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FATIGUE TESTING OF SURGICAL STAINLESS STEEL IN A SIMULATED PHYSIOLOGICAL ENVIRONMENT

by

RICHARD N. HOLTE, B.Sc. (M.E.)

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ABSTRACT

Despite the fact that fatigue failure of 316L stainless steel orthopedic implants is still a problem, it has received scant attention. Tests were performed in air and distilled water, to provide baseline data, and in Ringer's physiological solution, which simulates the extracellular fluid of the body. Results show that the apparent fatigue limit in Ringer's solution is 10% lower than the fatigue limit in air or distilled water which could explain some of the failures in orthopedic implants. A theoretical model based on enhancement of stage I crack growth rates by crevice corrosion is proposed to account for the experimental observations.

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CHAPTER ONE

1. INTRODUCTION

1.1 Historical Background

Metals have been surgically implanted in the human body for many years: in 1562 Petronius used a gold prosthesis to repair a cleft palate (1). Infection was a major problem, however, and early attempts often failed for this reason. The work of Pasteur and Lister in the nineteenth century reduced the possibility of surgical infection, and with the advent of asceptic operations, experimentation with different materials for implanting began in earnest. By 1910, most materials had been eliminated as possible orthopedic supplements for reasons of expense, weakness, or corrosivity. Steels were popular with the surgeons of the day: Lane specified a "stout (high Carbon) steel" (2), while Sherman declared that a new Vandium tool steel was the best available for internal prostheses (3). Thus we see the surgeon searching for a material sufficiently strong and corrosion-resistant for service in the body environment.

In 1926, 18-8 SMo stainless steel was patented (1), and was reviewed by Large (4) as having a good potential as an implantable material. Slow to gain acceptance, in 1947 this steel had been recommended by the American College of Physicians and Surgeons (3) along with Titanium and the Cobalt-based alloy Vitallium, as being suitable for orthopedic repair and supplement. Today these same materials are still effectively and routinely implanted in the body.

1.2 Incidence of Failures

Many clinical surveys of excised orthopedic implants have been done recently. Cahoon and Paxton (5) performed metallurgical examinations

of thirteen failed orthopedic implants and found five to have failed by either a fatigue or a corrosion-fatigue mechanism. They cite poor design and fabrication techniques as major contributory causes. Colangelo (6) and Colangelo and Greene (7) found three fatigue failures in 155 excised implant components. They do not indicate how many of the excised prostheses performed satisfactorily. Brettle and Hughes (8), examining four "apparently random" examples of failed orthopedic implants, report that all of the devices failed by either a fatigue or a corrosion-fatigue mechanism. Of four En58J (British equivalent of AISI 316L) stainless steel implants examined by Hughes and Jordan (9), one had failed due to a corrosion-fatigue mechanism, and another due to a fatigue mechanism, both with failures initiating at section changes. Another study, by Weinstein et. al. (10), reports six of 84 failures attributable to fatigue or corrosion-fatigue.

Failure of orthopedic implants is still a problem, as indicated by the preceeding surveys. Fatigue and corrosion-fatigue account for a significant number of these failures.

1.3 Recent Work

Corrosion of surgical stainless steel in the body has received much attention, both in surveys (Scales, Winter, and Shirley (11, 12), Cohen (13)) and in vitro experiments approximating body conditions (Rama Char (14), Cahoon, Chaturvedi, and Tennese (15)). Considerably less interest has been shown in the fatigue behaviour of 316L stainless steel under simulated body environment conditions.

Laing and O'Donnell (16) conducted static and fatigue tests of several different hip-nail cross-sections machined from rods of

surgical stainless steel. Their work was conducted from a design viewpoint, rather than from a materials selection interest. Consequently, no attempt was made to approximate the harsh environment in which these implants would ultimately find service. On the other hand, Grover (17) dealt with the question of fatigue life of implants from a materials standpoint. He conducted fatigue tests not only of 316L stainless steel but also of Vitallium and a Titanium alloy (Ti-6Al-4V), and prepared S-N curves using the results. Grover's tests were all run in air at room temperature. The possibly detrimental effects of cycling in the warm, moist, chloride environment of the body could not be estimated from his work.

Cohen (18) performed fatigue tests on Sherman plates and surgical nuts and bolts of both Vitallium and 316 stainless steel. His experiment was designed to test relative corrosion rates of the different metals stressed in a saline solution.

