

EVALUATION OF CLINICAL AND RADIOLOGICAL OUTCOMES IN DEGENERATIVE LUMBAR SPINE DISORDERS TREATED WITH PEEK ROD

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ABSTRACT

Objective: This study aimed to evaluate the clinical and radiological outcomes of patients undergoing transpedicular screw and polyetheretherketone (PEEK) rod stabilization for the surgical treatment of degenerative diseases of the lumbar spine.

Materials and Methods: A retrospective analysis was conducted on 51 patients diagnosed with degenerative spine disease, such as recurrent disc herniation, spinal stenosis, spondylolisthesis, and adjacent segment disease, who underwent bilateral transpedicular screw-PEEK rod stabilization between May 2017 and November 2020. Preoperative and postoperative assessments included lumbar lordosis angles, sacral slope, pelvic incidence, pelvic tilt, visual analog scale (VAS) scores, PROLO economic and social scores, and the presence of adjacent segments and fusion.

Results: The study included 51 patients with a mean age of 62.5 years (range: 18-85 years), with 56.8% (29 patients) being female and 43.2% (22 patients) being male. Surgical procedures involved single-level stabilization in 16 patients, two-level stabilization in 21 patients, three-level stabilization in 9 patients, and four-level stabilization in 5 patients. The mean follow-up period was 52.4 months. Postoperatively, there was a significant reduction in VAS scores from a mean of 8.2±1.3 to 3.4±1.7 ($p<0.01$). No significant changes were observed in the lumbar lordosis angle, sacral slope, pelvic tilt angle, and pelvic incidence angle. The mean PROLO score improved from 3.5±1.2 preoperatively to 7.6±1.5 postoperatively. Fusion was observed in 43 patients during the follow-up period.

Conclusion: The use of PEEK rods in the surgical treatment of degenerative lumbar spine diseases may lead to improved postoperative quality of life and reduced implant-related complications. Furthermore, our findings suggest that patients without sagittal balance impairment may benefit from PEEK rod stabilization without significant changes in spinal alignment. However, further comparative and long-term studies are required to better understand the efficacy and outcomes of PEEK rod systems in this treatment approach.

Keywords: Degenerative lumbar spine, PEEK, dynamic stabilization, VAS, PROLO

INTRODUCTION

Degenerative lumbar spine diseases, such as spinal stenosis, disc degeneration, and spondylolisthesis, affect millions of people worldwide and can significantly impact their quality of life⁽¹⁾. With the advancement of medical technology, various surgical interventions have been developed to alleviate symptoms and restore spinal stability. One such innovation is the use of polyetheretherketone (PEEK) rods in the treatment of these conditions⁽²⁾.

PEEK, a high-performance polymer, has gained popularity in spinal surgery due to its biocompatibility, radiolucency, and mechanical properties resembling human bone⁽³⁾. The use of PEEK rods as an alternative to traditional metallic rods has

shown promising results in the management of degenerative lumbar spine diseases. This article aims to provide an overview of the outcomes and clinical experiences associated with the utilization of PEEK rods in the treatment of these conditions. The utilization of PEEK rod systems in spinal surgery gained Food and Drug Administration approval for transpedicular screw instrumentation as early as 2007. PEEK material exhibits minimal *in vivo* toxicity and possesses remarkable resistance to chemical and radiation damage⁽⁴⁾. In comparison to titanium rods, which have a high rigidity of 114 GPa, the less rigid PEEK rods with a stiffness of 3.2 GPa have demonstrated the ability to effectively distribute load-bearing forces. Additionally, PEEK rods have been suggested to enhance the rate of intervertebral bone fusion according to established principles⁽⁵⁾. Several studies in the literature have reported satisfactory fusion

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outcomes with the use of PEEK rod systems⁽⁶⁻⁸⁾. Nevertheless, the findings of these studies remain contentious due to limitations such as short follow-up durations, small sample sizes, and conflicting clinical results.

Rigid stabilization techniques in spinal surgery have been associated with a decrease in the range of motion of the spinal column, which can subsequently lead to increased stress on adjacent segments following the operation. This heightened stress on the bone-screw interface has been known to contribute to instrumentation issues and the development of pseudoarthrosis⁽⁹⁾.

