Long-Term Health-Related Quality of Life After Harrington Instrumentation and Fusion for Adolescent Idiopathic Scoliosis

A Minimum 40-Year Follow-up

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Background: Despite its importance for clinical decisions, the long-term consequences of posterior spinal instrumentation and fusion (PSIF) for adolescent idiopathic scoliosis (AIS), particularly in the lower lumbar spine, remain unclear. This study evaluates the long-term health-related quality of life and the need for a further surgical procedure in patients treated with Harrington instrumentation from 1961 to 1977 according to the lowest instrumented vertebra (LIV) and in comparison with age-matched norms.

Methods: A search was performed to identify and contact the 314 identified patients with AIS treated with PSIF by Dr. L.A. Goldstein. The assessment included identified subsequent spine surgery, the Oswestry Disability Index (ODI), Scoliosis Research Society-7 (SRS-7), EuroQol-5 Dimensions (EQ-5D), and Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29). The health-related quality of life was compared with U.S. norms and, within the cohort, was compared by patient factors, LIV, and subsequent spine surgery.

Results: In this study, 134 patients (42.7%) were identified; 24 (7.6%) had died, 81 (25.8%) consented to participate in the study, and 29 (9.2%) declined participation. The mean follow-up was 45.4 years (range, 40 to 56 years). There were 81 patients who completed the surveys, 77 patients who completed the SRS-7, 77 patients who completed the ODI, and 76 patients who completed the PROMIS-29 and EQ-5D. There were 12.8% of patients with LIV L3 or proximal and 36.4% with LIV L4 or distal who had an additional surgical procedure (odds ratio, 3.98). Comparing the ODI of patients who had undergone an additional surgical procedure with those who had not showed 42% and 73% minimal disability, 53% and 23% moderate disability, and 5% and 2% severe disability. Of the patients who had not undergone an additional surgical procedure, those with LIV L3 or proximal had mean scores of 14.12 points for the ODI and 23.3 points for the SRS-7 and those with LIV L4 or distal had mean scores of 17.9 points for the ODI and 22.7 points for the SRS-7; these differences were not significant. The mean PROMIS-29 and EQ-5D scores were not different from normal U.S. age-based means.

Conclusions: Patients with AIS treated with PSIF at a mean 45-year follow-up and LIV L4 or distal had a higher rate of undergoing an additional surgical procedure than those with LIV L3 or proximal. Patients undergoing an additional surgical procedure had lower health-related quality of life than those who did not. Despite this, there was no difference in health-related quality of life for patients with LIV L4 or distal compared with patients with LIV L3 or proximal. This cohort of patients with AIS treated with PSIF demonstrates normal self-reported health-related quality of life compared with the age-matched general population. These long-term outcomes of PSIF for AIS are encouraging.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Harrington developed the first successful instrumentation, composed of rods and hooks, to correct scoliosis by distraction and, with further development, compression. After reporting his early results in 1962[1], the technique was adopted by other surgeons[2-5], with improved results compared with prior procedures[6]. Despite the success in improving scoliosis curves

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and obtaining successful fusion, 2 principal issues have arisen, neither fully understood. First, how does a fusion resulting in a straighter spine with limited motion change patient function in the long term? Second, does Harrington instrumentation extending into the lumbar spine with correction by distraction and resultant lumbar flattening result in poor long-term outcomes[7,8]? A 2015 systematic review and meta-analysis of medium-term, 20-year follow-up was unable to confirm or refute an association between lower levels of instrumentation and increasing pain or disability[9].

Louis A. Goldstein adopted Harrington instrumentation around 1960, publishing his experience in 1966[4]. Records and radiographs are, with few exceptions, extant. His patients are the basis of this study evaluating the long-term health-related quality of life after Harrington instrumentation and fusion for adolescent idiopathic scoliosis (AIS) according to the lowest instrumented vertebrae (LIV).

Materials and Methods

Study Cohort

Through outpatient and hospital records, we identified all patients with AIS treated with Harrington instrumentation and fusion between 1961 and 1977 by Dr. Goldstein. The original radiographs and medical records were reviewed to identify patient demographic characteristics, etiology, treatment, and radiographic measurements, including the lowest level of instrumentation.

With institutional review board approval, subjects were located by reviewing the current medical records if still within the University of Rochester system and online search engines for the others. The National Death Index was queried for any patients not located.

