Although conventional laminectomy is the standard posterior decompressive procedure for treating lumbar spinal stenosis (LSS), it involves intraoperative damage, such as extensive detachment of the multifidus muscle from the spinous process bilaterally, resulting in postoperative back muscle induration associated with fat infiltration in the paravertebral muscles and removal of the posterior supporting structures of the lumbar spine, including the spinous process and interspinous ligaments.11 Removal of the posterior elements as well as excessive facetectomy can cause spinal instability following posterior decompressive surgery.9,10 Therefore, a minimally invasive decompressive surgery should be used in the treatment of LSS to preserve the paravertebral muscles and posterior supporting structures, including the facet joint, as much as possible.

Since 2005, we have performed microscopic lumbar spinous process–splitting laminectomy (LSPSL), in which the spinous process is split longitudinally into 2 halves, without detaching the paravertebral muscles from the process. In single-level decompression, a tubular retractor from the METRx microdiscectomy system (Medtronic Sofamor Danek Co., Ltd.) is inserted between the split process.
the halved spinous process via a small incision. Since the halved process is reconstructed after decompression, most of the posterior supporting structures can be preserved in microscopic LSPSL.

Here, we report the clinical outcome of microscopic LSPSL, focusing on symptomatic improvement, occurrence of postoperative spinal instability, rate of bony union of the reconstructed spinous process, and postoperative signal change of the multifidus muscle on MRI.

Methods

Patient Population

Between July 2005 and October 2010, 147 patients with LSS underwent LSPSL at Hiroshima Red Cross Hospital & Atomic-Bomb Survivors Hospital; of these, 124 patients (73 men, 51 women) whose individual follow-up period was greater than 12 months were assessed for the present study (follow-up rate 84%). The surgeries were performed for patients with symptoms of intermittent claudication of the cauda equina (n = 86) or radiculopathy (n = 38). We excluded patients with LSS associated with only low-back pain (LBP) or spondylolisthesis-type LSS associated with severe LBP caused by dynamic movement of the lumbar spine, apparent spinal instability, or a degree of slippage higher than Meyerding Grade II in the sagittal plane on flexion radiographs. In the study population, the mean age (± SD) at the time of surgery was 71 ± 9.5 years (range 30–93 years), the overall mean follow-up period was 31 ± 15 months (range 12–65 months), and the mean number of decompressed levels was 1.5 ± 0.6 (1 level in 67 patients; 2 levels in 52 patients; and 3 levels in 5 patients). In terms of clinical symptoms, all patients were divided into 2 groups: 1) those with intermittent claudication (n = 86) and 2) those with radiculopathy (n = 38). In terms of radiographic classification, all patients were divided into 2 groups: 1) the “slip” group (n = 51), comprising patients with spondylolisthesis-type LSS with vertebral body slippage, and 2) the “nonslip” group (n = 73), comprising patients with spondylosis-type LSS without vertebral body slippage or with LSS due to central protrusion of lumbar disc herniation. In this study, a slipped vertebral body was defined as radiographic evidence that a superior vertebral body at a surgical level had slipped anteriorly over 2 mm to an inferior vertebral body in the neutral position in the sagittal plane. The latest postoperative radiograph was obtained 30 ± 16 months (range 12–65 months) after surgery.

