



SHORT TERM RESULTS OF CERVICAL DISC PROSTHESES

SERVİKAL DİSK PROTEZİ KISA DÖNEM SONUÇLARI

Alper GOKCE*, Cengiz BECERİR**, Nevzat Selim GOKAY*,
Mehmet Burak YALCIN***, Rumeysa TASCI****

SUMMARY:

The classical applied therapy for cervical spondylosis and symptomatic radiculopathy is anterior decompression (AD) and interbody fusion (IF). Cervical arthroplasty with total disc prosthesis (TDP) after AD is a treatment suggested as an alternative to anterior cervical fusion. We have retrospectively evaluated the clinical and radiological outcomes of 51 consecutive patients whom we have treated with 52 TDP due to neck pains and radiculopathy. 34 patients (28 female, 6 male) were followed up for an average of 25.76 months (12 – 36 months). The clinical and radiological success we have achieved in our study support our decision to head towards dynamic stabilization. The necessity of support for our series through the results of long term randomized studies is still valid.

Key Words: Cervical spine, surgical treatment, cervical disc prosthesis,

Level of evidence: Retrospective clinical study, Level III

ÖZET:

Servikal spondilozun ve semptomatik radikülopatinin klasik olarak uygulanan tedavisi anterior dekompresyon (AD) ve omurga cisimler arası füzyondur (İF). Anterior dekompresyon (AD) sonrası total disk proteziyle (TDP) servikal artroplasti, anterior servikal füzyona alternatif olarak öne sürülen bir tedavidir. Boyun ağrısı ve radikülopati nedeniyle AD sonrasında 52 TDP uyguladığımız birbirini izleyen 51 hastanın klinik ve radyolojik sonuçlarını geriye dönük olarak değerlendirdik. 34 hasta (28 kadın, 6 erkek) ortalama 25.76 ay izlendi (12-36 ay). Bizim çalışmamızda elde ettiğimiz klinik ve radyolojik başarı dinamik stabilizasyona yönelme kararımızı destekler niteliktedir. Serimizin uzun dönem randomize çalışmaların sonuçları ile desteklenmesi halen gerekliliğini sürdürmektedir.

Anahtar Kelimeler: Servikal vertebra, cerrahi tedavi, füzyon, servikal disk protezi.

Kanıt düzeyi: Retrospektif klinik çalışma, Düzey III

(*) Namık Kemal University, Department of Orthopaedics and Traumatology, Tekirdağ

(**) Tekirdağ State Hospital, Tekirdağ

(***) Nusaybin State Hospital, Mardin

(****) Namık Kemal University, Tekirdağ

INTRODUCTION:

The classical applied therapy for cervical spondylosis and symptomatic radiculopathy is anterior decompression (AD) and interbody fusion (IF) ^(1,4,9). Cervical arthroplasty with total disc prosthesis (TDP) after AD is a treatment suggested as an alternative to anterior cervical fusion. Cervical disc arthroplasty is a relatively new technology in retaining the level of motion at the treated level in vertebra surgery ⁽⁶⁾.

The primary purpose of this treatment is the achievement of segmental motion after the treatment of the local pathology. The secondary purpose is to protect normal mobility at the adjacent level and to prevent degeneration in the adjacent segment after surgery ⁽¹⁴⁾.

Currently, the universal demand for a better solution beyond arthrodesis in the treatment of symptomatic cervical radiculopathy is increasing. It is asserted that TDP is advantageous in regaining the patient's mobility and in protecting the segmental anatomy and functionality as well as successfully treating radicular symptoms. In this study, we have targeted evaluating patients whom we have treated with disc prostheses. In this study, we have investigated patient satisfaction, progress of pain complaints and the changes in time of spine mobility during the period of observation.

MATERIALS AND METHOD:

We have retrospectively evaluated the clinical and radiological outcomes of 51 consecutive patients whom we have treated with 52 TDP due to neck pains and radiculopathy.

