Correlation of Clinical and Radiological Outcome After Anterior Cervical Discectomy and Fusion With a Polyetheretherketone Cage

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Abstract

Background: Anterior cervical discectomy and fusion (ACDF) with a polyetheretherketone (PEEK) cage is considered as the gold standard for patients with cervical disc disease. However, there are limited in vivo data on the impact of ACDF on the cervical kinematics and its association with patient-reported clinical outcomes. The purpose of this study was to investigate the impact of altered cervical sagittal alignment (cervical lordosis) and sagittal range of motion (ROM) on patients’ self-reported pain and functional disability, after ACDF with a PEEK cage.

Methods: We prospectively studied 74 patients, who underwent single-, or consecutive two-level ACDF with a PEEK interbody cage. The clinical outcomes were assessed by using the pain numeric rating scale (NRS) and the neck disability index (NDI). Radiological outcomes included cervical lordosis and C2-C7 sagittal ROM. The outcome measures were collected preoperatively, at the day of patients’ hospital discharge, and also at 6 and 12 months postoperatively.

Results: There was a statistically significant reduction of the NRS and NDI scores postoperatively at each time point (P < 0.005). Cervical lordosis and also ROM significantly reduced until the last follow-up (P < 0.005). There was significant positive correlation between NRS and NDI preoperatively, as well as at 6 and 12 months postoperatively (P < 0.005). In regard to the ROM and the NDI scores, there was no correlation preoperatively (P = 0.199) or postoperatively (6 months, P = 0.322; 12 months, P = 0.476). Additionally, there was no preoperative (P = 0.134) or postoperative (6 months, P = 0.772; 12 months, P = 0.335) correlation between the NDI scores and cervical lordosis.

Conclusions: In our study, reduction of cervical lordosis and sagittal ROM did not appear to significantly influence on patients’ self-reported disability. Such findings further highlight the greater role of pain level over the mechanical limitations of ACDF with a PEEK cage on patients’ own perceived recovery.

Keywords: Anterior cervical discectomy and fusion; Cervical ROM; Neck disability index; Numeric rating scale; Pain; PEEK cage; Cervical lordosis

Introduction

Anterior cervical discectomy with fusion (ACDF) constitutes one of the most commonly performed procedures in spine surgery, characterized by quite high success and low complication rates. ACDF is regarded as the standard surgical treatment option for cervical spondylosis with myelopathy, radiculopathy and/or symptomatic disc herniation, when conservative management has failed. The reported results for ACDFs are excellent for the patients, as this is generally stated in the pertinent literature [1, 2]. ACDF in the vast majority of cases successfully reduces neck and arm pain, restores both vertebral disc height and foraminal height, and also leads to an osseous fusion [3, 4].

ACDF using a polyetheretherketone (PEEK) cage is considered by many spinal surgeons, as the gold standard for patients with cervical disc herniation. PEEK is biocompatible, radiolucent, and has a modulus of elasticity similar to that of the bone. PEEK cages may achieve a significant increase in the disc space height and the neural foramina, contributing to nerve root decompression and, thereby, further controlling pain. In addition, the implantation of a PEEK cage is char-
acterized by a significantly lower infection rate, compared to ACDF with an autologous bone graft [5, 6].

On the other hand, partial fusion of the cervical spine inevitably resulted in alternations to the physiological biomechanics of the area [7]. Inadequate cervical lordosis and reduced cervical range of motion (ROM) have been suggested to be significant negative contributors in the outcome of ACDF surgery [8].

Although there are several clinical and radiological studies in the literature regarding the progress of fusion, as well as the clinical improvement of patients undergoing ACDF with a PEEK cage, there are a limited number of studies, investigating the correlation of clinical improvement with cervical lordosis, and also with cervical ROM of such patients.

The purpose of our current study was to investigate the impact of altered cervical sagittal alignment (cervical lordosis) as well as the impact of cervical sagittal ROM changes, on patients' self-reported pain and functional disability, in patients undergoing ACDF with a PEEK cage.

