

**Changes in Cervical Range of Motion
and Sagittal Alignment at Early and
Late Phases after ProDisc-C Total Disc
Replacement: Radiographic Follow-up
for Over 2 Years**

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Changes in Cervical Range of Motion and Sagittal Alignment at Early and Late Phases after ProDisc-C Total Disc Replacement: Radiographic Follow-up for Over 2 Years

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Sincerely,
Poong Gee Ahn

<TABLE OF CONTENTS>

ABSTRACT.....	1
I. INTRODUCTION	4
II. PATIENTS AND METHODS	7
1. Surgical Indications and Techniques	8
2. Radiographic Assessment of Surgical and Adjacent segments	9
3. Radiographic Measurements of Cervical Alignments	10
4. Statistical Analysis	11
III. RESULTS	12
1. Changes of C2-7 ROM and C5-6 ROM.....	12
2. Changes of ROM at upper and Lower Adjacent Segments	14
3. Changes of Sagittal l Alignments after Prodisc-C or Cage insertion.....	17
IV.DISCUSSION	20
V.CONCLUSION	24
REFERENCES	25
ABSTRACT (IN KOREAN)	29

<LIST OF FIGURES, LIST TABLE>

LIST OF FIGURES

Figure 1. Plain lateral X-ray film of cervical spine with C5/6 Prodisc-C arthroplasty	10
Figure 2. The percentage of C5/6 ROM of FSU to the C2-7 ROM	13
Figure 3. The percentage of C5/6 ROM of FSU to the C2-7 ROM	14
Figure 4. The ROM of the adjacent segment	16
Figure 5. The contribution percentages of adjacent ROMs to the overall C2-7 ROM	17
Figure 6. Sagittal alignment of cervical spine.....	18

LIST OF TABLE

Table 1. Patient demographics of ProDisc-C and fusion groups...	7
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<ABSTRACT>

Changes in Cervical Range of Motion and Sagittal Alignment at Early and Late Phases after ProDisc-C Total Disc Replacement: Radiographic Follow-up for Over 2 Years

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Objectives: Cervical total disc replacement (C-TDR) using an artificial disc has been suggested as a promising alternative to traditional arthrodesis for saving spinal mobility at the functional segment and protecting against degeneration at adjacent segments. This was a retrospective clinical study with a follow-up of more than 2 years to investigate the time-course of radiographic changes in the range of motion (ROM) at functional and adjacent levels as well as whole neck motion after C-TDR using a ProDisc-C artificial disc (Synthes Spine, Paoli, PA, USA).

Methods: Eighteen patients (15 men and 3 women; mean age 37.7 years) with C5–6 C-TDR using the ProDisc-C were followed up for 27 months (range 24–35). Digitized cervical neutral and flexion–extension lateral X-ray images

were obtained before and at 1 and 3 months after surgery for ‘early phase’ observations and at the last follow-up for a ‘late phase’ observation. Segmental ROM values in the operated, upper and lower adjacent segments were measured. For whole neck motion, the ROM for C2–7 was also measured. The percentage contributions of ROM at functional and adjacent segments to whole neck motion were expressed as each segmental ROM/C2–7 ROM \times 100. For evaluating postoperative sagittal alignment, we measured the Cobb angles of the C2–7 and C5–6 segments. We compared all data from patients receiving a ProDisc-C with the results from 22 patients undergoing conventional C5–6 anterior cervical discectomy and fusion (ACDF; 9 men, 11 women; mean age 45 years; defined as the ‘cage group’) using a Solis cage (Stryker Howmedica GmbH, Mulheim, Germany), who were followed up for 25 months (range 24–32).

Results: In the ProDisc-C group, C2–7 and C5–6 ROM values decreased at the early phase after surgery and returned to preoperative levels at the late phase ($P > 0.1$). Both upper and lower adjacent segments showed slightly decreased ROM measures at the acute phase after surgery and nonsignificantly increased the ROM at final follow-up ($P > 0.05$). In terms of contributions to whole neck motion, the ROM values of the functional and adjacent segments did not show any significant change compared with the preoperative value (P

> 0.05). In the cage group, C2–7 ROM was unchanged ($P > 0.5$). Both upper and lower adjacent segments showed significantly increased ROM values and percentage contributions to whole neck motion at the early and late phases ($P < 0.05$). Alignment of the entire cervical spine was not significantly changed in either group ($P > 0.05$). The C5–6 Cobb angle became significantly lordotic in the ProDisc-C group ($P < 0.05$), whereas there was no significant change in C5–6 angle in the cage group ($P > 0.1$).

Conclusions: In the early phase after ProDisc-C replacement, the ROM of the entire neck as well as functional and adjacent segments decreased but, at the late phase, they returned to the preoperative state. Contributions of functional and adjacent segments to whole neck motion were not changed after ProDisc-C replacement. Adjacent segmental motion could be saved by ProDisc-C replacement instead of ACDF using a Solis cage. Segmental degenerative kyphosis was significantly corrected by ProDisc-C replacement.

Key Words: cervical spine; artificial disc; adjacent segmental degeneration; interbody fusion

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I . INTRODUCTION

To date, anterior cervical discectomy and fusion (ACDF) has been accepted as a standard procedure for anterior cervical spine surgery¹⁻³. However, fusion surgery has the disadvantage of converting a functionally movable segment into a fixed and immovable spinal unit, and disc degeneration at an adjacent segment after ACDF has been described by several authors⁴⁻⁶. Recently, cervical total disc replacement (C-TDR) using various types of artificial disc has been suggested as a promising alternative to traditional arthrodesis for saving spinal mobility in the treated segment and for reducing the strain on the adjacent segments⁷⁻¹¹.

Currently, several cervical artificial discs are available on the market. They vary in terms of design, materials, range of motion (ROM) and surgical ease of use. Among them, ProDisc-C (Synthes Spine, West Chester, PA, USA) is a metal-on-polyethylene articulating device. Mechanically, it is a semiconstrained ball-and-socket type artificial disc that needs a keeling procedure for insertion into the upper

and lower vertebral endplates to stabilize it^{12,13}.

