

**Cervical Double-door Laminoplasty
with a Hydroxy-apatite Spacer:
Time-course of Radiographic
Findings and Clinical Outcomes
over 30 Months**

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Department of Medicine

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Directed by Professor Keun Su Kim

The Masters Thesis
submitted to the Department of Medicine,
Graduate School of Yonsei University
in partial fulfillment of the requirements for the degree
of Master of Medical Science

Young-Mok Park

December 2010

This certifies that the Master's Thesis of
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December 2010

ACKNOWLEDGEMENTS

I would like to express my deepest gratitude to my supervisor, Professor Kun-Sue Kim, for his warm encouragement and careful consideration throughout this study. I also want to express my warmest thanks to Professors Yong-Eun Jo, Byoung-Ho Jin, Young-Seol Yoon, Dong-Gyu Chin and Sung-ook Koo for their invaluable advice and support. Most of all, I wish to thank the people closest to me. I want to express my deepest and most heartfelt gratitude to my parents and sister for their love and support throughout my life. I extend my thanks also to my parents-in-law for their support and care.

Finally and most importantly, my heartfelt gratitude belongs to my beloved wife, Yun-Yeong NA, for her loving support and encouragement and to our lovely daughter, Ji-Sue Park, for giving me such happiness.

Seoul, December 2010

Young-Mok Park

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ABSTRACT

Cervical Double-door Laminoplasty with a Hydroxy-apatite Spacer: Time-course of Radiographic Findings and Clinical Outcomes over 30 Months

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Objective: Various kinds of cervical laminoplasty have been attempted on patients with long segment cervical stenosis. The purpose of this study was to evaluate the time-course of radiologic findings and clinical outcomes during a 30-month follow-up following three- or four-level double-door laminoplasty using a hydroxyl-apatite (HA) spacer.

Methods: We followed 29 patients (male to female ratio 24:5; mean age 52.2; 105 total laminoplasty levels) who had undergone double-door cervical laminoplasty from 2004 to 2007. Preoperative diagnoses included 21 cases of OPLL and eight cases of degenerative spondylosis. Patients were divided into three groups in order to estimate time-coursed radiologic alterations and clinical outcomes according to the follow-up periods: early (12-<18 months), middle (18-30 months), and late (>30 months). All cervical laminoplasty was performed using HA spacers. Neutral and flexion-extension cervical lateral radiographs and CT scans were taken at the final follow-up. Stability of HA

spacers, C2-7 range of motion (ROM) and kyphosis were evaluated. Bone fusion status between the HA spacer and laminae were estimated using a five-point classification from A to E. Types C, D and E were considered to be successful HA-laminae fusion. Bone fusion on the bilateral gutters was also evaluated. Nurick grade and JOA score were determined to evaluate neurological improvement preoperatively and at the final follow-up. A visual analogue scale (VAS, 0-10) was used to measure post-operative neck pain and radiating pain in all patients.

Results: The numbers of patients in the early, middle, and late groups were 9, 11 and 9, respectively. The successful HA-laminae fusion rate was 24%, 42% and 69% in early, middle and late groups, respectively. Bilateral gutter fusion was 95% in the early group and 100% in both the middle and late groups. Of the 105 levels, only two showed unstable HA position on flexion-extension lateral films. ROM of C2-C7 was significantly decreased after surgery: 10, 11 and 13 degrees of reduction compared to preoperative ROM were observed in the early, middle and late groups, respectively. Kyphotic change was slightly increased after surgery, although the change was not significant. Nurick grade, JOA score and VAS of radiating pain were significantly improved after surgery, but there were no differences between the three groups. The VAS for neck pain improved in the group with severe preoperative neck pain but worsened in the group with mild neck pain. There was no direct clinical correlation between HA-laminae fusion rate and clinical improvement.

Conclusions: We believe that double-door laminoplasty using an HA spacer is a very safe and effective method for improving neurological status. This method resulted in a decrease in cervical ROM and a constant but acceptable degree of neck pain after surgery. HA-laminae fusion progressed very slowly; however, HA spacers showed stable positions and improved clinical outcomes regardless of fusion status. The stability of HA-laminae seems to be maintained by early successful bone fusion at the bilateral gutters.

