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Rehabilitation R & D Progress Reports 1990

XI. Orthopedic Implants

A. General

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XI. Orthopedic Implants

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A. General

[353] Percutaneous Prosthetic Limb Attachment

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A487-RA)*

Purpose—This project was initiated in order to develop a method for the attachment of prosthetic limbs to veteran amputees without the necessity of fitting the anatomy of the residual stump and incurring the inherent functional and cost limitations of current prosthetic practices. Utilization of residual muscle capability through a percutaneous implant is an ultimate goal.

A sheep model was chosen for initial investigations because of prior work in Spanish goats and because of the extensive use of sheep for bone-healing research.

Progress—An initial conception of the requirements of a transitional zone from internal to external milieu in order to eliminate infection led to the development of microvascular techniques for free vascularized transplant of small bowel, omentum, or parietal peritoneum to the site of a midtibial amputation. A four-fluted, self-tapping, stainless steel intramedullary device with a percutaneous pylon for prosthetic attachment was designed and implanted with transplant of tissue with the potential for reducing infection. This led to a classical osteomyelitis with extrusion of the implant and failure in 25 cases.

The implant was revised to a flat broach to preserve the endosteal blood supply and while the periosteal reaction and osteomyelitis developed more slowly and to a lesser extent in five cases, the outcome was, qualitatively, the same.

A review of the literature regarding mandibular implants led to exploration of the use of hydroxylapatite coating of the implant (without free vascularized transplants to establish a baseline of bone and tissue reaction). The initial results are qualitatively different from any previous experience. The animals are healthier, they bear weight more readily, there is less drainage from the amputation site, fractures heal, and preliminary histologic data reveal new bone in close approximation to the implant. There is no apparent osteomyelitis at 2 months (previously readily apparent) and the skin appears to grow tightly around the stem of the implant.

Methodology—The sheep were acclimatized to the facility for 72 hours prior to surgery. Food was withheld for 48 hours and water for 24 hours. Preoperative sedation was with ketamine 1.5 g intramuscular. Induction for intubation was accomplished with 500 mg of intravenous, short-acting barbiturate and the anesthetic agent was Fluothane 1.5–2.5% with 4–5 liters of oxygen.

After routine clipping, without shaving, and skin preparation with iodine, tibial amputation at the isthmus was accomplished by a guillotine technique at a level distal to the final site. The periosteum was reflected from the distal shaft before amputation of the bone at the isthmus so that it could be reflected over the cut end of the bone into a recess in the implant.

A number of 316 L stainless steel implant broach sizes from 8 to 13 mm were precoated with hydroxylapatite by a plasma spray technique and sterilized with ethylene oxide. The maximum diameter of the tibia at the amputation site was measured and the next size larger implant was driven into the intramedullary canal without preliminary preparation.

Tendons were resected at the amputation level and the skin was closed tightly around the stem of the implant in contact with the hydroxylapatite coating. A simple

pylon prosthesis was friction-coupled to the stem of the implant. Aminoglycoside and cephalosporin were injected intramuscular at the end of the procedure and the animals were placed in a sling for 3 weeks.

Results—Three of five animals were walking with some weightbearing at 60 days. One animal has broken the prosthesis three times.

One animal fractured the distal tibia in the sling and did not heal.

One animal broke the implant at 5 weeks and was necropsied. There was firm fixation of the proximal stem of the implant in the endosteal canal and ground section of the implant plus bone revealed very close approximation of new bone to coating. There was no evidence of infection.

Future Plans/Implications—The long-term history of these implants must still be evaluated, the prosthesis must be revised to tolerate the increased use imposed by a successful interface, and the possibility of attachment of the residual muscles and tendons to the prosthesis, through the implant, must be investigated.

[354] Fracture Healing and Bone Remodeling in Plated Long-Bones

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A294-2RA)*

Purpose—The objectives of this study are to develop models of the fracture-healing process for both conservatively treated and internally plated longbone fractures.

Methodology—Both mathematical and experimental models of fracture healing are used to study the fracture healing process. The mathematical models utilize the finite element technique. Models of conservatively treated long-bone fractures and plated long-bone fractures have been developed. An osteogenic index is used to predict the regions of a fracture callus which will ossify first.

Laboratory models will be used to assess the efficacy of using shortened screws at the outer screw locations compared with using full-length screws for plated fractures. A strain gauge based torque-measuring screwdriver has been designed to monitor the insertion and removal torque of the screws which attach the fixation plate to the bone.

Results—Finite element models of plated long-bones show that slippage between the plate and the bone influences to a great extent the amount of stress shielding. Plate slippage is a direct function of screw tightness. A time-dependent, incremental remodeling program has been developed to predict the changes in density distribution caused by the implantation of orthopedic implants. Preliminary models of nonplated long-bones subjected to bending, axial, and torsional loads have been analyzed.

In the experimental phase of the study, plates have been applied to phenolic tubes modeling the human radius. The use of unicortical end screws results in a plated bone construct that is 40% stronger in the bending-open loading mode, and 10% weaker in the bending-closed loading mode.

Future Plans/Implications—Future plans include the use of the strain gauge based screwdriver in surgery to compare insertion and removal torques of plated forearm fractures. It is anticipated that low values of removal torque will indicate that stress shielding is minimal and the risk of refracture will be low. The use of an incremental remodeling program will allow the prediction of changes in the density distribution caused by plate fixation.

Recent Publications Resulting from This Research

A Bone Surface Area Controlled Time-Dependent Theory for Remodeling (Abstract). Beaupre GS et al., Transactions of the Orthopedic Research Society, 14:311, 1989.

Fracture Healing Patterns Calculated from Stress Analyses of Bone Loading Histories (Abstract). Blenman PR, Carter DR, Beaupre GS, Transactions of the Orthopedic Research Society, 14:469, 1989.

The Role of Mechanical Loading in the Progressive Ossification of a Fracture Callus. Blenman PR, Carter DR, Beaupre GS, J Orthop Res 7:398407, 1989.

An Approach for Time-Dependent Bone Modeling and Remodeling—Application: A Preliminary Remodeling Simulation. Beaupre GS, Orr TE, Carter DR, J Orthop Res 8:662-670, 1990.

An Approach for Time-Dependent Bone Modeling and Remodeling—Theoretical Development. Beaupre GS, Orr TE, Carter DR, J Orthop Res 8:651-661, 1990.

Mechanical Stress Histories and Connective Tissue Differentiation (Abstract). Carter DR et al., First World Congress of Biomechanics, II:80, 1990.

Numerical Methods for Emulating Stress-Induced Remodeling in the Femur (Abstract). Beaupre GS, Orr TE, Carter DR, First World Congress of Biomechanics, II:200, 1990.

[355] Bone Ingrowth and Remodeling with Porous Coated Implants

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Purpose—The purpose of this work is to formulate a comprehensive theory consistent with many features of skeletal growth and development, maintenance, regeneration, and degeneration. The results of our previous investigations indicate that tissue stress histories play a major role in regulating the biology of skeletal tissues, and that these influences are stronger and appear earlier in skeletal development than has been previously thought. The equations used to predict cartilage, bone, and mesenchymal tissue biology are similar to those that account for mechanical energy dissipation or the accumulation of fatigue damage in all materials. Our results may thus reflect fundamental characteristics of the transduction of mechanical energy to chemical energy in living organisms. The context in which this work is being conducted is porous coated/bony ingrowth prosthetic replacement of the proximal femur and tibia. The end product of this research will be a consistent framework of computer analyses which can be applied to predict the biological events associated with initial ingrowth and subsequent bone remodeling. We anticipate that it will be possible to apply these approaches to the design and evaluation of any implant in the body.

Methodology—In the course of our investigations, we will generate three-dimensional finite element models of the proximal femur and proximal tibia. The loading history over some period (e.g., an "average" day) will be specified by a series of discrete load cases applied for a specific number of load cycles. The entire bone will be represented initially by a solid, homogeneous structure with a constant bone density. Using a time-incremental bone remodeling technique, we will remodel the bone computer models to create an internal distribution of bone density and morphology which conforms to our bone remodeling theory. The resulting prediction of bone density distributions will be compared to those measured from cadaveric specimens. Our theory and computer approaches may then be modified so that our predictions correlate better with normal bone anatomy.

The proximal tibia and femur models will then be altered to represent the initial implantation of various uncemented porous coated components. A thin layer of pluripotential tissue will be represented at the bone/prosthesis interface. The multiple loading, stress history approach will then be applied and the differentiation of the interface tissue will be predicted. Using different stress history criteria, we will thus predict the extent and locations of bone ingrowth along the interfaces. Our criteria will be adjusted and varied parametrically to represent the types of results which have been observed by others in experimental animal studies and clinical retrievals. Subsequent bone remodeling around the prostheses will be calculated using the same algorithms which had been previously verified for the normal tibia and femur.

It is apparent that some design features may provide good initial fixation and encourage bone ingrowth, yet lead to subsequent bone remodeling which is deleterious. We will be able to address this issue with computer methods and thereby achieve a broad perspective of the overall implications of various design features. We anticipate that from the analyses that we perform, certain design features will begin to emerge which will suggest the evolution of cogent design principles for bony ingrowth total joint replacement. The proposed work represents a melding of basic and applied research. Our theoretical approach to the regulation of skeletal tissue by mechanical stresses will be explored and refined while it is being applied to solve immediate design problems which have a direct clinical impact.

Recent Publications Resulting from This Research

A Bone Surface Area Controlled Time-Dependent Theory for Remodeling (Abstract). Beaupre GS et al., Transactions of the Orthopedic Research Society, 14:311, 1989.

Femoral Bone Architecture Computed from 3-D Models Relating Bone Remodeling to Stress Histories (Abstract). Orr TE, Beaupre GS, Carter DR, in Proceedings of the XII International Congress of Biomechanics, 167, 1989.