In C-TDR using an artificial disc, determining any changes in the ROM in surgically treated and adjacent segments as well as in the entire cervical spine is important as it can affect degeneration in adjacent discs. There have been several in vivo studies on the ROM in functional and adjacent segments after C-TDR using the ProDisc-C^{8,12,14-16}. However, those studies had limitations in that they had a follow-up of only around 1 year^{8,12,15,16}, only carried out transaxial observation at a specific time point^{8,15,16} or described only the ROM of the functional segment^{8,14-16}. The ROM measured on full flexion–extension radiographs can differ at each time, particularly at early and late phases after surgery because of postoperative neck pain or from the patient's decreased compliance for fear of extreme neck motion. In addition to the various ROM values measured directly on radiographs, the individual contributions of the functional and adjacent segments to whole neck motion are other significant factors because they might represent indirectly the strain on a specific disc space during a given neck motion.

The first objective of this study was to investigate the time-course changes in ROMs of the entire cervical spine as well as functional and adjacent segments by over 2 years follow-up after C-TDR using ProDisc-C. We also evaluated the contributions of functional and adjacent segments to whole neck motion.

Postoperative cervical kyphosis has been reported after arthroplasty using unconstrained cervical artificial discs^{11,17}. Compared with such devices, the semiconstrained ProDisc-C leads to some limitations in axial movement and

anteroposterior translation¹⁵. Therefore, the second objective of this study was to determine the changes in cervical sagittal alignments after ProDisc-C replacement.

II. PATIENTS AND METHODS

Between March 2005 and August 2006, we performed C-TDR using ProDisc-C on 38 patients (ProDisc-C group). Among them, we retrospectively reviewed 18 patients (15 men and 3 women) receiving C5–6 C-TDR with a mean age of 37.7 years (range 27–50; Table 1). We selected this procedure because the C5–6 level always permits ROM to be measured at functional and adjacent segments and there would be no level-associated bias in comparing the data. All 18 patients had been diagnosed with intervertebral disc herniation. The mean duration of follow-up was 27.5 months (range 24–35).

To highlight the changes in ROM, we compared the results from 18 ProDisc-C replacements with 20 patients (9 men and 11 women) receiving ACDF at C5–6 using a stand-alone Solis cage (Stryker Howmedica GmbH, Mulheim, Germany). These patients (cage group) had a mean age of 45 years (range 28–65). Preoperative diagnoses were mainly of a herniated cervical disc with minimal spondylosis. The mean duration of follow-up was 25.3 months (range 24–32).

Table 1. Patient demographics of ProDisc-C and fusion groups

	ProDisc-C	Cage
Parameters	(N = 18)	(N = 20)
Male-to-female ratio	15 : 3	9 : 11
Age (years)	37.7 (27 - 50)	45.0 (28 - 65)

Follow-up period (months)	27.5 (24 - 35)	25.3 (24 - 32)
Preoperative diagnosis		
Herniated cervical disc		
Soft	11	15
Hard or mixed	7	5
Postoperative complication	1 (hematoma)	0

1. Surgical Indications and Techniques

Inclusion criteria for surgery in both groups were degenerative disc diseases with radiculopathy or myelopathy, which had not responded to conservative treatment. Exclusion criteria included trauma, preoperative radiographic instability, active infections, severe osteoporosis, inability to visualize the affected disc space on optimized lateral fluoroscopy because of artifacts involving the shoulders, or severe kyphotic alignment¹². Patients with multiple cervical lesions or previous cervical spine surgery were also excluded from both groups.

In both groups, a standard right-sided anterior approach was used for removing the symptomatic disc or bony spur but the posterior longitudinal ligament was retained as much as possible. For ACDF, a cage filled with autologous iliac cancellous bone was inserted into the intervertebral disc space and not reinforced using any other instrument. The basic procedures for inserting the ProDisc-C into the disc space were as described by Bertagnoli et al.⁸. Briefly, a prosthesis trial is inserted into the disc space after total removal of disc material. Upper and lower channels for the keels of the ProDisc-C are made in the center of disc space using the keel cutting

chisel and then the ProDisc-C prosthesis is inserted into the disc space. All procedures for keeling and inserting an artificial disc for C-TDR and inserting a cage for ACDF were performed under the control of a fluoroscopic image intensifier.

2. Radiographic Assessment of Surgical and Adjacent segments

Digitized cervical neutral and flexion–extension lateral X-ray images were obtained before surgery, 1 and 3 months after surgery for ‘early phase’ observation and over 2 years after surgery for a ‘late phase’ observation in both ProDisc-C and cage groups.

For lateral flexion–extension cervical images, patients were instructed to flex and extend their neck as much as possible. The ROM of a specific cervical segment was defined as the difference in angles measured on flexion and extension lateral cervical X-ray films (Fig. 1). We measured the angles using quantitative measurement analysis software in a picture archiving and communication system PACS workstation (Centricity 3.0, General Electrics Medical Systems, Milwaukee, WI, USA). All angles were measured twice by 2 investigators independently. The ROM values were measured at the surgically treated (C5–6) and at the adjacent upper (C4–5) and lower (C6–7) segments. For whole neck motion, the ROM of C2–7 was also measured.

For ROM at the C5–6 segment (C5–6 ROM) on which arthroplasty or ACDF was performed, we used the angle of the functional spinal unit (FSU)^{11,18}. The angle of the C5–6 FSU is formed by lines drawn parallel to the upper endplate of the C5

body and the lower endplate of the C6 body. For ROM of the C2–7 (C2–7 ROM), the angle was measured between lines parallel to the C2 lower and C7 upper end plates. For ROM values at adjacent upper (C4–5 ROM) and lower (C6–7 ROM) segments, angles were measured using lines parallel to the endplates of disc spaces.

The percentage contribution of ROM at surgically treated and adjacent segments to whole neck motion was expressed as each segmental ROM/C2–7 ROM \times 100.

