

BIOMECHANICAL TESTING OF POSTERIOR SPINAL IMPLANTS PAST, PRESENT, AND FUTURE

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ABSTRACT:

Implant testing protocols should be developed with the surgical goals in mind, making every attempt to model the in vivo conditions accurately. The mechanical realities of biomechanical testing of spinal implants, can be summarized as:

1. *No single biomechanical test fully characterizes the ultimate surgical performance of an implant. In fact, it can be argued that the biomechanical testing results reported to date on spinal implants suffer from many limitations.*
2. *No test, regardless of complexity, completely characterizes the in vivo situation. In most tests, loading tends to be simplified, the models used have been animals or ligamentous human cadaver material, and the numbers and types of implants tested have been small.*
3. *All biomechanical models, whether in vitro or in vivo are just that, models. Even if in vivo tests are performed, one must still ask the question, how well does the test model the clinical situation. Furthermore, the results may still be difficult to generalize to overall population.*
4. *Spinal implants are no different than other mechanical device. They obey the basic laws of physics and engineering principals. For example, larger implants tend to be stiffer and stronger, stress concentrations increase a device's risk of fatigue failure, implants utilizing more points of attachment to the spine tend to be stiffer and stronger, or the static strength of any method of fixation is no greater than the bone it is attached to.*
5. *Performance standarts of spinal implants are difficult to define due to a lack of knowledge about the in vivo situation. However, the relative performance of various implant designs to different tests has been found to be an effective method of judging performance.*
6. *The regulatory concerns of the US FDA do not necessarily follow the concerns of surgeons, researchers, designers, or manufactures. For example, the FDA often requires test results relative to pre 1976 devices. Such testing is of little interest to surgeons who have abandoned the older devices. Hence, testing performed for regulatory considerations is often considered separately.*
7. *Without appropriate statistical treatments, any conclusion is possible. Biomechanical testing must be subjected to the same rigors of the scientific method as any other field.*
8. *From the surgeon's standpoint, the most relevant testing is that which directly assess the surgical goals.*
 - a) *Can an implant impart corrective forces to a spine?*
 - b) *What is the stability of the device, both in terms of immediate and long term performance?*
 - c) *What effect will the implant have on fusion?*

Key Words: *Posterior implants, Biomechanical testing*

INTRODUCTION

The field of spinal implant testing has increased significantly during the last few years due the rapid proliferation of spinal implant devices (1). Implant testing includes the evaluation of metallic spinal implants for arthrodesis (2-45), comparisons of graft and fusion techniques (46-50), and the evaluation of more functional spinal implants (e.g. disc replacement) (51). However, this presentation which was drawn in large part from Ashman (52, 53), will be limited to the mechanical testing of spinal arthrodesis implants.

HISTORY

The modern history of posterior spinal implant components can be briefly summarized choronologically as "first there were hooks, then wires, then screws". At present, these three components represent basically the only methods of attaching implants to the posterior aspect of the spine. Each with relative merits and draw backs. Historically biomechanical testing of these spinal implant devices can be summarized as in Table 1.

SURGICAL GOALS

In a simplistic mechanical context, the surgical

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goals of spinal arthrodesis implants are similar for all implant designs: 1) to realign vertebrae, 2) to maintain alignment, both initially and for a period of time during the course of spinal fusion, and 3) to promote the development of a solid bony fusion. Mechanical testing of spinal implants should address each of these surgical goals.

As yet, optimal standards of implant performance have not been established. Until performance standards can be defined, the only means available to judge a particular implant is relative to other implants with similar indications, on which clinical experience is available (53). The U.S. Food and Drug Administration (FDA) requires this same approach in basing approval of new devices on their relative performance compared to existing devices. Recently, several articles (31, 53, 54) and the Spinal Implant Subcommittee of the ASTM, have begun the task of developing standard spinal implant test protocols. When developing mechanical test protocols, it is often useful to consider the surgical goals separately, and design tests to address each. However, some tests may address more than one goal.

Goal 1. Correction, and Alignment

Alignment of vertebrae requires corrective forces to be applied in specific directions depending on the surgical indications (55). For example, correction of a burst fracture or loss of anterior column stability due to tumor resection requires the application of extensile moments (55). Reduction of spondylolisthesis requires the application of both extensile moments and posterior shear forces (56). Scoliosis correction requires transverse, A-P, and torsional corrective moments to be applied (57).

