Journal of Rehabilitation Research and Development

Rehabilitation R & D Progress Reports 1983

Prosthetics / Amputation

A. Comprehensive Amputation Management

B. Lower Limb Prosthetics

C. Upper Limb Prosthetics

D. Orthotics

E. Hip and Knee Joint Replacements

F. Lower Limb Prosthetics

1. Gait Analysis

2. Miscellaneous

G. Upper Limb General

H. Maxillofacial Prosthetics

Prosthetics/Amputation R&D

In this section, under the broad heading of Prosthetics/Amputation R&D, reports in the following general area will be found: **Comprehensive Amputation Management; Lower Limb Prosthetics; Upper Limb Prosthetics; Orthotics; Hip and Knee Joint Replacements; Lower Limb — General,** including **Gait Analysis** and **Miscellaneous; Upper Limb — General; Maxillofacial Prosthetics.**

COMPREHENSIVE AMPUTATION MANAGEMENT

VAMC TUCSON

COMPREHENSIVE MANAGEMENT OF UPPER AND LOWER EXTREMITY AMPUTATION

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The six main objectives of our Amputation Rehabilitation Program are (i) amputation level determination, (ii) development of temporary prostheses, (iii) immediate postsurgical fitting after upper extremity amputation, (iv) definition of application of upper extremity prosthetic components, (v) elective amputation for neurologic dysfunction; and (vi) Regional Amputation and Training Center.

Amputation Level Determination — Xenon^{133} skin clearance techniques still continue to be the most reliable test for amputation level determination. The validity of this technique has recenly been documented by the Surgery/Radiology Group at the University of Cincinnati who have not only confirmed the value of Xenon^{133} for amputation level selection, but also reaffirmed our previously published level of 2.6 ml/100 g tissue/min blood flow as the baseline which is adequate to ensure amputation healing. During the past year, we have analyzed Xenon^{133} clearance techniques as compared to the laser doppler and skin fluorescence. Although skin fluorescence does have some predictive value, there is not a sharp demarcation such as one sees with Xenon^{133}. Our preliminary laser doppler tests similarly suggest that there is not a fine discriminative point for the laser doppler. During the upcoming year, we plan to expand our laser doppler analysis and also compare Xenon clearance techniques with tissue oxygen skin tension.

Development of Temporary Prostheses — During the last 2 years we have developed and finalized techniques which utilize lightweight casting materials for the design and development of lightweight, cool, durable lower-limb temporary prostheses.

Immediate Fit After Upper-Limb Amputation — Preliminary data on immediate fit after upper-limb amputation has been verified by our subsequent patient population. More importantly, data from the Tucson VA Medical Center and from the Atlanta VA Medical Center (Emory University) was analyzed by both principal investigators (James Malone & Lamar Fleming) and similar data were found.

Definition of Application of Upper Limb Prosthetic Components — Our preliminary data would suggest that there is not a cost benefit to external powered prosthetic components and, in fact (as noted above) our general approach is to fit conventional components first and only after a patient has proved to be successfully rehabilitated will we then commit ourselves to powered components. This is not to imply that there is not a role for externally powered upper-limb components for the high or multilevel amputee. However, for the unilateral amputee, externally powered components have, perhaps, only a marginal value as compared to conventional components.

Elective Amputation for Neurologic Dysfunction — During the past year we have done two more amputations on patients with brachial plexus injuries. Our surgical approach involves shoulder fusion, elective amputation, and rapid fitting of upper-limb components. These patients have gone back to work, and we are continuing to be extremely impressed with the rehabilitation potential for upper-limb amputation in patients with non-recoverable neurologic impairment of the upper limb.

Regional Amputation and Training Center — We have added an Occupational Therapist/Program Coordinator to our program during the last year. We

are beginning to advertise indirectly for residents, students, and faculty who are interested in spending time in a dedicated Amputation Program in order to improve their diagnostic, surgical, and rehabilitative skills. Clearly, the rehabilitation results from Centers interested in amputation surgery continue to surpass the results from Centers wherein there is not a dedicated, interested team available ■

LOWER LIMB PROSTHETICS

VAMC SAN FRANCISCO

DEVELOPMENT, TESTING, AND EVALUATION OF NEW PROSTHETIC DEVICES

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Survey of Problems & Needs — The first of these was a survey of 179 veteran lower-limb amputees from two Veterans Administration medical centers, in order to determine their prosthetic problems and needs. Individual prosthetic evaluations of 54 respondents by the research team defined more precisely the status of their prosthetic care.

The most striking finding from this study was the high incidence of residual limb discomfort. Fifty-four percent of both traumatic and dysvascular amputees complained of moderate-to-severe discomfort.About one half of the respondents noted difficulty in obtaining a comfortable socket fit. Among the 54 amputees evaluated individually, evidence of improper socket fit was found in 59 percent of the below-knee and 78 percent of the above-knee prostheses. Most of these problems were related to improper socket construction initially. The remainder were due to amputee-related factors such as changes in the size of the residual limb or deterioration of the socket and liner due to wear. Mechanical skin irritation or breakdown was found in 41 percent of the below-knee and 22 percent of the above-knee residual limbs. Deficiencies in prosthetic suspension, alignment, and foot function were common, and were often associated with compensatory gait deviations.

Excessive stiffness in the heel cushions of SACH feet was a frequent finding and this is being further evaluated in our on-going studies.

It is suggested that, in order to reduce the incidence of residual limb complaints in the veteran amputee population, the quality of the prosthetic care that is being provided needs improvement. Greater emphasis should be placed on earlier identification and correction of problems of prosthetic wear and maintenance — by both the amputee and outpatient personnel.

Clinical Study of UCBL Knee Linkage — The second of these studies was a clinical study of the UCBL 4-Bar polycentric prosthetic knee linkage. The mean follow-up period was 12.3 months. Very positive subjective responses were reported by 75 percent of the amputees, and more than one third stated that the device was superior to any that they had used previously.

Studies in Progress — Design of the Moveable Ankle Cushion Heel (MACH) foot has progressed to the modeling phase. A study of the properties of available foamed polymers, to optimize energy absorption stability and wear in such an application, has been started. Also included in this study is an evaluation of the static loadbearing properties of commercially available SACH feet.

We have concluded that there is no static difference in response between some "regular" and "medium" heels, and are planning to study the dynamic response in future studies.

In response to problems encountered with air leaks in the air cushion socket, we have developed a construction technique for the air cushion socket which improves the airtight seal. This socket, when properly fabricated, is highly successful for below-knee amputees with problem stumps, but the success is dependent on determination of the proper volume of enclosed air space for any patient and the major criticism has been air leakage.

The root of the problem lies with the interface between the elastic sleeve and the plastic socket. Even under the best of conditions there is a minor air leakage, due to the fact that there is no chemical bonding between the Dow Corning 3110 elastomer and the polyester resin at the proximal border of the elastic sleeve. The air leakage becomes worse with constant use of the socket, because the elastomer/polyester resin interface begins to break down or erode.

Several changes in the fabrication technique were devised as a solution to this problem. The first con-

sists of the lamination of a thin polyester resin shell (Banlon and fiberglass) which encapsulates the proximal portion of the plaster model to point 3/8 of an inch distal to the level of the tibial tubercle. The elastic sleeve is now laminated over the model to a level 3/8 of an inch proximal to the distal edge of the polyester shell. The lamination procedure for the elastic sleeve has also been changed. A 1/16-inch-diameter nylon cord loop is placed over the outer layer of the Banlon at the level of the tibial tubercle, prior to pulling on the outer PVA bag. The nylon cord has a dual purpose; it serves as a collection point for the R.T.V. rubber (thus forming a slight bulge) and helps prevent the R.T.V. from bleeding into the fabric beyond the desired point of lamination. The fabrication procedure now continues as previously outlined by Wilson et al. The R.T.V. bulge at the proximal border of the elastic sleeve is now sandwiched between two polyester resin laminates (the outer socket and the inner proximal shell), which forms an airtight barrier ■

NIHR REC

PROSTHETIC INTRAMEDULLARY PYLON: LONG-TERM IMPLANTATION STUDIES

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Objective: The goals of this research project were to investigate selected materials, optimize mechanical design, and develop surgical techniques for long-term endoskeletal attachment of prosthetic limbs.

Summary: The final design represents a compromise between considerations for (i) minimizing bone stresses during loading, (ii) providing minimal disruption of the endosteum, and (iii) machining limitations/expense. The design results in stress distribution through the pylon below ultimate failure strengths for cortical and woven bone up to load levels of 7000 pounds and 600 pounds, respectively, in axial and torque loading.

Radiograph, gross photographic, and histological evidence have been positive in terms of analyzing tissue reaction to the implant. Light and scanning electron microscopy have confirmed that normally ossified tissue is forming in areas that were removed during tapping of the bone. Although there is a thin fibrous layer adjacent to some portions of the implant, in general the tissues appear healthy and richly vascularized.

Overall, the results obtained in these implantation studies of the carbon-coated titanium pylon have been extremely encouraging. Stable bone implants have persisted for periods up to 5 years ■

NSF

MICROCOMPUTER-CONTROLLED, INDIVIDUALIZED MULTIMODE PROSTHESES FOR LOWER-EXTREMITY AMPUTEES

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The research effort involved in this program is a continuation of an effort to improve amputee mobility through development of control schemes and interactive simulation systems. As a spin-off from use of the interactive simulators, electrically modulated knee-torque controllers have been shown to be viable with regard to size, weight, and power consumption. The research contributes to a new generation of artificial legs, and also to improved robotic manipulators. Through microcomputer control, the prosthetic devices are expected to have a versatility and adaptability far beyond previously existing prostheses.

The program aims to elucidate the basic control algorithms and also the hardward configuration required for laboratory experimentation. This is the first year of a 3-year continuing grant ■

VAMC SEATTLE

PHYSIOLOGIC SUSPENSION FACTORS IN BELOW-KNEE AMPUTEES EVALUATED

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This project has shown that suspension by physiologic mechanisms alone is achievable. The goals now are to develop a protocol to determine the physiologic suspension potential of any amputee by clinically measuring stump and socket factors contributing to suspension. Prosthetic modifications and training techniques are also proposed to take maximum advantage of this potential.

Methods — We have accumulated a data base of suspension parameters and suspension function on 60 definitve and 28 research prostheses. Co-variance

analysis has been applied to the data. Subjective input with regard to suspension function has been gathered through the use of a questionnaire. An isometric training protocol has been used to improve physiologic suspension.

Five prostheses were made incorporating physiologic suspension factors.

Definition and description of data base parameters can be found in our last report. Co-variance analysis did not identify any of these as clear predictors of suspension performance. The questionnaire has also been published.

Subjects were issued ankle weights for isometric training. The training protocol consists of lifting the prosthesis/weight by physiologic components alone, holding it up for 10 seconds, then resting.This is repeated 10 times, twice per day. Subjects are evaluated serially during training.

Definitive physiologically suspending prostheses are produced by a standard two-stage casting technique with the following modifications: muscle bulges are marked before casting; residual limb musculature is contracted for the first stage and relaxed during the second; muscle bulges are accentuated to predetermined dimensions during the model rectification process, with care to avoid bony areas.

A clear thermovac socket is attached with Otto Bock endoskeletal components to a foot provided by the amputee.

Comprehensive evaluation of limb fit and function is carried out at initial fitting. Residual limb and socket factors are noted. Function is evaluated by having the subject lift calibrated weights (Fig. 1). Gait analysis, alignment, and dynamic evaluation of the physiologic suspension are carried out concurrently. The subject must be able to ambulate comfortably without distal gapping (Fig. 2) and be able to apply a tensile force of at least 25 Newtons, physiologically, to the prosthesis. Ancillary suspension is added at this time if necessary. The amount of weight the subject can lift serves as a baseline by which to gauge progress. (Lifting is accomplished with the knee bent to eliminate the contribution of a taut patellar tendon and hamstrings to overall suspension.)

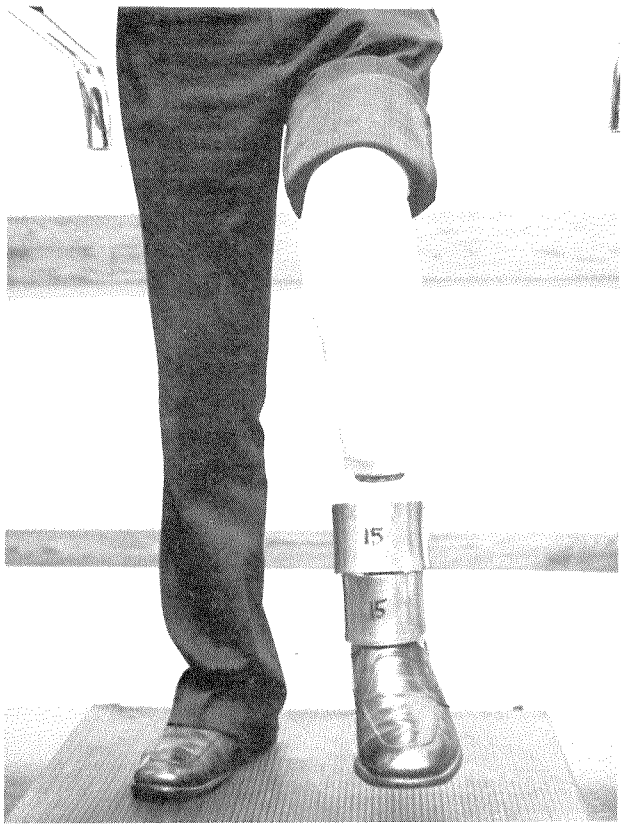

FIGURE 1
Calibrated weights aid in the evaluation of the effectiveness of physiologic suspension.

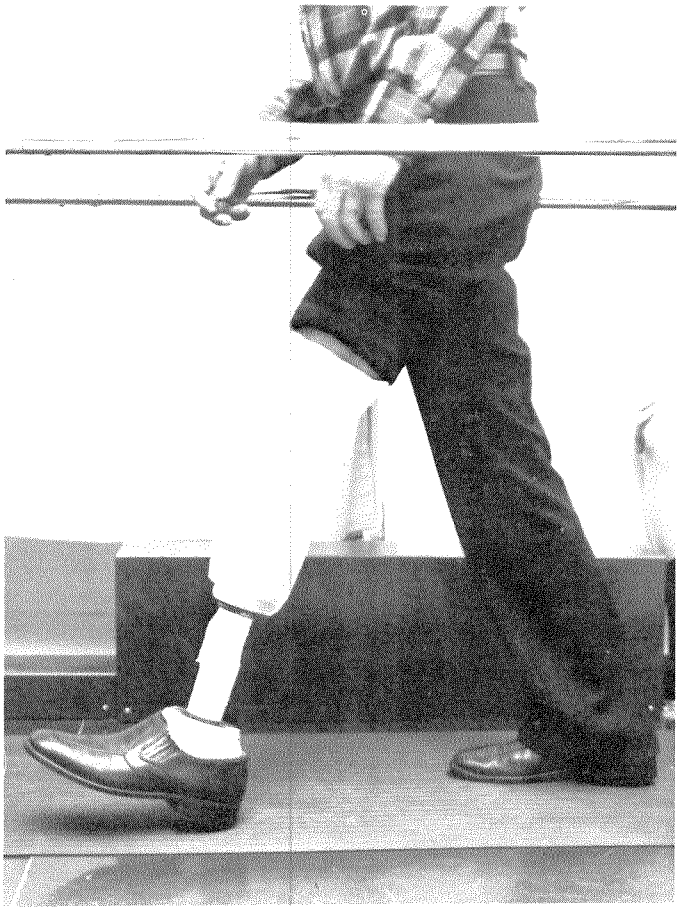

FIGURE 2
The subject must be able to ambulate comfortably without distal gapping.

Impact — Of the 60 subjects measured in unmodified prostheses, 6 produced better-than-average suspension by physiologic components alone. Isometric training within the socket improved suspension in 9 of 10 selected subjects. Physiologic suspension can also be improved by the addition of pads proximal to muscle bulges within the socket.

Unexpectedly, 50 percent of subjects ejected their unmodified definitive prostheses by contraction of the residual limb musculature; this occurs if the contracting muscle mass presses against the socket distally. Our modified sockets enhance physiologic suspension even where the contraction potential of the musculature is small.

Prosthetic modifications which take into consideration physiologic suspension factors, as well as training within the prosthetic socket, improve amputee function ■

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VA CONTRACT

DEVELOPMENT AND IMPROVEMENT OF RUNNING SKILL IN UNILATERAL BELOW-KNEE AMPUTEES

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This 2-year project is concerned with procedures for developing and improving the running gait of unilateral below-knee amputees. The ability to run or jog at least short distances permits the ambulatory amputee to participate in games and sports, with potential associated benefits of weight control, cardiovascular conditioning, stress management, and the enhancement of self-esteem.

General Protocol — The protocol involves between 15 and 20 amputees and consists of three major phases: a comprehensive preliminary evaluation of functional status, social-psychological variables, and running skills of each participant; a formal program to improve running performance of these individuals; and a final assessment of success achieved. Continued efforts are also being made to provide additional information on the biomechanics of amputee running.

A questionnaire has been developed to assess possible mediators of self-esteem change and social psychological factors that may affect the extent to which subjects successfully complete the running-skill program. Among the variables assessed by this questionnaire are subjects' program goals, performance expectancies, perceptions of current ability, current physical activities, and certain aspects of relationships with family and peers.

