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LONG-TERM FAILURE OF DYNAMIC RODS USED IN FULL DYNAMIC STABILIZATION

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ABSTRACT

Objective: Dynamic stabilization systems, which prevent degeneration and deformation of the lumbar spine by limiting segmental movement, have been used with increasing frequency over the years and have become an alternative to spinal fusion surgery. For a standard dynamic stabilization and for the system to work fully, the mechanical structure and material selection must be developed together. Our aim in this study was to compare clinically and radiologically the cases in which dynamic screws and different types of dynamic rods were used.

Materials and Methods: We retrospectively analyzed 57 patients who underwent surgery between 2012 and 2015 using dynamic transpedicular screw (Safinaz, Medikon) and dynamic rod [dream/agile/polyetheretherketone (PEEK)] systems. The patients were diagnosed following detailed neurological and radiological imaging examinations to determine the location of pain. Demographic data and visual analogue scale-oswestry disability index scores were obtained.

Results: The patients consisted of 23 (40.4%) males and 34 (59.6%) females with a mean age of 63.3±12.0 years (range 51-83 years) at initial symptom onset. The mean duration of clinical symptoms of the patients was 9.6 months. The mean follow-up period was 49.12 months. A dynamic transpedicular screw system was used in all patients. After the 3rd year postoperatively, rod breakage was detected in 3 patients in the agile rod group (20%) and in 4 patients in the dream rod group (22.2%). In the PEEK rod group, there were no patients with rod breakage.

Conclusion: The combination of dynamic pedicle screw and dynamic rod implants, obtained from the right material and properly designed, will be an important alternative among non-fusion dynamic implants, especially in patients with multi-segment degenerative disease.

Keywords: Dynamic screw, stabilization, dynamic rod, degenerative, disc disease

INTRODUCTION

Although there are many options for fracture, deformity, and degenerative spine surgery, decompression, and complementary posterior spinal instrumentation are seen as the gold standard treatment technique[1]. However, complications such as infection, instrumentation failure, failed back syndrome, adjacent segment disease, and pseudoarthrosis may be encountered after fusion surgery. The most important reason is the limitation of the physiologic movement after fixation and the increase in the load on the adjacent spine segment[2].

Rod failure, which frequently causes revision surgeries, is among the important instrument complications. While the risk of fracture increases especially in long segment fusions involving transitional regions, the other causes are advanced age, increase in body mass index, and presence of connectors[3]. Another important factor is the material of construction of the rod. It has been reported in the literature that rods made of titanium alloy or stainless steel are more durable than cobalt chrome or other materials[4].

Dynamic stabilization systems, which prevent degeneration and deformation of the lumbar spine by limiting segmental movement, have been used with increasing frequency over the years and have become an alternative option to spinal fusion surgery. With the preservation of segmental motion, stress at adjacent levels will decrease and the development of autism spectrum disorder can be prevented automatically. However, adequate spinal stability is necessary for successful results[5].

Dynesys system, which is one of the most widely used dynamic systems, has been used for more than ten years and is based on artificial ligament system technology[6]. As a result of tightening the rod (thread) by the surgeon, very hard or vice versa loose rods may occur. For this reason, the failure to provide a standard procedure has led to the emergence of disadvantages over time. For a standard dynamic stabilization and for the system to work fully, the mechanical structure and material selection must be developed together. For this reason, dynamic rods [dream/agile/polyetheretherketone (PEEK)] have been introduced and the use of full dynamic systems has gradually increased. There are publications in the literature that the rods break and lose

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their function because of the use of dynamic rods with a rigid screw system. However, to the best of our knowledge, there is no clinical study on the long-term results and functions of rods in cases where dynamic screws and dynamic rods are used. In this study, we aimed to report the long-term clinical results of 3 different dynamic rod systems.

MATERIALS AND METHODS

In this study, all procedures performed were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study was approved by the Atatürk University Clinical Research Ethics Committee (decision no: 12, date: 27.01.2022). Informed consent was obtained from all participants included in the study.

We retrospectively analyzed 57 patients who were operated on between 2012 and 2015, using dynamic transpedicular screw (Safinaz, Medikon) and dynamic rod (dream/agile/PEEK) systems (Figure 1). Patients with complete clinical and radiological follow-ups were included in the study. The cases that had been operated with at least 2 segments due to various lumbar pathologies were divided into 3 groups according to the type of dynamic rods used.

