Original Article

Global Spine Journal
2022, Vol. 12(4) 654–662

DOI: 10.1177/2192568220960759
journals.sagepub.com/home/gsj

Revision Strategies for Harrington Rod Instrumentation: Radiographic Outcomes and Complications

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Abstract

Study Design: Retrospective case series.

Objective: The purpose of this study is to evaluate the clinical and radiographic outcomes following revision surgery following Harrington rod instrumentation.

Methods: Patients who underwent revision surgery with a minimum of 1-year follow-up for flatback syndrome following Harrington rod instrumentation for adolescent idiopathic scoliosis were identified from a multicenter dataset. Baseline demographics and intraoperative information were obtained. Preoperative, initial postoperative, and most recent spinopelvic parameters were compared. Postoperative complications and reoperations were subsequently evaluated.

Results: A total of 41 patients met the inclusion criteria with an average follow-up of 27.7 months. Overall, 14 patients (34.1%) underwent a combined anterior-posterior fusion, and 27 (65.9%) underwent an osteotomy for correction. Preoperatively, the most common lower instrumented vertebra (LIV) was at L3 and L4 (61%), whereas 85% had a LIV to the pelvis after revision. The mean preoperative pelvic incidence–lumbar lordosis mismatch and C7 sagittal vertical axis were 23.7° and 89.6 mm. This was corrected to 8.1° and 28.9 mm and maintained to 9.04° and 34.4 mm at latest follow-up. Complications included deep wound infection (12.2%), durotomy (14.6%), implant related failures (14.6%), and temporary neurologic deficits (22.0%). Eight patients underwent further revision surgery at an average of 7.4 months after initial revision.

Conclusions: There are multiple surgical techniques to address symptomatic flatback syndrome in patients with previous Harrington rod instrumentation for adolescent idiopathic scoliosis. At an average of 27.7 months follow-up, pelvic incidence–lumbar lordosis mismatch and C7 sagittal vertical axis can be successfully corrected and maintained. However, complication and reoperation rates remain high.

Keywords
harrington rod instrumentation, revision surgery, adult spinal deformity, adjacent segment degeneration

Introduction

From the early 1960s until the early 1980s, Harrington rod instrumentation (HRI) was considered the standard of care for the surgical management of idiopathic scoliosis (IS). Early and long-term outcome studies revealed excellent correction and maintenance of coronal deformity.[1-5] With HRI, distraction instrumentation allowed for greater correction and maintenance in the coronal plane, but the combination of a straight

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rod and distractive forces caused a loss of lumbar lordosis with subsequent anterior translation of the vertical axis and the body's center of gravity.[1,4] The patient attempts to compensate locally by hyperextending any segments not included in the instrumentation as well as the cervical spine and by pelvic retroversion and flexing knees in order to stand upright or to maintain horizontal gaze. Lordosis was observed to decrease progressively with more caudal instrumentation.[6] However, the increase in lordosis below the fusion cannot always compensate for the overall loss of lordosis in the fused portion of the spine.[7,8] The progressive positive sagittal malalignment and subsequent symptoms that develop has been termed "flatback syndrome."[2,6,8-11]

The progressive sagittal malalignment with concurrent back and leg pain can necessitate revision surgical intervention. The corrective technique of flatback syndrome has been well described, often requiring a concomitant osteotomy.[8,9,11,12] However, revision surgery in the setting of prior Harrington rod instrumentation presents with unique challenges due to the presence of a prior fusion mass obscuring anatomic landmarks for pedicle screw instrumentation, significant defects in the iliac wing making iliac fixation challenging at times in addition to the quandary of deciding if the entirety of the prior instrumentation needs to be removed, or if parts can be retained.

There are some small case reports on outcomes following revision of patients that only underwent Harrington rod constructs for IS; however, no formal case series or comparison of surgical techniques for revision in this specific patient population have been described in the literature.[13-15] The purpose of this study is to evaluate the clinical and radiographic outcomes after revision surgery for flatback syndrome following HRI.

Methods and Materials

Patients who underwent revision spine surgery in the setting of HRI for IS were evaluated from 5 participating research sites in the United States that are enrolled into a prospective, multicenter ASD (adult spinal deformity) database and a separate series from an additional tertiary academic hospital from January 2012 to August 2018. Of note, all 6 sites received institutional review board approval prior to enrolling patients. All patients were older than 18 years with inclusion criteria that match at least of the following: scoliosis greater than 20°, sagittal vertical axis (SVA) greater than 5 cm, pelvic tilt (PT) greater than 25°, and/or thoracic kyphosis (TK) more than 60°. Patients were then provided with the option of surgical versus nonoperative care at the discretion and counseling process of the treating surgeon. Patients were excluded from the study if they had previously undergone another revision spine surgery after HRI. Demographic data collected included age, sex, body mass index, and American Society of Anesthesiologists (ASA) physical status score.

