

Cost-Effectiveness of Corrective Fusion Surgeries for Adult Spinal Deformities: Does Unexpected Revision Surgery Affect Cost-Effectiveness?

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Abstract:

Introduction: Previous research has demonstrated that mid- to long-term health-related quality of life following corrective fusion surgery for adult spinal deformity (ASD) can be improved by appropriate revision surgery. In this study, we aim to compare the cost-effectiveness of corrective fusion surgery for ASD with and without unexpected revision surgery 5 years postoperatively.

Methods: In total, 79 patients with ASD (mean age, 68.7 years) who underwent corrective fusion surgery between 2013 and 2015 were included in this study. Cost-effectiveness was evaluated based on the cost of obtaining 1 quality-adjusted life year (QALY). Patients were divided into two groups according to the presence or absence of unexpected revision surgery following corrective fusion and were subjected for comparison.

Results: As per our study findings, 26 (33%) of the 79 ASD patients underwent unexpected revision surgery during the first 5 years following surgery. Although there was no significant difference in terms of inpatient medical costs at the time of initial surgery for 5 years after surgery between the two groups (no-revision group, revision group; inpatient medical costs at the time of initial surgery: USD 69,854 vs. USD 72,685, $P=0.344$), the total medical expenses up to 5 years after surgery were found to be higher in the revision group (USD 72,704 vs. USD 104,287, $P<0.001$). The medical expenses required to improve 1 QALY 5 years after surgery were USD 178,476 in the no-revision group, whereas it was USD 222,081 in the revision group.

Conclusions: Although the total medical expenses were higher in the revision group, no significant difference was observed in the cumulative QALY improvement between the revision and no-revision groups. Moreover, the medical expenses required to improve 1 QALY were higher in the revision group, with a difference of approximately 20%.

Keywords:

adult spinal deformity, cost-effectiveness, quality-adjusted life year, corrective fusion surgery, medical expenses, spinal instrumentation, revision surgery, rod fractures

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Introduction

In adult spinal deformity (ASD), degeneration of the spine and intervertebral discs is known to progress with age, which, in turn, may interfere with one's daily life. With its hyper-aged society, Japan is expected to see an increase in

the number of patients with ASD. Symptoms associated with ASD include pain in the lower back and lower limbs, functional disability, mental problems, respiratory dysfunction, gastroesophageal reflux disease, gait disturbance, and difficulty in maintaining a standing position¹⁻⁵⁾. Despite recent advancements in medication and medical devices, it re-

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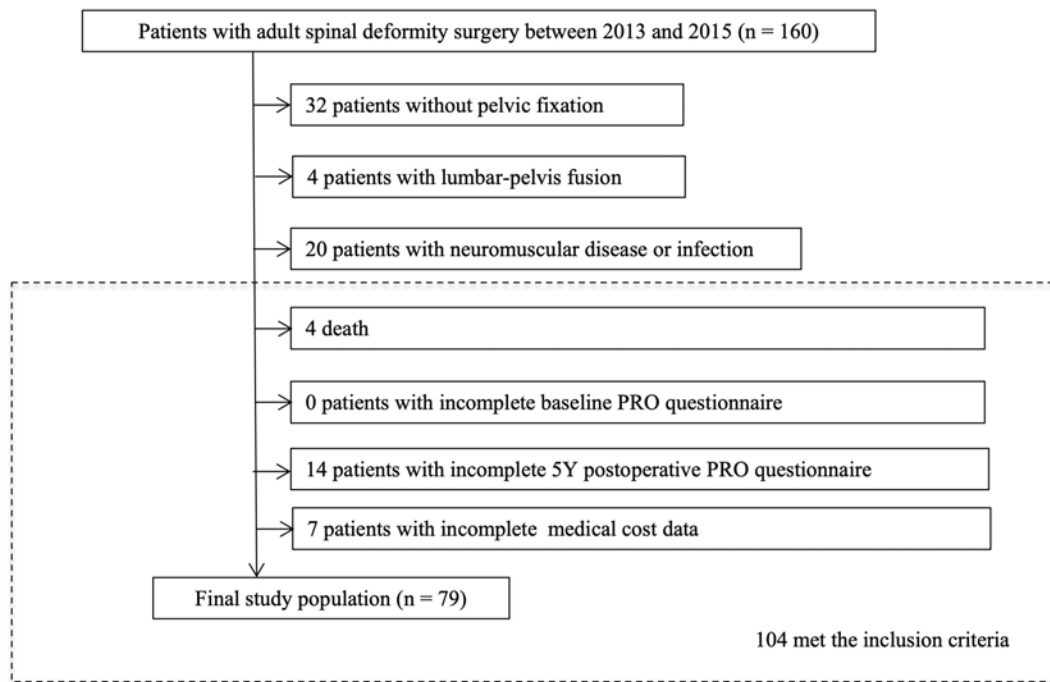


