의학석사 학위논문

경추 인공 디스크 치환술 이후 시간에 따른 수술 분절의 움직임의 변화

Longitudinal changes in segmental range of motion following cervical artificial disc replacement

2017년 2월

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지도교수 정 영 섭

이 논문을 문 정 현 석사학위논문으로 제출함

2017년 2월

서울대학교 대학원

신 경 외 과 학

문 정 현

문 정 현의 석사학위논문을 인준함

2017년 2월

위 원 장 정 천 기 (인)

부위원장 정 영 섭 (인)

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Abstract

Longitudinal changes in segmental range of motion following cervical artificial disc replacement

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Background

Cervical artificial disc replacement (ADR) has emerged as a popular new treatment because of its potential benefit of averting an adjacent segment disease following ACDF. However, ADR also has problems such as heterotopic ossification, or mechanical failure, which raises concerns that the artificial disc would lose its function at some point.

Purpose

To estimate the life expectancy of artificial disc, we analyzed longitudinal changes in the range of motion at the implanted segment during follow-up in a cohort of patients with healthy facet joints before surgery.

Patients and methods

We reviewed the charts and radiologic studies of 30 patients operated upon by ADR with Mobi-C® in single level since 2006. All patients had healthy cervical facet joints (less than or equal to grade 1 according to grading systems for cervical facet joint degeneration) preoperatively. We assessed clinical outcomes with neck disability index (NDI) and visual analogue pain score (VAS) on neck and arm over follow-up and also measured the ROM at the implanted segment on dynamic radiographs during follow-up. The mean follow-up period was 42.4 ± 15.9 months. We then assessed the linearity of the changes in the ROM at the implanted segment in a linear mixed model.

Results

All patients showed improved clinical outcomes. On average, the NDI, VAS on neck and arm improved with representing 74%, 76% and 92% improvement.

ROMs at the implanted segment were maintained at slightly increased levels until 24 months postoperatively (P=0.529). However, after 24 months, ROMs at the implanted segment decreased significantly until last follow-up (P<0.001). In addition, the decreasing pattern after 24 months showed a regular regression (P<0.001). Based on this regular regression, we estimated that ROMs at the implanted segments would be less than 2 degrees at 10.24 years postoperatively.

Conclusion

In the present study, we could assume that the implanted segment would lose its motion at 10.24 years after artificial disc replacement. In other words, an artificial disc may lose its function someday.

Keywords: anterior cervical; discectomy; artificial disc replacement (ADR); range of motion (ROM); implanted; segment; longitudinal

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Introduction

Anterior cervical discectomy and fusion (ACDF) is the gold standard for the treatment of degenerative cervical spine disease [1]. However, long term results after ACDF have shown developing adjacent segment disease because of the loss of range of motion (ROM) in fused segments [2-5]. Therefore, cervical artificial disc replacement (ADR) has been suggested as an alternative to ACDF due to the preservation of mobility and the function of implanted segments. There are numerous studies that have revealed the preservation of segmental ROM over follow-up without the development of adjacent segment disease after ADR [6, 7]. Cervical artificial disc replacement offers several theoretical and obvious advantages compared with ACDF. However, ADR also has problems such as heterotopic ossification or mechanical failure, which may raise concerns about the long-term fate of artificial discs [8]. Nevertheless, there are few papers that show how ROM at the implanted segment changes with the passage of time after ADR [9].

The purpose of this study was to depict changing ROM patterns at the implanted segment over follow-up after ADR and to estimate the life expectancy of artificial cervical discs. We performed this study in a cohort in which all patients had a healthy facet joint before surgery.

Patients and methods

Patient cohort and surgical technique

The Institutional Review Board (1610-104-801) approved our study. We reviewed the charts and radiological studies of 30 consecutive patients who were operated on using ADR at a single institute since 2006.