In conformity with the permission granted by the hospital ethical committee, the files were taken out of the archives and studied. The physical examination findings, Oswestry and Visual Analog Scale (VAS) informations, pre-surgery two-way direct graphs and cervical magnetic resonance analyses of all patients were available in their files. 34 patients that responded positively to the call sent out to all patients and with a minimal follow up one year period were included in the study. None of the patients included in the study had any condition contraindicative of cervical disc prosthesis such as ankylosing spondylitis, rheumatoid arthritis, ossification in the posterior longitudinal ligament or diffuse idiopathic skeletal hyperostosis, insulin dependent diabetes mellitus, prior spinal infections, chronic use of steroids, metal allergies, morbid obesity, or pregnancy before surgery.

Age, pre-surgery complaints, localization of the disorder, severity of symptoms, performed surgery and implanted prosthesis were recorded in the file information.

The patients were asked about their complaints during the follow-up controls and detailed physical examinations were repeated. Pre- and post-operative pain inquiry was standardized using VAS and Oswestry clinical evaluation forms. The improvement in the scores was evaluated statistically by using Mann-Whitney U test.

Besides the subjective evaluations of the patients, their neurological conditions were examined and the range of movement in the implantation area was evaluated with standard lateral graphs taken at maximal flexion and extension (Fig.-1, 2).

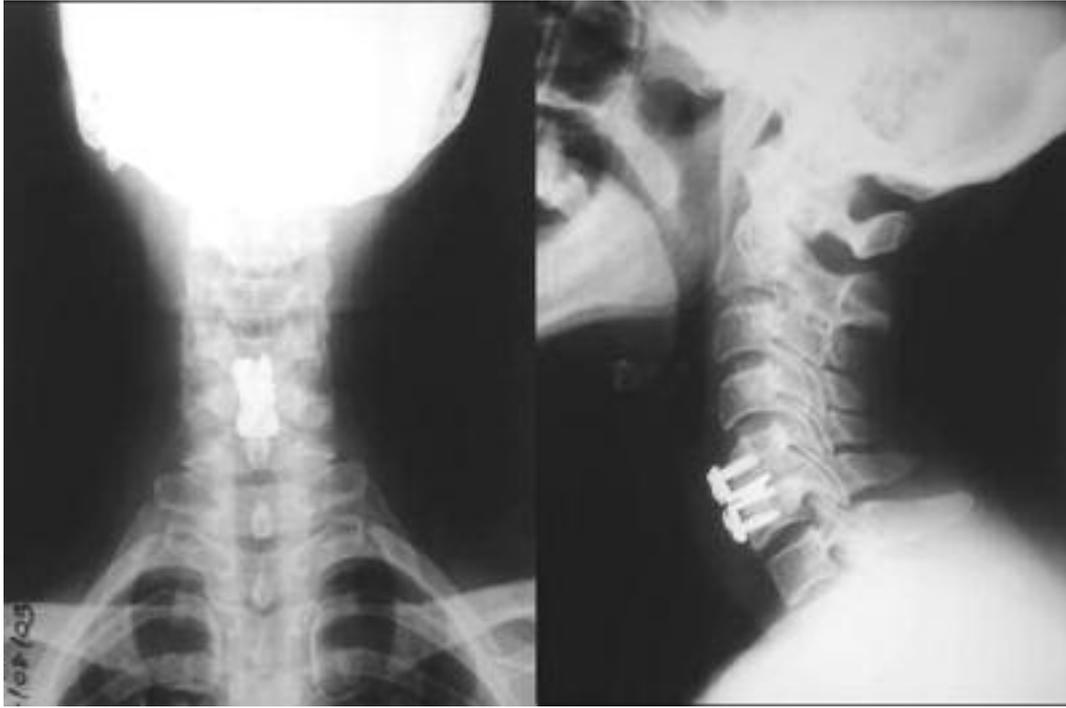


Figure-1. Standard AP and lateral direct graphs taken in the 31st month after surgery of patient N.G. showing the TDP applied at the C5-C6 level.

