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DEFORMITY

Functional Alignment Within the Fusion in Adult Spinal Deformity (ASD) Improves Outcomes and Minimizes Mechanical Failures

Fares Ani, MD, Ethan W. Ayres, MD, MPH, Alex Soroceanu, MD, MPH, Gregory M. Mundis, MD, Justin S. Smith, MD, PhD, Jeffrey L. Gum, MD, Alan H. Daniels, MD, Eric O. Klineberg, MD, Christopher P. Ames, MD, Shay Bess, MD, Christopher I. Shaffrey, MD, Frank J. Schwab, MD, Virginie Lafage, PhD, Themistocles S. Protopsaltis, MD, and International Spine Study Group

Study Design. Retrospective review of an adult deformity database.

Objective. To identify pelvic incidence (PI) and age-appropriate physical function alignment targets using a component angle of T1-pelvic angle within the fusion to define correction and their relationship to proximal junctional kyphosis (PJK) and clinical outcomes.

Summary of Background Data. In preoperative planning, a patient's PI is often utilized to determine the alignment target. In a trend toward more patient-specific planning, age-specific alignment has been shown to reduce the risk of mechanical failures. PI and age have not been analyzed with respect to defining a functional alignment.

Methods. A database of patients with operative adult spinal deformity was analyzed. Patients fused to the pelvis and upper-instrumented vertebrae above T11 were included. Alignment within the fusion correlated with clinical outcomes and PI. Short form 36-Physical Component Score (SF36-PCS) normative data and PI were used to compute functional alignment for each patient. Overcorrected, under-corrected, and functionally corrected groups were determined using T10-pelvic angle (T10PA).

Results. In all, 1052 patients met the inclusion criteria. T10PA correlated with SF36-PCS and PI (R = 0.601). At six weeks, 40.7% were functionally corrected, 39.4% were overcorrected, and 20.9% were under-corrected. The PJK incidence rate was 13.6%. Overcorrected patients had the highest PJK rate (18.1%) compared with functionally (11.3%) and under-corrected (9.5%) patients ($P < 0.05$). Overcorrected patients had a trend toward more PJK revisions. All groups improved in HRQL; however, under-corrected patients had the worst 1-year SF36-PCS offset relative to normative patients of equivalent age (−8.1) *versus* functional (−6.1) and overcorrected (−4.5), $P < 0.05$.

Conclusions. T10PA was used to determine functional alignment, an alignment based on PI and age-appropriate physical function. Correcting patients to functional alignment produced improvements in clinical outcomes, with the lowest rates of PJK. This patient-specific approach to spinal alignment provides adult spinal deformity correction targets that can be used intraoperatively.

From the Department of Orthopaedic Surgery, NYU Langone Orthopedic Hospital, New York, NY.

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Address correspondence and reprint requests to Themistocles S. Protopsaltis, MD, 301 E17th. Street, Rm 413, New York, NY 10003; E-mail: Themistocles.Protopsaltis@nyumc.org

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Surgical treatment of adult spinal deformity generally consists of interbody and posterolateral fusions to restore a patient to a normal level of pain and function. Although this method helps alleviate most problems associated with Adult spinal Deformity (ASD), it is subject to other complications that may arise with an instrumented spine. An often-discussed complication of deformity correction is proximal junctional kyphosis (PJK) or proximal junctional failure (PJF), which can potentially lead to pain, disability, functional or neurological deficits, and in some cases, reoperation.[1,2] PJK often occurs within the first 90 days after surgical realignment, with 80% occurring within 18 months.[3–5] Although PJK is not fully understood, many risk factors for PJK have been described in the literature, such as age, correction magnitude, and selection of upper-instrumented vertebrae (UIV).[6] Many potential solutions have been proposed to reduce the rate of PJK, such as vertebroplasty, pedicle hooks, tethering, tendonous grafting, and alignment parameters.[7–13]

The definition of "optimal alignment" continues to be a topic of great contention in the community. Several different alignment targets have been proposed: Schwab criteria, global alignment and proportion score, and age-adjusted alignment.[14,15] Previous studies have used sagittal vertical axis (SVA) to measure overcorrection or under-correction; however, in patients with PJK, SVA underestimates the overcorrection because of patient compensation, and PJK itself increases the SVA. Recent studies have also highlighted the importance of age when planning correction in ASD surgery. Age-specific alignment targets have been shown to improve patient outcomes and reduce the risk of mechanical failures such as PJK.[16] Similarly, research has also shown that pelvic incidence is an important determinant of spinal alignment; therefore, it is a parameter that must also be considered when planning deformity correction. However, PI and age have not been analyzed simultaneously with respect to defining functional alignment and its effect on clinical outcomes and rates of complications, including PJK.[17]

