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INTERMEDIATE TO LONG-TERM CLINICAL AND RADIOLOGICAL RESULTS OF CERVICAL DISC PROSTHESIS: A COMPARATIVE STUDY WITH ANTERIOR CERVICAL DISCECTOMY AND FUSION

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ABSTRACT

Objective: As an alternative to anterior cervical discectomy and fusion (ACDF), cervical disc replacement (CDR) has become more popular over time because it is more suitable for cervical biomechanics. The aim of this study was to evaluate the intermediate- to long-term clinical and radiological results of polyetheretherketone cage CDR and compare them with the results of ACDF.

Materials and Methods: We retrospectively analyzed 39 cases following single-level CDR and 36 cases following single-level ACDF. Surgical levels treated in both groups included C3-4, C4-5, and C5-6, without any procedure performed on C6-7. Evaluations included adjacent segment disease (ASD), segmental range of motion (ROM), disc height, cervical lordosis, neck disability index (NDI), and the Visual Analogue Scale (VAS).

Results: At a mean follow-up of over 5 years, both groups were significantly improved in VAS and NDI ($p<0.01$). Both groups had an increase in cervical lordosis and disc height, albeit greater in the CDR group ($p<0.05$). Segmental ROM was maintained in the CDR group (9.0°), whereas it was significantly restricted in the ACDF group (1.1°, $p<0.001$). Moreover, the rate of postoperative ASD was significantly lower in the CDR group (2.6%) than that in the ACDF group (16.7%, $p=0.03$). Heterotopic ossification developed in 10.2% of the CDR group, without any symptomatic manifestations. Two revision surgeries were needed in the ACDF group, whereas none were needed in the CDR group.

Conclusion: CDR provides comparable symptom alleviation to ACDF, and also enables greater maintenance of motion, better alignment, and significantly less risk of ASD.

Keywords: Cervical disc prosthesis, disc height, cervical lordosis, motion preserve, spine motion

INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) has been the gold standard treatment method for many years in the treatment of cervical degenerative disc disease (CDDD) refractory to conservative treatment[1]. However, in the future, a secondary surgery may be needed to treat the adjacent segment disease (ASD) that develops in patients. In addition, complications such as instrument related complications and failure to develop fusion may create disadvantages in fusion surgery[2]. On the other hand, as an alternative to arthrodesis, cervical disc replacement (CDR) has become more popular over time because it is more suitable for cervical biomechanics[3]. CDR theoretically provides anatomical disc space, normal segmental lordosis, and demonstrates a physiological movement pattern[4]. It is a new generation cervical disc prosthesis and is used in the surgical treatment of symptomatic CDDD. This study aims the compare the intermediate to long-term outcomes of polyetheretherketone (PEEK)-based disc prostheses to the clinical and radiologic outcomes of ACDF in a matched cohort.

MATERIALS AND METHODS

This was a retrospective study of 39 patients (21 males and 18 females, of mean age 38.9 years, range, 26-58 years) underwent single-level CDR using a PEEK cervical disc prosthesis. In another group 36 patients (19 males, 17 females; mean age: 39.3 years, range: 27-60) underwent single-level ACDF. In the ACDF group, a standard PEEK interbody cage was used for fusion at the operated level. Surgical levels were C3-4 in 3 CDR (7.7%) and 4 ACDF (11.1%) cases, C4-5 in 9 CDR (23.1%) and 8 ACDF (22.2%) cases, C5-6 in 22 CDR (56.4%) and 19 ACDF (52.8%) cases, and C6-7 in 5 CDR (12.8%) and 5 ACDF (13.9%) cases.

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All participants were observed for at least 18 months. Informed consent was obtained from each of them and the study was approved by the Ağrı İbrahim Çeçen University Institutional Ethics Committee (decision number: 189, date: 28.09.2023). All procedures were strictly followed in accordance with relevant guidelines and regulations.

