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# III. Total Joint Replacement and Other Orthopaedic Implants

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# III. Total Joint Replacement and other Orthopaedic Implants

## A. General

### Evaluation and Development of Biomaterials Used in Total Joint Replacement

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**Sponsor:** Northwestern University
Rehabilitation Engineering Program

At a recent meeting, an announcement was made that by centrifuging acrylic bone cement inherent porosity was removed and the mechanical properties were significantly increased. For several years, efforts have also been directed in these laboratories toward the removal of porosity to improve physical properties. However, medium vacuum has been employed, since it was felt that such an apparatus could be introduced to the surgical suite much more readily than a centrifuge. Moreover, preliminary results indicate that vacuum may have the additional advantages of removing more of the micropores, removing excess monomer that might have been transferred to the patient, and preventing the monomer vapor from reaching the clinical personnel.

Prototype vacuum mixers have been fabricated and are ready for simulated clinical trials. The necessary vacuum pumps have been purchased (the so-called suction vacuum, available in the surgical suites, is far too weak to be effective in the current mixing system). The decrease in porosity via vacuum mixing presently appears to work best in the more fluid cement mixtures. While porosity appears to have been removed in large boluses of dough-type cements, bubbles and holes seem to reappear in small ASTM F451 specimens. Studies are currently underway to see if the nature of the multiple-hole specimen dyes and plates inherently introduce defects to setting acrylic bone cement specimens.

Also under scrutiny during the reporting period are the evaluations of corrosion resistance of various porous metal prosthesis components. The methodology being employed is that of anodic polarization in body-simulated electrolytes, following procedures similar to those being developed in these laboratories and with others for ASTM F746 Standard on Pitting and Crevice Corrosion in Surgical Implant Metals.

Preliminary results are showing corrosion electrical currents of porous coatings to be at least one order of magnitude greater than that of bulk material of the same composition. This is probably due to the significant increase in surface area presented by a porous material. However, during our corrosion evaluations, several coatings were found to strip easily from their parent prosthesis. This, and the findings of others, has caused several models to be temporarily withdrawn from the market until more suitable sintering techniques can be discovered. In the meantime, with a temporary hiatus in the supply of freshly coated porous prostheses, further pursuit in performing all potentiostatic testing via Apple personal computers equipped with appropriate A/D boards is ongoing.

### Investigation of the Bone/Bone Cement/Implant Interface Formed by Total Joint Replacement

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The objective of this project was to identify the causes of late loosening of total joint replacement components by examining three aspects of the interface system:

1. Investigations of the major factors affecting the mechanics of bone/bone cement interface failure. A series of control and experimental tensile tests on the bone/bone cement interface had been reported previously. A paper detailing results of these tests has been accepted for publication by the Journal of Orthopaedic Research.

2. Investigation of mechanical and histological properties of the soft interface tissue commonly found at the bone/cement interface system and how load is transferred across this interface. A paper presenting the permeability results and soft-tissue mathematical model reported last year has been accepted for publication in the Annals of Biomedical Engineering.

Also, the tissue response to unloaded cylindrical titanium implants in rabbit tibiae was investigated as

a precursor to future experiments. The response was seen to be no different from ordinary fracture healing, with a bony shell surrounding the metal and no fibrous liner observed.

3. The development of an evaluation methodology based on fracture mechanics, for bone cement/metal implant interface failure, and its utilization to evaluate various metal surface preparations. Titanium bar stock has been machined to four-point bent bar dimensions and the bar's surfaces either grit-blasted (which is the normal implant's surface state) or flame-sprayed (which is a porous surface state). These specimens await testing, and therefore no data is available.

## Structural Analysis of Total Joint Replacement

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The finite element method was used for the structural design and analysis of total joint replacements and was specifically used to address the following two subproject areas:

**Surface Replacement Hip Arthroplasty**—The surface replacement hip arthroplasty is a promising procedure for the younger, more active population. The objective of this project is to better understand the causes of surface hip arthroplasty failures and to develop improved designs. Finite element analysis is being used to calculate the three-dimensional stresses in the remaining portion of the head and neck of the femur after physiological loads are applied to the prosthesis. The purpose of this analysis is to find a design for the surface hip replacement that will minimize changes in stress distributions from the preoperative hip. It is hypothesized that, by maintaining the same stress distribution, the mechanically induced resorption of bone will be minimized. Several designs have been analyzed and more remain under consideration. These studies have been done using a typical human femur as their basis. A parallel study also is being conducted, using dogs for the basis of analysis as well as for corroborating experiments. These experiments will be used to test the hypothesis and, hence, put confidence levels on the validity of this approach for prosthesis design.

**Finite Element Analysis of the Proximal Femur and Femoral Component of a Total Hip Replacement**—The objective of this project is to determine the consequence of the fibrous tissue layer on the stress distribution of the total hip implant system. A realistic element that models the fluid-filled interface tissue has not been developed to date. In the past, two extreme (three-dimensional) finite element cases have been run, modeling a hip with a perfect interface bond (a porous implant with 100 percent ingrowth) and one where there was no interface bonding on the distal half of the stem. It is presumed that these two cases represent the more typical behavior. To perform a more realistic model of this fluid-filled fibrous interface material, a project has been undertaken to develop an element that considers biphasic (that is, fluid and solid) material properties. The current effort on this project is implementing and validating this element so that better biomechanical models can be implemented in the future.

## Development of a Biologic Cement for Fixation of Skeletal Implants

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Implants with porous surfaces intended to allow ingrowth by bone have been developed as a way to avoid the problems of loosening that have been encountered when implants are held in place by acrylic cement. A disadvantage of the "porous" implants as used presently is the large inventory required to have the correct size available. To alleviate this problem, a fixation medium is needed that can be replaced by new bone as the fixation material is resorbed gradually. To achieve this, experiments are being carried out on dogs using various filler materials, such as decalcified bone paste, autogenous ground bone paste, and tricalcium phosphate crystals.

Results to date are very encouraging.

## Late Loosening in Total Joint Replacement in the Lower Extremities

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**Summary**—A biplane radiography technique was developed to measure the motion at the cement-bone interface of patients who had either a total knee replacement or a total hip replacement. Spherical cobalt-chromium markers were embedded in the cement and in cortical bone. The relative position of the balls was measured radiographically postoperatively and at 6 months intervals thereafter. The resolution of the measurement was 0.2 mm. Of the 68 patients who volunteered for this program, 54 patients were suitable for the study. Reversible displacement (relative motion during a change from weight bearing to non-weight bearing) and migration (relative motion over time from one non-bearing study to another) were calculated. The range for symptomatic reversible displacement was 0.4 to 4.5 mm, while that for asymptomatic reversible displacement was 0.3 to 1.9 mm. All reversible displacement of less than 0.4 mm was asymptomatic. Migration of as much as 2.1 mm occurred without concomitant reversible displacement. All radiolucent lines correlated with measured reversible displacement. Half of the patients who were evaluated 2 weeks postoperatively had measurable reversible displacement.

**Conclusions**—(i) Biplane radiography is a useful clinical technique; (ii) The incidence of measured reversible displacement (75 percent) is higher than the incidence of clinical loosening (9.6 percent in this series)■

## Diagnosis of Loose or Damaged Total Joint Replacement

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It has been demonstrated that information gathered from acoustic emission monitoring of total joint replacements can contribute to the other clinical findings in diagnosing mechanical degradation. During the next year of support, the technique of correlation plots to examine the acoustic emission waveform characteristics will be applied to data from the increasing population of total joint patients monitored at the Hospital for Special Surgery. The objectives will be to further identify the most significant characteristics (in terms of correlation with clinical findings) and to describe the in vivo acoustic emission data in a manner that could allow separation between signals from different damage mechanisms.

