



Cost-effectiveness of corrective fusion surgeries for adult spinal deformities: a comparison by operative method

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- Title: Cost-effectiveness of corrective fusion surgeries for adult spinal deformities: a comparison by
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## 1 Key points

2	٠	The average medical expenses for the initial surgery were USD 72,240, and the total medical expenses
3		over the 2 years after the initial surgery were USD 76,294 on average.
4	•	Regarding total medical expenses over the 2-year period, the 3-column osteotomy group and the lateral
<b>5</b>		lumbar interbody fusion (LLIF) group had higher costs than the multiple Grade-2 osteotomy group.
6	•	The cumulative improvement in quality-adjusted life years (QALY) over the 2 years was 0.16 on average
7		(0.13 for the multiple Grade-2 osteotomy group, 0.15 for the 3-column osteotomy group, and 0.18 for the
8		LLIF group).
9	•	Cost/QALY 2 years after surgery was USD 492,276 on average (USD 509,370 for the multiple Grade-2
10		osteotomy group, USD 518,406 for the 3-column osteotomy group, and USD 463,798 for the LLIF
11		group).
12		

### Cost-effectiveness of ASD surgery

## 1 Mini abstract

- 2 We summarized the cost-effectiveness of surgical treatment for adult spinal deformity by operative method over
- 3 2 years post-surgery. Cost/ QALY 2 years after surgery was USD 492,276 on average (USD 509,370 for the
- 4 multiple Grade-2 osteotomy, USD 518,406 for the 3-column osteotomy, and USD 463,798 for the LLIF group).

 $\mathbf{5}$ 

#### **1** Structured abstract

2 *Study design*: Retrospective cohort study.

3 *Objective*: To summarize the cost-effectiveness of surgical treatment for adult spinal deformity (ASD) according
4 to the operative method over 2 years postoperatively.

5 Summary of background data: Extensive corrective fusion surgery for ASD requires numerous expensive 6 implants, greatly contributing toward the national medical expenses. Previous national studies reported high 7 complication rates in spinal surgeries using instrumentation. However, the cost-effectiveness of such procedures 8 has not been scrutinized.

9 Methods: In total, 173 ASD patients (151 women; mean age 69.1 years) who underwent corrective fusion 10 between 2010 and 2017 were included. Cost-effectiveness was evaluated according to the cost of obtaining 1 11 quality-adjusted life year (QALY). Patients were divided into three groups, the "corrective fusion surgery using 12 multiple Grade 2 osteotomy" (Grade-2) group, 3-column osteotomy group (3-column), and lateral lumbar 13 interbody fusion (LLIF) group.

*Results*: The average medical cost for the initial surgery was USD 72,240, and that during the 2 years after the initial surgery was USD 76,294. The medical expenses for the initial surgery and those over the 2 years were higher in the LLIF group. The cumulative improvement in QALY over the 2 years did not significantly differ among the groups (0.13, 0.15, and 0.18 in the Grade-2, 3-column, and LLIF groups, respectively). Cost/QALY 2 years after the surgery was USD 509,370, 518,406, and 463,798 in the Grade-2, 3-column, and LLIF groups, respectively.

20 Conclusion: We summarized the medical costs and cost-effectiveness of three different surgical methods for 21 ASD in patients with different backgrounds over 2 years postoperatively. The medical expense for the initial 22 surgery was highest in the LLIF group, and the cumulative improvement in QALY over the 2 years tended to be 23 higher in the LLIF group, but the difference was not significant; the overall cost-effectiveness was lowest in the 24 LLIF group.

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- 26

### Cost-effectiveness of ASD surgery

- 1 **KEYWORDS:** adult spinal deformity, cost effectiveness, Incremental cost-effectiveness ratio, Quality-adjusted
- 2 life year, corrective fusion surgery, Grade II osteotomy, 3-column osteotomy, lateral lumbar interbody fusion,
- 3 medical expense, spinal instrumentation
- 4 Level of evidence: 3

#### **1** INTRODUCTION

 $\mathbf{2}$ Adult spinal deformity (ASD) is a general term for spinal deformities in adult patients, and includes various 3 pathological conditions such as remnants of idiopathic scoliosis, de novo kyphoscoliosis associated with disc degeneration, kyphosis after vertebral body fracture, and iatrogenic kyphosis after spinal fusion.<sup>1,2</sup> ENREF 2 4  $\mathbf{5}$ Symptoms associated with ASD include gait disorder, back pain, leg pain, visceral disorders, and psychological 6 disorders.<sup>1,3-5</sup> Conservative treatments for moderate to severe ASD have poor efficacy and surgical treatment is 7 required to improve health-related quality of life (HROOL) and gait disturbance.<sup>6,7</sup> ENREF 6 It has been 8 reported that surgical treatment improves HROOL compared to conservative treatments.<sup>8</sup> The surgical treatment 9 for ASD often requires posterior spinal fusion from the thoracic spine to the pelvis.<sup>9</sup> This extensive posterior 10 corrective fusion for ASD can be expected to have a therapeutic effect, but the financial burden is large as many 11 expensive implants are used. Previous national surveys also reported a high incidence of complications in spinal 12surgeries using spinal instrumentation.<sup>10</sup> Therefore, it is important to clarify the cost-effectiveness of the a high-13cost extensive corrective fusion surgeries for ASD. In recent years, it has been reported that ASD surgical 14treatments are more cost effective than conservative treatments at 4 and 5 years after the surgery.<sup>11</sup> For surgical 15treatment of ASD, there is a method of corrective fusion using multiple Grade 2 osteotomy or 3-column osteotomy (Grade 4 or 5) depending on the pathological condition<sup>12</sup>. The usefulness of staged surgeries using 16 17lateral lumbar interbody fusion (LLIF) has also been reported.<sup>13</sup> The cost-effectiveness of each procedure has 18 not yet been scrutinized. In this study, we summarized the cost-effectiveness of surgical treatment for ASD by 19 operative method over 2 years post-surgery.