Mechanical Stresses in Skeletal Morphogenesis and Maintenance (Abstract). Carter DR et al., in Tissue Engineering 1989, BED-14:55-58, S.L-Y. Woo, Y. Seguchi (Eds.). New York: ASME, 1989.
An Approach for Time-Dependent Bone Modeling and Remodeling—Application: A Preliminary Remodeling Simulation. Beaupre GS, Orr TE, Carter DR, J Orthop Res 8:662-670, 1990.
An Approach for Time-Dependent Bone Modeling and Remodeling—Theoretical Development. Beaupre GS, Orr TE, Carter DR, J Orthop Res 8:651-661, 1990.
Computer-Aided Implant Design Using Bone Remodeling Algorithms (Abstract). Orr TE, Beaupre GS, Carter DR, First World Congress of Biomechanics, II:192, 1990.
Computer Predictions of Bone Remodeling Around Porous-Coated Implants. Orr TE et al., J Arthroplasty 5(3), 1990.
Femoral Bone Architecture Computed from 3-D Models Relating Bone Remodeling to Stress Histories (Abstract). Orr TE, Beaupre GS, Carter DR, Orthop Res Soc 15:77, 1990.
Mechanical Stress Histories and Connective Tissue Differentiation (Abstract). Carter DR et al., First World Congress of Biomechanics, II:80, 1990.
Numerical Methods for Emulating Stress-Induced Remodeling in the Femur (Abstract). Beaupre GS, Orr TE, Carter DR, First World Congress of Biomechanics, II:200, 1990.

[356] High Viscosity Cooler Acrylic Bone Cement

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Purpose—The fundamental purpose of this work has been to identify methods to improve the fixation of prostheses to bone in order to reduce the rate of failure of cemented joint replacements, which are increasingly required in the aging VA patient population. The effort is even more important at present than originally in that cement*less* fixation of total joint prostheses, which was very prevalent in the mid-portion of the 1980s, has become less popular because of the frequency of intra-operative complications and a 20–30% incidence of postoperative thigh pain.

Methodology—Previously, we have shown that external pressure applied to polymerizing bone cement: 1) increases the shear strength of the cement itself; 2) increases the shear strength of the bone cement interface; and, 3) increases the penetration of cement into cancellous bone. Conversely, we have shown that increasing the depth of penetration: 1) does not result in an improvement in the shear strength of the bone-cement interface; and, 2) most recently in work just completed we have shown, *in vivo,* that the area of the interface fibrous membrane (an indicator of fixation failure) is directly related to the depth of cement penetration into bone.

With these observations in mind, we reasoned that the advantages of external pressure on the bone cement could be achieved without the disadvantage of excessive penetration by increasing the viscosity of the cement itself. This can be achieved by reducing the amount of monomer in the monomer/polymer mixture to increase the powder-to-liquid ratio. Although our primary intent was to produce a high viscosity cement, we find that changing the standard powder-to-liquid ratio from 2.0 to 2.7 also affects other physical properties that should be beneficial to long-term fixation of implants. Specifically: 1) the strength in compression is increased; 2) the density is increased; and, 3) most importantly, the peak exotherm of the polymerizing composite is reduced by approximately 20 percent.

Currently, we are developing a delivery system that can be utilized in the clinical situation. Our canine and goat total-knee model had a short (2 cm) cannulated stem, and it was relatively easy to inject the high viscosity cement. For cemented hip replacement, retrograde injection of the femur requires a tube approximately 8 inches (20 cm) long. Since resistance to flow increases markedly with length, we had to design and fabricate a new delivery system. This has been accomplished by utilizing a hydraulic system that can be used to apply the concept of high viscosity cement in the clinical setting.

Future Plans—The delivery system works well in the laboratory, but before using it on humans we want to refine the technique and establish the concept *in vivo,* which is the primary thrust of our current work.

Recent Publications Resulting from This Research

A Comparison of Intramedullary Plugs Used in Total Hip Arthroplasty. Beim GM, Lavernia C, Convery FR, J Arthroplasty 4(2):139-141, 1989.
High Viscosity Acrylic Bone Cement. Hadjari M, Reindell ES, Convery FR, Transactions of the 36th Annual Meeting of the Orthopaedic Research Society, 29, 1990.

The Effects of Cement Penetration on the Bone-Cement Interface Membrane. Hadjari M et al., Transactions of the 36th Annual Meeting of the Orthopaedic Research Society, 439, 1990.

Cardiopulmonary Function During Canine Total Knee Replacement Using Sustained Pressurization of Bone Cement. Weiner GM et al., J Arthroplasty (accepted for publication).

[357] Effects of Treatment for Heterotopic Bone Formation on Biological Fixation

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Purpose—The purpose of this study is to evaluate the effects of several short-term and chronic indomethacin therapies on the amount of bone growth into a porous surface and the bone-implant attachment strength.

Ectopic ossification following total hip arthroplasty is a frequently reported complication. Treatments for the prevention of heterotopic bone have included diphosphonate, radiation, and indomethacin therapies. Clinically, indomethacin has been shown to be effective in reducing ectopic bone formation, and effective in preventing heterotopic bone formation induced by demineralized bone matrix. Chronic indomethacin may significantly reduce the amount of bone growth into a porous implant, as well as reduce the bone-implant attachment strength. Since indomethacin is also used as an anti-inflammatory drug in several patient groups, the question arises as to what duration and at what period postoperatively does indomethacin usage prohibit effective bone-porous implant attachment.

Methodology—The animal model used was the skeletally mature mongrel canine approximately 18 to 22 kg in weight. Cylindrical Ti-6Al-4V alloy implants, 5.1mm in diameter by either 18mm or 20mm length, were coated with a two-layer spherical bead Ti-6Al-4V alloy porous coating. The implants were placed in the femoral bone through both cortices using strict aseptic techniques; each animal received 5 to 6 implants bilaterally.

Animals were randomly assigned to the following groups: 1) *Controls*—no drugs; 2) *Chronic*—indomethacin daily for 2 weeks preoperative until sacrifice; 3) *Heterotopic*—indomethacin immediately postoperative continued daily for 6 weeks; 4) *3-week delay*—indomethacin daily beginning 3 weeks postoperative until sacrifice; 5) *6-week delay*—indomethacin daily beginning 6 weeks postoperative until sacrifice; 6) *9-week delay*—indomethacin daily beginning 9 weeks postoperative until sacrifice; and, 7) *18-week delay*—indomethacin daily beginning 18 weeks postoperative until sacrifice. Implantation periods included 3, 6, 12, 18, and 24 weeks. This experimental design resulted in 26 treatments (combinations of drug/implantation time) to be evaluated.

All animals (except controls) received 1.0mm/kg/day of indomethacin orally in two divided doses. Blood was drawn at regular intervals during therapy to confirm blood/indomethacin levels.

After sacrifice, the implants were harvested and subjected to mechanical push-out testing to determine interface attachment strength. The resulting data was analyzed separately to examine the effects of implantation time and drug treatment groups.

Intact and tested samples were evaluated using standard undecalcified histologic techniques. The evaluations were based on qualitative gradings of mineralization and osteoid formation, and computerized quantitative percent bone ingrowth measurements.

Results—For each of the seven drug treatments there was a significant effect of time of implantation upon shear strength (all $p<0.0025$) as follows: *Control* group—significant increase in strength from 6 to 12 to 18 weeks; *Heterotopic* indomethacin group—average strengths significantly lower at 6 weeks as compared to 12 and 18 weeks; *Chronic* indomethacin group—strength data increased significantly from 3 to 6 to 24 weeks. Strengths for animals receiving indomethacin after a *3-*, *6-*, or *9-week delay* were significantly greater at the 24-week interval.

Evaluation of the strength data after 6 weeks demonstrated a significant drug group effect ($p<0.05$), with the strength values for the *Chronic* indomethacin group significantly greater than the *Control* and *Heterotopic* groups. Similar results were observed at the 24-week time period, with the strengths for the *Chronic* in

domethacin group significantly greater than the *3-,6-, 9-,* and *18-week delay* groups. After 12 and 18 weeks implantation, there were no significant differences in strength among the drug groups (p=0.25).

Implications—These results indicate that indomethacin given strictly postoperatively has no consistent detrimental effect upon fixation strength. It was unexpected that animals receiving chronic indomethacin would exhibit greater strength values; perhaps a longer preoperative therapy would have altered these findings. While the effect of indomethacin given strictly postoperatively remains unclear, strengths appear to be unaffected by a delay of 6 weeks or longer.

Recent Publications Resulting from This Research

Effects of Treatments for Heterotopic Bone Formation on Biologic Ingrowth Fixation. Thomas KA, Cook SD, Brinker MR, Digest of Papers Eighth Southern Biomedical Engineering Conference, Richmond, VA, 1989. (Abstract published in Biomater Artif Cells Artif Organs 17:515, 1989.)

Effects of Indomethacin on Biologic Ingrowth Fixation. Poster exhibit, 16th Annual Meeting of the Society for Biomaterials, Charleston, SC, 1990. (Abstract published in Transactions, XIII:231, 1990.)

[358] Effect of Surgical Fit on the Biological and Mechanical Response to Porous-Surfaced Implants

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Purpose—The purpose of this study is to investigate the effects of a uniform gap space between a porous implant and surrounding bone on the degree and maturity of bone growth into the porous surface, and to determine the effect of the gap upon interface attachment strength. The implant design assures the presence of uniform gap spaces of varying sizes between the implant surface and the surrounding bone, and also allows for evaluation in regions of cortical and cancellous bone.

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 development of significant fixation strength may be delayed and the ultimate attachment strength adversely affected.