The assessment of an implant's ability to align vertebrae has been expressed as the "power of correction" - the relationship between the primary corrective force supplied by an implant, to the deflection of the corrected vertebrae. For scoliosis, White and Panjabi (58) calculated the relative corrective moment as a function of both transverse correction, and distraction. Their results showed distraction was more powerful for larger deformities and transverse correction was more powerful for smaller curves.

Vertebral correction can also be assessed by a construct's ability to resist deflection, such as in the measurement of the yield strength of spinal rods or plates. If a spinal rod or plate exhibits low yield strength, it may not be able to resist deforming under *in vivo*

loads. The ASTM "Standard Test Method for Static Bending Properties of Metallic Bone Plates", F382 - 86, describes a four point bending yield strength measurement that can be applied directly to longitudinal (e.g. rods, or plates) spinal components.

Another measure relevant to correction would be the axial and rotational strength of hooks or screws on rods. Hooks have been known to rotate in very rigid King II type scoliotic curves. The ability of this construct to correct the lumbar deformity is limited by the rotational strength of the hook relative to the rod. The relative axial and rotational interconnection strength of various implant designs would therefore relate to a system's ability to provide correction.

The power of correction of various implant designs is often limited by the strength of the bone rather than the strength of the implant. To fully assess the power of correction, both strength of the implants alone and the strength of the bony attachments must be considered.

Goal 2. Maintenance of Correction

In order to maintain alignment during the course of fusion, implants must resist 1) permanent bending of metal components (i.e. yield strength), 2) metal or bone/metal fracture under abnormally high load conditions (i.e. ultimate strength), and 3) fatigue failure of metal under normal clinical loading conditions (i.e. fatigue strength). The first two types of short term failure were addressed to some degree in the consideration of the power of correction. Short term performance can often be assessed using static (or quasistatic) loading, while fatigue failure can be addressed with cyclic loading over longer periods of time.

Short Term Stability

Static testing is defined merely as slow, noncyclic loading where inertia has little effect on the results. Generally, load rates less than 440 N/sec (100 lb/sec) when applied to spine constructs would be considered static. However, depending on the specific test, results may be dependent on loading rate.

Permanent bending of metal components (i.e. yield strength), was addressed above. Metal or bone/metal fracture under abnormally high load conditions is usually characterized as ultimate strength. Measurements of construct strengths have been reported by Wenger et al. (43) as being related to an implant's post operative stability. In 1975, Stauffer and Neil (38) exam-

pression, distraction and Weiss compression springs with the objective of comparing the "structural efficacy" of the different system. Compression rods were found to be strongest in flexion loading. However, it is hard to establish how these results relate to the "structural efficacy" of the different systems. Though construct strength is easy to measure, few implants fail by the mechanism of slow loading until a hook pops off a lamina. Also, it should be noted that the load at which the first bony fracture is reached may not be equal to the maximum load that an implant construct could withstand. Determining failure as deflection above some predetermined maximum, rather than looking for a peak in load, has been used effectively as the criteria for determining failure. Whichever method is used, the precise technique used to characterize "failure" must be specifically reported.

Bone/metal failure is directly related to short term stability as well as the power of correction. For example, much of the work the measure *in vivo* stresses and forces in Harrington rods was directed at lessening the chance of interoperative fracturing of the laminae (59, 60, 61). Similarly, the strength of hooks on laminae or of claw type constructs on laminae has been addressed by Tencer et al. (39) and by Roach et al. (73), respectively. For example, Tencer et al. (39) showed clamp (or claw) type configurations to be greater in strength than either bifid hooks or wired hooks.

Long Term Stability

Fatigue strength is a bit more difficult to determine compared to static strength. In a strict mechanical sense, fatigue is defined as failure of a mechanical device after cyclic at loads below yield (62, 63). In most fatigue failures, the device can perform its function perfectly with no obvious deflection or fault until its fracture. Fatigue usually involves slow crack growth through the part until the point at which a sudden static failure occurs.

Cyclical loading of constructs to failure would seem the most direct method to test an implant's ability to resist cyclic loading (4, 5, 21, 25, 30). However, logistical and practical limitations related to time constraints and biological degradation of specimens make cyclic testing on cadaver specimens technically difficult. Because of the time required to conduct such a test, biologic deterioration of specimens becomes the limiting factor. The bone-implant interface usually fails before implant failure occurs (37, 39, 64). Con-

sider that if a patient cycles his construct once every five seconds (0.2 Hz) for 16 hours a day over four months (a generally accepted time for fusion to occur), more than 10^6 cycles will be applied to the instrumentation. The actual production of fatigue failure has been observed only rarely on cadaveric constructs in the laboratory, due to inability to cycle the constructs long enough. Most cyclical studies using cadaver bone have not gone beyond 10^4 cycles; only 1/10 to 1/100 as many cycles as a patient. Only in studies where cycling to more than 10^5 cycles was accomplished were fatigue failures noted (21, 65, 66). Cyclic testing using plastic models has allowed higher numbers of cycles to be applied *in vitro* (6).

