osteoinductive activity the same as CHO-derived rhBMP-2 both in vivo and in vitro [45]. However, these reports included only results for E-BMP-2-induced ectopic bone formation. Our question in this study was whether E-BMP-2-adsorbed β-TCP can achieve lumbar spinal fusion in a rabbit model the same as autogenous bone graft. Our findings suggest E-BMP-2-adsorbed β-TCP granules can effectively achieve posterolateral spinal fusion in a rabbit model the same as autogenous bone graft. On the other hand, from the original phase of preclinical and clinical application of BMPs, they have been locally delivered with Type I collagen sponges [5, 6, 10]. Although it is now possible to generate large amounts of recombinant human BMPs for medical use, the major challenge remains in the development of optimal local delivery systems for these proteins. To address this issue, we have investigated a biodegradable polymer as a carrier for BMPs yielding slow release and increasing the effects of BMPs [30], while Seeherman et al. have investigated the efficacy of calcium phosphate paste as a carrier for rhBMP-2 for the treatment of osteotomy [35]. We have generated an osteoinductive composite consisting of rhBMP-2, β-TCP powder, and biodegradable polymer for the treatment of various skeletal disorder models [12, 26, 36]. However, the results of these investigations are not yet clinically applicable because of the use of agents not approved for clinical use, such as biodegradable polymers. To address this problem, we used β-TCP, which is widely applied clinically, as a delivery system for BMP. As a result the necessary amount of BMP-2 to obtain lumbar spinal fusion is higher than that reported in our previous study [26]. We found lumbar spinal fusion occurred with the use of β-TCP and extended release of E-BMP-2 as previously described [32, 43]. Large quantities of BMPs facilitated osteoclast formation and resultant resorption and remodeling of newly formed bone in a dose-dependent manner (Figs. 5, 6), as previously reported [36]. This excessive osteoclast differentiation and bone resorption is an indirect effect of osteoblast differentiation and RANKL (receptor activator of NFκB ligand) expression induced by BMP stimulation [28, 37, 46] and a direct effect of BMP on osteoclastogenesis [44]. As previously described [21], these observations also indicate that excessive amounts of BMP might fail to yield required new bone formation, and that it is important to use optimal doses of BMP in clinical situations such as spinal fusion. E-BMP-2-adsorbed β-TCP granules may thus be useful as new materials for osteogenesis, especially for spinal fusion, and successfully address issues related to the clinical application of BMPs noted above.

Our preliminary findings suggest E-BMP-2-adsorbed porous β-TCP could be an effective alternative to autogenous bone grafting for generation of new bone and promotion of regenerative repair of bone, and potentially utilizable in the clinical setting for the treatment of spinal disorders.

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ORIGINAL ARTICLE

Factors affecting neurological deficits and intractable back pain in patients with insufficient bone union following osteoporotic vertebral fracture

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Abstract The purpose of this study was to examine factors affecting the severity of neurological deficits and intractable back pain in patients with insufficient bone union following osteoporotic vertebral fracture (OVF). Reports of insufficient union following OVF have recently increased. Patients with this lesion have various degrees of neurological deficits and back pain. However, the factors contributing to the severity of these are still unknown. A total of 45 patients with insufficient union following OVF were included in this study. Insufficient union was diagnosed based on the findings of vertebral cleft on plain radiography or CT, as well as fluid collection indicating high-intensity change on T2-weighted MRI. Multivariate logistic regression analysis was performed to determine the factors contributing to the severity of neurological deficits and back pain in the patients. Age, sex, level of fracture, duration after onset of symptoms, degree of local kyphosis, degree of angular instability, ratio of occupation by bony fragments, presence or absence of protrusion of flavum, and presence or absence of ossification of the anterior longitudinal ligament (OALL) in the adjacent level were used as explanatory variables, while severity of neurological deficits and back pain were response variables. On multivariate analysis, factors significantly affecting the severity of neurological deficits were angular instability of more than 15° [adjusted odds ratio (OR), 9.24 (95% confidence interval, CI 1.49–57.2); $P < 0.05$] and ratio of occupation by bony fragments in the spinal canal of more than 42% [adjusted OR 9.23 (95%CI 1.15–74.1); $P < 0.05$]. The factor significantly affecting the severity of back pain was angular instability of more than 15° [adjusted OR 14.9 (95%CI 2.11–105); $P < 0.01$]. On the other hand, presence of OALL in the adjacent level reduced degree of back pain [adjusted OR 0.14 (95%CI 0.03–0.76); $P < 0.05$]. In this study, pronounced angular instability and marked posterior protrusion of bony fragments in the canal were factors affecting neurological deficits. In addition, marked angular instability was a factor affecting back pain. These findings are useful in determining treatment options for patients with insufficient union following OVF.

Keywords Osteoporotic vertebral fracture · Risk factor · Insufficient bone union · Neurological deficit · Back pain

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Introduction

Fracture associated with osteoporosis has become a major problem because the population of elderly individuals has been increasing [4]. Modalities efficacious in preventing as well as treating osteoporosis-associated fractures are thus desired in the coming decade [7]. Among such fractures, vertebral fractures are the most common type with significant morbidity [24].

The osteoporotic vertebral fracture (OVF) has severe impact on activities of daily living and quality of life in elderly patients and is the beginning of a long-lasting deterioration of the patient's health [28]. Some patients present with intractable back pain for prolonged periods of time, while others suffer from neurological deficits within a few months' time after fracture. In such cases, insufficient union is often noted on plain radiography and/or MRI [18, 22]. Recently, reports of insufficient union have been increasing [13, 15, 19, 26, 29].

Patients with insufficient union following OVF have been treated with various methods conservatively and surgically. Surgical procedures include resection of fractured vertebral bodies and grafting of autologous bone with implants through the anterior approach are one option, while closed-wedge osteotomy through the posterior approach has been another [9, 20, 25, 27]. However, considering the age and comorbidities of affected patients, each of these procedures is rather invasive. Vertebroplasty is less invasive and has been reported to yield successful clinical results for painful OVF, but not to yield satisfactory results for patients with neurological deficits [2, 8, 14, 23].

Thus, the treatment options for insufficient union following OVF have not been clearly established. To elucidate useful treatment options for this lesion, it is necessary to evaluate the factors contributing to neurological deficits and/or intractable back pain associated with this type of fracture. The purpose of this study was to elucidate the factors affecting the severity of neurological deficits and intractable back pain in patients with insufficient bone union following OVF.

Material and methods

Patient population

A total of 45 patients treated for insufficient union following OVF were retrospectively reviewed. Insufficient union was diagnosed based on intravertebral vacuum cleft on plain radiography or CT, as well as fluid collection on T2-weighted MRI within the vertebral body. All patients had continued to complain of symptoms for longer than 2 months (range 2–36 months, mean 6.9 months).

There were 10 men and 35 women whose mean age at the time of diagnosis was 74 years (range 56–87 years). The fracture levels were T9 in 1 patient, T11 in 3, T12 in 22, L1 in 11, L2 in 6, L4 in 1, and L5 in 1. In these patients, bone mineral density was measured in the lumbar spine or femoral neck, and the diagnosis of osteoporosis was confirmed. Other metabolic bone diseases and malignancies such as myeloma and metastatic cancer were excluded. The precipitating events leading to the fracture were fall in 22 patients (48.8%), lift of a heavy object in 5 (11.1%), and no recollection of trauma in 18 (40%). The comorbidities were diabetes in 12 patients (26.7%) and rheumatoid arthritis in four (8.9%) take steroids. For neurological findings, 10 patients had a hyperreflexia and 19 a hyporeflexia in their legs. Twenty-five patients had a sensory deficit. Eleven patients had a sphincter dysfunction.

Eight patients were managed with posterior decompression and fusion surgery, 23 vertebroplasty, and 14 conservative therapies such as a corset or analgesics.