Two papers (6, 19) have been published using the fracture mechanics approach to the problem of fatigue in the physiological environment. Wheeler and James (19) showed a distinctly lower crack growth rate in air than under simulated physiological conditions. They chose a sinusoidal forcing function for their baseline (air) tests, but changed to a square waveform for the simulated physiological test. This change in forcing function is regrettable, as it clouds the significance of their results: one is unsure as to how much of the difference between the crack propagation rate in air and that in Ringer's physiological solution is due to the difference in environments, and how much is

attributable to the change in applied waveforms (20). Because of the longer times at peak stress, and the impact loading of every cycle, the square wave is likely to accelerate the rate of crack propagation, precisely the effect that Wheeler and James wish to attribute to the increased harshness of the artificial physiological environment. It seems reasonable to infer that the difference is, at best, not so great as reported in their paper. The other fracture mechanics study, by Colangelo (6), showed a higher crack propagation rate in air than in a saline solution. Curiously, his baseline data do not agree with those of Wheeler and James, despite the generally comparable testing conditions chosen by the respective authors. Commenting on this seeming contradiction, Williams (3) emphasized the statistical nature of fatigue, noting that both authors had tested only one specimen. Brettle concluded that "it seems unreasonable to expect good correlation, or even meaningful results, on the basis of so little data" (21). Colangelo (6) and Wheeler and James (19) have laid the groundwork, showing the range of values that may be expected. Subsequent confirmatory studies are as yet wanting.

1.4 Raison d'être

Surgical stainless steel is widely used for orthopedic repair and supplement. The surveys quoted (5-10) give evidence of significant numbers of in vivo failures by a fatigue mechanism. Work to date (6, 16-19) has left unanswered the possibility of a detrimental effect on fatigue life of repeated loading in the corrosive environment of the body. Both Williams (3) and Brettle (21) have commented on this lack of information available concerning the corrosion-fatigue characteristics

of implant materials. This study will add to the state of the art by investigating the effects of service under physiological conditions on the fatigue behaviour of surgical stainless steel.

2. HUMAN PHYSIOLOGY*

2.1 Body Fluids

The human body is composed of millions of cells, specialized to perform certain functions, and variously aggregated into the macroscopic tissues and organs. Despite their many differences, the cells have several similarities, including the composition of their intracellular fluid, and the metabolic process. The nutrients required for metabolism and the waste products evolved therefrom are transported by extracellular fluid surrounding the cells, which also has a nearly constant composition throughout the body. Extracellular fluid is in constant motion as it transports the nutrients and the waste products between the circulatory system and the cells. Thus the internal environment is a dynamic equilibrium between the intracellular and extracellular fluids, separated by permeable membranes of the cell walls. The temperature is a constant 98.6°F (37°C) throughout.

Extracellular fluid contains quantities of ions of sodium and chlorine, moderate amounts of bicarbonate, and traces of potassium, calcium, magnesium, phosphate, sulfate, and organic acid ions. Blood plasma contains a significant amount of protein, found only in trace quantities in interstitial fluid. Nonelectrolytes, mainly lipids and glucose, make up 60% by weight of interstitial fluid, and 90% of plasma.

Potassium and phosphate are the major constituents of intracellular fluid, with moderate amounts of magnesium and sulfate ions, and only traces of sodium, bicarbonate, and chloride ions present. Additionally, intracellular fluid contains about four times as much

* Note: Most of the information in this section is derived from Guyton's Textbook of Medical Physiology (22), Crouch's Functional Human Anatomy (23), and Basic Physiology and Anatomy by Chaffee and Greisheimer (24).

protein as does blood plasma. Non-electrolytes comprise 97% by weight of intracellular fluid. Figures 1 and 2 give the complete composition of intracellular and extracellular fluids.

Oxygen is required for the metabolic process, and carbon dioxide is a waste product. These gases are present in both intracellular and interstitial fluid, carbon dioxide having a partial pressure of 45 mm Hg in the extracellular fluid and 46 mm Hg in the intracellular fluid, and oxygen having a partial pressure of 40 mm Hg in the extracellular fluid and varying between 0 and 40 mm Hg in the intracellular fluid. These values are subject to variations in available healthy lung surface area, blood composition and flow rate, and basal metabolic rate.