Keywords: Cervical laminoplasty, Hydroxy-apatite spacer, Bone fusion

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I. INTRODUCTION

Since Dr. Kurokawa first introduced double-door laminoplasty in 1982¹, cervical laminoplasty has been widely used in surgery for cervical spondylotic myelopathy (CSM) and ossification of posterior longitudinal ligament (OPLL). A variety of technical methods of cervical laminoplasty have been introduced, and spacer or supporting materials have been developed to maintain the position of the distracted cervical laminae. Since a hydroxy-apatite (HA) spacer for double-door laminoplasty was first used by Nakano et al. in 1992², the use of an HA spacer has gradually increased. The efficacy and excellent stability of the HA spacer in cervical laminoplasty have been reported in several biomechanical and clinical studies using plain X-ray films^{3,4,5,6}. However, there have been very few long-term clinical studies of the fusion rate between the HA spacer and split lamina using computed tomography (CT) scans⁵.

Since Dr. Hirabayashi introduced open-door cervical laminoplasty, the

C3-C7 laminoplasty procedure has been identified as a standard surgical method. In comparison to anterior decompression and fusion, one of the disadvantages of C3-C7 cervical laminoplasty is axial neck pain. Recently, muscular dissection of the C2 and C7 laminae has been shown to be an important contributing factor to axial neck pain after cervical laminoplasty.

In the present study, we retrospectively evaluated the time-course of radiographic changes at HA-laminae sites and lateral hinges using CT images over 30 months after double-door laminoplasty surgery. We additionally evaluated the clinical outcomes of the four-level (C3-C6) double-door cervical laminoplasty technique which spares the C2 and C7 muscular attachments.

II. MATERIALS AND METHODS

1. Patient Population

Between 2004 and 2007, 29 of 60 patients who underwent cervical double-door laminoplasty using an HA spacer in our institution were followed-up with interviews and CT scanning. An HA spacer was used for a total of 105 laminae, and all selected patients were followed for more than one year. Cervical myelopathy was present in all patients in whom no previous spinal surgery had been performed. There were 24 men and five women with a mean age of 52.2 years (range, 23 to 67 years). The preoperative diagnoses were CSM in eight patients and OPLL in 21 patients. We divided all patients into three groups according to the length of the follow-up period: early; 12-18 months, middle; 18-30 months, and late; more than 30 months. The numbers of

patients in the early, middle and late follow-up groups were nine, 11 and nine, respectively, and the numbers of operated laminae in each group were 37, 36 and 32, respectively (Table 1). Radiologic findings and clinical outcomes were evaluated for each group in order to determine any time-course effect after surgery.

Table 1. Demographics of the patient groups

	<18 months Early Group	18-30 months Middle Group	>30 months Late Group
Mean age (range)	46.0 (23-58)	56.0 (39-65)	56.7 (43-67)
No. of patients (Male:Female)	9 (7:2)	11 (8:3)	9 (9:0)
No. of operated laminae	36	37	32
Preoperative Diagnosis			
OPLL	8	8	5
Spondylotic Stenosis	1	3	4

2. Surgical Procedure

For the surgery, the patients were placed in the prone position with Mayfield head clamp fixation under general endotracheal anesthesia. Three-level or four-level cervical double-door (midline splitting) laminoplasty was performed from the C3 to C6 laminae. Careful attention was paid to preserve the muscles attached to the spinous processes of C2 and C7 and not to dissect the muscles beyond the facets. The bottoms of the spinous processes were horizontally divided with an oscillating saw. Sublaminar undercutting of C2 and C7 was performed using high-speed air drilling, and the ligament flavum was removed using a Kerrison rongeur. Then, mid-lamina splitting and bilateral gutter formation were carried out on the C3-C6 laminae. HA spacers were inserted

into the separated inter-laminar space, and monofilament nylon 2-0 was used to fix the 40% porosity HA spacer (APACERAM spinal process spacer B-251-158, Pentax, Tokyo, Japan) to the laminae in all operations.

3. Clinical and Radiographic Evaluations

The JOA scoring system and Nurick grading system were used to determine the severity of cervical myelopathy^{7,8,9}. The visual analogue scale (VAS, 0-10) was used to assess posterior neck pain and radiating arm pain to determine the postoperative disability levels of the patients. All scores were measured before surgery and at the time of final follow-up.

In order to determine the success of the fusion between the HA spacer and laminae, we performed CT scans on all 29 patients. The bone fusion status between the HA spacer and laminae was estimated using a five-level classification from A to E, according to the Ichikawa classification⁵ (Figure 1). Levels C, D and E were accepted as successful HA-laminae fusion. Bone fusion at the bilateral hinge sites was also evaluated on CT images.

