

**SPINAL ROD FATIGUE TESTING AND ANALYSIS**

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## **Abstract**

The objectives of the proposed study are to measure and compare the fatigue behavior of titanium and stainless steel alloys used for surgically implanted spinal rods and to publish the results for possible use by physicians, patients, engineers, and scientists. Orthopedic surgeon Andres Munk, M.D., is a collaborating researcher on the proposed study.

Medical patients with spinal injuries or conditions such as scoliosis, degenerative disc disease, spinal trauma or hernia(s) may require surgery to implant spinal rods to give the vertebra and spine needed structural support and to ensure proper bone growth. With movement, these rods are subjected to cyclical loading and fatigue, the primary cause of spinal rod failure. A person with a low intensity level of daily activity can easily walk one million steps and subject a spinal rod to one million loading cycles in six months. Over time, the cyclic loading can lead to fatigue crack initiation and growth and even fracture of the rod. For physicians and patients considering spinal rod implants, there are three different metallic alloy rods available: titanium, stainless steel and vitallium. However, little has been published on the behavior of the alloys or their relative merits. By using fatigue crack growth rate testing, this study will provide a basis for the comparison of the fatigue behavior of the titanium and stainless steel rods.

The fatigue process will be initiated by introducing a circumferential pre-crack to the rod. Rotating bending fatigue will imitate the loading that a spinal rod experiences while implanted. One rotation will be considered to be one cycle and will simulate one walking step of a spinal rod patient. The load and number of cycles will be applied, and the amount of crack growth will be measured. To accurately measure crack growth, a technique called heat tinting will be used—when the alloy is heated to a moderately high temperature, the external surfaces of the alloy oxidize and change color. This will mark the initial crack length. After cycling, the specimen will be broken, and both the initial and final fatigue crack lengths will be measured. The amount of crack growth will be determined from the difference between the initial and final crack lengths. Testing will consist of varying the magnitude of the load and number of cycles.

The surgical spinal rods are expensive. To reduce costs, the rotating bending fatigue test protocol will be refined using common round bar stock specimens—the actual surgical spinal rod specimens will not be used until the test method is sufficiently refined to ensure the successful testing of each surgical spinal rod sample.

The fatigue crack growth rate will be correlated with the load, number of cycles, and crack length for each material. It is anticipated that the fatigue behavior will depend upon the metallic alloy. The results of the study will be useful to surgeons and patients considering spinal rod implantation and to engineers and scientists working in biomedicine.