Figure 1. A chart showing participant flow through the study eligibility criteria.

mains difficult to fundamentally improve the aforementioned ASD-related symptoms with medication therapy. Corrective surgical treatment for ASD has been known to improve health-related quality of life (HRQOL); however, it requires long-range fusion surgery to correct the deformity, resulting in loss of physiological spinal mobility and requiring significant invasiveness^{6,7)}. Recently, remarkable advances have been made in surgical support devices, such as intraoperative spinal cord monitoring, spinal navigation systems, ultrasonic surgical instruments, minimally invasive wound openers, and hemostats, which contribute to improved surgical safety and minimally invasive procedures, thus increasing the number of patients who can benefit from surgical treatment^{8,9)}.

Japan has a universal health insurance system, which guarantees the provision of necessary medical care to all patients. However, financial resources for medical care are not inexhaustible; thus, to maintain the Japanese universal health insurance system, an “efficient” medical care system that raises the quality of medical care while controlling increasing medical costs is required; this necessitates an economic health evaluation in many fields. In extensive corrective fusion for ASD, mid- to long-term postoperative HRQOL can improve with appropriate revision surgery, even if rod fractures or adjacent intervertebral disorders occur. However, the mid- to long-term medical economics of ASD surgery with and without unexpected revision surgery are yet to be fully elucidated. Thus, in this study, we aimed to compare the cost-effectiveness of extensive corrective fusion for ASD with and without unexpected revision surgery 5 years after the initial surgery.

Materials and Methods

Patient population

This study was reviewed and approved by our Institutional Review Board; moreover, this study was conducted in accordance to the principles of the Declaration of Helsinki. A comprehensive agreement for the academic use of information, including treatment type, treatment progress, or any other treatment data, was obtained from the patients by the hospital at the time of their hospitalization, and it was made sure that no identifiable information of the participants was included in the manuscript. Herein, patients were diagnosed with ASD if they were aged ≥ 50 years, with the confirmed presence of at least one of the following: coronal scoliosis with Cobb angle $\geq 20^\circ$, sagittal vertical axis (SVA) ≥ 5 cm, pelvic tilt (PT) $\geq 25^\circ$, or thoracic kyphosis $\geq 60^\circ$. In this study, we included patients with ASD who underwent extensive corrective fixation surgery between 2013 and 2015 at a single institution (Fig. 1). For inclusion, patients had to have undergone posterior instrumented fusion from the thoracic spine to the pelvis and had available HRQOL data collected before and 5 years after surgery. Moreover, patients were examined to determine if he or she has osteoporosis at the time of initial surgery. Osteoporosis was defined as a T-score of -2.5 or less at the femoral neck or existing fragility fractures of the spine or proximal femur at the time of surgery, or patients who had already started osteoporosis treatment. We have also investigated the use of anabolic agents and antiresorptive agents for osteoporosis within 5 years of the initial surgery. Patients were divided into two groups: those who did not undergo unexpected revision surgery within 5 years of the initial surgery and those who did.