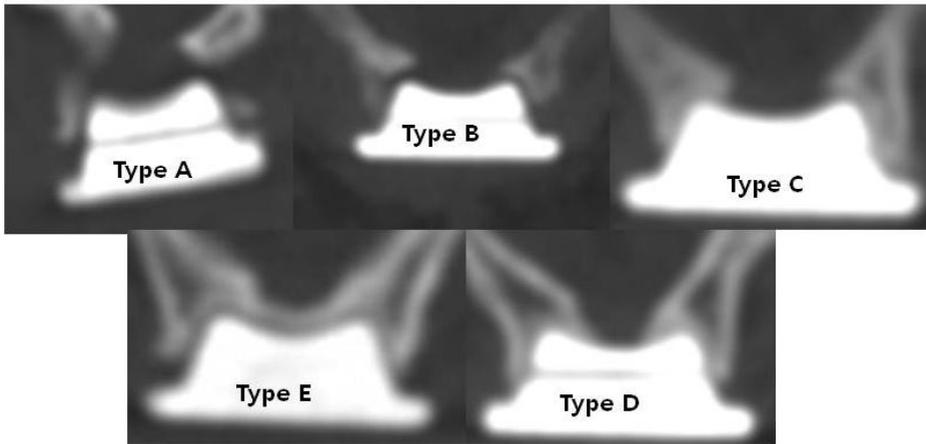


Figure 1. Typical examples of the classifications of the radiologic findings at a bone fusion site (Ichikawa classification)⁹. Type A: Bone resorption around the HA spacer. Type B: Radiolucent space between the HA spacer and split lamina with no new bone formation. Type C: Radiolucent line between the HA spacer and split lamina with new bone formation at the inner surface of the spinal canal. Type D: No radiolucent line between the HA spacer and split lamina with new bone formation. Type E: No radiolucent line between the HA spacer and split lamina with bridging bone formation at the inner surface of the spinal canal. When different types were present at both interfaces, a lower classification level was applied.

Helical CT (Somatom, Siemens, Berlin, Germany) scanning was performed to examine each lamina with a 2-mm collimation. To control the qualities of CT images, the window level and width were set at 670 HU and 2300 HU, respectively. All images were examined by a single radiologist.

Neutral (AP and lateral view) and flexion-extension cervical lateral radiographs were taken before surgery and at the time of the final follow-up to evaluate the stabilities of the HA spacers, the C2-7 range of motion (ROM) and the C2-7 kyphosis. The cervical curvature was measured as the angle between

the posterior line between C-2 and C-7 on a lateral radiograph in a neutral position (Ishihara method)¹⁰. C2-7 ROM was defined as the sum of the flexion and extension angles on a lateral radiograph (Figure 2). We evaluated the changes in the position of the HA spacer to determine its stability.

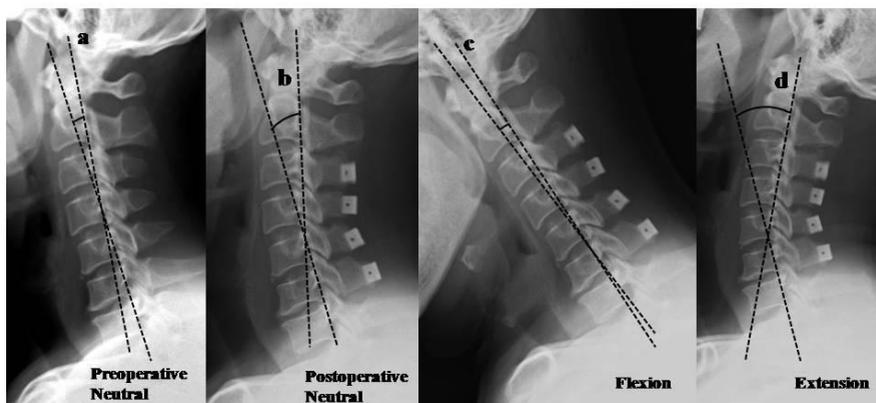


Figure 2. The change in cervical curvature in the C2-C7 angle in a neutral position was calculated by subtracting the angle in the preoperative neutral position (a) from the angle in the postoperative neutral position (b). The ROM was defined as the sum of the angles on flexion (c) and extension (d) ($ROM=c+d$).

4. Statistical Analysis

SPSS for Windows version 13.0K (SPSS, Inc.) was used for statistical analysis. Between-group (or intragroup) comparisons were conducted using the Chi-square test, the Wilcoxon test, and the Kruskal-Wallis test. The Spearman correlation coefficient was used for correlation analysis between parameters. A p-value of less than 0.05 was considered statistically significant.