The patients were diagnosed following detailed neurological and radiological imaging examinations to determine the location of the pain. Demographic data and visual analogue scale-oswestry disability index (VAS-ODI) scores were obtained. Pre-procedural VAS-ODI scores were documented before the procedure and after the operation at the following time points: 3 months, 1 year, and year after that. The stability of the system was checked with the imagings taken at periodic intervals. Computed tomography (CT), magnetic resonance imaging, and direct X-ray were performed on all patients both preoperatively and postoperatively. In case of failure in any part of the dynamic system, time and patient complaints were noted.

During routine controls, fusion was evaluated by CT and dynamic radiographs in all patients at the 6th month follow-up. In addition, stability was subjectively confirmed by the absence of axial pain. The patients were followed up routinely in the outpatient clinic conditions. Detailed neurological examinations were performed and their complaints were compared. If there was improvement in the physical examination and symptoms of the patients, these patients were included in the group of those who benefited from the surgery. The groups were compared within themselves before and after dynamic stabilization.

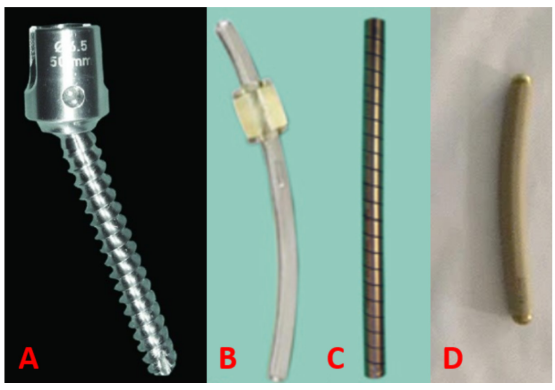

Figure 1. A) Safinaz screw, **B)** Agile rod, **C)** Dream rod, **D)** PEEK rod
PEEK: Polyetheretherketone

Surgical Procedure

All procedures were supervised and/or performed by the senior author (AFO). Participants were positioned prone on a radiolucent fluoroscopy table with general anaesthesia. The transpedicular screw system was performed with the aid of fluoroscopy, accompanied by anteroposterior and lateral images, after paravertebral muscle dissection with the Wiltse method. Additional microdiscectomy with the median approach was performed in patients who had disc extrusion or protrusion. Dynamic transpedicular screws and dynamic rods were used in all patients. The rigid segment of the agile rod was used in the microdiscectomy region, and the spacer segment of the agile rod was used in the degenerative disc disease region.

Statistical Analysis

All statistical analyses were performed using IBM SPSS 20.0 software (IBM Corp., Armonk, NY, USA). For the significant values, which groups were different from each other and what the source of this difference was between the groups were examined by postoperative comparison tests, including Tukey's honestly significant difference test. Since the variables in the data were obtained with a proportional or intermittent scale and were normally distributed, Pearson correlation analysis was performed. A two-tailed $p<0.05$ was considered to indicate statistically significant differences.

RESULTS

The patients consisted of 23 (40.4%) males and 34 (59.6%) females with a mean age of 63.3±12.0 years (range 51-83 years) at initial symptom onset. When the family histories of the patients were examined, no spinal trauma or oncological surgery was found. The patients also had no previous history of spinal surgery. Among the symptoms, low back pain was dominant, while sciatica was the most common accompanying symptom. The mean duration of clinical symptoms of the patients was 9.6 months. The mean follow-up period was 49.12 months.

A dynamic transpedicular screw system was used in all patients. Agile rod system was used in 15 (26.3%) patients, dream rod in 18 (31.6%) patients, and PEEK rod system in 24 (42.1%) patients. Stabilization operation including at least 2 segments was applied to all patients. While degenerative disc disease was the predominant pathology, stenosis was the pathology that followed it. Baseline demographic and procedural characteristics by localization are summarized in Table 1.

When the VAS-ODI scores were examined, a significant improvement was observed at the 3rd month control (p<0.05) (Table 2). No statistically significant change was observed in their scores in routine follow-ups. There was no significant difference between gender, including segment and pathology in terms of both VAS-ODI score changes, and also there was no significant correlation between age and VAS-ODI score changes (p>0.05).

