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Original Investigation

A Rehabilitation Protocol for Patients with Lumbar Degenerative Disc Disease Treated with Posterior Transpedicular Dynamic Stabilization

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ABSTRACT

AIM: To evaluate the efficacy of the rehabilitation protocol on patients with lumbar degenerative disc disease after posterior transpedicular dynamic stabilization (PTDS) surgery.

MATERIAL and METHODS: Patients (N=50) with single level lumbar degenerative disc disease were recruited for this study. Patients had PTDS surgery with hinged screws. A rehabilitation program was applied for all patients. Phase 1 was the preoperative evaluation phase. Phase 2 (active rest phase) was the first 6 weeks after surgery. During phase 3 (minimal movement phase, 6-12 weeks) pelvic tilt exercises initiated. In phase 4 (dynamic phase, 3-6 months) dynamic lumbar stabilization exercises were started. Phase 5 (return to sports phase) began after the 6th month. The primary outcome criteria were the Visual Analogue Pain Score (VAS) and the Oswestry Disability Index (ODI). Patients were evaluated preoperatively, postoperative 3rd, 12th and 24th months.

RESULTS: The mean preoperative VAS and ODI scores were 7.52±0.97 and 60.96±8.74, respectively. During the 3rd month, VAS and ODI scores decreased to 2.62±1.05 and 26.2±7.93, respectively. VAS and ODI scores continued to decrease during the 12th month after surgery to 1.4±0.81 and 13.72±6.68, respectively. At the last follow-up (mean 34.1 months) the VAS and ODI scores were found to be 0.68±0.62 and 7.88±3.32, respectively. (p=0.0001).

CONCLUSION: The protocol was designed for a postoperative rehabilitation program after PTDS surgery for patients with lumbar degenerative disc disease. The good outcomes are the result of a combination of very careful and restrictive patient selection, surgical technique, and the presented rehabilitation program.

KEYWORDS: Dynamic lumbar stabilization, Posterior transpedicular dynamic stabilization, Exercise after spine surgery, Rehabilitation after spine surgery, Degenerative disc disease

INTRODUCTION

Intervertebral discs serve as the primary stabilizers of the functional spinal unit (1). Disc degeneration and loss of disc height may result in segmental instability, which is one of the major causes of chronic low back pain (7,18,33).

Until recently, surgical fusion was the gold standard. Reported unsatisfactory clinical outcomes such as acceleration of adjacent segment disease, increased risk of pseudoarthrosis and restriction of spinal motion have caused surgeons to consider alternative surgical options (8,19,25,27,34). However, a new study pointed out that adjacent segment disease

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development following fusion surgery may have no influence on patients' self-rated clinical outcome in terms of pain and disability (26). Nowadays, motion preservation surgery has been attempted in the treatment of lumbar degenerative disc diseases to eliminate or minimize the complications observed with the fusion procedure. There are numerous newly developed different dynamic systems such as interspinous devices, total facet replacement systems, artificial disc replacement systems and pedicle screw based stabilization systems (5,9,10).

Posterior transpedicular dynamic stabilization (PTDS) systems have become increasingly popular as an alternative to fusion. These are minimally invasive techniques and have the advantage of retention and protection of intervertebral discs. The most prominent advantage of dynamic stabilization systems is the ability to maintain or restore controlled motion at the operated level. This contributes to increased total range of motion and natural anatomic alignment in addition to reduced risk of accelerated degeneration of adjacent segments (6,32,40).

Patients treated with dynamic stabilization systems for degenerative disc disease need a well-planned rehabilitation program to return to normal daily living activities. Rehabilitation programs following PTDS surgery should include assessment and treatment of the entire kinetic chain (2,4,14,37).

The aim of this prospective study was to define the characteristics, outcomes, postoperative care and rehabilitation principles of patients who had PTDS surgery for lumbar degenerative disc disease. We have designed a protocol to rehabilitate these patients because there is no standard protocol for the purpose. We have hypothesized that well-controlled dynamic lumbar stabilization exercises can provide a safe, secure and effective rehabilitation program after PTDS surgery.

MATERIAL and METHODS

This was an open prospective auto-controlled trial. Patients younger than 65 years of age with degenerative disc disease, which was confirmed by magnetic resonance imaging (MRI), were included in the study. All patients had axial low back pain without radicular components. Provocative discography procedures were performed to identify the painful disc in patients with more than one black disc on the MRI (Nineteen out of 50 patients had more than one black disc) (Figure 1A-C).

All patients had been unresponsive to a minimum of 6 months of conservative treatment consisting of a physiotherapy program, core strengthening exercises, and minimally invasive procedures such as radiofrequency denervation of the disc (Appendix 1).