The patients had presented with radiating pain, paresthesia or weakness caused by cervical degenerative disease. We included patients who underwent ADR in a single level and excluded patients who underwent hybrid surgery (ADR and ACDF). We also excluded patients with trauma or tumors. All patients underwent ADR with Mobi-C® prosthesis (LDR medical, France) in a single level. The mean follow-up period was 42.4 ± 15.9 months.

The Mobi-C®, cervical artificial disc is a semiconstrained mobile-bearing bone-sparing device. It is composed of two spinal plates consisting of cobalt, chromium, 29 molybdenum alloy (CoCrMo, ISO 5832-12) and an ultra-high-molecular-weight polyethylene (UHMWPE) mobile insert [10]. ADR was performed by 3 experienced surgeons at a single institute. The surgical technique consisted of a conventional anterior approach and discectomy followed by neural decompression. After decompression, the prosthesis was gently inserted into the disc space using a specific inserter. The primary anchoring optimization was obtained through compression with the Casper distractor. An X-ray (AP and lateral view) confirmed the adequate positioning of the implant. There were no differences in postoperative management among the 3 surgeons.

Radiological assessment

Preoperatively, MRI, CT, and dynamic X-rays of the cervical spine were taken in all patients. Cervical facet joint degeneration was graded according to the literature [11, 12]. As shown in Table 1, cervical facet joint degeneration was classified into grades 0 to 4 according to presence/absence of osteophytes, subchondral sclerosis, and the irregularity of the apophyseal joints. With the careful screening of the preoperative CT, we included only patients who had healthy cervical facet joints (less than or equal to grade 1) (Fig. 1A) and excluded patients with tumor or trauma. The follow-up dynamic X-rays were also taken in all patients. All patients were requested to flex and extend their necks to the extent they could tolerate for dynamic X-rays. Dynamic measurements with flexion and extension from a lateral view were subsequently taken at 3 months, 6 months, 9 months, 12 months, 2 years, 3 years, 4 years, and 5 years postoperatively.

We measured the flexion-extension ROM at the implanted segment on the lateral radiograph by a tangent method [13]. We also confirmed whether the implanted segment was fused or not by measuring the difference in interspinous processes on dynamic lateral radiographs. We considered an implanted segment to be fused if the difference in interspinous processes was below 2 mm on dynamic views [14]. The development of HO was assessed on lateral radiographs and graded according to McAfee's criteria [15]. Two experienced observers measured all views. Because the values of the two observers were consistent statistically significant (Fig. 1B), we performed an analysis with the median value of the two observers.

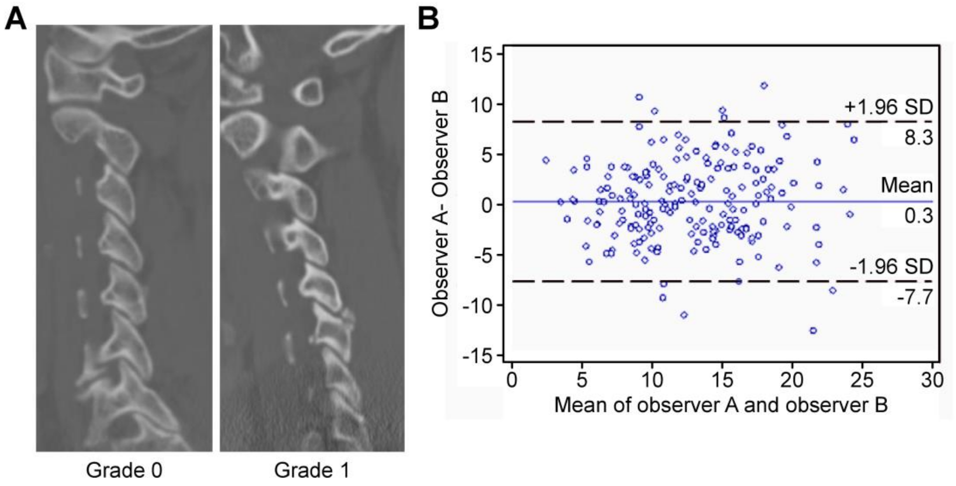

Fig.1.

