X. Wound and Fracture Healing

Stress Analysis of Internal Fracture Fixation of Long Bones

Gary S. Beaupré, Ph.D.; Dennis Carter, Ph.D.; Tracy Orr, M.E.; John Csongradi, M.D.
Rehabilitation Research and Development Center, Veterans Administration Medical Center, Palo Alto, CA 94304
Sponsor: VA Rehabilitation Research and Development Service

Purpose—The objectives of this study are to develop accurate, nonlinear, three-dimensional finite element models of long bones treated with compression plate fixation.

Progress—Using mathematical models, we are investigating the influence of plate fixation on the internal stresses in long bones subjected to all known in vivo loading modes. The variables we are studying include: plate geometry, plate/bone fixity, and screw tightness. The mathematical models are based upon the finite element technique. The models will be subjected to all physiological loading modes, i.e., axial, bending and torsion loads. Plate geometry is studied by designating either stainless steel or titanium in the finite element model. Coulomb friction is used to vary the amount of plate to bone and screw to plate fixity. Screw tightness will be varied from zero to the maximum value found in the literature from clinical studies. Idealized in vitro bone models have been made from magnesium and phenolic tubing. These will have fixation plates and strain gauges attached and be subjected to the same loads as for the mathematical models.

Results—Finite element models of idealized plated long bones have been created. The effects of screw tightness and plate material have been studied. The models have been analyzed using three different quarter-symmetric loading conditions and two half-symmetric loading conditions. Numerous publications resulting from the research have been presented, published, or are in the process of being published.

Future Plans—Two different mechanisms used to alter the transfer of load from bone to plate will be studied next. Mathematical models have already been developed. Results from these models will be compared with physical models using plates attached to osteotomized phenolic tubes using full-length screws and using shortened outer screws.

Publications Resulting from This Research


Rehabilitation R&D Progress Reports 1987

Testing of Design Parameters for a Prototype Piezoelectric Internal Fixation Plate

Orthopaedic Engineering and Research Center, Helen Hayes Hospital, W. Haverstraw, NY 10993 and Surgical Research Service, Veterans Administration Medical Center, Castle Point, NY 12511

Sponsor: VA Rehabilitation Research and Development Service; Walter Scott & Lyons Foundation; New York State Department of Health

Purpose—Stimulation of bone healing by microampere electric currents is now a recognized form of clinical treatment. For this purpose, various devices are available that aim to improve the healing of bone in problem cases, particularly for individuals with delayed nonunion. Typically, the stimulatory current is provided by a battery-powered device that delivers current to bone via electrodes or by an external electromagnetic device that induces currents in bone. Our purpose is to develop a novel approach to electrical stimulation of bone healing that employs microampere currents generated during physiological loading by a piezoelectric material that is incorporated as part of an internal fixation plate. Alternatively, current can also be generated by external application of ultrasound to the skin over the plate. Because piezoelectric materials produce an electrical charge under mechanical loading, the “piezoplate” will represent an implant that will not only stabilize bone but also will provide an internal source of electrical stimulation in response to physiological loading or low level ultrasound.

Progress—To date we have designed and tested several versions of the “piezoplate.” Initial tests showed that piezoelectric materials placed on the plate (so as to be in direct contact with bone) were not effective, probably because charge density over the surface was too low. Accordingly, we developed a device in which the piezoelectric material is sealed within the plate and all charge developed is collected and delivered to bone via electrodes. During the past year we have continued to concentrate on electronic and mechanical design considerations necessary to create a prototype that could be used for trials in large animals as a precursor to fabricating an initial model for clinical use. These results have been reported recently in detail (see below). In another series of tests, we showed that an implanted piezoelectric material can be activated by external, low-power ultrasound to generate currents as high as 1mA following rectification. This study suggests that external ultrasound may represent a practical source of power for implanted bone stimulation devices. In another ongoing series of tests, we are utilizing the well-recognized rabbit tibia model to test effects of ultrasonically generated current on intramedullary bone formation.

Preliminary Results—To date we have determined that (rectified) 20μA currents generated by ultrasonic activation of a piezoelectric ceramic have effects similar to battery generated currents but that non-rectified 2.4mHz currents at 20μA RMS have no effect.

Future Plans/Implications—Further studies in progress with the rabbit tibia model will determine the effects of non-rectified ultrasonically generated currents at higher levels as well as low frequency currents, as would be generated by physiological loading. Also, we are developing a delayed union model in the radius of large canines and plan to test effects of the piezoelectric plates on altering the natural history of healing of these defects.

