% at the 6-month and 1-year follow-up intervals, respec-
tively (Fig. 8B). The mean ZCQ score was 57% initially and decreased progressively to 26% at 1 year (Fig. 8C).

Radiographic Analysis

The radiographic findings were reviewed by an independent panel of radiographic specialists at 6-week, 3-month, 6-month, and 1-year intervals. These studies revealed that all of the motion segments instrumented with the TOPS device were stable and that no device migrations or malfunctions occurred. The preoperative disc heights at the treatment and adjacent levels were measured and recorded using plain x-ray films and confirmed with sagittal CT scans. This was re-evaluated at 3 months and 1 year and no subsequent disc height loss was observed. The degree of spondylolisthesis was recorded at all time points and no cases of slip progression were observed. The screw–bone interface was analyzed using thin-slice CT scans. In this independent analysis, none of the 29 patients exhibited signs of screw loosening at any time point. Global spinal motion was also evaluated using flexion and extension films taken at 3 and 12 months postoperatively (Fig. 9). This evaluation confirmed that global motion was preserved in all patients (11 individuals) through the 1-year follow-up visit.

Postoperative Complications

Safety analysis revealed no device-related adverse events during this study. Adverse events not related to the implanted device included three dural tears, four postoperative seromas, and one neurological deficit. The adverse events not related to the TOPS device occurred during the normal course of decompression and were not due to implant insertion. None of the dural tears or seromas led to long-term sequelae. None of these adverse events required additional surgery. During the study, one patient experienced a transient neurological deficit 1 day postsurgery. The CT evaluation demonstrated that the position of the TOPS device and pedicle screws were normal. However, it also revealed the presence of a postoperative hematoma that was causing central canal compression. Although the preoperative blood coagulation parameters were normal, the patient reported similar postoperative bleeding complications following previous knee surgery, with a late hemorrhage that required surgical intervention. The patient has been treated conservatively and has demonstrated rapid improvement in neurological function.

Discussion

In the current era, the mainstay for treatment of degenerative spine disease has been decompression of the neural elements and fusion, with or without instrumentation, of

TABLE 2
Follow-up distribution per study site in 29 patients as of October 20, 2006

<table>
<thead>
<tr>
<th>Distribution*</th>
<th>Baseline</th>
<th>6 Wks</th>
<th>3 Mos</th>
<th>6 Mos</th>
<th>12 Mos</th>
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</thead>
<tbody>
<tr>
<td>theoretical</td>
<td>29</td>
<td>29</td>
<td>29</td>
<td>25</td>
<td>17</td>
</tr>
<tr>
<td>expected</td>
<td>29</td>
<td>29</td>
<td>28</td>
<td>20</td>
<td>12</td>
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<tr>
<td>actual</td>
<td>29</td>
<td>25</td>
<td>18</td>
<td>18</td>
<td>11</td>
</tr>
<tr>
<td>% w/ follow up</td>
<td>86</td>
<td>79</td>
<td>90</td>
<td>92</td>
<td></td>
</tr>
</tbody>
</table>

Fig. 8. Bar graphs showing postoperative outcomes after TOPS implantation. A: The mean VAS leg score was 88 mm at baseline, 21 mm at 6 weeks, 19 mm at 3 months, 18 mm at 6 months, and 12 mm at 1 year. B: The ODI scores were 20 and 16% at the 6-month and 1-year follow-up intervals, respectively. C: The mean Zurich Claudication Questionnaire score was 57% initially and 26% at 1 year.
destabilized vertebral levels. The annual incidence of lumbar and lumbosacral fusions in the US has doubled in the last decade.\textsuperscript{24,25} Although it successfully eliminates motion across the treated segment, spinal fusion has been shown to induce alterations in load-bearing and stresses in adjacent, unfused motion segments.\textsuperscript{9,14–18,19,22} Studies in cadavers demonstrate that the levels immediately adjacent to the fused segment compensate for the loss of motion, thus experiencing greater than physiological stresses.\textsuperscript{23} Our review of clinical studies supports the suggestion that the incidence of adjacent-segment disease in lumbosacral fusion varies from 5.2 to 100%, and that the incidence of symptomatic adjacent-segment disease varies from 5.2 to 18.5% over 44.8 to 164 months of follow-up observation. Ghiselli et al.\textsuperscript{7} reported a 27.4% rate of repeated operations as a result of adjacent-segment disease in lumbar posterolateral fusions. In the cervical spine, symptomatic adjacent-segment disease was observed to occur at a relatively constant rate of 2.9% per year, with 25.6% of patients developing clinically significant adjacent-segment disease at 10 years after the original operation.\textsuperscript{9}

