**Clinical Investigation Program, RCS MED-300 (R1)**

**Author(s):**
KENT M. PLOWMAN, M.D., PhD
Lieutenant Colonel, Medical Corps
Chief, Department of Clinical Investigation

**Performing Organization Name and Address:**
Department of Clinical Investigation
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905-5650

**Performing Organization Name and Address (if different from Controlling Office):**
Commander
US Army Health Care Studies and Clinical Investigation Activity
Fort Sam Houston, Texas 78234-6060

**Security Class. (of this report):**
UNCLASSIFIED

**Distribution Statement (of this Report):**
APPROVED FOR PUBLIC RELEASE: DISTRIBUTION UNLIMITED

**Abstract:**
Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1986, and other known publications and presentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and progress is presented.
FOREWORD

The illustration on this year's cover comes from Dr. Hans Gersdorff's sixteenth century treatise on orthopaedic surgery. It was chosen to commemorate the initial, full accreditation of Eisenhower's Orthopaedic Surgery training program. This full accreditation was achieved only on appeal of a prior adverse action by the Accreditation Council for Graduate Medical Education. At the heart of the stated reasons for the initial rejection of the program was a lack of basic science and scholarly activity. Our appeal was aimed at refuting these claims. We actually had a very active research and teaching program jointly involving Clinical Investigation and Orthopaedic Surgery. The Board of Appeals was suitably impressed with the volume and quality of this research program to reverse the previous action.

Only rarely does one have the opportunity to experience the personal and corporate sense of vindication that comes with a major reversal of this nature. It is a tribute to those staff and residents who had worked so diligently at pursuing scholarly goals despite heavy clinical demands. Inasmuch as this challenge lies at the heart of the Clinical Investigation mission, it was especially gratifying to know that our efforts were not in vain. My personal view is that this type of challenge will become more common and that research will be the weapon of choice. Pro-active efforts must be started immediately.

Orthopaedic surgery has traditionally been viewed both from within and without as a very practical division of surgery which is oriented towards mechanical reconstruction. Biological and psychological issues were of only secondary importance generally. However, the past decade of advances in materials science, in microsurgical technique, and in the demand for maintenance of athletic prowess have all worked to produce a new, sophisticated orthopaedist. He is savy in biological interaction with the materials of a total joint replacement, in limb reconstruction using distant flaps, and in performance oriented management of complex connective tissue injuries by means of sophisticated diagnostic methods ranging from fiberoptic arthroscopy to MRI imaging.

Our congratulations extend to COL Roberto H. Barja, MC and to his faculty in the Orthopaedic Surgery training program for their persistence in keeping research at the forefront of this exciting and burgeoning program.

The largest problem facing the Clinical Investigation program at DDEAMC is the continuing postponement of funds for a new laboratory animal facility. This lack of animal facilities is a major handicap to developing the kind of program consistent with the excellence of a medical center which has stepped up to take seriously its major new responsibilities as the military medical center for the Southeastern United States containing a heavy military concentration. The present leadership of DDEAMC has superbly represented the case for this building as well as the other facilities needed to permit DDEAMC to perform its major responsibility to the Army and to the Department of Defense. Other issues at higher levels of the Army have frustrated these efforts.
A special note of thanks is extended to BG Alcide M. LaNoue, MC as he leaves us to assume important new duties as Commandant of the Academy of Health Sciences. We are saddened at the loss of his leadership which has put DDEAMC on the map and instilled a new pride in her despite the chronic shortage of resources. We also know that his unique talents are needed elsewhere to help solve the larger problems facing Army medicine. Our best wishes go with him along with our gratitude for his support of teaching and research.

KENT M. PLOWMAN
LTC, MC
Chief, Department of Clinical Investigation

Accession For
NTIS GRA&I  
DTIC T&I  
Unclassified  

Justification

Per CALL EC

The title on the DD Form 1473 is correct
Per Lt. Col. Kent M. Plowman, DDEAMC
UNIT SUMMARY - FISCAL YEAR 1986

A. Objective.

The Department of Clinical Investigation is responsible to the Deputy Commander for Clinical Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

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‡PCS Sep 86
*PCS Jun 86
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D. Funding.

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*Includes Clinical Investigation personnel plus other paper presentations from Dwight David Eisenhower Army Medical Center staff and residents.

E. Progress.

### Protocol Disposition FY 86

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One study not included in the totals above has been withdrawn.
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<td>Control of Gonadotropin Secretion in the Male Rat. (O)</td>
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<td>Gastrointestinal Hormones in Non-Ionic Surface Active Agent Induced Delay of Gastric Emptying. (O) (PR) (P)</td>
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<td>The Experimental Fat Embolism Syndrome: An Electron Microscopic Study of Lung in Three Models. (O)</td>
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<td>Correlations Between Amount of Information Feedback and Success of Biofeedback Treatments. (O)</td>
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<td>Correlations Between Extent of Patient Involvement and Effectiveness of Published Behavioral Treatments of Hypertension. (C)</td>
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<td>Ultrastructural Alterations to Human Skin Stored at 40°C in Nutrient Medium and Saline. (T)</td>
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<td>Effect of Sodium Salicylate on Nonenzymatic Glucosylation of Human Serum Albumin. (C) (PR)</td>
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<td>Computer Assisted Infrared Imaging in the Diagnosis and Management of Military Basic Training Injuries. (O)</td>
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**DEPARTMENT OF DENTISTRY**

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<td>Mandibular Lingual Vertical Releasing Incisions. (C)</td>
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<td>The Role of Excessive Sympathetic Stimulation on Penicillin Blood Levels After P.O. Administration. (C)</td>
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<td>Masseter Muscle Silent Period in Patients with Internal Derangements of the Temporomandibular Joint Before and After TMJ Surgery. (C)</td>
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<td>Long Term Effectiveness of Sodium Fluoride on Tooth Hypersensitivity with and without Iontophoresis. (O)</td>
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<td>The Use of Ultrasound for Diagnosis in Periodontal Bone Morphology. (C)</td>
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<td>The Effect of Tobacco Smoke on the Attachment of Human Gingival Fibroblasts to Root Surfaces in vitro. (C)</td>
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<td>Gutta-percha Root Canal Obturation Followed by Apical Root Resection Alone vs Cold Burnishing Gutta-percha After Apical Root Resection: A comparison of the Seal. (C)</td>
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<td>Total Intravenous Anesthesia. (O)</td>
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<td>Determination of Nicotine Levels in the Gingival Crevicular Fluid of Cigarette Smokers with Periodontal Disease.</td>
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<td>SEM Evaluation of the Root Surface Following Apical Root Resection Techniques.</td>
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<td>The Interrelationship of Exercise and Fitness During Pregnancy and the Postpartum Period.</td>
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<td>Cornea Donation: Enhancing &quot;Military Recruitment.&quot;</td>
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<td>Use of Isotretinoin in Prevention of Basal Cell Carcinoma. (O)</td>
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<td>Protracted Peripheral Infusion of 5 Fluorouracil With Intermittennt Cis-Platinum: A Phase II Trial to Test for Synergic Anti-Neoplastic Activity in Colon Metastatic Colon Cancer. (T)</td>
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<td>Protracted Venous Infusion of 5 Fluorouracil With Intermittennt Cis-Platinum: A Phase II Trial to Test for Synergistic Anti-Neoplastic Activity in Metastatic Non-Small Cell Lung Cancer. (T)</td>
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<td>Effect of Ketoconazole Therapy on the Susceptibility of Enteric Fungi to Amphotericin B and Ketoconazole. (O)</td>
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<td>Extravascular Penetration of Antimicrobial Agents in New Zealand White Rabbits. (O)</td>
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<td>Comparison of Rehabilitation Benefits of Supervised Hospital Based Exercise and Unsupervised At-Home Exercise After Myocardial Infarction. (T)</td>
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<td>Comparison of Test for the Diagnosis of Imported Fire Ant (IFA) Allergy. (O)</td>
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<td>Comparison of Single Dose Cefoxitin Prophylaxis for Cesarean Section. (C)</td>
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<td>Training Laboratory for Obstetrics and Gynecologic Residents Utilizing Rabbits. (T)</td>
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<td>A Multicenter Study Comparing Intravenously Administered Apalacillin and Piperacillin in the Treatment of Hospitalized Patients with Infections Caused by Susceptible Aerobic and Anaerobic Bacteria. (T)</td>
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<td>A Multicenter Double-Blind Comparison of Intravenously Administered Apalacillin and Cefoxitin for the Prevention of Postoperative Infection in Patients Undergoing Vaginal or Abdominal Hysterectomy. (T)</td>
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<td>Metastatic Adenocarcinoma of Unknown Primary Site. (O)</td>
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<td>The Effect of Normal Plasma Dilution Upon the Prothrombin Time and Activated Partial Thromboplastin Time of Heparinized Blood.</td>
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<td>Androgen Responsiveness to LH/RH Infusion in Adolescent Females with Polycystic Ovarian Syndrome. (O)</td>
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<td>AML Porocot® Acetabular Cup Investigation. (T)</td>
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<td>Ultrasound Evaluation of the Rotator Cuff. (O)</td>
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<td>Recovery Time Following the Use of Low Dose Fentanyl vs Low Dose Sufentanil in a Balanced Technique of General Anesthesia. (C)</td>
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<td>Omental Splenic Autotransplantation: Optimal Transplant Size for Maximal Protective Effect Against Pneumococcal Bacteremia. (O)</td>
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**USA MEDDAC, FORT BENNING, GEORGIA**

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Distribution List

Code:
- O - Ongoing
- C - Completed
- W - Withdrawn
- T - Terminated
- P - Published
- PR - Presented


Barja RH, Sherman R: What to expect when you lose a limb. GPO#008-020-01083-9, 1986.


ACCEPTED


Jennings B, Sherman R: Anxiety, locus of control, and satisfaction in patients undergoing ambulatory surgery. Accepted - Mil Med.


Redmond MD, DiBenedetto M: Hypoglossal nerve conduction. Accepted - Muscle Nerve.

SUBMITTED


Sherman R, Ernst J, Markowski J: Differences between trunk heat patterns shown by complete and incomplete spinal cord injured veterans. Submitted to Paraplegia.


DENTAL ACTIVITY


ACCEPTED


Palou M, McQuade M, Rossmann JA: The use of ultrasound for the determination of periodontal bone morphology. Accepted by J Periodontology.

SUBMITTED


DEPARTMENT OF FAMILY PRACTICE


ACCEPTED

Madlon-Kay DJ: Family physician recognition and treatment of severe hypercholesterolemia. Accepted by J Fam Prac.

Light DE: Cornea donation: Increasing tissue supplies. Accepted by Southern Medical Journal. (C)

DEPARTMENT OF MEDICINE

Office of the Chief


Dermatology Service


Posner DI, Guill MA: The coexistence of leprosy and lupus erythematosus. CUTIS. (Submitted)


Lesher JL Jr, Guill MA: Eccrine hidrocystoma: Report of an unusual case with a brief review of the literature. CUTIS. (Submitted)

Internal Medicine

Lamb A: Pulmonary microembolism presenting as an acute infectious process. Accepted by Heart Lung J Critical Care.


5
Pulmonary Service


Johnson WM: Asbestos-related diseases: Diagnosis, treatment, and prevention. Hospital Medicine. (Accepted)

DEPARTMENT OF NURSING


DEPARTMENT OF PATHOLOGY


ACCEPTED


Weir GT, Monihan JM: Candida parapsilopsis diagnosed by peripheral blood smear. Accepted - Arch Pathol Lab Med 1986.

SUBMITTED


DEPARTMENT OF PEDIATRICS


SUBMITTED

Southgate WM, Benton FR: Early onset chlamydia conjunctivitis and pneumonitis in a newborn. Submitted to Pediatric Infec Dis.


DEPARTMENT OF PSYCHIATRY AND NEUROLOGY


SUBMITTED


Jensen PS, Wymes MR, Shaw R, et al: Residents at risk versus risky environments-Staff agreement in perceptions of training program milieu. Submitted to Arch Gen Psychiatry.


DEPARTMENT OF RADIOLOGY


DEPARTMENT OF SURGERY

Anesthesia and Operative Services

Audiology


General Surgery Service


Orthopedic Surgery Service


Barja RH: Amputations. Update and review for the NATO Emergency War Surgery, Chapter XX.

Barja RH, Sherman RA: Thermographic visualization of chronic pain: Analysis of 125 sequential subjects incorporating evaluations by a blind panel. Accepted by Arch phys Med Rehab.

Otolaryngology


MARTIN ARMY COMMUNITY HOSPITAL
FORT BENNING, GEORGIA


Fogarty JP, Billingsley J, Ginnett C: Combat lifesaver training for the non-medical soldier. Accepted by Mil Med.

Saultz JW, Wright JB: Are patients attracted to family physicians by the AAFP's competitive edge marketing materials? Accepted by Fam Prac Res J.

Epperly TD: Needle aspiration in management of cellulitis. Accepted by J Fam Prac.


Aiken AC: Evaluation of exhaust hoods in military dining facilities at Fort Benning, GA. Submitted to J Environmental Health.

Code: (C) - Results of clinical study
PRESENTATIONS FY 86

1986 Recipient of the Annual Resident Research Award: CPT William M. Steely, MC, Department of Surgery, for his paper entitled "Comparison of Omental Splenic Autotransplant to Partial Splenectomy Protective Effect Against Septic Death." (C)

DEPARTMENT OF CLINICAL INVESTIGATION


Sherman RA: Phantom pain. Presented at University of Charleston, SC, 7 Nov 1985. (C)

Sherman RA: Low back pain. Presented to Biofeedback Regional Assn, Southern States, 8 Nov 1985. (C)


DEPARTMENT OF DENTISTRY


DEPARTMENT OF FAMILY PRACTICE


DEPARTMENT OF MEDICINE

Office of the Chief


Allergy Service


Internal Medicine


Nuclear Medicine

DEPARTMENT OF PATHOLOGY


DEPARTMENT OF PSYCHIATRY AND NEUROLOGY


SOCIAL WORK SERVICE


DEPARTMENT OF SURGERY

Anesthesia and Operative Service


Audiology


General Surgery Service


Steely WM, Satava RM, Harris RW, Quispe G: Comparison of omental splenic autotransplant to partial splenectomy: Protective effect against septic death. Am College Surgeons Committee on Trauma Meeting, Fort Lauderdale, FL, Mar 1986.


Brigham RA: Aortoenteric fistula, University Hospital, Univ Florida, Jacksonville, FL, Dec 1985.


Brigham RA: Thoracic outlet syndrome, Medical College of Georgia, Augusta, GA, Apr 1986.


Orthopedic Surgery Service


Otolaryngology Service


MARTIN ARMY COMMUNITY HOSPITAL
FORT BENNING, GEORGIA


Harvey K: Insight of occupational therapy in the comunity. The Good Day Show, Channel 9 TV, Columbus, GA, 28 Apr 1986.


Title: Control of Gonadotropin Secretion in the Male Rat.

Start Date: May 79

Principal Investigator(s)
James C. McPherson III, PhD

Facility:
Eisenhower Army Medical Center

Dept/Svc:
Clinical Investigation

Associate Investigators:

Key Words:
Gonadotropins
Steroids

Study Objective: To determine the role of estrogens, progestins and androgens either alone or in combination in the regulation of gonadotropin secretion.

Technical Approach: Immature male and female rats and neonatally androgenized female rats are castrated and given replacement steroid therapy beginning immediately and continuing for five days. These animal models are utilized to study the effects of various steroids both individually and in combination on the control of gonadotropin secretion, including the pituitary sensitivity to LHRH, peptide and neurotransmitter roles. Secondary sex organs are removed and weighed as a measure of biological activity of the steroids. Serum and tissue samples are analyzed for a variety of endocrine components including gonadotropins, peptides, steroids and neurotransmitters.

Progress: No progress has been accomplished on this protocol during FY 86 due to priority of other resident research protocols.
Title: Gastrointestinal Hormones in Non-Ionic Surface Active Agent Induced Delay of Gastric Emptying.

Study Objective: To determine the effect of non-ionic surface active agents on gastric emptying, voluntary food consumption, body weight and blood chemistries.

Technical Approach: Groups of fasted rats were given non-ionic surface active agents followed 30 minutes later by a commercial rat tube feeding diet. Animals were sacrificed at various times after feeding and gastric emptying compared to control groups. In another series of experiments, rats were injected daily for four days with non-ionic surface active agents. Voluntary food consumption before and during treatment was measured. Twenty-four hours following the last injection, the animals were sacrificed and blood drawn for blood chemistries. In an additional series of experiments the effect of non-ionic surface active agents on gastric secretion is being assessed. Cimetidine, a known gastric secretion inhibitor and metoclopramide, a known agent that stimulates motility of the upper gastrointestinal tract without stimulating gastric secretion, have been utilized to access the actions of these non-ionic surface active agents on delayed gastric emptying. Serum gastrin levels were assayed by radioimmunoassay in fed and non-fed rats given saline or Triton WR-1339 (a non-ionic surface active agent which delays gastric emptying).