Extracellular fluid normally has a pH of 7.4. The pH of the intracellular fluid has been estimated at between 4.5 and 8.0: Guyton (22) gives 7.0 as an average value.

The composition of the extracellular fluid is closely monitored to protect against any detrimental deviations from the norm. For example, sodium and potassium ion concentrations are regulated by hormones, chiefly aldosterone. Dissolved oxygen and carbon dioxide levels in the blood are monitored by the respiratory centre in the medulla. Variations in pH may be modified by the ubiquitous buffer systems, by regulation of ventilation, and by kidney response.

Despite these elaborate control mechanisms, deviations from the norm do occur, especially with traumas. Upon injury, histamine is liberated by damaged cells, increasing the local blood flow and permeability of capillaries. Large quantities of fluid and protein infuse the area,

and clotting of the extracellular and lymphatic fluids takes place. This closure of the injured area prevents the spread of any foreign bacteria that may be present, and reduces fluid flow to a very low level. This brings a rise in the local pCO_2, and a decrease in the pO_2. Local pH may drop as low as 5.5, and remain thus for ten days, before slowly returning to the normal level (Murray (25), Crimmins (26), Laing (27)).

The intra- and extracellular fluids, and the ions and gases dissolved in them, are the basic internal environment of the body. Numerous effective monitoring and regulatory mechanisms maintain a steady state composition of these dynamic fluids. Deviations from the norm occur locally upon trauma.

2.2 Nerves

Neurons are cells which have specialized to conduct electrochemical impulses through the body. They vary in length from a fraction of an inch to several feet. Basically, neurons consist of a cell body with elongated processes, known as nerve fibres. Dendrites are nerve fibres which receive impulses and transmit them toward the cell body, while axons carry impulses away. Neurons have only one axon, although it may throw off collateral branches. Axons and dendrites may develop sheaths of myelin and neurilemma. Myelin is an excellant insulator, but its sheaths are discontinuous, being periodically interrupted at constrictions known as nodes of Ranvier. Neurilemma sheaths are found on all nerves outside the central nervous system. They protect the nerve fibres, are much better conductors than myelin sheaths, and play an important role in the regrowth of severed nerve fibres.

An electrical potential of -85 mv exists between the extracellular fluid and the intracellular fluid of nerve fibres. This is known as the normal resting potential, and results form the action of the sodium and potassium ion pump within the nerve fibre membrane, and the selective permeability of the membrane. Potassium diffuses through the resting nerve membrane 50 to 100 times more easily than sodium.

The transmission of nerve impulses is initiated by a sudden increase in the permeability of the membrane to sodium ions, thought to be caused by the emigration of calcium ions. The great difference of sodium ion concentrations across the cell wall causes a large influx of these ions into the cell, temporarily making the intracellular fluid 50 mv positive with respect to the extracellular fluid. This provides a repulsive force to stop the flow of sodium ions into the nerve fibre. At this time the membrane appears to resume its former impermeability to sodium ions, while allowing potassium ions to diffuse at 30 to 40 times their former rate. The conjoint action of the sodium pump and the increased potassium diffusion results in an excess of cations in the extracellular fluid immediately adjacent to this portion of the nerve fibre. This cation excess is characterized by a positive after potential of -90 mv. As the membrane permeability to potassium ions returns to normal, the potential slowly resumes its normal resting value. On a time scale, the peak reversal or action potential is achieved in about .5 milliseconds, the positive after potential follows in another 8 milliseconds, and the resting potential is regained no sooner than 50 milliseconds and as long as several seconds after the initial change in sodium ion permeability in

the nerve fibre membrane. The electric current that accompanies the moving ions is thought to stimulate this change in permeability in neighbouring cells. Thus conduction of a nerve impulse is a self-sustaining propagation: the moving ions cause a current which changes the permeability of the neighbouring membrane, starting the depolarization of the adjacent portion of the nerve fibre, and propagating the impulse further. A threshold level of stimulation is required to initiate depolarization. Conduction may occur in all directions along the nerve fibres. There is an absolute refractory period of 1/2500 of a second during which no amount of stimulation will cause depolarization of the nerve fibre. The velocity of conduction varies from 2 to 400 feet/second, the higher values being typical of saltatory conduction in myelinated fibres which depolarize only at the nodes of Ranvier, thus lengthening the jumps of each depolarization process.