Biomechanical Analysis of Running Skill — Subjects are filmed at approximately 100 fps as they run across a .6 m x .9 m force platform connected on-line to a laboratory computer which samples the ground reaction force output at 1000 Hz. Between 10 and 20 trials at varying speeds are recorded. Approximately half of the trials represent prosthetic foot strikes on the force platform. Ground reaction force components and center-of-pressure paths are output in digital and graphic formats. Films are analyzed both qualitatively and quantitatively. At the first level of quantitative analysis, temporal and length characteristics of the stride are noted. At the second and more complex level, linear and angular position-, velocity-, and acceleration-time histories are determined, and resultant torques and forces at the ankle, and knee, and hip joints calculated.

Maximum ground reaction forces recorded on the prosthesis, while they are between two and three times body weight, are not significantly different from those on the intact foot or for nonamputee runners.

The most common anomaly in the running patterns of those below-knee amputees who do not run on a regular basis continues to be the maintenance of an excessively straight residual knee during the majority of stance on the artificial limb.

In summary, findings from this study regarding physical performance characteristics of amputee running and psychological mediators of self-esteem change and performance success should have important implications for the physical rehabilitation of lower-limb amputees who want to return to a physically active lifestyle ■

UPPER LIMB PROSTHETICS

NUREP

MICHIGAN ARM

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This project has been a cooperative effort by NUREP and the Area Child Amputee Program, Grand Rapids, Michigan. The objective of this project is to design, develop, and clinically evaluate electrically powered prostheses for a child who has congenital bilateral amputations at shoulder level.

The first phase of this project, which is completed, was to develop the prosthesis which has powered elbow flexion coupled with wrist motion to maintain the terminal device in a fixed attitude in relation to a horizontal surface (table) at all elbow positions. The terminal device is the commercially available Michigan Hook, and both hook and elbow are controlled by switches. To conserve battery energy, a timing circuit will shut off the motors if they are in a stalled condition for more than 5 seconds. The humeral section length can be adjusted to compensate for growth. Three prototypes have been fabricated and are now being fitted to children for clinical evaluation.

The second phase of this project is to apply the principles of extended physiological proprioception to the control of the prosthesis ■

VA-NUPRL

BELOW-ELBOW PROSTHETIC SYSTEM

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The objective of this project is to develop a below-elbow prosthetic system with hook/hand interchangeability and easily removable modular components. The components consist of the terminal device, battery, electronics package, electrode package, and wrist connector.

A rigid cover is being fabricated for the synergetic hook to protect the mechanism from contaminants and mechanical damage. The cover is to be "technological" in appearance rather than cosmetic. The rationale is that the hook is a technological device and not a replica of a hand.

The wrist connector, which combines the electrical connection with the mechanical connection between the terminal device and the forearm, has been redesigned. It fits within the structure of commercially available prosthetic wrists and the terminal device mounting stud. More importantly, this arrangement does not increase the length of the wrist or the terminal device. The three-conductor electrical connector used in this assembly is commercially available. The terminal device can be rotated 1¼ turns and yet maintain electrical contact.

The electrode package is the "Myotrode" described elsewhere in this publication under the NUREP Progress Report. The development of this electrode/amplifier assembly has been completed and a laminating technique to mount the assembly in the prosthesis is being investigated ■

NUREP

MYOPROCESSOR

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The objective of this project is to develop a single-site signal processor with a single output. This permits control of one motor in one direction. There are at present, two devices commercially available to which this controller can be applied: the Michigan Hook, and the Hosmer Dorrance Prosthetic Assist (PA) which will operate any voluntary opening hook.

When used with the Michigan Hook, a timer circuit is added to turn the motor off and conserve energy after approximately 3 seconds of stall. Powered by a nine-volt rechargeable battery, the hook will give about 3 days usage between charges. The quiescent current is 46 micro amperes at nine volts.

When used with the PA system, a timer circuit is not required because of a cut-off circuit built into the device. In this system the quiescent current is 29 microamperes at 6.25 volts.

The myoprocessor will operate at from 1.5 volts to 18.0 volts. This wide operating range ensures that the electronics will remain stable and operational until the battery voltage will no longer open the hook ■

LIBERTY MUTUAL, NIHR, SWEDEN

MYOELECTRIC PROSTHESES FOR CHILDREN

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During the past year, we have constructed and fitted a myoelectrically controlled mechanical hand for a 3-year-old girl. Mara is a congenital amputee. The hand was obtained from Systemteknik AB of Sweden.

This development was noteworthy for three reasons. First, few such prostheses have been fitted on children so young. Second, Mara had a petite physical stature (weight = 11 kg, height = 86 cm). Third, her forearm stump was exceptionally short, and only approximately 7 cm^2 of flexor and extensor muscle tissue in total was present. The technical complications were satisfactorily resolved. She is reportedly actively using the prosthesis.

The fitting of a similar prosthetic hand to a 7-year-old child is underway, and we are contemplating the design of a myoelectric prosthesis for a 13-year-old ■

NUREP

MYOTRODE

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This is an active electrode package that places the amplifier at the electrode site to eliminate electrical interference problems and give greater flexibility in placing the electronics in different prostheses. The electrode buttons are removable from the package to allow a choice of button heights to maintain optimum skin contact. This also allows the use of other electrode material such as conductive rubber for use with other systems such as environmental controllers or communication aids.

Several Myotrodes have been built using Surface Mounted Device (SMD) techniques. These will be utilized in the modular Below Elbow Prosthetic System discussed elsewhere in this publication under the NUPRL Progress Report ■

ORTHOTICS

VAMC ROXBURY

A MOTION-GUIDING, LOAD-BEARING, EXTERNAL FRAME FOR THE KNEE

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Internal joints must allow the ligaments to act at correct lengths, while external joints must guide motion and prevent unwanted ligament tensions. Thus key questions for implant design are: what is the geometry of the natural joint surfaces and how much sliding occurs in flexion-extension? For external orthoses and hinge distractors, extra questions are: to what boney landmarks can the joints be lined up, what external points should be guided, and what is their motion?

Materials and Methods — Twenty-two distal femurs were aligned to defined axes, embedded, and cut into 16 equal sagittal slices. The 17 sections of each bone were digitized into a computer. The points articulating from 15–105 degrees flexion of sections 3-6 (lateral) and 12-15 (medial) were determined. The best-fit sphere was determined by iterations of x,y,z of the center and radius r. The criterion was the minimum sum of the absolute distances of the points to the sphere. On 14 other knees, the sagittal radii of the posterior condyles were measured, and in frontal profiles 0,30,60,90 degrees of flexion. Radius gauges spaced by 1 mm, enclosing a 90 degree arc, were used. The m-1 spacing of the condyles was also measured.

It was essential that the motion measurement be applicable to normal subjects as well as specimens. The 14 fresh intact knees were mounted in a rig and sagittal X-rays taken at from 0 to 120 degrees of flexion under quadriceps tension. Key reference points were digitized, with 6 points on the lat. and med. femoral condyle peripheries. The center of the best-fit circular arc was computed. A similar analysis was carried out from movie X-rays of 8 normal males ascending a steep step.

The two centers of the medial and lateral 'spheres' defined the femoral x-axis; the y-axis was vertical at 0 degrees of flexion, and the z-axis was anterior at 0 degrees of flexion. Using an Eulerian system with minor approxns. int-ext rotation, varus-valgus a-p and vertical translations were computed as a function of flexion. Accuracy analysis showed the centers of the circular arcs were to ± 1 mm for specimens and ± 1.5 mm for volunteers.

Results — The geometry was standardized to an m-1 femoral dimension of 80 mm, and an a-p tibial dimension of 50 mm. The points on the lateral and medial condyles deviated from the best fit sphere by only 0.53 ± .20 and 0.63 ± .22 mm respectively.

Thus, a spherical surface of 20-mm radius for the posterior femoral condlyes of standard sized knee was a close representation.

The motion of the cadaveric knees from 0-120 degrees showed a posterior displacement of the femoral origin of 7.4 mm: the lateral sphere center moved back 17.0 mm but the medial sphere center moved forwards 4.5 mm to mid-range, than back to a net 2.2 mm. The transverse femoral axis rotated 20.2 degrees on average (equiv. to an internal tibial rotation). The origin moved downwards net 2 mm from 0-120 degrees of flexion, most occurring from 0-30 degrees of flexion. From 0-45 degrees of flexion there was a 4.2-degree varus movement of the femoral axis, thereafter decreasing to 2.2 degrees.

The motion in the volunteers was statistically indistinguishable ($p<.01$) from that of the specimens. The lateral sphere center moved back 14.1 mm and the medial forwards net .3 mm. Transverse rotation was 16.9 degrees.

Applications — A 3-D computergraphics display program was written and a condylar knee design was input to show the internal-external rotation contact geometry. An external linkage was designed, which controlled the transverse femoral axis on the medial and lateral sides independently, using a cam mechanism. These will be shown.

Conclusions:

1. The posterior femoral condyles can be accurately modelled as spherical, and the centers used as reference points for motion studies.
2. Internal joints should allow for translation and rotation patterns, as well as additional 'laxity' in each position.
3. External linkages can use the spheres for location and can guide motion by controlling the projection of the transverse femoral axis ■

NUREP

DESIGN & EVALUATION OF A KNEE ORTHOSIS

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The primary objective of this project is to improve orthotic treatment in the rehabilitation of the knee joint.

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

During this reporting period, several refinements to the above basic design were completed, including the incorporation of different types of plastics into the interface (depending upon the clinical application of the orthosis), the redesigning of potential structurally-weak areas in the orthosis (attachment methods for ligament straps, ligament attachment plate, etc.), and the use of a thermoplastic thermobonding technique to attach joint sidebars to the interface components.

For the purpose of guiding further design improvements and modifications, a general series of clinical trials was initiated. A formal clinical evaluation has now been initiated. Approximately 70 people have been fitted with orthosis. Further design modifications continue to be made ■

VAMC SAN FRANCISCO

THERAPEUTIC MOLDED SHOE PROJECT

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Introduction — It has long been recognized that molded shoes have a definite place in the treatment of static foot deformities, trophic lesions, and ulcerations in diabetics and others with compromised circulation in the lower extremities. This is accomplished, essentially, by redistributing pressure on the plantar aspect of the foot, from concentrated localized areas such as beneath a metatarsal head or other bony prominence, to a much larger surface — with resultant decrease in pressure over the local pressure point.

Two major problems associated with molded shoes are high cost and lengthy delivery time. This project directs itself to these two problem areas.

The VA provides thousands of pairs of molded and other types of shoes at a cost ranging from $150 to $350 a pair, and with a delivery time of 4-12 weeks ■

HIP AND KNEE JOINT REPLACEMENTS

VAMC WOOD

STUDIES OF NORMAL AND ABNORMAL MOTION

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During the period of January 1, 1982, to June 30, 1983, the Kinesiology Research Laboratory continued its investigations into the nature, rate, and extent of change in functional performance in patients with total joint replacements.

Total Hip Approach Study — The purpose of one study was to identify the functional advantages or disadvantages between the anterolateral and posterior approaches to total hip arthroplasty. Prosthetic position, hip muscle strength, and hip joint mobility were measured after Muller total hip arthroplasty without osteotomy in 52 patients operated through a posterior approach and 41 patients operated through an anterolateral approach.

When the posterior approach was used, the men and women had less prosthetic component anteversion and longer neck lengths, with resultant more lateral and distal placement of the greater trochanter than when the anterolateral approach was used. Groups operated through the posterior approach had more normal hip-abductor-muscle strength and more inward rotation of the affected side than groups operated through the anterolateral approach.

Groups with an anterolateral approach had more outward rotation on the affected side than groups with the posterior approach.

These differences in function were related to the surgical approach rather than to differences in prosthetic component position. An understanding of these observations should be useful for selection of the surgical approach for the patient on an individual basis.

Knee Joint Replacement Study — A second study measured the preoperative and postoperative functional performance of a group of patients with an unconstrained type of knee joint replacement. The purpose was to provde an objective evaluation of functional change as a result of surgery ■

NUREP

STRUCTURAL ANALYSIS OF TOTAL JOINT REPLACEMENTS

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Surface Replacement Hip Arthroplasty — The objective of this project is to use a three-dimensional finite element analysis to better understand the causes of surface hip arthroplasty failures, and to develop improved designs. During this reporting period, a three-dimensional finite element model of the proximal femur and surface hip component was generated, accurately modelling the geometry of the actual system. Two cases have been run; the natural femur and the femur with implant. Data post-processing has been completed. The data has not been analyzed to date; however, it appears to qualitatively agree with other investigators.

Finite Element Analysis of Proximal Femur and Femoral Component of a Total Hip Replacement, with Inclusion of a Fibrous Tissue Layer at the Bone/Cement Interface The objective of this project is to determine the consequence of the fibrous tissue layer on the stress distribution of the total hip implant system. A realistic element modelling the fluid-filled interface tissue has not been developed to date, since the major effort has been directed into the experimental measurement of the fluid flow properties of the interface tissue. However, two extreme finite element (three-dimensional) cases have been run, modelling a total hip with a perfect interface bond along the distal one half of the stem, and with no interface bond at all (i.e., no cement between the metal and bone). Eventual inclusion of the fibrous tissue element in the model will yield results somewhere in between these two extreme cases. The bond/no bond comparision results showed increased cancellous bone stresses at the distal end of the bonded region, but otherwise, little difference occurred between the two analysis cases.

Stress Analysis of Total Hip Prostheses By Finite Element Methods The objective of this subproject was to use previously generated three-dimensional finite element data to address specific questions regarding the analysis of total hips, such as the effect of neck length, magnitude of adductor muscle force relative to head contact force, and anterior-posterior directed head force versus inferior directed head force ■

NUREP

PROSPECTIVE CLINICAL STUDY OF THE KINEMATIC KNEE DESIGN

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This is an ongoing project to follow Kinematic Knee patients in an attempt to identify quantitative relationships between clinical data and the eventual outcome of Kinematic Knee replacements, and to evaluate the effectiveness of this particular prosthesis in eliminating pain and restoring and rehabilitating severely disabled individuals to normal active lives.

Data was collected from hospital and operating surgeon files. Data included component type, patient history, posterior cruciate retaining, anterior cruciate retaining, and stabilizer type, as well as physical, surgical, and X-ray findings. Investigation of developing radiographic radiolucent lines between implants and bone has also been implemented, along with a conversion program which converts our data into the Knee Evaluation scale of the Hospital for Special Surgery.

To date, 92 patient cases have been included in the study. Of these, initial statistical analysis has been performed in 82 cases. These cases have been followed-up in an ongoing fashion in attempt to achieve a 6 month, 1-year, and 2-year followup at minimum. However, the number of cases not yet possessing a 2-year followup is large. For that reason, significant statistical analysis has not yet been performed. Preliminary demographic and statistical analyses have been performed ■

NIH/VAMC CLEVELAND

IN VIVO LOADING ON TOTAL KNEE JOINT REPLACEMENTS*

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This project is to determine in-vivo loading data in total knee joint replacements. The new joint replacements will have, incorporated within the body of the tibial component, the required circuitry to telemeter seven channels of loading data, allowing for the determination of the three forces and the three moments on the tibial component. As shown in Figure 1, the project requires two basic systems; the implanted mechanical and electronic portion, and the external portion which handles telemetry reception, demodulation and digitizing. This progress report will detail the work accomplished and the work proposed on each of these requisite sections.

Current Status — The hybrid microcircuit for the implantable transmitters and subcarrier oscillators is being fabricated in a collaborative effort with the General Electric Co. We have also received batteries from Battery Engineering Inc. (manufacturer of Medtronic's pacemaker batteries) which were developed to our specifications.

The problem of keeping the electronics hermetically isolated, and all other materials biocompatible, has been solved through a cooperative effort with the Inco Corp., BLH Electronics, and the Glasseal Corp. As a result of this collaboration, it has been decided to use platinum as the conductor for all wiring external to the actual electronics package. Glasseal Corp. is engineering a 16-pin hermetic header having platinum pins in a titanium disk, for use as a signal path between the load-cell strain gages and the encapsulated electronics in the stem. BLH has agrees to construct special strain gages with insulated platinum leads for use on the load cells; they are also supplying the special tip needed to allow us to spot-weld all interconnections to these gages. We are currently supplying BLH with the insulated platinum wire to fabricate these gages.

We have also addressed to the problem of switch failure, previously encountered in this project. Axialite Engineering is fabricating for us a new switch with rhodium plating on the contact area of the reeds. This is intended to preclude any possibility of the previously noted gold degradation which could affect switch reliability.

In the area of mechanical development, we have contracted with a firm to manufacture our housing and tray assemblies from stock supplied by us, using EDM machining techniques. Because of that technique we have made minor revisions to noncritical areas of the design of these components, at the company's request. The minor revisions took the form of relaxation of some tolerances where allowable, changes in the dimension and location of specific radii and fillets, and surface-finish modifications ■

*Dr. Brown reports that this project now has a funding designation of NIH #AM-21559-05 and all funding is currently being administered by the National Institutes of Health. However, he notes, "a significant portion of the funds are derived from the original VA sources." Readers may recall seeing the project listed in the Bulletin of Prosthetics Research, Fall 1981, under both VA and NIH auspices. For previous years the reports will be found in the BPR's VA Progress Reports pages.

