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Clinical study

Regenos spacers are not suitable for open-door laminoplasty because of serious adverse events caused by their insufficient mechanical strength

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ABSTRACT

We used a newly developed, high-porosity unidirectional porous hydroxyapatite spacer (Regenos spacer, not approved by the FDA). The aim of the present study was to elucidate the effectiveness of Regenos laminar spacers for open-door type laminoplasty. The present study included 39 patients who underwent open-door type laminoplasty with Regenos spacers from April 2015 to December 2016 and were followed up for at least 6 months after surgery. We grafted 68 Regenos spacers in 39 patients. Pre- and postoperative neurological status of patients were evaluated using JOA score and recovery rate. Breakage of Regenos spacers, laminar closure, and bone-hydroxyapatite spacer bonding were assessed using 12-month postoperative sagittal and axial CT images.

The average preoperative JOA score was 9.5 ± 3.2/17, and the average postoperative JOA score was 12.5 ± 2.9/17. JOA score recovery rate was 34 ± 41% at the latest follow-up visit. The bony fusion rate of the hinge sides was 87%. Breakage and deformity of implanted spacers was observed in 69% of patients and 59% of spacers with a CT sagittal view, and CT axial view at 12 months revealed fine cracks and collapse in 17 spacers in 14 patients. The average angle was −2.4 ± 4.8°, including 46 of 68 spacers showing a negative value, resulting in a rate of laminar reclosure of 35%.

Postoperative CT demonstrated good bone bonding rate. Nevertheless, clinical results with low recovery rates were obtained with complications related to the use of Regenos spacers.

1. Introduction

Various types of laminoplasty have been reported. In general, laminoplasty can be divided into two main categories according to the surgical procedures to open the laminae: open-door and double-door. In open-door procedures, various techniques have been reported to prevent laminar closure, which is one of the major postoperative complications specific to open-door laminoplasty. Strut grafting using autologous bone from spinous processes is a widely accepted procedure to avoid laminar closure. At our institute, we employ open-door laminoplasty with strut grafting using resected spinous process (Tsuji-Itoh) [1].

However, it has been reported that preservation of the C7 spinous process and insertion of a nuchal ligament can suppress postoperative axial symptoms. Therefore, the C7 spinous process, which is large enough to be used as strut graft, is preserved in most patients who undergo laminoplasty. Where a C6 spinous process is not sufficiently large for a strut graft, some substitution is needed. Therefore, a hydroxyapatite spacer is used as a substitute for the spinous process as a strut graft for open-door type laminoplasty.

Various kinds of hydroxyapatite spacers have been used for open-door type laminoplasty [2–4]. Exploration for an optimal biomaterial suitable for lamina spacer is ongoing, because a criterion standard has not yet been established.

We used a newly developed, high-porosity unidirectional porous hydroxyapatite spacer (Regenos, Kuraray, Tokyo, Japan, medical device approval number: 22100BZX00818000, not approved by the FDA) with expectation of high bone conductive potential and

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biomechanical strength, both of which are essential for a lamina spacer for open-door type laminoplasty [5,6].

The aim of the present study was to elucidate the effectiveness of Regenos laminar spacers for open-door type laminoplasty.

2. Methods

2.1. Patients

The present study included 39 patients who underwent open-door type laminoplasty with Regenos spacers from April 2015 to December 2016 and were followed up for at least 6 months after surgery. We grafted 68 Regenos spacers in 39 patients. The demographic data of the present series of patients are shown in Table 1. Our study was approved by the appropriate ethics review board for all institutions.

2.2. Surgery

We adopted a method described by Itoh and Tsuji for en bloc laminoplasty. In the present study, we used a Regenos spacer with a modified shape (Fig. 1(A)), for open-door type laminoplasty. Non-absorbable sutures, passed through the suture port at the center of the spacer, were used to anchor the spacer to the elevated vertebral arches and lateral masses. The size of the spacer was determined intraoperatively according to a trial for the spacer. The hinge side was also grafted using bone harvested from a spinous process (Fig. 1B).

2.3. Outcome measures

2.3.1. Clinical evaluation

Pre- and postoperative (at final follow-up visit) neurological status of patients were evaluated using the Japanese Orthopedic Association score for cervical myelopathy (JOA score) and recovery rate of this score was assessed according to the following formula: Recovery rate = (postoperative JOA score − preoperative JOA score)/(17 − preoperative JOA score) × 100 (%) [7].