Study Measurements

Existing radiographs and clinical and operative notes from the entire cohort were reviewed. All available preoperative and postoperative radiographs were individually reviewed, digitized, and placed into a research repository. LIV and preoperative radiographic parameters were determined through initial non-digital postoperative radiographs (Fig. 1). We recorded the preoperative and postoperative residual Cobb angles, the thoracic and lumbar apices, and the fused levels, including the LIV. Radiographs were measured using Surgimap measurement

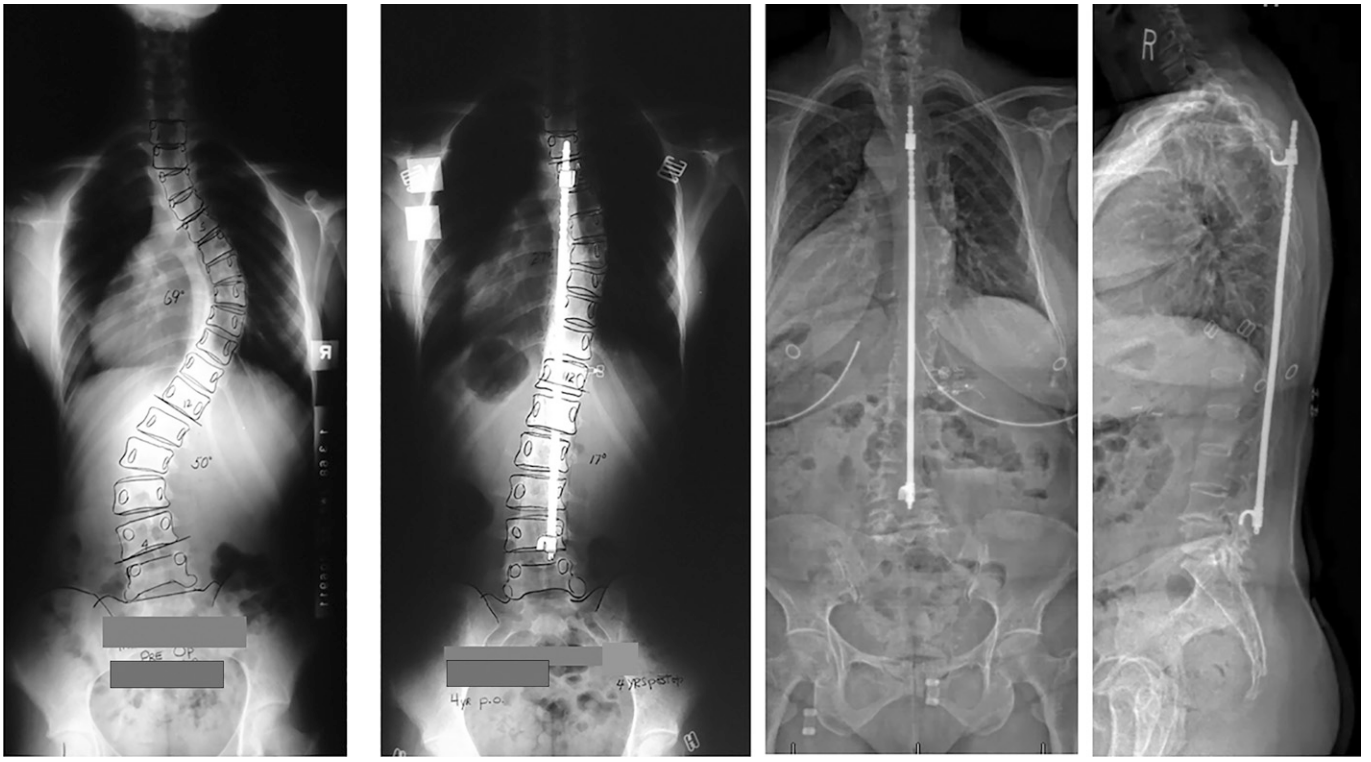

Fig. 1

A series of radiographs of a patient with instrumentation and fusion from T4 to L4. (Early lateral preoperative or postoperative radiographs rarely exist.) Despite the superior junctional kyphosis and lumbar flatback, the ODI was 2 (minimal disability), the SRS-7 was 86.2 (of 100), and the PROMIS-29 physical function was 48 and pain interference was 52, which are all within the normal limits at the 49-year follow-up. The markings on the early radiographs were on the originals. **Fig. 1-A** A preoperative anteroposterior radiograph showing a 69° thoracic curve and a 50° lumbar curve. **Fig. 1-B** An anteroposterior radiograph showing excellent correction and LIV of L4 at 4 years postoperatively. **Fig. 1-C** An anteroposterior radiograph showing maintained correction at 49 years postoperatively. **Fig. 1-D** A lateral radiograph showing superior junctional kyphosis, lumbar flattening, and L5-S1 degenerative changes at 49 years postoperatively.