The T1-pelvic angle (TPA) has been proposed as a useful perioperative planning parameter because it is unaffected by patient compensation. Utilizing a component angle of TPA within the fusion, T10PA allows for measuring spinopelvic alignment separately from that of the unfused thoracic spine and is therefore unaffected by the development of PJK postoperatively. T10PA also has the advantage of being able to be measured intraoperatively, enabling the simultaneous visualization of both femoral heads and the T10 vertebral body within a single plain radiograph. Furthermore, as a result of the fusion, its measurements will have limited variability in both erect and prone positions. The purpose of this study was to identify age-functional and PI-functional alignment targets using the component angle of TPA within the fusion to define overcorrection and under-correction and their relationship to mechanical complications and clinical outcomes. Specifically, we examined the development of severe PJK (change $>21.6°$), reoperations, and patient-reported outcome measures in relation to T10PA target alignments.

METHODS

Study Design

This study is a retrospective analysis of prospectively collected data from ASD patients conducted through a collaboration of spine surgeons from 11 sites across the United States. Patients were enrolled through an Institutional Review Board-approved protocol at each site. Patients older than 18 years were retrospectively included if they underwent three-column osteotomy or prospectively enrolled if they had radiographic evidence of spinal deformity (coronal cobb angle $\geq 20°$, SVA ≥ 5 cm, pelvic tilt $\geq 25°$, or thoracic kyphosis $\geq 60°$). All ASD patients with radiographic and health-related quality of life (HRQOL) data at baseline, six weeks, and one year were included in the analysis to develop an equation for functional alignment. The analysis that looked at functional correction and PJK rates only included patients with UIV at T10 or above. In the PJK analysis, overcorrection, functional correction, and under-correction were determined from the 6-week postoperative radiographs. Patients who underwent revision surgery before the 6-week time point were excluded from the study. Patients were excluded if they had neuromuscular, traumatic, infectious, or malignant causes of scoliosis.

Radiographic Analysis and Data collection

Data collection at baseline included standardized HRQL questionnaires as well as clinical, demographic, and radiographic information. Basic demographic and clinical data included patient age, sex, body mass index, smoking status, American Society of Anesthesiologists physical status classification, and history of spine surgery. All subjects had 36-inch standing scoliosis x-rays for which the patients had no external support, such as walkers. All radiographic measurements were performed at a location using standard techniques to establish parameters. Radiographic analysis was performed on baseline x-rays using dedicated and validated software (Spineview, SpineLab, ENSAM).[18,19]

The radiographic parameters recorded were TPA, T10PA, pelvic tilt, and PI (Fig. 1). For this study, PJK was defined in Glattes *et al.* as kyphotic angle of >10 degrees between UIV and UIV+2, and PJF was defined as severe PJK (kyphotic change >21.6 degrees), UIV olithesis, or proximal junctional fracture.[20] HRQOL assessment tools