Progress: The effect of intravenously administered non-ionic surface-active agents on voluntary food consumption in the rat has received very little investigation although some toxicity studies (LD50) have been reported. Administration of Tween 20 and Tween 80 had no effect but Triton WR-1339 caused a significant decrease in voluntary food consumption which was dose related. Triton injections result in an intense hyperlipemia by blocking the removal of the circulating blood lipids and by increasing their rate of synthesis. This increased rate of lipogenesis would be expected to increase food intake because rats are known to eat calories if fed an adequate diet. The blood $pO_2$ levels in the Triton-treated rats were found to be lowered in a dose related manner. Hypoxia has previously been reported to decrease food intake and result in a loss of body weight. It appears that hypoxia is one possible mechanism for the decrease in voluntary food consumption in Triton-treated rats. Other mechanisms which control appetite or food intake cannot be ruled out however.
Study Objective: Experimental fat embolism syndrome is usually induced by one of five techniques: 1) fracture of the femur of an animal, 2) injection of extracted or homogenized adipose tissue from a same species donor, 3) injections of olive oil or purified triolein, 4) injection of oleic acid, or 5) injection of mineral oil (all injections given intravenously). In this study the similarity and differences, if any, in these last three techniques (olive oil, oleic acid, and mineral oil) will be investigated.

Technical Approach: Fat embolism is a major (although frequently undiagnosed unless severe) complication in patients with fractures of the long bones and/or severe trauma. The etiological mechanism of this syndrome is still unsettled. The two mechanisms most widely accepted are: 1) fat from the bone marrow of fractured bones or traumatized adipose tissue enter into small broken veins and travel to the lung where blockage of the capillaries and arterioles occur, and 2) after trauma, the circulating lipoproteins in blood coalesce to form globules of fat large enough to block the capillaries of the lung. In addition, once the fat has blocked a capillary or arteriole, the pathogenic events which follow are unclear. The major effect may be a simple blockage, but some investigators believe the most harmful effects result from the release of free fatty acids from the "trapped" fat globules in the lung. This study will attempt to establish the differences which could be important in the clinical syndrome by examining a mineral oil model (pure blockage with no possible release of free fatty acid from the globules), oleic acid (effect of free fatty acid only), and olive oil (fat capable of hydrolysis to yield free fatty acids). This study may add to our basic understanding of the events in the pathogenesis of the clinical fat embolism syndrome and suggest the basis of new methods of treatment.

Progress: Full resumption of this study was deferred while new techniques were being perfected by the EM technicians. These techniques are now in place and the study will resume in FY 87.
Title: Correlations Between Amount of Information Feedback and Success of Biofeedback Treatments.

Start Date: Feb 81

Principal Investigator(s)
Richard A. Sherman, PhD, CPT, MSC

Facility:
Eisenhower Army Medical Center

Dept/Svc:
Clinical Investigation
Psychology Service

Associate Investigators:
Anthony Ficara, DDS, COL, DC
Roberto Barja, MD, COL, MC
Benjamin Hanson, DDS, MAJ, DC

Key Words:
Accumulative MEDCASE
Cost: OMA Cost: Review Results Continue
Periodic Mar 86

Study Objective: To determine whether increasing the amount of information about muscle tension given to patients with muscular control problems will shorten treatment times and increase the overall effectiveness of the treatment.

Technical Approach: For patients with bruxism, half receive muscle tension feedback from the masseter muscle, weekly in the laboratory, and wear a masseter tension monitor nightly at home. The other half does the same with the addition of receiving feedback from the night monitor when they begin tensing their jaws. For patients with subluxation of the patella, muscle tension in the vastus medialis and lateralis will be recorded. Half will receive a combined feedback proportional to their relative tension and half will receive two independent signals juxtaposed in various ways indicating both relative and absolute muscle tension.

Number of subjects enrolled to date: 182
Number of subjects enrolled for reporting period: 15

Progress: This study needs 16 more patients with jaw pain in order to complete the blind portion of the project. The study was delayed due to inadequate technical support. It will be completed when these subjects are obtained. The portion of the study dealing with subluxation of the patella will not be completed due to unavailability of technical support.
**Detail Summary Sheet**

<table>
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<th>Prot No.: 81-18</th>
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<td><strong>Title:</strong> Environmental Stress and Electromyographic Correlates of Chronic Posterior Trunk Muscle Pain.</td>
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<td><strong>Start Date:</strong> Feb 81</td>
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<td><strong>Principal Investigator(s):</strong> Richard A. Sherman, PhD, CPT, MSC</td>
<td><strong>Facility:</strong> Eisenhower Army Medical Center</td>
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<tr>
<td><strong>Dept/Svc:</strong> Clinical Investigation Psychology, Orthopedics</td>
<td><strong>Associate Investigators:</strong> Roberto Barja, MD, COL, MC</td>
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<td><strong>Key Words:</strong> Low back pain Upper back pain Muscle tension</td>
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<td><strong>Accumulative MEDCASE Cost:</strong> $19,000</td>
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<td><strong>Periodic Mar 86 Review Results Continue</strong></td>
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**Study Objective:** To record those muscles in the posterior trunk of patients with lower and upper back, shoulder, or neck pain related to abnormal muscle tension in order to ascertain relationships between stress, pain, and tension as well as evaluate the effectiveness of muscular relaxation training as a treatment for these problems. The relative effectiveness of these treatments for pain in the above areas with and without underlying muscle tension problems will be evaluated.

**Technical Approach:** Recordings of muscle tension; objective psychosomatic measures of stress, anxiety, functional locus and other factors; discomfort logs; and other measures will be made before, during and after muscle relaxation treatments of individuals with the problems described above. These progressive measures will be compared with identical measures made of individuals with: 1) musculoskeletal related pain in other areas; 2) high anxiety but no musculoskeletal pain; and 3) posterior trunk pain but no muscle tension problem. A second phase of the study will consist of continuous muscle tension recordings made throughout the day using wearable EMG recorders. These measures will be related to a continuously tape recorded log of environmental loci and stresses.

**Number of subjects enrolled to date:** 286  
**Number of subjects enrolled for reporting period:** 9

**Progress:** This study was only carried out at a minimal level this year due to inadequate technical support. On 1 October, the VA will begin funding the chronic low back pain evaluation portions of the study. The funding includes technical support for carrying out the physiological evaluations and evaluating the data. We have applied to the Army's Medical R&D Command for support of the environmental stress portions of the protocol. Both of these projects will have heavy participation by orthopedic residents and have co-investigators from EAMC Orthopedic Service. The current protocol will be terminated coincident with the approval of the new protocols by the IRC.
**Detail Summary Sheet**

**Date:** 1 Oct 86  
**Prot No.:** 81-19  
**Status:** Ongoing

**Title:** Investigations of Chronic Phantom Pain.

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**Principal Investigator(s):** Richard A. Sherman, PhD, CPT, MS

**Facility:** Eisenhower Army Medical Center

**Associate Investigators:**
- Norman Gall, M.D., AMVAH San Antonio
- Roberto H. Barja, M.D., COL, MC
- Jeff Ernst, PhD, VA, Augusta

**Dept/Svc:**

**Key Words:** Phantom pain

**Accumulative MEDCASE Cost:** $18,000  
**Est Accumulative OMA Cost:** $900  
**Periodic Mar 86 Review Results Continue**

**Study Objective:**
1. Develop an understanding of the underlying causes of chronic phantom pain.
2. Determine the extent of chronic phantom pain among the amputee population.
3. Develop comparative differential profiles of amputees with and without chronic phantom pain.
4. Evaluate new treatments of chronic phantom pain.

**Technical Approach:**
All service-connected amputees who can be located receive a mail survey requesting information about their amputation, stump pain, phantom pain, etc. All service-connected veterans living near DDEAMC and all amputees treated at DDEAMC or VAMC Augusta are asked to participate in a psychometric and psychophysiologic profile. All phantom pain patients seen at any participating center receive the same profile as part of the pretreatment workup.

**Number of subjects enrolled to date:** 119

**Number of subjects enrolled this reporting period:** 93

**Progress:**
This project is now fully supported by the VA and is making excellent progress. It has EAMC orthopedic staff as co-investigators and is making progressively more use of orthopedic residents. The protocol has two major portions, each of which is covered by a separate grant. This protocol will be terminated coincident with the approval of the two new protocols by the IRC. We will shortly request approval of a new protocol concerning treatments based on our initial findings.


Detail Summary Sheet

Date: 15 Oct 85  Prot No.: 81-42  Status: Ongoing

Title: Experimental Fat Embolism Syndrome: Basic Studies and Evaluation of Currently Available Therapies and New Agents.

Start Date: Oct 81  Est Comp Date:

Principal Investigator(s)  Facility:
James C. McPherson III, PhD  Eisenhower Army Medical Center

Dept/Svc:  Associate Investigators:
Clinical Investigation  Jack A. Horner

Key Words:
Fat embolism
Surfactants

Accumulative MEDCASE  Est Accumulative
Cost:  OMA Cost:  Periodic

Study Objective: Evaluation of current therapies and new therapies for treatment of fat embolism syndrome in an experimental animal model.

Technical Approach: This project is being investigated in five phases. Metabolic evaluation of the non-ionic surface active agents is being conducted using an eleven parameter profile developed to screen these agents and analyzed by a Technicon RA-1000 (a mini-SMA instrument). The profile includes cholesterol, triglyceride, glucose, urea N, creatinine, uric acid, bilirubin, LDH, SGOT, CPK and ALT. Electrolyte blood cell indices and other parameters are under investigation or consideration.

Progress: Part I. Gastric ulcers and/or hemorrhage have been observed in both clinical and experimental fat embolism syndromes. In this study the effect of fat embolism on gastric emptying in rats was investigated. Various non-lethal dose levels of intravenous olive oil delayed gastric emptying in a dose related manner. All animals in this study had fat embolism as characterized by pulmonary hemorrhages, pulmonary edema and microscopic demonstration of fat globules in lung samples. The most likely mechanism to explain the effect of fat embolism on gastric emptying is the characteristic arterial hypoxia of the syndrome since hypoxia from other causes has been found to delay gastric emptying. A decrease in the rate of gastric emptying appears to be a pathophysiologic characteristic of the fat embolism syndrome.

Part II. Triton WR-1339 has been used as an endogenous hyperlipemic agent in several hundred reports since it was introduced in the early 1950's. In this study we gave groups of ten rats daily iv injections of Triton at dose levels of 100 to 800 mg/kg bd wt for four injections and obtained blood 24 hours after the last injection. The blood was analyzed for the hematocrit and pO2 levels and the serum for total cholesterol and bilirubin. A saline injected group served as controls. At the end of the experiment period, the rats in the groups receiving 400 and 800 mg/kg dose levels appeared clinically anemic, i.e., white ears (not the usual pink color) and very pale pink eyes as compared to the control rats with reddish pink eyes. The hematocrits decreased progressively from 50% (controls) to 19% (800 mg/kg dose level) and the pO2 levels from 65 mm Hg to 34 mm Hg confirming the clinical diagnosis of anemia.
The cholesterol levels increased from 87 mg% (controls) to 2700 mg% (800 mg/kg dose level) confirming the hyperlipemic effect of Triton. The effect of Triton on the cholesterol level, hematocrit and blood pO₂ level was dose related. Urinary bilirubin and serum bilirubin levels were normal. None of the animals had hematuria. This suggests that Triton WR-1339 injections cause a secondary anemia in rats due to the mechanical displacement of serum water and red cell mass rather than due to a massive hemolysis of the red blood cells.

Part III. A method for measuring the mechanical fragility of red blood cells suitable for use in small laboratory animals (rats) has been proposed in this report because of lack of such data in the literature. Whole blood is mixed with phosphate buffered saline in a tube containing glass beads. The tubes are rocked for 90 minutes, centrifuged and the percent hemolysis determined. Varying the osmolality of the saline suspending medium had little effect on the mechanical fragility of rat red cells prior to the NaCl concentrations at which a significant change in osmotic hemolysis occurred. The duration of rocking increased the mechanical fragility. Varying the pH (6.4 - 8.0) had no effect. The size of the glass beads changed the mechanical fragility as did varying temperature. The mean mechanical fragility of rat red blood cells was 46% hemolysis (80 adult male animals). Because of the small volume of blood required with this method, mechanical fragility of red cells of other small laboratory animals may also be determined.
Detail Summary Sheet

Date: 1 Oct 86  Prot No.: 82-20  Status: Completed
Title: Correlations Between Extent of Patient Involvement and Effectiveness of Published Behavioral Treatments of Hypertension.

Start Date: Nov 81  Est Comp Date: 
Principal Investigator(s)  Facility:
Richard A. Sherman, PhD, CPT, MS  Eisenhower Army Medical Center
Dept/Svc:  Associate Investigators:
Clinical Investigation

Key Words:
Patient involvement
Hypertension
Behavioral treatment

Accumulative MEDCASE  Est Accumulative Periodic Cost:
OMA Cost:  Review Results

Cost:

Study Objective: To determine whether the extent of patient in behavioral treatment of hypertension affects treatment success.

Technical Approach: The methods and results sections of all published articles on behavioral treatment of hypertension containing sufficient detail to permit analysis are sorted into "blind" booklets for rating. Physician and PhD groups are asked to "blind" rate each method and result section without knowing which are related to each other.

Progress: The data has been partially reduced and will be analyzed as soon as resources are available. The project is completed.
Title: Development of an Animal Model of Phantom Pain.

Technical Approach: Rats are trained to respond to gentle, harmless, shocks by pressing different levers depending on where along the foreleg the shock is given in order to receive a milk reward. After training is successful, the foreleg is amputated by a combined veterinary-orthopedic surgery team while the animal is under anesthesia. Following recovery, the shocks are presented to the remaining portion of the foreleg. The number of responses to stimulation of areas no longer present are compared with the previous number of incorrect responses.

Progress: This project was terminated due to the lack of technical support.
Date: 1 Oct 86  Prot No.: 83-8  Status: Terminated

Title: Effects of the Psychophysiologic Recording Environment on Stress Labile Physiologic Systems.

Start Date:  
Principal Investigator(s): Richard A. Sherman, PhD, CPT, MSC
Dept/Svc: Clinical Investigation
Associate Investigators: Jack A. Horner, B.S.

Facility: Eisenhower Army Medical Center

Key Words:  
Accumulative MEDCASE
Cost:
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OMA Cost:
Periodic Jan 86
Review Results Continue

Study Objective: 1) To determine the placebo value of an electronic device used with several physiologic dysfunctions in which stress is the major independent variable underlying temporal patterns of severity. 2) To evaluate habituation to the environment through repeated recording of the parameters over time.

Technical Approach: Forty, newly diagnosed, unmedicated borderline hypertensives (BPs in range of 140/90 - 160/110) and 40 chronic tension headache patients will participate in the study. All participants will be basically free of other disorders at the start of the study and will be dropped from the study if need for medication occurs, or other problems develop.

Progress: This project has been terminated due to lack of technical support.
Date: 3 Oct 86  Prot No.: 83-37  Status: Terminated

Title: Determination of Glomerular and Nonglomerular Bleeding by Examination of RBC's in Urine Using Scanning Electron Microscope (SEM).

Start Date: Jul 83  Est Comp Date:  
Principal Investigator(s):  
Jack A. Horner  
James A. Hasbargen, M.D., MAJ, MC  
Facility:  
Eisenhower Army Medical Center

Dept/Svc:  
Clinical Investigation  
Associate Investigators:  

Key Words: Electron microscopy, Kidney biopsy, Glomerular bleeding

Accumulative MEDCASE  
Cost:  
Est Accumulative  
DMA Cost:  
Periodic Review Results

Study Objective: It has recently been suggested that red blood cells (RBC) from glomerular causes appear different than RBC from nonglomerular causes. Our goal is twofold: a) to insure the differences are not secondary to osmotic or fixation artifacts, and b) to quantitate and confirm the prior observations.

Technical Approach: This study consists of two parts, a study of urine bound red blood cell (RBC) morphological changes as a result of urine parameters (e.g., holding time, pH, osmolarity, etc.), and a characterization of RBC morphology in urine from patients with hematuria both with and without glomerular bleeding. In the first part, normal peripheral blood is placed in urines of varying pH, osmolarity, etc., for varying times. The samples are then spun down, fixed in glutaraldehyde, dehydrated, filtered onto nucleopore 0.2 filters, critical point dried, gold sputtered, and examined in the scanning electron microscope. A minimum of 100 RBC's from each sample will be examined, then morphology noted, and representative cells photographed to determine the effect of urine parameters on RBC morphology. In the second part the same processing regimen is employed on patient urine samples and the resultant RBC morphology recorded.

Progress: The earlier reported progress on this study showed conclusively the value of the technique. Additional samples were to be included in the study but Dr. Hasbargen has PCS'd.
Title: A Scanning and Transmission Electron Microscopic Study of the Effects of Cadmium on the Early Developmental Components of the Craniofacial Region of the Hamster Embryo

Start Date: Jul 84

Principal Investigator(s)
Jack A. Horner, B.S.
Thomas F. Gale, PhD

Facility:
Eisenhower Army Medical Center
Medical College of Georgia

Dept/Svc:
Clinical Investigation
Anatomy Dept, MCG

Associate Investigators:

Key Words: Electron microscopy, Cadmium, Teratology

Accumulative MEDCASE Cost: OMA Cost:

Study Objective: To utilize electron microscopy to compare the fine structural features of the component tissues of 13 different regions of the face at selected timed-intervals during the early development of the craniofacial region in cadmium-exposed vs control hamster embryos.

