III. Total Joint Replacement and Other Orthopaedic Implants

A. General

The Effect of Notching of Simplex-P Bone Cement on the Fatigue Lives of Regular Versus Vacuum-Mixed Specimens

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Sponsor: National Institute of Handicapped Research

Purpose—It has been shown that a partial-vacuum slow-speed system for blending of the liquid and powder components of Simplex-P produces set acrylic bone cement specimens of less than 1 percent porosity with significantly improved uniaxial tensile fatigue lives over regularly mixed cement. However, those tests were conducted using smooth-machined specimens, which may not necessarily be clinically comparable to the in vivo condition of an irregular interface with cancellous bone. In the present study, the influence of cement surface condition on fatigue life was investigated with specimens having either machined 60-degree notches or cast into collars of cancellous bovine bone. These were compared with smooth-machined specimens.

Progress—Vacuum-mixed fatigue specimens were prepared from iced, prechilled components by pouring the powder into the entire quantity of liquid. A vacuum of 550 mm Hg was then applied to a high-strength reinforced bowl for 90 seconds, during which mixing was done at 1 blade revolution per second. Regular mixtures were prepared by hand spatulating room-temperature powder and liquid. Fatigue specimens were made by placing the admixtures into a caulking-gun-type syringe and extruding the material into 8-mm-ID x 80-mm-long glass tubes. For the collar specimens, an 8-mm-OD, 6-mm-ID x 20-mm-long bone tube was centrally positioned in the glass tube prior to cement insertion. After 1 week storage in 37-degree Centigrade water, the machined specimens were reduced to 6 mm diameter in the central 20 mm. Additionally, the notched specimens received a centrally placed 0.25-mm-deep, 60-degree, 0.08-mm-tip radius notch. Testing was conducted at room temperature at 2 Hz in a Model 1350 Instron cycling sinusoidally from 1.5 to 20 MPa until fracture.

Preliminary Results—The results of the fatigue studies show the data for all eight specimens of each group are drawn as slopes on Weibull paper. Machine notching reduces the fatigue life of bone cement, and the machine also increases the scatter in the data. However, even in the machine-notched condition, vacuum mixing was significantly better than regular mixing.

Loosening, with breakdown at the bone/cement interface, remains a major cause of long-term failure of total joints. It is not yet known if stronger cements, achieved by mixing under partial vacuum, will reduce the incidence
of loosening. This study does show that even with areas of increased stress concentration from surface irregularities similar to that at a bone/cement interface, vacuum mixing allows the use of a more fatigue-resistant material for cemented total joints.

**Bone Remodeling Around Ingrowth Joint Implants**

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**Sponsor:** National Institute of Handicapped Research

**Purpose**—The objective of this project was to develop an animal model for studying bone remodeling around ingrowth implants and then to compare cancellous bone remodeling with a three-dimensional finite-element model of the animal model. The purpose of the comparison was to determine if remodeling could be predicted by a simple linear elastic model.

**Progress**—An animal model consisting of a surface replacement hip component in the dog was developed. Components with porous surface and surgical tools for installation were designed and manufactured. The components were implanted in four animals, two sacrificed at 3 months, and two at 6 months. The femoral heads of each animal were sectioned, with metal in place, and specimens prepared for histology, microradiography, and mechanical stiffness testing. Control specimens from the contralateral limb were also tested. A three-dimensional finite-element model of one of the femoral heads was constructed and run.

**Preliminary Results**—Results showed poor reproducibility of the bone remodeling response, even though the surgical technique was considered to be quite precise and relatively reproducible. All four animals showed remodeling, but there were significant differences between each pair of animals. This variability precluded any meaningful prediction of remodeling with the finite-element model. There was positive, but weak, correlation between changes in mechanical stiffness and area fraction. The results suggest that some other variable not controlled in the experiment was influencing bone remodeling. This factor, or factors, must be understood before useful predictions of bone remodeling can be done.

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

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**Purpose**—The objective is to identify and quantify the causes of late loosening of total joint replacement components by examining several aspects of the interface system.

**Progress**—Factors Affecting the Mechanics of Bone/Bone Cement/Interface Failure: Fatigue data were generated for bimaterial (bone-poly(methylmethacrylate)) four-point bending test specimens. Conceptualization of crack growth data was achieved as a series of stable growth periods interrupted by discrete occurrences of cement posts characterized by zero crack growth. Results of previous finite-element models of the test specimen with and without a cohesive zone present at the bone-PMMA interface were employed in determining the cyclic stress intensity factor (ΔK) at the crack tip.
Preliminary Results—Multivariate statistical analysis was performed on the data in attempts to: 1) relate crack propagation rate ($\Delta a/\Delta N$) to $\Delta K$, PMMA penetration depth, and bone strength for the stable crack growth periods and 2) relate the same factors to the number ($Post_N$) and duration ($\Delta N_{post}$) of zero crack growth periods. A predictive equation was obtained along with statistical significance levels for the modeled crack growth behavior. In all, 26 specimens were tested. In general, results indicated an inevitable formation of an interface crack. Crack growth, however, was retarded by increased cement penetration, bone strength, and $Post_N$, whereas the inclusion of a cohesive zone played little role in the final results.

It was proposed to enhance the interface by the introduction of artificial posts. The proposed post density was obtained by optimization of the predictive equation for $Post_N$. Based upon the optimized results and several biomechanical considerations, a “crack arrestor” device was designed for and tested qualitatively in the four-point bending test specimen. Results were very encouraging, and work is continuing on further development and study of the “crack arrestor” concept. An abstract was prepared and submitted to the 1987 Orthopaedic Research Society meeting.

Failure Mechanisms in PMMA Around Tibial Components: A demonstration pilot project was undertaken to examine failure mechanisms in PMMA around loaded tibial components. Tibiae with cemented components were cyclically loaded, sectioned, and examined with a scanning electron microscope. Residual gaps between cement and implant were noted as well as microcracks surrounding cement voids and inclusions.


Fixation of Noncemented Knee Components: This study attempted to quantify the motion occurring between bone and ingrowth component to better understand the role of relative motion in ingrowth failure.

Fresh tibial specimens were potted in PMMA 12 cm below the joint line. The proximal articular surface was milled flat and perpendicular to the sagittal long axis of the bone. The appropriate porous component was impacted axially for rigid fixation in the 12-percent interference fit of the fixation pegs. Liquid metal strain gauges were cemented to the tibial plate and proximal 5 mm of the tibia anteromedially, anterolaterally, posteromedially and posterolaterally, and anteriorly in a stepwise fashion from 10 to 2000 Newtons. Testing was aborted at .5 mm bone/plate separation. The plate and gauges were then removed and the prosthesis cemented into place. The gauges were remounted and the loading sequence repeated.

Motion between the implant and bone was reliably detectable with the naked eye at 200 to 300 microns. Visible separation between the implant and bone of > 0.3 mm occurred with posterolateral loads of 20 to 200 N. Medial separation with posterolateral loading occurred at higher loads, from 150 to 1500 N. Noncemented anterior loading was performed in four cases, and posterior separation was noted between 20 to 200 N. The medial peg was consistently difficult to extract, even after visible separation of the implant from the plateau, suggesting the interference fit remained secure. Gross bone/implant motion was not observed in cemented applications.

