



# Total disc prosthesis for painful degenerative lumbar disc disease

## *Lomber dejeneratif disk hastalığının total disk protezi ile tedavisi*

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**Amaç:** Ağrılı dejeneratif lomber disk hastalığı nedeniyle ProDisc II total disk protezi (TDP) uygulanan olguların klinik ve radyografik sonuçları değerlendirildi.

**Çalışma planı:** Dejeneratif disk hastalığı (DDH) tanısıyla lomber TDP uygulanan 34 hasta (25 kadın, 9 erkek; ort. yaş 44; dağılım 37-54) çalışmaya alındı. Toplam 62 TDP prosedürü olmak üzere, 12 olguya tek, 17 olguya iki, dört olguya üç, bir olguya ise dört seviyeli lomber TDP uygulandı. Olgular ameliyat öncesinde ve ameliyat sonrası 3, 6, 12, 24. aylarda klinik ve radyografik olarak değerlendirildi. Klinik değerlendirmede görsel analog skala (GAS) ve Oswestry Engellilik İndeksi (OEİ) kullanıldı. Radyografik değerlendirmede, lomber lordoz açısı, tutulan diskin yüksekliği ile fleksiyon-ekstansiyon açıları ölçüldü. Ortalama takip süresi 29.3 ay (dağılım 24-39 ay) idi.

**Sonuçlar:** Olguların bel ve bacak ağrıları en geç üçüncü ayda tama yakın düzeldi. Klinik değerlendirmede, ameliyat öncesi 59.6 olan OEİ skoru ameliyat sonrası 24. ayda 19.8'e, GAS skoru ise 7.8'den 1.0'e geriledi. Lomber lordoz ameliyat öncesinde 52.6°, ameliyat sonrasında 57.1° olarak ölçüldü. Disk yüksekliği implantasyon yapılan seviyelerde 4.6 mm'den 12.1 mm'ye yükseldi. Fleksiyon-ekstansiyon açısı L<sub>5</sub>-S<sub>1</sub> seviyesinde 2.8 dereceden 8.4 dereceye; L<sub>4,5</sub> seviyesinde ise 2.6 dereceden 9.8 dereceye yükseldi. Total disk protezi uygulanan tüm disklerde fleksiyon-ekstansiyon açısında düzelme ortalama 7.2° bulundu.

**Çıkarımlar:** Lomber disk protezi, dejeneratif disk hastalığının cerrahi tedavisinde hastaların fonksiyonları ve yaşam kalitelerinin sürdürülmesi açısından önemli avantajlara sahiptir.

**Anahtar sözcükler:** Artroplasti, replasman; diskektomi/enstrümantasyon; intervertebral disk/patoloji/cerrahi; bel ağrısı/etiyoloji; lomber vertebra/cerrahi; protez ve implant.

**Objectives:** We evaluated clinical and radiographic results of patients treated by the ProDisc II total disc prosthesis (TDP) for painful degenerative lumbar disc disease.

**Methods:** The study included 34 patients (25 females, 9 males; mean age 44 years; range 37 to 54 years) who underwent a total of 62 lumbar TDP procedures for degenerative lumbar disc disease. Lumbar disc replacement involved one level in 12 cases, two levels in 17 cases, three levels in four cases, and four levels in one case. Clinical and radiographic assessments were made preoperatively and at 3, 6, 12, and 24 months postoperatively. Clinical evaluations were made with a visual analog scale (VAS) and the Oswestry Disability Index (ODI). Radiographic parameters included lumbar lordotic angle, the height and flexion-extension range of the affected discs. The mean follow-up period was 29.3 months (range 24 to 39 months).

**Results:** Low back pain and lower extremity pain showed near-complete improvement up to the third postoperative month. At the end of the 24th month, preoperative ODI and VAS scores of 59.6 and 7.8 decreased to 19.8 and 1.0, respectively. Preoperative and postoperative lumbar lordotic angles were 52.6° and 57.1°, respectively. The mean disc height of implanted discs increased from 4.6 mm to 12.1 mm postoperatively. The mean flexion-extension angle increased from 2.8° to 8.4° at L<sub>5</sub>-S<sub>1</sub>, and from 2.6° to 9.8° at L<sub>4,5</sub>. The overall improvement in the mean flexion-extension angle was 7.2°.

