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Direct real-time measurement of in vivo forces in the lumbar spine

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Abstract

BACKGROUND CONTEXT: Accurate knowledge of the mechanical loads in the lumbar spine is critical to understanding the causes of degenerative disc disease and to developing suitable treatment options and functional disc replacements. To date, only indirect methods have been used to measure the forces developed in the spine in vivo. These methods are fraught with error, and results have never been validated using direct experimental measurements.

PURPOSE: The major aims of this study were to develop a methodology to directly measure, in real time, the in vivo loading in the lumbar spine, to determine if the forces developed in the lumbar spine are dependent on activity and/or posture and to assess the baboon as an animal model for human lumbar spine research based on in vivo mechanical loading.

STUDY DESIGN: Real-time telemetered data were collected from sensor-imbedded implants that were placed in the interbody space of the lumbar spines of two baboons.

METHODS: An interbody spinal implant was designed and instrumented with strain gauges to be used as a load cell. The implant was placed anteriorly in the lumbar spine of the baboon. Strain data were collected in vivo during normal activities and transmitted by means of a telemetry system to a receiver. The forces transmitted through the implant were calculated from the measured strain based on precalibration of the load cell. Measured forces were correlated to videotaped activities to elucidate trends in force level as a function of activity and posture over a 6-week period. The procedure was repeated in a second baboon, and data were recorded for similar activities.

RESULTS: Implants measured in vivo forces developed in the lumbar spine with less than 10% error. Loads in the lumbar spine are dependent on activity and posture. The maximum loads developed in the lumbar spine during normal (baboon) activities exceeded four times body weight and were recorded while animals were sitting flexed. Force data indicate similar trends between the human lumbar spine and the baboon lumbar spine.

CONCLUSIONS: It is possible to monitor the real-time forces present in the lumbar spine. Force data correlate well to trends previously reported for in vivo pressure data. Results also indicate that the baboon may be an appropriate animal model for study of the human lumbar spine.

Keywords: Lumbar spine; Biomechanics; Telemetry; Interbody implant; Load cell; Baboon; Degenerative disc disease

Introduction

Degenerative disc disease is a common pathology, yet the causes remain controversial. Both biochemical and mechanical factors are thought to contribute to the cascade of events resulting in degeneration [1,2]. However, the primary stimulus for degeneration is unknown. Biochemical changes in the disc may occur in response to an initial mechanical failure, or discs may fail mechanically in response to biochemical changes [3].

The association between mechanical loading of the spine and intervertebral disc degeneration has been well documented [1,4,5]. Repetitive loading and acute overloading have both been correlated with a high incidence of degenerative disc disease [1,4,6]. Although the existence of an association between mechanical loading and low back

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pain has been found, quantitative details describing the forces in the spine are not well understood [7].

Because of the inherent complexity of the spinal column both physiologically and mechanically, simplistic models are not able to predict accurately functional changes of the spine given a specific stimulus. Complex finite element models (FEM) predict the reaction of the spine to various loads, but the loads themselves cannot be predicted by means of FEM [8,9]. Similarly, there are inherent limitations associated with in vitro studies in that loads are not necessarily applied in a physiologic manner because in vivo loading remains unknown [10]. It has been suggested that without in vivo experimentation to support models and in vitro research, the validity of the models is questionable [11]. Without knowledge of the normal and pathologic biomechanics of the spine, accurate predictive models of injury and degeneration are not possible and design criteria for the next generation of implants remain vague.

For decades, researchers have sought to characterize the mechanical environment of the spine in vivo. Many techniques have been implemented to indirectly determine in vivo loading, and models of varying sophistication have been developed to predict the forces in the spine.

A simplistic indirect estimate of the loads in the lumbar spine is based on the partial weight of the body superior to a specific motion segment, which has been measured to be 55% to 60% of the total body weight [2]. However, this simplistic model is extremely limited in that it does not take into account the complex forces developed by the musculature, intra-abdominal pressure or externally applied loads [12].

The single vector moment arm model assumes that the extensor muscles can be approximated as a vector that counteracts loads on the spine [13,14]. The model is limited in that it neglects complex stabilizing muscle forces and intra-abdominal pressure that contribute significantly to the forces developed across a motion segment [15–17].

More complex dynamic chain models use kinematic representations of the musculoskeletal system coupled with experimental measures of applied loads and ground reaction forces to predict loading at each joint in the resulting dynamic chain [13,18]. Dynamic chain models do not account for stabilizing muscle forces that may be a significant contributor to the reactionary forces applied to the spine [19].

Electromyogram (EMG) techniques involve direct measurement of muscle electrical activity, which can be correlated to the contractile force of the muscles [10,20]. Like other indirect measurement techniques, EMG models have limitations. EMG models do not account for inertial forces and have inherent electrical noise [14,18]. Force estimates from raw EMG signals are only estimates partially because muscle areas and contractile forces vary from individual to individual, muscles do not pull in straight lines (as typically assumed), and it is difficult to know exactly which muscles are contributing at any given time [13,21,22].

Based on these methodologies of indirect measurement, the forces developed in the spine during both static and dynamic activities have been estimated. The complexity and accuracy of the techniques used to model the relevant structures varies widely from study to study. Not surprisingly, the magnitude of the predicted forces developed in the spine also varies greatly. Table 1 summarizes the findings reported as a result of using various indirect in vivo measurements, such as fractional body weight, muscle moment arms, dynamic chain models, EMG models, as well as complex combinations of these techniques. All of these experimental techniques for indirect measurement of spine loading have one thing in common: none have been validated by direct experimental measurement. Thus, the normal mechanics of the lumbar spine has not achieved a common consensus among the spine community [13].

The pioneering work of Nachemson has provided some of the most comprehensive in vivo data describing spine biomechanics. Nachemson and Elfstrom [1] measured pressure in the intervertebral disc in vivo and in real time. Nachemson and Elfstrom's data from more than 100 human subjects over 20 years generally indicated that sitting caused higher pressures than standing, both of which caused higher pressure than lying supine. Higher pressures were recorded when subjects were sitting flexed and lifting weights. Highest pressures were measured during simultaneous forward flexion of 20 degrees and rotation of 20 degrees while lifting a weight [37,38].