Methodology—Femoral intramedullary implants were constructed by threading Ti-6Al-4V alloy porous coated discs of 6.0, 8.0, 9.0, and 10.0mm diameters onto a central 2mm threaded rod. Each implant consisted of four 4.0mm thick discs of each diameter, separated by solid acrylic spacers 10.0mm in diameter and approximately 2.0mm thick. The assembled implants were approximately 100.0mm long. Three different disc arrangements were used for each time period, allowing two discs of each diameter to reside in the cancellous (metaphyseal) region and the cortical (diaphyseal) region of the femur.

The animal model was the skeletally mature mongrel canine ranging in weight from approximately 18 to 22kg. Identical implants were inserted bilaterally into the femoral intramedullary canal using standard aseptic techniques. Five animals at each implantation period (4, 8, 12, 24, and 52 weeks) were randomly assigned one of three implant arrangements.

Harvested femurs were sectioned by cutting through the acrylic spacers to produce individual test specimens. These specimens were mechanically tested with a specially designed push-out fixture to determine interface shear attachment strength.

Future Plans/Implications—Both tested and intact specimens will be processed using undecalcified techniques to produce histologic and microradiographic sections for evaluation. The amount of maturing bone growth in apposition to and within the porous surface, as well as the amount of gap filling will be quantified on all histologic specimens. The data will be analyzed to determine differences among the implants in cortical and cancellous bone regions as well as any differences in medial, lateral, posterior, or anterior locations.

This study will determine the limits of the ability of new bone growth to fill a gap space at various time periods. The effects of bone ingrowth and gap filling upon the resultant interface attachment strength will also be determined, as well as evaluating how the response may differ between cortical and cancellous bone. This information will help answer many questions critical to the design and use of noncemented porous-coated devices in the clinical setting.

[359] Optimization of Orderly Oriented Wire Mesh for Prosthetic Arthroplasty

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A356-2RA)*

Purpose—Orderly oriented wire mesh (OOWM) is a pure titanium porous coating which represents a unique approach to the biologic fixation of hip or knee implants. Prior work supported the utility of the material for biologic fixation of implants in a canine model. This study seeks to optimize the performance of material through the use of both *in vivo* and *in vitro* models.

Methodology—Three hypotheses will be studied: 1) that optimization of the geometry of the mesh-substrate interface will minimize the reduction in fatigue strength of the sintered implant; 2) that biologic fixation of the OOWM can be optimized by appropriate manipulation of the dimensions of the mesh wires and weave; and, 3) that OOWM-coated prostheses will offer enhanced fixation of the implant to PMMA bone cement, without compromising cement fatigue and static properties.

The first hypothesis will be investigated through development of a two-dimensional finite element model of the stress concentration (K_t) at the sinterneck interface. The optimized K_t developed from this model will then be validated through the mechanical testing of a range of sinterneck radii to validate the results of the FEA model. This will then allow the design of an OOWM that should minimize reduction in fatigue strength over traditional sintered surfaces.

The second hypothesis will be investigated using *in vivo* analysis of pull-out resistance of implants with pore structures different in size from that already investigated, in an attempt to optimize the strength of biologic fixation of OOWM-coated implants. Two additional OOWMs with substantially different pore sizes will be investigated.

The third hypothesis will examine the fatigue strength of the OOWM-PMMA cement interface, in an effort to demonstrate enhancement of cement implant shear and fatigue performance compared with uncoated implants. This will require *in vitro* mechanical testing and fractographic analysis in order to validate the use of OOWM for cemented implants.

[360] Evaluation and Examination of Retrieved Porous-Coated Orthopaedic Prostheses

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A473-DA)*

Purpose—The overall objective of this study is to assess the long-term feasibility of porous coating as a mechanism for fixing orthopaedic prostheses to bone.

This examination of clinically retrieved, porous-coated hip and knee prostheses will assess the importance of such variables as material composition (cobalt and titanium-based alloy systems), design (implant geometry), location of porous coating on the prosthesis, coating pore size, pore geometry, pore density, and surface roughness on the resulting interface between the prosthesis and bone. The study will address the issues of stress shielding, ion release and wear debris formation, and, where possible, clarify causal relationships with prosthesis parameters.

Methodology—Retrieved prostheses are fixed in formalin for 48 hours, examined macroscopically for both soft and hard tissue apposition to the prosthesis and mapped for the location of this tissue. The prosthesis is coarsely sectioned and the large sections are dried in a series of alcohol and acetone solutions. Fully dried prosthetic components are embedded in ethyl-methacrylate and cut into sections approximately 1 mm thick. These sections are hand-ground to between 20 and 40μ in thickness and hand polished. Specimens are stained with either hematoxylin and eosin (H and E) or acid phosphatase, cover-glassed and photographed on a Zeiss photomicroscope III. The interface is mapped and evaluated for bone and fibrous tissue ingrowth, osteoblastic and bone resorptive activity, and the presence of polyethylene or metal wear debris.

Results—In the past 12 months, we have examined 378 retrieved, porous-coated orthopaedic prostheses. This compares favorably with the 249 prostheses examined in the first year of this project. One hundred and ninety-five hip prostheses were received from 85 surgeons; 183 knee prostheses were received from 48 surgeons. Eighteen of the 378 prostheses were retrieved post mortem from cadaver specimens.

Bone ingrowth of large and small pore sizes of both titanium and cobalt alloy was demonstrated. The amount extent of bone ingrowth was found to be a function of implantation duration and implant design and fixation mechanisms.

Bone ingrowth of femoral hip prostheses, femoral knee prostheses, and patellar prostheses was frequently seen. Bone ingrowth of acetabular prostheses was much less frequently seen; bone ingrowth of tibial prostheses was seen least frequently of those device types evaluated. Tibial prostheses with porous-coated central pegs demonstrated bone ingrowth of the central peg more frequently than ingrowth of the porous-coated plateau. The most frequent bone ingrowth of the underside of the tibial plateau was seen with prostheses fixed with four metal screws. Generally, there was evidence of metal fretting between the screws and the screw holes and the local tissue had often turned black. Metal ion concentrations in this tissue was measured as greater than 1% by weight in several cases.

Worn polyethylene articular surfaces and the development of significant amounts of polyethylene wear debris was seen in a high percentage of knee prostheses. Mechanisms of failure of patellar and tibial components included: separation of polyethylene from the metal backing, wear-through of the polyethylene, cracking, pitting, and delamination of the articulating surface, as well as deformation of the polymer due to creep. Examination of the ingrowth surfaces of tibial and patellar prostheses which had been retrieved for reasons of polyethylene failure often demonstrated polyethylene wear debris at the margins of the porous coating which appears to be associated with localized osteoclastic activity and bone resorption.

Several surprising phenomena not previously reported were documented through the prosthesis examination process this year. These included: 1) the deformation and high wear rate of the thin polyethylene inserts used in metal-backed acetabular components; 2) the considerable wear of titanium heads used in femoral hip prostheses; 3) corrosion at the interface between cobalt alloy heads and titanium alloy femoral hip stems; 4) separation of bone-ingrown titanium wire mesh pads from the substrate of femoral hip prostheses; and, 5) the loss of material from some plasma-sprayed and sintered bead porous coatings that migrated to the articular surfaces resulting in early failure of the polyethylene and significant wear of the metal components.

Recent Publications Resulting from This Research

The Case for Pressfit Femoral Stem Fixation. McCutchen JW, Collier JP, presented at the 18th Open Scientific Meeting of The Hip Society, New Orleans, 1990.

Early Failure of Polyethylene Components in Uncemented Total Knees. Surprenant VA et al., presented at the 57th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, 1990.

Examination of Porous-Coated Patellar Components and Analysis of the Reasons for Their Retrieval. Collier JP et al., presented at the 57th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, 1990.

The Success of Pegs, Stems and Screws as Adjuvant Means of Fixation of Tibial Prostheses as Measured by Radiographic and Histological Examination. Collier JP et al., presented at the 57th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, 1990.

Biological Ingrowth of Porous-Coated Knee Prostheses. Collier JP et al., in Controversies of Total Knee Arthroplasty: Issues of the Nineties. New York: Raven Press (in press).

The Biomechanical Problems of Polyethylene as a Bearing Surface. Collier JP et al., Clin Orthop Rel Res (in press).

The Case for Pressfit Femoral Stem Fixation. McCutchen JW, Collier JP, Clin Orthop Rel Res (in press).

Corrosion at the Interface of Cobalt-Alloy Heads on Titanium-Alloy Stems. Collier JP et al., J Bone Joint Surg (in press).

[361] Surface Failure in UHMWPE Joint Components

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Sponsor: *National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health*

Purpose—The purpose of this research is to establish failure criteria for the articulating surfaces of ultrahigh molecular weight polyethylene (UHMWPE) components used in total joint replacement systems, and to apply these criteria to optimize implant design. Observations of retrieved components have revealed distinct patterns of damage, apparently caused by fatigue fracture mechanisms. The design decisions for UHMWPE components are based on the assumption that particular stresses and stress distributions (i.e., the maximum shear stress and the range of maximum principal stress) are responsible for causing damage. To verify the direct relationship between specific stress states and the production of surface damage, the conditions under which growing fatigue cracks in UHMWPE will change direction must be established. Our goal is to determine the cyclic loading conditions which will cause small defects on and below the surface to propagate and create the observed damage. The approach is based upon principles of fracture mechanics.

Methodology—Test variables will be the angle of inclination of the crack relative to the direction of the applied loading and the state of preconditioning of the material under uniaxial cyclic loading prior to testing. Tests will be conducted on specimens made from both conventional UHMWPE and enhanced forms of UHMWPE. Empirical relationships will be used as input to a numerical model to demonstrate that the method correctly predicts fatigue crack propagation in UHMWPE. This will be accomplished by modeling the test specimen geometry and loading conditions from the fatigue tests and comparing the computed crack propagation rates and direction with those measured experimentally. If fatigue crack propagation in UHMWPE cannot be described on the basis of linear elastic fracture mechanics, the analytical method will be modified to include nonlinear material behavior around the crack tip.

