

REAL-TIME IN VIVO LOADING IN THE BABOON LUMBAR SPINE USING AN INTERBODY IMPLANT LOAD CELL

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Background: Mechanical properties of the spine have been characterized from previous *in vitro* studies on the spine and spinal implants. Many techniques have been implemented to indirectly determine *in vivo* loading. However, the actual loading in the anterior aspect of the lumbar spine has not been experimentally determined *in vivo*, nor in real-time.

Because the loading of the spine which is associated with everyday activities and specific postures is currently unknown, the activities which cause peak loading are also unknown. Additionally, it is unknown whether synthetic intradiscal implants, bone grafts, and intervertebral disc prostheses that are used clinically, are designed appropriately to withstand the compressive loading in the lumbar spine during normal activities. Under such conditions, the implant must maintain the pre-operative disc height during load. An implant whose intrinsic compressive strength is not sufficient to withstand the load placed on the spine is not mechanically suitable as an intradiscal spacer.

No comprehensive *in vivo* studies have been performed to determine the real-time loading on the spine. There is a need for spinal research to go beyond the limitations of *in vitro* studies such that the loading under normal *in vivo* conditions can be accurately described.

Therefore the purpose of this study was to directly measure the loads imposed on the lumbar spine of a baboon, a semi-upright animal, during the healing time course of interbody fusion.

Methods: A miniature load cell was fabricated from carbon fiber and from titanium intradiscal spinal implants (DePuy Acromed, Cleveland, OH) and instrumented with strain gages. The instrumented implant was inserted into the lumbar spine of four skeletally mature baboons following anterior discectomy and arthrodesis. Loading on the anterior aspect of the lumbar spine during different activities was determined in real-time *in vivo* via a telemetry device implanted in the baboon.

Dorsal-ventral and lateral plain radiographs were taken monthly to assess the progress of healing over a 24 week period. Strain data was collected from the instrumented implants approximately 3 times weekly. As data from the implants were being collected, the animal's activities were recorded electronically in real-time to correlate spinal loading to sitting, standing upright (on two legs), standing (on four legs), laying down, hanging, bending laterally, and bending sagittally. Correlations between changes in load during specific activities were determined.

Following euthanasia, the fused segments were grossly inspected, radiographed and placed in a combined axial compression and sagittal plane bending jig and mounted into a mechanical testing machine. The fused segment was loaded non-destructively in combined axial compression and sagittal plane bending, while load, disc compression, and rotation were measured. The load (via testing machine load cell and implant), displacement (via extensometer), and rotation (via potentiometer) were measured and the stiffness of the fused segments was calculated.

Results: Results from this study indicate that the implant/load cell is sufficiently sensitive to monitor changes in strain during normal activities of the animal. Furthermore, the strain on the implant was highly dependent on the activity of the animal, as shown below. During extreme activity, the strain values exceeded the range that the system was able to measure. Although the exact load on the implants during these extreme cases is unknown, the highest measurable strain values are indicative of loads in excess of 2.8 times body weight for the 40 kg animals.

Preliminary histologic analysis and gross analysis indicate that the uniquely designed implant/load cell did not prohibit bone formation in the

intervertebral disc space. These findings are consistent with radiographic indications that bony formation had occurred.

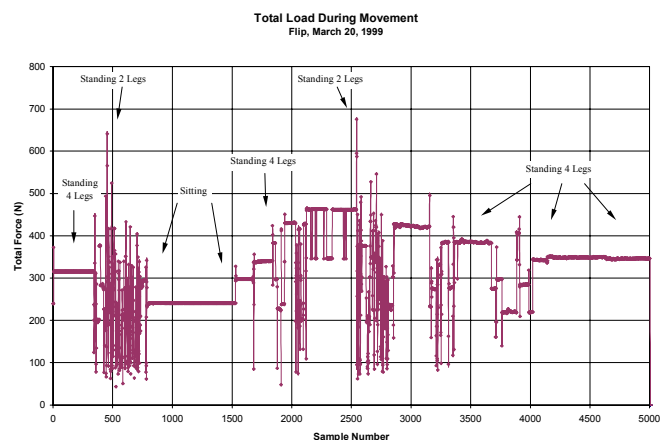
Discussion: The purpose of this pilot study was to develop an implant with a known relationship between strain, which was measured on the implant, and load which was applied to the implant. The data was then transmitted via a telemetry system such that *in vivo* loads were measured in real-time. The magnitude of these loads have not previously been measured. The system was designed to measure a range of loads based on previously reported models. However, the actual loads were higher than those anticipated.

Results from this study will help to predict the loading on the lumbar spine during everyday activities. This may assist physicians in understanding causes of chronic degenerative disc disease and may facilitate prevention.

Based on this pilot study, we have shown that our technique and technology are sufficient for measuring real-time *in vivo* loads in the spine. The range of loads is higher than expected; therefore the implant/load cell was modified to measure these higher loads. The high loads may also indicate that the performance demands on the intervertebral disc and interbody implants are higher than expected.

A means of measuring the load on an intradiscal implant over the course of healing, provides key information about the mechanics of this process. Because the implant/load cell is initially the only weight bearing entity, the loading on the implant immediately following discectomy describes the full loading on the anterior aspect of the spine. By measuring the load imposed on the implant over the full course of fusion, the steady state load demands on implants can also be determined. This can be used as an indicator of the total load that a normal intervertebral disc undergoes and can be used for performance and design criteria of intradiscal implants and artificial discs.

The future design of spinal implants and disc prostheses can be improved if the mechanical environment in which they are to perform is better understood. Further investigations are necessary to determine the specific forces imposed on the spine during the entire time course of fusion.



Real-time loading on the ventral aspect of the baboon lumbar spine during regular activities. Sample rate is approximately 5 Hz.

Acknowledgement: This study was supported by a grant from the North American Spine Society.

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