A. Preoperative facet joint grade of patients. Grade 0, absence of degeneration in the apophysial joints: Grade 1, doubtful osteophytes on margins of the articular facets of the apophysial joints.

B. A Bland-Altman plot to confirm a correspondence

Outcome assessments

Clinical outcomes were assessed with the neck disability index score (NDI) and with visual analog scales (VAS) for neck and arm pain. The NDI score was measured preoperatively and over follow-up. NDI success was defined as an improvement of scores greater than or equal to 15 points after surgery, which was used to evaluate a functional recovery. VAS for neck and arm pain was measured preoperatively and over follow-up. Neurologic status was also evaluated by the investigator through reflex test, motor and sensory function. Neurological success was defined as the absence of significant neurologic deterioration.

Statistical analysis

To correct the intraobserver and interobserver reliability of the radiologic measurement, two experienced observers independently evaluated the radiographs of patients. We then analyzed the values with a Bland-Altman plot to confirm a correspondence.

We used the linear mixed model to assess the longitudinal changes of ROMs at the implanted segments and compensated for missing values in our data. Additionally, to assume when the implanted segment would lose its motion, we used regression analysis. We also used Kaplan-Meier curve analysis to analyze how many of the implanted segments maintained their motion during the follow-up period and when the risk of decreased ROMs at the implanted segment increased, compared to the normal segmental ROMs, which were based on a study by Lind et al. [16] (Table 2).

Statistical analysis was carried out using SPSS software for Windows (ver.21.0; SPSS Inc., Chicago, IL, USA). The results were considered as statistically significant at $P < 0.05$ (two-sided).

The demographics of the patients are shown in Table 1.

Table 1. Patient characteristics

Number of patients (No.)	30
Male:female (No.)	21:9
Mean age at surgery (years of age)	44
Mean follow-up length (months)	42.4
Grade for cervical facet joint degeneration (No.)	Grade 0: 28 Grade 1: 2
Implanted level (No.)	C3-4: 1 C4-5: 6 C5-6: 15 C6-7: 8

Results

Clinical results

All patients achieved an improvement in their symptoms. The NDI, on average, improved from 20.5 to 5.08 at the last follow-up, which represents a 74% improvement. Fifteen of 30 patients achieved an improvement in their NDI scores higher than or equal to 15 points (Fig. 2A).

The VAS score was reduced on average at each follow-up period. The neck VAS score on average reduced from 6.3 to 1.5 at the last follow-up, representing a 76% improvement, and the arm VAS score on average was also reduced from 6.9 to 0.5 at the last follow-up, representing a 92% improvement (Fig. 2B).

All patients also achieved neurological success at the last follow-up.

There were no reoperations due to device failure or postoperative bleeding in our cohort.