**Conclusion:** Lumbar disc prosthesis offers significant advantages in terms of functional improvement and increased quality of life in the surgical treatment of degenerative disc disease.

**Key words:** Arthroplasty, replacement; diskectomy/instrumentation; intervertebral disk/pathology/surgery; low back pain/etiology; lumbar vertebrae/surgery; prostheses and implants.

Treatment of choice in chronic low back pain is still a controversial issue. There are numerous studies which report successful outcomes by either fusion or conservative treatment for degenerative spinal pathologies.<sup>[1-3]</sup>

Idea of preservation of mobility has gained popularity in spinal surgery due to prevention of degeneration in the adjacent vertebral segments. First disc prosthesis developed through this concept was used by Fernström in 1966. Various types of prosthesis made up of metal, ceramic and silicon has been tried during 1970s<sup>[3,4]</sup>. Contemporary disc prostheses are designed to restore range of motion and reduced disc height.<sup>[3]</sup> Disc prostheses available at present are classified according to number of components (2, 3 or 4 component), type of prosthetic surface (metal-polymer or metal-metal) or its kinematic properties (low-constrained or high-constrained)<sup>[5]</sup>

In this study we retrospectively analyzed the clinical and radiological outcomes of patients treated for painful degenerative lumbar disc disease by a semi-constrained, three component

## Patients and method

Study included 34 patients (25 female, 9 male, mean age 44, range 37 to 54) with symptoms of chronic low back pain or radiculopathy that were diagnosed as degenerative disc disease by MRI, CT and provocative discography between 2003 and 2005. A total of 62 lumbar total disc prosthesis (TDP) were inserted.

Indications for TDP were painful degenerative disc disease (DDD) with or without central disc protrusion that emerged between the ages of 25 and 55, painful DDD with failed disc surgery, DDD in vertebral segments adjacent to fusion and DDD with slight spinal deformities. Study also included TDP patients that had a history of previous disc surgery but no facet joint resection. TDP was performed for patients with Modic I disc degeneration [6]. Contraindications were spinal stenosis with prominent radicular or cauda equina symptoms, metabolic bone disease (osteoporosis, osteomalacia, osteopenia), previous fusion or major abdominal surgery, presence of severe spinal deformity, chronic infection, metal allergy, arthrosis of the facet joints, small or deformed end plate, body-mass index greater than 35, spondylolisthesis more than grade I and history of radiotherapy.

Instability was assessed in all cases by preoperative AP-lateral and dynamic radiographs according to Iguuchi criteria.<sup>[7]</sup> Degree of degeneration and anatomy of major vascular structures were evaluated by MRI and 3D CT. If MRI showed involvement of more than one levels, symptomatic disc was determined by provocative discography. Patients that had T scores of -2.5 or less in bone mineral density were not operated. All patients were mobilized and physiotherapy was initiated in the first postoperative day. Brace was not used in any case. Postoperatively indomethacin 100 mg/day was used for 21 days in all patients to prevent heterotopic ossification.

Clinical and radiographic examination was performed preoperatively and postoperatively at 3, 6, 12 and 24 months. Turkish versions of Visual Analogous Scale (VAS) and Oswestry Disability Index (ODI) were used for clinical evaluation. Daily need for analgesic was also recorded. Lumbar lordosis angle, height and flexion-extension range of the involved disc was measured for radiological evaluation. Position of the implant, pathologies in adjacent segments and heterotopic ossification was also investigated. Mean follow-up period was 29.3 months (range 24 to 39 months.)