Progress/Preliminary Results—Fatigue crack propagation resistance of enhanced polyethylene was determined to be isotropic and more resistant to crack propagation than conventional polyethylene. Preconditioning was found to affect crack failure properties. Extensive evaluations were made of various stresses produced in joint surface contact between the metal and polyethylene components. Complex stress patterns were measured and predicted with finite element modeling. Maximum shear stress was located at a depth of 1 or 2 mm in tibial components. This compares favorably with the depth of pits and delaminations seen in these materials. Nonconforming surfaces in some modern knee joint designs (e.g., cruciate ligament sparing devices) have much larger stress on the components.

Future Plans/Implications—We plan to determine the relationship between the crack growth rate and the applied cyclic stress intensity. Previous work showed that this relationship is insensitive to standard processing techniques in the opening mode. This work will examine: 1) effects of mixed-mode loading conditions, under which the propagating crack could be expected to change direction, with the fatigue crack propagation rate and crack trajectory being a function of both the opening mode (Mode I) and sliding mode (Mode II) stress intensity factors; 2) effects of a new type of UHMWPE, made by a processing technique which alters the mechanical and physical properties, and can be expected to alter the fatigue crack propagation behavior beyond the inconsequential differences found previously between the extruded and molded versions of conventional UHMWPE; and, 3) effects of preconditioning or working the material, which will occur under the high intensity cyclic loads applied to the articulating surface of an implant prior to crack initiation, and which can be expected to affect the material properties and the fatigue crack propagation relationship for UHMWPE.

We will then use the empirical relationships in a two-dimensional, plane strain, numerical method based on linear elastic fracture mechanics and demonstrate that the numerical method correctly predicts fatigue crack propagation in UHMWPE by modeling the test specimen geometry and loading conditions from aim one and comparing the computed crack propagation rates and directions with those measured experimentally.

Recent Publications Resulting from This Research

The Effect of Waveform and Compressive Loading on the Fatigue Crack Propagation Behavior of UHMWPE. Rimnac CM, Wright TM, Klein RW, in Transactions of the 35th Orthopedic Research Society Meeting, 14:487, 1989.

[362] Cell Response to Modified Ti Surfaces (Rats)

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Sponsor: *National Institute of Dental Research, National Institutes of Health*

Purpose—Dental implants fabricated from titanium (Ti) and Ti-6Al-4V alloy are widely used in clinical practice, yet there is no consensus or established criterion regarding the design or fabrication of implant surfaces. As a result, there is little information currently available concerning specific biological responses, such as deposition of extracellular matrix molecules and attachment of cells, which occur during the initial stages of wound healing at the intimate implant and hard and soft tissue interfaces.

The overall objective of this research is to investigate some of the cell responses to standard, commercially available implant surfaces, as well as to modified Ti-based implant surfaces. Preliminary data from our lab suggest that available implant systems vary widely in surface topography and that molecular interactions and attachment of cells at these surfaces are affected by the nature of the substrate.

The experiments in this project are specifically designed to study a number of variables by surface characterization techniques, including scanning electron microscopy (SEM/EDAX), electron spectroscopy for chemical analysis (ESCA), auger electron spectroscopy (AES), and surface energy (contact angle) measurements. The effects of variables such as type of metal, surface topography, oxide structure and composition, and surface charge and energy on fundamental biological events (such as matrix adhesion, cellular attachment, and spreading and proliferation on these surfaces) will be ascertained. We hypothesize that chemical and biochemical modifications of the implant surface will result in enhanced biological acceptance and long-term tissue integration.

Implications—This type of research has far-reaching clinical implications in that it will define a model implant surface which can foster improved tissue reactions, thereby potentially decreasing the long healing periods now necessary with most commercial implant systems.

Recent Publications Resulting from This Research

Characterization of Acid Passivated cpTi Surfaces. Keller JC et al., J Dent Res 68:872, 1989.
In Vitro Cell Attachment to Characterized cpTitanium Surfaces. Keller JC et al., J Adhesion 28:115-133, 1989.
Surface Characteristics of Prepared cpTi Implants. Keller JC et al., Transactions of the First International Congress on Dental Materials, 271-272, 1989.
Bacterial Adhesion to Titanium Surfaces: Development of an In Vitro Model. (Abstract) Patel M, Drake DR, Keller JC, J Dent Res 69:369, 1990.
Development of a Model for Cell Attachment. (Abstract) Clavin TJ et al., J Dent Res 69:369, 1990.
In Vitro PDL Fibroblast Attachment to Plasma Cleaned cpTi Surfaces. (Abstract) Michaels CM et al., J Dent Res 69:369, 1990.
Protein Adsorption is Decreased on Glow Discharged Treated cpTi. (Abstract) Stanford CM et al., J Dent Res 69:369, 1990.
Role of Integrin Receptors in Osteoblast Attachment to cpTi. Stanford CM, Keller JC, Solursh M, J Dent Res 69:109, 1990.

[363] Titanium and Ti-6Al-4V Alloy Implant Fabrication (Rabbits)

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Purpose—The long-term objective of this investigation is to use a new process, electro-discharge compaction, for custom designing porous titanium and titanium alloy implants and superstructures. The ultimate goal is to develop a method whereby tooth roots can be duplicated and the resulting implants can be placed in extraction sockets within 24 hours of extraction. This would minimize surgical complications and provide an inexpensive means for replacing teeth. The method should also provide the mechanism for constructing superstructures for any titanium or titanium alloy implants to minimize corrosion.

Methodology—Preforms will be developed that will satisfy criteria for titanium and titanium alloy dental implants by varying energy input. This project will evaluate the surface characteristics of the preforms to determine the character of the surface, the oxide layer,

the chemical composition of the contaminants, pore size, and grain structure as the energy input is varied. When the preform technique is perfected and consistent results can be attained, the electro-discharge compaction method will be used to prepare preforms of titanium and titanium alloys that can be used to evaluate the biocompatibility of the preforms fabricated with the new technique. Rabbits will be used to determine soft tissue and bone tissue compatibilities. Osseointegration capabilities will be determined.

[364] Ion Sputter Deposition of Ca-P Thin Films

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Sponsor: *National Science Foundation*

Purpose—The overall goal of this research project has been to coat metallic materials with biocompatible Ca-P ceramic materials using the ion-beam sputter deposition process. Most orthopedic and dental implants are constructed of metallic materials such as titanium or cobalt-based alloys. A number of ceramic materials containing calcium and phosphorus have found increasing use for biomedical applications due to their biocompatibility and ability to form a chemical bond with bone. However, these particular ceramics are brittle and are not suitable for use in load-bearing implant applications, so their optimum use for most medical and dental applications may be as coatings on metals.

Methodology—The ion-beam sputter coating process used in this study employs high velocity gas ions to dislodge atomic fragments of ceramic target materials, which in turn will coat metallic implants placed in the path of the sputtered material. For this study, three target materials have been used: a hydroxyapatite-fluorapatite (HA-FA) target, and two high phosphorus glass targets. The HA-FA target has a Ca/P ratio of 1.67, whereas Glass-I, a calcium metaphosphate glass with the chemical formula $Ca(PO_3)_2$, and Glass-II, a commercially obtained calcium phosphate glass (Glass-II) with a 2% silica addition, have a Ca/P ratio of 0.5. Titanium discs (1 cm diameter, 2 mm thick) were coated by sputtering each of the three targets. As the sputtered coatings are amorphous, heat treatments were employed to obtain crystalline phases in the coatings.

Results—The bond strengths and solubility of as-sputtered and heat-treated specimens have been evaluated. Bond strength of the coatings to the substrates were determined using the Sebastian V z-axis tensile bond tester. Reflected light microscopy was used to find the exact failure location of each coated specimen. For the solubility studies, coated samples were exposed to a 0.9% NaCl solution for varying time periods after which the coatings were evaluated using SEM and EDS analyses.

In general, the as-sputtered coatings produced the highest bond strengths while the heat treatments significantly reduced the adhesion of the coatings. One exception was observed. The heat-treated coatings produced with Glass-II exhibited bond strengths as high as those observed for the as-sputtered coatings. For the solubility evaluations, all as-sputtered coatings dissolved within 1 to 3 hours after immersion in the saline solution. The heat-treated coatings produced with the HA-FA target remained after 6 weeks and thus had the lowest solubility. The heat-treated coatings produced with Glass-I and Glass-II targets dissolved within 1 to 4 days.

Future Plans—Additional efforts on this study will concentrate on the optimization of coating chemistry and structure. Coating chemistry will be controlled by the use of different ceramic targets such as: 1) glasses containing higher Ca content materials; and, 2) glass and ceramic targets containing F. By controlling the composition of these glass targets, a coating chemistry more similar to hydroxylapatite may be obtained. The structure of the coatings will be controlled by optimizing post deposition heat treatments used for the production of crystalline phases in the as-sputtered coatings. The use of vacuum and controlled atmosphere heat treatments will be investigated to determine if both high crystallinity and high bond strength of the Ca-P coatings can be achieved. The most important goal in next year's work is to maximize crystallinity as a means of reducing coating solubility while maintaining a sufficiently high bond strength of the coating to the metallic substrate.

Recent Publications Resulting from This Research

Characterization of an Ion-Beam Sputter Deposited Calcium Phosphate Coating. Rigney ED et al., International Association for Dental Research Program and Abstracts, 835, 1990.

The Effect of Heat Treatments of Ion-Beam Sputter Deposited Calcium Phosphate Coatings. Rigney ED et al., Transactions of the Sixteenth Annual Meeting of the Society for Biomaterials, 13, 1990.

ESCA Analysis of Passivated Titanium and Ca-P Surfaces. Harris JL et al., Transactions of the Sixteenth Annual Meeting of the Society for Biomaterials, 44, 1990.