Data collection in terms of surgical strategy included approach (posterior, anterior, or both), performance of a 3-column osteotomy, and biologic adjunct. Perioperatively, the length of hospital stay, estimated blood loss, and operative time were obtained for all procedures. Preoperative and postoperative standing posteroanterior and lateral full-length radiographs of the spine were evaluated by 2 observers. Spinal measurements were performed using the SpineView software (ENSAM ParisTech) preoperatively, at 6 weeks postoperative, and 1-year postoperative intervals measuring lumbar lordosis (LL), pelvic incidence (PI), PI-LL mismatch, PT, sacral slope (SS), C7-S1 SVA, and TK. The Oswestry Disability Index (ODI) scores were obtained preoperatively, at 6 weeks postoperative, and 1-year postoperative intervals. Complications were recorded, which included infection, dural tear, implant-related, cardiopulmonary, or neurologic. Any subsequent reoperations were recorded as well.

Description of the preoperative information, including demographic data, ASA grade, location of previous posterior fusion and preoperative alignment were performed using mean and standard deviation for continuous variables and rate for categorical variables. Postoperative outcomes were also investigated. Change in radiographic alignment between pre- and postoperative visits was performed using repeated measure with Bonferroni adjustment for multiple comparison. Statistical analysis was performed using SPSS 20.0 and $P < .05$ was considered statistically significant.

Results

A total of 41 patients with a mean age of 55.7 ± 8.6 years (range 32-74 years) were studied with an average follow-up of 27.7 months (12-121 months). In total, the mean ASA score was 2.2 ± 0.6 (61% had an ASA score of 2, and 24% had an ASA score of 3+) and 36 patients (87.8%) were female. Mean body mass index for the cohort was 29.1 ± 6.9 kg/m^2. Preoperative upper instrumented vertebra (UIV) levels and lower instrumented vertebra (LIV) levels as well as the postoperative LIV of the revision surgery are presented in Figure 1. Of the 41 patients that were included in the study, 32 patients underwent surgery for iatrogenic-related flatback, whereas 9 patients underwent surgery for adjacent segment degenerative pathology. Prior to the revision surgery, the most common LIV was at L3 and L4 (61%), and 60% of the patient had an UIV located between T3 and T5. Preoperative alignment demonstrated a moderate sagittal malalignment according to Scoliosis Research Society (SRS)–Schwab classification with 72.5% of the patient with PT modifier at + or ++, 80.0% with PI-LL modifier at + or ++ and 77.5% with SVA modifier at + or ++.

Overall, 14 patients (34.1%) underwent a combined anterior-posterior (AP) fusion and 27 (65.9%) underwent an osteotomy for correction (Table 1). Bone morphogenetic protein (BMP) was used in 31 (73%) cases. Mean estimated blood loss (EBL) was 2000 ± 1240 mL, while mean operative time varied greatly (802 ± 731 minutes). All patients underwent a posterior fusion. Five patients underwent a proximal extension (mean number level extended 4.4 ± 1.5) and 100% of the patients underwent a distal extension (2.7 ± 1.3 level, ranging from 1 to 6), with 85.4% instrumented to the ilium. The