Technical Approach: Cadmium sulfate solution is injected (IV) into timed pregnant golden hamsters on the eighth gestation day (8 AM) and embryos are collected at selected times during the period of early facial development, i.e., day 8 at 6PM; day 9 at 8AM; day 10 at 8 AM; day 10 at 6PM; day 11 at 8 AM. The embryos are fixed, dehydrated by critical point drying, coated with gold, and examined and photographed in the scanning electron microscope. Comparisons between embryos from the control (sham-injected) and experimental (cadmium-injected) pregnant hamsters will reveal the teratogenic effects of cadmium on the developing embryonic face. The comparisons will be both qualitative and quantitative. Collection of the quantitative data on surface area measurements will be accomplished by utilization of a computer interfaced morphometric digitometer system.

Progress: The results of the first phase of this study, regarding the data on the surface area measurements of the frontal views of the gestation day 10 - 8 AM embryos, were presented at the 1985 Teratology Society Meetings (Gale TF, Horner JA. Teratology 31:52A, 1985), and paper was submitted for publication to the Teratology Journal in 1986. The reviewers for the submitted manuscript requested additional measurements on the surface areas of the mandibular prominences of the day 10 - 8 AM faces. This data is now being collected. Data is also being collected on earlier stages of the development of the hamster embryo craniofacial region to determine whether cadmium damages this portion of the embryo before the facial prominences are formed. This work will require a morphological, embryo, staging system based on equivalent somite numbers and/or crown rump lengths in order to determine whether the detrimental effect of cadmium is site specific or due to growth retardation.
Detail Summary Sheet

Date: 3 Oct 86  Prot No.: 85-18  Status: Terminated
Title: Ultrastructural Alterations to Human Skin Stored at 40°C in Nutrient Medium and Saline.
Start Date: Apr 85
Est Comp Date: 
Principal Investigator(s)  Facility:
S. Randolph May, PhD  Eisenhower Army Medical Center
Jack A. Horner
Dept/Svc:  Associate Investigators:
Clinical Investigation
Key Words: 
Accumulative MEDCASE  Est Accumulative Periodic
Cost:  OMA Cost:  Review Results
Study Objective: To determine the structural nature of the degradation of human skin stored at 40°C in Eagle's Minimal Essential Medium, with particular reference to the vascular elements.

Technical Approach:

Progress: This study was not implemented due to the departure of Dr. May. The study has been terminated.
Date: 7 Oct 86  Prot No.: 85-31  Status: Completed

Title: Effect of Sodium Salicylate on Nonenzymatic Glucosylation of Human Serum Albumin.

Start Date: Jul 85

Principal Investigator(s)
Kulthoum A. Mereish, PhD, CPT, MS

Facility:
Eisenhower Army Medical Center

Dept/Svc:
Clinical Investigation

Associate Investigators:

Key Words:
Sodium salicylate, Serum albumin, Glucosylated albumin

Accumulative MEDCASE Est Accumulative Periodic
Cost: I OMA Cost: Review Results

Study Objective: To determine the effect of salicylate on the nonenzymatic reaction, the glucosylation of human serum albumin in vitro.

Technical Approach: Human serum albumin will be incubated for 90 minutes with different levels of sodium salicylates. Glucose concentration that simulate normal and diabetic levels will be added to salicylate-albumin and incubated at 37°C for several days. At the end of the incubation period, free salicylate and glucose will be dialyzed and the amount of glucosylated albumin will be determined.

Progress: The rate of glucosylation of bovine albumin in vitro appears to be first order with respect to glucose concentration, but slows down abruptly after approximately 15 mg/ml. The addition of aspirin (acetylsalicylic acid) was found to reduce the glucosylation reaction. The inhibition was concentration dependent. The inhibition of glucosylation by aspirin suggests that at least some glucose is being incorporated at the lysine residue in albumin, the site of acetylation by aspirin. The studied aspirin levels on albumin glucosylation were much higher than therapeutic levels. However, it might be possible to observe an effect in patients with long term aspirin therapy on their total glucosylation of plasma albumin. Such cases could be found in arthritic and combined arthritic-diabetic patients. An assessment of glucosylated plasma protein in these patients needs to be investigated.
Date: 1 Oct 86  Prot No.: 86-28  Status: Ongoing
Title: Computer Assisted Infrared Imaging in the Diagnosis and Management of Military Basic Training Injuries.
Start Date:  
Est Comp Date:  
Principal Investigator(s): Margarete DiBenedetto, MD, COL MC
Facility: USAMEDDAC, Ft Jackson, SC
Dept/Svc: Physical Medicine
Associate Investigators:
Key Words: Accumulative MEDCASE  
Cost:  
Est Accumulative Periodic Review Results
OMA Cost:  
Study Objective:  

Technical Approach:  

Progress: Study approved Sep 86, not yet implemented.
Detail Summary Sheet

Date: 18 Jun 86  Prot No.: 83-32  Status: Completed
Title: Mandibular Lingual Vertical Releasing Incisions.

<table>
<thead>
<tr>
<th>Start Date: Aug 83</th>
<th>Est Comp Date: Jun 86</th>
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</thead>
</table>
Principal Investigator(s) | Facility: |
William M. Ekvall, MAJ, DC | Eisenhower Army Medical Center |
Dept/Svc: | Associate Investigators: |
Dental Activity | |
Key Words: | |
Accumulative MEDCASE | Est Accumulative Periodic Review Results |
Cost: | OMA Cost: |
Study Objective: To compare the short-term post-operative pain and healing of a full thickness mucoperiosteal envelope flap to those of similar flap with a mandibular lingual vertical releasing incision (ML-VRI).

Technical Approach: Using a split mouth design, 12 adult periodontal patients received bilateral posterior mandibular surgery with an envelope flap on one side and a flap with a ML-VRI on the contralateral side. Surgeries were performed at separate appointments, varied, in order, and performed an equal number of times on the right and the left sides. Postoperative pain was scored by the patients and scores for each technique were compared using an analysis of variance and covariance with repeated measures. Healing was evaluated by grading the degree of closure after suturing, and at one and two weeks postoperatively. Healing grades of the two techniques were compared using the paired T-test.

Number of subjects enrolled to date: 12
Number of subjects enrolled for reporting period: 2

No adverse complications occurred.

Progress: All patients completed the symptom data log properly. Two patients reported swelling three days after the periodontal surgery. This swelling was confined to the facial site and did not involve the lingual surgical site. Statistical analysis of pain levels indicated no significant difference (p > 0.05) between the two surgical techniques. Statistical analysis of the graded degree of closure of the surgical sites immediately after suturing and at 7 and 14 days indicated no statistical difference (p > 0.5) between the two surgical techniques. A ML-VRI with exposed bone healed rapidly and without apparent defect.

The findings of this study indicate that the ML-VRI is a valid surgical procedure. The pain intensity experienced by the patients was similar and the tissue healed equally well for both surgical techniques. The ML-VRI maximizes access to desired surgical sites while avoiding nondiseased areas. Since access and flap reflection on the mandibular lingual can often be difficult, the use of a ML-VRI with the surgical flap becomes essential.


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Study Objective: To determine the effects, if any, of nervousness and apprehension on the absorption and subsequent blood levels of antibiotics given by mouth. Many patients have heart defects or conditions that require that they receive antibiotics before they undergo dental procedures or other surgical therapy. These antibiotics can be given orally. This study will attempt to determine if nervousness affects the rate at which these antibiotics enter the blood stream.

Technical Approach: Healthy volunteers who have twice previously been given penicillin and are negative by allergy skin test will be chosen for the study. Two grams of penicillin-V will be taken orally the morning of surgery and a peripheral line with a heparin lock started. Samples are taken at time 0, 30 minutes, 60 minutes, 90 minutes, and 120 minutes after closing. One 5 ml sample for a red-topped tube will be drawn for an EDTA tube. Serum will be analyzed by bioassay for penicillin concentration. Plasma will be evaluated by HPLC for catecholamine levels and by RIA for ACTH concentrations. All patients will fill out a self-evaluation stress questionnaire prior to surgery.

Number of patients enrolled to date: 21
Number of patients for reporting period: 3

Progress: Twenty-one patients were evaluated to determine if, during a period of anxiety, the serum concentration of penicillin VK, when administered as recommended by the American Heart Association under the actual conditions of impending oral surgery would reach therapeutic levels. Adequate blood levels were achieved in all patients.
Date: 1 Oct 86  Prot No.: 85-10  Status: Completed

Title: Masseter Muscle Silent Period in Patients with Internal Derangements of the Temporomandibular Joint Before and After TMJ Surgery.

Start Date: Jan 85  Est Comp Date:

Principal Investigator(s)  Facility:
Jerry Schwartz, MAJ, DC  Eisenhower Army Medical Center

Dept/Svc:  Associate Investigators:
Dentistry, Clinical Investigation  Richard A. Sherman, CPT, MS

Key Words:

Accumulative MEDCASE  Est Accumulative OMA Cost:
Cost:  Periodic Review Results

Study Objective: To assess the usefulness of EMG silent period measurements when evaluating TMJ patients for surgery.

Technical Approach: The subjects will be those patients scheduled for TMJ surgery due to internal derangements of their joint. No medications or invasive techniques will be employed that are not routinely used for this surgical procedure. The EMG masseter muscle silent period will be recorded before surgery, after recovery from surgery, and during follow-ups. EMG results will be correlated with pain intensity and jaw function measurements.

Number of subjects enrolled to date: 19
Number of subjects enrolled during reporting period: 7

Progress: For this reporting period, there has been a completion of seven patients to include the post surgical measurement of the patient's silent period. Raw data has been collected, collated, and a statistical analysis has been completed. The current plan is to have the final draft of the research paper ready for submission to the Journal of Prosthetic Dentistry by 31 October 1986.
Study Objective: To enhance the effectiveness of current treatment modalities for hypersensitive teeth.

Technical Approach: The iontophoresor will be connected to the teeth in both treatment groups, but will be activated in only one. This procedure will help to blind the patient to the procedure. Mechanical and thermal stimulation will be used to quantitate a patient response and assess the efficacy of the treatment modalities.

Number of subjects enrolled to date: 21

No adverse reactions.

Progress: Data collection ongoing. All required patients have been entered into the project. Six subjects have been completed.
Date: 3 Jun 86  
Prot No.: 85-17  
Status: Completed

Title: The Use of Ultrasound for Diagnosis in Periodontal Bone Morphology.

Study Objective: To provide more accurate diagnostic measurements for periodontal bone morphology.

Technical Approach: The project consists of measuring the alveolar bone height from the free gingival margin. This measurement is done with the ultrasound machine Ocu-Scan 400 located at the Ophthalmology Clinic at Eisenhower. Population: patients scheduled to undergo periodontal surgery. At the time of surgery, with the aid of an acrylic stent, the bone height is measured once the mucoperiosteal flap has been resected. The ultrasound measurement and the clinical measurement will then be compared for accuracy.

Subjects enrolled to date: 4
Subjects enrolled during reporting period: 2

Progress: Four patients scheduled for periodontal surgery were selected for the study. The Ocu-Scan 400 machine was used and adjusted according to the manufacturer's instructions. Teeth involved in the study were measured on the facial aspect at three different points: mesial, mid, and distal (except one tooth measured only at the mesial). Two different pre-surgical measurements were made with the use of ultrasound. The distance between the gingival margin and the crest of alveolar bone was measured during the surgical procedure. No correlation could be made between the different measurements obtained. From the results the following was concluded: (1) measurement of alveolar bone topography with the presently available ultrasound probe is not accurate, (2) ultrasound measurement is a fast and pinless procedure, and (3) with a redesigned tip this may be a valuable non-invasive technique for noting changes in alveolar bone height.

Date: 12 Jun 86  Prot No.: 85-22  Status: Completed
Title: The Effect of Tobacco Smoke on the Attachment of Human Gingival Fibroblasts to Root Surfaces in vitro.
Start Date: May 1985  Est Comp Date: May 1986
Principal Investigator(s)  Facility: Leslie A. Raulin, DMD, MAJ, DC  Dental Activity, DDEAMC
Dept/Svc: Dentistry  Associate Investigators: Clinical Investigation  Michael McQuade, DDS, COL, DC
Key Words: Accumulative MEDCASE  Est Accumulative OMA Cost:  Periodic Review Results
Study Objective: To investigate the effect of tobacco smoke on the attachment of human gingival fibroblasts to non-diseased human root surfaces.

Technical Approach: Human foreskin fibroblasts (HFF) were trypsinized; suspended in RPMI 1640 medium; and incubated with autoclaved human root sections and nicotine concentrations of zero (control), 25, 50, 100, 200, or 400 ng/ml. The root sections were examined for fibroblast attachment at 24, 48 and 72 hours by light microscopy and scanning electron microscopy. Additional trypsinized HFF were incubated on glass surfaces with the same concentrations of nicotine and examined at one week by light microscopy.

Progress: HFF attached and grew on glass and root surfaces at all concentrations of nicotine. Controls on glass surfaces exhibited a normal monolayer of long spindle shaped fibroblasts with a parallel alignment and minimal overlapping. Nicotine treated HFF exhibited a haphazard arrangement with cell overlapping and vacuolization of the cytoplasm. Under SEM, the controls had smooth surfaces and appeared firmly attached to the root surface via (1) microvilli and filopodia on the cell boundaries, and (2) short, branched, thin-to-medium width cytoplasmic processes with microvilli and filopodia on their boundaries. Few microvilli were noted on the control cell surfaces.

HFF exposed to nicotine and microvilli and filopodia on the cell surfaces, and long thin and long broad cytoplasmic processes with many microvilli and filopodia that projected away from the root surface. These findings suggest that the nature of fibroblast attachment to glass and root surfaces is altered by nicotine. A similar disturbance in fibroblast attachment may occur in humans who use nicotine-containing products, making them more susceptible to destruction of the periodontium and less responsive to new attachment after periodontal therapy.

Date: 3 Oct 86  Prot No.: 86-4  Status: Completed

Title: Gutta-percha Root Canal Obturation Followed by Apical Root Resection
       Alone vs Cold Burnishing Gutta-percha after Apical Root Resection: A Compa-
       rison of the Seal.

Start Date: Nov 85  Est Comp Date:

Principal Investigator(s):
Scott G. Minnich, MAJ, DC

Facility:
Tingay Dental Clinic

Dept/Svc:
Dentistry/Endodontic

Associate Investigators:
Frank Portell, MAJ, DC
Gary Hartwell, COL, DC

Key Words:

Accumulative MEDCASE Est Accumulative OMA Cost:
Cost: Periodic Review Results

Study Objective: To compare the seal of cold burnished gutta-percha with that of apical gutta-percha present after root resection, but with no further mani- pulation. The study will be conducted in vitro using single rooted teeth which have already been extracted as a result of severe caries or other clini-
cal conditions rendering them non-restorable.

Technical Approach:

Progress: Study completed. Paper in preparation for publication.
Date: 29 Sep 86  Prot No.: 86-5  Status: Completed
Title: An Evaluation of Initial Leakage of Temporary Restorations.

Start Date: Nov 85  Est Comp Date:  
Principal Investigator(s)  
Rufus Y. Bandy, MAJ, DC  
Associate Investigators:  
Facility:  
Tingay Dental Clinic  
Dentistry/Endodontics  
Key Words:  
Accumulative MEDCASE Cost:  
Est Accumulative OMA Cost:  
Periodic Review Results  
Study Objective: To evaluate the marginal leakage of Cavit, a Cavit-water mixture, and IRM in endodontic access preparations immediately and 5 minutes after placement.

Technical Approach:  
Progress: The research is complete, statistical analysis complete, paper is being prepared for publication.
Study Objective: To investigate, in vitro, the nature of the attachment and the relationship between most commonly used intra-osseous implant materials and surrounding connective tissue. Also to quantitate the elements of adhesion.

Technical Approach: Fibroblast cells obtained from commercial sources will be made to grow on most commonly used bone graft materials namely Interpore, Synthograft, Calcitite and Freeze Dried Bone in vitro to study the attachment elements.

Progress: The results of a pilot study showed that fibroblast started attaching to graft materials within two hours. Interpore - a porous hydroxy-appetite graft material appeared to enhance more fibroblast cells per surface area than other graft materials. Synthograft - a tricalcium phosphate allograft material appeared to be the least conducive to cell attachment as seen through 2-6 hour time frame. The number of fibroblast cells per surface area will be counted to quantitate the data. A method to calculate the surface area of these bone graft granules is being formulated.
**Detail Summary Sheet**

**Date:** 3 Oct 86  |  **Prot No.:** 86-12  |  **Status:** Ongoing  
**Title:** Total Intravenous Anesthesia.  

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>Jul 86</th>
<th>Est Comp Date:</th>
<th>Feb 86</th>
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<tr>
<td><strong>Principal Investigator(s):</strong></td>
<td>Henry S. Plautz, LTC, DC</td>
<td><strong>Facility:</strong></td>
<td>Eisenhower Army Medical Center</td>
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<tr>
<td><strong>Dept/Svc:</strong></td>
<td>Dentistry/Anesthesia</td>
<td><strong>Associate Investigators:</strong></td>
<td>G. Lee Brookshire, MD, MAJ, MC</td>
</tr>
<tr>
<td><strong>Key Words:</strong></td>
<td></td>
<td><strong>Edson O. Parker, MD</strong></td>
<td>USA Valley Medical Center</td>
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<tr>
<td></td>
<td></td>
<td><strong>Las Vegas, Nevada</strong></td>
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**Study Objective:** To assess the effects of a total intravenous anesthesia technique (TIVA) using only a narcotic, barbiturate and oxygen or compressed air. The TIVA technique will be compared to the routine standard inhalational anesthetic technique.

