

# The Essence of Clinical Practice Guidelines for Lumbar Spinal Stenosis, 2021: 4. Surgical Treatment

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## Surgical Treatment of Lumbar Spinal Stenosis

### Summary

- Surgical procedures should be selected with patient consent based on comprehensive evaluations, including short-term and long-term clinical outcomes, risk of complications, and cost-effectiveness. Surgical treatment is indicated when conservative treatments are less effective or severe neurological symptoms in the cauda equina, such as bladder and bowel dysfunction, are noted.
- Several reports have indicated that decompression for lumbar spinal stenosis (LSS) produces better clinical outcomes than conservative treatment. It is suggested to perform decompression for patients with LSS without spinal segmental instability diagnosed by physical findings and imaging, in whom conservative treatment is ineffective.
- While decompression with fusion is useful for patients with spinal instability and the improvement of Quality of Life (QOL)/Activities of Daily Living (ADL) is expected, the cost is higher than that of decompression alone, and the return-to-work rate is slightly poorer. The rates of complications and reoperation are also higher than those of decompression alone. So, fully considering pathological conditions and surgical proce-

dures to examine indications is necessary, such as instability and the need for long-segment fusion.

- The bone union state may affect clinical outcomes, but a clear recommendation cannot currently be presented.
- It is suggested to use local bone and to combine the use of artificial bone, demineralized bone matrix, and allogenic bone as the bone graft material for spinal fusion.
- A clear recommendation cannot be made as to whether surgical treatment using Interspinous Process Devices (IPDs) or dynamic stabilization using pedicle screws is more useful than conservative treatment, decompression, or fusion surgery for LSS.
- For patients with LSS, minimally invasive spine surgery may be more useful for preventing the occurrence of iatrogenic instability, alleviating low back pain, and reducing the bleeding volume than conventional surgery, and it is suggested to perform it.
- Even in the very elderly aged  $\geq 80$  years (octagenarian and over), surgical treatment for LSS improves their clinical symptoms.

### Commentary

#### *Comparison between surgical treatment and conservative treatment*

Two systematic reviews that compared surgical treatment with conservative treatment were adopted. In a meta-analysis that extracted five RCTs, the Oswestry Disability Index (ODI) revealed no significant differences at either 6- or 12-month follow-up but was significantly improved by 24 months postoperatively in the surgical treatment group that

underwent decompression surgery compared with that in the conservative treatment group<sup>1</sup>). In the other systematic review of nine RCTs that included 1,658 patients, a meta-analysis indicated the rate of complications after the therapeutic intervention was 0%-24% and was slightly higher in the surgical group throughout follow-up from 3 months to 6 years<sup>2</sup>). However, no significant differences were found between the groups within 72 h after intervention. The ODI revealed no significant differences in clinical outcomes at 3- or 6-month follow-up. The surgical treatment group had superior results one and two years after the surgical intervention than the conservative treatment group. It can be concluded that although the difference between the surgical and conservative treatment groups was small for approximately six months, the outcomes of the surgical treatment group were better than those of the conservative treatment group after two years.

#### *Surgical complications (adverse events)*

There was no significant difference in complication rate between the surgical and nonsurgical groups. Adverse events during or after therapeutic intervention were found in 12.1% of patients in the decompression group and 8.5% in those with epidural steroid injection<sup>3</sup>). Another study reported adverse events in 33 of 74 patients (44.6%) who were followed for two years after surgery. However, this study included reoperations due to wound healing failure and surgical site infections, so a simple comparison is inappropriate<sup>4</sup>). An analysis that combined RCTs and observational cohort studies reported a 9% incidence of the dural tear and a reoperation rate of 8% in the surgical group two years postoperatively<sup>5</sup>). A simple comparison between studies is impossible because there is a considerable difference in the incidences and definitions of adverse events in surgery. However, most studies have concluded that it is necessary to include information about complications when explaining surgical treatment to patients as a treatment option. No specific adverse event has been reported in the conservative treatment group, but it is necessary to consider the relatively high crossover to surgery due to symptom exacerbation. Surgical treatment is considered more effective for patients with severe symptoms or for whom conservative treatment is less effective. Thus it is necessary to reevaluate the appropriateness of conservative treatment that may be less effective.

#### *Medical economic effects*

In a comparison of the medical costs of 170 patients in the surgical group and 264 patients in the conservative treatment group, including CT-guided block, physiotherapy, and medication<sup>6</sup>), the average treatment cost was slightly higher in the conservative treatment group than that in the simple decompression surgery group. This could be due to a certain percentage of patients in the conservative treatment group required multiple sessions of block therapy, and 191 patients (72.4%) who were initially treated conservatively underwent surgery subsequently. The cost for the group that improved

following a single injection was low initially, whereas the cost for the group that required multiple injections was higher than that for group with a single injection.

