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Abstract

Study Design: Retrospective study.

Objective: To investigate the long-term clinical outcome and incidence of iliac screw-related complications in patients with adult spinal deformity (ASD).

Summary of Background Data: Rigid lumbosacral fixation is crucial to achieve optimal global alignment and successful long-term clinical outcomes.

Methods: The data of eligible patients with ASD who underwent spinopelvic fixation using bilateral iliac screws with at least 5-year follow-up periods were retrospectively analyzed. Iliac screw loosening and rod breakage between the S1 and iliac (S1/IL) screws were defined as distal instability (DI). Demographic data, health-related quality of life scores, and spinopelvic parameters in the DI group were compared with those in the non-DI group. Sub-group analyses were performed between the cases with and without alignment change after rod fracture at S1/IL.

Results: Of the 159 patients, the data of 110 patients (15 men, 95 women; mean age, 67.8 years) were analyzed. The follow-up rate was 69%. Forty-five (41%) patients showed DI (29 cases [26%] in screw loosening, 16 cases [15%] in rod breakage). Eight patients (7.3%) required revision surgery because of iliac screw-related complications. No significant differences were observed in the Oswestry Disability Index and Scoliosis Research Society questionnaire (revised) scores between the DI and non-DI groups. The patients with iliac screw loosening showed significantly greater values of preoperative pelvic incidence, pelvic tilt (PT) and postoperative PT, and T1-pelvic angle. In patients with rod breakage at S1/IL, five patients (31%) who had associated mechanical complications showed an alignment change between pre and post rod breakage. They showed significantly higher and lower rates of high-grade osteotomies and L5/S interbody fusion, respectively.

Conclusion: The incidence rate of iliac screw-related complications was relatively high. However, they had a little effect on sagittal alignment deterioration and there were few cases that required revision surgery.

Keywords: adult spinal deformity, complication, surgery, sagittal alignment, iliac screw, loosening, rod breakage, incidence rate, osteotomy, pelvic tilt, interbody fusion

Level of Evidence: Level IV

Key points:

- We investigated the incidence of iliac screw-related complications and the effect on sagittal alignment and clinical outcomes for patients with adult spinal deformity (ASD).
- Data of 110 patients with ASD (15 men, 95 women; mean age, 67.8 years) who underwent spinal deformity surgeries using bilateral iliac screws with at least 5-year follow-up periods were examined.
- Forty-five (41%) patients showed distal instability (29 cases [26%] in screw loosening, 16 cases [15%] in rod breakage).
- The incidence of revision surgery because of iliac screw-related complications was low (7.3%)
- Iliac screw loosening and rod breakage at S1/IL had a little effect on sagittal alignment deterioration.

Mini abstract:

Long fusion surgery with pelvic fixation using iliac screw resulted in higher incidence rates of iliac screw-related complications; however, the cases that required revision surgery were limited (7.3%). Iliac screw loosening and rod breakage at S1/IL had little effect on sagittal alignment deterioration.

Introduction

For corrective fusion surgeries with a long construct, rigid lumbosacral fixation is crucial to achieve optimal global alignment and successful long-term clinical outcomes in patients with adult spinal deformity (ASD).[1-3] Whether spinal long fusion was stopped at L5 or extended to the pelvis remains controversial[4,5]; however, several studies have recommended that pelvic fixation should achieve the solid distal fusion and prevent distal junctional failure.[2,6]

Pelvic fixation using bilateral iliac screws presents an established history and biomechanical advantage compared to the previously performed technique.[7,8] The advantages of iliac screw are the following: large diameter and length, easier freehand placement, and preservation of the sacroiliac joint. Therefore, lumbosacral fixation using iliac and S1 screws was considered the common procedure in the setting of long constructs and good surgical outcomes in patients with ASD.[9-11] However, despite the advances in surgical techniques and instruments, achieving solid lumbosacral fixation remains a challenge.[12]

Iliac screw-related complications, such as iliac screw loosening and rod breakage between the S1 and iliac screws, often occur after surgery because of the concentration of the long lever arm of fused segments. They result in a decreased rigidity of long constructs and could cause a loss of restored alignment.

Iliac screw loosening reportedly develops in 28%–49% of patients who underwent ASD surgery within 2 years[10,11,13]; however, the long-term outcome of pelvic fixation using the iliac screw for such patients and the effect of iliac screw-related complications on global alignment and clinical outcomes remain unclear. Therefore, we aimed to assess the incidence of iliac screw-related complications and the effect on long-term alignment and clinical outcomes in patients with ASD who underwent long fusion surgery with iliac screw fixation.

Materials and methods

Enrollment of patients

This study was approved by the Ethical Review Board of our institution (Approval No.: 20-358) and adhered to the principles of the Declaration of Helsinki. The cohort included patients with ASD who underwent corrective fusion surgeries between March 2010 and March 2016 in our department. The data of patients who underwent posterior instrumented fusion surgery from the thoracic spine to the pelvis using bilateral iliac screws and had available full-length standing radiographs and health-related quality of life (HRQOL) data collected at baseline and at 2 and 5 years postoperatively, were examined. We excluded patients with neuromuscular disease, congenital and syndromic deformity, infection, and spinal tumor, and those who needed pelvic fixation using more than two iliac screws.