Our exclusion criteria were prior lumbar spinal surgery at any level, painful multi-level degenerative disc disease, radicular pain, osteoporosis, metabolic bone disease, degenerative spondylolisthesis, spinal stenosis, scoliosis, spinal tumors, or fracture due to previous trauma, and active systemic or surgical site infection. Additional exclusion criteria were chronic steroid use, metal allergy, pregnancy, autoimmune

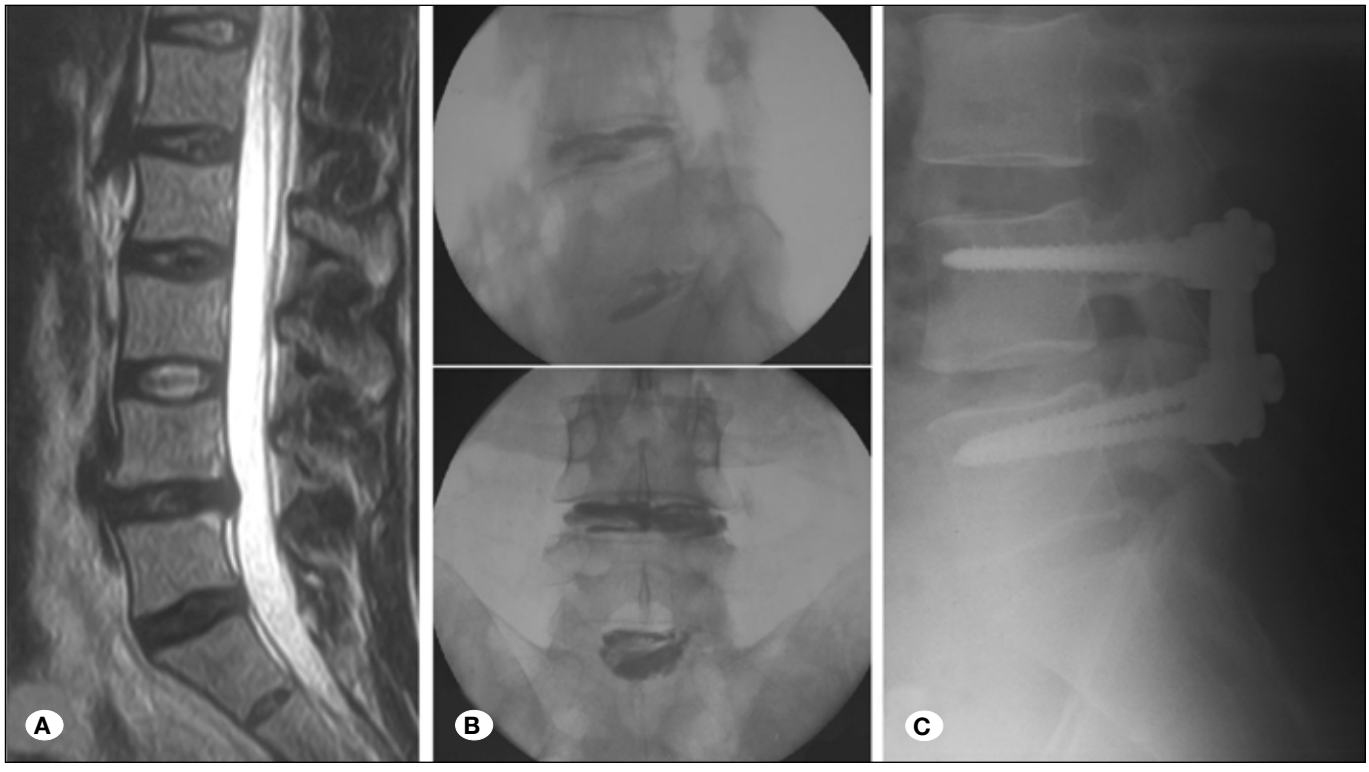

Figure 1: A) Sagittal T2 lumbar MRI showed L4-5 and L5-S1 degenerative disc disease **B)** Discography showed normal findings at L5-S1 level. There was a leakage at the L4-5 level. **C)** Therefore only the L4-5 level was stabilized with dynamic instrumentation.

disorders, psychosocial disorders, and morbid obesity (body mass index >40%) (Appendix 2).

Participants had undergone PTDS surgery between 2004 and 2012. Surgery had been performed on 50 participating patients (26 men, 24 women) with a mean age of 44±9.85 years (range, 24-63 years). The mean weight of the patients was 67.7 kg (range 52-85 kg). The mean follow-up time was 34.1 months (range 24-60 months).

In a previous article, we published the surgical technique and outcome of our pilot study (30). The study presented here reports the rehabilitation protocol applied to 50 patients.

All patients were operated with the use of PTDS at single level. The dynamics of the system depend on hinged screws (Cosmic, Ulrich AG, Germany and Saphinas, Medikon Ankara, Turkey) (Figure 2A, B). Twenty-seven patients had posterior dynamic stabilization at the L4-L5 level, and 23 patients had stabilization at the L5-S1 level.

Surgical Procedure

All operations were performed under general anesthesia on a spinal operation table. The surgical approach was through a double incision (20/50 patients), which was approximately 3 cm lateral to the median line on both sides or through a midline incision (30/50 patients) (Figure 3A, B). The fascia was opened approximately 3 cm lateral to the median line on both sides. The instrumentation was performed as a minimally invasive technique through transmuscular approach because there was no need of decompression (30). Following blunt dissection of the muscles, the screws were placed as per routine of transpedicular instrumentation. The C-arm fluoroscopy control (50/50 patients) and neuromonitoring technique (30/50 patients) were used to achieve proper screw position (Figure 4A-C).