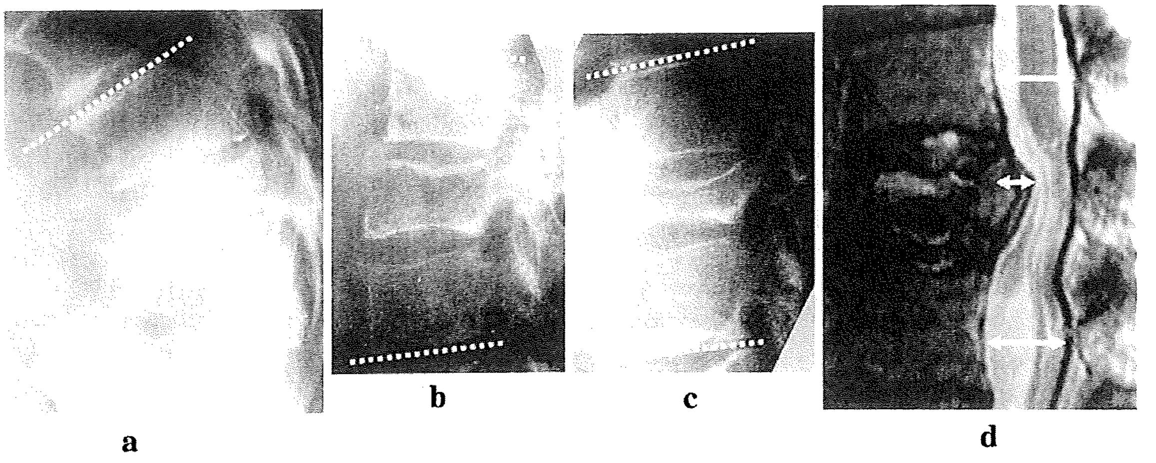

Fig. 1 Radiological assessment. **a** Local kyphosis was calculated as Cobb angle between the upper endplate of the vertebra just cranial to the fractured vertebra and the inferior endplate of the vertebra just caudal to the fractured vertebra on lateral plain X-ray films. **b, c** Angular instability was calculated as change in Cobb angle on lateral dynamic radiography (**b** extension, **c** flexion). **d** Ratio of occupation by bony fragments of the spinal canal was calculated as ratio in percentage of bony fragment diameter to adjacent normal canal diameter on mid-sagittal MR images

Table 1 Patient demographics

Characteristics	No. of subjects	Mean or percent
Mean age (years)		74.0
Mean duration of fracture (months)		6.9
Sex		
Male	10	22.2%
Female	35	77.8%
Level of injury		
L2 or below	8	17.8%
L1	11	24.4%
T12 or above	26	57.8%
Mean local kyphosis (°)		24.8
Mean angular instability (°)		11.4
Mean ratio of occupation by bony fragments (%)		38.1
Protrusion of flavum		
Absent	36	80%
Present	9	20%
Adjacent OALL		
Absent	31	71.1%
Present	13	28.9%
Neurological deficits		
None	24	53.3%
Mild	10	22.2%
Severe	11	24.5%
Back pain		
None or mild	7	15.6%
Moderate	16	35.6%
Severe	22	48.8%

Radiological assessment

Local kyphosis was calculated as the Cobb angle between the cranial endplate of the vertebra just cranial to the fracture and the caudal endplate of the vertebra just caudal to the fractured vertebra on lateral plain X-ray films (Fig. 1). Angular instability was calculated as change in vertebral wedge angle on lateral dynamic radiography. Ratio of occupation by bony fragments of the spinal canal was calculated as the ratio in percentage of sagittal diameter of bony fragments to sagittal diameter of the spinal canal on mid-sagittal MR images.

Statistical analysis

As response variables, severities of neurological deficits and of back pain were each graded using three levels. For neurological deficits, "none" was defined as no neurological deficit, "mild" as Manual Muscle Test (MMT) score of grade 4, and "severe" as MMT score of grade 3 or less. For back pain, "none or mild" was defined as VAS score less than 30, "moderate" as VAS score from 30 to 70, and "severe" as VAS score above 70.

Explanatory variables included age, sex, level of fracture, duration of symptoms after onset, angle of local kyphosis, degree of angular instability, ratio of occupation by bony fragments of the spinal canal, presence or absence of protrusion of flavum in the spinal canal, and presence or absence of ossification of the anterior longitudinal ligament (OALL) in the adjacent level. Continuous variables (angle of local kyphosis, degree of angular instability, and ratio of occupation by bony fragments of the spinal canal) were categorized by approximate tertile, except for age, and duration of fracture. Levels of fracture were divided into three categories. The first category was the level cranial to T12, that of the spinal cord. The second category was the level of L1, that of the conus medullaris. The third category was L2 and caudal to L2, the levels of the cauda equina. Other characteristics were treated as dichotomous variables (male/female for sex, present/absent for protrusion of flavum, or adjacent OALL).

To express the associations between severe neurological deficits or severe back pain and explanatory variables, odds ratio (ORs) and their 95% confidence intervals (CIs) were computed using the proportional odds model in logistic regression. We calculated P values for the scores to test the proportional odds assumption in order to confirm that use of the proportional odds model would be appropriate for these models.

All analyses were performed using Statistical Analysis System Version 9.1 (SAS Institute, Inc., Cary, NC, USA). Findings of $P < 0.05$ were considered significant.

Results

Patient demographic variables are shown in Table 1. Overall, 46.7% of patients exhibited mild or severe neurological deficits, with findings of less than grade 4 on MMT, and 84.4% had moderate or severe back pain, with a VAS score of more than 30.

Neurological deficits

Table 2 shows the associations between explanatory variables and severity of neurological deficits. Univariate analysis showed that pronounced angular instability within the affected vertebral body of more than 15° significantly increased the OR of neurological deficits [crude OR, 10.0 (95%CI 2.12–47.7); $P < 0.01$]. Marked spinal canal encroachment by protruding bony fragments was also a factor significantly contributing to neurological deficits. ORs were 6.74 (95%CI 1.11–40.9, $P < 0.05$) for moderate protrusion from 33 to 41% and 11.9 [(95%CI 2.11–68.0);

Table 2 Univariate and multivariate ORs for severity of neurological deficits

Characteristics	Neurological deficits			Univariate		Multivariate	
	None *n*	Mild *n*	Severe *n*	OR (95%CI)	*P* value	OR (95%CI)	*P* value
Age (year) per 1 year				0.96 (0.89–1.04)	0.341	0.91 (0.82–1.02)	0.106
Sex							
Male	5	4	1	1		1	
Female	19	6	10	1.20 (0.31–4.66)	0.794	0.66 (0.12–3.69)	0.634
Level of injury							
L2 or below	4	4	0	1		1	
L1	6	2	3	2.09 (0.37–11.8)	0.406	3.31 (0.31–35.6)	0.323
T12 or above	14	4	8	2.06 (0.47–9.05)	0.341	4.87 (0.66–35.9)	0.120
Duration of fracture (month) per 1 month				0.96 (0.85–1.08)	0.532	0.99 (0.84–1.18)	0.932
Local kyphosis (°)							
−21	5	6	2	1		1	
22–28	10	3	2	0.45 (0.10–1.94)	0.281	0.31 (0.04–2.44)	0.263
29+	9	1	7	1.14 (0.29–4.37)	0.855	0.62 (0.08–4.97)	0.653
Angular instability(°)							
−7	12	1	2	1		1	
8–14	7	5	1	2.59 (0.51–13.2)	0.252	2.20 (0.25–19.6)	0.479
15+	5	4	8	10.0 (2.12–47.7)	0.004	9.24 (1.49–57.2)	0.017
Ratio of occupation by bony fragments (%)							
−32	12	1	1	1		1	
33–41	5	6	2	6.74 (1.11–40.9)	0.038	2.35 (0.29–18.9)	0.421
42+	7	3	8	11.9 (2.11–68.0)	0.005	9.23 (1.15–74.1)	0.037
Protrusion of flavum							
Absent	21	7	8	1		1	
Present	3	3	3	2.27 (0.58–8.94)	0.241	0.56 (0.08–4.06)	0.569
Adjacent OALL							
Absent	17	8	7	1		1	
Present	7	2	4	1.15 (0.34–3.89)	0.828	1.79 (0.35–9.26)	0.483

OR odds ratio, *CI* confidence interval

$P < 0.01$] for severe protrusion of more than 42%. No other explanatory variables examined significantly contributed to neurological deficits on univariate analysis.

Multivariate analysis showed that pronounced angular instability in the upper tertile, of more than 15°, and high ratio of occupation by bony fragments, in the upper tertile of more than 42%, were factors significantly contributing to the degree of neurological deficit [adjusted OR 9.24 (95%CI 1.49–57.2); $P < 0.05$ and adjusted OR 9.23 (95%CI 1.15–74.1); $P < 0.05$, respectively]. No other variables examined were significant factors on multivariate analysis (Fig. 2).