The difference about the clinical relief between at the end of third month and at the end of the twelfth, and twenty-fourth months were not statistically significant (p>0.05). No additional complaints were detected in the last clinical evaluation of the patients. In the instrumentation system, no signs of insufficiency were detected in all patients until the 3rd year. The absence of additional pain complaints in the patients was used for subjective evaluation of fusion. It was also confirmed with routine imaging modalities.

However, after the 3rd year postoperatively, some patients from agile and dream rod groups showed worsening in the VAS-ODI score values, and in the control images, insufficiency and fracture of the rod systems were observed in each group. Rod breakage was detected in 3 patients in the agile rod group (20%) and in 4 patients in the dream rod group (22.2%). In the PEEK rod group, there was no patient with rod breakage (Table 1).

In total patient cohort, except for subcutaneous hematoma and superficial tissue infection, no serious complications were encountered. Screw loosening was found on plain radiographs in one patient in the PEEK rod group (Table 3). Except for rod breaks and secondary revision cases, none of the cases required revision surgery secondary to screw malposition, adjacent segment disease, or screw loosening. At the last follow-up visit, no implant-related complications requiring revision were observed. Some of the illustrative case in this series are shown in Figures 2-4.

DISCUSSION

Disc tissue is one of the most important structures that play a role in the mobility and stability of the spine. As a result of degeneration, the disc structure deteriorates, so pain inevitably arises in the deteriorated joint. Although there are many factors that predispose to degeneration, instability is among the most common causes in pathophysiological mechanisms. Degenerative instability develops as a result of numerous causes, including disc degeneration, expansion in hypertrophic

Table 1. Summarized data of patients

		Mean ± SD	Median (IQR)
Age (years)		63.3±12.0	67.0 (51.0-83.0)
Clinical and radiological follow-up (month)		49.12±4.3	-
Duration of clinical symptoms (month)		9.3±3.7	-
		n	%
Gender	Female	34	59.6
	Male	23	40.3
Stabilization	Short segment (2)	20	35.1
	Long segment (2-4)	37	64.9
Localization	Lumbosacral	27	47.3
	Lumbar	30	52.7
Type of rods/break	Agile	15/3	26.3/20
	Dream	18/4	31.6/22.2
	PEEK	24/-	42.1/-

SD: Standard deviation, PEEK: Polyetheretherketone, IQR: Interquartile range

Table 2. Comparison of VAS-ODI scores of patients before and after treatment (3rd year control)

		Preoperative		Postoperative		Change		
		Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	p
Dream rod	**VAS score**	8.5±0.6	8.0 (8.0-9.0)	3.3±0.8	3.0 (3.0-3.0)	5.2±1.2	5.0 (5.0-6.0)	0.006
	ODI score	65.2±15.4	66.0 (56.0-72.0)	23.9±11.4	20.0 (16.0-24.0)	41.3±15.0	44.0 (34.0-48.0)	0.007
Agile rod	**VAS score**	8.2±0.4	8.1 (8.0-9.0)	3.6±0.9	3.1(3.0-3.3)	4.6±1.2	5.2 (5.0-6.3)	0.008
	ODI score	64.1±16.6	67.0 (55.0-73.0)	24.3±12.1	21.0 (17.0-23.0)	39.8±15.9	43.0 (33.0-47.0)	0.009
PEEK rod	**VAS score**	8.3±0.2	8.0 (8.0-9.0)	3.1±0.5	3.0 (3.0-3.3)	5.2±1.0	5.0 (5.0-6.3)	0.007
	ODI score	62.7±18	66.0 (54.0-72.0)	22.8±11.7	21.0 (18.0-24.0)	39.9±15.9	43.8 (34.0-48.0)	0.008

SD: Standard deviation, IQR: Interquartile range, VAS-ODI: Visual analogue scale-oswestry disability index

posterior facet joints, looseness in ligaments and increased movement[7].

Today, fusion surgeries are still accepted as the "gold standard" in the treatment of painful low back syndrome all over the world. Good results have been obtained from fusion surgeries performed to treat the disc and relieve this pain. However, one of the biggest problems of these surgeries is adjacent segment disease, causing early degeneration of the discs adjacent to the fusion distance due to overload and fusion surgeries. Fusion surgeries also cause the destruction of a motion segment and thus adversely affect the lumbar biomechanics. Despite the positive results of fusion surgeries, these complications have made the current method controversial[8].