Surgical Procedure

Referring to a lateral view of the lumbar spine on an image intensifier, the surgeon inserted 6 cm of a K-wire into the spinal process of the patient, who was placed in the prone position to measure the cutting length of the process. After making a 20-mm skin incision, the tip of the process was marked where the K-wire was exposed. After removing the K-wire, a caudal part of the process was cut longitudinally into the base using a 12-mm-wide straight chisel and then a 15-mm-wide straight chisel in the same cutting line. Then, the base was cut using a curved chisel. While maintaining attachment to the rostral part of the process, the caudal part was opened in a V shape using a Cobb elevator. For single-level decompression, an 18-mm-diameter tubular retractor from the METRx microdiscectomy system was inserted between the halved process (Figs. 1–3A). In the decompressive procedure, the laminectomy was started from the caudal edge of the basal portion of the spinous process and rostral lamina using a high-speed air drill and straight Kerrison rongeur under a microscope to expose the whole dorsal aspect of the ligamentum flavum beneath the rostral lamina. For lateral decompression, trumpet laminectomy was performed using a curved Kerrison rongeur to preserve the facet joints, when possible. With a slight angling of the retractor to the caudal side, the rostral edge of the caudal lamina was exposed using a sharp curette and removed using a curved Kerrison rongeur to detach the ligamentum flavum, which was then removed circumferentially. With a slight angling of the retractor to the lateral side, the lateral recess decompressed minimally, protecting the spinal nerve root by using a nerve root retractor under direct microscopic visualization, until the nerve root was adequately loosened (Fig. 4A and B). In cases requiring more than a 2-level decompression, a cervical retractor (Trimline, Medtronic Sofamor Danek Co., Ltd.) was used to open the caudal parts of the individual halved spinous processes through a single incision (Fig. 4C). After completing the decompressive procedure, the process was reconstructed using nonabsorbable sutures (SurgiOn, Covidien), as described below. First, 2 nonabsorbable sutures were placed individually along each halved process, from the outside to the inside, using Deschamps ligature needles (Fig. 3B). After the inside of the sutures was tied, either side of the tied suture was pulled up to knot the suture outside of the halved process (Fig. 3C). Then, a surgical drain was placed between the halved process using a microscope to confirm the accuracy of its placement. Finally, the suture was tied to close the spinous process.
Microscopic lumbar spinous process–splitting laminectomy

(Fig. 3D). All patients were allowed to walk the day after surgery without a brace; 2 days after surgery, the drain was removed.

Clinical Assessment

Clinical improvement in neurological symptoms was evaluated using the Japanese Orthopaedic Association (JOA) scale, which has possible values ranging from −6 to 29. Concomitant LBP was evaluated using particular items from the JOA scale referring to symptomatic assessment of LBP (LBP-JOA score), which has possible values ranging from 0 to 9.

Measurement of Spinal Instability After LSPSL

In the slip group (51 patients, 56 decompression levels), the slippage rate was calculated by using radiographic findings in the sagittal plane with the patient in the neutral position as follows: slip distance (a)/length of lower vertebral body (b) x 100 (Fig. 5A). The spinal instability rate was calculated on the basis of radiographic findings in the sagittal plane in 3 positions (neutral, trunk extension, and trunk flexion) as follows. First, slippage distance in each of the 3 positions was measured. Then, maximal (a-max) and minimal (a-min) distances were chosen individually. Finally, the instability rate was calculated using the following equation: (a-max – a-min)/length of upper vertebral body x 100 (Fig. 5B–D). This process followed the method reported by White and Panjabi.21 Slippage and instability rates were determined both preoperatively and latest postoperatively.

Bony Union of the Split Spinous Process

Sixty-eight patients (103 decompression levels) underwent postoperative CT to evaluate bony union of the split process. Postoperative axial and sagittal CT images were used to evaluate bony union at 2 sites: the region between the left and right portions of the halved process (Fig. 6 left) and the region between the base of the halved process and the vertebral arch (Fig. 6 right).

MRI Signal Change of the Multifidus Muscle After LSPSL

Eighty-one patients (123 decompression levels) underwent postoperative T1- and T2-weighted MRI so that signal change of the multifidus muscle at individual decompression levels could be compared to preoperative MRI findings. Scores were assigned as follows: 0, same signal intensity; 1+, slight increase; 2+, moderate increase; or 3+, strong increase of signal intensity of the multifidus muscle after surgery on T2-weighted images compared with preoperative findings.

Statistical Analysis

Differences between the 2 groups were analyzed using the Mann-Whitney U-test. Statistical analysis was

Fig. 2. Intraoperative photograph showing the tubular retractor mounted on the surgical table.

Fig. 3. Schematic demonstration of the LSPSL using a tubular retractor for single-level decompression (A) and reconstruction of the split spinous process (B–D). The tubular retractor is inserted between the halved spinous process (A). After decompression was completed, 2 nonabsorbable sutures are placed separately along each half of the split process, from the outside to the inside (B). After the sutures within the spinous process are tied, either side of the tied suture is pulled up to knot the suture outside of the split process (C). Finally, the suture is tied to close the processes (D). Copyright Hiroshi Nomura. Published with permission.
performed using Sigma Plot 10.0 and Sigma Stat 3.5 for Windows (Microsoft Corp.). Mean values are presented ± SDs.

