

Technical Review

Use of instrumented pedicle screws to evaluate load sharing in posterior dynamic stabilization systems

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Abstract

BACKGROUND CONTEXT: Dynamic stabilization is an alternative to fusion intended to eliminate or at least minimize the potential for adjacent level degeneration. Different design approaches are used in pedicle screw-based systems that should have very different effects on the loading of the posterior column and intervertebral disc. If the implant system distributes these loads more evenly, loads in the pedicle screws will be reduced, and screw loosening will be prevented.

PURPOSE: The purpose of this study was to determine how two different design approaches to dynamic stabilization systems, Dynesys System and the Total Posterior Spine (TOPS) System, affect the load carried by the pedicle screws.

STUDY DESIGN/SETTING: A controlled laboratory study in which the magnitude of the moments on pedicle screws during flexion–extension and lateral bending were measured after implantation of two posterior dynamic stabilization devices into cadaveric spines.

METHODS: Five lumbar spines were tested in flexion–extension and lateral bending. Specimens were tested sequentially: first intact, then with the Dynesys system implanted, and finally with the TOPS system implanted. Range of motion (ROM) for each construct was measured with a 210 N and 630 N compressive load. The pedicle screws were instrumented with strain gages, which were calibrated so that the moments on the screws could be determined from the strain measurements.

RESULTS: Compared with intact values, ROM decreased in flexion–extension and lateral bending when the Dynesys System was implanted. With implantation of the TOPS System, ROM returned to values that were not significantly different from the intact values. The moments in the screws with the Dynesys System were significantly higher than with the TOPS System with increases of as much as 56% in flexion–extension and 86% in lateral bending.

CONCLUSIONS: The design of the posterior stabilization device influences the amount of load seen by the pedicle screws and therefore the load sharing between spinal implant and bone. © 2008 Elsevier Inc. All rights reserved.

Keywords: Pedicle screw; Lumbar; Posterior stabilization

FDA device/drug status: investigational/not approved (Dynesys[®] and TOPS[™] System).

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Introduction

Lumbar spinal fusion is a commonly performed surgical procedure for the treatment of spinal disorders, including degenerative conditions that could lead to instability or misalignment of the spine. The principle of fusion is to stabilize the affected segment(s) by eliminating motion at the joint. However, fusion has the potential to accelerate adjacent level degeneration [1–3]. Dynamic stabilization is an alternative to fusion intended to eliminate or at least minimize adjacent level degeneration by restoring stability

while maintaining restricted motion at the affected segment [4]. Although the focus of surgical treatment has been on restricting motion, many investigators now believe that abnormal loading also affects disc quality [5,6]. A variety of implants are currently in development and on the market that focus on restricting motion of the spine, but little is known about how these implants affect the loads seen by the spine.

Dynamic stabilization devices can be divided into two groups based on their intended constraint and the way in which they are attached to the spine: interspinous mechanisms and pedicle screw-based systems. Examples of interspinous systems are the X Stop (St. Francis Medical Technologies, Concord, CA), Diam (Sofamor Danek, Memphis, TN), and the Wallis (Spine Next, Bordeaux, France). Pedicle screw-based systems include the Graf Ligament (Neoligaments, Leeds, United Kingdom), Dynesys System (Zimmer Spine, Warsaw, IN), Fulcrum-assisted Soft Stabilization (AO International, Davos, Switzerland), and the Total Posterior Spine System (TOPS System, Implant, Ramat Poleg, Israel). Pedicle screw-based systems provide pain relief despite allowing movement [4]. Unlike in the case of a fusion, in which the healed bone withstands the majority of the dynamic load, pedicle screws in a dynamic stabilization system must withstand cyclic loading indefinitely, which is more likely to produce screw loosening [7].

