THE MICROSTRUCTURAL AND BIOMECHANICAL PROPERTY DIFFERENCES OF SPINAL RODS FROM DIFFERENT LOTS

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Abstract:

The objective of this project is to obtain a qualitative and quantitative comparison of the static biomechanical behavior of stainless steel and titanium spinal rods from different lots. Static testing will be done in a controlled environment, which will then provide data for analysis and conclusion.

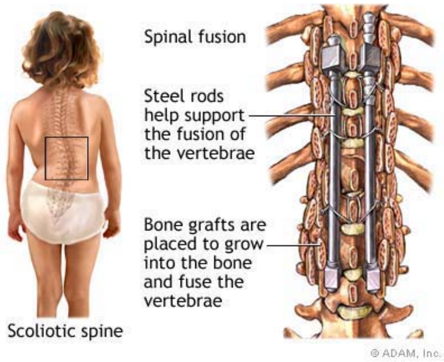

Figure 1 Spinal rods are used to help support the fusion of the vertebrae. (nytimes.com)

The spinal rod is a surgical device used to correct deformities of the spine due to medical conditions such as scoliosis and degenerative disc disease. Commonly, rods are implanted along the spinal column to support the fusion of the vertebrae, as shown in Figure 1. The spine is fixed when the grafted bone fuses into a solid bone mass, immobilizing the vertebrae. Since this takes up to a year to develop, the instrumentation aids in allowing the fusion to occur by making the spine stiff. When the fusion is solid, the instrumentation can be removed, although it is usually left in place. The instrumentation may eventually fatigue and fail if fusion is not achieved. Rigid internal fixation is required to enhance fusion rates and ensure mechanical stability.

Spinal rods are mass produced in lots. It was observed during a previous study by the Faculty Advisor that the behavior of the rods during cutting, bending, and testing varied significantly from one lot number to another. It was concluded that although rods are produced to meet the established ASTM standards, there are significant variations in the biomechanical properties of the rods from different lots.

Due to variations in the manufacturing process—including small variations in chemical composition and variations in heat treatment, cold work, and surface treatment from one lot number to another—there will be variations in the microstructure of the rods. Variations in microstructure result in variations in the biomechanical properties. This project will examine those differences in biomechanical properties and microstructure both qualitatively and quantitatively and discuss their effects on clinical performance.

Samples of the spinal rods will be obtained and subjected to biomechanical and microstructural testing. Each of the rods from different batches will be tested for their yield strength, tensile strength, ductility, metallography and hardness. Tensile tests will be performed using an MTS Universal Test Machine. Metallographic equipment will be used to determine the microstructure of the rods. Hardness tests will be performed using a Rockwell Hardness Tester.

The goal of this study is to determine the difference in microstructural and biomechanical properties of the titanium and stainless steel rods from different lots used for spinal instrumentation. A better understanding of the biomechanical behavior of spinal rods is important to physicians and patients considering rod implants, as well as to the engineers and scientists who are researching and designing spinal rod systems. To better understand spinal instrumentation from the clinical perspective, orthopedic surgeon Dr. Andres Munk, M.D., Macomb Orthopedic Surgeons, will serve as a collaborating researcher.

The results of the study will be published in a formal report and submitted for dissemination through conference and journal publication.

Introduction:

The spinal rods that are manufactured by Johnson & Johnson DePuy AcroMed are available in two materials, titanium and stainless steel, and are produced in lots. As part of a previous research project (Paris et al 2004), spinal rods were cut and bent using surgical tools to simulate the form of the spine. While doing so, it was observed that the spinal rods varied qualitatively in behavior from one lot number to another. It was concluded that although there are standards for these alloys (ASTM), there are significant variations in the biomechanical properties from different lots. This study proposes to compare the biomechanical and microstructural properties of titanium and stainless steel rods from different lots both qualitatively and quantitatively.

Figure 2 The MTS Universal Test Machine (UAA SOE) used to determine rod tensile properties

Previous studies have been done to test the mechanical behaviour of 316L steel. In 1973, Dieter Fahr studied the differences in mechanical behaviour with varying temperature. However, there is no known published research on tests of property variations in different lots for spinal rods. Benzel (2001) briefly describes implant properties including the chemical composition and qualitative characteristics of commonly used titanium and stainless steel alloys. Kim (2005) looked at the *flexibility* and *rigidity* mechanical properties of rods. A direct qualitative and quantitative comparison of spinal rod fundamental biomechanical and microstructural properties from one lot number to another as is proposed here would be a nice contribution to the literature.