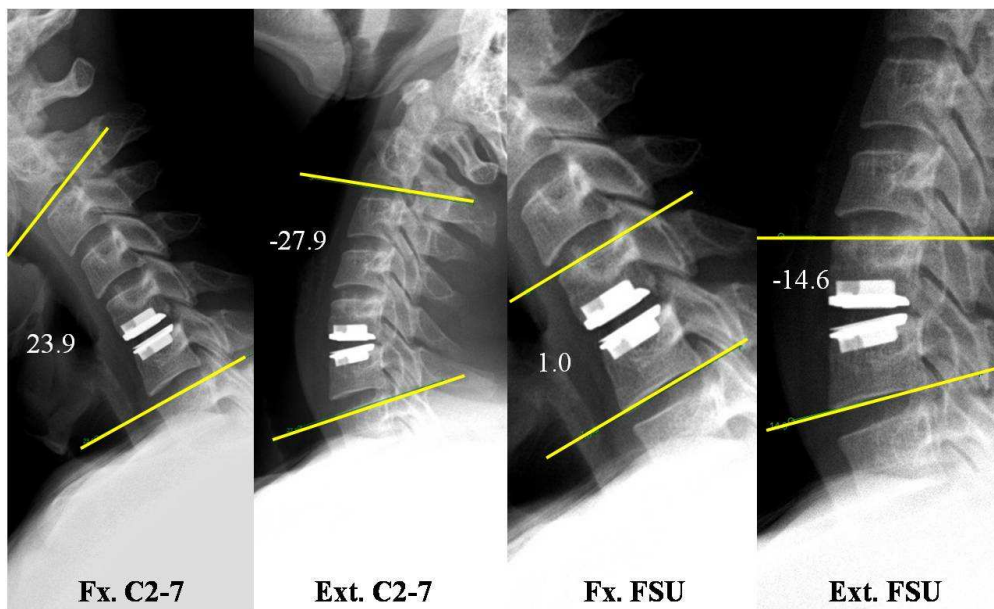


Figure 1. Cervical flexion–extension lateral X-ray films after a C5–6 ProDisc-C replacement. The range of motion (ROM) of the cervical spine was defined as the difference between the Cobb's angles of the flexion and extension lateral radiographs at the C2–7 segments (Fx. C2–7 and Ext. C2–7) and the C5–6 functional spinal unit (Fx. FSU and Ext. FSU). Fx., flexion; Ext., extension; FSU, functional spinal unit.

3. Radiographic Measurements of Cervical Alignments

The effects of ProDisc-C or cage insertion on cervical sagittal alignment were evaluated. On cervical lateral X-ray films in neutral position, a sagittal Cobb angle with lordosis or kyphosis was expressed as a negative or positive value, respectively. The C2–7 Cobb angle was measured for a sagittal alignment of the whole cervical spine. The Cobb angle at C5–6 FSU was measured for a sagittal alignment of the surgically treated segment.

4. Statistical Analysis

We used a mixed model analysis of repeated measures using SAS software for Windows (SAS version 9.1, SAS Institute Inc., Cary, NC, USA). The p-value below 0.05 was accepted as significant.

III. RESULTS

1. Changes of C2-7 ROM and C5-6 ROM

The C2–7 ROM and C5–6 ROM values were measured preoperatively, at 1 and 3 months after surgery and at the final follow-up. In the ProDisc-C group, the C2–7 ROM measures were $47.5 \pm 16.5^\circ$, $36.0 \pm 15.4^\circ$, $42.6 \pm 14.8^\circ$ and $52.1 \pm 12.2^\circ$, respectively. The C5–6 ROM values were $13.0 \pm 6.2^\circ$, $12.2 \pm 4.9^\circ$, $13.1 \pm 5.3^\circ$ and $14.4 \pm 5.8^\circ$, respectively (Fig. 2). Thus, the C2–7 and C5–6 ROM values decreased at the early phase after ProDisc-C replacement and then returned to the preoperative value at the late phase but this was without statistical significance when compared with preoperative values ($P > 0.1$). In the cage group, C2–7 ROM values were $42.3 \pm 12.3^\circ$, $36.7 \pm 12.6^\circ$, $40.2 \pm 10.6^\circ$ and $42.5 \pm 9.8^\circ$, respectively, at the time points given above and the C5–6 ROM values were $10.9 \pm 4.8^\circ$, $0.3 \pm 0.5^\circ$, $0.3 \pm 0.2^\circ$ and $0.3 \pm 0.3^\circ$, respectively (Fig. 2). In the cage group, the C2–7 ROM also decreased slightly at the early phase and returned to almost the same as the preoperative value at the late phase ($P > 0.5$). C5–6 ROM was close to 0° after surgery ($P < 0.0001$).

In terms of the percentage contribution of the ROM at C5–6 to whole neck motion in the ProDisc-C group, the ratios were $27.8 \pm 12.5\%$, $36.4 \pm 13.2\%$, $31.5 \pm 8.8\%$ and $27.8 \pm 9.5\%$, respectively (Fig. 3). Thus, the ROM at C5–6 contributed significantly to whole neck motion at the early phase after ProDisc-C replacement ($P < 0.05$) but returned to the preoperative ratio at the late phase ($P > 0.5$).

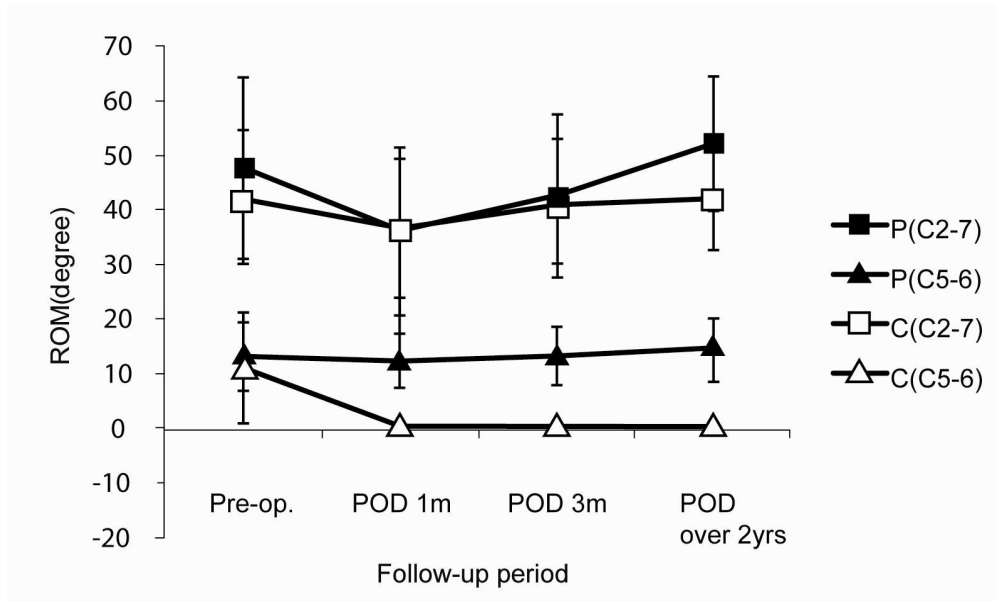


Figure 2. Changes in the range of motion (ROM) at the C2–7 and C5–6 segments. In the ProDisc-C group, the ROM values at C2–7 and C5–6 decreased at the early phase after surgery and then returned to the preoperative value at the late phase ($P > 0.1$). In the cage group, the ROM at C2–7 was unchanged at the late phase compared with the preoperative value ($P > 0.5$). P, ProDisc-C group; C, cage group.

