

Corrective Long Spinal Fusion to the Ilium for Patients with Adult Spinal Deformity Results in Good Physical Function after Mid- to Long-Term Postoperative Follow-Up

Masahiro Sawada¹⁾, Yu Yamato²⁾, Tomohiko Hasegawa³⁾, Go Yoshida²⁾, Tomohiro Banno²⁾, Hideyuki Arima²⁾, Shin Oe³⁾, Tetsuyuki Nagafusa⁴⁾, Katsuya Yamauchi⁴⁾, Toshiyuki Ojima⁵⁾ and Yukihiro Matsuyama²⁾

1) Division of Orthopaedic Surgery, Hamamatsu University Graduate School of Medicine, Shizuoka, Japan

2) Department of Orthopaedic Surgery, Hamamatsu University School of Medicine, Shizuoka, Japan

3) Division of Geriatric Musculoskeletal Health, Hamamatsu University School of Medicine, Hamamatsu, Japan

4) Department of Rehabilitation, Hamamatsu University School of Medicine, Hamamatsu, Japan

5) Department of Community Health and Preventive Medicine, Hamamatsu University School of Medicine, Hamamatsu, Japan

Abstract:

Introduction: This study investigated the mid- to long-term postoperative outcomes of patients with adult spinal deformity (ASD), focusing on physical function and quality of life (QOL). We also compared age-related changes between patients aged 75 years or older (high elderly) and those younger than 75 years (low elderly).

Methods: A total of 47 patients with ASD underwent thoracic-iliac long spinal fusion between August 2013 and September 2014. The study spanned from the preoperative period to at least 5 years postoperatively. Physical function was assessed using isometric hip flexion and knee extension muscle strength, the 6-min walk distance test, the 10-m walk test, and the timed up and go test. QOL was assessed using the Scoliosis Research Society-22 and Oswestry Disability Index. Repeated-measures analysis of variance with a mixed model approach, corrected for multiple comparisons using Bonferroni, was performed.

Results: Of the 47 patients, 21 participated in the study. Patients with ASD showed improved gait ability postoperatively. Hip flexor strength decreased at more than 5 years postoperatively compared with the preoperative strength. Patient-reported outcome (PRO) scores showed continuous improvement postoperatively, regardless of age. Although older patients had lower preoperative and postoperative physical function, their PRO scores significantly improved and remained favorable for more than 5 years postoperatively.

Conclusions: Patients with ASD experienced sustained improvements in walking ability and PRO for more than 5 years postoperatively. The results of this study showed that even among the elderly, PRO scores consistently improved after surgery and remained positive for an extended period.

Keywords:

adult spinal deformity, gait ability, physical function, patient-reported outcome, spino-pelvic parameters

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Introduction

Among the aging population, the proportion of patients diagnosed with adult spinal deformity (ASD) is increasing, resulting in significant disability in daily life¹⁾. They exhibit reduced physical performance and increased sagittal spinal malalignment²⁾, which limit various activities of daily living

(ADL), such as gait, ultimately resulting in reduced quality of life (QOL) and walking disability³⁾. Spinal reconstructive surgery has recently become a common treatment option for adults with advanced thoracolumbar spinal deformity⁴⁾. Schwab et al. reported that optimal sagittal alignment and improved sagittal balance during motion are critical for corrective spinal fusion surgery, as a sagittal vertical axis (SVA)

Corresponding author: Masahiro Sawada, D21014@hama-med.ac.jp

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of 50 mm or less is associated with good health-related QOL⁵). Despite early rehabilitation, patients with ASD who have extensively fused spines have limited mobility, resulting in decreased independence in ADL and impaired physical function⁶). Although previous research has examined the effects of corrective spinal fusion surgery on physical function, QOL, and ADL, there is a lack of studies that examine mid- to long-term postoperative outcomes⁷). Age-related muscle weakness adversely affects the gait and other physical abilities of the elderly population. A prospective study of the elderly reported an accelerated decline in walking speed, beginning at age 75 years⁸). To date, no studies have examined the effect of aging on mid- to long-term postoperative physical function and QOL course in patients with ASD.

We hypothesized that the physical function and patient-reported outcome (PRO) of patients with ASD following corrective spinal surgery would show mid- to long-term improvement at more than 5 years postoperatively compared with preoperative results. This study aimed to investigate the effects of corrective spinal fusion surgery on mid- to long-term physical function in patients with ASD.

