III. Total Joint Replacement and Other Orthopedic Implants

A. General

B. Hip

C. Knee
III. Total Joint Replacement and Other Orthopedic Implants

A. General

Absorbable Fixation Devices: Orthopaedic and Reconstructive Surgery (Pilot Study)

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Sponsor: VA Rehabilitation Research and Development Service (Pilot Proposal #A940-PA)

Purpose—The goal of this pilot study is to demonstrate that recent advances in polymer sciences, glass science, composite fabrication and biomechanics can be synthesized into a process for the manufacture of functional absorbable fixation devices. In addition, the effectiveness of the devices for the stabilization of osteotomies will be demonstrated in animal studies.

Absorbable fixation devices could replace a large portion of the metal devices which are now in use and which must often be removed for cause (e.g., stress shielding osteopenia, late infection, etc.). The absorbable device would dissolve slowly after healing of the lesions thus obviating the removal operation. The material for the implant will be a composite consisting of a polylactic acid (PLA) polymer matrix stiffened with 15 μm fibers of a phosphate glass called Metaglass (metabolizable glass). The Metaglass has better stiffness and dissolution behavior than the Ca metaphosphate glasses used by previous investigators.

In this study, the fibers will be produced in Kg quantities and be combined with the PLA to yield composite intramedullary rods. The strength of the rods will be determined by mechanical testing and their ability to stabilize femoral osteotomies in cats will be evaluated. If this pilot study is successful, it will be followed by a request for a full scale, type I study to optimize the fabrication process, complete characterization of the materials and devices and assess long-term in vivo effects.

Determination of the Effects of Implant Interface Mechanics on Bone Remodeling

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Purpose—The relationship between bone remodeling and mechanical stresses in bone has vital implications with respect to the interaction between orthopaedic implants and bone, especially with regard to loosening of joint replacement prostheses. The objective of this study is to gain knowledge of the morphological and physiological reactions of bone in relation to mechanical stress at the interface between bone and an orthopaedic implant.

Progress—Our research is attacking 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 permanent fixation in bone, this study represents an unusual attempt to improve implant design by examining the effect of local stresses and micromotion on interfacial bone.

Preliminary Results—In the prior phase 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. At present, for physiological applications, mechanical bonding must be considered as not present. Under special circumstances, there may be direct bonding or "osseointegration" between smooth titanium and bone surfaces but further research on this possibility is required. In addition, we developed techniques applying programmed loading to the bone-implant interface and assessing results. These techniques were tested on a series of special screw implants in canine radius and mandible. Under the loading regime employed (50-110N at 1/2Hz for 500 cycles/day over 5-7 days), we found direct bone opposition to titanium surfaces in the range of 37-72 percent. Furthermore, evidence of elevated fluorescence labels in the interfacial region was clear, but no significant differences were noted between loaded and nonloaded implants on a group basis under the regime tested. At present, loading techniques are being tested further and calibrated for a sequential series of implant loadings.

Future Plans/Implications—Three types of test are planned for the grant period. In one, the same special screw implants in canine tibia will be loaded in a manner similar to the experiment already completed but under a different regime, including higher loads and allowing a greater period for remodeling events to take place prior to sacrifice. In a second experiment, direct bone bonding (osseointegration) will be examined in relation to smooth (press fit) titanium implants in canine tibia. In the third series of tests, a similar experiment will be done but selected implants will be subjected to loading to cause micro-motion at the interface.

Publications Resulting from This Research


Implant Fixation by Postinsertion Pressurization of Polymethylmethacrylate

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—The problems associated with failure of the bone-cement interface after total joint replacement are well documented. Early studies in our laboratory have shown increasing strength of this interface with sustained pressurization of PMMA up to 80 psi.

An in vitro study has just been concluded comparing sustained pressurization of PMMA at 100 psi to a regulated handpacking technique that simulates what is currently being performed clinically. The
objective was to study the biomechanical characteristics of the bone-cement interface using the canine knee model. After subchondral osteotomy, the canal was reamed, brushed, lavaged, and a cement plug was placed. One side was pressurized at 100 psi using a cannulated prosthesis designed in this laboratory, and the contralateral side was hand-packed. Specimens were sliced into eight 5-mm sections, which were then loaded and tested to failure at a deformation rate of 0.1 cm/min. Results showed that apparent strength and stiffness of the interface were 20-40 percent higher for the 100 psi side than for the handpacked side.

**Progress**—Based on the above results, we are beginning the long-term *in vivo* phase of our project. A number of modifications have been made to our constrained total knee prosthesis. The efficacy of this model has been shown in our last canine which was ambulatory with full weightbearing for 4 months following a unilateral TKR. Under general anesthesia, a TKR will be performed on one hind leg. The side and the technique (either sustained high pressure or hand packing) will be randomly assigned. The animals will be followed radiographically and will be sacrificed on a schedule of 4, 8, or 12 months. The bones will be retrieved, sliced into eight 5mm sections, and either tested to failure or used for histology.

Retired racing greyhounds will be the animal of choice, although mongrel dogs may be required. (A study is under way to look at variation of bone between greyhounds and mongrels. We are examining bone quality and density using the Hologic Excaliber Radiographic Imager, the calcium-ash percentage, and biomechanical properties of the bone.)

A study that will be completed in August 1987 is examining *in vivo* time zero canines versus *in vitro* canine knees. This study is assessing differences in penetration and biomechanical characteristics of the bone-cement interface under surgical conditions where a bone-blood barrier affects cement penetration.

Another study in the lab involves the measurement of plug migration during sustained pressurization. Four different types of plugs are used: bone, PMMA, and 2 commercial silastic plugs. Human cadaver femurs are harvested, reamed, lavaged, plugs are sized, and inserted. The bones are then pressurized at a sustained 100 psi. Plug migration is measured radiographically.