20

#### 21 MATERIALS AND METHODS

22 Patient population

This study was reviewed and approved by our Institutional Review Board and adhered to the principles of the
Declaration of Helsinki. We obtained written informed consent from all participants. In this study, patients
were diagnosed with ASD if they were 50 years old or older with the confirmed presence of at least 1 of the

1	following: coronal scoliosis with Cobb angle $\geq 20^{\circ}$ , sagittal vertical axis (SVA) $\geq 5$ cm, pelvic tilt (PT) $\geq 25^{\circ}$ , or
2	thoracic kyphosis (TK) $\geq$ 60°. The cohort included patients with ASD who underwent extensive corrective
3	fixation surgeries between 2010 and 2017 at a single institution. To be included in our cohort, patients had to
4	have received posterior instrumented fusion from the thoracic spine to the pelvis and have available full-length
<b>5</b>	standing radiographs and HRQOL data collected before and 2 years after the surgery. Cases of spinal
6	deformities associated with infection, malignancy, and neuromuscular disease were excluded from the study.
7	Patients with incomplete outcome data were excluded. Data on the following patient characteristics were
8	extracted: age, sex, body mass index (BMI) (kg/m <sup>2</sup> ), Charlson Comorbidity Index (CCI) <sup>14</sup> , and American
9	Society of Anesthesiologists (ASA) classification. The pathology of patients was investigated. Patients were
10	divided into the following 3 groups and summarized: the corrective fusion surgery using multiple Grade 2
11	osteotomy (Grade-2), 3-column osteotomy group (3-column), or lateral lumbar interbody fusion (LLIF) group.
12	Surgery data
13	Regarding surgery data, the number of fused vertebrae, the upper instrumented vertebrae (UIV) level, the
14	number of pedicle screws, screw density, presence or absence of iliac screws, whether surgery was performed
$14\\15$	number of pedicle screws, screw density, presence or absence of iliac screws, whether surgery was performed in 2 stages, total surgery time, total intraoperative blood loss, length of hospital stay, perioperative
14 15 16	number of pedicle screws, screw density, presence or absence of iliac screws, whether surgery was performed in 2 stages, total surgery time, total intraoperative blood loss, length of hospital stay, perioperative complications (surgical complications, neurological complications, and medical complications), and revision
14 15 16 17	number of pedicle screws, screw density, presence or absence of iliac screws, whether surgery was performed in 2 stages, total surgery time, total intraoperative blood loss, length of hospital stay, perioperative complications (surgical complications, neurological complications, and medical complications), and revision surgery within 2 years of the initial surgery were investigated. Screw density was defined as the number of
14 15 16 17 18	number of pedicle screws, screw density, presence or absence of iliac screws, whether surgery was performed in 2 stages, total surgery time, total intraoperative blood loss, length of hospital stay, perioperative complications (surgical complications, neurological complications, and medical complications), and revision surgery within 2 years of the initial surgery were investigated. Screw density was defined as the number of implanted pedicle screws per vertebrae. <sup>15</sup>
14 15 16 17 18 19	number of pedicle screws, screw density, presence or absence of iliac screws, whether surgery was performed in 2 stages, total surgery time, total intraoperative blood loss, length of hospital stay, perioperative complications (surgical complications, neurological complications, and medical complications), and revision surgery within 2 years of the initial surgery were investigated. Screw density was defined as the number of implanted pedicle screws per vertebrae. <sup>15</sup> <b>Surgical procedures</b>
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> </ol>	number of pedicle screws, screw density, presence or absence of iliac screws, whether surgery was performed in 2 stages, total surgery time, total intraoperative blood loss, length of hospital stay, perioperative complications (surgical complications, neurological complications, and medical complications), and revision surgery within 2 years of the initial surgery were investigated. Screw density was defined as the number of implanted pedicle screws per vertebrae. <sup>15</sup> <b>Surgical procedures</b> In the Grade-2 group, dissociation, screw placement, correction, and interbody fusion were performed using
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> </ol>	number of pedicle screws, screw density, presence or absence of iliac screws, whether surgery was performed in 2 stages, total surgery time, total intraoperative blood loss, length of hospital stay, perioperative complications (surgical complications, neurological complications, and medical complications), and revision surgery within 2 years of the initial surgery were investigated. Screw density was defined as the number of implanted pedicle screws per vertebrae. <sup>15</sup> <b>Surgical procedures</b> In the Grade-2 group, dissociation, screw placement, correction, and interbody fusion were performed using the posterior approach in one or two stages. Patients who had a rigid kyphosis or wedge-shaped vertebra

23 vertebral body of the apex of the kyphosis deformity or the lower vertebral body if the apex of the kyphosis

24 deformity was located at disk level. Screw placement, dissociation with 3-column osteotomy under the local

25 temporary rod, correction, and interbody fusion were performed using the posterior approach in one or two

stage.<sup>16</sup> In the LLIF group, we performed LLIF via the lateral approach in 2 to 4 intervertebral discs. Large

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cages were inserted to correct and stabilize the intervertebral bodies. In the second stage, posterior corrective
 1
 \mathbf{2}
       fusion with posterior interbody fusion at L5/S1 was performed.
 3
       Data collection of medical expenses
 4
       All inpatient medical costs for ASD, including laboratory admissions for ASD surgery, were extracted from the
 \mathbf{5}
       medical fee data. We also investigated the cost of hospitalization for revision surgery up to 2 years after the
 6
       initial surgery. Total medical expenses included surgery costs, hospitalization costs, examination costs, and
 7
       others such as physical therapy or medical management fees. Surgical costs included all costs during surgery,
 8
       including anesthesia management fees and the implants used. The examination costs included examination
 9
       charges including blood sampling, X-ray, CT, and MRI. Hospital costs include perioperative centralized
10
       management costs, costs for pharmaceutical treatments, meal costs, and room costs. Costs not included in
11
       these items included physical therapy costs, medical management fees, wound treatment fees, and private room
12
       difference costs. The total cost of hospitalization for any separate hospital admission for an examination prior
13
       to surgery was included in the examination cost.
14
       Radiographic measurements
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15Full-length freestanding posteroanterior and lateral spine radiographs obtained before and 2 years after surgery 16were analyzed. Board-certified spine surgeons used standard techniques to measure spinopelvic parameters, 17including: TK (Cobb angle between the superior endplate of T-5 and inferior endplate of T-12), lumbar lordosis 18 (LL) (Cobb angle between the superior endplate of L-1 and superior endplate of S-1), PT (angle subtended by 19a vertical reference line originating from the center of the femoral head and the midpoint of the sacral 20endplate), mismatch between pelvic incidence (PI) (angle between the line perpendicular to the sacral plate at 21its midpoint and the line connecting this point to the femoral head axis), and SVA (C-7 plumb line relative to 22S-1).<sup>17,18</sup> The inter-observer correlation coefficient for TK, LL, PT, PI, SS, and SVA was 0.751, 0.736, 0.882, 230.744, 0.730, and 0.837, respectively.<sup>6</sup>