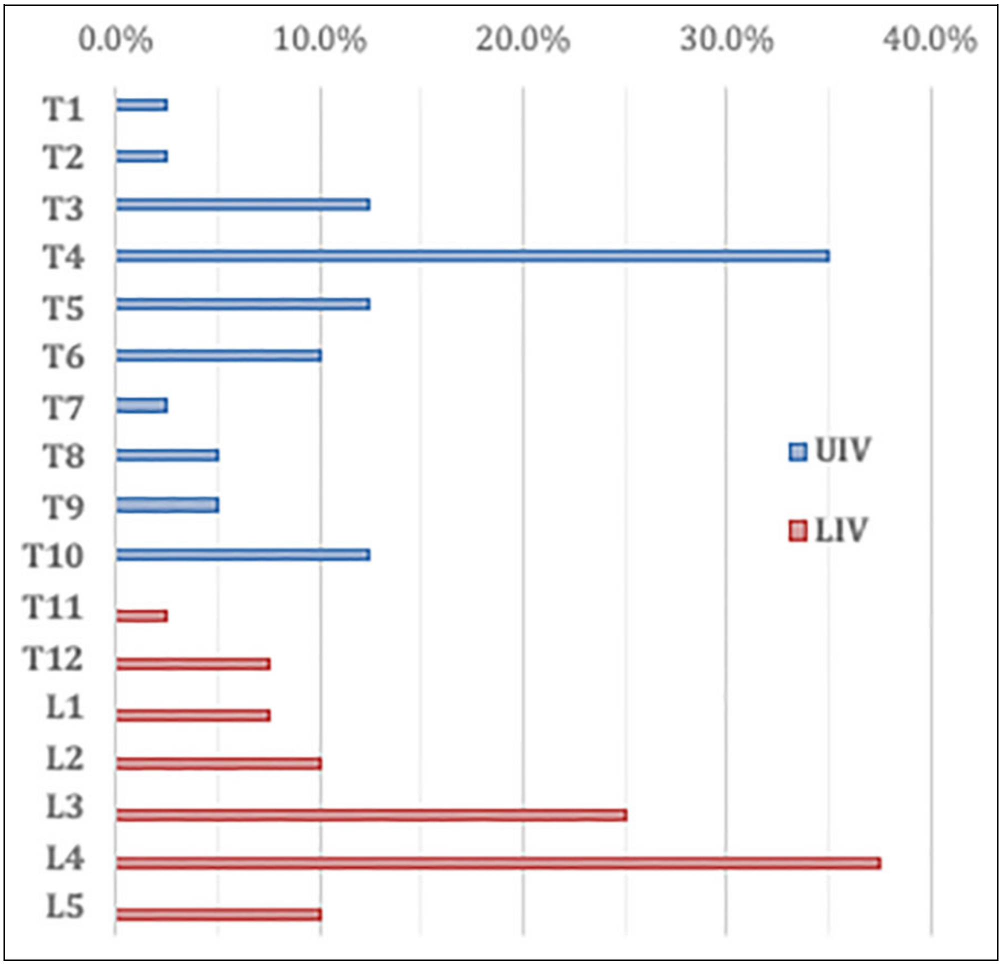

Figure 1. Preoperative upper instrumented vertebra (UIV) and lower instrumented vertebra (LIV) for the entire cohort.

Table 1. Surgical Information for Entire Cohort.

	n	Percentage
Combined approach	14	34.1
Staged procedure	4	10.3
Osteotomy	27	65.9
Smith-Peterson osteotomy	17	41.5
Vertebral column resection	0	0.0
Posterior subtraction osteotomy	10	24.4
Bone morphogenetic protein	30	73.2
Transforaminal lumbar interbody fusion	16	39.0
Anterior lumbar interbody fusion	14	34.1
	Mean	SD
Length of stay (days)	7.9	3.2
Estimated blood loss (liters)	2.0	1.2
Operation time (minutes)	802.9	732.6

hospital stay averaged 7.8 ± 3.2 days (median 7 days) following surgery.

Postoperative radiographic outcomes are shown in Table 2. Preoperatively, the mean PI-LL mismatch was 23.8° (−13.0° to 61.9°) and the mean C7-SVA was 89.6 mm (−45.5 to 313.0 mm). This was corrected to 8.1° and 28.9 mm and maintained to 9.04° and 34.4 mm at latest follow-up. On average, ODI scores were 40.6 ± 17.7 preoperatively and improved to 23.5 ± 21.1 at 1-year follow-up.

The overall complication rate was 61%. Complications included deep wound infection (12.2%), durotomy (14.6%), implant related failures (14.6%), and temporary neurologic deficits (22.0%) (Table 3). Eight patients (19.5%) underwent further revision surgery at an average of 7.4 months after the initial revision. Four patients that underwent an all-posterior revision surgery experienced pseudarthrosis at L4-5 and/or L5-S1, one of which included bilateral rod fractures. All 4 patients underwent anterior lumbar interbody fusions at the pseudarthrosis levels. Two patients that underwent combined anterior-posterior approaches, with a caudal level of fusion at L4 in 1 patient and L5 in the second patient, experienced debilitating symptoms related to adjacent segment degeneration (1 at L4-5 and 1 at L5-S1, respectively). Both underwent anterior lumbar interbody fusion procedures at the adjacent level with extension of the posterior instrumentation. Last, 2 patients experienced lower extremity radicular symptoms that required revision open posterior decompressions.