Several other projects have been completed over the last year. These include two studies done in conjunction with the Department of Radiology. The first involved a correlation of various scanning techniques (QCT, DPA) with compressive strength in human cadaver spinal bodies. The second involved scanning human cadaver femoral necks using the same techniques and the subsequent fracturing of the necks to measure biomechanical characteristics.

As deep venous thrombosis continues to be a major concern in total joint surgery, another study looked at the effects of Sodium Warfarin, a highly used anticoagulant and Vitamin K antagonist that interferes with the actions of Osteocalcinin (BGH), which is probably involved in the calcification of bone. Porous-coated devices were implanted into the distal ends of rabbit femurs. The rabbits were then placed on a regime of Sodium Warfarin, IM, until they were sacrificed at 3 and 6 weeks. The implants were then pushed out on a universal testing apparatus to determine whether the Warfarin had affected the bone ingrowth. Histology and serum BGH levels are still to be completed. A similar completed study examined three-point bending on bones from rats kept on a Warfarin regime.

A list of abstracts of presentations and publications is available from the authors.

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**The Effect of Surgical Fit on the Biological and Mechanical Response to Porous Surfaced Implants**

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Sponsor: VA Rehabilitation Research and Development Service (Project #XA136-3RZ)

**Purpose**—Ideally, a porous surfaced implant relying on bone ingrowth fixation should make initial apposition with the surrounding bone. Unfortunately, this is not always achieved surgically at all locations
and a space between the implant and bone is present. This space may be the result of deficiencies in instrumentation design, implant design or surgical technique. The gap may severely alter the type, amount, and rate at which tissue infiltrates the porous implant surface. Thus, the achievement of significant fixation strength may be delayed or ultimate attachment strength affected. A model to study the effect of such gaps on the quantity and quality of bone growth into a porous surfaced implants in both the cancellous and cortical bone regions has been developed and will be used to study these parameters including the interface attachment strength.

Implants will be constructed by threading varying diameter porous coated titanium alloy discs on a central rod. The implants will be surgically placed bilaterally in the femoral intramedullary canals of 25 adult dogs. Uniform gap spaces of 0.0, 0.25, 0.5, 1.0, and 2.0 mm in width will be produced in both the cancellous and cortical bone regions of each femur. At intervals of 4, 8, 12, 24, and 52 weeks postoperatively, 5 animals will be sacrificed and implant specimens will be mechanically tested to determine interface shear stiffness and strength of attachment. All specimens will be tested on a MTS closed-loop hydraulic system using a ramp type load below interface failure to first determine the interface shear stiffness. Subsequent loading to interface failure will then determine the ultimate strength. Intact specimens as well as those mechanically tested, will then be processed using undecalcified techniques to produce histological and microradiographic sections for microscopic evaluation. The amount of bone growth within the porous surface as well as the amount of bone filling the gaps will be quantified on all specimens using a computer aided microscopic image analysis system. The study will yield differences in the biological and mechanical characteristics between varying gap spaces in both the cortical and cancellous regions as a function of time. Differences in the tissue ingrowth characteristics in the lateral, medial, anterior, and posterior locations in the cortical and cancellous regions will also be determined.

The Mechanical Properties of Porous-Coated Orthopaedic Alloy

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Purpose—Numerous studies have shown that porous titanium and Ti-6Al-4V alloy systems provide a biocompatible interface between substrate and bone, resulting in firm implant fixation and potential long-term retention. In order to achieve an acceptable pore size for bone ingrowth, Ti-6Al-4V alloy systems often must be heat-treated above the beta transus (992° C). This transforms the as-received, equiaxed microstructure, recommended for surgical implants, to a lamellar alpha-beta distribution which has been shown to demonstrate the worst fatigue properties of the most common structures attainable in Ti-6Al-4V alloy. However, post-sintering heat treatments may be used to produce microstructures more resistant to crack initiation and propagation than the lamellar microstructure. The objective of this study was to investigate the influence of microstructural variations on the fatigue properties of uncoated and porous-coated Ti-6Al-4V alloy material through the use of post-sintering heat treatments.

Progress—Uncoated and porous-coated Ti-6Al-4V alloy fatigue specimens were subjected to a sintering heat treatment to produce a lamellar microstructure. In addition, two post-sintering heat treatments were used to produce coarse and fine acicular microstructures in uncoated and porous-coated specimens. The heat treatments were as follows: 1) lamellar: 2 hr. soak at 1300° C; slow cool; 2) coarse acicular: 2 hr. soak at 1300° C; slow cool through the beta transus; Argon quench; 4 hr. anneal (low in the alpha-beta region); Argon quench; 3) fine acicular: 2 hr. soak at 1300° C; Argon quench; 4 hr. anneal (just below the beta transus); Argon quench.

Rotating beam (reversed bending) fatigue testing was performed on the specimens using an R.R.
Moore High Speed Fatigue Testing Machine. All specimens were tested to $10^7$ cycles or to failure, whichever occurred first. As-received, equiaxed specimens were tested to provide a reference strength for the microstructures examined, as well as to study the effect of porous coating. The strengths for the porous-coated specimens were calculated using the original substrate diameter. Statistical analysis was performed, using the Probit method by obtaining sets of tests at the same stress level performed above and below an endurance limit. The percentage of specimens which survived $10^7$ cycles was plotted on probability paper versus the stress at which the samples were tested. A regression line was determined through these survival data points, and the stress at which the probability of survival was 50 percent was obtained from this line. This value was defined as the endurance limit.

The lamellar microstructure obtained from the sintering heat treatment consisted of platelike alpha in a retained beta matrix. The acicular microstructures contained alpha grain spikes in a beta matrix, with the fine acicular structure consisting of smaller alpha needles and less beta.

