Biomechanical and Histological Evaluation of an Allograft Anchor for Pedicle Screw Augmentation in an Ovine Model

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INTRODUCTION

Achieving solid implant fixation to osteoporotic bone presents a challenge to both spinal surgeons and hardware designers. Loss of surgical construct stability as a result of screw loosening is a well-known complication [1,2], particularly in patients with poor bone quality [3,4]. Thus, the development of novel strategies to address the issue of obtaining enhanced bone-to-screw purchase to achieve necessary construct integrity is an important issue. In the current work, we investigated the effect of lumbar pedicle screws augmented with a bone allograft anchor in an ovine model with temporal biomechanical testing and histological analyses. We hypothesized that the allograft sheath would be gradually incorporated by the host, thereby promoting enhanced pedicle screw purchase.

METHODS

A total of thirty-six bone allograft anchor-augmented pedicle screws implanted in the lumbar vertebral bodies (L3-L5) of 6 sheep were evaluated after 3, 6 and 12 weeks of healing (n=12 screws/time point). Twenty-four (n=8/time point) screws were allocated for biomechanics and 12 (n=4/time point) screws were allocated for histology. Eight additional screws were implanted into cadaver spines and tested biomechanically serving as time zero specimens. Pullout Testing: For pullout tests, the vertebral body was coupled to a six degree of freedom (DOF) load cell (AMTI, Waltham, MA) via a custom-designed fixture that constrained the body. A custom-designed steel extractor gripped by hydraulic clamps coupled the constrained vertebral body to the materials testing machine actuator (MTS, Eden Prairie, MN). Additional uniaxial alignment was accomplished through the use of an adjustable X–Y table. The extractor was then withdrawn uniaxially at a rate of 10 mm/min until a sharp drop in the monotonically increasing force profile was noted and/or there was clear observable bone failure. After failure, the contralateral pedicle screw was tested in an identical fashion. A non-Parametric Kruskal-Wallis one-way ANOVA on ranks and Mann-Whitney rank sum multiple comparison test were used to identify significant differences (p<0.05, Sigmastat, San Jose, CA) Histopathology and Histomorphometry: After fixation and processing, specimens were done in vivo with intimate new bone formation along the entire profile of the pedicle screw. Initial sections were cut using an Exakt diamond blade bone saw to a thickness of approximately 300-400 µm and then ground to a thickness of approximately 50 µm. One section was cut from each screw for a total of 12 undecalciﬁed sections. Sections were stained with Sanderson’s Rapid Bone stain and counterstained with Van Gieson’s. Bone morphology and incorporation of the allograft sheath was pathologically assessed. Histomorphometric measurements were also made to quantify allograft resorption and bone formation temporally.

RESULTS

With increased time in vivo, the force required for pedicle screw pull out increased (Table 1). There was no statistical increase in pull-out force after 3 weeks of healing compared to time 0 specimens (p=0.878). However, after 6 and 12 weeks of healing there was a statistically significant increase in pullout force compared to 3 weeks of healing (p<0.001), with a non-significant increase in pull-out force observed after 12 weeks compared to 6 weeks (p=0.279).

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>n</th>
<th>Pullout Force (N)</th>
<th>% Screw length covered in bone + allograft</th>
<th>% Screw length covered in bone</th>
<th>% Screw length covered in allograft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (time zero)</td>
<td>8</td>
<td>579.19 ± 55.84 a</td>
<td>25.8 ± 2.0</td>
<td>25.8 ± 2.0</td>
<td>25.8 ± 2.0</td>
</tr>
<tr>
<td>3 weeks</td>
<td>8</td>
<td>560.49 ± 68.95 b</td>
<td>34.3 ± 3.0</td>
<td>34.3 ± 3.0</td>
<td>34.3 ± 3.0</td>
</tr>
<tr>
<td>6 weeks</td>
<td>8</td>
<td>1644.82 ± 126.36 c</td>
<td>45.7 ± 2.9</td>
<td>45.7 ± 2.9</td>
<td>45.7 ± 2.9</td>
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<tr>
<td>12 weeks</td>
<td>8</td>
<td>1934.31 ± 224.89 d</td>
<td>50.0 ± 4.0</td>
<td>50.0 ± 4.0</td>
<td>50.0 ± 4.0</td>
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</table>

After 3 weeks of healing the allograft sheath was visible over approximately 50% of the screw length (Fig. 1, top left). After 6 and 12 weeks, there was less allograft present compared to 3 weeks, and by 6 weeks there was excellent incorporation of any remaining allograft by the surrounding bone. New bone was observed directly on the surface of the allograft. As healing time increased, resorption of the allograft sheath was observed, manifested histologically as a decrease in length and thickness. Generally, as healing time increased, there was more bone present due to sclerosis, less allograft present due to resorption, and less void space (non-bone, non-allograft) within the standardized area of interest immediately adjacent to the screw surface (Fig. 2).

DISCUSSION

The current study sought to quantify the biomechanical performance of a novel bone allograft-augmented lumbar pedicle screw. The results presented herein demonstrated a 190% increase in pullout force after six weeks in vivo with no appreciable increase thereafter, indicating that bone-screw fixation is maximized at this timepoint. The biomechanical findings were corroborated with temporal histomorphometric analyses indicating almost complete incorporation of the allograft anchor after six weeks in vivo concomitant with intimate new bone formation along the entire profile of the pedicle screw. This preliminary study supports further investigation of a bone allograft-augmented lumbar pedicle screw for use in patients with poor trabecular bone quality.

REFERENCES


Paper No. 12 • 56th Annual Meeting of the Orthopaedic Research Society