III. RESULTS

1. Fusion Rate: HA-laminae and Hinge Sites (Figure 3)

Successful bone fusion at the HA-lamina site occurred at nine laminae (24.3%), 15 laminae (41.7%) and 22 laminae (68.8%) in the early, middle, and late follow-up groups, respectively. For all three groups, the fusion rate significantly increased over time ($p < 0.001$).

The successful bone fusion rates at the bilateral hinge sites were 94.6%, 100% and 100% in the early, middle and late follow-up groups, respectively.

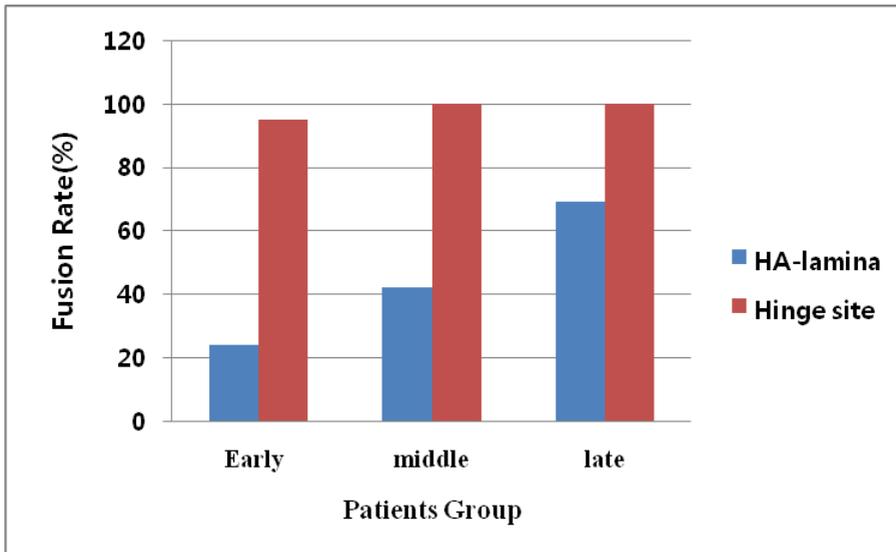


Figure 3. Fusion Rates at HA-laminae and Hinge Sites.

Fusion rates at HA-Laminae significantly increased over time (p -value <0.0001 according to the Chi-square test).

For a total of 105 operated levels, only two levels showed an unstable position of the HA spacer on flexion-extension lateral films. Both of those levels showed type A fusion.

2. Radiographic Changes in C2-7 ROM and C2-7 Kyphosis

The change in the mean C2-7 kyphotic angle between the preoperative value and follow-up values increased over time: $3.5^{\circ} \pm 5.6^{\circ}$ for the early group, $3.7^{\circ} \pm 7.8^{\circ}$ for the middle group, and $4.3^{\circ} \pm 4.7^{\circ}$ for the late group. There were no significant differences among the three groups ($p = 0.783$). However, the kyphosis of each of the three groups significantly increased after surgery ($p < 0.05$).

The mean C2-7 ROM decreased with time, by $10.3^{\circ} \pm 9.0^{\circ}$ in the early group, $11.5^{\circ} \pm 8.1^{\circ}$ for the middle group and $13.8^{\circ} \pm 10.6^{\circ}$ for the late group. The difference among the three groups was not statistically significant ($p = 0.554$). However, the mean ROM for the three groups significantly decreased after surgery ($p < 0.01$) (Table 2).

Table 2. Radiographic changes in C2-7 ROM and C2-7 Kyphosis

	Early Group		Middle Group		Late Group		<i>p</i> -value
	Preop	Final F/U	Preop	Final F/U	Preop	Final F/U	
C2-7 angle (degrees)	13.5±12.9	9.9±10.9	12.5±9.9	8.8±6.8	10.8±6.8	6.5±9.8	<0.05*
<i>Neutral Flexion</i>	-13.5±12.0	-10.6±15.4	-9.0±4.8	-1.6±4.7	-10.2±13.8	-5.4±9.0	<0.05*
<i>Extension</i>	26.7±8.5	16.9±9.8	24.2±13.8	18.2±9.9	21.8±9.4	13.0±10.4	<0.05*
C2-7 ROM (<i>Flexion+ Extension</i>)	38.1±18.2	27.5±13.4	33.4±12.9	21.0±8.2	32.0±13.7	18.1±8.3	<0.05*
Change in C2-7 ROM (<i>Final F/U - Preop</i>)	10.6±9.0		11.6±8.1		13.9±10.6		0.554#
Change in Lordosis (<i>Kyphosis</i> ↑)	3.6±5.6		3.7±7.8		4.3±4.7		0.783#