Results—As expected, the as-received specimens exhibited the best fatigue properties. For the uncoated-treated specimens, the lamellar specimens displayed the lowest endurance limit value, while the acicular specimens displayed the highest endurance limits and differed only slightly. The endurance limit for the fine acicular specimens showed a marked 25.4 percent increase over the lamellar specimens.

For the porous-coated specimens, stress concentration sites were introduced at the sintered areas of contact between powder particles and substrate. This notch effect caused a significant decrease in endurance limit, particularly for the lamellar specimens. Again, the acicular specimens exhibited endurance limits which differed very slightly. The endurance limit for the fine acicular specimens displayed a 15.7 percent increase over the lamellar specimens.

Future Plans/Implications—This investigation revealed that the fatigue properties of Ti-6Al-4V alloy improved as alpha grain size decreased in the heat-treated material. Reduction in the alpha grain size resulted in minimization of the mean free slip path for crack initiation and propagation. Therefore, while a porous structure strongly affects fatigue behavior, the strength of the substrate, often left uncoated on the lateral (tensile) aspect of femoral hip components, can be significantly improved by reducing alpha grain size.
average time *in situ* 4 months); the Dow Corning Wright Whiteside Knee (11 patients, 9 femoral, 10 tibial, and 3 patellar components, average patient age 65 years, average time *in situ* 13 months); and the DePuy New Jersey LCS and Synatomic Knees (4 patients, 1 femoral, 1 tibial, and 3 patellar components, average patient age 52 years, average time *in situ* 3 months).

The total hip components included specimens from: the Howmedica, Inc. PCA Hip (13 patients, 6 femoral stems, and 8 acetabular cups, average patient age 53 years, average time *in situ* 7 months); the DePuy AML Hip (7 patients, 5 femoral stems, and 4 acetabular cups, average patient age 49 years, average time *in situ* 15 months); and the Zimmer Harris-Galante Hip (3 patients, 3 femoral stems, and 1 acetabular cup, average patient age 50 years, time *in situ* 8 months); and the Implant Technology LSF Hip System (1 patient, 1 femoral stem, patient age 52 years, time *in situ* 1 month).

All retrieved components were inserted without the use of bone cement and in no case was the retrieved component removed due to clinically apparent loosening. Six knee components and one femoral stem were recovered post mortem or following amputation. The remaining 65 components were obtained following a revision surgical procedure.

The removed components, along with any adhering tissue, were immediately fixed in a 10 percent buffered formalin solution, followed by dehydration in graduated ethyl alcohol and embedded in methylmethacrylate. Undecalciﬁed histologic and corresponding microradiographic sections were then produced, with the implants in place, using diamond cutting and grinding techniques. Serial sections were cut from regions of interest with a high speed diamond saw and mounted onto acrylic slides. The sections were first ground to 100-microns thickness using a precision swivel head grinder and microradiographs were produced. The sections were further ground to 50-microns thickness and stained with toluidine blue and basic fuchsin. The sections were then qualitatively examined in transmitted and polarized light for type, degree, and distribution of tissue ingrowth.

**Results**—The histologic sections revealed varying amounts of bone growth into the porous coating, with no component having more than 10 percent of the available porous material ingrown with bone in any case. No bone ingrowth was observed in approximately one third of all the components, while in one third less than 2 percent of the available porous surface had bone ingrowth. The remaining one third of the components had between 2 and 10 percent of their porous surface containing bone. In all cases, a dense connective tissue layer separated the majority of the implant surface from the underlying bone, which often displayed marked resorption. The fibrous tissue layer varied in thickness up to approximately 2 mm; this layer was in general acellular and was of an encapsulating nature in components with little or no bone ingrowth. In components with greater bone ingrowth, the fibrous tissue orientation observed in polarized light indicated a radial orientation from the implant surface indicative of some load-transmitting ability. Fibrous tissue which contained macrophages and multinucleated foreign body giant cells, was found within the porous structure in a limited number of samples. This occurred primarily in implants with no bone ingrowth. In the knee components, bone ingrowth was found to occur only in isolated areas, most commonly around the fixation pegs on the femoral and tibial components, while rarely occurring under the tibial tray portion. However, no difference in either the incidence or amount of bone ingrowth was observed between the different components (i.e., tibial, femoral or patellar) or the different manufacturers.

Analyses of the histologic sections from the total hip components revealed similar results to knee components with respect to the incidence of bone ingrowth. Approximately one third of all hip components had no bone ingrowth, one third had less than 2 percent bone ingrowth, and one third had 2-10 percent of their available porous surface ingrown with bone. In general, greater bone ingrowth was observed in the femoral stems with little or no bone ingrowth found in the acetabular components. The exception was the Zimmer Harris/Galante cup which had approximately 8 percent of its surface ingrown with bone. This component uses adjunct screw fixation for initial stability, the greatest bone ingrowth observed in the femoral components was at the distal tip of a fully porous-coated DePuy AML femoral stem. Femoral components, in general, had the greatest bone ingrowth at the distal portion of their porous coating. The type and amount of tissue
ingrowth varied extensively among different sections from any device, and even within a single section, although most femoral stems had some medial bone ingrowth. The bone at the fibrous tissue interface often showed marked resorption with numerous areas of osteoclastic activity. This was similar to that observed in the knee components. With time, further bone resorption and an increase in fibrous layer thickness might be expected in a number of these cases. There were no vast differences in ingrowth characteristics among the different porous coating implant designs.

Future Plans/Implications—The goal of total joint replacement is the long-term restoration of pain-free function. It is evident from the results of these retrievals that extensive bone ingrowth will most likely not occur in any component; yet it appears that the combination of limited bone and fibrous tissue ingrowth is adequate for implant fixation, providing an effective means of stress transfer. The long term success of this type of biological fixation remains unknown.