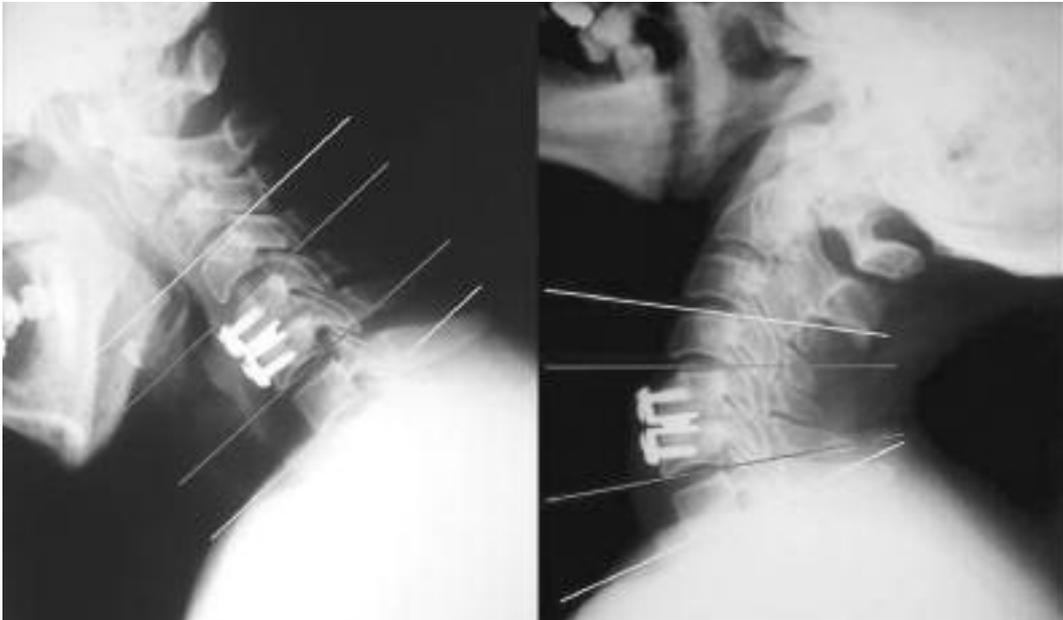


Figure-2. The neck movement range of the patient N.G. seen in the graphs taken in maximal extension and flexion.

Surgical Technique:

The disc space was accessed through a right anterolateral approach in all cases. After the anterior longitudinal ligament was sectioned with a scalpel, discectomy was performed with a pituitary rongeur. The posterior longitudinal ligament was opened confirming that the herniated material was noncontained. No technical difficulties were encountered during insertion of the prosthesis. Inserting the prosthesis added 10 minutes to the duration of the operative procedure.

All cases were operated on by the same surgeon with the same technique by applying anterior cervical microdiscectomy. The same prosthesis (Manufacturer Neuro France) was used for all patients.

RESULTS:

34 patients (28 female, 6 male) were followed up for an average of 25.76 months (12 – 36 months). The average age of the patients at the time of the surgery was 42.79 (29 – 54). While TDP was applied at one level in all patients, the implant was at C4-C5 in 1 patient, C5-C6 in 27 patients, and C6-C7 in 6 patients. 91.3 % of the patients expressed satisfaction after the surgery. Pre-operative average VAS scores of the patients was 9.26 (7-10) and average VAS scores during the follow-ups were 2.45 (0-8). There was significant improvement in the VAS scores of the patients compared to pre-operative values ($p<0,05$). Pre-operative average Oswestry scala of the patients was 33,23 (12-46) and the follow-up average Oswestry scala of the patients was 7.67 (1-17). There was significant improvement in comparison to pre-operative values also ($p<0,05$). No

neurological deficits were observed in any of the patients. Implant survival was 100 %. None of these showed any osteolysis or loosening. Measurements showed an average joint movement range (flexion/extension) of 7.2 degrees and a front-to-back translation range of 0.8 mm.

After the operation, surface tissue infections developed in two of the patients. Those patients were cured with medical treatment. The BOS fistula that developed in one patient was cured by medical treatment. No major neurological or vascular complications developed in any of the patients.

DISCUSSION:

The cervical disc prosthesis has several advantages over fusion. Firstly, less soft tissue dissection is carried out and the esophagus is retracted less. Secondly, with arthroplasty, there is less load and tension on adjacent cervical vertebra levels. Intradiscal pressures in cases where arthroplasty has been applied and cases that have never been operated are similar. Thirdly, in wide series there are higher rates of reoperation after cervical arthrodesis in comparison to arthroplasty due to adjacent segment problems. Fourthly, while successful treatment outcomes decrease with an increase in the number of involved segments in arthrodesis, this rate remains fixed in arthroplasty⁽⁵⁾. Furthermore, it takes a shorter time for patients to return to their normal lives when TDP is applied.