Intractable back pain

Table 3 shows the associations between explanatory variables and severity of back pain in patients with insufficient union following OVF. Univariate analysis revealed that moderate angular instability ranging from 8° to 14° had an OR of 4.45 [(95%CI 1.01–19.6); $P < 0.05$)] while marked angular instability of more than 15° had an OR of 9.83 [(95%CI 2.19–44.1); $P < 0.01$). No other variables examined were significant factors on univariate analysis.

Multivariate analysis showed that pronounced angular instability of more than 15° was a factor significantly contributing to intractable pain [adjusted OR 14.9 (95%CI 2.11–105); $P < 0.01$]. On the other hand, the existence of OALL in the level adjacent to the fracture was a factor reducing the degree of back pain [adjusted OR 0.14 (95%CI 0.03–0.76); $P < 0.05$]. No other variables examined were significant factors on multivariate analysis.

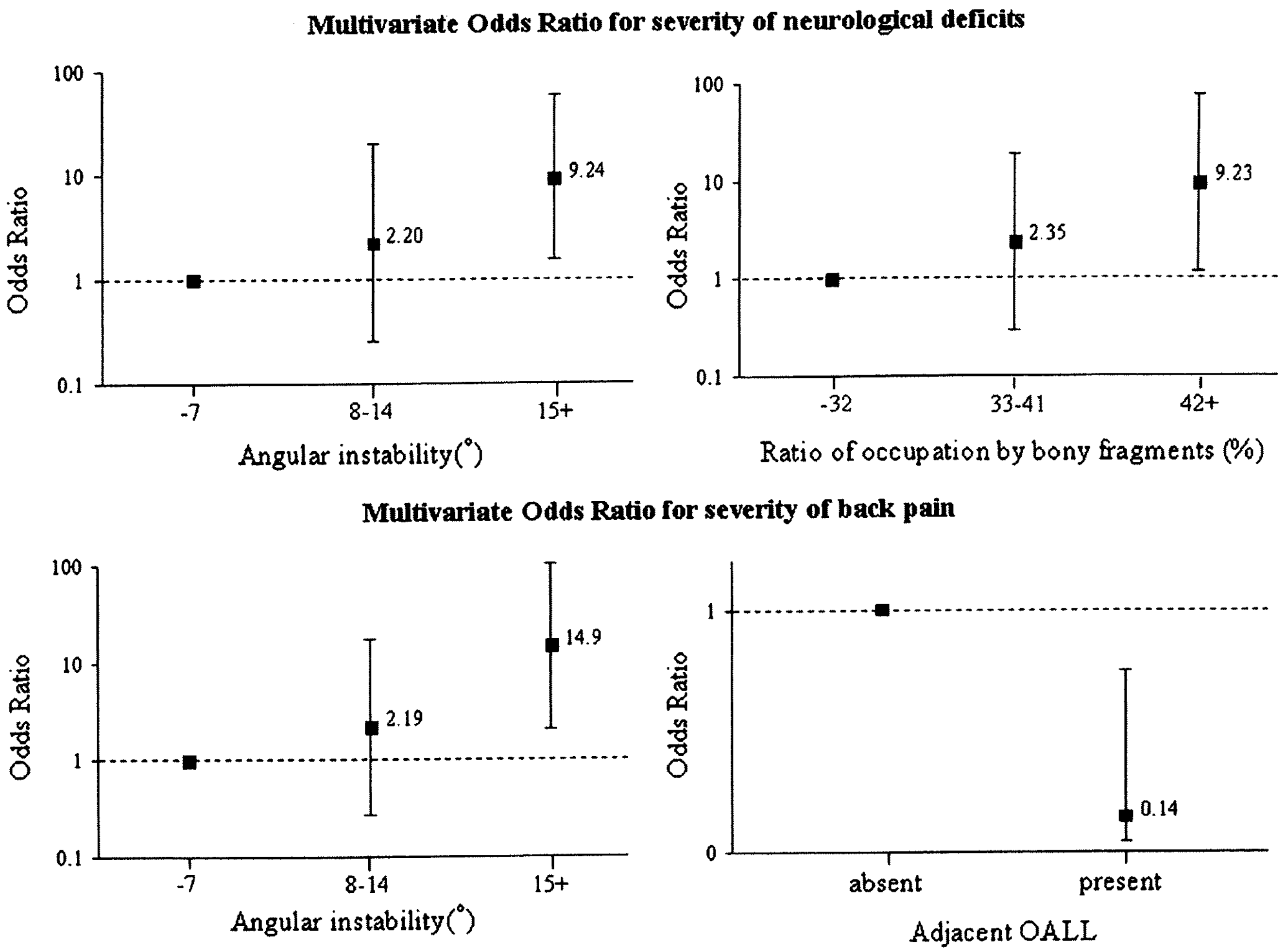

Fig. 2 Multivariate odds ratios for severity of neurological deficits and back pain. The *y* axis is on a log scale. The *I bars* denote 95% confidence intervals

Discussion

The pain associated with OVF usually improves if there is no severe residual deformity. Ettinger et al. reported that vertebral deformities cause marked back pain if vertebral height ratios fall four standard deviations below the normal mean [6]. However, pseudoarthrosis following OVF has recently come to be considered a poor prognostic factor for prolonged and intractable pain [10, 14, 16]. On the other hand, Hashidate et al. reported that in 66.7% of patients back pain decreased naturally despite the presence of vertebral instability in cases of vertebral pseudoarthrosis [11]. Thus, not all patients with non-union exhibited prolonged and intractable back pain. As noted above, the factors causing prolonged and intractable back pain in the case of insufficient bone union following OVF are still unknown. Toyone et al. reported a significant correlation between back pain and changes in wedging rate from supine to standing positions for OVF of recent onset [31]. In the present study, marked angular instability of the affected vertebral body significantly contributed to severity of back pain.

The presence of an intravertebral cleft had been reported to be a risk factor for progressive vertebral collapse inducing neurological deficits [15, 17]. A few previous studies investigated the relationship between neurological deficits and radiological findings. Hashimoto et al. reported that ratios of occupation by bone fragments in the spinal canal of more than 35% at epiconus level, more than 45% at conus medullaris level, and more than 55% at cauda equina level were factors significantly associated with neurological impairment in traumatic burst fracture [12]. Trafton et al. reported that burst fracture at T12 or L1 with canal encroachment of more than 50% of mid-sagittal canal diameter was a significant risk factor for neurological impairment [32]. These reports were both on acute traumatic vertebral fracture. Nguyen et al. reported a series of ten patients with osteoporotic vertebral burst fracture, which led to varying degrees of neurologic compromise. In their cases, mean

Table 3 Univariate and multivariate ORs for severity of back pain

Characteristics	Back pain			Univariate		Multivariate	
	None or mild *n*	Moderate *n*	Severe *n*	OR (95%CI)	*P* value	OR (95%CI)	*P* value
Age (year) per 1 year				0.98 (0.91–1.06)	0.658	1.05 (0.94–1.18)	0.406
Sex							
Male	2	4	4	1		1	
Female	5	12	18	1.56 (0.42–5.84)	0.509	2.15 (0.43–10.6)	0.348
Level of injury							
L2 or below	0	2	6	1		1	
L1	1	7	3	0.24 (0.04–1.48)	0.125	0.15 (0.01–213)	0.160
T12 or above	6	7	13	0.30 (0.06–1.44)	0.133	0.20 (0.02–1.96)	0.165
Duration of fracture (month) per 1 month				0.96 (0.87–1.07)	0.459	0.97 (0.83–1.14)	0.715
Local kyphosis (°)							
−21	1	3	9	1		1	
22–28	3	5	7	0.36 (0.08–1.63)	0.186	0.72 (0.10–5.35)	0.751
29+	3	8	6	0.28 (0.06–1.20)	0.086	0.37 (0.04–3.36)	0.377
Angular instability(°)							
−7	6	5	4	1		1	
8–14	0	7	6	4.45 (1.01–19.6)	0.048	2.19 (0.28–17.2)	0.456
15+	1	4	12	9.83 (2.19–44.1)	0.003	14.9 (2.11–105)	0.007
Ratio of occupation by bony fragments (%)							
−32	3	5	6	1		1	
33–41	1	3	9	3.19 (0.69–14.7)	0.137	4.72 (0.65–34.2)	0.124
42+	3	8	7	0.99 (0.27–3.63)	0.983	0.47 (0.07–3.29)	0.445
Protrusion of flavum							
Absent	5	13	18	1		1	
Present	2	3	4	0.72 (0.18–2.84)	0.958	4.04 (0.47–34.6)	0.202
Adjacent OALL							
Absent	3	11	18	1		1	
Present	4	5	4	0.30 (0.09–1.05)	0.059	0.14 (0.03–0.76)	0.023

OR odds ratio, *CI* confidence interval

canal compromise was 41% [21]. No reports were found in our review of the literature on the relationship between neurological deficits and intravertebral instability. Baba et al. reported 27 patients who suffered osteoporotic vertebral collapse with late neurological complications. They considered the pathology in this lesion to involve abnormal hypermobility at the fractured spinal level with gradual retropulsion of fractured fragments into the spinal canal, resulting in late paralysis [1].