The limitations of implant retrieval studies of this type are many, including limited information concerning the size and nature of the subject population, incomplete patient histories, and unknown reasons for implant removal. A significant number of postmortem specimens would obviously be desirable, since the majority of the specimens in the study were removed at revision surgery, often due to poor implant position. However, in spite of limitations, the analyses of retrieved specimens represents the best means for evaluating biological ingrowth systems and provides a mechanism for evaluating and assessing their long-term potential.

A Model to Study the Mechanical Behavior of Osteoporotic Bone

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—The loss of bone mass, and consequently, bone strength, in persons aged forty and beyond is a continuing problem to the orthopaedic community. This progressive loss has been documented by radiographs, autopsy materials, CAT scans, and single or dual photon absorptiometry. Orthopaedic problems arising from osteoporosis include fractures of the lumbar spine, distal radius, and the femoral neck. Likewise, this age group represents the fraction of the population that will require prosthetic replacement of a joint. Unfortunately, little information is available concerning the mechanical properties of osteoporotic bones and its interaction with prosthetic devices.

Nutritional secondary hyperparathyroidism (NSH) provides an excellent mode for studying the behavior of osteoporotic bone. NSH is a generalized metabolic bone disease characterized by osteopenia which may be induced by a diet which is either too low in calcium and/or too high in phosphorus. Krook et al. used such a diet in small laboratory animals and determined that early hypocalcemia was produced by low dietary calcium alone which induced hyperparathyroidism. Henrikson also reported that dietary hyperparathyroidism induced by feeding small laboratory animals a diet of 0.12 percent calcium and 1.2 percent phosphorus resulted in generalized skeletal lesions which were more accentuated in the jaws. Cook et al., using the diet of Henrikson, reported the development of an osteoporotic condition produced by NSH as histologic, histomorphometric and biochemical analysis. They reported that in situ mechanical testing indicated significant differences in the strain state for NSH and control diet animal femora. Further, the in vitro introduction of a Co-Cr-Mo alloy femoral head prosthesis was reported to significantly alter the stress state in the control and NSH femurs. However, this study was limited to a duration of 20 weeks and no mechanical or histologic data was obtained concerning the in vivo response to a prosthetic device. The objective of the current study was to investigate the long term consequences of NSH-induced osteopenia. Also the effects of porous hip endopasty implanted in vitro and in vivo were investigated.
Progress—The study involved 22 skeletally mature, colony-reared female beagles with an average age of 18 months. Twelve of the animals were placed on a low calcium/high phosphorus (experimental) diet. Ten of the animals were placed on control diets. After six weeks on their respective diets, the “control” and “experimental” animals were implanted with a porous coated hip endoprosthesis with or without bone cement. The animals were followed radiographically and blood chemistries were taken bimonthly. Parathyroid hormone (PTH) levels were determined, as were serum calcium and phosphorus levels. Soft and hard tissue biopsies were evaluated. Mechanical testing involved placement of five uniaxial strain gauges (3 medial and 2 lateral) on the femurs under fluoroscopic control to assure uniform gauge placement relative to the porous device. The most proximal medial and lateral gauges were placed at the level at which the porous coating ended. Distally medial and lateral gauges were positioned at the device tip. A final medial gauge was located one centimeter distal to the device tip. Gauges were placed at corresponding locations along both femurs and then loaded in a specially designed test fixture to 100 lbs. This loading was applied for five cycles with the specimen kept wet with saline. Following testing, the unoperated limb was prepared for hemiarthroplasty. A Richards Canine II Co-Cr-Mo alloy femoral hip prosthesis (small) was then cemented into place using polymethyl methacrylate. These femurs were then reloaded using the identical protocol as for the intact and operated femurs.

Preliminary Results—Analysis of blood chemistry levels indicated statistically significant differences between the PTH levels of the “control” and “experimental” animals. At two weeks post-diet initiation, the animals having been fed the low calcium/high phosphorus diet exhibited significantly higher PTH levels throughout the entire duration of the study. There were no differences observed between the serum phosphorus levels of the two groups. Serum calcium levels tended to decrease over time for the experimental animals, although those values were not observed to be significantly lower at each chemistry test interval. It is thus assumed from the blood test results that hyperparathyroidism resulted in the experimental animals secondary to calcium deficient diet induction.

The results of the mechanical testing indicated that there was no significant difference between the control and experimental unoperated femurs at the three-month time period. At the 4.5-month period the strains were higher in the low calcium diet animals. The strains in the 6-month animals were approximately the same as the 4.5-month animals for the unoperated limbs. Subsequent to in vitro device implantation, the strains in the femurs generally increased. This increase may be in part due to the stress rising effect of the tip of the device and the end of the porous coating. Histologically, the region between the most proximal and distal medial gauge location in the retrieved operated, femur was typically an area of bony hypertrophy. Generally, the strains were lower in the devices which had been inserted with bone cement when compared to those relying solely on the porous coating for fixation.

Ferrographic and Biochemical Analysis of Wear Particles in Human Joints

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—This project aims to investigate wear particles within human synovial fluid, both as diagnostic indicators and as participants in intra-articular pathophysiological changes.

Progress—Ferrography is being used for the former purpose, while the latter aspect is being addressed through the use of biochemical, cellular, and animal studies.

Results—Our results clearly show that the wear particles contain valuable diagnostic information, and that ferrography can be used to obtain this information. The biochemical studies have provided
good evidence for an involvement of wear particles in the pathophysiology of arthritis. We are presently investigating the molecular mechanisms through which wear particles modulate synovial metabolism. In particular, a cDNA probe to the collagenase mRNA is being employed to help investigate the way in which the particles promote the synthesis of collagenase.