Clinical Evaluation

The patients were evaluated preoperatively by the same multidisciplinary team composed of a neurosurgeon, a pain specialist and a psychiatrist. Patients were operated on by the same surgical team. The primary outcome criteria were the Visual Analogue Pain Score (VAS) and the Oswestry Disability Index (ODI). Pain evaluated with VAS ranging from 0 to 10, with 0 representing no pain and 10 the worst pain that could be experienced. We evaluated functional disability with the ODI, which has previously been validated. This is a patient-completed questionnaire that gives a subjective percentage

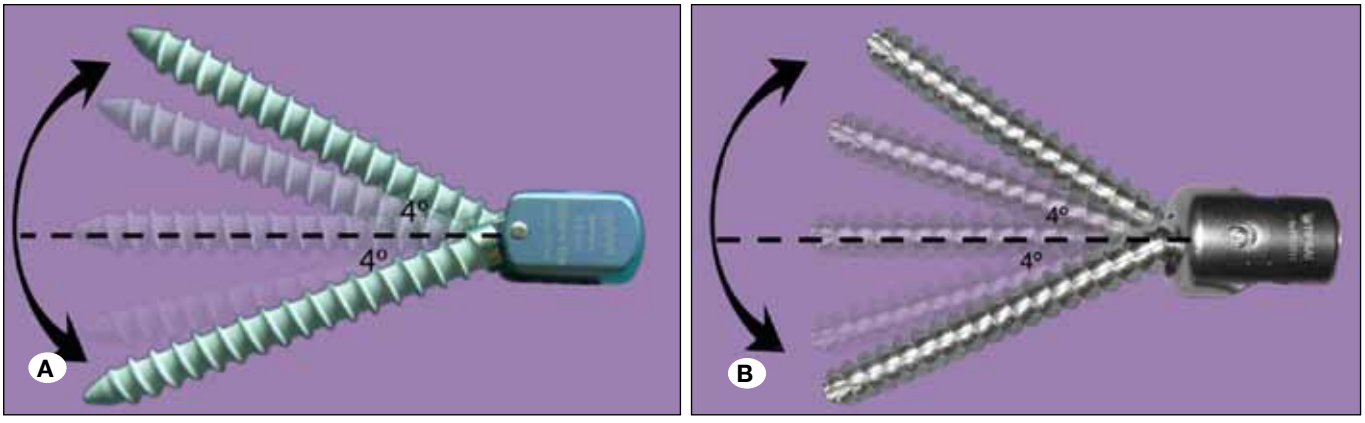

Figure 2: Both Cosmic **(A)** and Saphinas **(B)** systems have hinged screws that allow controlled motion.

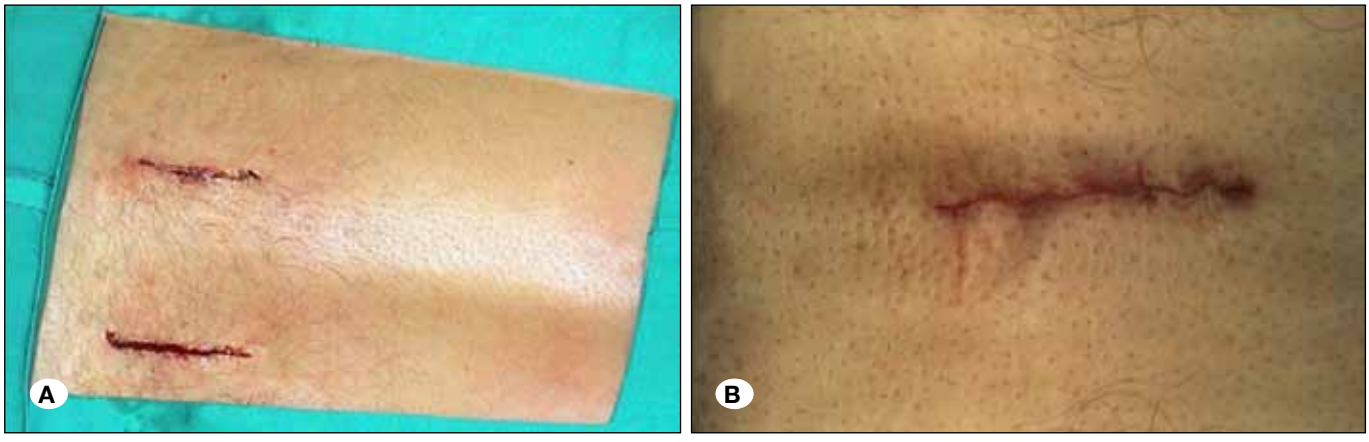

Figure 3: A) 20 patients operated with the bilateral approach and **B)** 30 patients operated with the single midline approach. In both approaches, the screws are placed through a transmuscular approach.