NIH MUSCULOSKELETAL

IN VIVO LOADING ON TOTAL KNEE JOINTS

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

NIH MUSCULOSKELETAL

BIOMECHANICS OF HIP AND KNEE

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The specific aims of this research are:

1. To investigate the effects of incorporating fiber length, fiber direction, and fiber type into the existing muscle model.
2. To investigate the effects of differing cost functions on muscle force predictions and to study the appropriateness of using differing cost functions for differing activities in normal subjects and in subjects with selected abnormal conditions.
3. To investigate, in a comprehensive manner, the effects of varus, valgus, displacement, and rotational proximal femoral osteotomies on three-dimensional hip joint forces.

The first specific aim will be accomplished with cadaver dissection and with a sensitivity analysis in the existing muscle model. In that sensitivity study, fiber length, fiber direction, and fiber type will be altered over a reasonably physiologic range of variation to determine the effects on muscle forces.

The second specific aim will be carried out with a parametric computer study in which identical kinematic and kinetic input is subjected to the muscle force predictions using varying cost functions. The differences in muscle forces will then be compared.

The data of the third specific aim is already completely collected and will be analyzed and reported in the coming budget year ■

NIH MUSCULOSKELETAL

TOTAL SURGICAL REPLACEMENT OF THE HUMAN HIP JOINT

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This project is directed to the study of skeletal fixation using porous metallic composites. Specifically, the ion metal release, transport phenomenon, and related systemic effects in porous sintered powder composites of cast cobalt chrome (ASTM F-75), wrought cobalt nickel chromium molybdenum (ASTM F-562), and Ti6A14V (ASTM F-136) alloys will be studied. The related organometallic complexes will be isolated and their toxicity assessed using in vitro fibroblast cultures.

It is also intended to evaluate the tumor induction risk of porous sintered powder cobalt chrome composite (ASTM F-75) and wrought cobalt-nickel-chromium-molybdenum (ASTM F-562 also know as MP35N) in solid, powder, and porous form.

The possibility of bone growth enhancement into fiber titanium composites by the use of hydroxyapatites, tricalcium phosphate, fluorides, bone marrow contents, bone morphogenetic protein, and direct current electrical stimulation will be evaluated.

The effectiveness of three different titanium porous configurations will be compared: fiber titanium composite as a total or partial coating, and sintered titanium spheres as a method of fixation of a total hip prosthesis. The ability of bone to remodel and related effects of the material on the surrounding cortex will be evaluated.

An acetabular prosthesis of a hemispherical design will also be evaluated in terms of its potential for bone ingrowth as a means of fixation ■

NIH MUSCULOSKELETAL

MECHANICS OF THE HUMAN ACETABULUM

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This investigation will elucidate the structural behavior of the normal human acetabulum and examine the alterations in acetabular mechanics after total hip replacement, surface replacement, and femoral endoprosthesis hip arthroplasty. The project will involve direct mechanical testing of cadaver specimens and the generation of two-dimensional/three-dimensional finite element models for numerical stress analysis.

An in vitro mechanical testing program will employ multiple strain gage rosettes to determine the strains in the acetabular region of four normal hip joints during one-legged stance. After testing, the pelvis will be embedded in acrylic resin and sectioned. The global geometry will be determined. Each section will then be examined under reflected light microscopy, and quantitative morphometric measurements of bone areal fraction and trabecular orientation will be mapped out for each section. Two two-dimensional and three three-dimensional finite element models (FEMs) will be constructed. The bone of the acetabular region will be modeled as a heterogeneous material. Material properties will be assigned to elements according to the morphometric parameters. The results of the FEMs will be compared to the mechanical testing data, and the models will be refined in an iterative manner to ensure good correlation between the experimental and theoretical results.

The experimentally verified FEMs of the acetabulum will then be used to calculate the deformations and stresses after total hip arthroplasty. Several different surgical techniques and prosthetic components wil be evaluated. Important findings from FEM analysis of hip arthroplasty will then be experimentally verified with additional in vitro mechanical testing using strain rosettes ■

NIH MUSCULOSKELETAL

VASCULAR RESPONSE TO HIP REPLACEMENT

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The incidence of postoperative deep vein thrombosis in persons undergoing hip replacement surgery is around 50 percent and is a major complication of this surgery. There is currently no generally accepted method of prophylaxis despite much work on hemostatic components of thrombi. Thus, other mechanisms should be considered.

The applicants postulate that hip replacement surgery in dogs (and probably in people) initiates a series of events that culminate in indirect injury to and reduced blood flow in veins distant from the site. Suggested mechanisms for lesion formation in canine veins is based on observations in canine models studied by the applicants. It is suggested that human and canine veins respond similarly to hip replacement surgery, since they developed identical lesions in one model in which both were available. Others have found that venous blood flow in dogs and people have similar characteristics and respond similarly to some factors. Thigh veins on the operated side may also suffer direct injury from manipulations required during surgery.

It is the applicants' long-term objective to elucidate mechanisms responsible for venous damage and reduced blood flow. Because of the complexity of the surgical situation, a systems approach will be employed. A canine model of hip replacement surgery will be used. Veins will be examined and lesions studied by scanning electron microscopy, and the same veins will then be processed for study of architecture by light and transmission electron microscopy. Venous responsiveness will be monitored noninvasively by a modified ultrasound instrument. Blood flow will be studied by electromagnetic flow and Doppler ultrasound. Veins will be examined for direct injury by radiography and scanning electron microscopy. Major cardiovascular components will be monitored by appropriate methods, as will body temperature. It is important to note that four clinically relevant anesthetic techniques will be compared in these studies. The two noninvasive ultrasound techniques will be applied to patients undergoing hip replacement surgery to provide some basis for estimating similarity of response in human and canine veins as well as possibly providing clinically relevant information on the patients ■

VAMC GAINESVILLE

QUANTITATIVE ANALYSIS OF THE EFFECT OF TOTAL HIP ARTHROPLASTY ON STRESS AND STRAIN IN THE HUMAN PELVIS

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Phase 1 of this investigation served to provide the first prototype system to analyze the effects of acetabular preparation techniques on strain in the cadaver pelvis. Current goals include the evaluation of the changes in strength and stiffness of the bony pelvis-acetabular component following different implantation techniques, including:

1. No cortical reaming (inner and outer cortices intact) compared to reaming through the lateral cortex; leaving the inner cortex intact.
2. Different use of keying holes (none, three large, and multiple small).
3. Use of uniform mantle of cement between the bone and prosthetic acetabulum.

4. Different techniques for cement insertion (pressure injection, hand insertion).
5. Different component thicknesses (thin-wall surface replacement components, smaller-diameter, thicker-wall, conventional components), and
6. Different encasement methods (metal-encased polyethylene acetabular components, standard components without metal encasement).
7. Methods of supporting the acetabular component where a deficient medial wall may exist (including use of a protrusio ring and wire mesh reinforcement).

Quantitative biomechanical evaluation is planned of the following new prosthetic designs or techniques:

1. Graphite-fiber-reinforced polyethylene acetabular prostheses.
2. Non-plastic aluminum oxide uncemented components.
3. The use of pressure-injected low-viscosity cement in place of standard cements placed at "dough stage."
4. Newly suggested reinforcing techniques for the deficient acetabulum ■

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VAMC CLEVELAND

LATE LOOSENING IN TOTAL JOINT REPLACEMENTS IN THE LOWER EXTREMITIES

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The objective of this study is to document in-vivo motion of the cement/bone interface in total hip and total knee replacements. A Biplane Radiographic Technique is used to measure the distance between markers implanted in bone and implanted in cement at the time of surgery. Weightbearing and non-weightbearing X-rays are taken postoperatively before discharge, at 2 and 4 months, and every 6 months thereafter. The X-rays are analyzed by computer. The data from each patient visit is stored in, and can be retrieved from, the computer's data bank.

Patients continue to volunteer to take part in this research program, so that the participating patients' lengths of time in the study vary from 2 weeks to 5 years. Approximately ⅔ of all patients studied have shown some motion at the cement-bone interface at some time during our study. Such motion may or may not be associated with clinical symptoms.

The patient pool is approaching a size that determines the relationship between loosening and various patient characteristics (e.g. weight, age, and activity). Thus, during the last 18 months, along with our continued patient monitoring we have been modifying our computer hardware and software to permit such statistical studies ■

NUREP

EVALUATION AND DEVELOPMENT OF BIOMATERIALS USED IN TOTAL JOINT REPLACEMENTS

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This project area was addressed during the reporting period by two subprojects, as described below.

New Implant Materials: The most common metal alloy used in total joint replacement and internal fixation devices, 316L stainless steel, displays undesirable pitting and crevice corrosion, particularly in implant environments where ion concentration is high. The objective of this subproject is to find and evaluate viable substitutes for the 316L alloy, with superior corrosion resistance without sacrifice of mechanical properties.

Ferritic and duplex austenitic ferritic stainless steels are promising candidates, as they have demonstrated superior corrosion resistance in other fields. E-brite (a 26Cr-1Mo ferritic stainless steel) was compared with 316L stainless steel by potentiostatic and potentio-dynamic polarization, linear polarization, and cyclic polarization (ASTM-F4 Pitting and Crevice Corrosion Standard). The results of these tests show that the E-brite alloy does indeed possess superior corrosion resistance in an electrolyte of biological interest (without loss of structural mechanical properties).

Relative Polymeric Radiopacity: Polymers cannot be visualized within the body by X-rays. Hazard to

patient population may result from undetectable polymers, such as untoward mobility of polymeric bone cement used in total joint replacements. Radiopacity of bone cements is increased by adding inert heavy metal salts — which weaken the mechanical properties of the polymer. At present, there is no adequate method for evaluating the radiopacity of a polymer. The objective of this subproject is to develop a consistent methodology for evaluating polymer X-radiopacity in order to optimize control of variables (kilovoltage, milliamperage, film type, developing conditions, and exposure time), to get better visualization and minimize patient X-ray dosage. X-rays were taken of samples of aluminum and bone cements (low viscosity and regular) of varying thicknesses, with ranges of kilovoltages and milliampere seconds. X-ray film and processing variables were kept constant. Combinations and permutations of these variables on the X-ray films were analyzed by a photoelectric densitometer. It was found that the radiopacity changes dramatically with the test variables. Further data will have to be taken, including the effects of film type and processing, and an attempt will be made to develop empirical solutions to fit the generated data ■

NUREP

INVESTIGATION OF THE BONE/BONE CEMENT/IMPLANT INTERFACE FORMED BY TOTAL JOINT REPLACEMENT

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The objective of this project was to identify the causes of late loosening of prosthetic components by examining three aspects of the interface system.

1. An investigation was made of the major factors affecting the mechanics of bone-cement interface failure. A series of control and experimental tensile tests on bone/cement interfaces was performed, varying cement application pressures, duration of pressure application, and bone surface condition while measuring bone strength, failure load, and cement penetration depth. Statistical analyses of these variables were then carried out.

The penetration and failure load results were dominated by the application pressure. However, the quality of the fixation is limited by the bone properties. Low-strength, porous bone supports low failure loads due to poor bone quality. Strong, dense bone limits fixation quality by its resistance to adequate cement penetration.

2. A study was made of mechanical and histological properties of the soft interface tissue commonly found at the bone-cement interface system and how load is transferred across this interface. The procedure followed was to implant metal tibial components of a plate-post design into dogs, remove the implant after 2 months and measure the surface permeability of the post cavity (plus that of freshly cut cancellous bone) and then use this measured permeability in a mathematical implant simulation to predict the relative load carried by the fluid and tissue matrix.

It was found that the permeability of the implant cavity is much less than that of freshly drilled cancellous bone. The body has responded to close off the implant cavity to fluid flow. Using this data, a theoretical model of the system was developed which predicts that nearly all of the load is carried by the fluid (90 percent) in the implant cavity while 27 percent of the load is carried in the fluid for the freshly drilled bone.

The test data and model results strongly support the hypothesis that fluid hydrostatic pressure plays a significant role in load transfer at the bone-implant interface.

3. An evaluation methodology was developed, based on fracture mechanics, for bone cement/metal implant interface failure and it was used to evaluate various metal surface preparations. A four-point bonding specimen configuration was decided upon. Titanium bar stock was obtained and will be machined into proper specimen size. Therefore, as of this report, no data has been obtained ■

HHS, NIGMS GRANT

FLEXIBLE GLOW-DISCHARGE POLYMER LEACHING BARRIERS

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The objective of this project is to study a method of reducing crosslink density in glow-discharge polymers used to modify the surface properties of plastics, without affecting their bulk properties. These studies will include the use of a greater variety of functional groups accessible to this type of polymerization. The reduced crosslinking of these surface polymers should greatly reduce micro-cracking of these materials when they are flexed ■

VAMC NEW ORLEANS

THE MECHANICAL PROPERTIES OF POROUS-COATED ORTHOPAEDIC ALLOY

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This progress report covers the period from 1/1/1982 to 6/3/1983.

Recently there has been increased concern about the use of polymethylmethacrylate (PMMA) cement fixation for orthpaedic devices. Due to problems associated with this system (primarily implant loosening and adverse bone remodeling) research over the past two decades has concentrated on the development of alternative methods of implant fixation. One such system is that of a porous-coated device. A porous metal coating applied to a solid substrate implant has been shown, in vivo, to offer several advantages. These include a higher interface shear strength between implant and bone and a more uniform distribution of stresses throughout the implant and surrounding tissue. However, these advantages may be lost in devices requiring a sintering heat treatment to apply the porous coating, since these heat treatments may have a detrimental effect on the substrate material's mechanical properties.

The objective of this study is to investigate the effects that application of a porous Ti-6Al-4V alloy coating has on the fatigue properties of a Ti-6Al-4V substrate system.

All specimens were tested on a standard R & R Moore High Speed Fatigue Testing Machine which rotates at approximately 10,000 revolutions per minute, while applying a uniform bending moment across the surface of the specimen. Alternating cycles of tension and compression of equal magnitude result in a mean stress equal to zero, and an R ratio equal to negative one. The results were recorded on standard strength versus log number of cycles-to-failure plots (S/N).

Endurance limits of 617 MN/m^2 (as received uncoated), 62 MN/m^2 (carbon coated), 220 MN/m^2 (notched), 377 MN/m^2 (sinter heat-treated) and 138 MN/m^2 (porous coated) were found in this study. There was no observed effect on fatigue properties of uncoated as-received or carbon-coated material when tested in saline compared to testing the air.

The uncoated as-received and notched specimens were found to have an equiaxed alpha-beta microstructure. After the sinter heat-treatment of the material (with or without the porous coating) the microstructure transformed into a lamellar structure. This microstructure was found to be continuous from the powder to the substrate in the porous coated samples.

In general, the smooth surfaced as-received material's fracture surfaces exhibited an initiation region, a region consisting of gross fatigue striations (about 25 percent of the surface), and a smooth final-failure region (about 75 percent of the surface). The fact that all initiation sites were found on the smooth surface indicates that the initiation of a crack was probably not related to pores or inclusions. This fact was confirmed by SEM analysis which revealed no evidence of subsurface initiation sites or foreign inclusions. Primary and secondary cracking was observed to occur in directions both perpendicular to and parallel to the alpha grains, for both the porous-coated and sinter heat-treated materials. SEM analysis confirmed that secondary cracking did occur at the alpha-beta interfaces. This fact was confirmed by measuring the average grain width in the fractographs (4.2 m), and comparing it to that found on metallographic sections (3.9 m).

Fatigue cracks in the porous coated material were found to initiate at one or more powder particles. SEM analysis revealed that the morphology of the porous coated fracture surface was similar to that of the heat-treated material in that the failures were generated from the surface, and were evidently crystallographically oriented. The failures differed in terms of the initiation sites. The porous coated samples were found to fail at one or more surface initiation sites associated with the area under the powder particles ■

VAMC SAN FRANCISCO

THE EFFICACY OF RADIOLUCENT TOTAL HIP SURFACE REPLACEMENT

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The theses to be tested in this research are: That (i) the use of materials with low moduli of elasticity will obviate the stress shielding problem, and (ii) that the use of radiolucent materials for the construction of this hip surface replacement prosthesis will allow X-ray visualization of the femoral head.

The research is intended to explore the efficacy of using an ultrahigh-molecular-weight polyethylene (UHMWPE) acetabular component and a carbon femoral component as a low-friction arthroplasty.

We will demonstrate bone response differences through a direct experimental comparison of conventional metal femoral cups and low modulus carbon femoral cups, and will correlate the findings of finite element stress analysis with the quantitative stereology and tetracycline labelling of the femoral head to test the stress-shielding concept.

This study uses dogs as the animal model. Phase 1 consists of 8 unilateral hip surface replacements, using a carbon femoral component and a polyethylene acetabular component to be maintained for 12 months postoperatively. Phase 2 consists of 12 dogs who will undergo bilateral surface replacement, to permit direct comparison of the carbon femoral component with the metal femoral component, each dog serving as its own control.

Evaluation studies of dogs will include forceplate gait analysis, roentgenographic studies and pathological evaluation at necropsy. At necropsy, gross pathological findings will be noted and the hips will be preserved for histological evaluation. Sections will be prepared using hard tissue techniques and quantitative trabecular stereology will be utilized to analyze the bone trabecular thickness and orientation.