Pedicle screw-based systems use different design approaches, depending on the intended function. For example, the Dynesys System, first described by Stoll et al. [7], tethers the pedicle screws to each other with polyester (Sulene-PET) cords that run through polycarbonate urethane (Sulene-PcU) tubes before attaching to the pedicle screws (Fig. 1). The cords are pulled intraoperatively with a 300 N force to secure the screw heads to the tube spacers and provide restraint in flexion. The tube spacers prevent excessive compression and bear compressive loads in extension [6]. The cylindrical tube is rigid, shifting the axis of rotation posteriorly causing disc compression in flexion; in extension, the anterior annulus experiences tension without compression of the posterior annulus [4]. Unfortunately,

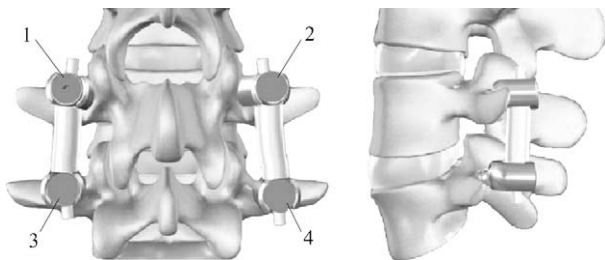


Fig. 1. The Dynesys System tethers the pedicle screws to each other while still allowing motion. Polyester cords run through polycarbonate urethane tubes before attaching to the pedicle screws. The cord is pulled intraoperatively with a 300 N force to secure the screw heads to the tube spacers. The cords provide restraint in flexion. The tube spacers prevent excessive compression and bear compressive loads.

compressive loads on the spacers can produce bending moments in the screws. Stoll et al. reported that 10% (7 out of 73) of patients experienced screw loosening as evaluated radiographically. Despite this complication, the clinical results were comparable with fusion. The Dynesys System has FDA approval for clinical use.

A different design approach is used in the TOPS System (Fig. 2), which consists of two titanium alloy plates with an intervening capsule. Within the capsule is an articulating construct made of titanium alloy and PcU that is intended to mimic the function of the posterior elements. The relative movement of the titanium plates allows axial rotation, lateral bending, and flexion–extension. The goal is to restrict motion of the spinal unit to within a normal range while blocking excessive posterior and anterior sagittal translation. The cross bar configuration used to connect the plates and capsule to the pedicle screws was designed to minimize screw loosening by better distributing the load in the bone-implant construct. This system is in clinical trials in the United States.

Though biomechanical testing has been performed on individual designs of dynamic stabilization systems, direct comparisons are difficult because of differences in testing protocols and test machines. Furthermore, performance has usually been based solely on the restriction in motion provided by the device compared with that with a fusion, without accounting for other performance measures. All these devices alter the motion of the spinal unit, but because of design differences, they should affect loading of the posterior column and intervertebral disc differently, which could result in differences in clinical performance.

Load sharing between the pedicle screw and the surrounding bone is difficult to determine. Instrumenting pedicle screws with strain gages has been used as a method for establishing their mechanical behavior. Ashman et al. [8,9] used this approach to establish the fatigue strength of pedicle screws based on stress calculations made from the measured strains at the base of the screw threads. Other studies have looked at the role of pedicle screws in load sharing in fusion systems [10,11]. These studies show that the construct design is important to the load sharing capabilities

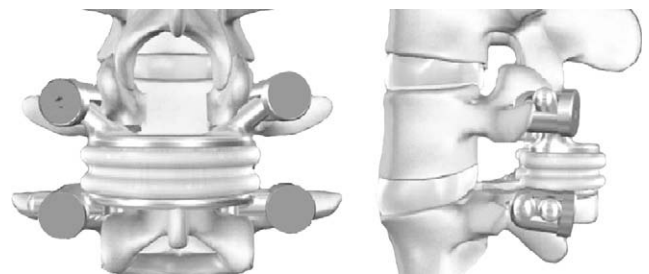


Fig. 2. The TOPS System consists of two titanium plates and an outer polycarbonate urethane capsule. Within the capsule is an articulating construct made of titanium and PcU that is intended to mimic the function of the posterior elements. The relative movement of the titanium plates allows axial rotation, lateral bending, and flexion–extension.

and stress levels seen at the pedicle screw. But the focus of these studies was on the design and mechanical properties of pedicle screws when used with fusion systems.