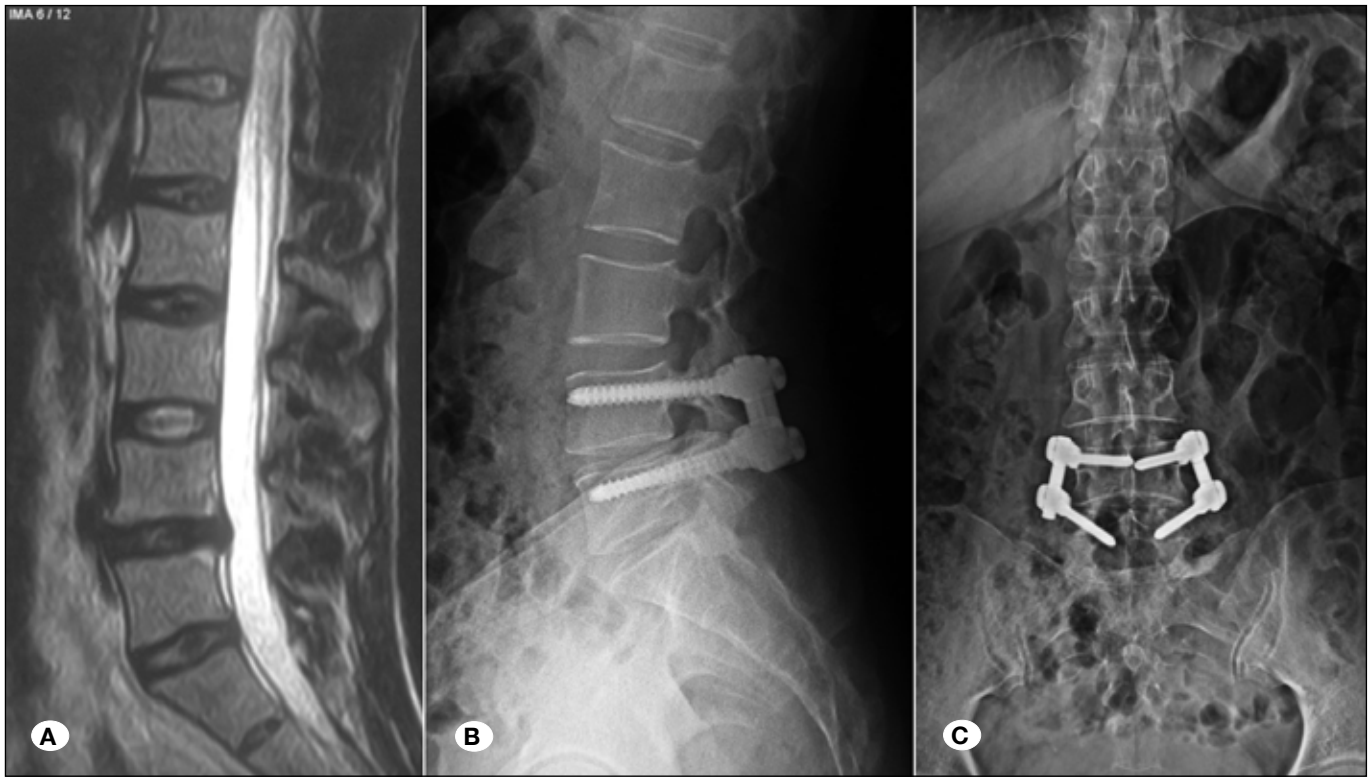

Figure 4: A 52-year-old female patient complained of severe low back pain, and lumbar MRI showed L4-5 degenerative disc disease **(A)**. PTDS was applied (Cosmic) **(B, C).**

score of the level of function in activities of daily living. It consisted of 10 questions related to pain, self-care, lifting, walking, sitting, standing, sleep, sexual life, social life, and traveling. Patients grade the level of discomfort on the ordinal scale (16,44).

Clinical evaluations were performed preoperatively and on the postoperative 3rd, 12th, and 24th months.

The same exercise program was given to each patient during the follow-up period. To determine the compliance of the patients with the exercise program, patients were invited to the rehabilitation department weekly between weeks 3 and 12. During these visits, patients were asked to stop the exercises that provoked pain and to continue with the pain-free exercises. Patients were instructed on how to apply the back protection principles during daily activities.

Stages of the Rehabilitation Protocol

Rehabilitation after PTDS surgery was composed of 5 main phases (Appendix 3) (Figure 5A-D).

Phase 1- Preoperative evaluation phase: Patients were informed about the details of the surgery and the postoperative period. Low back protection principles were explained in detail (Appendix 4).

Phase 2- Active rest phase (0-6 weeks): Patients were mobilized on the first postoperative day. Correct posture was taught, and the patients were informed about the movements aggravating the pain. Prolonged sitting and standing in the same position, axial rotation, lumbar hyperflexion and hyperextension, and heavy-lifting are undesirable during this period.

Phase 3- Minimum movement phase (6-12 weeks): Pelvic tilt exercises were initiated during this phase. Walking and swimming in pain-free limits were suggested. Duration and frequency of walking and swimming were advised based on the patient's tolerance.

Phase 4- Dynamic Phase (12 weeks-6 months): This phase was initiated after the consultation with the surgical team. Dynamic lumbar stabilization exercises were started. Avoidance of movements rotating the lower back is important. Exercises stabilizing the spine by only moving arms and legs in supine and standing positions were initiated. Exercises were progressed based on the patient's tolerance.

Phase 5- Return to sports phase (after 6 months): Patients were allowed to participate in low resistance and high repetition sport activities. Contact sports were allowed, but the risks of falling and impact were explained to the patients. Special precautions were taken according to the preferred sports activity, and the training program was individualized.

Statistical Analysis

Statistical calculations were performed with (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) program for Windows. In addition to standard descriptive statistical calculations (mean and standard deviation, median,

interquartile range), the variables indicate a normal distribution and repeated one-way ANOVA was used in the comparison time groups. The post hoc Newman Keuls multiple comparison test was utilized in the comparison of subgroups of variables that did not indicate a normal distribution. The Friedman test was used in the comparison of time groups, and post hoc Dunn's multiple comparison test was utilized to compare subgroups. Statistical significance level was established at $p<0.05$.

