III. Total Joint Replacement and Other Orthopaedic Implants

A. General

B. Hip

C. Knee
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A. General

Development of Biologic Cement for Fixation of Skeletal Implants

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Purpose — The objective of the project is the development of biologic cement substances that can be used to stabilize artificial implants in bone and joint replacement surgery and to augment bone growth. Most of the current investigation is performed in animals. The work has direct clinical application in the fitting of porous coated prostheses in bone deficient elderly patients and in surgery involving failed prostheses.

Progress — Several specific substances have been tested for their short- and long-term efficacy in the fixation of porous coated implants. Tricalcium phosphate, demineralized bone matrix, and milled autogenous bone graft have been tested and evaluated for stabilizing effect. Among these, demineralized bone matrix was found to be the most effective, probably because of its osteoconductive and osteoinductive properties.

In general, the methods involve the use of biologic cement mixed with a biologic binding substance (whole blood or blood plasma) and packed around the porous implant in an over-reamed intramedullary canal of the femur. The control femur on the opposite side is implanted with a similar porous rod but without the cementing substance. The union of the implant-bone composites are evaluated serially using radiographs, thin section histology, and mechanical pull-out tests.

Currently, work is in progress to compare osteoinductive properties and biocompatibility of autoclaved and freeze-dried donor bone powder with decalcified bone matrix and autogenous milled bone.

A series of experiments are also in progress for evaluating combinations of materials that are osteoconductors (acting as scaffold for bone growth) and osteoinductors (materials stimulating natural bone production). Tricalcium phosphate, an osteoconductor, is being compared to: 1) demineralized bone that is osteoinductive; 2) a protein extract of demineralized bone with osteoinductive character; and 3) demineralized bone enhanced with the protein extract.

Preliminary Results — Results thus far indicate a nearly three times increase in the pull-out strength of a donor-bone stabilized prosthesis when compared to the unstabilized control at 6 weeks post-implantation. The effect of long-term (24 weeks) strength of the milled autogenous bone graft also is being studied. Early results, however, show only a modest improvement on the stabilized side over the
control, suggesting that the stabilizing effect of this biologic cement is more pronounced early and the control and cemented side approach the same pull-out strength in the long term.

A previous hypothesis indicated that cortical bone produced stronger interface between implant and bone than cancellous bone ingrowth. Currently, quantitative analysis of AP and ML X-rays is conducted to record bone and implant relationships in the control, over-reamed but un-biocemented femurs. From measurement of bone and implant diameters an index of cortical nearness is calculated for each specimen and related to the pull-out strength. The results show stronger bone ingrowth when the cortex is nearer to the implant, confirming the cortical influence on growing bone strength.

Vacuum Mixing of Acrylic Bone Cement

**Purpose** — Since the introduction of poly(methylmethacrylate) in 1960 for use as a bone cement to fix total joint prosthesis, such as total hips and total knees, there has been virtually no change in the basic material nor its method of preparation. Approximately 200,000 total joints are currently being implanted each year with a great deal of success. However, since long-term failures do occur and, when this happens, the bone cement is often implicated in the aseptic loosening of the component parts of the total joints. A stronger, tougher, more fatigue resistant cement is needed. Since under the present drug laws the introduction of a cement of new chemical basis could be very costly, it seems logical to attempt to optimize the physical properties of the current acrylic bone cements through fabrication, processing, and handling modifications.

The present work will describe processing the admixture of cement powder and liquid under a partial vacuum in order to remove much of the inherent porosity and thereby significantly improve the mechanical properties over cements prepared by the conventional mixing techniques of hand spatulation.

**Progress** — Initially, large amounts of air lying between the powder particles appear necessary to facilitate wetting when combining with liquid. Additionally, air can be folded into an admixture during stirring. While other sources of porosity can be controlled (e.g., prevent boiling of monomer during exothermic polymerization by using sufficiently small specimen cross-sections; avoid entrapment of air during specimen fabrication by syringe injection and properly vented molds), the original powder air and the mixing air must be removed with a device. Tests have shown significant reductions in porosity using a high vacuum device, but the high mixing speeds employed generated excess heat that shortens the cement working time. Other tests have shown reduced porosity through the use of centrifugation.

The present device consists of a 550 mm Hg vacuum bowl with a one revolution per second blade designed to lift bubbles to the surface while avoiding further enfolding of air. Significant differences in porosity are obtained with three different mixing techniques: regular, centrifuge, and vacuum. Densities were
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determined from weight and volume measurements of three groups of 40 specimens fabricated in compliance with ASTM F451-76 molds for six mm diameter times 12 mm mechanical test specimens. The porous defects then were analyzed by stereologic computer programs. Essentially, when compared to regular mixing, centrifugation removes the larger pores while vacuum removes most of both of the large and small pores. This observation also may serve as a basis for the significant differences in mechanical properties. The uniaxial tensile fatigue specimens were machined into hour glass shapes, and the stresses represented the maximum in a zero to maximum sinusoidal cycling program. At these high stress levels, vacuum and centrifuge mixing produce vastly improved fatigue lives over regularly mixed cements. Lower stress, more clinically relevant fatigue tests are now in progress.

Examination of Implants by Photoelastic Techniques

Progress — The photoelastic technique is being used to examine the stresses in surgical implants. These stresses in femoral implants have been examined in relation to implant position and support conditions. Stresses in bone cement have been examined around various cross-sectional profiles of femoral stem. There also has been an examination of the stresses in bone, which were compared with trabecular structure and bone strength.