The first objective is aimed at optimizing the clinical application of the acoustic emission equipment. The second objective will examine whether or not acoustic emission monitoring can be used to identify not only the presence of mechanical degradation but the source of the degradation as well. This source identification requires information on acoustic emission from the mechanisms contributing to the degradation. A third objective will be, therefore, to begin to examine static and cyclic failure in cancellous bone and in the bone-cement interface and to continue to examine damage at the prosthesis-cement interface. Specimen geometries for the biomaterial bone-cement and prosthesis-cement tests will first be modeled with further finite element studies to verify failure locations and to establish test configurations in which the same specimens can be used to produce more than one type of damage mechanism■

## Cementless Hip and Knee Prostheses

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The long-term results of conventional cemented total hip replacement show a deterioration with time, such that beyond 10 to 15 years the failure rate may rise to as high as 40 percent. In younger, more active patients, a failure rate of 50 percent at only 5 years has been reported. Revision surgery is difficult and most often leads to a result which, radiographically at least, will be much shorter lived than the primary case. Sometimes revision surgery involves serious bone loss, jeopardizing the future viability of the entire reconstruction. Neither surface replacement nor bone ingrowth is seen as the answer.

However, there now has been 30 years of clinical experience with noncemented femoral components, such as the Austin-Moore. While the failure rates are

not lower than with cemented stems, a large proportion of the failures are associated with acetabular protrusion, while in many other failures a poor fit of the stem in the canal is implicated. The loss of bone associated with failure and removal is generally much less than with cemented stems.

It is proposed that a stem designed to be a close fit in specific load-bearing areas, a "close-fit stem," may well provide the answer to reliably obtaining a durable result. Our aims are to determine the required sizes and shapes of such a stem to test the fit and the load transfer in vitro and the biological response in vivo. Color computer graphics will be used to model the shape and size ranges of the femoral canal, while a stem fit program will determine the number of stems required to specified accuracies. Closeness of fit will be tested on actual bones using sectioning techniques. Bone strains and stem-bone shear movements will be compared for cemented stems, the Austin-Moore, a metallic close-fit stem, and close-fit stems with a polymeric coating.

These designs will be tested in a bovine model to observe the differences in bone response and to test whether the bone appears to adapt more satisfactorily to the close-fit stems. For possible augmentation of closeness of fit and encasement of a close-fit stem with new load-bearing bone, osteogenic stimulating demineralized bone powder (DBP) will be used as a filler. This work will provide valuable data of the viability of a close-fit stem. If such a scheme is successful, it will have an invaluable place in hip surgery.

## Mechanisms of Orthopaedic Implant Loosening

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Orthopaedic joint reconstruction with an implanted artificial prosthesis is an increasingly common surgical procedure. Unfortunately, at least 7 percent of patients receiving such prostheses will experience implant loosening and, ultimately, failure within 5 to 7 years of surgery.

The precise reasons for this high rate of failure are unknown. However, histological studies of the tissues surrounding loosened implants suggest that mononuclear phagocytes (MOs) and foreign body giant cells (GCs) play an important role in the rejection process. Specifically, these cells, which seem to be recruited by implant-derived particles, are believed to be directly responsible for resorbing the bone immediately surrounding the implant and are perhaps instrumental in the development of an inappropriately thick connective tissue capsule between the implant and the supporting tissue.

However tenable the hypothesis regarding the role of MOs and GCs in implant loosening, it is based upon histological observations and is therefore, at best, intuitive. The aim of the present proposal is to directly assess the potential of MOs and GCs to affect those changes believed essential to the prosthetic loosening, particularly when exposed to implant-derived materials. These studies will focus on use of in vitro assay systems, established in this laboratory, with which we have previously (i) documented the ability of MOs to resorb vital and devitalized bone, (ii) demonstrated that bone matrix degradation can be precisely quantitated, and (iii) shown that MO- and GC-mediated bone resorption can be regulated by systemic bone-seeking agents (e.g., cortisol) and by, as yet, undefined factors released by other cells. In this application, we propose to extend the use of these techniques and experience to: (i) evaluate the action of implant materials on MO- and GC-mediated bone; (ii) identify the enzyme(s) responsible for bone collagen degradation by MO and GC and explore the regulation of this enzyme(s) by implant materials; (iii) study the potential of MOs, GCs, and endothelial cells exposed to implant-derived material to modulate (stimulate) bone resorption by other cells, including osteoclasts; and (iv) establish whether phagocytosis of implant particles by MOs promotes the release of agents capable of stimulating giant cell formation and fibroblast proliferation.

## The Mechanical Properties of Porous-Coated Orthopaedic Alloy

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**Introduction**—The development of porous-coated orthopaedic implant devices for attachment by bone ingrowth has been the subject of much research. A porous metal coating applied to a solid substance has been shown, in vivo, to offer advantages over current methods of fixation. These include a higher interface shear strength between implant and bone and a more

uniform distribution of stresses. These devices, however, require a sintering heat treatment to apply the porous coating. Sintering heat treatments have been shown to have a detrimental effect on the material mechanical properties of some orthopaedic alloys.

One of the materials of choice for porous-coated systems is Ti-6A1-4V alloy. This is based upon its high corrosion resistance, low toxicity, and favorable mechanical properties. However, the fatigue strength, the most important mechanical property when considering the design of a load-bearing orthopaedic device, has been found to decrease due to both the sintering heat treatment and the porous coating.

In our previous studies, uncoated Ti-6A1-4V orthopaedic alloy was found to have an endurance limit of 605 MN/mV. The application of a porous Ti-6A1-4V coating decreased the endurance limit of the system by approximately 77 percent, and when the uncoated substrate material was only heat treated to the same temperature as the porous-coated samples (125°C for 2 hours), a degradation of approximately 34 percent in fatigue strength was observed. The great difference between the porous-coated samples and the only heat-treated samples was theorized to be due to the porous coating acting as a notch, since the introduction of a machined notch was found to decrease the endurance limit of the material by 65 percent.

The reduction of fatigue properties by the heat treatment is due to the transition from the as-received equiaxed microstructure to the lamellar structure upon sintering. This lamellar structure has been shown to have inferior fatigue properties relative to the equiaxed structure. Thus, the need for a heat treatment to improve the fatigue properties after sintering seems apparent.

**Methods**—In the present study, microstructural analysis was performed on six different post-sintering (1250°C for 2 hours) heat treatments of Ti-6A1-4V in an attempt to improve the fatigue properties. The heat treatments were:

1. Argon quench;
2. Argon quench, followed by a 4-hour anneal at a temperature low in the $\alpha$ and $\beta$ region with a subsequent Argon quench;
3. Cool to just above $\beta$-transus, slowly cooled through $\beta$-transus, and furnace cooled;
4. Argon quench followed by a 15-minute anneal slightly above $\beta$-transus, slowly cooled through $\beta$-transus, and furnace cooled;
5. Argon quench preceding an anneal at just below $\beta$-transus for 4 hours followed by an Argon quench;
6. Argon quench, then anneal at slightly below $\beta$-transus, cooled very slowly to a temperature low in the $\alpha$ and $\beta$ region, then Argon quenched.

**Results**—The six heat treatments produced alternative microstructures from the lamellar structure obtained in the sintering heat treatment where slow cooling from the sintering temperature took place. Quenching from sintering temperature (heat treatment 1) resulted in shorter, fine interwoven $\alpha$ plates with localized areas of equiaxed $\alpha$ and fewer colony boundaries. Annealling this structure in the low $\alpha$ and $\beta$ region for 4 hours (heat treatment 2) produced a microstructure with large $\alpha$ plates of varying dimensions and orientation differing from a lamellar structure. Annealling at a temperature just below the $\beta$-transus (heat treatment 5) resulted in large $\alpha$ plates which became more globular and equiaxed, and the retained $\beta$ more dispersed. The outside of the sample exhibited a 0.12 mm layer of an acicular $\alpha$ in a $\beta$ or finely transformed $\beta$ matrix with a few small globular $\alpha$ particles dispersed in the layer.