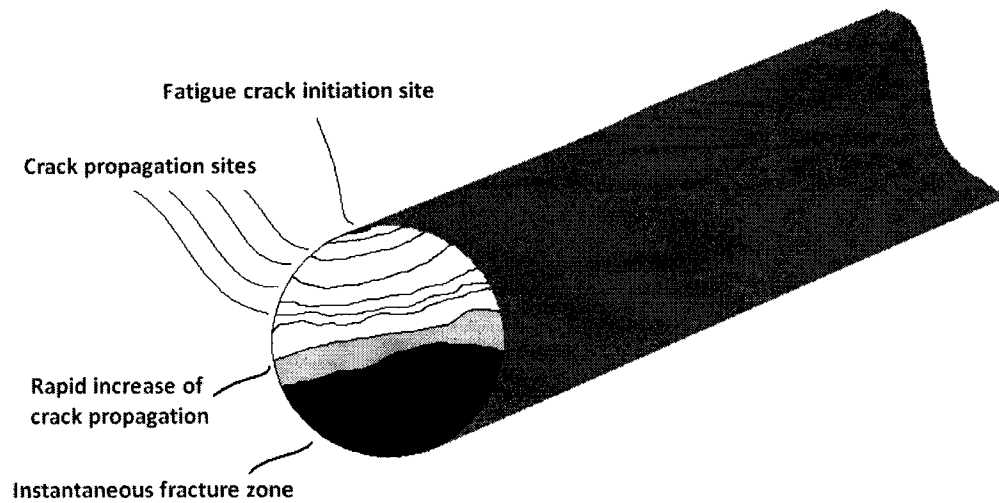
## Introduction

It is not uncommon for spinal rods to break within a six month to one year period following surgical implantation—many rod failures have been experienced by patients. With every step a person walks, the spine endures a stress. An adult with a low activity lifestyle walks from 5,000 to 7,500 steps per day (Fussell 2007). Over a period of six months, this amounts to 900,000 to 1,350,000 cycles of stress, and this does not include the stresses caused by bending the spine from front and back or side to side, lifting objects, or other activities. Although rod breakage is both an individual and public health issue, few studies have been published on the behavior of surgical spinal rods or their constitutive alloys. It can be speculated that manufacturers may be unwilling to publish in-house test data because of liability concerns.

Many of the biomechanical properties of the stainless steel and titanium alloys are specified by the American Society of Testing and Materials (ASTM). ASTM Standards F136 for the stainless steel alloy and F138 for the titanium alloy do not prescribe methods for cyclic load or fatigue testing. A third alloy, vitallium is comprised of 60% cobalt, 20% chromium, 5% molybdenum and other trace substances has been used in dental applications for over 80 years and has recently started being used as a surgical implant material. Hertzberg (1989) describes a general fatigue test method for materials. Miller et al (1982) published a case study of the fracture failure of a forged vitallium prosthesis and compared the tensile properties of stainless steel, titanium, and vitallium, but a fracture approach to fatigue was not included in the study. A practical method of fatigue testing for small diameter round bars like surgical spinal rods is rotating bending fatigue, but an ASTM standard has not been established. Scibetta (1999) developed and experimentally verified a method of rotating bending fatigue testing in his PhD dissertation. His work focused on the fatigue and fracture testing of circumferentially cracked round bar pressure vessel steels. Ebara et al studied the corrosion-fatigue behavior of Ti-6Al-4V in a sodium chloride aqueous solution. These standards and papers establish the test methods to be interpreted and applied in this proposed study.

In addition to the metallic alloy spinal rods, there are two non-metallic spinal rods available to physicians and patients. The DePuy Spine, Inc, EXPEDIUM™ PEEK Rod System uses polyetheretherketone (PEEK) rods. The other system, named “XIA,” is manufactured by Stryker and has an option to use vitallium rods. However, Stryker still uses either titanium or stainless steel screws and other hardware.

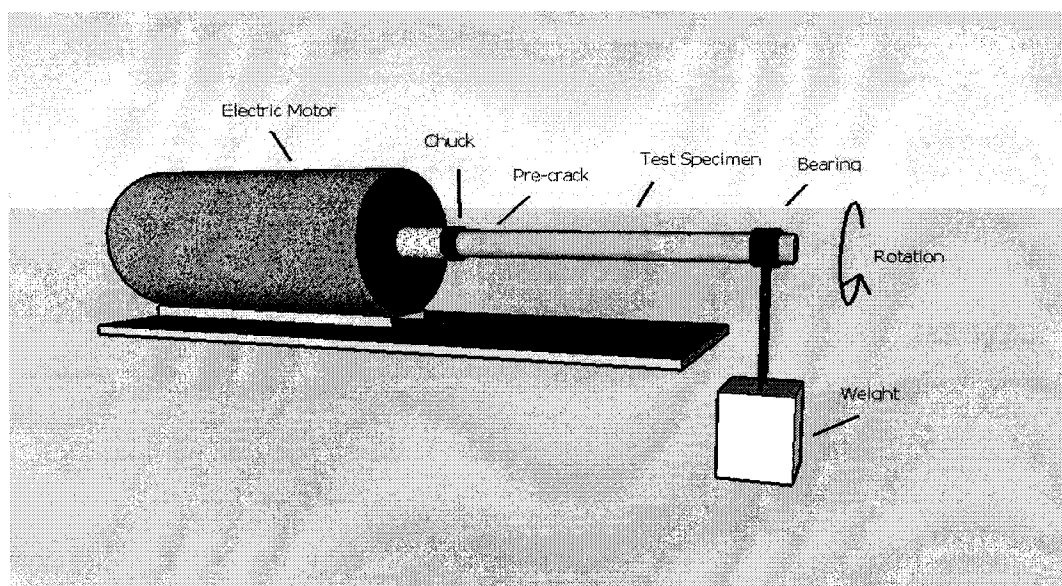
Figure 1 shows a cross sectional view of fatigue crack propagation. Fatigue crack propagation starts at a crack initiation site. As the stress exceeds the material’s maximum yield stress, the crack grows and propagates through the material. The stress and fatigue crack growth rate often increase with increasing crack length. Fatigue results in unique and distinctive successive lines that contour each wave of crack growth (beach marks).



