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Original Investigation

Utilizing Dynamic Rods with Dynamic Screws in the Surgical Treatment of Chronic Instability: A Prospective Clinical Study

Kronik İnstabilitenin Cerrahi Tedavisinde Dinamik Vidalar ile Dinamik Rodların Kullanımı: Prospektif Klinik Çalışma

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ABSTRACT

AIM: In this study, we examined the results of utilizing the agile posterior dynamic stabilization system with dynamic transpedicular screws in our patients.

MATERIAL and METHODS: Posterior dynamic instrumentation with agile rods and dynamic transpedicular screws was employed in 15 (seven male and eight female) patients (mean age = 42, ranging from 30 to 53). The average follow-up duration was 19 months (ranging from 12 to 25). The primary purpose for the surgery was degenerative disc disease. For subjective evaluation, patients underwent a physical examination utilizing the Oswestry disability index (ODI) and visual analogue scale (VAS). Radiographic parameters, including the angle of lumbar lordosis (LL), angle of segmental lordosis (α) and intervertebral space (IVS), were also evaluated. Both subjective patient evaluations and radiographic parameters were assessed at the 3rd and 12th postoperative months.

RESULTS: Significant postoperative improvements were observed in the ODI and VAS measurements ($P<0.05$). There were no significant differences in the LL, α and IVS parameters. One patient experienced a broken screw.

CONCLUSION: We obtained good clinical results by utilizing dynamic rods with dynamic transpedicular screws.

KEYWORDS: Dynamic stabilization, Lumbar spine, Surgical treatment, Dynamic rod, Dynamic screw

ÖZ

AMAÇ: Bu çalışmada, hastalarımızda uyguladığımız dinamik transpediküler vidalar ile agile posterior dinamik stabilizasyon sisteminin sonuçlarını inceledik.

YÖNTEM ve GEREÇ: Agile rodlar ve dinamik transpediküler vidalardan oluşan posterior dinamik enstrümantasyon 15 (yedi erkek, sekiz bayan)hastada(ortalama yaş=42, 30 ile 53 arasında)kullanıldı. Ortalama takip süresi 19 aydır(12 ile 25 ay arasında). Cerrahi uygulamadaki primer amaç dejeneratif disk hastalığıydı. Subjektif değerlendirmelerde fizik muayene, Oswestry sakatlık indeksi (ODI) ve visual analog skala (VAS) kullanıldı.Radyolojik parametreler olarak lomber lordoz açısı (LL),segmental lordoz açısı (α) ve intervertebral mesafe (IVS) değerlendirildi. Hem subjektif hasta değerlendirmeleri hem de radyolojik parametreler postoperatif 3. ve 12. aylarda değerlendirildi.

BULGULAR: ODI ve VAS ölçümlerinde önemli postoperatif düzelmeler gözlendi ($P<0.05$).LL, α ve IVS parametrelerinde önemli farklılıklar yoktu. Bir hastada vida kırılması gözlendi.

SONUÇ: Dinamik transpediküler vidalar ile dinamik rodların beraber kullanımında iyi klinik sonuçlar gözledik.

ANAHTAR SÖZCÜKLER: Dinamik stabilizasyon, Lomber omurga, Cerrahi tedavi, Dinamik rod, Dinamik vida

INTRODUCTION

The dynamic stabilization system for the spine, also known as the non-fusion pedicle screw stabilization system, was developed to overcome the inherent disadvantages of rigid instrumentation and fusion, such as pseudoarthrosis and adjacent segment degeneration. Dynamic stabilization systems restrict segmental motion, preventing degeneration and deformation of the lumbar spine, and fail to alleviate pain due to segmental instability (30,31). The concept of dynamic stabilization was first described by Graf (16), who used artificial ligaments instead of rods. Graf claimed that rigid stabilization of the degenerative discs along with dynamic support would relieve patient pain. His system, however, is not commonly used. The Dynesys dynamic fixation system is a well-developed artificial ligament system that has been widely used in the treatment of degenerative segmental disease of the lumbar spine for more than ten years (5,8). Biomechanical ligament support relieves stresses in the anterior annulus due to increased loading (1). In the Dynesys system, the rod is tightened by the surgeon. As a result, rods that are overtightened may be too rigid. Conversely, when less than enough force is applied, the rod will remain loose. Because the surgical use of the system is dependent on the surgeon employing it and because a standard procedure has not been achieved, some disadvantages have emerged over time. More recently, a new agile (Medtronic CD Horizon Agile) dynamic stabilization system has been developed, and its usage has been standardized (23). When employed with the rigid screw system, deformity occurred, likely due to an increased load on the rods. As a result, the agile dynamic system was removed from the market. We postulated that dynamic screws would decrease stress and loading on the dynamic rods while providing a firm posterior tension band. In this report, we evaluate and discuss the clinical results of 15 patients in whom dynamic rods and dynamic screws were used together.