Maximum oscillatory, inducible, elastic deformation of noncemented components ranged from 6 to 290 microns, as compared with the cemented range of 0 to 99 microns over an increasing axial central load of 10 to 2000 Newtons ($p < .04$). Posterolateral loads from 10 to 300 Newtons resulted in maximum noncemented inducible motion of 30 to 200 microns as compared to cemented motion of 4 to 93 microns ($p < .05$).
Mechanical Properties of Trabecular Bone Tissue

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Purpose—Bone remodels around total joint implants, changing the mechanical state of the load transfer across the bone-implant interface. It is of interest whether the cancellous bone changes its porosity only or the mechanical properties of the trabecular tissue as well. The objective of this project is to develop a test technique to measure the stiffness of individual trabecula and then to use this technique to measure the stiffness of trabecular tissue from the proximal tibia of normal and diseased subjects.

Progress—The method chosen was to first measure the load deflection of a single trabecular piece as a cantilever beam, to model this piece of bone by a three-dimensional finite element model, and then to simulate the mechanical test on the model. Stiffness of the bone piece is determined by matching the experimental and finite-element models. During this report period, each of these tasks was accomplished.

The procedure consisted of: 1) isolate a single piece of trabecular bone shaped like a rod or beam (the piece need not be of exact regular shape); 2) pot one end of the piece in epoxy, forming a cantilever beam; 3) fix the potted specimen in a test fixture with a movable stage, an LVDT displacement transducer, and a 60-g load cell; 4) perform a load-deflection test on the bone piece. The specimen was then removed from the fixture, potted in a cylindrical mold to totally encapsulate the bone piece, and ground down axially, with photographs taken of cross-section every 0.25 mm. These sections were then digitized and used to create a three-dimensional finite-element mesh using the program NUFIG. Boundary conditions appropriate to the experiment were then added and the program run to predict a deflection due to the experimental force. Stiffness of cortical bone was assumed for the run. Actual stiffness of the trabecular bone was deduced by matching the experimental and finite-element deflection by changing the material stiffness (this could be done because the problem was linear).

Preliminary Results—Five specimens have been tested, three from a dried and rewetted tibia, and two from a fresh tibia. Average Young's Modulus predicted was $0.53 \times 10^{10} \text{ N/m}^2$, (with a range of 0.12 - 0.2), compared to 1.5 x $10^{10} \text{ N/m}^2$ for cortical bone. The results suggest that cancellous bone has a different stiffness than cortical bone and cannot be considered simply as cortical bone with holes in it. The work is continuing to further verify the technique and to measure more specimens.

Expert Manufacturing System for Custom Prosthesis

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Sponsor: VA Rehabilitation Research and Development Service and Bioengineering Alliance of South Carolina

Purpose—In many degenerative joint and bone diseases of the disabled veteran there is the need for a custom-designed prosthesis to accommodate patient anatomical peculiarities. Presently, 6 to 8 weeks are required to manufacture a custom prosthesis. Several research centers in the United States have attempted recently to utilize computer-aided design/computer-aided manufacturing (CAD/CAM) technology to reduce the manufacturing time for a custom device. They have had limited success because the design activity requires interdisciplinary expertise in biomaterials, biomechanics, orthopedics, and CAD/CAM.
**Progress**—We are investigating using artificial intelligence (AI) technology combined with CAD/CAM to create a prosthesis design expert system. We are developing radiographic techniques combined with special 3-D computer graphics software that will enable a patient's joints to be modeled on the computer screen. By using AI, finite-element stress analysis, a database of normal joints, and interaction with the clinician, the expert system will determine dynamic joint forces and evaluate off-the-shelf prosthetic devices. If an off-the-shelf prosthetic device is determined to be unacceptable, a prosthetic device will be fabricated using machine tools controlled by the computer.

**Preliminary Results**—Preliminary software development is proceeding. Results to date are very encouraging.

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**Porous Polyethylene as a Reconstructive Material**

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**Purpose**—Porous polyethylene (PPE) can be cut and fabricated into a desired shape by the surgeon at the time of implantation and therefore appears to be an excellent material for reconstructive surgery. The goal of the project is to evaluate the tissue reaction of PPE and to determine its applicability in reconstructive surgery. To evaluate the material, the cartilage in the external ear of the baboon (*Papio cynocephalus*) was removed and replaced with PPE. The stability of PPE in this location was used as an indicator of tissue response and applicability of PPE.

**Progress**—Sixteen test specimens were implanted in eight baboons. Eight-mm-diameter cartilage plugs were punched out of the external ear and replaced with a similar size PPE disc. Silastic rubber discs were used as controls. The test specimen implants were removed 8 weeks postoperative.

The removed implants were subjected to light and electron microscopic analysis. Light microscopy showed minimal capsule formation and vascularized tissue ingrowth in the well-stabilized PPE implants. TEM analysis sustained our tissue response and stability hypothesis. Mature collagen fibers were found adjacent to the implant material. The SEM study demonstrated that PPE could be cut on the operating table with a scalpel. The cut surface is smoother and results in less tissue reaction. The second group of eight implants were recently implanted in four baboons. The results are not currently available. PPE used for this experiment is characterized physically and chemically.

PPE appears to be an excellent material for reconstructive surgery. Our studies indicate no adverse tissue reaction, and the material is approved by the Food and Drug Administration for surgical use.

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**Bone Remodelling Around Porous-Ingrowth Implant**

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**Sponsor:** VA Rehabilitation Research and Development Service

**Purpose**—This project investigates the remodeling behavior of a rabbit femur model in response to changes in bone stiffness. The rabbit femur model involves implanting a porous-coated metal rod, attached to a hind limb, in immature (10 weeks) rabbits. After 16 weeks...
the rabbits are sacrificed and the mechanical and physiological changes in the bone are assessed using tetracycline labels and radiographic, mechanical, and histomorphometric methods. Questions to be answered are:

1. What are the initial changes in cyclic strains in the rodded and contralateral femurs?
2. What are the temporal changes of bone mass in response?
3. How do the bone changes manifest themselves in the structural properties of the bones?
4. Does the contralateral limb hypertrophy in response to changes in loading?

The ongoing work of our research program has resulted in the development of a conceptual framework in which the structural adaption of cortical bone can be viewed. This framework has been formed with an appreciation of the mechanical role of bone in living animals and the response of whole bones, bone tissue, and bone microstructure to various loading histories. This study will be the first step in the continuation of our research in understanding the mechanisms of bone remodeling and could have implications in the design of porous-ingrowth prostheses.

Fracture plate implantation has been used to study stress-related bone loss and recovery. However, the trauma imposed by the implantation procedure (even without osteotomy) clouds the issue of bone stress- or strain-related remodeling. Plates which provide little stress shielding can actually cause new bone deposition and a net increase in whole bone structural rigidity. Those results indicate that caution should be exercised when evaluating bone hypertrophy in response to invasive procedures designed to increase bone loading—hypertrophy may be wholly or partly achieved by non-stress-related phenomena. It is for this reason that a less destructive animal model has been designed and developed.