It is proposed to extend the study to boundary conditions at the bone/cement/prosthesis interfaces. The method has been found to provide a useful additional tool for the analysis of prosthetic implants and their design.

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

Purpose — The objectives of these projects are to identify the causes of late loosening of total joint replacement components by examining several aspects of the interface system.

Progress —

1) Investigations of the factors affecting the mechanics of bone/bone cement interface failure — A paper detailing the results of experimental tensile tests on the interface has been published in the Journal of Orthopaedic Research. Complete effort has not turned towards quantifying the interface using a fatigue/fracture methodology that is hoped to prove more clinically relevant. The interface is studied in four point bending cyclic fracture mechanics tests. Attempts are being made to measure crack propagation through the interface as a function of stress intensity factor, cement penetration, and bone strength. Two recent abstracts have been published detailing initial results (1985 ASME Biomechanics Symposium, 1985 ORS Meeting). The study uses published interface crack models developed at Northwestern. Specimen testing continues on a variety of
interface formation states. When testing is complete, a comprehensive report on the subject will be prepared.

2) Investigation of mechanical, histological, and load transfer properties of the soft interface tissue commonly found at the bone/cement interface — A paper detailing results of this project has been published in the Annals of Biomedical Engineering. No further work in this area has been done.

3) The testing of the interface between various metal surface preparations and bone cement via a fracture mechanics methodology — No progress has been made on this project although its implementation is still planned. Specimens will be tested using four point bending cyclic fracture mechanics tests.

Orthograft Large Granular (LG) Study

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Progress — Orthograft is a large granular synthetic bone graft substitute consisting of calcium phosphate. Under protocol, it is to be utilized for the filling in of voids within bones. This has been used in dentistry.

To date, we have not had a surgical case with the indications for the use of orthograft in the institution. However, we intend to keep the protocol in effect and in anticipation of cases that will be suitable for this study in accordance with the original protocol.

Implant Fixation by Post-Insertion Pressurization of Polymethylmethacrylate

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Purpose — The purpose of this project is to assess the premise that sustained high pressure applied to polymethylmethacrylate (PMMA) bone cement will increase the strength of the cement and the bone cement interface.

Progress — A specially designed injection system was developed with which cement could be injected into human cadaver femora with pressures up to 100 PSI and maintained until late in the polymerization (i.e., eight to twelve minutes after mixing). The proximal portion below the lesser trochanter of paired human cadaver femora were used. Simplex P (Howmedica) was injected into one and low viscosity cement (LVC — Zimmer) was injected into the opposite of the pair. Shear strength of the bone-cement interface was determined by preparing 10 mm times 5 mm specimens of cortical bone and cement which were sheared to failure in a specially designed shear testing clamp with a 1.5 mm window centered over the interface using a servohydraulic testing (Mateo) machine at a deformation rate of 0.5 mm/second, strain rate of 0.33/second. The shear strength of the cement alone was determined in identical fashion. Penetration of the cement into bone was determined by first photographing cross-sections of the femora and digitizing at 10X magnification the cortical area. The slices then were placed in a 10 molar hydrochloric acid solution. The bone was partially dissolved leaving the
medullary canal cement and cortical cement spicules intact. The specimens were then photographed a second time and digitized for the cortical cement area.

In order to provide clinical relevance, a single pair of femurs was prepared with contemporary techniques, the two cements were injected with a clinically used cement gun and “pressurized” for 10 seconds before a Charnley-type total hip prosthesis was inserted. The mean bone-cement interface shear strength was $3.18 \pm 2.36$ MPa for LVC and $2.85 \pm 1.86$ MPa for Simplex P.

Twelve pairs of femurs were divided into four groups of three each and pressurized at 20, 40, 60 and 80 PSI. There was a progressive increase in the bone-cement shear strength with increasing pressure up to 60 PSI but no further increase at 80 PSI. More importantly, no significant difference was found between Simplex and LVC. The mean strength at 20 PSI was approximately 7.5 MPa and at 60 PSI, approximately 11.5 MPa. The shear strength of the PMMA alone ranged from 50 to 60 MPa but there was no significant difference with increasing pressure beyond 20 PSI and no difference between cements.

There was relatively little cancellous bone in the portions of the femora studied but, where present, penetration of the cement was nearly 100 percent at all pressures. With both cements, cortical penetration of LVC cement was significantly greater than with Simplex at all pressure levels and, at 80 PSI, approached 80 percent of the cortical area.

It was concluded that:

1) Sustained pressurization of PMMA in human cadaver femora increased the shear strength of the bone cement interface by a factor of two to three magnitudes over conventional techniques.

2) There was no significant difference in interface shear strength between Simplex P and LVC cements.

3) Penetration of LVC cement into cortical bone was significantly greater than the penetration of Simplex but was not associated with an increase in interface shear strength.

### Intermolecular Bonding and Microphase Separation in Polyurethane Block Polymers

**Purpose** — This research deals with structure property relations of segmented polyurethanes and related multiphase elastomers. The researchers are involved in the synthesis of novel polyurethanes and their characterization by small angle X-rays scattering, infrared spectroscopy, and a variety of other methods involving thermal, mechanical, and viscoelastic analysis. Polyurethanes are well known for their outstanding physical properties such as unusually high strength, fatigue resistance, abrasion resistance, and impact absorption characteristics. They also can be prepared in quite pure form and free from the typical vulcanization additives other rubbery systems require for their care.