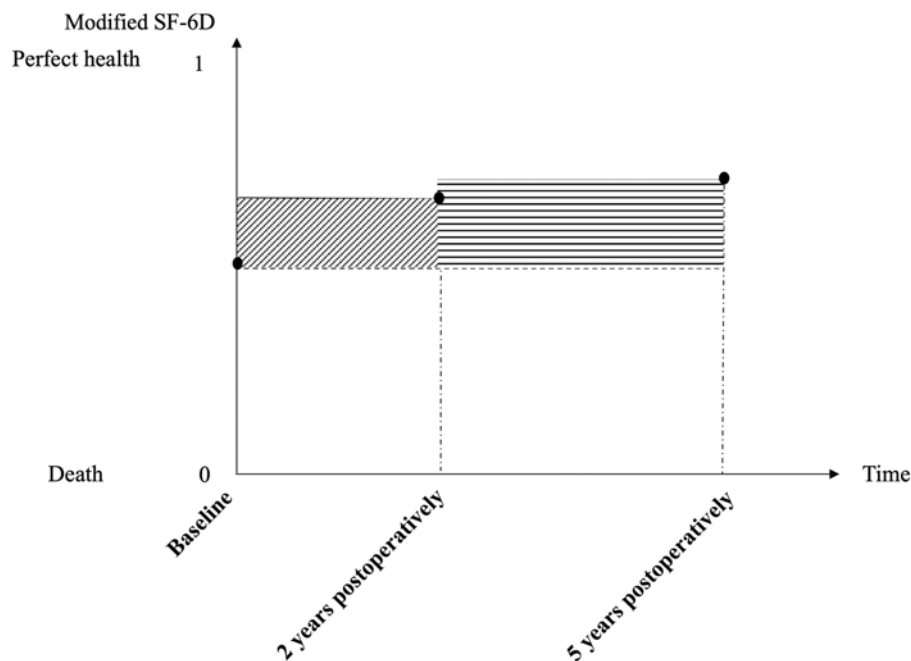


Figure 2. Calculation of quality-adjusted life years gained in 5 years following initial surgery.

Data collection of medical expenses

All inpatient medical costs for ASD, including laboratory admissions for ASD surgery, were extracted from the medical fee data. We have also looked into the cost of hospitalization for revision surgery up to 5 years after initial surgery. The total medical expenses covered the total inpatient and outpatient medical expenses. Total inpatient expenses included surgery, hospitalization, examination, physical therapy, and medical management fees. Surgical costs included all intraoperative expenses, including surgical technique fees, anesthesia management fees, and the cost of implants used such as pedicle screws, hooks, rods, connectors, transverse fixators, and sublaminar tape, as well as hemostatic agents used during the procedure. Examination costs included charges for blood sampling, X-ray, computed tomography, and magnetic resonance imaging. Hospital costs included perioperative centralized management costs, pharmaceutical treatment costs, meal costs, and room costs. The total cost of hospitalization for all separate hospital admission events prior to surgery was included in the examination costs. The total outpatient medical expenses included consultation, examination, physical therapy, and pharmaceutical treatment expenses for outpatient visits during the first 5 years after the initial surgery. However, the cost of hospitalization in nursing care facilities and other facilities after discharge from acute care hospitals was not included in these calculations.

Radiographic measurements

Full-length freestanding posteroanterior and lateral spine radiographs obtained before and 5 years after the surgery were analyzed. Measurement of spinopelvic parameters were

performed by board-certified spine surgeons using standard techniques^{10,11}.

Patient-reported outcome measures (PROMs)

HRQOL data derived from the Scoliosis Research Society (SRS)-22r^{12,13} and the Oswestry Disability Index (ODI) were evaluated. The SRS-22r is a scoliosis-specific HRQOL questionnaire, which has been reported to be representative, reliable, and valid in populations with ASD¹⁴⁻¹⁶. The ODI is also a recommended PRO measurement for patients with spinal disorders; in fact, it has been widely used to assess ASD¹⁷.

Cost-effectiveness analysis

Cost-effectiveness was determined using quality-adjusted life years (QALY). Cost/QALY was calculated by dividing the total hospitalization medical expenses for 5 years by the acquired QALY. The reference's willingness to pay the threshold amount was assumed to be JPY 5,000,000 (USD 50,000)^{18,19}. QALY was calculated by converting the ODI into a short-form survey-6D, in accordance with a previously published regression model²⁰. The 2-year QALYs were calculated by doubling the difference between the modified SF-6D at 2 years postoperatively and the modified SF-6D before surgery. The 5-year gained QALYs were calculated by adding the difference between the 5-year postoperative modified SF-6D and the preoperative modified SF-6D multiplied by 3- to the 2-year gained QALYs (Fig. 2). The exchange rate between the US dollar and the Japanese yen was set at US\$1=¥100 in order to simplify the calculation, as the exchange rate on July 1, 2014, the median date of this study period, was ¥101 yen to US \$1.

Table 1. Patient Background.