Nerve fibres have a resting potential of -85 mv. The conduction of a nerve impulse raises this briefly to +50 mv, from where it drops quickly to -90 mv, and then slowly returns to the normal resting potential. Ion exchange across the nerve fibre membrane play an integral part in impulse propagation.

2.3 Bones

The bones of the skeleton are the structural framework of the body. They give the body shape, act as levers in the transmission of force generated by the muscles, protect softer interior tissues and organs, and act as a storehouse and supplier of various organic and inorganic compounds. Structurally, a bone consists of a matrix of cancellous (spongy) bone surrounded by a dense layer of compact bone. Periosteum forms the majority of the outer covering.

Bone is composed of a tough organic matrix that is greatly strengthened by deposits of crystalline salts. Collagen fibres, comprising 97% of the organic material, have good tensile strength, and tend to grow along the lines of tensional stress. The crystalline salts, mainly hydroxyapatites of calcium and phosphate, are strong in compression. Intimate contact of the collagen fibres and the inorganic salts, and cross-bonding of collagen fibres, makes bone strong in tension, compression, and shear. Morral (28) gives the ultimate strengths of femur bone as 13 to 17.7 ksi in tension and 18 to 24 ksi in compression, with a Young's modulus of from 2.82 to 2.98 psi x 10^6. These figures are subject to variations of age, sex, and racial type: men have stronger bones than women, Negroes more so than Caucasians (29). Furthermore, as a person ages, the mineral salts replace the collagen fibres, decreasing the organic content of bone below its normal 30%, and resulting in decreased strength and increased brittleness.

Because bone is a living, growing tissue, it reacts to external stimuli. Through the action of osteoclasts and osteoblasts, bone is continually resorped and replaced. In this way, bones optimize their structure to accomodate the loads they must carry. The action of the bone-altering cells is thought to be guided by piezoelectric current generated by the compression of bone. Other authors (26, 30) have commented on this effect, but it has yet to be measured quantitatively.

Marrow is found in the hollow shafts of the long bones and within the cavities of cancellous bone. Red marrow produces red and white blood cells and platelets, and is responsible for the destruction

of old worn-out cells through phagocytosis. Consequently, the marrow communicates freely with the circulatory system. This rich blood supply also connects to the haversian system and canaliculi of the bone, supplying nutrients and removing metabolic wastes. Through this contact with the circulatory system, inorganic salts may be deposited in or removed from the bones, depending on the particular needs of the body as determined by the person's activities and nutrient intake.

The bones provide a framework for the body. They are able to modify their structure in response to the differing loads they are required to carry. Many organic and inorganic compounds are either stored in the bones, or manufactured there. Because of this, bones play a dynamic role in the maintenance of normal body fluid composition. Variations in strength of bone tissue occur particularly with advancing age, as the organic fibres are replaced with inorganic salts, rendering the bones weaker and more brittle.

2.4 Skeletal Muscles

The skeletal muscles, which account for 40% of the body weight, produce all of the voluntary movements. The muscles consist of many muscle fibres running the length of the muscle, innervated usually at one point only. The muscle fibres, of diameter 10 to 100 microns, are in turn made up of from 100 to several thousand myofibrils, suspended in a sarcoplasm matrix. Each myofibril is composed of about 1500 myosin filaments and twice as many actin filaments, Matrices of myosin filaments interdigitate with matrices of actin filaments, which are cross linked at their centre points by Z membranes. Thus the motor units, or sarcomeres, are found between adjacent Z membranes.

Muscular contractions originate at the myosin and actin filament level. The normal muscle resting potential of -85 mv is excited to +100 mv by an electrochemical nerve impulse of duration 5 to 10 milliseconds, transmitted from the nerve to the motor point of the muscle and thence to all of the myosin and actin filaments by way of T tubules that permeate the entire muscle. The excitation potential is thought to cause, in conjunction with calcium ions and ATP, an electrical attraction along the myosin fibrils and sliding together and overlapping of the associated actin fibrils. The conjugate action of the slight shortening of all of the sarcomeres results in a macroscopic contraction of the muscle. Force and duration of contraction are affected by the number of muscle fibres stimulated, and the frequency of stimulation.