Also under evaluation is the possibility that mechanisms, analogous to those we have identified as contributing to arthritic degeneration, may also be involved in the loosening of prosthetic joint replacements.

Publications Resulting from This Research


B. Hip

Design Stress Analysis of Porous Ingrowth Hip Replacements

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Purpose—The objective of this study is to develop design concepts for porous ingrowth total hip replacements based upon a knowledge of the stress fields in the hip before and after joint arthroplasty. In analyzing and interpreting results, attention will be paid to 1) consistency between the calculated stress fields and bone trabecular morphology, 2) contact areas at the joint and implant interfaces, 3) initial stability of the implants under various loading conditions, 4) the types of stresses created at the porous ingrowth surfaces, and most importantly, 5) the manner in which bone may remodel in response to the change in bone stress caused by the implant.

Progress—Anatomical specimens were sectioned, X-rayed, and photographed to document geometry, distribution of bone density, and trabecular orientations. From these sections, 2-D finite element models of the acetabulum and femur were generated. Similar models with various porous implant components were also constructed. We have developed a remodeling theory using a multi-load stress history approach which predicts the distribution of bone density in the natural and prosthetic femur. The technique is an iterative approach in which the bone is initially a solid, homogeneous structure with a constant bone density. The results are compared with normal bone anatomy and with findings from clinical studies.

Results—Our finite element results of the acetabular region have provided new insights into how stresses are transmitted from the head of the femur to the pelvis. By simulating the implantation of an acetabular cup component, we were able to reconfirm some of the design principles that have been evolving
Concerning metal backing of this component. The application of our iterative bone remodeling theory has proven to be a major benefit in trying to establish how the bone may redistribute itself after implantation of the prosthesis. Using this theory, we find that we can recreate, on the computer, the natural bone morphology of the proximal femur. Starting with a solid block of bone, the remodeling routine predicted the development of a diaphyseal cortex and the dense compressive trabecular column through the head. The dense trabecular bone corresponding to the arcuate system in the lateral superior neck was also formed.

Application of our remodeling techniques to porous ingrowth components has confirmed some of the experimental results that have been reported by others. Our computer examinations of the surface replacement component with the central peg has predicted bone remodeling that is characterized by a dense deposition of bone around the peg. Our remodeling technique has also indicated that our recently developed epiphyseal replacement prosthesis may be very well designed to avoid adverse remodeling influences after implantation. We have made prototype implants with this new design and are planning some experimental implantations.

**Future Plans**—We intend to further develop our remodeling theory and improve the computer codes which implement this theory. More extensive examinations of bone remodeling around prosthetic components will be conducted in two-dimensional as well as three-dimensional analyses. We are proceeding with the manufacture of epiphyseal replacement prosthetic components based on some of the results of our analyses.

**Publications Resulting from This Research**

- **Femoral Head Apparent Density Predicted from Bone Stresses.** Fyhrie DP and Carter DR, J Biomech, (in press).

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**Effects of Treatments for Heterotopic Bone Formation on Biological Fixation**

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**Sponsor:** VA Rehabilitation Research and Development Service (Project #XA450-R)

**Purpose**—Ectopic ossification following total hip arthroplasty is a frequently reported complication, with occurrences ranging from 1 to 62 percent. The basic process of this phenomenon involves the laying down of osteoid matrix by osteogenic-competent mesenchymal cells. This is followed by crystal deposition and ultimate mineralization of the matrix. Considerable research has manifested controversial results regarding treatment modalities for the prevention of heterotopic bone formation. Recommendations for its prevention include the use of diphosphonates, indomethacin and radiation therapy.

Diphosphonates have been shown to inhibit growth of hydroxyapatite crystals in vitro and have been thought to prevent pathological calcification in vivo.

Although widely used clinically, two investigations have concluded that the use of diphosphonates is ineffective in preventing heterotopic bone formation.

The purpose of the proposed research is to elucidate biomechanical and histological effects of drugs and radiotherapy on bone growth into porous coated Ti-6Al-4V alloy implants in canines. The study will include 50 adult beagles which will receive 4 bilateral transcutical porous coated implants. The animals will be divided into 5 groups, four of which will undergo therapeutic treatments for heterotopic ossification. Group A will serve as the control group. Group B will undergo 2 weeks of pre-operative dosages of diphosphonates, followed by 4 weeks of
post-operative treatments. Group C will undergo 4 weeks of post-operative diphosphonate therapy with no pre-operative treatments. Group D will be treated for 4 weeks post-operatively with indomethacin. Group E will undergo radiation treatments to bilateral femora for 5 consecutive days post-operative for a total dosage of 250 rads.

Implantation surgery will consist of the surgical placement of 4 transcortical porous coated implants per femora. Each animal will undergo bilateral procedures. At 4, 8, 12, 24 and 48 weeks post-operative, the animals will be sacrificed. Bilateral femora will be harvested and prepared for push-out testing in order to determine the mechanical shear strength of the bone/implant interface. Some sections will remain intact for quantitative histologic evaluations of direct bone apposition and bone growth into the porous coated implants. The effect of each treatment modality will be evaluated in relation to implantation time, radiographic appearances, and *ex vivo* testing. The results of this investigation will help elucidate the optimal treatment for ectopic ossification with the minimal hindrance to bone ingrowth and stability of implant fixation.

Human In Vivo Acetabular Pressure Movement

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**Purpose**—Major hip surgery is conducted several hundred thousand times each year in the United States, including repairing the natural joint following fracture, replacing the femoral head only, and total hip joint replacement. Despite the frequency of these procedures and the dominant role the hip joint plays in human mobility, there has been virtually no reliable experimental data on the mechanical environment the hip joint experiences in life. Over the past two decades, several attempts to instrument components of partial or total hip replacement to measure the force vector at the hip joint have produced either meager or contradictory data over a very short postoperative period—or have failed completely.