**Progress** — A major application of these high performance elastomers is as biomaterials. Such uses of polyurethanes include the more routine, such as orthodontic mouthpieces and elastomeric support hose, to the more frontier areas
of restorative surgery. These latter applications include a wide variety of uses which range from plastic surgery (artificial ears, hands, and miscellaneous body parts), treatment of burns (artificial skin during wound healing), orthopaedics (support materials, finger joints), vascular surgery (artificial blood vessels), general surgery (catheters, balloon catheters, artificial trachea, heart assist devices), to the total artificial heart. Currently, the researchers are carrying out the synthesis and characterization of silicone rubber-polyurethane block polymers and ultra-violet or electron beam curable polyurethane oligomers. Silicone polyurethanes may find ultimate use as a material for plastic surgery reconstructions, possibly as artificial ears or skin coverings. The researchers also believe the radiation curable polyurethanes may be considered as new generation materials for lightweight bone healing cast applications.

The research on polyurethanes as biomaterials, which is partially supported by the National Institutes of Health, focuses mainly on understanding the mechanism of artificial surface-induced thrombosis. Through this research, the investigators hope to learn more about the process of blood clotting on polymer surfaces and to design materials which remain patent when serving as 5.0 mm or smaller vascular grafts. Success here would significantly reduce lower leg amputations in those patients suffering from various vascular disease states. This aspect of the research would act to prevent the necessity of creating a state of greater handicap (by amputation) for a small fraction of elderly patients with severe circulatory disorders.

### Diagnosis of Loose or Damaged Total Joint Replacement (Human)

**Purpose** — The need exists to correctly diagnose mechanical degradation of total joint replacements. The efficacy of *in vivo* joint monitoring by means of acoustic emission has been demonstrated. To further develop the technique of *in vivo* monitoring, the acoustic emission waveform characteristics will be analyzed using correlation plots and together with the attenuation results will be used to optimize the electronic equipment through proper choice of waveform filters.

**Progress** — The development of acoustic emission monitoring requires continuation of an ongoing program to monitor patients from the Hip and Knee Clinics of The Hospital for Special Surgery who are clinically considered to be at high risk of mechanical failure. Correlation of acoustic emission results with other clinical findings will provide a basis for clinical interpretation of acoustic emission results. The mechanisms which generate acoustic emission will be further examined.

Acoustic emission resulting from failures in implant materials such as bone and polymethylmethacrylate did not correlate well with results from *in vivo* monitoring. Therefore, the contribution of interface failure and cancellous bone failure as the most probable sources of acoustic emission will be investigated with *in vitro* experiments and finite element analysis. Composite models will be
monitored during loading. Specialized finite element analysis capabilities aimed at determining failure loads and locations in interfaces will be used to correlate acoustic emission results (both experimental and clinical) with analytical predictions.

**Ultrasonic Study of the Cement-Cancellous Bone Interface (Cattle, Human)**

**Purpose** — Most current designs of total joint replacements make use of bone cement to fix the artificial joint component to the bone. Prostheses primarily fixed to the porous inner part of the bone, called cancellous bone, sometimes fail after several years of use, causing much suffering to patients and a high financial cost for additional surgery to remove the failed prosthesis. Loosening of the prosthesis has been indicated as a primary cause of mechanical failure. Stress analysis of prosthesis designs is carried out numerically using the finite element method. To make use of this method, accurate three-dimensional stiffness data are needed for all components of the prosthesis-cement-bone structure. It has been suggested that deeper penetration of the cement into the pores of cancellous bone will enhance the success rate of the prosthesis. This idea creates a layer of a cement-bone composite, the properties of which are not known.

**Progress** — In this study the elastic constants of the cement-bone composites will be determined by a pulse transmission ultrasonic technique. Specimens of bovine and human cancellous bone will be cut in the form of 5 mm cubes from larger segments of cancellous bone, after filling the pores of the bone with bone cement. The composite material thus obtained will be assumed to be orthotropic and all nine elastic constants will be determined. This information is expected to be of direct use in finite-element analyses of orthopaedic implants.

**Mechanisms of Orthopaedic Implant Loosening (Rats)**

**Purpose** — Orthopaedic joint reconstruction with an implanted artificial prosthesis is an increasingly common surgical procedure. Unfortunately, at least seven percent of patients receiving such prostheses will experience implant loosening and, ultimately, failure within five to seven 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 (MO) 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 is the hypothesis regarding the role of MOs and GCs in implant loosening, it is based upon histological observations and is therefore, at best, intuitive.
Progress — The aim of the present proposal is to directly assess the potential of MOs and GCs to affect those changes believed essential to 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 documented the ability of MOs to resorb vital and devitalized bone, demonstrated that bone matrix degradation can be precisely quantitated, and 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:

1) evaluate the action of implant materials on MO- and GC-mediated bone;
2) identify the enzyme(s) responsible for bone collagen degradation by MO and GC, and explore the regulation of this enzyme(s) by implant materials;
3) study the potential of MO, GCs and endothelial cells exposed to implant derived material to modulate (stimulate) bone resorption by other cells, including osteoclasts; and
4) establish whether phagocytosis of implant particles by MOs promotes the release of agents capable of stimulating giant cell formation and fibroblast proliferation.

Orthopaedic Implant Retrieval and Analysis

Progress — The implant retrieval and analysis research program continues to collect orthopaedic hardware from Veterans Administration-affiliated medical centers. To date, 5,235 patient records have been accumulated. During 1984, 656 devices were inserted in four VA-affiliated hospitals and 220 implants were removed routinely or due to cause-related reasons.

