Biomechanics of Spinal Hemiepiphysiodesis For Early Adolescent Idiopathic Scoliosis Using Clinically Relevant Construct

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Introduction: Mechanical growth modification is under investigation for non-fusion treatment of early adolescent idiopathic scoliosis. In preclinical studies, clip-screw implants altered spine curvature in vitro and in vivo [1,2,3]. A prospective clinical safety study (IRB approved, FDA IDE, clinicaltrials.gov NCT01465295) has been completed on a titanium version of the device [4]. Biomechanical tests using this titanium device in single motion segments have been reported [5]. However, the typical surgical construct consists of six implants placed across successive mid-thoracic levels. To more completely evaluate biomechanical changes following instrumentation, as well as adjacent level effects, requires a full set of implants in a simulated surgical construct. Therefore, the purpose of this study was to determine the immediate post-operative biomechanical changes due to implantation of titanium clip-screw implants in a construct similar to the clinical study. The hypotheses were that range of motion (ROM) would decrease in instrumented levels and increase in adjacent un-instrumented levels, yet most of the flexibility of the spine would be retained.

Methods: In vitro biomechanical tests were conducted on six thoracic spines harvested from skeletally immature domestic swine (2-4 months, ~ 40 kg), sectioned to include vertebrae T2-T14. Specimens were tested before and after instrumentation with six titanium clip-screw devices, placed at successive levels from T5-6 to T10-11. Two open intervertebral joints remained above and below the surgical construct. Specimens were tested in lateral bending (LB) and flexion-extension (FE) by applying moments using a materials test system with cable-pulley attachments. Minimum peak moment magnitude was ±5 Nm. Vertebral position and orientation were determined for vertebral bodies T4 - T12, and for proximal and distal ends of each specimen. Vertebral rotations were calculated using a custom program (MATLAB). ROM, the maximum side-to-side rotation, were determined for the instrumented region (T5-T11) and for the adjacent un-instrumented regions (T4-5 and T11-12). In the instrumented region, the limits of motion were determined by sense, ie towards and away from the implant side for LB, and flexion versus extension. Differences between control and instrumented ROM were determined by two-tailed paired t-tests with Bonferroni correction (α=0.05/6, or α=0.05/24 when direction and sense were taken into account).

Results: ROM decreased in instrumented levels for LB and FE, and increased in adjacent un-instrumented levels, following treatment. In the treated region, ROM for LB decreased 36% (p<0.001), from 7.3° (±2.1) to 4.9° (±2.7), and for FE ROM decreased 16% (p<0.001), from 5.9° (±1.2) to 4.8° (±1.8). In the adjacent un-instrumented regions, LB ROM increased 12% (p<0.001) from 8.4° (±2.0) to 9.3° (±1.9) and FE ROM increased 3% from 7.6° (±1.0) to 7.9° (±1.4). In LB towards and away from the treated side, respectively, limits of rotation in the treated region decreased 49% (p<0.001), from 3.6° (±1.0) to 2.0° (±1.2), and 21% (p<0.003), from 3.6° (±1.2) to 3.0° (±1.7). In flexion, limits of rotation in the treated region decreased 21% (p<0.002), from 3.3° (±1.3) to 2.6° (±1.3) and in extension, the decrease was 15%, from 2.6° (±0.5) to 2.2° (±0.6).

Discussion: Titanium clip-screw implants in a clinically relevant construct on a porcine spine decreased ROM in the treated region by <40%, and increased ROM in adjacent untreated regions by <15%. These results indicate that most spinal flexibility is retained in the immediate post-operative period, with relatively small increases in motion in adjacent levels. Reductions were greater when rotating towards the surgical construct than away from it, and greater in flexion than in extension. Sources of motion include the flexibility and elasticity of the clip bridge, and that the implants do not interconnect. In order to maintain appropriate stresses and strains on the growth plate to alter growth and maintain long-term viability of the intervertebral joint, fusionless mechanical growth modification devices must restrict disc motion yet not eliminate it. Multi-segment in vitro biomechanical tests using nitinol staples at contiguous segments, or a contiguous tether-type construct, have been performed using similar loading protocols as the current study [6,7]. For ROM over the treatment region in both LB and FE, nitinol staples [7] had the least effect, followed by the titanium clip screw device of the current study, using group mean differences. The contiguous tether decreased range of motion the most in LB and FE, but not axial rotation [6]. Limitations of all these studies include in vitro tests that model immediate post-operative conditions only, and differences in test conditions may limit direct comparisons. In the current work, no axial rotation tests were performed, and displacement analysis was restricted to one plane. Further, implant placement in the animal model was more anterior compared to humans due to differences between species in vertebral shape in the transverse plane, so that the plane of maximum decrease was likely not in a cardinal plane. More generally, whether biomechanical conditions exist that allow for redirected growth without concomitant disc
degernation is not yet known. However, titanium clip screw implants in a simulated clinical construct preserved most spinal flexibility within the instrumented region, with the greatest changes in bending toward the construct, and relatively small changes in the adjacent un-instrumented levels.

**Significance:** The amount of motion needed to maintain disc health is not yet known. However biomechanical changes due to proposed fusionless scoliosis techniques are required to understand the mechanisms of action, and to guide any future design changes that may alter clinical results.

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**References:**