TABLE I The Instruments and History Obtained from Patients*

Type of Instrument	Instrument/Data
Health status	Rochester Health Questionnaire
	PROMIS-29
	EQ-5D
	Iowa Medical History
Disease-specific	ODI
	SRS-7
	Modified Medical Research Council Dyspnea Scale
Personal history	Date of birth
	Sex
	Consent
	Occupation
Medical history	Detailed cardiac history
	Detailed pulmonary history
	Diabetes
	Cancer
	Smoking status
	Alcohol use
	Additional spine surgery

*Only those measurements specified in the Materials and Methods section were reported in this article.

software (Nemaris). The LIV was identified by 2 investigators (S.T.L. and A.S.) and was confirmed by the senior investigator (J.O.S.) and was cross-referenced with office records and operative reports.

Patients were mailed invitations to accept or decline study participation or to be contacted. All willing participants were contacted by telephone or mail, based on their preference, and invited to participate by mail or a visit for further assessment including functional outcome scores, spine radiographs, and pulmonary function tests. Patients could elect or decline to participate in any or all aspects of the study protocol. Patients who agreed to participate were sent the instruments shown in Table I, which they either returned by mail or completed during a visit. This portion of the study focuses solely on patient-reported outcomes according to the LIV.

Outcomes

The 4 patient-reported outcome measures used in this study were: (1) individual domain T-scores from the Patient-Reported Outcomes Measurement Information System-29 (PROMIS-29), which included continuous measures for anxiety, depression, fatigue, pain interference, physical function, sleep disturbance, and satisfaction with social roles[10,11]; (2) the EuroQol-5 Dimensions (EQ-5D), which included binary indicator outcomes for problems with mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, and continuous measures representing the overall health rating and an index value for the health state[12-14]; (3) the Oswestry Disability Index[15] (ODI); and (4) the Scoliosis Research Society-7 (SRS-7), a short, valid, unidimensional instrument with superior psychometrics to the SRS-22 instrument[16-18]. The EQ-5D overall health rating and the index value for health state were compared with U.S. population-based norms of individuals with similar age. The key disease-specific outcomes were the composite scores from the ODI and the SRS-7.

Key Independent Variable

The key independent variables were binary indicators of LIV L3 or proximal compared with L4 or distal and whether the patient underwent an additional spine surgery.

Covariates

Our analysis controlled for patient-level covariates such as age at the time of the surgical procedure, sex, subsequent spine surgery, number of vertebrae fused, clinical comorbidities, major profession, history of tobacco and alcohol use, marital status, and whether the patient had children.

Statistical Analysis

For unadjusted analysis, we used chi-square tests for categorical variables, Kruskal-Wallis tests for continuous variables to examine the distribution of outcomes and characteristics across the key independent variables, and t tests to compare the EQ-5D overall health rating and index value with age-based norms[14]. In adjusted analysis, we estimated separate multivariable linear and logistic regression models to estimate the association between the patient scores and age-based norms with regard to the LIV and additional spine surgery with the outcomes of interest.

Source of Funding

There was no source of funding for this study.

Results

Of the 314 patients with AIS identified, 134 patients (42.7%) or their families responded; of the 314 patients, 24 (7.6%) had died, 81 (25.8%) agreed to participate in our study, and 29 (9.2%) declined to participate. Of the 80 patients who were analyzed, 70 (87.5%) were female. The mean follow-up was 45.4 years (range, 40 to 56 years), and the mean patient age at follow-up was 60 years (median, 60.5 years [range, 52 to 72 years]).

There were 81 patients who completed the surveys, 77 patients who completed the SRS-7, 77 patients who completed the ODI, and 76 patients who completed the PROMIS-29 and EQ-5D. There were 12.8% of patients with LIV L3 or proximal and 36.4% with LIV L4 or distal who underwent an additional surgical spine procedure (odds ratio, 3.98). Comparing the ODI of patients who had undergone an additional surgical procedure with that of patients who had not showed 42% and 73% minimal disability, 53% and 23% moderate disability, and 5% and 2% severe disability. Of the patients who had not undergone an additional surgical procedure, those with LIV L3 or proximal had mean scores of 14.12 points for the ODI and 23.3 points for the SRS-7 and those with LIV L4 or distal had mean scores of 17.9 points for the ODI and 22.7 points for the

TABLE II Patient Characteristics Based on Level of Fusion to L3 or Proximal and L4 or Distal