In their studies, Nachemson and colleagues measured pressure, but not force. They proposed a method to calculate applied force from measured pressure, which was based on an empirical equation from experiments performed in vitro in cadavers [16]. However, this methodology has been criticized, and Nachemson himself noted the limitations of his early work, citing that his data concentrated more on the relative pressure changes as a function of posture and not the absolute value of forces [10,37].

As shown in Table 1, little progress has been made collecting in vivo data since Nachemson's landmark studies. In 1994, Rohlmann et al. [39] introduced an instrumented spinal fixation device that stabilizes the spine posteriorly and serves as a multiaxis load cell. The technology developed by Rohlmann et al. has a reported high degree of accuracy and has successfully measured chronic in vivo forces developed in the implant in several human subjects. However, the device is placed in parallel with the spinal column and thus is load sharing. The relative proportion of forces transmitted through the spine compared with those through the implant are variable and depend on the stiffness of the implant relative to the stiffness of the spine [21,33,40]. The same limitation is valid for the forces measured in instrumented Harrington rods by Elfstrom and Nachemson [41] and Waugh [23], as well as the forces measured in the strut graft by DiAngelo et al. [42].

The data collected by Rohlmann differ from Nachemson in that forces developed in the instrumented implant are not

Table 1
Estimates of in vivo forces in the lumbar spine based on various techniques

Investigator	Conditions under which load was determined	Technique by which load was determined	Load on disc, % body weight for 70 kg subject
Waugh [23]	Postoperative recovery, vomiting	Strain gauge instrumented Harrington rod	20–99
Nachemson [16]	Various tasks	In vivo pressure measurement	29–386
Nachemson, Elfstrom [1]	Various tasks	In vivo pressure measurement	97–369
Schultz et al. [24]	Resting or lifting 8 kg	In vivo pressure measurement, EMG	50–343
Schultz et al. [25]	Twisting, bending	EMG	69–380
Leskinen et al. [26]	Lifting 15 kg	5 cm moment arm	1,145
Kromodihardjo et al. [27]	Lifting	Dynamic chain	238–642
Granhed et al. [28]	Very heavy lifting	Dynamic chain	2,741–5,306
Goel, Weinstein [4]	Externally applied moment of 58 Nm	Mathematical model	152–174
Goel et al. [9]	Lifting 50 N	In vivo pressure measurement	204
Cholewicki et al. [29]	Very heavy lifting	Dynamic chain	2,506
McGill [30]	Lateral bending	EMG, dynamic chain	274–364
Han et al. [31]	Lifting up to 180 N	Dynamic chain and EMG	340–539
Sanan, Rengachary [32]	Axial load on cervical spine	Mathematical model	802
Rohlmann et al. [33]	Walking tasks	Strain gauge instrumented AO dick fixator	0–54
Dolan, Adams [34]	Repetitive lifting 10 kg	EMG	456–523
Morlock, Sehneider [35]	Everyday activities	Dynamic chain	495–743
Dolan et al. [18]	Lifting 15.7 kg	EMG, dynamic chain	364–656
Ledet et al. [36]	Various (baboon) tasks	Strain gauge instrumented interbody implant	13–280
Rohlmann et al. [12]	Various tasks	Strain gauge instrumented AO dick fixator	0–60

EMG=electromyogram.

higher for sitting than for standing, although standing did produce higher forces than lying down [40,43]. The highest loads were encountered when patients were standing up contracting their abdominal or back muscles [21]. During sagittal bending, maximum moments were measured in the implant during flexion at 20 degrees from neutral standing position. High axial forces were also measured during extension [12].

Rohlmann later teamed with Wilke et al. [44], who had collected in vivo intradiscal pressure data from a single subject. They combined data from their studies to compare them to those of Nachemson [45]. Data from Rohlmann and Wilke indicate that loads are greater during standing as compared to sitting. The authors propose that the discrepancy is because Nachemson's original data were only "rough estimates."

Although the research of neither Nachemson nor Rohlmann specifically measure the forces developed in spine directly, both have interpreted their data to draw conclusions on what activities and postures cause highest loads. Their data are generally lacking in agreement.

To determine the clinically relevant biomechanics of the lumbar spine, there is a need for spinal research to go beyond the limitations of in vitro studies and indirect in vivo measurements such that the normal in vivo mechanical environment in the interbody space can be accurately determined. Only recently has technology in microsensors, electronics packaging and wireless data transmission evolved to the extent that reliable measurement of real-time in vivo data is possible. However, to date, there have been no comprehensive data reported on the real-time in vivo loads developed in the spine.

The purpose of this study was to develop a methodology to accurately measure, in real time, the in vivo loading in the lumbar spine, to determine if the forces developed in the lumbar spine are dependent on activity or posture and to assess the baboon as an animal model for human lumbar spine research.

Materials and methods

After approval from the Institutional Animal Care and Use Committee of The Albany Medical College, two skeletally mature, 32+ kg, intact male baboons (*Papio anubus*) were obtained for use in this study. Under general anesthesia (acepromazine 1.0 mg/kg intramuscularly and ketamine 10 to 15 mg/kg body weight [BW] intramuscularly, followed by endotrachael intubation and isoflurane inhalation), biplanar plain radiographs were taken of the lumbar spine with scale markers to screen for pathology and to size the lumbar intervertebral disc spaces.

An interbody implant/load cell was designed for insertion into the L4–L5 disc space of the animals. The implant/load cell was designed to facilitate two distinct functions: 1) to act as a stand-alone interbody spacer that would allow interbody fusion, and 2) to measure forces developed in the lumbar spine in real time with high fidelity. The implant design was based conceptually on open box–type interbody cage implants because of their successful clinical history [46]. The dimensions of the implant were dictated by disc height and dorsal/ventral and lateral dimensions of the disc space, determined from plain radiographs. Implants were designed to fit the disc spaces of the baboons, to undergo finite deformation (greater than 25 microstrain) under the expected (but unknown) in vivo loads, and were also designed to be robust enough to prevent fatigue failure and plastic deformation [36]. An analytical model, based on beam theory, was developed to provide a functional relationship between implant surface strain and applied load. To validate the analytical relationship, a solid model of the implant (Fig. 1, top) was used to conduct a finite element analysis. To simulate spinal loading during various activities and postures, uniformly and nonuniformly distributed loads ranging from 200 N to 2,000 N were applied to the implant model using a finite element analysis (Fig. 1, bottom). Data from the finite element model were used to revise the analytical relationship until measured strain could accurately predict applied load with less than 10% error. Implant prototypes were fabricated out of titanium. Sixteen strain gauges each with a grid length of 0.78 mm (Part Number EA-06-031EC-350; Micro-Measurements Group, Raleigh, NC) were mounted to the vertical faces of the implant to measure surface strain. Two 12 conductor polyvinyl chloride insulated cables, approximately 35 cm in length and 3 mm in diameter, were electrically connected to the strain gauges. As shown in Fig. 2, the implant, strain gauges and lead wire junctions were coated in sequential layers of conformal epoxy and Parylene C (Cookson Electronics, London, England) for environmental protection.