The Optimization of Ca-P Ion-Sputtered Thin Films. Gantenberg B et al., International Association for Dental Research Program and Abstracts, 197, 1990.

[365] Ion Implantation to Reduce Wear on Polyethylene Prosthetic Devices

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Sponsor: *National Science Foundation*

Purpose—Spire Corporation is continuing its research in the surface modification of Ultra-High-Molecular-Weight-Polyethylene (UHMWPE) through the use of ion beam processing. The National Science Foundation (NSF) Phase I program was successful in identifying the ion beam processing parameters which can provide UHMWPE with increased microhardness and reduced coefficient of friction. The goal of the NSF Phase II effort, which commenced August 1, 1989, has been to investigate the modified surface properties of ion beam-processed UHMWPE. The treated UHMWPE will be studied in wear simulation against Ti-6Al-4V and Co-Cr alloys.

Methodology—Based on the preliminary results from the Phase I study, the Phase II effort concentrated on studying the wear performance of ion beam-processed UHMWPE in simulated wear environments. The Phase I program showed that ion implantation of various ion species into UHMWPE increased microhardness and reduced coefficient of friction. The ion beam parameters for this processing were established. In the Phase II program, ion-implanted UHMWPE test disks were tested against Ti-6Al-4V and Co-Cr alloy pins. The pin-on-disk apparatus was specially designed to enable testing in both Ringer's solution and bovine serum. Physiological loads were used in the testing. Test results showed a 60% reduction in polyethylene wear tracks and a marked reduction in the UHMWPE wear debris generation. Coefficient of friction measurements were also made during testing, and results showed a 15% improvement in both the Ringer's solution and bovine serum.

Results—Ongoing investigation has included studies of the relationship of the surface finish of the UHMWPE to the wear results. Initial findings indicated a strong interrelationship between surface finish and wear results. The effect of the vacuum environment during and after processing on the performance of the UHMWPE was also studied. Raman spectroscopy has been used to analyze the modified surface microstructure. Rutherford backscattering spectroscopy (RBS) is used as an additional analysis tool. RBS has shown a significant increase in carbon at the surface of the treated UHMWPE which indicates a densification of the near surface region. This phenomenon contributes to the improved properties of the material.

Future Plans—Based on the results of the Phase I and II studies, several large orthopedic firms have expressed considerable interest in applying the ion implantation process to the articulating surfaces of UHMWPE components of prosthetic devices. To date, our research has mainly been from a materials approach, while the orthopedic manufacturers must approach new processes with the goal of ultimate FDA approval and widespread use. For these reasons, they must address concerns such as biological response to the treated UHMWPE and potential harmful effects, if any. Additionally, since the marketing of orthopedic devices is a major consideration, the cosmetic implications of a "different" material must be assessed. These concerns are being studied in parallel with the NSF program in hopes of reducing the time to market.

Following the Phase II program, it is our goal to team up with an orthopedic manufacturer and test the ion beam-processed UHMWPE in knee and hip joint simulators.

Patents

Ion Implantation of Plastics. Patent Number: 4,743,493; Date of Patent: May 10, 1988.

Ion Implantation of Polyethylene Orthopedic Implants. Patent applied for: July 31, 1990.

B. Hip

[366] Epiphyseal Hip Replacement: A Pilot Study

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Sponsor: *VA Rehabilitation Research and Development Service (Pilot Project #B987-PA)*

Purpose—Conventional total hip joint replacement is a highly successful surgical procedure for treatment of severe arthritis of the hip. However, the incidence of mechanical loosening and stem fracture has become an increasingly significant problem, especially in younger patients. This has renewed interest in conservative alternatives. One such alternative is our epiphyseal replacement prosthesis, a new research-based design which incorporates the interface contours suggested by the geometry of the epiphyseal plate or scar.

Methodology—Using engineering design and finite element analysis techniques, we have attempted to improve on the generic type of hip surface replacement by critical design changes which appear to be of major benefit on a theoretical basis.

Progress—During this 1-year pilot project, computer modeling and laboratory testing of a new epiphyseal hip surface replacement was completed. The results of the computer modeling are reported in the article listed below. The computer analyses used a state-of-the-art bone remodeling algorithm to simulate the bony adaptation caused by the presence of the prosthetic implant. As a result of these bone remodeling simulations, initial design modifications could be made prior to implantations in animals or humans.

In conjunction with the computer modeling studies, a series of laboratory prototypes was also created. The prototypes were used to: 1) develop the necessary surgical instrumentation; and, 2) test different designs used for initial implant stability. The instrumentation consists of two reamers that are used sequentially to prepare the femoral head for prosthetic seating. A set of nine spikes (1.0 mm in diameter and 5 mm in length) is used to provide initial stability and to encourage bony ingrowth.

Due to unforeseen manufacturing difficulties, titanium prototype prostheses for the *in vivo* animal study have not yet been completed. Additional computer models and laboratory prototypes have been completed. Although it is not possible to obtain the precise time course of bone remodeling without the use of *in vivo* implantation, the computer simulations lend additional support for the efficacy of the epiphyseal replacement concept.

Recent Publications Resulting from This Research

Computer Predictions of Bone Remodeling Around Porous-Coated Implants. Orr TE et al., J Arthroplasty 5(3), 1990.

[367] Quantitative Analysis of Total Hip Arthroplasty on Stress and Strain

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A100-4RA)*

Purpose—Total hip arthroplasty design continues to evolve as the need for long-term reconstruction performance enhancement persists. Assessment of new design features requires quantitative comparative data on the effect of both design and materials selection on the stresses and strains seen by the bone so that a biologically effective reconstruction can be affected.

Preliminary Results—Assessment of the overall strain distributions, using optical methods for strain assessments to replace strain gauges, has been carried out. This noncontact full-field assessment tool would be of great value in continued research in total joint replacement. Holographic interferometry (HI) allowed for the successful qualitative assessment. Finite element comparisons

correlated well with these preliminary results. In an effort to gain more quantitative information, speckle shearing interferometry (SSI), another optical method, has been utilized. It allows optical differentiation of displacement data so that errors of mathematical differentiation may be reduced. To date, a simplified cylindrical Plexiglas™ model of the femur has been tested. Theoretical predictions and finite element modeling and strain gauge data have correlated well. These results also show excellent reproducibility. Effective utilization of SSI, however, requires the development of computerized automated fringe interpretation methodologies to allow quantified analysis of the alteration of surface strain following prosthesis implantation. In addition, early work using SSI was applied to flat two-dimensional (2-D) objects. To validate our technique for three-dimensional (3-D) objects, a series of experiments has been carried out over the last year. Double exposure plates yielded data for analysis using a prototype computer system. Calibration of the prototype system of fringe analysis indicates ±4% accuracy. Defocusing led to significant errors. These problems were obviated by using f/stops that were smaller (increasing depth of field), and increasing exposure time.

Future Plans/Implications—The next step of the experiments will be to auto-acquire speckle data with a video camera system. This system allows electronic filtering of the frequency modulated speckle patterns, thus improving the fringe location and subsequent strain assessments. Development of these computerized assessment tools continues as cadaveric proximal femurs with implants are assessed. This will allow assessment of press-fit porous-coated devices with various geometric configurations, including "off the shelf" designs and custom prostheses, thus leading to quantitative information on the effects of these new implant designs on femoral bone strain in this immediate postoperative model.

Recent Publications Resulting from This Research

Applied Optics in Biomechanics. Wheeler D, Chitsaz B, in Proceedings of the Photo-Mechanics Conference, Blacksburg, VA, 15-17, 1990.

Biomechanical Assessment of "Screw-In" Metal-Backed Acetabular Prostheses. Miller GJ, Wheeler D, Petty RW, in Proceedings of 1st World Congress of Biomechanics, San Diego, 1990.

Evaluation of Allograft Fixation. Vander Griend R, Sollaci C, Miller GJ, in Proceedings of 5th International Symposium on Limb Salvage Surgery (in press).

Total Hip Replacement: Biomechanics and Design. Miller GJ, in Total Joint Replacement, W. Petty (Ed.). Philadelphia: W.B. Saunders Company (in press).

[368] Rehabilitation Implications of In Vivo Hip Pressure Measurements: Part 1

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A352-2RA)*

Purpose—How cartilage distributes the time- and position-varying load across a synovial joint is of interest clinically as it relates to the longevity of endoprosthesis implantation following femoral head or neck trauma or necrosis. Migration of the implant through the acetabular cartilage is common: a 50% incidence of protrusion four years postoperatively has been reported. Pathologically, cartilage pressure distribution is central to the possible role of mechanical factors in the etiology of osteoarthritis, acting either directly (e.g., collagen fiber rupture), or through mechanical/biological coupling (e.g., the influence of the mechanical microenvironment on chondrocyte metabolism and expression). Scientifically, pressure distribution information is a crucial element in the basic understanding of how the mechanical and biological characteristics of cartilage, bone, and synovial fluid synergize locally and globally to achieve high load capacity, low-friction, long-wearing skeletal bearings.

Prior to our research, only sparse *in vitro* data from rather gross experiments were available on the magnitude and distribution of contact stress in synovial joints. In general, these studies described the natural global joint as distributing the load vector into a more-or-less uniform or axisymmetrical distribution with maximum pressures not much higher than that calculated by dividing estimates of the load magnitude by estimates of the area of interarticular cartilage contact. This "average" pressure is about 2 to 3 megapascals (MPa).

Cartilage *per se* is a relatively soft, poroelastic matrix which is saturated with fluid. When small plugs

of cartilage are loaded to permit fluid drainage, the intrinsic or network modulus is measured at about one MPa. Mathematical models of simplified joints studying fluid circulation have in fact postulated free-draining or porous sliders, influenced apparently by the plug experiments.

