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ORIGINAL ARTICLE

Seven years follow-up for total lumbar facet joint replacement (TOPS) in the management of lumbar spinal stenosis and degenerative spondylolisthesis

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Abstract
Purpose To evaluate the feasibility and clinical improvement of a total posterior arthroplasty system in the surgical management of lumbar degenerative spondylolisthesis and or spinal stenosis.
Methods During a 1-year period (June 2006 to July 2007), ten patients were enrolled in a non-randomized prospective clinical study. The primary indication was neurogenic claudication due to spinal stenosis with single-level degenerative spondylolisthesis. Patients were evaluated with X-rays and MRI scans, visual analog scale (VAS) for back and leg pain, the Oswestry disability questionnaire, and the SF-36 health survey preoperatively, at 6 weeks, 3 months and 6 months and at 1, 2, 3 and 7 years postoperatively.
Results The VAS score for back pain dropped from 56.2 preoperatively to 12.5 at 6 weeks and 19 at 7 years follow-up. The VAS score for worse leg pain dropped from 83.5 before surgery to 13 at 6 weeks and 8.8 at 7 years follow-up. The ODI dropped from 49.1 preoperatively to 13.5 at 6 weeks and 7.8 at 7 years follow-up. MRI examination at 7 years after surgery did not demonstrate stenosis adjacent to the stabilized segment. Spondylolisthesis did not progress in any of the cases. One patient had a symptomatic L3–L4 far lateral disc herniation 5 years after surgery whose symptoms resolved with non-operative treatment. In one patient, conversion to posterolateral fusion was performed due to an early device malfunction.
Conclusion In patients with spinal stenosis and degenerative spondylolisthesis, decompression and posterior arthroplasty with the TOPS System can maintain clinical improvement and radiologic stability over time.

Keywords Degenerative spondylolisthesis · Spinal stenosis · Neurogenic claudication · TOPS

Introduction

Lumbar spinal stenosis due to degeneration of the lumbar motion segment typically affects individuals over the age of 60 years [3]. It is usually the end stage of the degenerative cascade, a concept that was formulated by Kirkaldy-Willis et al. [15]. In the final common pathway of the cascade, both the intervertebral disc and the posterior joints are affected and may lead to spinal stenosis. Degenerative spondylolisthesis, in which one vertebral body translates anteriorly with respect to its inferior vertebral body, can also occur exacerbating the canal narrowing and segmental instability.

Patient with spinal stenosis present with complaints of neurogenic claudication or with pain in the buttock/s, thigh/s, and leg/s [1]. Surgery is indicated if conservative treatment fails or when the quality of life is progressively

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impaired [10, 19]. The classic surgical treatment is decompression to relieve radicular symptoms and neurogenic claudication [13, 14, 18]. Fusion is added to prevent progression of spondylolisthesis and to allow wide decompression which will include partial removal of the hypertrophic facet joints. Several studies have showed that decompression and fusion significantly improved patient outcome compared with decompression alone [4, 5, 11]. However, fusion has its limitations. Fusion increases stress at the neighboring mobile segments and may accelerate adjacent level degeneration [6, 17, 22]. Solid fusion is not always achieved and pseudoarthrosis may lead to inferior clinical outcomes [16]. Posterior arthroplasty is an alternative to fusion intended to eliminate or at least minimize adjacent level degeneration by restoring stability while maintaining motion at the affected segment [24, 26].

The TOPS System (Premia Spine Ltd., Ramat Poleg, Israel) features a motion preservation solution for patients undergoing surgery for degenerative spondylolisthesis and lumbar spinal stenosis. The device is a mobile total posterior arthroplasty which is designed to stabilize, but not fuse, the affected segment. The TOPS device is a unitary implant comprised of two titanium plates with an interlocking flexible articulating core and a circumferential polyurethane elastomer cover. Its metal arms connect horizontally to four polyaxial pedicle screws (Fig. 1a). The device is implanted after a total laminectomy and facetectomy. The device recreates physiologic motion in flexion, extension, lateral bending and axial rotation. The TOPS System mechanically resists translation and shear forces. The biomechanical and kinematic characteristics of the TOPS device in vitro were thoroughly studied [20, 27].

A prospective clinical trial with 7 years follow-up was carried out to evaluate if the TOPS System can assist in the treatment of degenerative spondylolisthesis and spinal stenosis and to determine whether total posterior arthroplasty provides enough stability to maintain significant clinical improvement and prevent progression of spondylolisthesis in a long-term follow-up.

