Spinal motion and intradiscal pressure measurements before and after lumbar spine instrumentation with titanium or PEEK rods

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A B S T R A C T
Spinal instrumentation and fusion have been incriminated as contributing to adjacent segment degeneration (ASD). It has been suggested that ASD results from increased range of motion and intradiscal pressure (IDP) adjacent to instrumentation. Posterior dynamic stabilization with polyetheretherketone (PEEK) rods has been proposed as potentially advantageous compared to rigid instrumentation with titanium (Ti) rods in reducing the incidence of ASD. We evaluated segmental motions in the cadaveric spine instrumented with PEEK or Ti rods from L3 to S1, as well as the adjacent segment motions and IDP at L1–2 and L2–3. Human cadaveric spines were potted at T12–L1 and S1–2. Spinal instrumentation from L3–S1 was accomplished using pedicle screws with either PEEK or Ti rods. Specimens were subjected to displacement controlled testing: 15° flexion, 15° extension, 10° lateral bending, and 5° right axial rotation using the MTS machine (MTS, Minneapolis, MN, USA). Intradiscal pressure was measured by placing pressure transducers into the intervertebral disc at L1–2 and L2–3. Spinal motion of L2 relative to L3 and L3 relative to S1 was tracked using a three dimensional motion analysis system. Instrumentation with PEEK and Ti rods was associated with a decrease in L3–S1 motion compared to the intact state that was significant in flexion (p = 0.002), and extension (p = 0.0075). Instrumentation with PEEK and Ti rods was associated with an increase in IDP at L1–2 that was significant in flexion (p = 0.0028). Instrumentation with either PEEK or Ti rods resulted in decreased motion at the instrumented levels while increasing IDP at the adjacent level.

1. Introduction

Vertebral segments compromised by deformity, trauma, or disease are treated surgically to alleviate pain when conservative measures fail. Spinal arthrodesis provides stability by limiting motion across the instrumented segments. Degeneration of the segments adjacent to spinal fusion and instrumentation, however, is well-documented in the literature [1–5]. Adjacent segment degeneration (ASD) was recognized as early as 1988 [4,5]. Schlegel et al. demonstrated that following a lengthy symptom-free period, the segments adjacent to the fusion began to show signs of degeneration on average 13 years following their initial lumbar fusion [6]. Moreover, they suggested that in time, these adjacent segments would likely necessitate a fusion as well. Although there are no randomized controlled studies showing the frequency of degenerative disease in an asymptomatic population compared to one with prior fusion, it is believed that the increased incidence of degeneration adjacent to fusion is in part attributed to the altered loading imparted on the segment as the result of the fusion. The cause of this adjacent deterioration is multifactorial, with contributing factors including an increase in motion, intradiscal pressure (IDP), and strain adjacent to fusion [6–8].

Instrumented spinal fusion devices are designed to provide immediate stability until biological fusion is achieved. Posterior pedicle screw systems used to augment interbody and posterolateral fusion is well established. Reports suggest that the stiffness imparted by such instrumentation contributes to the abnormal loads transferred to the adjacent segments [9,10]. Traditional instrumentation eventually evolved from stainless steel to titanium (Ti) rods. More recently, the use of non-metallic materials and novel rod geometries have been implemented in an attempt to promote improved load sharing.

Polyetheretherketone (PEEK) has emerged as a promising material alternative to Ti. The material properties of PEEK are attractive for several reasons: it is biologically inert; it remains stable at high temperatures; it is resistant to chemical and radiation damage; it is radiolucent; and has an elastic modulus (E = 3.6 GPa) closer to that
of cortical bone (\(E = 12 \, \text{GPa}\)), as compared to Ti (\(E = 110 \, \text{GPa}\)) [10,11].

Although there have been some reports of the use of PEEK rods for posterior fusion with promising outcomes, these are limited [12]. Literature reporting on the biomechanics of PEEK rods is not plentiful [6,13–15]. Although studies on range of motion (ROM) and IDP adjacent to PEEK rod instrumentation have been done, these have been with finite element models of the spine involving anterior lumbar fusions, or posterior short segment fixation involving one segment [16,17]. To our knowledge there are currently no reports on the biomechanics of a four level PEEK instrumentation.