Surgical procedure for iliac screw insertion

The surgeries were performed by board-certified spine surgeons in our institute. The iliac screw placement was performed using the freehand technique. The iliac screw was inserted from the posterior superior iliac spine (PSIS) without any separate skin incision. The PSIS was exposed by periosteal dissection of the soft tissues, and the PSIS tips were removed with a rongeur. A blunt probe was gently and carefully inserted into the cancellous bone of the ilium, preventing the penetration of the table. The used iliac screws were measured 7.5 mm in diameter and 70 mm in length with open polyaxial head. The screw was inserted deep to prevent a prominent screw head and attached the main longitudinal rod using a rod connector. All patients received posterior bone graft using a local bone, with or without L5/S interbody fusion.

A commercially pure titanium rod (φ6.0 mm or φ6.35 mm) was mainly used for less mechanical stress and to avoid the screw pulling out.

Patients' data acquisition

The following demographic data were extracted: age, sex, and bone mineral density of the proximal femur assessed by dual-energy X-ray absorptiometry. Additionally, the following operative data were extracted: the number of fusion segments, incidence of high-grade osteotomies[14] (pedicle subtraction osteotomy [PSO] or vertebral column resection [VCR]), rod number (two-rod or multi-rod), and the status of L5/S interbody fusion.

The Oswestry Disability Index (ODI) and the 22-item Scoliosis Research Society questionnaire (revised) (SRS-22r) were calculated to assess the HRQOL before the surgery and at the 2-year and 5-year postoperative follow-up visits.

Radiographic assessment

Iliac, S1, and upper instrumented vertebra (UIV) screw loosening were assessed using anteroposterior X-ray at 2 and 5 years postoperatively. Screw loosening was defined as a radiolucent area (≥1 mm in circumference) around the screw, noted on the plain radiograph by at least two observers.[15,16] In addition to iliac screw loosening, screw head prominent and screw breakage were investigated as iliac screw-related complications. Concerning mechanical complications, the incidence of rod breakage and proximal junctional kyphosis (PJK) were also assessed in the postoperative follow-up period. Iliac screw loosening and rod breakage between the S1 and iliac screws (S1/IL) were defined as distal instability (DI) (Figure 1).

The following radiographic parameters were measured preoperatively, immediately after the operation (first standing) and at 2 and 5 years postoperatively for the assessment of sagittal alignment: T1-pelvic angle (TPA), sagittal vertical axis (SVA), pelvic tilt (PT), pelvic incidence (PI), lumbar lordosis, and thoracic kyphosis.

Statistical analysis

Patients with DI were divided into two groups according to the cause (i.e., the iliac screw loosening and rod breakage at S1/IL groups). Demographic data, HRQOL scores, and spinopelvic parameters were compared with the non-DI group. Moreover, for patients with rod breakage at S1/IL, spinopelvic parameters were evaluated between pre and post rod breakage. The patients whose PT change was ≥3° were defined as having an alignment change and compared to those without an alignment change.

Independent and paired t-tests were used for continuous variables, whereas the chi-squared and Fisher's exact tests were applied for categorical data. The differences between the three groups were assessed using one-way analysis of variance. Post-hoc comparisons were made using the Tukey test. All statistical analyses were performed using SPSS version 22.0 (IBM Corp., Armonk, NY, USA). A P-value <0.05 was considered significant.

Results

Of the 316 eligible patients identified during the study period, data from 146 patients were excluded owing to the following factors: non-pelvic fusion, neuromuscular disease, dual iliac screws, and unable to stand (116, 28, 10, and three patients, respectively). Of the 159 patients who met the study criteria, 49 patients were lost to follow-up; thus, the follow-up rate was 69%. The data of the remaining 110 patients (15 men, 95 women; age range, 37–82 years; mean age, 67.8 years) were analyzed. The mean follow-up period was 7.4 years (range, 5.1–10.1 years). High-grade osteotomies were performed in 42 patients (29 PSO and 13 VCR cases) and the mean fusion length was 9.9 (range, 8–15) segments. Posterior lumbar interbody fusion (PLIF) at L5/S1 was performed in 88 patients (80%). The UIV was T4, T5, T6, T7, T8, T9, T10, and T11 in four, four, one, two, 11, 26, 60, and two patients, respectively. All patients underwent sacroiliac fusion using bilateral S1 and iliac screws. Eighty-one (74%) patients underwent corrective fusion surgery using a conventional two-rod construct, whereas 29 (26%) patients received a multi-rod construct. Although all spinopelvic parameters improved soon after surgery, the values deteriorated to some degree over the 5-year follow-up period (Table 1). The ODI and SRS-22r scores obtained at 2 and 5 years postoperatively were significantly improved compared to the preoperative values ($p<0.01$;

Table 1).