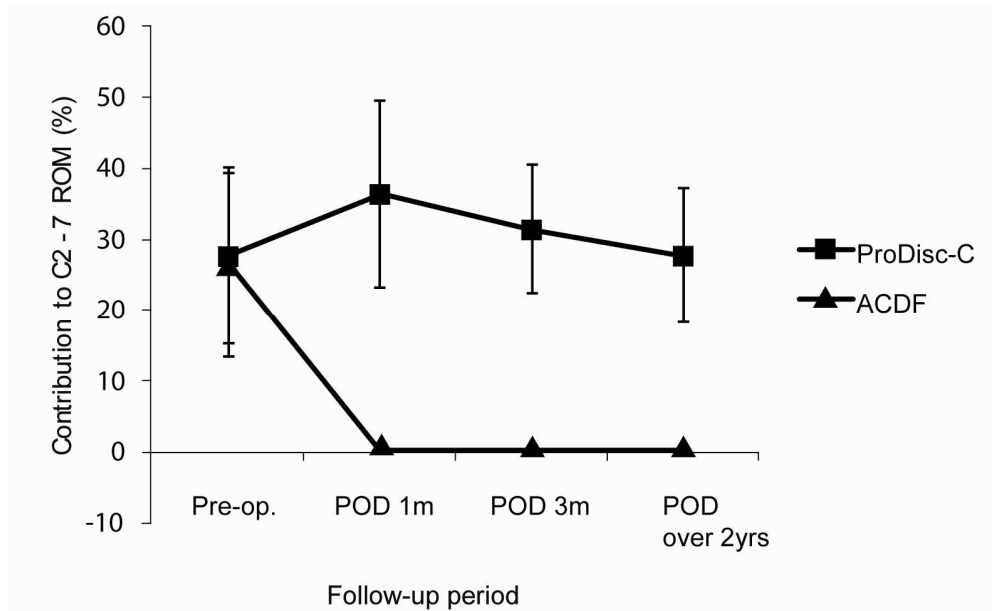


Figure 3. The percentage contribution of C5–6 ROM to the entire neck motion. The ROM at C5–6 contributed significantly to the entire neck motion at the early phase after ProDisc-C replacement ($P < 0.05$) but returned to the preoperative state at the late phase ($P > 0.5$). *Statistically significant difference ($P < 0.05$) compared with preoperative values.

2. Changes of ROM at upper and Lower Adjacent Segments

ROM values at upper (C4–5) and lower (C6–7) adjacent segments were measured preoperatively, 1 and 3 months after surgery and at the final follow-up. In the ProDisc-C group, C4–5 ROM values were $9.7 \pm 5.5^\circ$, $9.2 \pm 4.7^\circ$, $10.1 \pm 3.0^\circ$ and $11.2 \pm 3.5^\circ$, respectively, and the C6–7 ROM values were $9.1 \pm 4.5^\circ$, $8.0 \pm 4.1^\circ$, $8.4 \pm 4.1^\circ$ and $9.7 \pm 4.3^\circ$, respectively. In the cage group, the C4–5 ROM values were $9.7 \pm 4.5^\circ$, $11.6 \pm 4.9^\circ$, $12.5 \pm 3.0^\circ$ and $12.9 \pm 3.9^\circ$, respectively, and the C6–7 ROM values were $8.1 \pm 3.4^\circ$, $9.7 \pm 4.5^\circ$, $10.1 \pm 3.9^\circ$ and $10.3 \pm 4.1^\circ$, respectively (Fig. 4).

In the ProDisc-C group, both upper and lower adjacent segments showed slightly decreased ROM measures at the early phase after surgery and a nonsignificantly increased ROM at the late phase ($P > 0.05$). At the late phase, there were no statistical differences between the ROM changes in the upper or lower adjacent segments ($P > 0.5$). On the other hand, in the cage group both upper and lower adjacent segments showed significantly increased ROM values at the early and late phases ($P < 0.05$). There were no statistical differences between the ROM changes in upper and lower adjacent segments ($P > 0.5$).

The percentage contributions of adjacent segments to whole neck motion in terms of the ROM at C2–7 were also measured at the above time points. In the ProDisc-C group, the C4–5 contributions were $23.1 \pm 19.7\%$, $24.8 \pm 11.0\%$, $25.2 \pm 7.5\%$ and $21.6 \pm 5.9\%$, respectively, and the C6–7 contributions were $19.3 \pm 9.6\%$, $23.1 \pm 9.5\%$, $20.3 \pm 12.8\%$ and $18.5 \pm 7.8\%$, respectively. In the cage group, the C4–5 contributions were $22.2 \pm 7.3\%$, $31.6 \pm 8.2\%$, $31.2 \pm 7.2\%$ and $30.2 \pm 5.8\%$, respectively, and the C6–7 contributions were $20.3 \pm 9.0\%$, $26.1 \pm 8.3\%$, $25.6 \pm 8.2\%$ and $23.6 \pm 7.5\%$, respectively (Fig. 5).

In the ProDisc-C group, percentage contributions of both upper and lower adjacent segments to whole neck motion increased slightly at the early phase after surgery but returned to the preoperative ratio at the late phase ($P > 0.1$). By contrast, in the cage group, the percentage contributions of both adjacent segments increased significantly at both the early and late phases ($P < 0.05$). In both groups, there were no statistical differences in contribution ratios between upper and lower adjacent

segments ($P > 0.1$).