In this study, a 40-mm-long Co-Cr alloy (a material used in existing clinical prostheses) rod with a porous coating is attached to the right femur of 10-week-old New Zealand white rabbits by banding the femur at each end of the rod. The left femur is used as a control.

**Progress**—The experimental procedure has been completed on 8 of the 14 rabbits currently under study. The femurs have been embedded and sectioned for thick-section microscopy.

**Future Plans**—Thin-sectioning and histological examination await the development of a more dependable thin-sectioning technique.

The next step will be to compare control animals (no rod implanted) with the experimental animals. During that phase, the effects of loading on bone remodeling will be studied by placing weights on the animals.

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**Biomechanics of Bone Resorption/Regeneration at a Bone Implant Interface**

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**Final Report**—The relationship between bone remodeling and mechanical stresses in bone has vital implications with respect to the interaction between surgical implants and bone. The objective of this study is to gain knowledge of the physiological reactions of bone in relation to mechanical stress at the interface between bone and an orthopaedic implant such as a joint replacement or device for fracture fixation. The research has attacked the problem by means of special titanium screw implants in canine bone. Three months following the insertion of the screws, they are subjected to a programmed loading regimen by an external device. Stresses at the interface and within adjacent bone are calculated by finite-element analysis, while the bone reactions are determined by quantitative histology and compared with local stresses. Because successful joint replacements are dependent on secure and per-
manent fixation in bone, this study represents an unusual attempt to improve implant design by examining the effect of local stresses on bone.

In the course of this project, we demonstrated that the state of bonding or adherence between bone and the implant is a major factor in the stress patterns produced. Thus, we identified this factor as a significant variable that must be controlled. In addition, we developed techniques for assessing the effects of loading on the bone-implant interface and applied them to special screw implants in canine radius and mandible. For both locations there were instances of statistically significant differences between loaded and unloaded cases, although no differences were detected on a group basis, the standard loading regimen for this study. Further work with these techniques should enable us to identify stress levels that encourage maintenance of a healthy bone-implant interface. Implants can then be designed to generate these stress levels during normal physiological activities such as walking.

The next phase of this project, “Determination of Effects of Implant Interface Mechanics on Bone Remodeling,” has recently been approved. During this study we will investigate effects of loading regimens producing higher stress levels over longer periods on our existing model, as well as investigate the interfacial bone response to micromotion.

Evaluation of Total Joint Implant Loosening Using X-Ray Photogrammetry

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Purpose—The purpose of this project is to develop a clinically-applicable system for measuring relative motion between the components of total joint implants and the bones into which they are placed in order to evaluate the loosening or migration of the components.

Progress—Radiographic markers are placed in the bone and total joint components and displacements are measured with two- and three-dimensional X-ray photogrammetry systems under various loading conditions or as a function of time since surgery. Research subjects are placed in a calibration framework and exposed to X-rays from two anodes. The images of the radiographic markers in the bone and components are measured on an accurate coordinateograph, and their three-dimensional coordinates calculated. Changes in the relative positions of the markers with time or loading indicate looseness or migration of the total joint components.

Results—No patients were studied this year. A new calibration frame was completed. This frame allows the X-ray cassettes to be positioned perpendicular to the anodes. The accuracy of the frame was tested using a cylinder containing two movable Plexiglas components. The position of the components was changed and measured with a micrometer. At the same time, X-ray photogrammetry was used to measure the same change in position. On the basis of these experiments, substantial improvement has been made in the ease and accuracy of this kind of X-ray photogrammetry measurement. In addition, software evolutions have made the computer phase more user-friendly.
The Efficacy of Radiolucent Low Modulus Total Hip Surface Replacement

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Purpose—The purpose of this project is to investigate the potential of using a radiolucent low-modulus surface replacement as a prosthesis for the hip. This study 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 that has been resurfaced with a cobalt chromium prosthesis of a much higher modulus.

Preliminary Results—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 were retrieved by January 1986. These then underwent histologic examination and quantitative trabecular stereology. Finite-element studies of the femoral head with the carbon and with the cobalt chromium prosthesis are under way, 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 will also 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. At present, work is progressing on using CT scan data to generate finite element meshes.

Implant Fixation by Postinsertion Pressurization of Polymethylmethacrylate

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Purpose—Aseptic loosening of cemented joint arthroplasties remains the major cause of long-term failure. Many investigators have demonstrated significant improvement of penetration and mechanical strength using higher cement injection pressures; however, other studies have shown increased local and systemic toxicity with increased pressure. This project was designed to evaluate the effects of clinical (20 p.s.i.) versus high (100 p.s.i.) sustained pressurization of cement on systemic toxicity, local toxicity, and structural properties.

Progress—The current investigation is twofold. First, an in vitro, dynamic testing of mechanical properties uses fresh canine stifle joints, with randomized sustained pressures of 20 versus 100 p.s.i.. Pull-out, push-in, and cyclic testing is evaluated for structural data. Second, an in vivo, time-0 canine study of 20 versus 100 p.s.i. sustained pressurization evaluated systemic and local toxicity, cement penetration, mechanical strength of the bone/cement composite, and an evaluation of weightbearing after total knee replacement.

Preliminary Results—Results of the in vitro structural and mechanical testing show a trend toward increasing stiffness at 100 p.s.i.. Load deformation and energy absorbed were not significantly different.

Results of the in vivo investigation show
that in this model there was no evidence of increased systemic toxicity with increased pressure. No significant difference was found for any of the measured cardiovascular parameters. There was no demonstrable hypotension or hypoxemia. Monomer blood levels were not significant, and fat droplet counts were low and unrelated to pressure. A transient change in one animal was later explained when postoperative X-rays demonstrated cement leakage around the medullary plug and filling of the unprepared diaphyseal canal. Histology for bone quality assessment, cement penetration, vascular disruption, osteonecrosis, and interface morphology is in progress. Microradiographs suggest increased filling of peripherally penetrated voids, greater osteonecrosis of the en tombed trabeculae, and increased devascularization at 100 p.s.i. This, with the early histology results, suggest a possibility of local toxicity, but it is too early to state whether this will be significant or have long-term effects.

A separate study has just been concluded investigating push-out and fatigue studies of the bone/cement interface using cross-sectional bone slices. No significant differences were found between pressures of 20 and 60 p.s.i.; however, proximal bone slices had a significantly greater interface shear strength than did distal slices. No significant difference was found for interface fatigue strengths.

Future Plans—Currently, plans for the project include the completion of the in vitro mechanical testing and the outstanding histology. Projected plans include a long-term loosening study of sustained pressurized cement. The canine model proved successful in the time-0 study; therefore, total knee arthroplasties are planned on mongrel canines with studies at 3-, 6-, and 12-month intervals. The pressure to be used will be derived from the time-0 study after all data have been evaluated.

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 resulting from failed prostheses.

Progress—Methods and materials to promote bone ingrowth into porous implants were investigated by immediate, short- and long-term (6-month) studies in a non-weightbearing canine model. The effect of two different preparations of an autogenous ground bone graft, demineralized bone matrix, and tricalcium phosphate, were studied. The main analytical technique involved measurement of forces required to pull the implant out.