In a fusion system, the screw must withstand moments only until fusion occurs, whereas in a dynamic stabilization system, the screw is intended to withstand the moments indefinitely. Thus, load sharing and stresses in the pedicle screws take on added importance. If the proper screw diameter is used and the system is designed to distribute these loads uniformly while maintaining screw stresses at a low level, screw loosening should be prevented. The manner in which load sharing will occur will depend on surgical technique, but also on the design of the dynamic stabilization system, namely the constraints it is intended to provide versus the motions it allows. The purpose of this study was to compare load sharing in two different designs of dynamic stabilization systems, the Dynesys System and TOPS System, to determine how design affects load carried by the pedicle screws.

Methods

Five L3–sacrum fresh frozen cadaver spines were thawed and stripped of all soft tissue except for ligamentous structures. The age range of the donors was 49 to 79 years. Dual energy X-ray absorptiometry (DEXA) analysis and radiographic evaluations were performed on the specimens to ensure that they were free of any structural deficiencies. The DEXA scans provided bone mineral density levels to determine whether any of the specimens were osteoporotic. Because the soft tissue had already been removed, the specimens were placed in a saline-filled Plexiglas box during the DEXA scans to simulate soft tissue.

The superior end plate of L3 and the distal end of the sacrum were plotted in two grips in a custom six degree of freedom spine testing apparatus [12]. This apparatus (Fig. 3) was connected to a servohydraulic load frame

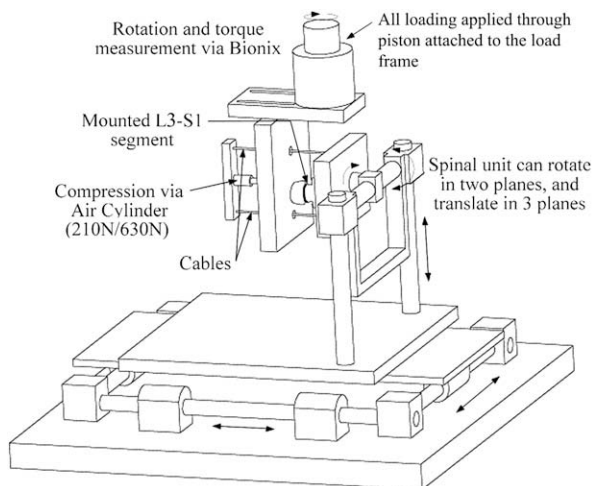


Fig. 3. Custom six degree of freedom spine testing apparatus.

(MTS, Eden Prairie, MN). During testing, the apparatus allowed freedom of translation in three planes and rotation about two axes, whereas the rotational third axis was controlled by the frame's actuator to provide flexion–extension or lateral bending.

Each intact specimen was tested for five cycles at 0.03 Hz in torque control to ± 10 Nm in flexion–extension and lateral bending. During the tests, additional compressive axial loads of 210 N and 630 N were applied (in random order) using air pressure to pull the two grips toward each other. Range of motion (ROM) and torque were recorded from the load frame controller at 15 Hz.

Four pedicle screws were then inserted into L4 and L5 (Fig. 1). The inferior screws (screws 3 and 4 in L5) were instrumented with four strain gages. The gages 180° from each other were wired in half-bridge configurations (Fig. 4). The half-bridge configuration eliminated errors from axial strain and provided temperature compensation. The screws must be inserted to an optimal depth and the screw-heads were kept in place in the same plane to attach the TOPS System. The exact positioning of the gages with respect to anatomic reference planes can not be predetermined because the insertion depth of the screws must be very accurate. All four screw-heads must also be in the same plane to accommodate the four arms of the TOPS device. When each screw was in place, it was statically loaded and the signal from both opposing pairs were measured. Data were collected from the pair with the higher reading. Testing was repeated with the Dynesys System attached to the pedicle screws via special adaptors. The PcU spacers lengths were determined by measuring 2 to 3 mm of distraction over the neutral position [13]. The head of the Dynesys System pedicle screw is different than the pedicle screw used for the TOPS System implant. Special adaptors were made that recreated the interface between the Dynesys PcU tube, PET cord, and Ti head of the screw. The adaptor had the same vertical hole and same set screw used in the Dynesys System, together with the same size contact plan for the interface with the PcU spacer. Thus, the adaptor