**Results**

The mean operating time in all patients was 187 ± 68 minutes, while the mean operating time for single-level decompression was 124 minutes. The mean operating times for patients who underwent surgery in the first and second half of the study period (first half, from July 2005 to October 2007; second half, from November 2007 to October 2010) were 183.8 ± 74.7 minutes and 190.6 ± 62.3 minutes, respectively. There was no significant difference in the operating time between the first and latter half of the study period (p = 0.486). The mean estimated blood loss in each patient was 90 ± 94 ml, while the mean estimated blood loss in patients who underwent a single-level decompression was 59.3 ml. With regard to major medical complications, there was 1 case of postoperative methicillin-resistant *Staphylococcus aureus* infection in a 93-year-old man, who was treated using surgical drainage and linezolid and whose infection was thereafter completely cured. In 2 cases, minor spinal fluid leakage occurred. In the first case, leakage resulted from an intraoperative dura mater injury during separation of the hypertrophic ligamentum flavum from the dura mater. This was treated by stitching the injured dura mater with a 7-0 nylon suture (Nescosuture; Alfresa Pharma Corporation) after we replaced the tubular retractor with the Trimline cervical retractor and after rostral extension of the skin incision by 1.5 cm to create a wider operative field for microsuturing; finally, a fibrin sealant (Beriplast P; CSL Behring) was applied. In the second case, although intraoperative spinal fluid leakage was not observed, postoperative leakage occurred and continued for 5 days and then spontaneously resolved without any additional treatment. There was no reoperation either for recurrence of LSS or for spinal instability at the decompressed level after LSPSL.

The mean JOA scores of all patients improved significantly, from 15.1 ± 4.9 before surgery to 24.4 ± 4 at the final follow-up (p < 0.001). The mean postoperative JOA scores of patients who underwent surgery in the first and second half of the study period were 23.8 ± 4.1 and 25.0 ± 3.9, respectively; there was no significant difference between groups (p = 0.07). The mean JOA scores

![Image](https://via.placeholder.com/150)

**Fig. 4.** Intraoperative photographs showing the LSPSL in which a tubular retractor is used for a single-level decompression (A and B) and 2-level decompression at the L3–4 and L4–5 (C). The dorsal dural tube is well expanded after circumferential decompression (A). The decompressed nerve root (arrow) is retracted medially, using a nerve root retractor to confirm adequate loosening (B). The halved L-3 and L-4 spinous processes are opened using muscle hooks and a cervical retractor, respectively, after circumferential decompression to confirm adequate expansion of the dural tube at the L3–4 and L4–5 (asterisk in C) level.

![Image](https://via.placeholder.com/150)

**Fig. 5.** Diagrams showing slippage (A) and instability (B–D) rates in the slip group. A: The slippage rate was calculated by using radiographic findings in the sagittal plane in the neutral position as follows: slip distance (a)/length of lower vertebral body (b) ×100. B–D: The instability rate was calculated by using radiographic findings in the sagittal plane in 3 positions (neutral, trunk extension, and trunk flexion) as follows: First, slip distance in each of the 3 positions was measured (a1, a2, and a3). Then, the maximal (a-max) and minimal (a-min) distances were chosen individually from a1, a2, and a3 and were used in the following formula: (a-max – a-min)/length of upper vertebral body (c) ×100.
in the intermittent claudication and radiculopathy groups improved significantly, from 14.9 ± 4.7 and 15.8 ± 5.1 before surgery to 24 ± 4.4 and 25.6 ± 2.6 at the final follow-up, respectively (each p < 0.001). Furthermore, the mean JOA scores in the nonslip and slip groups improved significantly, from 15 ± 5.1 and 15.2 ± 4.5 before surgery to 24.7 ± 3.9 and 24 ± 4.2 at the final follow-up, respectively (each p < 0.001). There was no significant difference in preoperative mean JOA scores between the intermittent claudication and radiculopathy groups (p < 0.254) or in preoperative LBP-JOA scores between the nonslip and slip groups (p < 0.743).