Methodology—After considering different approaches to experimentally quantify local pressures and their distribution in the human hip joint, we chose to integrate multiple pressure transducers into the load-bearing surface of a pseudofemoral head, in part because hemiarthroplasty is a common surgical response to femoral head or neck damage. Thus, *in vivo* instrumented endoprosthesis data are relevant to a significant patient population and the surgeons who service them. These data are also pertinent to scientific understanding of normal and pathological synovial joint tribology and the etiology of osteoarthritis.

Results—The first prosthesis was implanted in 1984, and produced extensive data for over 5 years (see Part 2).

A second prosthesis was implanted in the fall of 1990. Significant design improvements have been incorporated based on experience with the first implant. The distribution of the 14 pressure transducers has been changed to include those locations on the femoral head which consistently reported data of interest as the subject performed a wide range of movements and loading patterns. The mounting of the single-silicon-crystal cantilever beams, the flexion of which measures cartilage pressure, was changed. The first design called for epoxy cementing, which exhibited cold flow and calibration deterioration on several of the transducers after several years. An all-mechanical clamping technique was devised and extensively tested which eliminates this problem. This new arrangement also facilitates the precalibration adjustment of the beams relative to the pressure diaphragms and the interconnecting push-pins.

Separate *in vitro* studies of temperature rise by "walking" human cadaver hip joints in the Hip Simulator had indicated significant temperature rise. Subsequent biochemical studies on chondrocyte response to these temperatures caused the expression of "heat-shock" proteins. The Berlin group has recently reported similar temperature rise *in vivo* from their force-instrumented total hip replacement prosthesis. To better monitor temperature on and in the endoprosthesis, a dummy pressure transducer diaphragm was added and instrumented with a thermistor. This detector will also be used in a feedback control system to reduce the power inductively transmitted from the external coil to the antenna on the stem of the prosthesis.

The electronic package which converts the pressures, expressed as the strain-gauge signals, from the individual flexing beams to a pulse-amplitude-modulated signal for frequency modulation telemetry outside the human body, was extensively redesigned. Restudy resulted in part from changes and improvements in electronic components since the original unit was designed (large-scale integrated circuit "chips") and in part to increase the number of channels from 16 to 32 to accommodate the temperature measurements, the power feedback control, and the future force vector and moment measurement.

Future Plans—A third prosthesis is underway. The major mechanical components are complete and fabrication will commence subsequent to implantation and completion of the early experiments with the second unit. During surgery, postsurgical management, and early rehabilitation, much data is acquired which requires the participation of all staff, with other tasks and assignments postponed.

Implications—Data from the second and third prostheses will confirm the consistency of data across subjects under similar experimental conditions.

Recent Publications Resulting from This Research

An Instrumented Endoprosthesis for Measuring Pressure on Acetabular Cartilage In Vivo. Mann RW, Burgess RG, in Proceedings of the Workshop on Implantable Telemetry in Orthopaedics, Berlin (in press).

[368a] Rehabilitation Implications of In Vivo Hip Pressure Measurements: Part 2

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A352-2RA); National Institute on Disability and Rehabilitation Research*

Purpose—Surgical reconstruction or replacement of the human hip joint following trauma or arthritis is a very common occurrence, involving (in the United States alone) over four hundred thousand people each year. The surgical procedures include total replacement of both femoral and acetabular components of the natural joint with artificial prostheses, replacement of only the femoral component (usually following femoral neck fracture), and osteotomies where the natural components of the joint are retained but realigned. Whatever the intervention, the patients must be managed during an immediate postsurgical period of immobility. They then progress through a transitional process of rehabilitation which takes them, in stages, through more demanding movement patterns, until they regain full capability and can perform other activities of daily living. The patient management and physical therapy protocols applied throughout this process are essentially similar, whatever the particular hip surgery. Subjective generalizations derived from past experience with similar patients determine the optimum ordering, best postoperative time for initiation, appropriate duration, and content of each protocol of these management and rehabilitation practices. Thus, protocols which are vital to the rapid, safe, and full recovery of the patient rest solely on qualitative observations and *ex post facto* outcomes. *De novo* quantitative objective data are now available to evaluate these traditional processes and to consider alternatives.

Progress—Novel data from a pressure-instrumented femoral head replacement procedure have now provided objective, quantitative information on the mechanical environment of the human hip joint during surgery, postoperative management, throughout the process of rehabilitation, and in the activities of daily living. These data are challenging contemporary patterns of patient care, therapy, and rehabilitation, and provide objective data on which to classify the strenuous character of many normal and common movement patterns.

Methodology—A pressure-instrumented prosthesis with 14 small sensors integral with the spherical, metal, pseudofemoral head measures the focal pressure experienced by acetabular cartilage as it articulates against the femoral component. The first unit was implanted in June 1984. Data were acquired during surgery, postoperative recovery, immobilization, mobilization while in bed, early muscle exercise, all stages of ambulation (i.e., parallel bars, walker, crutches, and cane), and then during normal gait and other movement patterns such as rising from a chair, stair-climbing, jumping, and jogging, for a total period of over 5 years. During movement protocols, the pressure data are complemented with six degree-of-freedom kinematic data from the body segments of the lower extremity and the pelvis, and the foot-floor forces measured on dual forceplates. Very high local pressures measured during certain movements indicate significant muscle cocontraction, which has been confirmed from concurrent electromyographic data from the major muscle groups crossing the hip joint.

The pressures measured during the various stages of recovery and rehabilitation are of direct relevance to the evaluation of traditional rehabilitation procedures. Much of the data demonstrates inconsistencies with what has been presumed to be meritorious and commonly accepted rehabilitation practice, both in ordering and timing. To cite several examples, most of the present immobilization practices produce higher maximum pressures than pedaling a stationary bicycle, a common early mobilization procedure. Muscle contraction exercises performed in bed, well before attempts at ambulation, produce pressures of the same magnitude as those during the stance phase of level walking measured a year postoperative. Little correlation exists between the recorded maximum pressures and the current sequence in ambulation therapy (i.e., first parallel bars, then walkers, then crutches, then canes). The measured hip pressure is little affected by the force applied to the partial-load-bearing cane. The maximum pressures measured during walking indicate no further rise after 6 months, which correlated with the

clinical observation of achieving normal gait. The highest pressure measured was 18 MPa when rising from a normal (45 cm) chair. Astoundingly, this high pressure is higher than that produced when a hydraulic jack lifts a car.

Implications—This new quantitative pressure data can provide the basis for a more rational definition of appropriate protocols applied during recovery and rehabilitation following major hip surgery. The longitudinal data may explain why acetabular protrusion sometimes occurs following femoral head replacement. We believe the congruence of the metal ball to the natural acetabular cavity —both diameter and geometry—is critical, as demonstrated in our *in vitro* studies. The new data are also influencing surgical practice by indicating the directions of maximum pressure; accordingly, surgeons are using bone grafts to strengthen challenged regions of the pelvis.

Future Plans—A second pressure-instrumented prosthesis which incorporates a number of design improvements is ready for implantation. A future, more extensive series of implants has been proposed which would augment the pressure data with direct measurement of the force vector across, and the moments about, the hip joint.

Recent Publications Resulting from This Research

Contact Pressures from an Instrumented Endoprosthesis. Hodge WA et al., J Bone Joint Surg 71-A(9):1378-1386, 1989.

Effects of Isokinetic and Isotonic Exercise on In Vivo Hip Contact Pressure. Elbaum LE et al., Transactions of the 35th Annual Meeting of the Orthopaedic Research Society, 225, 1989.

The Effects of Running and Gaining Weight in Comparison with Normal Gait on Pressures Measured in the Human Hip Joint. Harris CL et al., in Proceedings of the 13th Annual Meeting of the American Society of Biomechanics, Burlington, VT, 174-175, 1989.

In Vivo Hip Contact Pressures During Exercise and ADL. Krebs DE et al., Phys Ther 69:384, 1989.

An Instrumented Endoprosthesis for Measuring Pressure on Acetabular Cartilage In Vivo. Mann RW, Burgess RG, in Proceedings of the Workshop on Implantable Telemetry in Orthopaedics, Berlin (in press).

In Vivo Pressures on Acetabular Cartilage Following Endoprosthesis Surgery, During Recovery and Rehabilitation, and in the Activities of Daily Living. Mann RW, Hodge WA, in Proceedings of the Workshop on Implantable Telemetry in Orthopaedics, Berlin (in press).

[369] Optimized Surface Bonding and Stiffness of Femoral Endoprostheses

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Purpose—Loosening of the femoral component is the most common complication of total hip replacement. The objective of this investigation is to determine the optimal surface characteristics and material properties for a femoral endoprosthesis to avoid loosening. The specific short-term objectives are to investigate the following design parameters using finite element modeling techniques: 1) the shape of the stem; 2) a presence of a collar for calcar contact; 3) the surface distribution of bone-prosthesis bonding for porous or ceramic coated stems; 4) the elastic modulus of the prosthesis; and, 5) the role of Coulomb friction at the bone-prosthesis interface.

Methodology—This investigation employs computer-based three-dimensional (3-D) structural models using the finite element method. Iterative solution procedures, based on mathematical optimization, are also being developed. New nonlinear contact surface algorithms, which include Coulomb friction, are also employed in two-dimensional (2-D) models.

Progress—A 3-D finite element model of an intact femur was developed. This model was then modified to include a conventional straight-stem femoral component with a collar for calcar contact. A third 3-D model was developed by replacing the straight-stem component with a contemporary canal-filling femoral stem. Two large series of analyses were performed in which the area of bone-implant interface bonding was incrementally varied. Nonlinear gap elements were used at unbonded areas to simulate frictionless contact. Separate analyses were performed for cobalt-chromium, titanium, and carbon composite implants. The applied loads represented three phases of gait, stair ascent, and various isometric exercises.

Most recently, a 2-D model of an axisymmetric stem in diaphyseal bone was developed. This model included

nonlinear contact surfaces. Unlike the gap elements used in the 3-D models, these contact surfaces are capable of large displacements and include Coulomb friction. Analyses are currently being performed of axisymmetric models and plane stress models with side plate elements to evaluate various modeling techniques.