RESULTS

Twenty-six men and 24 women with an average age of 44±9.85 years (range, 24-63 years) formed the study group.

Clinical Outcome

Table I shows the VAS and ODI scores for the preoperative and postoperative data obtained during the 3rd, 12th and 24th month follow-up. The mean preoperative VAS and ODI scores were 7.52±0.97 and 60.96±8.74, respectively. During the 3rd month, VAS and ODI scores decreased to 2.62±1.05 and 26.2±7.93, respectively. VAS and ODI scores continued to decrease during the 12th month after surgery to 1.4±0.81 and 13.72±6.68, respectively. In addition to these, at the last follow-up the VAS and ODI scores were found to be 0.68±0.62 and 7.88±3.32, respectively. There was a statistically significant difference between preoperative, 3rd month, 12th month and 24th month ODI scores (p=0.0001). Preoperative ODI scores were significantly higher than ODI scores during the 3rd, 12th, 24th months (p=0.0001). The ODI scores during

Table I: a) Oswestry and VAS Scores Preoperatively and 3, 12, and 24 Months Postoperatively

	Oswestry	VAS	
	mean±SD	**mean±SD**	**Median (IQR)**
Preop	60.96±8.74	7.52±0.97	8 (7-8)
3. mo	26.2±7.93	2.62±1.05	3 (2-4)
12. mo	13.72±6.68	1.4±0.81	1 (1-2)
24. mo	7.88±3.32	0.68±0.62	1 (0-1)
P	0.0001	0.0001	

b) P Values of Changes in VAS and ODI Scores Between Preoperative and Postoperative Months 3, 12, and 24

	Oswestry	VAS
Preop / 3. mo	0.0001	0.0001
Preop / 12. mo	0.0001	0.0001
Preop / 24. mo	0.0001	0.0001
3. mo / 12. mo	0.0001	0.0001
3. mo/ 24. mo	0.0001	0.0001
12. mo / 24. mo	0.0001	0.0001

Repeated ANOVA was used to compare groups, post hoc Newman Keuls multiple comparison test was utilized to compare subgroups with variables that did not indicate a normal distribution; the Friedman test was used to compare groups, and post hoc Dunn's multiple comparison test was utilized to compare subgroups. Statistical significance level was established at p<0.05.

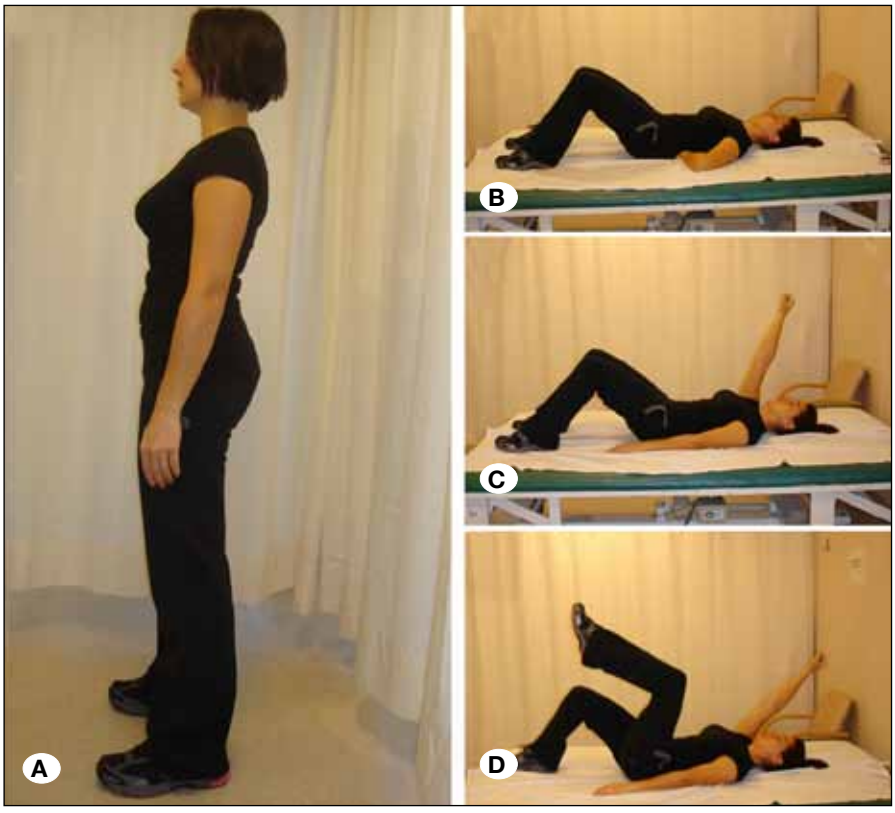

Figure 5: A) Phase 2, correct posture; **B)** Phase 3, pelvic tilt exercises; **C-D)** Phase 4-5, dynamic phase exercises.

the third month were significantly higher than during the 12th and 24th months (p=0.0001). The ODI scores during the 12th month were significantly higher than during the 24th month (p=0.0001) Mean ODI scores (Figure 6) were significantly different between preoperative values and postoperative months 3, 12 and 24. (p=0.0001) (Table I).