Materials, methods, implant design, surgical technique and clinical outcome

Implant design

The TOPS implant is made of two titanium plates. Each plate has a mating spherical protrusion, creating an articulating function similar to the native facet joints. The sliding motion takes place around a theoretical axis of rotation to replicate the true motion of the posterior column in flexion, extension, lateral bending and axial rotation. The axis was designed to approximate the true physiological instantaneous axis of rotation. The articulating surfaces are covered with a polycarbonate urethane (PcU) component. The moving parts of the implant are sealed within a PcU boot (Fig. 1a). The boot resists motion and therefore imitates the elastic properties of the facet capsule and posterior ligaments. It also creates a closed compartment to contain possible wear debris. The PcU boot incorporates a PEEK ribbon that acts as a restraint for excessive flexion of the motion segment, thus preventing the dislocation of the articulating surfaces under extreme loads. Metal arms project laterally from the titanium plates for anchorage of the implant to the spine via polyaxial pedicle screws. The pedicle screws are blasted with calcium phosphate particles, leaving a roughened titanium surface for bone apposition.

Surgical technique

The patient is placed prone on a Jackson operative frame in a neutral lordotic position. A 6- to 12-cm midline skin incision is made. Subperiosteal dissection is then carried out exposing the posterior elements. TOPS implantation requires exposure and retraction of the paravertebral musculature only to the lateral aspect of the facet complex without fully exposing the transverse processes. The decompression of the spinal canal is achieved by removing the lamina and facet joints. In this study, a total laminectomy and total bilateral facetectomy were performed. The neural foramina were unroofed by removing both articular processes without the need for nerve root manipulation. Following the thorough decompression, a trial template is used to confirm adequacy of bone excision for subsequent prosthesis implantation. The pedicle screw entry points are then identified and prepared. Intraoperative fluoroscopy is encouraged as accurate position of the screws is mandatory. A unique pendulum-type guide (Fig. 1b) is used to ensure that the screw trajectory in the axial plane remains within the range of the polyaxial tulip-head screws relative to the geometry of the implant's four arms. The pedicles are then instrumented with the cannulated screws that are provided with the TOPS System. A two-part alignment gauge is used to adjust the dorsal height of the pedicle screws so that they are in the same coronal plane. This gauge is also used as a trial for selecting the correct implant size. The gauge is removed and the appropriate size TOPS device is prepared for implantation (Fig. 1c). 1.7 cc of sterile saline are injected through a small port in the implant to fill the central boot. The prosthesis is then implanted and secured to the screw heads by set screws which are tightened to the appropriate torque force (Fig. 2). Final bi-planar fluoroscopic confirmation of the device position and screws is obtained. A suction drain is inserted as a relatively large dead space is created by the procedure. The