Slow cooling through the $\beta$-transus (heat treatments 3 and 4) produced a transient structure that showed some areas of an equiaxed structure. The differences between the two heat treatments were minimal, and thus the Agron quench before the $\beta$ annealling and slow cooling through the $\beta$-transus makes little difference. The recrystallization annealling (heat treatment 6) resulted in a structure of coarse $\alpha$ plates in an abundant and very fine martensitic matrix. This structure was uniform throughout, free of any type of colony boundary.

**Discussion**—In previous studies, where the sintering heat treatment was followed by a slow furnace cool to room temperature, a lamellar structure consisting of large colonies of $\alpha$ plates in the same crystallographic orientation with $\beta$ retained between them was obtained. It has been shown that crack propagation can occur easily in both parallel and perpendicular directions to the long axis of the alpha grains. The heat treatments described above provide microstructures somewhat different from the original sintering heat treatment, with some exhibiting considerably different microstructures. Thus, these heat treatments may help in resistance to crack initiation and propagation during the cyclic loading of porous Ti-6A1-4V orthopaedic devices, and thus result in improved fatigue properties. To date, limited fatigue testing has shown an improved endurance limit for some cases. However, more tests are being performed to determine statistical significance■

## Biomechanics of Bone Resorption/ Regeneration at a Bone-Implant Interface

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**Introduction**—It is generally acknowledged that loosening of orthopaedic implants in bone is a leading cause of failure of joint replacements. However, while there have been suggestions that mechanical factors influence the response of bone at implant-tissue interfaces, and thereby relate to the loosening problem, little has been done to clarify the quantitative role of such variables as relative motion or stress concentrations at the interface. Therefore, this project has been aimed at elucidating relationships between bone remodeling and mechanics at a bone-implant interface.

**Methods**—The plan involves use of an animal model, together with engineering methods and quantitative histomorphometry to perform an in vivo experiment. The rationale is to create well characterized states of stress in the interfacial region of implants in bone using specially designed implants and loading protocols, then to utilize histomorphometry to assess remodeling activities in relation to the in vivo loading history. Both trabecular and cortical bone sites are being used. To create well defined mechanics at bone-implant interfaces, the implants are placed in bone using special atraumatic techniques and left undisturbed for 2 to 3 months to establish a direct, or very nearly direct, bone-implant contact interfacially. Subsequently, the implants are directly loaded with a controlled loading pattern for a fixed period of time. The interfacial mechanics related to the controlled loading are predicted using finite element analysis (FEA). The histomorphometry includes analyses of fluorescent labeling plus osteoblastic and osteoclastic activity in tissue sections taken from each region of the interface that has been quantified as to mechanical history. The experiments employ beagle dogs (mandibular trabecular bone and radial cortical bone) and special implants of a screw shape made of implant-grade pure titanium.

**Preliminary Findings**—As part of the engineering phase of the project, finite element analyses have been made of relevant implant-bone problems. In these analyses, the initial goals have been to investigate the stress fields around certain implant shapes and to document the importance of the assumptions about contact at the bone-implant interface. Three implant problems were simulated: (i) bone screws in cortical bone, (ii) coronal sections through a dog mandible containing an inverted T-shaped implant, and (iii) sagittal sections through the same type of implant. Each problem was run for infinite friction (bonding) and no friction (nonbonding) interfacial assumptions using isoparametric elements with quadratic shape functions. Frictionless contact was introduced via an algorithm based on Lagrange multipliers.

**Results**—For the same stress analysis problem, the interfacial stresses are very different for the bonding versus nonbonding assumptions. Not only are the stresses quantitatively changed, but also they show important qualitative differences. For example, in the case of an axially loaded mandibular implant that resembles an inverted T-shaped beam embedded in bone, the bonded case shows maximum compressive principal stresses near the neck and ends of the implant, while the nonbonded case shows these same interfacial regions to experience maximal tensile principal stresses. Also, for both the dental implant and bone screw analyses, those models with nonbonded interfaces show regions where actual gaps develop between bone and implant, while in the bonded cases, such gaps do not appear because of the tensile stresses that can develop across a bone-implant interface in the bonded case.

**Discussion and Future Plans**—From these initial studies, it is clear that the predictions of FE models of implants in bone are dependent on whether or not bonding (i.e., infinite interface friction) exists at bone-implant interfaces. This fact must be considered when evaluating the fidelity with which an FE model represents a particular bone-implant situation. Hence, we have been able to design the implant experiment with more confidence in our ability to model the actual conditions that may arise at bone-implant interfaces. With the initial engineering analyses in hand, the next step is to conduct the in vivo study. A loading apparatus for the implants is being designed, and the implant locations and actual loading protocols are being tested. The in vivo loading will be applied to the implants under microcomputer control for half an hour per day for 5 days, with a 0.5 Hz cyclic pattern involving loads of magnitudes sufficient to create meaningful stress fields in interfacial bone, as judged from our initial finite element studies.

## Evaluation of Total Joint Loosening Using X-Ray Photogrammetry

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Loosening of the prosthetic components continues to be the largest problem with total joint replacement surgery. Our research project has developed a method which can accurately measure the distance that a prosthetic component settles after it has been placed in the bone, or the amount of loosening that has occurred with use. Our efforts this year have focused on developing the equipment to perform X-ray photogrammetry measurements in a clinical setting, and on convincing the companies that manufacture prosthetic components to add markers that will show on X-ray films.

**Methods**—X-ray photogrammetry is the process of accurately determining the three-dimensional coordinates of marker points in the bone and on the prosthetic components from two radiographs taken simultaneously. By using 1 millimeter-diameter stainless steel spheres in the bone and marker points on the prosthetic components, an accuracy of 0.1 mm can be achieved in determining the spatial locations and movements of the bones and total joint components. The equipment necessary to achieve this accuracy consists of a calibration frame that puts reference marks on the X-ray films, a high-accuracy digitizer to determine the coordinates of the marks on the film with an accuracy of ▲10 μm, and a computer program to transform the two-dimensional coordinate data from two films into three-dimensional coordinates.

**Progress**—Since the digitizers currently available do not have the necessary accuracy (the standard is a resolution of ▲μm and accuracy of ▲125 μm), we have developed a digitizer, using optical linear encoders for the x- and y-axes, which has a resolution of 1μm and accuracy of ▲10 μm. The digital output from the encoders is translated into x- and y-coordinates and transmitted to the computer program for storage with the reference number of the marker. The system has been tested and found accurate for measuring motions in three dimensions as small as 0.1 mm.

Our current efforts consist of measuring patients, who have had total joint replacement surgery, with markers placed in their bones around the prosthetic components to track the subsidence of the components over a period of time, or loosening of the components with use. Our other effort consists of attempting to find a manufacturer who can produce the hardware for the X-ray photogrammetry system so that it can be made available for use in a clinical trial. This also involves convincing the implant manufacturers to add the markers to their prosthetic joint components■

## Bacterial Colonization of Surgical Biomaterials

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Significant progress has been made to demonstrate that biomaterials act as a substrate for microbial adherence and colonization and that the process is a fundamental cause of sepsis in biomaterial-related surgery. As a corollary objective, our studies also show preliminary evidence that diseased or compromised tissue (i.e., bone-joint synovium, diseased tissue, etc.) also serves as similar nidi or substrate for colonization and the septic process (i.e., primary or secondary osteomyelitis, septic arthritis, post-nonbiomaterial surgical sepsis).