	Total (n=79)	No revision (n=53)	Revision (n=26)	P-value†
Number	79	53	26	
Age	68.7±7.8	69.3±7.4	67.4±8.6	0.322
Female N (%)	66 (84)	46 (87)	20 (77)	0.213
Body mass index	23.5±4.2	23.2±4.4	24.1±3.7	0.365
Charlson Comorbidity Index	0.3±0.6	0.3±0.6	0.4±0.6	0.646
ASA classification N (%)				
ASA 1	13 (17)	8 (15)	5 (19)	0.756
ASA 2	61 (77)	41 (77)	20 (77)	
ASA 3	5 (6)	4 (8)	1 (4)	
Osteoporosis N (%)	38 (48)	22 (42)	16 (62)	0.094
Use of anabolic agents N (%)	38 (48)	24 (45)	14 (54)	0.474
Use of antiresorptive agents N (%)	38 (48)	27 (51)	11 (42)	0.470
Pathology N (%)				
Degenerative kyphoscoliosis	32 (41)	24 (45)	8 (31)	0.002
Degenerative kyphosis	25 (32)	20 (38)	5 (19)	
Kyphosis after vertebral fracture	12 (15)	2 (4)	10 (39)	
Iatrogenic kyphosis	6 (8)	4 (8)	2 (8)	
Adult scoliosis	4 (5)	3 (6)	1 (4)	

Values are presented as mean±SD. Bold type indicates statistical significance. †Comparison between groups. ASA, American Society of Anesthesiologists

Statistical analyses

All values are expressed as the mean±standard deviation (SD). Shapiro-Wilk test was utilized to verify normal data distribution. The chi-square/Fisher's exact test was further used to test for significant differences in categorical study parameters between groups. Meanwhile, differences between groups were evaluated using the unpaired two-sample t-test or Mann-Whitney U test. The statistical significance of between-group differences between groups was examined using one-way analysis of variance. Post hoc comparisons were conducted using Tukey's test or the Games-Howell test. Statistical significance was set at $P<0.05$. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) software (version 27.0; SPSS, Chicago, IL, USA).

Results

Participant characteristics

Of the 160 patients aged ≥ 50 years who underwent corrective fusion surgery for ASD during the study period, 104 were able to meet the inclusion criteria, while 79 (76.0% of eligible patients) could be followed up on the HRQOL questionnaire and medical costs for 5 years postoperatively (Fig. 1). The average age of the patients was 68.7±7.8 years (66 female patients). The pathologies of patients undergoing extensive corrective fusion surgery for ASD are summarized in Table 1. As per our study findings, unexpected revision surgery was performed in 26 (33%) of the 79 patients with ASD during the first 5 years postinitial surgery. In the no-

revision and revision groups, the baseline prevalence of osteoporosis was 42% vs. 62% ($P=0.094$). No significant difference was noted between the two groups in terms of the use of anabolic agents or antiresorptive agents for osteoporosis during the 5-year postoperative period.

Surgical details and outcomes

Surgical details are summarized in Table 2. As per our data, 26 patients (34%) with ASD underwent revision surgeries 29 times; of these cases, 22 were rod fractures, 2 were proximal junctional failure (PJF), 2 were implant-related disorders, 1 was hematomas, 1 was malalignment, and 1 was a neurological deficit. No significant differences were determined between the nonrevision and revision groups with regard to the number of fused vertebrae, upper instrumented vertebra level, the number of rods, or overall perioperative complication rate.

Radiographic parameters

Radiological parameters were measured preoperatively in all 79 patients and 5 years postoperatively in 41 (73%) and 22 (85%) patients in the no-revision and revision group, respectively. As per our findings, the mean postoperative lumbar lordosis (LL), PT, pelvic incidence minus LL, SVA, and coronal Cobb significantly improved (all $P<0.001$, Table 3). Moreover, no significant differences were determined between the no-revision and revision groups in terms of radiographic parameters, except for the Cobb angle, both preoperatively (no-revision group, revision group; 30.3° vs. 19.5°, $P=0.042$) and 5 years postoperatively (no-revision group, revision group; 11.4° vs. 7.4°, $P=0.043$).

Table 2. Surgical Details.