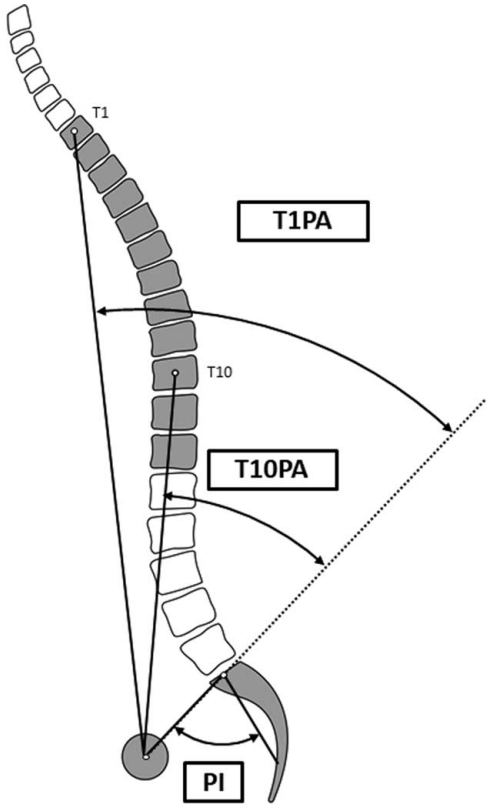

Figure 1. Measurement of pelvic incidence, T1-pelvic angle (TPA), and T10-pelvic angle (T10PA) on lateral spine radiograph in the standing position. As a component angle of TPA, within the fusion, T10PA can be measured separately from that of the unfused spine and is therefore unaffected by the development of PJK postoperatively. PJK indicates proximal junctional kyphosis; PI, pelvic incidence; T10PA, T10-pelvic angle; TPA, T1-pelvic angle.

included the Oswetry Disability Index, Scoliosis Research Society-22, and Short Form (SF)-36 questionnaires. The Physical Component Score (PCS), a standard summary score based on the Short Form 36 Survey (SF36), was also calculated.

Statistical Analysis

Determining Functional T10PA

All patients with operative ASD who met the inclusion criteria were evaluated. Using preoperative alignment and HRQLs, linear regression modeling was used to define the relationships between T10PA, PI, Short form 36-Physical Component Score (SF36-PCS), and age. Using previously published age-normative SF36-PCS scores, an equation to determine a patient's functional T10PA for a given age and PI was developed via linear regression.

Assessing Postoperative Alignment

Using patients with fusions from the pelvis to UIV caudal to T11, decision tree analysis was then used to define over-correction, under-correction, and functional correction based on T10PA at six weeks postoperation. Decision tree analysis was performed using the "ctree" function, a recursive binary partitioning algorithms within the R "party" package (R, version 3.2.4, R Foundation for Statistical Computing, Vienna, Austria).

Comparing Outcomes vs. Functional Correction

The patients were stratified into three groups based on whether their postoperative alignment was overcorrection, under-correction, or functionally corrected for age and PI. These groups were then compared in terms of the one-year rates of PJK, severe PJK, and rates of revision for PJK. We also evaluated HRQLs at one year postoperation, including SF36 PCS scores, the change in PCS scores from baseline, and the difference between one year postoperative PCS score and age-normative PCS score (PCS offset). Continuous variables were compared between groups using one-way ANOVA and post hoc Tukey tests. χ^2 was used to compare categorical variables. Extreme overcorrected or under-corrected patients (>2 SD from the mean postoperative T10PA) were excluded from the analysis, as were patients who underwent a revision earlier than six weeks after their index surgery.

All statistical analyses were performed using SPSS, except for decision tree analysis. Statistical significance was set at $P < 0.05$.

RESULTS

Linear Regression Analysis

In all, 1052 patients met the inclusion criteria (mean age = 60 y (range:18—86 y); 74% female; Oswetry Disability Index range:0–92). Alignment within the fusion correlated with SF36-PCS score, age, and PI. Baseline T10PA was significantly correlated with PI ($R = 0.533$), SF36-PCS ($R = -0.284$), and age ($R = 0.308$). The linear relationship among T10PA, PI, and age was used to generate a regression to develop the following formula:

$$\text{T10PA} = (0.5 \bullet \text{PI}) - (0.1 \bullet \text{Age}) - 24.7 \; (R = 0.601 \; R^2 = 0.360).$$

Using this equation, PI- and age-adjusted-functional T10PA were calculated for each patient (Table 1). Decision tree analysis was performed to define the boundaries of functional correction, yielding an interval of $\pm 3.5°$.

Radiographic Analysis

A total of 608 patients with fusions to the pelvis and a UIV above T10 were evaluated. Based on the results of the decision tree analysis, patients were grouped into over-corrected ($>3.5°$), functionally aligned (within $\pm 3.5°$ of target alignment), and under-corrected ($<-3.5°$). At six weeks, 39.6% of patients were functionally corrected, 39.1% were overcorrected, and 21.2% were under-corrected. The overall incidence rate of severe PJK was 13.6% (Table 2). Overcorrected patients had the highest severe PJK rate (18.1%) compared with functionally

TABLE 1. Functional T10PA Targets (°) Stratified by PI for Different Age Categories Corresponding to US-normative SF36 PCS

	Age (y)					
	< 35	35–44	45–54	55–64	65–74	> = 74
Pelvic Incidence (°)						
40–50	0.54	1.03	1.82	2.99	3.80	5.51
50–60	5.56	6.05	6.84	8.01	8.82	10.53
60–70	10.58	11.07	11.86	13.03	13.84	15.55
70–80	15.60	16.09	16.88	18.05	18.86	20.57
> =80	21.62	22.11	22.90	24.08	24.88	26.59

PI indicates pelvic incidence.