Preliminary Results—Autogenous bone graft of large particles was no more effective than the control at 6 weeks. Bone milled to a much finer and more uniform particle size had 125 percent more pullout strength at 6 weeks. Tricalcium phosphate packed around the implant produced a significant increase of fixation strength and provided as much stability as a press fit or as autograft immediately after implantation. At 6 weeks there was no significant difference between TCP augmentation and controls, but at 6 months, the TCP side was much stronger. The results with decalcified bone paste (biocement) were not significant at 2 weeks, but at 6 weeks showed a 44 percent increase in extraction force above the average control-side value and at 6 months the difference was further increased. Our conclusion is that ingrowth effects
are influenced by particle size and configuration. We also found that inorganic TCP filler enhances the immediate strength and that de-calcified bone matrix significantly increases the long-term bony fixation of porous implants in the femoral bony canal of the dog.

Segmental Bone and Joint Replacement After Tumor Resection

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Purpose—The emerging advances in adjuvant therapies for malignant bone and soft tissue tumors and the introduction of a surgical staging system to rationalize the extent and margin of tissue resection have renewed the interest in limb-saving procedures. The use of prosthetic implants based on the most advanced biomechanical design concepts and new implant materials appears to be very promising, not only to provide useful limb function for curable cancer patients but also as a palliative treatment to benefit those with metastatic lesions.

Progress—Two systems of metallic tumor prostheses were developed, but our clinical and laboratory results have demonstrated significant residual problems associated with these devices. Therefore, the currently proposed renewal is to achieve the following specific aims: 1) to develop a new nonporous coated modular tumor prosthetic system; 2) to modify the previous porous-coated modular prosthetic system and to examine the efficacy of extracortical fixation through bony ingrowth; 3) to investigate the adjuvant therapy effects on tissue incorporation into the porous implant; 4) to develop a method to attach soft tissue to the prosthesis; 5) to correlate patients' clinical assessment results with their biomechanical functional evaluation results; and 6) to develop booklets for better patient home care and to write instructional manuals describing surgical techniques involving these prostheses. Bone geometric study and theoretical and experimental stress analyses will be performed to optimize the design of the modular systems. Dogs will be used as the models to investigate the biological, functional, and adjuvant therapy effects on prosthesis fixation through radiographic, histologic, and biomechanical analyses of the specimens. Established objective functional evaluation methods and techniques will be used to study the patient's functions and to correlate them with the clinical assessment criteria proposed by Dr. W. Enneking.

Future Plans—We plan to initiate a multi-institutional trial program after the new prosthetic systems are developed and tested. The long-term objective is to perfect two segmental bone/joint prosthetic systems that can be safely used on the majority of the patients with resectable primary tumors for restoration of function and on those with metastatic lesions for palliative purposes.

Weight Distribution in the Foot Before and After Surgical and Orthotic Intervention for Hallux Rigidus

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Sponsor: Langer Biomechanics, Inc.

Progress—Hallux valgus deformity with limited motion and pain in the first metatarsophalangeal joint is associated with abnormal weight distribution through the foot in ambulation. A common treatment modality for this condition is the Keller surgical procedure with
a total implant and the use of a functional posted foot orthosis postoperatively.

The goal of our study is to evaluate the efficacy of both the surgical technique and the functional posted foot orthosis in improving the biomechanics of the pathological foot in ambulation. We will measure the parameters characterizing the development of weight distribution patterns in the foot within the environment of the shoe, using the electrodynogram. Our subjects will be patients who have been scheduled for the Keller procedure with a total implant at the Hines VA Hospital. We will complete the study over 12 months both pre- and postoperatively as well as with and without the orthosis after surgery.

Orthopedic Implant Retrieval and Analysis

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Purpose—The implant retrieval and analysis research program continues to collect orthopaedic hardware from VA-affiliated medical centers. To date 6,233 patients’ records have been accumulated. During 1985, 607 devices were inserted in patients at 3 VA-affiliated hospitals and 198 implants were removed routinely for justifiable causes.

Progress—An analysis of retrieved IM rods of the Kuntscher design based on clinical performance, metallurgical properties and corrosion characteristics was recently conducted. Dye penetrant failure showed no evidence of mid-shaft cracking in any rod; however, microstructural examination demonstrated the formation of small crevice corrosion cracks at the inside surface of the crimp in 10 of 18 rods. Increased surface corrosion was significantly correlated to inclusion content. Surface corrosion also increased with time in situ reflecting the use of inferior materials in early rods. This study also suggests that asymptomatic rods not routinely removed are likely to be removed later for implant related complications.

The clinical and metallurgical performance of five fractured total hip stems has also been recently investigated to determine the mode of failure. Fatigue failure occurred in the cast cobalt-chromium-molybdenum hip stems after an average time of 7 years. Moderate to severe levels of gas porosities, interdendritic shrinkages and nonmetallic inclusions may have contributed to the failure of the device.

Results—Improper placement and material selection were the factors in the failure of fractured cast stainless steel unicompont knee component evaluated. Due to posterior placement, only the anterior portion of the device was loadbearing, causing the distal portion of the device to be in tension. These tensile stresses coupled with observed carbides, inhomogenous grain size, nonmetallic inclusions and wear patterns lead to crack initiation and propagation and ultimately mechanical failure.

The Mechanical Properties of Porous-Coated Orthopaedic Alloy

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Purpose—This application of a porous-coating to a solid substrate offers advantages over current methods of implant fixation. However, fabrication of these devices commonly requires a sintering heat treatment which causes a significant decrease in mechanical properties. Sintering Ti-6A1-4V alloy above the beta transus (992 degrees C) transforms the equiaxed microstruc-
ture, recommended for surgical implants, to a lamellar alpha-beta structure, which exhibits a significantly reduced fatigue strength.

Progress—In our studies to date, uncoated Ti-6Al-4V alloy having an equiaxed microstructure was found to have an endurance limit of 605 MPa. Both uncoated and coated samples were also examined after being subjected to a sintering heat treatment to produce a lamellar structure. The uncoated substrates displayed a 34 percent reduction in endurance limit and the porous-coated samples showed a large 77 percent decrease.

In an attempt to improve the mechanical properties of Ti-6Al-4V alloy, two different post-sintering heat treatments were used to produce microstructures different from the lamellar structure. The resulting microstructures were a fine and a coarse acicular. Mechanical properties such as yield strength, ultimate tensile strength, percent elongation, and hardness were determined from tensile tests performed on these two microstructures as well as the lamellar and 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 hardness value of 32.90 R_c. The lamellar structure and both the acicular structures displayed comparable ultimate tensile strengths (~950 MPa) and hardness values (~26.86 R_c). The acicular structures showed slightly lower yield strengths (~735 MPa) than the lamellar structure (~825 MPa).

The most significant result was in the percent elongation. Both acicular structures exhibited greater elongation than the lamellar structure. The value for the fine acicular microstructure (9.8 percent) was statistically higher than for the lamellar (5.1 percent) and coarse acicular (6.6 percent) structures.