The necessary equipment has been procured and experimental protocols have been defined and locally approved. The components for the hip arthroplasty have been purchased and implantation of the devices for the Phase I studies is scheduled for July and August 1983 with device retrieval August 1984. Phase 2 implantation will commence as soon as possible ■

VAMC SALT LAKE CITY

INVESTIGATION OF CEMENTATION TECHNIQUES FOR HIP RESURFACING PROSTHESES

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This is an initial report for a project which began just 3 months before the end of the specified reporting date. Therefore, the principal purpose of this report is to describe the work proposed.

Loosening has proved to be a major clinical problem in the use of hip resurfacing prostheses. However, modified cementing techniques have been reported to decrease loosening in conventional total hip arthroplasty. In this project it is proposed to investigate the effect of such modified techniques on the attachment of Wagner hip resurfacing prostheses to host bone. The techniques or parameters to be investigated are:

(a) Variation in cement thickness;
(b) Pressurized application of low viscosity cement;
(c) Perforation of residual bone tissue with anchoring holes;
(d) Preservation of subchondral bone; and
(e) Metal backing of the acetabular component.

These factors will be investigated, both individually and in combination, in human hip specimens. The specimens will be removed from available cadavers at the time of autopsy, frozen, and then thawed as needed for experimentation. Strength of fixation of both femoral and acetabular components will be determined after subjecting the specimens to an experimental protocol designed to simulate dynamic loading in vivo during the immediate postoperative period.

It is expected that this study will help identify optimum cementing techniques that will improve clinical performance of hip resurfacing prostheses with respect to security of fixation.

The principal project activities during this start-up period have been initial procurement of required cadaver specimens, and the design of fixtures for securing the prepared specimens for cyclic loading and for subsequently testing the strength of fixation ■

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NIH MUSCULOSKELETAL

POROUS PLASTER-COATED FEMORAL PROSTHESES

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The objective of the proposed research is to test the hypothesis that the bone ingrowth into porous plastic coatings on femoral prosthesis (in dogs) can serve as the attachment vehicle for the cement-free fixation of joint implants. Specific aims include the determination of the change in tissue response (including bone ingrowth) with (i) position along the medial and lateral aspects of the prostheses, and (ii) wth implantation time (through 2 years).

Thirty porous polysulfone-coated cobalt-chrome canine femoral prostheses will be implanted into 30 adult male English foxhounds (2 years old; 30–35 kg). Clinical evaluations will include radiography and radionuclide bone imaging. Postoperatively, the ani-

mals will be maintained on an active, quantitated exercise program.

Five dogs will be sacrificed at 1, 2, 4, 6, 12, and 24 months. Perfusion fixation of the hind limbs will be performed to insure preservation of tissue structure. Femoral specimens will be allocated for microradiography and ground sectioning, undecalcified Jung Model K microtomy, and decalcification and conventional paraffin techniques. The microscopy sections will be analyzed using histomorphometric techniques. Linear and areal measurements of features in the histological sections will be obtained using a digitizer board/computer system in conjunction with a drawing tube mounted in a light microscope. Histomorphometric parameters, including the percentage each of bone, osteoblastic activity, osteoclastic activity, marrow, fibrous tissue, cellular infiltrates, and others, will be computed for the tissue within and adjacent to the porosity along the medial and lateral aspects of the prosthesis. Fluorochrome bone labeling will be employed to determine rates of bone turnover.

The quantitative histology procedure will allow for the distinction of differences in the tissue response to the prosthesis: (i) at different points along the femoral stem; and (ii) with implantation time. These data will not only serve to begin to qualify porous coated prostheses for clinical use, but should also provide a better understanding of bone formation and remodeling behavior. Unoperated femurs will serve as controls ■

NIH MUSCULOSKELETAL

MECHANICS OF NORMAL, ARTHRITIC, AND PROSTHETIC KNEES

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Osteoarthritis, particularly of the knee, is a major crippling disease. Although mechanical factors are universally assumed to play a major role in the pathogenesis of osteoarthritis, its initiating mechanisms remain obscure. From available evidence, it is plausible to assume that disturbances in articular contact pressures serve as a common pathway in the degenerative process. Yet few direct measurements of contact pressures in normal and pathological knees are available. Existing data are derived from cumbersome experimental procedures which cannot be used effectively in large scale investigations. In addition, few studies have been directed toward the experimental evaluation of pressures following surgical reconstructive procedures commonly applied to the knee. As a result, despite recent improvements in diagnostic accuracy from arthroscopy, there remain major uncertainties and controversies in the clinical treatment of chondromalacia, meniscal and ligamentous lesions, and in the use of tibial osteotomy for the treatment of degenerative arthritis. Since the clinical outcomes of these procedures often cannot be evaluated for more than 10 years, experimental evidence on which to base objective treatment approaches to the knee is urgently needed.

This investigation uses pressure-sensitive films (PSF) in loaded cadaver knee joints to address these clinical issues. The PSF is evaluated by computer processing of its image obtained with a videodigitizing system. Bi-planar radiography of knees with implanted metal markers is used to monitor changes in knee kinematics due to the experimental manipulations. These methods are used to evaluate the efficacy of capsular reconstructive procedures, distal realignment, and elevation of the tibial tubercle in the treatment of chondromalacia. Normal tibiofemoral contact pressures are also measured, the effects of meniscal injury and ACL (anterior cruciate ligament) laxity and separate are studied. The use of partial vs. total menisectomy is compared, and changes in contact pressure with primary ACL repair are evaluated.

The long-term objectives are to resolve these clinical uncertainties in treatment of the knee and to shed light on the role of cartilage contact pressures in the pathogenesis of osteoarthritis ■

VAMC NEW ORLEANS

RETRIEVAL AND ANALYSIS OF ORTHOPAEDIC IMPLANTS

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Period covered, 1/1/83–6/30/83.

As part of an on-going implant retrieval and analysis program, the clinical performance, corrosion characteristics, and metallurgical properties of 83 bone plates have been studied. These implants were all fabricated from 316L stainless steel.

Summary — Clinical histories indicate that many surgeons consider bone plates as permanent implant devices. However, the results of this study demonstrate that a high percentage of the devices are performing unsatisfactorily at all time periods. This was due, no doubt, in some part to the significant corrosion exhibited by the stainless steel material used to fabricate the devices.

The need for corrosion reduction is apparent. It is possible to reduce the degree of corrosion by the use of a smaller grained and microscopically cleaner 316L stainless steel in the manufacture of these devices. Therefore, higher standards for the stainless steel used for implant devices and a higher level of quality-control by the manufacturer seem appropriate. Our data suggests a standard of 7.5 or finer for the grain size and no more than 1.0 for the thin inclusion content as an improvement over the current ASTM standard (F138-76) ■

NSF

THE STUDY OF FATIGUE MECHANISMS IN A 3D CARBON COMPOSITE

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This research program seeks to learn the failure mechanisms of multidirectionally-woven carbon-carbon composites when subjected to fatigue loading, and characterize this material's potential for use in internal prosthetic devices, e.g., hip and knee implants.

The major objectives in this initial phase are to:

1. Discover failure mechanisms and fatigue strengths of a typical fine weave 3D carbon-carbon to determine which parameters (density, matrix pocket shapes, etc.) bear most heavily on fatigue life. Where is the breakdown occurring and at what stress level, cycle, etc?

2. Make a quantitative assessment on the suitability of multi-directional carbon-carbons for implants from a strength and fatigue properties point-of-view.

This is Phase I of research solicited under the Small Business Innovation Research program. If this preliminary work shows a potential for carbon-carbon, follow-on effort will focus on all the design parameters for specific applications such as hip or knee implants ■

NUREP

THE INTERACTION BETWEEN TOTAL KNEE REPLACEMENT GEOMETRY AND KNEE LIGAMENTS

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Loosening of the tibial component is a major factor in the failure of total knee replacements (TKR). This project is intended to identify those ligamentous constraint forces which increase interface stresses to a level which may contribute to the loosening process and thus to ultimate failure of the TKR. The resulting information from this project will form the basis for potential implant design changes, alterations of TKR surgical procedures, guidelines for choosing existing knee implant designs when faced with various clinical situations, and recommendations for improved rehabilitation and orthotic treatment of postoperative knee implant recipients.

The current specific question to be investigated is whether or not the geometry of a knee implant's tibial component should allow retention of one, both, or neither of the cruciate ligaments. Two methodologies are being used to address this issue.

One portion of this project involves the development of an improved biplanar radiographic technique, and the application of this technique to predict in vivo ligament lengths and forces in human subjects with total knee prostheses during actual static joint load conditions. This information will help answer the above cruciate problem statement: keep ligaments if they are functionally load-bearing, and sacrifice them if they are not.

During this reporting period, different and improved computational schemes for the biplanar radiographic technique utilizing alternate algorithms were developed. A mechanical calibration device was built and used to determine the sensitivity of the technique to various error sources.

The biplanar radiographic technique was also applied to in vitro knee specimens containing actual implant components. The ligaments of these specimens were instrumented with force-measuring buckle transducers, such that during application of external load states to the knees, the prediction of ligament forces by the biplanar radiographic technique could be compared with the directly-measured buckle forces. Significant ligament forces (or their absence) were correctly predicted in 14 of 18 ligament load states. After further refinement, the radiographic procedure will be applied to actual patients.

The second phase of this project is to investigate the initial postsurgical state of the knee with a TKR by experimentally using an electrogoniometer (and computer-based data acquisition system) and buckle transducers in a series of knee specimens, in conjunction with an analytical force analysis and finite element stress analysis, to determine ligament and joint contact forces, as well as interface stresses (potential for loosening), for various existing ligament-TKR design combinations. During this reporting period, a prototype of an improved electrogoniometer was constructed, and the development of calibration and data reduction schemes were initiated. An improved external load device was designed and is being built. Also during this period, several

preliminary analyses were performed using buckle transducers (without motion measurement) to measure ligament forces in knee specimens with/without TRK components during various external load states. It was found that (i) ligament forces were near normal in a knee with a semiconstrained implant when both cruciate ligaments were present, and (ii) when the anterior cruciate was excised, the sum of both collateral forces increased an average of two and a half times, implying that the joint contact forces also increased for equilibrum to occur ■

VAMC NASHVILLE

PATHOKINESIOLOGY OF ANTERIOR CRUCIATE LIGAMENT DEFICIENCY

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Rotational instability of the knee joint following rupture of the anterior cruciate ligament is recognized by many orthopedists as a major problem in the active individual. In many persons, absence of this ligament leads to progressive instability, functional disability, and knee-joint deterioration.

To prevent that sequence of events, numerous technical solutions (including repair and/or reconstruction of the anterior cruciate ligament and rehabilitative strengthening) have been proposed. However, a significant percentage of patients with an absent anterior cruciate ligament have no functional disability and have little or no objective instability. In these individuals, progressive instability and knee joint deterioration do not seem to occur.

This obvious discrepancy in the clinical course of patients raises multiple questions regarding the nature of the knee with an absent anterior cruciate ligament and the appropriate treatment for this deficiency. A major problem for the orthopedist in attempting to evaluate the multiple alternatives available is an incomplete knowledge of the biomechanical alterations of the knee joint produced by an anterior cruciate ligament tear. In addition, little is known about the response of the patient to these alterations in order to compensate for this injury. Documentation of instability has been largely clinical in nature, based upon nonfunctional evaluations and using inexact descriptive tools. The inability to precisely describe the deficit involved has made evaluation of treatment modalities even more difficult.

The objectives of this project are to define the knee kinematics and kinesiology in normal individuals and in both the functionally compromised and the functionally able patients with anterior cruciate ligament deficiency. The testing tasks will be level walking, pivoting, and controlled exercising, using gait analysis and isokinetic techniques ■

VAMC EAST ORANGE

STUDENT PROJECTS IN THE DEVELOPMENT OF REPLACEMENT LIGAMENTS AND TENDONS

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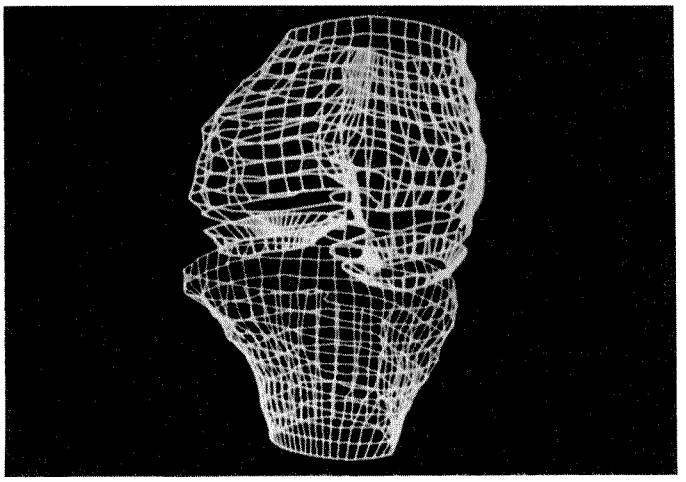
Computer Graphics Analysis of Knee-Joint Kinematics — The purpose of this study is to develop a computer graphics procedure which will perform three-dimensional kinematics of the knee joint. Computerized tomography was used to generate the geometry and the shape of the joint. A three-dimensional computer graphical representation of a knee joint is developed.



An analytical method is developed that includes the computations to obtain cross-sectional shapes of the tibia and femur at given locations, a pictorial representation of the two bones from any viewpoint (360 degrees of azimuth, 90 degrees of elevation), and the kinematics of coupled joint motion using Euler angle transformations. Realistic coupled rotations have been simulated. The procedure demonstrates that if the coupled rotations are not chosen properly, bone-to-bone interference results.

The two major factors considered in this kinematic analysis were the flexion/exterior-rotation coupling curve, and the position and direction of movement of the instant center. The kinematic analysis was performed for a maximum of 130 degrees of flexion, with maximum exterior rotations of either 8.8 degrees or 15 degrees. Two types of coupling curves, straight line and exponential approximations, were utilized. The instant center was allowed to move either 10 mm distally and 10 mm posteriorly, or 10 mm distally only. It was found that the coupling curves with maximum exterior rotations of 8.8 degrees or 15 degrees have little effect on the kinematics and it appears to be a less significant factor. The proper instant center height for the knee under investigation was 30 mm. If this height was reduced, interference was observed. The movement of the instant center is also an important consideration; when the instant center was allowed to move posteriorly and distally, interference was observed at the higher flexion angles. However, when it was allowed to move posteriorly only, the interference disappeared. This result tends to agree with Crowninshield's.

In Vitro Fibroblast Cell Culture System — The second project facilitates the study of degradation rate and tissue regrowth rate control. With a fibroblast cell culture system, the degradation of the implant can be quantified and the various methods of acceleration of tissue growth (i.e., growth hormones, Vitamin C) can be studied in an in-vitro model.

The experimental model utilizes 14-day-old Sprague-Dawley rat tendon fibroblasts. The extensor tendons have been removed from the hind legs of the young rats and grown as explants on implant surfaces. It has been found that the cells do not adhere to PLA sheets since the surface is continually dissolving away. This property of PLA may become an advantage in gliding tendon repair and replacement. However, when the tendon explants are placed on a sheet of 10-μm carbon fibers, cells rapidly migrate out along the fibers. Within 1-3 days after the start of the explant culture, fibroblasts from the explant begin migrating out of the tissue onto the carbon fiber substrate.

In a second series of experiments, RTF cells were cultured on filamentous carbon, Dacron, polyethylene and nylon.

The third series of experiments was designed to determine whether the cell orientation previously reported had an effect on the rate of tissue outgrowth on these fibers in vitro. RTF cell colony formation rates were quantified on filamentous carbon, Dacron and polyethylene. Rat tendon explants were cultured on single fibers of the three substrates and the distance from the explant to the cell farthest from the explant on each fiber was measured at 24-hour intervals on live cultures over a 9-day period. There were no statistical differences in the outgrowth rates of RTF cells of the three substrates. These results indicate that the surface characteristics of these fibers affected cell orientation but not outgrowth rates.

In a fourth series of experiments, RTF cells were cultured on standard dishes and on filmentous carbon and the cell growth rates were quantitated. When RTF cells were cultured on standard dishes their numbers increased slowly from days 0 to 3. Between days 3 and 6 the number of cells increased very rapidly. From days 6 through 8, when the cell monolayers became very dense, the increase in cell numbers slowed and stopped as the cell monolayers reached confluence. The growth rates of these cells were similar to the growth rates of other types of cells cultured on collagen fiber lattices.