Publications Resulting from This Research


External Ultrasound Can Generate Microampere Direct Currents In Vivo from Implanted Piezoelectric Materials. Cochran GVB, Kadaba MP, Palmieri VR, Accepted for publication, Journal Orthopedic Research.

Synthetic Bone Graft Materials in Segmental Defect Fractures

Kenneth D. Johnson, M.D.
Veterans Administration Medical Center, Dallas, TX 75216

Sponsor: VA Rehabilitation Research and Development Service

Purpose—The object of this study is to define the healing parameters of synthetic bone graft substitutes when used in a previously developed canine model of bilateral segmental defect fracture healing. These synthetic bone graft materials are compared to the previously defined ideal bone graft material, autogenous cancellous bone graft.

Progress—Prior work has determined that autogenous cancellous bone graft consistently results in 100 percent solid union. Ground autogenous and allograft cortical bone have been shown to be ineffective in uniting this segmental defect fracture. Several synthetic bone graft substitutes have been used, including calcium hydroxyapatite (HA), tricalcium phosphate (TCP), and a combination of bovine collagen with hydroxyapatite and TCP. These materials were used both with and without additional bone marrow aspirate. Surgery is performed on bilateral dog radii, creating a 2-centimeter defect at the junction of the middle and distal third of the radius. This defect is stabilized with an external fixator. Periosteum is totally excised from the defect, and cancellous bone graft obtained from the contralateral humeral head is placed in one defect while the synthetic bone substitute material is placed in the other defect. Half of the animals have bone marrow aspiration performed from the ipsilateral humeral head and placed into the segmental defect with the synthetic bone graft material, the other half do not.

After periods of 12 and 24 weeks, the dog is sacrificed, and the radius is studied for mechanical strength as well as histomorphometry. This model allows a controlled study in individual animals. The significance of this study is that bone graft substitutes are increasing in popularity in the United States and other countries. They serve a need to decrease the morbidity of obtaining autogenous cancellous bone graft used in the segmental defects. The efficacy of these synthetic materials has been shown in metaphyseal defects, which are less stressful and result in more consistent union than diaphyseal defects. There are limited reports demonstrating the efficacy of these synthetic materials in segmental diaphyseal defects without periosteum present.

Preliminary Results—Preliminary findings (clinical evaluation, X-ray, and biomechanical data) demonstrate that hydroxyapatite and TCP without bone marrow aspirate, have little effect in achieving union in segmental diaphyseal defects. Collagen with hydroxyapatite and TCP has an increased ability to achieve union. With the addition of bone marrow aspirate, all materials studied have an improved ability to achieve union. Collagen with HA and TCP plus bone marrow aspirate nearly approaches the effectiveness of autogenous cancellous bone in this model. All animals in this part of the project have been sacrificed. Current work progresses with completion of biomechanical and histomorphometric data on all explanted dog radii.

Future Plans/Implications—Future plans have begun with initiation of the third phase of this project. Several dogs have had prototype variable stiffness external fixators applied to segmental defects and are being evaluated for variables that may need to be improved prior to beginning surgery on multiple dogs.

The first phase of this project will be submitted to the Journal of Orthopaedic Research in early 1988. The second phase (synthetic materials) will be submitted to the Orthopaedic Research Society for presentation at the 1989 annual meeting.
Noninvasive Assessment of Fracture Healing

R.E. Jones; M.G. Strauss, Ph.D.; K.L. Lawrence, Ph.D.; R.W. Bucholz, M.D.
Veterans Administration Medical Center, Dallas, TX 75216
Sponsor: VA Rehabilitation Research and Development Service

Purpose—Previous work has shown that the impact resonant frequency of normal healing fractured human tibiae increase with healing time. Delayed unions show a resonant frequency versus time healing pattern significantly different than normal healing fractures. The current work discussed investigates the relationship between the resonant frequency and callus strength of 21 osteomized canine radii. A finite element model relating resonant frequency to leg and callus parameters is discussed.

Progress—Twenty-one healthy mongrel dogs in the weight range between 20 and 40 kg underwent unilateral left radius osteotomies. Spoon splints were used to immobilize the bone. Under general anesthetic, each dog was tested for their right and left radius resonant frequencies at weekly intervals. This was accomplished by holding a PCB-303A02 2gm accelerometer against the lateral part of the distal radius and impacting the lateral part of the proximal radius with PCB-208A03 impact hammer. Both signals were processed by an HP5420B Digital Signal Analyzer. From the displayed transfer function, the resonant frequencies were determined. At approximately weekly intervals, a dog was sacrificed and both radii were excised. CT scans of the radius were obtained before the radii were subjected to destructive torsional strength testing. A finite element model of the *in vitro* canine radius was constructed from 19 beam elements and one truss element: the boundary conditions were hinged-free where the truss element approximated a very weak spring at the “free” end. The effect of varying bone length, fracture site, callus geometry, and material properties were investigated.