Assessing the fatigue susceptibility of a device can be accomplished using methods other than cyclic loading. For example, by measuring stresses using strain gauges, comparing the measured stresses with the endurance limit of the device's material, then applying finite life design criteria (5, 8, 22, 62, 63) the relative performance of an implant can be assessed. For example, Brunski et al. (8) applied strain gauges near the first ratchet joint of Harrington rods, and calculated stress as a function both of distraction load and the number of ratchet positions the top hook was extended. The increased stress due to extending the hook position from the third to fifteenth ratchet can be appreciated. Their results followed fractures in cases where the top hook was extended far from the first ratchet joint. This result along with the clinical experience has caused implant manufacturers to now only offer Harrington rods with fewer numbers of ratchets. Of Brunski's analysis was performed during the development of the Harrington systems, several clinical rod fractures might have been avoided.

Similarly, by applying theoretical stress analysis, beam theory, or finite element modelling to calculate maximum tensile stresses and comparing these to the endurance limit of the material as measure of a device's performance can be estimated (5, 67). Theoretical stress analysis is most effective in the design stages since it does not require prototypes to be constructed.

In designing a cyclic loading protocol, the obvious first question is how much load to apply? Weiler (41) estimated the axial load on the spine to be in the range of 68 percent of body weight. For a 660 N (150 lb) adult, axial load would be on the order of 440 N (100 lb). This amount is well below the experimentally determined L3-L4 disc loads of 882 - 1176 N (198 - 164 lb) reported by Nachemson and Morris (68) and Ca-

pozzo's (69) measures of compressive loads on the lumbar spine as high as 250 percent of body weight during walking resulting in 1650 N for a 600 N adult. Compressive loads calculated at the L-3 motion segment by Schultz et al., (70) using a ten muscle model, were found to be 500 - 1460 N for maneuvers ranging from relaxed standing to 44 N-m of forward flexion. Lateral shear loads were similarly calculated to be 110 N for 31 N-m of lateral bending. Anterior-posterior shear loads were calculated to be +/- 150 N for 40 N-m of flexion extension. The amount of load to apply can be addressed simply by performing cyclic loading tests at several loads starting at relatively high loads (70-90 % of static failure) and reducing the load of each test until no failure is noted before 10^6 cycles (6, 71). From a clinical standpoint, a plot of applied load versus the number of cycles to failure is a useful presentation of fatigue results. To compare load - number of cycles to failure results for different systems, least square fit lines should be calculated for each system and compared using statistical methods. Running this type of analysis out to very high numbers of cycles (10^7 cycles) generally does not change the relative performance of one device compared to another. If all implant components are made of the same material (e.g. 316LVM stainless steel), testing all implants in a simulated physiological solution should not alter the relative results.

Considering the second and third methods, measuring stresses and applying theoretical stress analysis, a great deal can be learned about the fatigue performance of an implant easily, without time consuming cyclic tests. However, these methods should not be considered complete alternative to cyclic testing. Individual variations in material properties, and stress concentrations due to design or machining can cause significant differences between the theoretical performance and the actual performance. However, the stress measurement and theoretical techniques can serve as valuable tools in the design phase, helping to move the designers towards a better device more quickly. As in any stress analysis, experimental verification should be performed to verify the analysis (5).

Goal 3. Promotion of Spinal Fusion

Since most implants are designed to be used as temporary fixation devices, failure would be expected if bone fusion does not occur (72). Through several studies, it is becoming evident that limiting motion between vertebrae is necessary for the development of

spinal fusion. For example, Nagel et al., (50, 74), in studying spinal fusions in the lumbo-sacral spine of sheep, reported at least 11.8 mm of motion (corresponding to a linear strain, change in length/original length, of 59%) between the L6-sacrum levels of seven animals. Fusions at this level did not solidify in 6 of the 7 animals. Conversely, they found only 3.7 mm of displacement (10% strain) in 21 lumbar levels that did fuse. It could be argued that interlaminar motions exhibiting less than 10% change of length/original length should go on to fusion while those levels that exhibit greater than 59% change in length/original length probably would not fuse. Similarly, in a clinical follow-up study, Lorenz et al. (75) evaluated 68 spinal fusion patients with and without pedicle screw instrumentation. They found a 58.6 % incidence of pseudarthrosis in the patients where fusion was attempted received instrumentation. Johnston et al. (76) showed increased stiffness of the posterior fusion in goats implanted with 10 level Wisconsin type constructs with respect to increased spinal rod diameter. Similarly, McAfee et al. (28) reported an increasing success of fusion with increasingly stiff implants in dogs. Hence, to estimate the effect that a particular implant may have on the development of a spinal fusion, the measurement of construct stiffness is believed to be important (i.e. a measure of the motion at the site of the bone graft).