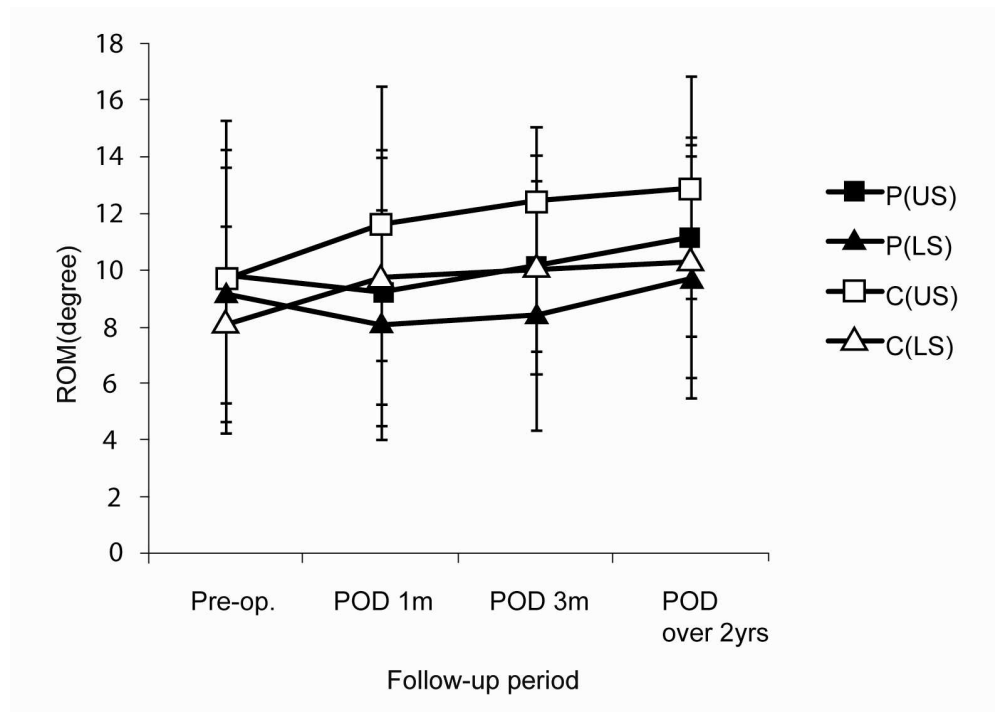


Figure 4. Changes in the range of motion (ROM) at the adjacent segments. In the ProDisc-C group, both upper and lower adjacent segments showed slightly decreased ROM values at the early phase after surgery and nonsignificantly increased ROM values at the late phase ($P > 0.05$). However, in the cage group, both upper and lower adjacent segments showed significantly increased ROM values at the early and late phase ($P < 0.05$). *Statistically significant difference ($P < 0.05$) compared with preoperative values. P, ProDisc-C group; C, cage group; US, upper segment; LS, lower segment; POD, postoperative date; Pre-op., preoperative.

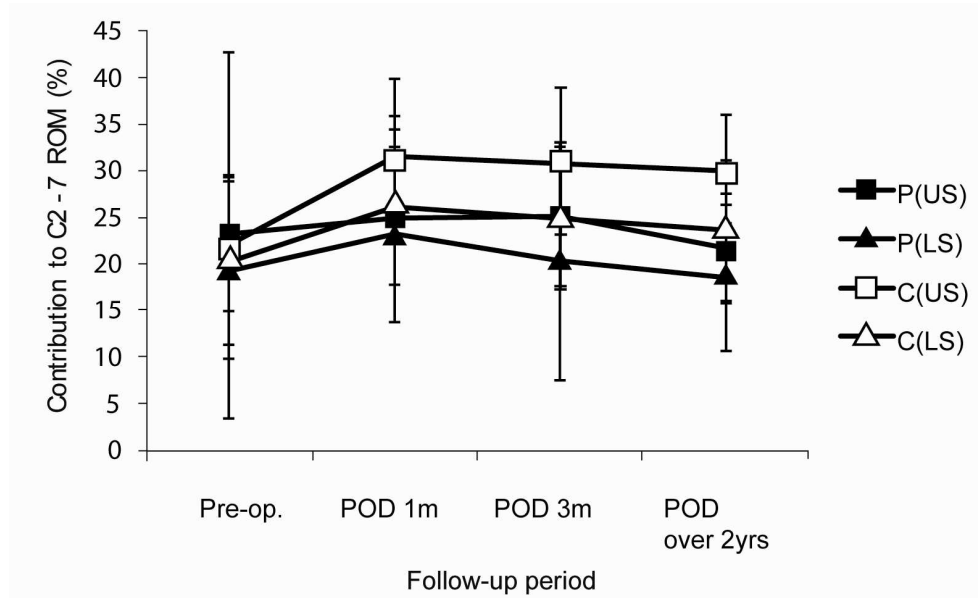


Figure 5. The percentage contributions of adjacent ROM values to whole neck motion. In the ProDisc-C group, contributions of both upper and lower adjacent segments increased slightly at an early phase after surgery but returned to the preoperative state at the late phase ($P > 0.1$). However, in the cage group, contributions of both adjacent segments increased significantly at both early and late phases ($P < 0.05$). Asterisks indicate statistically significant differences compared with the preoperative values. P, ProDisc-C group; C, cage group; US, upper segment; LS, lower segment; POD, postoperative date; Pre-op., preoperative.

3. Changes of Sagittal Alignment after Prodisc-C or Cage insertion

Cobb angles of C2–7 and C5–6 were measured for the sagittal alignments of whole cervical spine and surgically treated segments preoperatively, 1 and 3 months after surgery and at final follow-up. In the ProDisc-C group, the C2–7 Cobb angles were $-6.6 \pm 11.1^\circ$, $-8.2 \pm 8.4^\circ$, $-10.2 \pm 9.4^\circ$ and $-11.5 \pm 8.9^\circ$, respectively. In the cage group the C2–7 Cobb angles were $-10.7 \pm 14.6^\circ$, $-13.2 \pm 11.0^\circ$, $-14.0 \pm 9.1^\circ$ and $-14.2 \pm 8.8^\circ$, respectively (Fig. 6). These results show that alignment of the whole

cervical spine became more lordotic after surgery in both groups; however, there was no statistical significance between preoperative and follow-up results ($P > 0.05$).

In terms of the C5–6 Cobb angle measured at the above time points, the ProDisc-C group showed $2.9 \pm 6.4^\circ$, $-3.7 \pm 4.9^\circ$, $-4.0 \pm 5.7^\circ$ and $-3.4 \pm 5.1^\circ$, respectively. The cage group showed $-1.8 \pm 5.5^\circ$, -1.0 ± 4.8 , $-0.5 \pm 4.2^\circ$ and -0.4 ± 4.5 , respectively. Thus, the C5–6 Cobb angle became significantly more lordotic at the early and late phases in the ProDisc-C group ($P < 0.05$), whereas there were no significant changes in the C5–6 Cobb angle in the cage group ($P > 0.1$).