Results—Left versus right normal radius resonant frequency prior to osteotomy had a correlation of \( r = 0.88 \). Modeling each of the dogs’s resonant frequency healing curves for those dogs tested more than four times after 20 days post-ostotomy, revealed three types of healing curves. Six dogs had statistically significant positive slopes, two had significant negative slopes and five had healing slopes judged not significant at the 0.05 level of significance. Of the two dogs with negative healing slopes, one of them was found to have a below-normal callus healing strength, the other demonstrated problems in maintaining fracture alignment early on. The pooled values for the normalized resonant frequencies for all dogs during 20 to 120 days post-injury showed a very significant increasing linear regression at the 0.0001 level of significance, indicating that the normalized resonant frequency increases with healing time. The normalized resonant frequency, \( N\text{Frequency} \), is defined as the ratio of the resonant frequencies of the fractured radius over the contralateral normal radius. Similarly for the normalized torsional breaking strength, \( N\text{Strength} \).

A linear model was fit to the normalized torsional breaking strength over healing time for the period between 20 and 120 days post-injury, DPI, and was found to be: \( N\text{Strength} = 0.017 \times \text{DPI} - 0.191 \), \( r = 0.86, p < 0.0001 \). Two models relating normalized torsional strength to normalized resonant frequency were developed which indicated that the resonant frequency does give an indication of callus strength.

By using the finite element model, parameters could be varied individually in order to evaluate their effect on the resonant frequencies. After experimental and theoretical validation of the model, the following results were found:

1) The location of the fracture affected the first two resonant frequencies differently. The lowest mode was most sensitive to midshaft fractures and the second mode was more sensitive to proximal and distal fractures.

2) When the modulus of elasticity was varied, both of the first two modes changed parabolically. The resonant frequencies were most sensitive to changes in low modulus. Sensitivity decreased significantly at higher values of Young’s modulus.

3) As the callus matures, it slowly calcifies, thus increasing its mass density. The model shows that the change in mass density is insufficient to affect either of the first two resonant frequencies sufficiently to deem it an important variable to follow.
4) Both of the first two modes showed extreme sensitivity to different bone lengths where the longer the bone, the lower the resonant frequency.

The last parameters studied were the combined moment of inertia and the cross sectional area of the callus. It was necessary to model both parameters simultaneously because one cannot separate one from the other in the maturing callus. The computerized axial tomographic images of the dog calluses were used to determine the cross sectional areas and moments of inertias at different callus ages. This information was then entered repetitively to the FEM in order to determine the resonant frequencies. It was found that both modes are sensitive to changing moment of inertia in that they both increase with an increase moment. The effect is greater on the second mode than on the first.

Enhancement of Wound Healing, Using Synthetic Skin, Electrical Stimulation and Hyperbaric Oxygen Therapy

Kao Su Kung, M.D.
Veterans Administration Medical Center, Lyons, NJ 07939

Sponsor: VA Rehabilitation Research and Development Service (Project #XA447-R)

Purpose—Loss of skin and other connective tissue as a result of either or mechanical pressure is a common problem. It has been estimated that 5 to 30 percent of the hospitalized population experiences loss of skin due to pressure. Several approaches have been developed to enhance healing—including treatment with hyperbaric oxygen, wound dressings, electrical currents, and artificial skin—in addition to surgery.

The purpose of this proposal is to develop a series of parallel studies directed at enhancing rates of dermal and epidermal healing. The short-term goal of this project will be to optimize the rate of dermal and epidermal healing using a collagen-based artificial skin developed at Robert Wood Johnson Medical School. The artificial skin will be studied in different physical forms in the presence and absence of electrical stimulation. Our long-term goal is to be able to replace the dermal and epidermal layers of skin with tissue culture grown equivalents.

Specifically this proposal involves studying the enhancement of healing in an animal model and in ulcer patients using a collagen-based material in the presence and absence of a low electrical current. These studies are an extension of preliminary studies conducted in the Biomaterials Center at Robert Wood Johnson Medical School. We will also study the rate of wound healing in an animal model and in ulcer patients with collagen-based beads having diameters of about 200-1000 μm.

In addition to preliminary animal studies on a porous sheet-like collagen-based material, Drs. Silver and Berg have developed methodology to produce porous beads of this material. This bead-like form needs to be tested in animal models; however, it has potential value in the coverage of wounds that do not have smooth contours. Since most ulcers have "hills and valleys," this form of the collagen-based material would be easier to apply.