Materials and Methods

This study is a retrospective cohort study that recruited patients from the inpatient orthopedic unit at the research institution, and they were followed up from the preoperative period to at least 5 years postoperatively. The study details were explained at the time of inpatient admission. We reported this study according to the Strengthening the Reporting of Observational Studies in Epidemiology statement. The sample size for the primary outcome of physical function, as measured by a 6-min walk distance (6MWD), expected to show improvement at more than 5 years from the preoperative measurements was calculated to be 18, based on an effect size of 0.5, power of 0.8, and a confidence level of 95%. A total of 47 patients with ASD who underwent thoracic-iliac long spinal fusion between August 2013 and September 2014 were enrolled. The inclusion criteria were as follows: (1) patients aged 40 years or older at the time of surgery and (2) patients scheduled for corrective thoracic to iliac long spinal fusion. The exclusion criteria were as follows: patients (1) who could not walk without assistance, (2) who could not be easily monitored for this study, (3) with neurological symptoms, (4) who died within the study period, (5) who refused to participate in this study, and (6) with a history of spinal surgery. The experimental protocol and signed informed consent form were approved by the Ethics Committee of our institution. The participants were informed of the objectives and methodology of the research in detail, and informed consent was obtained before the assessments began. In this study, we also compared age-related changes in physical function and QOL from the preoperative period to more than 5 years postoperatively. The participants were divided into two groups: the high elderly group (H group; 75 years or older at the at least 5 years

postoperative assessment) and the low elderly group (L group; younger than 75 years).

Physical function outcome measures

Physical function was evaluated by assessing maximum isometric muscle strength (bilateral hip flexion and knee extension), walking ability using the 6MWD and 10-m walk test (10MWT), and the timed up and go test (TUG). Low back pain was assessed using the visual analog scale (VAS) to measure pain with movement. We measured these physical function outcomes preoperatively and 6 months, 1 year, 2 years, and at least 5 years postoperatively. Postoperative measurements were performed during the participants' outpatient visits. Maximal isometric muscle strength was measured, in both hip flexion and knee extension movements, using a dynamometer (μ TAS F-1, Anima Corp, Chofu, Tokyo)⁹). The TUG test assessed the time the participant took to rise from the chair, walk for 3 m, turn around, return to the chair, and sit¹⁰). The 10MWT was administered to assess each patient's maximum walking speed¹¹). The 6MWD is considered a useful test due to its ease of administration and similarity to normal daily activities. The test was performed according to the American Thoracic Society protocol¹²). The VAS score was obtained by each participant marking a 100-mm line to indicate their pain intensity and measurement of the distance from the origin of the line to the marked point¹³). The muscle strength test shows better results with increasing numerical values, while the 6MWD, 10MWT, TUG, and VAS show better performance with decreasing numerical values. Seven orthopedic surgeons evaluated spinal alignment, and radiographs of the entire spine and pelvis, measured in the standing position, were obtained using Surgimap software (Nemaris Corporation, New York, United States). Radiographic parameters such as SVA, lumbar lordosis (LL), thoracic kyphosis (TK), sacral slope (SS), pelvic incidence, pelvic tilt (PT), and Cobb angle were preoperatively and postoperatively assessed. Each variable was measured twice, and the results were averaged for analysis.

Clinical outcome measures

Clinical outcomes, which were PROs, were assessed by a trained physiotherapist and included the Oswestry Disability Index and Scoliosis Research Society-22 scores^{14,15}). These variables were assessed preoperatively and 6 months, 1 year, 2 years, and at least 5 years postoperatively.

Statistical analysis

Changes in physical function and PRO scores at 6 months, 1 year, 2 years, and at least 5 years postoperatively were compared with preoperative values using a mixed model repeated-measures analysis of variance with Bonferroni correction for multiple comparisons, reported as p-values. Independent t-tests were used to assess the differences between the two groups (H group vs. L group), while a two-way analysis of variance was used to assess changes in both groups over time. Missing data in longitudinal meas-