* statistical analysis between preoperative angle and final follow-up angle in each group (using Wilcoxon test)

statistical analysis among the three groups (using Kruskal-Wallis test)

3. Clinical Outcomes

The mean JOA score improved from 9.11 to 14.33 for the early group, 11.55 to 14.18 for the middle group, and 10.67 to 14.22 for the late group. The mean Nurick grade improved from 2.44 to 0.56 for the early group, 2.36 to 1.18 for the middle group, and 2.00 to 0.78 for the late group. The JOA and Nurick scores of the three groups were significantly improved after surgery ($p < 0.01$); however, there was no statistically significant difference between the three groups in JOA scores and Nurick grades. These results imply that clinical neurologic improvement is independent of time (Figure 4).

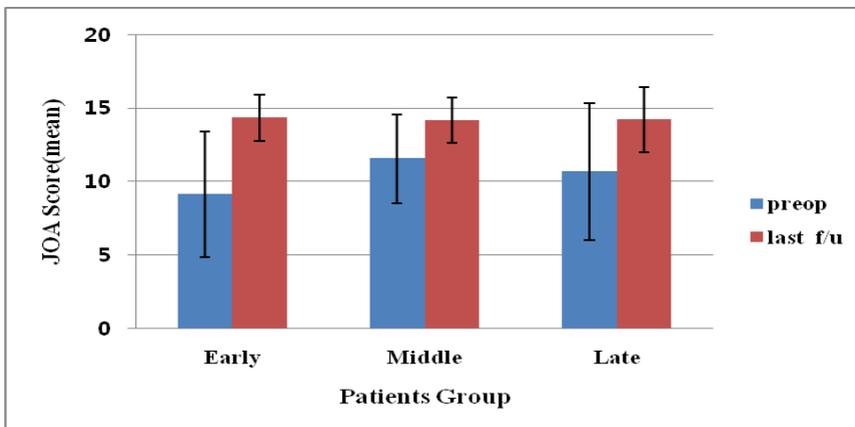


Figure 4-a: JOA score with time course

The JOA scores of the three groups significantly improved after surgery ($p < 0.01$), but there was no significant difference among the three groups.

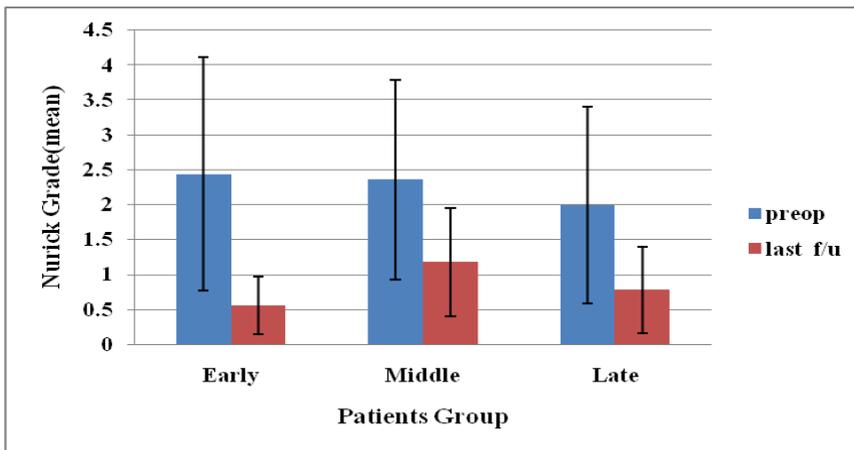


Figure 4-b: Nurick grade with time course

The Nurick grades of the three groups significantly improved after surgery ($p < 0.01$), but there was no significant difference among the three groups.

The mean VAS of radiating upper extremity pain significantly improved after surgery in each of the three groups ($p < 0.01$), although there was no significant difference among the three groups ($p = 0.580$). For axial neck pain, the mean VAS was aggravated immediately after surgery in each of the three groups: from 3.22 to 4.56, 0.36 to 2.73, and 3.22 to 3.67 for the early, middle, and late group, respectively. However, at the time of the final follow-up, the mean VASs of axial neck pain differed among the three groups. The mean VAS of axial neck pain improved from 3.22 to 2.11 and from 3.22 to 2.44 in the early and late groups, respectively. In the middle group, axial neck pain was aggravated at the final follow-up from 0.36 to 1.36. There was no significant difference among the three groups ($p = 0.300$) (Figure 5).