Results—The bone-prosthesis interface properties had a strong influence on the stresses in the supporting bone. Cementing the femoral component resulted in the most stress protection of the metaphyseal cortical and trabecular bone, followed by the fully-ingrown porous-coated implant, while the press-fit implant resulted in the least stress protection. In the more distal sections, the differences were small. The predicted stress protection in the metaphysis and proximal diaphysis agreed with published data.

The location of the maximum predicted interface normal stress in the bone was highly dependent on the region of interface surface bonding. It generally occurred at the distal boundary of the bonded region, due to the transfer of stress from the prosthesis to the bone. However, the peak principal stresses in the cortical bone proximally, were not highly dependent on the amount of surface bonding, and their magnitudes leveled off as the region of bonding extended to the distal stem. The peak shear stress at the interface consistently occurred at the distal edge of the bonded area. As the surface area of bonding was limited to proximal regions of the stem, large compressive interface stresses were predicted, which could exceed the strength of the supporting bone.

Future Plans—Our current objective is to apply various objective functions and constraints to determine the best distribution of bonding from the existing analyses. We will then make incremental changes and perform additional analyses to determine the optimal solution. Several objective functions will be tested, including minimization of the stress differences between the intact femur and the femur with the endoprosthesis, subject to constraints on the shear stresses at the bone-implant interface. The 2-D models will be completed in order to investigate the relationships between Coulomb friction and subsidence and micromotion.

Recent Publications Resulting from This Research

Parametric Analysis of the Interface Mechanics and Material Properties of a Straight-Stem Femoral Component for Total Hip Arthroplasty. Cheal EJ et al., First World Congress of Biomechanics, 1990.

[370] Use of Proximal Femoral Allografts in Total Hip Revision

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A548-RA)*

Purpose—Insufficient bone stock in the proximal femur is a frequently encountered problem in revision hip replacement, leading many surgeons to replace deficient host bone with a proximal femoral allograft. A major problem, however, is establishing union between host femur and allograft. A nonunion rate of 10% has been reported with cemented fixation. If the distal stem is press fit into the host bone, substantially different mechanics would likely occur at the allograft-host bone interface, differences which may enhance their union. The purpose of this study is to compare these alternative methods of distal stem fixation when used with a proximal femoral allograft in total hip replacement.

Progress—The first phase of this project (an *ex vivo* study comparing mechanics at the allograft-host bone interface for cemented versus press fit distal fixation) has been completed.

Methodology—Ten large cadaveric canine femora were used to simulate preoperative and acutely postoperative conditions. Allografts were simulated with proximal femoral autografts, making the bone graft ideally sized. Femoral components were press fit into each medullary canal. Three stacked rosette strain gages and three eddy current transducers (ECTs) were adhesively bonded to the bone, measuring strains near the allograft-host bone interface and relative displacements of the allograft, respectively. Axial loads and transverse loads (torsion producing) were applied to the femoral (or implant) head.

Testing on each femur was performed in the following sequence: 1) control (intact femur); 2) press fit femoral

implant (no graft); 3) femoral implant cemented to proximal autograft and press fit distally; and, 4) femoral implant cemented proximally and distally. From the strain gage data, principal strains and strain energy densities (SED) were calculated.

Results—As a general trend, maximum compressive principal strains decreased as the testing sequence progressed for axial loading cases. A similar behavior was observed with SEDs. In each case, the cemented group consistently produced the lowest absolute strain. This effect was significant in all minimum principal strain comparisons at two of the three rosette locations. For torsional loads, the absolute strain in the cemented group was always smaller than the press fit group.

The distally cemented group had small relative displacements of the allografts. In contrast, each specimen in the press fit group had high relative displacements in at least one ECT for at least one loading condition. The transverse ECT typically measured relative displacements greater than 1 mm for both axial and transverse loadings.

Future Plans/Implications—Cemented distal fixation provides a stable structure for allograft augmented total hip revisions, but it reduces the load transfer at the allograft-host bone interface, when compared with a distal press fit. This decreased load transfer may contribute to nonunions. The alternative of a distal press fit was unstable in at least one mode of loading in our experiments. The design of the distal stem used in this study probably contributed to this instability. If stability can be obtained with an alternative (press fit) stem design, load transfer advantages may exist at the host bone-allograft interface. Therefore, an alternative design for the distal stem was formulated. This design is currently being manufactured and will be used in future *in vivo* canine studies.

[371] Dynamic Implant for the Development of a Cementless Prosthesis

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Sponsor: *National Science Foundation*

Purpose—The aim of this project is to develop a biocompatible material with a range of mechanical properties similar to those of human compact bone. The ultimate goal is to use the new material as cementless prostheses, for example, joint implants.

Progress/Methodology—The general composition of this dynamic implant is a hydrophilic, crosslinked matrix reinforced with a three-dimensional (3-D) braided fiber structure. The stages of the development of the material system include the design and use of 3-D braid to achieve the desired degree of structural reinforcement; the selection of a candidate material for use as the matrix polymer base; formulation and optimization of the composition and the crosslinking scheme of the base polymer; development of a mechanical model to represent and predict the behavior of the composite structure under load; verification of the analytical prediction by testing the mechanical properties of the neat polymer and the polymer/braid-reinforced composite; and, evaluation of the interfacial pressure level to be utilized for *in-situ* implant fixation. Progress in each of these areas is discussed below.

Braid Design. Selection of braiding parameters is necessary to achieve the required degree of base-polymer reinforcement. The braid angle, the type and volume fraction of fibers, and the degree of fiber packing (beat-up) are optimized to provide a high level of compressive strength while retaining the high tensile strength inherent in braided structures.

Polymer Systems. Two different crosslinking agents are blended with the base monomer (acrylic acid) prior to its polymerization. The first crosslinking step occurs by a free radical mechanism during polymerization, while the second step involves using glycerol in a condensation reaction to be completed in the solid state by a postpolymerization heat-curing cycle which induces ester bond formation between the glycerol and the pendant acid groups in the matrix. Formation of the ester bonds is used as a final control on the resulting equilibrium pressure and is measured using TGA and FTIR techniques which are currently in progress.

Mechanical Testing and Evaluation. The crosslinking reaction of glycerol enhances polymer strength and modulus. However, unreacted glycerol acts as a plasticizer, lowering the same properties. To date, the mechanical

properties of the neat resin have remained significantly below those of compact bone. When a fiber network is introduced in the above system, it enhances both the strength and modulus of the matrix, and brings these properties within the target range for compact bone.

Evaluation of Interfacial Pressure. The interfacial pressure between the implant and surrounding bone is used to affix and hold the structure in place and accelerate bone response and densification. Thus, radial stresses are being measured as a function of time using cylindrical specimens incubated in Ringer's solution, while fitted in a metallic mold of the same size as the dry sample.

Development of a Finite Element Model. In the present analysis, a 3-D orthotropic braided structure is taken into consideration. The procedure to determine the geometry and mechanical properties requires an initial postulation of a set of mechanical parameters. The braided geometry is then estimated by minimizing the total strain energy, or employment of the Tsai-Hill yield criteria. Currently, attempts are being made to estimate the overall stresses due to swelling of the hydrophilic matrix.

Recent Publications Resulting from This Research

A Dynamic Implant for the Development of a Hip Stem Prosthesis. Sharda AN, Kamel IL, presented at the Annual Conference of the IEEE Engineering in Medicine and Biology Society, Philadelphia, 1990.

[372] Correlation of In Vivo Synovial Joint Pressure Data with that from Posthumous Hemipelvis and Proximal Femur Including Pressure-Instrumented Endoprosthesis

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Sponsor: *Whitaker Foundation, Health Sciences Fund*

Purpose—Only one pressure-instrumented femoral head prosthesis has ever been implanted; that prosthesis has been retrieved posthumously together with the proximal femur and hemipelvis. Data was acquired from this prosthesis for a broad spectrum of activities and positions throughout the five years that it was implanted. This extensive array of *in vivo* data can now be compared with *in vitro* data that can be taken during comparable experiments in the laboratory. *In vitro* experiments afford control over experimental conditions which are not possible *in vivo,* and which will assist in further interpretation of *in vivo* data. Evaluation of the state of the acetabular cartilage following five years of contact with a well-matched femoral head replacement will also provide information never previously obtained and relevant to longevity of this orthopaedic procedure.

Methodology—Hardware required for high-pressure calibration of pressure sensors in the prosthesis has been built and tested. Software for acquisition of data from the prosthesis is functional on a personal computer; thus, pressure calibration can proceed. Calibration of the effect of temperature on pressure sensor output has also begun. The techniques for obtaining acetabular geometry measurements are being tested prior to application on the excised acetabulum. Static tests in the Hip Simulator, a multi-axis, electrohydraulic testing facility will follow, followed by dynamic experiments with the Hip Simulator under computer control.

Implications—Correlation of *in vivo* and posthumous *in vitro* data will permit confident quantification of the forces experienced at the hip joint in life. This information and the knowledge gained from the acetabular measurements are expected to influence the design of femoral head replacements and surgical procedures, both of which involve endoprosthesis and total joint replacement.

Recent Publications Resulting from This Research

Optical Verification of a Technique for In Situ Ultrasonic Measurement of Articular Cartilage Thickness. Modest VE, Murphy MC, Mann RW, J Biomech 22(2):171-176, 1989.

[373] Synovial Joint Biomechanics and the Pathogenesis of Osteoarthritis

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Sponsor: *Whitaker Foundation, Whitaker Professorship of Biomedical Engineering, Newman Laboratory Fund*

Purpose—Osteoarthritis, or degenerative arthritis, disables more Americans than any other disease, producing much pain and loss of mobility while causing the greatest loss of worker productivity. This project is exploring how the human hip joint accommodates the forces and displacements of normal movement, and whether, and how, these mechanical factors contribute to the pathogenesis of osteoarthritis, either directly or by affecting the biology of cartilage.