Muscular contractions are the macroscopic manifestations of a microscopic electrochemical reaction. Stimulation by a nerve impulse briefly depolarizes the normal muscle resting potential of -85 mv to +100 mv.

2.5 Modelling the Body Environment

The chemical composition of the extracellular fluid, noted in Figure 1, is closely approximated by Ringer's physiological solution (Table 1). The dissolved gas partial pressure of both oxygen and carbon dioxide is roughly 40 mm Hg. Extracellular fluid normally has a pH of 7.4, although this may drop as low as 5.5 during the initial post-trauma period.

Body temperature is essentially constant at 98.6°F (37°C).

Electrical impulses originating in muscle or nerve cells briefly change the normal resting potential from -85 mv to as much as +100 mv. The piezoelectric properties of bone have not been determined quantitatively. Modelling these various electrical signals will not be necessary, however, as the difference in rest and breakdown potentials for 316L stainless steel in a physiological environment is five times greater than the magnitude of the normal resting potential (15).

Bones of the leg have an ultimate tensile strength of approximately 15 ksi. Because of restrictions of size, geometry, and stress concentrations inherent in fastening, orthopedic implants are subjected to much higher peak stresses. Furthermore, these stresses are applied often: level walking at 51 cpm (31) is repeated many hundreds of times daily.

Surgical stainless steel implants are subject to high stress, low frequency fatigue in a warm, aggressive environment. Electrical impulses associated with nerve and muscle activity are likely insignificant in magnitude, and can be ignored in modelling.

3. EXPERIMENTAL APPARATUS AND PROCEDURE

3.1 Philosophy of Testing

It was anticipated that stressing in the aggressive simulated body fluids would result in lower fatigue life than would be predicted in air under the same loading conditions. This could be verified by constructing S-N curves based on tests run in 37°C air and under simulated body conditions. As a further comparison, tests would be performed using distilled water rather than simulated physiological fluid as the testing medium. In this way, the effect of the aggressive physiological environment on fatigue life of 316L stainless steel could be isolated and identified.

3.2 Specimen Preparation

Specimens were lathed from half-inch diameter 316L rod. Uniform surface finish was ensured by consecutive polishing with 200, 400 and 600 grit emery papers. Finished specimens had a diameter of .138 inch and an overall length of 2.25 inch. Just prior to testing, the specimens were degreased in trichlorethylene, washed in hot water, rinsed in cold water and ethanol, and dried under a hot-air blower. Specimen configuration and dimensions are given in Figure 3.

3.3 Apparatus

Fatigue tests were performed on an Amsler high-frequency Vibraphore (Photo 1), type HFP22, fitted with a two-ton optical dynamometer. The specimens were axially loaded form zero to peak tensile stress (stress ratio, R = 0) at approximately 8500 cpm, the forcing function being sinusoidal in nature. Failure criterion was complete fracture, with run-out at five million cycles.

To accomodate the different environments, a seven-inch cube of UPVC with removable lid and 'O' ring seal was constructed (Photo 2). Adaptors of one inch diameter type 304 stainless steel (Figure 4) held the specimens in place in the environmental cell. Initially, the adaptors were accorded the same cleaning treatment as previously described for the specimens. The environmental cell and heating chamber were sterilized with a .2 N HCl solution, washed with soap and warm water, rinsed in warm and cold water, and air-dried. When the different testing media were changed, this procedure was repeated, and fresh distilled water was allowed to circulate for 30 minutes before being drained off.

The temperature of all tests was $37 \pm \frac{1}{2}^{\circ}$ C. A Yellow Springs Instrument Co. Model 63 RC (Photo 3) relay, used in combination with either a T2900 or T2930 thermoprobe, monitored the temperature of the medium in the environmental cell. Heating of the air was performed by an Oster air blower (Photo 4), whereas the liquids were warmed in a separate chamber by a Briskeat heater, and circulated through PVC tubing by a Manostatic Veristaltic Junior model peristaltic pump delivering .3 litre/min.

Distilled water for use as a testing medium and in preparation of Ringer's physiological solution was prepared by passing tap water through a Pako Super Life Water Filter and distilling it in a glass, single-pass Corning AG-1b distillation unit.

For the tests done in an aqueous or physiological environment, commercial purity argon, oxygen, and carbon dioxide were bubbled through airstones placed in the heating chamber (Photo 5). A PHM-71 Acid-Base