MATERIALS AND METHODS

In this retrospective analysis, conducted between May 2017 and November 2020, a total of 51 patients who sought treatment for degenerative spine disease and underwent bilateral transpedicular screw-PEEK rod stabilization were included. The patients were selected from Ankara Numune Training and Research Hospital, Ankara Bilkent City Hospital, and Marmara University Medical Faculty Neurosurgery Clinics. Ethical approval for this study was obtained from the Ankara City Hospital No. 2 Clinical Research Ethics Committee (decision no: E2-21-05, date: 10.03.2021).

Radiological and clinical data of the patients were collected retrospectively. The study specifically focused on patients diagnosed with degenerative spine diseases in the lumbar region, such as recurrent disc herniation, lumbar spinal stenosis, spondylolisthesis, adjacent segment disease, scoliosis, among others. Patients with active infection or pathological vertebral fractures, those with a body mass index exceeding 40 kg/m², and individuals diagnosed with ankylosing spondylitis were excluded from the study. Additional exclusion criteria included patients with a follow-up period of less than 12 months postoperatively or those lacking preoperative and postoperative visual analog scale (VAS) and PROLO scores.

In this article, various spinal and pelvic parameters, including lumbar lordosis, sacral slope, pelvic tilt, and pelvic incidence, were assessed and compared before and after surgery. These measurements play a crucial role in understanding spinal alignment and pelvic orientation. By comparing these measurements in the preoperative and postoperative periods, the authors can evaluate the effectiveness of surgical interventions and their impact on spinal alignment and pelvic orientation. This information is vital for tailoring treatment plans and ensuring optimal patient outcomes.

All surgical procedures were performed by experienced surgical teams at two different centers, with patients under general anesthesia and positioned prone, using a median midline skin incision. Nerve decompression and discectomy were performed as needed. Transpedicular titanium screws were inserted and verified with fluoroscopy during surgery. Subsequently, the levels with screw fixation were stabilized using a PEEK rod. The deliberate decision was made to steer

clear of fusion procedures in order to maintain the innate mobility of the vertebrae. Instead, a dynamic stabilization approach was adopted. However, a one-level PEEK cage was employed to stabilize spinal movement in 14 patients with spondylolisthesis and to reinstate disc space in 9 patients with recurrent disc issues, a strategy recognized for enhancing the likelihood of achieving interbody fusion. Concurrently, autologous bone grafts were strategically placed at the bases of the screws to mitigate the risk of screw pull-out. The selection of autologous bone grafts included the utilization of bone graft material from the surgical site's vicinity in some instances, known as local bone grafting. This approach encompassed the use of bone that was extracted during spinal decompression or harvested from nearby anatomical structures. Additionally, in cases where a segment of a vertebra had been excised, this excised bone was repurposed as graft material through a technique referred to as vertebral body grafting. This multifaceted approach underscored the emphasis on both maintaining vertebral motion physiology and ensuring the structural integrity of the procedure.

In the context of lumbar spondylosis management, a precise surgical approach was undertaken involving medial facetectomy. It is important to note that a complete facetectomy procedure was not executed in any of the patients. This distinction in surgical methodology reflects the deliberate and tailored nature of the interventions employed, highlighting the clinical expertise and patient-centered care that guided the treatment decisions in this cohort.

An aspiration drain was placed at the surgical site, and following hemostasis, closure was performed in accordance with the anatomical plan. Postoperatively, patients received intravenous antibiotics for 24-48 hours. Mobilization of patients with a lumbosacral corset containing four steel underwires began at the 6th postoperative hour. Patients continued to use these corsets for approximately 3 weeks during mobilization. Clinical evaluations of the patients were conducted using the VAS and PROLO economic and functional scoring systems. Retrospectively, preoperative and postoperative scores were collected from patient files. Radiological assessments included measurements of lumbar lordosis, sacral slope, pelvic tilt, and pelvic incidence angles, performed by two different individuals before and after the surgery. Additionally, postoperative computed tomography (CT) images were reviewed to evaluate screw loosening and fusion in patients.

A comprehensive radiologic imaging protocol was established for the postoperative monitoring of patients in this study. Specifically, radiologic imaging was performed on postoperative day 1, followed by a subsequent assessment at the first follow-up visit on postoperative day 45. Subsequently, additional assessments took place at the 6-month and 1-year milestones post-surgery. Beyond the first year, patients were scheduled for annual radiologic evaluations, unless they presented with any specific complaints or concerns warranting more frequent assessments.