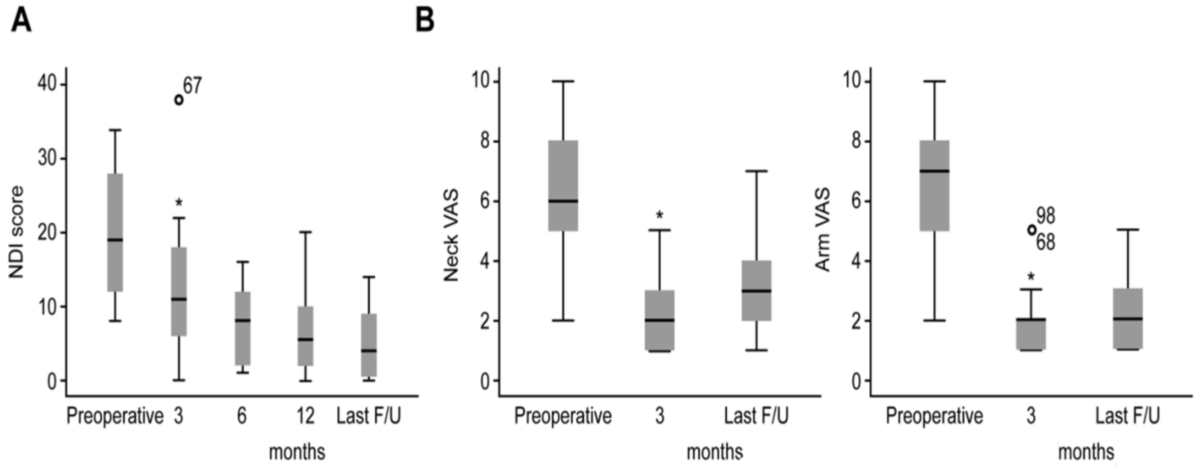

Fig. 2.

A. The change of a Neck Disability Index (NDI) over follow-up period. *The decrease of NDI was statistically significant.

B. The change of visual analogue pain score (VAS) on neck (left) and arm (right) over follow-up period. *The decrease of VAS on neck and arm was statistically significant.

Radiographic results

The radiologic measurement was statistically correlated between the intraobserver and interobserver observations. Preoperatively, of the total 30 patients, 28 patients had grade 0 cervical facet joints; 2 patients had grade 1 cervical facet joints. This argues for the fact that most patients in our cohort had relatively healthy facet joints preoperatively [11, 12].

Heterotopic ossification (HO) was found in 13 of 30 patients at the last follow-up. Eight patients had an HO grade of 3, 4 patients had a grade of 2, and 1 patient had a grade of 1. There were no grade-4 HO patients in our cohort. The incidence of HO was 43%.

The longitudinal changes of ROMs at the implanted segments are shown in Figure 3A. We analyzed this longitudinal change with median values from two measurers. ROMs at the implanted segments did not change for 24 months, compared to the preoperative segmental ROMs (P=0.529). However, ROMs at the implanted segments decreased significantly from 24 months to the last follow-up with regular regression (P=0.01) (Fig. 3B). Based on this regression, we could assume that cervical artificial disc would lose their function after 10.24 years postoperatively (less than 2°) (Fig. 4A). The linear mixed model revealed this trend.

Since we found that segmental ROMs decreased after 24 months, we analyzed how many of the implanted segments maintained their motion during the follow-up period compared to the normal segmental ROMs by using a Kaplan–Meier curve analysis. In the Kaplan–Meier curve analysis, the event was defined to be beyond a standard deviation of the normal ROM at each segment, which was based on a study by Lind et al. [16] (Table 2).

Table 2. Normal cervical flexion and extension angles by Lind et al. [17]

	No.	Mean ± SD(°)				
		C2-3	C3-4	C4-5	C5-6	C6-7
Lind et al. [17]	70	10 ± 4	14 ± 6	16 ± 6	15 ± 8	11 ± 7

In survival analysis, 80% of the implanted segments maintained their motion comparable to normal segmental ROMs until the last follow-up. However, a hazard function revealed that the probability of a less-than-normal segmental ROM began to increase after 48 months (Fig. 4B).