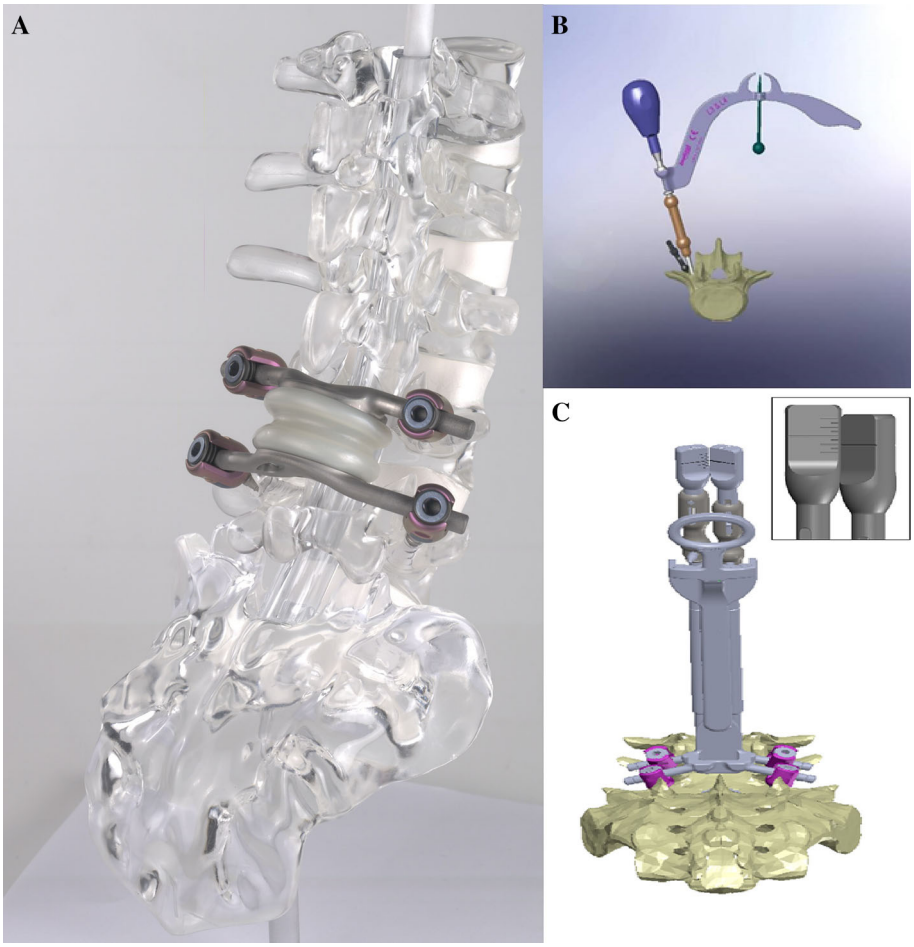

Fig. 1 **a** The TOPS system–total posterior arthroplasty prosthesis (Premia Spine Ltd., Ramat Poleg, Israel). **b** The pendulum instrument. **c** A special gauge which is used to adjust the dorsal height of the pedicle screws so that they will all be in the same coronal plane

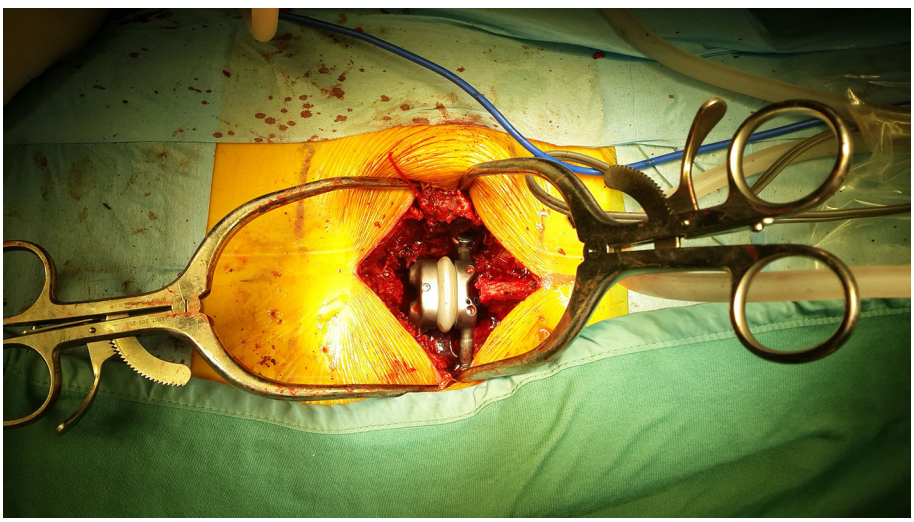

Fig. 2 An intraoperative figure of the TOPS

wound is then closed in a standard fashion ensuring a tight deep fascia closure. Patients are mobilized on the first day after surgery. No postoperative external immobilization is needed, and no activity restrictions are required as the patients may sit, bend and lift as tolerated.

Clinical trial

During a 1-year period (June 2006 to July 2007) ten patients (5 males and 5 females) aged 52–69 years (average 61.3) were enrolled in a non-randomized prospective

clinical study after approval by the local institutional review board. The primary indication was neurogenic claudication of more than 3 months due to spinal stenosis with single-level grade 1 degenerative spondylolisthesis at the L3–L4 or L4–L5 levels. Preoperative bone density was evaluated with a DEXA scan. Those with a T score lower than −1.5 SD were excluded. Other contraindications for posterior arthroplasty were disc herniation or discogenic back pain, previous surgery at L3–L5 levels, scoliosis greater than 10° or isthmic spondylolisthesis.

Patients were evaluated with X-rays (including flexion–extension and lateral bending views), visual analog scale (VAS) for back and leg pain, the Oswestry disability questionnaire, and the SF-36 health survey preoperatively and at 6 weeks, 3 months and 6 months and at 1, 2, 3 and 7 years postoperatively. Patients were evaluated by an independent observer, spine surgeon (Y.S), who was not involved in the surgical procedure. Up to 3 years, pre- and postoperative radiographs were evaluated by Medical Metrics (Medical Metrics, Inc. Houston, Tx). Seven years postoperative radiographs were evaluated by an independent radiologist. On flexion–extension radiographs any anterior or posterior translation was documented. Changes of more than 3 mm were considered as significant [2]. Implant failures, such as screw loosening or breakage, were looked for. All patients underwent preoperative CT scan and MRI of the lumbar spine. A follow-up MRI was obtained in all patients at 2 and 7 years. Degenerative changes at adjacent levels were evaluated. Seven years' results were compared with preoperative and 2-year follow-up data.