Results—In the present study, fatigue tests were performed on uncoated and coated specimens subjected to the two post-sintering heat treatments to produce the acicular microstructures. The results were compared to those previously obtained for the uncoated samples having the equiaxed structure and for the coated and uncoated samples having the lamellar structure. The endurance limit was found to be approximately 500 MPa for the uncoated fine acicular substrate and approximately 485 MPa for the uncoated coarse acicular substrate. This demonstrates a 25 percent increase for the coarse acicular structure when compared to the endurance limit of the lamellar structure. The porous-coated specimens for both acicular structures displayed similar results which exhibited an 18 percent improvement over the results obtained for the porous-coated lamellar specimens.

Based on the results of this investigation, it can be concluded that variations in mechanical properties occur due to microstructural changes. An improvement in resistance to crack initiation and propagation was observed for the microstructures produced by the two post-sintering heat treatments.
B. Hip

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

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Purpose—With the advent of new acetabular cup designs and techniques for implantation, researchers hope to improve the overall performance of total hip arthroplasty. Historically, little objective experimental information is available concerning the effect of implantation of these devices on the stresses and strains developed in the human pelvis.

Using strain-gauge instrumentation, this long-term investigation quantifies the effect of available prosthetic components on the strains in the cadaver hemipelvis. Pelvic strain changes following implantation may predict the long-term success or failure of arthroplasties of the hip by delineating those implant designs or techniques that do not significantly alter the normal strain distribution of the pelvis.

Progress—Initial work has led to the development of an automated computerized data acquisition system and customized loading fixtures. This novel instrumentation allows for the simultaneous application of prosthesis loading and simulated muscle pull to allow assessment of surgical techniques and cup designs on pelvic strain during the simulation of single-limb stance.

In the early stages of this research endeavor, implantation techniques were carefully considered. More recently, the evaluation of cup designs has given rise to considerable information concerning the effect of implant rigidity on pelvic strain. Our most recent results would indicate that the compliant standard polyethylene components tend to increase the pelvic strains considerably, whereas thick walled cobalt-chrome metal-backed components actually unload or stress-protect the cadaver hemipelvis. Over the past year, titanium metal-backed components and thin-shelled cobalt-chrome metal-backed components with spacers have been evaluated. These more intermediate compliance components result in only small changes to acetabular strain.

Thus, it would appear, that strain changes in the pelvis may be controlled with implant compliance. This information, coupled with early clinical results obtained from utilization of these implant designs, should allow for determination of the design and methods that will lead to minimal strain changes and therefore improvement in the longevity of total hip arthroplasties.

Design Analysis of Porous-Ingrowth Hip Replacement

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Purpose—Cementless fixation of artificial joint components is one of the most potentially rewarding areas of research in orthopaedic research today.

It is well recognized that loosening is the major clinical problem associated with cemented total-joint components. Loosening occurs much more frequently, and sooner, with active
Total Joint Replacement and Other Orthopaedic Implants

young individuals. Much evidence suggests that loosening is either directly or indirectly related to the use of acrylic bone cement as a grouting agent to secure the implants in the bone. If total joint arthroplasty is to be improved and to be extended to younger, more active patients, it is likely that new prosthesis designs that incorporate porous-ingrowth technology will play a major role.

Ingrowth of the bone into the surface of the implant will result in a very firm fixation and often a continuous, intimate interface that is efficient for stress transfer. However, if such an interface is achieved with current prosthesis designs, the stress fields in the surrounding bone tissue can be radically changed from those in the normal skeleton. In animals, this condition has led to severe remodeling that eventually led to implant failure. More advanced designs are needed that would avoid failures of this type while taking advantage of the potential long service life the porous-ingrowth technique is believed to offer.

The ability to predict the response of cancellous bone to applied stress is critical to the evaluation of porous-ingrowth prosthesis designs. If the bone response to implantation of a new prosthesis can be accurately predicted, the reliability of porous-ingrowth joint prostheses will be greatly improved, and the time required for design and testing of new design concepts could be dramatically reduced.

Progress—Two-dimensional studies of the normal and prosthetically replaced hip joint have been conducted using nonlinear sliding interface elements at the joint surface. The findings of the normal hip study showed the sensitivity of hip contact pressures and stresses to imposed boundary conditions and indicated that care should be taken to simulate anatomical conditions in experimental and theoretical studies. The study of porous-ingrowth acetabular cups, among other findings, indicated that addition of a flange to the component might result in an improved design.

Three-dimensional studies of an idealized normal femoral head and neck, and of several idealized prosthesis designs using sliding interfaces at the juncture of the bone and metal, have been used successfully to predict the response of cancellous bone to loading. The results of these two- and three-dimensional studies are very encouraging.

Future Plans—More accurate models, incorporating the improvements suggested by the results of these studies, are now under development for future evaluation.

Skeletal Aging and Disease in Failure of Hip Surface Replacement

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Purpose—Surface Replacement Hip Arthroplasty (SRHA), in comparison to conventional Total Hip Arthroplasty (THA), has the advantages of replacing the diseased hip surface while preserving normal bone stock, maintaining more normal physiological bone loading patterns, providing an easier method for replacement of failed implants, and decreasing the occurrence of deep infection in the femur subsequent to surgery. However, these advantages have been offset in clinical practice 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
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(age/disease-related) initial bone strength; and 4) bone remodeling due to stress redistribution, related either to prosthesis design or to processes of aging and disease.

Preliminary Results—The data obtained from this study will be used to determine the viability of SRHA and, if possible, to design improved components and techniques. The major accomplishments for this study to date are:

1) Three-dimensional mapping of the local trabecular bone mechanical compressive strengths of the femoral head has been completed. The regions of high compressive strength were similar for both healthy and diseased bone and were located in the superior medial portions of the femoral head. The anterior half of the femoral head had a slightly larger compressive strength than the posterior half. A paper with additional information will be submitted for publication to the VA Journal of Rehabilitation Research and Development (JRRD).

2) To assist with the speed and accuracy of histological specimen analysis, a computerized digitization program has been developed.

3) A presentation entitled “Increased Endosteal Bone Loss After Hip Arthroplasty” was given at the 1986 Orthopedic Research Society meeting. The results of this study will be submitted to the JRRD.

4) A preliminary study has been completed for radioisotope-based determination of femoral head vascularity in SRHA patients. Technetium-99m (T-99m) HDP- and MDP-based bone-scanning and tissue-scintillation-counting techniques were applied to canines subjected to mock SRHA surgery 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 acutely inhibited blood flow and reduced vascularity by 30 to 70 percent in the surface bone of the femoral head. This study is currently being completed and will be submitted for publication to the JRRD.

In addition to the canine studies, the femoral heads and failed prostheses from two consenting SRHA patients were retrieved and analyzed. Both patients had intact femoral and failed acetabular components. Immediately after a normal bone scan, the femoral heads and prostheses were surgically removed, the bone was separated from the prostheses, scanned, and the scintillation counts were compared. The results of these analyses showed that no appreciable differences existed between the proximal and distal portions of the femoral heads after a failure of the SRHA acetabular components. Histological analyses of these acetabular specimens are currently underway.

5) A preliminary study has been initiated to correlate remodeling of bone with prosthesis materials and design. Test cylinders of either porous or smooth cobalt-chrome, titanium, and hydroxyapatite are being implanted into the iliac crests of consenting bilateral total hip patients. After 6 to 8 weeks, these test cylinders are removed with a small portion of attached bone for histomorphometrical analysis of the bone-implant interface.