Table 2. Preoperative, 6 Weeks Postoperative, and 1-Year Postoperative Radiographic Alignment.[a]

	Preoperative	6 weeks postoperative	1 year postoperative	Preoperative to 6 weeks	Preoperative to 1 year
Pelvic tilt	27.7 ± 10.5	20.1 ± 9.6	21.5 ± 10.8	0.000	0.000
Pelvic incidence	57.2 ± 13.6	56.9 ± 13.4	57.1 ± 13.7	1.000	1.000
Sacral slope	29.5 ± 10.2	36.8 ± 8.8	35.6 ± 8.2	0.000	0.000
L1-S1 (LL)	−33.4 ± 17.0	−48.9 ± 12.2	−48 ± 10.9	0.000	0.000
PI minus LL	23.8 ± 16.9	8.1 ± 12.9	9.0 ± 13.6	0.000	0.000
T2-T12 (TK)	34.4 ± 15.8	35.4 ± 15.0	37.0 ± 15.0	1.000	0.050
SVA	89.6 ± 80.7	28.9 ± 60.1	34.4 ± 64.2	0.000	0.000

Abbreviations: PI, pelvic incidence; LL, lumbar lordosis; TK, thoracic kyphosis; SVA, sagittal vertical axis.
[a] Comparison pre- to multiple postoperative alignment using repeated-measures model with Bonferroni adjustment for multiple comparison.

Table 3. Post-operative Complication and Reoperation Rates.

	n	Percentage
Infection	5	12.2
Dural tear	6	14.6
Implant-related complication	6	14.6
Cardiopulmonary infection	0	0.0
Neurological complication	9	22.0
First reoperation rate	8	19.5
Second reoperation rate	1	2.4

When comparing patients undergoing a combined AP versus an all-posterior approach, there were no significant differences in the demographics, length of hospitalization, or operative time. However, the AP fusion group did experience great EBL compared to the all-posterior group ($P = .010$). Radiographically, apart from preoperative TK (post 37.9° ± 16.9°, AP 27.8° ± 11.4°; $P = .031$) and SVA (post 67.9 ± 63.2 mm, AP 129.9 ± 95.8 mm; $P = .042$), there were no significant differences between the preoperative, 6-week postoperative, and 1-year postoperative radiographic parameters (Table 4). When evaluating ODI scores, there were no differences between the 2 groups at preoperative (post 45.8 ± 16.9, AP 50.0 ± 17.3) and 1-year postoperative (post 27.2 ± 19.9, AP 31.1 ± 17.6) time points. Similarly, there was no significant difference in complication (post 63.0% vs AP 64.4%) and reoperation (25.9% vs 7.1%) rates between the 2 groups.

Table 4. All-Posterior Versus Anterior-Posterior Combined Surgery Outcomes.

	Posterior, deg		Anterior-posterior, deg		
	Mean (deg)	SD	Mean (deg)	SD	P^a
Preoperative					
PT	28.11	9.49	26.84	12.44	.720
PI	58.05	14.09	55.53	13.06	.583
SS	29.94	10.68	28.68	9.63	.716
L1-S1	−37.00	16.96	−26.71	15.64	.068
PI-LL	21.05	18.15	28.82	13.45	.169
T2-T12	37.94	16.88	27.84	11.44	**.031**
SVA	67.90	63.17	129.91	95.78	**.042**
6 weeks postoperative					
PT	21.37	9.04	17.71	10.47	.255
PI	57.68	14.33	55.55	11.78	.637
SS	36.31	9.68	37.84	7.22	.608
L1-S1	−51.51	12.53	−43.95	10.06	.060
PI-LL	6.17	12.59	11.60	13.25	.209
T2-T12	38.66	15.26	29.33	12.91	.060
SVA	16.05	42.92	52.76	79.60	.064
1 year postoperative					
PT	22.39	9.82	19.74	12.81	.491
PI	57.32	14.31	56.59	13.05	.882
SS	34.93	8.79	36.85	7.05	.514
L1-S1	−49.77	11.22	−44.45	9.64	.168
PI-LL	7.55	13.83	12.14	13.01	.343
T2-T12	38.80	15.79	32.79	12.86	.275
SVA	26.98	50.57	49.99	86.63	.314
	Total	%	Total	%	*P*
Complications					
Total	17	63.0	9	64.3	0.757
Infection	3	11.1	2	14.3	0.564
Dural tear	3	11.1	3	21.4	0.328
Implant related	5	18.5	1	7.1	0.317
Cardiopulmonary	0	0.0	0	0.0	—
Neurologic	6	22.2	3	21.4	0.640
Reoperations	7	25.9	1	7.1	0.153

Abbreviations: Abbreviations: PT, pelvic tilt; PI, pelvic incidence; SS, sacral slope; LL, lumbar lordosis; SVA, sagittal vertical axis.
[a] Boldfaced *P* values indicate statistical significance ($P < .05$).