The project will be broken into four parts: 1) continued clinical testing of collagen-based material used as a covering for decubitus ulcers; 2) animal and clinical testing of an electrically stimulated collagen-based material; 3) animal and clinical testing of porous collagen-based beads; and, 4) control clinical testing of hyperbaric oxygen treatment.

Results of preliminary clinical studies suggest that the rate of healing of decubitus ulcers treated with a type I collagen-based material is markedly increased even in the absence of fibronectin, hyaluronic acid, and electrical stimulation (Doillon et al., 1987). We propose to further evaluate use of a collagen-based material in the presence and absence of low D.C. electrical current to stimulate healing of full thickness wounds in animals and decubitus ulcers in humans. Our long-term goal is to grow host skin cells on collagen-based material in cell culture for use as skin grafts on humans.
Circulatory and Mechanical Response of Skin to Compression Loading

Frederick A. Matsen, III, M.D.; Theodore K. Greenlee, M.D.; Ernest M. Burgess, M.D.; Craig R. Wyss, Ph.D.; Richard M. Harrington, M.S.
University of Washington; Veterans Administration Medical Center, Seattle, WA 98108 and Prosthetics Research Study, Seattle, WA 98195

Sponsor: VA Rehabilitation Research and Development Service

Purpose—Amputations in the treatment of peripheral vascular disease (PVD) and diabetes present a major challenge in the patient population served by the Veterans Administration. The restoration of gait in these amputees requires loading areas of skin that do not normally sustain weightbearing loads and that may already be at risk due to circulatory compromise. The purpose of this study is to investigate how compression loading of skin produces local ischemia, and how different mechanical properties of the skin and underlying tissues affect this relationship.

The study encompasses four projects: 1) determining these relationships in normal skin subjected to static compression loads; 2) determining these relationships in normal skin subjected to cyclic compression loads; 3) determining these relationships in the skin of patients with PVD and diabetes, as well as in the skin of residual limbs after amputation; and, 4) developing a method for testing patients prior to prosthetic fitting, to determine areas where their skin response to applied compression loads may leave them especially vulnerable to breakdown due to local ischemia.

Progress—The experimental method utilizes transcutaneous partial pressure of oxygen (TcPO₂) sensors to monitor the status of the subcutaneous circulation. Previous investigations in our laboratory have shown that TcPO₂ is a useful predictor of amputation wound healing in patients with peripheral vascular disease. A 22-gauge catheter is placed in the subcutaneous tissue below the TcPO₂ sensor to measure subcutaneous pressure by the infusion technique. Loads are applied directly to the TcPO₂ sensor by an Instron 1122 Universal Testing System and skin displacement is measured by a linear variable differential transformer (LVDT). The average applied pressure is calculated from the applied compression load and the contact area of the TcPO₂ sensor at the skin surface.

We have investigated skin over the anterior crest of the tibia and over the tibialis anterior muscle 12 centimeters distal to the patella approximating the usual below-knee amputation level in ten normal human volunteers (ages 25-43 years). A range of pressures from 0 to 125 mmHg was applied and the TcPO₂ allowed to stabilize for three minutes. The load was then removed and the TcPO₂ allowed to return to baseline value. Ankle systolic blood pressures were measured with a Doppler flow sensor and ankle pneumatic cuff. The TcPO₂ values were plotted against both the applied pressure and the subcutaneous pressure. Regression analysis was used to calculate the pressure and displacement at which TcPO₂ reached zero. Zero TcPO₂ indicates the point at which the skin circulation has been reduced to the point that the metabolic needs of the skin are just being met and no excess oxygen is available to diffuse through the skin. Any additional pressure beyond this level will begin to produce local ischemia.

Preliminary Results—The following results have been achieved: 1) The skin over bone showed a significantly different load-deformation relationship than the skin over muscle. Initial stiffness for applied pressures less than 20 mmHg over bone was 2.5 times stiffer than skin over muscle. For applied pressures greater than 40 mmHg, skin over bone was 7 times stiffer than skin over muscle. 2) The resting TcPO₂ values for the skin over muscle and the skin over bone were similar for the ten subjects (57 ± 14 mmHg as compared to 61 ± 7 mmHg). 3) The average ankle blood pressures for the ten subjects was 137 ± 10 mmHg. 4) The applied pressure at which the TcPO₂ reached zero was significantly greater for skin over muscle than for skin over bone (74 ± 16 mmHg as compared to 42 ± 8 mmHg, p < .001). 5) The subcutaneous pressure at which TcPO₂ reached zero was not significantly different for skin over muscle and skin over bone (31 ± 13 mmHg as compared to 28 ± 10 mmHg). 6) The displacement at which TcPO₂ reached zero
was significantly more in skin over muscle than in skin over bone (5.6 ± 1.0 mm as compared to 1.1 ± 0.3 mm, p < .001).

