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Development of a 4-axis load cell used for lumbar interbody load measurements

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ABSTRACT

Numerous studies have assessed lumbar interbody fusion, but little data from direct interbody load measurements exists. This manuscript describes an interbody fusion cage with integrated 4-axis load cell that can simulate implant heights of 13, 15, 17, 19 and 21 mm. The calibrated load cell was accurate to within 7.9% for point compressive loads over the central 8 mm × 8 mm region, but up to 26.8% for eccentric loads on the outer 16 mm × 16 mm rim of the device (although typically errors were less than half). Anterior–posterior shear and lateral shear loads did not affect compressive load measurement (<1.0% and <3.5%, respectively). Moments calculated from 4 load sensing corner pillars demonstrated errors below 2.3% in lateral bending and 2.1% in flexion-extension. Although this device does not have the accuracy of other much larger corpectomy implants, it incorporates four channels of load and simulates multiple implant heights, making for a favorable comparison in this restricted space. This device has immediate use in cadaveric testing, providing data previously not attainable, and serves as a novel technological step towards an implantable interbody device with multi-axis load sensing capability. As per the authors' knowledge, no such device has previously been described.

1. Introduction

While numerous studies have assessed lumbar fusions using interbody devices, little data from direct measurements of loads on interbody devices exists. This manuscript details the development of a 4-axis load cell integrated within a standard interbody fusion cage. As per the authors' knowledge, no such device has previously been described in the literature.

1.1. Clinical applications

Measurement of load transmission through interbody devices is of immense clinical importance. Kumar et al. [1] described how interbody fusion cages with larger contact areas between cage and vertebral endplate produce lower peak stress distribution patterns across the contact surface with the vertebral endplate. Polikeit et al. [2] described that inserting an interbody cage increased peak von Mises stresses and altered load distribution in adjacent structures. A stiffer cage led to an increased concentration of the peak stresses, and higher stresses were propagated further into the vertebral body, in areas that would not usually experience such loading. This may be related to persistent back pain despite fusion, or subsidence of the cage. Kim [3] described the effects of posterior instrumentation on bone stress levels and the relative motion at the bone–cage interface, along with the resultant effects that determine the race between fusion and subsidence. Vadapalli et al. [4] described that in interbody fusions using PEEK vs. titanium cages, the peak centroidal von Mises stresses in the endplates increased by at least 2.4-fold with titanium spacers as compared to PEEK spacers. Quigley et al. [5] reported that offset positioning of interbody cages places higher strains upon posterior instrumentation than a central cage, and lower load to failure than an anteriorly placed cage. In another study, Chen et al. [6] described how polyaxial screw systems used in conjunction with anterior cage support yield higher contact ratios, compressive stiffness and flexion stiffness of spinal constructs than monoaxial screw systems do in the same model when the spinal segment is set at large lordotic angles. The authors used strain gauges attached to the posterior surface of the cage and to the posterior rod connecting the pedicle screws. The plethora of literature studying load transmission across interbody cages establishes the importance of the precise and valid measurement of load in the clinical application of the interbody devices. It is interesting to note that all of the above studies were performed using finite element models except for the last two studies, where the load was measured indirectly using strain gauges on the adjacent vertebrae. It is imperative to validate these models

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with direct measurements of the loads applied to interbody cages during cadaveric testing, as well as during human *in vivo* experiments.

1.2. Implantable sensors

The use of telemetry systems to measure loading [7] in conjunction with fully implanted load sensing devices has become more common in the literature [8–16], and the use of inductive coils has made the need for batteries and their inherent risks for volunteer human subjects avoidable. In addition to prototype devices that are developed exclusively by a group of investigators, commercially available inductively powered implantable telemetry systems have become available and utilized in various studies including Ledet et al. in 2000 [10] (MicroStrain, Inc., Williston, VT) and Ledet et al. in 2005 [11] (Advanced Telemetrics International, Inc., Spring Valley, OH).