MATERIALS and METHODS

All patients were diagnosed by magnetic resonance imaging (MRI) and discogram. In addition, lumbosacral X rays were taken of all patients. The primary symptoms were lower back and leg pain due to degenerative disc disease in 15 patients. Isthmic spondylolisthesis, traumatic broken vertebrae, infections, and overt instabilities due to tumors were excluded from the study group.

The ODI and the VAS were used for preoperative and postoperative subjective patient evaluations (6,19). Physical examinations, direct radiographic views (antero-posterior and lateral) and MRI studies prior to and after surgery were conducted consecutively and recorded at 3 months and 12 months postoperatively. LL, α and IVS were used to evaluate patient outcome (Figure 1).

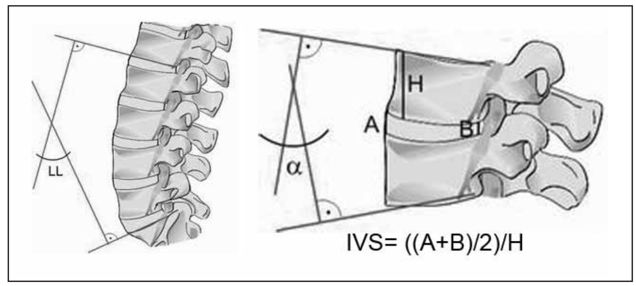

Figure 1: *Measurement of segmental lordotic angles (α), lumbar lordosis angle (LL) and intervertebral space (IVS).*

Patients with degenerative disc disease (15 patients) were treated with the agile posterior dynamic stabilization system between 2007 and 2008 at the Istanbul American Hospital. The Safinaz (Medikon, Turkey) dynamic transpedicular screw was used together with the agile dynamic rod in all patients (Figure 2,4). The rigid segment of the agile rod was used at the microdiscectomy region and the spacer segment of the agile rod was used at the degenerative disc disease region. The average age of the study group was 42 (ranging from 30 to 53; seven males and eight females). The average follow-up duration was 19 months (ranging from 12 to 25). Four of the 15 patients (27%) had a history of spinal surgery. Seven percent of the cases had one level of instrumentation, 80% had two levels and 13% of the cases had three. In addition, 13 of the 15 cases (87%) had a microdiscectomy (Table I).

Figure 2: *Safinaz (Medikon, Turkey) dynamic transpedicular screw.*

The summary of patients' preoperative and postoperative Oswestry scores, VAS scores and LL, α and IVS measurements are given in (Table II).

<u>Surgical Procedure</u>

The transpedicular approach was performed using the Wiltse (33) approach (from inside postero-