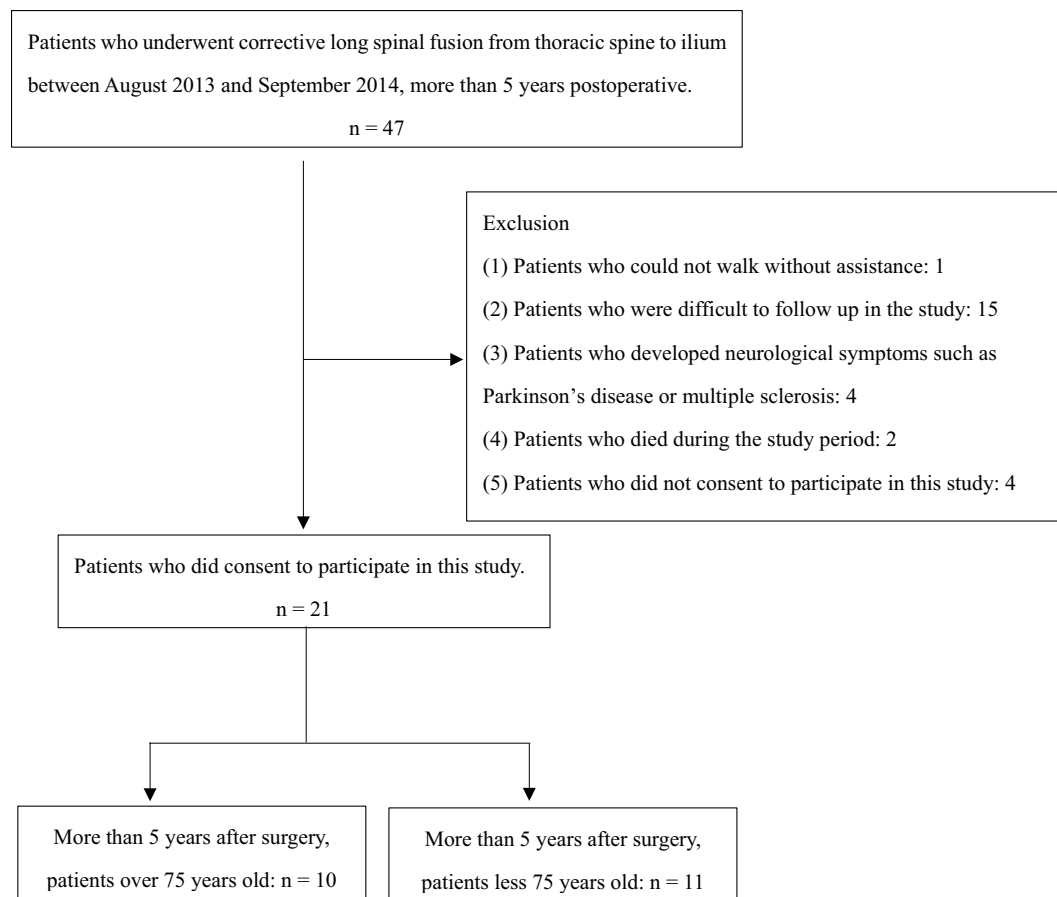


Figure 1. Flow diagram of the patient selection and exclusion process.

ures were assumed to be missing at random and were accounted for by analyzing the data with a mixed model. A p-value of <0.05 was considered statistically significant. Statistical analyses were performed using SPSS ver. 25.0 (IBM Corp, Armonk, New York, United States).

Results

Flowchart of the patient selection and exclusion process

Of the 47 patients who underwent surgery between August 2013 and September 2014, 26 were excluded (patients who could not walk without assistance, 1; could not be followed up easily, 15; developed Parkinson's disease, 4; died during the study period, 2; did not consent to participate in this study, 4), resulting in the analysis of data on 21 patients (Fig. 1). The number of missing participants for each variable is as follows: knee extensor strength (7), hip flexor strength (7), 10MWT (9), TUG (8), 6MWD (10), and VAS (13). Postoperative complications in our study participants included none (6), rod fracture (12), proximal junctional kyphosis (PJK) (1), proximal junctional failure (1), postoperative lower limb paralysis (1), and postoperative pneumothorax (1). All 12 patients with rod fractures underwent revision surgery. Table 1 shows the clinical and demographic characteristics of patients with ASD before and after surgery.

Change in radiographic data, physical function assessment, and PRO scores over time from the preoperative measurement to more than 5 years postoperatively

The mean period from the preoperative period to the point of measurement, which was more than 5 years after the surgery, was 84.2 ± 13.1 months. Radiographic findings showed significant improvements in SVA, LL, TK, PT, and Cobb angle after corrective spinal fusion in all patients ($p < 0.05$; Table 2). Patients with ASD showed improvement in postoperative physical function, particularly in walking ability (Fig. 2). The 6MWD showed a significant increase in walking ability at 6 months postoperatively compared with the preoperative distance (pre-op: 341.7 ± 123.9 m, P.O.6M: 411.6 ± 84.3 m, P.O.1Y: 450.0 ± 86.5 m, P.O.2Y: 469.4 ± 101.3 m, and P.O.5Y and over: 430.0 ± 111.2 m). This improvement was maintained in the mid- to long-term, which was more than 5 years postoperatively. In addition, VAS scores during movement showed a remarkable improvement at all postoperative time points compared with the preoperative scores (pre-op: 5.4 ± 2.5 , P.O.6M: 2.1 ± 2.2 , P.O.1Y: 1.6 ± 2.0 , P.O.2Y: 2.2 ± 2.3 , and P.O.5Y and over: 1.0 ± 1.7). This positive trend persisted for more than 5 years postoperatively (Fig. 2a). The TUG results showed improvement at the 2-year follow-up compared with the preoperative results, although no discernible discrepancy was observed after more than 5 years postoperatively (pre-op: 10.4 ± 2.9 s, P.O.6M: 9.1 ± 2.3 s, P.O.1Y: $8.3 \pm$

Table 1. Average Pre- and Postoperative Clinical and Demographic Characteristics of Patients with Adult Spinal Deformity.