There was a statistically significant difference between preoperative VAS scores and scores during postoperative months 3, 12 and 24 (p=0.0001). Preoperative VAS scores were significantly higher than VAS scores during the 3rd, 12th, 24th months (p=0.0001). The VAS scores during the 3rd month were significantly higher than during the 12th and 24th months (p=0.0001). The VAS scores during the 12th month were significantly higher than during the 24th month (p=0.0001). Mean VAS scores (Figure 7) were significantly different during the preoperative times and postoperative months 3, 12 and 24. (p=0.0001) (Table I).

Complications

Two patients required reoperation on postoperative day 2 due to screw malposition (Figure 8). One patient had wound infection and treated with antibiotics. There was a screw fracture in one patient and screw loosening in two patients (Figure 9A,B) during postoperative months 11 and 14, respectively. The fractured and loose screws were replaced with larger diameter screws.

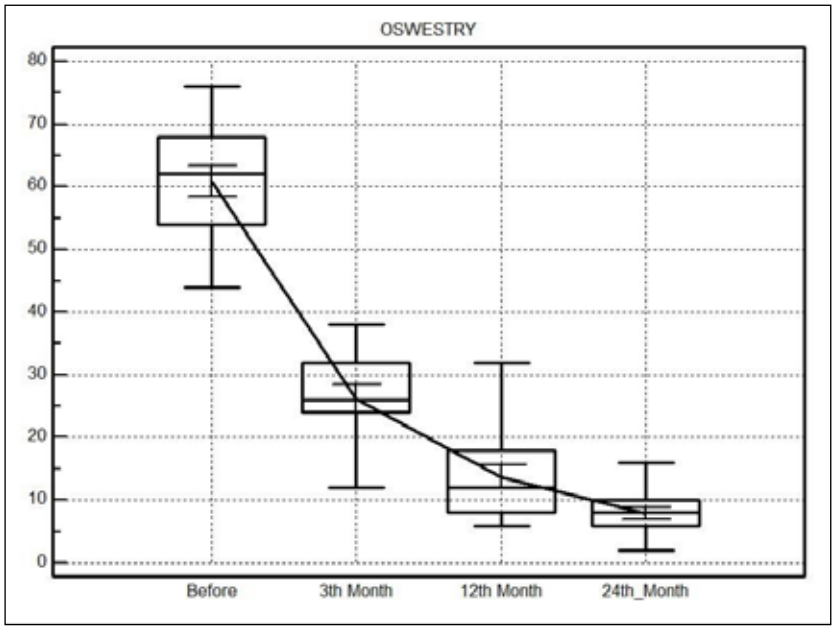

Figure 6: Oswestry scores preoperatively and on postoperative months 3, 12, and 24.

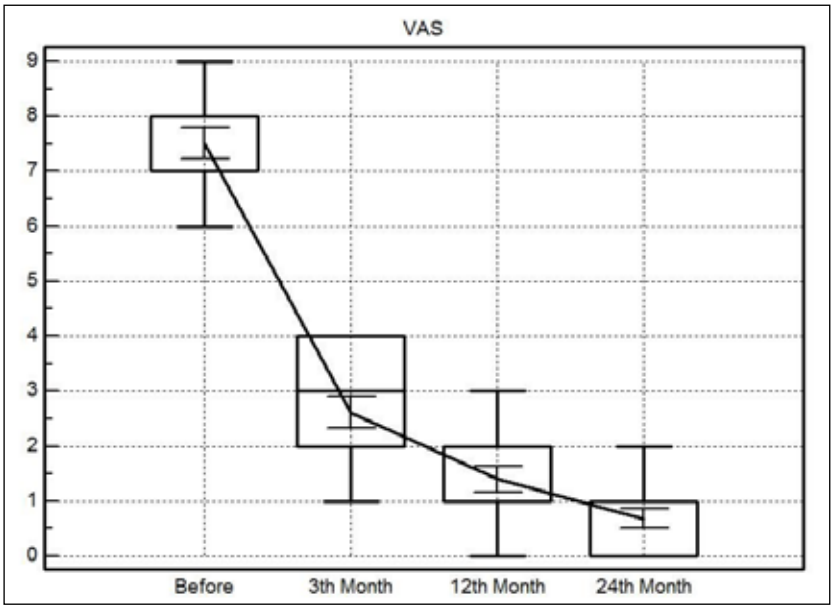

Figure 7: VAS scores preoperatively and on postoperative months 3, 12, and 24.

DISCUSSION

Fusion surgery, which is the standard surgical treatment option for painful lumbar degenerative disc disease, has a 30% risk of pseudoarthrosis, a 25% risk of adjacent segment disease, and use of a postoperative orthotic device results in a 4-12 month period of limited activity and donor site morbidity (13,21,42). Suboptimal clinical satisfaction rates reported even in patients with radiologically observed fusion have led some authors to search for new alternative surgical options (3,17,24,41).