### 24 Patient-reported outcome measures (PROMs)

25 HRQOL data derived from the Scoliosis Research Society(SRS)-22r<sup>19,20</sup> and Oswestry Disability Index (ODI)

26 were evaluated. The SRS-22r is a scoliosis-specific HRQOL questionnaire with 22 items and 5 domains

1	including Function, Pain, Self-image, Mental Health, and Satisfaction. <sup>20</sup> The scale has been reported as
2	representative, reliable, and valid in populations with ASD. <sup>21-23</sup>
3	Cost-effectiveness analysis
4	Cost-effectiveness was determined using quality-adjusted life years (QALY). Cost/QALY was calculated by
5	dividing the total amount of hospitalized medical expenses for 2 years by the acquired QALY. The reference
6	willingness to pay threshold was assumed to be USD 50,000(JPY 5,000,000 ). <sup>24,25</sup> QALY was calculated by
7	converting ODI into a short form survey-6D (SF-6D) according to a previously published regression model. <sup>26</sup>
8	The average exchange rate between the US dollar and Japanese yen was $1 \text{ USD} = 100 \text{ JPY}$ .
9	Sub analysis
10	We compared complications, revision surgery rate, and cost effectiveness according to differences in the lower
11	instrumented vertebrae (LIV). In addition, since 3 groups represent different pathologies, we focused on
12	patients with degenerative kyphoscoliosis and compared the complication rate, revision surgery rate, QALY
13	improvement, and cost-effectiveness.
14	Statistical analyses
15	All values are expressed as mean ± standard deviation (SD). The Shapiro-Wilk test was used to verify the
16	assumption about normal distribution of the data. Chi-square/Fisher exact test was used to test for significant
17	differences in categorical study parameter between groups. The statistical significance of the differences
18	between groups were examined using a one-way ANOVA. Post hoc comparisons were made using the Tukey
19	test, and post-hoc power analysis was performed. A $p$ -value of <0.05 was considered to be statistically
20	significant. Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS)
$\begin{array}{c} 21 \\ 22 \end{array}$	software (version 26.0; SPSS, Chicago, IL, USA) and G*Power 3.1 (software freely available on the Internet).
23	RESULTS
24	Participant characteristics
25	Of the 311 patients aged 50 years or older who underwent corrective fusion surgery for ASD during the study

26 period, 220 met the inclusion criteria, of whom 173 (78.6% of eligible patients) could be followed up using

27 radiographs and HRQOL questionnaires for 2 years postoperatively (Figure 1). The patients' average age was

1	$69.1 \pm 7.3$ years (151 females). The cohort's average BMI was $22.8 \pm 3.6$ kg/m <sup>2</sup> . The pathology of patients
2	undergoing extensive corrective fusion surgery for ASD involved degenerative kyphoscoliosis in 94 cases,
3	degenerative kyphosis in 39 cases, kyphosis after vertebral fracture in 23 cases, iatrogenic kyphosis in 9 cases,
4	and adult scoliosis in 8 cases (Table 1). There were 54 cases in the Grade-2 group, 54 cases in the 3-column
5	group, and 65 cases in the LLIF group. There was no significant difference in age, sex, BMI, CCI, or ASA
6	classification between the 3 groups. The LLIF group had significantly more degenerative kyphoscoliosis and
7	3-column group had significantly more degenerative kyphosis, kyphosis after vertebral fracture, and
8	iatrogenic kyphosis.
9	Surgical details and outcomes
10	Surgical details are described in Table 2. The mean number of fused vertebrae was $9.8 \pm 1.2$ . The mean
11	number of pedicle screws was $20.9 \pm 3.4$ , and the mean screw density was $2.1 \pm 0.3$ . In the lower instrumented
12	vertebra, 94% of all cases used iliac screws. Seventy-two cases (42%) underwent staged surgery. Overall
13	complications occurred in 55 cases (32%), including surgical complications in 13 cases (8%), neurological
14	complications in 15 cases (9%), and medical complications in 36 cases (21%). Revision surgeries were
15	performed a total of 32 times in a total of 29 ASD patients (17%). There were 16 cases of rod fracture, 4 of
16	proximal junctional failure (PJF), 3 of distal junctional failure (DJF), 3 of implant-related disorders, 4 of
17	hematomas, 1 of malalignment, and 1 of infection. There were no significant differences between the 3 groups
18	with regard to the number of fused vertebrae, UIV level, length of hospital stay, or overall perioperative
19	complication rate. Compared with the other 2 groups, the LLIF group had a significantly higher rate of staged
20	surgeries and greater surgery time, but less intraoperative blood loss. The revision surgery rate was
21	significantly higher in the 3-column group.
22	Radiographic parameters
23	The mean postoperative LL, PT, PI minus LL, SVA, coronal cobb significantly improved from 10.7° to 42.4°,
24	35.7° to 25.5°, 40.9° to 11.0°, 116.3 mm to 57.2 mm, and 29.1° to 9.3°, respectively (all p<0.001) (Table 3).
25	Preoperative PI-LL and SVA were significantly worse in the 3-column group. Even 2 years after surgery, PI-LL

26 and SVA were worse in the 3-column group compared with the LLIF group.