Diagnosis and treatment methods for disc origin pain have made great progress especially in the last two decades. Conservative methods have become more popular due to the problems caused by fusion surgeries, and fusion surgeries have been avoided unless necessary[9]. However, with the concept of dynamic system becoming a reality in the treatment of degenerative spine, dynamic stabilization has become an increasingly popular approach in the surgical treatment of chronic low back pain due to disc degeneration. Graf[10] thought that if hypermobility in facet joints due to degeneration is removed, its rotation will be controlled. Therefore, he compressed the facet joints with an artificial ligament named after him, using pedicular screws, and he laid the foundations of dynamic stabilization by compressing the facet joints with using artificial ligament and transpedicular screw system[10].

Then, with the emergence of the system's deficiencies, the Dynesis system was developed. However, the surgeon's adjustment of the tension of the spacers used in the Dynesis system has led to the questioning of the dynamism of the system, especially in long-segment stabilization cases[11]. Later, von Strempel et al.[12] introduced a new concept in dynamic stabilization by adding a joint to the screw head. In addition, rods capable of flexion and extension despite various loads have also been produced. PEEK and carbon fiber rods are movable and are offered to compress the bone graft for fusion purposes. However, it is not yet known what features the ideal moving rod should have. Posterior dynamic stabilization may provide an advantage over rigid fixation when used as a complement to the posterior tension band in lumbar fusion surgery[13].

Along with the proliferation of rods produced from different styles and materials, studies have been revealed in the literature, especially on rigid screws and the use of these dynamic rods. Traditional fixation systems made of titanium alloy or stainless

Table 3. Complications by groups

	Screw loose	Rod breakage/ time (mn)	Subcutaneous hematoma/infection
Agile	-	3/39	1/1
Dream	-	4/38.75	-/1
PEEK	1	-/-	1/-

PEEK: Polyetheretherketone

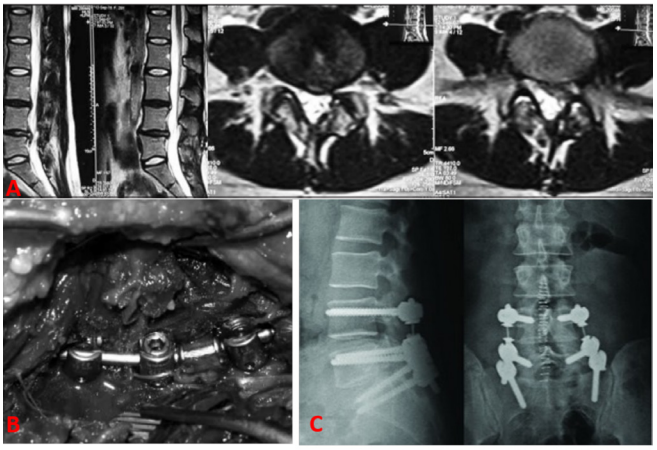

Figure 2. Thirty-year-old male patient with severe left leg pain and recurrent disc hernia. Sagittal and axial section MRIs **(A)** and intraoperative view **(B)** are seen. An agile rod was used with dynamic screws. Antero-posterior and lateral radiographic views after the operation **(C)**
MRI: Magnetic resonance imaging

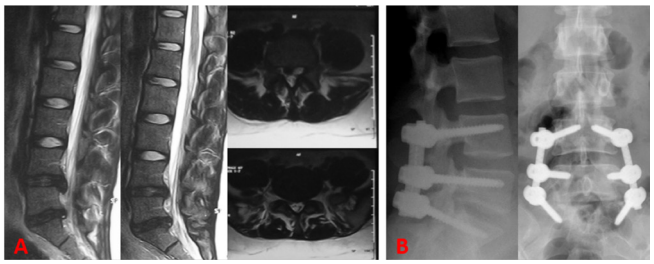

Figure 3. Forty-year-old male patient with back and right leg pain. Sagittal and axial section MRIs **(A)** are seen. A dream rod was used with dynamic screws. Antero-posterior and lateral radiographic views after the operation **(B)**
MRI: Magnetic resonance imaging