Nine patients had spinal stenosis and degenerative spondylolisthesis, one patient had spinal stenosis with facet arthrosis with a facet cyst, all at the L4–5 level. All 10 patients underwent surgery at the involved level. There were no intraoperative complications. Blood loss did not exceed 700 cc. Average operative time was 3.17 h (range 1.5–4 h). All patients were mobilized 1–2 days after surgery and discharged shortly thereafter.

The paired t test was used to analyze the difference in pre- and postoperative VAS, Oswestry disability questionnaire and SF-36 scores. The ANOVA with repeated measures test was used to analyze the differences between 6 weeks, 3 months and 6 months and 1, 2, 3 and 7 years VAS, Oswestry disability questionnaire and SF-36 scores. All statistical tests were performed at a 5 % significance level. Statistical analyses were performed using SPSS (version 21.0; SPSS, Inc. Chicago, IL).

Results

All ten patients returned for complete follow-up visits at 6 weeks, 3 months and 6 months. There was one case of a device-related failure which occurred 3 months after surgery. This patient underwent fusion surgery 6 months after the index procedure so that 9 patients were seen at 1, 2, 3 and 7 years follow-up. The VAS score for back pain dropped from 56.2 preoperatively to 12.5 at 6 weeks ($p < 0.05$) to 13.7 at 1-year follow-up, and 3.6 at 2 years follow-up and 19 at 7 years follow-up. The VAS score for worse leg pain dropped from 83.5 before surgery to 13 at 6 weeks ($p < 0.05$), 9.2 at 1 year, 3.6 at 2 years and 8.8 at 7 years follow-up. The ODI dropped from 49.1 preoperatively to 13.5 at 6 weeks ($p < 0.05$) and 8.6 at 1-year follow-up, 3.3 at 2 years follow-up and 7.8 at 7 years follow-up. The SF-36 score increased from 43.2 preoperatively to 69.9 at 6 weeks after surgery ($p < 0.05$), to 80.2 at 1-year follow-up, 82.8 at 2 years follow-up. At 7 years follow-up, it was 74.8 (Fig. 3). All outcome measures demonstrated a statistically significant difference between pre- and postoperative scores ($p < 0.05$). There was not any statistically significant difference, between immediate postoperative outcome measures scores, and 3 and 6 months and 1, 2, 3 and 7 years outcome measures scores ($p > 0.05$).

Independent analysis of postoperative radiographic images did not reveal any evidence of spontaneous fusion or of screw loosening or breakage at 7 years follow-up. Flexion/extension and lateral bending views showed the TOPS implant to be mobile (Fig. 4). The average flexion–extension range of motion decreased from 6.1° before surgery to 3.6 at 3 months follow-up and 5 at 1 year follow-up (Fig. 5). It dropped back to 4.8 at 7 years follow-up (Table 1). Clinically, all nine patients exhibited well-preserved lumbar motion. The flexion–extension radiographs did not demonstrate progression of the spondylolisthesis.

MRIs of the lumbar spine were obtained for all patients at 2 and 7 years post-surgery. The results were compared to the preoperative MRI images. There were no cases of stenosis or spondylolisthesis adjacent to the stabilized segment at the 7 years follow-up (Figs. 6, 7). In 4 patients, fluid was demonstrated in the adjacent segment facet joints (44 %). Progressive disc degeneration at either the second, third or fourth level above the index level was observed in three patients (33 %).

As mentioned there was one case of an early device-related failure. Routine postoperative X-rays 6 weeks after surgery demonstrated a locked device. The screws were found to be solidly anchored to the spine. The internal PcU component was damaged leading to internal locking of the device, thus preventing motion. The TOPS implant was revised to a fusion by rotating the screws 90° and replacing the motion implant with fusion rods. The fusion procedure was smooth and without complications. At the most recent clinic visit, the VAS back pain score was 40 and VAS leg pain score was 0. A minor design change in the prosthesis