Variables	Total (n=79)	No revision (n=53)	Revision (n=26)	P-value†
No. of fused vertebrae	10.0±1.7	10.1±1.7	9.8±1.6	0.539
UIV level N (%)				
T4	4 (5)	3 (6)	1 (4)	0.939
T5	5 (6)	4 (8)	1 (4)	
T6	1 (1)	1 (2)	0 (0)	
T7	2 (3)	1 (2)	1 (4)	
T8	5 (6)	4 (8)	1 (4)	
T9	17 (22)	12 (23)	5 (19)	
T10	43 (54)	27 (51)	16 (62)	
T11	2 (3)	1 (2)	1 (4)	
Iliac screw N (%)	79 (100)	53 (100)	26 (100)	NA
No. of rods	2.6±0.8	2.5±0.8	2.6±0.7	0.703
Staged surgery N (%)	34 (43)	24 (45)	10 (39)	0.565
Pedicle subtraction osteotomy	21 (27)	13 (25)	8 (31)	0.555
Vertebral column resection	11 (14)	2 (4)	9 (35)	0.001
Total operation time (min)	430.6±82.0	432.5±83.7	426.8±80.1	0.776
Total intraoperative blood loss (ml)	1,480.3±890.5	1,430.0±900.9	1,583.0±877.5	0.476
Length of hospital stay (days)	41.6±15.6	39.2±14.5	46.4±16.8	0.055
Overall perioperative complication N (%)	29 (37)	17 (32)	12 (46)	0.223
Surgical complication	4 (5)	2 (4)	2 (8)	0.400
Neurological complication	9 (11)	5 (9)	4 (15)	0.333
Medical complication	20 (25)	12 (23)	8 (31)	0.435
Revision surgery N (%)	26 (33)	0 (0)	29 (100)	NA

Values are presented as mean±SD. Bold type indicates statistical significance. †Comparison between groups. NA, not applicable; UIV, upper instrumented vertebra

Table 3. Radiographic Findings between Groups.

Parameter	Total (n=79)	No revision (n=53)	Revision (n=26)	P-value†
Baseline				
Thoracic kyphosis (°)	23.9±21.2	26.4±21.2	18.8±20.6	0.133
Lumbar lordosis (°)	11.5±21.1	14.7±18.7	5.1±24.3	0.057
Pelvic tilt (°)	37.0±10.2	36.7±11.0	37.6±8.5	0.721
Pelvic incidence minus lumbar lordosis (°)	43.0±20.8	40.0±18.0	49.2±25.0	0.067
Sagittal vertical axis (mm)	122.3±71.0	113.6±62.1	139.8±84.7	0.125
Cobb angle (°)	26.7±22.2	30.3±23.1	19.5±18.8	0.042
5 years postsurgery				
Thoracic kyphosis (°)	42.9±16.0	45.4±17.5	38.3±11.7	0.060
Lumbar lordosis (°)	42.0±11.3	43.5±11.5	39.1±10.5	0.146
Pelvic tilt (°)	26.6±8.4	25.9±9.1	27.7±6.9	0.419
Pelvic incidence minus lumbar lordosis (°)	11.7±12.7	10.4±14.3	14.1±9.0	0.205
Sagittal vertical axis (mm)	65.1±52.1	71.4±58.1	53.4±37.1	0.141
Cobb angle (°)	10.1±7.3	11.4±7.5	7.4±6.3	0.043

Values are presented as mean±SD. Bold type indicates statistical significance. †Comparison between groups. P<0.05 was considered as significant.

PROMs parameters

As per our findings, values of all SRS-22r domains and ODI have significantly improved 5 years after surgery (all P <0.001) (Table 4). There was no significant difference in PROMs parameters between the two groups. The cumulative QALY gains over 2 and 5 years were noted to average 0.16 and 0.43, respectively, with no significant difference be-

tween the two groups. Furthermore, the cumulative improvement in the QALYs 5 years after surgery exhibited no significant difference between the two groups (0.41 vs. 0.47, P =0.570).

Medical expenses and cost-effectiveness of ASD surgery

The average inpatient medical cost at the time of initial surgery was USD 70,786±12,412, whereas the average total

Table 4. Clinical Outcomes between Groups.