**Future Plans/Implications**—These results demonstrate that statically applied pressures in normal subjects compromise local circulation as reflected by the TcPO$_2$ values. Skin over muscle tolerates higher values of applied pressure than skin over bone before TcPO$_2$ falls to zero. Similarly, skin over muscle tolerates a higher amount of indentation than skin over bone. Similar experiments will be conducted for cyclically applied loads in normal subjects and then the skin of patients with peripheral vascular disease and/or diabetes will be studied.

**Morphologic and Ultrasonic Analysis of Normal and Ischemic Human Wounds**

John Olerud, M.D.; George Odland, M.D.; Ernest Burgess, M.D.; Roger Pecoraro, M.D.; Greg Raugi, M.D.; Lloyd Fisher, M.D.; Allen Gown, M.D.
Veterans Administration Medical Center, Seattle, WA 98108
Sponsor: VA Rehabilitation Research and Development Service

**Purpose**—For the past four years we have engaged in the investigation of deficiencies in the wound healing process in individuals with peripheral vascular disease (PVD) and diabetes mellitus (DM). We hope to identify abnormalities in the repair process which may suggest clinical interventions.

**Progress**—We have utilized standard incised wounds created with a Simplate II bleeding time device to produce uniform wounds on normal elderly subjects as well as patients with PVD or DM who are awaiting amputation. A variety of time points following wounding have been evaluated. In addition to morphological and immunochemical evaluation of the repair process, we are currently investigating the use of high frequency ultrasound as a method for noninvasive evaluation of the repair process. A scanning laser acoustic microscope (SLAM) is being used for the latter studies.

**Results**—We have now studied 40 individuals with PVD or DM and ten normal elderly subjects. We have developed a time table for morphological and immunochemical events of repair on the lower extremities of elderly normal subjects and are using those standards for comparative studies in individuals with PVD and DM. We currently have a major interest in assessing the role of nonenzymatic glycosylation in the abnormal repair process for individuals with DM. We have succeeded in immuno-staining of tissue sections with a monoclonal antibody specific for the glucitol-lysine linkage which is the site of nonenzymatic glycosylation of proteins. We are now evaluating the location of nonenzymatic glycosylation in diabetic skin, nerves, and blood vessels as well as wound tissue.

**Future Plans/Implications**—We hope to be able to use our monoclonal marker for nonenzymatic glycosylation to identify specific cells and perhaps areas in the wound matrix which may be most affected by nonenzymatic glycosylation. This is particularly relevant since it has been shown that nonenzymatic glycosylation specifically affects certain structural and regulatory proteins. Elevated glucose levels affect the function of cells such as neutrophils, monocytes, and fibroblasts. We are also hopeful that we can identify morphologic abnormalities in the repair process by comparing normal elderly subjects with individuals with PVD and DM. Experiments are also underway to assess the utility of high frequency ultrasound in assessing wound maturation. It may be possible to assess abnormalities in the material properties of wounds such as tensile strength and collagen content as well as assessing images which may identify early evidence of wound failure.

**Publications Resulting from This Research**


High-Frequency Ultrasonic Imaging and Backscatter Attenuation Techniques for Determination of Thermal Injury to the Skin. Forster FK, Olerud JE, Pomajevich GR, Holmes AW,
Altered Collagen and Wound Metabolism in Non-Healing Diabetic Ulcers

Roger E. Pecoraro, M.D.; John Olerud, M.D.; Mary Ann Riederer-Henderson, Ph.D.; Ernest Burgess, M.D.; Frederick A. Matsen, M.D.; Craig Wyss, Ph.D.
Veterans Administration Medical Center, Seattle, WA 98108

Sponsor: VA Rehabilitation Research and Development Service

Purpose—This project is designed to test the hypothesis that potentially correctable metabolic abnormalities may interact with ischemia, neuropathy, and infection to obstruct healing of diabetic ulcers. Subjects include diabetic and nondiabetic patients admitted to the Seattle VA Medical Center Amputation Service who may require lower extremity amputation as a result of diabetes and/or vascular disease. We will test whether recent poor glycemic control, abnormal ascorbic acid metabolism, altered zinc availability to injured tissue, and increased nonenzymatic glycosylation of dermal collagen are associated with, and potentially responsible for, failure of wound healing which leads to amputation in diabetic individuals.