	All study patients at postoperative	H group at more than 5 years postoperative	L group at more than 5 years postoperative
No. of cases	21	10	11
Sex (female/male)	20:1	9:1	10:0
Age (years)	65.1±10.8	81.1±5.1*	64.6±8.4
Assistive device (cane/none)	1:20	0:10	1:10
Diagnosis			
KS:K:VF:AS:CD	8:5:3:3:2	3:3:3:1:0	5:2:0:2:2
Surgical variables			
Osteotomy (PSO:VCR:PCO)	4:4:13	3:2:5	1:2:8
Number of fused levels	8.9±2.1	8.7±1.6	9.1±2.6
Operating time (min)	402.4±70.8	386.2±68.3	417.1±73.1
Total blood loss (cc)	1,427.1±995.5	1,475.6±1,094.6	1,383.0±948.4

H group: patients over 75, over 5 years after surgery; L group: patients under 75, over 5 years after surgery.

Values are presented as mean±standard deviation.

KS, kyphoscoliosis kyphosis; VF, vertebral fracture; AS, adult scoliosis; CD, congenital deformity; PSO, pedicle subtraction osteotomy; VCR, vertebral column resection; PCO, posterior column osteotomy

*Significant difference between the H and L groups ($p<0.05$).

Table 2. Average Radiographic Measurements for Patients with Adult Spinal Deformity.

	Before surgery	1 year after surgery	2 years after surgery	More than 5 years after surgery	p-value
SVA (mm)	113.7±98.9	20.0±38.9*	28.4±34.9*	44.5±39.0*	0.001
LL (degrees)	17.5±25.3	48.5±11.0*	48.2±11.7*	41.8±11.1*	0.001
TK (degrees)	24.0±22.9	40.0±16.1*	41.7±15.8*	40.1±15.0*	0.001
SS (degrees)	21.1±13.6	30.8±9.6*	29.0±7.0*	26.7±5.8*	0.001
PI (degrees)	54.2±10.4	52.9±9.5*	52.0±8.0*	49.9±7.5*	0.001
PT (degrees)	32.9±10.9	22.0±6.5*	23.0±6.3*	25.1±8.7*	0.001
Cobb angle (degrees)	37.5±25.2	13.1±11.7*	12.0±12.1*	10.7±7.5*	0.001

Values are presented as mean±standard deviation.

SVA, sagittal vertical axis; LL, lumbar lordosis; TK, thoracic kyphosis; SS, sacral slope; PI, pelvic incidence; PT, pelvic tilt

*Significant difference compared to the preoperative value ($p<0.001$).

2.3 s, P.O.2Y: 7.8±2.1 s, and P.O.5Y and over: 11.1±5.9 s; Fig. 2b). The 10MWT showed no significant change postoperatively from the preoperative time point (pre-op: 10.3±1.9 s, P.O.6M: 9.8±2.4 s, P.O.1Y: 8.8±1.3 s, P.O.2Y: 8.4±1.8 s, and P.O.5Y and over: 10.0±5.1 s; Fig. 2c). Muscle strength assessment showed a decrease in hip flexor strength at more than 5 years postoperatively compared with the preoperative strength (hip flexion Rt; pre-op: 0.29±0.1 kgf/kg, P.O.6M: 0.25±0.1 kgf/kg, P.O.1Y: 0.27±0.1 kgf/kg, P.O.2Y: 0.28±0.1 kgf/kg, and P.O.5Y and over: 0.22±0.1 kgf/kg and hip flexion Lt; pre-op: 0.27±0.1 kgf/kg, P.O.6M: 0.24±0.1 kgf/kg, P.O.1Y: 0.25±0.1 kgf/kg, P.O.2Y: 0.27±0.1 kgf/kg, and P.O.5Y and over: 0.20±0.1 kgf/kg; Fig. 2d, 2e). There was no significant difference in isometric knee muscle strength over time (Rt knee extension; pre-op: 0.38±0.1 kgf/kg, P.O.6M: 0.39±0.9 kgf/kg, P.O.1Y: 0.44±0.1 kgf/kg, P.O.2Y: 0.41±0.1 kgf/kg, and P.O.5Y and over: 0.39±0.1 kgf/kg and Lt knee extension; pre-op: 0.40±0.1 kgf/kg, P.O.6M: 0.38±0.1 kgf/kg, P.O.1Y: 0.40±0.1 kgf/kg, P.O.2Y: 0.39±0.1 kgf/kg, and P.O.5Y and over: 0.36±0.1 kgf/kg; Fig.