Characteristics	L3 or Proximal (N = 47)	L4 or Distal (N = 33)	Total (N = 80)	P Value
Age at surgery* *(yr)*	15.31 ± 4.67	14.97 ± 1.89	15.17 ± 3.77	0.69
Age at follow-up* *(yr)*	60.23 ± 10.15	59.26 ± 4.96	59.83 ± 8.38	0.08
Female sex†	41 (87.23%)	29 (87.88%)	70 (87.5%)	0.83
≥1 comorbidities†	36 (76.60%)	23 (69.70%)	59 (73.75%)	0.78
Major profession†				0.77
Professional	30 (63.83%)	20 (60.61%)	50 (62.50%)	
Other (including factory, homemaker, manual labor)	9 (19.15%)	6 (18.18%)	15 (18.75%)	
History of tobacco use†	12 (25.53%)	10 (30.30%)	22 (27.50%)	0.81
Alcohol consumption per week†				0.15
None	24 (51.06%)	9 (27.27%)	33 (41.25%)	
<6 drinks	18 (38.30%)	17 (51.52%)	35 (43.75%)	
6 to 12 drinks	1 (2.13%)	4 (12.12%)	5 (6.25%)	
12‡ to 24 drinks	2 (4.26%)	1 (3.03%)	3 (3.75%)	
Married†	26 (55.32%)	25 (75.76%)	51 (63.75%)	0.14
Have children†	33 (70.21%)	25 (75.76%)	58 (72.50%)	0.71
LIV†				
T12	3 (6.38%)	0 (0.00%)	3 (3.75%)	
L1	25 (53.19%)	0 (0.00%)	25 (31.25%)	
L2	11 (23.40%)	0 (0.00%)	11 (13.75%)	
L3	8 (17.02%)	0 (0.00%)	8 (10.00%)	
L4	0 (0.00%)	29 (87.88%)	29 (36.25%)	
L5	0 (0.00%)	4 (12.12%)	4 (5.00%)	
No. of levels fused*	8.62 ± 1.38	10.06 ± 2.32	9.21 ± 1.95	

*The values are given as the mean and the standard deviation †The values are given as the number of patients, with the percentage in parentheses ‡The overlap of 12 drinks appeared in the original survey.

SRS-7; these differences were not significant. The mean PROMIS-29 and EQ-5D scores were not different from normal U.S. age-based means.

Unadjusted and Descriptive Results

The mean age at the time of the surgical procedure was 15.2 years. Of the 80 patients with an identifiable LIV, 47 (58.75%) had fusion to L3 or proximal and 33 (41.25%) had fusion at L4 or distal (Table II). The mean number of levels fused (and standard deviation) was greater for the group with LIV of L4 or distal (10.06 ± 2.32) compared with those with LIV of L3 or proximal (8.62 ± 1.38) ($p < 0.001$). At the time of the survey completion, 73.75% of patients reported ≥1 comorbidities, 62.50% reported that they had worked in a professional job, 27.50% reported tobacco use, 43.75% reported consuming <6 alcoholic drinks a week, 63.75% were married, and 74.3% of women had children. There were no significant differences in these characteristics between those with LIV of L3 or proximal compared with those with LIV of L4 or distal. There were no significant differences in the health-related quality of life, including PROMIS-29 and EQ-5D outcomes and disease-specific outcomes, between the L3 or proximal group and the L4 or distal group (Table III), although the L4 or distal group had a higher probability of an additional spine surgery (36.36% compared with 12.77%; $p = 0.01$).

Adjusted, Multivariable Results

Using age-based norms for the EQ-5D[14] overall health rating and the index value for health state, the Goldstein cohort had no significant differences compared with the population-based means. PROMIS-29 scores according to comorbidities, fusion levels, and other factors are shown in Table IV. ODI and SRS-7 scores are shown in a similar fashion in Table V. After adjusting for relevant confounders, we found no significant differences in any health-related quality-of-life outcomes between the LIV groups or according to the need for an additional spine surgery. The ODI total score was 9.10 points (95% confidence interval [CI], 1.07 to 17.13 points; $p = 0.03$) higher, and the SRS-7 score was 10.40 points (95% CI, 0.86 to 19.93 points) lower ($p = 0.03$) among those who underwent an additional spine surgery compared with those who did not. Comorbidities were strongly correlated with poorer ODI and SRS-7 scores. Alcohol

TABLE III Health-Related Quality of Life and Need for Further Surgery According to Level of Instrumentation and Fusion