#### *Comparison between decompression with fusion and decompression alone*

There was no significant difference between the decompression with fusion group and the decompression alone group in terms of SF-36 score, ODI, low back and leg pain, and reoperation rate over approximately two years. Thus, the analgesic effect of the combination with fusion leads to better clinical outcomes than decompression alone<sup>7-11</sup>) remains inconclusive. Meanwhile, bleeding volume was significantly greater and operative time was significantly longer in the fusion combination group<sup>12-16</sup>). Thus, it is important to thoroughly consider the necessity of the combination with fusion. Additionally, in patients with lumbar spinal stenosis (LSS) without spondylolisthesis, the postoperative outcomes tended to be poor even after fusion in cases with dominant low back pain before surgery<sup>17</sup>). Based on a retrospective cohort study of the work rehabilitation of 364 workers who had taken leave and undergone surgery due to low back pain, a comparison of surgical treatment outcomes between decompression alone or with fusion for LSS without deformity or instability showed that the decompression alone group returned to work within two years after surgery and worked for a minimum of 6 months. Conversely, combination with fusion was significantly more costly and was associated with a lower return-to-work rate<sup>18</sup>), thereby suggesting the possibility that fusion should not be combined for patients without deformity or instability. Meanwhile, the combination with fusion may be useful when instability, such as isthmic/degenerative spondylolisthesis, is involved. In a meta-analysis conducted using extracted papers, while the combination with fusion was useful for low back pain, no significant difference was found regarding leg pain with or without fusion<sup>19</sup>). Thus, the combined use of fusion may alleviate pain and improve Activities of Daily Living (ADL) in patients with low back/leg pain associated with instability. However, when leg pain is dominant, fusion is not necessarily recommended. Compared with decompression, adverse events associated with fusion are also an important element. Up to 25% of patients who had undergone fusion underwent reoperation within five years due to progressive adjacent segment disease. However, multiple prospective randomized database analyses reported that the reoperation rate within five years after surgery with or without fusion was approximately 14%. This could be linked to risk factors leading to reoperation, including preoperative symptoms for 12 months. Thus, the important factors for deciding whether reoperation is required after surgery may include the presence or absence of fusion and adjacent segment disease, the course of the pathological conditions, and the associated degenerative findings<sup>15,20-22</sup>).

### *Comparison between natural course/conservative treatment and decompression alone*

Evidence comparing fusion with a complete natural course without any conservative treatment was not extracted from the literature. However, five papers compared conservative treatment and decompression with fusion (two were Cochrane reviews). Papers dealing with conservative treatment included pharmacotherapy, epidural injection, orthosis therapy, and shiatsu therapy, but there was no comparison using unified criteria. Taken together, although no significant differences were observed in the ODI, Zurich Claudication Questionnaire, or Visual Analogue Scale (VAS) scores between the group that underwent surgical treatment (with or without the combination with fusion) and the conservative treatment group at 6- or 12-month follow-up, significant improvement was observed in the surgical group 24 months after surgery. Surgical treatment was more effective than conservative treatment for alleviating neurological symptoms, such as intermittent claudication with instability or stenosis<sup>1,23-25</sup>.

### *Effects of postoperative long-term bone nonunion on surgical outcomes*

A persistent state of long-term postoperative bone nonunion (pseudarthrosis) has been reported to worsen the surgical outcomes of posterolateral fusion (PLF) without spinal instrumentation. In a report of 47 patients with a mean postoperative follow-up of 7 years and 8 months, 25 patients (53%) with pseudarthrosis assessed by plain X-ray had poorer clinical outcomes in the four-level comprehensive clinical evaluation and poorer VAS scores on low back and leg pain than the bone union group<sup>26</sup>. In another report of 42 patients with a mean postoperative follow-up of 9.5 years, clinical outcomes of 11 patients (26%) with pseudarthrosis assessed by plain X-ray showed no difference compared to the bone union group up to three years after surgery. However, significantly less improvement in the JOA score was observed five years or more after surgery<sup>27</sup>. There is no report on the relationship between long-term bone union and clinical outcomes in patients who received fusion surgery with spinal instrumentation.

### *Comparison of bone graft materials used for fusion surgery*

In a retrospective case series of patients who underwent single-level posterior lumbar interbody fusion (PLIF), the use of autologous iliac graft or local bone graft did not result in differences in the bone union rate (96.3% for autologous iliac bone and 98.3% for local bone) two years postoperatively<sup>28</sup>. Another study evaluated fusion rate after PLF with unilateral autologous iliac bone grafting on one side and local autograft bone with bone marrow aspirate to the opposite side one year postoperatively. Bone fusion rates were equivalent essentially, with 90.5% for the side with autologous iliac bone and 85.7% for the side with local bone and bone marrow aspirate<sup>29</sup>.