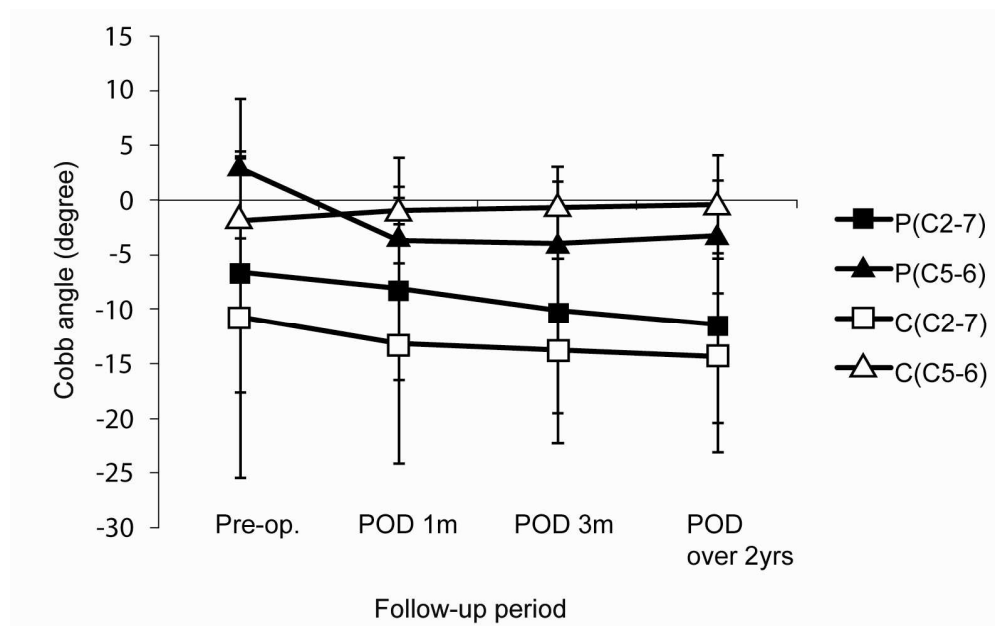


Figure 6. Changes in sagittal alignments. Sagittal alignments of whole cervical spine (C2–7 Cobb’s angle) became slightly lordotic after surgery in both ProDisc-C and cage groups; however, there was no statistical significance between preoperative and follow-up results ($P > 0.05$). The C5–6 angle became significantly more lordotic at

the early and late phases in the ProDisc-C group ($P < 0.05$), whereas there was no significant change in the cage group ($P > 0.1$). *Statistically significant difference ($P < 0.05$) compared with preoperative values. P, ProDisc-C group; C, cage group.

IV. DISCUSSION

The recently introduced C-TDR procedure using an artificial disc is surgery aimed to restore normal motion in the operated segment and to avoid degeneration in adjacent segments. However, the real clinical effects of C-TDR on the degeneration of adjacent segments need to be confirmed by long-term follow-up. In this study, radiographic observations over 2 years including the early and late phases show that cervical ROM values and sagittal alignments change as time after surgery passes.

For this study, we selected the cases operated on at the C5–6 level only, so that we would avoid any bias associated with the cervical spine level when comparing the data and to make it simple to understand basic biological phenomena after C-TDR using ProDisc-C. Moreover, the C5–6 level is the most common site for a herniated cervical disc, stenosis and kyphotic lesions in the cervical spine^{18,19}. Based on in vivo data, this level has also been reported by several authors to have the greatest ROM^{19,20} and this is related to the highest rate of degeneration²¹⁻²³. At that time, C-TDR of C5–6 using the ProDisc-C was the most common procedure (47.4%) in our institute. Estimating the ROM at the adjacent segments was easy for C5–6 arthroplasty because all of the C6–7 levels were identifiable on the lateral X-ray films.

In this study, the C2–7 and C5–6 ROM values decreased at an early phase after ProDisc-C replacement. This might have been because patients sometimes do not cooperate in full flexion–extension X-ray studies because of postoperative neck

discomfort. However, at the late phase more than 2 years after surgery, all cervical ROM values in the ProDisc-C group had returned to the preoperative state. We think sufficient time is needed for the postoperative neck discomfort associated with mechanical segmental motion to be resolved. Rousseau et al.¹⁶ reported that the ROM at ProDisc-C level decreased from an average of 13.4° in a control group to 3.6° after 10.5 months follow-up, whereas Rabin et al.¹² and Bertagnoli et al.⁸ reported that ROM at ProDisc-C level increased significantly after 12 months follow-up. So far, there are no reported clinical data about the change in whole neck motion after ProDisc-C replacement. For the Bryan cervical disc arthroplasty (Medtronic Sofamor Danek, Memphis, TN, USA), Yoon et al.¹¹ reported that the ROM at C2–7 decreased in the acute phase after surgery and returned to preoperative values by 1 year. From those and our results, we assume that at least 1 year might be needed for postoperative adaptation of neck motion after C-TDR using the ProDisc-C.

In most clinical studies on ProDisc-C replacements, the ROM at the level of surgery has either increased or been maintained at preoperative values. It is controversial whether the increased ROM at the ProDisc-C level is a good clinical outcome for the patients. Of note in this study is that the ROM at the ProDisc-C level showed almost the same contribution to whole neck motion at the late phase as at the preoperative state. We think that the ratio of segmental contribution to whole neck motion is important because it indirectly represents the strain on the disc space during a neck motion. In the study by Miazaki et al.²⁴ the C5–6 segmental unit showed the highest contribution to total neck motion at a low grade of degeneration and

eventually gave rise to the most severely degenerated segments. The result of our study means that cervical segmental motion can be saved by ProDisc-C replacement without changes in functional ROM and segmental strain compared with the preoperative state.