### Materials and Methods

This was a prospective, same subjects, repeated-measures study.

### Study group

The study group exclusively consisted of patients that fully completed the research protocol (6 and 12 months follow-ups). Therefore we analyzed the clinical and radiological outcomes of 74 patients, who underwent single-, or consecutive two-level ACDF using a PEEK interbody cage filled with allograft. All participants suffered cervical radiculopathy or myelopathy, which had remained unresponsive to any conservative treatment, for at least a 3-month period. The eligibility of the patients was assessed and determined by the same neurosurgeon. Demographic variables such as age, sex, and smoking habits were recorded. Radiological and clinical evaluation of the patients was preoperatively performed, at the day of their hospital discharge, and then at 6 and 12 months postoperatively. A signed informed consent was obtained from all participants before their enrolment in the study. The study protocol was conducted in agreement with the Declaration of Helsinki and approved by the scientific council of our hospital.

### Assessment of outcome

#### Clinical evaluation

Intraoperative and postoperative complications were noted. Numeric rating scale (NRS) and the neck disability index (NDI) were used in order to obtain a time series of self-reported neck/arm pain severity and cervical spine function changes. NRS and NDI are two of the most commonly cited instruments for assessing self-rated pain and disability in patients with neck pain [9]. The above clinical outcome instruments were administered by the single blinded research assistant and without the presence of the treating surgeon.

#### Radiologic evaluation

The radiologic evaluation of the cervical spine in the pre- and postoperative period included lateral radiographs in neutral, and also in full active flexion-extension, in order to obtain a time series of cervical lordosis and sagittal ROM changes. On the basis of the radiographic images, we calculated the cervical lordosis in neutral and sagittal ROM of C2-C7, using the Cobb method. The Cobb angle was determined as the angle of intersection of two tangential lines drawn along the inferior end plate of the C2 and the inferior end plate of the C7. Lordosis was expressed as a positive value and kyphosis was expressed as a negative value so as sagittal ROM was determined by measuring the difference in alignment between maximum flexion and extension. Radiographic measurement data were collected from an independent observer, who was not involved in the management of these patients. Representations of the clinical and radiologic evaluation are illustrated in Table 1.

### Statistical analysis

The collected data were processed using the Statistical Package for the Social Sciences software (SPSS version 20, IBM Corporation, NY, USA). All results are presented as the mean value ± SD. The Friedman’s two-way analysis of variance methodology for non-parametric data, and the repeated measures ANOVA methodology as well as the paired samples t-test methodology for parametric data, were carried out to assess
the effect of ACDF on time-related changes (preoperative, postoperative, 6, and 12 months) in cervical lordosis, sagittal ROM, pain NRS and NDI. Pearson product moment correlation coefficient methodology for parametric data and the Spearman rank order correlation coefficient methodology for non-parametric data were also used to determine the relationship between NDI and, NRS, cervical lordosis and sagittal ROM, respectively. Additionally, the statistical significance of the observed differences of the mean between subgroups was calculated by using the independent samples t-test methodology. A P value of < 0.05 was considered to be significant in all the above statistical tests.

**Results**

**Patient demographics and surgical data**

Using the inclusion/exclusion criteria presented in Table 2, 74 patients (36 males and 38 females; mean age 50.09 ± 13.54 years) with cervical radiculopathy or myelopathy, were enrolled. There was a minimum (< 20 mL) blood loss in 37 (49.3%) patients, and a mean of 75.66 ± 31.56 mL in the remaining 38 (50.7%) patients. Sixty-five patients (86.7%) used only hard cervical collar postoperatively, while the other 10 (13.3%) used hard and soft collar, sequentially. A summary of the demographics and the surgical details are presented in Table 3.