6) A pilot implant-retrieval study has been initiated to help determine the long-term changes that occur in total joint replacement components and adjacent tissues. The information obtained should be of considerable value in the design of improved prostheses.

Future Plans—Principal project activities for the next few months will include continued collection and processing of specimens and analysis of data for relationships between prosthetic design and bone remodeling. Whenever possible, SRHA patients who suffer from failed prostheses and are scheduled for hip replacement surgery will undergo both histological and scanning analysis. Efforts will be continued to increase the size and effectiveness of the implant-retrieval program to provide more specimens for study.
Photoelastic Investigation of Hip Replacements

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Sponsor: The Department of Mechanical Engineering, Queen's University, Belfast, Northern Ireland

Purpose—The effects of forces on models of hip replacements are being investigated by means of photoelasticity. Preliminary studies of the effects of stem cross-sectional profile on bone cement have been reported. The effects of medio-lateral rotation on stresses in an artificial hip have also been reported. Further investigation is being undertaken on the stresses at the bone/cement and the cement/stem interfaces, using photoelastic analysis.

A New Method of Hip Function Assessment

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Sponsor: University of Strathclyde

Progress—It is difficult to measure the success of total joint replacement in restoring function to the arthritic hip. A number of clinical rating scales have been proposed, including the Harris system, but these methods are subjective and intuitive in nature. In order to overcome some of these objections, a new portable microcomputer-based system has been developed and used in a clinical environment to evaluate the hip joint function of total hip replacement patients. Flexion/extension angles are measured for each hip and knee using four flexible electrogoniometers. The temporal parameters of gait are recorded using foot switches, and supportive forces are measured using instrumented walking aids. The instruments are linked to the microcomputer using a long trailing cable.

Preliminary Results—The results showed that provided there are no major postoperative complications or pain, 60 percent of normal hip motion is restored 6 weeks postoperatively. This improvement continues with typically 75 percent of normal motion being obtained after 6 months and 80 percent after 12 months. There is a decrease in compensatory movements leading to an increase in walking velocity, step symmetry, and efficiency.

Comparisons have been made between these results and the Harris index and full biomechanical analyses, and it is suggested that the system provides a more accurate assessment of hip function than conventional clinical indices.

Future Plans—Future work will involve a full-scale clinical trial. Sixty patients will be examined prior to and at intervals following surgery, and the clinical significance of the results will be determined.

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 that is positioned in the vi-
cinity of the prosthesis tip, thus eliminating the need for internal batteries or connecting cables. This is a collaborative effort involving the Research Service of the Wadsworth VA Medical Center, the UCLA Division of Orthopaedics/Biomechanics Research Section, and the Jet Propulsion Laboratory (JPL).

**Progress**—Since the last report, the contracts and funding for the program have expired. The following represents the items that have been completed:

Of the original six partially machined prosthesis housings, two have been completed and instrumented with the full complement of strain gauges and electronic assemblies. One additional unit is fully strain gauged but has not been fitted with the electronic subassemblies. Four additional sets of electronic subassemblies have been manufactured and tested under accelerated life testing but have not been incorporated into the prosthesis housings. These completed devices as well as the power induction system, the electronic receiver/antenna system and additional subassemblies have been delivered by JPL. Failure of a single gauge element was detected during final electronic testing of one of the fully instrumented devices. The cause of the failure has not been determined, but it is believed to be irreparable. This unit will be used for mechanical in vitro tests and development of the data-processing aspects of the program.

**Future Plans**—Several tasks remain to be completed. The two functional units will be loaded mechanically to ensure sufficient gauge sensitivity and to perform direct mechanical calibration of the output. Depending on the outcome of the tests, these units may be returned to JPL for modification of the internal gain settings to maximize the signal-to-noise ratio. Next, the femoral cap will be E-beam welded to the units, and the hermeticity of the units verified. Final machining will be conducted on these units and the integrity of the electronics verified. The unit with a single channel failure will be subjected to a mechanical test program under a variety of loading conditions that will be used for development of the data recovery aspects of the program. Upon completion of these tasks and in the absence of significant problems, all data will be submitted to the appropriate Human Use Committees for approval for in vivo implantation of the fully functional device.

### C. Knee

**Investigation of a Simplified Internal Knee Prosthesis**

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**Sponsor:** VA Rehabilitation Research and Development Service

**Purpose**—This study proceeded on a number of fronts to facilitate the design and evaluation of a Press-fit total knee. The data were applied to a design that was produced in limited quantity by a major manufacturer and tested clinically in patients under an IRB procedure. Lack of FDA approval has prevented further clinical expansion at this time, but this has been planned.

**Progress**—Seventeen Press-fit uncemented total knee replacements were reviewed at 6 months to 2 years to determine if this was a viable alternative to conventionally cemented total knee replacement. Indications for the procedure were youth, postsepsis, requiring bone graft, and overweight and/or high-demand patients. Results showed good pain relief and independent ambulation at 3 months postopera-
tive with an average range of motion of (-) 0.7 degree extension (0 degree to -5 degrees) and 100 degrees flexion (80 degrees to 117 degrees). There were no significant complications. Conclusions are that there are no important differences between Press-fit and cemented knee arthroplasty regarding pain relief, time on crutches, function, blood loss, or operating time.

Optimum Design—Since the time of the clinical evaluations, the design of the prosthesis has been refined.

In the design of condylar surfaces for TKR, there are several conflicting requirements. Normal knee motion involves 15 degrees of tibial rotation and 8 mm of rollback, from 0 to 120 degrees flexion; about any position, there is 20 to 30 degrees and 5 to 10 mm of laxity; uncertainty of component placement at surgery might require additional laxity. These factors suggest that low-constraint tibial surfaces are needed. One advantage is the low shear and torque forces transmitted to the interface. However, the surfaces will be more unstable than normal, placing undue reliance on the remaining soft tissues. Low conformity gives high contact stresses on the plastic, which could lead to catastrophic material breakdown in the long term. We measured contact stresses of current TKRs. We then computer-generated tibial surfaces with different motion-laxity-stability criteria and calculated the contact stresses in an attempt to determine the most acceptable geometry from all aspects.

The contact area and stresses in current TKRs were determined at 0 degrees and 60 degrees flexion by placing Fujifilm between the surfaces and loading to 1500 N. The prostheses evaluated were Cloutier, I-B, RMC, PCA, Kinematic Condylar, Kin Total Condylar, and Microlok.

