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Total Disc Replacement in the Treatment of Lumbar Discogenic Pain with Disc Herniation: A Prospective Clinical Study

Diskojenik Bel Ağrısı Olan Lumbar Disk Herniasyonunun Tedavisinde Total Disk Protezi Uygulanması: Prospektif Klinik Çalışma

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ABSTRACT

BACKGROUND: Biomechanical benefits of Total Disc Replacement (TDR) including both the restoration of normal segmental range of motion and the prevention of physiological lumbar lordosis encourage spine surgeons to perform TDR for lumbar disc disease.

METHODS: A total of twenty patients (mean age: 39.5) who had degenerative disc disease with unilateral disc herniation were operated on between 2003 and 2006. Microscopic anterior lumbar discectomy with TDR placement via a transperitoneal approach were performed. Each patient was evaluated using a VAS and the Oswestry index.

RESULTS: Mean ODI improved from 73.3 preoperatively to 35.0 and 20.4 at 3 and 12 months of follow-up respectively ($P < 0.001$). The mean VAS score improved from 8.65 preoperatively to 2.6 and 1.9 at 3 and 12 months respectively ($P < 0.001$).

CONCLUSIONS: Results from this series are promising and indicate that placement of TDR for degenerative disc disease with lumbar disc herniation is a valuable alternative to conventional techniques. The main advantages of this application are preservation of spinal stability, early mobilization, restoration of normal segmental range of motion and elimination of problems related to intervertebral disc tissue such as discogenic pain and recurrence of disc herniation.

KEYWORDS: Lumbar spine, İntervertebral disc, Artificial disc placement, Discogenic pain, Lumbar disc herniation

ÖZ

Biyomekanik açıdan total disk protezinin, fizyolojik lomber lordozun korunması ve normal segmental hareketin restorasyonu gibi iki önemli faydası vardır. Bu özelliklerinden dolayı total disk protezinin uygulanması omurga cerrahisi açısından gündeme gelmiştir. Bu çalışmada, diskojenik bel ağrısı olan lomber disk herniasyonunun tedavisinde total disk protezinin rolü incelenmiştir. 2003-2006 tarihleri arasında dejeneratif bel hastalığı ile birlikte lomber disk herniasyonu olan toplam 20 hastaya (ortalama yaş: 39,5) total disk protezi uygulandı. Transperitoneal yol ile mikroskopik anterior lomber diskektomi ve total disk protezi uygulandı. Hastaların klinik değerlendirmelerinde görsel analog skala (VAS) ve Oswestry indeksi (ODI) kullanıldı. Ameliyat öncesi ortalama 73,3 olan ODI ameliyat sonrası 3. ay ortalama 35 ve 12. ay 20,4 olarak saptandı ($p<0,001$). Aynı şekilde VAS sonucunda da iyileşme görüldü. Ameliyat öncesi 8,65 olan VAS ortalama değeri ameliyat sonrası 3. ay 26 ve 12. ay 1,9 olarak saptandı ($p<0,001$). Bir hastada ameliyat esnasında protez ile ilgili komplikasyon oldu. Bu çalışma serisinde elde edilen sonuçlarla dejeneratif bel hastalığı ile birlikte olan lomber disk herniasyonunda total disk protezi uygulamaları konvansiyonel yöntemlere alternatif olarak sayılabilir. Bu yöntemin stabiliteyi koruma, erken mobilizasyon, normal segmental hareket açısının restorasyonu ve intervertebral disk dokusu kaynaklı olan diskojenik ağrı ve disk herniasyon rekürrensi gibi sorunların giderilmesi gibi önemli yararları vardır.

ANAHTAR SÖZCÜKLER: Lomber omurga, İntervertebral disk, Artifisiyel disk protezi, Diskojenik ağrı, Lomber disk herniasyonu

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INTRODUCTION

Lumbar disc surgery is one of the most frequent procedures performed by spine surgeons. The first technique for lumbar discectomy was described in 1934, and it involved an aggressive surgical approach (22). An initial attempt at a minimally invasive procedure was reported in 1977 (37). In the 1990s, some authors stated that extensive posterior removal of herniated lumbar discs prevented symptom recurrence and achieved better clinical results (36). In contrast, others suggested that the best results were attained when only extruded fragments of the spinal canal were removed via a posterior approach (35). Subsequent research has shown, however, that both of these methods produce similar recurrence rates (1,32).

