DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES, PHYSIOLOGY AND BIOMEDICAL ENGINEERING PROGRAM*

Americo Rivera, Ph. D., Program Administrator

Bone-Implant Interface Analysis

Regular Grant: 7 RO1 GM 29785
Cleveland Research Institute
Cleveland, OH 44115

A. Seth Greenwald, D. Phil. (Oxon), Principal Investigator

This project seeks to evaluate the use of microporous coated implant materials which allow bone tissue ingrowth into the pores to anchor the device, as an alternative to bone cement. Previous long-term animal studies have demonstrated sufficient fixation capability of the microporous system. Studies are to be performed to demonstrate the stabilizing ability of low and high modulus microporous systems, in weightbearing and non-weightbearing animal environments, over short-time periods (0,1,2,3 and 4 weeks). Early implant stabilization which allows early mobility would be of immense clinical importance. The group will also study in vitro bone cell cultures to elucidate the initial cellular responses to the microporous materials.

Structural and Mechanical Properties of the Spine

Regular Grant: 5 R01 GM 20201
Wayne State University
Detroit, MI 48202

Albert I. King, Ph. D., Principal Investigator

The aim of this research project is to extend the finite-element model of a vertebra to that of a vertebral segment. To this end, it is proposed to continue the measurements of end-plate and intradiscal pressure at various locations of the vertebral segment. It is also proposed to document the mechanical properties of vertebral cortical and spongy bone. These data are to be incorporated in the finite-element model of the vertebral segment and used to simulate those conditions which would fracture the vertebra or portions thereof.

Development of a Microporous Tracheal Prosthesis

Regular Grant: 2 R01 GM 24300
University of California Los Angeles Medical Center
Torrance, CA 90509

Ronald J. Nelson, M.D., Principal Investigator

The objective of this project is the development of a microporous tracheal prosthesis that will be permanently bioincorporated by the host and lined with epithelium. The prosthesis is fabricated from the negative replication of the naturally occurring microporous exoskeletons of coral and sea urchins in biomedical polymers. The project is divided into three interrelating phases which will be addressed simultaneously by the group: (i) the biology of ingrowth of tissue cells into a matrix will be studied by implanting porous test cylinders in experimental animals; (ii) the influence of primary variables (polymer and pore characteristics) and secondary variables (site of implantation, biodegradable porous phase filler, antibiotic dispersion in polymer, and "wrapping") on ingrowth of tissue will be evaluated quantitatively and qualitatively in dogs and rabbits; (iii) favorable combinations of variables will be tested in 3-cm prostheses implanted in the thoracic tracheae of dogs for 1 to 2 months. The healing processes will be followed by bronchoscopic and biopsy examinations.

Finally, those designs which show excellent healing in 1 to 2 months will undergo long-term evaluation in 8-cm lengths.

Biomedical Engineering Center for Polymeric Implants

Program Project Grant: 2 P01 GM 24487
University of Utah
Salt Lake City, UT 84112

Donald J. Lyman, Ph. D., Program Director

The objectives of this program project are the acquisition of a basic understanding of events occurring at the interface between polymers and living systems. To this end, the group develops and synthesizes new or modified polymers for specific implant applications. The core facility provides for in-depth basic and applied studies of the polymers in relation to their use as implant materials. Bulk and surface chemical and physical properties and morphology are studied, to determine how these are affected by fabrication variables. Polymer-protein and polymer-biological molecule surface interactions and polymer degradation in vivo and in vitro are to be studied. Small-diameter vascular prostheses and nerve prostheses are being prepared and studied. These prosthetic devices have been implanted and their outcomes have been correlated with the bulk and surface, physical and chemical properties of the polymers. Ureter, bladder, bile duct, and esophageal repair prosthetic devices have been studied.