Progress—Fasting plasma glucose and glycosylated hemoglobin measurements estimated glycemic control in diabetic patients. Ascorbic acid levels were measured by high performance liquid chromatography in samples of plasma from all patients and in skin and dermal tissue from selected patients. Zinc levels were measured in samples of plasma, skin, and wound tissue by atomic absorption spectrophotometry. Collagen fractions were extracted from skin and wound tissue specimens from amputated limbs for subsequent measurement of the extent of glycosylation of collagen. Nutritional status was evaluated by a laboratory panel of nutritional indicators. Vascular status of diabetic and nondiabetic amputation subjects has been documented by standardized measurements of limb transcutaneous oxygen tension (TcPO₂) and segmental Doppler blood pressures.

We have studied 82 diabetic individuals who have received limb amputations. Sixty nondiabetic amputees, all with peripheral vascular disease, have been enrolled. In addition, many of the biochemical and vascular measurements have been standardized in ten healthy non-smoking elderly males without diabetes or vascular impairment. Vascular and plasma metabolic measurements have been made in 220 control diabetic individuals admitted to the same hospital but who have not had amputations or lower extremity ulcers.

Preliminary Results—Both diabetic and nondiabetic amputation patients have shown significant deficiencies in plasma zinc and ascorbic acid levels. Analyses of ascorbic acid and zinc in tissue extracts suggests depleted levels occur in nonhealing ulcer tissue, with depletion more marked with poor diabetic control.

Future Plans/Implications—Further studies are in progress to determine if tissue concentrations of ascorbate and zinc in these patients are suboptimal for adequate wound healing. Experimental iatrogenic microwounds have been inflicted on the limbs of a volunteer subgroup of patients seven days prior to amputation; histologic evaluation of those tissues will provide a semi-quantitative independent index of cutaneous wound healing to correlate versus the metabolic parameters.

The objective of these cumulative investigations is an attempt to identify metabolic abnormalities which are potentially correctable and which may contribute to limb loss and wound failure in diabetic individuals.
Edinburgh Unilateral External Fracture Fixation Device

E.R.C. Draper B.Sc., (Hons) M.B.E.S.
Bioengineering Centre, Princess Margaret Rose Orthopaedic Hospital, Edinburgh EH10 7ED, Scotland

Sponsor: Lothian Health Board

Purpose—A new external fracture fixation device is being developed in conjunction with the Department of Orthopaedic Surgery of the University of Edinburgh. It is designed to be simple, highly adaptable, and easy to apply. It is also possible to vary the axial stiffness from being rigid, to being completely free in the axial direction, while any other movement is prevented. Incorporated into the design is the ability to monitor the mechanical properties of the fracture site and so allow the healing to be monitored, which should give a clearer indication as to when to remove the fixator or to give an early indication of late or non-union.

Progress—The fixator is manufactured in stainless steel: the bar is 420 mm long and 22 mm in diameter, and uses 4.8 mm diameter pins. The pin clamps have an adjustment of 360 degrees about all three axes, so that they can be mounted anywhere along the length of the fixator bar or pin and have an adjustment of 10 mm in a direction perpendicular to the bar and pin.

Preliminary Results—The initial testing of this device shows that it is mechanically robust enough to withstand all normal loads which it will be expected to withstand throughout the fracture management.

Future Plans/Implications—Once the device has been fully tested, it will be evaluated clinically. It is hoped that the fracture monitoring will be useful as soon as it is started.

Enhancement of Ulcerated Tissue Healing by Electrical Stimulation

E. Kardelj University, University Rehabilitation Institute, Jožef Stefan Institute, 61000 Ljubljana, Yugoslavia

Sponsor: National Institute on Disability and Rehabilitation Research; Slovene Research Community, Ljubljana, Yugoslavia

Purpose—The association of endogenous currents with healing processes has led to considerable efforts to enhance soft tissue healing by exogenous currents. However, obtaining the quantitative data and statistical analysis of the results is complicated, due to the variety of pathophysiological and physical factors involved in wound healing processes. In the Rehabilitation R&D Progress Reports - 1986 we presented the decrease in size after application of electrical stimulation of all treated wounds. Progress had been made toward the evaluation of the effects of electrical stimulation compared to those obtained in the control group.