## Surgical technique

Patients were placed in supine position and legs were abducted to get AP and lateral views of the spine by fluoroscopy. Transverse or left paramedian longitudinal incision was used for L<sub>5</sub>-S<sub>1</sub>, and left paramedian longitudinal incision was preferred for other levels. Complete anterior discectomy was performed. Posterior longitudinal ligament was excised to provide wide decompression and better restoration of disc height. Only cartilage was removed from the end plates. Trials were used to check midline position, intervertebral height and size of prosthesis in the AP/lateral planes by fluoroscopy. Keel cut of the prosthesis was performed and prosthesis of appropriate size was driven into sufficient depth under fluoroscopic control. Polyethylene insert was placed by distraction of the end plates of the prosthesis.

## Results

Types of pathologies in the disc levels that prosthesis were placed were as follows: DDD in 22 cases, DDD and disc herniation in 29 cases, DDD with previous disc surgery in 5 cases, DDD with minimal deformity in 6 cases. TDP was inserted to one level

**Table 1.** Oswestry and VAS results of the cases

	Preop.		3. mo.		6. mo.		12. mo.		24. mo.	
	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range
ODI	7.8	5-11	1.8	1-2	1.4	0-2	1.2	0-2	1.0	0-2
VAS	59.6	48-66	29.2	20-36	19.9	16-22	21.1	18-22	19.8	16-22

in 12 cases, to two levels in 17 cases, to three levels in 4 cases and to four levels 1 case. TDP was inserted to L<sub>2</sub>-L<sub>3</sub> level in 4 cases, L<sub>3</sub>-L<sub>4</sub> level in 10 cases, L<sub>4</sub>-L<sub>5</sub> level in 31 cases, L<sub>5</sub>-S<sub>1</sub> level in 17 cases (Figure 1).

Clinical assessment showed that preoperative ODI score of 59.6 (range 48 to 66) was reduced to 19.8 at the postoperative 24th month (range 16 to 22). VAS score was reduced from 7.8 to 1.0 during the same period (Table 1). Low back pain and leg pain were almost completely resolved in all cases within postoperative 3 months, gabapentin was used for 3 months in 4 patients that reported mild leg pain. None of the cases required continuous analgesia (such as narcotics, morphine derivatives, gabapentin and NSAIDs). No vascular complication developed in any case during the intraoperative and postoperative period.

Preoperative lumbar lordosis of 52.6° was measured as 57.1° postoperatively. Disc height of mean 4.6 mm before surgery was postoperatively increased to 12.1 mm in the disc levels that prosthesis were implanted. Flexion-extension angles at L<sub>5</sub>-S<sub>1</sub> level was increased from mean preoperative 2.8° (range 1° to 4°) to postoperative 8.4° (range 3° to 12°); and mean preoperative 2.6° (range 1°-3°) was increased to postoperative 9.8° (range 8°-17°) at L4-5 level. Mean preoperative flexion-extension angles of all disc levels that TDP were implanted was increased from 2.9° to mean 7.1° (range 6°-8°) postoperatively (Table 2).

Radiological examination did not demonstrate any radiolucent zones or sclerotic lines around the implants. Periannular ossification or mechanic failure did not develop in any case. Malposition, subsidence, loosening, failure or dislocation in metal or polyethylene components of the implant and heterotopic ossificati-

on was not observed. One-level fusion was performed in one case due to intraoperative fracture of the end plate. None of the patients developed retrograde ejaculation or infection.

## Discussion

Reduction in the hydrostatic pressure of nucleus and release of inflammatory mediators in degenerative disc disease may trigger chronic low back pain. Progression of degeneration may lead to instability, loss of disc height, foraminal and central stenosis, and facet joint arthrosis.<sup>[8,9]</sup> Initiation or acceleration of degeneration in the adjacent segments after spinal fusion has been reported in many studies. Excess mobility and load on the adjacent segments may create new instability areas after a certain period of time.<sup>[3-5,9]</sup>

Bertagnoli et al.<sup>[10]</sup> published short term outcomes of 104 patients treated with Prodisc II in their prospective study. Authors reported 41% mean reduction of pain according to VAS scores, 24% mean reduction in ODI and 96% patient satisfaction; rate of return to work was found to be 50% in two years follow-up. In radiographic evaluation mean preoperative disc height of 4 mm. was increased to 13 mm postoperatively, preoperative range of motion was increased from 3 to 7 degrees postoperatively. No implant-related complication was reported in any case included in the study, but two cases developed retroperitoneal hematoma at the perioperative period and one case experienced temporary retrograde ejaculation.<sup>[10]</sup>