In the present study, it was found that intravertebral instability contributes to the degree of neurological deficits in cases of insufficient union following OVF. Stabilization of the lesion site without decompression is, thus, a treatment option for this condition. Some studies have reported that treatment with immobilization without decompression, such as conservative management using a plaster body cast, vertebroplasty, or posterior in situ stabilization, could result in neurological improvement with progression of bone union [3, 5, 30]. These findings suggest that spinal instability is related to the pathogenesis of neurological deficits.

In this study, the factors significantly contributing to neurological deficits were angular instability of more than 15° and ratio of occupation by bony fragments of the spinal canal of more than 42%. The factors contributing to severity of back pain were angular instability of more than 15° and absence of OALL in the adjacent segment. As noted above, intravertebral angular instability was a factor common to neurological deficits and back pain. Stabilization of the fractured vertebra thus appears to be the most important treatment option for insufficient fracture following OVF. In patients with bony encroachment of higher percentage, decompression is needed to obtain satisfactory surgical results.

Conclusions

In conclusion, we investigated the factors contributing to the severity of symptoms in patients with insufficient union following OVF. Factors significantly contributing to the severity of neurological deficits were angular instability of more than 15° within the affected vertebral body and ratio of occupation by bony fragments in the spinal canal of more than 42%. Factors significantly contributing to the severity of back pain were angular instability of more than 15° and absence of adjacent OALL. Angular instability was thus a factor common to both neurological deficits and prolonged back pain.

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Recovery Process Following Cervical Laminoplasty in Patients With Cervical Compression Myelopathy

Prospective Cohort Study

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Study Design. Prospective cohort study.

Objective. To investigate the recovery process after laminoplasty in patients with cervical myelopathy, and the effects of patient age and duration of symptoms before surgery on the recovery process.

Summary of Background Data. The surgical results of laminoplasty for cervical myelopathy have been well documented, but there have been few reports on the recovery process after cervical laminoplasty.

Methods. The study group consisted of 98 patients who underwent double-door laminoplasty for cervical myelopathy. All cases were followed for a minimum of 5 years. The JOA score, 10 seconds grip and release test (10-second test), and grasp strength were evaluated at "fixed points" after surgery, and the recovery process in each subject was assessed. The maximum recovery time point, defined as the time point when the value just reached a plateau after surgery, was evaluated in each subject.

Patients were divided into 2 groups by age (<70 years and ≥ 70 years) or duration of symptoms before surgery (<1 year and ≥ 1 year), and the effects of these factors on surgical results were investigated.

Results. The preoperative values of all parameters significantly improved 5 years after surgery. The JOA score reached a plateau earlier (8.7 months) than did the grasp strength (21.7 months) and 10-second test (25.6 months). The maximum recovery time point of the JOA score was statistically late in the elder group (≥70 years) compared to the younger group (<70 years). The recovery rates of the JOA score and the degree of recovery for the 10-second test in patients with symptoms lasting <1 year were statistically greater than those in patients with symptoms lasting ≥1 year.

Conclusion. The functional status assessed by the JOA score recovered within 1 year after surgery but further recovery can be expected up to 2 years after surgery. The comparative study suggested that patient age influenced the process of recovery, and the duration of symptoms before surgery influenced the degree of recovery.

Key words: cervical myelopathy, recovery process, laminoplasty, age, duration of symptoms. **Spine 2009;34: 2874–2879**

Cervical laminoplasty is the treatment of choice for cervical compression myelopathy, and satisfactory surgical outcomes have been reported even after long follow-up periods.[1–5] Clinically, functional recovery is not rapid after surgical treatment, and the process varies depending on each patient's conditions.

The duration after surgery required to achieve maximum recovery and the factors influencing the recovery process are the greatest concerns for both physicians and patients, even though little relevant information has been reported. Therefore, we prospectively investigated and evaluated the recovery process of cervical myelopathy after laminoplasty, using the Japanese Orthopedic Association (JOA) score as an index of functional and neurologic status, the 10 seconds grip and release test (10-second test) as an index of hand coordination, and the grasp strength as an index of muscle strength at selected time points. Furthermore, we analyzed the effects of age and duration of symptoms before surgery on the recovery process.

■ Materials and Methods

All patients diagnosed with compressive cervical myelopathy from February 1995 to February 2002, who provided consent for the operation and were followed for more than 5 years were included in this study. Exclusion criteria at enrollment were cervical kyphosis (more than 10°), radicular pain of the upper extremity due to radiculopathy, and ossified posterior longitudinal ligament occupying more than 70% of the spinal canal. A total of 116 consecutive patients undergoing double-door laminoplasty for cervical compressive myelopathy were enrolled in this study. Among these patients, 2 patients who died during the follow-up period and 5 patients who could not be evaluated because of another neuromuscular disease (amyotrophic lateral sclerosis, 1 case; spinocerebellar degeneration, 1 case; myodystrophy, 1 case) or trauma (distal radius fracture, 2 cases) during the follow-up period were excluded from the study. Another 11 patients were excluded because they could not be followed up at one or more time points during the follow-up period. As a result, a total of 98 patients with complete data (69 men and 29 women; mean age, 59.6 years) were included in the study. The follow-up period ranged from 5 to 12 years with a mean of 6.8 years. The lesions inducing myelopathy were cervical

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spondylosis in 60 patients, cervical disc herniation in 20 patients, and ossification of the posterior longitudinal ligament in 18 patients. Double-door laminoplasty was performed by 3 of the authors (H.M., M.S., and T.T.), using the technique described by Kurokawa.[2] Briefly, the patient was placed in the prone position on the operating table, using a Mayfield fixator, and the spinous processes and laminae of the involved level were exposed subperiosteally using a midline incision. The spinous processes were split sagittally with a high-speed burr. Bilateral gutters for the hinges were carefully made with a high-speed burr at the transitional area between the facet joint and laminae. Next, spinal canal enlargement was achieved by opening the split laminae bilaterally with a spreader and positioning an apatite wollastonite-containing glass ceramic or hydroxyapatite spacer that was held in place with nonabsorbable sutures. Surgery was performed at the C3–C7 levels in 88 patients, C2–C7 levels in 4 patients, C3–Th1 levels in 4 patients, C3–C6 levels in 1 patient and C2–Th1 levels in 1 patient.

The JOA score for assessment of cervical myelopathy (Table 1), 10-second test (numbers of grip and release cycles within 10 seconds) and grasp strength were evaluated before the surgery and at 3, 6, 9, 12, 18, 24, 36, 48, and 60 months after the surgery. The evaluations were randomly performed by 1 of 3 physicians (H.M., M.S. or T.T.) at each time point. The grasp strength was measured by an electrical dynamometer (TKK5401; HATA Sporting Goods Industry Co., Osaka, Japan) with elbow extension in the standing position (or sitting position if the patient could not stand), and the 10-second test was evaluated with the sitting position on a chair. The scores of the 10-second test and grasp strength were determined as the means for both hands. The maximum recovery time point was determined as the time point when maximum recovery was obtained (point at which the score just reached its plateau), and was evaluated for each patient. If the curve of the scores had double peaks and the difference between the 2 scores was less than 1 point, the earlier time point was determined as the maximum recovery time point. If the later score was 1 point or more higher than the earlier score, the later time point was determined as the maximum recovery time point. The recovery rates of the JOA scores were calculated by the Hirabayashi method. The degrees of recovery for the 10-second test and the grasp strength were determined as the differences between the preoperative scores and the scores at 60 months after surgery.