The opposite end of the two cables were then connected electrically to an implantable 16-channel, multiplexing, battery-operated telemetry system capable of transmitting digital strain data at a net sample rate of 10 Hz (Advanced Telemetrics International, Inc., Spring Valley, OH). The telemetry system and lead wire junctions were coated in epoxy for environmental protection. To reduce power consumption, the system would “wake up” and transmit data for approximately 25 minutes only after a magnet was passed within approximately 7.5 cm of an inline reed switch. Data were received by an external unit and converted from digital to analog. A 16-channel portable data acquisition system was used to collect data for postprocessing.

Before implantation, each implant and telemetry system was calibrated in a mechanical testing machine for final

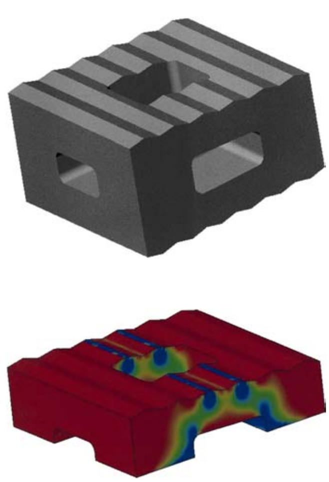

Fig. 1. (Top) A solid model and (bottom) finite element model of the interbody implant were used for preliminary analysis and validation of the analytical model.

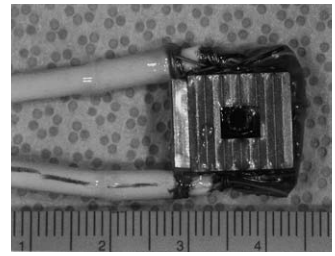

Fig. 2. Implants, strain gauges and lead wires were coated with several layers of environmental protection before final calibration and surgical implantation.

validation of the analytical model. To simulate spinal loading during various activities and postures, uniformly and nonuniformly distributed loads ranging from 100 N to 1,500 N were applied using the mechanical testing machine. During calibration, the applied force was measured both by the testing machine’s load cell and the implant. Forces on the implant were calculated from measured strain using the analytical model. The calculated force was compared with the actual applied force to determine errors in the model. Data from the calibration were used to make final adjustments to the analytical relationship until measured strain could accurately predict applied load with less than 10% error under all loading conditions. Once the calibration process was complete, each implant and its associated transmitter were placed in a 37°C bath for 7 days to determine the quiescent strain values under no load. After this offset measurement, the implants were packed in an instrument tray and underwent low temperature (less than 38°C) ethylene oxide gas sterilization in preparation for surgical placement.

Under general anesthesia, the abdomen and left hip of each baboon were shaven and prepared in standard sterile fashion. An incision was made over the left iliac crest, and corticocancellous autogenous bone graft was harvested using osteotomes and curettes. After closure of the bone harvest site, a mid-longitudinal vertical incision was made from the infraumbilical area to the suprapubic region for a retroperitoneal approach to the lumbar spine. The ventral disc space was visualized, and an intraoperative X-ray was taken to verify the L4–L5 disc level. The anterior longitudinal ligament was removed along with the anterior annulus through sharp dissection. A complete discectomy was performed, and the bony vertebral end plates were scraped to remove cartilage and provide a vascular supply to the disc space. The end plates were then shaped to accommodate the implant using a wedged rasp. A trial implant was inserted into the disc space to test for fit. If needed, further preparation of the end plate was achieved with the rasp.

A small opening was then made laterally through the peritoneum to provide a passageway for the electrical cables connecting the implant to the transmitter. The implant was then passed through the opening, outside to inside, while the transmitter remained outside of the peritoneum. The interbody implant/load cell was then inserted into the disc space and gently impacted into position. The orientation of witness marks on the implant relative to the animal (right/left) was noted and recorded. An interference screw was placed ventrally into the superior vertebral body with a carbon fiber epoxy composite washer overhanging the disc space. The washer served as a "kickplate" to prevent displacement of the implant. The autologous bone graft was then packed lateral to the cage in the disc space and ventral to the cage and washer.

The cables from the implant were manipulated to exit ventrally out of the disc space, around the great vessels, through the peritoneum and were brought up along the sides of the abdomen. The telemetry transmitter, batteries and switches were placed in subcutaneous pouches created outside of the abdominal muscle wall and were sutured to the muscle walls to prevent migration. To demarcate the location of the switches, marks were made on the skin superficial to their location with a sterile skin marker. Several times during the surgical procedure, and just before closing, a magnet was passed in close proximity to one of the switches and a reading of the telemetry system was made.

Postoperative dorsal/ventral and lateral plain radiographs were taken to verify implant placement. Buprenorphine (0.01 mg/kg BW, intramuscularly) and enrofloxacin (5 mg/kg BW, orally) were administered for 3 and 5 days postoperatively, respectively.

At least three times weekly for 6 weeks, force data were collected from the instrumented implants while the animals were active in an exercise pen. The telemetry system was awakened by passing a magnet through the bars of the pen to within several centimeters of the transmitter switch. While force data were being collected from the implant, a video of the animal's activities was recorded onto Mini DV tape using a digital camcorder. At the beginning and end of each video session, a time stamp was recorded for several seconds to later synchronize the video with the force data.

During data collection, food was used to encourage the animals to perform repeatable activities, such as sitting upright (in neutral position), sitting while flexing, standing upright (on two legs), standing upright and reaching (in extension), standing (on four legs), walking (on four legs) and lying down (supine).

Using the previously defined analytical relationship, forces developed in the spine were calculated based on the measured strain. Force data were synchronized to and displayed in real time with the video of the animals' activities. Mean and peak force values were determined for each repeatable activity and normalized to the weight of the animal. Additional analyses were conducted to look for trends in the distribution of loading on the implant as a function of activity.