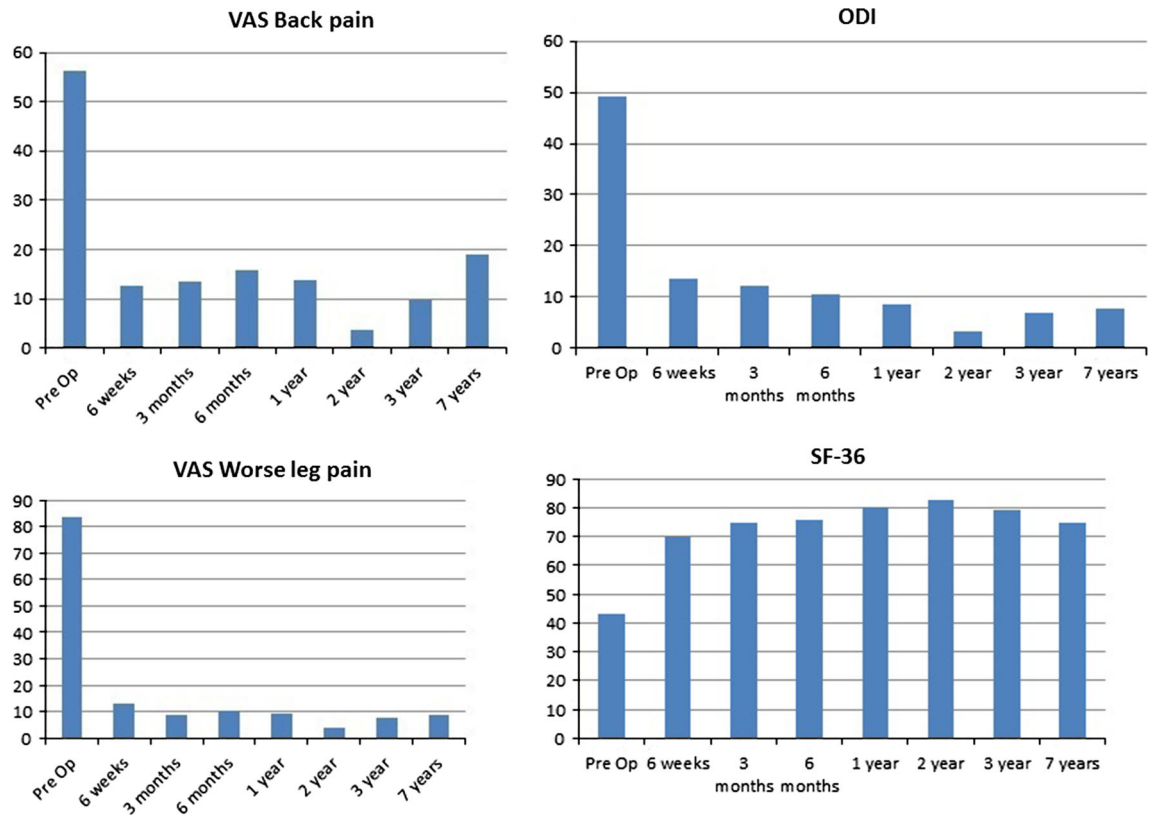

Fig. 3 Visual analog scale (VAS) for back and worse leg pain, Oswestry disability index (ODI) and SF-36 for up to 7 years follow-up

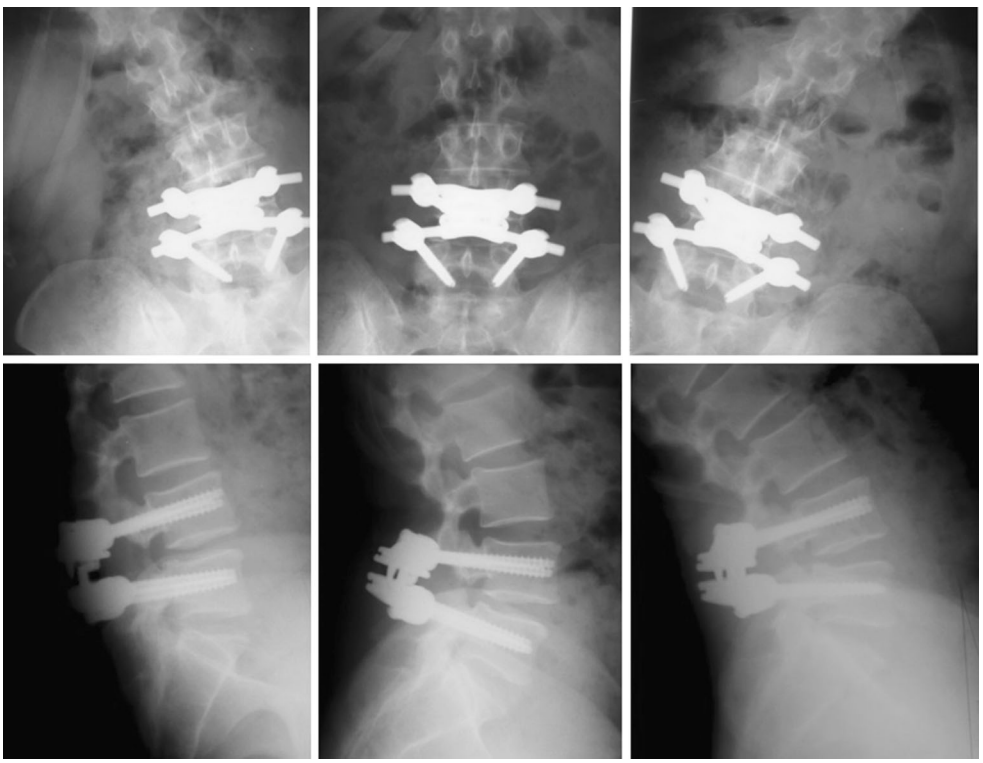

Fig. 4 Lateral bending and flexion/extension X-rays 3 months after the index procedure