During the follow-up period, rod breakage occurred in 57 (52%) patients and revision surgery was required in 28 (25%) patients. PJK occurred in 32 (29%) patients and revision surgery was required in eight (7%) patients. Concerning iliac screw-related complications, iliac screw removal was required in two cases because of a prominent screw head, whereas there was no case with screw breakage. Rod breakage at S1/IL occurred in 16 (15%) patients with an average period of 28 (range, 10–58) months postoperatively; among them, 10 patients felt back pain after rod breakage. Six patients required rod replacement because of persistent pain, and the remaining four patients were observed conservatively because of spontaneous pain relief. Iliac screw loosening was observed in 31 (28%) patients, of whom, eight (7.3%) patients had associated S1 screw loosening; however, no patient required revision surgery because none complained of severe back pain because of screw loosening. Two patients had iliac screw loosening after rod replacement following breakage from the rod breakage group. Thus, 45 (41%) and 47 (43%) patients showed DI (iliac screw loosening and rod breakage at S1/IL) and iliac screw-related complications (DI and screw head prominent), respectively. In 72% of the cases, iliac screw loosening occurred within 2 years, whereas in 56% of the cases, rod breakage occurred after >2 years.

Among the patients with non-DI and DI, no inter-group differences were observed in demographic data and in the incidence of other adverse events (Table 2). However, those with iliac screw loosening had significantly higher values of preoperative PI and PT. Moreover, they showed improved postoperative TPA and PT, 2-year TPA and PT, and 5-year TPA values, whereas no significant differences were observed in the ODI and SRS-22r scores (Table 3, Figure 2). The patients with DI showed a slight deterioration of TPA within 2 years postoperatively; however, no further progression was observed compared to the non-DI group (Figure 2). Out of 16 patients with rod breakage at S1/IL, five patients (31%) showed alignment change between the pre and post rod breakage, and presented significantly deteriorated TPA, SVA, and PT (Figure 3). All patients with alignment change felt back pain at rod breakage, whereas, six of 11 (55%) patients without alignment change were asymptomatic (Table 4). The incidence rates of osteotomies and L5/S interbody fusions were significantly higher and lower in patients with than in those without alignment change, respectively (Table 4). Patients with alignment change had other mechanical complications simultaneously occurring with rod breakage at S1/IL (Table 5).

Discussion

Improved HRQOL and global alignment were maintained with some correction loss over 5 years postoperatively in 110 patients with ASD after undergoing corrective surgery involving pelvic fixation using iliac screws (Table 1). Iliac screw loosening and rod breakage at S1/IL were observed in 32 (31%) and 16 (15%) patients, respectively, 5 years after thoracic to pelvic fusion. Interestingly, these two complications occurred at different times: most of the iliac screw loosening occurred within 2 years postoperatively, whereas rod breakage occurred after >2 years in more than half of the cases. These results suggested that screw loosening could be an early-phase complication, whereas rod breakage was a late-phase complication.

Although we could not determine the effect of DI on HRQOL, patients with postoperative iliac screw loosening had significantly greater values of preoperative PI, PT, and postoperative PT, TPA (Table 3). In previous studies,[10,11,13] iliac screw loosening occurred in 26%–49% of the patients who underwent long fusion surgery with follow-up periods >2 years. The ensuing cantilevering force for the restoration of the pelvis and insufficient correction of the pelvis may cause high mechanical stress and lead to iliac screw loosening. During the postoperative follow-up period, patients with DI showed mild deterioration of TPA within 2 years postoperatively; however, no further progression was observed compared to the non-DI group (Figure 2).

Of 16 patients with rod breakage at S1/IL, five showed alignment change after rod breakage. They had a higher prevalence of high-grade osteotomies and lower prevalence of L5/S PLIF. High-grade osteotomies reportedly are a risk factor for rod breakage.[17-19] These procedures are powerful techniques to provide substantial correction of sagittal deformity that may produce much mechanical stress and contribute to higher rates of rod breakage and correction loss. For the maintenance of sagittal alignment, rigid lumbosacral fixation using L5/S interbody fusion is also crucial.[7] Other mechanical complications occurred simultaneously that could cause deterioration of sagittal alignment (Table 5, Figure 3). Conversely, patients without alignment change had no other mechanical complications simultaneously. These results suggested that rod breakage at S1/IL had little effect on sagittal alignment deterioration unlike rod breakage in other parts because of limited sacroiliac joint motion.

Herein, 10 of 16 patients (63%) experienced pain at rod breakage at S1/IL. All patients with alignment change experienced back pain, whereas 6 of 11 (55%) patients without alignment change were asymptomatic (Table 4). Yamato et al.[20] showed that the pain continued in cases of severe correction loss in rod breakage. Conversely, only minor correction loss was observed in asymptomatic patients. Therefore, loss of correction and alignment deterioration accompanied by other mechanical complications could be an indicator for the necessity of revision surgery.

Conversely, pelvic fixation by iliac screw preserved sacroiliac joint that had physiologically slight mobility in the directions of rotation and translation depending on the positioning and distribution of load.[21] This movement may affect the development of iliac screw loosening and rod breakage between the S1 and iliac screws.