According to postoperative JOA scores, all patients were further divided into 2 groups: 1) those with an excellent outcome, comprising patients with scores above 20 (n = 110; 66 men, 44 women; 73 with intermittent claudication, 37 with radiculopathy) and 2) those with a fair outcome, comprising patients with scores below 20 (n = 14; 7 men, 7 women; 13 intermittent claudication, 1 radiculopathy). These 2 groups were compared according to age at the time of surgery, number of levels decompressed, operating time, and preoperative and postoperative JOA and LBP-JOA scores. The age at the time of surgery, number of levels decompressed, and operating time in the excellent and fair groups were 70.6 ± 11.6 years and 74.1 ± 11.6 years, 1.5 ± 0.6 levels and 1.6 ± 0.5 levels, and 210 ± 72.4 minutes and 210 ± 72.4 minutes, respectively. There was no significant difference in any parameter between the 2 groups (p = 0.10, 0.22, and 0.18, respectively). In the excellent-outcome and fair-outcome groups, preoperative JOA/LBP-JOA scores were 15.5 ± 4.9/6.5 ± 2.0 and 11.8 ± 3.5/4.5 ± 1.3, respectively. There were significant differences in preoperative JOA and LBP-JOA scores between the groups (p = 0.002 and p < 0.001, respectively). In addition, postoperative JOA and LBP-JOA scores in the excellent-outcome (25.5 ± 2.5 and 8.1 ± 0.9) and fair-outcome (15.6 ± 2.7 and 5.9 ± 1.9) groups, respectively, were significantly different (each p < 0.001).

In the slip group, there was no significant difference in the vertebral body slippage rate between preoperative (14.9% ± 6.6%) and postoperative (15.4% ± 7.0%) conditions (p = 0.721; Table 1). In addition, there was no significant difference in the instability rate between preoperative (5.8% ± 3.7%) and postoperative (5.7% ± 3.6%) conditions (p = 0.684).

The rate of bony union at a region between the left and right portions of the halved process was 97.1% (101 of 104) (Fig. 6 left, Table 2), while the rate at a region between the base of the halved process and vertebral arch was 82.7% (86 of 104) (Fig. 6 right). The union rates in the nonslip and slip groups were 87% (60 of 69) and 74.3% (26 of 35), respectively. In the group of patients with no floating of the spinous process (that is, the base of the halved process and vertebral arch were united) (n = 52) and in the group of patients with floating of the spinous process (n = 16), the LBP-JOA scores at the final follow-up were 8.1 ± 1.0 and 7.6 ± 1.2, respectively; there was no significant difference in the LBP-JOA scores between these groups (p = 0.076). The union rates at the region

**TABLE 1: Vertebral body slippage and instability rates between preoperative and postoperative conditions in the slip group**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>slip rate</td>
<td>14.9 ± 6.6</td>
</tr>
<tr>
<td>instability rate</td>
<td>5.8 ± 3.7</td>
</tr>
</tbody>
</table>

* Rates are presented as the mean ± SD.

Fig. 6. Schematic demonstration of the region between the left and right portions of the split process (arrow, left) and the region between the base of the halved process and vertebral arch (arrows, right) for evaluation of bony union on CT scans. Copyright Hiroshi Nomura. Published with permission.

Fig. 7. Axial (left) and sagittal (right) CT scans obtained 33 months after an LSPSL was performed to decompress the L3–4 and L4–5 levels in a 73-year-old patient with L4 spondylolisthesis. Bony union in the region between the left and right portions of the halved process was noted (arrow, left). Bony union in the region between the base of the halved process and vertebral arch was demonstrated at the L3 process but not the L4 process owing to slippage of the L4 vertebra (arrow, right).
between the left and right portions of the halved process in patients who underwent surgery in the first and second half of the study period were 94.3% (50 of 53) and 100% (0 of 51), and the rates at the region between the base of the halved process and the vertebral arch were 81.1% (43 of 53) and 84.3% (43 of 51), respectively.

Postoperative T2-weighted MRI showed no signal intensity change (score of 0) in the multifidus muscle compared with preoperative findings at 106 (86.2%) of 123 decompression levels (Table 3, Fig. 8). We found a slight increase in signal intensity (score of 1+) in 17 (13.8%) of 123 decompression levels. No moderate (score of 2+) or strong (score of 3+) increase was detected. Of the 17 cases in which the signal increase was slight, 15 also demonstrated a slight signal increase on T1-weighted images at the corresponding area of the multifidus muscle. In other words, both T1- and T2-weighted images showed a slight increase in signal intensity of the multifidus muscle after surgery in 12.2% of the total cases, implicating a small amount of fat infiltration. In the 2 cases (1.6%) in which there was a slight signal increase on T2-weighted images alone, an insignificant edematous change of the multifidus muscle was implicated.