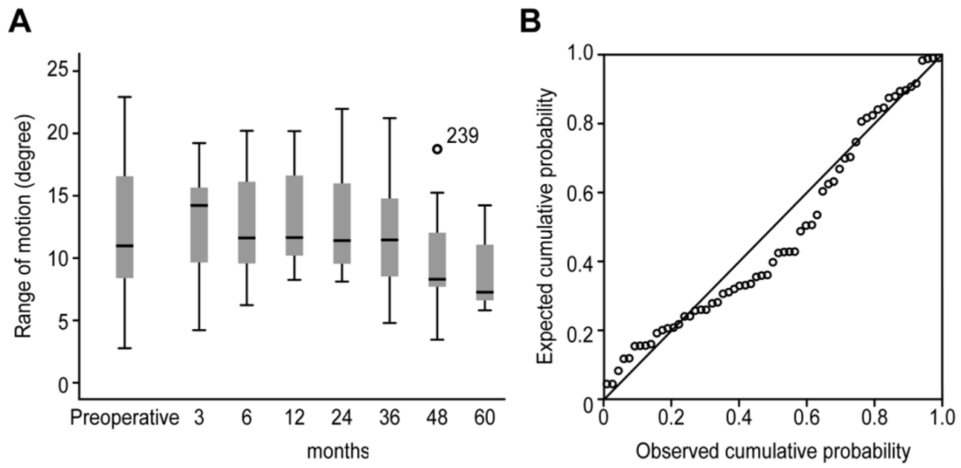

Fig. 3.

A. Longitudinal changes of range of motion (ROM) at implanted segment from preoperative to postoperative 60 months. This graph showed that ROM at implanted segment decreased significantly after 24 months.

B. Regular regression graph. The decreasing pattern of ROM at implanted segment after 24 months showed a regular regression.

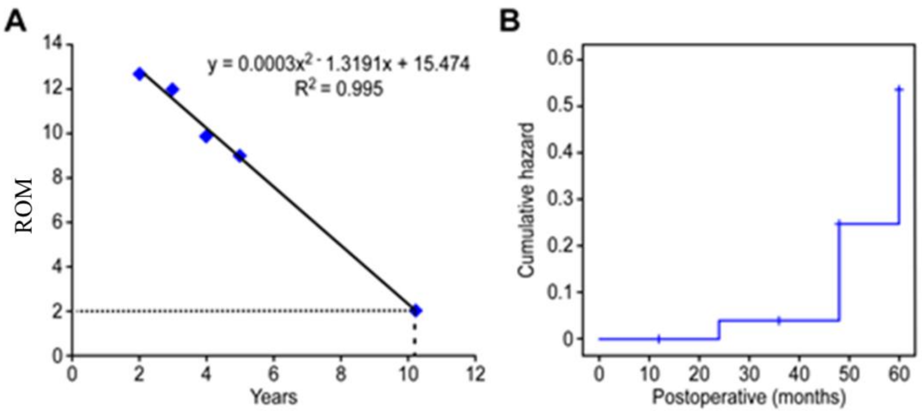

Fig. 4.

A. The trend line that showed when the range of motion (ROM) at implanted segment would be less than 2 degrees. This graph showed that ROM at implanted segment would be less than 2 degrees at 10.24 years postoperatively.

B. Hazard function. The event was defined to be beyond standard deviation of the normal ROM at each segment. This graph showed that the probability of a less than normal segmental ROM began to increase after 48 months.

Discussion

Even though ACDF is the gold standard for the treatment of degenerative cervical disease, many surgeons are searching for alternatives because of likelihood of the development of adjacent segment diseases following ACDF.

Because the loss of operated segmental motion caused adjacent segment diseases, ADR has been in the limelight as an alternative to ACDF.

There are numerous studies reporting that ADR is able to maintain segmental ROM at the implanted segment during follow-up [9, 17, 18]. However, there are also studies reporting that segmental ROM at the implanted segment tended to decrease with time [19-21].

To address this controversial issue, we performed a retrospective analysis to look at how the segmental ROMs at the implanted segments change during the follow-up period in a cohort that consisted of patients who had minimal facet degeneration and were operated upon with Mobi-C® .

Since we tried to elucidate the change of ROM by only ADR, excluding the effect by facet joint degeneration, we included only patients who had healthy cervical facet joints preoperatively [11, 12]. The incidence of heterotopic ossification, which is known as one of the major issues to cause the loss of motion after ADR, was 43%, which was similar to what has been reported in other studies [22, 23]. There were only 3 patients who lost their ROM at the implanted segment at the last follow-up. Nevertheless, there was a clear decreasing trend in ROMs at the implanted segments from postoperative 24 months.