Results

Experimental calibration of the final instrumented implants resulted in the unique characterization of each implant and subsequent final correction of the analytical model. The maximum error for Implant 1 from all loading cases was 7.94%. Similarly, the maximum error for Implant 2 was 9.34%. Maximum signal noise levels for force were ±35 N for each implant. After surgery, the animals recovered with no surgical or anesthesia-related complications. Immediate postoperative radiographs, as shown in Fig. 3, indicated proper placement of the interbody cages in the disc spaces with satisfactory alignment and positioning. The telemetry system was awakened several times during and immediately after surgery to confirm its operational status. In one animal, data were collected during insertion of the implant into the disc space at the time of surgery. An axial compressive force of 223 N (0.71 × BW) was immediately imposed on the implant during insertion as a result of annular tension. Regular data collection began on the first postoperative day. As shown in Fig. 4, data sets ranged from approximately 30 seconds in duration to 15 minutes depending on the animal's activity level.

Force data from repeatable activities and postures were analyzed across time points to determine mean values and ranges. Only activities that were repeated at least three times were included for analysis. The number of replicates for each activity or posture ranged from 3 to 17. Thus, although only two animals were used in this study, the sample size for data analysis ranged from 3 to 17. The activities, mean force values and force ranges are shown in Fig. 5. Data indicate that forces measured in the spine were dependent on activity and posture. In general, postures and activities that necessitated spinal flexion resulted in higher forces than those with the spine in neutral position or extension. Sitting resulted in higher loading than standing, while sitting in a flexed position resulted in higher loading than sitting upright. Highest forces of 4.7 times body weight (mean, 3.9±0.76)

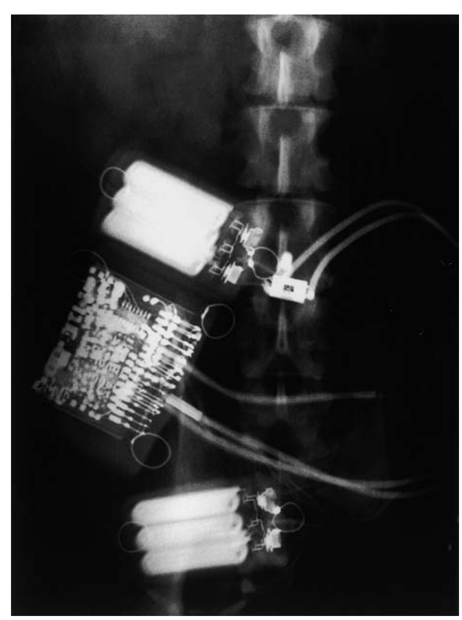

Fig. 3. A postoperative plain radiograph showing the implant, lead wires, batteries and telemetry system.

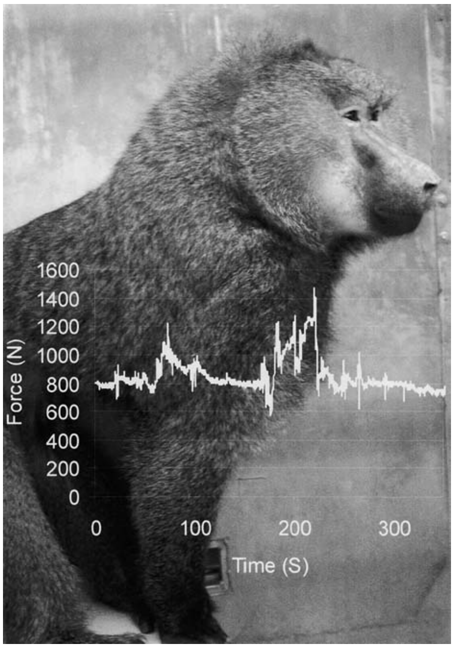

Fig. 4. Real-time force data collected over a 6-minute period from the implant/load cell shows dynamic changes in forces during normal daily activities. Data were synchronized with video to determine what activities correspond to the forces shown.

were observed when the animals were sitting flexed and twisting axially.

For each of the activities shown in Fig. 5, the relative distribution of forces on the four vertical members of the implant (anterior left, anterior right, posterior left, posterior right) were determined and trends analyzed. Results indicated that the implants were loaded nonuniformly, and under most loading conditions, regions of the implant sustained loads that varied by up to three orders of magnitude (from approximately 0 N to approximately 1,000 N).

Distribution of forces did fluctuate as a function of activity, but only general trends could be observed. When the animals transitioned from standing up to standing down on four legs, the distribution of forces was increased anteriorly on the implant and decreased posteriorly. The opposite trend was observed when the animals transitioned from standing on four legs to standing up (forces were shifted posteriorly). When the animals used their arms to pull themselves up to the standing position, there was a shift in force distribution from anterior to posterior. These trends were consistent with all activities that caused the center of gravity of the animals to be shifted. In general, when the center of gravity of the upper body was shifted forward, this corresponded to an increased proportion of force shifted anteriorly on the implant. When the weight of the upper body was shifted back, forces on the implant shifted posteriorly. An exception to this trend appeared to correspond with twisting of the upper body. When the body was twisted axially (with no apparent change in the center of gravity of the upper body), a substantial shift in forces to the anterior aspect of the implant was observed.

During the fourth week of data collection from Implant 1, the integrity of a single strain gauge signal was lost. Because of redundancies incorporated into the design of the system, forces transmitted through the implant were still measurable. During the fifth week, a second signal from an adjacent strain gauge was lost, but the system remained functional because of redundancies. During the sixth week, a critical adjacent third gauge was lost and the system became inoperable. The malfunctioning gauges were located in close proximity to the location of a known defect in the implant coating. It is presumed that the defect in the coating resulted in moisture penetration and a subsequent electrical short of the strain signal.

During the sixth week of data collection from Implant 2, erratic signals were received from the implanted system for several days, followed by no signal. Several unsuccessful attempts were made to wake up the system using the external magnet. To determine the cause of the failure, the transmitter, batteries, switches and cables were retrieved from the animal. Under general anesthesia, a small incision was made in the abdomen and the telemetry system was exposed. The cables connecting the transmitter to the implant were cut and the telemetry transmitter, batteries and switches were removed while the implant was left in the spine. The animal recovered from the procedure without incident. Analysis of the retrieved components revealed small cracks at the strain relief interface between the cables and the epoxy-coated transmitter. Using a dissecting microscope, fluid was observed within the epoxy coating in close proximity to the cracks. The system was then cleaned and allowed to dry for several days. Upon drying, no residual moisture was observed in the epoxy and the transmitter resumed function.