Surgical indications included single-level symptomatic CDDD between C3 and T1, with radiculopathy or myelopathy that failed to improve after at least 6 weeks of conservative treatment. Patients were excluded from the study if they were older than 65 years of age, had osteoporosis, metabolic bone disease, congenital or post-traumatic deformity, segmental instability (translation >3.5 mm or angulation >11°), or if they had a history of cervical surgery. Patients without complete preoperative or follow-up clinical data were also excluded from analysis.

A clinical assessment, which included the Visual Analog Scale (VAS) and neck disability index (NDI), was obtained preoperatively and upon final follow-up. Radiologic parameters were disc height (measured as the average of the anterior and posterior vertebral heights), cervical lordosis (range of C2-C7 Cobb angle), segmental range of motion (ROM), and assessment of ASD. Preoperative modalities included anterior-posterior (AP) and dynamic X-rays, computed tomography, and magnetic resonance imaging. Follow-up was assessed using AP, lateral, and dynamic lateral X-rays (Figure 1). ROM was recorded using the Cobb method as obtained on flexion-extension X-rays. In 10 cases, segmental ROM in C6-7 was impossible to measure due to shoulder overlap. Measurements were conducted using QMA™ software (Medical Metrics, Inc., Houston, TX) by two blinded spine surgeons.

The patients were assisted in walking on the day of discharge from the operation and drains were removed in 24 hours. Patients were active but wore a collars for 3 weeks. Patients were able to resume working depending on how fast they recovered. Meloxicam (15 mg twice a day) was administered postoperatively for 6 weeks in a bid to prevent heterotopic ossification (HO).

Statistical Analysis

Statistical analysis was carried out using IBM SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA). Continuous data was expressed as mean ± standard deviation, while categorical data was expressed in the form of frequencies and percentages. Paired samples t-test was used to compare preoperative and postoperative parameters among both groups (ACDF and CDR) including of NDI, VAS, lordosis of the cervical spine, disc height, and segmental ROM. An independent samples t-test for was used to compare the continuous postoperative outcomes between both groups, which included the last follow-up NDI, VAS, ROM, disc height, and cervical lordosis. Analysis of categorical data, namely distribution of gender, occurrence of HO, presence of ASD, and requirement of revision surgery, was done using the chi-square test or, where appropriate, Fisher's exact test. A p-value of <0.05 was considered statistically significant for all the analyses done.

RESULTS

The mean age of the participants in the CDR group was 38.9 years (range 26-58 years) and 39.3 years (range 27-60 years) in the ACDF group. Gender distribution was similar in both groups (CDR: 21 males, 18 females; ACDF: 19 males, 17 females).