Presently, the clinical performance, corrosion characteristics and metallurgical properties of retrieved femoral and total knee prostheses are being evaluated. These properties have recently been examined in 82 retrieved bone plates which were in situ for periods of one to 169 months. Fifty-one of the 82 plates were removed for cause-related reasons, while only 24 were removed on a routine basis. (The removal reasons for seven plates were unknown). Stereomicroscopic examination revealed that over 89 percent of the recovered implants displayed some degree of pitting, crevice, and/or fretting corrosion. Statistical analysis revealed that metallurgical properties correlated significantly with all types of corrosion. This evaluation suggested revision of current ASTM standards to improve the corrosion resistance or orthopaedic implants.

Other recently completed studies evaluated the clinical performance and metallurgical characteristics of retrieved hip plate devices and intramedullary rods. The 61 hip plates studied included two commonly used designs: the Jewett nail-plate and the Richards screw-plate. These devices were in situ for two to 156 months, yet only 10 percent were removed on a routine basis. Our data suggested that surgeons consider these devices to be permanent implants with removal undertaken only for causative factors. No statistically significant differences were
found between the metallurgical and corrosion properties of the two designs studied, however four devices of each design were out of ASTM specification. Also, four of the Jewett devices fractured in situ.

Similar evaluations were made on 16 A-O intramedullary rods. Cracking and/or fracture was observed in four of the 16 rods. This study revealed that structural and material characteristics were responsible for implant mechanical failures, thus warranting improvements in fabrication techniques. Also, our data suggested careful assessment of a painful IM rod and routine removal after fracture healing.

A clinical analysis of 28 retrieved Harrington rods also has been completed. Fifteen rods fractured in situ, yet our data revealed that material defects were probably not contributory to the implant failure. Emphasis on attention to surgical detail in order to obtain early graft healing and solid hook placement was suggested.

Evaluation of Total Joint Loosening Using X-Ray Photogrammetry

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Progress — Our research has developed a method that can accurately measure the distance that a prosthetic component settles after it has been placed in the bone. The equipment required to perform such measurements include: 1) a device to insert stainless steel landmarks into the components and surrounding bone; 2) a jig to position the X-ray anodes with respect to patient; 3) a calibration cage which holds the X-ray cassettes in proper alignment to the X-ray beams for optical linear encoders for measuring the X/Y coordinates of each landmark of the X-rays; and, 4) software for determining displacement of components with respect to bone.

This past year the software has been further refined and simplified. We continue trying to interest manufacturing companies in bringing this system to a commercial level.

B. Hip

Load Transfer of Non-Fixed Close-Fit Femoral Stems (Sheep)

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Purpose — 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 five years has been reported. Revision surgery is difficult, most often leads to a result which radiographically at least will be much shorter-lived than the primary case, and sometimes 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 has now been 30 years of clinical
experience with non-cemented 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. 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.

Progress — 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 and 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 an ovine 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 (DPB) 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 and have far-reaching applications even in the older population.

Skeletal Aging and Disease in Failure of Hip Surface Replacement

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Purpose — Surface Replacement Hip Arthroplasty (SRHA) in comparison to Total Hip Arthroplasty has the advantages of replacing the diseased hip surface while preserving normal bone stock and maintaining more normal physiological bone loading patterns. This provides an easier method for replacement of failed implants and decreases the occurrence of deep infection in the femur subsequent to surgery. However, these advantages have been offset by high failure rates mainly due to early loosening of the femoral and/or acetabular components.

The objectives of this project are to determine causes of early loosening in SRHA and relationships between these causes and skeletal aging and disease. The possible causes for SRHA failure include: 1) poor initial fixation due to inadequate operative technique and instrumentation; 2) bone necrosis secondary to disruption of the blood supply; 3) inadequate initial bone strength; and, 4) bone remodelling due to stress redistribution related to prosthesis design or to processes of aging and disease.

Progress — Femoral head and acetabular specimens obtained from osteo and rheumatoid arthritic patients in conjunction with total hip replacement from cadavers are subjected to one or more of the following procedures:

1) Mock SRHA is performed on the femoral head and the strength of mechanical fixation is determined using torsional failure tests.
2) Radioisotope scans and tissue scintillation counts are performed on THR femoral heads and necks obtained from patients injected with T-99m directly after capsular stripping. These techniques are used to localize acute changes in femoral head vascularity due to disruption of the reticular blood supply.

3) Femoral head, acetabular and iliac create specimens are sectioned and analyzed via mechanical tests or bone histomorphometry. These tests are used to determine and compare the mechanical, structural, and physiological properties of diseased and normal hip bone. The results of these analyses will be mathematically modeled to determine the ability of underlying hip bone to chronically support current SRHA components.

The data obtained from this study will be used to determine the viability of SRHA and if possible, to design improved components and techniques.

**Preliminary Results** — The major accomplishments of this study to date are:

1) The capabilities of the new Orthopedic Histomorphometric Laboratory to perform hard tissue histology in accord with the protocol have been enhanced by equipment acquisition using non-VA funds. This new equipment includes a diamond wire saw for cutting thin sections, a precision histological grinder capable of reducing large plastic sections to 15 μm, and a microradiographic unit for bone density analysis.

2) Tetracycline-based histomorphometric analyses are now being performed on hip bone samples.