**Technical Approach:** The approach is well standardized for both the intravenous and inhalation techniques.

**Number of subjects enrolled to date:** 42  
**Number of subjects enrolled for reporting period:** 42

**Progress:** Data is collected for 34 patients in the TIVA technique and for 8 patients in the inhalation technique. There have been no adverse reactions for any patient in the study group. All that remains is to collect the remaining data for the standard technique, analyze it and support our thesis regarding the viability of a total intravenous technique using Sufenta/Brevital.

**Remaining data requirement:** 22 cases/standard technique.
Date: 30 Sep 86  Prot No.: 86-14  Status: Ongoing
Title: Determination of Nicotine Levels in the Gingival Crevicular Fluid of Cigarette Smokers with Periodontal Disease.

Start Date: Mar 86  Est Comp Date: Jul 87
Principal Investigator(s)  Facility:
James R. McGuire, MAJ, DC  Tingay Dental Clinic
Dept/Svc:  Associate Investigators:
Dentistry, Clinical Investigation  Michael McQuade, COL, DC
Key Words:  Anthony Ficara, COL, DC
Accumulative MEDCASE Cost:  Accumulative Periodic OMA Cost:
Nicotine, Crevicular fluid  Review Results

Study Objective: To determine if nicotine resides in the gingival crevicular fluid of smokers with periodontal disease, and if so, at what concentration.

Technical Approach: Sample collection technique was modified to use filter papers instead of micropipettes. Five Periotron filter papers are separately inserted into the gingival sulcus of periodontal patients at Tingay Dental Clinic as part of the examination process. Fluid is absorbed onto the papers over a 60-second period, the papers are removed, weighed, and analyzed for nicotine and its metabolite cotinine using High Performance Liquid Chromatography at Clinical Investigation Lab. Saliva samples are also taken.

Number of subjects enrolled to date: 7

Progress: Thus far only seven patient samples have been obtained and are presently in the deep freeze at Clinical Investigation Lab pending suitable development of standards. MAJ Don Sutherland and two technicians are presently developing standards, then the patient samples will be analyzed using a methanol/water extraction technique. After this analysis, additional samples will be obtained from approximately 15 smokers and 15 nonsmokers for comparison.
### Title:
A Dye Leakage Comparison Study Using IRM, High Copper Amalgam Alloy, and Thermoplastic Gutta Percha Retrograde Filling Materials.

### Study Objective:
To evaluate and compare the seal created by IRM, thermoplastic gutta percha, and high copper amalgam alloy following apical root resection. This study will be conducted in vitro using single rooted teeth which have already been extracted as a result of severe caries or other clinical conditions rendering them non-restorable.

### Technical Approach:
All obturated experimental teeth will be stored in saline for 14 days at 37°C, then two coats of sticky wax and nail polish will be applied to the crown and root surfaces except for the area of the apical foramen. The apical one-half of all roots will be emerged in 2% methylene blue dye for 48 hours. After exposure to the dye, the teeth will be removed and dried. The sticky wax and nail polish will be removed and the tooth structure cleared. The specimens will be decalcified, then dehydrated in a series of ethyl alcohol rinses. The dehydrated teeth will then be placed in methyl salicylate to make them transparent. Penetration of methylene blue dye into the canal system will then be measure linearly using a 50 X stereolight microscope.

### Progress:
Teeth have been instrumented and obturated with root canal filling material. Presently are in the process of placing the retrograde materials and anticipate completion of the leakage study in approximately two months. Progress is satisfactory.
Title: SEM Evaluation of the Root Surface Following Apical Root Resection Techniques.

Start Date: May 86

Principal Investigator(s) 
Theodore A. Nedderman, DDS, MAJ, DC

Dept/Svc: Dentistry, Clinical Investigation

Key Words: Jack A. Horner

Study Objective: To qualitatively and quantitatively evaluate the root surface following apical root resection with three different burs in both high speed and low speed air rotor handpieces.

Technical Approach: The study will be conducted in vitro using the palatal roots of human maxillary molar teeth which previously extracted due to caries or other clinical conditions which rendered them non-restorable.

Progress: All roots in control and experimental groups have been instrumented, filled, and resected. Observations and photographs are currently being made using Scanning Electron Microscopy and stereomicroscope. Study is progressing satisfactorily.
Study Objective: To assess whether the maintenance of an organized exercise program during the second half of pregnancy with result in improved fitness in the postpartum period. This study is a prospective trial of active duty and dependent women, ages 18 to 35, whose pregnancies are uncomplicated.

Technical Approach: Randomly assigned exercise and control groups will be given a baseline fitness test at 16 weeks gestation and will have this test repeated at 32 weeks gestation and six weeks postpartum. The program for the exercise group involves aerobics (aquatics), stretching exercises and non-water aerobic exercises.

Number of subjects enrolled to date: 33
Number of subjects enrolled during reporting period: 16

Progress: Referrals to this program are extremely low and patient followup to complete testing is unacceptably low. Need to design better followup for testing of enrolled patients. Will consider change in time that exercise is offered to increase referrals.
Title: Cornea Donation: Enhancing "Military Recruitment."

Start Date: Dec 85
Est Comp Date:

Principal Investigator(s):
Dawn E. Light, CPT, MC

Facility:
Eisenhower Army Medical Center

Dept/Svc:
Family Practice

Associate Investigators:

Key Words:
Accumulative MEDCASE

Cost:
Est Accumulative OMA Cost:

Review Results

Study Objective: Retrospective cross-sectional study will compare the number of corneas recovered per hundred potential donors at the Medical College of Georgia and Eisenhower Army Medical Center during 1981 - 1984.

Technical Approach: A prospective cohort study was carried to measure the effectiveness of providing cornea donation instructions to the physicians in attendance at the time of patient death, in an effort to increase cornea donation rates. Cornea donation instructions and a questionnaire about donation requesting will then be provided in the death packet during the study period to the DDEAMC housestaff at the time of each patient's death. At the end of the study period, cornea donations per hundred potential donors was then compared to the baseline rates as previously determined.

Progress: Post-mortem cornea retrieval rates are inadequate to meet transplantation demands. Comparison of annual deaths versus donations between Eisenhower Army Medical Center and the Medical College of Georgia, reveals that Eisenhower had lower rates of cornea donations. Attitudinal surveys showed that physicians omitting organ donation requests rarely identified personal objections to the request. Few housestaff initially identified correct cornea donation criteria. Presentation of cornea donation information to physicians attending patient death increased donation requests and subsequent organ retrieval. This trial's success prompted requests for expansion of donation information to include other tissues.

**Title:** Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Human Immunologic Reactivity to Fire Ant Antigens. 

**Start Date:** Feb 85  
**Est Comp Date:** 

**Principal Investigator(s):**  
Antonio L. Bunker-Soler, LTC, MC  
Robert B. Rhoades, MD, Medical Medicine/Immunology  
Chester T. Stafford, MD, Medical College of Georgia

**Facility:** Eisenhower Army Medical Center

**Associate Investigators:**  
Robert B. Rhoades, MD, Medical College of Georgia

**Key Words:**  
Accumulative MEDCASE:  
Est Accumulative OMA Cost:  
Periodic Mar 86  
Review Results Continue

**Cost:** IOMA Cost: 

**Study Objective:** 1) To compare the skin test reactivity of fire ant venom and its components with whole body extracts (WBE) of fire ants in patients allergic to stings of the imported fire ant. 2) To compare skin test reactivity with in vitro immunologic studies (RAST and Histamine release). 3) To determine the pretreatment immunologic status of fire ant sensitive patients prior to their participation in studies comparing the relative efficacy of immunotherapy with fire ant venom (Part III protocol) versus whole body extracts (Part II protocol) versus placebo; pending DA approval.

**Technical Approach:** The following imported fire ant (*S. invicta*) antigens have been prepared:  
1) 96-1 ml vials of freeze-dried whole venom (1:1000 w/v after reconstitution).  
2) 146-1 ml vials of freeze-dried front end (FE) body segment extract (1:10 w/v after reconstitution).  
3) 145-1 ml vials of freeze-dried anterior end (AE) body segment extract (1:10 w/v after reconstitution).

**Number of subjects enrolled to date:** 3  
**Number of subjects enrolled for reporting period:** 0  
**No adverse reactions.**

**Progress:** Part II and III initiated. Double blind immunotherapy started on 3 subjects. Objectives 1, 2, and 3 are being completed in Protocol 86-2.

**Title:** Use of Isotretinoin in Prevention of Basal Cell Carcinoma.

**Start Date:** Feb 85  
**Principal Investigator(s):** Marshall A. Guill, M.D., LTC, MC  
**Facility:** Eisenhower Army Medical Center  
**Dept/Svc:** Medicine/Dermatology  
**Associate Investigators:** James K. Aton, Jr., M.D., COL, MC  
**Key Words:** John R. Cook, M.D., LTC, MC

**Study Objective:** To evaluate the effectiveness of low dosage levels of isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population. To examine possible side effects associated with long term administration of low doses of isotretinoin.

**Technical Approach:** Patients with two or more basal cell carcinomas (BCC) in the past five years are eligible for inclusion in the study. They must be between the ages of 40 and 75 and incapable of bearing children. After a thorough physical examination, including basic laboratory data, participants are randomized to either the treatment group or the placebo group. The medication is provided by the National Cancer Institute and is double-blinded. Participants take medication for 36 months, continuing to be followed for the following 24 months for a total of 60 months in the study. We hope to enroll a total of 150 patients during the 18-month enrollment period.

**Number of subjects enrolled to date:** 96  
**Number of subjects enrolled for reporting period:** 46  
**Progress:** We have continued to accrue patients at an acceptable rate although the rate has slowed since the number of eligible patients waiting for enrollment has been exhausted. We have added over 200 names to our card file but the majority of these had one BCC and were, therefore, ineligible. We have randomized 46 more patients to total 96. Since the protocol change requiring two normal triglycerides prior to baseline, we have not screened anyone who was not randomized. We have been working closely with the Fort Stewart/Hunter Army Air Field facilities in Savannah, Georgia and conducted a site visit in August where we did follow up on patients we have recruited from the area and we are in the process of recruiting more. Recruitment will end 31 March 1987. The next method of recruitment will be to contact each of the patients with one BCC who has not been seen in the clinic for the last six months. We will also canvas the Fort Jackson are in Columbia, South Carolina for patients. We are presently randomizing a few patients who were previously ineligible due to high GGT's and tubal ligation, but are eligible under the current protocol. We continue to have excellent ancillary support from within our hospital and with the laboratory and x-ray departments of Fort McPherson and Fort Stewart/HAAF. The long delay previously experienced by our patients in x-ray has been alleviated by the increase in contracted personnel in that department. There have been no problems in maintaining quality control within those areas.
The microcomputer and laser printer which we will be acquiring with NIH contract modification funds should be on board by the early part of FY 87. Plans are being made to locate the equipment in the room adjoining the study office.

We have continued to experience a few adverse reactions. Two patients were taken off medication very soon after randomization for non-cutaneous reactions. The severe arthralgia experienced by one patient and the lightheadedness in the other were, according to the protocol, definitely related to the study medication. In these cases, the patients were taken off the study medication. The symptoms in each case recurred 24 to 48 hours after rechallenge with medication. One patient had a history of arthralgia and the other had the flu, was on blood pressure medicines and has since been diagnosed as having mild cortical atrophy. Both patients chose to remain in the study. One patient died due to a GI bleed while he was awaiting coronary artery bypass surgery after experiencing a myocardial infarction. Another patient simply decided he didn't want to take the medication anymore. This same patient had taken isotretinoin (Accutane) six months prior to randomization, but it was unknown at the time that this was in violation of study protocol. Another patient stopped taking the medicine without notifying us because he became so uncomfortable with cracked feet and dry lips even on one pill. This patient is also diabetic. In addition to those patients, we have noted cutaneous adverse reactions which are probably related to the study medication such as dry, chapped lips and dry nasal and ocular mucosa. Four patients were placed on dose modification to one pill after symptomatic treatment did not allay the symptoms. They have been more comfortable with the dose modification. Currently, we have 6 patients on dose modification (one pill) for cutaneous reactions and 3 for non-cutaneous reactions. We have 6 patients off medications completely, but 5 are being followed.

We have found the majority of our patients to be compliant in taking the study medication. Patients in general continue to be enthusiastic about the study. We are pleased with the progress of the study. Though we would like to have a higher rate of continued accrual, it is probably not a realistic expectation at this point in time. We continue to be pleased with the study, and feel that on a day to day basis, it is running very smoothly.
Date: 22 Sep 86   Prot No.: 85-13   Status: Terminated

Title: Protracted Venous Infusion of 5 Fluorouracil with Intermittent Cis-Platinum: A Phase II Trial to Test for Synergistic Anti-Neoplastic Activity in Metastatic Colon Cancer.

Start Date:          Est Comp Date:                    Facility: Eisenhower Army Medical Center
Principal Investigator(s)         Associate Investigators:  
Richard P. Mansour, MAJ, MC    Steven A. Madden, MAJ, MC
Marcus L. Troxell, CPT, MC    Jannet M. Schoch, MAJ, ANC
                       Mr. Lyle M. Glascock
Dept/Svc:                 Key Words:                
Medicine/Hematology-Oncology                       

Accumulative MEDCASE | Est Accumulative | Periodic  
Cost:                          OMA Cost:          Review Results

Study Objective: 1) To study the efficacy of prolonged (28 day) 5 fluorouracil infusion with intermittent cis-platinum in metastatic colon cancer. 2) To reduce the need for hospital confinement for chemotherapy administration.

Technical Approach:

Number of subjects enrolled to date: 2 (FY85)
Number of subjects enrolled during reporting period: 0

Progress: This protocol has been closed due to lack of patient accrual.
Date: 22 Sep 86  Prot No.: 85-14  Status: Terminated

Title: Protracted Venous Infusion of 5 Fluorourcil with Intermittent Cis-Platinum: A Phase II Trial to Test for Synergistic Anti-Neoplastic Activity in Metastatic Non-Small Cell Lung Cancer.

Start Date:  
Est Comp Date:  

Principal Investigator(s)  
Marcus L. Troxell, CPT, MC  
Richard P. Mansour, MAJ, MC  

Facility: Eisenhower Army Medical Center

Dept/Svc: Medicine/Hematology-Oncology

Associate Investigators:  
Steven A. Madden, MAJ, MC  
Jannet M. Schoch, MAJ, ANC  
Mr. Lyle M. Glascock

Key Words:  
Accumulative MEDCASE  
Est Accumulative Cost:  
OMA Cost:  
Periodic Review Results

Study Objective: This study proposes the use of protracted constant venous infusion of 5FU for 28 consecutive days with intermittent administration of cis-platinum as therapy for metastatic non-small cell lung cancer. Response rates and survival will hopefully be increased while toxicity from therapy is minimized. Morbidity from the procedure is expected to be minimal. The silastic centrasil and intrasil catheters used in this study are known to be associated with fewer infectious and thrombotic complications than the polyvinyl chloride catheters used in Lokich's studies.

Technical Approach: This is a nonrandomized, single-arm phase II study designed to assess response rates of patients with nonoat cell lung cancer to protracted infusion 5-FU and intermittent Cis-platinum. The study is being conducted by the staff and ancillary personnel in the Oncology Clinic with no other personnel being required. Ten Cormed Pumps were purchased during the last year at a cost of $1200 each to accommodate the patients on this and the colon cancer study. These pumps are also in use for other patients who are not on protocol. Ten patients have been enrolled on the lung cancer study to date, nine of these were enrolled for the reporting period ending 30 September 85. Protracted infusion 5-FU has been generally well tolerated with a few patients developing mild to moderate mucositis requiring a one step dose reduction. The intermittent Cis-platinum produced the expected side effects of moderate to severe nausea and vomiting which was controlled by high dose Metaclopramide on 1 to 2/3 of the patients. Approximately 1 of the patients are able to receive their Cis-platinum as an outpatient in the clinic. The tunnel Centrasil Elastic Catheters have been problem-free. One catheter was exchanged in a protocol patient because of a cracked hub. No other patient on protocol has had problems related to his subclavian catheter.

Number of subjects enrolled: 0

Progress: This protocol has been closed due to lack of patient accrual and response to treatment.
Date: 1 Oct 86 Prot No.: 85-23 Status: Ongoing

Title: Effect of Ketoconazole Therapy on the Susceptibility of Enteric Fungi to Amphotericin B and Ketoconazole.

Start Date: June 1985 Est Comp Date: June 1986

Principal Investigator(s)
Ruth Marie E. Fincher, MD

Facility: Eisenhower Army Medical Center, Medical College of GA

Dept/Svc:
Medicine/Dermatology

Associate Investigators:
Marshall Guill, MD, LTC, MC
John F. Fisher, MD

Key Words:

Accumulative MEDCASE Est Accumulative OMA Cost: Periodic Review Results

Study Objective: To ascertain ketoconazole and AMB susceptibility patterns of stool fungal isolates in patients prior to and following treatment with ketoconazole.