In the forthcoming year, work will continue in Aim #1, "To isolate pathogenic bacteria from infected biomaterials," with the inclusion of nonorthopaedic biomaterials. Our initial studies show that biofilm formation is a general phenomenon in the colonization of inert surfaces of cardiac pacemakers, urinary catheters, intrauterine contraceptive devices, vascular catheters, and vascular grafts, and that this mode of growth confers on these pathogens resistance to host defense mechanisms and antibacterial agents. We have expanded our original sampling to include, in the absence of biomaterials, diseased and compromised tissue (i.e., dead or damaged bone, joint synovium, etc.).

Aim #2, "To maintain isolated pathogens in an adherent form," and Aim #5, "Behavior of macrophages towards biomaterials," have been achieved during the past 2 years. Aim #3, "Chemical characterization of the exopolysaccharides of pathogenic isolates," will be completed without modification. Special attention will be focused on Aim #4, in which the

proposed study of the kinetics of biomaterials development also will assess the inherent antibiotic resistance of cells in mature biofilms.

In summary, we can say that Aims #2 and #5 have been achieved, that work continues in Aim #4 by means of an expanded and improved methodology, and that Aims #1, #3, and #6 will be completed.

## In Vitro and In Vivo Corrosion of Orthopaedic Implants

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The long-term use of metallic orthopaedic implants is associated with a small but finite risk of adverse biologic reactions to metal ions released as corrosion products. The proposed continuation of this research program is designed to: improve our understanding of the mechanisms of and methods for measuring corrosion and the biologic distribution of and reactions to corrosion products; to explore methods for reducing corrosion rates and diagnosing conditions indicative of excessive corrosion; and, to investigate reactions to corrosion products.

Laboratory corrosion-rate measurement experiments utilizing electrochemical techniques will be continued to examine in more detail the interactions between static and fretting corrosion of stainless steel, cobalt alloy, and titanium and specific proteins at pH values associated with inflammation and wound healing. Laboratory and animal studies with sheep will continue to examine the role of fracture stability and screw tightness on the amount of and temporal changes in fretting corrosion of osteosynthesis plates and screws.

Metabolic studies with hamsters injected with metal salts or corrosion products will be continued. These studies will focus on the question of whether metal ions remain at the site of release, whether they are transported in the blood to other sites where they could cause an adverse reaction, or whether they are excreted in the feces or urine. Similarly, these studies will determine if the distribution of metal salts is different when the metal salts are given a second time. Answers to these questions will improve our understanding of location of potential biologic reactions associated with corrosion, as well as determine the validity of chemical analysis of excretions for assessment of in vivo corrosion rates.

Biomechanical and histological studies with rabbits injected with metal salts or corrosion products, in which metal screws are then implanted and tibial fractures are stabilized with intramedullary rods, will be continued to determine the functional significance of reactions associated with corrosion and metal allergy. These studies also will examine the question of whether the incidence and nature of biologic reactions are related to the type of metal used for internal fixation of fractures, and whether an animal with an allergy to one metal can be treated with an implant alloy not containing that particular element.

## Intermediate Organometallic Corrosion Products

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**Sponsor:** National Institutes of Health
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Metallic implants are used in large numbers in the practice of orthopaedic surgery. All metals in use have finite corrosion rates. A variety of clinical problems have been proposed involving metabolic, immunologic, bacteriologic, and carcinogenic responses associated with release of metal by corrosion or other reactions. Research to elucidate the possible connections has been hampered by a lack of knowledge of the molecular form that the corrosion products take and the concentrations in which they are present in patients. In particular, it has been proposed that a variety of biologically active organometallic intermediate compounds exist as a result of corrosion in vivo.

The object of this proposed research project is to detect, isolate, quantitate, and partially identify the blood-borne organometallic compounds that arise from the corrosion of the two most common orthopaedic metallic alloy systems: stainless steel and cobalt-chromium.

The studies proposed involve HPLC fractionation of serum and treated tissue fragments followed by atomic absorption spectroscopy. The studies use a small animal/microsphere implant model to examine the effects of implant area/animal body weight ratio on the production of organometallic complexes and to predict the possible findings in patients.

## Study of Wear Particle Analysis in Human Artificial Joints

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During the past year investigations have continued into the ferrographic analysis of the wear particles of human joints and their pathophysiological implications. A series of synovial fluids taken from end-stage osteoarthritic knee joints at the time of surgery for total joint replacement have been examined by ferrography. These samples provided unexpectedly few particles, possibly because of the restricted use of the joints prior to surgery. Histological examination of the synovia confirmed the ferrographic analysis.

Following our demonstration that wear particles could elicit the production and secretion of chondrolytic enzymes by cultured synovial cells, we have recently shown that particles of lapine articular cartilage produce an experimental arthritis when injected into the knees of rabbits. We are now attempting to identify the components of cartilaginous particles that produce these effects. In preliminary work, we have found that purified cartilage proteoglycans activate cultured synovial cells and produce an inflammatory response when injected into rabbits' knees.

## Retrieval and Analysis of Orthopaedic Implants

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As part of our ongoing implant retrieval and analysis program, the correlation of tissue reaction to the degree of corrosion in retrieved stainless steel osteosynthetic devices was evaluated.

**Methods**—Clinical materials were obtained from 11 patients, of which seven were male and four were female, with a mean age of 28.8 years (range: 4 to 61 yrs.). These patients had 13 stainless steel (316L) internal fixation devices that were removed. Ten devices were inserted for acute trauma, two for hip fusion, and one for a fracture nonunion. Seven of the devices were removed routinely after fracture healing, while the remaining six devices were removed for symptomatic reasons. Of these removals, four plates were removed because of pain localized to the area of the implant after fracture healing was complete, one device was removed because of an infected nonunion of a hip fusion, and one plate was removed at 3 months because of a secondary fracture in the same extremity which required surgical treatment.

At removal surgery, a biopsy of the fibrous tissue strip overlaying the plate was taken. Bacterial cultures also were taken at this time. The strip of tissue and the plate were marked at the proximal ends with silk sutures for identification purposes. The tissue was then placed in a buffered formalin solution. Each screw was returned to its respective hole in the plate and was fixed in place with tape to enable a direct correlation of screw and plate corrosion. These 13 plates had 70 screw plate junctions with adequate corresponding soft tissue biopsy for histologic evaluation.

The soft tissue biopsies were embedded in paraffin, sectioned to a thickness of 6 μm, and stained with either hematoxylin and eosin, Gomoris Trichrome, Perl's Iron, or Bathophenanthroline Iron. The sections were then graded on a scale of 0 to 5 for degree of tissue reaction.

Upon receipt, the retrieved implant devices were thoroughly cleaned with a mild detergent and water. When necessary, a soft brush was used to remove adherent tissue and blood. Each screw-plate interface was then examined under a stereomicroscope and graded on a 0 to 5 point scale for degree of corrosion.

Three major components of the host-implant interaction were then examined using linear and nonlinear regression analyses. They were the relationship of corrosion to tissue reaction, the change in corrosion with time, and the change in tissue reaction with time.

**Results**—The mean scores and standard deviations of tissue reaction and corrosion were calculated. The means of the tissue reaction and corrosion scores for the entire study and for symptomatic and asymptomatic removals are given in Table 1. The normality of distribution was evaluated by the Kolmogorov-Smirnov Method. Linear and nonlinear regression analyses of corrosion score, tissue score, mean tissue score, mean corrosion score, and the ratio of tissue to corrosion score (T/C) were performed.