The starting point was to determine average femoral surface geometry by slicing 23 knees and 25 sections, digitizing, and averaging. The surfaces were represented by a piecewise mathematical analog of spherical, toroidal, and conical surfaces. Average knee motion was determined by flexing and extending 23 knees dynamically under quadriceps action. Interior-exterior rotation and anterior-posterior displacement were expressed as a function of flexion: \( Y = BX + CX^2 + DX^3 \) (\( X \) = flexion). Equations for laxity curves of intact knees, were similarly expressed. To reproduce laxity with the TKR, the criterion was that the surfaces alone would provide the same laxity curves as the intact knee. The theory was based on energy considerations. For example, for a-p motion, the laxity equation was \( S = f(X) \). The motion of the femur on the tibial surface is given by \( Y = \frac{1}{p} \int f(X).dx \). (\( S \) = shearforce or torque, \( X \) = horizontal displacement or rotation, \( p \) = compressive load). This equation defined the vertical height of the femoral surface as a function of a-p displacement Similar equations were derived for interior-exterior rotation and medial-lateral displacement. The expressions were obtained for all flexion angles. To generate a tibial surface, the femoral surface was moved in the computer through a prescribed path of motion and/or laxity in multiple discrete steps. A horizontal gridwork was defined on the tibial surface, and the lowest Y-values at each node were collected to define the tibial surface. The femur was then placed through its original motion path. The contact points were determined, and the local radii of curvature along a-p and m-l axes calculated. Using elasticity theory, the contact areas and maximum compressive stresses were calculated (\( E_{\text{plastic}} = 600 \text{ MPa} \)).

Results—The maximum compressive stresses (1.5 x average) for total joints exceeded the maximum strength (15 MPa) by 3 to 7 times in flexion. Even in extension, with more conformity, the values were from 1.9 to 6 times. The high stresses occurred even for “line-contact” of a cylinder on a flat. The computer-generated tibial surfaces gave a range of stresses depending on the input motion and laxity. The least stresses occurred when the femoral component was moved uniaxially—a maximally constrained condylar knee. A cylinder-on-flat gave moderately high stresses on lateral and medial sides. The highest stresses were with the biconvex femoral condyles on a flat surface. For a laxity-only surface, stresses in the full range were moderate. For average knee motion, the lateral stresses were high due to the flat “roll-
back” area. With average knee motion and laxity combined, the stresses were similar to average knee motion. Halving the anterior-posterior motion and interior-exterior rotation, and making the laxity twice as stiff as normal, resulted in moderate stresses.

All geometrics produced stresses that were higher than the compressive strength of the plastic. Geometries that allow free anterior-posterior motion by flat tibial surfaces have both high stresses and excessive laxity. For uniaxial motion, the stresses were much lower, but at the expense of laxity. “Laxity only” surfaces gave only slightly higher stresses. A reasonable compromise was to reduce the freedom of motion in anterior-posterior and rotation as prescribed by normal knee motion and instead to build in this motion in the form of laxity, which resulted in more curved surfaces with reduced stresses.

Stiffness and Porosity of Cancellous Bone from Total Knee Patients

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Purpose—This project is a continuation of a project originally funded by the Multipurpose Arthritis Center of Northwestern University. The objective was to measure the stiffness of cancellous bone plugs taken from patients undergoing total joint replacement and to compare this with published values for normals.

Progress—During the current report period, several additional specimens were tested, bringing the total to 132 specimens, and the data analyzed. For each specimen, Young’s Modulus, ultimate stress, and area fraction of bone were measured. Patient age, sex, weight, disease, and joint deformity were recorded as well. Careful statistical analysis showed no correlation of area fraction with any of the recorded variables. Stiffness and strength were highly correlated, with a significant difference between osteoarthritic and rheumatoid bone. Stiffness of all of the patient bone was either equal to or less than normal bone stiffness, except that bone from the lateral side of valgus knees was above normal. These data are still being analyzed, and a paper reporting the results is being prepared.

Synatomic Knee Clinical Investigation

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Purpose—This project is designed to obtain sufficient clinical data for a premarket approval application to the FDA for approval of the Synatomic Knee Porous Coated Noncemented Replacement. The sponsor has approval to admit up to 200 subjects into this clinical investigation, with 120 subjects entered at this date. It is expected that a study population of 500 subjects will be required for sufficient clinical data to meet the goal of this project.

Progress—It is believed from the data compiled from the 120 cases entered into the clinical investigation to date that the porocoat synatomic knee appears to be a safe and effective prosthesis when utilized under the guidelines set forth in the study protocol. The risks associated with this device appear to be no greater than those risks associated with a cemented knee arthroplasty.
Design Concepts for a Porous-Ingrowth, Prosthetic Tibial Component

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Purpose—In 1976 it is estimated that 40,000 total knee replacements were performed in the United States alone. With improvement in designs and techniques, it can only be estimated that many more replacements are being performed today. In spite of this fact, the rate of long-term success, especially in young, active patients, is alarmingly low. The most frequent cause of failure is tibial component loosening. Most evidence points to the fact that loosening is either directly or indirectly related to the use of polymethylmethacrylate cement as a grouting agent to secure the implant to the bone.

Progress—In recent years much effort has gone into research aimed at developing techniques and designs that would eliminate the use of acrylic bone cement. It is now being recognized that cementless fixation (e.g. using porous ingrowth technology) of artificial joint components is one of the most challenging and potentially rewarding areas of research in orthopaedic surgery today. In spite of this, there is a paucity of studies which carefully and critically assess various cementless, prosthetic designs in a quantitative manner. Our goals are to evaluate present tibial component designs and to make modifications resulting in new designs having improved expected lifetimes.

Since total joint replacement primarily affects the aged, it is important to note that there are presently about 5 million veterans of age 65 and older. It is estimated that by the year 1990 more than half of all American men of age 65 and over will be veterans. From these statistics it is clear that the veteran population will be a significant beneficiary of improvements in total joint design.

A technique that has been immensely successful in recent years in the design process of prosthetic joint components is the Finite Element Method (FEM). The FEM for both allows the bone and the prosthesis to be modeled mathematically and enables the designer to compare different designs quantitatively. Stress distributions within the bone surrounding the prosthesis can easily be compared to the stress distributions which exist within the normal joint. Areas of bone which are likely to fail can be pointed out and designs can be modified in order to alleviate these potential failures.

It is believed that the optimum prosthetic design is one in which the internal bone stresses are distributed similarly to those in the non-prosthetic joint. When such designs are used, extensive bone remodeling can be avoided, resulting in improved expected lifetimes.

Results—Cadaver tibiae are sliced in order to obtain bone geometry and material properties. A finite element mesh is then generated and anatomic loading and boundary conditions are applied. Both frontal and sagittal plane models are created. The results of the anatomic or non-prosthetic tibia are compared with a number of different prosthetic designs. Several types of finite element models are going to be studied, including: two-dimensional equivalent thickness models, two-dimensional non-linear contact models, and full three-dimensional models.

Linear, two-dimensional, equivalent-thickness models have been completed.

Results indicate that conventional prosthetic designs with large posts or multiple pegs lead to non-physiologic stress distributions which predispose the implant/bone interface to failure. A new implant whose design is based upon the internal architecture of the tibia presents a more benign stress distribution implying less extensive bone remodeling. Non-linear models are now under development to see if this new design also performs better in the immediate post-operative stage (before bony ingrowth occurs) when the effects of the lack of a grouting agent will be most pronounced.
D. Other

Evaluation of Elbow Joint Function Post-Elbow Joint Arthroplasty

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Sponsor: The Arthritis and Rheumatism Council

Purpose—Improvement of function is of primary concern in the treatment of the rheumatoid elbow joint by surgical means. In 1977 the first Souter-Strathclyde elbow joint replacement was inserted into a patient. To date 135 prostheses have been implanted, and of the groups assessed for a period of 2 to 5 years the postoperative results have been encouraging. However, it has been recognized that present clinical methods of evaluating the success of the arthroplasty postoperatively do not measure the overall performance of the elbow joint as an objective measurement of what the patient actually does in his own home or work.