To evaluate the effects of age at surgery on the surgical results, the patients were classified into 2 age groups: <70 years (n = 73) and ≥70 years (n = 25). To evaluate the effects of the duration of symptoms before surgery on the surgical results, the patients were classified into 2 groups according to the duration of symptoms: <1 year (n = 65) and ≥1 year (n = 33). The maximum recovery time points and degrees of recovery for each parameter were compared between the groups. No significant intergroup differences in the patient demographics were observed between the groups according to the age at the time of surgery and the duration of symptoms before surgery.

Table 1. Scoring System for the Treatment of Cervical Myelopathy by the Japanese Orthopaedic Association (JOA Score)

I Motor function of upper extremity
- 0 unable to feed oneself with any tableware including chopsticks, spoon, or fork, and/or unable to fasten buttons of any size
- 1 can manage to feed oneself with spoon and/or fork but not with chopsticks
- 2 either chopstick feeding or writing is possible but not practical, and/or large buttons can be fastened
- 3 either chopstick feeding or writing is clumsy but practical, and/or cuff buttons can be fastened
- 4 Normal

II Motor function of lower extremity
- 0 unable to stand and walk by any means
- 1 unable to walk without a cane or other support on a level
- 2 walks independently on a level but needs support on stairs
- 3 capable of fast but clumsy walking
- 4 Normal

III Sensory function
- A Upper extremity
  - 0 Apparent sensory loss
  - 1 Minimal sensory loss
  - 2 Normal
- B Lower extremity (same as A)
- C Trunk (same as A)

IV Bladder function
- 0 urinary retention and/or incontinence
- 1 sense of retention and/or dribbling and/or thin stream and/or incomplete continence
- 2 urinary retardation and/or pollakiuria
- 3 Normal

Total points = 17

Statistical Analysis

Data are presented as means ± SEM. Statistical analyses were performed using STATVIEW 5.5 (Abacus Concepts, Berkeley, CA) and the unpaired nonparametric Mann-Whitney U test at a 95% confidence level or the Bonferroni method. Values of $P < 0.05$ were considered significant.

■ Results

The preoperative JOA score of 11.1 ± 0.4 improved to 14.3 ± 0.2 at 5 years after surgery ($P < 0.0001$), and the mean recovery rate was 50.1 ± 3.8% (Figure 1).

In 80 patients (81%), the JOA score reached its maximum recovery within 12 months after surgery, with a mean time point of 8.7 ± 0.9 months (see figure, Supplemental Digital Content 1, http://links.lww.com/BRS/A397). The preoperative 10-second test of 16.3 ± 0.6 times improved to 25.4 ± 0.7 times at 5 years after surgery ($P < 0.0001$), with a mean maximum recovery time point of 25.6 ± 0.7 months (Figure 1). The preoperative grasp strength of

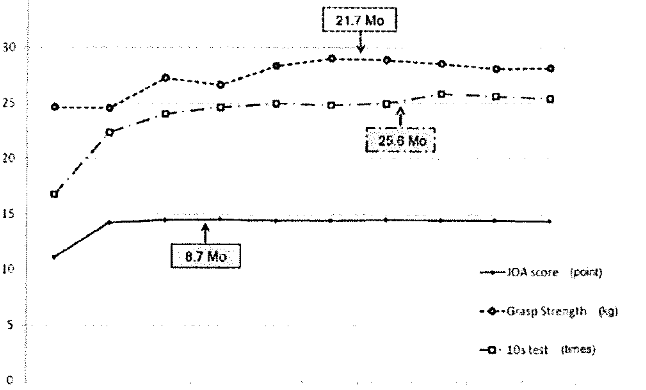

Figure 1. Changes in the JOA score, grasp strength, and 10-second test before and after surgery. Each arrow and number indicates the mean maximum recovery time point (months).

Table 2. Demographic Data of the Patient With and Without Temporal Weakness of Grasp Strength

Temporal Weakness of Grasp Strength	(+) (n = 34)	(−) (n = 64)	P
Sex			
Male (%)	26 (76.4)	44 (68.8)	NS
Female(%)	8 (23.6)	20 (31.2)	NS
Age	57.6 ± 1.7	60.6 ± 1.6	NS
Diagnosis (%)			
CSM	67.6	57.8	NS
CDH	14.7	17.2	NS
OPLL	17.6	21.9	NS
Duration of symptom	25.9 ± 4.6	12.4 ± 2.8	$P = 0.0038$

NS indicates not significant (Man-Whitney *U* test); CSM, cervical spondylosis; CDH, cervical disc herniation; OPLL, ossification of posterior longitudinal ligament.

24.6 ± 1.2 kg improved to 28.0 ± 1.1 kg at 5 years after surgery ($P < 0.0001$), with a mean maximum recovery time point of 21.7 ± 1.4 months (Figure 1). The recoveries of the 10-second test and grasp strength continued for a longer period than the JOA score.

In 34 patients (34.7%), the grasp strength at 3 months after surgery decreased to <90% of the preoperative value. However, 97% of the patients recovered their grasp strength to the preoperative score within 2 years. The demographic data for the patients with or without temporary deterioration in grasp strength are shown in Table 2. The duration of symptoms was significantly longer in patients with temporary deterioration than in patients without temporary deterioration (25.9 ± 4.6 *vs.* 12.4 ± 2.8 months, $P = 0.0038$).

There were no significant differences in the maximum recovery time points or degrees of recovery for each value among the patients with cervical spondylosis, cervical disc herniation, and ossification of the posterior longitudinal ligament (Table 3).

Effects of Age at Surgery (<70 Years vs. *≥70 Years) on the Surgical Results*

Although the preoperative values of the JOA score and grasp strength were lower in the older patient group, there were no differences in the recovery rates of the JOA score and the degrees of recovery for the 10-second test and grasp strength. The maximum recovery time point of the JOA score was significantly later in the older group than in the younger group (10.5 ± 1.6 *vs.* 8.1 ± 1.1 month, $P = 0.016$) (Figure 2, Table 4), whereas there were no differences in the recovery time points of the grasp strength and 10-second test between the 2 groups. Among the JOA scores, the maximum recovery time point of motor function of the lower extremity showed the largest difference between the older and younger groups (10.8 ± 2.4 *vs.* 6.0 ± 1.0 months, $P = 0.0005$) (Table 4). In the older group, the mean motor function score of the lower extremities deteriorated within 60 months after the maximum recovery time point while that in the younger group was maintained (Figure 2). The mean grasp strength in the older group also deteriorated within 60 months after the maximum recovery time point.

Table 3. Comparison of Each Peak and Degree of Recovery Between the Causes of Myelopathy

	CS (n = 60)	CDH (n = 20)	OPLL (n = 18)	P
JOA score				
Max recovery time point				
Total	8.8 ± 1.1	7.7 ± 1.8	9.9 ± 2.4	NS
Recovery rate	50.4 ± 4.5	60.5 ± 8.1	36.1 ± 11.8	NS
Grasp strength				
Max recovery time point	20.0 ± 1.8	17.5 ± 2.0	25.4 ± 4.4	NS
Degree of recovery	3.1 ± 1.6	2.5 ± 1.6	5.9 ± 3.7	NS
10 s test				
Max recovery time point	21.3 ± 2.5	19.7 ± 3.9	19.1 ± 3.5	NS
Degree of recovery	7.9 ± 0.8	10.9 ± 1.4	8.4 ± 1.8	NS

NS indicates not significant (Bonferroni method); CSM, cervical spondylosis; CDH, cervical disc herniation; OPLL, ossification of posterior longitudinal ligament.

Effects of the Duration of Symptoms Before Surgery (<1 Year vs. *≥1 Year) on the Surgical Results*

The recovery rate of the JOA score and degree of recovery for the 10-second test were significantly greater in patients with symptoms lasting <1 year than in patients with symptoms lasting ≥1 year (56.1% *vs.* 38.7%, $P = 0.047$; 6.3 *vs.* 9.8 times, $P = 0.026$) (Figure 3, Table 5). Although there was no difference in the degrees of recovery of the grasp strength between the 2 groups, transient weakness of the grasp strength at 3 months after surgery (<90% of the preoperative value) was observed more often in patients with symptoms lasting ≥1 year than in patients with symptoms lasting <1 year (55.8% *vs.* 20.3%, $P = 0.0006$) (Figure 4). There was no significant difference in the maximum recovery time points between the 2 groups.

Discussion

There have been many reports describing satisfactory surgical outcomes of laminoplasty for cervical stenotic myelopathy even after long-term follow-up periods.[1–5] Most of these reports were based on evaluations of the surgical outcomes at various but only a few time points after the surgery (*e.g.*, final follow-up), and few reports have referred to the recovery process. The duration of functional recovery following cervical laminoplasty is one of the greatest concerns for both patients and surgeons.