**Figure 1. Cross sectional view of fatigue crack propagation.**

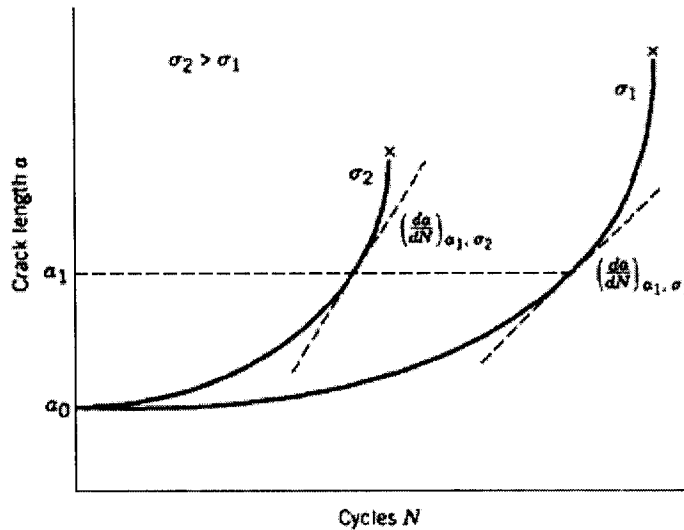
### Experimental/Project Design

A rotating bending fatigue apparatus consisting primarily of a motor, a plate, a chuck, a bearing, and a weight was designed and is shown in Figure 2. The motor bottom is fixed to the plate, the chuck is attached to the shaft of the motor and holds one end of the specimen, and the bearing and weight load is applied to the other end of the specimen. The motor turns at approximately 1750 rpm, allowing the specimen to experience  $10^8$  cycles in under 4 days.



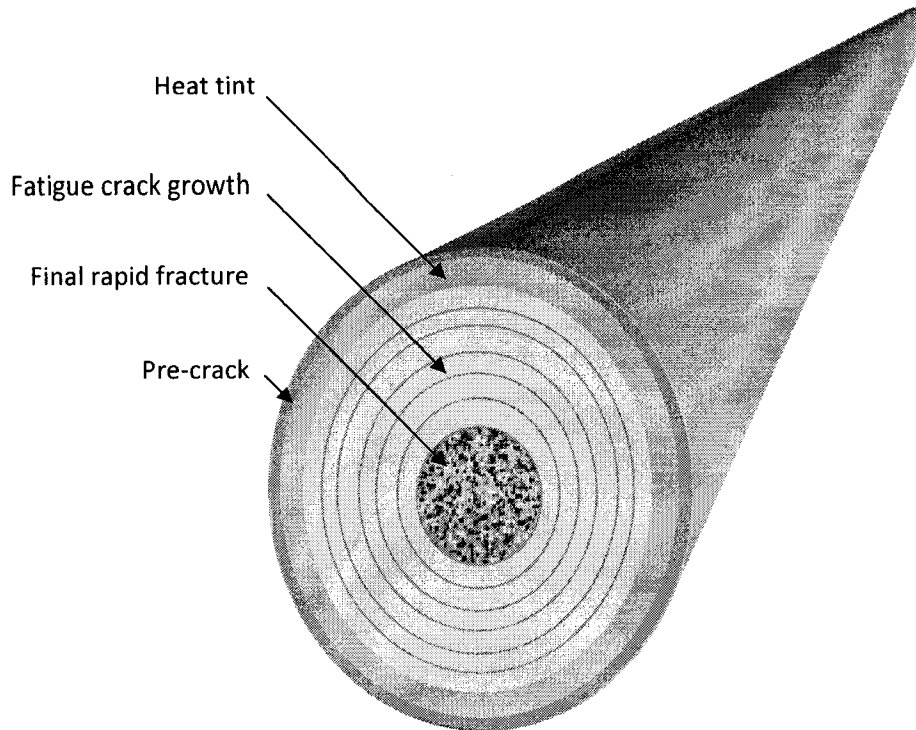
**Figure 2. Rotating Bending Fatigue Apparatus.**