	L3 or Proximal (N = 47)	L4 or Distal (N = 33)	Total (N = 80)	P Value
PROMIS outcomes* *(points)*				
Anxiety	47.25 ± 8.70	47.42 ± 9.43	47.32 ± 8.95	0.96
Depression	46.12 ± 7.24	45.33 ± 8.87	45.79 ± 7.91	0.46
Fatigue	46.67 ± 11.26	48.62 ± 11.31	47.49 ± 11.25	0.50
Pain interference	51.65 ± 9.53	50.98 ± 9.11	51.37 ± 9.30	0.69
Physical function	47.29 ± 8.61	46.58 ± 7.41	46.99 ± 8.09	0.74
Sleep disturbance	55.84 ± 2.27	55.63 ± 3.01	55.75 ± 2.58	0.94
Satisfaction with social roles	55.26 ± 8.08	54.93 ± 8.73	55.14 ± 8.24	0.95
EQ-5D outcomes†				
Problems with mobility‡	19 (43.18%)	14 (45.16%)	33 (44.00%)	0.86
Problems with self-care‡	6 (13.33%)	4 (12.90%)	10 (13.16%)	0.96
Problems with usual activities‡	21 (46.67%)	11 (35.48%)	32 (42.11%)	0.33
Problems with pain/discomfort‡	32 (71.11%)	24 (77.42%)	56 (73.68%)	0.54
Problems with anxiety/depression‡	17 (37.78%)	10 (32.26%)	27 (35.53%)	0.62
Overall health rating*	82.36 ± 17.39	82.13 ± 12.16	82.26 ± 15.38	0.39
Index value for health state*	0.82 ± 0.13	0.83 ± 0.11	0.82 ± 0.12	0.82
ODI total score*	14.87 ± 15.67	15.46 ± 14.60	15.11 ± 15.15	0.6
ODI score disability category†				0.91
Minimal disability	30 (63.83%)	20 (60.61%)	50 (62.50%)	
Moderate disability	13 (27.66%)	10 (30.30%)	23 (28.75%)	
Severe disability	1 (2.13%)	1 (3.03%)	2 (2.50%)	
Crippled§	1 (2.13%)	0 (0.00%)	1 (1.25%)	
Missing data	2 (4.26%)	2 (6.06%)	4 (5.00%)	
SRS-7 total score*	60.29 ± 21.93	56.47 ± 18.04	58.70 ± 20.37	0.42
Additional spine surgery‡	6 (12.77%)	12 (36.36%)	18 (22.50%)	0.01

*The values are given as the mean and the standard deviation †Any value below the top score of no problem with the domain was recorded as the percentage of patients expressing the problem to any degree; there were missing responses from some patients, so the denominators used to obtain the percentages do not match the column totals ‡The values are given as the number of patients, with the percentage in parentheses. §This is the term used in the ODI.

consumption was associated with better scores, although only 8 subjects reported consuming ≥6 drinks per week.

Discussion

The evidence base for LIV selection in AIS is poor because studies are unable to control for curve magnitude, rotation, sagittal alignment, or patient factors. Consequently, fusion level decisions are expert opinions with judgment based on the surgeon's impressions of the natural history. Ultimately, the results justifying treatment must be those important to patients, specifically pain and function, which are discernable in current health-related quality-of-life instruments, rather than radiographic appearance. The series by Danielsson et al. of Harrington instrumentation from 1968 to 1972 had at least a 20-year follow-up[19-23]. Our current study represents a substantially longer follow-up of a similar cohort and uses modern, validated, patient-reported outcome instruments.

Since the study in 1983 by Cochran et al.[24] with 9-year follow-up on 100 patients with Harrington instrumentation revealed that 75% of patients fused to L5 had pain compared with 25% of those fused to L1, there has been concern that lumbar fusion may create subsequent back problems. A subsequent description of Harrington instrumentation-generated lumbar flatback[7] raised concerns and emphasized the importance of preserving lumbar lordosis. In a 25-year follow-up on the functional and radiographic outcomes of 61 patients who underwent uninstrumented fusion for scoliosis, Moskowitz et al.[25] found that the low back pain incidence was similar to that of the age-matched population. However, the outcomes at 20 to 25 years for Harrington instrumentation[22,23] found by Danielsson et al. were much more favorable. Because segmental instrumentation with the ability to preserve lumbar lordosis was developed later, the longest follow-up to date of segmental instrumentation is 15 to 20 years[26] and longer study is required to determine whether it prevents subsequent lumbar spine issues.

Goldstein and Evarts[4] reported follow-up of 18 months to 5 years of 107 patients with idiopathic scoliosis treated with

TABLE IV Multiple Logistic Regression of PROMIS Scores in Each Domain Based on Study Variables*