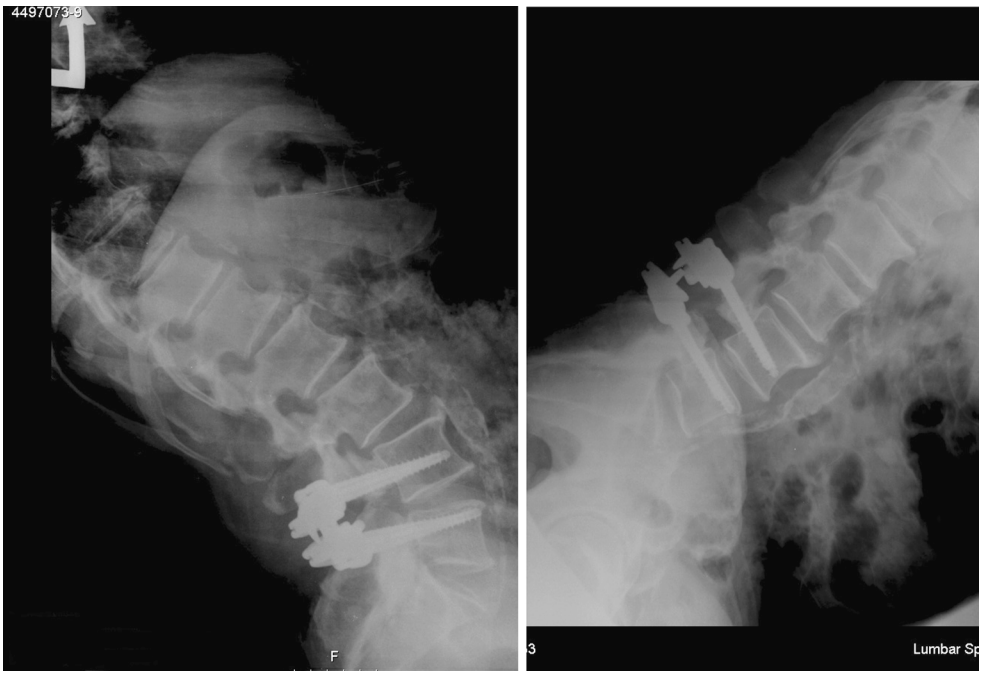

Fig. 5 Flexion and extension lateral X-rays after 7 years follow-up

Table 1 Flexion extension range of motion (in degrees) at the L4–L5 segment

Patient no.	Pre-operation	3 months	1 year	7 years
1	10.5	1.7	6.5	5.0
2	12.4	5.3	8.7	8.8
3	2.6	7.1	6.8	4
4	2.0	2.3	2.4	2.4
5	3.6	4.3	5	2.9
6	9.8	0.1	1.4	3.1
7	6.1	6.4	3.8	5.1
8	2.8	2.3	2.2	1.4
9	5.2	2.8	9	10.4
Average	6.1	3.58	5.08	4.78

provided a solution to this rare complication. Further biomechanical tests confirmed the effectiveness of the mechanical alteration. Another patient developed an L3–L4 disc herniation 5 years after the index procedure, which resolved with physical therapy and a non-steroidal anti-inflammatory drug.

Discussion

The TOPS System is designed to replace the posterior elements of a functional spinal unit following decompression surgery, and to provide mobile re-stabilization of the motion segment. The TOPS System is comprised of a unitary mechanical device affixed to the spine with four pedicle screws. It allows axial rotation, lateral bending, extension, and flexion while blocking excessive sagittal translation. The System was developed as an alternative to fusion surgery for patients with moderate to severe spinal stenosis and degenerative spondylolisthesis. The device enables a complete posterior surgical decompression similar to the posterior decompression achieved with bilateral transforaminal lumbar interbody fusion (TLIF). The decompression performed with the TOPS is not equivalent to bilateral TLIF, because TLIF also involves discectomy. On the other hand, when using the TOPS there is no need to retract the nerve roots or breach the anterior disc space. The device re-establishes stability and preserves near normal physiological range of motion and biomechanical properties. After the implantation of the TOPS System, no activity restrictions are needed as the patients may sit, bend and lift as tolerated.