As shown in this study, ACDF has been reported to increase the ROM at the upper and lower adjacent segments^{25,26}. Increased ROM at adjacent segments after ACDF is also known to provoke disc degeneration^{4,21-23,27}. Consequently, reducing the ROM of the adjacent segment has been suggested—in theory—to prevent or inhibit adjacent disc degeneration²⁸. In previous in vitro biomechanical studies with ProDisc-C, the ROM of adjacent segments decreased or stayed the same as preoperative values^{29,30}. Our study also showed that the ROM of adjacent segments and their relative contributions to whole neck motion were not changed after ProDisc-C replacement. One impressive result of our study is that the adjacent segmental ROM values in the cage group increased significantly compared with the preoperative values. In other words, in contrast to ACDF using a cage, ProDisc-C replacement preserves adjacent segmental ROM values and their contributions to whole neck motion.

As the intervertebral disc space loses its height and lordotic angle during degeneration, restoring the normal degree of lordosis at a surgical level is very important. Alignment of the surgically treated level and the overall cervical spine affects the long-term clinical outcome and adjacent degenerative disease. Katsuura et al.³¹ reported that degeneration in adjacent segmental levels was significantly

associated with the loss of normal cervical lordosis. Cervical interbody fusion is an accepted surgical method for correcting the preoperative kyphosis associated with the disc space degeneration and muscle spasms produced by neck pain^{32,33}. Others have reported on cervical spinal alignment after C-TDR using artificial discs^{12,18}. For the ProDisc-C, Rabin et al. reported that the Cobb angle at C2–7 and the Shell angle between superior and inferior articulating surfaces became lordotic after about 14 months follow-up¹². Our results also showed that the Cobb angles at the ProDisc-C level and the whole cervical spine became lordotic compared with preoperative values.

For the nonconstrained Bryan cervical disc, several authors reported on a problem of segmental kyphotic angulation after surgery even though there was no change in overall cervical alignment^{17,34}. In our series of patients, changes in the C5–6 Cobb angle show that any segmental degenerative kyphosis was corrected shortly after ProDisc-C replacement and there was no case of aggravated kyphosis compared with the preoperative angle for over 2 years of follow-up. It is not clear whether correcting the segmental degenerative kyphosis was directly related to the biomechanical function of ProDisc-C. However, when considering the postoperative segmental kyphosis associated with nonconstrained artificial discs, it is possible that correcting effect of ProDisc-C on degenerative segmental kyphosis is related to the semiconstrained ball-and-socket joint that has some limitations in axial and anteroposterior translation¹⁵.

V. CONCLUSION

In the early phase after ProDisc-C replacement, the ROM values of whole neck motion as well as functional and adjacent segments decreased. Two years after surgery, all of the motions had been restored to the same ROM values as preoperatively. Contributions of the functional and adjacent segments to whole neck motion were not changed by ProDisc-C replacement. Adjacent segmental motion could be preserved by ProDisc-C replacement but not by ACDF using a cage approach. In sagittal alignment, segmental degenerative kyphosis at a functional level was significantly corrected by ProDisc-C replacement.

References

1. Bohlman HH, Emery SE, Goodfellow DB, et al. Robinson anterior cervical discectomy and arthrodesis for cervical radiculopathy. Long-term follow-up of one hundred and twenty-two patients. *J Bone Joint Surg Am.* 1993;75:1298-307.
2. Bose B. Anterior cervical fusion using Caspar plating: analysis of results and review of the literature. *Surg Neurol.* 1998;49:25-31.
3. Clements DH, O'Leary PF. Anterior cervical discectomy and fusion. *Spine.* 1990;15:1023-5.
4. Baba H, Furusawa N, Imura S, et al. Late radiographic findings after anterior cervical fusion for spondylotic myeloradiculopathy. *Spine.* 1993;18:2167-73.
5. Hilibrand AS, Yoo JU, Carlson GD, et al. The success of anterior cervical arthrodesis adjacent to a previous fusion. *Spine.* 1997;22:1574-9.
6. Wigfield CC, Skrzypiec D, Jackowski A, et al. Internal stress distribution in cervical intervertebral discs: the influence of an artificial cervical joint and simulated anterior interbody fusion. *J Spinal Disord Tech.* 2003;16:441-9.
7. Anderson PA, Rouleau JP. Intervertebral disc arthroplasty. *Spine.* 2004;29:2779-86.
8. Bertagnoli R, Yue JJ, Pfeiffer F, et al. Early results after ProDisc-C cervical disc replacement. *J Neurosurg Spine.* 2005;2:403-10.
9. Goffin J, Casey A, Kehr P, et al. Preliminary clinical experience with the Bryan Cervical Disc Prosthesis. *Neurosurgery.* 2002;51:840-5; discussion 5-7.

10. Shim CS, Lee SH, Park HJ, et al. Early clinical and radiologic outcomes of cervical arthroplasty with Bryan Cervical Disc prosthesis. *J Spinal Disord Tech.* 2006;19:465-70.
11. Yoon DH, Yi S, Shin HC, et al. Clinical and radiological results following cervical arthroplasty. *Acta Neurochir (Wien).* 2006;148:943-50.
12. Rabin D, Bertagnoli R, Wharton N, et al. Sagittal balance influences range of motion: an in vivo study with the ProDisc-C. *Spine J.* 2008.
13. Bertagnoli R, Duggal N, Pickett GE, et al. Cervical total disc replacement, part two: clinical results. *Orthop Clin North Am.* 2005;36:355-62.
14. Murrey D, Janssen M, Delamarter R, et al. Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. *Spine J.* 2008.
15. Nabhan A, Ahlhelm F, Shariat K, et al. The ProDisc-C prosthesis: clinical and radiological experience 1 year after surgery. *Spine.* 2007;32:1935-41.
16. Rousseau MA, Cottin P, Levante S, et al. In vivo kinematics of two types of ball-and-socket cervical disc replacements in the sagittal plane: cranial versus caudal geometric center. *Spine.* 2008;33:E6-9.
17. Kim SW, Shin JH, Arbatin JJ, et al. 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;17:20-9.