Technical Approach: Stool specimens are obtained before and after treatment with ketoconazole. These are then cultured and fungal isolates are tested for amphotericin B susceptibility.

No excess Eisenhower manpower is required for the study. All cultures and sensitivity tests are done at the Medical College Laboratories.

No funding is required.

Number of subjects enrolled to date: 8

Progress: There have been a number of problems in completing this study. Compliance has been a major problem as patients are reluctant to bring in a second stool specimen once they complete their ketoconazole. We have also had some problem culturing yeast out of the stool of patients who have completed 5-7 days of ketoconazole. We are continuing to solicit patients for this study.
Title: Extravascular Penetration of Antimicrobial Agents in New Zealand White Rabbits.

Study Objective: To examine new antimicrobial agents to determine the comparative ability to penetrate into intraperitoneal and subcutaneous extravascular compartments.

Technical Approach: Sterile plastic capsules will be implanted intraperitoneally and subcutaneously into New Zealand white rabbits. Six weeks following surgery, a three-day therapy will be initiated by i.p. injection to achieve equilibrium plasma levels. Drug profile in plasma and capsule will be monitored. Pharmacokinetic evaluation of drug plasma levels and drug capsule levels will be performed.

Progress: Comparison of two-compartment pharmacokinetic parameters of aztreonam in normal rabbits with an implanted capsule received only aztreonam (group 1), and rabbits with an implanted capsule and coadministered with amoxicillin (group 2). The coadministration of amoxicillin seemed to have no significant effect on the total aztreonam accumulated in the extracellular fluids from 15 to 300 minutes post treatment. On the other hand, the coadministration of amoxicillin and aztreonam caused a significant (p>0.05) increase in the elimination half life of both alpha and beta phase. The distribution volume (Vc and Vd) of aztreonam was also higher than those obtained in control group (group 1). Aztreonam shows a rapid initial distribution phase and a slow elimination phase. The elimination half life of the beta phase was in hours while the alpha phase was within 3 to 15 minutes. The total body clearance of aztreonam when administered with amoxicillin was also decreased. The effect of amoxicillin on aztreonam kinetics may be due to an effect on aztreonam liver metabolism, protein binding or on its elimination process. The hepatic clearance of $\beta$-lactam antibiotics is dependent on and may reflect liver metabolism or biliary excretion. In addition, it is documented that liver disease increases the volume of distribution of $\beta$-lactam antibiotics by several mechanisms. This may indicate that the attenuation in aztreonam kinetics may be associated with an effect of CA on liver perfusion or aztreonam liver metabolism. This may conclude that dose adjustment might be necessary in combined amoxicillin and aztreonam treatment.
Title: Comparison of rehabilitation Benefits of Supervised Hospital-Based Exercise and Unsupervised At-Home Exercise After Myocardial Infarction.

Start Date: Oct 85

Principal Investigator(s)
Carolyn G. Bernheim, MSN, CPT, ANC
Gaetano G. Scotece, RPT, CPT, SP

Dept/Svc:
Medicine/Cardiology
Surgery/Physical Therapy

Key Words:

Accumulative MEDCASE: Est Accumulative
Cost: OMA Cost:

Facility: Eisenhower Army Medical Center

Associate Investigators:
James Jenkins, Jr., MD, CPT, MC
Kenneth A. Kaplin, MD, MAJ, MC

Study Objective: To compare the rehabilitation benefits of supervised hospital-based exercise and unsupervised at home exercise after MI. This study is a prospective clinical trial of active duty, dependent and retired men and women, age 30 to 70, who have sustained a MI.

Technical Approach: Three cardiac tests to be done on subjects 6-8 weeks after their discharge from EAMC (stress test, Muga, and Holter monitoring).

Number of subjects enrolled: 6.

Progress: These tests were impossible to obtain from the patients returning to our regional MEDDACs. Further, physicians were releasing the supervised exercise patients back to work after only 2-3 weeks of cardiac rehabilitation which eliminated them from the study. The investigators feel it is necessary to terminate the study as data collection has become impossible.
**Title:** Comparison of Test for the Diagnosis of Imported Fire Ant (IFA) Allergy.

**Study Objective:** To compare the validity and reliability of currently available in vivo and in vitro tests with newly developed test using standardized allergens for the diagnosis of IFA allergy.

**Technical Approach:** Patients referred to the Allergy Services of Eisenhower and the Medical College of Georgia into two groups. Those with no history of systemic reaction to fire ants served as the control group and the comparison group consisted of patients with a history of such reactions. Both were tested (in vivo studies) to whole body extract from Greer Labs and aqueous extract available at Eisenhower. Blood was obtained for RAST (in vitro studies) to whole body tests performed by Mayo Med Lab and aqueous venom by Dr. Donald Hoffman, East Carolina University School of Medicine.

**Manpower:** Technical assistance provided by personnel in Allergy Services, MCG and Eisenhower Army Medical Center.

**Number of subjects enrolled to date:** 36  
**Number of subjects enrolled during reporting period:** 36  

**No adverse reactions.**

**Progress:** Data is being gathered and analyzed. Preliminary data suggest significant correlation between RAST and skin test reactivity.

**Presentations being prepared for Southeastern Allergy Society 2-4 Oct 86 and American Academy of Allergy Mar 87.**
Title: Transition into Military Nursing: An Evaluation of A Preceptorship Program.

Study Objective: Examine those factors which facilitate the integration of new ANC officers into a hospital nursing milieu. Determine whether locus of control, as well as affective states of anxiety, hostility, and depression are prime factors in the integration of new ANC officers. Develop a protocol which examines whether there are any differences among nurse preceptees within the same preceptorship program who are judged to be a success. The literature reflects that participants in such programs evaluate the programs as successful. Locus of control and multiple affective states may underscore differences in participants' evaluation of a program as successful. A preceptorship program is geared to ease transition phenomenal among new nurses who are prone to affective states associated with change such as anxiety, hostility, and depression.

Technical Approach: The data collection for each preceptee occurs over a period of 26 weeks. The plan is evaluation research using a time-series design. The effects of the program will be examined against the goals through a series of measurements during week 1, 4, 8, 9, 13, and 24 after arrival at DDEAMC. These points of time include before the program begins, during the program, and after the program ends. The principal investigator administers the tools.

Subjects enrolled to date: 42
Subjects enrolled for reporting period: 16

Progress: A total of 42 AN officers completed the preceptorship program and all phases of data collection. This completes the projected "N" in the design. A summary sheet was devised to facilitate the recording of the counted items. It is being reviewed by the co-investigator to determine the ease of its use as a device to input data for computerization. It is anticipated that data will be run by the end of December 1986.
Date: 23 Sep 86  Prot No.: 86-25  Status: Ongoing

Title: The Effects of the Heating and Humidifying of Anesthetic Gases on the Maintenance of Body Temperature: A Replication.

Start Date: Aug 86  Est Comp Date: Jan 86

Principal Investigator(s): Jacqueline Newman, CPT, AN

Facility: Eisenhower Army Medical Center

Dept/Svc: Nursing/Anesthesia & Operative Svc

Associate Investigators: 

Key Words: Hypothermia, Heat, Humidity

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Cost: OMA Cost:

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Study Objective: To investigate the effects of the heating and humidifying of inspired anesthetic gases to 40°C and 100% relative humidity on body temperature of adults undergoing open abdominal surgery under general anesthesia.

Technical Approach: Temperature is measured using the aural canal site and esophageal site. An electronically controlled heater humidifier system is inserted in the breathing circuit of the experimental group. Airway temperature is monitored at the endotracheal tube site.

Number of subjects enrolled to date: 6

No adverse reactions have been encountered.

Progress: Three control group patients and three experimental group patients have been enrolled at this time. No conclusions can be drawn yet, study was just started in Aug 86.
Date: 18 Sep 86  Prot No.: 85-12  Status: Completed
Title: Comparison of Single Dose Cefoxitin Prophylaxis for Cesarean Section.

Start Date: Jan 85  Est Comp Date: Oct 86
Principal Investigator(s)  Facility: DDEAMC, Talmadge Memorial and University Hospitals
James F. Flaherty, MAJ, MC
Dept/Svc: Obstetrics-Gynecology
Associate Investigators:
Charles Brown, M.D.
Hamid A. Hadi, M.D.

Key Words:

Accumulative MEDCASE Cost: Est Accumulative OMA Cost: Periodic Review Results

Study Objective: This randomized prospective investigation will evaluate the efficacy of a single two gram dose of cefoxitin at time of cesarean section by IV bolus injection after cord clamping or by lavage administration.

Technical Approach: Three treatment groups are defined: a control group will receive no antibiotics; one antibiotic group will receive a bolus injection of two grams of cefoxitin after the umbilical cord is clamped; the second antibiotic group treatment group will receive uterine and peritoneal lavage of two grams cefoxitin in one liter of normal saline after the placenta is delivered.

Subject population. Any gravid adult female patient with labor and/or rupture of membranes longer than three hours will be candidates for the investigation.

Number of subjects enrolled: 60

Progress: Study completed, manuscript in preparation.
Date: 18 Sep 86  Prot No.: 85-27  Status: Terminate
Title: Training Laboratory for Obstetrics and Gynecologic Residents Utilizing Rabbits.

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<th>Principal Investigator(s)</th>
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<tr>
<td>Adolphus Foreman, M.D., LTC, MC</td>
<td>Eisenhower Army Medical Center</td>
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<td>Dept/Svc:</td>
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<td>OB/GYN, Clinical Investigation</td>
<td>James Flaherty, M.D., MAJ, MC</td>
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<td>Key Words:</td>
<td>William Aultman, M.D.</td>
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Study Objective: To familiarize residents in the Department of Obstetrics and Gynecology with microsurgery techniques in tubal reanastomosis.

Technical Approach: Rabbits will be anesthetized and a laparotomy will be performed. The fallopian tubes will be incised and reanastomosed. Animals will be euthanized one week post surgery and histology of fallopian tubes performed.

Progress: Due to PCS of investigators, the study is terminated.
**Detail Summary Sheet**

**Date:** 29 Jan 86  
**Prot No.:** 85-28  
**Status:** Terminated

**Title:** A Multicenter Study Comparing Intravenously Administered Apalcillin and Piperacillin in the Treatment of Hospitalized Patients with Infections Caused by Susceptible Aerobic and Anaerobic Bacteria.

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<td>James F. Flaherty, M.D., MAJ, MC</td>
<td>Eisenhower Army Medical Center</td>
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<td>Gerald Holzman, M.D.</td>
<td>Associate Investigators:</td>
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**Study Objective:**

**Technical Approach:**

**Progress:** Study terminated due to discontinued use of apalcillin by Wyeth Laboratories. No patients were enrolled at Eisenhower.
**Detail Summary Sheet**

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<th>Date: 29 Jan 86</th>
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<tr>
<td><strong>Title:</strong> A Multicenter Double-Blind Comparison of Intravenously Administered Apalcillin and Cefoxitin for the Prevention of Postoperative Infection in Patients Undergoing Vaginal or Abdominal Hysterectomy.</td>
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**Study Objective:**

**Technical Approach:**

**Progress:** Study terminated due to discontinued use of apalcillin by Wyeth Laboratories. No patients were enrolled at Eisenhower.
Title: Metastatic Adenocarcinoma of Unknown Primary Site.

Start Date: Nov 83
Est Comp Date: May 85
Facility: Eisenhower Army Medical Center

Principal Investigator(s)
Ricky Reaves, M.D., CPT, MC
Phyllis Brewer
Jack A. Horner

Dept/Svc:
Pathology
Clinical Investigation

Key Words:
Accumulative MEDCASE Cost:
Est Accumulative OMA Cost:
Periodic Review Results

Study Objective: To determine whether or not the primary site of a metastatic adenocarcinoma of unknown origin can be determined with a high degree of accuracy.

Technical Approach: (1) Gathering cases where primary tumor site is unequivocal.
(2) Manpower: Three.
(3) Morphometric measurements will be made on tumors from known primary sites (adenocarcinomas only) to determine if a statistically significant difference in microvillus size can be assigned to the various primary organs.

Progress: Morphometric measurements are being made as suitable specimens become available. To date the total number of samples is insufficient to statistically determine the significance of the results. Preliminary indications, however, are encouraging that some correlation can be shown between microvillar size and primary site.
Date: 30 Sep 86  Prot No.: 86-15  Status: Ongoing

Title: The Effect of Normal Plasma Dilution Upon the Prothrombin Time and Activated Partial Thromboplastin Time of Heparinized Blood.

Start Date: Apr 86  Est Comp Date:

Principal Investigator(s)  Facility:
James M. Monihan, M.D., CPT, MC  Eisenhower Army Medical Center
Dept/Svc:  Associate Investigators:
Pathology

Key Words:

Accumulative MEDCASE  Est Accumulative  Periodic
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Study Objective: To help delineate the effect of normal plasma dilution on heparin's effects in vitro, thereby improving the ability of the clinical laboratory to evaluate coagulopathic patients.

Technical Approach: Plasma samples are obtained from normal volunteers presenting to the Blood Donor Center. These are then divided into experimental and control groups at random. Baseline PT/APTT tests are then obtained, following which the experimental samples are heparinized with 0.3u sodium heparin per 1cc of plasma. The PT/APTT is then repeated. A 1:1 mix of sample with known normal plasma is then performed and a third PT/APTT obtained.

No funding has been or is expected to be utilized. Manpower requirements have been met to date by utilization, on a voluntary basis, of regular day shift laboratory technicians.

No adverse reactions have been encountered.

Number of subjects enrolled to date is 10.

Progress: The data obtained from the first group of subjects has confirmed our experimental hypothesis. Namely, we have demonstrated partial correction of APTT and virtually total correction of PT by plasma dilution of a circulating anticoagulant (heparin). These findings contradict accepted teachings in this field. Further groups are currently being obtained. In addition, expansion of the study to review differing effects by other reagent brands is under consideration.
Date: 1 Oct 86  Prot No.: 85-4  Status: Ongoing
Title: Training Laboratory for Neonatal Procedures.

Start Date:  Est Comp Date:
Principal Investigator(s)  Facility:
Thomas M. Martinko, MD, CPT, MC  Eisenhower Army Medical Center
Dept/Svc:  Associate Investigators:
Pediatrics, Clinical Investigation
Key Words:

Accumulative MEDCASE  Est Accumulative OMA Cost:  Periodic Review Results
Cost:

Study Objective: To familiarize residents on rotation through the Department of Pediatrics with endotracheal intubation procedures in the newborn.

Technical Approach: Practice placement of endotracheal tubes. Involves two technicians in Clinical Investigation, staff pediatrician and three to five students.

Progress: Each new group of interns, residents, and new students rotating through pediatrics are instructed in the method of tracheal intubation used in neonates. In addition to this, the students see a comprehensive film on newborn resuscitation and practice placing umbilical artery catheters into severed, preserved umbilical cords.
**Date**: 1 Oct 86  
**Prot No.**: 86-16  
**Status**: Ongoing

**Title**: Androgen Responsiveness to LHRH Infusion in Adolescent Females with Polycystic Ovarian Syndrome.

**Start Date**: Apr 86  
**Est Comp Date**:  
**Facility**:  
**Associate Investigators**:  
**Key Words**:  
**Accumulative MEDCASE**  
**OMA Cost**  
**Periodic Review Results**

**Study Objective**: To evaluate this effect over 24 hours, with maximal doses of LHRH (100 micrograms), under conditions where ovarian production alone may be studied (dexamethasone suppression), and by including free testosterone levels, to exclude any interference by changing sex steroid binding globulin levels.

**Technical Approach**: Blood sampling will be taken for androgen levels following the standard LHRH stimulation test. Population will include all adolescent and young adult women referred for evaluation of hirsutism, oligoamenorrhea, or obesity who have given consent.

**Number of subjects enrolled to date**: 4  
**Number of subjects enrolled for reporting period**: 4

**Progress** To date two subjects have been identified, enrolled and undergone complete testing. Two additional subjects have been identified, one will finish studies this week and the other within two weeks. To date no hormonal assays have been done to save time and money until the first patient samples were available. We anticipate that hormone levels will be completed this month on the first group and provide a basis for pursuing further studies.
**Date:** 1 Oct 86  
**Prot No.:** 86-23  
**Status:** Ongoing

**Title:** Androgen Binding and Reductase Activity in Hair Follicles from Hirsute Females.

**Start Date:**  
**Est Comp Date:** Jun 88

**Principal Investigator(s):** Gary L. Francis, MD, MAJ, MC  
**Facility:** DDEAMC

**Dept/Svc:** Pediatrics  
**Associate Investigators:** Alan Getts, MD, CPT, MC  
James C. McPherson III, PhD

**Key Words:**

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**Study Objective:** To evaluate the potential role of androgen binding and conversion of testosterone to the more potent androgen dihydrotestosterone, in the pathophysiology of hirsutism.