**Progress**—More recently, a pressure-instrumented femoral head replacement was designed, fabricated, and tested at MIT. It was inserted into a consenting patient who required femoral head replacement at the Massachusetts General Hospital and has consistently produced reliable data over the entire period from implantation through 3 years of successful performance as a replacement joint and a research instrument. The prosthesis telemeters pressure at 10 discrete locations on the artificial femoral head, thus establishing the pressures experienced by the spatially corresponding locations on the natural acetabular cartilage against which the femoral head articulates. Each transducer is sampled 250 times a second, thus faithfully recording all transient and dynamic events.

Pressure data were acquired during surgery, during immediate post-surgical recovery, during pre-rehabilitation bedrest and patient management, through all phases of rehabilitation and mobility training, and periodically as the subject progressed into normal activity. During all movement-related experiments, the pressure data were augmented by concurrent body-segment kinematic data using the MIT-developed TRACK system, dual forceplates, and more recently the myoelectric signals from the major muscular groups crossing the hip.

**Results**—Certain aspects of this *de novo in vivo* pressure data were anticipated, based on extensive prior *in vitro* series on cadaverous joints in the MIT Newman Laboratory. However, other features of the pressure data *in vivo* have been surprising—in particular the extreme pressures experienced and their orientation during certain activities such as rising from a low chair, when high muscle co-contraction forces across the joint are added to normal gravitational and inertial forces.

The data from this single implantation are already influencing surgical procedures in hip reconstruction, in particular the buttressing of the pelvic structure, and is challenging many rehabilitation
protocols that traditionally are based on subjective evaluation, patient recovery, and performance. The data from the implanted subject has also been followed very carefully as a source of information on which to base alterations and improvements in the design, fabrication, and implantation of subsequent prostheses.

**Future Plans/Implications**—Since hip reconstruction is a very common procedure among the aging veteran population, the Veterans Administration Rehabilitation Research and Development Service has funded an effort that will prepare and implant up to six more prostheses. This will generate more statistically significant data and provide the basis for recommending changes in surgical and rehabilitation practices following hip repair and partial and total hip replacement.

The extraordinarily high pressures (recorded during movements such as stair climbing and rising from a low chair) which require stabilization of the hip joint, presumably by means of co-contraction of the major muscle groups across the joint, have resulted in a decision to add electromyographic muscle activity information—the pressure kinematic and foot-floor force data flow. Given the complexity and high rate of the extant data flow and computer acquisition thereof, the addition of synchronized multichannel EMG was not a trivial task. A custom multiplexor was designed and fabricated to both reduce the number of wires connecting the experimental subject to the data acquisition system and to more efficiently integrate the EMG data into the data recovery, management and storage system. During several subsequent experimental periods, EMG data was acquired successfully and confirmed the role of co-contraction as the major source (beyond gravitational weight and inertial contributions) to the very high pressure magnitudes and directions observed during certain movement patterns.

Although the implanted prosthesis has performed extraordinarily well, certain improvements and alterations are under design consideration. These include mechanical clamping versus epoxy cementing of the transducer solid-state sensor, a channel in the head hemisphere to provide stress relief during equatorial welding, relocation of the pressure transducers to more optimal positions in relation to acetabulum cartilage, incorporation of a temperature-sensing data channel, use of recently available commercial large-scale integrated circuit components, and improvements in the welding and polishing techniques. Following long-term testing *in vitro*, these will be incorporated into the prosthesis design.

The data acquired thus far and the performance of the instrumentation provides high assurance that additional implantations and subsequent testing will generate a novel and extremely valuable source of data that, for the first time, will establish with confidence the mechanical environment of the human hip joint in life, and that will provide the basis for quantitatively-based recommendations for improvements in surgical and rehabilitation protocols.

**Publications Resulting from This Research**

Initial Stability of Orderly Oriented Wire Mesh Porous-Coated Implants

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—Three-dimensional finite element analyses have been performed to evaluate the comparative long-term stress distribution in canine hips revised with various porous titanium materials, versus canine hips reconstructed with only bone cement. In addition, the placement of the porous structure was also varied with respect to a cortical medial defect created to mimic the situation at revision of a loosened prosthesis.

Progress—In a first phase, perfect bonding is assumed. This assumption benefits the case with bone cement, as clinical evidence clearly indicates considerable loosening with the revision prosthesis as well. A slight beneficial effect is noted with the use of the porous materials; at the distal stem tip, stresses considerably closer to the physiologic stresses are noted.

In clinical practice, bone cement is unable to achieve good bonding with the smooth endosteal cortex present at revision surgery. Thus, we are expanding our calculations to allow for debonding at the cement interfaces. We insert frictional gap elements at the interface between cement and bone. The theoretical stress data are analyzed in conjunction with experimental mechanical test data obtained on actual canine hip reconstructions using the modeled materials, and excised at 3 weeks and 3 months after surgery.

Skeletal Aging and Disease in Failure of Hip Surface Replacement

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Sponsor: VA Rehabilitation Research and Development Service and Division of Orthopedic Surgery, University of Utah School of Medicine

Purpose—Surface Replacement Hip Arthroplasty (SRHA), in comparison to conventional Total Hip Arthroplasty, has the advantages of replacing the diseased hip surface while preserving normal bone stock, maintaining more normal physiological bone load 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 techniques and instrumentation; 2) Bone necrosis secondary to disruption of the blood supply; 3) Inadequate (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.

Progress/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 during the past year for this study are:

1) Three-dimensional mapping of the trabecular bone mechanical compressive strength 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 manuscript entitled "Compressive Strength Mapping of Femoral Head Trabecular Bone" has been submitted to the VA Journal of Rehabilitation Research and Development (JRRD).