Statistical Analysis

Statistical analysis was performed using two software packages: IBM SPSS 25.0 (Armonk, NY: IBM Corp.) and MedCalc 15.8 (MedCalc Software byba, Ostend, Belgium). Descriptive statistics, such as frequency, percentage, mean, standard deviation, median, and minimum-maximum values, were calculated to summarize the data. To compare qualitative data, chi-square tests, including Pearson’s chi-square test, Yates’ Corrected chi-square test, and Fisher’s Exact test, were utilized. The normality of data distribution was assessed using the Smirnov test, skewness-kurtosis analysis, and graphical methods such as histograms, Q-Q Plots, Stem-and-Leaf plots, and Boxplots. Independent Samples t-tests were employed for comparing normally distributed quantitative data between groups, while the Mann-Whitney U test was used for non-normally distributed data. The relationship between variables was examined using Spearman’s rho Correlation test. A statistical significance level of $p=0.05$ was considered for all analyzes.

RESULTS

The study included a total of 51 patients with a mean age of 62.5 years (ranging from 18 to 85 years). Among the participants, 56.8% (29 patients) were female, and 43.2% (22 patients) were male. The diagnoses of the patient of 11 cases of adjacent segment disease, 14 cases of spondylolisthesis, 14 cases of lumbar spinal stenosis, 9 cases of recurrent disc herniations, and 1 case of instrument revision. In terms of surgical procedures, single-level stabilization was performed in 16 patients (one disc-2 vertebral segments), two-level stabilization in 21 patients, three-level stabilization in 9 patients, and four-level stabilization in 5 patients. In addition to the PEEK rod stabilization, intervertebral PEEK cage placement was performed in 23 cases. The patients were followed for a minimum of 32 months, with a mean postoperative observation period of 52.4 months. None of the cases required revision surgery. Two patients experienced dural injuries during the operation, which were not amenable to primary suturing. These injuries were managed by closure using fibrin tissue glue and muscle graft. No complications were observed during the postoperative wound follow-up, including wound infection or abscess formation in any of the patients (Table 1).

The preoperative mean VAS score, which measures pain intensity, was found to be 8.2 ± 1.3 . Moreover, postoperatively, there was a substantial reduction in pain, with the mean VAS score decreasing to 3.4 ± 1.7 . This change was statistically significant ($p\leq 0.01$), indicating that the surgical intervention effectively alleviated pain in the patients. Furthermore, the PROLO Economic and Functional Scoring system, which assesses the economic and functional aspects of treatment, demonstrated a significant improvement in patients’ scores. The preoperative mean PROLO score was 3.5 ± 1.2 , whereas the postoperative mean score increased to 7.6 ± 1.5 and it’s statistically significant

($p\leq 0.01$), indicating positive outcomes in both economic and functional domains (Table 2).

Regarding the radiological parameters analyzed, there were no statistically significant changes in the mean lumbar lordosis angle, sacral slope, pelvic tilt angle, or pelvic incidence angle. The mean preoperative lumbar lordosis angle was 45.4, which increased slightly to 48.2 postoperatively ($p>0.05$). Similarly, there were minimal changes in the sacral slope (32.4 to 35.9), pelvic tilt angle (24.9 to 24.2), and pelvic incidence angle (58.2 to 56.4), all of which were not statistically significant ($p>0.05$) (Table 2). Also, no statistically significant difference were observed between the groups concerning etiologic parameters. In 23 patients, a noteworthy approach was employed involving the application of single-level PEEK cages. These PEEK cages were exclusively utilized in patients requiring multilevel stabilization procedures, with a distinct focus on employing them solely for single-level applications. This distinctive approach underscores the commitment to preserving dynamic spinal function, even in cases where a single-level fusion was necessary. Consequently, this method prioritized dynamic stabilization across the entire spectrum of spinal stabilization needs, offering a comprehensive and patient-centered solution. Upon conducting a thorough comparison between two distinct

Table 1. Patient characteristics

Parameter	Value
Total patients	51
Mean age	62.5 years (range: 18 to 85 years)
Gender distribution	Female: 56.8% (29 patients) Male: 43.2% (22 patients)
Diagnoses	- Adjacent segment disease: 11 cases - Spondylolisthesis: 14 cases - Lumbar spinal stenosis: 14 cases - Recurrent disc herniations: 9 cases - Instrument revision: 1 case
Follow-up period	Minimum: 32 months Mean: 52.4 months
Dural injuries	4 cases (managed with fibrin tissue glue and muscle graft)
Postoperative complications	2 cases (CSF fistula)