Figure 3 Metallography equipment

The purpose of this study is to make a qualitative and quantitative comparison of the biomechanical tensile, hardness, and microstructural properties (Callister 2007) of titanium and stainless steel rods from several lot numbers. This is important because the mechanical and microstructural properties of the rod influence its performance during and after the surgery, in particular the safety of the structural support the implant is intended to provide.


Figure 4 Rockwell Hardness Tester (wilsoninstruments.com)

Samples of the spinal rods coming from different lot numbers will be tested for yield strength, tensile strength, ductility, hardness and metallography. The MTS Universal Test Machine, shown in Figure 2, is available at the UAA School of Engineering and will be used to measure the yield strength, tensile strength, and ductility. Metallography equipment shown in Figure 3 will be used to study microstructural composition, grain size, shape and orientation within the rods. Hardness will be measured using a Rockwell Hardness Tester shown in Figure 4 (currently on order). The differences in the microstructural properties of the rods will be determined, and variance analysis performed.

The results of the study will be published in a formal report, at the UAA Undergraduate Research Symposium, and submitted for dissemination through conference and journal publication.

Experimental/Project Design:

The titanium and stainless steel spinal rods will be provided by Johnson & Johnson DePuy AcroMed. These are the same rods that are used for spinal instrumentation. For each material, one spinal rod from five different lots will be used. Each rod is 45 centimeters in length and is 6.35 mm in diameter and will be cut into 4 pieces at 11.25 cm each. The samples will be tested for several mechanical properties namely: the yield stress, the tensile strength, ductility, hardness and the metallography. At the end of the research, comparisons will be made using the data gathered.

A tensile test will provide much of the information about the mechanical properties of the rods. Prior to testing, the original cross sectional area and gauge length of a sample rod will be measured. It will be mounted on the MTS Universal Test Machine, where a gradually increasing load will be applied until fracture is attained. The applied load and gauge displacement are automatically measured throughout the test by the Test Machine. Using the continuous data obtained, the engineering stress-strain curve can be generated, shown in Figure 5.

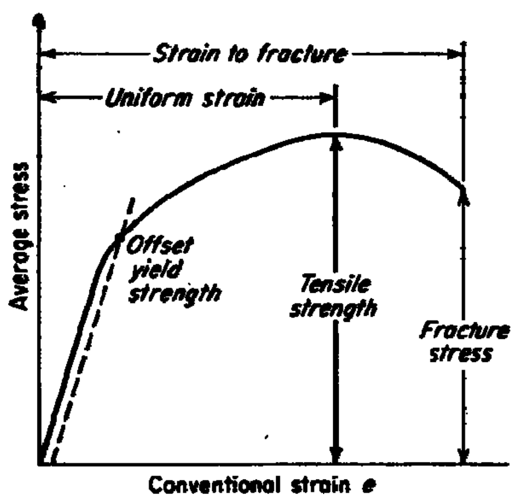

Figure 5 Stress-strain curve

This curve will be used to determine the mechanical properties such as the yield strength and tensile strength. The MTS Universal Test Machine imposes a displacement δ and the load P is measured. If the original gage length is L and the original cross-sectional area is A, for elastic deformations the stress $\sigma = P/A$ and strain $\varepsilon = \delta/L$ are related by Hooke's Law,

$$\sigma = E\varepsilon \quad (1)$$

where E is the elastic modulus. Yield stress is the maximum stress that can be applied to the specimen at which no permanent deformation occurs. The determination of the yield stress is essential because most structures are designed so that only elastic deformation occurs. When a material experiences elastic deformation, it goes back to its original shape and size when the stress is removed. When yield stress is exceeded, permanent deformation occurs, and the structure may not be capable of functioning as originally intended.

The tensile strength is the maximum tensile stress that the specimen can withstand due to an applied load. Necking, or a localized reduction in cross-sectional area of the material, begins to occur at this maximum stress.

Ductility can be expressed qualitatively as the percent elongation or percent reduction in area. In other words, ductility corresponds to the plastic deformation that has occurred at fracture. The sample gage length will be measured using a caliper to obtain an accurate value for the original gage length L_o and the gage length after fracture has occured L_f. Percent elongation *%EL* is defined as

$$\%EL = \frac{L_f - L_o}{L_o} \times 100\% \quad (2)$$

On the other hand, the percent reduction in cross sectional area *%RA* is determined by measuring the diameter of the rod gage section before deformation D_o and the minimum diameter of the rod gage section after fracture has occurred D_f. The percent reduction in area *%RA* is defined as

$$\%RA = \frac{A_o - A_f}{A_o} \times 100\% \quad (3)$$

where $A_o = \pi D_o^2/4$ and $A_f = \pi D_f^2/4$. Ductility is an important concept because it can be used as an indication as to how much deformation can occur before fracture.

