Evaluating patient specific rods in adult spinal deformity surgery using patient reported outcome measures: a prospective observational study

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***Background Context*:**

Surgical intervention for ASD is widely accepted, after non-operative management, to correct deformity and improve disability. A relatively new surgical technique utilized pre-bent patient-specific rods (PSR). These have been developed with software allowing preoperative deformity correction planning and provide the surgeon with an intraoperative deformity correction consistent with the surgical plan. Notably, there are reduced operation times because PSR do not require contouring during surgery which results in less rod microfractures and decreased fatigue-life. The literature surrounding PSR surgery lacks reporting on PROMs and rather focuses on radiological outcomes.

Aim

To report clinical outcomes using PSR, comparing pre-operative to post-operative PROMs to mid-term follow-up. Specifically, we investigated rates of junctional complications both proximally (kyphosis/failure) and distally (failure).

Study Design and Method

Prospective study of all consecutive patients who underwent ASD surgery with PSR at a single institution between Jan 2019 and June 2020. The minimum follow-up was 2 years. Ethics was obtained. Patients with surgery at >4 levels and thoracolumbar deformity according to the Schwab criteria were included. VAS Back/VAS Leg, ODI, SF-12 (mental/physical), and the Ottawa decision regret questionnaire were evaluated preoperatively, at 6 weeks, 6 months, 12 months and final follow-up postoperatively. Sagittal spinopelvic parameters measured by EOS scans were performed at the same time points reported by independent radiologists (figure 1).

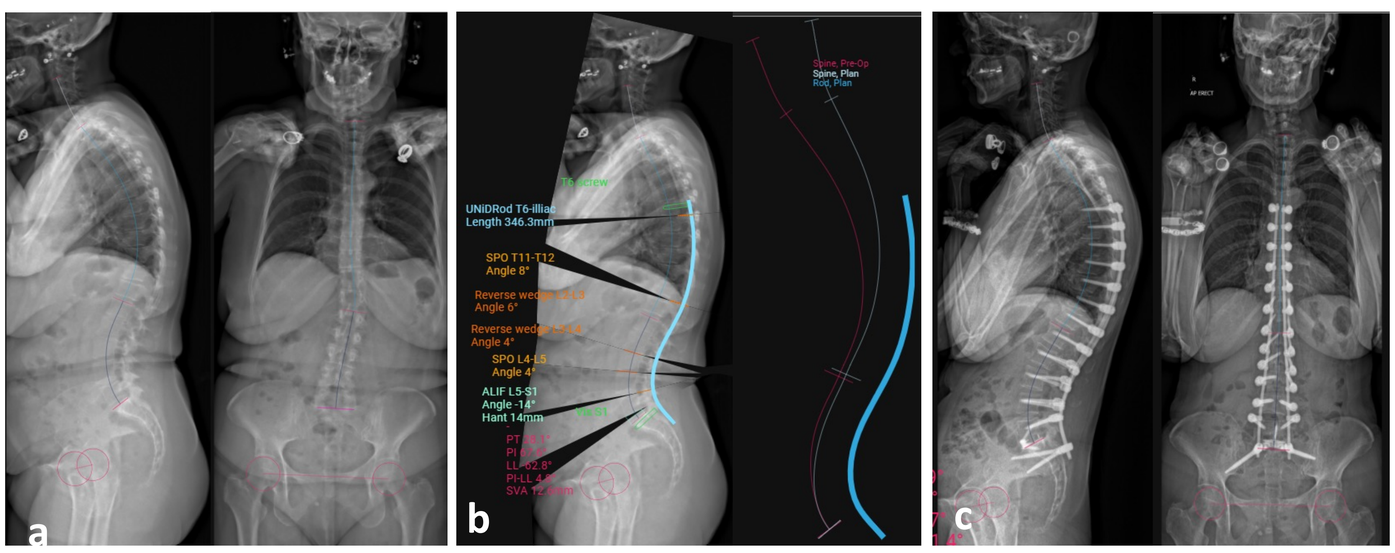

Figure 1 a coronal and sagittal EOS scan preoperatively **b** surgical plan **c** coronal and sagittal EOS scan 24-month post-operatively