**Complications**

In one patient (1.35%) an accidental intraoperative esophageal perforation occurred, and a surgical repair of the iatrogenic esophageal tear was performed at a different surgical setting, by a cardiothoracic surgeon. The patient stayed with no oral intake and parenteral alimentation for 6 days after his second surgery, and recovered with no further consequences. His follow-up revealed no dysphagia or any other esophageal motility difficulties. Two patients (2.7%) developed postoperatively a clinically evident soft tissue hematoma, which was conservatively managed with close observation, requiring no surgical evacuation. These two patients recovered with no further con-

**Clinical outcome**

Neck/arm NRS scores and NDI scores were available from

| Characteristic                  | No. of patients/value (%) |
|---------------------------------|---------------------------|
| No. of patients                 | 74                        |
| Male/female ratio               | 36:38                     |
| Age (years)                     |                           |
| Mean                            | 50.09 ± 13.54             |
| Range                           | 28 - 86                   |
| Body mass index (BMI)           |                           |
| Mean                            | 27.82 ± 4.73              |
| Range                           | 20.3 - 42.0               |
| No. of smokers                  | 37 (50)                   |
| Radiculopathy/myelopathy ratio  | 36:38                     |
| Single-level ACDF               | 66 (89.19)                |
| Two-level ACDF                  | 8 (10.81)                 |
| ACDF (disc level)               |                           |
| C3-4                            | 14 (17.07)                |
| C4-5                            | 16 (19.51)                |
| C5-6                            | 38 (46.34)                |
| C6-7                            | 14 (17.07)                |
| Duration of postoperative brace (days) |                     |
| Mean                            | 34.44 ± 17.56             |
| Range                           | 30 - 120                  |
all participants. The difference of the observed mean between subgroups (smokers/non-smokers, myelopathy/radiculopathy, single-level fusion/two-level fusion) was statistically insignificant for any of the explored clinical parameters (Table 4). Therefore, we calculated the sample (n = 74) as homogeneous.

The observed mean NRS score immediately after surgery demonstrated a significant reduction from the preoperative one (P = 0.000). This reduction was maintained significant at 6 months (P = 0.000) and 12 months postoperatively (P = 0.000). Moreover, the calculated mean NDI score at the 6-month evaluation showed statistically significant reduction from the preoperative one (P = 0.000) and this reduction was maintained significant at the 12-month follow-up evaluation (P = 0.000). The changes of the clinical outcomes over time are illustrated in Figure 1 and are summarized in Table 5. Additionally, there was significant positive correlation between NRS and NDI preoperatively (r = 0.351, P = 0.001), at 6-month follow-up evaluation (r = 0.241, P = 0.004), as well as at the 12-month follow-up evaluation (r = 0.250, P = 0.003).

**Radiological outcome**

There was a successful implantation of a PEEK cage in all participants, with no mechanical failures or other implant associated malfunctions. Additionally, there was a successful fusion in all participants, with no pseudoarthrosis at the implantation levels until the last follow-up (12 months). The difference of the observed mean between subgroups was statistically insignificant for any of the explored radiologic parameters (Table 6). Therefore, we calculated the sample (n = 74) as homogeneous, too. A summary of the radiological results is presented in Table 5.

**Cervical lordosis**

The mean postoperative Cobb angle from the C2 to the C7 in neutral (index of the cervical lordosis) was found to be slightly increased compared to the preoperative one. However, this difference was statistically insignificant (P = 0.429). Interestingly, the mean Cobb angle at 6 months postoperatively was lower than the respective preoperative one. However, this difference was statistically insignificant (P = 0.0095) (a P value of < 0.0083 was considered to be significant due to Bonferroni correction). At the 12-month postoperative evaluation, the mean Cobb angle was again lower than the preoperative one, and this difference reached the levels of statistical significance (P = 0.008). Additionally, there was no significant correlation between the NDI scores and the Cobb angle preoperatively (r = 0.175, P = 0.134), at 6 months postoperatively (r = 0.034, P = 0.772), and also at 12 months (r = -0.113, P = 0.335) postoperatively.