**Technical Approach:** Female subjects aged 18-40 will have several facial hairs, body hairs, and pubic hairs removed by traction. Adult female and male normal volunteers will have control samples obtained in an identical fashion. Hair follicles will then be assayed for binding of $^3$H-dihydrotestosterone and conversion of testosterone to dihydrotestosterone. Data will then be analyzed as to: a) correlation with hirsutism scores, b) correlation with age, and c) correlation with specific etiology of hirsutism.

**Progress:** Study approved late FY 86, not yet implemented.
Study Objective: To evaluate the potential role of elevated BA-PRL in the pathogenesis of neonatal galactorrhea and breast engorgement. It will also define a normal range for BA-PRL in human cord blood.

Technical Approach:

Progress: Study approved late Sep 1986, not yet implemented.
Detail Summary Sheet

Date: 2 Oct 86  Prot No.: 84-1  Status: Ongoing

Title: The DDEAMC Alcohol Residential Treatment Facility Patient Outcome Study.

Start Date: Oct 83  Est Comp Date: 

Principal Investigator(s)
Peter S. Jensen, M.D., MAJ, MC
Daniel Hendricks, M.D., CPT, MC
Lou Van Osdel, M.D., LTC, MC

Facility: Eisenhower Army Medical Center

Dept/Svc: Psychiatry and Neurology

Associate Investigators:

Key Words: Accumulative MEDCASE

Est Accumulative Periodic May 86

Cost: OMA Cost: Review Results Continue

Study Objective: To better understand alcoholism and its treatment by assessing some of its biological, psychological, and social concomitants, and determining their diagnostic and prognostic validity.

Technical Approach:

1. Summary of Experimental Design: This study is prospective in design. Measures of the above mentioned variables will be taken prior to, and upon completion of, treatment. Additionally, follow-up questionnaires are to be completed by the patient, spouse, and patient's commander at intervals of three, six, nine, twelve, and twenty-four months after discharge. Relationships will be measured using analysis of variance and analysis of covariance procedures.

2. Manpower: Personnel required to gather, collate, and interpret the data are, at a minimum, one 91G Behavioral Science Specialist, one Medical Records Technician, and one Clinical Psychologist.

3. Funding: Not applicable.

4. Number of subjects enrolled to date: 460

5. Number of subjects enrolled during reporting period: 152

6. Adverse reactions: None.

Progress: Pre-treatment, discharge and partial follow-up data have been collected on 460 subjects. Compilation of this data for 160 subjects is proceeding. Arrangements have been made for statistical analysis via the Medical College of Georgia.

72
Title: Reliability and Agreement of Reports of Children's Symptoms.

Start Date: Apr 84  
Est Comp Date:

Principal Investigator(s):  
Peter S. Jensen, MD, MAJ, MC  
Stephen N. Xenakis, MD, COL, MC

Facility: Eisenhower Army Medical Center

Dept/Svc: Psychiatry-Neprology

Key Words:

Accumulative MEDCASE  |  Est Accumulative Periodic Mar 86
Cost:  |  OMA Cost:  |  Review Results Continue

Study Objective: To examine the effects of parent and child gender and parental depressive symptoms on the reliability and agreement of children's and parents' reports of children's symptoms and behavior problems.

Technical Approach: (1) One hundred 2-parent families will be selected from on-post housing lists to participate in a study of children's depressive symptoms. To be eligible, families must have a child age 8-12. Also, 100 parents and children who are referred to the Child, Adolescent and Family Psychiatry Service at DDEAMC will also participate in the study. Both groups of families will be compared vis a vis then reports of children's depressive symptoms (Scales used are well-standardized instruments including the Child Behavior Checklist, the Child Depression Inventory, and the Beck Depression Inventory). Reliability and agreement between mother's, father's and children's reports will be analyzed to determine how these indices are affected by sex of parent and child, and depression in the parent.

(2) Manpower required is limited to the two current principal investigators.

(3) Funding required is to provide computer support and statistical analysis.

(4) No adverse reactions.

(5) Subjects enrolled to date: 140

(6) Subjects enrolled for reporting period: 50

Progress: One hundred families have been enrolled to date. All data has been scored, and statistical analysis is proceeding. Forty additional families referred to CAFPS are also participating. An additional 60 referrals will be gathered, and data from these two groups will be compared.
Date: 2 Oct 86  Prot No.: 85-30  Status: Ongoing

Title: Family Risk and Protective Factors: A Prospective Study of Obstetric Patients and Their Families.

Start Date: Aug 85  Est Comp Date:

Principal Investigator(s)
Peter S. Jensen, M.D., MAJ, MC
Stephen N. Xenakis, M.D., LTC, MC

Facility: Eisenhower Army Medical Center

Dept/Svc:
Psychiatry-Neurology/Social Work Service

Associate Investigators:
Kent M. Plowman, MD, LTC, MC

Key Words:
Accumulative MEDCASE
Cost: I OMA Cost: Review Results Continue

Study Objective: This study will determine the additive effects of stress, lack of social supports, parental history, parental coping skills, and marital communication on complications of pregnancy in the mother and newborn, and effects of these factors on the child's growth and development.

Technical Approach: One hundred nulliparous women in the first or second trimester of pregnancy and their husbands will be invited to participate in the study. Subjects and spouses will complete surveys to determine their level of social supports, stress, coping skills, marital relationships, etc. These families will be followed prospectively through the course of pregnancy, into the child's first year of life. Statistical analyses will be performed to assess the relationship between interior (stress, supports, coping, etc.) variables and outcome measures (complications of pregnancy, child's growth and development, frequency of illness, etc.).

Number of subjects enrolled to date: 27
Number of subjects enrolled for reporting period: 27

Adverse reactions: None.

Progress: Data from 27 patients has been scored, but not yet analyzed.
Date: 3 Oct 86   Prot No.: 78-14   Status: Ongoing

Title: Intraocular Lens Study.

Start Date: May 78   Est Comp Date: 

Principal Investigator(s)  Facility:
Ophelia Patterson, MD, MAJ, MC
Keith C. Moses, MD, CPT, MC
Kenneth Y. Gleitsmann, MD, MAJ, MC
John Pope, Jr., MD, LTC, MC

Dept/Svc: Surgery/Ophthalmology

Key Words:
Intraocular Lens  Implant  Ophthalmology
Aphakia  Surgery

Accumulative MEDCASE  Est Accumulative Cost:  OMA Cost:  Periodic Mar 86
Review Results Continue

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Number of subjects enrolled to date: 683
Number of subjects enrolled for reporting period: 139

Progress: There were virtually no complications noted for all lens types and surgeons during this period. Implants were 112 of the 34S style (posterior chamber lens) and 17 of the 70S style (anterior chamber lens). In February 1986, the 34S posterior chamber lens was removed by the FDA from investigational status to general use. The 70S anterior chamber has been replaced by the new 78A anterior chamber which is more flexible and associated with even less complications.
Detail Summary Sheet

Date: 3 Oct 86  Prot No.: 83-24  Status: Ongoing
Title: Assessment of Vertical Banded Gastroplasty in Treatment of Morbid Obesity.
Start Date: Apr 83  Est Comp Date:
Principal Investigator(s)  Facility:
Ross S. Davies, M.D., COL, MC  Eisenhower Army Medical Center
Robert Chadband, M.D., MAJ, MC
Dept/Svc:  Associate Investigators:
Surgery
Medicine
Psychiatry and Neurology
Key Words:

Accumulative MEDCASE  Est Accumulative Cost:  I
Cost:  OMA Cost:

Study Objective: To determine if vertical banded stapling is an effective treatment modality for morbid obesity, to determine its long term effectiveness and complications, and to determine if it will prevent the detrimental effects of morbid obesity.

Technical Approach: Weight loss post bypass will be studied in each patient and compared to average weight loss from other centers following the same procedure. Psychologic testing post-operative will be compared to pre-operative results to examine patient self-image pre and post weight loss.

Subjects enrolled to date: 115
Subjects enrolled for reporting period: 40

Progress: Weight loss postoperatively is consistent with reported results.

Date: 3 Oct 86  Prot No.: 83-27  Status: Ongoing
Title: Microsurgery Skill Lab.

Start Date: Nov 83  Est Comp Date:
Principal Investigator(s)  Facility:
Allan Goodrich, M.D., MAJ, MC  Eisenhower Army Medical Center
Dept/Svc:  Associate Investigators:
Surgery/Orthopedic  Orthopedic Residents

Key Words:

Accumulative MEDCASE  Est Accumulative
Cost:  OMA Cost:  Periodic

Study Objective: In depth exposure to the principles and techniques of microsurgery in a laboratory setting - skills developed being transferable to clinical setting - may also stimulate interest in further research related to field of microsurgery.

Technical Approach: Monthly orthopedic rotation in microvascular surgery for residents with special emphasis on microvascular repair of rat femoral arteries. Surgical application: suture of very small vessels and nerves. The project is being done in periods of 30 to 60 days by one resident and one staff.

Progress: To date four residents have completed their objective. Four new residents will start the project in January 1987.
Title: Reflux Esophagitis in Morbid Obesity and the Effects of Vertical Banded Gastroplasty.

Start Date: Jul 83
Est Comp Date: Mar 86

Principal Investigator(s)
Frank G. Opelka, CPT, MC
Ross S. Davies, COL, MC

Facility:
Eisenhower Army Medical Center

Dept/Svc:
Surgery

Associate Investigators:

Key Words:
Accumulative MEDCASE: Est Accumulative OMA Cost: Periodic Jan 85 Review Results Continue

Study Objective: To evaluate the potential for reflux esophagitis in the morbidly obese patient, before and after vertical banded gastroplasty.

Technical Approach: In addition to a preoperative history and physical, each patient will be evaluated and scored for symptoms of gastroesophageal reflux according to the method of Lascone et al.

Subjects enrolled to date: 101
Subjects enrolled for reporting period: 26

Progress: Symptoms of gastroesophageal reflux were uncommon in our morbidly obese population. Objective testing for gastroesophageal reflux failed to reveal an increased incidence of this pathology in our patients. Surgical manipulation of the GE junction as required for the performance of vertical banded gastroplasty does not produce GE reflux.

Detail Summary Sheet

Date: 1 Oct 86 Prot No.: 84-25 Status: Ongoing

Title: Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Peripheral Vascular Disease and Disorders Marked by Altered Patterns of Peripheral Blood Flow.

Start Date: Mar 84 Est Comp Date:

Principal Investigator(s): Roberto H. Barja, MD, COL, MC
Richard A. Sherman, PhD, CPT, MS

Facility: Eisenhower Army Medical Center

Dept/Svc: Surgery/Orthopedics
Clinical Investigation

Associate Investigators: Robert Anderson, MD, LTC, MC
Larry Walker, MD, CPT, MC
J. Allan Goodrich, MD, MAJ, MC
Larry Donovan, MD, CPT, MC

Key Words: J. Allain Goodrich, MD, MAJ, MC
Larry Donovan, MD, CPT, MC

Accumulative MEDCASE Est Accumulative Periodic Mar 85
Cost: I OMA Cost: Review Results

Study Objective: To determine the optimal utilization of thermography in clinical evaluation of the vascular status of the affected area. This phase of the project is concentrating on correlating near surface blood flow patterns with reports of pain having varied diagnostic etiologies. The aim is to determine whether thermography is a more sensitive and objective method for initially diagnostic and subsequently tracking pain problems with vascular components than current methods.

Technical Approach: Subjects are recorded thermographically as soon as a patient meeting the eligibility criteria requests treatment. This forms a part of the regular work-up for diagnosis of pain in the Orthopedic Clinic. A series of recordings are made as the patient progresses through treatment and follow-up. The results are then compared with the results of the standard clinical evaluation.

Number of subjects enrolled to date: 229
Number of subjects enrolled for reporting period: 83

Progress: This project requires the heavy participation of orthopedic staff and residents. It is going slowly, but well. Its success in trials during which groups of patients with various disorders are being followed from initial diagnosis through resolution of the problem has created sufficient interest to result in the creation of several spin off projects which are being submitted to the IRC by orthopedic residents as independent protocols. We have completed a "blind rater" study of clinical thermograms in which the raters had to order thermograph series for individual subjects by amount of pain or sort thermographs of subjects in pain from those not in pain. This is the first objective test of thermography as a clinical technique as all previous clinical publications used raters who were not blind to the problems of the participating subjects.

Title: Clinical Investigation of the Long Term Effects of Arthroscopic Knee Surgery in the Military Hospital Population.

Study Objective: To analyze the results in patients treated with knee surgery under arthroscopic surgical control during the period 1 January 1980 to 15 July 1983 at Ft Benning, GA.

Technical Approach: A survey has been done of 100 patients treated by arthroscopic surgery.

Progress: A variety of knee injuries that occur in the training soldier are amenable to arthroscopic surgery. In addition, the diagnostic value of evaluation of chronic non-specific knee pain in the early weeks of intense physical training is great. This examination often allows early diagnosis and treatment of problems and return to duty. Finally, arthroscopy has the added advantage of planning other procedures or avoiding unnecessary surgery. The value of arthroscopy as a diagnostic and surgical procedure has established it as an almost essential tool of the military orthopedic surgeon.
Study Objective: To analyze the natural history of a group of patients who sustained femoral neck stress fractures while training at Ft Benning, GA during the period July 1979 to July 1983.

Technical Approach: Questionnaires have been sent to all patients. Examination, when possible of 48 patients with 54 femoral neck stress fractures has been done.

Progress: Fifty-four femoral neck stress fractures were prospectively studied to evaluate treatment methods. A modification of existing classification schemes was developed based on radiographic findings and treatment. Differences from earlier studies were noted in racial predilection, in non-progression of tension-side fractures and in return to function.
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Date: 1 Oct 86  Prot No.: 84-45  Status: Ongoing
Title: Endoscopic Training Lab.

Start Date: Apr 84  Est Comp Date:
Principal Investigator(s)  Facility:
Richard M. Satava, M.D., LTC, MC  Eisenhower Army Medical Center
Dept/Svc:
Surgery  Associate Investigators:
Clinical Investigation
Key Words:

Accumulative MEDCASE Cost:  Est Accumulative Periodic Review Results
Cost:  OMA Cost:

Study Objective: Entry level acquaintance with endoscopic skills. The performance of both diagnostic and therapeutic endoscopy on laboratory animals (dogs) in order to develop clinical skills in endoscopy. Also, creation of clinical gastrointestinal entities (pathology, surgical procedures) which can be studied endoscopically for the purpose of training and research.

Progress: There are currently 8 animal models which are maintained on an ongoing basis for endoscopic training of surgical residents and available for training residents from other DDEAMC residency programs on an ad hoc basis. Animal models include: Nissen fundoplication, gastric polyps, antrectomy with Billroth 1 gastroenterostomy, subtotal gastric resection with Billroth 2 gastroenterostomy, vertical banded gastroplasty, cholecystoduodenostomy, gastroenterostomy, right hemicolectomy, colectomy with ileo-anal anastomosis. These animals have been maintained in excellent health throughout FY 86.

Concurrent training of surgical residents in PGY-2 and PGY-3 level in the endoscopic procedures is throughout the year. Preparations for a Surgical Endoscopy Workshop which would utilize the animals and laboratory continues. We are awaiting arrival of MEDCASE 86 videoendoscopy equipment to further expand our research potential.
Detail Summary Sheet

Date: 1 Oct 86  Prot No.: 85-1  Status: Completed
Title: Implantable Artificial Anal Sphincter (Phase I)

Start Date: Dec 84  Est Comp Date: May 86

Principal Investigator(s)
Michael P. Byrne, MAJ, MC
Richard M. Satava, LTC, MC

Facility:
Eisenhower Army Medical Center

Dept/Svc:
Surgery
Clinical Investigation

Associate Investigators:

Key Words:

Accumulative MEDCASE Cost:  Est Accumulative OMA Cost:  Periodic Review Results

Study Objective: To develop a hydraulic artificial anal sphincter and implant the sphincter in animals with abdominal or perineal colostomies in order to achieve fecal continence of the stomas.

Technical Approach: Low anterior resection accomplished in standard fashion. Then Group 2 animals have Hartman's procedure with anal sphincter placed intra-abdominally just proximal to colostomy and wrapped with omentum. Group 3 animals have an endo-rectal pullthrough procedure, with the artificial sphincter just proximal to the anastomosis (located at the pelvic floor of the perineum).

Progress: Data is being collated, to be sent for statistical analysis. There is a 3-month delay in the review of pathologic material because the Pathology resident on the project has PCS'd, and new resident has not arrived and settled. Also, principal investigator (Dr. Byrne) is on a 2-month rotation at Walter Reed Army Medical Center. Project completion of manuscript to be submitted for publication by 1 January 1987.
### Study Objective:
To develop a satisfactory system for resurfacing the acetabular fossa. To increase hip joint range of motion and eliminate pain.

### Technical Approach:
No patients enrolled and study discontinued because other better equipment is available and newer instrumentation and modification of the existing system is pending.
Date: 19 Sep 86  Prot No.: 85-5  Status: Ongoing
Title: Advanced Trauma Life Support Course.