	PROMIS Domains†						
	Physical Function (N = 72‡)	Anxiety (N = 73‡)	Depression (N = 73‡)	Fatigue (N = 72‡)	Sleep Disturbance (N = 67‡)	Social (N = 46‡)	Pain Interference (N = 72‡)
LIV							
L3 or proximal	Reference	Reference	Reference	Reference	Reference	Reference	Reference
L4 or distal	−3.77 (−8.09 to 0.54)	2.23 (−3.09 to 7.55)	0.89 (−3.71 to 5.49)	4.97 (−1.19 to 11.13)	−0.38 (−1.74 to 0.98)	−1.53 (−7.42 to 4.37)	−0.13 (−5.18 to 4.92)
Age at surgery	0.18 (−0.31 to 0.66)	−0.21 (−0.83 to 0.41)	−0.26 (−0.80 to 0.27)	−0.18 (−0.88 to 0.52)	−0.06 (−0.21 to 0.10)	0.25 (−0.43 to 0.92)	−0.37 (−0.95 to 0.21)
Additional spine surgery							
No	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Yes	−2.33 (−6.90 to 2.24)	3.5 (−2.38 to 9.37)	2.52 (−2.56 to 7.60)	3.74 (−2.88 to 10.37)	−0.58 (−1.98 to 0.82)	−4.06 (−11.47 to 3.35)	1.95 (−3.57 to 7.48)
Sex							
Male	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Female	−1.28 (−7.80 to 5.24)	−2.08 (−10.35 to 6.18)	−2.23 (−9.38 to 4.91)	0.34 (−8.40 to 9.09)	−0.06 (−2.24 to 2.13)	−1.26 (−9.34 to 6.82)	−0.95 (−9.13 to 7.24)
No. of levels fused	0.01 (−1.00 to 1.02)	−0.62 (−1.90 to 0.67)	−0.44 (−1.55 to 0.67)	−0.79 (−2.24 to 0.67)	−0.26 (−0.56 to 0.05)	−0.44 (−1.82 to 0.94)	0.71 (−0.51 to 1.93)
Comorbidities							
None	Reference	Reference	Reference	Reference	Reference	Reference	Reference
≥1	−5.27§ (−9.84 to −0.69)	1.18 (−4.43 to 6.79)	2.48 (−2.37 to 7.33)	5.57 (−0.83 to 11.97)	−0.77 (−2.12 to 0.59)	−4.33 (−10.93 to 2.26)	4.29 (−0.98 to 9.57)
Major profession							
Factory	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Homemaker	1.69 (−16.90 to 20.29)	7.11 (−16.84 to 31.05)	−2.44 (−23.13 to 18.26)	−25.9 (−52.85 to 1.06)	−11.11# (−16.64 to −5.58)	0 (0.00 to 0.00)	−12.08 (−34.57 to 10.42)
Manual laborer or farmer	1.17 (−18.32 to 20.67)	6.16 (−18.94 to 31.25)	−6.12 (−27.82 to 15.57)	−13.34 (−41.61 to 14.93)	−11.02# (−16.83 to −5.22)	0 (0.00 to 0.00)	−5.02 (−28.59 to 18.54)
Professional	3.08 (−14.33 to 20.49)	5.56 (−16.81 to 27.92)	−0.86 (−20.19 to 18.47)	−28.80§ (−54.02 to −3.58)	−10.74# (−16.02 to −5.46)	7.19 (−8.92 to 23.30)	−12.45 (−33.51 to 8.60)
Other	5.66 (−11.19 to 22.51)	8.15 (−13.55 to 29.84)	0.21 (−18.54 to 18.97)	−27.61§ (−52.01 to −3.21)	−11.60# (−16.65 to −6.56)	2.72 (−11.08 to 16.53)	−11.96 (−32.32 to 8.41)
History of tobacco use							
No	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Yes	−2.63 (−6.98 to 1.72)	0.79 (−4.96 to 6.54)	−0.72 (−5.69 to 4.24)	−5.88 (−12.17 to 0.42)	1.05 (−0.28 to 2.38)	−1.03 (−7.31 to 5.24)	1.36 (−4.04 to 6.76)
Alcohol use per week							
None	Reference	Reference	Reference	Reference	Reference	Reference	Reference
<6 drinks	5.23§ (0.87 to 9.58)	−5.07 (−10.53 to 0.39)	−4.7 (−9.43 to 0.02)	−5.92 (−12.06 to 0.21)	0.6 (−0.67 to 1.88)	2.8 (−3.27 to 8.88)	−3.87 (−9.00 to 1.27)
6 to 12 drinks	11.94§ (4.14 to 19.73)	−10.24§ (−20.22 to −0.26)	−9.68§ (−18.31 to −1.05)	−15.37§ (−27.86 to −2.88)	0.73 (−1.59 to 3.04)	15.24** (5.22 to 25.26)	−10.18§ (−19.56 to −0.79)
12†† to 24 drinks	9.67 (−0.61 to 19.96)	−4.33 (−17.58 to 8.92)	4.8 (−6.66 to 16.25)	−0.04 (−14.92 to 14.85)	1.89 (−1.72 to 5.49)	15.14§ (0.14 to 30.15)	−11.69 (−24.17 to 0.78)
Marital status							
No	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Yes	2.74 (−2.18 to 7.66)	−0.27 (−6.59 to 6.05)	−0.32 (−5.78 to 5.15)	−5.71 (−12.89 to 1.47)	−1.62§ (−3.16 to −0.07)	1.14 (−6.14 to 8.43)	−5.7 (−11.64 to 0.23)
Have children							
No	Reference	Reference	Reference	Reference	Reference	Reference	Reference
Yes	−1.96 (−7.39 to 3.47)	0.53 (−6.67 to 7.73)	5.02 (−1.21 to 11.25)	8.50§ (0.65 to 16.34)	2.83** (1.12 to 4.54)	−5.94 (−15.09 to 3.22)	3.47 (−3.33 to 10.26)