**C2-C7 sagittal ROM**

The 6-month follow-up mean sagittal ROM was significantly reduced compared to the preoperative one (P = 0.000) and the observed difference remained significant (P = 0.000) at the 12-month follow-up evaluation. Further processing of our data demonstrated that this reduction of the ROM was more prominent in patients undergoing two-level ACDF than those undergoing single-level ACDF (Fig. 2, Table 6). Additionally, in regard to the calculated ROM and NDI scores, there was no correlation preoperatively (r = 0.099, P = 0.199), at 6 months postoperatively (r = 0.034, P = 0.772), and also at 12 months (r = -0.007, P = 0.476) postoperatively.

**Discussion**

To our knowledge, there is limited number of studies to evaluate the association of cervical lordosis and ROM with patient-reported functional disability. Contrary to the generally accepted clinical deduction, the results of the current study indicated that cervical lordosis and ROM do not exert a significant impact on patient-reported functional capacity. On the other hand, our results indicated that pain level exerts a significant impact on patient-reported functional capacity.

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Table 4. Outcomes of Clinical Parameters for Subgroups (Mean ± SD) and the Significance of the Differences Between Subgroups

| Subgroups                  | NRS Preoperative | NRS Postoperative | NRS 6 M | NRS 12 M | NDI Preoperative | NDI 6 M | NDI 12 M |
|----------------------------|------------------|-------------------|---------|---------|-----------------|---------|---------|
| Smokers (n = 37)           | 6.32 ± 2.86      | 2.38 ± 1.74       | 0.79 ± 1.52 | 0.19 ± 0.74 | 23.89 ± 12.54 | 2.35 ± 3.12 | 0.57 ± 1.72 |
| Non-smokers (n = 37)       | 6.00 ± 2.59      | 2.41 ± 1.54       | 0.62 ± 1.14 | 0.16 ± 0.73 | 24.08 ± 16.35 | 4.54 ± 6.18 | 1.97 ± 5.66 |
| P value                    | 0.611            | 0.944             | 0.582   | 0.874   | 0.956           | 0.058   | 0.156   |
| Myelopathy (n = 38)        | 5.79 ± 2.91      | 2.16 ± 1.42       | 0.51 ± 1.03 | 0.03 ± 0.16 | 23.32 ± 15.82 | 3.76 ± 6.13 | 1.63 ± 5.27 |
| Radiculopathy (n = 36)     | 6.57 ± 2.50      | 2.71 ± 1.77       | 0.94 ± 1.61 | 0.34 ± 1.03 | 24.46 ± 13.19 | 3.20 ± 3.44 | 0.91 ± 2.77 |
| P value                    | 0.225            | 0.143             | 0.181   | 0.080   | 0.740           | 0.634   | 0.475   |
| Single-level fusion (n = 66)| 6.33 ± 2.75      | 2.44 ± 1.67       | 0.79 ± 1.39 | 0.20 ± 0.77 | 23.29 ± 14.27 | 3.38 ± 4.47 | 1.12 ± 3.79 |
| Two-level fusion (n = 8)   | 4.75 ± 2.05      | 2.00 ± 1.19       | 0.00 ± 0.00 | 0.00 ± 0.00 | 29.75 ± 15.80 | 4.00 ± 8.55 | 2.50 ± 7.07 |
| P value                    | 0.120            | 0.475             | 0.095   | 0.474   | 0.235           | 0.845   | 0.386   |

M indicates months. NDI (%).
The essential purpose of ACDF with a PEEK cage is to decompress the spinal cord and other neural structures whilst to maintain the stability of the cervical spine. Additionally, there is strong body of evidence that PEEK cage implantation restores and successfully maintains the intervertebral disc height and also the neural foramina height, postoperatively [4, 10-12]. Therefore, the achieved mechanical decompression of the compressed cervical roots and the possible restoration of the local micro-circulation may result in pain reduction [13]. Consistent with other clinical series [4, 10, 11, 14-16], our current data clearly indicated that there was a statistically significant reduction of neck/arm pain among our patients at their discharge from the hospital. This effect was maintained during their 12-month follow-up period.