These studies indicate that synthetic fiber materials such as filamentous carbon have a strong influence on the growth characteristics of RTF cells in vitro. This type of cell-substrate interaction has been largely unexplored. The experiments reported here are expected to help make it possible to use synthetic fiber implants to rebuild damaged tissues in vivo ■

LOWER LIMB GENERAL

VAMC DALLAS

FRACTURE FIXATION AND HEALING

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Results — Initial testing showed that the impact, using a soft rubber tip on the instrumented hammer, although comfortable to the patient, did not contain a frequency spectrum broad enough to stimulate the higher natural frequencies reported in the literature. The half-power frequency of an impact utilizing a

rubber tip was 128 Hz and did not contain any energy after 350 Hz. In contrast, a hard plastic tip on the hammer produced a half-power frequency of 290 Hz with energy content to 1000 Hz. The hard plastic tip not only excited the higher natural frequencies but increased the overall signal strength ■

VAMC KANSAS CITY

BIOENGINEERING ASPECTS OF FRACTURE HEALING: QUANTITATIVE ASSESSMENT

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A quantitative method of evaluating bone healing would greatly aid not only clinical management but also the assessment of new methods for stimulating bone healing. (Radiographic evaluation has been shown to correlate poorly with bone strength. We have previously published a clinical pilot study suggesting that dynamic bone scanning could distinguish between normally healing fractures and delayed healing or non-unions

Bilateral osteotomies at the junction of the proximal and middle thirds of the ulna were made, using a power saw, in eight canine subjects (hound dogs). Measurements were made pre-osteotomy and periodically for up to 20 weeks.

Measurement of fracture healing of long bones using the resonant frequency response. — A method for monitoring the healing of long-bone fractures has been developed and is being evaluated. The method is based upon the percussing and auscultation method originally proposed some 60 years ago, but the device used to monitor the healing is a microprocessor-based instrument which uses charge-coupled-device technology to perform, in real time, the Fourier transform of the impulse response of a bone.

Tests on 38 patients at the University of Kansas Medical Center and 7 patients at the VA Hospital in Kansas City showed significant differences between normal and fractured limbs.

Modal analysis characterization as a toll for assessment of fracture healing in long bone. — Due to their anisotropic material structure, complex geometrical shapes, and the complex damping characteristics of the surrounding tissue, the vibrational behavior of long bones is extremely complicated. A better understanding of the sonic method can be achieved by first applying the technique to similar but less complex structural systems and then progressing, one step at a time, to the complete long-bone system.

Initial tests were conducted on 18-inch-long, one-inch outside diameter, cylindrical specimens of seven different types of material.

Three different instrumented impacting systems were investigated: (i) a hard plastic-tipped hammer; (ii) a physician's reflex hammer; and (iii) a soft rubber hammer. Both a microphone pickup and an accelerometer were used for the output signal. The input impulse signal was monitored with a force transducer.

The comparison between pickups (i.e., accelerometer versus microphone) indicated that both do an adequate job in providing amplitude and frequency information: however, determination of the modal shapes requires the use of an accelerometer because the microphone cannot distinguish between positive and negative signals.

In vitro resonant frequency measurements of the human tibia. — Osteotomies of the right and left tibia of six cadavers were studied to simulate conditions during fracture healing as a "reverse fracture healing" process. Data were taken on the intact leg (thigh removed); on the tibia and fibula with the interosseous membrane intact but with the foot and all soft tissue removed; on the tibia alone; and on the tibia alone with progressively deeper transverse cuts at a site ⅓ the length of the tibia from the distal end. In every case, the major resonant frequency peak increased and became more sharp as the soft tissues were removed. The damped frequency is equal to the undamped frequency times the square root of one minus the square of the samping factor.

These preliminary results support the use of this method in the assessment of fracture healing. Frequency changes are large, which reduces the requirement for extreme accuracy in their measurement.

Assessment of fracture healing by dynamic bone scanning and resonant frequency analysis. — Using the criterion of the return of resonant frequency to the normal value, this technique agreed with the histologic data in 13 of 16 cases. Of the 11 cases in which union was indicated by both the resonant frequency technique as well as the histological findings, in 10 cases the techniques identified the time of union

within 2 weeks of each other. The dynamic bone scan data failed to precisely determine the time of union.

One of the shortcomings of this study was the difficulty of obtaining animal cooperation during the awake resonant-frequency determination. Therefore a second study has been conducted during which the resonant frequency studies, as well as dynamic bone scan data, have been collected under short-acting anesthesia. Furthermore, animals have been sacrificed both early and late to allow mechanical determination of fracture site stiffness which will be correlated with the resonant frequency data.

A more suitable study would be one in which fracture site stiffness is obtained in vivo throughout the fracture healing period. To accomplish this an in vivo four-point bending device has been fabricated. This device has been tested and is now being used in a third phase, in which fracture site stiffness and resonant frequency changes will be measured throughout the fracture healing period ■

NIH MUSCULOSKELETAL

INTERNAL FIXATION PLATES FOR FRACTURE MANAGEMENT

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The objective of this research is to improve the understanding of stiffness requirements of internal fixation plates used for long-bone fracture management. The hypothesis, based on the numerical analyses and bench experiments performed during the current funding period, is that moderate plate bending and torsional stiffnesses are important for early treatment of fracture.

Another hypothesis to be tested is that the low axial plate stiffness may play a significant role in the structural and mechanical properties of the underlying bone during its recovery following plate removal.

The experimental animals will be sacrificed at various time intervals, and the plated and control bones will be evaluated by a multidisciplinary approach. Specifically, stiffness parameters of whole bone, and mechanical and structural properties of bone from various anatomical quadrants, will be evaluated. The vascularity of bone — in the area beneath the plate in particular — will be studied. Hard tissue processing for microradiography and tetracycline labeling for quantitative estimation of new bone formation as well as cortical porosity will be done. In addition, the morpho-metric evaluation procedure will yield dimensional properties, such as cortical area, medullary canal size, and cortical thickness. The biochemical analyses will include ash content, bone mineral, and organic matrix contents. This correlative study will be of importance in order to evaluate the quality and quantity of bone during healing and remodeling and its relationship to the variables of various plate stiffnesses. Ultimately, the experimental data will be used as a basis for the recommendation of clinical treatment of long bone fractures with internal fixation plates ■

NIH MUSCULOSKELETAL

HEMODYNAMIC FACTORS IN FRACTURE HEALING

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The principal purpose of the project is to examine the interaction between mechanical and biological factors in fracture healing. The effect of the type and the stiffness of the fixation device on new bone formation in fracture healing will be studied. The major techniques will be morphometric to quantitate and qualitate new bone formation, biomechanical testing of the strength of the healed bone, and microsphere arteriolar blockade for blood flow measurements.

Initially, plates will be compared to external fixators by using each on a standard tibial osteotomy in the same animal. Then the effects of stiffness of immobilization will be examined by using varying configurations of percutaneous pins with the external devices. Six half-pins (three above and three below the fracture site) will be compared to four half-pins (two above and two below), and biplanar fixation will be compared to one-plane fixation. Finally, the possible benefits of compression of the external fixation device on fracture healing over fixation in neutral position will be explored. Possible bone pressure necrosis due to localized high stresses, both at the fracture site and at the pin bone interface, will be studied. Pin curvature shown on the X-ray will be used to assess the compressive forces, and titanium pins will be used to prevent permanent deformation.

Blood flow will be measured at stated intervals using labeled microspheres. At the end of the experimental period, 120 days, the fracture will be examined for strength of healing by biomechanical testing, and the amount and quality of new bone will be estimated by morphometric examination ■

NIH MUSCULOSKELETAL

MOLECULAR BIOLOGY OF FRACTURE INJURY AND REPAIR

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The overall objectives of this project are: (i) to identify and characterize the critical events of osseous repair in animal models following fracture, and (ii) to assess the effect on the biological repair process of different fracture stabilization modes and/or altered bone metabolism. The goals for the proposed 3-year period fall into two areas:

1. Completion of characterization of the biochemical events that demarcate the stages of fracture healing and the correlation of these events with morphological, radiographic, and biomechanical changes during healing as affected by degree and mode of fixation. Chemical parameters to be measured are the composition and concentration of proteoglycan, collagen, mineral, and lipid. Techniques include molecular sieve chromatography, SDS slab electrophoresis, indirect immunofluorescence, crystal analysis, and biomechanical torque testing.

2. Determination of the biochemical and biomechanical effects of altered nutritional and metabolic status (local and distant) on fracture repair in experimental animals. Examples of such alterations are: nutritional osteomalacia, inhibition of prostaglandin synthesis, and systemic fluoride administration.

Current orthopedic approaches to osseous injury, which have been derived from clinical experience and histological characterization of skeletal injury, do not consistently result in adequate fracture healing. Recently developed methodology for studying the biochemistry, histochemistry, and biomechanics of skeletal tissues should permit the characterization of the critical molecular events necessary for successful fracture union both in normal and altered osseous metabolism. Those results will be helpful in developing a nutritional and therapeutic strategy to improve the success rate of clinical fracture healing ■

NIH MUSCULOSKELETAL

ACCELERATION OF FRACTURE HEALING BY ELECTRIC FIELDS

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The objective of this research is to continue to investigate the effects of applied electrical fields on the acceleration of fracture healing in laboratory animals.

The proposed research is designed —

1. To determine the optimum parameters of an applied capacitively coupled field required to accelerate fracture healing in an osteotomized rabbit fibula model stimulated both locally and remotely.

2. To determine the mechanism(s) of electrically induced osteogenesis at the cell level by determining: (i) the responding cell; (ii) the microenvironmental changes occurring in the vicinity of a cathode; (iii) the effect of direct current on the mitochondrial release of calcium from callus chondrocytes; and (iv) cyclic AMP, calcium flux, and surface charge of the cell membrane of osteoblasts grown in monolayer in various capacitively coupled fields.

Methods to be used include histologic, roentgenographic, and mechanical testing of osteotomized rabbit fibulae subjected to various capacitively coupled fields: H^3 thymidine, C^{14} proline, and S^{35} uptake and the protein, DNA, and calcium content (via atomic absorption) of various isolated cells grown in diffusion chambers in the rabbit peritoneal cavity and stimulated with direct current; needle-electrode determination of pO^2 and pH of medullary canal contents in the vicinity of an active cathode, and correlation of these microenvironmental changes with bone formation (as determined by point counting analysis); electron microscopic changes in mitochondrial calcium release in fracture callus chondrocytes stained with potassium pyroantimonate when subjected to direct current; changes in cyclic AMP, calcium flux (using metallochromic calcium indicators and dual wavelength spectrophotometry), and surface charge of cell membranes (as determined from electron micrographs after staining with polycationic ferritin) in isolated osteoblasts grown in monolayer in various capacitively coupled fields ■

VAMC SEATTLE

THE INFLUENCE OF AGE, DIET, AND ACTIVITY ON CORTICAL BONE STRUCTURE AND PROPERTIES

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Previous research efforts centered on acquiring a data base for normal (caged) rats with which the effects of daily moderate (0.05 km/day) and intensive (0.50 km/day) involuntary exercise on bone matura-

tion could be compared. Results showed that rat cortical bone exhibited allometric growth in all parameters measured (animal age and weight, bone length, and structural and material properties). Intensive exercise produced significant ($P<0.01$) bone hypotrophy (decreased cross-sectional growth rate and decreased bone length) as well as significant changes in material and geometric properties, the former attributed to increased bone mineral content. In addition, intensive-exercise animals showed a marked increase in in vitro failure shear strains (in response to applied torsion) over moderate and control (caged) animals. Preliminary results of "nonstressed" (voluntary) exercise, in which the animals are permitted to exercise as often as they wish in specially designed cages with attached exercise wheels, indicate trends similar to those observed for the involuntary exercise group (some animals were observed to run up to 4 km/day).

These results question the prevailing belief that exercise in the growing animal is always beneficial.

Current studies are directed toward in vitro mechanical testing of immature **primate** cortical bone. In addition to determination of anthropomorphic data, torsion and bending test techniques identical to those performed on rat long bones for evaluation of structural and material properties, are being utilized. Furthermore, in vitro cyclic fatigue (strain controlled, physiological rate — 0.6% strain, 0.02 sec^{-1}) and monotonic tensile failure tests are being conducted on turned primate cortical bone specimens obtained from anatomically different regions within the same bone. Results of the latter indicate that (i) fatigue damage accumulates in the tensile phase of fatigue, (ii) fatigue resistance decreases logarithmically with age, and (iii) the fatigue resistance and strength of Ant. > Post. > Lat. > Med. > sections. Results of the torsion and bending tests revealed allometric relationships which parallel relationships developed for rat cortical bone, indicating that scalar differences between animal species for many bone properties exist. In particular, cortical bone appears to optimize structural properties as a function of torque, body weight, and bone length ■

VAMC CASTLE POINT

STIMULATION OF REPAIR OF CORTICAL BONE TRANSPLANTS BY IMPLANTATION OF PIEZOELECTRIC MATERIALS: A PILOT STUDY

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The overall goal of this project was to develop and evaluate a new technique applicable to electrical stimulation of repair of those fractures, osteotomies and nonunions in which surgical intervention for structural bone transplantation and/or internal fixation is indicated. Work during the project was divided into two main parts:

1. Evaluation of Osteostim™ Implantable Bone Growth Stimulators (S12 Model), and
2. Pilot Studies on Devices for Bone Stimulation by Implantation of Piezoelectric Materials.

Osteostim™ S12 Evaluation

At the time this investigation began, the Osteostim S12 stimulator, developed by Patterson in Australia, had just been introduced into the USA commercially and was being recommended for use in treatment of nonunions, and bone defects. The encapsulated power supply was designed to deliver a constant current of approximately 20 microamperes. A titanium cathode was designed to be trimmed to appropriate length and inserted as a small coil at the nonunion site. It was felt that this totally implantable unit might be well suited to the needs of VA patients, and deserved evaluation as a preliminary to work with piezoelectric materials.

Results — Electrical failures and wire breakage of the commercial implants limited results, as stimulation was not in progress for an adequate time in several instances.

While these experiments were not entirely satisfactory due to technical difficulties, the overall impression in both the bone defect and bone transplant models was that the d.c. stimulation did not have a major effect on the healing or remodeling pattern. In both models, there were variations but no obvious preponderance of new bone formation or increased remodeling activity on the stimulated side. Furthermore, at 8 weeks, no consistent differences were noted between those stimulated the full 8 weeks and those in whom stimulation ceased at 1-4 weeks due to breakage of equipment.

In view of the many studies which demonstrate effects of electrical stimulation on bone, the negative results found here deserve some comment as follows.

1. In all cases, stimulation was started on Day 1 of surgery. Therefore, the model is not strictly comparable to adding stimulation to an existing nonunion or earlier transplant.
2. In all cases, the cathode location was essentially devoid of pre-existing living bone cells. The results tend to confirm earlier impressions of the Principal Investigator that direct electrical stimulation is ineffective unless the cathode lies adjacent to living bone.
3. In view of the long cathode wire, the current densities applied were very low. The lack of effect seen with these units is consistent with a study reported by Connolly.
4. The S12 stimulator, as first employed, had serious defects due to lead fragility (they were designed for use in areas of minimum lead movement). Suggestions submitted as a result of this study apparently influenced the subsequent manufacturer to incorporate them into a mechanically improved model.

Implantation of Piezoelectric Materials

The purpose of this pilot study was to determine if piezoelecric materials, placed in contact with bone and deformed with bone by physiological loads, can generate potentials which can affect bone healing and remodeling. Due to time limitations, the primary accomplishment of this work was to design and test various modes for implementing this concept, and to lay the groundwork for continuing studies in progress at present. The most promising mode is use of a piezoelectric material bonded to a relatively flexible internal fixation plate.

Results — In total, various plate designs and configurations were tested in a series of 13 dogs as development work proceeded. In brief, in these experiments, no significant differences on bone healing or remodeling were noted between active and control piezoelectric devices, but output was probably inadequate.

The experience gained in working with this new concept in internal fixation during this pilot study is now being extended in an ongoing development project utilizing a modified experimental design, with evaluation by histomorphometric procedures. Quantitative data on output of the piezoelectric devices in vitro and in vivo also is being obtained ■

BONE/GELATIN PARTICULATE COMPOSITE FOR FRACTURE FIXATION

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Three main research objectives exist for the next project period.

The first objective is to seek a better understanding of the relationship between structural composition and material properties of composites. Both theory and experimental evidence indicate that denser particulate packing should give higher composite material strengths. Spherical glass beads 50 to 500 microns in diameter will be used initially at the particulate phase to simplify experimental variables while studying the effects of size, volume fraction, and particle size on material strength properties. Based on these results, appropriately shaped hydroxyapatite and bone chip particles can be produced using turbulent flow abrasion techniques.

Second, a more biologically compatible composite matrix will be developed. Although formaldehyde and resorcinol make up only 3 percent by weight of the current composite and combine to form an inert product, some biologic toxicity may exist. A synthetic polypeptide that cross-links with itself to form a rigid biodegradable material will be studied for use as a truly nontoxic, resorbable matrix. In addition, more effective cross-linking of the fiber reinforcement will be attempted by using a solubilized form of collagen.

Third, in vivo experimentation will continue concurrently with development efforts in particulate technology and matrix biocompatibility. The host response to implants is crucial and cannot be duplicated by in vitro conditions. Determining a particle size for optimum compressive strength, for instance, may conflict with the best particle size for inducing bony ingrowth. Rabbit models will be used for economy of long-term testing. Sheep will be used when larger models are required for mechanical testing of the in vivo structural performance of the particulate composite ■

VAMC SAN DIEGO

EFFECT OF STRESS AND MOTION ON REPAIR OF HARD AND SOFT TISSUES

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This research program is designed to pursue Wolff's Law on tissue healing and remodeling. It is well known that initial immobilization is necessary for tissue healing purposes, but it is also known that prolonged and/or over-immobilization can retard the repair process and also induce the disuse atrophy of the surrounding tissues.