Anterior lumbar discectomy is a viable and feasible alternative to the posterior approach for treating herniated lumbar discs. Numerous studies have supported anterior lumbar discectomy with or without intervertebral fusion, performed with an operating microscope or endoscope, as a method for treating virgin or recurrent lumbar disc herniation (13). The anterior portion of the lumbar intervertebral disc space is wider than the posterior portion, and the anterior approach therefore allows better access to lumbar disc tissue than the posterior approach does. The anterior approach also allows for almost total disc tissue removal while still preserving the facets and paravertebral muscles. A disadvantage of the anterior approach is separation of abdominal organs to expose the disc. Separation may increase the complexity of the anterior approach.

The biomechanical perspective states that stress in the posterior side of the vertebral column is increased after posterior lumbar disc surgery. Conversely, stress in the anterior side of the vertebral column is reduced after surgery. The idea of achieving a physiological stress distribution in the spinal column by Total Disc Replacement (TDR) or replacement of the nucleus pulposus encouraged spine surgeons to change their surgical approach to lumbar disc disease. Preliminary reports with positive clinical results support this new strategy (2,6,9,11,18,21,28,38).

Biomechanical benefits of TDR include both the restoration of normal segmental range of motion and the prevention of physiological lumbar lordosis. These prostheses ensure that compressive loads are transmitted optimally. They also protect the posterior elements, thus decreasing the possibility of adjacent disc disease (4). There is no risk of pseudoarthrois, which is present after fusion surgery. Pain disappears, and there is no need to use a brace or other motion-restricting device in daily life. Postoperative rehabilitation may be started early.

The purpose of this preliminary prospective clinical study was to assess the efficacy and practicality of using TDR to treat patients suffering from degenerative disc disease with herniated lumbar discs.

MATERIAL and METHODS

Patient Selection

Subjects were twenty patients who underwent a single-level anterior lumbar microdiscectomy with TDR between 2003 and 2006. All patients were informed about the details of the surgery and gave written informed consent.

The criteria for the surgery were as follows: patients were younger than 50 years of age; a single-level median or paramedian disc herniation at (single level) L4-5 or L5-S1 confirmed by magnetic resonance imaging was present; patients displayed back and radicular pain, unaccompanied by neurological deficit; patients showed no response to at least six weeks of conservative treatment; no facet joint arthrosis, spinal stenosis, spondilolisthesis, osteoporosis, or systemic disease was present.

Data Collection

For each subject, we recorded the duration of symptoms, results from static and dynamic lumbosacral radiographic exams after and before surgery, level of herniation on magnetic resonance imaging, preoperative aortoiliac configuration on three-dimensional computerized tomographic angiography (to detect the anatomic position of major vessels), operative time, peroperative blood loss, hospitalization period, and interval between surgery and return to work.

Physical assessment procedure

Severity of back or radicular pain was evaluated using a visual analogue scale (VAS) that ranged from 0 (no pain) to 10 (worst pain imaginable) (14). Level of disability was assessed using the Oswestry Disability Index (ODI), version 2.0 (7). The ODI is a questionnaire comprised of ten items designed to assess daily living activities that are most likely to be impaired in patients with low-back pain; a high ODI percentage indicates high disability. Each patient's VAS scores and ODI values were recorded before the surgery and at three, six and twelve months after the operation.

Surgical Procedure

In each case, anterior lumbar microdiscectomy was performed using the open mini-ALIF method described by Mayer, with modification (3,20).

Briefly, the anterior lumbar disc space was exposed through a 5-cm horizontal skin incision at the midline beneath the umbilicus, followed by the standard muscle-splitting and transperitoneal approach. An operating microscope was used during the discectomy procedure. All of the herniated disc tissue was removed by pituitary rongeurs, and then a small portion of each posterior endplate was resected using a high-speed drill and Kerrison rongeurs. A Penfield dissector and nerve hook were then used to detach any disc tissue that remained on the posterior longitudinal ligament. The posterior longitudinal ligament was released when necessary. After completing the discectomy procedure, a TDR (Maverick, Medtronic Sofamor Danek, Memphis, TN, USA) was placed in the intervertebral disc space, according to the manufacturer's instructions.

Final clinical outcome was assessed using the Prolo scale (26), based on a telephone interview that took place prior to preparation of this manuscript.

Statistical Analysis

The results for the various scoring systems were statistically analyzed using the t-test.