Fig. 4. Four strain gages were attached to the pedicle screws. Data were collected from the pair (180° from each other) with the higher reading after a static load was applied.

accurately mimicked the original Dynesys screw. This adaptor was attached to the standard screw-head when the Dynesys System was tested, then removed (leaving the standard pedicle screw head) for the TOPS System. The orientation of the screw head differs for the Dynesys System from that of the TOPS System. This difference was minimized because the screws used had polyaxial heads, so only the position of the heads had to be changed from one test to the other to accommodate the different shape of the implants. This approach allowed the same screws with the same location/fixation on the same cadaver to be used for both test articles.

Once testing was finished, the Dynesys System was removed, a total laminectomy and total facetectomy were performed, and the TOPS System was attached to the same pedicle screws. The cyclic testing was repeated once more with rotation and torque measurements were again recorded from the biaxial load frame. Strains were recorded continuously throughout the tests. The magnitude of the moment was defined as the difference between the minimum and maximum moments on the screws (Fig. 5). In situ calibration of the strain gages was then performed. The specimens were positioned upright so that the L3 vertebrae were superior to the sacrum, and a series of known weights (2.2, 8.9, 13.3, 17.8, 22.2, and 26.7 N) were attached at a measured distances (0.1 and 0.2 m) from the strain gages posterior to the spine to create a known moment. Strain was calculated using the equation $\epsilon = Mc/EI$ where ϵ is strain, M is the known moment, c is the distance to the neutral surface, E is the elastic modulus, and I is the moment of inertia. These strain measurements were then correlated with the output voltages from the strain gages. This calibration method ensured that the screw position and strain gage orientation was preserved.

Load versus angular displacement data from the test apparatus were plotted to determine the ROM for the fifth cycle of testing for each configuration (intact, Dynesys System, and TOPS System) at both compressive loads (210 and 630 N) in both flexion–extension and lateral bending (Fig. 6). Data were analyzed between ± 8 Nm.

Two-way repeated measures analysis of variance was used to compare the ROM found in each testing configuration at both compressive loads in both flexion–extension and lateral bending. Two-way repeated measures analysis of variance was also used to determine the significance of differences between the moment magnitudes from screws 3 and 4 (Fig. 1) in flexion–extension and lateral bending at 210 N and 630 N. Spearman rank order correlation was used to determine if a significant correlation existed between the specimens' T-scores determined from the DEXA scans and the moment in the screw when specimens were evaluated between ± 8 Nm. Only screw 3 was evaluated, because both screws were in the same vertebral body (with the same T-score). Significance was set at alpha less than .05 for all statistical analyses.

Results

ROM decreased 2° to 5° in flexion–extension and lateral bending in the Dynesys System construct when compared with the intact spine (Fig. 7). With the TOPS System, ROM was restored to within a degree of the intact value in flexion–extension, but increased 2° to 4° in lateral bending. The larger decreases with the Dynesys System occurred with the higher axial compressive load (630 N vs. 210 N); with the TOPS System, the increases that occurred in lateral bending were smaller at the higher axial compressive load. The effect of axial compressive load