This research program is divided into two areas of concentration. One is the study of the effect of the use of sturdy and large internal fixation plates to immobilize long-bone fractures. These devices are effective in immobilizing long-bone fractures. However, once the fracture is healed, such a "rigid" internal fixation system may be detrimental to normal bone remodeling because the underlying bone is overprotected from normal physiological stresses, and because of that becomes atrophic or osteoporotic.

The second study is to evaluate the effects of motion and stress on ligament repair. Early immobilization is necessary to facilitate soft tissue healing, but prolonged immobilization can result in joint stiffness manifested as contractures. On the other hand, uncontrolled motion may cause increase in ligament length and joint laxity as well as disrupt the repair. Thus, a suitable amount of immobilization, motion, and exercise all seem to be required in order to determine the optimal modality in the repair of failed ligaments.

Tubular Plate Design — In the internal fixation plate study, an experimental plate made of titanium alloy designed to have a tubular cross-section filled with high-density polyethylene is being investigated. A tubular cross-section will permit the desired combination of high bending stiffness and torsional plate stiffnesses to facilitate fixation for fracture union, and at the same time will provide low axial stiffness to minimize stress-bypass effects on bone, to permit more normal bone remodeling.

It has been demonstrated in our laboratory that such a tubular plate, made of stainless steel, has been successful in treating experimental fractures.

The experimental titanium tubular plate, and traditional "rigid" stainless steel solid plates, will both be used to immobilize unilateral mid-shaft femoral osteotomy of dogs. Both the experimental and control plates will be of similar dimensions with respect to length, number and spacing of screw holes, etc. The goals will be to study the effects of short-term (4 and 6 months) and longer terms (9, 12, and 18 months) of plate application. Fracture healing will be evaluated by bioengineering, morphometric, and biomechanical methods.

In the ligament repair study, the medial-collateral ligaments (MCL) of the dogs and rabbits have been studied and a variety of activity conditions have been imposed to determine which set of conditions will maximize the speed and strength of the ligament healing. These regimens include rigid immobilization, cage activity, immobilization plus activity, etc. The method of evaluation includes morphologic, bioengineering, and biochemical techniques.

During this past year, 18 adult mongrel dogs have been used as experimental animals. The MCL's were cut. The animals were divided into three groups: (i) MCL were repaired and the knee was immobilized for 6 weeks, (ii) same as (i) but the knee was immobilized for 3 weeks and left free for 3 weeks activity, and (iii) no repair of the ligament and no immobilization of the knee for 6 weeks. The emphasis of this study is on evaluation of the different treatment regimens. Biomechanical studies include the evaluation of the strength of the repair site using an Instron testing machine; and the varus-valgus laxity of the knee joint using a new device that attaches to the Instron. The tensile test results, and those obtained using the newly constructed laxity device, suggest the following conclusions: (1) early immobilization may have a positive effect in reducing joint laxity, and that complete immobilization may be detrimental after 6 weeks; (ii) immobilization may have an adverse effect on the healing ligament's structural properties compared to groups with earlier mobilization; and (iii) immobilization may aid in the mechanical properties of ligament scar ■

VA RR&D CENTER HINES

A BIOMECHANICAL STUDY OF FIBULAR MALUNION

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Fracture of the ankle-joint complex is a common orthopedic injury. There is clinical evidence that inaccurate fixation of a fractured fibula leads to arthritic and/or degenerative changes in the ankle joint. The purpose of this study is to quantify the amount of fibular shortening or rotation that would significantly

alter the normal pressure patterns in the ankle joint.

A pressure-sensitive film is used to measure the contact area and pressure distribution within the ankle joint of cadaver speciments under compressive loads. The fibula is fractured just above the ankle, and surgical fracture fixation is simulated using a special plate. This plate allows for control of fibular rotation and shortening. The pressure-sensitive film is inserted in the ankle joint and compressive loads are applied to the specimen corresponding to the physiologic loads during the normal gait cycle. The film is later analyzed for contact area and pressure distribution for each loading condition.

Preliminary results indicate that changes in contact area, average pressure, and pressure distribution begin with as little as 2 mm of shortening or 15 degrees of rotation of the fibula. Data from this study is intended to provide an objective treatment criterion for fracture fixation of the ankle joint complex ■

NIH MUSCULOSKELETAL

ORTHOPEDIC SEPSIS: PATHOGENESIS, DIAGNOSIS, AND TREATMENT

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The overall objectives of this project include the examination of the mechanism of sepsis involving polymethyl methacrylate, determination if the hosts' inflammatory or immunological mechanism may be compromised by this polymer, the evaluation of local bone flow following the surgical treatment of osteomyelitis, and the investigation of the ability of the newer noninvasive scintigraphic techniques to differentiate acute hematogenous osteomyelitis from trauma.

The initial objective of this project is to show that methylacrylic acid, the byproduct of unpolymerized methylmethacrylate, is bactericidal and offers protection against wound infection. Acrylic cements such as Palacos® , which leach little methylmethacrylate, are more susceptible to sepsis than Simplex P cement. This objective will be accomplished by quantitating the chronologic leaching of unpolymerized methylmethacrylate and its hydrolysis methylacrylic acid per cm^2 of Palacos® and Simplex P bone cements. The bactericidal activity of methylacrylic acid against common pathogenic microorganisms — *S. aureus, S. epidermidis, E. coli,* and *P. aeruginosa* — will be documented. Finally, the effect methylacrylic acid and the monomer methylmethacrylate leaching from Palacos® and Simplex P have on white blood cell subtype viability and their functional inflammatory and immunological activities when exposed in vitro to amounts felt to represent that occurring from its in vivo utilization will be determined.

The second objective of this project is to evaluate blood flow to osteomyelitic bone with a noninvasive technique (dynamic 99m technetium scintigraphy) and an invasive technique (85 Sr microspheres) following debridement with or without a local muscle flap and antibiotics in the dog. The goal of this study is to determine if the efficacy of a local muscle flap is related to increased local bone blood flow, and if dynamic 99m technetium scintigraphy can be used to monitor treatment with a noninvasive technique.

The third objective of this project is to determine if 111-indium-labeled white blood cell imaging, or dynamic 99m technetium scintigraphy, can diagnose acute hematogenous osteomyelitis between 6 and 168 hours following initiation of the infection in the dog ■

NIH MUSCULOSKELETAL

HEMATOGENOUS OSTEOMYELITIS: ETIOLOGY AND TREATMENT

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The purpose of this project is to study the etiology, pathophysiology, natural history, and treatment of acute hematogenous osteomyelitis and other factors which may influence the direction and duration of this disease.

A standard experimental rabbit osteomyelitic model was developed and was reported in preliminary results. Further refinement and standardization of the model are needed. The model relies on systemically administered bacteria which will create a subclinical bacteremia. One limb is traumatized by minimally slipping the epiphyseal plate of the tibia on a specially constructed press which does not create instability, bone damage, or hemorrhage to the plate. As the bacteria appear to be localized below the area of traumatization in the metaphysis, a typical clinical osteomyelitic condition occurs and prevails. With this model, one is able to control the severity of the disease, predicting and locating lesions.

Using this model, the pathophysiology may be studied at daily intervals, enabling a better understanding of the natural history of the disease. Once an understanding of the progression of the disease has been obtained, other influencing factors such as trauma, immunosuppressants, and dietary deficiences may be applied and the effects carefully monitored.

When the model has been perfected, standard forms of treatment may be applied to the model and their effects studied. This knowledge will give the surgeon greater ability in treating the disease. It is known that early administration of antibiotics is effective in treatment, but later administration is not. These studies are intended to answer the question of whether antibiotics are useful after a certain length of time following the onset of the disease. They could also indicate a point in time when surgery must be used, and predict its success.

The information yielded from this project can enhance understanding of the disease in humans and enable the orthpedic surgeon to treat the disease more scientifically ■

NIH MUSCULOSKELETAL

BACTERIAL COLONIZATION OF SURGICAL BIOMATERIALS

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A variety of biomedical materials, many of which are plastics or metals, are implanted into large numbers of patients in many forms. A disturbingly large proportion of patients implanted with surgical biomaterials (e.g., 1 to 11 percent of all prosthetic hip devices, or 15,000 to 30,000 patients per year) become chronically infected. These infections respond notoriously poorly to antibiotic therapy and may necessitate the removal of the biomaterial with unfortunate sequelae.

Recently developed insights in microbiology have shown that surface adhesion is the first step of the pathogenic process, suggesting that bacteria may colonize an inert surface within the body if they are introduced during implantation of the device or if they are carried to the area by transient bacteremia. It is known that bacteria adhere to inert surfaces (e.g., pipes in cooling towers, rocks in alpine streams, and dental enamel) by means of exopolysaccharide fibers, the glycocalyx.

The discrimination of these processes has obvious importance. It is proposed to continue to recover these adherent bacteria from actual cases of infected surgical biomedical implants and to establish them as adherent populations on a variety of metal and plastic surfaces in vitro. A preliminary direct observation of material from infected internal fixation devices has demonstrated adherent bacteria surrounded by extracellular fibers. These bacteria have been isolated; their adhesion to metal and plastic surfaces by means of their surface polysaccharide has been demonstrated. It is proposed to study the effect of this mode of growth on resistance to clearance by macrophages and on resistance to antibiotics. Development of an understanding of the bacterial colonization of a wide variety of surgical materials should make it possible to select materials and finishing processes that minimize bacterial adhesion and maximize clearance by macrophages. By studying the chemistry of the bacterial exopolysaccharide and its role in antibiotic resistance, one seeks to optimize antimicrobial therapy ■

NIH MUSCULOSKELETAL

STUDIES OF FACTORS AFFECTING ORTHOPAEDIC INFECTIONS

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The research being undertaken is designed to investigate problems of infections in orthopedic patients. One goal of the study is a better understanding of factors leading to wound contamination in open fractures and any infections that might follow such contamination. Various factors including the use of internal fixation devices, methods of irrigation, time between injury and treatment, and underlying diseases are being compared with infection rates and with level of tissue contamination.

An animal model involving open fractures of the hamster femur using an osteotomy saw has been developed to clarify the role of internal fixation in infection. Studies have been done with staphylococcus aureus and will be done with proteus and an anaerobic streptococcus. Studies are also being undertaken in the hamster to investigate host responses, such as sensitivity reactions to the implant, on infection rates. Finally, rapid diagnostic techniques are being investigated for diagnosis of osteomyelitis and septic arthritis using blood, joint fluid, and aspirates. These studies should provide information on the management of patients likely to develop infections ■

NIH MUSCULOSKELETAL

DISTRIBUTION AND PHARMACOKINETICS OF DRUGS IN BONE

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The purpose of this study is to identify and refine those procedures with which the pharmacokinetics of drugs in bone can be accurately and reproducibly studied. This information will then be applied to the study of normal, infected, and avascular bone, and the common principles of antibiotic distribution within bony tissues will be sought.

Bioassay and radioassay procedures in combination with histological and autoradiographic methods will be used.

The end result is intended to provide a clear, practical picture of the location, availability, and quantity of antibiotic in bone, and to provide pertinent scientific information that will be directly applicable to clinical situations ■

VAMC GAINESVILLE

FOREIGN BODY REACTION IN THE LUNG TO INTRAVENOUSLY INJECTED BIOMATERIALS

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During the period from January 1 to June 30, 1983, the standard bead model previously defined in this project has been used to continue studies on the assessment of cellular changes during granuloma formation and the relative effectiveness of both steroidal and nonsteriodal anti-inflammatory drugs. In these experiments, sieved 45-53 μm divinyl copolymer beads were injected into the tail veins of mice, from whence they embolized to the lung. The granulomatous reaction to the beads was quantitated by use of a computerized digitizer. This model system has been used in these studies for observation of the cellular events in granuloma formation and for continued quantitative testing of the effectiveness of anti-inflammatory agents.

Results — Initial adherence of neutrophils could be seen at 3 hours after bead injection and many were still present at 24 hours with few monocytes observed. At 48 hours, when the maximum reaction was observed, both neutrophils and monocytes could be observed in the granuloma ■

VAMC PHILADELPHIA

FLUOROMETRIC PREDICTION OF SUCCESSFUL AMPUTATION LEVEL IN THE ISCHEMIC EXTREMITY

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The adequacy of nutritive capillary blood flow to the skin at an amputation site is a major determinant of the optimum level of amputation. Techniques such as plethysmography, waveform analysis, dye dilution, and oscillometry measure "total" blood flow or pressure to an area but do not document capillary flow to specific tissues. Temperature measurements reflect arteriovenous shunt flow — not nutritive capillary flow. Ultrasound doppler, one of the most popular techniques, assesses arterial pressure; moreover, doppler readings may be spuriously high in patients with noncompliant arteries, a common feature in diabetic patients.

Twenty patients with severely compromised extremities, in whom the optimal level for amputation was not clear, were referred for this study. Each patient was evaluated in two ways:

1. Standard clinical assessment (SCA); this included clinical inspection, ankle/brachial pressures by ultrasound, angiography, photoplethysmography, and pulse volume recordings;
2. Fluorometry (FLUOR); 15 minutes after injection of fluorescein, dye delivery was quantified by placing the fiberoptic probe of the perfusion fluorometer on as many as 75 reading points per leg (3 sec/reading).

All amputations were performed based on SCA. Of the 20 amputations performed, 16 healed without complication; 4 did not heal and required revision. Thus, SCA had an 80 percent overall accuracy with a 20 percent false-negative rate. FLUOR was significantly more accurate ($P<0.05$ by the Chi-squared method) with a 100 percent accuracy rate, despite being shortened to a 20-30 minute test.

Conclusion — Initial studies suggest that fluorometry is a highly accurate way to predict proper amputation levels. It is minimally invasive and accurate. With refinement, fluorometry may prove to be the optimal technique for this assessment ■

VAMC SEATTLE

MORPHOLOGICAL AND CLINICAL STUDIES OF MICROWOUNDS IN ISCHEMIC HUMAN TISSUE

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The purpose of this project is to study in a systematic fashion morphological and clinical features of small standardized wounds created on the lower limbs of patients with severe peripheral-vascular disease (PVD) necessitating amputation. The wounds wil be created with Simplate II bleeding-time device under sterile conditions at locations immediately distal to the planned site of amputation, and at a variety of clinically and biologically relevant time periods, for a study of wound healing.

Wounds will be examined clinically at the time of surgery, then excised from the amputation specimen and fixed for morphological studies. Light and electron microscopy will be performed on the samples. Morphological events of healing will then be compared with normal controls from previous studies, transcutaneous oxygen tension ($TCPO_2$) at the microwound site, the clinical appearance of the microwounds, the outcome of the amputation — and will be related to a variety of risk factors for PVD such as smoking, diabetes, and hypertension ■

VAMC CASTLE POINT

THE USE OF HYDROGEN-CLEARANCE TECHNIQUE IN MONITORING MUSCLE BLOOD FLOW: EFFECTS OF LUMBAR SYMPATHECTOMY ON MUSCLE BLOOD FLOW

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Abstract — The technique of hydrogen clearance has been used in five canines to monitor blood flow in gastrocnemius muscle following sympathectomy. The contralateral nonsympathectomized limb was used as a control. Average blood flow was based on 22 pairs of desaturation data. Average blood flow in the left control limb was 6.08 ± 2.22 ml/min/100g tissue and the right sympathectomized limb was 9.54 ± 3.97 ml/min/100g tissue. Average blood flow increase was statistically significant ($p<.005$) in the sympathectomized limb over the contralateral control. The increase in muscle blood flow following lumbar sympathectomy, if of prolonged duration, may be a valuable adjunct to direct reconstructive arterial surgery in the management of symptomatic arteriosclerotic occlusive disease. The technique of hydrogen clearance is excellently suited for the monitoring of muscle blood flow and may be equally applicable in determining level of amputation ■

VAMC SEATTLE

TRANSCUTANEOUS OXYGEN TENSION AS PREDICTOR OF WOUND HEALING

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Transcutaneous oxygen tension, a noninvasive means to determine local cutaneous perfusion, has been studied for its usefulness in predicting wound healing potential and correlated with the severity of peripheral vascular disease. Transcutaneous PO_2 measurements were made segmentally on the limbs of diabetic and nondiabetic patients with varying degrees of peripheral vascular disease. Results indicate that nondiabetic limbs with $TcPO_2$ values on the foot or below-the-knee less than 20 mmHg are significantly more likely to have rest pain or ulcers, to need an amputation, and to have failure of amputation healing than those limbs with $TcPO_2$ values above 40 mmHg. Results from diabetic patients were similar; however, many diabetic patients have ulcers in the presence of high (greater than 40 mmHg) limb $TcPO_2$. This suggests that ulceration in many diabetic limbs may result from factors other than insufficient cutaneous oxygen delivery.

The healing characteristics of below-the-knee amputations resulting from peripheral vascular insufficiency were correlated with transcutaneous PO_2 values at that level. Results indicate a strong correlation between transcutaneous PO_2 values and amputation healing below-the-knee. All patients with below-the-knee $TcPO_2$ above 40 mmHg healed, healing rate where below-the-knee $TcPO_2$ was between 20 and 40 mmHg was 93 percent and healing rate where $TcPO_2$ was below 20 mmHg was 50 percent.