Parameter	Total (n=79)	No revision (n=53)	Revision (n=26)	P-value†
Baseline				
SRS-22r function	2.49±0.66	2.56±0.72	2.35±0.49	0.178
SRS-22r pain	3.07±0.87	2.96±0.87	3.30±0.85	0.097
SRS-22r self-image	1.98±0.75	2.00±0.74	1.95±0.78	0.782
SRS-22r mental	2.52±0.95	2.57±0.96	2.42±0.95	0.517
SRS-22r satisfaction	NA	NA	NA	NA
SRS-22r subtotal	2.50±0.59	2.51±0.60	2.49±0.56	0.885
Oswestry Disability Index	43.2±15.9	43.2±16.7	43.2±14.4	0.997
Modeled SF-6D scores	0.56±0.08	0.56±0.09	0.56±0.07	0.997
2 years post-surgery				
SRS-22r function	3.24±0.80	3.26±0.86	3.20±0.73	0.794
SRS-22r pain	3.90±0.80	3.95±0.76	3.79±0.87	0.433
SRS-22r self-image	3.46±0.80	3.48±0.78	3.43±0.85	0.813
SRS-22r mental	3.33±0.90	3.29±0.85	3.40±1.01	0.629
SRS-22r satisfaction	3.53±0.87	3.51±0.90	3.58±0.82	0.749
SRS-22r subtotal	3.48±0.69	3.49±0.69	3.46±0.71	0.880
Oswestry Disability Index	28.0±18.5	28.3±18.4	27.4±19.1	0.834
Modeled SF-6D scores	0.64±0.10	0.64±0.10	0.64±0.10	0.834
5 years post-surgery				
SRS-22r function	3.34±0.87	3.35±0.89	3.32±0.83	0.868
SRS-22r pain	3.90±0.92	3.86±0.91	3.97±0.95	0.622
SRS-22r self-image	3.28±0.86	3.26±0.89	3.34±0.81	0.706
SRS-22r mental	3.36±0.98	3.36±0.95	3.36±1.07	0.994
SRS-22r satisfaction	3.46±0.94	3.45±0.92	3.48±0.98	0.896
SRS-22r subtotal	3.46±0.80	3.44±0.80	3.50±0.80	0.752
Oswestry Disability Index	25.9±20.7	27.0±21.3	23.6±19.6	0.496
Modeled SF-6D scores	0.65±0.11	0.64±0.11	0.66±0.10	0.496
QALY gained				
2-year postoperative	0.16±0.19	0.15±0.19	0.16±0.21	0.838
5-year postoperative	0.43±0.45	0.41±0.46	0.47±0.46	0.570

Values are presented as mean±SD. †Comparison between groups. NA, not applicable; QALY, quality-adjusted life year; SRS, Scoliosis Research Society

Table 5. Comparison of 5-year Direct Cost between Groups.

Direct costs (USD)	Total (n=79)	No revision (n=53)	Revision (n=26)	P-value†
Medical expenses for initial surgery	70,786±12,412	69,854±13,270	72,685±10,431	0.344
Breakdown of the initial surgery costs				
Surgical costs	57,914±7,449	58,381±7,681	56,963±7,000	0.430
Examination costs	1,188±350	1,141±282	1,285±450	0.086
Hospital costs	8,205±2,150	7,819±1,947	8,993±2,363	0.022
Hospitalization costs for revision surgery	NA	NA	28,339±12,463	NA
Total outpatient medical expenses	2,986±2,022	2,850±2,232	3,262±1,510	0.399
Consultation costs	377±477	301±383	530±606	0.087
Examination costs	1,768±696	1,602±593	2,107±776	0.002
Pharmaceutical treatment costs	604±1,397	691±1,676	425±436	0.430
5-year total medical expenses	83,099±20,957	72,704±13,640	104,287±16,952	<0.001
Cost per QALY (USD/QALY)				
5-year postoperative	194,227	178,476	222,081	NA

Values are presented as mean±SD. Bold type indicates statistical significance. †Comparison between groups. P<0.05 was considered as significant. QALY, quality-adjusted life years; NA, not applicable

inpatient medical expenses including outpatient costs for up to 5 years after initial surgery was USD 83,099±20,957 (Ta-

ble 5). Although no significant difference was noted in the inpatient medical cost at the time of initial surgery and the

total outpatient medical cost for 5 years after surgery between the two groups (no-revision group, revision group; inpatient medical cost at the time of initial surgery: USD 69,854±13,270 vs. USD 72,685±10,431, P=0.344; total outpatient medical expenses: USD 2,850±2,232 vs. USD 3,262±1,510, P=0.399), the total medical expenses up to 5 years after surgery was found to be higher in the revision group (USD 72,704±13,640 vs. USD 104,287±16,952, P<0.001). The medical expenses required to improve patient outcome by 1 QALY 5 years after surgery were USD 178,476 in the no-revision group and USD 222,081 in the revision group.