Recently, the S2 alar iliac (S2AI) screw, which can provide durable pelvic fixation with a low-profile, in-line technique, has been widely used as an alternative to iliac screw.[22] As the S2AI screw penetrates the sacroiliac joint, it could reduce such screw-related complications. The S2AI screw reportedly shows a lower rate of revision surgery and wound infection than the iliac screw.[23,24] In this study, although the incidence rate of iliac screw-related complications was high (43%), only eight cases (7.3%; six and two cases with rod breakage and screw head prominent, respectively) required revision surgery; hence, this rate was lower than that of the S2AI screw.[24,25] Guler et al.[12] reported that the failure rate of the S2AI and iliac screws were 35% and 12%, respectively, and all broken screws were associated with the S2AI technique. Ha et al.[26] reported that the rate of S2AI screw-related complications after ASD surgery was 10.8%, with screw loosening, breakage, and bending observed in 6.0%, 3.6%, and 1.2% of patients, respectively. Conversely, no iliac screw breakage case was observed. As the S2AI screw penetrates the sacroiliac joint, mechanical stress may be concentrated on the screw, thereby causing screw breakage. The long-term outcome of S2AI remains unknown, and once screw breakage occurs, revision surgery may become difficult. Thus, we prefer to use an iliac screw rather than the S2AI screw. Nevertheless, screw-head prominence was one of the major drawbacks of iliac screws that causes pain and infection, necessitating implant removal in 6%–22% of patients.[27-30] However, in this study, only two patients (1.4%) required removal for screw head prominence, which is a relatively low rate. Surgeons should consider reducing the screw-head prominence by placing the screw deep enough to hide its head below the iliac crest.

The main purpose of the iliac screw was to protect the S1 screw and achieve solid distal fusion.[28,29,31] Despite performing L5/S anterior support, we encountered eight patients (7.3%) with S1 and iliac screw loosening because of the concentration of the long lever arm of fused segments. No patient required revision surgery, indicating L5/S pseudarthrosis. Banno et al.[32] revealed that patients with iliac and S1 screw loosening, had a significantly worse sagittal alignment, indicating high instability of the lumbosacral junction and possible pseudarthrosis. Conversely, iliac screw loosening without S1 screw loosening could not affect the global alignment because of the limited sacroiliac joint motion. To improve the anchoring strength of screws, dual-screw placement[33] or polymethylmethacrylate augmentation[34] should be considered in patients with osteoporosis in addition to osteoporotic treatment.

This study had several limitations. First, we could not determine how to prevent the occurrence of DI. For preventing iliac screw loosening, Ebata et al.[33] recommended the insertion of dual iliac screws to achieve the long-term stability for spinopelvic fusion in patients with ASD with a lower prevalence of iliac screw loosening (11%). For preventing rod breakage, the use of a multi-rod construct reportedly provides increased stability and reduces the incidence of rod breakage compared with a two-rod construct.[35-37] However, Yamato et al.[37] revealed that a short additional rod that covered only the osteotomy site increased the rod breakage incidence in the uncovered area; thus, rod constructs should cover the lumbosacral junction. Second, we could not determine the effect of DI on the clinical outcome at 5 years postoperatively; moreover, the effect of DI on further long-term clinical outcomes remains unknown. Finally, further studies are needed regarding the long-term results compared to S2AI screws.

In conclusion, long fusion surgery with pelvic fixation using iliac screw resulted in more iliac screw-related complications (43%) but resulted in a lower incidence rate (7.3%) of revision surgery at >5 years postoperatively. Iliac screw loosening and rod breakage at S1/IL had little effect on sagittal alignment deterioration.

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Figure legends

Figure 1

A: Assessment of the iliac screw loosening. There is a radiolucent area around the iliac screw (white arrows).

B: Assessment of the rod breakage. There is a rod breakage between the S1 and iliac screws (white arrow).

Figure 2

Time-course changes in the sagittal vertical axis (SVA) (A), T1-pelvic angle (TPA) (B), and pelvic tilt (PT) (C) among the patients with non-distal instability (DI) and DI (iliac screw loosening, rod breakage at S1/IL).

* Statistically significant differences in changes.

† Statistically significant differences at each timepoint.

Figure 3

The comparison of radiographic parameters between the patients with and without alignment change after rod breakage at S1/IL; sagittal vertical axis (SVA) (A), T1-pelvic angle (TPA) (B), and pelvic tilt (PT) (C)

† Statistically significant differences at each time point.

Tables

Table 1 Time course changes of radiographic parameters and health-related quality of life.

	Pre-op	Post-op	2 y post-op	5 y post-op
SVA (mm)	104.2 ± 71.5	31.5 ± 41.3*	50.1 ± 49.9*	63.7 ± 55.8*
TPA (°)	36.8 ± 14.3	16.4 ± 8.7*	22.3 ± 11.0*	24.9 ± 10.7*
LL (°)	13.1 ± 21.5	46.2 ± 10.5*	43.9 ± 12.6*	41.2 ± 11.1*
TK (°)	23.3 ± 20.4	35.8 ± 12.1*	42.8 ± 14.9*	43.5 ± 15.8*
PT (°)	34.8 ± 11.3	19.3 ± 8.7*	24.7 ± 9.7*	25.9 ± 9.3*

	Pre-op	2 y post-op	5 y post-op
ODI	43.0 ± 16.4	28.2 ± 19.7*	27.8 ± 19.5*
SRS-22r	2.6 ± 0.6	3.5 ± 0.7*	3.4 ± 0.7*

Mean values are presented as ± standard deviation. Abbreviations: SVA, sagittal vertical axis; TPA, T1-pelvic angle; LL, lumbar lordosis; TK, thoracic kyphosis; PT, pelvic tilt; ODI, Oswestry disability index; SRS-22r: the 22-item Scoliosis Research Society questionnaire (revised).