Start Date: Jan 85  Est Comp Date:
Principal Investigator(s)  Facility:
Robert Brigham, LTC, MC  Eisenhower Army Medical Center
Dept/Svc:  Associate Investigators:
Surgery
Clinical Investigation
Key Words:

Accumulative MEDCASE  Est Accumulative Periodic
Cost:  OMA Cost:  Review Results

Study Objective: To provide training for physicians who are not dealing with major trauma on a day-to-day basis, and who may have to evaluate the seriously injured patient during the period immediately after injury. Also, it is intended to provide the basic knowledge and skills necessary to identify those patients whose need is for rapid assessment, resuscitation, and stabilization.

Technical Approach:

a. Design: The Advanced Trauma Life Support Course is a two day training session in which participants are given didactic instruction followed by practical skill stations and an animal lab. Testing is accomplished by a written exam and a practical exercise in which a simulated trauma victim is resuscitated.

b. Manpower: Requirements are as follows:
   - Course Director (1 MC)
   - Course Administrator (MS)
   - Instructors (6 MC)
   - Logistical Support (2 EM)
   - Moulage patients (4 EM)

c. Funding: Administrative cost derived from Office of Medical Education.

Progress: The project continues to be very successful. During the past year we conducted one Advanced Trauma Life Support Instructor Course which resulted in the training of 16 physicians and 4 nurses. Participants included representatives from each of our local referring institutions. These instructors have subsequently helped support other ATLS Courses.
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<th>Prot No.: 85-15</th>
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<tr>
<td>Title: The Treatment of Segmental Bone Loss in Rabbit Femora with AlveograFR.</td>
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<td>Larry T. Donovan, CPT, MC</td>
<td>Eisenhower Army Medical Center</td>
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<td>J. Allan Goodrich, MAJ, MC</td>
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Study Objective: To determine if union can be achieved after segmental resection of bone from rabbit femora using a non-resorbable ceramic bone grafting implant as a scaffold for bone ingrowth with and without supplemental autogenous bone graft from the animal’s iliac crest.

Technical Approach: Rabbits will undergo segmental resection of 10% and 20% of the femoral diaphysis to simulate traumatic loss of bone. These defects will be replaced by Alveograft, a non-resorbable ceramic bone grafting implant material.

Progress: Expect to complete this academic year.
Detail Summary Sheet

Date: 1 Oct 86  Prot No.: 85-36  Status: Ongoing
Title: Implantable Artificial Anal Sphincter (Swine) (Phase II).
Start Date: Nov 85  Est Comp Date:
Principal Investigator(s)  Facility:
Richard M. Satava, LTC, MC  Eisenhower Army Medical Center
Dept/Svc: Surgery
Clinical Investigation
Associate Investigators:
Surgery  Michael P. Byrne, MAJ, MC
Clinical Investigation

Key Words:

Accumulative MEDCASE  Est Accumulative Periodic
Cost:  OMA Cost:  Review Results

Study Objective: Phase II will focus on developing the technique of implanting the sphincter in the pelvis, and overcoming the minor technical complications associated with intraabdominal implantation. In addition, by using a commercially available valve and reservoir, the entire sphincter mechanism will be investigated as a totally implantable system.

Progress: To date there have been implantation of 15 artificial anal sphincters in the pelvic (perineal) position. It is anticipated that the remaining 15 procedures will be completed over the next 6 months. Progress has been greatly hampered by the loss of the Chief Veterinarian, LTC Wilson, with no replacement due until October 1986 - an underlap of nearly 3 months. In addition, unexpected adverse finding of sloughing of the sphincters, which occurred in only 2 of the previous animals, mandates careful investigation into the cause, thereby slowing the progress. In spite of the above unforeseen difficulties, it is anticipated that this phase of the experiment can be wrapped up by April 1987, with a view to publication before July 1987.
Title: A Comparison of Sympathetic Block Versus Adenosine Monophosphate in the Treatment and Prevention of Shingles and Post Herpetic Neuralgia.

Progress: A total of six patients were enrolled in the study, 2 AMP - one resolved, one had ophthalmic involvement and was dropped from the study and placed on acyclovir therapy and did well; 3 nerve blocks - one resolved, two had post herpetic neuralgia which necessitated AMP crossover and resolved; 1 placebo - crossed over to AMP and even after three months had a very low grade post herpetic neuralgia. She is now having neurolytic blocks performed. Study terminated due to inability to obtain sufficient number of subjects.
**Detail Summary Sheet**

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<td><strong>Title:</strong> Ultrasound Evaluation of the Rotator Cuff.</td>
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<td>Principal Investigator(s)</td>
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<tr>
<td>Timothy R. Young, COL, MC</td>
<td>Eisenhower Army Medical Center</td>
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<td>Roberto H. Barja, COL, MC</td>
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<td>Dept/Svc:</td>
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<tr>
<td>Surgery/Orthopedic</td>
<td>Michael J. Quinn, MAJ, MC</td>
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<td>Key Words:</td>
<td>Robert C. Anderson, MAJ, MC</td>
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<td>Michael Drafeford, CPT, MC</td>
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<td>Stephen L. Simpson, CPT, MC</td>
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**Study Objective:** Attempt to determine the sensitivity and specificity of ultrasound in diagnosing rotator cuff tears and pathology.

**Technical Approach:** The experimental design is to compare the diagnostic value of blind noninvasive ultrasound with subsequent arthrogram and arthroscopy in shoulders with symptomatic rotator cuff disease. Additionally, the blind ultrasound studies of the symptomatic shoulders will be compared with the blind ultrasound studies of 50 clinically asymptomatic shoulders in individuals 18-35 years of age.

Manpower involves one radiologist who will do all of the ultrasound studies and four orthopedists who will accomplish the examinations and referrals.

No specific funding has been required.

Number of subjects enrolled to date: 14
Number of subjects enrolled for reporting period: 14

No adverse reactions noted.

**Progress:** Seven symptomatic and 7 asymptomatic shoulders were studied. No conclusions have been drawn because of the low number of patients, but analysis thus far seems to indicate a definite positive consistency of noninvasive ultrasound.
**Study Objective:** To determine whether sufentanil provides more rapid recovery than fentanyl when administered in low doses as part of a balanced anesthetic technique for ASA I or II patients undergoing elective surgical procedures.

**Technical Approach:** Data regarding recovery from anesthesia were collected by PARR staff. A modified Aldrete scoring system and a simple psychomotor test were used to assess recovery from anesthesia. Assessments of recovery were made upon arrival in PARR and every 15 minutes thereafter until patients met all criteria for recovery.

**Methods of data analysis:** A significant difference between mean recovery time of the sufentanil and fentanyl groups was tested for using a student's t-test (LOS = 0.05).

**Number of subjects enrolled to date:** 28
**Number of subjects enrolled for reporting period:** 28

**No adverse reactions.**

**Progress:** Those patients who received fentanyl demonstrated a mean recovery time of 1.66+/-.07 (SEM) hours, while those who received sufentanil demonstrated a mean recovery time of 1.92+/-.07 (SEM) hours. The difference in recovery times was not significant.

**Conclusions and recommendations:** These data suggest that sufentanil, used in low doses as part of a balanced anesthetic technique does not provide a more rapid recovery than fentanyl. In fact, mean time to recovery with sufentanil in this study was prolonged compared to fentanyl, though not significantly so.
Date: 1 Oct 86          Prot No.: 86-11          Status: Ongoing
Title: Omental Splenic Autotransplantation: Optimal Transplant Size for
Maximal Protective Effect Against Pneumococcal Bacteremia.
Start Date: Jan 86     Est Comp Date:
Principal Investigator(s):
William M. Steely, CPT, MC
Richard M. Satava, LTC, MC
Facility:
Eisenhower Army Medical Center
Dept/Svc:
Surgery, Clinical Investigation
Associate Investigators:
Key Words:
Splenectomy, Autotransplantation
Accumulative MEDCASE Est Accumulative Periodic OMA Cost: Review Results
Cost: Study Objective: To compare five quantities of splenic tissue autotransplantation in order to establish the optimal splenic transplant for the maximal protective effect against a challenge of Streptococcus pneumoniae.

Technical Approach: Rats will be divided into eight groups of 24 animals each. After its removal, the spleen will be diced into small 1mm x 2mm x 2mm pieces. Autotransplantation will consist of 20%, 40%, 60%, 80% and 100% of the spleen transplanted in an omental pocket. The edge of the omentum will be folded over and will be sutured to the anterior surface of the stomach along the greater curvature to create the omental pocket. All rats will be challenged with S pneumoniae after 16 weeks. All splenic tissue from the splenic transplant will be measured, weighed and histologically examined to confirm the presence of splenic tissue and to describe the architecture.

Progress: This project is nearing completion. The actual animal laboratory portion is being carried out at this time. The survival data thus far would indicate an increasing survival with an increasing percentage of splenic autotransplant. This is supported by our initial blood culture data. Statistical analysis of this data is beginning, but no significance is known at this point. Pathology of the autopsied survivors and mortalities of the pneumococcal sepsis is presently at the Department of Pathology, and is being processed. The projected completion of the project with data in presentation form is two months.
Title: The Effects of Pentoxifylline (Trental) on Vasculogenic Impotence.

Study Objective: To determine if Pentoxifylline, an agent that has been shown to improve capillary blood flow, will improve vasculogenic erectile impotence.

Technical Approach: Experimental design - Fifty male subjects with vasculogenic impotence will be randomized in a double-blind trial to evaluate Pentoxifylline (Trental) as a treatment modality. Data will be evaluated on the basis of subjective improvement in impotence as well as objective changes in penile doppler studies.

Manpower - Urology and Vascular Surgery Service.
Vascular Lab Technicians.
Pharmacy

Funding - From existing Pharmacy supplies of Trental and placebo (multi-vitamin): about $4,000.

Number of subjects enrolled to date: 3
Number of subjects enrolled for reporting period: 3

No significant adverse reactions.

Progress: Currently, three patients have been enrolled in the study and are in the first 3-month evaluation period.
Date: 2 Oct 86  Prot No.: 86-20  Status: Completed
Title: Comparison of Conservative Treatments for Grade I and Grade II for Ankle Sprains.
Start Date: May 86  Est Comp Date: 
Principal Investigator(s)  Facility:  Gaetano G. Scotece, MPT, CPT, SP  Eisenhower Army Medical Center
Dept/Svc:  Surgery/Physical Therapy  Associate Investigators:  Paul Anctil, SP4

Key Words:
Accumulative MEDCASE  Est Accumulative Cost:  OMA Cost:  Periodic Review Results

Study Objective: To compare the efficacy of four different treatment programs for Grade I and Grade II ankle sprains.

Technical Approach: Patients with a diagnosis of an acute Grade I or Grade II ankle sprain were randomly assigned to one of three treatment groups, one group was treated with a 3-day ankle strapping, the second group with a gel cast, and the third group with a double ankle strap. Otherwise all three groups were treated according to clinic protocol for ankle sprains.

Number of subjects enrolled to date: 185
Number of subjects enrolled for reporting period: 185

Progress: Active duty soldiers, ages 17-35, with a diagnosis of Grade I or Grade II ankle sprains were randomly assigned to one of three groups. Data collection was completed indicating group 3 treatment had a greater efficacy.

Paper being prepared for submission.
**Title:** Investigation of Dose Related Tissue Response to Dimethylsiloxane in Rabbits.

**Study Objective:** To further the knowledge as to the biocompatibility of dimethylsiloxane with rabbit subcutaneous tissue in the hope that this will provide useful knowledge relevant to humans.

**Technical Approach:**

**Progress:** Study has been withdrawn.
Title: Intraocular Lens Study.

Start Date: Nov 80

Principal Investigator(s): Brian T. Nolan, MAJ, MC

Facility: USA MEDDAC, Ft Benning, GA

Dept/Svc: Surgery/Ophthalmology

Associate Investigators:

Key Words:

Accumulative MEDCASE Cost:

Est Accumulative Periodic Mar 86

OMA Cost: Review Results Continue

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens. Presently, the lenses used have been a Pannu Anterior/Posterior Chamber Lens, an IOLAB J-Loop Lens, the McGhan 34S Modified Sheet Lens and a Liteflex Lens. McGhan/3M models 30, 34S, and 77.

Number of subjects enrolled to date: 422
Number of subjects enrolled for reporting period: 61

Progress:
1. Introduction of UV absorbing lens implants which protect the retina from harmful UV irradiation.

2. Implementation of SITE TXR 2200 (MEDCASE purchase).

3. MAJ Brian T. Nolan has PCS'd. An amendment to add MAJ William C. Lloyd III, MC, as principal investigator has been prepared and will be presented to IRB at the next meeting.
### Study Objective
To determine whether smoking adversely affects successful completion of Infantry One Station Unit Training (OSUT).

### Technical Approach
Administrative questionnaires regarding smoking given to troops of Infantry One Station Unit Training (OSUT). These troops will be followed until the conclusion of OSUT.

### Number of subjects enrolled
- **Enrolled to date:** 1000
- **Enrolled for reporting period:** 0

### Progress
Data gathering for this project has been completed but analysis has been very slow due to the lack of adequate statistical support. The principal investigator has made arrangements with the University of Oklahoma to assist with data analysis.
Date: 6 Oct 86    Prot No.: 85-6    Status: Terminated
Title: Evaluating Communication Skills of Medical Students.

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<th>Principal Investigator(s)</th>
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<tr>
<td>Edward M. Friedler, MAJ, MC</td>
<td>MEDDAC, Ft Benning, GA</td>
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<th>Dept/Svc:</th>
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<tr>
<td>Family Practice</td>
<td>Perry Wolf, CPT, MSC</td>
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Key Words: Accumulative MEDCASE, Est Accumulative Periodic Review Results, OMA Cost:

Study Objective: 1) Observe specific communication behaviors of medical students at the beginning of their Family Medicine Clerkship; 2) present a structured experiential course on techniques of communication skills; 3) observe the students' specific communication behaviors after the course; 4) study the associations of student communication behaviors with their success in meeting the course objectives.

Technical Approach: Videotaping.

Number of subjects enrolled to date: 20
Number of subjects enrolled for reporting period: 0

Progress: This study is terminated at this MEDDAC due to the PCS of the associate investigator to Eisenhower Army Medical Center. The study will still be continued at Fort Belvoir by the principal investigator.

Start Date: Dec 1984

Principal Investigator(s): Theodore G. Brana, Jr., CPT, MC

Facility: USA MEDDAC, Ft Benning, GA

Dept/Svc: Family Practice

Associate Investigators:

Key Words:

Study Objective: To determine whether antepartum instruction in education (in the form of a "Child Safety Kit") will improve maternal knowledge of child safety practices as demonstrated by improvement in scores on a pre and post delivery test.

Technical Approach: The study group will consist of 400 primiparous mothers. In the 3-5 day postpartum period each mother will be given a questionnaire to determine their "baseline" knowledge in certain areas of child safety. Upon leaving the hospital, half of the new mothers will be given a "Child Safety Kit" according to an assigned random digit number in a sealed envelope. At the six week follow-up visit for her infant, each mother will be given the same questionnaire with addition of one subjective question about the kit's effectiveness.

Number of subjects enrolled to date: 227
Number of subjects enrolled for reporting period: 7

Progress: This study is now complete in that all questionnaires and safety kits have been given out and no more subjects will be added. Data from the pre and post hospital discharge questionnaires has been analyzed. Preliminary reports from the 53 questionnaires that passed internal consistency screens (27 receiving educational material 26 "controls" not receiving this material) indicate that both "control" (not receiving safety kits) and "experimental" (receiving safety kits) groups improved on post hospital questionnaires in knowledge of child safety as measured by test (questionnaires) scores; however, there was no significant difference between amount of improvement between control and experimental groups as measured by test scores. Assessment of biases and other factors contributing to these results is in progress as is the final paper documenting results of the study.
Knowing the Child's Gender Prior to Birth: Disentangling the Effect of Infant Cues and Parental Behavior on Sex Role Stereotyping.

Study Objective: Over the last decade numerous researchers have examined the process of sex role development and have theorized about the importance of biological versus environmental inputs as they affect sex role development. The present study attempted to better understand the effects of sex role socialization by reducing the effects of infant biological cues from this process. A sample of parents who learned the sex of their infant before birth, as additional information gained from prenatal ultrasonography, were compared with parents who did not have this prior knowledge. The purposes of this study were: 1) to investigate whether parents perceive their infants differently over the course of pregnancy; 2) to determine if there are differences in the ways that fathers and mothers view their infants; 3) to assess whether infants' gender affects parental perception of infants over the course of pregnancy; 4) to examine whether learning the infant's gender before birth affects parental stereotyping over the course of the pregnancy.

Technical Approach: Demographic data was gathered on 36 expectant couples: 12 couples did not have an ultrasound as part of their prenatal; 24 couples did have the ultrasound. Of these ultrasound couples, 12 couples learned their child's gender prior to birth, while 12 did not. Both ultrasound groups were asked to complete paper and pencil measures on three occasions. The first set of measures was given after the ultrasound, the second set was given after the ultrasound, and the third set was administered after the birth of their baby. The instruments used measured parental sex role attitudes and perceptions of their child. Apgar scores and birth weights were also obtained on the newborns. Data was analyzed using descriptive statistics, t-tests, and four-way repeated measures analysis of variance.