2.3.2. Radiological evaluations

Computed tomography (CT) obtained preoperatively and an average 1 year after surgery were evaluated (Fig. 2).

Table 1
Basal characteristics of 39 patients who underwent open-door laminoplasty using Regenos spacers.

Patient demographics (N = 39)	
Age (years)	66.7 (47–82)
Male: female	29:10
Diagnosis	
Cervical spondylotic myelopathy	24
Ossification of posterior longitudinal ligament	10
Atlantoaxial subluxation	1
Dialysis-associated spondylosis	1
Spinal tumor	1
Spinal cord injury	1
Cervical spondylotic amyotrophy	1
Method of cervical surgery	
Open-door laminoplasty (LP)	30
LP with foraminotomy	4
LP with occipitocervical spinal posterior fusion	3
LP with spinal cord tumor resection	1
LP with anterior cervical discectomy and fusion	1
Number of Regenos spacers	
2 spacers per patient	29
1 spacer per patient	10

Breakage of hydroxyapatite spacers: Deformity and/or breakage of Regenos spacers was assessed using axial and sagittal CT multiplanar reconstructed images (2 mm interval reconstruction slices passing through the spacer in both axial and sagittal images).

Laminar closure in the axial plane: Laminar closure was assessed using axial CT with multiplanar reconstruction. In an axial image passing through the center of the spacer (total length of thread hole was seen), the angle between the elevated lamina and posterior wall of the vertebral body was measured 1–2 weeks after surgery and 1 year after surgery and was defined as angle α [8]; angle $\Delta\alpha$ was defined as the subtraction of angle α 1 week after surgery from that 1 year after surgery.

Bone-hydroxyapatite spacer bonding: Bony fusion between the implanted Regenos spacers and the host lateral mass and/or elevated laminae was assessed by visible continuity in at least one CT axial image at 2 mm interval serial slices. Bony fusion on the hinge side was also assessed in the same CT axial images.

3. Results

3.1. Clinical outcomes

The average preoperative JOA score was 9.5 ± 3.2/17 (one case was excluded because of spinal cord injury). Gross neurological improvement was observed; the average postoperative JOA score was 12.5 ± 2.9/17. JOA score recovery rate was a mean (SD) 34 ± 41% at the latest follow-up visit.

3.2. Radiological results

Imaging revealed that the bony fusion rate of the hinge sides was 87% (59/68 spacers). The mean bone bonding rates between the hydroxyapatite spacer and lamina at 12 months postoperatively were 54% (37/68 spacers), and 56% (38/68 spacers) between the HA spacer and the lateral mass. In 23 of 66 spacers, bone ingrowth into the Regenos spacer was also observed. Some cases in which lamina remodeling was achieved by osseous crosslinking have also been found.

Breakage and deformity of implanted spacers was observed in 69% (27/39) of patients and 59% (40/68) of spacers with a CT sagittal view, and CT axial view at 12 months revealed fine cracks and collapse in 17 spacers (25%) in 14 patients. We found 12 spacers had breakages at the inner wall of the spacer inside the suture port, 3 spacers had peripheral compression, and 2 spacers were split in two at the suture port. Absorption of these spacers had not occurred 1 year postoperatively.

The average Δangle α was −2.4 ± 4.8°, including 46 of 68 spacers showing a negative value of Δangle α, resulting in a rate of laminar reclosure (lamina reclosure was considered to be present when enlarged laminae approximated with Δangle α <−5°) of 35%. In particular, 12 of 17 spacers with cracks and collapse were found with laminar reclosure.

3.3. Representative case

A 41-year-old man underwent laminoplasty using a Regenos laminar spacer for progressive cervical myelopathy and had a preoperative JOA score of 13 points. The initial surgery was performed uneventfully. After surgery, his neurological condition remained at the same level. However, 2 months after the initial surgery, he experienced progression of numbness and muscle weakness bilaterally in his upper extremities and presented spastic gait without any inducement, in which JOA score dropped to 10 points. CT revealed lamina reclosure narrower than the presurgical level and breakage of the spacers implanted at C4 and C6 (Fig. 3). We

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