Tropiano et al.<sup>[4]</sup> reported patient satisfaction as 87% and rate of return to daily activities and previous job was 72% in his study of Prodisc II after minimum one year follow-up. In the same study, lumbar VAS scores

**Table 2.** Radiological evaluation of the cases

	Preop.		3. mo.		6. mo.		24. mo.	
	Mean	Range	Mean	Range	Mean	Range	Mean	Range
Lumbar lordosis (°)	52.6	44-59	54.7	48-60	57.4	45-61	57.1	46-61
Disc heights (mm)	4.6	4-5	12.0	11-12	12.2	11-13	12.1	11-13
Flex-Ext angle (°)	2.9	2-4	6.9	6-9	7.2	7-9	7.1	6-8



**Figure 1.** Forty-six years old male patient presented with severe low back pain radiating to his right leg. Preoperative (a) AP and (b) lateral X-rays (c) preoperative sagittal magnetic resonance images showed Modic type I disc degeneration. Discectomy was performed and Prodisc II lumbar total disc prosthesis were inserted to L<sub>2-3</sub> and L<sub>3-4</sub>. Postoperative (d) AP and (e) lateral X-rays after 24 months. Pre-operative Oswestry Disability Index and Visual Analogous Scale of 54 and 10 respectively, were reduced to 17 and 0.

were decreased from preoperative 7.4 to 1.3 after 1.4 year follow-up; radicular VAS scores were decreased from 6.7 to 1.9; ODI scores were decreased from 56 to 14. Postoperative mean flexion-extension angles were measured as 8° at L5-S1 level and 10° in L4-L5 level. Complication rate was 9% and re-operation rate was 6%.<sup>[4]</sup> Satisfactory outcomes after fusion for degenerative spinal diseases was reported as 68%, whereas rates of fusion-related complications were 0.2% for mortality, 1.5% for deep infection, 3.7% for deep vein thrombosis, 2.8% for neurologic injury and 7.3% for implant failure.<sup>[11-13]</sup>

Yamashita et al.<sup>[2]</sup> reviewed 5-year outcomes of surgical treatment in degenerative lumbar spinal stenosis in their study they observed an improvement of VAS scores in the first 6 months, which further increased between 6 to 60 months. TDP was used for two or more levels in 64.7% (22/34) of our cases and 66.8% reduction was achieved for ODI with 87.2% improvement in VAS scores. Flexion-extension angle of the TDP-inserted mobile segments were increased 2.5 times; whereas disc height was increased 2.6 times. Global lordosis angle did not present a significant change after operation. No patient involved in the study required re-operation. These results show that lumbar disc prosthesis provide significant advantages in the surgical treatment of DDD in terms of function and quality of life and these results may be considered as encouraging compared to results of other treatment methods reported in the literature.

Different rates of adjacent segment degeneration after TDP have been reported in the literature.<sup>[14-16]</sup> Bertagnoli and Kumar<sup>[18]</sup> reported rate of adjacent disc and facet joint degeneration as 9.2% in their study, where they follow-up period of half of the cases was more than one year. Degeneration in the adjacent segments after Prodisc II lumbar disc prosthesis ranged from 4.6 to 25.6% in the short-term follow-up in one study.<sup>[5]</sup> Huang et al<sup>[9]</sup> have reported adjacent segment degeneration rate as 24% after 8.6 years of follow-up. We believe that follow-up period for our study is not sufficient to make a conclusion for adjacent segment degeneration.

Preoperative visualization of major abdominal vascular anatomy and assessment of implant size by 3D-CT is crucial to decrease intraoperative complications. We also believe that total disc prosthesis should be performed in the operation rooms with advanced facilities and by the teams that have sufficient experience in anterior spinal procedures.