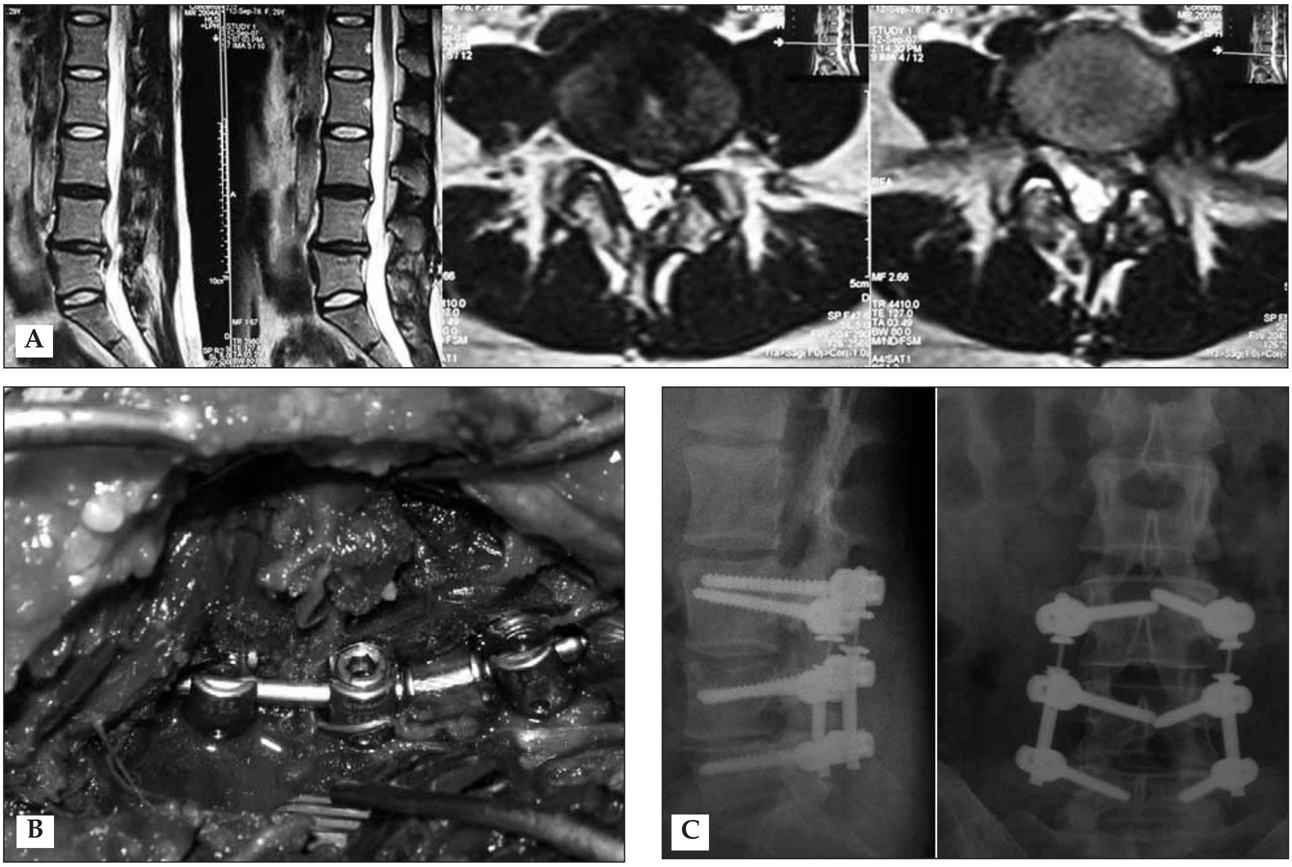

Figure 3: *A 30-year-old female patient was operated on two years previously due to a herniated lumbar disc (patient #6). The patient had severe back and left leg pain.* ***A****) MRI examination showed a recurrence at the same level and a painful black disc at the adjacent segment (confirmed with discography).* ***B****) An agile rod was used with dynamic screws. The mobile part is facing the painful black disc.* ***C****) Antero-posterior and lateral radiographic views after the operation.*

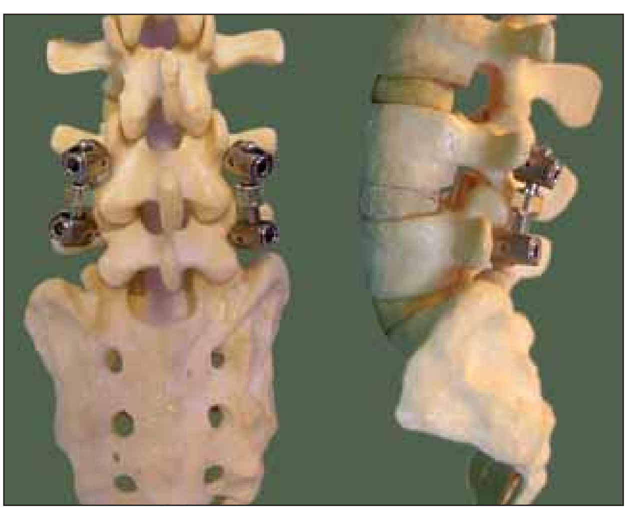

Figure 4: *Agile rod system with safinaz dynamic screws in a saw bone.*

lateral paravertebral muscle tissue). Additional microdiscectomy with the median approach was performed in patients who had disc extrusion or disc protrusion, and dynamic transpedicular screws were placed with a postero-lateral approach. All patients were treated by the same experienced surgeon. The transpedicular screw placement procedure was performed with the aid of a scope. Dynamic transpedicular screws and dynamic agile rods were used in all patients (Figure 3A,B,C).

Statistical Methods

The preoperative and postoperative subjective patient evaluations (VAS and ODI) were compared using the Wilcoxon ranked sum test.