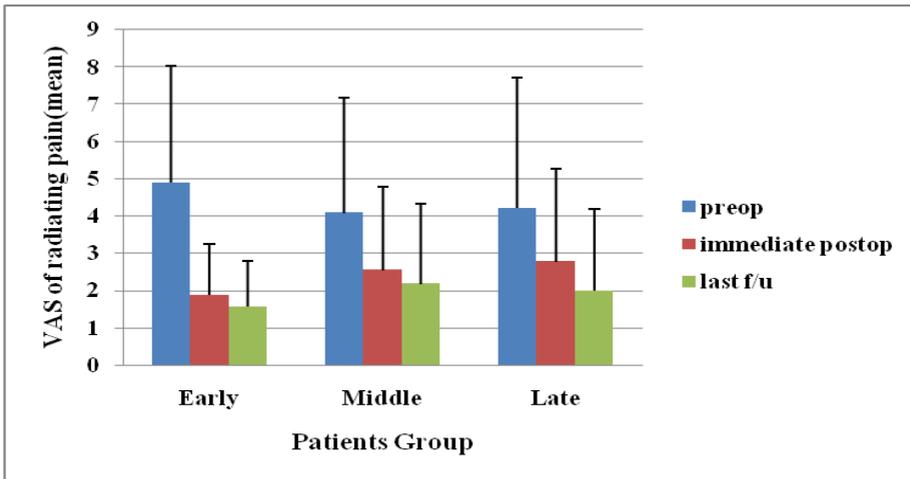


Figure 5-a. VAS of radiating pain with time

The mean VAS of radiating upper extremity pain significantly improved after surgery in each of the three groups ($p < 0.01$). There was no significant difference among the three groups at the final follow-up ($p = 0.580$).

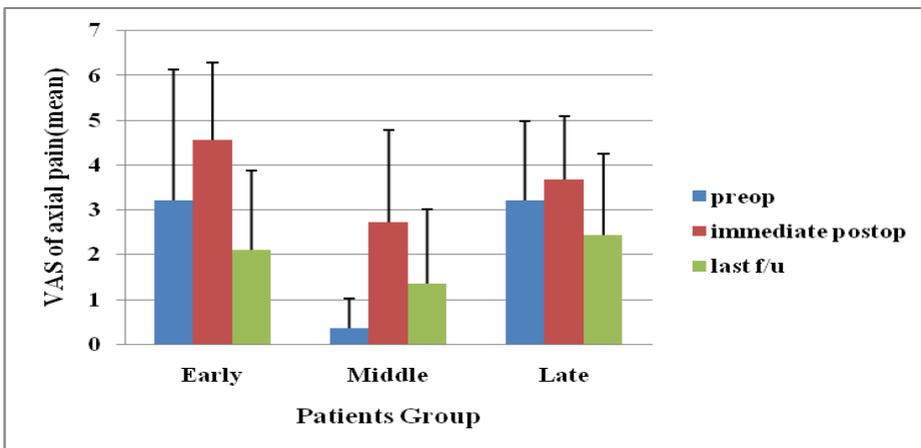


Figure 5-b. VAS of axial neck pain with time

The mean VAS of axial neck pain was aggravated immediately after surgery in each of the three groups: from 3.22 to 4.56, 0.36 to 2.73, and 3.22 to 3.67 for the early, middle, and late group, respectively. There was no significant difference among the three groups ($p = 0.300$).

Based on the Spearman correlation analysis, there was no direct clinical correlation between the HA-laminae fusion rate and the clinical improvement according to JOA, Nurick, and VAS scores of axial and radiating pain.

4. Complications

Two patients demonstrated radiographic signs of non-union at the HA-laminae site; however, the HA-spacer did not involve the neural canal. There were no major complications such as neural injury, vascular injury, or postoperative infection in the operated patients.

IV. DISCUSSION

Since Hirabayashi introduced expansive open-door laminoplasty in 1972, cervical laminoplasty has been the standard treatment for compressive myelopathy using CSM or OPLL for more than 20 years¹¹. Many variations of laminoplasty have been developed, and many spacer materials have been used.