2) To increase the analysis speed and accuracy of data obtained from studies using histological and/or Back-Scattered Electron Imaging (BEI) techniques, a PC-compatible, computerized digitization program has been developed.

3) Following a presentation entitled "Increased Endosteal Bone Loss After Hip Arthroplasty," given at the 1986 Orthopedic Research Society meeting, a manuscript, entitled "Increased Endosteal Bone Loss After Hip Arthroplasty," has been submitted to Clinical Orthopedics.

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 indicated that canine capsule disruption acutely inhibited blood flow and reduced vascularity by 30 to 70 percent in the surface bone of the femoral head. A manuscript is being submitted to the VA Journal of Rehabilitation Research and Development.

5) A study to correlate bone remodeling with prosthesis materials and design is in progress. Test cylinders of either porous cobalt-chrome, porous titanium, or hydroxyapatite-coated porous titanium are being implanted into the cancellous crests of consenting bilateral total joint replacement patients. After 6 to 8 weeks, these test plugs are removed with a small portion of attached bone for backscattered electron imaging and histomorphometric analysis of the bone-implant interface. Initial results indicate that hydroxyapatite-coated porous titanium implants induce the fastest rate of bone ingrowth and bone ingrowth into cobalt-chrome was slowest. Abstracts, entitled "Histological Analysis of Tissue Ingrowth into Porous and Hydroxyapatite-Coated Metal Test Plugs Implanted into Human Cancellous Bone" and "Human Cancellous Bone Ingrowth into CC and Ti Porous Coated Implants—A Backscattered Electron Microscopic Analysis," were submitted for presentation at the 1988 Orthopedic Research Society meeting.

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. To date, 53 patients have consented to participate in this study, and 19 joint prostheses have been retrieved during revision surgery and are under analyses. The information obtained will be of considerable value in the design of improved prostheses.

Future Plans/Implications—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.

Quantitative Analysis of Total Hip Arthroplasty on Cadaver Pelvis Stress and Strain

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Purpose—With the advent of new acetabular cup designs and techniques for total hip arthroplasty, researchers have hoped to improve the overall performance of this treatment modality for the arthritic hip. Historically, little objective experimental information is available concerning the effect of the implantation of these devices on the stresses and strains developed in the human pelvis.
Progress—Using strain-gauge instrumentation, this long term investigation has quantified the effects of available prosthetic components on the strains in the cadaver hemipelvis. Based on the premise that pelvic strain changes following implantation may predict the long-term success or failure of arthroplasties of the hip, various implant designs and techniques that do not significantly alter normal strain distributions of the pelvis have been determined.

Following the initial work, which led to the development of automated, computerized data acquisition systems and customized loading fixtures, assessment of various surgical techniques and cup designs on pelvic wall strains during simulation of single limb stance phase were recorded. Various techniques of implantation that were considered included the use of pilot holes, various reaming levels of subchondral plate, cement restrictors, and the use of spacers for insuring a uniform cement mantle.

Results—Our results indicated that the use of pilot holes and substantial reaming would lead to large increases in pelvic strain per unit applied load. An even cement mantle led to minimal changes in pelvic strain if the compliance of the acetabular component itself was appropriate.

The evaluation of cup design as it relates to implant compliance and the effect it has on pelvic strain was also determined. These results indicated that the early low-compliance standard polyethylene components tend to increase pelvic strain considerably, while thick CoCr metal-backed components led to unloading or stress protection of the cadaver hemipelvis in this loading configuration. Titanium-metal-backed prostheses and thin-shelled CoCr-metal-backed components with spacers were found to lead to an intermediate result. Most recently, the evaluation of noncemented “screw-in” CoCr implants indicated that, while their compliance behavior was somewhat akin to the thicker CoCr, considerable hoop stresses were generated due to the insertion of the components themselves. Further research in this area is continuing with the evaluation of porous-coated metal-backed components and several newer designs. Thus, on the acetabular side, it appears that strain changes in the pelvis may be controlled with the control of implant compliance and insertion methodology.

Future Plans/Implications—This information, when coupled with early clinical results, should allow the determination of designs and methods of insertion that lead to minimal strain changes, and may therefore infer increased longevity of acetabular components.

Our evaluation of press-fit noncemented femoral components has initiated the use of a newly developed holographic interferometry technique. The clinical goal for this portion of the effort is to attempt to understand the complaints of thigh pain cited by many patients receiving these devices. Early results indicate discontinuities in curvature appearing at the distal tip of the prosthesis, and further work is continuing to determine the effect of quality of fit on these observed strain changes along the femoral shaft. The long-term goal of this portion of the research program is to develop a “noncontact” method for the evaluation of strains in bone for biomechanical applications in our continued desire to understand the performance of total hip arthroplasties and their interaction with the host skeletal system.
C. Knee

Design Concepts for a Porous-Ingrowth, Prosthetic Tibial Component

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Purpose—The objective of this study is to develop design concepts for a porous-coated/bony-ingrowth tibial component of a total knee prosthesis.

Progress—Using mathematical models, we will develop design criteria for total knee replacements. Both the early and late stages of bony-ingrowth will be studied. The shortcomings of conventional implants will be examined and the predicted response using presently available implants will be compared to newly developed designs. We plan to used the bony architecture of the natural tibia as a design guideline.

The mathematical models are based upon the finite element technique. These models will provide us with information about the stress fields which exist in the proximal tibia before and after joint arthroplasty. We will use linear models to simulate the firmly attached prosthesis and nonlinear, friction interface models to study the newly implanted prosthesis. These later models will provide new data on the stress fields which exist immediately after a porous-coated prosthesis has been implanted, before bony-ingrowth has occurred.

For all models, the predicted stress distributions for each implant design will be compared with the trabecular morphology from cadaver tibiae to determine which designs will likely result in the least amount of remodeling.