In accordance to other clinical series with similar samples and follow-up periods [17-19], our data demonstrated that there was statistically significant postoperative improvement of the NDI score. It has been postulated that the postoperative pain reduction is strongly associated with the patient’s satisfaction [14, 20]. Additionally, it is well known that NDI was designed to measure disability in activities of daily living due to neck pain [21, 22]. The above would be an explanation of our findings regarding the parallel significant reduction in neck/arm pain mean scores and NDI mean scores (Table 5, Fig. 1). There are several studies supporting the concept that NDI reduction is associated to pain reduction through the postoperative period [10, 16, 23-25] and our study results strongly support this. More specifically, there was statistically significant correlation

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**Figure 1.** Line graphs illustrating: (a) the pain NRS mean scores and (b) the NDI mean scores preoperatively and then at 6- and 12-month time points. There was significant difference between time points for both instruments.
between these variables (NDI and NRS) in the preoperatively obtained scores as well as in the postoperatively obtained scores (6- and 12-month).

It is well known that lordotic sagittal alignment of the cervical spine is absolutely necessary, in order the spine to sustain the mechanical stresses of daily-living activities. McAviney et al [26] reported statistically significant correlation between neck pain and cervical lordosis less than 20°. Additionally, according to Wu et al [27], the restoration or the maintenance of acceptable cervical lordosis after ACDF affects the long-term

Table 5. Outcomes of Clinical and Radiological Parameters for the Sample as a Whole (Mean ± SD)

| Outcome       | Preoperative | Postoperative | 6 M | 12 M |
|---------------|--------------|---------------|-----|-----|
| NRS (n = 74)  | 6.16 ± 2.7 (0 - 10) | 2.40 ± 1.62 (0 - 6) | 0.70 ± 1.33 (0 - 6) | 0.17 ± 0.72 (0 - 4) |
| NDI (n = 74)  | 23.88 ± 14.4 (0 - 74) | 3.40 ± 4.96 (0 - 25) | 1.25 ± 4.29 (0 - 25) |
| Cobb angle (n = 74) | 14.7 ± 9.36 (-22.0 - 42.0) | 14.88 ± 8.36 (2.0 - 43.0) | 12.0 ± 9.56 (-9.0 - 46.0) | 11.96 ± 9.55 (-9.0 - 46.0) |
| ROM (n = 74)  | 50.8 ± 12.59 (15.0 - 68.0) | 41.25 ± 12.24 (12.0 - 63.5) | 41.22 ± 11.82 (12.0 - 60.0) |

**Table 6. Outcomes of Radiological Parameters for Subgroups (Mean ± SD) and the Significance of the Differences Between Subgroups**

| Subgroups          | Cobb angle | ROM |
|--------------------|------------|-----|
|                    | Preoperative | Postoperative | 6 M | 12 M | Preoperative | 6 M | 12 M |
| Smokers (n = 37)   | 14.95 ± 11.26 | 16.40 ± 8.74 | 11.40 ± 10.33 | 11.39 ± 10.29 | 51.45 ± 11.04 | 42.54 ± 10.91 | 42.80 ± 10.42 |
| Non-smokers (n = 37) | 13.93 ± 6.50 | 12.70 ± 6.71 | 12.01 ± 8.24 | 11.93 ± 8.22 | 48.50 ± 14.06 | 40.00 ± 13.45 | 39.68 ± 13.01 |
| P value            | 0.637 | 0.805 | 0.780 | 0.804 | 0.320 | 0.386 | 0.269 |
| Myelopathy (n = 38) | 16.80 ± 7.89 | 15.55 ± 8.72 | 12.62 ± 8.61 | 12.58 ± 8.60 | 52.37 ± 10.93 | 42.26 ± 12.20 | 42.19 ± 11.32 |
| P value            | 0.037 | 0.328 | 0.360 | 0.354 | 0.069 | 0.390 | 0.269 |
| Radiculopathy (n = 36) | 11.71 ± 9.85 | 13.33 ± 7.06 | 10.60 ± 10.9 | 10.54 ± 10.03 | 47.00 ± 13.87 | 39.74 ± 12.13 | 39.74 ± 12.13 |
| P value            | 0.079 | 0.238 | 0.360 | 0.354 | 0.069 | 0.390 | 0.387 |
| Single-level fusion (n = 66) | 13.86 ± 9.10 | 14.39 ± 7.36 | 11.26 ± 8.70 | 11.21 ± 8.65 | 49.88 ± 12.68 | 41.62 ± 12.49 | 41.50 ± 12.06 |
| P value            | 0.121 | 0.622 | 0.232 | 0.232 | 0.867 | 0.453 | 0.548 |
| Two-level fusion (n = 8) | 19.19 ± 8.62 | 15.87 ± 12.45 | 15.44 ± 13.35 | 15.37 ± 13.41 | 50.69 ± 13.14 | 37.93 ± 9.79 | 38.64 ± 9.79 |

