DIRECT EXPERIMENTAL MEASUREMENT OF THE REAL TIME *IN VIVO* LOADS IMPOSED ON AN INTERBODY FUSION IMPLANT IN THE BABOON LUMBAR SPINE

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BACKGROUND

The biomechanics of the spine and of spinal implants have been well characterized *in vitro*, while for decades researchers have sought to characterize the mechanical environment of the spine *in vivo*. Many techniques have been implemented to indirectly determine the physiologic forces developed in the spine *in vivo*, and models of varying sophistication have been developed to predict these mechanical parameters. Based on these models however, there is great disparity reported in the literature on the range of loads developed in the lumbar spine *in vivo*. Most models have not been validated by direct experimental measure and the actual forces developed in the lumbar spine have never been determined experimentally *in vivo*, and in real time.

PURPOSE

The purpose of this study was to develop a novel load cell/interbody spinal implant to measure directly, via telemetric data transmission, the *in vivo* loads developed in the spine. The implant was then used to measure real time forces in the spines of two baboons. The measured loads were correlated to the activity of the animal and were monitored for changes over the four month course of lumbar interbody fusion.

METHODS

A titanium interbody cage implant was developed for use in this study. The interbody cage implant was designed to serve two purposes: to act as an interbody spacer facilitating fusion as it would clinically; and to act as a load cell for the measurement of real time *in vivo* loads in the lumbar spine. An analytical model of the implant was developed and the relationship between applied load and surface strain on the implant was determined. A finite element analysis was used to validate the analytical model. Sixteen strain gages were then mounted on the implant to measure surface strain. The implant was calibrated experimentally using a mechanical testing machine to further validate the analytical model. The sixteen sensors were then electrically connected to a battery operated, magnetic reed switch actuated, sixteen channel, multiplexing, digital radio transmitter. The transmitter, batteries, and switches were coated in epoxy and parylene; the implant and lead wires were coated with parylene. A test system was submerged in 37° C saline for six months to evaluate the electronic packaging and environmental protection. The system was ETO gas sterilized and prepared for implantation.

Under general anesthesia and using aseptic technique, two skeletally mature male baboons underwent transperitoneal anterior exposure of the lumbar spine. A complete discectomy was performed at L_{45} or L_{56} and the experimental implant was impacted anteriorly into the vacated disc space. Autologous iliac crest corticocancellous bone was packed in the disc space around the implant to facilitate interbody fusion. To prevent ventral migration of the implant, a screw was placed anteriorly in the superior vertebral body and a radiolucent washer was allowed to overhand the disc space and implant. The lead wires extended anteriorly from the disc space, were routed around the great vessels, and passed through the peritoneum to the transmitter. The transmitter and batteries were placed in muscle pouches in the flanks.

Animals were radiographed immediately post-operatively and at 1, 2, 3, and 4 months following surgery to monitor the progress of fusion. Load data were collected approximately three times weekly, at which time the animals were also video taped to monitor activity. At 4 months, animals were euthanized and the lumbar spine and radiotransmitter were retrieved. The excised spines were tested mechanically to determine the dynamic response of the implant to external loads. Motion segments were analyzed histologically to determine the quality of fusion.

RESULTS

During experimental calibration of the implant, measured loads were within ± 8% of applied loads. After an initial two week stabilization period, there was no appreciable drift in strain signals during the six month submersion of the test unit in saline.

The animals tolerated the surgical procedure well and the implants remained functional *in vivo*. During insertion, impaction of the implants into the disc space under annular tension resulted in an acute compressive load of as much as 325 N. During the healing time course, forces were recorded for: laying supine, sitting upright, standing on four legs, standing on two legs, and walking. Preliminary data indicate that changes in activity correlate well to changes in load on the implant. Loads imposed on the implant during normal activities range from 2.5 to 4 times body weight for the 30 kg animals. Forces are high during rapid extension when animals move from a four legged stance to a standing position. Loads on the implant corresponding to specific activity changed over the fusion time course.

DISCUSSION

Pressures developed in the intervertebral disc have been measured *in vivo* previously. Forces generated in the lumbar spine have been estimated using techniques which have included analysis of distribution of body weight, kinematic linkages, EMG signals, and others. However, forces developed in the spine have not been measured directly *in vivo*. Direct measurement of these forces and their correlation to activity provides valuable information for planning post-operative care regimens and for the design of the next generation of interbody implants.

CLINICAL SIGNIFICANCE

Interbody implants are designed to withstand the acute and chronic mechanical demands of the *in vivo* environment in the lumbar spine. However, it has been hypothesized that overdesigned implants with high stiffness and strength may cause stress shielding and subsequently result in poor clinical outcomes. An interbody implant which is sufficiently strong to avoid *in vivo* failure, but also minimizes stress shielding may be optimal. The design criteria for such an implant may be determined if the *in vivo* loading environment is known. However, the *in vivo* loads imposed on interbody implants are unknown and previously have not been measured directly.