As shown in Figure 3A, ROMs at the implanted segments were maintained until 24 months without a significant decrease (P=0.529). After that, however, ROMs at the implanted segments started to decrease significantly until last follow-up (P<0.001).

Since we found that segmental ROMs decreased with time after 24 months, we analyzed how many of the implanted segments maintained their motion until the last follow-up, compared to segmental ROMs in a normal cohort. In survival analysis, 80% of the implanted segments were within the normal range, comparable to the segments in a normal cohort during follow-up. However, we found that the probability of less-than-segmental ROMs in a normal cohort began to increase sharply after 48 months (Fig. 4B).

In addition, we noticed that the decreasing pattern of ROMs at the implanted segments after 24 months showed a regular regression (P=0.01) (Fig. 3B). Although this regression did not include all ROMs at the implanted segments, we tried to estimate when ROMs at the implanted segments would lose their motion (less than 2°). We found that ROMs at the implanted segments would lose their motion after 10.24 years postoperatively, based on the regression (Fig. 4A).

There are numerous studies that advocate cervical artificial disc replacement due to its preservation of motion. These studies have tried to reinforce the power of evidence using multicenter studies [10, 19, 24]. Most of these studies insisted that an artificial disc replacement was superior to ACDF by comparing a preoperative segmental ROM with a postoperative ROM at the implanted segment, especially at the last follow-up. In other words, they explained how great a proportion of the implanted segments would maintain their motion at the last follow-up compared to a preoperative segmental ROM.

Although a multicenter analysis is a useful and powerful method for the limited-time comparison between pre- and post-operation, an analysis of a longitudinal trend in multicenter study is not easy. In the present study at a single center, we were able to analyze the long-term longitudinal change in ROM at implanted segments, even though it would be insufficiently powerful as a multicenter study. As a time point analysis, our results were similar to those of other multicenter studies because 80% of implanted segments maintained their motion comparable to a normal segment until the last follow-up in our study. However, we analyzed the longitudinal change of ROM at the implanted segments and thus confirmed that ROM at the implanted segments decreased significantly after 24 months postoperatively.

It is unclear whether ROM at the implanted segments will decrease continuously according to this pattern after 60 months or not. However, Putzier et al. reported that a Charité total disc replacement in the lumbar spine resulted in a high rate (60%) of spontaneous fusion or arthrodesis after an average follow-up of 17 years [25].

Although the kinetics of the cervical spine are different from those of the lumbar spine, we can assume that implanted segments with an artificial disc would lose their motion eventually.

In addition, there are also several studies showing a decreasing trend of segmental ROM after implantation even though ROM at the implanted segments were relatively preserved until the last follow-up [17, 18]. Burkus et al. [18] reported that ROM at the implanted segment were preserved until the last follow-up in their prospective randomized controlled study. They analyzed segmental ROMs at the implanted segment preoperatively and at 1.5 months, 3 months, 6 months, 12 months, 24 months, 36 months, and 60 months postoperatively. In their study, the mean ROMs at the implanted segments were 7.5° preoperatively, 7.3° at 36 months, and 6.4° at 60 months postoperatively. Although the implanted segmental ROM at 48 months postoperatively was not analyzed, it was clear that ROMs at the implanted segment decreased during the follow-up period, especially after 36 months. This result also shows that ROM at the implanted segments would decrease with time, even though this result did not perfectly coincide with our result.

Limitations of the study

There were some limitations in the present study.

First, this study was a retrospective analysis at a single center. The selection bias and limited statistical power should be considered. Additionally, not all patients underwent serial radiographs during the follow-up period. Therefore, we tried to compensate the missing data with a statistical method (linear mixed model analysis). Prospective analysis was necessary to increase the reliability of our results. Second, a decreasing pattern does not mean the loss of segmental ROMs. Therefore, it is necessary to study whether the degree of ROM should be maintained to prevent adjacent segment disease even though the ROM would not be within the range of a normal segment ROM. Third, we performed the study with a single device, the Mobi-C®, which cannot represent all artificial disc devices.