Progress—The stimulation technique is the same as described in our previous progress report. The volume of the wound was measured once weekly by measuring its surface and depth and wound surface was approximated by an ellipse. Additional data was obtained by photographing the wound surface. The data of the surface was stored by means of a digitizing tablet after projection of the slides. CAD program was used for entering the shape and calculation of the skin area. Twelve spinal cord injury patients with fifteen decubitus ulcers were included in the study. Seven of them, with nine ulcers, were treated by electrical stimulation. Five other patients with six ulcers were included in the control group. For four weeks the wounds were treated by conventional methods and measured once weekly. After this period, electrical stimulation was added to these patients as well. The patients had developed these wounds over several weeks (from 2 days to 86 weeks).

Results—The healing process, once triggered by electrical stimulation, has an exponential behavior. During the study, it became clear that consistent
evaluation of the results required not only careful distinction between the patient population, but also between the location of the observed wound. The estimated values of the time constant are 4.7 ± 0.9 weeks for sacral wounds and 2.4 ± 0.4 for trochanter wounds. Time-histories of wounds treated by conventional treatment are rather constant, however, and at present a lack of data has not allowed an estimation of the time constant with statistical significance.

Acceleration of Fracture Healing by Electrical Fields

Carl T. Brighton
University of Pennsylvania, Medical Education Building, Philadelphia, PA 19104

Sponsor: National Institutes of Health

Purpose—The object of the proposed research is to continue to investigate the stimulation of fracture healing with a capacitively coupled electrical field and to determine the mechanisms of action of electrically induced osteogenesis. The proposed research is designed 1) to determine the most efficient duty cycle in applying a capacitively coupled electrical signal to stimulate fracture healing in an osteotomized rabbit fibula model, and 2) to determine the mechanism(s) for electrically induced osteogenesis by evaluating a) the microenvironmental changes (pO2, pH) occurring in the vicinity of a cathode, b) possible responding cells (bone cell, capillary endothelial cell, pericyte, and polymorphic cells), and c) intracellular calcium, cyclic AMP, and prostaglandin (PGE2).

Methods to be used include:
1) histologic, roentgenographic, and mechanical testing of osteotomized rabbit fibula;
2) mathematic modeling using finite element analysis to calculate electric fields in rabbit fibula callus;
3) microscopic morphologic digitabilization (Zeiss MOP-3) of newly formed bone in the vicinity of a cathode in the rabbit tibial medullary canal;
4) needle electrode determination of pO2 and pH of medullary canal in the vicinity of an active cathode;
5) Coulter cell counting, S35 and C14proline uptake, and collagen typing of isolated rat calvarial bone cells, calf brain capillary endothelial cells and pericytes, and rabbit tibia post-traumatic polymorph cells exposed to various capacitively coupled electrical fields;
6) histologic examination and collagen content and typing of bone cells, endothelial cells, pericytes, and polymorphs grown in Algire diffusion chambers placed within the rabbit tibia medullary canal and exposed to direct current;
7) electron microscopic evaluation of the role of the polymorph cell as an osteoblast precursor cell and of the role of the endothelial cell and pericyte as possible origins of the polymorphic cell and correlating these findings with histologic staining for factor VIII, antimyosin muscle actin antibody, and for alkaline phosphatase; cAMP, prostaglandin, and intracellular ionized calcium changes induced by an electric field;
8) Fura 2 fluorescence and quantitative digitized fluorescent microscopy to determine the relationship of chondrocyte intracellular calcium to matrix mineralization in the fracture callus.

A Study on Disintegration of Carpal Bones in Leprosy

S.B. Sane, M.S.; V.N. Kulkarni, B.Sc.(PT)PGDR; R.C. Sharangpani, M.S. Dip. Sports Medicine; J.M. Mehta, M.B.B.S.
Dr. Bandorawalla Leprosy Hospital, Kondhawa, Pune 411022, India

Sponsor: Poona District Leprosy Committee

Purpose—Visibly deformed and disorganized wrists were observed in some of the advanced cases of tarsal disintegration (TD) with bad foot ulcers and amputation. Three patients admitted that they were
using their disintegrated limbs to get up from the ground or to walk for many years. These patients had gross structural abnormality of the carpus. Carpal disintegration (CD) results from compressive and shearing forces transmitted across the wrist of a neuropathic hand of leprosy super-imposed on the carpal architecture already weakened by the ligamentous attenuation following infection, osteoporosis, fracture, etc. It may manifest itself as a ‘wrist-sprain’ in early stages or as a grossly disorganized swollen wrist-joint with total loss of normal configuration and bony architecture in late stages. The possible sequence of events in the occurrence and progression of CD can be described in two stages. 1) A patient may neglect minor fractures, sustained due to lack of pain. Hence, a haematoma forms and the joint space increases due to this effusion, resulting in a haemarthrosis. 2) There is calcification in the clot, articular surfaces become irregular and sclerotic and the joint capsule becomes lax followed by subluxation or dislocation.