Contrary to fusion surgery, in which the healed bone bears the majority of the dynamic load, pedicle screws in other dynamic stabilization and or posterior arthroplasty systems must withstand loads and peak moments indefinitely. This cyclic loading has been shown to produce screw loosening [24]. The unique TOPS design mitigates peak moments by sharing loads across all four pedicle screws to minimize the risk of loosening at the bone-screw interface [20]. The double horizontal cross bar configuration connects pedicle screws of the same vertebra to create

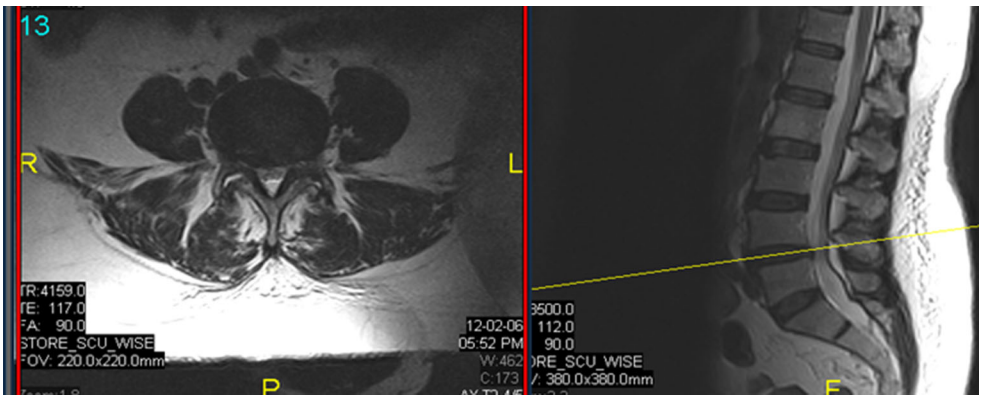

Fig. 6 Sagittal and axial T2 images before surgery

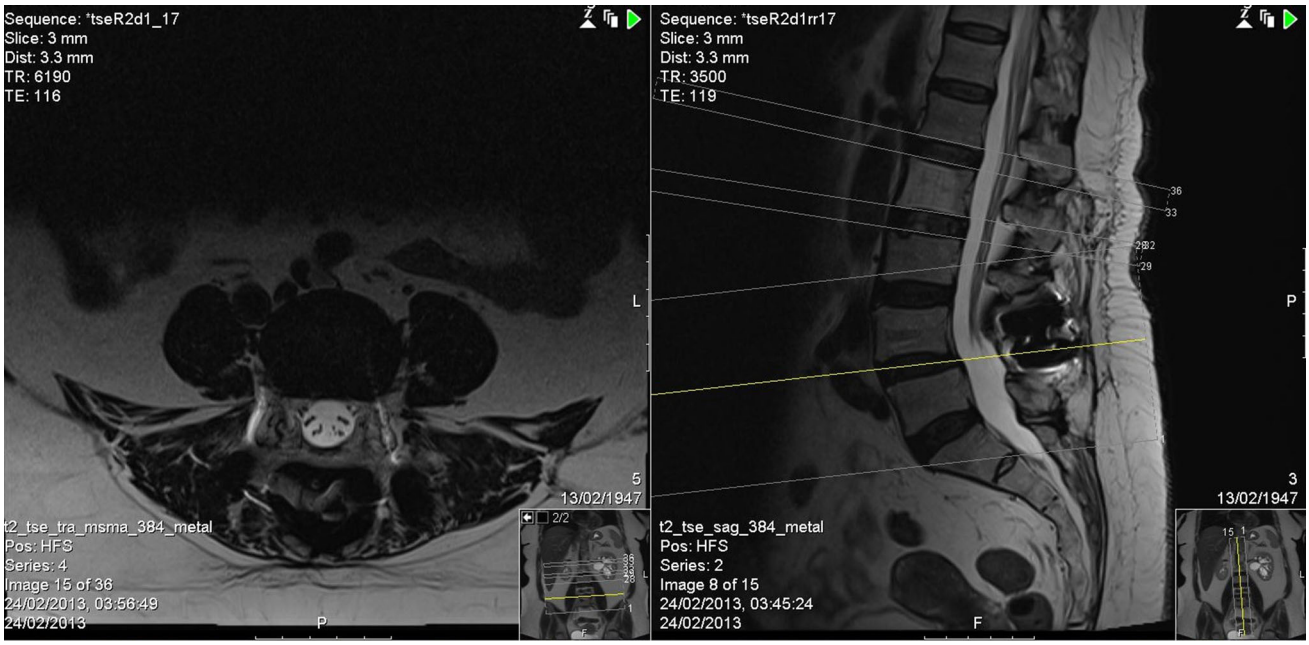

Fig. 7 Sagittal and axial T2 images at 7 years follow-up

better load sharing characteristics and eliminate screw head torque, contrary to the traditional vertical rod design of fusion and dynamic stabilization systems that connects two pedicle screws of adjacent vertebrae. This configuration reduces the risk of screw loosening [20]. To improve the bony integration of the pedicle screws, the screws are blasted with calcium phosphate particles that are removed by a chemical process, leaving a roughened surface similar to cementless hip prostheses or dental implants.

Wright [28] as well as Meyers et al. [20] conducted in vitro dynamic cadaveric comparative testing with the TOPS System and the Dynesys System (Zimmer Corporation, USA). Compressive loads were applied and peak moments were measured on each pedicle screw. The main purpose of the experiment was to determine if the TOPS design lends itself to better load sharing among all four pedicle screws. The results demonstrated that the peak moments on the screws were significantly lower and more evenly distributed with the TOPS System when compared to the Dynesys device. The moment on the screw heads was thus reduced by 36 and 46 % in flexion–extension and lateral bending, respectively. No screw loosening or breakage was observed during the 7-year follow-up. This confirms that a mobile system which is designed to distribute loads evenly and maintain low stresses on the pedicle screws can prevent implant failure.

Our clinical results are highly encouraging. All patients had significant improvement in their leg and back visual analog scores as well as in their SF-36 and Oswestry Disability Index scores (Fig. 3). These good clinical results did not deteriorate in the 7-year follow-up. Our data match favorably with the results of decompression and