#### **1 PROMs parameters**

 $\mathbf{2}$ Values of all SRS-22r domains significantly improved 2 years after surgery (all p<0.001) (Table 4). 3 Preoperatively, SRS-22r pain was worse in the Grade-2 group than in the other two groups, but there was no 4 significant difference in other parameters between the 3 groups. Postoperatively, SRS-22r pain was significantly  $\mathbf{5}$ worse in the Grade-2 group than that in the LLIF group, but there was no significant difference in other 6 parameters between the 3 groups. The cumulative improvement in QALY over the two years was 0.16 on average, 7 0.13 for the Grade-2 group, 0.15 for the 3-column group, and 0.18 for the LLIF group, with no significant 8 difference between the 3 groups. Post-hoc power analysis calculated power (1-βerror probability) as 0.83 when 9 the effect size was 0.25, and the  $\alpha$ -error probability was 0.05, showing a sufficient power. 10 Medical expense and cost effectiveness for ASD surgery 11 The average medical expenses for the initial surgery were USD 72,240 and the average total medical expenses

12over the 2 years after the initial surgery were USD 76,294 (Table 5). Medical expenses for the initial surgery 13were significantly higher in the LLIF group. The average surgical cost was USD 58,541 (81% of the total cost) 14and the average medical expenses for revision surgeries were USD 21,917 per hospitalization. Regarding the 15total medical expenses over the 2 years after the initial surgery, the 3-column group and the LLIF group had 16higher costs than the Grade-2 group. The cost/QALY 2 years after surgery was USD 492,276 on average (USD 17509,370 for the Grade-2 group, USD 518,406 for the 3-column group, and USD 463,798 for the LLIF group). 18 Comparison of complications, revision surgery rate, and cost effectiveness according to the different 19LIV

20 The group with only S1 screw as LIV (S1 group) and the group with S1 screw and iliac screw as LIV (Iliac

21 group) were compared (Supplementary table 1). Overall perioperative complications did not occur in the S1

22 group but occurred in 55 cases (34%) in the iliac group at a significantly higher rate (p=0.018). Three patients

23 (27%) in the S1 group and 26 patients (16%) in the iliac group required revision surgery; however, there was

24 no statistically significant difference (p=0.335). The iliac group had higher total medical expenses than the S1

- group (p=0.015). The cost/QALY of surgery after 2 years was USD 1,141,234 for the S1 group and USD
- 26 476,876 for the iliac group.

## 1 Comparison of complications, revision surgery rate, and cost effectiveness of different surgical

### 2 procedures for degenerative kyphoscoliosis

3 There were no significant differences between the 3 groups in the overall perioperative complication rate

4 (Supplementary table 2). The revision surgery rate was significantly higher in the 3-column group (40%). The

5 3-column and LLIF groups had higher total medical expenses over the 2 years after the initial surgery than the

6 Grade-2 group. The cost/QALY of surgery after 2 years was USD 524,899 for the Grade-2 group, USD

7 611,253 for the 3-column group, and USD 442,888 for the LLIF group.

8

#### 9 **DISCUSSION**

10 A thorough understanding of treatment costs is important in an evidence-based treatment approach. In recent 11 years, value, defined as quality of care compared to cost, has become an increasingly important factor in 12healthcare debates.<sup>26,27</sup> In our study, we summarized the medical costs and cost-effectiveness of three different 13surgical methods for ASD in patients with different backgrounds over 2 years postoperatively. The strength of 14this study is the mid-term outcome of 2 years postoperatively, but the follow-up rate is high at 78.6%; the follow-15up assessment was based on a complete whole spine standing radiographs and HRQOL questionnaires. The 16clinical outcome significantly improved postoperatively in the Grade-2, 3-column, and posterior corrective 17fusion with LLIF groups. The 2-year cumulative QALY improvement tended to be higher in the LLIF group, 18although the difference was not significant. The highest medical expenses for the initial surgery were noted in 19the LLIF group. Over the 2-year period, higher costs were noted in the 3-column and LLIF groups than in the 20Grade-2 group. The overall cost/QALY 2 years after surgery was lowest in the LLIF group, although no statistical 21comparison was performed (USD 509,370, 518,406, and 463,798 in the Grade-2, 3-column, and LLIF groups, 22respectively). The reference willingness to pay threshold was assumed to be USD 50,000 (JPY 5,000,000).<sup>24,25</sup> 23The cost/QALY of surgery for ASD 2 years after the procedure was well above this threshold, averaging about 2410 times higher. This is consistent with previous reports that initial surgery for ASD could not be achieved 1-2 25years after surgery as the procedure results in high costs over the first 2 years, as shown in our analysis and other studies.<sup>11,28,29</sup> The majority of ASD care costs stem from medical expenses related to the initial surgery. 26

Compared to the medical expenses of surgery, hospitalization costs are less than 20%. In this study, 29% of patients underwent revision surgery, and as a result, the average medical expenses for the initial surgery were USD 72,240, and the average total medical expenses over the 2-year period were USD 76,294. This means that the overall average increase 2 years after surgery was USD 4,300 accounting for roughly 6% of the medical expenses for the initial surgery.