Hardness is a measure of a material's resistance to localized plastic deformation. To measure hardness, the Rockwell Hardness Test will be performed. It is a simple and inexpensive test wherein a small indenter is forced into the surface of the material under a small minor load, followed by a larger major load. The depth of the indentation is then related to a hardness number, *HB*. The hardness testing is nondestructive, making it a useful tool to estimate other mechanical properties such as tensile strength. It will be investigated as a method of spinal rod quality control by correlating tensile properties with hardness. For steel, the tensile strength *TS* as a function of the hardness number, *HB* is as follows:

$$TS\ (MPa) = 3.45 * HB \quad (4)$$

$$TS\ (psi) = 500 * HB \quad (5)$$

Microscopic techniques will also be employed to study the structural elements that affect the properties of the titanium and stainless steel. Both the titanium and the steel that composes the spinal rods are alloys—impurity atoms have been added to manipulate the properties of the rod. The samples will be studied under a microscope to examine composition, grain size, shape and orientation. A relationship between the microstructural properties of the rods and the tensile and hardness properties will be drawn. The grain size is correlated approximately with the yield stress using the Hall-Petch equation:

$$\sigma_y = \sigma_o + k_y d^{-1/2} \quad (6)$$

In this equation, σ_y is the yield stress, d is the average grain diameter and σ_o and k_y are constants for the material.

There will then be two materials, titanium and stainless steel, five lot numbers of each material, five specimens for each lot number, for a total of 50 specimens to be tested. All testing will be done in a controlled laboratory environment and in standard operating conditions. Standard testing methods will be observed as specified by the American Society for Testing and Materials (ASTM). At the end of testing, statistical analyses will compare the mechanical properties of the samples. Orthopedic surgeon Dr. Andres Munk, M.D., will collaborate and provide guidance throughout the project and assist in determining the clinical significance of the results.

Anticipated Results:

Experience in a prior study suggests that spinal rod biomechanical properties vary significantly from lot to lot. It is anticipated that there will be significant variation in the mechanical and microstructural properties of rods coming from different lot numbers. It is anticipated that those differences will correlate well with differences in the microstructure of the material. It is anticipated that the differences in the biomechanical behavior may have clinical significance and may be of use to physicians and patients considering implants and to engineers and scientists analyzing and designing implant systems. The results of the study will be published in a formal report, presented at the UAA Undergraduate Research Symposium and submitted for dissemination through conference and journal publication.

Project Budget:

Material	Quantity	Cost/Unit $	Total Cost $
Spinal Rods	12	200	2400
Machining			1000
Tensile Testing Supplies			1000
Metallography Supplies			600
Total Expected Cost			$5,000

Budget Justification:

The Total Budget for the project is $5000. Twelve spinal rods (two metals, one rod each from five different lots, one extra rod of each material for optimizing the test protocol) estimated at $200 each will be needed for the project. Machining the rods into tensile test specimens is estimated at $1000. Tensile testing supplies including materials, fixtures and instrumentation, due to the small size of the specimens, will be needed estimated at $1000. Metallography supplies for cutting, polishing, and etching the metallographic specimens will be needed estimated at $600.

Project Timeline:

Task Name	Duration	Start	Finish	Predecessors	Resource Names
Acquire rods	4 wks	8/10/2009	9/4/2009		Johnson & Johnson DePuy,Inc. and Orthopedic Surgeon
Machine rods into tensile test specimens	3 wks	9/7/2009	9/25/2009	1	Machine shop
Acquire tensile test and metallography supplies	1 wk	9/28/2009	10/2/2009	2	MTS, machine shop and UAA SOE

Prepare and set up laboratory materials	1 wk	9/28/2009	10/2/2009	3	UAA SOE
Testing and Recording Data	2 wks	10/5/2009	10/16/2009	4	UAA SOE
Data Analysis	7.5 wks	10/19/2009	12/9/2009	5	Faculty Advisor, Orthopedic Surgeon
Write Report	5 wks	12/9/2009	1/13/2010	6	Faculty Advisor, Orthopedic Surgeon
Presentation	1 day	4/26/2010	4/26/2010	7	Faculty Advisor, Orthopedic Surgeon

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