A good correlation of corrosion-to-tissue reaction was found that was improved by removing the symptomatic cases from the regression sample. Tissue reaction was directly proportional to the increased corrosion in the asymptomatic group. There was no correlation of symptomatic corrosion and tissue score. There was no correlation of corrosion with time; however, both asymptomatic tissue reaction and a symptomatic tissue reaction showed a good negative correlation over time. This indicated that a slight decrease in the tissue reaction occurred as the duration of implantation increased. The four patients having symptomatic removals for pain located in the area of the implant had complete pain relief following removal.

**Discussion**—What is the clinical significance of local tissue toxicity around stainless steel implants? Corrosion occurs only in the small area of the screw-plate interface, and even within this area the corrosion may be very localized. There was no correlation of the severity of corrosion with the duration of implantation. This implies that the major corrosion probably occurs during the period immediately after implantation and then remains at a constant level. Another finding that is of critical importance is that the amount of tissue reaction decreases with time.

Therefore, it appears that the body has an adequate method for removing toxic metals at a rate greater than the rate of release. Even in the plates removed for pain, there is a significant tendency toward decreasing tissue reaction at $p<0.025$. Correlating tissue reaction to corrosion suggested that there were two groups of patients in this study. The first group demonstrated a positive correlation of tissue score with corrosion. The second group's tissue score did not correlate with corrosion. This finding suggests an abnormality in the host's response to the implant.

One patient, a 31-year-old female with internal fixation of a radius with device removed at 18 months after surgery, was found to have moderately severe tissue reaction and lymphocytic perivascular infiltrates. Typically, a perivascular infiltrate is associated with allergic processes. The relation of tissue reaction and corrosion and the presence of a lymphocytic infiltrate suggest that some of the cases in this study may have a metal allergy.

On this basis of our findings, we do not recommend routine removal of stainless steel implants to prevent metal toxicity; however, in the case of a painful implant that is not associated with infection or nonunion, removal will probably relieve the pain. In the event removal is not possible, evaluation for metal allergy and replacing the implant with a nonallergenic implant may be beneficial.

TABLE 1
**Tissue and Corrosion Scores Evaluated by Mean, Standard Deviation, and Kolmogorov-Smirnov (K-S) Testing**

| Tissue Score | Mean | Standard Deviation | Number | Normality Distribution |
|---|---|---|---|---|
| all devices | 2.37 | 1.18 | 13 Plates (70 Holes) | $p<0.05$ |
| asymptomatic removals | 2.32 | 1.18 | 9 Plates (49 Holes) | $p<0.05$ |
| symptomatic removals | 2.48 | 1.17 | 4 Plates (21 Holes) | $p<0.05$ |
| **Corrosion Score** | | | | |
| all devices | 1.87 | 1.63 | 13 Plates (70 Holes) | $p<0.05$ |
| asymptomatic removals | 2.06 | 1.65 | 9 Plates (49 Holes) | $p<0.05$ |
| symptomatic removals | 1.43 | 1.58 | 4 Plates (21 Holes) | $p<0.05$ |

## Implant Fixation by Post-Insertion Pressurization of Polymethylmethacrylate

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**Sponsor:** Veterans Administration Rehabilitation Research and Development Service

Loosening and clinical failure of total joint prostheses is a multifactorial problem, but the single most common cause of loosening is failure of the bone cement interface. The purpose of this project is to develop a clinically feasible method by which acrylic bone cement can be injected into bone under pressure with maintenance of the pressure until polymerization is complete. Factors that relate to the incidence of loosening are cement porosity, the depth of penetration of the cement into bone, motion of the implant during polymerization, and the quality of the bone into which the cement is injected.

A total knee replacement for use in the canine has been developed, which incorporates the following features:

1. A single axis of motion, a design known to be associated with a high rate of loosening, to provide a worst case analysis of the data.

2. Short stems which do not reach the diaphysis of either the tibia or femur to avoid the known propensity of the canine femur to produce an excessive amount of periosteal new bone and cortical resorption after diaphyseal implantation.
3. Rigid fixation of the implant to bone before and during insertion of the cement.
4. Canulated stems through which the cement is injected.

A new hand-driven delivery system has been designed which is capable of generating and maintaining an injection pressure of up to 100 PSI.

Preliminary in vitro studies with human femora are underway in order to establish optimal pressure and cement-type for future canine application.

Acrylic bone cement, Zimmer LVC or Howmedica Simplex, is being injected into the proximal femur from paired fresh human cadavers under pressures of 20, 40, 60, and 80 PSI. The pressure is maintained with the hand-driven delivery system for 8 to 9 minutes with LVC and 12 to 14 minutes with Simplex.

The femora are cut into predetemined cross-sections for analysis as follows:

1. Porosity of the bone cement,
2. Shear strength of the cement,
3. Shear strength of the bone-cement interface,
4. Ash and calcium content of the bone,
5. Depth of cement penetration into bone.

At the present time, limited preliminary data are available on cement porosity and the shear strength of the bone-cement interface.

The specimens for porosity determination are spray painted, polished with silicon carbide sandpaper, and photographed. The slides obtained are projected at a magnification of 40X, and the pores digitized (Summagraphics 2000). The data are computerized to provide a porosity index (percentage of cement core occupied by pores), the average pore diameter, and number of pores counted.

Cross-sections for shear testing of the interface are further cut into 10 mm by 5 mm sections. The sections are mounted in a specially designed testing device and sheared to failure at the bone-cement interface in a MMED Matco hydraulic press at a constant head speed of 0.5 mm/sec.

### Results

**Porosity**—At this point, with data on a very small number of specimens, the type of cement used seems to be more significant than the level of pressure applied. We could see no reduction in porosity between 20 and 80 PSI, whereas the number of pores was greater but the porosity index and average pore size were considerably less in LVC, as compared to Simplex.

**Shear Strength**—The initial data seem to indicate that the nature and quality of the bone are more significant than the pressure with which the cement is introduced. Statistical evaluation is not yet possible because of sample size, but it does appear that the shear strength and total energy absorbed increases more with LVC as compared to Simplex cement in response to pressure of injection.

[See also **VII. Wound and Fracture Healing**, Effect of Stress and Motion and Repair of Hard and Soft Tissues]

# B. Hip

## Biomechanical Assessment of Patients Treated by Joint Surgery

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**Sponsor:** Bioengineering Unit,
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Surgical replacement of lower limb joints has been practiced for 20 years, although there is little quantitative information on loads transmitted either by implants or by other related joints. The results of tests presented evaluate the variation in external forces developed between the ground and foot during walking, together with the configuration of the lower limbs and the moments acting about the hips and knees.

Two groups of patients were investigated: patients who were assessed prior to joint replacement and at intervals thereafter, and patients for whom the Girdlestone procedure was performed following a failed implant. The results are compared with those from similar tests on clinically normal subjects. There is a significant improvement postoperatively in the mechanical aspects of hip function for the replacement patients. The improvement continues after the first 6 months postoperatively and may result in abnormally high loading at other joints. At 12 months the performance of the patients with joint replacement differs significantly from the normal subjects, and is generally better than the Girdlestone patients.

Further modeling to determine muscle and resultant joint forces shows that in the joint replacement group, the hip, and particularly the medial compartment of the knee of the contralateral limb, may be subjected to significantly higher loads than those seen in either the operated limb or in the normals. This elevated loading may predispose these joints to the accelerated degeneration seen in patients with rheumatoid arthritis.