* $p<0.05$: statistically significant compared with preoperative value

Table 2 Demographic and baseline characteristics of distal instability (DI) and non-DI groups.

	Non-DI (n=65)	DI (n=45)		p-value
		Iliac screw loosening (n=29)	Rod breakage at S1/IL (n=16)	
Age (years)	67.1 ± 10.0	70.2 ± 8.7	66.0 ± 10.6	0.278
Female	56 (86%)	26 (89%)	13 (81%)	0.680
BMD (T-score)	-1.7 ± 1.1	-2.0 ± 1.4	-1.2 ± 1.0	0.522
Fusion segments	9.8 ± 1.4	10.4 ± 2.1	9.4 ± 0.6	0.091
high grade osteotomies	27 (42%)	11 (37%)	4 (25%)	0.509
Initial rod number (2-rod / multi-rod)	51 / 14	19 / 10	11 / 5	0.379
L5/S interbody fusion	50 (77%)	25 (86%)	13 (81%)	0.558
Adverse event				
PJK	18 (28%)	10 (34%)	4 (25%)	0.796
PJK revision	4 (6%)	2 (7%)	2 (13%)	0.597
UIV screw loosening	13 (20%)	6 (21%)	7 (44%)	0.137

Continuous data are presented as mean ± standard deviation of median. Categorical data are presented as number (%). Abbreviations: DI, distal instability; BMD, bone mineral density; PJK, proximal junctional kyphosis; UIV, upper instrumented vertebra.

Table 3 Radiographic parameters and health-related quality of life scores of distal instability (DI) and non-DI groups.

		Non-DI (n=65)	DI (n=45)		p-value
			Iliac screw loosening (n=29)	Rod breakage at S1/IL (n=16)	
SVA (mm)	Pre-op	106.1 ± 76.9	95.2 ± 68.8	112.6 ± 53.1	0.611
	Post-op	30.6 ± 37.2	43.3 ± 52.3	14.6 ± 30.4	0.083
	2y	43.1 ± 40.8	65.7 ± 67.8	49.9 ± 40.6	0.129
	5y	58.0 ± 51.3	79.2 ± 64.0	59.6 ± 57.0	0.281
TPA (°)	Pre-op	35.5 ± 14.9	40.1 ± 14.4	35.5 ±10.6	0.333
	Post-op	15.6 ± 7.8	20.6 ±10.4	12.4 ± 6.4	0.007* 0.024 †
	2y	20.2 ± 9.4	27.5 ± 13.6	21.0 ± 8.3	0.007 †
	5y	22.8 ± 9.7	29.9 ± 12.3	24.5 ± 9.1	0.013 †
LL (°)	Pre-op	12.7 ± 21.5	15.1 ± 21.0	11.1 ± 23.3	0.816
	Post-op	45.7 ± 10.0	48.0 ± 9.9	45.1 ± 13.2	0.564
	2y	44.3 ± 11.9	45.2 ± 11.9	40.0 ± 16.4	0.386
	5y	41.9 ± 10.8	40.6 ± 10.1	39.4 ± 14.2	0.719
TK (°)	Pre-op	22.7 ± 20.2	25.8 ± 21.6	20.9 ± 19.4	0.708
	Post-op	34.5 ± 11.2	38.3 ± 13.1	36.7 ± 14.0	0.381
	2y	43.7 ± 14.3	42.9 ± 15.6	38.8 ± 16.1	0.493
	5y	45.2 ± 15.2	41.0 ± 17.3	40.8 ± 15.8	0.414
PT (°)	Pre-op	32.9 ± 10.3	39.9 ± 12.7	33.4 ± 9.7	0.013 †
	Post-op	18.2 ± 8.7	23.2 ± 9.1	16.8 ± 6.1	0.047* 0.027 †
	2y	23.4 ± 8.4	29.1 ± 12.3	22.3 ± 5.8	0.019 †
	5y	24.3 ± 9.1	29.3 ± 10.3	25.9 ± 6.9	0.075
PI (°)	Pre-op	50.1 ± 12.5	57.8 ± 10.3	48.8 ± 10.0	0.039* 0.011 †
ODI	Pre-op	42.9 ± 16.6	44.6 ± 17.1	40.4 ± 14.8	0.781
	2y	29.6 ± 19.7	27.5 ± 19.8	20.4 ± 14.8	0.225
	5y	28.0 ± 19.2	27.5 ± 20.2	23.9 ± 16.9	0.768
SRS-22r total	Pre-op	2.6 ± 0.6	2.4 ± 0.5	2.7 ± 0.6	0.097
	2y	3.5 ± 0.7	3.4 ± 0.7	3.7 ± 0.7	0.250
	5y	3.4 ± 0.7	3.3 ± 0.8	3.6 ± 0.8	0.300

Mean values are presented as ± standard deviation.

