Dynamic Stabilization of the Lumbar Spine and Its Effects on Adjacent Segments

An In Vitro Experiment

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Summary: In recent years, nonfusion stabilization of the lumbar spine has gained more and more popularity. These nonfusion systems intend to maintain or restore the intersegmental motions to magnitudes of the intact spine and have no negative effects on the segments adjacent to the stabilized one. This study investigated the DYNEYS, a dynamic nonfusion system, which is designed to stabilize the bridged segments while maintaining the disc and the facet joints. To determine the magnitude of stabilization and the effect of the stabilization on the adjacent segment, six lumbar cadaver spines were fixed in a spine tester and loaded with pure moments in the three main motion planes. For each spine, four different stages were tested: intact, defect of the middle segment, fixation with the DYNEYS, and fixation with the internal fixator. Intersegmental motions were measured at all levels. For the bridged segment, the DYNEYS stabilized the spine and was more flexible than the internal fixator. This difference between the internal fixator and the DYNEYS was most pronounced in extension (P < 0.05), with the DYNEYS restoring the motion back to the level of the intact spine. The motion in the adjacent segments was not influenced by either stabilization method. Our results suggest that the DYNEYS provides substantial stability in case of degenerative spinal pathologies and can therefore be considered as an alternative method to fusion surgery in these indications while the motion segment is preserved. Key Words: lumbar spine, surgical treatment, biomechanics, mobility of adjacent segments

INTRODUCTION

The internal fixator is still the golden standard in the stabilization of the lumbar spine. However, in recent years, ideas of dynamic neutralization of the lumbar spine have become more and more popular. These ideas of nonfusion systems range from replacing the disc with complete excision of the disc, replacing the disc while maintaining the annulus, to maintaining the disc with a controlled motion of the segment. Internal fixators are generally used as an adjunct to fusion, where in many instances the disc is replaced by either intervertebral cages, allograft, or autologous bone graft. From the clinical point of view, the sacrifice of a moderately degenerated disc and—in case of the use of autologous bone graft—donor site morbidity may not be desirable. Only few surgeons use the internal fixator but try to preserve the disc. One of the complications that may arise with the implantation of an internal fixator without achieving fusion of the bridged segment is the possible fatigue failure of the implant system.

The DYNEYS Spinal System (Centerpulse Orthopedics Ltd., Winterthur, Switzerland) is indicated to provide spinal alignment and dynamic restabilization in skeletally mature patients up to five contiguous levels from L1 to S1.
while preserving the disc as well as the facet joints (dynamic neutralization). The selection criteria for the procedure include patients with neurogenic, radicular pain, and/or chronic low back pain resistant to conservative treatment, presenting with some form of instability, where stabilization was judged beneficial.5

The system is composed of pedicle screws, polyethylene-terephthalate (PET) cords, and polycarbonate-urethane (PCU) spacers (Fig. 1). The spacers are placed bilaterally between the pedicle screw heads to withstand compressive loads. The cords are run through the hollow core of the spacers and stabilize the construct by a tensile preload.

Fixation or stabilization usually limits the intersegmental motion in the bridged segment. In vitro experiments performed with displacement controlled loading of the specimens showed increased motion in the adjacent segments.12–14 However, for in vitro testing under load control with pure moments, there is still a controversy in the literature about the effects of stabilization on the adjacent segments. Bastian et al15 showed a significant increase of motion in segments adjacent to the fusion, whereas, applying pure moments Rohlmann et al found no statistically significant increase of motion in the adjacent segments in their in vitro experiment16 and finite-element study.17

The aims of this in vitro study were 1) to compare the intersegmental motions of the intact specimen with those of the dynamic stabilization system and the internal fixator and 2) to investigate the effects of both stabilization methods on the adjacent segments.

MATERIALS AND METHODS

Specimen Preparation

Six fresh-frozen lumbar spines (L2–L5) were used for testing. The age of the specimens ranged from 33 to 59 years with a mean age of 43. All soft tissue was dissected, keeping the capsules, ligaments, and supporting structures intact. For the fixation in the spine tester, the L2 and L5 vertebra were embedded in PMMA (Polymethylmethacrylate) cement (Technovit 3040, Heraeus Kulzer, Wehrheim/Ts, Germany) in such manner that the L3–L4 disc was in the horizontal plane. The specimens were frozen in triple sealed plastic bags at −20 °C and thawed at 6 °C before testing.