3) Mechanical compressive testing techniques for analysis of femoral head sections have been developed and verified. These techniques provide reproducible three-dimensional maps of femoral head bone mechanical properties. Tests are being completed on selected specimens.

4) In preparation for the use of radioisotope-based determination of femoral head vascularity in THR patients, a preliminary study was completed. Technetium-99m (T-99m) HDP and MDP-based bone scanning and tissue scintillation counting techniques were applied to dogs subjected to THR in order to evaluate the ability of such techniques to measure changes in femoral head vascularity due to surgical stripping of the hip capsule. Results from these studies indicated that for the dog capsule disruption reduces blood flow to the surface bone of the femoral head. The scans and counts provided sufficient data to map the location of vascular compromise. These preliminary results in the dog support the use of such techniques for vascular assessment in THR patients.

Principle project activities for the next few months will be continued collection and processing of specimens and analysis of data.

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**Porous Coated Dual-Lock Cementless Hip Clinical Investigation**

**Purpose** — This study uses a standardized operative protocol for the implanting of porous metal total hip components. Periodic analysis of radiographs and of function is used to document the results. The objective of biologic fixation is to obviate a high failure rate seen in cemented systems.
Progress — To date we have implanted about 50 of these hips with no failures through loosening or infections. One hip dislocated and was reduced closed. Recovery and function equalled the old cemented systems with operative time reduced. Late infection is much less. Early infection was probably about the same or less as in the cemented system.

Preliminary Results — The conclusion to date is that this system is superior to the cemented system in at least three ways: 1) reduced operative time; 2) fewer late infections; and 3) reduction in mechanical failure. No unique complications have been noted. Bone remodeling may be enhanced. The program is successful and should be a continuing study.

The Mechanical Properties of Porous Coated Orthopaedic Alloy

Purpose — The porous metal coating applied to a solid substrate has been shown in vivo to offer advantages over current methods of implant fixation. However, these advantages may be lost in devices requiring a sintering heat treatment to apply the porous coating. In our studies to date, uncoated Ti-6Al-4V orthopaedic alloy was found to have an endurance limit of 605 MN/m². The application of a porous coating decreased the endurance limit by approximately 77 percent, and when the uncoated substrate material was heat treated to the same temperature as the porous coated samples, a degradation of approximately 34 percent was observed. The difference was that the porous coating acted as a notch.

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. In the present study, microstructural analysis was performed on three different post sintering heat treatments of Ti-6Al-4V in an attempt to improve the fatigue properties. The heat treatments investigated provide microstructures somewhat different from the original sintering heat treatment. These heat treatments may help in resistance to crack initiation and propagation during the cyclic loading of porous Ti-6Al-4V orthopaedic devices and thus result in improved fatigue properties.

The microstructures obtained from the heat treatments were lamellar, coarse acicular, and fine acicular. Mechanical properties such as yield strength, ultimate tensile strength, percent elongation, and hardness were investigated and compared to those of the as-received equiaxed structures. As expected, the equiaxed structure exhibited the best properties: yield strength of 965 MPa, ultimate tensile strength of 1140 MPa, elongation of 13.50 percent, and Rockwell Hardness C of 32.90; whereas the lamellar structure produced the poorest properties: yield strength of 824 MPa, ultimate tensile strength of 954 MPa, elongation of 5.10 percent, and Rockwell Hardness C of 26.20. The acicular microstructures displayed mechanical properties that ranged between those of the equiaxed and lamellar structure. Overall, the fine acicular structure was stronger than the coarse acicular structure.
The Efficacy of Radiolucent Low Modulus Total Hip Surface Replacement

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Purpose — The objective of this project is to investigate the potential of using a radiolucent low-modulus surface replacement as a prosthesis for the hip. This work is a bone remodeling study in that a comparison of the cancellous bone under a carbon femoral surface replacement is to be compared to the normal cancellous bone in the contralateral hip. In addition, the bone under a carbon femoral prosthesis is to be compared directly to the cancellous bone of the contralateral femoral head which has been resurfaced with a cobalt chromium prosthesis of a much higher modulus.

Progress — At this point all of the unilateral carbon replacements have been retrieved and are undergoing quantitative trabecular stereology. All of the bilateral replacements have been implanted and will have been retrieved by January, 1986. These then will undergo histologic examination and quantitative trabecular stereology. In the meantime, finite element studies of the femoral head with the carbon and with the cobalt chromium prosthesis are underway and preliminary results have been obtained that must eventually be compared to the results of the quantitative trabecular stereology.

Computerized tomographic scanning of the unilateral and normal control hips has been performed. The data obtained from these studies also will be compared to the results of the quantitative trabecular stereology for those animals with a carbon surface replacement.

In an attempt to improve the finite element studies, an algorithm has been developed for use on CT scan data to define trabecular pattern so that this information may be included in finite element modeling.Presently, work is progressing on using CT scan data to generate finite element meshes. It is anticipated that the histologic studies will be completed early in 1986.

Total Hip Biotelemetry

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Purpose — The objective of this project is the design and development of a special total hip femoral component that contains within it a miniaturized biotelemetry system capable of broadcasting signals received from strain gauges mounted inside the neck of the prosthesis. The prosthesis will be inductively powered by an external coil thus eliminating the need for internal batteries or connecting cables. This is a collaborative effort involving the Research Service of the Wadsworth VAMC, the UCLA Division of Orthopaedic Surgery/Biomechanics Research Section, and the Jet Propulsion Laboratory.