(11.3%) and under-corrected (9.5%) patients ($P < 0.05$), and overcorrected patients had a trend toward more PJK revisions (2.1% vs. 1.2% vs. 0%, $P = 0.09$). All groups improved in HRQL from baseline to one year (all $P < .05$), but under-corrected patients had the worst one year SF36-PCS offset relative to normative patients of equivalent age (–8.1) *versus* functional (–6.1) and overcorrected (–4.5), $P < 0.05$, respectively (Table 3).

Early Revision Sub-analysis

Of the entire cohort, 15 patients (2.47% overall) were excluded because they underwent revision surgery within six weeks of their initial operation. Within this subset, 73.3% were female, and the mean age was 64.0 ± 6.3 years and the average body mass index stood at 30.4 ± 5.4 kg/m^2. The primary reason for reoperation within the first six weeks was neurologic complications; specifically, nine patients (60%) presented symptoms like radiculopathy or motor deficits. Implant misalignment and medial breaches were observed in three cases (20%), with another patient showing a deficit from a wound-related issue. Revisions due to sagittal imbalance accounted for four cases (26.7%), with three of these (20%) attributed to PJF; these were distributed uniformly across the three alignment categories. In addition, implant failure and screw loosening were evident in two patients, which is 13.3% of this group.

DISCUSSION

Postsurgical quality of life is one of the most important metrics of effective treatment. Although a patient's alignment may be considered "ideal" to reduce the likelihood of complications, it does not necessarily guarantee the best quality of life a patient could achieve. The risk and effect of each complication on the patient's quality of life must be considered, as certain complications may be temporary or have a minor effect on overall patient satisfaction. For example, a systematic review conducted by *Kim et. al.* (2012) has demonstrated that PJK does not have a strong effect on HRQLs.[21] Despite this, surgical practice has favored more aggressive radiographic realignment

TABLE 2. Comparison of Baseline Demographic, Radiographic, Patient-reported Characteristics, and Rates of PJK Between Those That Were Overcorrected, Under-corrected or Aligned Functionally

	Overcorrected	Functional	Under-corrected	*P*
N = 608, n (%)	238 (39.1)	241 (39.6)	129(21.2)	—
Age (y)	64.5 ± 10.3	63.3 ± 8.9	62.4 ± 9.9	0.12
BMI (kg/m2)	27.0 ± 5.2	28.9 ± 7.0	30.3 ± 6.8	< 0.05
Sex (%female)	69.8	77.4	84.7	< 0.05
ODI	45.8 ± 17.2	49.7 ± 16.8	50.7 ± 14.3	< 0.05
PCS	30.5 ± 8.4	28.6 ± 8.3	27.6 ± 7.6	< 0.05
Pelvic incidence	56.8 ± 13.1	56.3 ± 12.8	56.0 ± 12.9	0.86
T1-pelvic angle	22.0 ± 11.5	27.6 ± 12.1	34.0 ± 11.8	< 0.05
SVA (mm)	67.7 ± 66.4	94.1 ± 72.9	113.0 ± 73.4	< 0.05
T10-pelvic angle	10.5 ± 11.3	16.8 ± 10.8	23.9 ± 11.5	< 0.05
Rate of PJK, %	18.1	11.3	9.5	< 0.05
Revision for PJK, %	2.1	1.2	0	0.09

BMI indicates body mass index; ODI, Oswetry Disability Index; PCS, Physical Component Score; PJK, proximal junctional kyphosis; SVA, sagittal vertical axis.

TABLE 3. Differences in SF36 Physical Component Score (PCS) When Compared Among Their Offset to Functional Alignment

	Overcorrected	Functional	Under-corrected	*P*
N = 608, n (%)	238 (39.1)	241 (39.6)	129 (21.2)	—
Baseline PCS	30.5 ± 8.4	28.6 ± 8.3	27.6 ± 7.6	< 0.05
1-year PCS	40.1 ± 9.5	39.0 ± 10.2	37.3 ± 10.0	0.11
1-YearPCS offset	−4.5	−6.1	−8.5	< 0.05
Change from baseline	9.2 ± 9.2	10.1 ± 10.5	9.8 ± 9.6	0.71

PCS indicates Physical Component Score.

parameters that sacrifice lifestyle and functionality to avoid the possibility of PJK.