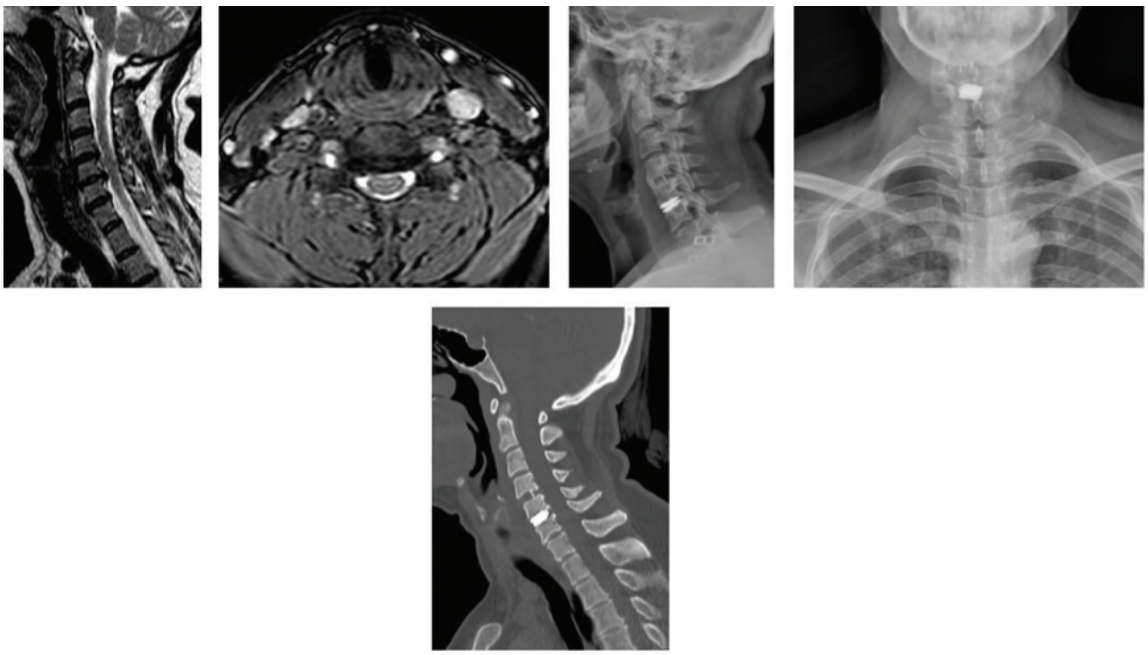

Figure 1. Preoperative magnetic resonance imaging (MRI) and postoperative X-ray-computed tomography and MRI of patient operated cervical disc prosthesis

Follow-up was of similar length in both groups (58.3±11.6 months in the CDR group and 56.9±10.9 months in the ACDF group; p=0.62). Hospital stay was also of similar length in both groups (2.6±1.1 days in the CDR group and 2.7±1.2 days in the ACDF group; p=0.77).

Both groups showed a statistically significant improvement in clinical scores after surgery. In the CDR group, the mean NDI score decreased from 50.8±12.1 to 10.2±5.1 (p<0.01), and the ACDF group showed a decrease from 49.6±11.7 to 11.1±5.3 (p<0.01); however, no statistically significant difference was found between the two groups in the final NDI scores (p=0.41). VAS scores improved, from 7.4±2.0 to 1.8±1.0 for the CDR group and from 7.3±1.9 to 2.0±1.1 for the ACDF group (both p<0.01), with no statistically significant difference found in the postoperative values (p=0.38).

Cervical lordosis improved significantly in both groups: it increased from 7.0°±9.6° to 14.8°±10.7° in the group which received CDR, and in the group that received ACDF, it increased from 6.5°±8.7° to 11.2°±9.4° (p<0.01 in both groups). Final lordosis was also significantly greater in the group that received CDR (p=0.034). Finally, disc height increased by 2.2±0.4 mm in the group that received CDR, and by 1.2±0.3 mm in the group that received ACDF (p<0.01 in both groups); the between-group difference in end-disc height was also significant (p<0.01).

Segmental ROM showed improvement in the cohort of CDR, from 5.5°±2.7° to 9.0°±3.1° (p<0.01), while that of the ACDF cohort decreased from 5.3°±2.5° to 1.1°±0.5° (p<0.001). Statistical analysis detected a significant postoperative ROM difference between both groups (p<0.001).

HO was observed in 4 patients (10.2%) in the CDR group, with no impact on motion or symptoms. No HO was detected in the ACDF group. ASD occurred in 1 patient (2.6%) in the CDR group and 6 patients (16.7%) in the ACDF group, which was statistically significant (p=0.03). Revision surgery was required in 2 ACDF patients (5.5%) due to pseudarthrosis, while no reoperations were needed in the CDR group (Table 1). Dysphagia was observed in 1 patient, and the patient did not have any problems in the last follow-up.

DISCUSSION

Results of this series demonstrate that CDR is a very effective and safe surgical procedure for CDDD. Relief in pain, improvement in functional outcome, and restoration of radiological parameters, including cervical lordosis, disc height, and ROM, were in accordance with the literature. CDR allows for the preservation of segmental motion unlike ACDF and might avoid the risk of ASD, which is the major drawback of the fusion techniques. These results strongly support CDR for both clinical and biomechanical success in properly selected patients.