## Quantitative Analysis of the Effect of Total Hip Arthroplasty on Stress and Strain in the Human Pelvis

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**Sponsor**: Veterans Administration Rehabilitation Research and Development Service

Two decades of experience with total hip arthroplasty have shown it to be one of the most successful procedures for treating the arthritic hip. While most patients achieve excellent results, a small percentage develop complications severe enough to cause failure of the arthroplasty. The most common cause of failure is loosening of either the femoral or acetabular component. Improvements in stem design and implantation techniques have increased the longevity of femoral components. With this increased longevity, failure of the acetabular components has become more prevalent. New acetabular cup designs and implantation techniques have been proposed to further improve the arthroplasty. However, there has been little objective experimental evaluation of the effects of these changes on the stresses and strains in the human pelvis.

The objective of this ongoing investigation is to quantitatively evaluate the effects of different insertion techniques and acetabular prosthesis designs on the strains in cadaver hemipelves. Initial work has led to the development of an automated computerized data acquisition system and customized loading fixtures. These innovative loading fixtures allow for simultaneous application of prosthesis loading and abductor muscle pull, simulating single leg stance.

Techniques that have been or will be studied during this investigation involve: perforation of the acetabulum with various size pilot holes; removal of varied amounts of subchondral plate and cancellous bone; use of keying holes of different sizes and placement; use of curette versus reaming; use of spacers to insure a uniform cement mantle; pressurization of the cement at implantation versus "hand-packing;" use of surface replacement prosthesis; use of protrusio rings, bone grafting, or wire mesh; and, modified acetabular cup types including metal backing, carbon fiber reinforced, attached spacers, and reconstructive techniques for deficient acetabuli.

Several general comments can be made:

1. The strain pattern in hemipelves without prostheses was consistent from specimen to specimen. Almost pure shear was observed.
2. The strain generally remained unaltered by the installation of standard prostheses if the acetabulum was not reamed or perforated by a central hole. The presence of the prosthesis appeared to be less significant than the disruption of the structure during installation.
3. A 10 mm central hole had a relatively small effect on the strain patterns. There was a shift in the distribution, with the bone anteromedial to the acetabulum being strained more highly. This shift was much more pronounced for bones with the larger (20 mm) central holes and further reaming. Further removal of bone by reaming elevated the strain levels more or less uniformly.
4. If all the cancellous bone was removed, the changes in strain from pre-implantation to post-implantation were quite variable.
5. The use of a protrusio ring to reinforce the acetabular implantation after moderate bone removal eliminated the anteromedial strain shift. Comprehensive strains were unaffected, but tensile and shear strains were almost uniformly increased by about ½ microstrain per Newton.
6. While curetting and reaming with a "cheese grater" caused significant increases in strains from the unaltered pelvis, they were not significantly different from each other.
7. The use of 7-4 mm keying holes (5 ilium, 1 ischium, 1 pubis) had a more pronounced effect on post-implantation strain than 3-12 mm holes (ilium, ischium, pubis).
8. No significant differences were observed with the use of moderate pressurization versus "hand-packing."
9. Spacers used to achieve a uniform mantle of cement led to greater increases in shear strain than "bottoming-out" the prosthesis. (This is contrary to initial thought and is being re-evaluated).
10. Preliminary results of the metal-backed cup indicate that its use reduced the amount of strain change.

Over the past 18 months significant modifications to the computer software and instrumentation have been implemented to streamline data acquisition and post-processing. New fixturing has been developed to allow for the use of a newly acquired Universal Testing Machine that will allow for better control of loading rate which is very important in the testing of these biological tissues.

## Vascular Responses to Hip Replacements

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**Sponsor:** National Institutes of Health
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We have two major objectives for the coming year. First, we will continue work with our canine model, in which we seek to correlate the very characteristic damage induced at venous confluences by hip replacement surgery with the responsiveness of venous smooth muscle and with the architecture of venous confluences. Second, we will extend monitoring of venous diameter by ultrasound to veins of persons undergoing hip replacement surgery, and will examine confluences of human veins harvested from the healthy proximal portion of freshly amputated legs.

Our specific aims and the methods to be used follow:

1. To continue to investigate the responsiveness of canine venous smooth muscle in vivo by the noninvasive observation and recording of venous diameter by a specially adapted ultrasound instrument. The instrument has two electronic gates. The first picks up the falling edge of the peak generated by the near wall, and the second, the rising edge of the peak generated by the far wall. The distance between is calculated and displayed continuously, and an analog signal is taken to a strip chart recorder. We will continue to use specific inhibitors to identify vasoactive substances released or generated during hip replacement surgery.

2. To investigate ex vivo the responsiveness of jugular and femoral vein smooth muscle by the use of vein strips in an isometric tissue bath system. This approach was added since the last progress report and has provided quantitative information on the potential of these veins to develop tension in response to vasoactive substances.

3. To complete light microscopic studies of the architecture of the area at which side branches join jugular and femoral veins (confluences). Vein segments that have been examined by scanning electron microscopy are detached from the stubs and small areas containing a confluence embedded in plastic for serial 10 μ thick sections. Sections are stained, examined, and photographed by light microscopy.

4. To extend our monitoring of venous diameter to patients before and during hip replacement surgery.

5. To study the architecture of human venous confluences by use of veins harvested from the limited healthy proximal portion of amputated legs.

[See also **VI. Biomechanics, A. Joint Studies, 2. Lower Limb**, Evaluation of Joint Loadings in the Use of Walking Aids in Total Hip Replacement, and **VII. Wound and Fracture Healing**, A Study of Intertrochanteric Fracture Fixation Methods]

## Total Surgical Replacement of the Human Hip Joint

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**Sponsor:** National Institutes of Health
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This study is directed to the evaluation of porous materials as a method for fixation of total joint replacement prostheses. An experimental canine total hip replacement model is used (i) to evaluate the abilities of different types of porous composites to provide satisfactory fixation and (ii) to study resulting bone remodeling in the femoral cortex and acetabulum. In a canine total knee replacement model, various methods of initial stabilization are evaluated in their ability to sustain satisfactory fixation. Metal ion release from porous materials is studied with cobalt-chrome porous composites made from powder metallurgy techniques and titanium composites made by fiber metallurgy.

The carcinogenic potential of materials used for porous applications is studied in rats, comparing the alloys in solid and porous composite forms. The potential of hydroxyapatite and electromagnetic stimulation to enhance initial bone formation into porous titanium composites is evaluated in a canine model by histology and mechanical testing. In a similar canine model, disodium etidronate is evaluated for its effects on early bone ingrowth into porous titanium composites.

## The Efficacy of Radiolucent Low Modulus Total Hip Surface Replacement

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The purpose of this project is to investigate the potential of using a radiolucent, low-modulus, surface replacement as a prosthesis for the hip. The radiolucent aspect of the prosthesis offers the advantage of being able to visualize the bone underneath the femoral component. The low modulus of the femoral component surface replacement is hypothesized to transmit stress to cancellous bone of the femoral head in a more physiologic manner than would be obtained with a metallic component. From that aspect then, this is a bone remodeling study. The low-elastic modulus (pyrolytic carbon) femoral component is to be compared directly to high-elastic modulus prosthesis of cobalt chromium to determine the effect on the bone of the femoral head and neck.

The research methodology includes a series of comparisons of the bone remodeling of the natural femoral head, a carbon surfaced femoral head, and a cobalt chromium surfaced femoral head. The first series of eight dogs was a comparison between the normal femoral head and the carbon surfaced replacement femoral head. These dogs are now 17 to 35 weeks post-surgery. One of the dogs has been sacrificed due to loosening of the acetabular component. The direct comparison of the carbon surface replacement to the high-modulus cobalt chromium surface replacement is underway. Three dogs have undergone bilateral hip surface replacements, and more dogs are scheduled at regular intervals. For a comparison of these two types of surface replacements to the normal femur, finite element analysis is planned. Loading conditions for the femoral head in vivo have been determined, and preliminary studies using finite element analysis have been performed. The data from the finite element studies will be compared to the histological results obtained from sections of the femoral heads of these dogs after sacrifice.