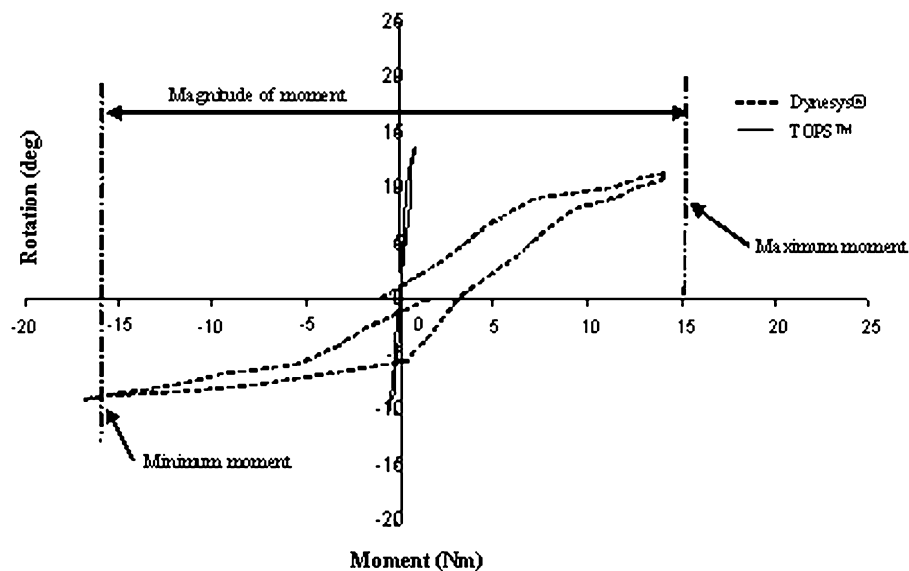


Fig. 5. Representative graph of moment measured in screw 3 plotted against rotation during flexion–extension with a 210 N compressive load. The magnitude of the moment was determined by subtracting the minimum moment from the maximum moment as illustrated.

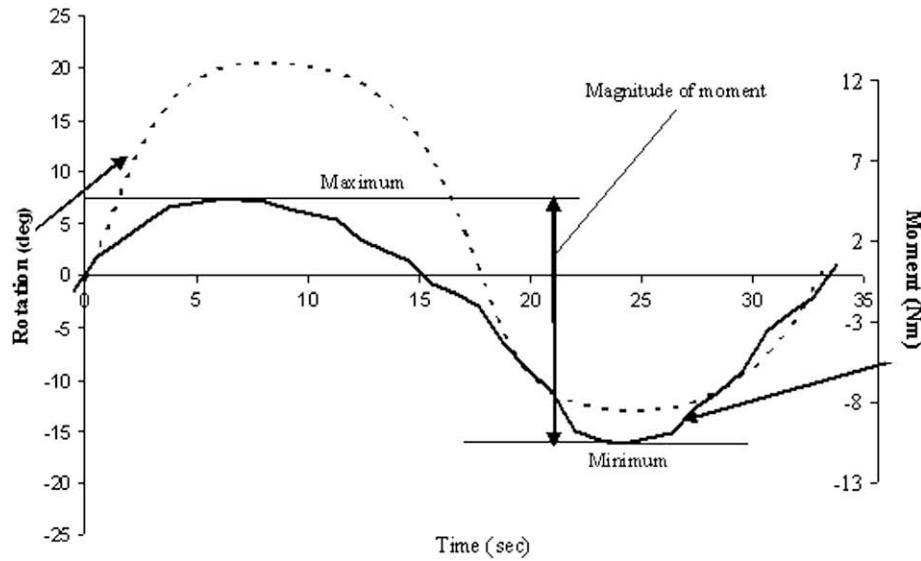


Fig. 6. Representative graph of the moment measured in screw 3 and the range of motion of the spine plotted against time when cycling in flexion–extension. The magnitude of the moment was defined as the maximum moment minus the minimum moment (as shown on the plot).

on ROM did not reach significance, however, in flexion–extension of the Dynesys System ($p=.09$) or in lateral bending of the TOPS System ($p=.08$).