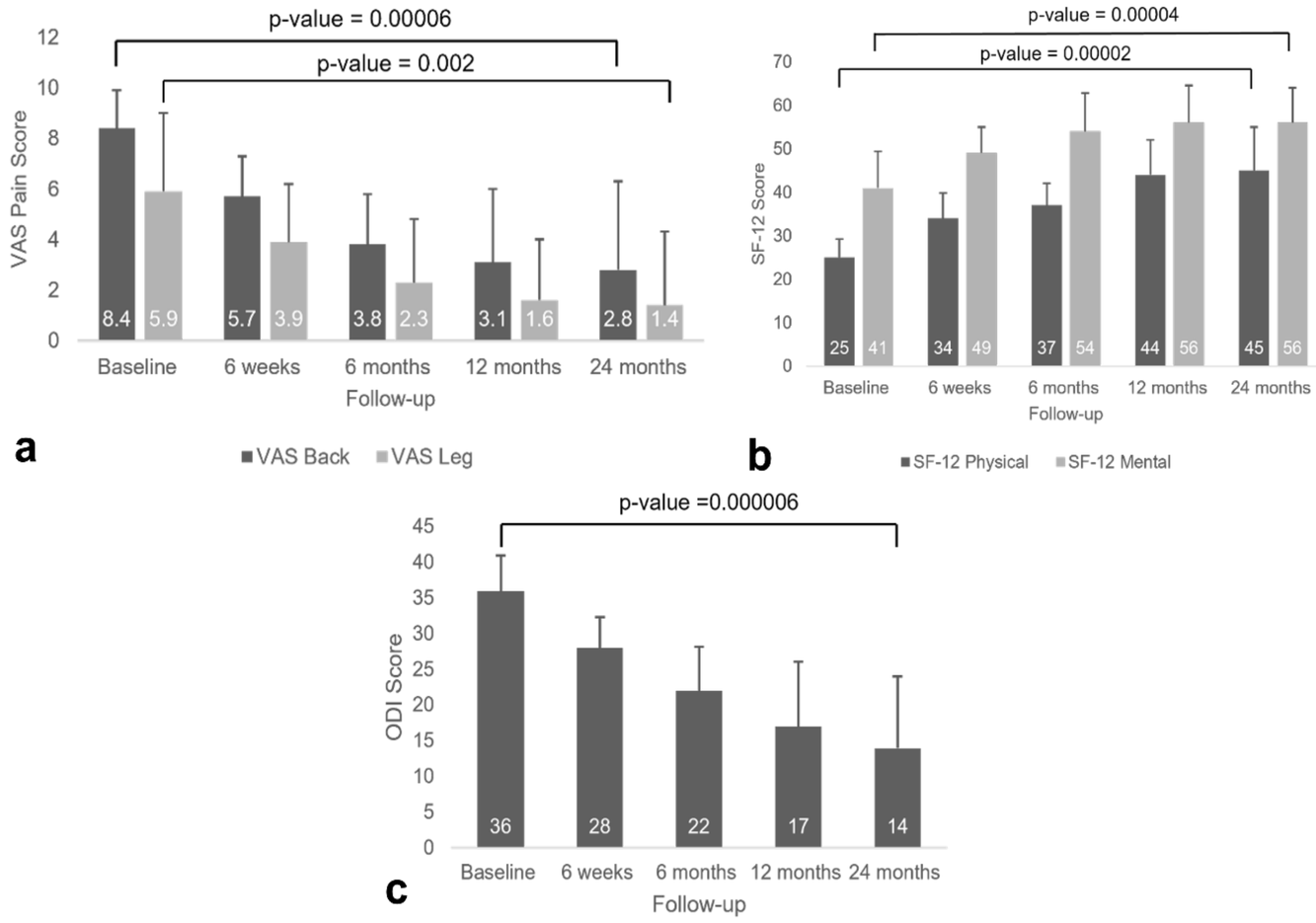

Figure 2 PROMS from baseline, 6 weeks, 6 months, 12 months, and 24 months follow-up. **a** VAS Back and Leg Score **b** SF-12 Physical / Mental **c** ODI.

Results:

Eighteen patients underwent PSR within the study period had a mean age of 70 (±6.9) years, 77% were female with a mean BMI of 28 (±5.1) kg/m2. Five of 18 patients were ex-smokers. Eleven out of 18 operations were two-stage approaches. All surgeries used titanium 5.5 mm rods without intraoperative bending. Preoperative mean VAS Back, VAS Leg, ODI, and SF-12 (physical/mental) showed statistically significant improvement post-operatively to 6-months, 12-months, and 2-years (figure 2). Three patients reported decisional regret to undergo the PSR surgery with a score of more than 60, they all suffered DJF. The remaining patients reported low regret scores.

Key findings:

Sagittal parameters (sagittal vertical axis (SVA), pelvic incidence/lumbar lordosis mismatch (PI-LL), and pelvic tilt (PT)) have been correlated to pain and disability in ASD. However, there is limited literature regarding the use of PSR and correlation to PROMs. Our study reported a statistically significant improvement in PROMs from baseline to final follow-up, demonstrating PSR as an effective intervention for ASD. Decisional regret, as evaluated by the Ottawa decision regret questionnaire, was reported in patients who suffered distal junctional failure (DJF) and required reoperation. All other patients were satisfied with their surgical outcomes.