Discussion

Corrective fusion for ASD has been determined to require extensive posterior fusion from the thoracic spine to the pelvis; moreover, the increased use of instrumentation results in high medical costs. Recently, the value of treatment, which is defined as the quality of medical care compared to cost, has become increasingly important in the consideration of medical costs²¹. The cost-effectiveness of surgical treatment over conservative treatment for ASD was previously reported in a North American multicenter study, wherein an incremental cost-effectiveness ratio of \$27,480 was determined at 5 years postsurgery, although this was below the threshold of \$50,000²². Extensive corrective fusion for ASD may result in mechanical complications in the mid to long term, which then requires unexpected revision surgery²³. The cost-effectiveness impact of unexpected revision surgery in extensive corrective fusion for ASD has rarely been reported in the past. Therefore, in this study, we aimed to determine how unexpected revision surgery affects the cost-effectiveness of extensive corrective fusion in patients with ASD.

As per our results, the total medical costs were found to be higher in the revision group; however, no significant difference was noted in the cumulative QALY improvement between the revision and no-revision groups. Moreover, the medical cost required to improve 1 QALY was higher in the revision group, with a difference of approximately 20%. Corrective fusion for ASD is known to be initially expensive because of the high instrumentation cost. Therefore, the initial treatment costs are expected to be high. Rod fractures, identified as the most common cause of revision surgery, are diagnosed an average of 21 months after initial surgery, while revision surgery is reported to be performed an average of 116 days thereafter²⁴. However, there are only few reports of revision surgery associated with rod fractures 5 years after initial surgery. Thus, long-term follow-ups are further needed to investigate the impact of unexpected revision surgery on cost-effectiveness.

There have been several reports examining the cost-effectiveness of corrective fusion for ASD. For example, Yagi et al. examined the effect of age at the time of surgery. In this Japanese multicenter retrospective study, patients were divided into two groups, that is, a middle-aged group

aged 50-64 years and an elderly group aged ≥70 years; they were thereafter subjected to analysis after adjusting for background factors using propensity score matching. This analysis reported inferior cost-effectiveness at 2 years postoperatively in the elderly group (Cost/QALY: elderly group \$211,636 vs. middle-aged group \$125,887 P=0.01)²⁵. Meanwhile, in a study examining the cost-effectiveness of ASD surgery by surgical technique, Ogura et al. compared the cost-effectiveness of the posterior approach alone versus the anterior-posterior approach in corrective fusion of five or more vertebrae for ASD in a multicenter retrospective study in North America²⁶. They reported that the cost for the posterior approach alone group was lower than that of the anteroposterior approach group (\$73,904 vs. \$89,824), with a similar effectiveness (QALY gained 0.21 vs. 0.17); thus, this indicates the superior cost-effectiveness of the former technique (Cost/QALY \$351,086 vs. \$525,080). In another multicenter retrospective study conducted by Yamamoto et al., wherein they examined the 2-year postoperative hospitalization costs of 49 cases of conventional posterior spinal fusion and 39 cases of posterior fusion with multilevel lateral interbody fusion combined with posterior spinal fusion for ASD²⁷, they reported that the total 2-year hospitalization costs were significantly higher in the multilevel lateral interbody fusion combined with posterior spinal fusion group than in the conventional posterior spinal fusion group (\$70,847 vs. \$52,560, P<0.01). However, the improvement in HRQOL was deemed comparable. Arima et al. divided 173 patients who underwent corrective fusion for ASD into three groups via surgical technique: Schwab grade 2 osteotomy group (Grade 2 group), three-column osteotomy group (three-column group), and posterior corrective fusion group with lateral lumbar interbody fusion (LLIF). The results of the cost-utility analysis at 2 years after surgery revealed that the LLIF group was more cost-effective among the three techniques (Cost/QALY: Grade 2 group, \$509,370; three-column group, \$518,406; and LLIF group, \$463,798)²⁸.

Herein, no significant differences were determined in terms of age, sex, body mass index, or comorbidities between the revision group and the no-revision group; however, there were significant differences in terms of pathophysiology, including greater kyphosis after vertebral fractures in the revision surgery group. In our facility, vertebral column resection was performed in patients with sharp rigid kyphosis of the thoracolumbar and lumbar spine, such as kyphosis after vertebral fracture or iatrogenic kyphosis²⁹. This has resulted in the revision group having a higher percentage of kyphosis with vertebral fracture kyphosis and therefore a higher percentage of vertebral column resection. Thus, it can be concluded that this difference in pathophysiology and initial surgery may have impacted cost-effectiveness. Furthermore, the revision group had more hospital stays and higher hospitalization costs. In cases of vertebral column osteotomy with bone fragility, physical therapy is slowly advanced in some cases. Although perioperative complications were not different between the no-revision

and revision groups, this difference in the way physical therapy is carried out for each pathology may also play a role in the differences in length of hospital stay and hospitalization costs. It was also observed that the prevalence of osteoporosis tended to be higher in the revision group than in the nonrevision group (62% vs. 42%, $P=0.094$). Recently, it has been reported that revision surgery for mechanical complications is significantly more common after corrective fusion for ASD in patients with osteoporosis³⁰. Recent guidelines for corrective fusion surgery for ASD recommend the importance of preoperative osteoporosis evaluation and appropriate osteoporosis treatment³¹. Although there was no significant difference in terms of the medication for osteoporosis between the two groups, this retrospective study may have lacked information on osteoporosis treatment at other clinics.