The present study has revealed the process of functional recovery after cervical laminoplasty in patients with myelopathy. Neurologic functions evaluated by the JOA score reached the maximum recovery point at an earlier time point (8.7 months) than those evaluated by the 10-second test (25.6 months) and grasp strength (21.7 months). The JOA score is a simple scoring system, and truly reflects the neurologic and functional status. However, the evaluation is expressed with discrete variables, and small differences in the patient's conditions cannot be detected by this scoring system. On the other hand, the grasp strength and 10-second test are evaluation methods with continuous variables. In addition,

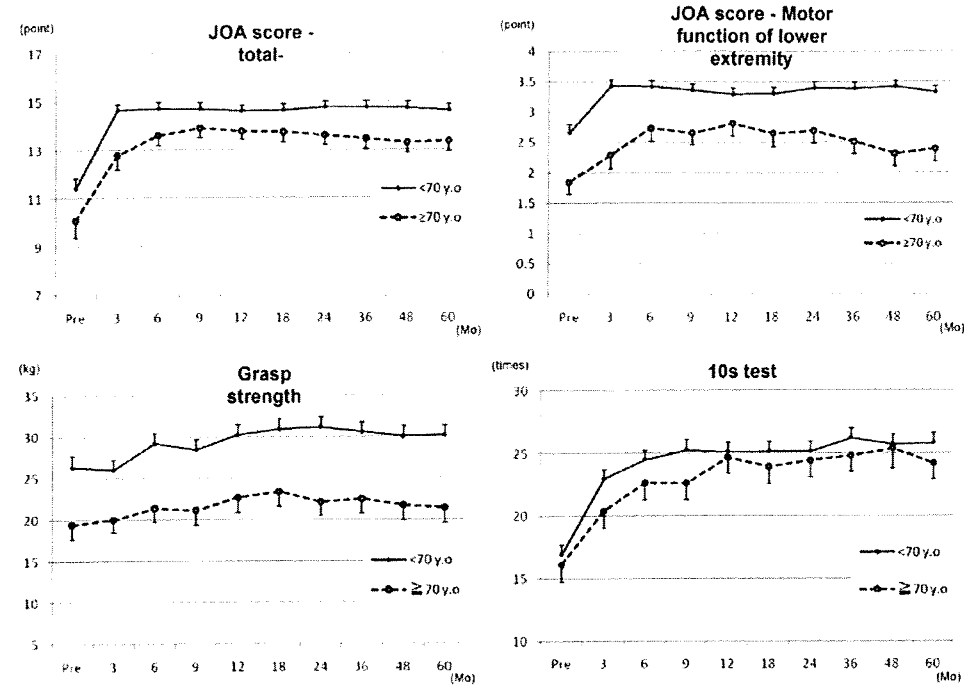

Figure 2. Comparisons of the JOA scores (total, motor function of the lower extremities), grasp strengths and 10-second tests between patients aged <70 years and patients aged ≥70 years. Although no differences are detected in the recovery rates of the JOA score, the maximum recovery time point of the JOA score is later in the older group than in the younger group.

JOA score mainly reflect the function of the upper and the lower extremities and the urinary tract, while the grasp strength and 10-second test represent the function of upper extremity only. The discrepancies in the maximum recovery time points among the parameters may be due to these characteristics. Although the validity was not evaluated in the present study, both the grasp strength and 10-second test were reported to be reliable and reproducible methods for evaluating the upper limb function of patients with myelopathy.[6,7] Functional recovery evaluated by the JOA score reached a plateau within 1 year after surgery, but we can still expect further functional recovery for up to about 2 years after surgery. This information may be useful for the rehabilitation of patients.

Table 4. Comparison of Each Peak and Degree of Recovery Between the Group That the Age Was Under 70 Years Old and That Was Over 70 Years Old

	≥70 yr (n = 73)	≥70 yr (n = 25)	*P*
JOA score			
Max recovery time point			
Total	8.1 ± 1.0	10.5 ± 1.6	*P* = 0.016
Category			
I	5.5 ± 0.7	6.8 ± 1.5	NS
II	6.0 ± 1.0	10.1 ± 2.4	*P* = 0.0005
III	7.4 ± 1.1	8.6 ± 2.0	NS
IV	3.1 ± 0.1	3.6 ± 0.3	NS
Recovery rate	53.4 ± 4.3	40.3 ± 8.3	NS
Grasp strength			
Max recovery time point	20.8 ± 1.6	19.3 ± 3.0	NS
Degree of recovery	3.8 ± 1.1	2.2 ± 1.0	NS
10 s test			
Max recovery time point	19.7 ± 2.1	21.1 ± 3.8	NS
Degree of recovery	8.9 ± 0.8	7.9 ± 1.3	NS

NS indicates not significant (Man-Whitney *U* test).

Although the influence of the patient's age at the time of surgery on the surgical outcome has been investigated in many studies, there is no agreement on this subject. Nagata *et al*[8] reported on the clinical outcomes of elderly patients (>65 years) with cervical myelopathy in whom anterior or posterior decompression was performed. They found significantly poorer outcomes in elderly patients than in younger patients. Hasegawa *et al*[9] performed a comparative study on the clinical outcomes after surgical treatment for cervical spondylotic myelopathy between patients older than 70 years and younger than 60 years, and described comparable surgical results between the 2 groups. In the present study, there were no significant differences in the recovery rates of the JOA score and the degrees of recovery for the 10-second test and grasp strength at 5 years after surgery between the older patients (≥70 years) and younger patients (<70 years). Regarding the recovery process of the JOA score, recovery was significantly slower in the older patients (≥70 years). In addition, the recoveries of the motor function of the lower extremities and grasp strength of the elderly patients were not maintained during the 60 months after surgery. These results suggest that the time point for evaluation is important when evaluating the effects of patient age at surgery on the surgical outcomes, and the results are influenced by that time point.

There have been some reports on the influence of the duration of symptoms before surgery on the surgical results.[10-12] Suzuki *et al*[11] analyzed the spastic gait in patients with cervical spondylotic myelopathy using a three-dimensional gait analysis system, and demonstrated that spasticity was increased in patients with a long duration of symptoms before surgery. Yamazaki *et al*[12] demonstrated that a short duration of symptoms

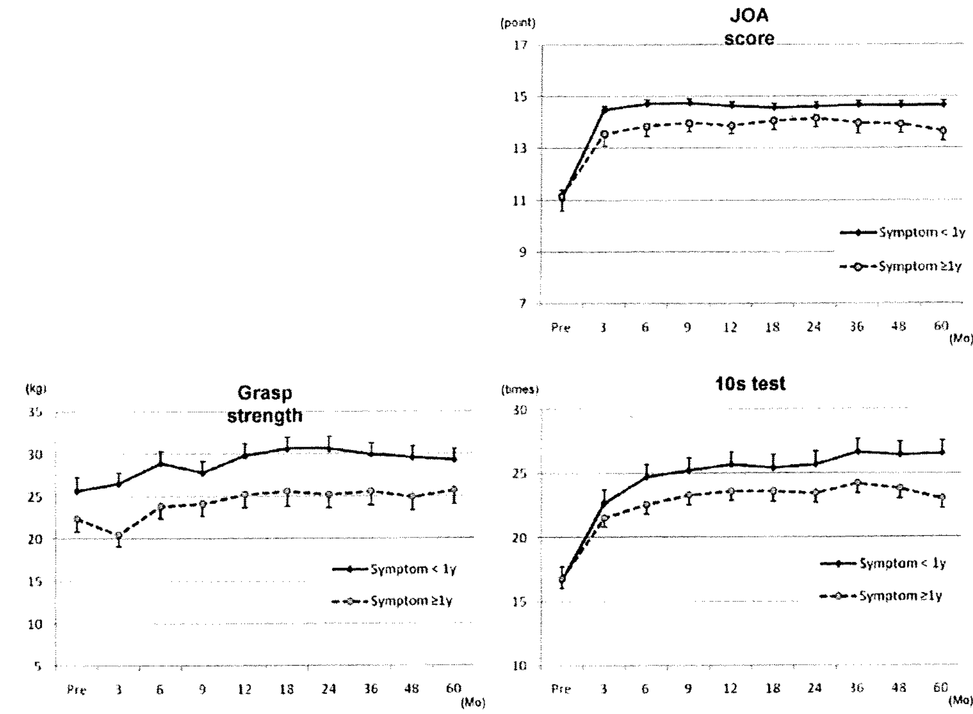

Figure 3. Comparisons of the JOA scores, grasp strengths, and 10-second tests between patients with symptoms lasting <1 year and patients with symptoms lasting ≥1 year. The postoperative scores of each parameter of the patients with symptoms lasting <1 year tend to be higher than those of patients with symptoms lasting ≥1 year, although there are no differences in the preoperative scores of each parameter between the 2 groups.

was one of the factors that predicted an excellent recovery for elderly patients with cervical spondylotic myelopathy after laminoplasty.