RESULTS

Table 1 summarizes the clinical data for the twenty patients. Eleven of the patients were female and nine male, with an average age of 39.5 years (range, 33-50 years). The average duration of symptoms before surgery was 3.9 months. One patient, a 38-year-old male (patient no: 10), had undergone the classical posterior approach (microlumbar discectomy with ligamentum flavum preservation) (25) for an L4-5 disc herniation three years prior to the procedure used in this study. Eight patients had persistent back pain without radicular pain for a mean duration of 4.8 months (range 2-12 months), and twelve patients had radicular pain for mean duration of 3.2 months (range 2-5 months). As noted, all patients had received at least six weeks of conservative treatment, for example various combinations of non-opioid medications, physical therapy, and exercise, at another health care center. In all cases, a preoperative neurological examination revealed no abnormalities other than back/radicular pain.

Range of motion (ROM) is important after the TDR. When we review the literature, the ROM of the prosthesis at the L5-S1 level is significantly lower compared to the ROM at the other levels. A satisfactory outcome was achieved for monosegmental L4-5 and L5-S1 disc replacement procedures with best results achieved following TDR at L4-5. The advantage of lumbar TDR might be minimal at L5-S1 in preserving ROM (16,19,24,31). We always use TDR only at one level in our cases. The clinical results of our patients were satisfactory.

Magnetic resonance imaging showed decreased signal intensity at the affected disc site on T2-weighted images. Eight patients had median disc herniation, and twelve had paramedian disc herniation (Figures 1A,B,C,D and 2A,B,C,D). Computerized tomographic angiography revealed no lower bifurcation of either the aorta or the vena cava in any of the twenty patients.

Thirteen patients were operated at L4-5, and 7 patients at L5-S1. The average operative time was 180 min, and the average volume of blood lost during surgery was 415 ml. Two patients (no: 6, 15) required blood transfusions intraoperatively. The average hospital stay was 3.5 days (Table I). There were two complications (patient no: 6, 15) related to either the surgery or the hardware used. A branch of the iliac vein was torn during implantation of the prosthesis in these

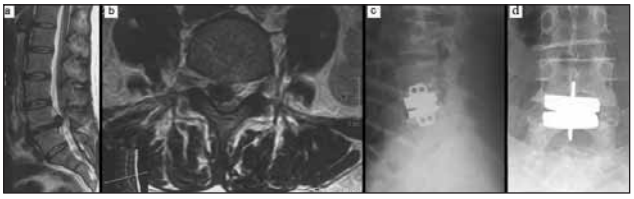

Figure 1: *The preoperative MRI of the patient showed recurrent disc herniation and degenerative disc disease at the L4-5 level (**A,B**). The postoperative plain radiographs show the Total Disc Replacement (**C,D**).*

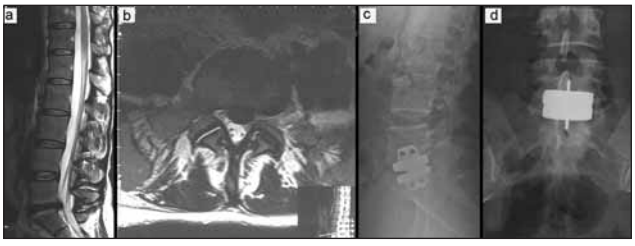

Figure 2: *The preoperative MRI of a patient with complaints of left leg and back pain (case 4, table1) showed degenerative disc disease with disc herniation at the L5-S1 level (**A,B**). The postoperative plain radiographs show the Total Disc Replacement (**C,D**).*

Table I: Clinical data of 20 patients operated with Total Disc Replacement (TDR) for herniated lumbar disc.

Patient No	Age/ Gender	Symptom	Duration of Symptom (month)	Herniated Level	Blood Loss (cc)	Length of Stay in Hospital (day)	Return to Work (day)
1	37-F	Back pain	2	L4-5	300	3	10
2	35-F	Back and Radicular pain	4	L5-S1	350	2	12
3	50-M	Back and Radicular pain	3	L5-S1	250	2	10
4	45-F	Back pain	4	L4-5	400	4	15
5	33-M	Back pain	6	L4-5	300	3	14
6	30-F	Back and Radicular pain	4	L4-5	1200	7	10
7	37-M	Back and Radicular pain	3	L5-S1	180	2	14
8	35-M	Back and Radicular pain	5	L5-S1	240	2	10
9	48-M	Back pain	6	L4-5	300	4	14
10	38-M	Back pain	12	L4-5 (recurrent)	350	3	12
11	44-F	Back pain	8	L4-5	400	5	10
12	35-M	Back and Radicular pain	3	L4-5	450	3	18
13	36-F	Back and Radicular pain	5	L5-S1	250	2	16
14	41-F	Back and Radicular pain	2	L4-5	350	2	15
15	50-F	Back pain	9	L4-5	1500	8	28
16	37-M	Back and Radicular pain	3	L5-S1	400	3	14
17	43-F	Back and Radicular pain	2	L4-5	200	5	10
18	44-M	Back pain	5	L4-5	190	4	16
19	36-F	Back and Radicular pain	2	L5-S1	250	3	20
20	37-F	Back and Radicular pain	3	L5-S1	250	3	14

two patients. The ruptures were repaired with a 6/0 suture. The average time before returning to work was 14.1 days.