Discussion

In this study, the baboon was chosen as the animal model because the anatomy and physiology of the baboon spine are similar to humans [47–49] and the in vitro mechanical properties of the baboon lumbar spine have also been shown to be similar to humans [50–52]. The baboon has smaller intervertebral discs than humans; however, the components of the intervertebral disc are similar to humans [50,52]. The natural pathology of the baboon lumbar spine has also been investigated, and the natural occurrence of spontaneous degenerative disc disease developed in the baboon was reported to be similar to humans [53]. The healing processes after lumbar disc surgery are also similar to humans [54]. There are differences between humans and other nonhuman primates associated with specific muscular structures; the hip extensors and glutei are more powerful in humans than in other primates and capable of generating higher forces [10]. In spite of this, the baboon has been suggested as an excellent model for studying degenerative disc disease, surgical intervention, spinal fusion and instrumentation because of similar anatomy, pathology and routine postures and activities [53].

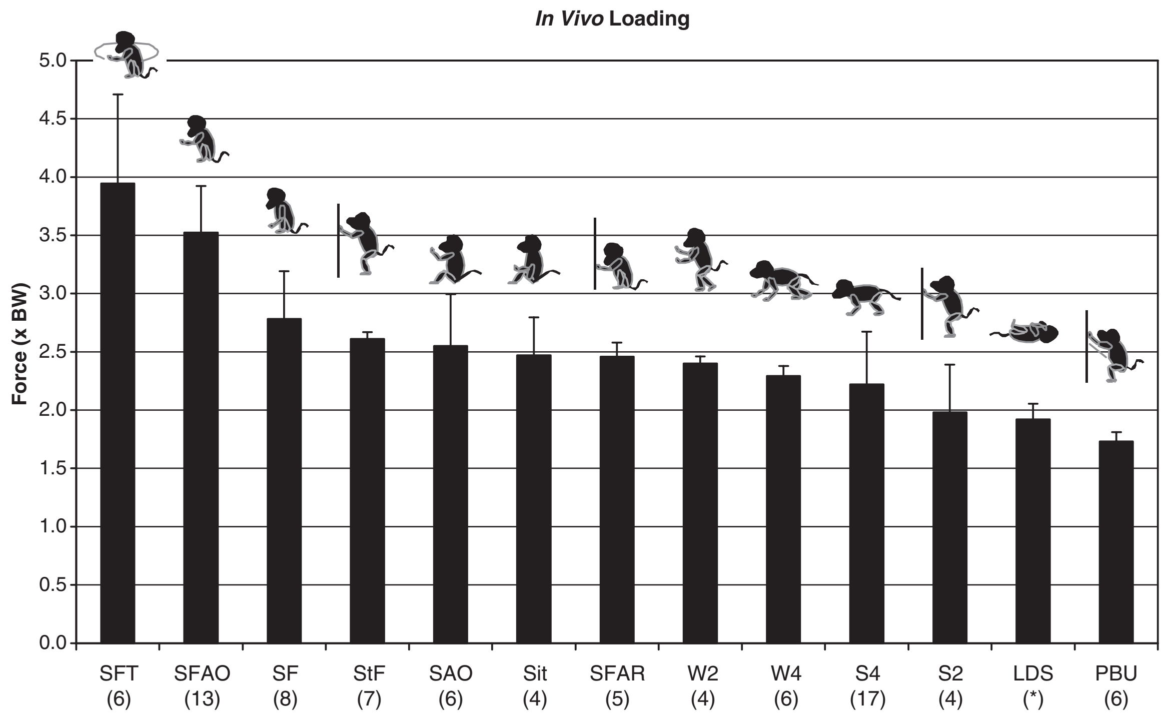

Fig. 5. A summary of real-time force data collected over 6 weeks. Forces are expressed as a multiple of body weight for repeatable postures and activities. LDS=lying down supine; PBU=pulling body up; S4=standing on four legs, standing on two legs; SAO=sitting arms out; SF=sitting flexed; SFAO=sitting flexed arms out; SFAR=sitting flexed arms resting; SFT=sitting flexed and twisting; Sit=sitting; StF=standing flexed; W2=walking on two legs; W4=walking on four legs. *Several minutes of data (collected at a sample rate of ~10 Hz) on six different days were averaged when the animal was lying supine sleeping.

In the current study, the interbody implant/load cell measured both the magnitude of forces and the relative force changes as a function of posture and activity in the lumbar spine of the baboon. Comparison of the relative force data from the current study to the results of Nachemson, and also to Wilke and Rohlmann, indicate excellent agreement with Nachemson's data: Forces measured during sitting were higher than standing; forces sitting flexed were higher than sitting upright.

Nachemson measured high pressures when his subjects were sitting flexed and lifting a weight. In the current study, the baboons were not trained to lift weights while sitting flexed but did routinely extend their arms out while sitting flexed, effectively lifting a weight. Forces measured in the spine were among the highest during this activity and correlated well to Nachemson's data. Lowest intervertebral disc pressures were recorded by Nachemson while his patients were laying relaxed in a supine position. Even lower pressures were measured in the disc by Ramos and Martin [55] when patients were lying supine and traction was applied. Again, these results correspond well to the relative forces measured in the current study. Low loads on the implant were recorded during lying supine, while lowest loads were recorded when the animal was using its arms to pull itself up. During pulling, the weight of the body below the implanted level of the spine effectively applied distractive forces.

Results from the current study and from Nachemson's intervertebral disc pressure data do not correspond well to data collected by Rohlmann's instrumented posterior fixator. The data from Rohlmann indicate higher forces during standing than sitting. However, these measured forces were developed in the implant, which is posterior and parallel to the spinal column, and not in series with the spine itself. Whereas Rohlmann's implant is placed posterior to the axis of rotation of the spine, the forces measured in the current study (and pressures by Nachemson) are in the intervertebral disc space and anterior to the center of rotation [56]. It has previously been shown that there is load sharing between the facet joints (posteriorly) and the intervertebral disc (anteriorly) [57]. The proportion of loads transmitted through the facets is dependent on the orientation of the spine [58]. The lower forces (and pressures) measured during activities, such as standing up relative to sitting or sitting flexed, could indicate either an overall decrease in the magnitude of forces developed in the spine or a shift in the proportion of forces from the disc to the facet joints (and posterior fixation device). The contrast in data between the current study and that reported by Rohlmann may indicate that there is a significant shift in the line of action of the axial forces through the spinal column, from anterior to posterior, from intervertebral disc to facet joints, associated with activity and posture.