In an attempt to maximize the data obtained from this series of dogs, quantitative bone densities underneath the carbon surface replacement have been obtained in vivo through the use of the research computerized tomographic scanner (CT scanner) at the University of California in San Francisco. Longitudinal studies of the bone density of the carbon surface replacements are underway. Use of phantom densities correlated with bone permit a quantitative absolute measurement of the bone densities, as well as the comparison of bone density with time to the normal femoral head. Studies have been started on the carbon surface replacement of the dogs with the cobalt chromium heads on the contralateral side. Although quantitative data will not be obtainable from the bone underneath the cobalt chromium surface replacement because of the X-ray shielding caused by the cobalt chromium, data can be obtained from the contralateral carbon surface replacements by avoiding overlap of the CT scan X-ray beam with the metallic component. CT scan densities are being measured for the normal contralateral sides in the unilateral hip surface replacement study.

It is expected that this study will reveal cancellous bone remodeling, which is indicative of the mechanical stress environment surrounding the cancellous bone. It is expected that, within the next 6 months, a sacrifice of the dogs that have undergone unilateral hip surface replacements will begin and histological data will be forthcoming. It also is anticipated that completion of the implantation of the bilateral hip surface replacement will be accomplished. CT scan studies at that point can be confirmed by the histologic data which is obtained from sacrifice.

## Total Hip Implant Biotelemetry

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The long-term clinical success of total joint replacement depends on the ability of the bone-implant system to withstand the forces applied to it. Mechanical complications of implant breakage, cement fracture, skeletal loosening, and component wear are directly related to the transmission of these forces across the joint. Explicit data on the magnitudes and directions of these forces during normal activities are lacking in the literature.

This report is a collaborative effort involving the Research Service of the Wadsworth VAMC, the UCLA Biomechanics Research Section, and the Jet Propulsion Laboratory in Pasadena. The express objective of this project is the design and development of a special total hip femoral component which will contain within it a miniaturized biotelemetry system capable of broadcasting signals received from strain gauges mounted within the neck of the prosthesis.

The prosthesis will be inductively powered by an external coil, thereby eliminating the need for internal batteries or connecting cables. These strain readings will be analyzed by computer and combined to display the three force components and the magnitude and orientation of the resultant force vector acting on the head of the prosthesis. The present project is directed toward the design of the implant, refinement of the telemetry system performance, development of the power induction system, assembly of a data recovery system, a mechanical testing program designed to assure the structural integrity of the implant, and, finally, a leak test program to assure the hermeticity of the total system. The experience of the Jet Propulsion Laboratory will be used to supply the microelectronic modules as well as the performance of the hermeticity program, while manufacture of the prostheses and structural tests will be carried out in the biomechanical testing facilities at UCLA. After instrumentation, some partial and some complete, the components will be subjected to static and fatigue loading patterns in vitro to establish factor of safety margins. External gauges will be utilized on some units to verify the calibration and operation of the internal instrumentation.

**Progress to Date**—Six partially machined T-6A1-4Vn prosthesis housings, one ball-neck unit, and integrated circuits were supplied to JPL for the initial instrumentation phase of the project. These deliverables have all been inspected and were found to be within acceptable limits of the specifications in most instances. Some of the semi-conductor gauges were found to be grossly misaligned, but are deemed salvageable through precise trimming operations. Broaching of the component necks for the strain gauge attachment is nearing completion. A slight delay in the bonding of the semi-conductor gauges has been encountered and assignment of task orders has been subject to personnel availability at JPL. This is expected to result in only a minor delay in the return of the static load unit to UCLA for initial structural testing.

Major tasks to be completed by JPL for the remainder of the first project year will be to: (i) develop a procedure for attachment of the semi-conductor gauges to the titanium inner neck surface, (ii) deliver to UCLA a sealed and partially instrumented prosthesis (static load unit), (iii) perform secondary seal tests on the static load unit, and (iv) initiate an accelerated life test of 12 telemetry submodules.

The major tasks for UCLA for the remainder of the project year are: (i) to design and manufacture the fixtures to house the static load unit for mechanical testing, (ii) to instrument the outer neck surface of this unit and to perform calibration of the internal gauges, and (iii) to load the unit to static failure to determine the ultimate loads and stresses.

All test data gathered from this project will be presented to the Veterans Administration Human Use Committee for their consideration and approval before proceeding into the patient implantation phase of the program■

# C. Knee

## Interaction of Total Knee Replacement Geometry with Knee Ligaments

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**Sponsor:** Northwestern University
Rehabilitation Engineering Program

Loosening of the tibial component is a major factor in the failure of total knee replacements (TKR). This project is intended to identify ligamentous constraint forces which increase interface stresses to a level that may contribute to the loosening process and ultimate failure of the TKR. The resulting information from this project will form the basis for potential implant design changes, alterations of TKR surgical procedures, guidelines for choosing existing knee implant designs when faced with various clinical situations, and recommendations for improved rehabilitation and orthotic treatment of postoperative knee implant recipients. The current specific question to be investigated is whether or not the geometry of a knee implant's tibial component should allow retention of one, both, or neither of the cruciate ligaments. Two methodologies are being used to address this issue.

The primary phase of this project is to investigate the initial postsurgical state of the knee with TKR by experimentally using an electrogoniometer (and computer-based data acquisition system) and buckle transducers in a series of knee specimens. This will be done in conjunction with an analytical force analysis and finite element stress analysis to determine ligament and joint contact forces, as well as interface stresses (potential for loosening) for various existing ligament-TKR design combinations.

During this reporting period, the in vitro experimental system needed to perform that project phase was being synthesized. Improved buckle transducers were designed and are being built. A new specimen loading apparatus was designed, and its construction is nearly completed. An improved six-degrees-of-freedom electrogoniometer was built, as well as a mechanical calibration device. A microprocessor, A/D converter transducer amplifiers, and a floppy disc drive were purchased and interfaced. The appropriate data collection and computational computer software are nearly completed. Testing will begin soon, and will be carried out during the coming reporting period.

The second project phase involves development of an improved biplanar radiographic technique and application of the technique to predict in vivo ligament lengths and forces in human subjects with total knee prostheses during actual static joint load conditions. This information will help answer the above cruciate problem statement: keep ligaments if they are functionally load bearing, and sacrifice them if they are not. Work in this phase during the current reporting period has been directed toward the design of total-knee prosthetic components with extensions or markers that can be easily seen on biplanar X-ray films, and which will not compromise the insertion of the prosthetic components, as they will eventually be implanted in vivo. Preliminary component designs have been made and will be refined during the coming reporting period.

## Prospective Clinical Study of the Kinematic Knee Design

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**Sponsor:** Northwestern University
Rehabilitation Engineering Program

This is an ongoing project to study kinematic knee patients in an attempt to identify quantitative relationships between clinical data and the eventual outcome of kinematic knee replacements, and to evaluate the effectiveness of this particular prosthesis in eliminating pain and restoring and rehabilitating severely disabled individuals to normal, active lives. Data were collected from hospital and operating surgeon's files. Data included component type and patient history, as well as preoperative and postoperative physical, functional, and X-ray findings. Each case outcome received a grade, using the Hospital for Special Surgery Knee Evaluation scale. Finally, the development of radiographic radiolucent lines between implant, cement, and knee was recorded.

To date, 103 patient cases have been included in the study. Of these, initial statistical analysis has been performed on 92 cases. These cases have been followed up in an ongoing fashion in an attempt to achieve a minimum 6-month, 1-year, and 2-year followup. Several cases await complete long-term followup data.