CSF: Cerebrospinal fluid

Table 2. Clinical and radiological findings

Measurements	Preoperative (mean ± SD)	Postoperative (mean ± SD)	P value
Lumbar lordosis	45.4±11.2	48.2±11.5	>0.05
Sacral slope	32.4±8	35±9.5	>0.05
Pelvic tilt angle	24.9±8.6	24.2±8.9	>0.05
Pelvic incidence	58.2±10.7	56.4±8.3	>0.05
VAS	8.2±1.3	3.4±1.7	≤0.01
PROLO	3.5±1.2	7.6±1.5	≤0.01

VAS: Visual analogue scale, SD: Standard deviation

groups, namely the single-level PEEK cage combined with multilevel PEEK rod group and the PEEK rod alone group, a noteworthy observation emerged. In all assessed parameters, no statistically significant differences were detected between these groups. This finding led to the considered conclusion that maintaining these groups as an undivided entity would not compromise the homogeneity of the study sample. Such a decision underscores the robustness of the study's design and ensures that the results are derived from a comprehensive and coherent dataset.

During the follow-up period, screw loosening was observed in four cases. Out of these, only one patient experienced symptomatic screw loosening, while the remaining cases were asymptomatic with only radiological evidence. Fortunately, no instances of rod breakage were reported throughout the follow-up period.

Additionally, fusion was observed in 43 cases during the follow-up period, indicating successful fusion at the treated segment. However, fusion was not yet observed in the facet joints in 8 cases, suggesting a need for further evaluation or longer follow-up to assess the fusion status in these areas.

Overall, the study demonstrated favorable surgical outcomes in terms of pain relief and functional improvement, as evidenced by significant reductions in VAS scores and improvements in PROLO scores. Although there were no significant changes in the analyzed radiological parameters. The occurrence of screw loosening was relatively low, with only one symptomatic case. These findings contribute to our understanding of surgical interventions for spinal disorders and highlight the importance of long-term follow-up to assess fusion and detect potential complications.

Early complications were detected in 7 instances. Among these, screw malposition was observed in four cases (7.8%) during the early period. Cerebrospinal fluid fistula occurred in 2 cases (3.8%), and 1 case (1.9%) necessitated reoperation. Late complications of adjacent segment disease in 7 cases (13.7%) and pseudoarthrosis in 9 cases (17.6%).

DISCUSSION

Lumbar degenerative disease commonly arises due to intricate degenerative conditions that exert pressure on the neural components. The alignment and inclination of facet joints are closely associated with disc degeneration in the lumbar spine⁽¹⁰⁾. In cases of mild lumbar stenosis, conservative treatment is typically initiated as the initial step, but its efficacy is limited due to symptom exacerbation during movement. However, in advanced cases, the degenerative process worsens neural stenosis, often necessitating surgical intervention. Microsurgery and lumbar stabilization using rigid and dynamic systems form the foundation of surgical treatment. Within our study, we conducted a comparison between preoperative and postoperative dynamic systems, evaluating clinical, radiological, and surgical complications. While there were no discernible

differences between the two groups in terms of Lumbar Lordosis, Sacral Slope, Pelvic Tilt Angle, and Pelvic Incidence, statistically significant differences were observed in VAS and PROLO scores.

In the treatment of degenerative lumbar diseases, there has been a growing trend in utilizing semi-rigid materials like PEEK rods to assist fusion procedures. PEEK polymer possesses an elasticity similar to that of bone (17 GPa) and offers adequate rigidity for promoting bone fusion without exerting excessive stress on the spinal columns, unlike titanium rods. This characteristic makes PEEK rods a favorable choice for supporting fusion in recent years^(11,12).

In a relevant clinical study by De lure et al.⁽¹³⁾, a retrospective analysis was performed on 30 cases who underwent stabilization utilizing a PEEK rod. The obtained clinical data during the 18-month follow-up period exhibited satisfactory outcomes. Similarly, Huang et al.⁽¹⁴⁾ performed a prospective evaluation on 31 cases, similar to our study population, who underwent PEEK rod stabilization. The clinical data collected during the 24-month follow-up period showed favorable results, particularly in terms of Japanese Orthopaedic Association (JOA) and Oswestry Disability Index scores.