This phenomenon is observed in the current study by analysis of the changes in force distribution during transition from one activity or posture to another. In general, data indicate that when the center of gravity of the upper body is shifted forward, there is an increased proportion of force shifted anteriorly on the implant. When the weight of the upper body is shifted back, a higher proportion of forces on the implant is shifted posteriorly.

Increases in force during transition from one activity to another not only correlated to a shift in center of gravity, but also correlated to contractile forces of the extensor muscles. During dynamic activities, such as running, jumping and "playing," highest forces were measured in the disc space during rapid acceleration or deceleration of the torso by the extensor muscles, typically during transition from one activity or posture to another. For example, the animals routinely jumped from height, contacting the ground first with their hind legs, then rotating their torso forward until the fore legs contacted the ground. Highest forces in the spine were consistently measured during deceleration of the torso just before the fore legs contacted the ground. Because the effects of extensor muscle activation appear to contribute significantly to the forces developed in the disc space, it is expected that the loads on the implant would be substantially greater if the animals performed forceful exertions, such as those expected during lifting.

Data from the current study were collected from two animals only. In spite of the small number of animals, forces associated with specific activities were measured at multiple points in time, thus providing a higher number of samples for analysis. Data indicate that the forces developed in the spine associated with each activity were repeatable. Standard deviations associated with 14 of the 21 routine activities and postures were less than 10% of the mean value, and all were less than 21%. It is unknown whether the force trends would be identical if more animals were used; however, the data from the two animals were similar to each other and consistent through the study time course.

The current results build on those reported by Ledet et al. [36] who used implants of a similar design but different materials. Because of reported technical problems with the earlier design, the highest measurable loads were 2.8 times body weight, whereas in the current study, highest loads exceeded 4.7 times body weight during normal activities. Data from these two studies consistently show that forces in the lumbar spine during two-legged stance were greater than four-legged stance and loads while sitting upright were greater than lying down. Activities in which the spine is flexed result in higher loads than when it is in neutral position.

The implant/load cell used in this study measures compressive forces only. Shear and torsional stresses also contribute to the mechanical demands imposed on a motion segment or interbody implant. The box type implant used in this study relies on a friction interface with the bony end plate to resist torsional or shear forces. Because there is no mechanical engagement between the implant and the adjacent bone, there would be no way to determine if there was relative motion in shear or torsion between the end plate and implant once implanted. Torsion and shear could be measured using a similar fusion implant or total disc replacement that is rigidly fixed to the super and subadjacent vertebral bodies.

The compressive forces measured in this study were collected after surgical intervention, including disruption of the anterior longitudinal ligament, annulus and nucleus. The iatrogenic alteration of these tissues does not change the development of loads in the spine, because there are only three sources of force: body weight, external loads and muscle forces [59]. The surgical procedure did not alter body weight or external loads, and the muscle-sparing approach minimized postoperative changes in muscle line of action and coactivation. However, the disruption of these tissues does change the inherent mechanical properties of the motion segment (including stiffness, range of motion and neutral zone) relative to a healthy intact segment. A potential result of this alteration is that the proportion of load sharing between the anterior spine and facet joints could be altered from an intact normal. If the center of rotation of the motion segment is altered and a higher proportion of forces is transmitted through the facet joints, then the forces measured by the implant/load cell may be lower than those generated in a normal healthy spine. Conversely, if a smaller proportion of the forces are transmitted through the facet joints, then the forces measured by the implant/load cell may be higher than those generated in a normal spine. In the current study, forces were measured in the anterior spine, and forces transmitted across the facet joints remain unknown.

As shown in Table 2, trends in interbody force data from the current study compared with that of Nachemson indicate that the relative trends as a function of posture and activity are similar to those of the human. The relative force data collected from the baboon correlate well to the pressure data collected from the human spine; however, discretion must be used in interpreting the data gathered from this study. Although both data sets imply what the in vivo forces may be in the human spine, neither have been validated experimentally. If Nachemson's pressure-based force data are accurate, then the data from this study indicate that the mechanical environment in the baboon spine is similar to that of the human spine (and hence the baboon may be an appropriate animal model of the human lumbar spine). If the forces developed in the baboon lumbar spine are similar to the human, it implies that Nachemson's pressure-based force calculations are accurate.

Activities that cause peak loading in the baboon spine, like the human spine, may indicate causes for the natural degenerative process that occurs with age. However, force has not yet been measured directly in the human spine in vivo; therefore, the absolute magnitude of these forces must be validated in humans. The materials and methods used in this study could be applied to human research subjects, with some modification. The implant design and associated analytical model relating applied force to surface strain are scalable and could easily be manufactured in sizes appropriate for the human lumbar spine.

Table 2
Comparison between human data collected by Nachemson and baboon data collected in the current study

Activity	Nachemson x Body weight	Nachemson % of Standing	Current study x Body weight	Current study % of Standing	Forces measured for standing flexed using different models* (x body weight)
Laying supine	0.2	29	1.9	95	1.1 [37]
Standing at ease	0.7	100	2.0	100	1.7 [24]
Sitting up	1.0	143	2.5	125	1.7 [61]
Standing flexed	1.1	157	2.6	130	2.2 [31]
Sitting flexed	1.3	186	2.8	140	2.6‡
Sitting flexed lifting weight†	1.9	271	3.5	175	
Flexed forward and rotating	2.9	414	3.9	195	

* For comparison to indirect measuring techniques, previously reported force values for human subjects standing flexed are shown.
† Although the baboons were not trained to lift weights, they frequently extended their arms out, effectively lifting a weight.
‡ Denotes the value from the current study.