On the other hand, clinical outcomes improved postoperatively, and the improvement was maintained for up to
5 years.<sup>30</sup> Therefore, index surgery for ASD is reported to be cost-effective 4 to 5 years after the initial surgery.<sup>11</sup>
Importantly, in order for surgery for ASD to be cost-effective, it does not increase in cost after the initial surgery.
Revision surgeries are often due to rod fractures or PJF, and measures to reduce revision surgeries as much as
possible are necessary in the future.<sup>31,32</sup>

11 There was no significant difference in age, sex, BMI, or comorbidities between the surgical procedure groups, 12but the pathological conditions were significantly different. Between 2010 and 2014 in our institute, posterior 13corrective fusion with multiple Grade-2 osteotomy was performed in patients with scoliosis of the 14thoracolumbar/lumbar spine and poor global sagittal plane alignment.<sup>12</sup> This changed in 2014 and since, we 15have performed staged surgeries with multi-level LLIF and posterior corrective fusions.<sup>13</sup> In the posterior 16corrective fusion with multi-level LLIF, a large cage is used for lumbar kyphosis and scoliosis correction with 17an anterior approach. This enables correction and fusion for multilevel intervertebral spaces with a small 18 amount of bleeding and a comparatively short surgical time.<sup>33</sup> Therefore, the proportion of degenerative 19kyphoscoliosis is high in the Grade-2 and LLIF groups. Strategic changes over the study period for 20degenerative kyphoscoliosis in this study may be a potential bias. On the other hand, for patients with flexible 21or rigid kyphosis of the thoracolumbar/lumbar spine, we primarily perform a 3-column osteotomy.<sup>12</sup> Therefore, 22the rate of 3-column osteotomy is high in degenerative kyphosis, kyphosis after vertebral body fracture, and 23iatrogenic kyphosis. In 3-column osteotomy, perform a staged surgery to mitigate surgical complications according to age and ASA classification.<sup>34</sup> Regarding the determination of the UIV level, we have a policy to 2425fuse the upper thoracic spine beyond the apex of kyphosis of the thoracic spine for cases with large thoracic 26kyphosis. In other cases, we fuse up to the inferior thoracic spine such as T9 or T10. Although there was no

1 statistically significant difference regarding UIV level between the 3 groups, UIV tended to be cephalad in the  $\mathbf{2}$ 3-column osteotomy group. The total operation time was longer in the 3-column osteotomy and the LLIF 3 groups. In the 3-column osteotomy group, osteotomy of vertebral body was took a significant amount of time 4 and as such, the total operation time and intraoperative blood loss were increased. On the other hand, all  $\mathbf{5}$ patients in the LLIF group underwent staged surgeries, and although the total surgery time was long, the total 6 intraoperative blood loss was small. This is because there are less numbers that we perform interbody fusion 7from posterior approach. The length of hospital stay was significantly longer in the LLIF group, which had a 8 higher proportion of staged surgeries. Overall the complication rate did not vary between the 3 groups, but 9 there were more neurological complications in the LLIF group. This is due to cases in which the traction 10 symptoms of the femoral nerve on the approach side, due to the lateral approach, occurred transiently in the 11 LLIF group. Since it improved within 2-3 months after surgery, there was no revision surgery for the 12neurological deficit. However, it might have affected the cost of administered neuropathic pain medications. 13The revision surgery rate was higher in the 3-column osteotomy group, which was associated with rod 14breakage.<sup>35</sup> In this study, the revision surgery rate was examined within 2 years after surgery in all groups. 15Therefore, there is no difference in the follow-up period among the 3 groups. 16 Radiographic outcomes showed significant postoperative improvement in all groups. Comparing the 3 groups, 17the preoperative 3-column osteotomy group had the worst lumbar lordosis and the sagittal plane was shifted to 18 the anterior. Postoperatively, there was less lumbar lordosis in the 3-column osteotomy group compared with 19 the LLIF group, and the global sagittal plane alignment was still shifted to the anterior postoperatively. Although 20a direct comparison cannot be made because the pathological conditions differed between the 3 groups, a good 21correction was obtained in all 3 groups. The clinical outcomes were improvements in postoperative SRS-22r and 22ODI. Comparing the 3 groups, SRS-22r pain was worse in the Grade-2 group before and after the surgery than 23in the LLIF group. However, there was no statistically significant difference in surgical satisfaction between the 243 groups, and the therapeutic satisfaction was improved by selecting the proper surgical method according to the 25pathological ASD condition. In the clinical evaluation of ASD, ODI is often used because it is the 26simplest among PROMs. However, although ODI can assess QOL with a focus on pain and

dysfunction, it is difficult to assess dysfunction, pain, mental status, etc. separately. In this study,
ODI tended to be similar to the pain and function domain of SRS-22r, but did not match the
evaluation of self-image and mental health domain. Since the symptoms of ASD are diverse, it is
desirable to evaluate not only ODI but also SRS-22r during a clinical evaluation. Since SF-6D
used in this study is calculated from ODI only by a regression equation, this is one of the
limitations of this study, and SF-6D or EuroQol 5 Dimension,<sup>36</sup> which assess the general HRQOL,
should be measured directly.

8 We sub-analyzed the cost-effectiveness of each surgical procedure, focusing only on degenerative kyphoscoliosis. 9 The highest initial medical expenses were noted in the LLIF group. Moreover, the QALY improvement over the 10 2-year period was 0.13, 0.14, and 0.19 in the Grade-2, 3-column, and LLIF groups, respectively, (P=0.294), and 11 the lowest overall cost/QALY 2 years after surgery was noted in the LLIF group, although no statistical 12comparison was performed (USD 524,899, 611,253, and 442,888 in the Grade-2, 3-column, and LLIF groups, 13respectively). In addition, as a sub-analysis, we compared complications according to different LIVs, revision 14 surgery rates, and cost-effectiveness. Compared to the iliac group, the S1 group had a relatively high revision 15surgery rate and a low QALY improvement 2 years after the initial surgery. Therefore, the cost/QALY was higher 16than that of the iliac group. This is due to the high mechanical failure at the lumbosacral junction when S1 is selected as the LIV in the long corrective fusion for ASD,<sup>37</sup> and the mechanical failure at the lumbosacral junction 1718may be associated with poor QALY improvement in the S1 group.