In this study, we investigated the ROM of L3 relative to S1 and L2 relative to L3 before and after L3–S1 instrumentation with Ti or PEEK rods. In addition, we documented IDP recordings at L1–2 and L2–3 before and after instrumentation.

2. Materials and methods

2.1. Specimen preparation

Nine human cadaveric lumbar spine specimens were obtained from the deeded body program from the Department of Anatomy, University of Iowa Hospitals and Clinics, IA, USA. The specimens were screened radiographically on anteroposterior and lateral planes to ensure the absence of fractures, deformities, and any metastatic disease. Age (mean ± standard deviation, 86.2 ± 14 years; range, 51–95), sex (eight women, one man), and bone mineral density (BMD) were recorded for each specimen. BMD was measured in the anteroposterior plane using dual energy absorptiometry with a bone densitometer (QDR-2000, Hologic Inc., Waltham, MA, USA), where the calculated BMD represents the average value for vertebrae L1–L4 (0.97 ± 0.35 g/cm²). Specimens were stored in double plastic bags at −20° Celsius and allowed to thaw at least 8 hours at room temperature prior to manipulation. The thawed specimens were denuded of paravertebral musculature avoiding disruption of spinal ligaments, joints, and discs in preparation for testing. Specimens were then potted at T12–L1 and at S1–2 using a mixture of Bondo and resin (Bondo Corporation, Atlanta, GA, USA) in a ratio of 70:30. After a setting time of 2 hours, the specimens were rigidly mounted to the materials testing machine for experimental testing.

2.2. Experimental setup

A servo hydraulic MTS Bionix 850 machine (MTS, Minneapolis, MN, USA) was retrofitted with a custom designed fixture (Fig. 1) for the application of predetermined unconstrained rotations in the sagittal, coronal, and axial planes (15° flexion, 10° extension, 10° left lateral bending, and 5° left axial rotation). In concert, intervertebral motions were garnered via a motion capture system and IDP ascertained via pressure transducers, while a six axis force/torque sensor, MC3A (AMTI, Inc., Watertown, MA, USA) mounted to the MTS platform, measured forces and moments acting on the spine.

2.3. Displacement controlled loading

A Vertical Biaxial Clinometer (Applied Geomechanics Inc. Santa Cruz, CA, USA) was fixed to the L1 potting surface to measure the rotation applied to the spine, which in turn enabled the vertical displacement of the MTS actuator necessary to achieve the desired rotation to be determined and applied. Thereafter the specimens were displaced at a rate of 1° per second for each rotational direction of interest. Three sequential trials were performed for each rotation to confirm repeatability. Data collected from the third trial were used for analysis. The order of the applied rotations was randomly assigned to each specimen.

2.4. Motion measurement

The three-dimensional segmental motions of L2 relative to L3 and L3 relative to S1 were measured using a Real Time 3 D Motion Analysis System (Fig. 1; Motion Analysis Corporation, Santa Rosa, CA, USA). Three high resolution digital video cameras, with a reported accuracy of 0.1 mm [18], recorded data at 60 Hz from sets of three light-reflecting markers securely attached to vertebrae L2, L3, and to S1 (the base plate). Load-displacement curves were analyzed to determine the segmental (L2–L3) and overall (L3–S1) ROM in flexion-extension, lateral bending, and axial rotation.

2.5. Pressure measurement

IDP at the rostral adjacent motion segments L1–2 and L2–3 was measured using SPR –24 pressure transducers (Millar Instruments, Houston, TX, USA). Dual transducers separated by 5 mm were advanced in an anterior to posterior direction to a depth of 15 mm in both adjacent intervertebral discs.