Progress — Since the last report, several design changes were necessitated to accomplish the specific objectives. The ball-neck unit was successfully broached with eight slots in the inner periphery of the neck. Eight active and four dummy semiconductor gauges were bonded in these slots as per a preliminarily approved attachment procedure. The dummy gauges are mechanically isolated from the
prosthesis with a slab of similar material and RTV Silastic. Static load tests were conducted on this unit by applying a 200-pound bending force acting at 90 degrees to the neck axis and the change in resistance of each of the gauges was recorded. This test was repeated for each 45 degree rotation of the unit about the axis of the neck. Axial force tests were also performed by applying 825 pounds force to the top of the ball along the axis of the neck.

Both the bending and axial tests indicated that the active gauges behaved as predicted. However, the isolated dummy gauges were changing by as much as 20 percent of the active gauge change. The dummy gauge attachment procedure was modified to increase the thickness of the carrier plate and the RTV layer. The tests were repeated with the modified gauge attachment procedure and the dummy gauge outputs were found to be less than 1 percent of that recorded for the active gauges. The remaining prosthesis housings were then broached and the gauges attached according to the modified procedure.

Due to questions concerning the biocompatibility of the material proposed as a secondary seal and the lack of commitment by the manufacturer to guarantee its biocompatibility, it was decided to include a primary glass feedthrough seal at the base of the hollowed out neck of the prostheses. This required a subsequent counterbore at the base of the neck and electron beam weld of the glass seal at this location. As a result of this design change, new glass seals with hollow feedthroughs were necessitated for the stem tip so that the platinum leads could be extracted. This revised procedure has been implemented for all the units including the ball neck unit. After electron beam welding of the feedthrough and the cap of the ball on the ball neck unit, it was subjected to hermetic testing to determine the hermeticity of the welds. Tests results indicated that the helium leak rate is less than $1.9 \times 10^{-7}$ cc/sec.

Tests of the transmitter submodule indicated a large deviation in oscillator frequency during bench tests. The stability problem was traced to a group of four capacitors used in the oscillator resonator network. The parts substituted for original parts that are no longer available exhibit a very high temperature coefficient. Replacement capacitors have been received and submodule refurbishment has now been completed.

Fixtures to hold the multiplexor and transmitter submodules have been assembled. Accelerated life tests of these submodules are scheduled to begin after sealing of the 12 units.

A static load unit which has been instrumented with strain gauges only, welded and the final machining completed is currently undergoing static and fatigue testing on the MTS-612 servohydraulic testing machine to determine the gauge bonding durability and to establish the structural performance criteria of the implant. The remaining units are having the primary feedthroughs welded and the electronic subassemblies incorporated. They will then be returned for final machining and polishing prior to cadaver implant testing.

Due to the substantial changes which have been necessitated a change in the scope of the project has been incorporated. The use of a primary seal at the base of the neck allows us to forego the proposed leach tests since the hermeticity of the unit has been verified. Due to the redirection of effort, the expansive data recovery system originally envisioned will not be possible with current funding.
Quantitative Analysis of the Effect of Total Hip Arthroplasty on Stress and Strain in the Human Pelvis

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Purpose — New acetabular cup designs and techniques for implantation have been proposed to further improve the overall performance of the arthroplasty. However, there has been little objective experimental work done to evaluate the effects of these changes on the stresses and strains developed in the human pelvis following implantation.

The long-term objective of this ongoing investigation is to quantitatively evaluate the effects of different insertion techniques and the use of currently available acetabular prosthesis designs on the strains in the cadaver hemipelvis. It is felt that pelvic strain changes may predict the long-term success or failure of arthroplasties of the hip. Thus, our investigative methods should prove to be an aid to predicting performance or for future screening of designs and techniques.

Progress — Initial work led to the development of an automated computerized data acquisition system and customized loading fixtures. This novel instrumentation allows for the simultaneous application of prosthetic loading and simulated muscle pull to allow assessment of surgical technique and device construction of pelvic strain during the simulation of single limb stance.

To date, techniques which have been studied involve: 1) the perforation of the acetabulum with various sized pilot holes; 2) removal of various amounts of subchondral bone and cancellous bone; 3) the use of keying holes of different sizes and placement configurations; 4) the use of hand curetting to prepare the site versus the use of mechanical reaming; 5) use of spacers to insure a uniform mantle of cement; and 6) pressurization of cement using various methods versus the use of hand packing.

Future Plans — To be studied in the future are: 1) use of surface replacement prosthesis; 2) bone grafting and 3) wire mesh reinforcement or plating. Titanium metal backing with attached plastic spacers have been evaluated. Reconstructive techniques for the deficient acetabulum are to be evaluated during our next phase of research.

Design Stress Analysis of Porous Ingrowth Hip Replacements

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Progress — Preliminary three-dimensional finite element studies of the normal proximal femur have been completed. We have begun 3D finite element investigation of the effects of porous ingrowth hip surface replacement and have begun development of a 3D model which includes both the femur and the pelvis.

Several publications and presentations have resulted from the completion of the two-dimensional finite element investigation of the stresses in the proximal femur and acetabulum due to implantation of a porous ingrowth hip surface replacement and acetabular cup.
C. **Knee**

### Minimal-Gliding Knee Endoprosthesis

**Purpose** — Two major problems expected to contribute to failure of artificial knee joints are loosening and wear of the prosthesis components. Both are partly generated by shear stresses that occur when mating surfaces are gliding. In an attempt to introduce an improved version of an artificial knee joint, we have proposed a model by which the opposing surfaces of the prosthesis components can be synthesized. The criterion applied is based on minimization of the gliding motion of the endoprosthesis (believed to be associated with wear) in the range of motions commonly performed by the natural knee joint.