Recent literature has described a series of intervertebral load cells that are implantable in the interbody space of a baboon model of interbody fusion [10,11]. These load cells are capable of compressive load measurements only. In the first of these papers, Ledet et al. [10] studied the use of bilateral interbody cages in a baboon L4–5 anterior lumbar interbody fusion (ALIF) model. In this case, the investigators used a 16-channel battery powered telemetry system to measure loads in a variety of postures over 6 weeks following implantation in two baboons. The telemetry system was implanted subcutaneously to record strains. Eight strain gages were placed on each of two cages made of carbon (DePuy AcroMed, Cleveland, OH), and a finite element model was used to determine compressive loads from strain data. Specific dimensions were not given. Error in the range of $\pm 6\%$ for compressive loads was reported. Validation was conducted using both uniformly and non-uniformly distributed compressive loads, but the effects of shear loads and eccentricity of these loads were not reported. *In vivo* measurements were taken for a period of 6 weeks prior to fatigue damage of the strain gages (as per the authors' observation), and animals were sacrificed at 24 weeks upon complete fusion. Subsequently, the authors designed a second generation ALIF implant [11]. This was a single ALIF spacer placed centrally in each of two baboons. Sixteen strain gages (previously eight per each of two bilateral cages) were used to assess strain across the ALIF spacer, and a wired, battery powered telemetry system was used to collect data. Again a finite element model of the device was used to determine compressive force. Compressive force was evaluated, with reported errors of less than 7.94% for the first ALIF transducer, and less than 9.34% for the second ALIF transducer used in the two baboons, respectively. Implants were custom fabricated and designed to record loads ranging from 200 to 2000 N. This work by Ledet et al. [10,11] was a landmarked step, building upon our existing understanding of anterior column spinal loading that was previously based principally on human *in vivo* volunteer intradiscal pressure measurements [17,18]. However, this data was obtained in a baboon lumbar spine model.

In a most recent series of studies, Rohlmann et al. [13] designed and built a custom lumbar corpectomy spacer using a telemetrized load measurement system. This device was fully contained and hermetically sealed in a tube by welding the load cell closed using an electron beam. The device stood 38.8–51.8 mm in height, and was able to achieve different heights to allow for intraoperative sizing. A custom seven-channel telemetry system and inductive power source [7] avoided the need for wiring and a secondary surgical site for a subcutaneous telemetry system. A series of six strain gages (two sets of -30°, 0°, $+30^\circ$ arrays) were mounted upon the interior of the cylindrical central hermetically sealed tube that constituted the body of the load cell. Calibration data and a finite element model of the device were used to calculate all three forces and all three moments. The assembled corpectomy spacer was designed to fully mimic that of a standard implant (Synthes Synex, Synthes GmbH, Oberdorf, Switzerland). Yet, unlike the previous work of Ledet et al. [10,11], this device was not miniaturized to fit into the interbody space. The corpectomy implant was designed to span from T12 to L2, across a vertebral body, and both superior and inferior adjacent disc spaces. This implant design allowed for the measurement of more channels, plus onboard electronics. Compared to the previous work, this device was able to record force data with a reported error of less than 2% for force and 5% for moment measurements [13]. Calibration and error measurements were conducted using a 21-point calibration frame. The corpectomy load cell was able to survive 6 months of implantation without damage following implantation in the first two subjects [15], this exceeds the 6-week survival of interbody devices discussed earlier [10,11]. The increased survival of these implants may be due in part to the hermetically sealed nature of this device, the higher load rating of this device (3000 N versus 2000 N) and the ability to space strain gages away from high localized peak loads at the ends of the device due in part to the greater height of the corpectomy spacer. Thus far, 1-month follow-up has been reported in the literature [14] for a total of three patients. This corpectomy spacer complements the authors' previous work in measuring posterior column loads in the lumbar spine using instrumented posterior rod constructs in an *in vivo* model [12,16,19]. Parallel work with this instrumented device in a cadaveric model served two purposes. First, it was used to assess the device under controlled laboratory conditions with simulated pathology that could not be ethically induced in a human volunteer [20] (i.e. a lumbar corpectomy and ligamentous injury were undertaken in a spine free of notable pathology). Second, it was used to assess the similarities and differences between *in vivo* and *in vitro* conditions [21] with the same transducer. While this device was able to measure six axes of loading with little error, its overall height precludes insertion into the interbody space.

Previous *in vivo* studies have measured loads in the anterior column of the lumbar spine. Ledet et al. [10,11] have investigated axial compressive loads in the intervertebral space in a baboon model. Rohlmann et al. [14,15] have investigated loads across a single level lumbar corpectomy in an *in vivo* human model, measuring all six axes of loading. The purpose of this study is to build on this work by developing a transducer capable of 4-axis load measurements (i.e. tension–compression, anterior–posterior shear, flexion–extension and lateral bending) that can assess loads across a single intervertebral space, with the ability to simulate a broad range of ALIF spacer sizes. This design must be able to survive the environment of a cadaveric experiment. Subsequent applications of this technology may include adaptation of the current design for telemetric measurements in a human *in vivo* model. Data obtained from this device may be utilized both for validating mathematical models, as well as a direct understanding of load sharing in a lumbar spine fusion model.

2. Methods

2.1. Design goals

In developing a load cell for this application, a series of design goals were considered. First, the endplate of load cell must interface with ends of simulated spacers to form 13, 15, 17, 19 and 21 mm ALIF spacers. Second, instrumented central pillars must be of maximum height for the allowable space and endplates of the load cell must be as rigid as possible to produce a uniform strain field in the load sensing central region. Third, there must be room for the egress of cables from the