For flexion–extension testing, the Dynesys System had significantly less ROM compared with the intact spine ($p=.04$) and to the spine with the TOPS System ($p=.03$). The ROM with the TOPS System was not significantly different from the intact spine ($p=.90$). Neither the Dynesys System ($p=.06$) nor the TOPS System ($p=.08$) significantly affected the ROM in lateral bending when compared with the intact spine, though the Dynesys System had a significantly smaller ROM than the TOPS System during lateral bending ($p=.02$). No significant difference in overall stiffness was found among groups for flexion–extension ($p=.60$) regardless of compressive load ($p=.33$) or for lateral bending ($p=.57$) regardless of load ($p=.93$).

The moments measured in the screws with the Dynesys System were significantly higher than the TOPS System (Tables 1 and 2). The increases were as much as 56% in

flexion–extension and 86% in lateral bending. One test did not show a difference in moments between the two systems, namely screw 4 in flexion–extension, but even that difference approached significance ($p=.06$). Compressive load did not significantly affect the moment in flexion–extension (screw 3: $p=.14$; screw 4: $p=.23$) or in lateral bending (screw 3: $p=.21$; screw 4: $p=.06$), regardless of implant. Though no statistical difference in ROM because of load was found, there was a trend toward smaller ROM with higher axial compressive loads in all test conditions.

The T-scores for the five specimens were 0.9, -2.7 , -3.3 , -3.3 , and -4.4 . No significant correlation was found between T-score and the moment in the screw, regardless of implant design or compressive axial load (flexion–extension—TOPS System: 210 N $p=.35$, 630 N $p=.45$, Dynesys System: 210 N $p=.78$, 630 N $p=.95$; lateral bending—TOPS System: 210 N $p=.08$, 630 N $p=.23$, Dynesys System: 210 N $p=.35$, 630 N $p=.35$).

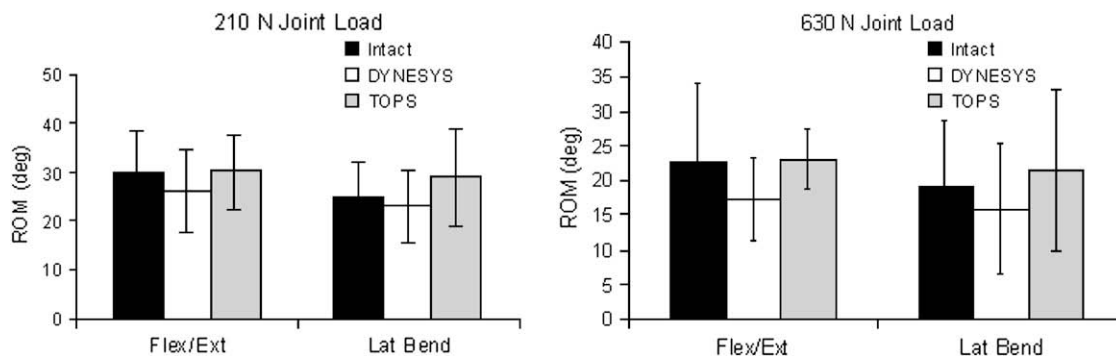


Fig. 7. Range of motion for each group at the two compressive joint loads.

Table 1

The moment (Nm) placed on the screws when cycling between ± 8 Nm of flexion–extension at two compressive axial loads (210 N and 630 N)

Specimen	TOPS				Dynesys			
	210 N		630 N		210 N		630 N	
	Screw		Screw		Screw		Screw	
	3	4	3	4	3	4	3	4
1	1.35	1.25	1.61	1.60	2.62	2.07	3.07	2.35
2	1.52	2.03	1.50	2.10	3.37	2.51	2.66	2.63
3	4.07	N/A	3.97	N/A	5.42	N/A	4.70	N/A
4	1.00	3.81	1.00	2.88	2.40	4.30	2.06	3.92
5	1.86	0.74	1.87	0.23	2.20	2.18	2.16	2.84

Discussion

The goal of a dynamic stabilization system is to allow restricted motion of the spinal unit while maintaining stability. Pedicle screw-based designs like the two devices tested in this study strive to reach this goal, but use different mechanisms to control the amount and direction of allowable motion. The constraint provided by these devices, however, transfers loads to the spine through the pedicle screws used for fixation. A key clinical requirement for these systems is that they remain well-fixed to the pedicles, a requirement that could be jeopardized in the face of high loads. Our underlying assumption was that better load sharing as reflected in reduced load in the pedicle screws will minimize the risk of loosening at the bone-screw interface.