In the present study, although the duration of symptoms did not affect the time course until maximum recovery, it significantly affected the recovery rate of the JOA score and the degree of recovery in the 10-second test. In patients with cervical stenotic myelopathy, repeated minor trauma and ischemia in the spinal cord and their accumulation lead to demyelination, necrosis, and/or cavitation.[13] The present results suggest that the accumulation of damage during a longer duration of symptoms is irreversible for the spinal cord.

Table 5. Comparison of Each Peak and Degree of Recovery Between the Group That Duration of Symptom Was <1 Year and That Was ≥1 Year

	<1 yr (n = 65)	≥1 yr (n = 33)	*P*
JOA score			
Max recovery time point			
Total	8.2 ± 1.1	9.8 ± 1.6	NS
Category			
I	5.7 ± 0.8	6.3 ± 0.9	NS
II	7.0 ± 1.2	7.6 ± 1.5	NS
III	7.6 ± 1.1	7.9 ± 1.7	NS
IV	3.1 ± 0.1	3.5 ± 0.3	NS
Recovery rate	56.1 ± 4.4	38.7 ± 7.1	*P* = 0.047
Grasp strength			
Max recovery time point	20.8 ± 1.7	19.7 ± 2.7	NS
Degree of recovery	3.6 ± 0.9	3.2 ± 1.7	NS
10 s test			
Max recovery time point	21.6 ± 2.4	18.6 ± 3.0	NS
Degree of recovery	9.8 ± 0.7	6.3 ± 1.4	*P* = 0.001

NS indicates not significant (Mann-Whitney *U* test).

The present study has revealed for the first time that transient weakness of grasp strength at 3 months after surgery occurred in 36.7% of all patients. This frequency was relatively high compared with those of other complications, even though it recovered within 2 years after surgery in 97% of the patients. Deterioration was more often seen in patients with symptoms lasting ≥1 year (53.1%) than in patients with symptoms lasting <1 year (18.4%). This deterioration could not be explained merely by muscle atrophy in the upper extremities due to long-term symptoms, and some segmental nerve root

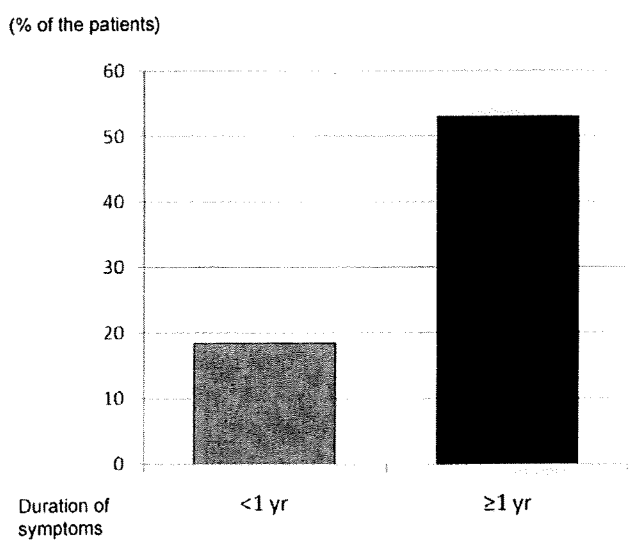

Figure 4. Percentages of patients with a decrease in grasp strength at 3 months after surgery. The occurrence of the deterioration is significantly higher in patients with symptoms lasting ≥1 year than in patients with symptoms lasting <1 year.

palsy such as C5 nerve root palsy after surgery or reperfusion injury in the spinal cord may also have influenced the grasp strength. Although the cause of this temporary deterioration was not clarified, this phenomenon should be kept in mind for cervical laminoplasty.

■ Conclusion

During the process of neurologic recovery after cervical laminoplasty in patients with compression myelopathy, the JOA score (8.7 months), grasp strength (21.7 months), and 10-second test (25.6 months) reached their maximum recovery points in that order. The functional recovery assessed by the JOA score reached a plateau within 1 year after surgery, but further recovery can be expected for up to 2 years after surgery. Comparative studies suggested that patient age at surgery influenced the process of the recovery and that the duration of symptoms before surgery influenced the degree of the recovery. These pieces of information appear to be useful for both patients and surgeons.

■ Key Points

- Functional recovery occurs within 1 year after surgical treatment in cervical compression myelopathy but further recovery can be expected up to 2 years after surgery.
- Age at the time of surgery influences the recovery process after surgery.
- The duration of symptoms before surgery influences the degree of recovery.
- The transient deterioration of grasp strength was seen in 35% of patients after laminoplasty.

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委員会報告

脊椎内視鏡下手術の現状
—2008年1月～12月 手術施行状況調査・インシデント報告集計結果—*

日本整形外科学会脊椎脊髄病委員会
(平成20年度脊椎内視鏡下手術・技術認定制度委員会)

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はじめに

日本整形外科学会脊椎内視鏡下手術技術認定制度および同委員会が平成2004年に発足し，安全性の高い内視鏡下手術を国民に提供するために医療安全対策小委員会が設置された[1,2]．同委員会は2005年から毎年脊椎内視鏡下手術の現状を詳細に把握するための全国アンケート調査を行い報告してきた[3-4]．

本報告の目的は2008年度のアンケート調査結果を過去の結果と比較し，脊椎内視鏡下手術の施行状況およびインシデント発生状況の現状を明らかにすることである．

Key words: Spine, Endoscopic Surgery, Complication

*Annual report 2008 of the spinal endoscopic surgery

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方　法

全国の2032施設にアンケート用紙を郵送し，1299施設から回答を得た(回答率63.9%)．そのうち2008年1月から12月までの1年間に脊椎内視鏡下手術が行われたのは264施設(回答施設の20.3%)であった．脊椎内視鏡下手術実施施設にはさらに，手術件数，手術内容，インシデント件数，インシデント内容，対処方法，転帰について調査票への記入を依頼し，その結果を集計し，過去の集計結果と比較した．

結　果

1．地区別手術施行施設数(表1)

2008年の1年間に脊椎内視鏡下手術が行われたのは264施設で，2007年の257施設に比べて1.03倍であった．

地区別に見ると，北海道地区14施設，東北地区23施設，関東地区53施設，中部地区38施設，近畿地区65施設，中国・四国地区37施設，九州・沖縄地区34施設であり，北海道，中部，近畿，中国・四国，九州・沖縄地区では前年比増で，東北，関東地区では同減であった．

2．地区別手術件数(表2)

2008年の総手術件数は6459件で，2007年の6239

表1 地区別施行施設数

	北海道	東北	関東	中部	近畿	中国・四国	九州・沖縄	全国
2005	14	24	26	34	64	29	17	208
2006	12	26	49	25	48	24	38	222
2007	8	27	67	34	64	28	29	257
2008	**14**	**23**	**53**	**38**	**65**	**37**	**34**	**264**
前年比	1.75	0.85	0.79	1.12	1.02	1.32	1.17	1.03

表2 地区別手術件数

	北海道	東北	関東	中部	近畿	中国・四国	九州・沖縄	全国
2005	330	601	1024	465	1115	366	314	4215
2006	242	469	1275	522	1060	461	582	4611
2007	238	698	1571	920	1666	588	558	6239
2008	**312**	**544**	**1323**	**1183**	**1448**	**791**	**858**	**6459**
前年比	1.31	0.78	0.84	1.29	0.87	1.35	1.54	1.04

件に比べて1.04倍であった．地区別に見ると，北海道地区312件，東北地区544件，関東地区1323件，中部地区1183件，近畿地区1448件，中国・四国地区791件，九州・沖縄地区858件で，2007年と比べるとそれぞれ，北海道地区1.31倍，東北地区0.78倍，関東地区0.84倍，中部地区1.29倍，近畿地区0.87倍，中国・四国地区1.35倍，九州・沖縄地区1.54倍であり，北海道，中部，中国・四国，九州・沖縄地区で増加，東北，関東，近畿地区で減少であった．