In the future, efforts will center on attempts to determine via multivariate analysis the subtle relationships between procedure outcome and variables recorded. In addition, patients will be called back to determine the accuracy of radiolucent line size measurement.

## Investigation of a Simplified Internal Knee Prosthesis

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**Sponsor:** Veterans Administration Rehabilitation
Research and Development Service

The objectives are to determine the optimum means of transferring loads from press-fit implant components to the bone surface, and to design a press-fit total knee replacement for clinical application.

The first part of the study was to model the bone structure in terms of its geometry and the properties of the trabecular bone. Twenty distal femurs were embedded, sliced sagittally, and input to a graphics computer using digitizing. Software was developed to enable three-dimensional reconstruction at required viewing angles. An attempt was made to model certain parts of the femur using geometrical surfaces. From direct measurements, the posterior femoral condyles, the bearing surfaces from 15 to 135 degrees of flexion, were found to resemble spherical surfaces. This was confirmed in the computer, the mean error of points on the surface from a perfect sphere being only half a millimeter. Each femur was then expanded or contracted based on a standard m-1 width; equivalent profiles were then superimposed, and then a contour averaging program was written to reach an average. In this way, the 'average distal femur' was constructed.

The morphological and mechanical properties of the trabecular bone were studied, especially the bone close to the joint surfaces. A sample knee was sliced in the sagittal and frontal planes; cubes of bone were removed and thoroughly cleaned for scanning electron microscopy. The increased density of the bone close to the surfaces was clearly seen, especially on the tibia. The bones oriented generally perpendicularly to the bearing surfaces, along the lines of principal compressive stress, and were usually in the form of perforated sheets or plates separated by struts.

Thus, it appeared that, by removing minimum bone from the joint surfaces, load could be transferred from a metallic implant directly to the sheets and plates for maximum load support. However, to achieve this, accurate geometrical fit would be needed. This was tested for the upper tibia by loading flat metallic components onto bony surfaces prepared by level re-section in a band saw. Fuji film pressure patterns showed that the load was transferred through localized regions of the bone surface, a function of the bone stiffness and the flatness of the cut. In surgical practice it was clear that such local load transfer would generally occur. Cyclic loading tests were carried out to determine whether the areas of load bearing would increase with time. It was found that, while there was an increase, certain areas that were previously load bearing were no longer so, apparently due to subsurface trabecular failure. This supported a rehabilitation period with low joint forces to enable biological remodeling to achieve an adequate area of load transfer to avoid component sinkage.

A Press-Fit Total Knee, based on a direct interface of metal to bone with no cement or porous beads, was designed. The first of these was implanted in a patient in February 1984.

## In Vivo Loading on Total Knee Joints

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**Sponsor:** National Institutes of Health
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The purpose of this project is to determine the in vivo loading data from total knee joint replacements. These new joint replacements will have incorporated within the body of the tibial components the required telemetry circuitry to telemeter seven channels of loading data from the device. These channels will be used to record the loads on the device, allowing for the determination of the three forces on the three moments on the tibial components.

## Biomechanical Study of Total Knee Replacement

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The objective for the coming year is to continue studying the biomechanics of the knee joint with respect to patient function, prosthetic design, and internal joint mechanics. The specific aims are:

1. Complete the analysis of functional measurements collected on patients with the posterior stabilized total condylar knee, two designs of unicompartmental knee, and additional patients with an anatomical unconstrained design (Cloutier) of total knee. This analysis will be used to test our original observations on a smaller population, and to evaluate the influence of a posterior cruciate substituting device (the posterior stabilized total condylar).

2. Test further our hypothesis that the function of total knee replacement patients is related to the interaction between the design of the prosthesis and the function of the quadriceps muscles. This hypothesis will be tested by applying the previously developed mathematical models of the knee along with some cadaver tests for validation of the models.

3. Continue our prospective analysis of the high tibial osteotomy procedure by analyzing preoperative and sequential postoperative function at 1-year intervals following surgery. This patient population will be evaluated during level walking and stair climbing.

The methodology for the functional studies utilizes a computerized optoelectronic system and force platform for kinetic measurement of level walking and stair climbing. Patients will be measured while walking over a range of speeds and while ascending and descending stairs. The model of the knee joint employs a numerical procedure to predict muscle forces based on external measurements of joint moments and motion. The model incorporates kinematic features of the knee that permit us to test for mechanical interactions between muscles, soft tissue, and kinematics of the articulating surfaces.

[See also **V. Functional Assessment**, The Efficacy of Surgical and Rehabilitative Procedures of the Knee]

# IV. Spinal Cord Injury

## A. General Rehabilitation

### A Research and Demonstration Project for Rehabilitation of Paraplegics in Madras

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**Background**—In developing nations such as India, the management of (SCI) patients is replete with difficulties at every stage of care because of the paucity of trained personnel and the meager facilities.

The proposal for this project was mooted in 1969 and finally started in 1978.

**Aims and Objectives**

1. The main aim of "Paraplegia Project, Madras" has been to develop simple methods of care of SCI patients in a general hospital setting without reliance on expensive equipment. While the need for and importance of centers exclusively devoted to a SCI population is recognized, establishment of such centers is unattainable in vast tracts of the world for several decades to come. In contrast, the methods of care at Government Hospital, Madras, if found effective and useful, have the merit that they can be immediately transferred as appropriate technology to other parts of India, and to other developing nations as well.

2. The Paraplegia Project was established for total care of SCI patients in Madras and adjoining districts within a radius of 200 miles. The multidisciplinary care of the patients, highlighted by a monthly Ward Rounds of all specialists, brought rich dividends by decreasing the mortality and morbidity. It increased function in terms of independence of SCI patients, and it decreased the duration and cost of acute and rehabilitation care.

**Findings**

1. Three hundred system cases and 200 non-system cases have been treated at the project. The final report is in preparation. It is hoped that the findings will highlight the place of "the art of the possible" in the care of SCI patients in developing nations.

2. SCI patients at Madras were mostly males in their second to fourth decades of life. The injuries were sustained mostly in villages; manual and agricultural laborers were affected mostly. Falls from trees or falls into wells have been the commonest causes of injury; road accidents have accounted for fewer than 10 percent of cases. Cervical spine has been involved in about 50 percent of cases.

3. Most of the patients were treated by conservative methods; operative treatment was done in a few cases where indicated.

4. Over the years there has been a significant reduction of complications, with gratifying results in the care of skin and bladder.

5. Psychiatric workup and counseling have added a new dimension to the care of SCI patients in the last year.

6. Mobility aids were given to nearly all needy patients through the help of governmental and social welfare agencies.

7. Vocational rehabilitation for self-employment with the aid of bank loans has enabled many patients to start anew.

**The Madras Method of Acute Care of Flexion Injuries of Dorsal and Lumbar Spine.**

The "Madras Method" of postural reduction with two pillows behind the apex of the gibbus has been found to be eminently suited for acute care of flexion injuries of the spine below the level of the fourth dorsal vertebra. The merits of the method are the reduction of the fracture or fracture dislocation, prevention of skin and lung complications, the fact that turning can be done by a single person, and, above all, its simplicity.

Two pillows as wide as the bed are arranged as a wedge at the level of the gibbus. The level of the gibbus is identified and a circumferential line is marked with gentian violet over the middle of the upper of the two pillows. The patient is positioned over the pillows so that the two lines, i.e., those on the patient and on the upper pillow, coincide. With the patient supine, the wedge of the pillows reduces the fracture and, in the course of a few hours, restores the alignment to an acceptable degree. The patient is turned every 2 hours by an attendant using the upper of the two pillows as a lever. No specially qualified person is required for such turning; anyone can be taught to do it. While the patient is in lateral recumbency, a large sandbag is laid over the back to restore the curvature of the spine.