A human model of peripheral vascular insufficiency has been developed where the brachial artery

*Dr. Matsen and Dr. Burgess, the principal investigators, are with the Limb Viability Laboratory and the Prosthetics Research Study, respectively. Dr. Wyss, associate investigator, is with the Limb Viability Laboratory. The research is a **VA Rehabilitation R&D** Program project.

is occluded while other major vessels remain open. Using this model, a hypertensive response to ischemic exercise and postexercise decrement in $TcPO_2$ was observed as observed in patients with peripheral vascular insufficiency. This model of claudication in normal human subjects appears to be a useful method to investigate the local and systemic effects of ischemic exercise. Results from this series of experiments suggest that $TcPO_2$ measurements made during or immediately after exercise stress may be more sensitive than resting $TcPO_2$ values in people with mild peripheral vascular insufficiency.

Development of a multiprobe transcutaneous oxygen tension monitor has allowed us to begin investigations mapping cutaneous perfusion in arterially insufficient limbs. These studies continue to elucidate the value of transcutaneous PO_2 measurements in the clinical assessment of the circulatory status of localized areas of skin ■

NIH MUSCULOSKELETAL

DIAGNOSIS OF LOOSE OR DAMAGED TOTAL JOINT REPLACEMENT

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

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

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

VAMC LITTLE ROCK

THE EFFICACY OF SURGICAL AND REHABILITATIVE PROCEDURES OF THE KNEE

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This project is in the second year and concerns the design and development of an instrument to test the efficacy of surgical and rehabilitative procedures of the knee, using cadaver specimens under as good a physiologic condition as possible. The instrument may also be used to determine the characteristics of implantable prostheses and the strength of various attachments for the knee.

The first research efforts to study the knee using a cadaver specimen were performed with a knee-test apparatus designed for this application. The experience with this "machine" led to the present effort to design a stronger and more versatile apparatus that could do a more effective job of testing the knee. Based on the experience with the earlier device, the specifications for the new test instrument were to be as follows:

1. body weight: 200 lb
2. quadraceps force: 500 lb
3. transverse tibial rotation: ±90°
4. tibial torque: ±200 inch-lb
5. medial/lateral tibial motion: ±26°
6. medial/lateral force: ±100 lb
7. flexion/extension: − 15° to + 130°
8. anterior/posterior angle: ±5°
9. anterior/posterior force: ±25 lb
10. specimen size: 6 to 20 inches overall

Other specifications were that the torque and force controls for the transverse and coronal planes were to have the ability for either or both to be easily disconnected without disturbing their angular measurement capability.

An additional and highly significant feature of the apparatus as compared to the old one is that the entire knee specimen may be rotated while under load about a vertical axis that passes through the

ankle and the hip. This will permit observing (or making incisions on) the posterior portions of the knee specimen while it is under load and while it is being observed from the posterior. Also, the knee may be X-rayed from any direction conveniently, due to this rotation about the vertical axis.

The data channels selected for measurement are as follows:

1. flexion/extension;
2. tibial rotation angle;
3. medial/lateral motion angle;
4. anterior/posterior motion angle;
5. anterior/posterior force;
6. rotational torque;
7. medial/lateral force;
8. body weight; and
9. quadraceps force.

This system will have a force-overload interlock applied to the quadraceps force (500 lb max.) and the body weight (200 lb max.). Any time either of these parameters exceeds the maximum level by 25 lb, the computer will automatically shut down the mechanism by which these parameters may be increased and will annunciate the fact that an overload has been achieved. At this time, only those controls which decrease the values of these parameters will be operable.

The system as described has been completely designed and is about 85 percent complete in its construction. It is anticipated that it will be in operation and taking data within the fourth quarter of this contract period. The greater load capacities and angular motions inherent in this device, as compared to the previous one, along with the ability to monitor all the data channels simultaneously, should provide a system which allows the knee to be studied in vitro under as good a condition as possible ■

HHS NIGMS GRANT

SURGICAL IMPLANTS FOR SUSTAINED MACROMOLECULAR RELEASE

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The objective of this proposal is the development of non-erodible and erodible biocompatible polymeric systems capable of delivering high molecular weight drugs (M.W. 1000), such as polypeptides and proteins, after implantation. The development of a system which would control the rate of release of drugs from implanted polymeric substances is also under investigation ■

NIHR REC

A SELF-CONTAINED PORTABLE FORCE AND MOVEMENT MEASUREMENT SYSTEM TO AID DIAGNOSIS AND REHABILITATION OF HUMAN MOVEMENT DISORDERS

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The work described here is a continuation of an effort which started with the specific aim of improving A/K amputee gait-training through development of instrumentation for measurement and biofeedback of gait parameters. As prototype hardware was completed, its general applicability became apparent. Although the immediate focus of the effort remains on A/K gait training, the criteria that guide design decisions are more global. A self-contained, portable, force and movement measurement system has many applications in diagnosis and rehabilitation.

The gait-training aid is a microcomputer-based instrument that has been programmed to provide the following:

1. Threshold and/or proportional audio biofeedback of the prosthesis weightbearing (Is the proper weight being applied to the prosthesis?).
2. Average peak weightbearing during a series of steps.
3. Percentage of stance cycles during which the adjustable weightbearing threshold was attained.
4. Threshold and/or proportional audio biofeedback of hip extension angle (Is the person standing erect during stance?); and
5. Percentage of cycles during which the hip extension threshold was exceeded during stance.

During the past year, several subtle changes have been made in the instrument's software, but the main effort has been directed toward improved force and movement transducers.

In order for a weightbearing transducer to be clinically acceptable, it must be compatible with existing postoperative prostheses and training procedures. Such a transducer has been designed and is currently being built. It uses a thin cylinder of elastomer to isolate the axial load on the prosthesis from the large bending moments which occur in the shank. This allows a strain gage to measure one type of loading without being substantially affected by large stresses in other directions.

The movement transducer has also changed dramatically. The new system is essentially a radio direction-finder. A small transmitting antenna is placed on one body segment and a crossed pair of receiving antennae is placed on another body seg-

ment. Appropriate processing of the signals from the two receiving antennae yields a very well-behaved indication of the angle between the transmitter and receiver.

A prototype of this radio goniometer has been built ■

VAMC DALLAS

ASSESSMENT OF ENDURANCE OF QUADRICEPS AND GASTROCNEMIUS MUSCLES BY POWER SPECTRUM DENSITY TECHNIQUES

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This project represents a continuation of previous work concerning the relationship between myoelectric signals and muscle function during exercise. The mission is to document, in normal individuals and rehabilitating patients, a decrease in mean or median power frequency during exercise as fatigue develops.

Power spectrum density analysis of myoelectric signals are done using a Digital Equipment Corp. (DEC) LSI 11/23 minicomputer. Analog signals are filtered and digitized at a sample rate of 2048 hertz and stored on floppy discs. A fast Fourier transform is done on consecutive 250-millisecond time segments to produce a 512-point power spectrum density periodogram. Consecutive sets of eight periodograms are averaged and used to obtain mean power frequency.

In a study with 14 young adult normal males we compared gastrocnemius muscle fatigue at 50 pecent MVC, along with contraction characteristics (maximal rate of torque development and electromechanical delay time), and muscle fiber types (from a single biopsy). Subjects included endurance athletes and athletes with explosive strength or speed. The latter athletes, as expected, had a greater relative proportion of fast-twitch fibers; also, they had a higher initial mean or median power frequency and a more rapid drop in frequency as fatigue progressed. End-of-trial frequencies were approximately the same for both types of athletes.

In another pilot study we examined quadriceps muscles following total knee replacement surgery of five patients seen up to 6 weeks after surgery. Data revealed that fatigue rates decreased and initial mean and median power frequencies increased consistently over time, indicating that the general test procedures were capable of monitoring post-surgical rehabilitation of lower limb function.

Studies to date indicate that a reasonably standard method (rms or integrated value of voltage associated with the myoelectric signal) that has been used to measure endurance is not as reliable as measurement of changes in mean or median power frequency. Little difference exists between mean power frequency shifts and median power frequency shifts. We remain optimistic that continued progress by investigators throughout the world may bring greater objectivity to analysis of muscle function in a clinical setting ■

VA RR&D CENTER HINES

EFFECTS OF FOOT ABNORMALITIES ON WEIGHT-FLOW AND PRESSURE DISTRIBUTION

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Structural and functional foot abnormalities are considered to play a significant role in the development of focal points of pressure and trauma. There is clinical evidence that points of pressure and trauma are areas most likely to undergo pathologic changes in the neurotrophic foot. This quite commonly leads to ulceration, infection, gangrene, and amputation. The treatment modalities for such pathologic changes include the use of foot orthoses, modification of shoes, and surgery. The objective of these treatments is to restore a more "normal" pattern of weight-flow and pressure distribution on the plantar surface of the foot within the environment of the shoe during gait.

The purpose of this study is to develop a measurement system to quantify weight-flow through the foot and the pressure distribution on the foot within the shoe environment. The feasibility of using this device in the clinic as a diagnostic and treatment evaluation tool will then be investigated.

A measurement system capable of quantifying this pressure distribution in real time is being developed, utilizing an insole instrumented with a flexible array of thin-film piezoelectric pressure transducers. Data from a control group of normal subjects and patients from the Hines VA Hospital will constitute the device evaluation study ■

LOWER LIMB PROSTHETICS
GAIT ANALYSIS

NIH MUSCULOSKELETAL

DEVELOPMENT OF CLINICALLY APPLICABLE MODEL OF GAIT

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The aim of this research is to improve current gait analysis techniques through the use of quantitative engineering and mathematical techniques. Specifically, it will be determined: (i) which clinical treatments would be expected to yield the greatest improvement in a pathological gait; (ii) what the predominant response of a patient is to treatment; and (iii) whether the subject's response to treatment is the same as that intended clinically when the treatment was prescribed. Each of the aims of this project will be evaluated in terms of the mechanical response to a model of the gait of the subject under consideration.

The treatment of pathological gait has been greatly aided by the development of the modern computer-based gait laboratory. However, gait laboratory measurements of isolated mechanical parameters yield an incomplete description of gait. Such a description is highly subjective. Employing a model for gait would lend a greater objectivity to such clinical analyses and greatly improve the potential of clinical treatment, which is the long-term objective of this research ■

NIHR REC

OBJECTIVE INTERPRETATION OF GAIT ANALYSIS DATA

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In the past year a random sample of 125 patients who were diagnosed as having cerebral palsy and had gait studies in our lab has been evaluated. The measurements associated with leg motions in three dimensions were used to form a time series, represented by a 13-term Fourier series for each frame, using the least squares method. For each patient the set of coefficients obtained for a given angle was used to describe the corresponding angular motion. Various statistical and clustering methodologies were then applied to the clinical gait kinematic data to determine if patient groupings of cerebral palsy could be established which would reflect a given patient's diagnosis and subdiagnosis. In the Kth nearest-neighbor clustering procedure, four subpopulations were identified from the modes of a uniformly consistent estimate of the underlying measurement-space density, and proved the most promising.

Analysis-of-various techniques were used to identify the key elements in the locomotor disorder that established the given dysfunction. A recursive partitioning classification scheme was utilized to examine how a given patient's gait pattern changed over time (with or without treatment). Graphical profiles and F-ratios were used to identify those individual measurements which were most useful in distinguishing the membership of the various observed clusters.

It was found that the four resulting clusters can be identified with different severeness levels of abnormal gait. Walking velocity, and patterns of hip and ankle movements, were seen to be markedly different for each cluster rather than for age or subdiagnosis (hemiplegia, diplegia, etc.). Traits associated with patients in two clusters were identified with severe gait pathologies, while the remaining three clusters exhibited characteristics more closely approximating normal gait. For the hip and ankle movements, it was seen that the absolute relative magnitudes of the Fourier coefficients for Cluster 3 tended to be small, indicating less angular motion in the hip and ankle than the other clusters.

No systematic pattern across clusters could be detected for knee coefficients.

Most of the patients in the two poorest-walking groups were diagnosed as having quadriplegia, while none of the patients in the best-walking group had that diagnosis. On the other hand, a patient diagnosed as having diplegia can be in any one of the five identified clusters; hence, the present diagnosis system is not suitable for indicating the functional status of a cerebral palsy patient.

Subsequent to cluster analysis which is useful for groupings-identification, it was important to develop a classification scheme so that new patients can be assigned to one of the identified clusters. Such a classification scheme was felt to provide a useful typology for classifying cerebral palsy patients. A recursive partitioning decision rule was used to construct a classification scheme based on the group-

ings obtained by the clustering method. Using this classification rule, it was demonstrated that the effects of corrective measures such as surgery or assistive devices on the gait patterns of individual patients can be examined. The results, in general, suggest that the effect of an operation or assistive device may well be more dependent on the classification scheme developed than upon the subjective evaluation of gait as determined by clinicians ■

NIHR REC

MECHANICAL ENERGY OF ABNORMAL GAIT (ANALYSIS)

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Normal walking minimizes energy expenditure. Since muscle forces are needed to change the mechanical energy levels of the body during walking, the amount of mechanical work during walking at a given speed would seem to indicate the minimum metabolic energy needed. Knowing this relationship, we would then be able to determine the relationship between lower limb joint abnormalities and oxygen consumption. No previous study was found to have evaluated this relationship.

A study was undertaken to determine the relationship between each of three mechanical work (energy) parameters and the metabolic energy cost of normal gait. These parameters were: (i) mechanical work done on the center of mass; (ii) total-body segmental mechanical work; and (iii) the sum of the average absolute joint moments present in the lower limbs.

Six normal adults (3 male and 3 female) between the ages of 29 and 36 were used as subjects. Each walked at 5 different speeds: very slow, slower than normal, normal, faster than normal and very fast (.87 m/sec to 2.28 m/sec). Five minutes were spent at each walking speed. The expired gases were analyzed continuously and the energy consumption rate (E) in joules per kilogram body mass per second was determined for the last minute of each walk.

Oxygen consumption/kg-sec was found to closely fit a quadratic equation and was highly correlated with velocity (v2r = .93). This relationship agrees well with that found by other investigators. The three mechanical parameters per kg and per second also closely fit quadratic equations and were highly correlated with velocity V2 (.91 for center of mass, .81 for segmental work per sec, and .92 for joint moment). They were also highly correlated with oxygen consumption/kg-sec (.89 for center of mass, .79 for segmental work, and .89 for joint member/kg-sec).

However, the correlation between energy consumption per meter and each of these mechanical parameters per meter is not high (only .28 for center of mass, .18 for total body segmental work and .17 for joint moment).

These results need to be confirmed in patients with spasticity to determine if similar types of relationships exist between energy consumption and these mechanical parameters. Since high levels of co-contraction of antagonistic muscles exist in these patients, relationships may differ somewhat from those found for normal gait ■

VA RR&D CENTER HINES

EVALUATION OF AN ULTRASONIC DEVICE FOR GAIT ANALYSIS

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The objective of this study is to evaluate the effectiveness of a device developed at this VA center to provide objective data for gait analysis of neurologically and orthopedically involved patients. This information is clinically useful to define altered gait patterns due to abnormal muscle activity and the patient's progression in rehabilitation. The device was initially developed to monitor the walking patterns of blind pedestrians. It consists of two ultrasonic transmitters and receivers which provide a continuous measure of inter-ankle distance (IAD). Temporal gait phase relationships can be determined from the resultant graph of IAD versus time.

A portable electromyography amplifier has been developed and is used in conjunction with the ultrasonic limb-position monitor to record muscle activity in the involved limb during ambulation. To date, 40 normal volunteers and approximately 20 patients with hemiplegia have been studied.

The data providing both temporal gait phase relationships and dynamic muscle activity compare quite favorably with the accepted norms. This information has proved useful in directing treatment and evaluating effectiveness of treatment. Plans are now near completion to commercialize the entire system. In the pre-production model, patient encumbrance will be diminished, while protability and clinical applicability will be enhanced ■

NIHR REC

QUANTIFICATION OF MOBILITY PERFORMANCE FOR FUNCTIONAL ASSESSMENT, DIAGNOSIS, AND THERAPY OF NEUROMUSCULAR, SKELETAL, AND SYNOVIAL JOINT DYSFUNCTIONS

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This project is addressing quantitative measures of the state of the musculoskeletal system in question, in order to derive patient-specific predictive models which will permit simulation of the consequences of skeletal alteration such as osteotomy or total joint replacement and/or muscular alteration such as tendon shortening or lengthening or muscle substitution.

Realization of the surgical simulation system requires precise kinematic data acquisition, accurate estimation of dynamic joint torques and forces which requires patient-specific mass and inertial properties, musculoskeletal models of the relevant human anatomy and means for making them patient-specific, and, finally, computer graphics which present the relevant anatomy to the physician, in familiar form, and animation programs which provide for simulation of locomotion changes consequent to simulated interventions.

The kinematic data acquisition system of requisite accuracy, rapidity, and automaticity has been achieved in the M.I.T. "TRACK" software coupled to the Selspot optoelectronic camera system. In the M.I.T. Mobility Facility, TRACK is being used in normal and pathological gait studies for upper and lower limb prosthesis research, and in sports biomechanics investigations. Currently the TRACK program is being adapted to the Selspot II cameras, which have the potential of reducing the current translational accuracy of 1 mm to a quarter of that value and similarly improving the current 40-milliradian rotational accuracy. The Selspot II camera system also provides greater flexibility in trade off between number of active LEDs and frame rate, providing for acquisition frequencies as high as 10 kHz.