**Progress** — The main assumptions of the model are: 1) area of the contact surfaces depend on the forces transmitted within the joint; 2) contact areas assume the shape of the femoral component, the deformation of which is negligible; and, 3) deflections within the joint space are mainly due to the tibial component, in view of its relatively low elastic modulus. Input data to the model include mechanics of the natural knee, namely kinematics in the types of motion commonly performed, frequency of occurrence of the various motions, and anatomical data related to geometry and architecture. To supplement the data available in the literature, kinematics of the knee joint are being studied by means of a 'Selspot' opto-electronic system.

A wear-index adapted to minimize gliding yields pairs of surfaces, one femoral and one tibial, is defined from which the most suitable pair is selected.

### Design Concepts for a Porous Ingrowth, Prosthetic, Tibial Component

**Purpose** — The objective of this study is to develop design concepts for a porous ingrowth tibial component of a total knee prosthesis based upon a knowledge of the stress fields in the proximal tibia before and after joint arthroplasty. Anatomical specimens will be sectioned, radiographed, and photographed to document geometry, distributions of bone density, and trabecular orientations. From these sections equivalent-thickness and axisymmetric two-dimensional (2-D), as well as full three-dimensional (3-D) finite element models of the proximal tibia will be generated. Similar models with various implant components in place will also be constructed. Linear models having rigid contact at all implant/bone interfaces and non-linear, contact models capable of simulating intermittent contact/separation at any or all implant/bone interfaces will be studied. With these non-linear models, the stresses in the implants, bone, and across interfaces can be determined at initial implantation and after partial or complete ingrowth has been achieved. Parametric studies will determine the effects of assumed load magnitudes and directions, implant geometries, and implant bone material properties.
In analyzing and interpreting the results, special attention will be paid to: 1) consistency between the calculated stress fields and bone trabecular morphology; 2) initial stability of the implants under various loading conditions; 3) the types of stresses created at the porous ingrowth surfaces (compression, tension, shear); 4) the pattern of bone stress change caused by the implant; and 5) the manner in which bone may remodel in response to the stress change.

New Jersey Knee Clinical Investigation

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**Purpose** — This project is designed to study the efficacy of non-cemented fixation of knee endoprosthetics and to define any unique problems. The study utilizes the New Jersey design knee in a porous coated model for bone ingrowth fixation. A standardized surgical protocol is followed with patient evaluation on a prescribed periodic basis. Radiographic analysis is done as well.

**Progress** — To date about 30 porous coated knees have been implanted with no failures, no infections, and no deaths. The recovery period is identical to the cemented type of fixation. The range of motion and patient functional level appears to be slightly better than the older method. No new problems have been noted. Patient satisfaction seems somewhat greater. To date no evidence of loosening or failure has been noted. The conclusion is that this method of fixation is better and more durable than cement fixation with no greater risk to the patient. Infection (late) may be less as well as obviating late cement failure.

Design and Evaluation of Knee Orthoses

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**Purpose** — The primary objective of this project is to improve orthotic treatment in the rehabilitation of the knee joint. Many knee orthosis designs do not achieve their intended goal because of mechanical or kinematic mismatches, leading to motion restriction or binding, misalignment of the orthosis on the limb, and discomfort due to skin-pressure problems. In response to the above situation, this laboratory has designed and developed an improved orthotic knee joint and complete knee orthosis. It was intended that this orthosis system be applied to total joint replacement cases, as well as the vast array of other ligament-related problems that afflict the human knee joint.

The improved orthotic joints are semi-constrained and anatomically-shaped, and were shown to have minimized the pistoning constraint normally associated with orthotic joints. Stability is added to the joints by the sequential tightening of a set of inextensible Dacron straps ("ligament" straps) crossing the joint, simulating the knee ligaments. Anterior cruciate, posterior cruciate, and collateral ligament strap configurations have been designed. Since the orthotic joints minimize the pistoning constraint, significant improvements to the orthotic interface can be realized, increasing its suspension to the lower limb. Interface
improvements, based on a four-point suspension principle, include the use of a medial femoral suspension pad and a proximal tibial suspension member, each with its associated strapping arrangement.

**Progress** — The design of the improved orthotic joints and orthosis was finalized during the previous reporting period. A competent and reputable manufacturer/orthotics laboratory was chosen to fabricate and market the device, along with providing education regarding its design, indications for its use, fitting, etc. A portion of our effort during this reporting period was devoted to interacting with this company, providing consultations on manufacturing, quality control, and education issues.

The remaining effort during this reporting period was spent on developing a three-dimensional finite element mathematical model of a lower limb and knee orthosis, as well as setting up an experimental system to provide a “laboratory” evaluation of knee orthoses. A series of parametric analyses were performed using the finite element model, with the purpose of looking at the effect of varying certain design features upon the orthotic interface/skin boundary. The laboratory evaluation system has been nearly complete. The evaluation will involve the use of an instrumented spatial linkage and microprocessor to measure knee motion both before/after application of an orthosis and to directly determine if the orthosis is actually performing as it should.

**Future Plans** — During the coming reporting period a group of suitable subjects with chronic knee laxity will be defined and evaluated, as they wear different designs of orthoses.