2f, 2 g).

PRO scores improved postoperatively and was well maintained for more than 5 years postoperatively compared with the preoperative scores (Table 3).

Mid- to long-term postoperative comparison of the H and L groups of patients with ASD

Regarding physical function, the H group showed inferior performance than that shown by the L group more than 5 years postoperatively. The 6MWD was notably different between the two groups within the 2-year postoperative time points; however, there was no similar difference in the more than 5 years postoperative scores between the groups (Fig. 3a). Gait assessment showed no significant difference in TUG and 10MWT results between the groups (Fig. 3b, 3 c). Notably, the PRO scores improved postoperatively from the preoperative time point, regardless of patient age, and remained favorable for more than 5 years postoperatively (Table 3).

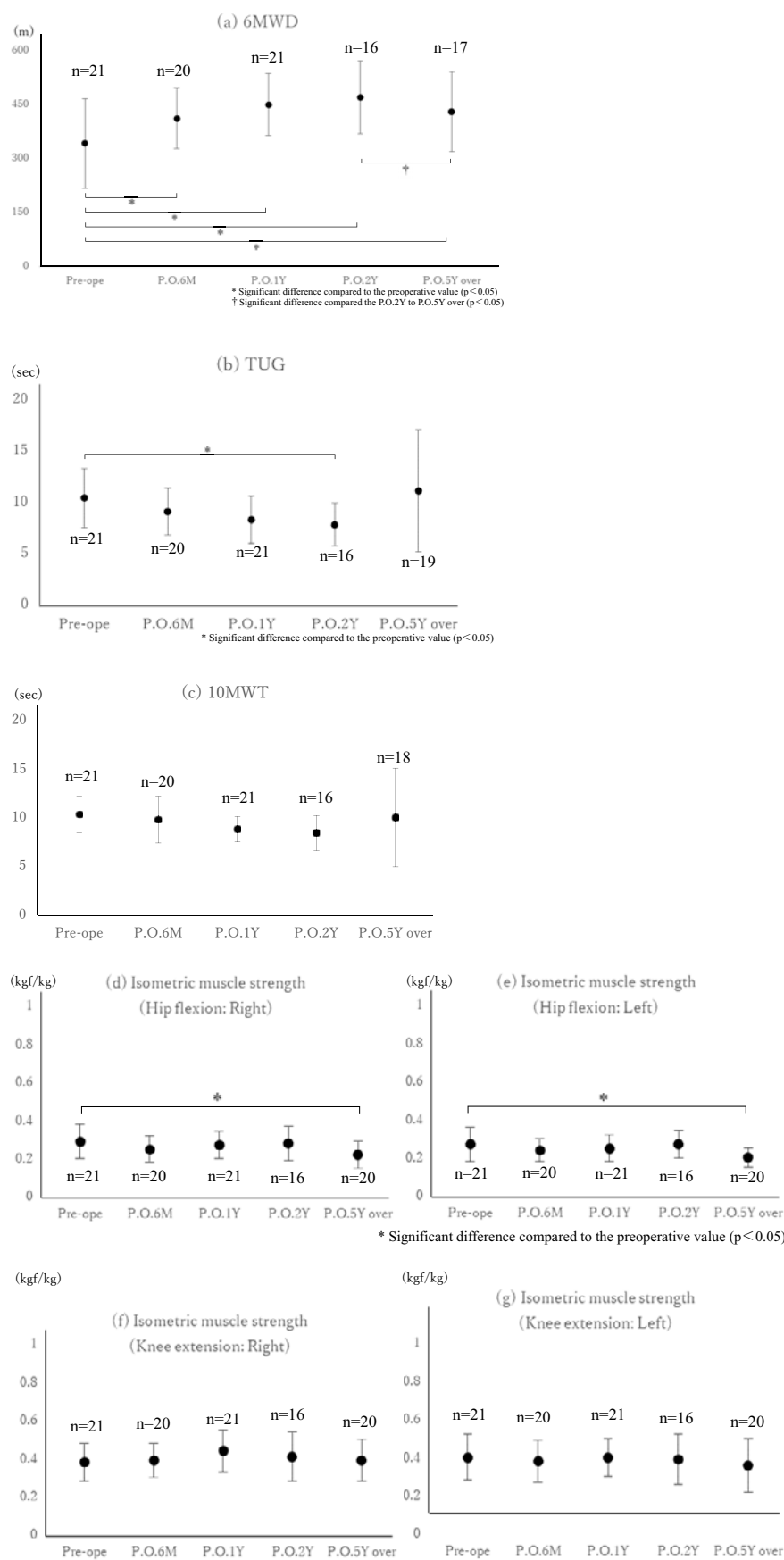


Figure 2. Change in physical function results over time from the preoperative assessment to more than 5 years postoperative assessment. (a): The 6-m walking distance results. (b): The time up and go test results. (c): The 10-m walking test results. (d), (e): Isometric muscle strength of the hip flexion. (f), (g): Isometric muscle strength of the knee extension muscle.

Table 3. Average PRO Measurements for Patients with Adult Spinal Deformity, from Preoperative to 5 Years after Surgery.

	Before surgery	6 months after surgery	1 year after surgery	2 years after surgery	More than 5 years after surgery
All study patients					
ODI	37.7±11.9	28.0±16.0*	25.8±15.6 [†]	24.3±18.1 [†]	22.2±18.6 [†]
SRS function	2.6±0.7	3.0±0.6	3.3±0.8 [†]	3.3±0.7 [†]	3.4±0.9 [†]