Results—Linear, two-dimensional, equivalent-thickness models in both the frontal and sagittal planes have been developed for the natural tibia and for a variety of conventional and new tibial component designs.

Future Plans—A preliminary study using sub-models aimed at determining an optimal interface geometry are being developed. In addition, an experimental testing system is being designed to generate in vitro data on competitive fixation systems.

A new iterative, bone remodeling technique is being developed which will be used to predict the apparent density distribution caused by the presence of different types of implants. This technique will permit a critical and quantitative comparison of different types of prosthesis designs.

Publications Resulting from This Research


Ligament Insertions: Relations in the Moving Knee

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Purpose—In the surgical reconstruction of knee ligaments, an important goal is that the reconstructed ligament be neither too tight nor too loose as the knee flexes through a normal range of motion. Such reconstructions are termed isometric, since the reconstructed ligament does not change length during knee motion. The purpose of our research is to identify all of the attachment sites in the knee which are nearly isometric.

Progress—Our methodology involves detailed measurements of three-dimensional knee anatomy and six-degree-of-freedom knee motion. We use a six-degree-of-freedom digitizing sensor for this purpose. For each cadaver knee in our study, we measure motion of the intact knee under eight different loading conditions. The knee is then dissected, and its anatomy is digitized by hand at more than two thousand separate points. We then inspect the data, using animated three-dimensional computer graphics on an IRIS workstation to display knee motion and anatomy. Computer search techniques are then used to determine all possible nearly isometric insertion sites. The results are displayed graphically as color-coded three-dimensional “isometry maps,” which show explicitly the degree of isometry available at each point on the femur or tibia.

To date we have measured ten knees, and have prepared and statistically analyzed more than fifteen hundred isometry maps for the anterior and posterior cruciate ligaments, for the medial and lateral collateral ligaments, and for lateral extra-articular tenodesis of the iliotibial band.

Results—We found three separate techniques suitable for isometric repair of the anterior cruciate ligament. These were: 1) tibial placement in the center of the anatomic ligament, with femoral placement high in the notch and 5mm forward from the back; 2) tibial placement at the anterior margin of the anatomic attachment, with femoral placement 5mm forward from the back and 8mm lateral to the roof of the notch; and 3) tibial placement in the center of the anatomic ligament, with over-the-top femoral placement. Technique (1) is presently our preferred clinical choice, because technique (2) has increased notch impingement, and technique (3) is isometric only from zero to thirty degrees of knee flexion.

For posterior cruciate ligament repair, we found that the isometric femoral sites were always located within the posterior margin of the anatomic attachment, approximately 15mm back from the front of the notch, 6mm medial and 5mm down from the roof. For lateral extra-articular tenodesis of the iliotibial band, we found that isometric femoral sites were located directly posterior to the lateral epicondyle, approximately 60 percent of the way to the articular margin.

Clinicians are cautioned that these results are valid only for single fibers. Real grafts are complex bundles of interacting fibers, and this must be taken into account when planning reconstructive surgery.

Future Plans/Implications—There is a clear need to better understand the behavior of both anatomic ligaments and grafts as complex structures, rather than single idealized fibers. We are currently developing a general theory of the mechanics of fiber-fiber interactions in flexible structures. With this theory, we hope to address a number of questions of potential clinical significance. These include: 1) nonuniform strain of peripheral fibers in a finite graft; 2) the effects of fiber bending at bone tunnels; and 3) the effect of deliberately inducing intra-articular twisting of the graft.

Publications Resulting from This Research

Design of External Joint Assemblies (EJAs)
Using CAD/CAM Techniques

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Sponsor: VA Rehabilitation Research and Development Service

Purpose—The goal of this project is to obtain an extended data base for 3-D knee motion on specimens and human subjects and to manufacture external knee surfaces using a CNC machine.

Progress—The work has involved the development of an automated method for measuring 3-D knee motion on human subjects, the design of an apparatus for describing 3-D body surface shape, and the use of these techniques to explore upper extremity orthoses.

Preliminary Results—A new 3-D knee motion analysis paradigm has been developed, using a unique tibial and femoral fixture, and data collection on human subjects is under way. An apparatus was designed and tested for measuring the 3-D body surface shape ("Magic Fingers"). We are at the stage of polishing the software that will be modifiable for various applications. A myoelectric upper extremity orthosis for C5-C7 SCI patients has been developed. The effort is concentrated around independent usage of the device that will enable a variety of shoulder, elbow and hand movements. Clinical testing of the hand orthosis alone is under way.

All-Plastic Total Knee Replacement

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Sponsor: VA Rehabilitation Research and Development Service

Progress—The objective is to develop a total knee replacement made entirely from injection-moldable polymer. The research plan is to measure the friction wear of candidate materials, to carry out cyclic load tests of fabricated joints, and to test out total knees in sheep. Multicomponent force transducers are used which will measure the frictional force and downward force administered to reciprocating wear samples. Data obtained are compared to that of physiological tissue in joints for ideal biocompatibility.

Results—The completed machine is currently undergoing instrumentation calibration. The test materials have been chosen and procured.

Evaluation of Knee Performance After Various Orthopaedic Procedures

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Purpose—The objective of this study was to quantify knee performance before and after various surgical procedures in order to provide the surgeon with guidelines as to the efficacy or superiority of one procedure over another, or possible modification of a procedure which would allow improvement of the patient's ability and performance in an optimal mode.
Progress—Several patients with chondromalacia, some who underwent simple debridement, and others who were treated with the Macquet procedure, were evaluated during maximal-effort, isokinetic knee flexion and extension with simultaneous recording of musculature EMG. Data of each patient was integrated with pre-surgical performance, radiological analysis, and compared with performance of normals in order to establish comparative evaluation guidelines.