Discussion

This study represents the largest case series examining revision strategies and outcomes following revision for adjacent segment degeneration and flatback syndrome following HRI. In a series of 41 patients, we show that treatment of HRI can successfully correct PI-LL mismatch and C7-SVA. However, complication and reoperation rates remain relatively high. Our strategies here can outline successful techniques to achieve improved radiographic and clinical outcomes.

Although flatback syndrome is a widely recognized complication following HRI, many patients also presented to the clinic with leg pain in the setting of adjacent segment degeneration. The overall effects of a long segment fusion can drastically affect the load, function, and motion within the caudal adjacent segments as well as the metabolism of the disc and facet cartilage at the motion segments adjacent to the fusions.[16,17] Literature supports changes in the adjacent level biomechanics,

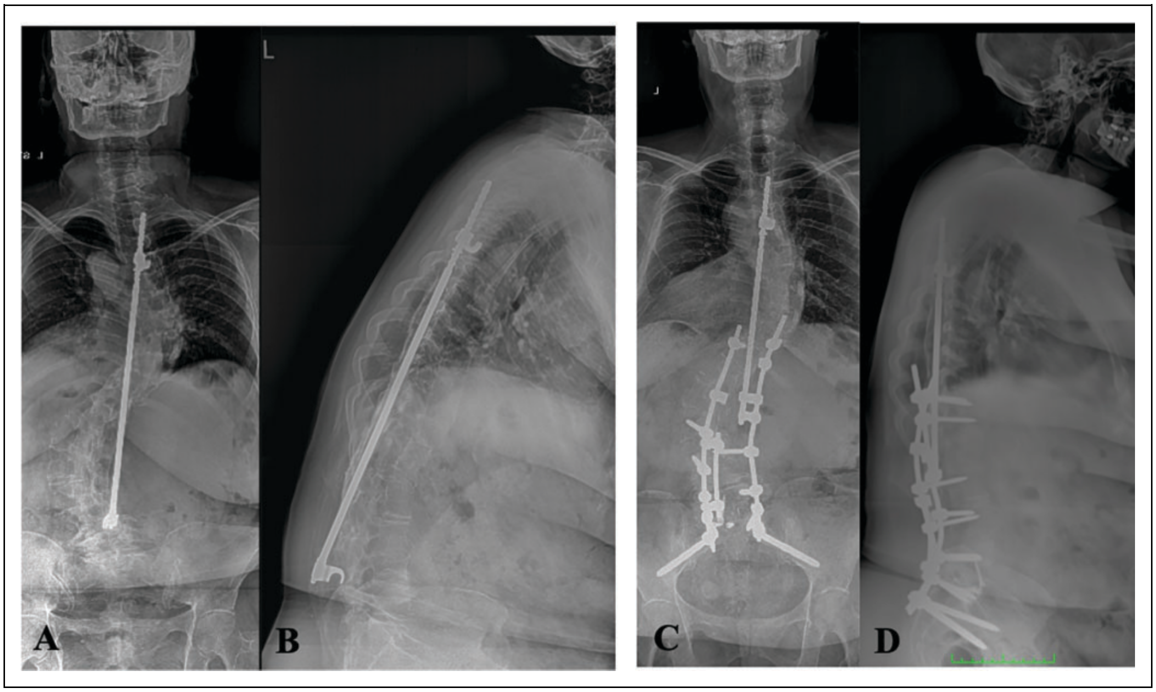

Figure 2. A 56-year-old female who presented with significant low back pain and bilateral buttock pain 40 years after her initial Harrington rod instrumentation for adolescent idipathic scoliosis. Preoperative anteroposterior (AP) (A) and lateral plain radiographs (B) of the full spine reveal Harrington rod instrumentation with a caudal hook at L4 in the setting of positive sagittal balance and loss of lordosis. She subsequently underwent a staged procedure with a revision T10-pelvis posterior spinal fusion with an L5-S1 anterior lumbar interbody fusion performed in the initial stage, then a L4 pedicle subtraction osteotomy performed 6 days later (C, D) with restoration of her lumbar lordosis and improvement in her overall sagittal alignment.

but no causal relationship has been firmly attributed with degeneration. One potential source for the biomechanical changes is altered sagittal alignment after arthrodesis (such as HRI), and this has been implicated to increase the rate of adjacent segment disease.[18-20] As most patients undergoing HRI for idiopathic scoliosis were young, degeneration in the unfused segments below the instrumented vertebra should be considered if they present with progressively worsening low back and leg pain.