Pain	3.1±0.8	3.7±0.9*	3.8±0.8*	3.9±0.9 [†]	3.8±1.0*
Self-image	1.8±0.5	3.5±0.6 [†]	3.6±0.6 [†]	3.4±0.6 [†]	3.3±0.6 [†]
Mental health	2.8±1.0	3.4±0.8*	3.6±0.8 [†]	3.4±0.8*	3.5±1.0 [†]
Satisfaction	3.2±0.8	3.7±0.6*	3.7±0.7*	3.7±0.7	3.6±1.0
Subtotal	2.6±0.6	3.4±0.6 [†]	3.6±0.6 [†]	3.5±0.6 [†]	3.5±0.8 [†]
Total	2.6±0.5	3.4±0.5 [†]	3.6±0.6 [†]	3.5±0.6 [†]	3.5±0.8 [†]
H group					
ODI	40.4±13.4	31.4±16.8	29.8±18.6	30.9±21.8	28.9±23.1
SRS function	2.3±0.7	2.8±0.7	3.0±0.8	3.0±0.6	3.1±1.1
Pain	3.2±1.0	3.8±1.1	3.7±0.9	3.5±1.1	3.5±1.4
Self-image	1.6±0.4	3.6±0.7	3.3±0.4	3.4±0.5	3.3±0.8
Mental health	2.6±1.0	3.3±1.1	3.4±1.0	3.2±0.9	3.3±1.4
Satisfaction	3.5±0.9	3.6±0.6	3.4±0.5	3.5±0.4	3.3±0.9
Subtotal	2.4±0.7	3.4±0.7 [†]	3.4±0.6 [†]	3.3±0.7 [†]	3.3±1.1 [†]
Total	2.5±0.6	3.4±0.6 [†]	3.4±0.6 [†]	3.3±0.6 [†]	3.3±1.0 [†]
L group					
ODI	35.3±10.3	24.8±15.4*	22.1±12.0 [†]	18.4±11.9 [†]	16.1±11.2 [†]
SRS function	2.9±0.6	3.1±0.6	3.7±0.8	3.6±0.8	3.7±0.5
Pain	3.0±0.5	3.6±0.7	4.0±0.7	4.3±0.6	4.2±0.6
Self-image	2.0±0.6	3.5±0.6	3.8±0.7	3.5±0.7	3.2±0.4
Mental health	3.0±1.1	3.5±0.7	3.7±0.7	3.7±0.6	3.7±0.6
Satisfaction	2.8±0.8	3.9±0.7	4.2±0.9	3.9±0.9	3.9±1.1
Subtotal	2.7±0.4	3.4±0.4 [†]	3.8±0.6 [†]	3.7±0.6 [†]	3.6±0.4 [†]
Total	2.7±0.3	3.5±0.4 [†]	3.8±0.6 [†]	3.7±0.6 [†]	3.7±0.5 [†]

H group: patients over 75, over 5 years after surgery; L group: patients under 75, over 5 years after surgery.

Values are presented as mean±standard deviation.

ODI, Oswestry Disability Index; SRS, Scoliosis Research Society-22

*Significant difference compared to the preoperative value ($p<0.05$).

[†]Significant difference compared to the preoperative value ($p<0.01$).