A general fatigue test method is described by Hertzberg (1989). A sharp crack is mechanically induced on the specimen and after an application of loading cycles; the change in crack length is recorded. The fatigue crack growth rate is determined from the plot of crack length versus loading cycles. Figure 3 shows crack length  $a$  versus the number of cycles  $N$ . Crack growth rate  $da/dN$  is indicated at crack length  $a_1$  for stress levels  $\sigma_1$  and  $\sigma_2$ . The curve of  $\sigma_2$  is much steeper than  $\sigma_1$  at crack length  $a_1$  when  $\sigma_2 > \sigma_1$ .



**Figure 3 Crack length  $a$  versus the number of cycles  $N$ .**

For the round spinal rod, the fatigue process will be initiated by introducing a circumferential pre-crack to the rod. Rotating bending fatigue will imitate the loading that a spinal rod experiences while implanted. The load and number of cycles will be applied, and the amount of crack growth will be measured. To accurately measure crack growth, a technique called heat tinting will be used—when the alloy is heated to a moderately high temperature, the external surfaces of the alloy oxidize and change color. This will mark the initial crack length. After cycling, the specimen will be broken, and both the initial and final fatigue crack lengths will be measured. The amount of crack growth will be determined from the difference between the initial and final crack lengths. Testing will consist of varying the magnitude of the load and number of cycles. Figure 4 shows a sketch of the anticipated fatigue and fracture surface of a rotating bending fatigue specimen. Crack length  $a$  will be plotted versus the number of cycles  $N$  for the rotating bending fatigue specimens for various loads.



**Figure 4. Fatigue and fracture surface of a rotating bending fatigue specimen**

Surgical spinal rods are expensive. To reduce material costs, trial tests will begin with common round bar stock (ground ¼ inch 306 Stainless Steel rods) until a sufficiently refined test protocol is achieved, and then the surgical rods will be tested. An additional benefit to carefully refining the test method is that the surgical rod data will be more accurate and precise and as a result be more valuable.

A general step by step procedure follows:

1. Assemble rotating-bending fatigue apparatus
2. Cut rod to length of four inches
3. Secure rod into the chuck
4. Cut a pre-crack into the rod near the chuck with a sharp cutting tool
5. Apply bearing and pre-crack weight load to the rod
6. Initiate minimum crack growth by rotating bending until crack growth is visually established
7. Heat tint rod to mark initial crack size
8. Apply fatigue crack growth weight load
9. Subject rod to rotating bending for the number of cycles
10. Induce final fracture
11. Inspect fatigue and fracture surface to measure initial and final fatigue crack lengths
12. Determine fatigue crack growth rate

At the end of testing, the growth rate will be determined by plotting the crack length versus cycles.

## Anticipated Results

Techniques used by Scibetta (1999) and Ebara (1982) for rotating bending fatigue were successful and it is anticipated that those methods are applicable for testing spinal rods. However, there is uncertainty in the outcome of the testing because corroborated data for these alloys and surgical rods is not available. Trial and error testing with the common round bar stock will lead to a refined test method for the surgical rods. Once insight is gained into the test method and appropriate load and cycle amounts, a schedule of cyclic loading for the surgical rods will be developed and testing will proceed. Under the appropriate load, each specimen is expected to be able to handle tens of thousands to hundreds of millions of loading cycles before failure—it is anticipated that the amount of crack growth will be greater in those samples subjected to higher cycling and larger loading and will depend upon the sample material. The results of this study will provide a direct comparison of the fatigue behavior of spinal rods composed of two of the three available metallic alloys: stainless steel and titanium. This will be of use to physicians and patients considering spinal rod implantation and to engineers and scientists conducting research or development related to the biomechanics of spine stabilization.