3．術式別手術件数(表3)

術式別には例年と同様に脊椎後方内視鏡下手術(経皮的手術を除く)が6271件と全体の97.1%と大半を占めた．このうち腰椎椎間板ヘルニア摘出が内側，外側合わせて4106例と大半を占め，腰椎椎弓切除術，開窓術が1666件，後方進入椎体間固定術(transforaminal lumbar interbody fusion/posterior lumbar interbody fusion，TLIF/PLIF)が332件，頚椎後方除圧術131例などであった．以下，胸腔鏡下手術36件，腹腔鏡下手術2件，後腹膜鏡下手術11件，経皮的手術139件であった．

4．インシデント件数および発生頻度(表4，5)

2008年度のインシデント件数は総数で161件であり，2007年度の133件と比べると1.21倍の増加になっている．手術件数自体も増加しているが発生頻度としても2.49%であり，2007年度の2.13%と比較すると増加した．

地域別に発生頻度を見ると，北海道地区1.6%，東北地区1.84%，関東地区1.59%，中部地区2.96%，近畿地区3.18%，中国・四国地区2.53%，九州・沖縄地区2.8%であり，北海道，東北で減少，関東で不変，その他の地区では増加した．

5．術式別インシデント件数(表6)

術式別インシデント件数は腰椎後方ヘルニア摘出術が82件(50.9%)，腰椎椎弓切除術・開窓術が57件(35.4%)，TLIF/PLIFが16件(9.9%)，胸腔鏡下手術2件(1.2%)，頚椎後方除圧術および経皮的内視鏡下ヘルニア摘出術各1件(0.6%)，その他2件(1.2%)であった．

6．術式別インシデント内容(表7)

インシデント内容は，硬膜損傷が109件(67.7%)，術後血腫13件(8.1%)，神経根障害10例(6.2%)，レベル誤認7件(4.3%)，馬尾障害3件(1.8%)，ドレーントラブルおよび関節突起骨折各2件(1.2%)，脊髄損傷，ケージ迷入，感染，大量出血，皮下漿液貯留，胸腔内血腫，歯牙損傷が各1件(0.6%)，従来法変更(硬膜損傷例を除く)8件(5.0%)であった．

術式別に見ると，腰椎後方ヘルニア摘出術および腰椎椎弓切除術・開窓術ともに硬膜損傷の頻度それぞれ

表3 術式別手術件数

	北海道	東北	関東	中部	近畿	中国・四国	九州・沖縄	合計
脊椎MED								
腰椎後方ヘルニア摘出術	210	393	716	684	924	512	503	3942
腰椎外側ヘルニア摘出術	16	14	22	31	29	23	29	164
腰椎椎弓切除・開窓術	68	79	303	293	429	223	271	1666
TLIF/PLIF	0	33	127	134	3	4	31	332
頚椎開窓術	0	21	4	11	17	13	13	79
頚椎椎弓形成術	1	3	0	7	26	10	5	52
嚢腫摘出術	0	0	5	2	4	2	0	13
その他(分離部除圧，椎間外狭窄，馬尾腫瘍など)	4	1	6	7	4	0	1	23
小計	**299**	**544**	**1183**	**1169**	**1436**	**787**	**853**	**6271**
胸腔鏡下								
生検・掻爬術	0	0	0	0	3	0	0	3
交感神経切除術	0	0	0	0	0	0	0	0
腫瘍摘出術	0	0	2	2	1	0	0	5
前方リリース	0	0	1	0	0	0	0	1
椎体固定術	0	0	6	4	4	1	1	16
矯正固定術	0	0	8	0	0	0	0	8
OPLL摘出術	0	0	0	3	0	0	0	3
その他	0	0	0	0	0	0	0	0
小計	**0**	**0**	**17**	**9**	**8**	**1**	**1**	**36**
腹腔鏡下								
生検・掻爬術	0	0	0	0	1	0	0	1
椎体固定術	0	0	0	1	0	0	0	1
その他	0	0	0	0	0	0	0	0
小計	**0**	**0**	**0**	**1**	**1**	**0**	**0**	**2**
後腹膜腔鏡下								
生検・掻爬術	0	0	0	0	0	0	0	0
腫瘍摘出術	0	0	0	0	0	0	0	0
前方リリース	0	0	0	0	0	0	0	0
椎体固定術	0	0	9	0	0	0	2	11
矯正固定術	0	0	0	0	0	0	0	0
OPLL摘出術	0	0	0	0	0	0	0	0
ヘルニア摘出術	0	0	0	0	0	0	0	0
その他	0	0	0	0	0	0	0	0
小計	**0**	**0**	**9**	**0**	**0**	**0**	**2**	**11**
経皮的進入								
PELD	13	0	106	4	0	3	0	126
その他	0	0	8	0	3	0	2	13
小計	**13**	**0**	**114**	**4**	**3**	**3**	**2**	**139**

表4　地区別インシデント件数

	北海道	東北	関東	中部	近畿	中国・四国	九州・沖縄	合計
2005	3	8	13	9	20	5	8	66
2006	4	10	32	19	39	10	10	124
2007	5	14	25	24	40	13	12	133
2008	**5**	**10**	**21**	**35**	**46**	**20**	**24**	**161**
前年比	1	0.71	0.84	1.46	1.15	1.54	2	1.21

表5　地区別インシデント発生頻度

	北海道	東北	関東	中部	近畿	中国・四国	九州・沖縄	合計
2005	0.91	1.33	1.27	1.94	1.79	1.37	2.54	1.57
2006	1.65	2.13	2.51	3.63	3.68	2.17	1.72	2.69
2007	2.1	2.01	1.59	2.61	2.4	2.21	2.15	2.13
2008	**1.6**	**1.84**	**1.59**	**2.96**	**3.18**	**2.53**	**2.8**	**2.49**
前年比	0.76	0.92	1	1.13	1.33	1.14	1.3	1.17

表6　術式別インシデント件数

	件数	発生率(%)
腰椎後方ヘルニア摘出術	82	2
腰椎椎弓切除術・開窓術	57	3.22
TLIF/PLIF	16	4.81
頚椎後方除圧術	1	0.76
経皮的内視鏡下ヘルニア摘出術	1	0.79
胸腔鏡下手術	2	5.56
経皮的椎体掻爬	1	・
分離部除圧	1	・
	161	2.49

61件，36件と最も高かった．全体のインシデント発生率は前者が2.0%，後者が3.42%で，後者で明らかに高かった．

インシデントレベル別に見ると，レベル1が9件，レベル2が23件，レベル3aが93件，レベル3bが28件，レベル4が7件で，不明1例でレベル5はなかった．レベル3b以上の発生は腰椎後方ヘルニア摘出術で13件(0.32%)，腰椎椎弓切除術・開窓術17件(1.02%)で，後者でより高頻度であった．

7. インシデントに対する対応

インシデント別に対応法について検討した．複数の対応が行われた症例もあったので重複を許して集計した．硬膜損傷への対応はフィブリン糊使用51例，従来法への変更29例，硬膜縫合31例，脂肪移植3例，再手術(硬膜縫合)1例，バイクリルメッシュ移植4例であった．術後血腫には10例に血腫除去，リハビリテーション，ベッド上安静が各1例に行われた．神経根障害に対しては再手術，リハビリテーション，短下肢装具が各1例に行われ，その他は経過観察が行われた．馬尾障害に対してはステロイド投与，open conversion，リハビリテーション，再手術が各1例に行われた．高位誤認に対しては5例が術中修正され，内視鏡下手術が続行されたが，2例は後日再手術が行われた．関節突起骨折は経過観察のみが行われた．

感染には前方掻爬固定術，大量出血はopen conversionおよび止血，胸腔内血腫は再手術・止血，皮下漿液貯留は掻爬・再縫合が各1例に行われた．脊髄損傷は経過観察が行われた．

ま と め

2008年の1年間では過去の調査に比べると，脊椎内視鏡下手術の施行施設および手術件数とも全国的にみると増加をしており，同手術が本邦に広く普及しつつある現状がわかる．ただ，施設は前年比1.03，件数は1.04と伸びは微増にとどまっており，過去に比べると増加がやや頭打ちになっている．地区別では北海道，中部，中国・四国九州・沖縄地区で手術件数が増加していた．