Abbreviations: DI, distal instability; SVA, sagittal vertical axis; TPA, T1-pelvic angle; LL, lumbar lordosis; TK, thoracic kyphosis; PT, pelvic tilt; PI, pelvic incidence; ODI, Oswestry disability index; SRS-22r: the

22-item Scoliosis Research Society questionnaire (revised).

* $p<0.05$: statistically significant: rod fracture vs screw loosening

[†] $p<0.05$: statistically significant: non-DI vs screw loosening

Table 4 Comparison of the sub-group with and without alignment change in patients with rod breakage at S1-IL

	Alignment change (n=5)	No alignment change (n=11)	p-value
Age (years)	63.2 ± 7.6	67.3 ± 11.9	0.221
Female	4 (80%)	9 (82%)	0.705
BMD (T-score)	-1.1 ± 1.1	-1.3 ± 1.1	0.859
Fusion length	9.8 ± 0.8	9.2 ± 0.4	0.180
High-grade osteotomies	4 (80%)	0	0.003*
Rod number (2-rod / multi-rod)	2 / 3	9 / 2	0.139
L5/S interbody fusion	2 (40%)	11 (100%)	0.018*
Date of occurrence (months)	24.8 ± 10.2	29.6 ± 16.2	0.827
Symptom at rod breakage	5 (100%)	5 (45%)	0.084
Revision	3 (60%)	3 (27%)	0.242

Continuous data are presented as mean ± standard deviation of median. Categorical data are presented as number (%). Abbreviations: BMD, bone mineral density; PJK, proximal junctional kyphosis; UIV, upper instrumented vertebra.

* $p<0.05$: statistically significant between 2 groups

Table 5 The cases with alignment change after rod breakage at S1/IL

Age (y)	Sex	UIV	High-grade osteotomy	The date of occurrence (months)	Other complication occurred at the same time	Treatment
51	M	T10	PSO (L2)	14	Rod breakage at osteotomy site	Revision
61	F	T8	VCR (L1)	40	Rod breakage at L5/S	Revision
68	F	T9	VCR (L1)	28	Sacral fracture	Revision
70	F	T9	VCR (L1)	17	PJK	Conservative
66	F	T10	-	25	Rod breakage at L4/5	Conservative

Abbreviations: UIV, upper instrumented vertebra; PSO, pedicle subtraction osteotomy; VCR, vertebral column resection; PJK, proximal junctional kyphosis.

Figure Legends

Figure 1
A: Assessment of the iliac screw loosening. There is a radiolucent area around the iliac screw (white arrows).
B: Assessment of the rod breakage. There is rod breakage between S1 and iliac screws (white arrow).

Figure 2
Time-course changes in the sagittal vertical axis (SVA) (**A**), T1-pelvic angle (TPA) (**B**), and pelvic tilt (PT) (**C**) among the patients with non-distal instability (DI) and DI (iliac screw loosening, rod breakage at S1/IL).
* Statistically significant differences in changes (non-DI vs rod breakage, non-DI vs iliac screw loosening).

† Statistically significant differences at each timepoint (iliac screw loosening vs rod breakage, iliac screw loosening vs non-DI).

Figure 3
The comparison of radiographic parameters between patients with and without alignment change after rod breakage at S1/IL; sagittal vertical axis (SVA) (**A**), T1-pelvic angle (TPA) (**B**), and pelvic tilt (PT) (**C**)

† Statistically significant differences at each time point.