In the hope of decreasing adjacent-segment forces, total anterior disc replacement devices such as the Charité III (Johnson & Johnson Co.) and the ProDisc II (Synthes) were developed in an attempt to preserve motion at the degenerated intervertebral disc. Based on results of the US Food and Drug Administration clinical investigational device exemption study, the Charité III was able to provide equivalent relief of low-back pain compared with patients in the randomized control arm of anterior fusion.\textsuperscript{26} However, numerous authors have asserted that severe facet arthropathy, spinal stenosis, neurogenic claudication, significant spinal canal disease, spondylolisthesis, or translational instability are all relative or absolute contraindications to placement of an anterior total disc replacement device.\textsuperscript{3,11} In a study by Huang et al.,\textsuperscript{10} in which the typical make-up of the patient cohort seen in a tertiary spinal clinic was examined, there was a preponderance of patients with dorsal disease, spinal stenosis, spondylolisthesis, and/or spinal instability. These patients were ideally suited for classic spinal decompression, and in many cases for posterior spinal fusion, and are not candidates for total disc replacement. Thus, it is clear that motion-preserving devices that can be used for patients requiring dorsal surgical treatment are needed.

When we examine the issue of posterior spinal disease and spinal stenosis, it is clear that we must treat not only the natural history of the disease process, but also the iatrogenic instability that results from surgical decompression in these patients. Because in a large majority of these patients the symptoms stem from radicular or central canal compression, they require decompression of the paramedian lamina and at least the medial third or half of the facet complex. Progressive resection for neural decompression can lead to progressive spinal instability in cases in which the facet orientation is more sagittal than coronal.\textsuperscript{1} In many patients with spinal stenosis who require aggressive decompression for extensive neural foraminal narrowing, spinal fusion is often necessitated after facet resection.\textsuperscript{23,31} In the analysis published by Fischgrund et al.,\textsuperscript{4} patients with spondylolisthesis and stenosis did better overall with regard to their low-back pain scores when they underwent a primary fusion in addition to decompression, as opposed to those who underwent decompression only.\textsuperscript{24,25} It is also clear, however, that many patients with stenosis and/or stenosis with spondylolisthesis do well without fusion and do not go on to have gross or glacial spinal instability after decompressive surgery. Therefore, a motion-preserving technology that can be placed via a standard posterior approach can help to avoid fusion in the many patients with stenosis in whom the spine is either only mildly unstable preoperatively or is made unstable after surgical decompressive destabilization of the facet complex.

With this in mind, the question remains as to the ideal nature of such a posterior motion-preserving stabilizer of the spine. Whereas numerous theories regarding the cause of low-back pain exist, perhaps the most developed of these is the concept of the biomechanical NZ, as postulated by Panjabi.\textsuperscript{20,21} In this useful heuristic system, a motion segment functions to share load, move, and impinge within a given set of mechanical parameters. During biomechanical testing, any given spinal motion segment will thus move a given amount per quantum of applied load as determined by the viscoelastic properties of the surrounding structures that bind the two vertebrae, such as the intervertebral nucleus and anulus, facet joint and capsule, interspinous ligaments, spinal longitudinal ligaments, attached paraspinal muscles, and truncal musculature. Plotted in any of three dimensions, this leads to a classic load-

![Fig. 9. Postoperative x-ray films. Global spinal motion was evaluated using flexion-extension films obtained at 3 months and 1 year, confirming that global motion was preserved in all patients through the 1-year follow-up interval.](image1)

![Fig. 10. Schematic and chart showing how, during biomechanical testing, any given spinal motion segment will move a given amount per quantum of applied load, which leads to a classic load-displacement plot of the NZ.](image2)
displacement plot of the NZ (Fig. 10). Degeneration, acute injury, or other pathological conditions alter the biomechanical limiters of the system, thereby leading to laxity, altered load-sharing, and a widening of the load-displacement curves, altering the NZ itself. As movement of the spinal segment begins to exceed its initial “set points,” joint, nociceptive, and stretch receptors begin to activate and signal pain and injury, which may lead to progressive pain and inflammation in that area. Induced injury of the ligaments or facets or disc complex will lead to a widened NZ, as seen on load-displacement curves during biomechanical cadaveric testing. This model thus provides a useful point of reference as to the cause of mechanical back pain in patients.

Whereas decompression will help to relieve classic radicular or neurogenic pain, surgical restoration of proper load-sharing and normalization of the NZ may help to decrease segmental pain and inflammatory stimuli in the treated spinal segment(s). Thus, the efficacy of rigid spinal fusion may ultimately result from its ability to provide radical correction of the load-displacement characteristics of the motion segment to near-zero movement for any applied load after rigid fusion and instrumentation. With this in mind, a proper motion-preserving stabilizer device must also be able to correct the load-displacement curves back to an anatomically natural NZ while still preserving some degree of native spinal mobility above that of rigid fusion. Additionally, by preserving load-sharing of the treated segment, it must also decrease the “stress-riser” effect on the adjacent, untreated levels to be able to minimize the incidence of adjacent-segment disease. Finally, an ideal motion-preserving dorsal device must also be secured to the spine in such a way that the device–bone interface remains stable over several million cycles. For example, transpedicularly implanted devices must therefore be designed to exert a minimum of stress at the screw–bone interface to prevent screw pullout. Thus, the motion-preserving device must be able not only to provide motion, but it must also do so in a way that does not load the screws in any significant fashion.