New dynamic techniques such as total disc replacement (TDR) and PTDS have been developed over the last two decades with promising clinical results (11,22,23,31,35,38,43). However, the results regarding outcomes after 5 years with the TDR method were not superior to the fusion method (20). TDR is major surgery, and surgical revision is very difficult. All these factors have made the PTDS method more appealing in the last few years because it is minimally invasive surgery compared to TDR and fusion techniques. Similar clinical outcomes are achieved with PTDS. Oktenoglu et al. published a study comparing the clinical results of anterior lumbar TDR and PTDS in the treatment of single level degenerative disc disease in 50 patients (25 in each group) (31). They concluded that both dynamic systems provided spine stability with the PTDS having a slight advantage over the TDR with less blood loss, shorter operative time and hospital stay. Our findings in VAS and ODI scores were concordant with this study. PTDS is a new technique and the literature therefore lacks randomized controlled studies. Biomechanical studies have shown that PTDS stabilizes the spine almost as strongly as rigid instrumentation systems (10,39). Oktenoglu et al. reported a unique biomechanical study and found that a dynamic system (dynamic rod and dynamic screws) restores the instable spinal segments to almost normal ROM (15,29). There are recent studies on PTDS with encouraging clinical results showing that PTDS provides stabilization similar to posterior rigid stabilization with fusion surgery (10,22,23,30,39).

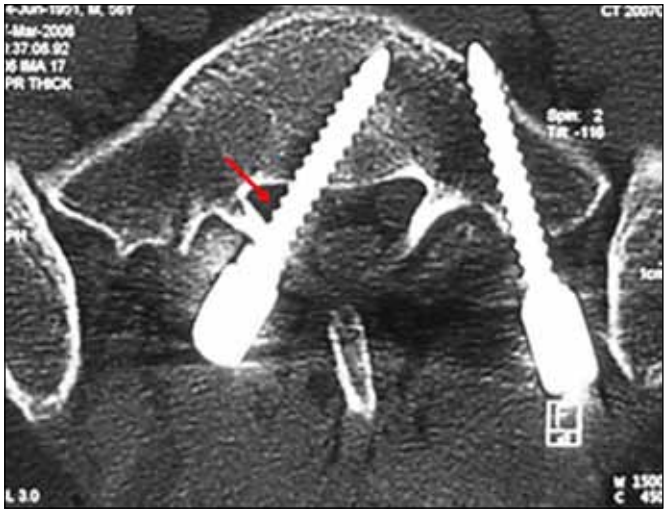

Figure 8: A postoperative CT scan shows malpositioning of the right L5 screw (red arrow).

In this open prospective, auto-controlled study we followed 50 patients younger than 65 years of age who had undergone PTDS surgery due to single level degenerative disc disease. VAS and ODI scores significantly improved following surgery (Table I).

Our findings regarding VAS and ODI scores were similar to study by Kaner et al. in which they compared PTDS and posterior rigid stabilization with fusion in patients with degenerative spondylolisthesis (22). They concluded that PTDS is an important alternative method to fusion in patients with chronic instability and degenerative spondylolisthesis.

Von Strempel et al. reported very encouraging results relating the stabilization of the degenerated lumbar spine in the non-fusion technique with the Cosmic posterior dynamic system (43). They compared the clinical and the radiological results of 96 patients who had Cosmic posterior dynamic system surgery with 75 patients with conventional posterolateral

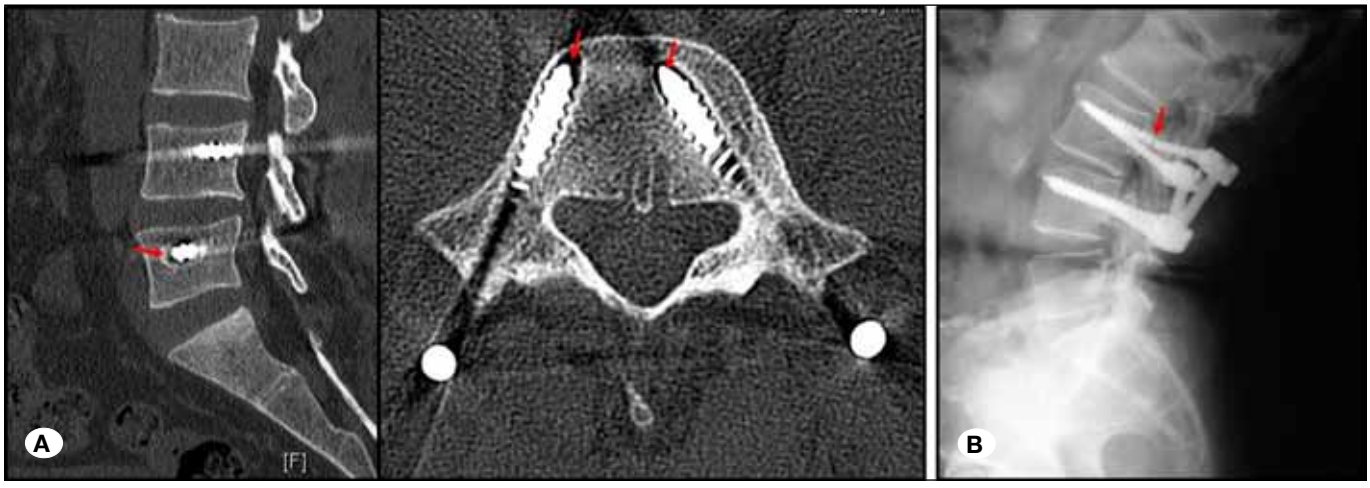

Figure 9: A) CT scan shows bilateral L5 screw loosening; radiolucent area around the screw depicts loosening (red arrow); **B)** X-ray shows screw fracture at the L3 vertebra.

fusion surgery, with a follow-up of 24 months. In the non-fusion group, VAS scores improved from 5.7 preoperatively to 2.9 postoperatively. In the fusion group, the VAS scores improved from 5.8 preoperatively to 3.4 postoperatively. ODI scores in the non-fusion group were 50.8 preoperatively and 34 postoperatively. In the fusion group, the ODI scores were 47.4 preoperatively and 29.4 postoperatively. The VAS and ODI scores in both groups showed good improvement without any significant differences, which is similar to our findings. They concluded that medium term results with the Cosmic system are very encouraging.