There are many studies in the literature comparing ACDF, which is the gold standard treatment method in CDDD, and CDR, which has been increasing in popularity and use in recent years[4-9]. In this article, many data about CDR are presented to the reader with comparative studies with ACDF. In the meta-analysis study of Aragonés et al.[10], it was reported that CDR had lower NDI scores compared to ACDF, SF-36 score was more favorable, adverse events were seen at half the rate, and revision surgery was performed much less frequently. Shangguan et al.[11] reported that there was no difference between clinical scores between CDR and ACDF, but ROM were higher in CDR. Zigler et al.[12] reported that there was a significant improvement in VAS and NDI scores in patients who underwent CDR after 5 years of follow-up. In our study, CDR provides comparable symptom alleviation to ACDF, and also enables greater maintenance of motion, superior alignment, and significantly less risk of ASD.

The most common reason for revision after CDDD surgery

Table 1. Comparison of clinical and radiological outcomes between cervical disc replacement and anterior cervical discectomy and fusion groups

Parameter	CDR Group	ACDF Group	p-value
Number of patients	39	36	
Mean age (years)	38.9 (26-58)	39.3 (27-60)	
Sex (M/F)	21/18	19/17	
Mean follow-up (months)	58.3±11.6	56.9±10.9	0.62
Hospital stay (days)	2.6±1.1	2.7±1.2	0.77
NDI (pre → post)	50.8±12.1 → 10.2±5.1	49.6±11.7 → 11.1±5.3	0.41
VAS (pre → post)	7.4±2.0 → 1.8±1.0	7.3±1.9 → 2.0±1.1	0.38
Cervical lordosis (°)	7.0±9.6 → 14.8±10.7	6.5±8.7 → 11.2±9.4	0.034
Disc height (mm)	3.1±0.5 → 5.3±0.6	3.0±0.4 → 4.2±0.5	<0.01 (post-op)
Segmental ROM (°)	5.5±2.7 → 9.0±3.1	5.3±2.5 → 1.1±0.5	<0.001 (post-op)
HO occurrence	4 patients (10.2%)	0	-
ASD incidence	1 patient (2.6%)	6 patients (16.7%)	0.03
Revision surgery	0	2 patients (5.5%)	-

NDI: Neck disability index, VAS: Visual Analogue Score, ROM: Range of motion, HO: Heterotopic ossification, ASD: Adjacent segment disease, CDR: Cervical disc replacement, ACDF: Anterior cervical discectomy and fusion, M: Male, F: Female

is ASD[3]. The biggest advantages of CDR over ACDF are preservation of motion and less incidence of ASD[13]. In the meta-analysis of Findlay et al.[4], it was found that CDR is as effective as ACDF, and even in the mid-long term clinical results of CDR, patient satisfaction is mora favorable and ASD is less common. Goffin et al.[14] reported that radiological evidence of degeneration was observed at a rate of 92% approximately 8.6 years after ACDF. In addition, Hilibrand et al.[15] stated that the rate of symptomatic ASD 10 years after ACDF was 25.6%, and 72% of these patients were operated on. In the literature review of Chang et al.[16], it was reported that while ASD requiring reoperation was 6% after ACDF, it was 3% after CDR. In another literature review, it was reported that the reoperation rate due to ASD was between 0% and 0.4% after 5 years of follow-up in CDR[7]. In the study of Shin et al.[3], it was reported that complication rates and reoperation rate were significantly lower when compared to ACDF, although many physicians had a bias against CDR.

Many studies in the literature shows improvement in neurological status in patients undergoing CDR[6,17,18]. Moreover, in the study of Lanman et al.[19], neurological recovery was found to be superior in patients who underwent CDR compared to patients who underwent ACDF (91.6% vs 82.1%).

Postoperative complications include cerebrospinal fluid leakage, esophageal injury, nerve root injury, prevertebral hematoma, dysphagia, prosthesis migration, implant collapse, hoarseness, and C5 paralysis[8]. In the study of Li et al.[20], 10.9% migration was determined. None of these complications, except dysphagia in 1 patient, were detected in our patients. In the study of Radcliff et al.[9], less mechanical complications were found in the CDR group in comparisons between the ACDF and CDR groups. At the same time, it was observed that the total overall cost was less in the CDR group. Shangguan et al.[11] found that dysphagia was found to be significantly less common in the CDR group compared to the patients who underwent ACDF, and they attributed this to less esophageal retraction in the CDR group. In our study, dysphagia was observed in 1 patient, and the patient did not have any problems in the last follow-up.