Utilization of HRQLs as a primary outcome in patients undergoing realignment surgery continues to grow as health care continues to become more patient-centered. The overall goal of realignment surgery is to relieve a patient's symptoms and pain caused by sagittal malalignment and maximize their cone of economy. This allows the patient to resume normal daily function and continue their preferred lifestyle without the hindrance of pain and neurological deficits. Owing to the large focus on pain-centered outcomes, planning surgical correction continues to transition toward a personally tailored operation. Past literature has identified that realignment targets should be tailored to patient age and pelvic incidence.[16,22,23] Having an alignment goal based on age-appropriate physical function has particular utility in older patients. Patients in this category may not require rigorous correction to achieve an age-appropriate physical function. Such rigid and elaborate constructs can result in additional complications and potentially higher PJK rates.

T10PA was chosen as the component angle of TPA within the fusion, as it allows for the evaluation of spinopelvic alignment separate from that of the unfused thoracic spine (Fig. 2). Our results showed a correlation between T10PA and physical function (R = –0.284). T10PA represents an anatomical angle that remains unaffected to the onset of proximal junctional kyphosis and can be visualized within a single radiograph. For patients with spinal deformity, the angle may be considered fixed across prone and standing radiographs; however, no research has directly compared the reliability of prone intraoperative radiographs to standing