RESULTS

Significant improvements were observed in the ODI and VAS measurements at 3 and 12 months after surgery. Over the first postoperative year, the average Oswestry score improved by 57.60 points, and the VAS score improved by 5.93 points (P<0.05). There were no significant changes for the LL, α and IVS parameters. The average LL and α angles decreased (6.50 and 2.60, respectively) over the first postoperative year (P>0.05), and the average IVS score increased by 0.02 points

Table I: Patient demographic data

Patient No	Age	Gender	Diagnose	Levels	Operation	Complication	Outcome (12 months)
1	34	F	L4-L5-S1 DDD, left L5-S1 RDH	L4-L5-S1	Left L5-S1 microlumbar discectomy, L4-L5-S1 PDTS	Breaking of S1 pedicular screws, bilaterally	Improved after revision surgery in postoperative month 11
2	51	M	L4-L5-S1 DDD, L4-L5 left disc protrusion	L4-L5-S1	Left L4-L5 microlumbar discectomy, L4-L5-S1 PDTS	None	Improved
3	41	M	L3-L4-L5 DDD, L3-L4 and L4-L5 right disc protrusions	L3-L4-L5	Right L3-L4 and L4-L5 microlumbar discectomy, L3-L4-L5 PDTS	None	Improved
4	55	M	L2-L3 and L3-L4 right disc protrusions	L2-L3-L4	Right L2-L3 and L3-L4 microlumbar discectomy, L2-L3-L4 PDTS	None	Improved
5	45	M	L4-L5-S1 DDD, L4-L5 left disc extrusion	L4-L5-S1	Left L4-L5 microlumbar discectomy, L4-L5-S1 PDTS	None	Improved
6	30	F	L3-L4-L5 DDD, L4-L5 left RDH	L3-L4-L5	Left L4-L5 microlumbar discectomy, L3-L4-L5 PDTS	None	Improved
7	38	F	L4-L5-S1 DDD, L5-S1 left disc protrusion	L4-L5-S1	Left L5-S1 microlumbar discectomy, L4-L5-S1 PDTS	None	Improved
8	53	F	L3-L4-L5 DDD, L5-S1 left RDH and L4-L5 right disc extrusion	L3-L4-L5	Left L5-S1 and right L4-L5 microlumbar discectomy,L3-L4-L5 PDTS	None	Improved
9	44	M	L3-L4-L5-S1 DDD	L3-L4-L5-S1	L3-L4-L5-S1 PDTS	None	Improved
10	47	F	L3-L4-L5-S1 DDD, L5-S1 right disc protrusion	L3-L4-L5-S1	Right L5-S1 microlumbar discectomy, L3-L4-L5-S1 PDTS	None	Improved
11	40	F	L3-L4-L5 DDD, L4-L5 left disc extrusion	L3-L4-L5	Left L4-L5 microlumbar discectomy, L3-L4-L5 PDTS	None	Improved
12	34	M	L3-L4-L5 DDD	L3-L4-L5	L3-L4-L5 PDTS	None	Improved
13	35	F	L4-L5-S1 DDD, L5-S1 left disc protrusion	L4-L5-S1	Left L5-S1 microlumbar discectomy, L4-L5-S1 PDTS	None	Improved
14	44	M	L4-L5 DDD, L4-L5 left disc protrusion	L4-L5	Left L4-L5 microlumbar discectomy, L4-L5 PDTS	None	Improved
15	36	F	L4-L5-S1 DDD, L4-L5 and L5-S1 left disc protrusion	L4-L5-S1	Left L4-L5 and L5-S1 microlumbar discectomy, L4-L5-S1 PDTS	None	Improved

DDD: degenerative disc disease RDH: recurrent disc herniation PDTS: posterior dynamic transpedicular stabilization.