Finally, a larger number of cases and an additional, longer follow-up period are necessary.

Conclusion

In summary, we confirmed that the operated segmental ROMs began to decrease significantly after 24 months even though they were preserved until 24 months. Based on this decreasing pattern, we could assume that the implanted segments would lose their motions at 10.24 years after artificial disc replacement, even though the 80% of implant segments maintained their motions within a normal range until 60 months. Although Mobi-C® is currently an approved implant and ADR is preferable due to motion preservation after implantation, this study raises the question of whether artificial discs would lose their functionality eventually.

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국문초록

경추 인공 디스크 치환술 이후 시간에 따른 수술 분절의 움직임의 변화

배경

경추 인공 디스크 치환술은 수술 이후 치환된 분절의 움직임을 어느 정도 보존할 수 있어서 일반적인 경추 전방 유합 수술 이후 발생되는 인접 분절의 퇴행성 질환을 예방할 수 있다고 알려져 있다. 하지만 경추 인공 디스크 치환술 역시 수술 후 수술 부위 골화 생성이나 인공디스크 자체의 물리적 문제 등이 대두 되고 있어 과연 인공 디스크가 얼마나 분절의 움직임 보존이라는 본연의 역할을 유지할 수 있을지 의문이 제기되고 있는 실정이다.

목적

순전한 인공 디스크의 수명을 예측하기 위해서 우리는 건강한 경추 후관절을 가진 환자군만을 대상으로 경추 인공 디스크 치환술을 하였고 추적관찰 규칙적인 추적 관찰 기간을 통하여 시간에 따른 인공 디스크 분절의 움직임을 후향적으로 분석하였다.

대상환자군 및 연구 방법

우리는 2006년부터 단일 분절에 인공디스크 치환술을 받은 환자 30명의 의무기록과

영상의학적 사진들을 후향적으로 살펴보았다. 모든 환자는 수술 전 후관절의 상태는 후관절 퇴행정도로 분류해 보았을 때 0 혹은 1 등급의 건강한 상태였다. 우리는 임상적 결과를 neck disability index (NDI) 및 목과 팔의 VAS를 가지고 측정하였고 추적 관찰 기간 중에 역동적 x-ray를 촬영하여 수술 분절의 움직임을 분석 하였다. 평균 추적관찰 기간은 42.4 ± 15.9 개월이었다. 또한 우리는 선형복합모델을 만들어서 추적 관찰 기간 동안의 수술분절의 움직임의 변화를 분석하였다.

결과

모든 환자가 향상된 임상적 결과를 얻었다. 평균 NDI, 목의 VAS 그리고 팔의 VAS가 수술 전과 비교했을 때 74%, 76%, 92% 향상되었다. 수술 분절의 움직임은 수술 후 24 개월 까지는 거의 변화 없이 유지되다가 24개월 이후부터 마지막 추적관찰 시점까지 통계학적으로 의미있게 감소하였다 ($P<0.001$). 이러한 감소는 일정한 패턴을 보이고 있었으며($P<0.001$) 이 패턴을 기반으로 수술 분절의 움직임이 2도 이하가 되는 시점을 예측해 보았을 때 10.24년 이라는 결과를 얻을 수 있었다.

결론

이 연구에서 우리는 경추 인공 디스크 치환술 후 10.24년이 지나면 인공 디스크의 움직임이 사라진다는 것을 (2도 이하) 예측 할 수 있었다. 다시 말해서 인공디스크는 언젠가 그 기능을 상실한다는 것을 확인하는 결과 이다.

주요어: 전방 경추, 디스크제거 수술, 인공 디스크 치환술, 분절의 움직임, 수술 분절, 시간에 따른 분석

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