Methodology—The *in vitro* phase of the investigation involved analysis and experiment on human hips from cadavers and the development of a detailed mathematical model of the cartilage and bone in this ball-and-socket synovial joint. Results include interarticular surface stress and strain, fluid exuded/imbibed, fluid pressures and the interarticular flow paths, solid matrix friction, entropy generation, and consequent temperature rise.

The *in vivo* phase includes five years of unique pressure data from the human hip (see "Rehabilitation Implications of *In Vivo* Hip Pressure Measurements," pp. 291-294). We now also have the unique opportunity to study *in vitro* the acetabulum and the pressure-instrumented endoprosthesis from which we acquired our five years of *in vivo* data. We plan to both replicate *in vivo* experiments and perform tests not feasible in life.

Results—Computer simulations of the human hip synovial joint and correlating experimental data confirm the role of the interarticular seal in maintaining the high pressures, which for a healthy joint carrier, are typically more than 90% of the load. The degeneration of this seal is, we believe, tantamount to osteoarthritis. Accordingly, we are focusing on understanding the nature of this remarkable resistance to fluid flow. The cartilage-to-cartilage spacing in synovial joints in life is thought to be very small, but has never been measured.

A feasibility study of a technique to measure the interarticular gap using ultrasound has been carried out. Theoretical analyses for the experiments, the instrumentation, digital signal processing algorithms, and experimental techniques, have been developed and applied to the measuring technique with encouraging results. New ultrasonic instrumentation to be installed in a pseudo femoral-head prosthesis, in order to measure *in vitro* the global distribution of clearance between the prosthesis and the natural cartilage of the pelvis of a hip joint, has been designed.

C. Knee

[374] All-Plastic Total Knee Replacement

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Purpose—Greatly altered distribution of strain in bone surrounding metallic total joint replacement prostheses can lead to a net decrease in bone density, and an adverse biological response might be elicited by metal ions released from the device.

Our overall goal is to develop a total knee replacement made entirely from polymeric material (including fiber-reinforced polymeric composites). A specific objective is to test the hypothesis that a more compliant polymeric total knee replacement prosthesis

leads to more physiological remodeling of underlying bone.

Methodology—A radiographic evaluation of metallic total knee replacement prostheses in humans was undertaken to determine the prevalence of bone loss that might be due to the high stiffness of the device. This would serve as rationale for the development of an all-plastic total knee replacement prosthesis. The tribological performance of candidate polymeric materials is being assessed in a laboratory apparatus designed to evaluate various combinations of polymer-polymer articulation. Another apparatus is evaluating the morphology and size of wear particles that are produced as candidate biomaterials are abraded against bone (as might occur if the all-plastic knee prosthesis is employed as a cementless device). Prototype polymeric total knee replacement prostheses are being designed for implantion in dogs to evaluate tissue response.

Progress—In a retrospective radiographic review of 147 total knee arthroplasties, bone loss was found to occur in a distal anterior femur in 68% of the cases reviewed. The prevalence of bone loss was independent of mode of fixation (porous-coated versus cemented) and the implant design. Radiographically detectable bone loss occurred within the first postoperative year and did not progress further. Three-dimensional finite element analysis performed by other investigators has demonstrated that the replacement of the bearing surface of the femur with a stiff metallic implant reduces the stress in the distal anterior femur by at least one order of magnitude. We conclude that the bone loss resulted from stress shielding.

One series of wear studies employed a six-channel pin on flat wear-test machine-abraded candidate polymers against cortical bone slabs. The polymer specimens included: ultrahigh molecular weight polyethylene (UHMWPE), polymethylmethacrylate (PMMA), polyetherether ketone (PEEK) with smooth and textured surfaces, carbon-reinforced PEEK composite in parallel and perpendicular orientations, and polysulfone (PSF) in bulk and porous form. Titanium alloy served as the control. The operating conditions were: applied stress = 0.22 MPa, sliding speed = 24 mm/sec, temperature = ambient, lubricant = distilled water, duration = 32,000 cycles. Particles collected after testing were analyzed using a laser light-scattering device and by scanning electron microscopy. The results of the wear debris analysis are: 1) porous PSF, size = 8.09 μm, SD = 3.37; 2) PSF, size = 6.96 μm, SD = 3.59; 3) textured PEEK, size = 22.67 μm, SD = 10.1; 4) smooth PEEK, size = 8.04 μm, SD = 4.81; and, 5) carbon-reinforced PEEK with perpendicular orientation, size = 10.44 μm, SD = 5.19. Statistically meaningful results were unobtainable for the titanium, UHMWPE, PMMA, and the carbon fiber-reinforced PEEK composite with parallel orientation. The size distribution for porous PSF and the bulk PSF were compared using an unpaired, two-tailed Student's *t*-test. No statistically significant difference was found to exist between the two materials. Results for the two different PEEK materials indicate that the particle size of the wear debris is much larger for the textured material than for the smooth. The two distributions were compared using an unpaired, two-tailed Student's *t*-test, with the result being significant at the $p < 0.0001$ level. Debris from the UHMWPE material exhibited a large aspect ratio (30:1). The particles were 10 to 15 μm in diameter. There were insufficient numbers of particles to determine the average size statistically. The isolated titanium particles have a plate-like morphology with a thickness of 5 to 10 μm. The wear-tracks in the bone counterface materials were examined using a depth-indicating device. The results for the parallel and perpendicular composite materials showed a large difference. The perpendicular material produced a wear-track that was larger by an order of magnitude. The cause for this difference is believed to be fiber orientation. Delamination occurs in perpendicular fiber orientation (as seen on the wear pin face), resulting in debris generation and an abrasive wear mechanism. In contrast, the parallel orientation shows no delamination and the wear-track results are similar to those of bulk PEEK.

A second wear apparatus comprises four pneumatically-driven cylinders capable of applying physiological loads to specimens sliding on flat plates in a reciprocating motion. This machine determines the function and wear characteristics of polymer-polymer bearings.

Future Plans—A design project is underway to develop prototype composite femoral condylar prostheses for implantation into dogs.

[375] Articular Cartilage Replacement Prosthesis for the War-Injured and Aging

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A424-RA)*

Purpose—Left untreated, focal defects in articular cartilage produced by excessive joint loading can grow to the extent that they lead to degeneration of the entire joint, and the need for total joint replacement. The objective of this investigation is to develop a prosthesis that can replace these focal defects in articular cartilage. In its initial form, this prosthesis would be a cylindrical implant inserted into holes drilled through the articular cartilage defects. The device would have a polymeric surface which would be capable of articulating against the apposing natural articular cartilage without causing accelerated degeneration of that or surrounding tissue.

Methodology—One task is to investigate the tribology of candidate materials to be employed for the articulating surface of the device. In a tribological apparatus, natural articular cartilage specimens are being rubbed against candidate polymeric substances. The coefficient of friction and the degradative changes of the articular cartilage are being determined.

Another task has been to develop a method to assess the "biocompatibility" of candidate polymeric materials to be employed for this application. Human peripheral blood monocytes, obtained from human volunteers, are being cultured on polymeric substrates. The production of inflammatory agents including prostaglandin E_2, interleukin-1 and interleukin-6 are being evaluated using radioimmunoassays.

An animal model is being developed to evaluate the efficacy of the articular cartilage replacement prosthesis (ACRP). Cylindrical holes drilled in the patella of dogs are to serve as the test sites for evaluating the performance of candidate ACRP constructs.

Progress—The fabrication of ACRP constructs has been accomplished by bonding elastomers (e.g., silicone and polyurethane) to a porous thermoplastic (e.g., polysulfone) substrate, which is to serve as the attachment vehicle to bone. Mechanical testing is being performed to compare the mechanical properties of the ACRP constructs with certain properties of natural articular cartilage.

Cell culture assessment of the relative "biocompatibility" of candidate polymers has revealed elevated levels of IL-1, IL-6, and PGE_2 produced by monocytes cultured on ultrahigh molecular weight polyethylene. Other polymers are undergoing evaluation.

A surgical procedure for implanting ACRP constructs into the dog patella has been developed. Animal implantation is underway.

[376] Improved Anchorage of Knee Replacements Based on Confirmed Design Rules

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Sponsor: *VA Rehabilitation Research and Development Service (Project #A546-RA)*

Purpose—The goal of the proposal is to develop a tibial component of an artificial knee joint for fixation by osseointegration. It has long been known that the anchorage of the tibial component in human knee implants tends to fail whether a cemented or a porous-coated design is used. In fact, loosening of the tibial component is the most frequent single cause of failure in total knee replacement.

Progress—We have developed a tibial stem with a surface design intended for cementless fixation by osseointegration. To date the prototype of the total knee replacement has been manufactured using computer-aided design and machining based on the dimensions of dog knee X-rays. A cemented femoral stem with a hinge is attached to the uncemented, "press-fit" tibial component. A total of four titanium knee joint prostheses have been implanted in

short-time survival dogs. One prosthesis has recently been implanted in a long-term survival dog. At present, histomorphometry equipment and the pertaining software for analysis of the efficacy of osseointegration at the bone implant interfaces are being tested. The system was operational by the end of September, 1990.

Methodology—The design will be tested in 40 dogs to be sacrificed at specific time intervals (1, 2, 4, and 8 months) postoperatively. The implant performance will be evaluated by mechanical testing of the strength of fixation of the bone-implant interface and by histomorphometric analysis.

Future Plans/Implications—The first 15 knees were implanted by the end of December 1990. It is anticipated that the remaining 25 knees will be implanted by July 1991. The mechanical and histomorphometric evaluations will be completed in December 1991. If successful, the design may form the basis for the development of human implants.