As in any neuroarthropathy, early detection and arrest of the process is an essential requirement in treating the ailment. The purpose of this study was to devise a radiological method to detect the early carpal involvement. A method of measurement of carpal height ratio (CHR) has been suggested.

**Progress**—In the initial study, we found three cases of advanced CD in patients whose wrist-joints were subjected to the trauma of weightbearing. With this in mind we examined the dominant wrists of high risk patients both clinically and radiologically.

The following high risk groups of patients were studied: 1) patients compelled to bear weight on the hand while getting up from the ground; and, 2) patients with a history of repeated sub-clinical trauma to the wrist-joint (such as those engaging in sports or heavy manual labor). X-rays (posterior-anterior P/A view) of the dominant wrists of these patients were taken and CHR was studied. (CHR is expressed as L₂/L₁ where L₂ is the Carpal Height and L₁ is length of 3rd M.C.; normal value being 0.54 ± 0.03. The Carpal Height or L₂ is the distance from the base of 3rd M.C. to the distal articular surface of radius, measured on P/A X-rays along the projected longitudinal axis of 3rd M.C. It is constant in the normal wrist in all positions of ulnar and radial deviation, when the deviation occurs in fixed plane).

**Results**—Twelve high risk patients were studied. Upon examination and calculation of CHR in these patients, 2 had early CD, 5 were borderline for CD and 5 were normal. The patients were kept under observation. Those with borderline CHR were advised a change of job, rest with plaster, etc. In some cases, CHR over a period of time was helpful in diagnosing slow progressive destruction.

**Graded Weightbearing in Tarsal Disintegration in Leprosy**

P.C. Sharangpani, M.S.; Dip. Sports Medicine; V.N. Kulkarni, B.Sc.(PT)PGDR; S.B. Sane, M.S.; J.M. Mehta, M.B.B.S.
Dr. Bandorawalla Leprosy Hospital, Kondhawa, Pune 411022, India

**Sponsor:** Poona District Leprosy Committee

**Purpose**—As in osteoporosis, the bony changes such as cystic cavities, are part of the disease in leprosy. For patients undergoing immobilization for ailments like tarsal disintegration tibialis, posterior transfer surgery or fractures of the lower limb and other soft tissue injuries add to the problem of osteoporosis inherent in the disease.

The tarsal disintegration (TD) process results in the destruction of the architecture of the bones along with the loss of bony matrix. With rest the healing processes predominate and the architecture is partially restored, but not strictly according to the weight transmission lines. Immobilization itself precludes bony matrix formation. Early and improper weightbearing leads to reversal of the process of healing or an outright fracture of the disintegrated tarsals in the neuropathic foot. In such cases proper stimulus for laying of bony matrix in weight transmission lines can come only through graded weightbearing (GWB). It is with this aim that for the first time this method of weightbearing has been tested in the neuropathic foot of leprosy.

**Progress**—Twenty-five patients with TD and tibialis
posterior transfer surgery were studied. In cases with severe involvement of tarsals, GWB was instituted at the end of the prolonged immobilization. In early cases of TD the GWB was started after the subsidence of clinical signs such as swelling, etc. GWB was commenced three weeks after the removal of plaster for tibialis posterior transfer surgery patients.

Taking advantage of the preserved proprioceptive and pressure sensations, the patients were asked to record the weight of the diseased foot. They practiced until they could reproduce the same weight without looking at the weighing scale. Patients then walked on crutches exerting no more than the recorded weight on that limb. Gradually the weight on the diseased limb was increased (every two to three weeks depending on clinical and radiological parameters). GWB was ended when patients could bear their full body weight on the diseased limb.

Results—All the cases had good results. They were followed for a period of six months to one year and were found to have stable lesions. They maintained good trabecular patterns (confirmed by X-ray) as compared to the time of completion of GWB. The area of the foot print (taken on a Harris Mat at every stage, i.e., percentage of weight of GWB) was calculated to show the relation of the Graded Weight to the area of the foot and pressure (weight per unit area). GWB increased with weight. The pressure in gm./Sqcm also showed a gradual increase with every stage of GWB.

Thus, it seemed that the body adapted to the submaximal stress of GWB and rehabilitation proceeded smoothly. GWB acted as a stimulus to the spatial structuring of the bony trabeculae in the lines of stress. The therapists and patients are confident about the rehabilitation with GWP over partial weight-bearing as the arbitrariness of the latter is eliminated.