Table II: Patient outcomes and radiological evaluations

Patient	PREOP					EARLY POSTOP			3 MONTHS POSTOP					12 MONTHS POSTOP				
No	ODI	VAS	LL°	α°	IVS	LL°	α°	IVS	ODI	VAS	LL°	α°	IVS	ODI	VAS	LL°	α°	IVS
1	68	7	63	3	0.342	60	1	0.452	16	3	60	2	0.357	8	1	61	3	0.327
2	64	8	42	8	0.360	47	2	0.444	24	3	33	2	0.428	12	1	30	0	0.270
3	72	7	57	6	0.403	36	3	0.409	16	3	29	3	0.287	8	2	32	4	0.397
4	64	6	32	16	0.117	25	17	0.140	12	2	31	15	0.171	8	1	32	15	0.157
5	56	7	42	4	0.157	36	1	0.160	18	2	34	3	0.343	6	0	32	3	0.327
6	72	7	23	6	0.250	18	4	0.157	26	4	16	3	0.125	16	2	33	3	0.118
7	76	5	52	21	0.237	49	18	0.285	16	2	45	16	0.173	12	2	44	18	0.187
8	68	8	36	5	0.297	33	3	0.350	8	1	38	11	0.365	6	1	37	4	0.321
9	62	7	31	8	0.125	25	3	0.330	16	2	30	7	0.217	4	0	32	7	0.137
10	56	6	48	12	0.375	41	7	0.363	24	3	22	4	0.281	14	1	32	6	0.311
11		6	32	8	0.250	14	6	0.266	6	1	26	7	0.257	6	0	30	7	0.247
12	68	7	45	9	0.257	30	4	0.274	32	4	43	11	0.264	4	0	32	3	0.307
13	68	8	41	5	0.217	39	3	0.167	26	3	27	6	0.267	*6*	*2*	*26*	*7*	*0.257*
14	58	7	55	8	0.231	54	9	0.227	18	2	52	7	0.222	6	1	50	7	0.221
15	72	8	57	14	0.327	62	11	0.314	16	2	61	14	0.296	*8*	*1*	*55*	*7*	*0.327*

ODI: Oswestry Disability Index; **VAS:** Visual Analogue Scale; **LL:** Lumbar Lordosis Angle; **α :** Segmental Lordosis Angle; **IVS:** Intervertebral Space

postoperatively (P>0.05). The averaged pre- and postoperative data are summarized in (Table III).

There were no complications and none of the patients died during surgery. One patient required a second surgery due to a broken screw.

DISCUSSION

Lumbar degenerative disc disease is quite common and presents with a complex pathology with high levels of morbidity. Back pain is most likely due to disc degeneration (18,20,24). According to Frymoyer, primary segmental instability develops due to degenerative disc disease (12). Notably, it is thought that degenerative disc disease is one of the major causes of spinal instability (11,12,13,21,24). The pathology of discogenic pain and degenerative instability has been described by Kirkaldy-Willis and Farfan (20). They postulated that minimal differences in segmental stability might lead to major dysfunctions. Degenerative instability develops as a result of numerous causes, including disc degeneration, expansion in hypertrophic posterior facet joints, looseness in ligaments and increased movement (20).

A number of treatment protocols have been used on such patients, although there is no agreement on the best treatment protocol. The most common symptoms

Table III: Averages of preoperative and postoperative data points

	VAS	ODI	LL	α	IVS
Preoperative	6.93	65.86	43.73	8.86	0.26
Early Postoperative (3rd Day)	-	-	37.93	6.13	0.28
3-Month Follow-up	2.46	18.26	36.46	7.40	0.27
12-Month Follow-up	1	8.26	37.20	6.26	0.28

VAS: Visual Analogue Scale, **ODI:** Oswestry Disability Index, **LL:** Lumbar Lordosis Angle, α : Segmental Lordosis Angle, **IVS:** Intervertebral Space.

of lumbar degenerative disc disease are lower back pain and/or radicular pain with or without neurological deficit. Medication, local injections, epidural steroid applications, physical therapy, and muscle extension exercises, given separately or in combination, are treatment options for such patients. Spinal surgery includes three main components to reduce pain and disability: decompression, stabilization and correction of deformity if needed. Various pathological conditions necessitate the combination of these procedures. Nonetheless, stabilization and fusion of spinal segments has become one of the most important methods in the treatment of spinal pathologies (3,30).

Although the state-of-the-art of surgical treatment has been the spinal fusion procedure, questionable clinical results have fueled research on spinal biomechanics. Adjacent segment degeneration is a known consequence of spinal fusion (3,9,10,14,15,25,30). Lehrman found that 30% of patients had a narrow spinal canal and 50% had instability in the upper adjacent segment in a long-term posterior fusion series (22). Although the fusion rate was found to be significantly different between the instrumented and non-instrumented groups, there was no significant difference in clinical outcome, suggesting poor correlation between clinical outcome and fusion (7). In his five-year follow-up study, Rahm reported that adjacent segment degeneration occurred in 31% of patients after lumbar fusion with instrumentation. Moreover, as a result of postero-lateral or interbody fusion with autogenous iliac crest graft, 39% of patients reportedly suffered from donor site morbidity (2,35). Persistent donor site pain in 55% of patients even one year after the operation has also been described (29). As a consequence of such complications after fusion, the search for an alternative treatment for lumbar degenerative disc disease widened, and the posterior dynamic transpedicular stabilization system, which is less rigid, has become more popular.