*The results are given as the difference relative to the reference category †The values are given as the estimate, with the 95% CI in parentheses ‡The differences in number of patients for each category compared with the overall number of patients reported in the text were due to items not being answered on either the demographic questionnaire or the health-related quality-of-life questionnaire §Significant at $p < 0.05$ #Significant at $p < 0.001$ **Significant at $p < 0.01$ ††This overlap appears in the original questionnaire.

TABLE V Multiple Logistic Regression of SRS-7 and ODI Scores Based on Study Variables*

	ODI Total Score† (N = 73‡)	SRS-7 Score† (N =73‡)
LIV		
L3 or proximal	Reference	Reference
L4 or distal	0.85 (−6.50 to 8.21)	−5.25 (−13.98 to 3.48)
Age at surgery	−0.97§ (−1.82 to 0.13)	1.18§ (0.17 to 2.19)
Additional spine surgery		
No	Reference	Reference
Yes	9.10§ (1.07 to 17.13)	−10.40§ (−19.93 to −0.86)
No. of levels fused	0.77 (−1.00 to 2.54)	−0.94 (−3.04 to 1.16)
Sex		
Male	Reference	Reference
Female	1.13 (−9.50 to 11.76)	1.95 (−10.67 to 14.57)
Comorbidities		
None	Reference	Reference
≥1	10.37§ (2.61 to 18.13)	−17.77# (−26.98 to −8.55)
Major profession		
Factory	Reference	Reference
Homemaker	−6.28 (−40.61 to 28.04)	1.62 (−39.12 to 42.37)
Manual laborer or farmer	−1.78 (−34.48 to 30.91)	−3.10 (−41.92 to 35.72)
Professional	−16.96 (−46.57 to 12.64)	8.02 (−27.12 to 43.17)
Other	−15.13 (−45.75 to 15.48)	13.19 (−23.15 to 49.53)
Tobacco use		
No	Reference	Reference
Yes	4.31 (−3.34 to 11.95)	−1.98 (−11.06 to 7.10)
Alcohol use per week		
None	Reference	Reference
<6 drinks	−7.87** (−15.32 to −0.41)	9.43§ (0.58 to 18.28)
6 to 12 drinks	−15.88§ (−29.57 to −2.18)	22.43§ (6.17 to 38.69)
12†† to 24 drinks	−27.61§ (−45.70 to −9.52)	23.61§ (2.13 to 45.08)
Marital status		
No	Reference	Reference
Yes	−2.01 (−10.70 to 6.67)	3.91 (−6.40 to 14.22)
Have children		
No	Reference	Reference
Yes	3.13 (−6.40 to 12.66)	−5.38 (−16.69 to 5.94)

*The results are given as the difference relative to the reference category †The values are given as the estimate, with the 95% CI in parentheses ‡The differences in the number of patients from the overall number of patients reported in the text were due to items not being answered on either the demographic questionnaire or the health-related quality-of-life questionnaire §Significant at $p < 0.05$ #Significant at $p < 0.001$ **Significant at $p < 0.01$ ††The overlap of 12 drinks appears in the original questionnaire.

Harrington instrumentation and fusion in 1966, although not all patients had AIS. Goldstein separately described his LIV selection as the first neutral vertebra at or distal to the end vertebra[5]. This is identical to the LIV recommended by King et al.[3] and formed the basis for their concept of the stable vertebrae. We have no evidence that Goldstein changed his approach throughout this series[5]. The Goldstein archive is a unique cohort of patients undergoing treatment of AIS from the early years of Harrington instrumentation. This cohort now ranges in age from 52 to 72 years and the surgical follow-up is between 40 and 56 years at the time of this study.

In our Goldstein cohort, 12.8% of patients with LIV at L3 or proximal had an additional spine surgery compared with 36.4% of patients with LIV at L4 or distal. Functional outcome scores from both the ODI and SRS-7 demonstrated that instrumentation to L4 or distal resulted in a higher level of disability compared with those L3 or proximal, although neither the ODI scores nor the SRS-7 achieved significance.

Patients with instrumentation ending at LIV L3 or proximal had a higher percentage of patients with a minimum disability (73%), and those with instrumentation to L4 or distal had significantly higher percentages of patients with both moderate disability at 53% and severe disability at 5%. Unfortunately, although commonly used in long-term scoliosis studies, the ODI does not have population or non-scoliotic comparators[27]. In a comparison between the Goldstein cohort and the age-matched U.S. general population, we found no significant difference between the 2 groups as measured by the PROMIS-29 evaluation[28,29] or the EQ-5D analysis[12].