A recurrent and unresolved question in gait analysis is whether externally mounted markers are true indications of the actual limb segment, e.g., of bone kinematics. (Or to put it another way, what is the effect of skin and soft-tissue movement on the motion of such markers?) To explore that question, data has been acquired by the TRACK system from 3 LED configurations around the human knee under identical conditions of passive and active movement including gait.

Understanding normal and pathological locomotion patterns demands detailed knowledge of the time course and force activity levels in the individual muscles whose coordinated activity produces human movement. To address this need, an anatomically correct, detailed musculoskeletal model of the human lower limb has undergone successive improvement and evaluation in our Laboratory over the past several years.

For the latter study, a two-degree-of-freedom ankle manipulandum was designed and implemented. Under computer-control, electrohydraulic servo systems generated torque and position profiles with active tracking by the human subject as EMGs were measured using both skin and needle electrodes.

Just as the limb segment, mass, and inertial properties must be made patient-specific, the parameters of the musculoskeletal model must be adapted to the individual patient's anatomy. The CAT-scan digital graphics data, used for the inertial property analysis, is a potential source for specializing anatomical details such as muscle length and cross sections, origins and insertions, bone geometries, etc.

Calculations of joint forces and moments cannot reflect muscular forces arising due to co-contraction of synergistic muscles about the same joint, since the kinematic data which drives the dynamic calculation relfects only the net muscular torque about the joint from the synergistic muscles. To explore the role of co-contraction in normal and pathological movement, and to verify kinematic-based dynamic calculations of joint force during non-co-contraction movement, data from an instrumented femoral-head prosthesis will be employed. The pressure-instrumented endoprosthesis was developed primarily for synovial joint research and osteoarthritis. However, the integration of the pressure measurements from the 14 integral transducers in the pseudo-femoral head produces the load vector across the human hip. The comparison of this direct experimental measurement with the dynamic-force calculation derived from the kinematic data is therefore possible, and will serve to validate TRACK/NEWTON analyses and establish the level of co-contraction in various movement tasks.

Both the instrumented prosthesis and extensive excitation, calibration, real-time display, and recording apparatus are ready.

Future clinical use of the surgical simulation system mandates computer graphic displays of anatomy, and computer-animated simulation of patient locomotion following simulated surgery, which appear "realistic" to the physician. Preliminary work on animation has started, but considerably augmented computer capability and more sophisticated color graphic displays will be necessary to present static and dynamic information in a fashion compatible with the physician's prior experience ■

NIHR REC

QUANTIFICATION OF RESULTS OF RECONSTRUCTIVE SURGERY IN RHEUMATOID ARTHRITIS

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Introduction — Reconstructive surgery is performed to relieve pain and reduce the consequences of disability. Because recovery of normal function often cannot be attained, the patient's postoperative functional level must be assessed. Traditionally, functional assessment has been made descriptively and subjectively. For this reason, comparison of data from different centers has been of limited value. An in-house calculation of the correlation of descriptive ratings and direct gait measurements for 149 arthritis hip patients proved modest ($r = .62$ $p<.001$).

Evaluation of metatarsal head resection has been limited to operative descriptions. Measured function has focused on more able patients with lesser surgery such as bunionectomies.

Methodology — Four pre-operative rheumatoid patients (seven limbs) and five healthy individuals (nine limbs) were tested. Stride and foot support measurements were obtained with insole footswitches inserted into the patient's shoes. The insoles contain compression-closing sensors located in the area of the heel, first and fifth metatarsal heads, and great toe.

Center-of-pressure data were acquired by means of a Kistler force plate (placed in the center of the walkway) and Apple II + computer system (Fig. 1). Four vertical, two progressional and two mediolateral

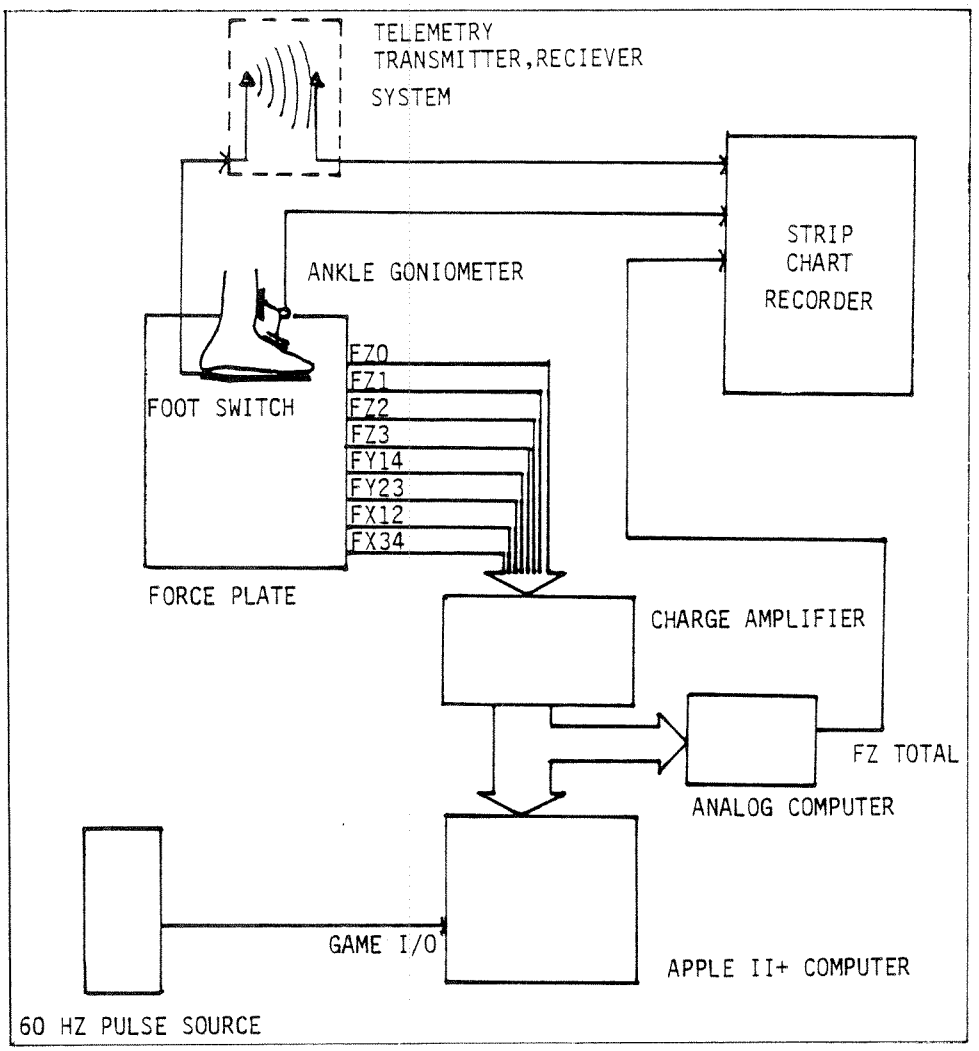

FIGURE 1.
Data acquisition block diagram for determination of center of pressure.

force component signals from the force plate were sampled by the computer at a rate of 60 Hz. Analog-to-digital conversion was accomplished by this system with a nominal accuracy of .098 pounds/bit. Data were stored on floppy disk.

Results—Three variables revealed that significant differences ($p<.01$) existed between the arthritic and the healthy groups. Single-limb support was initiated at 11.8 percent of the gait cycle in the healthy group compared to 21.7 percent for rheumatoid subjects. The rheumatoid group allowed the center of pressure under the foot to progress only half the distance to the metatarsal heads during single limb support. In contrast, progression in the healthy group was 131 percent of the functional weight-bearing area, well beyond the metatarsal heads. Finally, the maximum loading under the foot (expressed as a percentage of body weight) was 17 percent less for the rheumatoid group than the healthy group. Velocity and stride length averaged about 50 percent less than comparable data for normals, while single limb support times averaged 70 percent of normal ■

LOWER LIMB PROSTHETICS MISCELLANEOUS

NIH MUSCULOSKELETAL

HUMAN RESPONSE AND LOWER EXTREMITY INJURY

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Human injury is a complex process whereby external forces are transmitted to the human musculoskeletal system, the system responds in the manner of displacements and rotations, stresses are induced in the tissues, and under some conditions the tissues are disrupted. When the forces are not constant, prediction of the likelihood of injury and the severity of the forces is difficult. This project presents a research program investigating the mechanics of lower-extremity injury, specifically injuries to the knee, tibia, and ankle that typically occur in snow skiing.

Snow skiiing is studied because the lower-extremity injury rate is high, because the forces transmitted to the foot can be measured, because response to the lower extremity can be measured, and because safety devices can reduce the high rate of injuries. Specialized laboratory and field test equipment have been developed to measure and analyze the forces between the boot and the ski, the rotations occurring at the ankle, knee, and pelvis, and the integrated EMG from muscle groups during skiing — and especially during falling when severe loading occurs and the likelihood of injury increases.

The field measurements identify the injury environment, and the laboratory experiments clarify how the lower extremity responds to dynamic loading. This is the "identification" problem for the lower extremity. The true severity of the typical skiing environment, and the contributions of the musculature in influencing the likelihood of injury will be clarified.

The common belief that the forces of skiing are small compared to typical tibia fracture strength and knee ligament strength will be tested. That belief is widespread, extending to standards organizations, the industry, and the public. If this is an error it is one which has major impact on the design of safety devices, on the evaluation and acceptance of safety devices, and on the training and instruction given the public. Efforts are directed to development of meaningful standards of safety ■

UPPER LIMB GENERAL

NIHR REC

QUANTIFICATION OF THE FUNCTIONAL CAPABILITIES OF UPPER EXTREMITY AMPUTEES

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The goal of this project is to develop a technique for quantification and measurement of the upper-limb functional capability of able and disabled persons. The technique being developed uses dynamic optimization theory to produce a single meaningful number derived from accessible measurements (such as myoelectric activity, speed, range of motion, etc.) and to provide an essential link between measured performance and inferred functional capability.

The next phase of this project is the experimental verification of the accuracy of that extended mathematical description of the maintenance of posture. To this end, state-of-the-art instrumentation for the real-time digital processing of myoelectric activity has been developed.

The processing technique is based on a mathematical model of surface myoelectric activity, from which the optimal (maximum likelihood) estimator of muscle force was derived. This optimal processor has been implemented, using digital microprocessor technology, and yields an order-of-magnitude improvement over conventional processing techniques. Experimental results indicate that muscle force can be estimated in 250 ms. with an RMS error about the mean of as little as 2 percent. A major advantage of digital microprocessor implementation is that the tedious but necessary calibration process is performed automatically ■

LIBERTY MUTUAL, NIHR, SWEDEN

THE MYOELECTRIC SIGNAL: DIFFERENCES DUE TO HANDEDNESS AND GENDER

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Previous work in our laboratory suggests that the initial median frequency of the myoelectric signal may be influenced by the handedness of an individual when comparing contralateral limbs. This observation resulted from tests on the first dorsal interosseous muscle of the hand in 15 right-handed subjects (10 male, 5 female) and 5 left-handed subjects (2 male, 3 female). Initial evaluation also indicated that female subjects appeared to have a higher initial median-frequency value than their male counterparts.

Additional experiments were conducted recently to effectively evaluate these results. The first dorsal interosseous muscle was tested in an additional 17 left-handed subjects (8 male, 9 female). Each subject was asked to isometrically abduct the index finger at various force levels and for different time durations. The force output and the signal were then recorded and subsequently analyzed using the Muscle Fatigue Monitor described previously.

Results from this experiment support our earlier findings that in left-handed subjects, no relationship was found between the initial median frequencies of the corresponding contralateral limb muscles. In right-handed subjects tested previously, however, the value of the initial median frequency did appear to be related to hand dominance. In this group of right-handers, the value of initial median frequency of the non-dominant hand was either equal to, or higher than, that of the corresponding muscle of the dominant hand at every level of contraction tested.

The relationship of hand dominance to initial median frequency may reflect changes in muscle fiber composition that results from the preferred use of the dominant hand over time. More direct measurements of muscle fiber types are necessary to verify these conclusions. The implication, however, for researchers and clinicians is clear: it may not always be appropriate to use the contralateral extremity as a reference when evaluating the affected limb.

Our recent findings, with regard to the relationship between gender and initial median frequency, contradict our earlier findings. No consistent differences in initial median frequency values appeared

when comparing male to female subjects. Further analysis, by pooling larger numbers of subjects tested, will be implemented to clarify this apparent contradiction in the data ■

MAXILLOFACIAL PROSTHETICS

VAMC WILMINGTON

MAXILLOFACIAL PROSTHETICS: TECHNIQUES AND CLINICAL APPLICATIONS

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Introduction — During the report period (Jan. 1, 1983–June 30, 1983) development and improvement of the human excised donor (HED) tissue culture technique was continued with the goal of providing a human-relevant affirmation of production lot quality control without dependence on long-term animal model testing. The HED test system, currently under review by the American Society for Testing and Materials (A.S.T.M.) Subcommittee on Medical and Surgical Devices, is at the stage of options in the use of specially and variably processed human serum targeted for specific cell metabolism and growth.

Attention is also being given to the use of PDM Siloxane in other areas of anatomical reconstruction which could potentially benefit from the high tear strength and elasticity of this material.

Product Development — A proposed guideline for the acceptance of PDM Siloxane for maxillofacial materials has been drafted and submitted to the American Dental Association and the American Academy of Maxillofacial Prosthetics.

The guidelines include four definitive requirements in conformity with the provisions of the Medical Devices Act on safe and effective medical and surgical materials and devices. The requirements, for the product and device acceptance, include appropriate standards in the areas of (i) generic chemical description, (ii) physical and mechanical properties, (iii) usefulness of product and (iv) evidence of safety.

Fabrication of prosthetic gloves — Because of its high tear resistance, up to threefold of that of skin tissue, along with flexibility, up to 800 percent elongation before tearing, and biocompatibility with human tissue, chemically defined PDM siloxane thus has the essential product attribute to replace polyvinylchloride (PVC) covering gloves for artificial hands.

Considering also its chemical resistance and resistance to light (which PVC cannot withstand beyond several months) its various features make the PDM siloxane a desirable substitute. As a consequence, consideration is being given to devising, (i) a fabrication system by the pressure molding technique in hardened stone and (ii) a new, modified fluid viscosity composition of PDM siloxane that would be adequately adapted to the latex dipping technique.

Pigmentation (internal shade stocks) — Cosmetic matching of prosthetic devices to duplicate the coloration of adjacent skin areas has not been accorded any official or authoritative reference standards. It is practised as an individual art, more often than not employing undefined colors, vehicle (thinner) diluents, and undefined (chemically) manufacturer's colorants, often derived from potentially toxic cadmium and lead pigments. In this project, a reference standard in terms of digital color difference indices is being included as an adjunct to the guidelines for acceptance described in previous section.

Toxicity-test procedure for biocompatibility — The present draft of the proposed ASTM Standard, using the HED tissue-culture testing system to affirm non-toxicity of PDM siloxane, provides several options employing processed human serum, in lieu of conventional animal, notably calf serum. The on-going effort involves developing a consequent series of specifications for standardized options in the use of processed human serum and its derived products.

The first option is the use of dialyzed human serum with the removal of toxicants at molecular exclusion by 3500 dalton membrane cut-off. However, the conventional usage of calf serum does not include its dialysis. The so dialyzed serum, along with the Holmes' A-3 chemically defined medium, is used to culture both established cell lines and primary cells for affirming the safe, non-toxic quality of production lots of PDM siloxane used for orofacial, reconstructive molded prostheses.

However, the current dialyzed human serum, even though appropriately specified and standardized in terms of dialysis, is obviously a human variable source, with undetermined cell growth and inhibitory factors. These molecular complexes include the lipids and lipoproteins that may be inhibitory or toxic in cell growth. On this account, two other options

are being developed to enhance the proposed ASTM standard with subsidiary human serum fraction standards.

The second option is the use of the Holmes' alpha-1-protein growth (AGF) factor, separates from the dialyzed human serum by glass bead chromatography. This second option has been consistently affirmed with an extensive series of human serum lots using established cell line, but has yet to be affirmed with human primary cells. The AGF is one of 7 to 8 protein factors separated by this chromatographic separation which have varying effects on the growth and morphology of test cells. In general, these factors appear as complexes with lipid structures which are suspect as cell-growth inhibitors and when used in culture give rise to variations in morphology of cultured cells. This of necessity imposes a need for delipidizing the dialyzed serum by gradient centrifugation in the presence of high-density medium.

The third option is the use of delipidized (using the same chromatographic separation) analogs of the second option. The delipidized growth factors are now under study for use with established cell lines and with primary cells.

In due course, the preference for one option or the other is expected to be determined by cell response most replicative of the mature, highly developed tissue cells.

Field (Clinical) Participation — PDM Siloxane has been provided to 56 VA and non-VA clinics having a participative interest in orofacial reconstruction. A technical service, consisting of color TV, videocassettes, publications, workshop sessions, and presentations, has been provided.

Production — The project has produced 680 one-pound units of internally pigmented and non-pigmented PDM siloxane, distributed to over 50 VA and non-VA clinics. Units are monitored by test moldings from which the determination of tensile properties and tear resistance are determined in accordance with the mandatory provisions of the FDA Good Manufacturing Practices ■