Testing Protocol

Biomechanical testing of the specimen was performed in a spine tester18 at room temperature (Fig. 2). The caudal vertebra (L5) was fixed rigidly to the loading frame of the spine tester. The cranial vertebra (L2) was mounted to a gimbal, which allowed rotation around all three coordinate axes as well as vertical translation. A traveling gantry and a secondary slide enabled translation in the remaining two planes. The specimens were loaded with pure moments of ±10 Nm in all the three principal motion planes with alternating sequences (flexion-extension, left-right lateral bending, left-right axial rotation). No axial preload was applied to follow the recommendation for the standardized testing of spinal implants.19 The moments were applied continuously with a constant rate of 1.0°/second. The
specimens moved unconstrained in the 5 uncontrolled degrees of freedom. During loading, the motion in each segment was recorded simultaneously by a three-dimensional ultrasound-based motion analysis system (Zebris, WinBioMechanics v.1.2, Isny, Germany).

Four situations were studied (with alternating sequences of 3 and 4):
1. Intact spine.
2. Destabilized spine. A controlled defect was created in the L3–L4 segment (dissection of ligamenta supraspinous, ligamenta interspinous, ligamenta flavum, tenotomy of facet joint capsules and nucletomy).
3. Stabilization of the defect in L3–L4 with the DYNESYS system.
4. Stabilization of the defect in L3–4 with an internal fixator.

All measurements were performed on the same day.

Both fixation systems were manufactured by Centerpulse Orthopedics Ltd. and implanted in the neutral position. The titanium alloy pedicle screws were used for the fixation of both stabilization systems, the internal fixator and the DYNESYS system. The surgical technique for the DYNESYS recommends use of a transpedicular approach (posterolateral) for the placement of the screws. In general, internal fixators are implanted through an intrapedicular approach. Therefore, a special connector was designed to fix the rod in a more medial position than the DYNESYS.

To exclude the influence of the strong temperature dependence of the polymeric spacer of the DYNESYS system, the spacers used in this study were manufactured in a different quality of the material to have the same stiffness as in vivo at body temperature (37 °C), since the testing was performed at room temperature (21 °C).

For all measurements, two precycles were applied to the specimens and the third cycle was used for data analysis. The range of motion (ROM) and neutral zone (NZ) for the bridged and the adjacent segments were determined from the third loading cycle. Wilcoxon matched-pairs signed rank tests were performed to check for significant differences between the four tested conditions. A correction for multiple comparisons (Bonferroni test) was not performed because all $P$ values would have exceeded the level of significance. Therefore, the $P$ values reported in the current study only indicate tendencies.

RESULTS

Bridged Segment (L3–L4)

For all three motion planes (lateral bending, flexion/extension, and axial rotation), the instability model showed an increased ROM ($P < 0.05$) and NZ compared with the intact state (Fig. 3). The DYNESYS and fixator both reduced the ROM and NZ below the magnitude of the intact spine for lateral bending and flexion ($P < 0.05$). In extension the ROM for the DYNESYS was in the range of the intact spine, while the fixator showed a decreased ROM. In axial rotation the fixator stabilized the segment to a ROM below the magnitude of the intact spine, whereas the DYNESYS stabilized the defect but showed an increased ROM ($P < 0.05$) compared with the intact spine.

In flexion the comparison of the DYNESYS with the fixator showed no difference; in extension the fixator was stiffer than the DYNESYS ($P < 0.05$), with the ROM of the DYNESYS being in the range of the intact spine. For lateral bending the DYNESYS was more flexible than the fixator ($P < 0.05$); however, both systems were not in the range of the intact spine. In axial rotation the DYNESYS was more flexible than the fixator ($P < 0.05$), with the DYNESYS allowing a ROM greater than the intact spine.