A better understanding of the mechanical environment in the interbody space of the lumbar spine may provide researchers with information necessary to help prevent the initiation and progression of degenerative disc disease, provide mechanical design criteria for the next generation of interbody fusion implants and total disc replacements, understand the effects of posterior instrumentation on loads transmitted through the anterior spine and allow for safer and more effective postoperative physical therapy to prevent implant migration and subsidence after treatment.

Chronic force data may also help to elucidate the temporal changes in loads imposed on implants over the course of interbody fusion. If the forces transmitted through implants diminish as load is shared by newly forming bone, as hypothesized by Benzel [60] and others, decreasing load on the implant may be used as an indicator of the progression of fusion. Additionally, if loads transmitted though the implant decrease significantly over time, the fatigue demands on the implant will be better understood and a new generation of implants may be designed that have a more minimal mechanical design.

Conclusion

Results from this study provide the first insight into the real-time forces measured in the lumbar spine. The distribution and magnitude of loads that correspond to routine activities and postures have been identified. Activities in which the spine is flexed result in higher loads than when it is in neutral position, but the distribution of forces is nonuniform and dynamic. Although the anatomy and physiology of the baboon spine may be similar to humans, results obtained from this study must be used cautiously and validated before application into clinical practice.

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References

[1] Nachemson A, Elfstrom G. Intravital dynamic pressure measurements in lumbar discs. Scand J Rehabil Med Suppl 1970;S1:1–40.
[2] Perey O. Fracture of the vertebral end-plate in the lumbar spine. Acta Orthop Scand 1957;S25:2–101.
[3] Adams MA, Freeman BJC, Morrison HP, Nelson IW, Dolan P. Mechanical initiation of intervertebral disc degeneration. Spine 2000; 25(13):2625–36.
[4] Goel VK, Weinstein JN. Time dependent biomechanical response of the spine. In: Goel VK, Weinstein JN, editors. Biomechanics of the spine: clinical and surgical perspective. Boca Raton: CRC Press, 1990.
[5] Gracovetsky S, Farfan HF, Lamy C. The mechanism of the lumbar spine. Spine 1981;6(3):249–62.
[6] Adams MA, Hutton WC. The relevance of torsion to the mechanical derangement of the lumbar spine. Spine 1981;6(3):241–8.
[7] Wilke HJ, Neef P, Hinz B, Seidel H, Claes L. Intradiscal pressure together with anthropometric data: a data set for the validation of models. Clin Biomech 2001;16(suppl 1):S111–26.
[8] Calisse J, Rohlmann A, Bergmann G. Estimation of trunk muscle forces using the finite element method and in vivo loads measured by telemeterized internal spine fixation devices. J Biomech 1999;32: 727–731.
[9] Goel VK, Weinstein JN, Patwardhan AG. Biomechanics of the intact ligamentous spine. In: Goel VK, Weinstein JN, editors. Biomechanics of the spine: clinical and surgical perspective. Boca Raton: CRC Press, 1990:97–156.
[10] Farfan HF. Form and function of the musculoskeletal system as revealed by mathematical analysis of the lumbar spine. Spine 1995; 20(13):1462–74.
[11] Chao EYS, An KN, Cooney WP. Instrumented devices for joint and muscle force measurement. In: Berme N, Cappozzo A, editors. Biomechanics of human movement: applications in rehabilitation sports and ergonomics. Worthington: Bertec Corporation, 1990.
[12] Rohlmann A, Bergmann G, Graichen F, Weber U. Changes in the loads on an internal spinal fixator after iliac crest autograft. J Bone Joint Surg 2000;82-B:445–9.
[13] McGill SM. Loads on the lumbar spine and associated tissues. In: Goel VK, Weinstein JN, editors. Biomechanics of the spine: clinical and surgical perspective. Boca Raton: CRC Press, 1990:65–96.
[14] Schultz AB, Ashton-Miller JA. Biomechanics of the human spine. In: Mow VC, Hayes WC, editors. Basic orthopaedic biomechanics. New York: Raven Press, Ltd, 1991:337–74.
[15] Miller JA, Schultz AB, Warwick DN, Spencer DL. Mechanical properties of lumbar spine motion segments under large loads. J Biomech 1986;19(1):79–84.
[16] Nachemson A. The load on lumbar disks in different positions of the body. Clin Orthop Rel Res 1966;45:107–22.
[17] Patwardhan AG, Havey RM, Meade KP, Lee B, Dunlap B. A follower load increases the load-carrying capacity of the lumbar spine in compression. Spine 1999;24(10):1003–9.