In addition, when referring to cost-effectiveness studies, it should be noted that healthcare systems and prices of medical services differ significantly from country to country. With regard to the cost-effectiveness of surgical treatment for ASD, it is thus important for spine surgeons to make correct judgments both medically and economically and to select and implement clinical practices that are deemed effective both medically and in terms of cost, in order to extend the quality of life of patients and the healthy life expectancy of the nation as a whole. Multicenter cost-effectiveness studies of surgical and conservative treatments for ASD in the medium to long term should be conducted throughout the country to accumulate more solid evidence.

In our study, radiographic examination exhibited significant postoperative improvement with or without unexpected revision surgery, with no significant difference in sagittal alignment between the two groups. With regard to clinical outcomes, the SRS-22r and ODI scores were found to significantly improve at 5 years postoperatively as compared to those preoperatively, with or without unexpected revision surgery; moreover, no statistically significant difference was noted in terms of treatment satisfaction between the two groups. This may indicate that even when mechanical failure occurs, clinical outcomes and treatment satisfaction are favorable when the patient is correctly diagnosed and undergoes revision surgery.

This study has several limitations. First, the retrospective, single-center design would have introduced inevitable bias. Second, the sample size was small, which could have impacted the robustness of our results. Further, the costs of nursing care facilities were not evaluated, and the calculated costs did not include indirect costs, thus limiting the accuracy of our overall cost findings. Indirect costs include social losses due to the inability to work or perform household chores because of ASD. Unfortunately, these could not be taken into account herein because of the large uncertainties. Finally, as SF-6D was not directly obtained here, we instead used the ODI-predicted value²⁰. The coefficient of determination for the prediction equation was 0.67, which indicates a potential underestimation of the QALYs gained that may

have affected the results. The advantage of this study, however, is the accuracy of the follow-up, including outpatient costs, over a relatively long period of 5 years.

Conclusions

In this 5-year study examining the extensive corrective fusion for ASD, we found that the total medical costs were higher in the revision group; however, no significant difference in the cumulative QALY improvement between the revision and no-revision groups was determined. Thus, the medical costs required to improve 1 QALY were higher in the revision group, with a difference of approximately 20%.

Conflicts of Interest: HA, TH, MK, GY, TB, KI, TY, KN, KK, and YM have nothing to disclose.

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Author Contributions: Arima and Matsuyama were involved in the conception and design of this study. Arima, Hasegawa, Yamato, Kato, Yoshida, Banno, Oe, Ide, Yamada, Nakai, Kurosu, and Matsuyama were responsible for the acquisition of data. Arima, Hasegawa, Yamato, and Matsuyama were in charge of the analysis and interpretation of data. Arima drafted the manuscript. Arima, Hasegawa, Yamato, Banno, and Oe critically revised the draft of this manuscript. Arima, Hasegawa, Yamato, Kato, Yoshida, Banno, Oe, Ide, Yamada, Nakai, Kurosu, and Matsuyama reviewed the submitted version of the manuscript. Arima did the statistical analysis and approved the final version of the manuscript on behalf of all the authors. Lastly, Hasegawa and Matsuyama supervised the conduct of the study.

Ethical Approval: IRB approval: This study was reviewed and approved by the Institutional Review Board of Hamamatsu University School of Medicine (IRB no. 20-052) and adhered to the principles of the Declaration of Helsinki.

Informed Consent: As this study utilized medical records and was conducted on an opt-out basis to ensure research subjects are given the chance to refuse to participate in this

study, written or verbal consent was not obtained. A comprehensive agreement for the academic use of information, such as the type of treatment, treatment progress, or any other data acquired during treatment, was obtained from the patients by the hospital at the time of their hospitalization. The agreement also included a clause that no identifiable information regarding the participants would be included in the manuscript.

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