The moments on the pedicle screws with the Dynesys System were significantly larger than with the TOPS System both in flexion–extension and lateral bending. These increased screw loads were accompanied by a decreased ROM, suggesting that the Dynesys System was a stiffer construct than the TOPS System in both planes of motion, and thus shared more of the load with the spine. Other researchers measured decreases of 3° to 6° in flexion–extension and 5° to 6° in lateral bending with the Dynesys System as compared with the motions of the intact spine [14–16]. These values compare favorably with our measurements, which ranged from 2° to 5° .

Table 2

The moment (Nm) placed on the screws when cycling between ± 8 Nm of right and left lateral bending at two compressive axial loads (210 N and 630 N)

Specimen	TOPS				Dynesys			
	210 N		630 N		210 N		630 N	
	Screw		Screw		Screw		Screw	
	3	4	3	4	3	4	3	4
1	0.27	0.23	0.30	0.21	2.09	2.33	1.91	2.41
2	0.47	0.90	0.49	0.98	2.18	3.94	2.57	4.34
3	0.37	0.45	0.72	0.64	0.91	1.54	1.29	2.10
4	0.83	0.74	0.75	0.39	2.21	2.35	2.68	2.32
5	1.22	N/A	0.55	N/A	2.77	N/A	4.48	N/A

The ROM decreased when increased axial compressive load was superimposed and then moments applied in flexion–extension and lateral bending, though the differences did not reach statistical significance. Patwardhan et al. [17] showed similar decreases (a 3° decrease when going from no compressive load to a 400 N compressive load and 5° when going from a 400 N compressive load to an 800 N load) in testing of 21 cadaver spines. Other researchers also found that flexion–extension ROM for a spinal unit decreases as axial compressive load increases [18,19].

We did not find a significant correlation between T-scores and the magnitude of the moment in the pedicle screw. Failure at the screw-bone interface would be expected to occur more rapidly in osteoporotic bone. This potential relationship was not a primary goal of our study. We would need many more specimens and would need to conduct high-cycle fatigue tests to examine the validity of such a relation. Nonetheless, we felt it was important to measure bone density in our specimens as a potential confounding variable.

Our study had limitations. One is the small number of specimens. We had adequate power to demonstrate significant differences between our primary variable, implant design, but some of the other relations we examined approached, but failed to reach significance. The number of levels used for each specimen is also limited. Specimens extending from L3 to S1 were plotted, but only L4–L5 was instrumented. This was necessary to allow room for the hardware being tested, but of course the extra levels meant that larger ROMs were recorded than probably would have occurred if only a single spinal unit had been tested. Because a direct comparison was made with both implants in the same specimen, however, this should not have affected our conclusions. Another limitation is the nonrandomized order of testing. We performed the comparison between designs within the same spine, necessitating that the TOPS System be tested last because implantation required removal of bone. A limitation in our testing modes is that specimens were not tested in axial rotation. This was because of experimental limitations in our measuring equipment. Finally, we measured the moments in the screws in only one plane. The total resultant moment acting on the screw may be larger. Placing strain gages on more than one plane of the screw would be arduous; we felt it most important to measure the moment in the primary plane of motion as determined by Rohlmann et al. [20]. The clinical relevance of our moment measurements in the pedicle screws is unknown, because we do not know what level of screw load is necessary for loosening. Ten percent of patients treated with a Dynesys System suffered screw loosening in a study by Stoll et al. [7], but whether the lower loads found with the TOPS System will relate to a lower incidence of loosening must await clinical experience with this system.

In conclusion, our results showed a marked interaction between the type and amount of constraint provided by

the device and subsequent load sharing with the spine. Using instrumented screws can provide valuable preclinical data for correlation with subsequent clinical findings.

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