There is a lot of knowledge in the literature about HO detected after CDR. In the meta-analysis of Hui et al.[21], the incidence of HO was 24.8%, and the incidence of HO cause ROM limitation was 11%. At the same time, they reported that it was more common in patients who underwent single-level CDR. They stated that cervical kinematics was provided better in patients with multiple-level disc prosthesis compared to patients with single-level disc prosthesis, and less HO was seen due to less deterioration in spinal biomechanics. In the meta-analysis of Chen et al.[22], HO was observed between 44.6% and 58.3% up to 2 years after surgery, while in another meta-analysis of Kong et al.[23], 38% HO was detected. As an undesirable complication after HO, spontaneous fusion may develop and may cause ROM limitation. In the study of Marques et al.[24] HO was detected in 92% of the patients after 5 years, and severe HO (grade 3-4) was reported in 71% and complete fusion (grade 4) was reported in 27% of the patients. In the study of Hou et al.[25], HO was not found in any of the 51 patients who underwent CDR at the end of a mean follow-up period of 61 months. In our study HO was observed in 4 patients (10.2%) in the CDR group, with no impact on motion or symptoms.

Many studies have been conducted on the types of cervical disc prosthesis. In the study of Miao et al.[26], Discover prosthesis (DePuy Spine, Raynham USA) was used and the VAS score decreased from 7.2 to 1.4 at the end of a 24-month follow-up. Obernauer et al.[27] reported that the clinical results were good and excellent at a rate of 95.7% at the end of the 24-month follow-up in patients who underwent ROTAIO Cervical Disc Prosthesis (SIGNUS Medizintechnik GmbH, Alzenau, Germany), and they mentioned that the need for painkillers decreased significantly. Other prostheses, the results of which have been reported quite successfully in the literature; Baguera®C (Spineart, Switzerland)[18], Bryan® (Medtronic Sofamor Danek, Memphis, USA)[28], Porous Coated Motion cervical disc (NuVasive Inc., San Diego, CA)[29], Prestige LP ADR (Medtronic Sofamor Danek)[30], Mobi-C (LDR Medical, Troyes, France)[31] and ProDisc-C (Synthes Spine USA Products; LLC, West Chester, PA)[12].

Study Limitations

Our study has several limitations. First, only one type of prosthesis was used, so it may not be correct to generalize to the results of all disc prostheses. Another limitation of the study in question is that the participants' neurological status, including specific motor and sensory findings, was not evaluated in a uniform manner by the use of standard neurological scoring systems. Lack of inclusion of the SF-36 assessment is a significant limitation in that it precludes thorough analysis of health-related quality of life.

CONCLUSION

CDR is a promising alternative to ACDF because it preserves motion and reduces ASD, Our midterm results has shown that there was a significant improvement in pain relief, functional outcome, and cervical alignment without implant-related complication or HO. This study confirm that the CDR procedure with PEEK prostheses ensures good clinical and radiological scores, proving its effectiveness and safety. On the other hand, the relatively small sample size and the lack of the control group in this series is a limitation to generalization of these results and would call for a larger series with longer follow-up in a variety of prosthesis designs in order to compare their effectiveness.

Ethics

Ethics Committee Approval: The study was approved by Ağrı İbrahim Çeçen University Institutional Ethics Committee (decision number: 189, date: 28.09.2023).

Informed Consent: Informed consent was obtained from all participants.

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Footnotes

Authorship Contributions

Surgical and Medical Practices: Y.K., E.B., Concept: Y.K., E.B., Design: Y.K., E.B., Data Collection or Processing: Y.K., Analysis or Interpretation: Y.K., E.B., Literature Search: Y.K., E.B., Writing: Y.K., E.B.

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