## References

1. Freeman BJ, Davenport J. Total disc replacement in the lumbar spine: a systematic review of the literature. *Eur Spine J* 2006;15 Suppl 3:S439-47.
2. Yamashita K, Ohzono K, Hiroshima K. Five-year outcomes of surgical treatment for degenerative lumbar spinal stenosis: a prospective observational study of symptom severity at standard intervals after surgery. *Spine* 2006;31:1484-90.
3. Guyer RD, Foley KT, Phillips FM, Ball PA. Minimally invasive fusion: summary statement. *Spine* 2003;28(15 Suppl):S44.
4. Tropiano P, Huang RC, Girardi FP, Marnay T. Lumbar disc replacement: preliminary results with ProDisc II after a minimum follow-up period of 1 year. *J Spinal Disord Tech* 2003;16:362-8.
5. German JW, Foley KT. Disc arthroplasty in the management of the painful lumbar motion segment. *Spine* 2005;30(16 Suppl):S60-7.
6. Boden SD. The use of radiographic imaging studies in the evaluation of patients who have degenerative disorders of the lumbar spine. *J Bone Joint Surg [Am]* 1996;78:114-24.
7. Iguchi T, Kanemura A, Kasahara K, Sato K, Kurihara A, Yoshiya S, et al. Lumbar instability and clinical symptoms: which is the more critical factor for symptoms: sagittal translation or segment angulation? *J Spinal Disord Tech* 2004;17:284-90.
8. Kettler A, Wilke HJ. Review of existing grading systems for cervical or lumbar disc and facet joint degeneration. *Eur Spine J* 2006;15:705-18.
9. Huang RC, Girardi FP, Cammisa FP Jr, Lim MR, Tropiano P, Marnay T. Correlation between range of motion and outcome after lumbar total disc replacement: 8.6-year follow-up. *Spine* 2005;30:1407-11.
10. Bertagnoli R, Yue JJ, Shah RV, Nanieva R, Pfeiffer F, Fenk-Mayer A, et al. The treatment of disabling multilevel lumbar discogenic low back pain with total disc arthroplasty utilizing the ProDisc prosthesis: a prospective study with 2-year minimum follow-up. *Spine* 2005;30:2192-9.
11. Rompe JD, Eysel P, Zollner J, Nafe B, Heine J. Degenerative lumbar spinal stenosis. Long-term results after undercutting decompression compared with decompressive laminectomy alone or with instrumented fusion. *Neurosurg Rev* 1999;22:102-6.
12. Herkowitz HN, Sidhu KS. Lumbar spine fusion in the treatment of degenerative conditions: current indications and recommendations. *J Am Acad Orthop Surg* 1995;3:123-35.
13. Kim KT, Lee SH, Lee YH, Bae SC, Suk KS. Clinical outcomes of 3 fusion methods through the posterior approach in the lumbar spine. *Spine* 2006;31:1351-7.
14. Pateder DB, Park YS, Kebaish KM, Cascio BM, Buchowski JM, Song EW, et al. Spinal fusion after revision surgery for pseudarthrosis in adult scoliosis. *Spine* 2006;31:E314-9.
15. Tropiano P, Huang RC, Girardi FP, Cammisa FP Jr, Marnay T. Lumbar total disc replacement. Surgical technique. *J Bone Joint Surg [Am]* 2006;88 Suppl 1 Pt 1:50-64.
16. Zigler JE, Burd TA, Vialle EN, Sachs BL, Rashbaum RF, Ohnmeiss DD. Lumbar spine arthroplasty: early results using the ProDisc II: a prospective randomized trial of arthroplasty versus fusion. *J Spinal Disord Tech* 2003;16:352-61.
17. Le Huec J, Basso Y, Mathews H, Mehbod A, Aunoble S, Friesem T, et al. The effect of single-level, total disc arthroplasty on sagittal balance parameters: a prospective study. *Eur Spine J* 2005;14:480-6.
18. Bertagnoli R, Kumar S. Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indications. *Eur Spine J* 2002;11 Suppl 2:S131-6.