One of the earliest devices designed for use in patients requiring dorsal spinal procedures such as decompression was the posterior dynamic stabilization system known as Dynesys (Zimmer). The Dynesys was designed to preserve intersegmental kinematics and to alleviate loading at the facet joints. The system uses standard closed-head conical pedicle screws, which are attached by a polyester microrotations within the bone, thereby reducing the risk of screw loosening or pullout in any of the patients. This is probably due to the horizontal crossbar design of the TOPS implant that connects to two pedicle screws on the same vertebra, rather than the typical bilateral construct of a posterior fusion or flexible rod device. This design minimizes the occurrence of screw micromotions and microrotations within the bone, thereby reducing the risk of screw loosening. The TOPS bone–screw interface is further enhanced by surface blasting of the pedicle screws with hydroxyapatite. This surface treatment, coupled with the triangulating medial convergence of the pedicle screws resulting from the TOPS crossbar design, creates an anchored foundation that maximizes the resistance to screw loosening and pullout forces.

One of the principal concerns for any posterior motion device is the effect the implant has on the disc. The fact that the average disc height was maintained at both the surgically treated and adjacent levels at 1 year suggests that the TOPS device does not place abnormal and excessive loads on the discs but rather works in concert with the anterior column, much like the native facets.

Our data also demonstrate a favorable safety profile, as evidenced by the absence of device-related adverse events during implantation or ongoing function. There were no device failures, malfunctions, or migrations at any point in the study. All of the adverse events observed were not device-related, and they were consistent with published
complication rates for posterior lumbar spinal surgery. The rate of dural tears observed in this study (10%) is below the 13 to 19% range published in the literature.\textsuperscript{3,29,30}

It is important to note that the surgical steps of exposure and decompression prior to TOPS implantation are the same as those required for a standard posterior spinal decompression and fusion in which pedicle screws and rods are used. Therefore, it is unreasonable to attribute the dural tears observed in this study to the TOPS device or its surgical technique. It should also be noted that all three patients who had dural tears during surgery experienced positive clinical outcomes with no adverse sequelae arising from the tears. Four cases of seroma (14%) were reported during the study, which is consistent with the 20% rate reported by Klink et al.\textsuperscript{12} for spine surgery. All of the seromas were experienced by patients treated by one surgeon who used a bilateral Wilse approach and did not use a postoperative drain. In comparison, the patients treated by investigators who performed the standard TOPS implantation technique via an open, midline approach experienced no seromas. Each case of seroma was treated conservatively and required no surgical intervention, and all four patients experienced significant clinical benefit from the device.

Conclusions

Although long-term, comparative data are needed, it is clear from these preliminary results that the TOPS total posterior arthroplasty device is a safe and effective alternative to fusion for patients who suffer from moderate to severe lumbar spinal stenosis. Clinical outcomes show significant improvement in ODI, VAS, and ZCQ scores at all intervals, as late as preliminary follow-up at 1 year. No device-related adverse events were reported, and all adverse events that were unrelated to the device were consistent with published rates. These promising preliminary results warrant further investigation through the recently initiated, prospective, multicenter, randomized Food and Drug Administration pivotal TOPS trial.

Disclosures

Dr. McAfee is a consultant for Implant, Inc., and is the primary investigator for the TOPS investigational device exemption clinical trial. Drs. Khoo, Pimenta, Capuccino, Hes, and Conix are consultants for Implant, Inc. Drs. Coric, Hamzaoglu, Mirowsky, Anekstein, and Asarzadie have no affiliations to disclose.

References

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VIDEO 1: Video of dynamic flexion–extension films showing the stabilized L4–5 motion segment (same patient as in Video 1) with 8° of motion at 12 months postoperatively.

VIDEO 2: Video of dynamic flexion–extension films showing the stabilized L4–5 motion segment with 8° of motion at 3 months postoperatively.

[AUTHOR: Please respond to previously sent reference query re: #17 (attached) or the reference will be deleted in the final version, necessitating extensive renumbering. References such as these must be cited in a Proceedings book; if not published they should be cited in text.

Also, please designate a place in text to insert the legends for the two videos.

You have indicated that you will be ordering reprints. You should be aware that certain figures will not reproduce well in print because of resolution issues. Instructions were given and replacement figures were requested, but the figures in question still remained substandard. These are Figures 4 and 10]