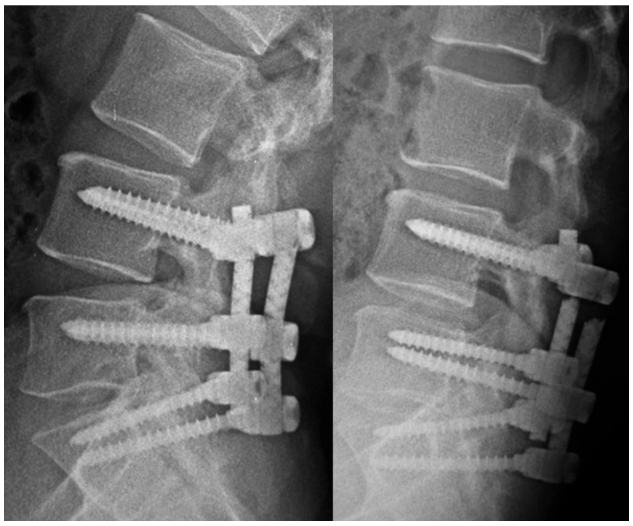

Figure 4. A 53-year-old male patient who was operated for lumbar stenosis. On the 38th month follow-up radiographs, it is observed that the dream rod is broken

steel, which have rigidity levels that are not compatible with bone, would cause abnormal kinematic behavior and load sharing locally. In their study, Wu et al.[14] reported that faster bone fusion and better fusion quality were obtained in the PEEK rod group when the Titanium rod group was compared with the PEEK rod group. Kang et al.[15] also conclude that the PEEK and carbon fiber reinforced-PEEK rod systems reduce the possibility of breakage of the pedicle screw and provide more flexibility to the lumbar spine, compared to titanium rod. Chang et al.[16] compared the PEEK rod system to titanium rod at (L3-L4) level under 10 Nm pure moment and also conclude the same. In the study of Li et al.[17], it was stated that both PEEK rods and titanium rods can provide reliable fixation in lumbar fusion surgery. It was also emphasized that PEEK rods may be better than titanium rods in improving postoperative dysfunction, reducing lower extremity pain, and improving bone graft fusion rate[17].

There is not much data in the literature regarding the use of dynamic screw dynamic rod systems in clinical practice. Our aim was to demonstrate the biomechanical adequacy of the dynamic screw and rod system through finite element and cadaver studies. We used a rod that we developed ourselves and named it the talin rod as the dynamic rod. In this study, the biomechanical effects of dynamic, semi-rigid, and rigid posterior stabilization systems on the lumbar spine were reported. The resulting range of motion (ROM), facet joint loads, intradiscal pressures, and stresses in pedicle screws were observed and compared for all cases. As a result, in hybrid moment flexion, extension, right and left lateral bending, the dynamic screw-dynamic rod combination yielded results closest to those of the intact spine. Similarly, when examining ROM values at the L4-5 segment, it was observed that the dynamic combination provided results close to those of the intact spine[18,19].

In our study, in cases where dynamic stabilization was applied with the dynamic screw dynamic rod system, despite the various dynamic rod structures used, if there was no problem in the system, very satisfactory clinical results were obtained. Significant clinical relief has been achieved in patients both in the early postoperative controls and in the long-term results. However, screw fractures were observed in the dream and agile rod groups after 3 years, and it was revealed that the complaints of the patients recurred. It has been observed that the complaints resolved after the broken rods were replaced with PEEK rods in revision surgeries. Although the use of dynamic screw-dynamic rod is an important alternative to fusion surgery in degenerative disc patients, it has been observed that the type of materials used is directly related to long-term clinical results.

Study Limitations

Clearer and more accurate results can be obtained with prospective randomized controlled studies with a higher number of patients. As it is not a standard operation, this study had to be performed with a small number of patients.

CONCLUSION

The combination of dynamic pedicle screw and dynamic rod implants, obtained from the right material and properly designed, will be an important alternative option among non-fusion dynamic implants, especially in patients with multi-segment degenerative disease.

Ethics

Ethics Committee Approval: This study was approved by the Atatürk University Clinical Research Ethics Committee (decision no: 12, date: 27.01.2022).

Informed Consent: Informed consent was obtained from all participants included in the study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: Ö.A., A.F.Ö., Concept: Ö.A., A.F.Ö., M.K.K., Design: Ö.A., A.F.Ö., Data Collection or Processing: M.Y.A., C.G., Analysis or Interpretation: M.Y.A., C.G., M.K.K., Literature Search: M.Y.A., C.G., Writing: M.Y.A., A.F.Ö.

Conflict of Interest: The authors have no conflicts of interest to declare.

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