18. Pickett GE, Mitsis DK, Sekhon LH, et al. Effects of a cervical disc prosthesis on segmental and cervical spine alignment. *Neurosurg Focus*. 2004;17:E5.
19. Lind B, Sihlbom H, Nordwall A, et al. Normal range of motion of the cervical spine. *Arch Phys Med Rehabil*. 1989;70:692-5.
20. Dvorak J, Froehlich D, Penning L, et al. Functional radiographic diagnosis of the cervical spine: flexion/extension. *Spine*. 1988;13:748-55.
21. Dohler JR, Kahn MR, Hughes SP. Instability of the cervical spine after anterior interbody fusion. A study on its incidence and clinical significance in 21 patients. *Arch Orthop Trauma Surg*. 1985;104:247-50.
22. Goffin J, van Loon J, Van Calenbergh F, et al. Long-term results after anterior cervical fusion and osteosynthetic stabilization for fractures and/or dislocations of the cervical spine. *J Spinal Disord*. 1995;8:500-8; discussion 499.
23. Hilibrand AS, Carlson GD, Palumbo MA, et al. Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. *J Bone Joint Surg Am*. 1999;81:519-28.
24. Miyazaki M, Hong SW, Yoon SH, et al. Kinematic analysis of the relationship between the grade of disc degeneration and motion unit of the cervical spine. *Spine*. 2008;33:187-93.
25. Fuller DA, Kirkpatrick JS, Emery SE, et al. A kinematic study of the cervical spine before and after segmental arthrodesis. *Spine*. 1998;23:1649-56.
26. Wu W, Thuomas KA, Hedlund R, et al. Degenerative changes following anterior cervical discectomy and fusion evaluated by fast spin-echo MR imaging.

Acta Radiol. 1996;37:614-7.

27. DiAngelo DJ, Roberston JT, Metcalf NH, et al. Biomechanical testing of an artificial cervical joint and an anterior cervical plate. *J Spinal Disord Tech.* 2003;16:314-23.
28. Hilibrand AS, Robbins M. Adjacent segment degeneration and adjacent segment disease: the consequences of spinal fusion? *Spine J.* 2004;4:190S-4S.
29. Chang UK, Kim DH, Lee MC, et al. Range of motion change after cervical arthroplasty with ProDisc-C and prestige artificial discs compared with anterior cervical discectomy and fusion. *J Neurosurg Spine.* 2007;7:40-6.
30. DiAngelo DJ, Foley KT, Morrow BR, et al. In vitro biomechanics of cervical disc arthroplasty with the ProDisc-C total disc implant. *Neurosurg Focus.* 2004;17:E7.
31. Katsuura A, Hukuda S, Saruhashi Y, et al. Kyphotic malalignment after anterior cervical fusion is one of the factors promoting the degenerative process in adjacent intervertebral levels. *Eur Spine J.* 2001;10:320-4.
32. Abd-Alrahman N, Dokmak AS, Abou-Madawi A. Anterior cervical discectomy (ACD) versus anterior cervical fusion (ACF), clinical and radiological outcome study. *Acta Neurochir (Wien).* 1999;141:1089-92.
33. Elsawaf A, Mastronardi L, Roperto R, et al. Effect of cervical dynamics on adjacent segment degeneration after anterior cervical fusion with cages. *Neurosurg Rev.* 2008.
34. Pickett GE, Sekhon LH, Sears WR, et al. Complications with cervical arthroplasty. *J Neurosurg Spine.* 2006;4:98-105.

Abstract <IN KOREAN>

경추 인공 관절 ProDisc-C 치환술 후의 방사선학적 예후
: 수술 및 인접마디의 운동성과 시상면 균형

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안 풍 기

경추의 인공디스크를 이용한 인공관절 치환술은 전통적인 유합술을 대체하여, 경추 수술 마디의 운동성 보존 및 인접마디의 퇴행을 예방해주는 역할을 하는 것으로 이용되고 있다. 우리는 semi-constraint type인 ProDisc-C 인공 관절 치환술 18명에 대한 방사선학적 결과로써 수술마디와 인접마디, 전체 경추 운동에 대한 대해 후향적 연구분석을 하였다.

ProDisc-C치환술을 받은 환자중 경추 5-6번간만 수술한 환자를 선별하여 총 18명(남자 15명, 여자 3명)의 환자군을 가지고 분석하였으며, 경추의 중립자세와 최대 굴전, 신전의 측면 일반촬영을 수술 전, 후 1개월, 3개월, 최종 추적관찰 시기(24-35개월) 별로 시행하였다. 이러한 자료를 대상으로 수술마디와 인접마디의 운동범위와 경추의 측면 Cobb angle을 측정하였고, 특히 수술마디와 인접마디의

운동성 변화는 전체 경추(경추2-7번간)의 운동성 변화에 대한 비율로 계산하여 오차를 최대한 줄이도록 하였다. 그리고 이와 함께 경추 전방 유합술을 받은 20명(남자 9명, 여자 11명, 최종 추적관찰 24-32개월)의 방사선학적 결과를 대조군으로 비교 분석하였다.

ProDisc-C에서 전체 경추(경추2-7번)와 수술마디(경추5-6번)의 운동성은 수술후 초기에 감소되었다가 최종 추적관찰시기에 다시 수술 전 정도의 상태로 회복되었다($p > 0.1$). 윗, 아래마디의 운동범위는 수술후 초기에는 약간 떨어졌다가 다시 증가하였으나 유의한 차이를 보이지 않았다($p > 0.05$). 전체 경추의 운동범위에 대한 비율로 산출한 수술마디와 인접마디의 공헌도는 모두 수술전하고 비교하여 유의한 차이를 보이지 않았다. 대조군인 경추 유합술 군에서는 전체 경추의 운동성은 변화가 없었으나($p > 0.5$) 인접마디의 운동범위에서는 수술후 통계학적으로 유의하게 증가하는 값을 확인하였다. 전체 경추의 시상면 각은 ProDisc-C와 유합술 군 모두 유의한 차이를 보이지 못하였으나, 수술마디인 경추5-6번의 Cobb angle은 ProDisc-C에서 유의하게 전만(lordosis) 변화를 보였으며 유합술 군에서는 유의한 차이를 보이지 않았다.

정리하면 ProDisc-C group에서는 전체 경추의 운동성과 수술마디와 인접마디의 운동성이 수술 직후에 감소하였다가 후기에는 수술 전 상태로 회복되는 양상을 보였다. 전체 경추 운동범위에 대한 수술마디와 인접마디의 운동성 비율은 ProDisc-C 치환술에서 수술 전후에

유의한 차이를 보이지 않았다. 인접마디의 운동성은 유합술군보다 더 유지 되었으며 수술마디의 후만각은 ProDisc-C에 의해 유의한 교정을 보였다.

핵심되는 말: 척추, 경추, 인공관절, 인접마디변성