While trying to maintain the motion in the joint, dynamic stabilization aims to remove the pain by distributing the weight between anterior and posterior elements of the spine. Mobile stabilization systems neutralize injurious forces and restore normal functions of the spine segments, protecting the adjacent segments (3,30).

Posterior dynamic transpedicular stabilization systems have stabilization effects in all three primary directions and tend to reduce mobility (i.e., flexion, extension and lateral bending). They also allow for motion in the axial rotation. In flexion and extension, however, the range-of-motion (RoM) of the dynamic device is clearly higher. The dynamic device provides a controlled motion that may allow more load to be distributed to the bridged segment and less stress to be concentrated on the implant, especially on the caudal side of the pedicle screws. These dynamic devices theoretically have the advantage of reduced stress-shielding, protecting the adjacent segment from degeneration and diminishing implant failure (34).

The dynamic concept was introduced when Graf (16) used artificial ligaments instead of a rod in the posterior dynamic system for the first time in 1984. Graf placed transpedicular screws together with artificial ligaments and stated that dynamically supporting degenerative discs would remove the pain. The Graf ligament system has three disadvantages: 1) loosening in the artificial ligaments, 2) failing to achieve standard ligament fixation, and 3) spinal stabilization by compression. In compression, the asymmetry of the stress distribution increases the eccentric load, causing degeneration (26). Fluctuations in load distribution put greater load on the facets in erect postures (27). Because of the aforementioned disadvantages, use of this system is currently limited.

The Dynesys dynamic fixation system is more advanced than other artificial ligament systems and has been widely used for the treatment of degenerative segmental disease of the lumbar spine since 1994 (5,8). Biomechanical ligament support relieves stress in the anterior annulus due to increased loading (1). One advantage of the Dynesys system over the Graf ligament system is that compression tension is prevented by the spacer placed in between while applying compression to the ligament. One disadvantage of the Dynesys system, however, is the failure to achieve a standard of compression stiffness, which is left to the discretion of the surgeon. The reliability of this system is under debate. It has, however, been employed in Europe for more than ten years, and some studies remain critical (3,17) or neutral (30) on Dynesys, while others support it (28,29,31).

The agile posterior dynamic stabilization system was developed in 2007 in order to overcome problems with the Dynesys system. It is simple to utilize the agile system with its standard usage. The agile system operates on the same principle as Dynesys. Biomechanical studies concluded that the agile rod provides stabilization in the spinal segment after the procedure, and studies have reported that the shifted rotation center returned to normal, and upper vertebrae performed normal rotation on lower vertebrae (23). After being introduced to the market, agile dynamic rods were used with rigid transpedicular screws. As a result, deformities of dynamic rods due to overloading and stress were observed. Finally, its production was terminated and the product was removed from the market.

The dynamic pedicular screw-rod system allows potential sagittal movement in the hinge area between the screw head and screw leg. In this system, reduced loading stress during flexion in the joint link between rod and screw leads to a lower rate of implant failure. Moreover, there is a reduced stress-shielding effect on bone, and some of the load can be transferred from the implant to (and be shared by) the spine (32).

Bozkus et al. found that using dynamic transpedicular screws with rigid rods produced more RoM than standard screws and that less load is transferred to standard screws leading to the reduced stress-shield (4). Bozkus et al. showed that stabilization with dynamic screws provides much the same stabilization as a rigid system (4). Dynamic screws with rigid rods may be accepted, as a semi-rigid system particularly increased the level of stabilization. Standardized agile rods with dynamic screws have been used to achieve a more dynamic system. The movable part of the standardized agile rod provides physiological movement, at least in one level.

We used dynamic rods with dynamic transpedicular screws in one-, two- and three-level stabilization. In our 19-month follow-ups, we observed that using dynamic screws and dynamic rods together prevented deformity in the dynamic rods because of a lower load transfer that was due to a decreased stress-shield. Previous studies have reported similar results (32,34). We were unable to compare our clinical results as we could not find similar studies in the literature.

There is a need for biomechanical and clinical studies to show that using dynamic transpedicular screws with dynamic rods produce positive results. We believe that the combination of dynamic pedicle screw and dynamic rod implants will be an important alternative option among non-fusion dynamic implants in the near future, especially in patients with multi-segmental degenerative disease.

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