Table 2 lists the follow-up findings for the twenty patients. All patients were strictly followed-up for 12 months and the follow up of some patients continued up to 32 months. The average follow-up period was 22.7 months (range, 12-32 months). The mean VAS and mean ODI values before the procedure differed significantly from the corresponding mean values at each time point assessed during follow-up ($P < 0.001$). When patients were categorized according to type of pain (back versus radicular), both these groups showed significant improvement. Movement VAS scores showed a preoperative mean of 8.6 (range 7-10), and postoperative means of 2.6 (range 1-8) and 1.9 (range 1-3) for 3 and 12 months after treatment, respectively. Correlation between these values was statistically significant ($P<0.001$). Mean ODI improved from a value of 73.3 (range 40-100) preoperatively to 35.0 (range 12-60) and 12 (range 10-58) at 3 and 12 months postoperatively, respectively. The mean ODI values at 3 and 12 months were both significantly lower than the mean at baseline ($P < 0.001$).

The Prolo scale values were 45% excellent, 50% good, 5% fair and 0% poor (Table II).

Table II: Follow-up assessment data of the patients indicates that $P<0.001$

Patient No:	Visual Analog Pain Scale						Oswestry Disability			Prolo Scale		
	Preop To Move	Preop To Rest	Postop 3 month To Move	Postop 3 month To Rest	Postop 12 month To Move	Postop 12 month To Rest	Preop	Postop 3 month	Postop 12 month	Telephone Interview Follow-up		
										Duration (Month)	Outcome	
											Preop	Postop
1	10	5	7	2	3	1	64	24	18	28	5	7 (good)
2	10	3	10	2	3	2	88	52	44	24	4	7 (good)
3	8	4	2	2	3	2	66	26	16	18	5	8 (good)
4	10	2	10	1	1	1	100	38	12	24	5	9 (excellent)
5	10	1	5	1	1	1	78	12	12	12	2	8 (good)
6	9	8	4	5	5	3	76	70	58	30	4	9 (excellent)
7	9	3	4	1	2	1	98	40	24	18	6	10 (excellent)
8	7	1	2	1	1	1	54	22	18	20	4	7 (good)
9	10	3	8	2	2	2	96	24	20	16	3	8 (good)
10	9	4	9	4	3	2	80	36	26	32	3	9 (excellent)
11	9	2	6	1	2	1	74	16	18	20	5	7 (good)
12	9	1	9	1	1	1	42	38	12	12	5	6 (fair)
13	9	1	8	1	1	1	64	42	24	18	2	9 (excellent)
14	8	1	5	1	1	1	40	26	10	20	2	9 (excellent)
15	8	1	6	1	1	0	78	22	14	28	3	7 (good)
16	7	2	3	1	1	1	52	16	10	30	4	8 (good)
17	9	2	6	1	2	1	84	60	40	32	4	9 (excellent)
18	8	3	4	2	2	1	72	48	10	24	4	9 (excellent)
19	7	2	5	1	1	0	66	40	10	18	3	9 (excellent)
20	7	3	7	3	2	1	64	48	12	30	2	7 (good)

DISCUSSION

The outcomes reported after both traditional techniques and microsurgery for lumbar disc herniation have generally been shown to be equal (23). Nevertheless, some patients have developed recurrent herniation at the operated level after these procedures, some have suffered prolonged radicular pain and have developed epidural fibrosis, and others have developed early degenerative spondilolisthesis or segmental instability (15). Studies indicate that 5%-11% of patients undergoing posterior disc excision suffer recurrent herniation (33). There are no published data examining recurrence after anterior lumbar disc surgery. It is likely that the wide exposure of the disc space after removal of all disc material eliminates recurrence in these patients.

The treatment of discogenic pain is always problematic for spine surgeons. Numerous treatment methods, ranging from conservative treatment to extensive surgical techniques like the application of posterior dynamic fixation (34), Total Disc Replacement (2,18,21,28,33), or fusion procedures (23,30) have been described. Clearly, more data is needed to choose the optimal surgical intervention for a patient with discogenic pain.