instrumented fusion published in the literature [25]. However, decompression and fusion surgery results may deteriorate with time due to adjacent level disease and factors that can reduce fusion rates, such as smoking or intake of non-steroidal anti-inflammatory drugs [1, 7]. Kornblum et al. showed that at 5–14 years postop the clinical outcomes were good or excellent in 86 % of patients with successful fusions while non-union patients had good or excellent outcomes in only 56 % of cases. The difference was statistically significant [16]. Fusion creates rigid sections in the lumbar spine that lead to increased stress on the motion segments adjacent to an arthrodesis. This additional stress causes premature degeneration of these adjacent segments, as demonstrated by in vivo and in vitro studies [22]. Harrop et al. emphasized the difference between radiographic adjacent segment degeneration and symptomatic adjacent segment degeneration after lumbar spinal fusion. The lack of distinction between these two conditions may explain the large range in the reported prevalence rates of adjacent segment degeneration, between 0 and 36 % [9]. Some authors have mentioned that a dynamic stabilization system preserves motion at the stabilized level and prevents degeneration of the adjacent segment [24, 26]. At 7 years follow-up, we did not find any cases of stenosis or spondylolisthesis adjacent to the stabilized segment. The overall annual incidence and predicted 10-year prevalence of further surgery for adjacent segment degeneration after lumbar arthrodesis were 2.5 and 22.2 %, respectively [23]. The rate of degeneration at adjacent motion segments in this study was lower than the rate of degeneration at adjacent motion segments seen after fusion surgery [9, 21, 23]. However, since this study did not have a control group and since the current study group is small, no conclusions can be drawn regarding the rate of degeneration at adjacent motion segments with posterior arthroplasty compared to fusion surgery. The rate of degeneration at the levels above the adjacent levels to the TOPS System in this study is similar to the rates reported in other studies [8, 23]. Thus, our data suggest that posterior arthroplasty may reduce the rate of adjacent segment degeneration, although it will not stop the aging of the spine.

While examining degeneration at the stabilized segment with MRI, the artifacts that are created by the implant were evaluated as well. Although the TOPS implant is relatively large, the MRI artifacts that were generated by the titanium components did not interfere with the assessment of the operated level or adjacent levels (Fig. 7). No annular tear, Modic-type changes, progression of olisthesis or any other sign of degeneration at the stabilized segment were observed.

Limitations of this study include the small number of patients and the fact that it is not a comparative study.

Conclusion

The results of this long-term study are encouraging. In patients with spinal stenosis and degenerative spondylolisthesis, decompression and posterior arthroplasty with the TOPS System can maintain clinical improvement and radiologic stability over time. The TOPS System preserves motion at the instrumented level and may prevent degeneration at adjacent motion segments.

Conflict of interest None.

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