19 This study had limitations. First, in this study, medical expense does not include outpatient costs. Most of the 20costs for surgical treatment of ASD are considered to be surgery-related hospitalization costs. However, the 21drawback of this study is that it does not include postoperative outpatient costs. In future, multicenter prospective 22studies should consider including postoperative outpatient consultation costs, pharmacy costs, and physiotherapy 23costs. Second, the cost of this study does not include indirect costs. The indirect costs include social loss due to 24the inability to work or do housework due to ASD. However, this study did not consider these factors due to the 25large uncertainty. Third, corrective fusion surgery for ASD has a high complication and revision surgery rate. 26Revision surgery due to mechanical failure occurs even beyond 2 years after surgery; therefore, conducting an 27evaluation 2 years after surgery may not be sufficient. Further investigations will focus on assessing longer

1 periods. Fourth, implant suppliers are not unified in this study. Differences between implant suppliers may have  $\mathbf{2}$ affected surgical outcomes in this study. However, the price of pedicle screws is standardized in Japan, and it 3 does not affect the medical cost. Fifth, this study was conducted in Japan, and the Japanese healthcare system is 4 entirely different from that of North America and Europe. In Japan, the universal insurance system is provided  $\mathbf{5}$ by the government and covers all citizens. Therefore, the results of this study may not be directly applicable in 6 other countries. Sixth, cost/QALY calculations cannot be calculated for patients with zero QALY improvement. 7Cost/QALY was calculated by dividing the total cost of all cases in each group by the sum of QALY improvement. 8 Therefore, it was not possible to compare groups using statistics on cost/QALY. The cost of zero QALY gain 9 signifies very poor cost-effectiveness. However, this group included elderly patients, and it is expected that the 10 OOL would gradually decline as part of the natural course of aging. Therefore, it would be necessary to compare 11 each surgery group with a conservative treatment group to calculate the actual cost effectiveness and determine 12whether a QALY gain of 0 is indeed poor in terms of cost-effectiveness. In the future, we will weigh surgical 13and conservative treatment groups to assess whether surgical interventions for adult spinal malformations are 14 truly cost-effective. Seventh, a sub-analysis focused on degenerative scoliosis was performed to match the 15background of the patients in the Grade-2, 3 column, and LLIF groups. However, the sub-analysis of 16 degenerative scoliosis did not completely match the patient backgrounds in the three groups, and their 17comparison may have involved bias.

#### 18 CONCLUSION

We summarized the medical costs and cost-effectiveness of three different surgical methods for ASD in patients with different backgrounds over 2 years postoperatively. The highest medical expense for the initial surgery was noted in the LLIF group. The cumulative improvement in QALY over the 2 years tended to be higher in the LLIF group, although the difference was not significant, and the lowest overall cost-effectiveness was noted in the LLIF group.

24

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## Cost-effectiveness of ASD surgery

- 1 Figure legend
- 2 Figure 1
- 3 A chart capturing participant flow through the study eligibility criteria

# Figure 1



Table 1 Demographic and clinical characteristics of patients undergoing extensive corrective fusion surgery for adult spinal deformit									
	Total	Grade 2 osteotomy (n=54)	3-column osteotomy (n=54)	LLIF (n=65)	P-value†	G2 vs. 3-c P-value‡	G2 vs. LLIF P-value§	3-c vs. LLIF P-value¶	
Number	173	54	54	65					
Age (years)	$69.1\pm7.3$	$69.3 \pm 7.3$	$68.6\pm7.0$	$69.4\pm7.5$	0.817	NS	NS	NS	
Female N (%)	151 (87)	47 (87)	47 (87)	57 (88)	0.992				
Body Mass Index (kg/m <sup>2</sup> )	$22.8\pm3.6$	$22.5\pm3.0$	$23.2 \pm 4.4$	$22.6\pm3.5$	0.584	NS	NS	NS	
Charlson Comorbidity Index	$0.4 \pm 0.8$	$0.5 \pm 1.0$	$0.4\pm0.6$	$0.4 \pm 0.8$	0.624	NS	NS	NS	
ASA classification N (%)									
Ι	24 (14)	6 (11)	6 (11)	12 (19)					
II	141(81)	45 (83)	45 (83)	51 (78)	0.692				
III	8 (5)	3 (6)	3 (6)	2 (3)					
Pathology N (%)									
Degenerative kyphoscoliosis	94 (54)	38 (70)	5 (9)	51 (79)					
Degenerative kyphosis	39 (23)	9 (17)	20 (37)	10 (15)					
Kyphosis after vertebral fracture	23 (13)	0 (0)	22 (41)	1 (2)	< 0.001				
Iatrogenic kyphosis	9 (5)	2 (4)	6 (11)	1 (2)					
Adult scoliosis	8 (5)	5 (9)	1 (2)	2 (3)					

Mean values are presented as mean  $\pm$  SD. †Comparison between groups.

<sup>‡</sup> Post hoc comparison between Grade 2 osteotomy and 3-column osteotomy. §Post hoc comparison between Grade 2 osteotomy and LLIF. ¶Post hoc comparison between 3-column osteotomy and LLIF. P < 0.05 was considered as significant. We defined scoliosis that started during teen years and progressed to adulthood as adult scoliosis. We defined kyphoscoliosis or kyphosis that developed during adulthood and that caused by the degeneration of spinal structures as adult degenerative kyphoscoliosis or degenerative kyphosis scoliosis. ASA, American Society of Anesthesiologists; G2, grade 2 osteotomy; LLIF, lateral lumbar interbody fusion; NS, not significant; 3-c, 3-cloumn osteotomy