TDP indications were the presence of symptomatic cervical disc disorder (hernia nucleus pulposus, spondylosis or loss of height in the discs) between C3-T1 diagnosed by one or two level imaging methods, receiving no

response to conservative treatment for six weeks or longer, and being between the ages of 20- 70 ⁽¹⁾.

For decades, the golden standard treatment for radiculopathy or myelopathy caused by cervical spondylosis had been AD and IF ⁽¹⁰⁾. However, the two most significant problems with this treatment are the segmental mobility loss and increased risk of degeneration in the adjacent segment. In a study, **Hilibrand, et al.**, have determined the adjacent segment morbidity development risk in patients that have had cervical anterior decompression and fusion to be 2.9 % per year ⁽³⁾. This causes, in comparison to TDP, increased need for reoperation. In the study by **Nabhan, et al.**, of a total of 33 patients with cervical disc hernia and an average age of 45, 17 were treated with arthroplasty with Pro-Disc c and 16 with ADIF. They have found significantly higher mobility in the patients treated with TDP in evaluations carried out at the 3rd, 6th, 12th and 24th weeks after the operation. Furthermore, an increase in pressure in the disc is observed after fusion ⁽⁶⁾. In a study by **Chang, et al.**, while the pressure inside the disc after arthroplasty was close to the pressure before the operation, they have determined an increase in facet joint force after arthroplasty ⁽²⁾. In a multi-center study by **Sasso et al.**, 115 patients were divided into two groups and one group treated with fusion and the other group with arthroplasty using Bryan disc prostheses, and the disc prostheses was found more advantageous after a follow-up of 24 months. Another study comparing TDP and AD-IF reports no significant difference in short term results ⁽¹³⁾. In this study, conducted by **Peng-Fei, et al.**, 24 patients with cervical disc disorders at the C5-6 level were separated into two groups,

and fusion was applied to one group and disc prostheses to the other. The two groups were evaluated by comparing effectiveness, stability and the segmental mobility in the cervical vertebrae. No statistical differences were determined in relation to clinical effectiveness and movement range. Although the follow-up period was short (17 months), they have reported that they found no superiority in the patients who had been treated with disc prostheses ⁽⁹⁾. However, these findings conflict with literature.

In our series, we have only been able to reach 34 patients for a follow-up. In the measurements of the patients with dynamic x-ray, the range of motion (ROM) (flexion/extension) was found to be 7.2 degrees, front-to-back translation 0.8mm. In the study evaluating the cervical kinematics after fusion and disc prostheses by **Sasso, et al.**, average ROM was found to be 6.7 degrees after two years in the prosthesis group 12. Nabhan, et al., found a front-to-back translation of 0.67 mm in the 24th month after prosthesis implantation ⁽⁶⁾. The measurement results of our patients are compatible with literature, when the difference in the implants used and the number of patients is taken into consideration. **Kim, et al.**, have investigated the effects of the cervical disc prosthesis on maintaining the sagittal alignment of the functional spinal unit and the overall sagittal balance of the cervical spine. In the study, all patients were implanted with Bryan cervical disc prostheses ⁽⁴⁾. Clinical results are very encouraging for the Bryan cervical disc. They determined that the mobility of the functional spinal unit was preserved and the general sagittal balance of the cervical spine was maintained with the Bryan disc prosthesis ⁽⁴⁾.

Pickett, et al., investigated the complications in the patients they treated with Bryan prostheses. They implanted 96 disc prostheses in 74 patients, and reported 6.2 % complications at one level during the operation. Later complications were, heterotrophic ossification in two patients, migration in one patient, revision in one patient due to serious segmental kyphosis, and insufficient extension in one patient. Segmental mobility was maintained in 96 % of the patients ⁽¹¹⁾. These complications were not observed in our series. Surface infections were observed in two of our patients, and BOS fistula in one other. However, the number of cases in the mentioned study is higher, and it is known that the application of the Bryan prosthesis is more difficult ⁽⁷⁾.

