INTRODUCTION:
Spine growth modification alters stress distributions in vertebral growth plates and discs, and one method has been approved for an early stage prospective clinical study. Quantification of stresses is required to help assess implant efficacy and disc health. More generally, despite widespread and necessary use of animals in preclinical studies of spine instrumentation, limited quantitative information is available on mechanobiological conditions in quadruped spines for comparisons to those of humans. The purpose of this study was to develop an in vivo model capable of determining physiological compressive stresses bilaterally in the intervertebral disc annulus, and preliminarily assess effects of a hemiepiphyseal implant.

METHODS:
Six skeletally immature domestic pigs were instrumented with one implant and four stress sensors (approved by IACUC). Custom MEMS stress sensors were inserted into left and right sides of the annulus at two thoracic levels. A titanium staple-screw construct was implanted at one level. Signals were acquired intra-operatively, post-operatively during normal activities, and biweekly with the animal under anesthesia, for up to 8 weeks.

Beginning the first postoperative day, stresses were measured three days per week. Each test run was 100 seconds in duration, and multiple runs were collected per day. Signals were sampled at 690 Hz during physiological activities of lying or sitting, standing, and walking. At 2, 4, 6, and 8 weeks postoperatively, stresses were measured with the animal anesthetized and in the prone position. This condition was used to assess baseline signal stability and reproducibility. At eight weeks, the spine was harvested and radiographed. Sensors were removed and recalibrated. Bilateral stresses at control and treated levels, means and standard deviations, were determined by run, day, animal, and activity.

RESULTS:
Intraoperatively, mean peak stress due to staple insertion was 1.6 MPa (±1.0) at the sensor nearest the staple. Mean stress at the end of surgery was 0.20 MPa (±0.13), whereas the mean stress standing, POS day 1, was 0.58 MPa (Fig. 1). Dynamic stresses were recorded at all locations, including the location nearest the implant (Fig. 2). Highest mean stresses were those on the ipsilateral side of the treated level. With the animal under anesthesia, the dynamic stress range was 0.1 MPa. By activity, on postoperative day 4, mean control stresses during sitting, standing, and walking were 0.56, 0.63, and 0.55 MPa, respectively, based on the average of the control level and the contralateral side of treated level.

Mean stresses during sitting, standing, and walking were highest at the ipsilateral location. The mean stress increase on the ipsilateral side of the treated level was 1.2 MPa. The difference between animals was greater than the difference between activities and between sensor locations. When stresses were normalized by animal using the average of the two measurements of the control level, the ipsilateral side mean normalized stress was greater than that of the contralateral (Fig. 3). Normalized mean stresses nearest the staple were 1.7 to 4.5 times higher than the control level, which increased with activity level for both animals. By contrast, on the contralateral side, normalized mean stresses were approximately the same as the average of the control level.

DISCUSSION:
Compressive stresses in the disc annulus were dynamic at both control and stapled levels, indicating that the disc was not immobilized by the hemiepiphyseal implant. Mean compressive stress was higher at the location nearest the implant within the first week. Stresses depended strongly on animal, and ranged up to levels measured in vivo in humans.

Limitations included that this was a developmental study, with improvements to sensor design and surgical and postoperative procedures implemented incrementally. Technical limitations included size of sensors relative to the disc, difficulty in placing the sensors symmetrically within the annulus, and locating the ipsilateral sensor directly between the blades of the implant.

SIGNIFICANCE:
These methods help define how nonfusion spinal systems affect static and dynamic compressive stresses and gradients transmitted to disc and physis, which impact disc health and efficacy of growth modification.

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