Table 2 Surgical details									
		Grade 2	3-column			C2 110 2 0	G2 vs.	3-c vs.	
	Total	osteotomy	osteotomy	LLIF (n=65)	P value <sup>†</sup>	D2 VS. 5-C	LLIF	LLIF	
		(n=54)	(n=54)			I value <sub>‡</sub>	P value§	P value¶	
No. of fused vertebrae	$10.1\pm1.8$	$9.8\pm1.7$	$10.5\pm2.0$	$10.0\pm1.8$	0.133	NS	NS	NS	
UIV level N (%)									
T4	10 (6)	2 (4)	5 (9)	3 (5)					
Т5	9 (5)	3 (6)	2 (4)	4 (6)					
T6	3 (2)	0 (0)	1 (2)	2 (3)					
T7	5 (3)	1 (2)	4 (7)	0 (0)					
T8	16 (9)	5 (9)	8 (15)	3 (5)	0.070				
T9	35 (20)	11 (20)	10 (19)	14 (22)					
T10	88 (51)	26 (48)	23 (43)	39 (60)					
T11	6 (3)	5 (9)	1 (2)	0 (0)					
T12	1 (1)	1 (2)	0 (0)	0 (0)					
No. of pedicle screws	$20.9 \pm 3.4$	$20.3 \pm 2.7$	$20.3 \pm 3.7$	$21.8 \pm 3.4$	0.021	1.000	0.048	0.045	
Screw density	$2.1 \pm 0.3$	$2.0 \pm 0.4$	$1.9 \pm 0.2$	$2.2 \pm 0.1$	< 0.001	0.185	0.053	< 0.001	
Iliac screw N (%)	162 (94)	43 (80)	54 (100)	65 (100)	< 0.001				
Staged surgery N (%)	72 (42)	4 (7)	3 (6)	65 (100)	< 0.001				
Total surgery time (min)	$436.0 \pm 81.0$	$402.6 \pm 79.7$	$442.8 \pm 87.5$	$460.8 \pm 66.6$	< 0.001	0.021	< 0.001	0.422	
Total intraoperative	$1624.8 \pm 1042.3$	1863 9 + 1166 7	$2018.9 \pm 1032.6$	1098 8 + 670 1	< 0.001	0.746	< 0.001	< 0.001	
blood loss(ml)	1024.0 ± 1042.5	1005.7 ± 1100.7	2010.7 ± 1052.0	1070.0 ± 070.1	< 0.001				
Length of hospital stay	37 6 + 12 7	365 + 92	$37.0 \pm 10.8$	391+162	0.488	NS	NS	NS	
(days)	5710 = 1217	50.5 _ 7.2	57.0 = 10.0	59.11 = 10.2	0.100				
Overall perioperative	55 (32)	14 (26)	16 (30)	25 (39)	0.316				
complication N (%)		11 (20)	10 (50)	20 (37)	0.010				
Surgical complication	13 (8)	4 (7)	3 (6)	6 (9)	0.750				
Neurological	15 (9)	3 (6)	2 (4)	10 (15)	0 049				
complication	15 (5)	5 (0)	2 (+)	10 (15)	0.047				
Medical complication	36 (21)	10 (19)	13 (24)	13 (20)	0.761				
Revision surgery N (%)	29 (17)	7 (13)	17 (31)	5 (8)	0.002				
Mean values are presented as mean ± SD. Bold type indicates statistical significance. †Comparison between groups. ‡Post hoc comparison between Grade 2									

osteotomy and 3-column osteotomy. §Post hoc comparison between Grade 2 osteotomy and LLIF. ¶Post hoc comparison between 3-column osteotomy and

LLIF. P < 0.05 was considered as significant. G2, grade 2 osteotomy; LLIF, lateral lumbar interbody fusion; NS, not significant; UIV, upper instrumented level; 3-c, 3-cloumn osteotomy

Table 3. Radiographic findings between groups										
Parameter	Total	Grade 2 osteotomy (n=54)	3-column osteotomy (n=54)	LLIF (n=65)	P value†	G2 vs. 3-c P value‡	G2 vs. LLIF P value§	3-c vs. LLIF P value¶		
Baseline										
Thoracic kyphosis (°)	$25.4\pm20.1$	$25.7 \pm 18.6$	$27.0\pm25.3$	$23.8 \pm 16.2$	0.681	NS	NS	NS		
Lumbar lordosis (°)	$10.7\pm20.4$	$15.2\pm15.6$	$4.2\pm27.3$	$12.3\pm15.7$	0.014	0.033	0.576	0.139		
Pelvic tilt (°)	35.7 ± 11.2	$33.7\pm10.9$	37.1 ± 12.8	$36.0 \pm 9.8$	0.278	NS	NS	NS		
Pelvic incidence minus lumbar lordosis (°)	$40.9 \pm 21.1$	$36.5 \pm 16.8$	$48.9\pm26.4$	38.1 ± 17.5	0.003	0.005	0.904	0.013		
Sagittal vertical axis (mm)	$116.3\pm75.9$	$104.1\pm 66.9$	149.7 ± 93.3	98.7 ± 56.3	< 0.001	0.012	0.882	0.002		
Cobb angle (°)	$29.1\pm21.0$	$36.0\pm21.5$	$15.4 \pm 13.5$	$34.9\pm20.5$	< 0.001	< 0.001	0.960	< 0.001		
2 years post-surgery										
Thoracic kyphosis (°)	$44.3 \pm 16.1$	$43.8 \pm 12.3$	$43.6 \pm 17.0$	$45.2\pm18.2$	0.828	NS	NS	NS		
Lumbar lordosis (°)	$42.4 \pm 12.2$	$43.0 \pm 10.7$	$40.1 \pm 14.0$	$43.9 \pm 11.7$	0.224	NS	NS	NS		
Pelvic tilt (°)	$25.5\pm9.6$	$26.1\pm9.3$	$27.2\pm9.5$	$23.7\pm9.7$	0.115	NS	NS	NS		
Pelvic incidence minus lumbar lordosis (°)	11.0 ± 14.2	$10.8 \pm 14.1$	15.8 ± 14.8	$7.2 \pm 12.7$	0.004	0.147	0.329	0.002		
Sagittal vertical axis (mm)	$57.9 \pm 55.2$	$62.1\pm56.3$	$78.5\pm67.4$	37.3 ± 31.6	< 0.001	0.244	0.031	< 0.001		
Cobb angle (°)	$9.3 \pm 8.6$	$10.7 \pm 10.7$	6.3 ± 6.2	$10.6 \pm 7.7$	0.007	0.026	0.997	0.003		
Values are presented as mean ± SD. Bold type indicates statistical significance. *Comparison between parameters at baseline and 2 years after surgery. †Comparison between groups. ‡Post hoc comparison between Grade 2 osteotomy and 3-column osteotomy. §Post hoc comparison between Grade 2										

osteotomy and LLIF. ¶Post hoc comparison between 3-column osteotomy and LLIF. P < 0.05 was considered as significant. G2, grade 2 osteotomy; LLIF, lateral lumbar interbody fusion; NS, not significant; UIV, upper instrumented level; 3-c, 3-cloumn osteotomy