In a prospective study carried out by Qi et al.⁽⁶⁾ in 2013, a comparison was made between posterior fusion surgery utilizing PEEK rods and surgery utilizing titanium rods. The study revealed positive changes in VAS and JOA scores in both groups. Moreover, no statistically significant difference was observed between the two groups regarding clinical outcomes. In the one-year follow-up, an absence of screw failure or pedicle fracture was observed in patients who underwent treatment with PEEK rods. Although PEEK rods possess a semirigid nature that carries a potential risk of pseudoarthrosis, all patients treated with PEEK rods achieved interbody fusion. This successful fusion is likely attributed to the anterior column load sharing and intervertebral space self-compressing characteristics of PEEK rods. The primary objective of the surgery, achieving lumbar fusion, was accomplished with the utilization of PEEK rods, leading to significant improvement in clinical outcomes for these patients. This outcome demonstrates the feasibility and efficacy of employing PEEK rods in surgical interventions. However, it is important to note that a loss of disc space height was observed during the follow-up period in the PEEK group. Nevertheless, PEEK rods effectively maintained lumbar lordosis and disc space height, meeting the required criteria. Overall, these findings highlight the potential of PEEK rods as a valuable modality in achieving successful lumbar fusion and improving patient outcomes.

These findings support the growing body of evidence highlighting the effectiveness and comparable clinical outcomes of PEEK rod stabilization in spinal surgeries. The utilization of PEEK rods presents a promising option for achieving satisfactory clinical results in patients undergoing spinal stabilization procedures. Further research and larger-scale studies are warranted to validate these findings and explore additional long-term outcomes.

One argument against non-fusion procedures is the potential risk of implant failure. However, in our study, three-dimensional CT scan reconstructions revealed no instances of rod breakage. This suggests that PEEK rod systems offer superior implant safety compared to pedicle-based dynamic stabilization procedures, as previous studies have indicated that screw loosening is a common complication in such procedures⁽¹⁵⁾. The use of PEEK rod systems has been shown to reduce the likelihood of implant failure, including screw loosening. This has been supported by cadaveric testing⁽¹⁶⁾ and finite element studies⁽¹⁷⁾, which have demonstrated optimized load sharing and reduced stress at the bone-screw interface with PEEK rods. While this study demonstrated statistical improvement in VAS and PROLO scores, it remains uncertain whether these results were solely attributed to posterior segmental stabilization or nerve decompression. Nonetheless, the utilization of PEEK rods holds the potential to enhance postoperative quality of life and reduce complications associated with implantation. Furthermore, our findings, which indicated no significant changes in lordosis angle and spinopelvic angles, suggest that individuals without pre-existing lordosis and spinopelvic angle distortions derived benefits from this treatment approach. Furthermore, the absence of significant changes in spinopelvic angles within our study implies that patients who are suitable candidates for PEEK rod utilization tend to exhibit normal spinopelvic angles. This observation suggests that individuals with pre-existing spinopelvic angle abnormalities may not experience substantial benefits from the use of PEEK rods. Considering spinopelvic angles in patient selection and treatment planning may contribute to optimizing outcomes in PEEK rod-based interventions. Further investigations are warranted to explore the relationship between spinopelvic angles and the effectiveness of PEEK rod stabilization, as well as to evaluate the potential impact on clinical outcomes in patients with abnormal spinopelvic parameters.

Study Limitations

There are several limitations to consider in this study. Firstly, the sample size was relatively small, which may limit the generalizability of the findings. A larger sample size would provide more robust results and improve the statistical power of the study. Secondly, the study only focused on comparing the outcomes of PEEK rod stabilization and did not include a comparison with stabilization systems utilizing rods made of other materials. A comparative analysis with different rod systems could provide valuable insights into the effectiveness of PEEK rods in comparison to other elements. Future studies should aim to address these limitations and incorporate a larger patient cohort with comparative analyzes to enhance the understanding of PEEK rod systems in the context of spinal stabilization procedures.

CONCLUSION

The utilization of PEEK rods holds promise in enhancing postoperative quality of life and minimizing implant-related complications. Furthermore, our study revealed that patients without pre-existing sagittal balance impairment derived benefits from PEEK rod stabilization, as there were no significant changes observed in lumbar lordosis and sagittal balance angles of the spine.

Ethics

Ethics Committee Approval: Ethical approval for this study was obtained from the Ankara City Hospital No. 2 Clinical Research Ethics Committee (decision no: E2-21-05, date: 10.03.2021).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: G.G., Y.G., A.D., Concept: G.G., İ.G., A.D., Design: İ.G., Ay.K., R.K., Data Collection or Processing: R.K., Ay.K., A.K., Analysis or Interpretation: E.Ç., A.K., Y.G., A.D., Literature Search: G.G., E.Ç., A.D., Writing: G.G., İ.G., E.Ç.

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