## Project Budget

<u>Items Needed</u>	<u>Quantity</u>	<u>Price (ea)</u>	<u>Total</u>
1. Johnson and Johnson Titanium alloy ¼ inch surgical rod One rod is 18" inches in length	3	\$200	\$600
2. Johnson and Johnson SS alloy ¼ inch surgical rod One rod is 18" inches in length	3	\$200	\$600
3. ¼ inch Stainless steel ground rod (common round bar stock) One rod is six feet in length	3	\$25	\$75
4. Leeson Electric motor Model A4P17NR1F	1	\$300	\$300
5. Parts to build rotating bending fatigue apparatus			\$50
6. Machining costs			\$250
7. Miscellaneous costs (shipping and additional parts)			\$100
		GRAND TOTAL	\$1975

## Justification

By cutting the surgical rods into four inch pieces we will be able to conduct 12 tests with both types of surgical rod alloys. Since the price of the surgical rod is very costly we will use the common round bar stock during the initial testing stages. As stated in our procedure, the testing will begin with machine ground ¼ inch 306 ground Stainless Steel rod to ensure proficiency in our procedure. An

electric motor by Leeson will be used to apply rotation to the rods for cyclic loading. We will most likely have to order some parts from out of state and will incur shipping costs as well. Specialized parts such as a mounting plate to which the motor is attached will be machined at a local machine shop. Bearings also have a limited life and will have to be replaced periodically as well.

## References

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- ASTM Standard F138, 2008, "Standard specification for wrought titanium-6 aluminum-4 vanadium ELI (Extra Low Interstitial) alloy for surgical implant applications (UNS R56401)," ASTM International, West Conshohocken, PA, [www.astm.org](http://www.astm.org)
- Ebara, R., Yamada, Y., & Goto, A. (1983). "Corrosion-Fatigue Behavior of Ti-6Al-4V in a Sodium Chloride Aqueous Solution," *Corrosion Fatigue: Mechanics, Metallurgy, Electrochemistry, and Engineering*, ASTM STP 801, T. W. Crooker and B. N. Leis, Eds., American Society for Testing and Materials, 135-146.
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- Miller, E.H., Shastri, R., & Shih, C.I. (1982). Fracture Failure of a Forged Vitallium Prosthesis. A Case Report." *The Journal of Bone and Joint Surgery*, 64, 1359-1363.
- Scibetta, Marc. (1999). Contribution to the Evaluation of the Circumferentially Cracked Round Bar for Fracture Toughness Determination of Reactor Pressure Vessel Steels. Doctoral dissertation, ULg Universite de Liege.



# Project Timeline

The proposed project timeline is shown in the Gantt Chart below.

	Name	Duration	Start	Finish
1	Gather supplies	42 days	12/1/08 8:00 AM	1/11/09 5:00 PM
2	Assembly/preparation	14 days	1/11/09 8:00 AM	1/24/09 5:00 PM
3	Introductory testing	21 days	1/27/09 8:00 AM	2/16/09 5:00 PM
4	Finalize testing procedures	7 days	2/10/09 8:00 AM	2/16/09 5:00 PM
5	Testing surgical rods	21 days	2/21/09 8:00 AM	3/13/09 5:00 PM
6	Compile data	5 days	3/11/09 8:00 AM	3/15/09 5:00 PM
7	Finalize results	4 days	3/15/09 8:00 AM	3/18/09 5:00 PM
8	Prepare presentation of results	5 days	3/20/09 8:00 AM	3/24/09 5:00 PM
9	Undergraduate Research Symposium	1 day	4/15/09 8:00 AM	4/15/09 5:00 PM
10	Expenditure deadline	1 day	5/31/09 8:00 AM	5/31/09 5:00 PM
11	Final written report	1 day	6/15/09 8:00 AM	6/15/09 5:00 PM