Table 4. Clinical outcomes between groups									
Parameter	Total	Grade 2 osteotomy (n=54)	3-column osteotomy (n=54)	LLIF (n=65)	P value†	G2 vs. 3-c P value‡	G2 vs. LLIF P value§	3-c vs. LLIF P value¶	
Baseline									
SRS-22r Function	$2.58\pm0.68$	$2.54\pm0.71$	$2.53 \pm 0.67$	$2.66\pm0.67$	0.527	NS	NS	NS	
SRS-22r Pain	$2.98 \pm 0.90$	$2.71\pm0.86$	$3.10\pm0.98$	$3.10\pm0.84$	0.034	0.065	0.054	1.000	
SRS-22r Self-image	$1.99\pm0.70$	$2.15\pm0.77$	$1.89 \pm 0.60$	$1.95 \pm 0.69$	0.121	NS	NS	NS	
SRS-22r Mental	$2.70\pm0.63$	$2.68\pm0.69$	$2.67 \pm 0.65$	$2.74\pm0.56$	0.783	NS	NS	NS	
SRS-22r Satisfaction	NA	NA	NA	NA	NA	NA	NA	NA	
SRS-22r Subtotal	22r Subtotal $2.51 \pm 0.61$ $2.45 \pm 0.67$ $2.51 \pm 0.60$ $2.57 \pm 0.57$ $0.550$						NS	NS	
Oswestry disability index	stry disability index $43.6 \pm 15.9$ $46.3 \pm 16.9$ $44.5 \pm 16.2$ $40.5 \pm 14.3$ $0.119$					NS	NS	NS	
Modelled SF-6D scores	$0.56\pm0.08$	$0.54\pm0.09$	$0.55\pm0.08$	$0.57\pm0.07$	0.119	NS	NS	NS	
2 years post-surgery									
SRS-22r Function	$3.23\pm0.74$	$3.07\pm0.80$	$3.28 \pm 0.67$	$3.33\pm0.73$	0.148	NS	NS	NS	
SRS-22r Pain	$3.82\pm0.85$	$3.62\pm0.96$	$3.76\pm0.80$	$4.04\pm0.75$	0.020	0.673	0.025	0.126	
SRS-22r Self-image	$3.39\pm0.80$	$3.23\pm0.78$	$3.55\pm0.73$	$3.39\pm0.86$	0.112	NS	NS	NS	
SRS-22r Mental	$3.40\pm0.88$	$3.22\pm0.93$	$3.50 \pm 0.74$	$3.47\pm0.94$	0.193	NS	NS	NS	
SRS-22r Satisfaction	$3.60\pm0.83$	$3.60\pm0.83$	$3.60 \pm 0.83$	$3.58\pm0.83$	0.991	NS	NS	NS	
SRS-22r Subtotal	$3.47\pm0.67$	$3.32 \pm 0.71$	$3.53 \pm 0.57$	$3.55\pm0.70$	0.125	NS	NS	NS	
Oswestry disability index	$28.6 \pm 18.1$	$33.6 \pm 18.3$	30.1 ± 19.1	$23.2\pm15.6$	0.005	0.550	0.004	0.086	
Modelled SF-6D scores	$0.63\pm0.09$	$0.61 \pm 0.09$	$0.63 \pm 0.10$	$0.66\pm0.08$	0.005	0.550	0.004	0.086	
QALY improvements									
2-year postoperative	$0.16 \pm 0.19$	$0.13 \pm 0.20$	$0.15 \pm 0.19$	$0.18\pm0.19$	0.376	NS	NS	NS	
Values are presented as mean $\pm$ SD. Bold type indicates statistical significance. ‡Post hoc comparison between Grade 2 osteotomy and 3-column osteotomy. §Post hoc comparison between Grade 2 osteotomy and LLIF. ¶Post hoc comparison between 3-column osteotomy and LLIF. p < 0.05 was considered as significant. NA, not applicable; NS, not significant; SRS, scoliosis research society †Comparison between groups.									

Table 5 Comparison of 2-year direct cost between groups											
Direct costs (USD)	Total	Grade 2 osteotomy (n=54)	3-column osteotomy (n=54)	LLIF (n=65)	P value†	G2 vs. 3-c P value‡	G2 vs. LLIF P value§	3-c vs. LLIF P value¶			
Medical expenses for initial surgery	$72,240 \pm 11,649$	$65,521 \pm 12,106$	68,387 ± 8,038	81,023 ± 7,801	<0.001	0.327	< 0.001	< 0.001			
Breakdown of the initial surgery costs (USD)											
Surgical costs	$58,541 \pm 9,385$	$51,\!414 \pm 7,\!435$	54,262 ± 5,335	67,380 ± 5,375	<0.001	0.050	< 0.001	< 0.001			
Examination costs	$1,288 \pm 647$	$1,083 \pm 536$	$1,241 \pm 406$	$1,482 \pm 812$	0.003	0.226	0.006	0.098			
Hospital costs	$7,842 \pm 1,850$	$7,096 \pm 1,947$	$7,974 \pm 1,632$	$7,974 \pm 1,779$	0.002	0.039	0.001	0.570			
2-year total medical expenses	76,294 ± 16,681	66,942 ± 12,040	77,378±20,550	83,162±12,463	<0.001	0.005	0.001	0.172			
Cost per QALY (USD/0	QALY)										
2-year postoperative	2-year postoperative 492,276 509,370 518,406 463,798 NA NA NA NA										
Values are presented as mean $\pm$ SD. Bold type indicates statistical significance. †Comparison between groups. ‡Post hoc comparison between Grade 2 osteotomy and 3-column osteotomy. §Post hoc comparison between Grade 2 osteotomy and LLIF. ¶Post hoc comparison between 3-column osteotomy and LLIF. p < 0.05 was considered as significant. QALY, quality adjusted life years; NA, not applicable; NS, not significant.											

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