Does Custom Instrumentation Reduce the Risk of Instrumenation Failure in Adult Cervical, Spinal Deformity, or Degenerative Lumbar Pathology Patients: A Multi-Center Predictive Analysis

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INTRODUCTION: Custom, pre-operatively constructed instrumentation has been increasingly utilized and studied due to the potential for decreased material strain and possible decreased risk of instrumentation failure in adult spinal deformity (ASD), cervical deformity (CD), or lumbar degenerative (Degen) surgery. Yet, there remains a paucity of literature assessing long-term failure rates.

METHODS: Operative CD and ASD patients ≥18yrs with pre-(BL) and minimum two-year (2Y) postop demographic/HRQL data were assessed. All patients were implanted with artificial intelligence-assisted pre-operatively planned custom rods. Patients were categorized as having suffered instrumentation failure (rod fracture, screw failure) (Failed) or not (Not Failed) at any point after index surgery. Mechanical failure was defined as: instrumentation. Bonferroni-adjusted ANOVA assessed differences in demographics and radiographic parameters. Conditional backstep binary regression and Conditional Inference Tree (CIT) analysis identified thresholds of predictors of mechanical failure.

RESULTS: 171 patients were included (59.3±12.7 yrs, 33% F, BMI:27.9±6.0 kg/m2). 43.3% of patients were ASD, 18.7% were CD, and 38.0% were Degen. At baseline, patient groups were significantly different in age (p=.018) and gender (p=.026), with ASD patients more likely to be older and female versus CD or Degen patients. By 2Y post-operatively, 4.7% of the cohort suffered instrumentation failure (mean time to failure: 17.8±13.9 months), with 8.1% of ASD, 3.1% of CD, and and 1.5% of Degen patients suffering failure (p=.171). 40.0% of Failed ASD patients underwent PSO versus 28.0% in Not Failed patients (p=.580). Adjusted for age and gender, ANCOVA revealed no significant differences in risk of failure by surgery type (p=.155), nor in time between index surgery and date of fracture (p=.428). The number of rods implanted and PSO frequency were not significantly different between Failed vs Not Failed cohorts (p=.105, .580). In ASD patients, no significant differences in baseline spinopelvic radiographic factors were identified. In CD patients, Failed patients maintained great C7-S1 SVA (p=.028), and in Degen patients, Failed patients presented with greater mean PT (p=.033), as well as magnitude of planned correction in PT (p=.002). Adjusted for gender, pelvic fixation, and magnitude of planned correction, logistic regression revealed patients with BL PT > 27.9° [OR: .831, (.733-.942), p=.004] in Degen patients and BL thoracic kyphosis > 39.3° [OR: .956, (.933-.980), p<.001] were signficiantly less likely to experience instrumentation failure by 2Y.

DISCUSSION AND CONCLUSION: Across adult spinal deformity, cervical deformity, and degenerative lumbar surgery, failure rates in patients implanted with custom instrumentation remain well below literature values. For patients who do suffer instrumentation failure, increased baseline thoracic kyphosis in ASD patients, and increased pelvic compensation in lumbar degenerative patients are predictive of decreased risk of failure by two-years post-operatively.