Putzier et al. investigated the effect of dynamic stabilization on the progression of segmental degeneration after nucleotomy (35). Eighty-four patients underwent nucleotomy of the lumbar spine for the treatment of symptomatic lumbar disc prolapse, and in 35 of these cases additional dynamic stabilization (DYNESYS) was performed. ODI and VAS scores improved significantly after 3 months. These findings are similar to our study.

In their pilot study, Oktenoglu et al. reported significant improvements in the clinical outcome measurements of VAS and ODI scores in patients treated with PTDS for lumbar degenerative disc disease (30). Our study has comparable results with a much larger number of patients.

In our study, rehabilitation planning after PTDS was based on the biomechanics of the dynamic system, collagen tissue healing timelines and the biology of implant osseointegration.

Collagen tissue healing is primarily divided into three phases including the inflammatory phase, proliferative phase and remodeling (maturation) phase. Remodeling of the collagen continues until permanent repair tissue is formed. The maturation phase varies in duration, and collagen healing takes from 12 to 16 weeks to up to 1 year to reach final tensile strength (12).

The osseointegration process refers to direct structural and functional connections between the living bone and the surface of a load-carrying implant. An implant is considered osseointegrated when there is no movement between the implant and the bone with which it has direct contact (28).

Tissue response to implant as peri-implant osteogenesis begins on the first day after implant fixation. Trabecular bone formation around the implant begins 10-14 days after surgery. Mixed bone texture of a woven and lamellar matrix can be found around titanium implants at three months post-implantation, and peri-implant bone remodeling may last up to one year (28,36).

Various factors may enhance or inhibit osseointegration (36).

Aggressive rehabilitation before the completion of osseointegration, and very early advanced exercise programs may result in loosening of the implant.

A rehabilitation program should consider all these factors. Our rehabilitation program following PTDS was divided into 5 main phases depending on the biomechanics of dynamic system, the collagen tissue healing timelines and biology of implant osseointegration.

A multidisciplinary approach is necessary in the management of patients with degenerative spine. Close communication and collaboration between the surgeon, pain specialist, rehabilitation team and patient is crucially important for the best functional outcome.

The limitation of this study was the lack of control group. Although our study did not include a control group, we compared our findings with relevant literature.

CONCLUSION

The protocol was designed for a postoperative rehabilitation program after posterior transpedicular dynamic stabilization for patients with lumbar degenerative disc disease. The good outcomes can be attributed to a combination of very careful and restrictive patient selection, surgical technique, and the presented rehabilitation program.

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Appendix 1: Inclusion Criteria

- Age <65 years
- Single-level disc degeneration at 1 level from L4-S1
- Patients with axial low back pain, without radicular pain
- Degenerative disc disease confirmed by magnetic resonance imaging
- Positive provocative discography findings at one level, in patients with more than one black disc in the MRI
- No spondylolisthesis at the disease level
- Unresponsive to 6 months of conservative treatment
- Unresponsive to minimally invasive procedures

Appendix 2: Exclusion Criteria

- Prior lumbar spinal surgery at any level
- Multilevel degenerative disc disease
- Radicular low back pain
- Osteoporosis or metabolic disease
- Degenerative Spondylolisthesis
- Spinal Stenosis
- Scoliosis
- Spinal tumors
- Previous trauma to L4 or L5, S1 levels (compression or burst)
- Active systemic/surgical site infection
- Chronic steroid use
- Metal allergy
- Pregnancy
- Autoimmune disorders
- Psychosocial disorders
- Morbid obesity, body mass index >40%

Appendix 3: Stages of the Rehabilitation Protocol After Posterior Transpedicular Dynamic Lumbar Stabilization Surgery

Phase I: Preoperative Evaluation Phase
- Information about the operation and postoperative period
- Patient education (low-back protection principles)

Phase II: Active Rest Phase (0-6 weeks)
- Mobilization on postoperative 1st day
- Teaching of correct posture
- Teaching of do's and don'ts (see appendix 4)
- Transcutaneous electrical nerve stimulation for analgesia (if needed)

Phase III: Minimum Movement Phase (6- 12 weeks)
- Pelvic-tilt exercises
- Walking
- Swimming

Phase IV: Dynamic Phase (12 weeks-6 months)
- Dynamic lumbar stabilization exercises
- Kinetic chain strengthening exercises
- Swimming
- Jogging

Phase V: Return to Sports Phase (after 6 months)
- Initially low resistance, high repetition activities
- Choosing sports activity according to patients' preference
- X Sport specific precautions
- X Individualization of training program

Appendix 4: Do's and Don'ts After Posterior Lumbar Dynamic Stabilization Surgery

- No rotation of the lumbar region for the first 12 weeks
- No curving of the lumbar region for the first 6 weeks
- No intense abdominal exercises for 12 weeks
- No participation in competitive sports for the first 6 months
- Avoid lifting, twisting, and hyperextending for the first 12 weeks
- Try to keep back straight
- Can swim after 6 weeks
- Can drive after 3 weeks