Subject to the aforementioned protocol, each specimen was tested in the following sequential order:

(1) Intact.
(2) L5–S1 transformaminal lumbar interbody fusion (right) with a carbon fiber reinforced polymer interbody graft (CFRP, 8 × 8 × 23 mm, DePuy Spine, Raynham, MA, USA), instrumented with pedicle screws (5.5 × 45 mm Ti pedicle screws) and 6.5 mm Ti rods (DePuy Spine) from L3–S1.
(3) Ti rods replaced with 6.5 mm PEEK rods (DePuy Spine), and the testing was repeated. The order of the PEEK and Ti rods were alternated for each subsequent specimen.

2.6. Statistical analysis

Using the SAS system (SAS Institute Inc., Cary, NC, USA) the IDP and angular displacement data were analyzed using a generalized
linear model. Using Tukey's Studentized Range the data was analyzed for statistical difference.

Results are presented as mean ± standard error of the mean.

3. Results

3.1. Kinematic results

The kinematic data are summarized in Fig. 2 and Table 1 for the fused levels. The motion across levels L3–S1 decreased for the instrumented specimens (as compared to intact), regardless of the rod, with the exception of the PEEK rod in lateral bending. During lateral bending an increase, over the intact motion, was observed with the PEEK rod. The rotation differences between the PEEK and Ti rods were not significant.

Figure 3 and Table 1 summarize the kinematic adjacent level response. Although not statistically significant, motion at the adjacent level increased for each of the instrumented specimens, with the exception of the Ti rod during axial rotation.

3.2. IDP

With the exception of flexion, L3–S1 instrumentation was associated with an increase in IDP at the L2–3. These increases with PEEK and Ti rods compared to intact and compared to one another were not statistically significant. IDP at maximal displacement in the intact, PEEK, and Ti constructs was 506 ± 493, 533 ± 608, and 376 ± 535 mmHg in flexion, 182 ± 201, 270 ± 375, and 347 ± 461 mmHg in extension, 157 ± 135, 220 ± 240, and 247 ± 285 mmHg in axial rotation, and 312 ± 562, 362 ± 852, and 418 ± 857 mmHg in lateral bending, respectively (Fig. 4, Table 2).

At L1–2 the mean IDP at maximal displacement in the intact, PEEK, and Ti states was 436 ± 389, 594 ± 366, and 613 ± 372 mmHg in flexion, 266 ± 441, 160 ± 272, and 335 ± 626 mmHg in extension, 167 ± 162, 188 ± 231, and 189 ± 238 mmHg in axial rotation, and 348 ± 666, 524 ± 848, and 512 ± 800 mmHg in lateral bending, respectively (Fig. 5, Table 2). Except in extension, L3–S1 instrumentation with PEEK and Ti rods was associated with an increase in IDP relative to the intact state. These increases in IDP with PEEK and Ti rods were significantly greater than the intact state only in flexion (p = 0.0028). There were no differences between the IDP values in the PEEK and Ti states.

4. Discussion

The problem of ASD can be attributed in part to the change in load distribution following fusion. This disease process can be seen in as little as 5 years, but more commonly 10 years after fusion...
The estimated frequency of occurrence of ASD can vary from 14.5% to 37% over 4–10 years subsequent to lumbar fusion [3,4]. In an attempt to address this delayed complication of fusion, some solutions have been conceived. These include total disc replacement [18] and posterior dynamic stabilization (PDS) [19] as potential methods for reducing ASD. By avoiding the rigidity characteristic of Ti and other rigid rods, it is thought that PDS using PEEK rods allows more loading of interbody grafts that could potentially avoid ASD. This is due to the flexibility of PEEK which has a modulus of elasticity between cortical and cancellous bone [10,11,20]. It is therefore of interest to determine the biomechanical effect of this implant compared to Ti rods.

The potential benefits of PEEK rods have also been demonstrated in a finite element model of the lumbar spine [19]. PDS with nitinol and PEEK rods was compared to instrumentation with Ti rods. The results showed a substantial reduction in stress-shielding characteristics with PDS. PDS devices were associated with higher axial loads across the anterior structure which could enhance fusion, slow the adjacent degenerative process, and lower the possibility of implant failure. Also PDS devices were able to lower the stress values of pedicle screws by 75–90% compared to rigid fixation systems [19]. Human cadaveric studies have compared Ti with PEEK rods and cage in a load-controlled design up to 8 Nm [13]. In a load controlled setup, 5.5 mm PEEK and Ti rods performed in a similar manner in regards to the stability provided. The authors hypothesized that flexible rods should bend and transfer more physiologic load anteriorly to the interbody space promoting fusion [13].