Figure 1

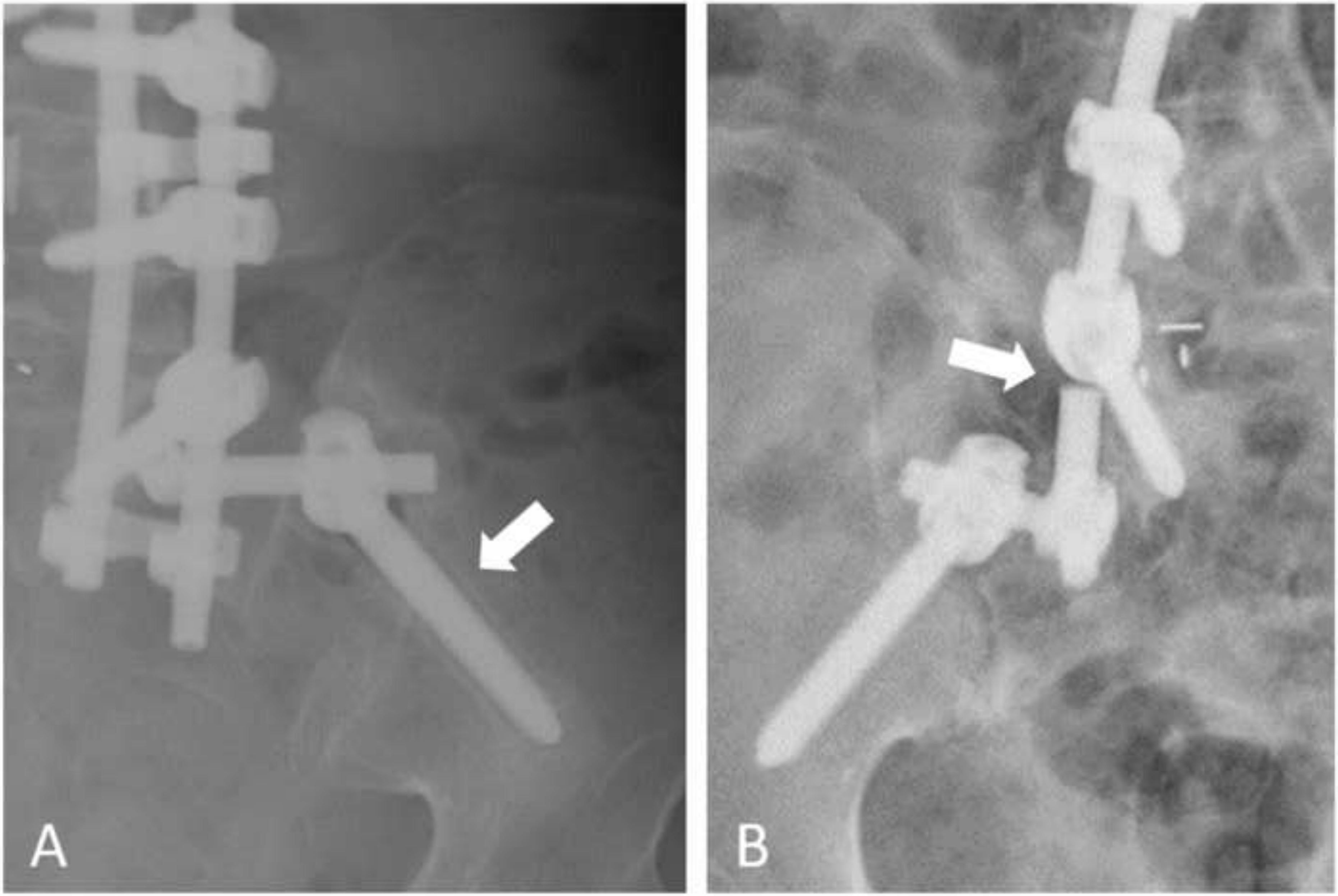


Figure 2 Click here to access/download;Figures;fig.2.tif

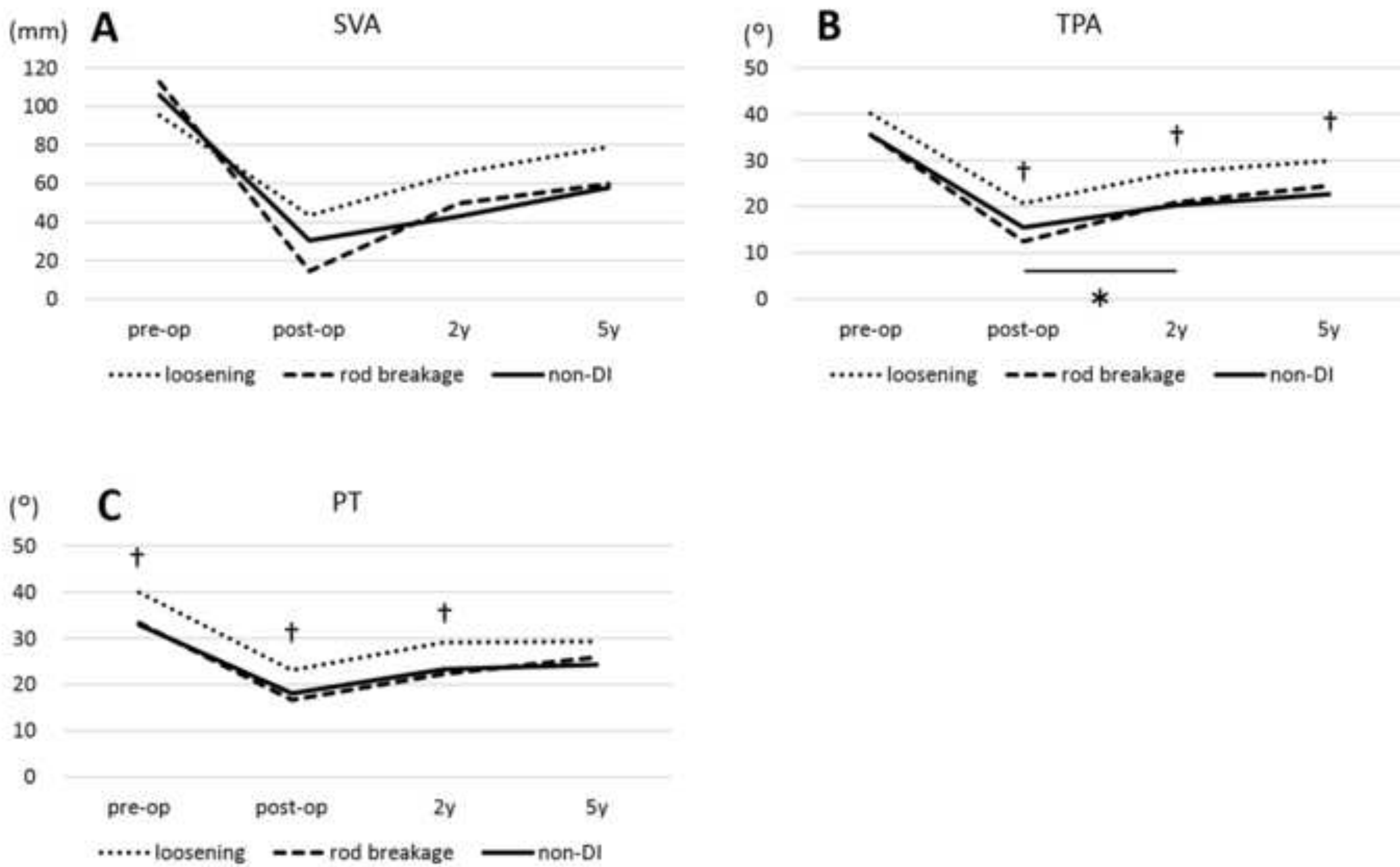
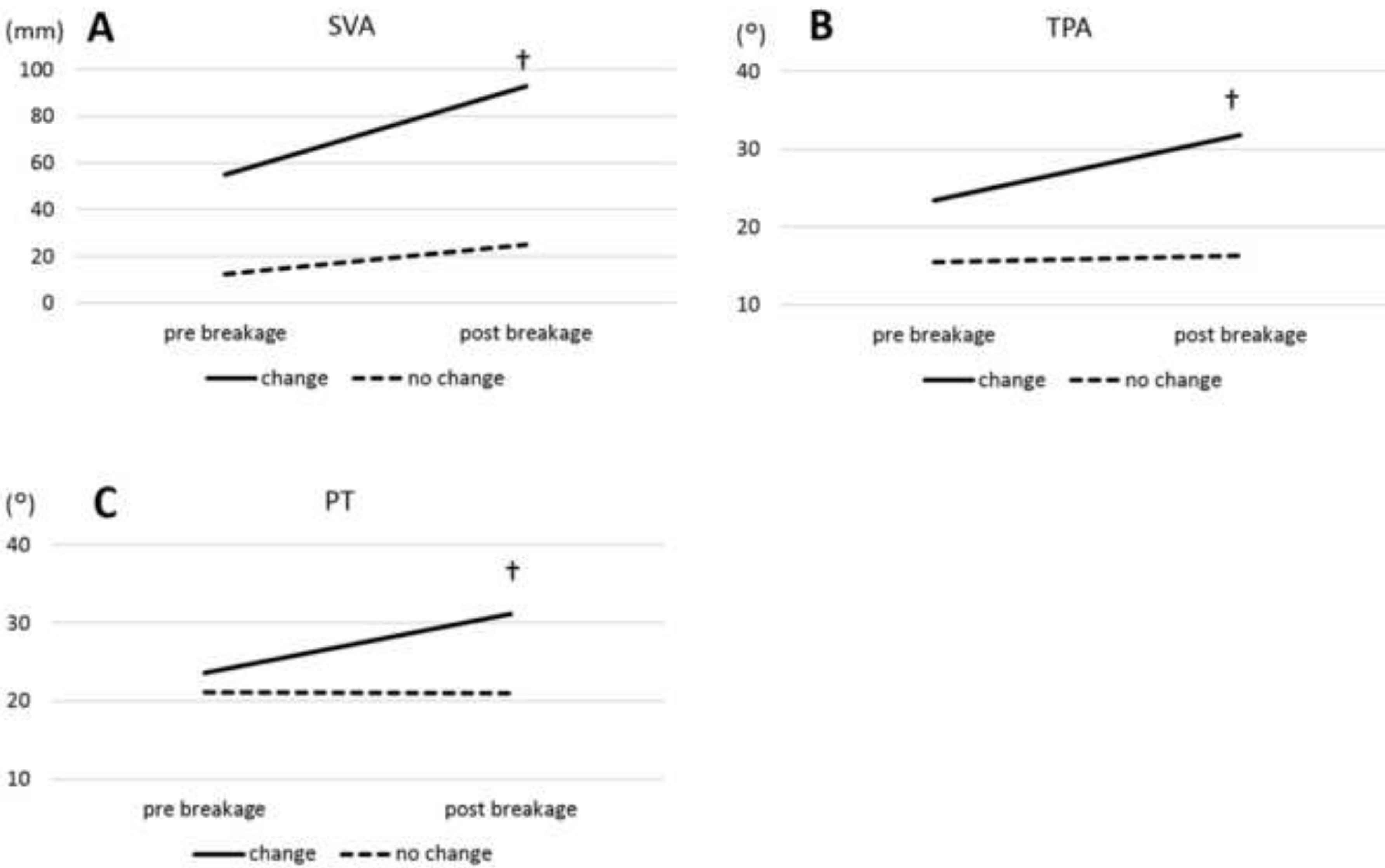


Figure 3


(mm)
A
SVA
100
80
60
40
20
0
†
pre breakage
post breakage
change
no change
(°)
B
TPA
40
30
20
10
†
pre breakage
post breakage
change
no change
(°)
C
PT
40
30
20
10
†
pre breakage
post breakage
change
no change