M indicates months. Cobb angle and ROM (°). Min-max in brackets.

**Figure 2.** Line graphs illustrating C2-C7 ROM for the single- and two-level ACDF groups preoperatively and then at 6- and 12-month time points. There was significant difference between time points for both conditions.
Decreased cervical lordotic angle seems to be associated with earlier adjacent degenerative changes [28]. There are several studies in the literature examining the effect of ACDF with a PEEK cage in the management of cervical lordosis. They resulted in significant lordosis restoration postoperatively that was maintained throughout the final follow-up (12 - 24 months) [16-19]. Contrariwise, our results showed that there was a slight increase of the mean Cobb angle in neutral immediately after surgery, which however was lost during the 12-month follow-up period (Table 5). Unfortunately, we cannot identify any factors for explaining these findings in our series. An explanation for this would be the possible adjacent level degeneration [28, 29], a factor that we did not explore. Nevertheless, our current Cobb angle measurements are into acceptable limits, since the reported in the pertinent literature predictable lordotic angle values are 13.90±12.30° for healthy subjects, while 11.40±9.80° for myelopathic patients [30].

In agreement with previous studies [31, 32], patients underwent ACDF in the current study demonstrated a statistically significant reduction of the C2-C7 sagittal ROM postoperatively (6-months follow-up) which remained reduced at the 12-month follow-up evaluation (Table 5). This reduction was more prominent among patients undergoing two-level ACDF (Fig. 2, Table 6). This is in contrast with previous findings, which have reported a significant improvement in ROM following ACDF, even in those with multilevel fusions [14, 33, 34]. According to Chien et al [31], one plausible explanation for the discrepancies may lie with the differences in the method of how the ROM was obtained. Results presented in our study were based on radiographs measured through C2-C7, where the other studies have utilized external wearable devices such as a helmet with goniometers or inclinometers to obtain the global ROM. Such devices commonly include the ROM contributed from the upper cervical and cranial junction [31]. Another plausible explanation is that in the patients who underwent ACDF for radiculopathy, a pathological condition in which the pain cause reduced ROM, decreased radicular pain postoperatively results into improved postoperative ROM. Finally, on the basis of the results of the current study and known in vitro data, ACDF with a PEEK cage is likely to be associated with a reduction of sagittal ROM, which is potentially correlated with the number of fused levels [31].

A cumulative interpretation of our data indicates that our patients had improved self-reported pain intensity (NRS) and disability (NDI) profile, maintained their C2-C7 lordosis at predictable values, while they had reduced sagittal cervical ROM. Similarly, Seng et al [32] documented postoperative reduction of patient-reported pain intensity and disability, along with sagittal cervical ROM reduction. It has been previously stated that there is a relation between cervical ROM, pain and finally, disability [33]. Moreover, it has been postulated that postoperative restoration of the cervical lordosis influences the overall, long-term, clinical outcome. Based on these hypotheses, the observed improvement of patient-reported disability (NDI) in our current study should be accompanied by a restored cervical lordosis postoperatively, as well as by an increased, or at least unchanged, sagittal cervical ROM. How-
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