The results of this experiment showed that compared to the intact state, PEEK and Ti rods significantly reduced ROM at L3–S1 in flexion (p = 0.002), and extension (p = 0.0075), but not in axial rotation or lateral bending. There was no significant difference between PEEK and Ti rods in terms of the rigidity they imparted to the L3–S1 spine. This lack of a significant difference between PEEK and Ti constructs may be attributed in part to the elderly spines (mean age 86.2 years and range of 51 to 95), and low BMD (0.97 ± 0.35 g/cm²), which impeded rigid fixation. Also, though PEEK rods have increased flexibility compared to Ti rods, the former may have been too stiff to demonstrate a significant difference compared to Ti rods in the above situations. These results are comparable to those of Bruner et al., Gornet et al. and Turner et al., also in the cadaveric spine [6,15,21]. In the adjacent segment L2–3, except in axial rotation, instrumentation with PEEK and Ti appeared to be associated with an increase in motion relative to the intact state, however these differences from the intact or one another were not significant. The lack of a significant difference at adjacent levels between instrumentation with PEEK and Ti is comparable to that of Turner et al. [15].

The increase in adjacent level IDP following instrumentation has been well documented by numerous authors including Crippon et al., Turner et al. and Auerback et al. [1,15,22]. Also, the increase in adjacent IDP has been associated with the increase as the number of levels fused. In this study we were able to demonstrate an increase in IDP in both the adjacent level of instrumentation and the level above although only statistically significant in flexion at L1–2 (p = 0.0028). Though IDP with PEEK rods were lower than with Ti rods in all ROM with the exception of flexion at L2–3, and lateral bending at L1–2, there were no statistically significant differences between PEEK and Ti rods. The lack of a significant difference in IDP adjacent to PEEK and Ti instrumentation is comparable to that encountered in the study of Turner et al. [15]. Because it has been suggested that ASD may be the result of increased IDP [18], this decrease in IDP with the use of PEEK compared to Ti rods has the potential to reduce its occurrence. While these minor differences may seem insignificant in the in vitro set-up, the long-term effect of these minor differences in pressure may significantly affect the progression of degeneration. To our knowledge, there are no studies that document the increase of IDP from the intact that will cause degeneration. It is difficult to determine the cause of the paradoxical increase in IDP with PEEK compared to Ti in flexion at the L2–3, and in lateral bending at L1–2. These aberrant results may be the result of shift in the position of the IDP transducer within the disc space relative to the center of rotation.

There are several limitations to this study design that should be noted. While this study is important in demonstrating the biomechanical changes that occur with PEEK and Ti rods, it is not possible to demonstrate the clinical advantage of these differences. The limited number of specimens used in this study further limits our ability to show statistical significance between PEEK and Ti rods. In addition, the high average age of these specimens and spondylosis may limit ROM in these specimens, even in the intact state. Compared to younger specimens, the low BMD may prevent rigid fixation of the screws with testing, although frank loosening was not encountered. Finally it is not clear how these results compare to in vivo studies where implants would be subjected to more severe, dynamic and coupled motions.

5. Conclusion

This study showed that in our model, instrumentation at L3–S1 with either PEEK or Ti rods were restrictive compared to the intact state, significantly in the sagittal plane. Motion at levels adjacent to instrumentation was increased, however failed to achieve significance. An increase in IDP adjacent to instrumentation was noted for both Ti and PEEK rods that achieved significance at L1–2 in flexion. Any potential benefits arising from the use of PEEK rods await more extensive clinical trials than the few thus far reported [12].

Conflicts of interest/disclosures

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The other authors declare that they have no financial or other conflicts of interest in relation to this research and its publication.

References