The back and leg pain associated with the progressive sagittal alignment can be debilitating to the point of requiring surgical intervention. Dangers and complications in these cases are related to the subverted anatomy of the spine due to the huge amount of bone fusion. The goal of corrective surgery in the treatment of flatback syndrome is to restore physiologic lordosis and sagittal balance such that the sagittal vertical axis intersects the posterior aspect of the sacrum. Obtaining the necessary correction to achieve sagittal balance allows the patient to stand and walk with their hips and knees in a physiologic posture, improves overall body function, and reduces fatigue-associated back and neck pain.[9,21] The literature has described a direct association between PI, LL, and health-related quality of life outcomes.[22,23] Concurrently, based on the data previously discussed by Lafage et al,[24] the threshold for which adults experience disability with sagittal alignment (SVA, PI-LL, and PT) increases with age. A variety of osteotomies and interbody fusion techniques are utilized to directly increase lordosis, especially in the setting of flatback syndrome. In this study, 27 of the 41 patients (66%) underwent an osteotomy for correction. Of those, 16 patients (40%) underwent a Smith-Petersen osteotomy (SPO), while 10 patients (24%) underwent a pedicle subtraction osteotomy (PSO; Figure 2). No vertebral column resections (VCRs) were performed. Single- or multilevel SPOs were performed at levels with mobile discs. Surgeons performed a PSO in the setting of more rigid deformities in which more focal lordosis correction was necessary. As with this report, studies that have looked at revision surgery for flatback syndrome (with diverse previous instrumentation or in native spines) show excellent correction and maintenance of the PI-LL mismatch and C7-SVA (Figure 3).[6,8,9,11,25,26] In this series, the flexibility of the flatback deformity also dictated the use of dual approaches. In the setting of a mobile disc spaces (previously unfused segment) at L4-L5 and/or L5-S1 the placement of hyperlordotic anterior lumbar interbody fusion grafts has been shown to also generate significant LL at the L4-S1 segments.[27-29] However, the approaches used and osteotomies performed were ultimately based on the pre-operative plan and judgment of the treating surgeon.

To date, there are no case series that describe the outcomes following revision of patients that underwent HRI for adolescent idiopathic scoliosis. However, there are some isolated case