One such spacer material is hydroxyapatite (HA), which was first used for double-door laminoplasty in 1992 by Nakano et al.². The use of an HA spacer has gradually increased because of its benefits over autologous spinous bone^{2,4,12,13,14}. The usefulness of the HA spacer for cervical laminoplasty has been reported in many other biomechanical and clinical studies^{3,4,5,6}. These previous studies revealed a high fusion rate between the HA and lamina^{4,5,15}. Iguchi et al. reported that the HA-laminae fusion rate was up to 91% one year

after surgery using 60% porosity HA spacers. However, he reported a 4.4% breakage rate of the HA spacer⁵. We used a low porosity (40%) HA spacer, and there was no breakage of the spacer due to the increased durability of the low porosity HA spacer.

Contrary to our expectations of a high fusion rate between the HA spacer and lamina bone, our study showed that the fusion rate between the HA spacer and lamina was not higher than those observed in previous laminoplasty studies^{4,5,15}. The early group, which was followed for 12 to 18 months after surgery, showed only a 24.3% HA-laminae fusion rate. Even 30 months after surgery, the successful HA-laminae fusion rate was only 68.8%. These results show that the fusion between the HA and laminae increases very slowly over time. Nonetheless, bone fusion at bilateral hinge sites is very successful in the early period after surgery. The fusion rate of the bilateral hinges was very high, even in the early group (95%). We think that successful bone fusion at the hinge site is important for spinal stability prior to bone fusion between the HA and laminae. Therefore, the long-term stability after laminoplasty with HA spacers may be obtained with solid fusion at the bilateral hinges, as well as with fusion of the HA spacer to the split lamina. In our opinion, there are two separate roles of the HA spacer over time. One role is to serve as a simple spacer for structural stabilization until fusion is achieved at the hinge sites, and the second role is as a fusion material for long-term stabilization.

Cervical laminoplasty has some advantages over laminectomy or multilevel

anterior cervical fusion. Cervical laminoplasty preserves more segmental motion compared to that of anterior fusion and reduces kyphosis in comparison to laminectomy^{16,17,18,19}. However, some reduction in the ROM and progression of kyphosis after laminoplasty have been reported^{12,20,21}. Hyun and Rhim²¹, in a prospective evaluation of 23 patients after open door laminoplasty, reported that the loss of cervical ROM is time-dependent and plateaus by 18 months after surgery. Our study also showed a reduction in C2-7 ROM and progression of kyphosis after surgery that both increased over time. However, the reduction in C2-7 ROM and the progression of kyphosis over time were not statistically significant. These results are similar to those of other studies^{12,20,21}.

Many authors have reported a similar neurological outcome between laminoplasty and laminectomy^{10,15}, implying that laminoplasty provides sufficient neural decompression compared to that of laminectomy. Furthermore, C2- and C7-preserving laminoplasty (C3-C6 double-door laminoplasty) results in sufficient neural decompression and a favorable neurologic outcome.

For axial neck pain immediately after surgery, it has been shown that the VAS is more aggravated compared to that prior to the operation^{22,23}. However, for the patients who had moderate preoperative axial neck pain (VAS >4), improvement in the mean VAS of axial pain was reported at the final follow-up. On the contrary, for patients who had no or mild preoperative axial pain, the mean VAS of axial pain had increased at the final follow-up. We think some axial neck pain is inevitable after cervical laminoplasty; however, the axial neck

pain at the final follow-up was tolerable in all patients after our surgical C2/C7-preserving method. Although the cause of the axial neck pain is unclear, preservation of the C7 spinous process and attached nuchal ligament have been suggested to reduce axial symptoms^{24,25,26}. Therefore, C3-6 laminoplasty which preserves the C7 spinous process has recently been performed to reduce postoperative axial symptoms^{24,25,27,26}. In addition, cervical laminoplasty needs to be extended to the C2 lamina in elderly patients and in patients with congenital stenosis. However, laminoplasty including the C2 lamina can also cause axial symptoms and worsening of the cervical alignment due to the detachment of muscles of the C2 lamina²⁸. In the present study, we performed modified C3-6, C3-5, or C4-6 laminoplasties combined with a deep undercutting of the C2 lower and C7 upper lamina. We assume that C2- and C7-sparing laminoplasty results in the best improvement in postoperative axial neck pain.