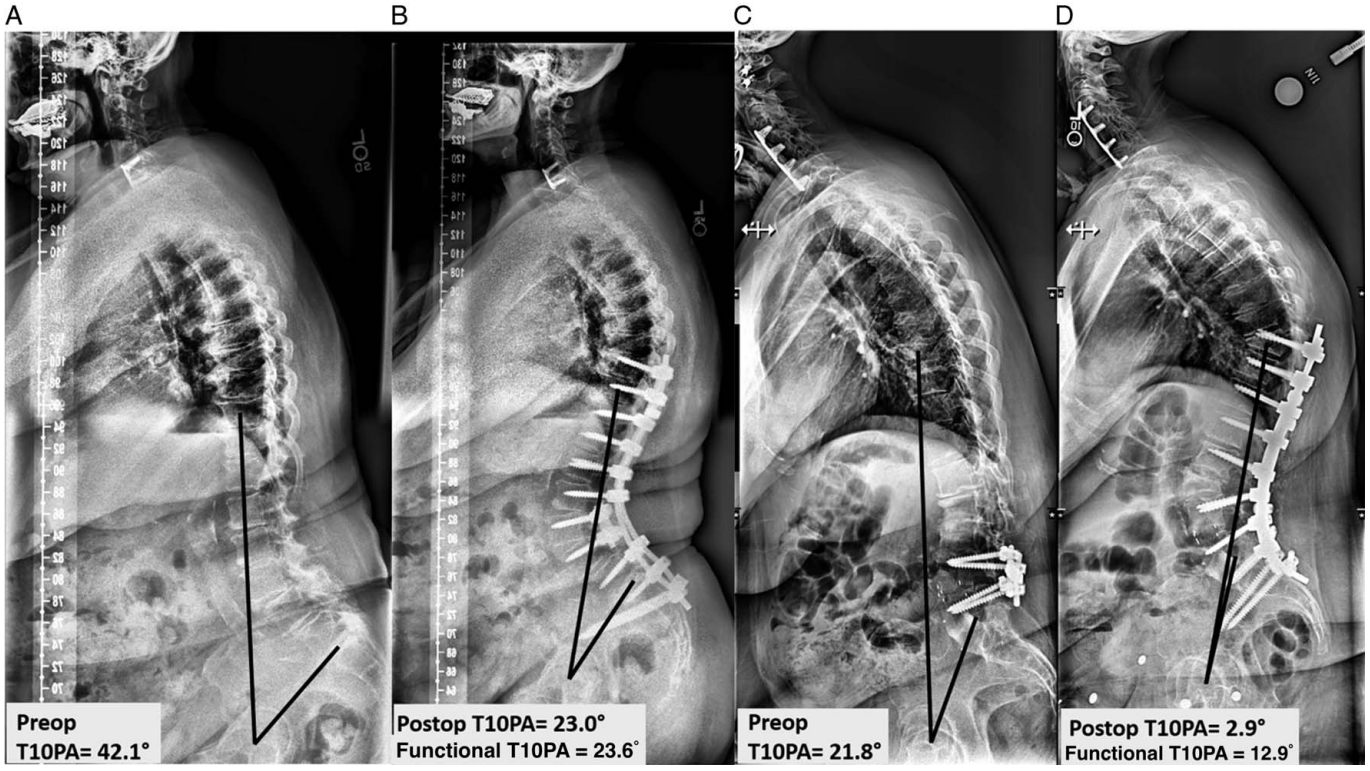

Figure 2. (A) Preoperative and (B) postoperative radiographs of a 60-year-old patient that was corrected to functional alignment based on T10PA and did not develop PJK. (C) Preoperative and (D) postoperative radiographs of a 64-year-old patient that was overcorrected (T10PA offset = 10°) and subsequently developed PJK. PJK indicates proximal junctional kyphosis; T10PA, T10-pelvic angle.

films within or external to the fusion construct. Thus, a more thorough evaluation of intraoperative radiographs could enhance our understanding of their applicability in such settings, paving the way for more precise surgical planning and postoperative care.

The use of patient-reported outcome scores and age to define the goals of measurement in spinal deformity is not novel. Over the past decade, surgeons have investigated the inclusion of quality-of-life outcomes and patient-specific metrics in spinal alignment goals.[24,25] The Scoliosis Research Society-Schwab classification was one of the first to do so and has shown great intraobserver and interobserver reliability.[26,27] More recently, the Sagittal Age-Adjusted Score (SAAS) for adult spinal deformity has continued the trend toward a focus on patient-reported outcomes.[25] As with the literature above, we hope the present study emphasizes the importance of incorporating patients' individualistic needs and functional outcomes into their alignment goals.

Although prospectively collected radiographic and HRQOL data were used, the primary limitation of this study was its retrospective design. Six-week postoperative radiographs were used for the postoperative alignment analysis as it was the most accurate alignment to the alignment the patient would have had immediately after surgery. This study utilized published age-specific normative values for the SF36 PCS and data from a multicenter database of ASD patients to determine the alignments that would correspond to the expected functional status of their similarly aged peers. To quantify health status in many different conditions or diseases, researchers have often opted to use SF36 health outcome measures. Since normative data are available for subjects of different ages, the SF36 can be used to compare patients with a specific pathology, in this case, ASD, to those of their age-matched asymptomatic peers. Although this methodology has flaws, there are few tools to appropriately quantify functional outcomes in such a population.

CONCLUSION

This study underscored the significance of a novel approach to spinal alignment within the fusion, using T10PA, a component angle of TPA, to determine PI-functional alignment. Correcting a patient with ASD to functional alignment is associated with reduced rates of PJK. This method, which considers age-appropriate physical functional and PI-specific factors, offers a personalized and effective surgical strategy for treating ASD. Intraoperative spinopelvic measurements derived from this approach could provide surgeons with more accurate correction targets specifically tailored to each patient's unique physiological parameters and functional needs. While these findings are promising, further investigations are necessary to ascertain the reliability and applicability of intraoperative spinopelvic measurements. Consequently, this will pave the way toward a more patient-centric surgical approach that maximizes postoperative quality of life and minimizes complication rates.

➢ Key Points

- ❑ T10PA, a component angle of TPA within the fusion was used to determine functional alignment, an alignment goal based on PI and age-appropriate physical function.
- ❑ The linear relationship between T10PA, PI, and age was used to generate a regression to develop the formula: $T10PA = (0.5 \bullet PI) - (0.1 \bullet Age) - 24.7$ ($R = 0.601$ $R^2 = 0.360$).
- ❑ Based on the decision tree analysis, patients were grouped into overcorrected (> 3.5°), functionally aligned (within ± 3.5° of target alignment), and under-corrected (< −3.5°).
- ❑ Overcorrected patients had the highest PJK rate (18.1%) compared with functionally (11.3%) and under-corrected (9.5%) patients ($P < 0.05$).
- ❑ All groups showed improvement in HRQL from baseline to one year (all $P < 0.05$); however, under-corrected patients had the worst one-year SF36-PCS offset relative to normative patients of equivalent age (−8.1) versus functional (−6.1) and overcorrected (−4.5), $P < 0.05$.

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