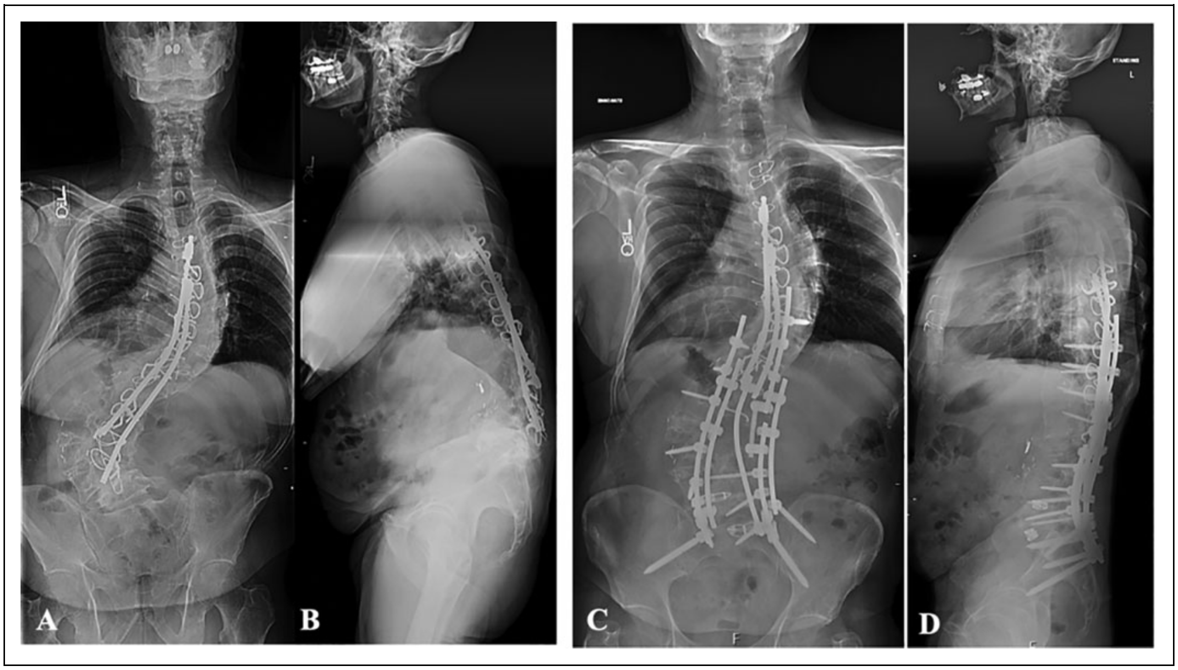

Figure 3. A 71-year old male who presented with chronic low back pain numbness/tingling in his bilateral legs and feet 31 years following Harrington rod instrumentation for idiopathic scoliosis. Preoperative anteroposterior (A) and lateral plain radiographs (B) of the full spine reveal Harrington rod instrumentation with a caudal hook at L4 in the setting of a right coronal shift, positive sagittal balance, and loss of lordosis. He subsequently underwent a single-staged T8-pelvis posterior spinal fusion with a left asymmetric pedicle subtraction osteotomy performed at the L4 level and a transforaminal lumbar interbody fusion at L4-5 (C, D) with restoration of his lumbar lordosis and improvement in her overall sagittal alignment. His symptoms remain significantly improved 14 months after the revision procedure.

reports that describe outcomes in this patient population aside from case series that describe flatback syndrome revision surgery due to various presentations and previous hardware techniques. Hedlund et al[30] described a case report on a patient that presented with flatback syndrome 38 years after undergoing HRI for adolescent IS. Following a L3 PSO, standing radiographs showed a restoration of lordosis by 35° and restoration of C7 plumb line to +2 cm; maintained at 6 months following surgery.[30] Marino et al[14] described 2 patients who presented with adjacent segment degeneration at L4-5 following Harrington rod placement 28 and 40 years ago. One underwent a combined anterior-posterior approach, and the other underwent a posterior-only decompression and fusion with successful correction and maintenance of the sagittal parameters 18 months following these revisions. Similarly, Liu et al[15] presented 3 cases of Harrington rod revisions for flatback syndrome that underwent various surgical approaches and osteotomies to obtain successful correction and maintenance of sagittal plane correction. The patients included in this study experienced similar mean operative times (802 ± 731 minutes) and EBL (2000 ± 1240 mL) as described in these case reports. However, no post-operative complications were described in those case reports following revision of previous HRI. In our study, 26 of 41 (63.4%) patients suffered a complication, including deep wound infection (12.2%), durotomy (14.6%), implant-related failures (14.6%), and temporary neurologic deficits (22.0%), while 8 patients (19.5%) underwent further revision surgery (Figure 4). The complication and reoperation rates are similar to other studies that describe revision surgery for flatback syndrome. Glassman et al[31] described a perioperative complication rate of 62% in revision spine surgery performed after previous operations for scoliosis. Similarly, Bridwell et al[11] described 14 early complications and 6 late complications in 27 patients that underwent a PSO for fixed sagittal imbalance. Overall, complication rates range from 25% to 72% and include pseudarthrosis, rod fracture, venous thromboembolism, myocardial infarction, infection, injury to major blood vessels, neurological injury, stroke, pneumonia, arrhythmia, and even death.[6,8,32,33]

As proximal junctional kyphosis or adjacent segment pathology cephalad to previous HRI is not common, if the previous fusion is solid and the rod is well fixed to the spine (often bone has grown over the rod itself, the HRI can be left in place with the new construct tied to the previous instrumentation. This frequent lack of proximal pathology is important because the revision surgery can also be performed with a more limited approach that does not require exposure of the entire previous HRI. Thus, we recommend maintaining the previous instrumentation (if well fixed and the previous fusion is solid) and performing a limited exposure as these techniques may reduce intraoperative blood loss and operative time, which are known to affect complication rates postoperatively. In our