Adjacent Segments

In general, the ROM and NZ of the adjacent segments were not affected by the instrumentation of the bridged
segment (Figs. 4 and 5). Compared with the intact spine, the defect and both fixation systems showed a slight increase in ROM for flexion and lateral bending. For comparison of the defect with the two fixation methods, no difference in the ROM was found in any of the three motion planes. There was also no difference in the ROM in the adjacent segments for the two fixation methods.

**DISCUSSION**

The current study examined the effects of two different spinal implants with different stiffness properties on the intersegmental motion of the bridged and the adjacent segments. Six lumbar cadaver spines were fixed in a spine tester and loaded with pure moments in three motion planes (flexion-extension, lateral bending, and axial rotation). Four different situations (intact, defect, DYNESYS, and fixator) were studied, and the intersegmental motion was measured.

In all three motion planes, the stabilization with the DYNESYS showed a greater intersegmental motion in the bridged segment than the internal fixator. The difference was most pronounced in extension, with the ROM of the DYNESYS in the range of the intact spine. However, in flexion both fixation systems led to the same segmental stiffness of the specimens. For lateral bending the DYNESYS allowed greater intersegmental motion than the fixator, but the flexibility of both fixation systems was well below those of the intact segment. Since the DYNESYS was implanted more laterally than the internal fixator, in lateral bending it has the larger lever arm and...
therefore a similar stabilizing effect on the segment, although its intrinsic stiffness is lower. In axial rotation the DYNESYS system had a stabilizing effect with respect to the defect, but did not reduce the intersegmental motion compared with the intact level.

Intersegmental motions determined in the current study are in the range of the values reported in the literature. In all three motion planes, ROMs obtained for intact segments are slightly lower, than the values reported in the literature by Panjabi et al²⁰ and Yamamoto et al²¹ for pure moments of 10 Nm, but higher than those reported by Wilke et al²²,²³ for pure moments of 7.5 Nm. Despite the effort of keeping the specimen moist during the time of testing, the small and continuous increase in ROM of the adjacent segments might be due to creep and a slight dehydration of the discs during the long period of testing.

The defect in the current study was chosen as a combination of former studies²³,²⁵ to create a standardized reproducible large defect, which causes a significant increase in the ROM of the unstable segment. The results of the destabilized segments show an increase in the ROM. Therefore, the present defect simulates the clinical condition for implanting the DYNESYS, as it was designed for clinical application of instabilities of the spine.

The slight increases in the ROM for the defect and both stabilization systems in the adjacent discs are probably due to multisegmental ligamentous structures cut during the creation of the defect. In the present study, we did not find differences in the intersegmental motion of the regions adjacent to the bridged one for both tested fixation systems. This is in line with the results of other in vitro and finite-element studies, which also found no significant differences in the adjacent discs for the loading with pure moments. This could be different for other more complex loading conditions, for example, the simulation of muscle forces. In vivo the spine is subjected to a combination of forces and moments originating from muscles and external loads. However, the magnitudes of the components in this complex load combination are largely unknown.

For the testing with a constant external moment, the effect of the fixation system on the adjacent segments should only have a negligible effect on their intersegmental motion. Applying a constant external deformation, the intersegmental motion of the adjacent segments could be expected to increase, as they would have to compensate for the lost motion of the bridged segment. However, this would assume that the patients would bend their spines to the same degree no matter if they have an intact or fused spine. To experimentally include this assumption, Panjabi recently suggested a so-called hybrid approach for testing dynamic spinal implants. In this approach the intact spine is loaded with pure moments in the three main planes and the overall ROMs are noted. In the second part the spinal construct (specimen plus implant) is loaded to the same ROM as the intact specimen. We believe that the reality is somewhere in between the two models and that during most daily activities patients are most likely to accept the limited motion. Standardized testing of spinal implants suggests testing under load-controlled pure moments. Therefore, we think for the initial testing of spinal implants, applying pure moments under load control is more adequate. Further testing of the implant systems might involve more complex loading protocols including the initiation of the motion by muscle forces to get a more physiologic loading of the specimens.

CONCLUSION

The results suggest that the DYNESYS system is capable of stabilizing an unstable segment sufficiently but
allows more motion in the segment than the internal fixator. The adjacent segment does not seem to be influenced by the stiffness of the fixation procedure under the described loading conditions.

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