The successful results of the studies that have been carried out and the early results of the randomized prospective studies have outcomes supporting TDP treatment. The simplified endplate preparation of the recently manufactured prostheses has reduced surgery time and per operative morbidity.

The clinical and radiological success we have achieved in our study support our decision to head towards dynamic stabilization. However, the retrospective nature of our study, not having evaluated the adjacent segment degeneration in every patient by postoperative magnetic resonance investigation, and not having been able to do regular follow-ups of the patients in order to study the changes in segment mobility through time are the weak points of our study.

In spite of all that, we believe that this is a successful treatment choice when the preservation of mobility and height, the

attainment of patient satisfaction and the neurological improvement are considered. The necessity of support for our series through the results of long term randomized studies is still valid.

REFERANCES:

1. Auerbach JD, Jones KJ, Fras CI, Balderston JR, Rushton SA, Chin KR. The prevalence of indications and contraindications to cervical total disc replacement. *Spine J* 2008; 8(5): 711-716.
2. Chang UK, Kim DH, Lee MC, Willenberg R, Kim SH, Lim J. Changes in adjacent-level disc pressure and facet joint force after cervical arthroplasty compared with cervical discectomy and fusion. *J Neurosurg Spine* 2007; 7(1): 33-39.
3. Hilibrand AS, Carlson GD, Palumbo MA, Jones PK, Bohlman HH. Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. *J Bone Joint Surg* 1999; 81-A (4): 519-528.
4. Kim SW, Shin JH, Arbatin JJ, Park MS, Chung YK, McAfee PC. Effects of a cervical disc prosthesis on maintaining sagittal alignment of the functional spinal unit and overall sagittal balance of the cervical spine. *Eur Spine J* 2008; 17(1): 20-29.
5. McAfee PC. Degenerative Disc Disease Cervical Disc Replacement Benefits. *Curr Opin Orthop* 2006; 1(3): 155-164.
6. Nabhan A, Ahlhelm F, Pitzen T, Steudel WI, Jung J, Shariat K, Steimer O, Bachelier F, Pape D. Disc replacement using Pro-Disc C versus fusion: a prospective randomised and controlled radiographic and clinical study. *Eur Spine J* 2007; 16(3): 423-430.
7. Özer AF, Öktenoğlu T, Sasani M, Bozkuş H, Canbulat N, Sarıoğlu AÇ. Cervical disc prosthesis. *Türk Nöroşir Derg* 2005; 15(3): 285-290.
8. Peng CWB, Quirnoa M, Bendo JA, Spivak JM, Goldstein JA. Effect of intervertebral disc height on postoperative motion and clinical outcomes

- after Prodisc-C cervical disc replacement. *Spine J* 2009; 9: 551–555.
9. Peng-Fei S, Yu-Hua J. Cervical disc prosthesis replacement and interbody fusion: a comparative study. *Int Orthop* 2008; 32(1): 103-106.
10. Phillips FM, Tzermiadianos MN, Voronov LI, Havey RM, Carandang G, Dooris A, Patwardhan AG. Effect of two-level total disc replacement on cervical spine kinematics. *Spine* 2009; 34(22): E794-E799.
11. Pickett GE, Sekhon LH, Sears WR, et al. Complications with cervical arthroplasty. *J Neurosurg Spine* 2006; 4(2): 98–105.
12. Sasso RC, Best NM, Cervical Kinematics After Fusion and Bryan Disc Arthroplasty. *J Spinal Disord Tech* 2008; 21: 19–22.
13. Sasso RC, Smucker JD, Hacker RJ, Heller JG. Clinical outcomes of Bryan cervical disc arthroplasty: a prospective, randomized, controlled, multicenter trial with 24-month follow-up. *J Spinal Disord Tech* 2007; 20(7): 481-491.
14. Shim CS, Lee SH, Park HJ, Kang HS, Hwang JH. Early clinical and radiologic outcomes of cervical arthroplasty with Bryan Cervical Disc prosthesis. *J Spinal Disord Tech* 2006; 19: 465-470.