**TABLE 2: Bony union rates at different regions**

<table>
<thead>
<tr>
<th>Group</th>
<th>Lt &amp; Rt*</th>
<th>Base &amp; Arch†</th>
</tr>
</thead>
<tbody>
<tr>
<td>overall cases</td>
<td>97.1</td>
<td>82.7</td>
</tr>
<tr>
<td>nonslip group</td>
<td>97.1</td>
<td>87.0</td>
</tr>
<tr>
<td>slip group</td>
<td>97.1</td>
<td>74.3</td>
</tr>
</tbody>
</table>

* Refers to the region between the left and right portions of the halved process.
† Refers to the region between the base of the halved process and the vertebral arch.

Postoperative T2-weighted MRI showed no signal intensity change (score of 0) in the multifidus muscle compared with preoperative findings at 106 (86.2%) of 123 decompression levels (Table 3, Fig. 8). We found a slight increase in signal intensity (score of 1+) in 17 (13.8%) of 123 decompression levels. No moderate (score of 2+) or strong (score of 3+) increase was detected. Of the 17 cases in which the signal increase was slight, 15 also demonstrated a slight signal increase on T1-weighted images at the corresponding area of the multifidus muscle. In other words, both T1- and T2-weighted images showed a slight increase in signal intensity of the multifidus muscle after surgery in 12.2% of the total cases, implicating a small amount of fat infiltration. In the 2 cases in which there was a slight signal increase on T2-weighted images alone, an insignificant edematous change of the multifidus muscle was implicated. There were no significant differences in preoperative or postoperative LBP-JOA scores between patients with no signal intensity change (6.1 ± 2.1 and 7.7 ± 1.4, respectively) and those with 1+ or 2+ signal intensity change (6.6 ± 1.9 and 8.4 ± 0.63, respectively).

**Discussion**

Lumbar spinal stenosis is a pathological condition in which the lumbar spinal canal narrows and encompasses the dural tube and cauda equina roots due to degenerative changes in the lumbar spine. Surgical decompression is indicated for patients with LSS who do not respond to conservative treatment. To avoid excessive surgical invasion, clinicians have recently developed various minimally invasive laminectomies to treat LSS. Among these techniques, one of the most promising is bilateral decompression via a unilateral approach in which a microscope/microendoscope and a tubular retractor from the METRx microdiscectomy system are used. This procedure is advantageous because it preserves the spinous process and interspinous ligaments; however, bilateral decompression with unilateral fenestration may possibly require excessive removal of the facet joint on the approach side to obtain a wide operative field. Recently, Hatta and colleagues reported on a new minimally invasive procedure for treating LSS, lumbar muscle-preserving interlaminar decompression (MILD). The basic concept of MILD is similar to that of LSPSL, but the caudal portion of the upper spinous process and the rostral portion of the lower spinous process have to be removed in MILD. Because the midline approach in LSPSL provides symmetrical surgical visualization of the lateral recesses, preserving the posterior structures, postoperative spinal instability due to excessive facetectomy can be avoided.
Lumbar spinous process–splitting laminectomy was first reported by Watanabe and colleagues in 2005; we modified this procedure by using a tubular retractor to achieve a more minimally invasive decompressive surgery. For single-level decompression, handling of the tubular retractor is not a problem; a wide operative view can be obtained with a slight angling of the retractor because the basal portion of the spinous process is cut completely. In addition, the combination of the tubular retractor and microscope enables minimally invasive fenestration within 2 cm of the small incision, even in obese patients.