Discussion

To our knowledge, this study is the first to assess the progression of physical function and PRO scores in patients with ASD from the preoperative period to more than 5 years postoperatively. The results indicated that patients with ASD showed improvement in their walking ability and experienced less back pain during motion. Specifically, the 6MWD significantly improved from the preoperative measurement point. In addition, good QOL was maintained in the mid- to long-term as spinal alignment improved postoperatively. Studies on the elderly have shown significant decline in muscle strength with age. In particular, decreased knee extensor strength is associated with reduced walking ability in the elderly¹⁶. Notably, there was no significant decrease in postoperative knee extensor strength in patients with ASD after more than 5 years postoperatively. Knee extensor strength has been reported to influence overall functional ability in late-life patients aged 75 years or older¹⁷. Thus, maintaining knee extensor muscle strength may impact

walking ability and maintain QOL.

In contrast, there was a significant reduction in hip flexion strength more than 5 years after ASD surgery compared with preoperative measurements. The two possible explanations are as follows: The first is the method of surgical fixation and the specific orientation of the muscle strength assessment. With extensive fixation from the thoracic spine to the ilium, patients are immobilized in a LL and anterior PT position, necessitating the assessment of isometric hip flexor strength in the seated position. Therefore, this assessment position may have contributed to the reduced hip flexor strength presentation. The second may be the influence of generalized muscular weakness resulting from aging. The significant improvement in the 6MWD was evident from the preoperative phase to the 2-year postoperative mark. This phenomenon suggests that improving spinal misalignment with surgery may have contributed to the observed increase in walking distance. However, there was a significant decrease in the 6MWD at more than 5 years postoperatively, accompanied by significant decrease in hip

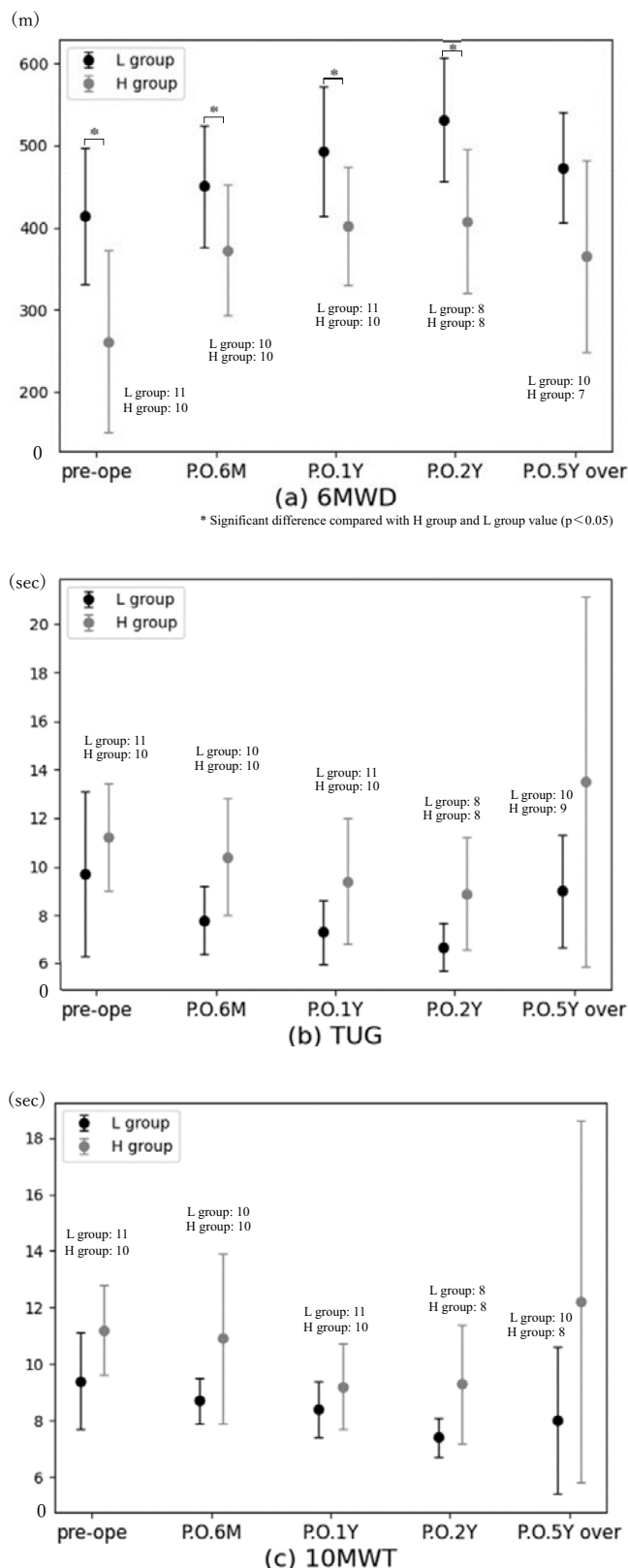


Figure 3. Mid- to long-term postoperative comparison of the H and L groups in patients with ASD.