Patients with more caudal instrumentation levels (LIV at L4 or distal) had a higher rate of undergoing additional spine surgical procedures and those patients who underwent additional spine surgery had lower functional outcome scores than those who did not undergo additional spine surgery. When compared with an age-matched U.S. population, there was no significant difference in functional outcomes between our cohort and the population at large. An example of the discordance between radiographs and function is given in Figure 1, which shows the radiographs of a patient with excellent function with instrumentation to L4, superior junctional kyphosis, and lumbar flatback. Although the current study does not solve the issue of spinal fusion versus sagittal contour as causative of subsequent adult issues in patients with AIS, it is very encouraging that patients with AIS treated using simple, early-generation spinal implants generally function very well through adult life. Biomechanically, Harrington instrumentation creates increased kyphosis, which, in the lumbar spine, results in lumbar flattening or flatback. In patients fused to L4 or distal, a majority of patients had good outcomes, indicating that disability is not inevitable with lumbar flattening. The evaluation of radiographic outcomes in this series found that spinal-pelvic mismatch with pelvic incidence − lumbar lordosis of >9° was associated with inferior health-related quality-of-life outcomes[30].

The limitations of our study included those inherent in a retrospective, long-term follow-up of pediatric orthopaedic disorders. Because AIS is a predominantly female disorder, a particular challenge in following patients results from marital changes in surname. Of eligible patients, 24 patients (7.6% of the total number of patients and 17.9% of the identified patients) had died, which is within the expected range for this cohort[31], and 29 patients (9.2%) declined to participate. The only comparable series reporting long-term scoliosis health-related quality of life is the nonoperative cohort from Weinstein et al.[32], which, similar to our approach, used a private contractor and public databases to identify their patients. Of 314 patients, they were able to identify 117 patients, of whom 36 had died. Their study with 37% follow-up is the best understanding we have of long-term scoliosis prognosis. Similarly, although we could not identify systematic differences between those patients who were not found, participated, declined, or had died that could have biased the results positively or negatively, we could not further clarify the potential for selection bias. As such, the results represent our best understanding of long-term function after posterior spinal instrumentation and fusion (PSIF) for AIS, with this clear limitation. Our patients all had Harrington instrumentation, but did not have immediate postoperative measurements or, typical of the time, any preoperative lateral radiographs to assess preoperative sagittal balance. Thus, we were unable to assess the role of immediate sagittal plane alignment, which may have contributed to the ultimate outcome. We also had few details with regard to the additional spine surgery and could not determine whether it was performed to address complications of the initial surgical procedure, long-term sequelae of the fusion, or an unrelated spine condition, as most patients were unable to specifically define their prior issues sufficiently to ascertain why a surgeon recommended revision.

Another limitation was the possible confounding of the functional outcome measures by other developing health conditions in this aging cohort[28,29]. The EQ-5D and PROMIS scores showed several areas with significant differences, especially in comorbidities. As patients age, other comorbidities may become much more prominent than the limitations imposed by the scoliosis. We do not know why alcohol intake was associated with improved scores, which was most prominent in those having 6 to 12 drinks per week, but, because only 8 patients reported having ≥6 drinks per week, with 3 of these patients having ≥12 drinks per week, we suspect a statistical aberration due to the small sample size (type-1 error).

A legitimate question arising from this series is whether the LIV should always be selected as L3 or proximal instead of L4 or distal. Strictly, we could not reach this conclusion because the originally selected LIV had specific criteria for each level. We can legitimately say that patients treated with Harrington instrumentation with LIV of L3 or proximal tended to have better results than those with LIV of L4 or distal, but we could not determine causality. Ultimately, to determine the influence of fusion or sagittal alignment or both as the keys to long-term success, a comparative study is essential. Because the selection of the LIV is not a random choice but is based on patient and curve characteristics, natural comparative cohorts are essential. As an example, we do not know the natural history of unfused scoliosis compared with an instrumented similar curve with LIV at L3 or L4, or how the results differ with newer segmental fixation compared with older Harrington instrumentation. Well-designed registry or comparative cohort studies are essential to sort out the various issues.

In summary, we present follow-up results (minimum follow-up, 40 years) from a unique cohort of patients treated for AIS in the early days of Harrington instrumentation. This study shows that patients fused to L4 or distal had a significantly increased rate of additional spine surgery compared with those fused to L3 or proximal. Also, patients who had additional spine surgery had lower functional outcomes than

patients who did not. However, as a whole, the available cohorts functioned well. This reinforces the value of the effort by surgeons to minimize the distal extent of spinal instrumentation during spinal fusion for AIS and provides important information for informed decisions. ■

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