It has been established that approximately 80% of axial compressive load transmits through the anterior portion of the vertebral column (5). Clearly, the removal of part of an intervertebral disc decreases that disc's buffering capacity. This change results in excessive load transfers through the facet joints, as well as an accumulation of pressure in the discs at adjacent levels. These effects can eventually lead to degenerative segmental instability over time. Placement of a TDR after complete disc removal at least partially restores the kinematics of the functional spine unit, and it facilitates optimal anterior-posterior column load sharing (4). However, we found limited movement at the L5-S1 level compared to the L4-5 level. The literature also supports this finding. We therefore cannot say TDR preserves lumbar segmental motion. In this study, we used a ball-and-socket (semiconstrained) design TDR that limits segmental translation under flexion-extension and lateral bending. This design is thought to minimize anteroposterior shear forces at the operative facet level, while still providing a fixed axis of rotation (12). This effect is the main biomechanical advantage of a TDR over other types of nuclear replacement products, such as prosthetic disc nucleus.

We performed three-dimensional computerized tomographic angiography in our study to evaluate each patient's aorta and iliac veins before TDR placement surgery. These studies helped us with surgical planning because they confirmed that none of the patients had vascular restrictions that might affect the procedure. In our twenty patients, the surgeon encountered no difficulties during disc excision; however, it is important to take great care and use the surgical microscope when using a high-speed drill deep within the intervertebral space. Rehabilitation after lumbar disc replacement surgery was as follows: All patients were educated concerning low back protection principles either preoperatively or on the first postoperative day. Patients were instructed on correct postural position, including methods for protecting the lower back, on the third postoperative day. The patients were discharged from the hospital on approximately the fourth postoperative day if there were no complications. The initial rehabilitation protocol prepared by the PMR Department suggested active rest and educated patients on the principles of low back protection. Initial instructions of the rehabilitation protocol are described below.

- No restriction in daily activities when the patient felt that he/she had recovered

- Swimming and running can start after six weeks.

- Dynamic lumbar stabilization exercises can start after three months.

The hospitalization period (an average of 3.5 days for our patients) was the same as that for traditional for lumbar microsurgery.

One of the major complications of this surgery is major vessel injury. The incidence of this complication in the anterior approach was found to be 1.9-2.9% following a literature review (8,10). In our limited series of two patients, there were two small vein ruptures in the branches of the iliac vein and very close to it.

Another important complication in the anterior lumbar approach is retrograde ejaculation due to destruction of the nerves of the sympathetic plexus. The incidence of retrograde ejaculation changes between 0 and 4.1% in the literature (27,29). Most of the cases heal about 6 to 10 months after the operation but in some cases the condition can persist. We had past experience of retrograde ejaculation after the anterior lumbar approach but not in these cases.

Postoperatively, our patients had no need for lumbar support, and all were mobilized the day after the

procedure. We placed no restrictions on daily activities.

The literature contains no data related to the use of TDR for primary or secondary lumbar disc herniation, but there is no absolute contraindication for TDR in these cases. Tropiano and coworkers reported a preliminary finding of a 90% success rate for total disc replacement in 53 patients. Our series included one such case (an L4-5 microdiscectomy three years earlier, patient no: 10), and we encountered no problems during this patient's surgery. The patient tolerated the surgery well and returned to work within 12 days (case 1).

Kim et al. (17) reported the usability of the TDR in patients without degenerative disc disease that had developed juxtafusional degeneration after posterior stabilization surgery. The neurological symptoms had completely resolved by six months after surgery. In our study, all the patients' back pain and radicular pain resolved after the procedure in all eleven patients described in that report.

Le Huec (18) reported a satisfactory outcome at a two-year follow-up with TDR. Similarly, Bertagnoli (2) documented a 93% satisfaction rate at a two-year follow-up for TDR treatment of single or multilevel discogenic pain. Lumbar disc herniation was not an exclusion criterion in Bertagnoli's study. We included patients with lumbar discogenic pain with disc herniation in our study.

The results from this series suggest that TDR placement in patients with lumbar disc herniation associated with degenerative disc disease is a valuable alternative to conventional techniques. The main advantage of inserting a TDR lies in the preservation of segmental motion and spine stability in young adults that exhibit early mobilization. TDR offers spine surgeons a safe and efficacious method to treat both radicular pain arising from disc herniation and discogenic pain arising from degenerative disc disease.

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