### Interaction of Total Knee Replacement Geometry with Knee Ligaments

**Purpose** — 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 that 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.

The protocol for this project is to experimentally investigate the initial post-surgical state of the knee with a TKR by using a six-degree-of-freedom instrumented spatial linkage (to measure joint motion) and buckle transducers (to measure ligament forces), in conjunction with an analytical force 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 combination.
Progress — During this reporting period the experimental system needed to perform this project has been synthesized. Improved buckle transducers have been designed, built, and evaluated. A new knee specimen external loading apparatus has been designed and constructed. An improved instrumented spatial linkage has been built, as well as a mechanical calibration device. A microprocessor data acquisition system has been purchased and installed. Computational and sampling software has been written and tested. The testing of specimens will be carried out during the coming reporting period.

A Motion-Guiding Load-Bearing External Frame for the Knee

Purpose — The goal of this work is to design external joints for the knee, which guide normal knee motion, and to incorporate them in a new leg brace design. The research plan will determine average knee motion to design external joints, to model knee mechanics with external joints of different design, and to design and evaluate a new leg brace.

Progress — Knee motion was determined using cineradiography on volunteers and using static and dynamic test rigs on specimens. Computer models were generated that displayed ligament length patterns and tibial-femoral contact joints, depending on external joint design. A computer program was written to optimally design the external joints.

External joints have been incorporated into a leg brace and are now being tested in patients with various knee problems.

It was proposed that a more effective external knee joint mechanism could be designed by taking into account the complex motion of the normal knee. Two separate studies determined the amounts of rotations and displacements which occurred as the knee flexed and extended. The normal ligament length patterns and the adverse effects of imposing abnormal motions also were determined. By using the above data and by constructing the 3-D geometry of the knee, using new sectioning techniques, a computer model of average knee mechanics was formulated. With this model, a computer-graphics program was written to design the external joints. The design is based on pins moving in slots to precisely guide the motion. The external joints have now been incorporated in an “Accuflex” knee brace. The brace is currently undergoing clinical evaluation for indications including chronic knee instability, protection after knee ligament injuries and surgery, and in prophylactic situations. It is expected that production will be expanded in the future and that there will be other applications of the external joints for the treatment of knee joint problems.

The work has made a scientific contribution at several key conferences and in journals. The new leg brace should result in improved treatment for knee instability and injury problems, and will help to stimulate improved designs from others in the field. This improvement in leg brace design should enable patients to be rehabilitated quicker and with better clinical results.
Investigation of a Simplified Internal Knee Prosthesis

Purpose — The goal was to determine whether a total knee replacement could be designed using press-fit of the components directly on to bone, or with a springy layer of velour interposed without the need for cement or porous ingrowth.

Progress — The first stage was to obtain a three-dimensional model of the average knee, including the structure and mechanical properties of the cancellous and cortical bone on to which the artificial knee would be affixed. A finite element analysis showed that press-fitting was equivalent to cementing only if a perfect fit was achieved at surgery. Experiments showed that this was not usually achieved but that a velour layer compensated for minor mismatch in fits. Experiments in sheep confirmed that a velour layer reproducibly formed a protective layer at the component-bone interface, but that a direct metal interface invoked a bone response where a natural fibrous layer formed.

Based on all of the data, a new Kinematic II Press-Fit Total Knee was designed. Special fins were added to carry the various shear and rotatory forces acting across the knee. This knee has now been used over the past 18 months on 20 patients. To obtain the best possible alignment at surgery, a new accurate instrumentation system has been developed. This system is extremely simple and compact, and is in keeping with the aims of reducing costs of the total knee procedure while maintaining high quality results.

Future Plans — Analysis of histological sections from sheep patella will be conducted to compare press-fit and compliant interfaces. Computer model and dynamic testing of generic type of press-fit total knee inserted in knees will show surgical and design variables. Clinical follow-ups of press-fit total knees that were started in patients in February 1984 will be made.

Prospective Clinical Study of the Kinematic Knee

Purpose — This is an ongoing project to follow 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.

Progress — Data were collected from hospital and operating surgeon’s files. Data included component type, 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.

The study has been capped at 105 cases. Many of the cases have reached five-
year follow-up, while nearly all cases have a minimum two-year follow-up. However, several cases still lack complete long-term follow-up data.

**Preliminary Results**—To date, almost all cases have shown a dramatic improvement in their evaluation scores. There have been no revisions. However, the results still tend to indicate an almost inevitable development and progression of radiolucent lines beneath the tibial component although their onset and severity may depend on component joint alignment, cement penetration, or several other factors. Present attempts to show these relationships with statistical multivariate analysis have been inconclusive.

Efforts of the project have turned towards quantifying the progression and size of radiolucent lines. Twenty patients were called back for both normal X-rays and X-rays taken under fluoroscopy. By the fluoro technique precise alignment of the components may be obtained, allowing assured direct viewing of the implant-cement-bone interface. Radiolucent lines were measured and graded for both types of radiographs and statistical comparisons made. While no increase in the number of lines was noted, an increase in apparent thickness was. An abstract presenting results of radiolucent lines will be submitted for presentation at the 1986 annual meeting of the Orthopaedic Research Society.

**Future Plans**—Efforts will center on attempts to correlate clinical radiolucent line data with interface crack propagation studies. In addition, attempts to determine the subtle relationships between procedure outcome and variables recorded will continue.