[18] Dolan P, Adams MA, Kingma I, de Looze MP, van Dieen J, Toussaint HM. The validity of measurements of spinal loading during manual handling. Proceedings of the 44th Annual Meeting of the Orthopaedic Research Society, March 16–19, New Orleans, Louisiana, Chicago: Orthopaedic Research Society, 1998.
[19] Cholewicki J, Juluru Krishna, McGill SM. Intra-abdominal pressure mechanism for stabilizing the lumbar spine. J Biomech 1999;32:13–7.
[20] Patwardhan AG, Meade KP, Lee B. A "follower load" increases the load carrying capacity of the lumbar spine in axial compression Part 2: muscle activation and stabilization. Proceedings of the 44th Annual Meeting of the Orthopaedic Research Society, March 16–19, New Orleans, Louisiana, Chicago: Orthopaedic Research Society, 1998.
[21] Rohlmann A, Bergmann G, Graichen F, Mayer HM. Influence of muscle forces on loads in internal spinal fixation devices. Spine 1998; 23(5):537–42.
[22] Taylor SJG, Walker PS. Forces and moments telemetered from two distal femoral replacements during various activities. J Biomech 2001;34:839–48.
[23] Waugh TR. Intravital measurements during instrumental correction of idiopathic scoliosis. Acta Orthop Scand 1966;93(S):58–75.
[24] Schultz A, Andersson G, Ortengren R, Haderspeck K, Nachemson A. Loads on the lumbar spine. J Bone Joint Surg 1982;64-A(5):713–20.
[25] Schultz AB, Andersson GBJ, Haderspeck K, Ortengren R, Nordin M, Bjork R. Analysis and measurement of lumbar trunk loads in tasks involving bends and twists. J Biomech 1982;15(9):669–75.
[26] Leskinen TPJ, Stalhammar HR, Kuorinka IAA, Troup JDG. A dynamic analysis of spinal compression with different lifting techniques. Ergonomics 1983;26:595–604.
[27] Kromodihardjo S, Mital A. A biomechanical analysis of manual lifting tasks. J Biomech 1987;109:132–8.
[28] Granhed H, Johson R, Hansson T. The loads on the lumbar spine during extreme weight lifting. Spine 1987;12(2):146–9.
[29] Cholewicki J, McGill SM, Norman RW. Lumbar spine loads during the lifting of extremely heavy weights. Med Sci Sports Exer 1991; 23(10):1179–86.
[30] McGill SM. A myoelectrically based dynamic three-dimensional model to predict loads on lumbar spine tissues during lateral bending. J Biomech 1992;25(4):395–414.
[31] Han JS, Goel VK, Ahn JY, et al. Loads in the spinal structures during lifting: development of a three-dimensional comprehensive biomechanical model. Eur Spine J 1995;4:153–68.
[32] Sanan A, Rengachary SS. The history of spinal biomechanics. Neurosurgery 1996;39(4):657–69.
[33] Rohlmann A, Bergmann G, Graichen F. Loads on an internal spinal fixation device during walking. J Biomech 1997;30(1):41–7.
[34] Dolan P, Adams MA. Repetitive lifting tasks fatigue the back muscles and increase the bending moment acting on the lumbar spine. J Biomech 1998;31:713–21.
[35] Morlock MM, Schneider E. Determination of the magnitude of lumbar spinal loading during different nursing activities. Proceedings of the 44th Annual Meeting of the Orthopaedic Research Society, March 16–19, New Orleans, Louisiana, Chicago: Orthopaedic Research Society, 1998.
[36] Ledet EH, Sachs BL, Brunski JB, Gatto CE, Donzelli P. Real time in vivo loading in the lumbar spine. Part 1: interbody implant load cell design and preliminary data. Spine 2000;25(20):2595–600.
[37] Nachemson AL. Disc pressure measurements. Spine 1981;6(1):93–7.
[38] Nachemson A, Morris JM. In vivo measurements of intradiscal pressure. J Bone Joint Surg 1964;46A(5):1077–92.
[39] Rohlmann A, Bergmann G, Graichen F. A spinal fixation device for in vivo load measurement. J Biomech 1994;27(7):961–7.
[40] Rohlmann A, Graichen F, Weber U, Bergmann G. Monitoring in vivo implant loads with a telemetrized internal spinal fixation device. Spine 2000;25(23):2981–6.
[41] Elfstrom G, Nachemson A. Telemetry recordings of forces in the Harrington distraction rod: a method for increasing safety in the operative treatment of scoliosis patients. Clin Orthop Rel Res 1973;93: 158–72.
[42] DiAngelo DJ, Foley KT, Faber HB. A multi-axis strut graft force sensor to study loading mechanics of the instrumented cervical spine. Proceedings of the 44th Annual Meeting of the Orthopaedic Research Society, March 16–19, New Orleans, Louisiana, Chicago: Orthopaedic Research Society, 1998.
[43] Rohlmann A, Bergmann G, Graichen F, Mayer HM. Telemetrized load measurement using instrumented spinal internal fixators in a patient with degenerative instability. Spine 1995;20(24):2683–9.
[44] Wilke HJ, Neef P, Caimi M, Hoogland T, Claes LE. New in vivo measurements of pressures in the intervertebral disc in daily life. Spine 1999;24(8):755–62.
[45] Wilke HJ, Rohlmann A, Bergmann G, Graichen F, Claes LE. Comparison of intradiscal pressures and spinal fixator loads for different body positions and exercises. J Biomech 2001;34:S37–42.
[46] Brantigan JW, Steffee AD. A carbon fiber implant to aid interbody lumbar fusion: two-year clinical results in the first 26 patients. Spine 1993;18(14):2106–17.
[47] Oxnard C. The order of man: a biomathematical anatomy of primates. Hong Kong: Hong Kong University Press, 1983:203–26.
[48] Schultz AH. Vertebral column and thorax. Primatloogia 1961;4(5): 1–65.
[49] Swindler DR, Wood CD. An atlas of baboon, chimpanzee, and man. Seattle: University of Washington Press, 1973.
[50] Gal JM. Mammalian spinal biomechanics: I. static and dynamic mechanical properties of intact intervertebral joints. J Exp Biol 1993; 174:247–80.
[51] Gal JM. Mammalian spinal biomechanics: II. intervertebral lesion experiments and mechanisms of bending resistance. J Exp Biol 1993; 174:281–97.
[52] Setton LA, Zhu W, Weidenbaum M, Ratcliffe A, Mow VC. Compressive properties of the cartilaginous end-plate of the baboon lumbar spine. J Orthop Res 1993;11:228–39.
[53] Lauerman WC, Platenberg RC, Cain JE, Deeney VFX. Age-related disk degeneration: preliminary report of a naturally occurring baboon model. J Spin Disord 1992;5(2):170–4.
[54] Ledet EH, DiRisio DJ, Tymeson MP, et al. The Raymedica PDN Prosthetic Disc Nucleus Device in the baboon lumbar spine. Spine J 2002;2:94S.
[55] Ramos G, Martin W. Effects of vertebral axial decompression on intradiscal pressure. J Neurosurg 1994;81:350–3.
[56] White AA, Panjabi MM. Physical properties and functional biomechanics of the spine. In: White AA, Panjabi MM, editors. Clinical biomechanics of the spine. 2nd ed. Philadelphia: J.B. Lippincott Company, 1990:3–84.
[57] Yang KH, King AI. Mechanism of facet load transmission as a hypothesis for low-back pain. Spine 1984;9(6):557–65.
[58] Tencer AF, Ahmed AM, Burke DL. Some static mechanical properties of the lumbar intervertebral joint, intact and injured. J Biomech Eng 1982;104:193–201.
[59] Rohlmann A, Bergmann G, Graichen F, Weber U. Comparison of loads on internal spinal fixation devices measured in vitro and in vivo. Med Eng Phys 1997;19(6):539–46.
[60] Benzel EC. Spinal fusion. In: Benzel EC, editor. Biomechanics of spine stabilization. New York: McGraw Hill, 1995:103–10.
[61] White AA, Panjabi MM. The clinical biomechanics of spine pain. In: White AA, Panjabi MM, editors. Clinical biomechanics of the spine. 2nd ed. Philadelphia: J.B. Lippincott Company, 1990:379–474.