Spinal instability after lumbar laminectomy has been reported frequently as a major complication of posterior decompressive surgery in cases of LSS. Several previous reports have shown that lumbar laminectomy for LSS, particularly spondylolisthesis-type LSS, significantly worsens slippage of the anteriorly slipped vertebral body after surgery. Conversely, it has also been reported that lumbar laminectomy, with preservation of the structural integrity of the pars interarticularis and articular processes, avoids postoperative vertebral slippage. Similarly, in the present study, LSPSL did not accelerate postoperative slippage or instability of the slipped vertebral body in the slip group. We suggest that most of the concomitant LBP in this study was caused by LSS and not by instability of the slipped vertebral body because there was no significant difference in preoperative LBP-JOA scores between the nonslip and slip groups and also because postoperative LBP-JOA scores in both groups were equally improved after the decompressive procedure. We chose decompression and transfornaminal interbody fusion with spinal instrumentation in cases of spondylolisthesis-type LSS in which the degree of slippage exceeded a Meyerding Grade II.

In the current study, the rate of bony union of the split spinous process at the region between the left and right portions of the halved process after LSPSL was extremely high. On the other hand, the union rate at the region between the base of the halved process and the vertebral arch was approximately 83%, which suggests floating, or nonunion, of the spinous process in 17% of the cases after LSPSL. Interestingly, spinous process floating tended to occur more often in the slip group (spondylolisthesis-type LSS with vertebral body slippage) than in the nonslip group. We suggest that spinous process floating was caused by short longitudinal cutting of the process, which creates some space between the split process and vertebral arch, or by an interspinous ligament attached to the lower spinous process pulling the split process backward, especially in patients in the slip group. We emphasize that accurate longitudinal cutting to the basal portion of the spinous process is the most important step in LSPSL. However, there was no direct evidence showing that spinous process floating was not associated with unfavorable clinical results as assessed by JOA or LBP-JOA scoring.

Lumbar decompressive surgery can cause neurogenic muscular atrophy and fat infiltration of the back muscle, especially in association with the application of muscle retractors during surgery. To estimate postoperative back muscle atrophy, several clinicians have performed quantitative analysis of a cross-sectional area of the paravertebral muscles on pre- and postoperative T2-weighted axial MR images. We, however, employed semiquantitative analysis using T1- and T2-weighted axial MR images to assess fat infiltration or edematous change in the multifidus muscle, reflecting even minor muscular degeneration, especially after minimally invasive surgery. Compared with the tubular retractor, the cervical retractor tends to cause increased muscle degeneration because the cervical retractor stretches the back muscle with more compressive force than does the tubular retractor. However, we found that both retractors offered equal protection to the multifidus muscle, and except for a small amount of fat infiltration in the multifidus muscle in some cases, degeneration of the paravertebral muscles was not apparent after LSPSL. We speculate that indirect compressive force, by applying the cervical retractor between the halved spinous process, is likely harmful to the back muscle. Furthermore, application of the retractor without detaching the multifidus muscle from the spinous process contributes to muscular protection. For more than 2-level decompression, we used the cervical retractor and a single skin incision, but we did not use the tubular retractor and multiple skin incisions because the space between individual incisions was too short to make multiple unconnected small incisions. Moreover, because a skin incision within 2 cm is sufficient to support and stabilize the tubular retractor during surgery, we did not use this device at individual surgical levels when we made a single skin incision longer than 2 cm in cases of multiple-level decompressions.

We found no obvious learning curve in LSPSL, because operating time, postoperative JOA scores, and the tendency for bony union of the split spinous process remained constant between the first and latter half of the study period. According to postoperative JOA scores, age at the time of surgery, number of decompression levels, and operating time did not affect the clinical results, and severity of the preoperative symptomatic condition, particularly in the cases of intermittent claudication, was likely more relevant to clinical improvement. Although there was no comparative assessment with another procedure such as conventional laminectomy in this study, our findings support the use of LSPSL as a more minimally invasive surgery based on not only the excellent clinical and radiographic results but also the relatively easy acquisition of the surgical technique.

Conclusions

We found that LSPSL led to significant clinical improvement in patients with LSS. Postoperative spinal instability did not occur, the rate of bony union of the split spinous process was high, and the multifidus muscle remained intact after LSPSL. Therefore, we recommend LSPSL as a promising minimally invasive decompressive surgery for the treatment of LSS.

Disclosure

The authors report no conflicts of interest concerning the materials or methods used in this study or the findings specified in this paper.
Author contributions to the study and manuscript preparation include the following: Conception and design: Nomura. Acquisition of data: Nomura. Analysis and interpretation of data: Nomura. Drafting the article: Nomura. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Nomura. Study supervision: Oga.

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