Within limits, greater construct stiffness would result in more rapid fusion with less chance of pseudarthrosis. The optimal spinal stiffness has not yet been determined. However, it may be possible to classify implant systems which are significantly less stiff than other well established designs as inappropriate for the tested indications. For example, Johnston et al. (77) investigated stiffness differences between Dwyer and Zielke anterior constructs in three point bending, and suggested differences in construct stiffness were related to the ability of an implant to aid the fusion process.

Increased understanding of the healing of long bone fractures has shown that the application of very stiff implants can lead to stress shielding of the bone (76). Fusion of the spine is expected to respond similarly (28, 36, 79). McAfee et al. (28) found decreased volumetric density in vertebral bodies in canine spines which fused compared to those which remained unfused. Similarly, Smith et al. (26) found lower bone mineral contents in vertebral bodies of dogs that received pedicle screw implants, after three and six

months, compared to dogs which did not receive implants. These results show the anterior portions of the spine are stress shielded to some extent, but the stress shielding in the front of the spine must be weighed against the development of the posterior fusion. Considering the seemingly low endurance limit of screw implants, compared to the measured loads in the spine, one realizes the fusion mass must take a significant portion of the load over time, or the implants would exhibit a much higher clinical failure rate. Furthermore, after the spine fuses it is unlikely that the original stiffness implant contributes significantly to the stiffness of the resulting construct. Evidence supporting this theory was presented by Goel et al (67) using a finite element model of pedicle screw and plate fixation to the spine. They found the load supported by an interbody graft was only decreased from 96 % to 80 % of the applied load, after pedicle screw instrumentation was applied.

SPECIFIC FAILURE MODELING

Aside from direct comparisons of implants, an important aspect of implant evaluation is the modeling and analysis of specific failure mechanisms. In this type of testing, a clinical failure is identified, biomechanically modeled in the lab so that the failure mechanism can be reproduced, and various modifications of the implant or surgical technique are then tested on the model (22, 42). Using this approach it may be possible to significantly improve future surgical outcomes.

As an example of this technique, Camp et al. (80) reviewed clinical failures of various sacral fixation techniques of scoliosis instrumentation. They found a 44% incidence of sacral screw failure, a 28 % incidence of C - D iliosacral screw failure, and no failures associated with Galveston type sacral fixation (81). The failure mechanism was thought to be associated with the static strength of the sacral components, when loaded in forward flexion. Calf spines were instrumented with the various systems and loaded in forward flexion. The strength in flexion was found to correspond well to the clinical result.

BIOMECHANICAL TEST RESULTS

Keeping in mind the realities of biomechanical testing of posterior spinal implant components, consider the following examples of what has been learned about the mechanical performance of spinal implants. *In vivo* measurements of spinal loading have been

made, offering some clue to the environment that implants are subjected. The relative power of correction between distraction and transverse correction has been established. Most current implant systems are now capable of providing both types of correction. Stress at the first ratchet joint of Harrington rods is now better understood. Both surgical techniques and manufacturing have been altered to limit the number of ratchets in Harrington rods. The need for fatigue analysis of spinal implants has been firmly established. Stress analysis has been used as an efficient alternative to cyclic testing. The relative stability of graft placement has been investigated. Relative differences in stiffness have been measured for various implant systems. Some devices have been shown to be clearly less stiff in axial or rotational loading compared to the more commonly used devices. This information has often lead to abandonment or redesign of the suspect devices. The assessment of the relative performance of screws in fatigue loading has been established. The fatigue resistance of various screw designs has been greatly improved. Specific failure mechanisms seen *in vivo* have been investigated. Standardization of basic test protocols has begun. The relationship between implant stiffness and fusion is better understood.

Table 1.

Harrington, testing based on techniques Luque v. Harrington Post 1985 comparative testing Multi-hook v. distraction Screws v. hooks Comparisons between similar systems Development of standard test Surgical technique related testing In vivo testing Fusion v. stiffness Comparison of clinical follow-up to biomechanical testing results Specific failure modeling Analysis of implant failures

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