V. CONCLUSIONS

We think that the majority of stability comes from early bone fusion at the hinge site after double-door cervical laminoplasty using an HA spacer. Bone fusion between the HA spacer and split laminae progresses very slowly. The HA spacer seems to play an important role as a fixating structural spacer until hinge fusion occurs in the early period. This method results in decreased cervical ROM and constant but acceptable neck pain after surgery. We think

that the double-door laminoplasty using an HA spacer is a safe and effective method for improving neurological status.

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ABSTRACT(IN KOREAN)

Hydroxy-apatite 를 사용한 경추 후방 중앙분리형 후궁성형술:
30개월 이상 추적관찰된 환자들을 대상으로한 시간경과에 따른
방사선학적 변화와 임상적호전의분석

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목적: 현재까지 긴분절의 경추 협착증환자의 치료에 있어서 여러 다양한 경추 후궁성형술이 소개되고 시도되어 왔다. 본 연구의 목적은 Hydroxy-apatite(HA)를 사용하여 3~4분절의 경추후방 중앙분리형 후궁성형술을 받은 환자중 30개월 이상 추적관찰된 환자들을 대상으로 시간경과에 따른 방사선학적 변화와 임상적 호전도를 알아보는 것이다.

연구방법: 2004년부터 2007년까지 본원에서 경추 후방 중앙 분리형 후궁성형술을 시행받은 29명의 환자(남:여=25:5, 평균나이:53.1세, 수술시행된 후궁의 분절수:105분절)를 대상으로 하였다. 수술전 진단은 경추 후종인대골화증이 21명, 퇴행성 경추증에 의한 협착증 환자가 8명이었다. 환자는 수술 후 경과시간에 따라 총 3개의 집단

으로 나누었다. 수술후 12개월에서 18개월이 지난 환자를 초기집단, 18개월에서 30개월이 지난 환자를 중기집단, 30개월 이상 지난 환자를 후기집단으로 구분하였다. 모든 환자는 Hydroxy-apatite 를 골대체제로 사용하였다. 모든 환자에서 컴퓨터 단층촬영, 단순방사선촬영(전후, 측면, 전굴, 후굴)을 시행하였다. 이를 통하여 이식된 Hydroxy-apatite의 안정성과 Hydroxy-apatite와 후궁골사이의 유합률, 수술후 경추 후만증, 운동각(전굴과 후굴시)의 변화를 조사하였다. 골유합정도는 5개의 형태로 구분하여 유합정도를 구분하였다. 또한 후궁의 양측 경첩부위의 골유합률도 같이 조사하였다. 환자들의 임상적 호전도는 신경기능회복평가에는 Nurick grade 와 JOA score를 사용하였고 통증호전도의 평가에는 경추 및 상지의 VAS score 를 사용하였다.

결과: 초기, 중기, 후기 집단인 환자수는 각각 9, 11, 9명이었다. HA와 후궁의 골유합률은 초기, 중기, 후기 집단에서 각각 24%, 42%, 69%로 나타났다. 후궁양측의 경첩부위의 골유합률은 초기, 중기, 후기 집단에서 각각 95%, 100%, 100% 로 조사되었다. 총 105개의 수술분절중에서 HA가 불안정성을 보인개수는 2개 에 불과했다. 경추 2번-7번사이의 운동각은 수술후 의미있게 감소하였고 시간이 지남

에 따라 약간씩 증가하는 소견을 보였으나 통계학적 의미는 없었다. 수술후 후만변형은 수술후 의미있게 진행하였으나 시간이 지남에 따라 증가하는 소견은 보이지 않았다. 환자의 임상증상은 경추부위의 통증을 제외한 상지통, 신경학적 마비증세는 모두 호전되었다. 하지만 HA-후궁골 사이의 유합률이 임상적 호전도와 상관관계가 없었다

결론: HA는 경추 후궁성형술에서 매우 안전하고 효과적인 골대체이다. 본연구에서 시행된 수술법과 수술재료는 경추의 운동각을 감소시키고 수술후 경추통증이 일부 악화 되는 결과를 보였으나 이는 그다지 심하지 않으며 추가적인 치료를 요하지는 않는다. 본 연구에 의하면 HA와 이식부위 골사이의 유합이 일어나기는 하나 그시간이 매우 오래걸리는 것을 알수 있었다. 하지만 이식된 HA의 안정성은 후궁 양측의 경첩부위의 골유합이 수술후 1년이내에 100% 가까이 일어나기 때문에 비록 HA와 이식부위골의 유합에 시간이 걸리더라도 그 안정성에는 문제가 없다고 하겠다.

핵심되는 말 : 경추 후궁 성형술, Hydroxy-apatite, 골유합