Progress—A system to investigate elbow joint usage while the subject is unsupervised in his own environment has been developed. The system involves fitting both elbows of the subject with strain-gauge electrogoniometers and collecting the data in a portable cassette recorder for later evaluation.

Preliminary Results—Results from preliminary investigations on 15 observed subjects performing selected functional activities including dressing, reading, and domestic tasks showed that individual activities could not be identified by individual patterns of motion obtained from the recording of the subject. On subsequent longer tests on unsupervised subjects it was found that elbow joint function could be defined in terms of: 1) patterns of motion; 2) range of movement; 3) amplitude of motion; 4) frequency of motion; and 5) summation of motion.

Further methods of analyzing the data are presently being investigated.

Future Plans—Over the next 3 years the above system will be used in an investigation of the postoperative performance of the elbow joint following insertion of the Souter-Strathclyde elbow prosthesis. Patients will be monitored prior to their joint replacement and then postoperatively at 1-, 3-, 6-, and 12-month intervals. To overcome day to day variability, three separate recordings will be made at each interval. Each patient will be fitted with the equipment in the morning of the test and at their own homes. The recorder will run continuously until the following morning, when the researcher will again visit the patient’s home and either refit the equipment for a further recording or collect the equipment. A control group will be set up similar in age, sex, occupation, and in other characteristics.

As a result of the intended investigation, it is hoped that the following information will be provided: 1) the frequency, motion type and range of movement of the elbow joint utilized by patients suffering from rheumatoid arthritis of the elbow prior to surgical replacement of the diseased joint; 2) the corresponding information relating to the elbow joint postoperatively following surgical replacement; 3) the progress of joint performance measure in this way at regular intervals postoperatively; and 4) a comparison of patient elbow function with that of normal individuals.
Stress Analysis for the Normal and Prosthetic Shoulder

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**Purpose**—For patients with arthritis and other crippling diseases, the total joint replacement has become a standard procedure to relieve pain and increase mobility. A new area of orthopaedics is the use of porous-coated prosthesis to secure the implant in the surrounding bone. The successful ingrowth of bone into the implant surface could result in firm fixation and a continuous interface which would be efficient in stress transfer. The two important aspects in using these devices are the initial control of the bony ingrowth, and the effects of bone remodeling due to changes in the stress fields.

It is important to achieve implant stability over a range of loading conditions, and to avoid shear and tensile loading at the prosthesis/bone interface. The stress fields in the surrounding bone tissue can be radically changed from those in the normal skeleton upon the implantation of a device which allows porous-ingrowth components. This has resulted in extreme bone remodelling and eventual implant failure in experimental animal models. Bone remodels to the extent that it can no longer support the implant. The supporting bone fractures and the interface bonding is destroyed.

Because of the importance of bone remodeling with the use of porous-ingrowth implants, the question has arisen of where to apply the porous coating so as to achieve its theoretical potential benefits.

The purpose of this study is to more fully understand the biomechanics of the shoulder joint and to analyze various prosthetic designs. Although there have been few reported clinical problems on the humerus surface, long-term results are not in. On the glenoid surface, there have been several cases of clinical loosening, and evidence (shown by a large number of radiolucent lines on X-rays) that loosening may become a serious problem in the future of total shoulder arthroplasty. Determining the underlying concepts behind an optimum design could lead to the shoulder replacement procedure being performed more often, lasting longer, and having little need for revision surgery.

In the approach adopted, cadaver humera and scapulae are sliced in order to obtain bone geometry and material properties. A finite element mesh is generated and anatomic loading and boundary conditions are applied to the model. The results of the anatomic humerus and glenoid are compared with a number of different prosthetic designs. Several types of finite element models can be used: plane stress, equivalent thickness, axisymmetric and nonlinear contact, and three-dimensional analysis.

**Progress**—Finite element analyses have been performed on both the humerus and the glenoid. The humerus model was analyzed using both a plane stress model and an equivalent thickness model. The principal stresses and von Mises' stress contours were determined for the normal humerus, and for three different prosthetic humeral head designs. Each prosthetic design was modeled to have a totally porous-coated surface, and a surface which was porous-coated underneath the femoral head. Three loading cases were used for each model.

The stresses in the bone at the prosthesis/bone interface were examined underneath the humeral head to determine which prosthetic design resulted in principal stresses at the interface, with the minimum of shear stresses. The glenoid side was modeled using a uniform thickness and plane stress analysis (a uniform thickness model was not appropriate for the glenoid side). Various design parameters were examined for the prosthetic models, including flange design, metal-backing of components, and superior constrained designs. A continuous, rigid prosthesis/bone interface which would be achieved by bony-ingrowth devices was assumed. Principal stresses and maximum normal stress contours were determined for
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Design of a Two-Component Finger Prosthesis

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—Approximately six percent of the population suffers from the disabling effects of arthritis of the hand. Rheumatoid arthritis accounts for the overwhelming majority of these cases. Destruction of the ligamentous structure and surrounding soft tissue and erosion of the articular surfaces cause pain and loss of function. Disruption of the delicate balance between the active muscle forces and the passive restraining forces of the soft tissues and articular surfaces results in eventual deformity.

The goal of this project is to design and develop a two-component metacarpophalangeal (MCP) prosthesis which restores function and strength to the joint. The MCP joint is considered the master joint of the hand and has been the focus for the majority of research efforts.

Finger implants have undergone three significant developments. The first prosthesis implanted was a double-stemmed metallic hinge. Although overall hand function improved initially, overconstrained joint rotation caused stem fractures and stem migration. As opposed to the first designs which were highly constrained, the second generation of prostheses functioned more as soft, flexible spacers. These have performed well in correcting deformity and eliminating pain, but they are incapable of returning the finger joint to full range of motion and strength. The impressive successes of total hip replacements have launched the current third generation of designs. We believe that a properly designed two-component system offers the best chance for success.

A reliable finger implant must address the problems of stem fixation, joint stability, and joint range-of-motion. We hypothesize that these criteria are best met with a two-component system that incorporates a more anatomical articulating surface geometry with bone or fibrous tissue ingrowth for stem fixation.

Progress—We have developed the capability to fabricate precision prototypes and we are currently concentrating on several articular surface geometry configurations. These will be implanted into cadavers to test for adequate range of motion and stability.

Design ideas for stem fixation are proceeding independently, and will eventually be combined with the appropriate articular surface for additional cadaver experiments.

Future Plans—The development of the finger prosthesis has been divided into five stages. Stage I involves the design and development of prototypes. Implantations of prostheses into cadavers in Stage II will overlap with Stage I to insure functional designs. These designs will be mechanically tested and compared to existing commercial implants in Stage III. Successful units will then be implanted into rabbit knees (Stage IV). If we achieve our expected results, we will initiate human implant studies in Stage V.