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Prospective Randomized Controlled Trial of Implant Density in AIS: Results of the Minimize Implants Maximize Outcomes Study

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Purpose: The role of implant density (anchors per level fused) has not been prospectively studied for a large cohort of AIS patients. In the Minimize Implants Maximize Outcomes (MIMO) Clinical Trial of equivalence, patients with Lenke 1A curve patterns were randomized to more versus fewer screws (high or low density) to determine if there was a difference in percent coronal Cobb angle correction within a 10% margin.

Methods: 14 sites accrued patients in the MIMO Clinical Trial (NCT01792609) which was designed as a trial of equivalence. Patients with Lenke 1A curves between 45-65 degrees were randomized to a high- (>1.8 screws per level fused, HD) vs. low- (<1.4 screws per level fused, LD) implant density and were followed for 2 years. Power analysis showed that 174 patients were needed to detect a difference in % correction with a 10% margin at each time point. Follow-up was performed at 3 month (189 patients), 1 year (156 patients), and 2 years (124 patients). Data was centrally collected and x-rays measured by trained reviewers.

Results: There was no difference in age, gender, preop curve magnitude, or race between the 2 groups. Mean % Cobb correction at 3 months was 74% in HD vs. 70% in LD (p=0.065, 95% CI -0.2 to 6.8%), 69% in HD vs. 66% in LD at 1 year (p=0.25, 95% CI, -1.7 to 6.7%), and 67% vs. 64% at 2 years (p=0.18, CI, -1.5 to 7.8%). There was no difference in operative time, blood loss, or length of stay amongst the two groups. There was no difference in pre- or postop thoracic kyphosis between the HD and LD groups. There were 6 reoperations in each group (p=1.0). Age was lower for patients who completed 2-year follow-up (11.6 years vs. 12.8, p<0.001), but there was no difference in race or preop curve magnitude.

Conclusions: For Lenke 1A curves between 45-65 degrees randomized to low vs. high implant density, this prospective, randomized, controlled study showed equivalent % coronal curve correction.

Significance: Given potential cost savings, surgeons could consider a low implant density construct (<1.4 screws/level fused) for posterior spinal fusion of Lenke 1A curves between 45-65 degrees.