(a): The 6-m walking distance results between the H and L group. (b): The time up and go test results. (c): The 10-m walking test results. H, high elderly; L, low elderly

flexor strength. In human gait, the role of the psoas muscle in hip flexion is considered important because it is the driv-

ing force for the forward swing of the leg¹⁸⁾. In older women, there was a significant correlation between the psoas major muscle strength, walking speed, and stride length, and it was suggested that a decrease in muscle mass leads to a decrease in stride length, which ultimately leads to a decrease in walking speed¹⁶⁾. Walking distance showed improvement up to 2 years postoperatively, but at the more than 5 years postoperative follow-up, walking ability may decrease due to age-related muscle weakness. Regarding spinal deformity treatment among the elderly, long-term postoperative follow-up and individualized rehabilitation programs that consider the physical changes associated with aging are important.

After ASD surgery, patients experienced improvements in back pain during motion, which corresponded to improvements in spinal alignment. Yagi et al. noted that many patients with ASD have prolonged period of inactivity prior to surgery, resulting in decreased muscle strength and power¹⁹⁾. Postoperatively, changes in spinal-pelvic alignment may have improved low back pain during exercise by altering the biomechanics of the spine. This pattern is emblematic of the improvement in ambulatory ability observed following corrective surgery for ASD. The results of this study showed significant improvement in the 6MWD postoperatively compared with the preoperative results. However, there was no improvement in the 10MWT and TUG. The 6MWD evaluates both endurance and holistic physiological capacity¹²⁾. In contrast, the 10MWT assesses the walking speed over a short distance, while the TUG score quantifies the speed of multiple functional maneuvers^{10,11)}. Patients with ASD are characterized by neurological symptoms such as intermittent claudication, decreased walking ability, and pain during walking due to spinal deformity^{20,21)}. The improvement in back pain during exercise and reduction in neurological symptoms due to improved spinal alignment may have facilitated endurance during long-distance walking and improved mid- to long-term walking ability.

In this study, although walking ability declined following ASD surgery, QOL remained well-preserved, and the observed results were inconsistent. The QOL assessment was specific to ASD-related problems, such as back pain with movement and posture-related issues, and may account for factors other than physical function that were observed in the preoperative period. In addition, there is high incidence of complications after ASD surgery²²⁾. Since few participants were followed up for the mid- to long-term, the impact of these complications is unclear. However, although many rod fractures occurred, they did not affect walking assessment, suggesting that complications had little impact on the results. More than 5 years after surgery for ASD, the patients developed new diseases, such as heart disease, mental disorders, and osteoarthritis of the knee. Physical function declined after ASD surgery, possibly due to aging or the development of other chronic diseases²³⁾, which may have affected the walking ability.

This study has potential limitations. First, only half of the

participants could be followed up for more than 5 years postoperatively. Of 47 participants, 26 were excluded from the study. This does not indicate poor postoperative outcomes. Geographic distance from the medical facility, not clinical results, primarily hindered follow-up. Second, comorbidities in elderly participants limited long-term tracking. This might have led to follow-up bias toward those with better progression. Finally, the small sample size and lack of a control group can reduce the validity of the observed results. Tracking and comparing spinal alignment and physical function in older individuals of the same age group in the future could enhance these findings. Despite these limitations, the strength of this study lies in its ability to assess physical function longitudinally.

To conclude, patients with ASD showed sustained improvements in walking ability and PROs for more than 5 years postoperatively. Older patients had reduced walking ability, but their postoperative PRO scores remained good for more than 5 years postoperatively, irrespective of age. This provides hope for elderly patients with ASD, as surgery can enhance their QOL.

Conflicts of Interest: A Yu Yamato, Shin Oe and Tomohiko Hasegawa work at a donation-endowed laboratory in the Division of Geriatric Musculoskeletal Health. Source of funding are listed below: Medtronic Sofamor Danek Inc., Japan Medical Dynamic Marketing Inc., and Meitoku Medical Institution Jyuzen Memorial Hospital

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Author Contributions: All authors contributed to the study conception and design. Masahiro Sawada performed material preparation and data collection and analysis. Masahiro Sawada wrote the first draft of the manuscript and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethical Approval: This study was approved by the institutional review board of Hamamatsu University School of Medicine (Approval Research No. 21-190).

Informed Consent: The participants were informed of the objectives and methodology of the research in detail, and informed consent was obtained before the assessments began.

Data Availability Statement: The datasets generated and/or analyzed during this study are available from the corresponding author on reasonable request.

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