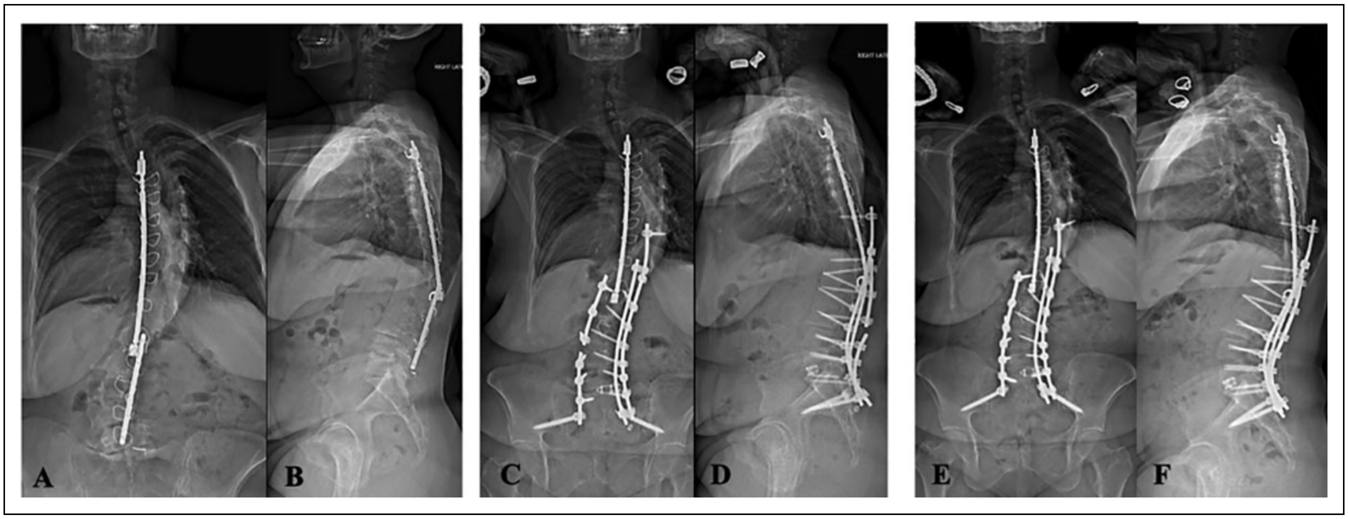

Figure 4. A 46-year-old female who presented with a weakness in her left ankle dorsiflexion and occasional right leg numbness with walking that had worsened over the past few months. On further questioning, she described that her right shoulder felt higher than the left shoulder and that she was increasingly pitched forward while standing. She had originally undergone Harrington rod instrumentation for adolescent idiopathic scoliosis at the age of 12. Preoperative anteroposterior (A) and lateral plain radiographs (B) of the full spine reveal fractured Harrington rod instrumentation with a caudal hook at L5 in the setting of significant loss of lordosis. Of note, a computed tomography scan showed pseudoarthrosis at L3-4 and L4-5 and a magnetic resonance imaging revealed foraminal narrowing secondary to residual scoliotic curve present at L5-S1, more severe on the left side. She subsequently underwent a removal of the caudal Harrington rod to effectively evaluate the fusion mass, in which revealed obvious pseudarthrosis at L3-4 and L4-5. Next, in the same stage, she underwent posterior instrumentation from T10-pelvis with posterior column osteotomies performed at L3-4 and L4-5 and transforaminal lumbar interbody fusion at L5-S1 with restoration of her lumbar lordosis and maintenance of her overall sagittal alignment. However, at 6 months following surgery, she bent over forward to pick up an object and felt a "snap" in her back, followed by worsening low back pain. Anteroposterior and lateral plain radiographs of the full spine reveal a left rod fracture at L3-4 and a right S1 screw fracture (C, D). She subsequently underwent removal of the broken rod and screw and a revision T10-pelvis PSF (E, F). Of note, a gross pseudarthrosis was encountered at L3-4 (the level of the broken rod).

limited cohort, reoperation rates in the all-posterior revision group was high (7 patients, 26%). In addition, 6 patients underwent a revision, posterior, instrumented fusion short of the sacrum and pelvis and 2 (33%) required a reoperation to extend the construct to the pelvis within 1 year. Given this, we would recommend posterior instrumentation extended to the sacrum and pelvis with interbody placement. Additionally, we would not hesitate to use an anterior approach for interbody placement if that technique is within the surgeon's skill set.

There are limitations in this study, including the small size of the cohort, which limit our ability to provide comparative analysis between the impact of different surgical approaches and techniques. However, these cases are the largest series to date focused solely on revision surgery for flatback syndrome in the setting of previous HRI for IS in a multicenter setting. As several surgeons in multiple centers were included in this study, the indications and technique of the various revision surgeries were based on the judgment and experience of the surgeons, thus no formal protocols dictated the specific surgical intervention. However, given this multicenter experience, we feel that the results are more representative to the general population. Additionally, our minimum follow-up is only 12 months, so other late complications or reoperations may present outside of this follow-up time frame. With an average follow-up of 27.7 months, we feel that we have adequately captured many of the early radiographic and clinical outcomes, must most likely are underreporting pseudarthrosis and rod fracture in cases with only 12 months of follow-up.

Conclusion

There are multiple surgical techniques to address symptomatic flatback syndrome in patients with previous Harrington rod instrumentation for adolescent idiopathic scoliosis. In a multicenter retrospective review of 41 patients with an average of 27.7 months follow-up, PI-LL mismatch and C7 sagittal vertical axis can be successfully corrected. However, complication and reoperation rates remain high.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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