The Traumatology of the Head and Spine

Regular Grant: 5 R01 GM 26608
University of Iowa
Iowa City, IA 52242

Y. King Liu, Ph. D., Principal Investigator

The objective of this project is the construction of a structural finite-element computer model of the head and neck of the rhesus monkey during direct head impact, based on the in vivo constituent and gross mechanical response data. The experimentally measured pressure and acceleration will serve to

*Leo H. von Euler, M.D., is the Acting Director. W. Sue Badman, Ph. D., is the Chief, Biomedical Engineering and Instrument Development Section. NIGMS is located at Bethesda, Maryland 20205.

validate this class of computer models for simulation purposes. The dynamic in vitro material properties and failure characteristics of the spine will be measured, with special emphasis on the cervical region. These studies will provide information for the validation of a human head and spine model to be used to investigate, through computer simulations, the prevention of head and spine injuries.

Porous Polyethylene—Tissue Tracheal Prosthesis

Regular Grant: 5 R01 GM 26963
University of Mississippi Medical Center
Jackson, MS 39216

Barry W. Sauer, D.V.M., Principal Investigator

The objective of this research is evaluation of three different types of composite tracheobronchial prostheses developed by the principal investigator. The prostheses will be used to reconstruct 5-cm-long circumferential defects in the cervical region of the canine trachea. The clinical performance of the prostheses will be determined by physical, radiographic and bronchoscopic examinations. These devices and bronchial sections will be removed after 6, 12 and 24 months and subjected to gross and microscopic examination. Postmortem examination of all animals will be performed. The results of all examinations will be correlated with the clinical studies, and comparisons of performance will be made among the three types of devices.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, NIH, MUSCULOSKELETAL DISEASES PROGRAM[a]

Stephen L. Gordon, Ph. D., Program Director

BONE HEALING

Study of Internal Fixation Devices for Fracture Healing

University Hospital of San Diego
La Jolla, California 92103

Wayne H. Akeson, M.D., Principal Investigator

The objective of this research is to determine whether significant advantages can be achieved in internal fixation plates of diaphyseal fractures through the use of internal fixation devices of improved design.

One hypothesis being tested is that internal fixation of plates of reduced axial stiffness are superior with respect to the late complication of stress-protection-induced decrease in bone density (osteopenia) usually observed with traditional management. Advantages exist with respect to biomechanical properties of canine radii and femora internally fixed with plates that have large reduction in bending and axial stiffness. These results are confirmed by quantitative histological and biochemical measurements.

Early versus late plate removal is a controversial question. The second objective of this project is to study the effects of plate stiffness on the ability of fracture repair to withstand physiological loads. The hypothesis being tested is that early plate removal will prevent stress bypass osteopenia and facilitate more normal bone remodeling.

Techniques used in this study include periodic X-rays to evaluate fracture healing in the plated canine femoral midshaft osteotomies. Nondestructive and destructive bioengineering tests, quantitative histological measurements using UV light microscopy to evaluate tetracycline labeling and microradiography and biochemical analysis of the organic and inorganic matrix of bone are being used to evaluate the influence of the different internal fixation devices employed.

Study of Bioelectrical Phenomena Controlling Bone Growth

Columbia University College of Physicians and Surgeons
New York, New York 10032

C. Andrew L. Bassett, M.D., Sc. D.

This project addresses several problems in which an expanded base of applied experiments serves to improve the scope of clinical usefulness of pulsing electromagnetic fields (PEMF's).

PEMF's are currently in use for ununited fractures and fusions. Time required by treatment and degree of disability can be reduced by increasing pulse effectiveness to speed mineralization of gap tissues and to augment the osteogenic phase of repair. In this study, effects of PEMF's on improving bone graft incorporation and fresh fracture healing are assessed. Return of mechanical stability in the nonunion, grafting, and fracture studies is monitored by a new, nondestructive, noninvasive sonic frequency testing method. These results are then correlated with mechanical testing and strain gage data to determine the ability of this new frequency analysis (via Fourier transformations) to predict the quality (strength) of bone repair.

PEMF effects in reducing stress-relief osteoporosis in plated dog radii also are being studied, along with their ability to affect longitudinal growth rates in epiphyses and apophyses. Furthermore, this phase of the project is focussing on the potential of induced pulsing currents to alter growth patterns in the immature spine and, thereby, to correct experimental scoliosis. Finally, one mechanism of PEMF action is being studied by following PEMF-induced changes in the calcium content of chondrocytes by isotype, transmission electron microscopy, and ion probe techniques.

[a]A program of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, Westwood Building, Room 407, Bethesda, Maryland 20205.