When PLF was performed with artificial bone alone, the bone union rate was lower than that with autologous bone grafting alone. The fusion rate with the combination of bone marrow aspirate and artificial bone (cylindrical calcium sulfate) was also significantly lower (45.5%) than the fusion rate (90.5%) on the side with autologous iliac bone graft<sup>29</sup>. Meanwhile, bone union was equivalent to autologous bone grafting when an artificial bone was used as the bone extender in combination with local bone and bone marrow aspirate. In an RCT in which PLF was performed with autologous bone grafting or local bone + artificial bone (b-TCP) grafting, bone union was confirmed in all cases in both groups one year after surgery<sup>30</sup>. In a study in which single-level PLF was performed comparing unilateral local bone grafting with the grafting of porous b-TCP in combination with bone marrow aspirate to the contralateral side, the fusion rate was higher with local bone grafting six months after surgery. Still, no difference was found two years after surgery<sup>31</sup>. In a prospective RCT comparing three groups of PLF with bilateral autologous iliac bone, autologous iliac bone/contralateral HA grafting, and bilateral contralateral HA grafting, bone union was confirmed in all cases one year after surgery<sup>32</sup>.

In a prospective RCT, PLF was performed with unilateral autologous iliac bone grafting and contralateral autologous bone + DBM grafting. The bone union rates two years after surgery were equivalent, with 54% for the side with autologous iliac bone grafting and 52% for the side with DBM grafting<sup>33</sup>. Additionally, in a multicenter RCT of PLF that compared the local bone + DBM combination group with autologous iliac bone grafting + DBM in combination with facet joint fusion, bone union rates two years after surgery were equivalent, with 86% for the DBM group and 92% for the autologous iliac bone group<sup>34</sup>. In another case series using DBM, the group with bilateral autologous bone (iliac bone + local bone) grafting for PLF and the group with bilateral autologous bone + DBM + bone marrow aspirate grafting were compared one year after surgery; no difference was found in the bone union rates<sup>35</sup>.

Autologous iliac or allogenic bone was grafted into the lumbar interbody fusion cage in patients treated with single-level PLIF. The bone union rate was determined up to one year after surgery using X-ray and CT. The bone union rate was significantly higher in the autologous iliac bone group 6 months after surgery, but no difference was found between the groups subsequently one year after surgery<sup>36</sup>. Additionally, although there was no comparison with autologous bone, in an RCT wherein PLF was performed with allogenic bone alone or allogenic bone + bone marrow aspirate, the combination of bone marrow aspirate significantly increased the bone union rate two years after surgery (40% for allogenic bone alone; 80% for allogenic bone + bone marrow aspirate)<sup>37</sup>.

### *Stabilization surgery using Interspinous Process Devices (IPDs) or pedicle screws*

Whether surgical treatment using IPDs is more useful than conservative treatment for LSS remains unclear, because no high-quality evidence showing complication rates and the sustainability of effects has been presented.

A meta-analysis showed no significant differences in low back pain, dysfunction, or complication rates between PIDs and decompression<sup>19</sup>. Conversely, the reoperation rate with IPDs was more than twice that of the decompression group. A systematic review and meta-analysis conducted in 2018 concluded that indications for using IPDs should be determined with care because they are associated with higher reoperation rates and are less cost-effective, with little evidence that their use leads to pain and functional improvements equivalent to those of decompression surgery<sup>38</sup>.

### *Comparison between minimally invasive spine surgery and conventional surgery*

We defined conventional surgery as total laminectomy for decompression and open surgery for fusion and defined minimally invasive surgery (MIS) as any surgery other than these. Two meta-analyses<sup>39,40</sup> and three systematic reviews<sup>41-43</sup> reported reduced slippage progression (a sign of postoperative instability; reported in three papers), reduction of reoperation (additional fusion surgery; two papers), shortening of operative time (two papers), reduction of bleeding volume (two papers), shortening of hospitalization period (two papers), and alleviation of postoperative low back pain (one paper). However, the evidence level was considered extremely low as most of the articles were retrospective studies, and the definition of MIS differed remarkably. Meanwhile, a new meta-analysis revealed that blood loss was lower and X-ray exposure dose (fluoroscopy time) was higher for MIS fusion than for open fusion<sup>19</sup>.

The level of evidence regarding the usefulness of MIS is low, and this technique is hardly useful in the current scenario. In the future, high-quality RCTs with uniformity in procedure, equipment, and comparison cohorts are required to obtain evidence. Also, there were no differences in most outcomes between conventional and minimally invasive spine surgery. The major issue is the lack of an established definition for minimally invasive spine surgery.

### *Effectiveness of surgical treatment for LSS in the octogenarian and over*

Nine papers compared the surgical outcomes of patients aged  $\geq 80$  years, with patients  $< 80$  as the controls<sup>44,52</sup>. The main surgical procedure was decompression alone, but two studies included fusion<sup>45,50</sup>. Through JOA score and recovery rate evaluation, many studies reported improvements in the group with their age  $\geq 80$  years equivalent to the younger cohort<sup>44,48,49,52</sup>. Meanwhile, one study concluded that the recovery rate of the JOA score was poorer in the group  $\geq 80$  years old<sup>50</sup>. No study has compared outcomes of decompression

and fusion with a high level of evidence. A meta-analysis of six papers revealed more postoperative complications in the octogenarian and over group than in the younger group<sup>19</sup>, even after excluding postoperative delirium. In the older group, surgery (mainly decompression) for LSS resulted in good clinical outcomes and is considered a useful treatment method. However, it should be performed cautiously because of perioperative and postoperative complications<sup>44,50,52-62</sup>.

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