Number of subjects enrolled to date: 36 (72 subjects).
Number of subjects enrolled for reporting period: 0

Progress: The study indicated little difference between couples solely on the basis of knowing or not knowing the infants' gender before birth. The results indicate that the time at which measurements were taken had a greater effect on parental perceptions of their infants than did prior knowledge of gender.
There were some indications that mothers and fathers viewed their infants differently. Another finding was the trend for parents' perceptions of their infant to be sex-typed; throughout the pregnancy boys were consistently described as larger, bigger, more excitable, more coordinated, more alert, and noisier than girls.
Study Objective: This study is an attempt to identify the expectations to provide care and the patient care skills of residents from Internal Medicine, Pediatrics and Family Practice.

Technical Approach: The study consists of a one-time survey evaluating desire and expectations to care for certain age groups, perceived ability to care for certain health problems within these age groups and perceived need for certain patient care skills and their ability at these same skills. The subject population consists of all Internal Medicine, Pediatric and Family Practice residents in US Army training programs.

Number of subjects enrolled to date: 40-50 in each study group.

Progress: A questionnaire was sent to all Internal Medicine, Family Practice, and Pediatric training programs in the US Army. The questionnaires were sent out in October - November 1985 and returned December 1985 to February 1986. Each questionnaire was screened for usability and logged into a self-designed data summation sheet. Lack of time due to clinical and family duties have stalled progress from this point.
Study Objective: Breastfeeding is recommended as the best mode of infant feeding. The Special Food Supplemental Program for Women, Infants, and Children (WIC) is currently encouraging breastfeeding, but these women breastfed less often and for shorter durations than the general U.S. population. Termination of breastfeeding usually occurred earlier than planned and within the first month. Breastfeeding duration rose significantly when routine postpartum instruction was frequent throughout the entire lactation experience. Studies using populations consisting primarily of upper- and middle-income women demonstrated that breastfeeding persistence can be influenced by feeding practices adopted by friends and that peer and family member attitudes toward breastfeeding can influence the duration of breastfeeding. Low income populations. The primary purpose of this study was to determine if these attitudes and support systems were associated with continued or early termination of breastfeeding.

Technical Approach: All primigravidae enrolled in the WIC Program who indicated a desire to breastfeed were studied. A preliminary questionnaire was administered before delivery to determine demographics pertinent to the study. A second questionnaire was administered when the mother terminated breastfeeding or at 3 months postpartum, whichever occurred first.

Number of subjects enrolled to date: 46

Progress: Low income, breastfeeding, primiparous women in a military community were interviewed with three months postpartum and then contacted bimonthly to determine continued breastfeeding. A second interview was conducted upon termination of breastfeeding to ascertain family member and peer attitudes toward breastfeeding, as well as the social or postpartum support available to them. Average breastfeeding duration was 20 weeks. Women breastfeeding less than 20 weeks terminated earlier than planned and did not participate in WIC during the breastfeeding experience. Fifty-eight percent of the women claimed to like or enjoy breastfeeding. Ninety-eight percent of the husbands, 83 percent of the women's mothers, and 81 percent of the women's best friends had positive attitudes toward breastfeeding. There were no correlations between duration of breastfeeding and any of the significant others' attitudes regarding
breastfeeding. The more breastfeeding friends the women had, the longer the breastfeeding duration of the subject \((r=0.32, p<0.05)\). There was an increase, but not a significant one \((p=0.059)\), in breastfeeding duration when an outside source of help was available during the first 2 weeks postpartum. There was no correlation \((r=-0.02)\) between this person's attitude regarding breastfeeding and breastfeeding duration.

Termination or continuance of breastfeeding was not due to negative or positive attitudes regarding breastfeeding perceived from family members and peers, but may have been due to the availability of role models and postpartum help in the home.
Title: A Phenomenological Study of Patients Receiving Initial Chemotherapy for Carcinoma of the Lung.

Start Date: Oct 85 Est Comp Date: Jun 87

Principal Investigator(s): Nancy Penaskovic
Facility: USA MEDDAC, Ft. Benning, GA

Dept/Svc: Auburn University
Associate Investigators: Nancy Oliver, RN

Key Words: Accumulative MEDCASE - Est Accumulative Periodic Review
OMA Cost: Results

Study Objective: The purpose of this study is to explore the patients' experience while receiving chemotherapy in order to:

a. Develop a more thorough knowledge base to understand how chemotherapy affects patients;

b. analyze the data to generate implications for improvement in the quality of care given to chemotherapy patients;

c. develop a conceptual analysis of the perceptive world of patients receiving chemotherapy; and

d. to suggest avenues for further research.

Technical Approach: Four male subjects with a known diagnosis of carcinoma of the lung between the ages of 45-78 will be selected in conjunction with the treating physician and will be interviewed before their therapy is begun, during the course of their chemotherapy, and at subsequent follow-up visits at the physician's office. The interaction with the patient will be taped with permission of the subject.

Number of subjects enrolled to date: 2

Progress: There is at least one more interview scheduled for one patient. The other patient expired after six months of interviews. The principal investigator hopes to collect data on at least two more patients.
**Detail Summary Sheet**

**Date:** 6 Oct 86  
**Prot No.:** 86-18  
**Status:** Ongoing

**Title:** Efficacy of Postpartum Uterine Exploration and Curretage.

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<td>USA MEDDAC, Ft Benning, GA</td>
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<td>John P. Fogarty, MD, LTC, MC</td>
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<td>Key Words:</td>
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<td>Postpartum, Exploration, Curretage</td>
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**Accumulative MEDCASE**  
**Est Accumulative OMA Cost:**  
**Periodic Review Results**

**Study Objective:** The study objective is to determine if it is necessary to explore and/or curretage postpartum uterine in uncomplicated vaginal deliveries.

**Technical Approach:** A questionnaire to be filled out by both nurse and physician will be placed in the charts of all vaginal deliveries done at Martin Army Community Hospital. The principal investigator and postpartum nurses will then follow-up all vaginally delivered patients for a period of 10 days to establish the incidence of postpartum hemorrhage and endometritis. Assessment of these entities will be done by means of attached data sheet, CBC, temperatures, antibiotics, and blood administration. Endometritis will be assessed by means of the fever index and bleeding by means of hematocrits and the lochia scale. Additionally, all women who underwent exploration and/or curretage will be given a questionnaire about this procedure prior to discharge.

**Number of subjects enrolled to date:** 90

**Progress:** Data collection still in progress. A quick review shows no statistical difference in the bleeding and infection between patients with exploratory curretage vs patients without the procedure.
Title: Health Risk Appraisal of Early Adolescents.

Study Objective: To identify the areas of increased biophysical and behavioral health risks in the study population.

Technical Approach: A two component Health Risk Appraisal questionnaire will be administered to eighth grade students at Faith School and ninth grade students at Spencer High School.

Number of subjects enrolled to date: 540

Progress: There will be one more school surveyed before the results of the questionnaire will be analyzed.
**Title:** A Randomized, Controlled Trial of Initially Treated Corneal Abrasions: Physician Mandated Every 24 Hours Follow-Up Versus Patient Initiated (PRN) Follow-Up.

**Start Date:** Jul 86  
**Est Comp Date:** Dec 86

**Principal Investigator(s):**  
Ted D. Epperly, MD, CPT, MC

**Facility:**  
USAMEDDAC, Ft Benning, GA

**Associate Investigators:**  
Mark A. Connelly, MD, CPT, MC  
Steven E. Reissman, DO, CPT, MC  
Frank Celestino, MD, Bowman Gray School of Med, Winston Salem, SC

**Study Objective:** To determine if patients need to be checked on a daily basis for healing of their corneal abrasion versus a PRN approach to follow-up if symptoms/signs develop.

**Technical Approach:** This study will be a randomized, prospective controlled trial involving patients with uncomplicated corneal abrasions. A full eye exam will be done on all patients and all patients will then be treated in a standardized fashion. Patients will then be randomized into two groups for follow-up: Group 1 will receive daily follow-up and reexamination until healing is documented (negative fluorescein) and symptoms are gone. Group 2 will be instructed to leave patch on for 36 hours and then remove. Upon patch removal, follow-up will be PRN and patient-initiated based on the patient's perception of persistent bothersome symptoms. Data will be analyzed using the chi-squared methodology for dichotomous variables. The measured outcome variables will be number of re-visits, complications, and days of symptoms in each group.

**Progress:** This study has not yet been started due to time constraints.
Date: 6 Oct 86  Prot No.: 86-27  Status: Ongoing
Title: The Effect of the Internship of Fitness

Start Date: Jun 86  Est Comp Date: Jul 87
Principal Investigator(s)  Facility:
John M. Henderson, DO, CPT, MC  USAMEDDAC, Ft Benning, GA
Dept/Svc:  Associate Investigators:
Family Practice
Key Words:

Accumulative MEDCASE  Est Accumulative Periodic
Cost:  OMA Cost:  Review Results

Study Objective: To assess a change in physiologic parameters during the internship year.

Technical Approach:

1. Assess several parameters of fitness prior to beginning duty in the PGY-1, prior to 1 July 1986.

2. Reassess these parameters 6 months into the PGY-1, and again 12 months into the PGY-1.

3. Compare each individual's performance against their earlier findings, against their confreres and against an age-matched national mean for the Army and the general civilian population.

Number of subjects enrolled to date: 9

Progress: Data collection is in progress.
Title: Intraocular Lens Study.

Start Date: Oct 81
Est Comp Date:

Principal Investigator(s):
John A. McCubbin, M.D., MAJ, MC

Facility:
USA MEDDAC, Ft Campbell, KY

Dept/Svc:
Surgery/Ophthalmology

Associate Investigators:

Key Words:
Accumulative MEDCASE
Est Accumulative
Cost:
OMA Cost:
Periodic
Review Results

Study Objective: To provide to cataract patients the latest development in ophthalmic surgery concerning the correction of surgical aphakia.

Technical Approach: Intracapsular or extracapsular cataract extraction followed by the implantation of an anterior chamber lens.

Cost per lens: $360 each.

Subjects enrolled to date: 107
Subjects enrolled for the reporting period: 44

Progress: No serious complications.
Detail Summary Sheet

Date: 16 Oct 86   Prot No.: 85-32   Status: Terminate
Title: Histoplasmosis Seroconversion Study.

Start Date: Sep 85   Est Comp Date: Dec 85
Principal Investigator(s):
Mark J. Wolcott, CPT, MS
Facility:
USA MEDDAC, Ft Campbell, KY
Dept/Svc:
Pathology
Associate Investigators:

Key Words:

Accumulative MEDCASE Cost: Est Accumulative OMA Cost: Periodic Review Results

Study Objective: To determine a seroconversion rate and time frame for histoplasmosis on newly arrived military personnel into the Ft Campbell, KY area.

Technical Approach: On 9 Sep 85 the project was started with the collection of blood samples from volunteer personnel that were inprocessing through the replacement detachment. A total of 84 personnel volunteered but two withdrew before an adequate specimen was obtained leaving 82 personnel for the project.

Summary of experimental design: a sample of newly arrived personnel into Ft Campbell are sampled for a blood specimen upon arrival, one month and two months later. The serum antibody levels to IgM, IgG and IgE will be measured to determine a rate of seroconversion and type of antibody response to exposure to histoplasmosis. The test procedure will be an EIA (ELISA) type test.

Manpower: CPT Mark Wolcott
Funding: 2660 supply money not expected to exceed $30.00.
Number of subjects enrolled to date: 82.
Number of subjects enrolled for reporting period: 
Nature of adverse reactions: one volunteer fainted during initial blood collection and was not further enrolled.

Progress: Terminate, unable to obtain report from investigator.
Date: 16 Oct 86 Prot No.: 86-7 Status: Completed
Title: A Comparative Study of Fetal Movement Perceptions in the Third Trimester of Multiparous and Primiparous Patients.
Start Date: Dec 85 Est Comp Date:

Principal Investigator(s) Facility:
Karen T. Ferguson, AN USA MEDDAC, Ft Campbell, KY
Dept/Svc: Associate Investigators:
Obstetrics-Gynecology Laurie Davis, MAJ, AN

Key Words:

Accumulative MEDCASE Est Accumulative Periodic
Cost: OMA Cost: Review Results

Study Objective: To compare the fetal movement perceptions of multigravidas and primigravidas at 32 weeks of gestation through the 36th week, determine when in gestation (32 weeks or later) patients are most apt to comply with keeping a written record of fetal movement, and determine if there is a time (morning or evening) that the fetus is more active.

Technical Approach: The subjects were given oral and written instructions on how to keep The Daily Fetal Movement Record. The instructions included: count the number of fetal movements for one hour in the morning, annotate the time started and completed, and the total number of fetal movements; count the number of fetal movements for one hour in the evening and record the time started and time completed, and total number of fetal movements on the form provided. Subjects were instructed to bring the Record to each prenatal appointment through the 36th week of gestation. Data was be analyzed using the chi-square and t-test statistic as appropriate. The PI made all evaluations.

Number of subjects enrolled in study: 61

Progress: There were no significant differences in perceptions of multigravidas and primigravidas at 32 weeks of gestation. There were no statistically significant differences of fetal movement perceptions between primigravidas and multigravidas at 36 weeks of gestation. There were no statistically significant differences in compliance of keeping a written record of fetal movements between primigravidas and multigravidas. Further study should be conducted to determine if use, earlier than 32 weeks of gestation, of the Daily Fetal Movement Record would make a difference in maternal subjective perceptions of primigravidas and multigravidas. Research on different types of population such as: women of different ethnic, cultural, socioeconomic backgrounds and high risk groups could be conducted to determine if findings would be the same as in this study. Replication of this study with a larger sample size to ascertain the generalizability of compliance would be advisable. More descriptive research is needed to determine if variation of lifestyle and periods of fetal activity are related. An experimental design could be implemented to study whether women using fetal movement counting as an indicator of fetal well-being would positively influence neonatal outcome.
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<td><strong>Principal Investigator(s):</strong></td>
<td>Milne, Henry L, M.D., MAJ, MC</td>
<td><strong>Facility:</strong></td>
<td>USA MEDDAC, Ft Jackson, SC</td>
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<td><strong>Associate Investigators:</strong></td>
<td>Dean Jacobs, M.D., MAJ, MC</td>
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**Study Objective:** Insertion in selected patients of Tennant Anterior Chamber Anchor Lens.

**Technical Approach:** Using routine intracapsular cataract techniques, the lens would be inserted prior to final closure of the wound.

**Subjects enrolled to date:** 448

**Subjects enrolled for reporting period:** 145

**Progress:** Retinal detachments - 3, vitreous hemorrhage - 1, recalcitrant CME CME - 1, and 2 wound leaks.
**Title:** Sudden Death in Young Adults With Unrecognized Heart Disease.

**Start Date:** Feb 85

**Principal Investigator(s)**
- Wesley Covitz, MD
- Albert C. Molnar, MD, COL, MC

**Facility:**
- USA MEDDAC, Ft Jackson, SC
- Medical College of Georgia

**Dept/Svc:**
- Pediatric Cardiology

**Associate Investigators:**
- E.J. Lovett, MAJ, MC

**Key Words:** Chest pain, Cardiac disease, Screening program

**Study Objective:**
1. To identify basic trainees with chest pain who are at risk for sudden death due to previously unrecognized cardiac disease;
2. To determine which elements of history, physical examination, and noninvasive laboratory evaluation are most likely to identify those who are at risk; and
3. To develop a sensitive screening program which may be practically applied to basic trainees and high school and college athletes.

**Technical Approach:**
Basic trainees who sought medical attention for chest pain were systematically evaluated to detect heart disease and identify risk factors. Subjects were drawn from a potential population of 14,000 trainees. They were equally divided by sex and race. Their mean age was 21 ± 3.8 years. The evaluation consisted of a brief screening exam (phase I), a comprehensive history and physical (phase II) and echocardiography and exercise radionuclide ventriculography (phase III). No funding has been received from the Army for this project. There were no adverse side effects.

Number of subjects enrolled to date: 218.
Number of subjects enrolled for reporting period: 0.

Progress: Study terminated because funds were not available.

Study Objective: To examine the relationship of patterns of feminine characteristics, self concept, perceived success in the mothering role and gender role identity from the second trimester of pregnancy to six weeks postpartum.

Technical Approach: The repeated measures survey design remains unchanged. Potential participants are contacted in a variety of prenatal settings. Subjects complete a packet of questionnaires during early pregnancy, the last trimester and at one month postpartum and six months postpartum. Home interviews at seven months postpartum are completed with those participants willing to do so. Funding for the second year of this three-year project was approved for September 15, 1986 to September 14, 1987 by the National Center for Nursing Research, PHS, DHHS. An initial sample of 140 participants has been obtained from all data collection sites since October 1985. Approximately 35 have been obtained from the Fort Jackson, SC prenatal clinic. No significant adverse reactions have been noted related to participation in this study.

Progress: As noted above, 140 participants have been obtained from all data collection sites since October 1985 with 35 from Fort Jackson, SC prenatal clinic. Initial data collection will be discontinued at the end of October 1986. Therefore, it will not be necessary to contact potential participants at data collection sites after that date. Questionnaire packets will continue to be mailed to participants during the third trimester, at one month postpartum and at six months postpartum for each participant as they progress through the prenatal and postpartum periods.

Nine 6-month home interviews have been completed. We will continue to ask all participants to consent to a home interview to collect qualitative data regarding pregnancy, birth, and postpartum experiences and feelings. It is expected that data collection by most participants will be completed by October 1987.

All data are coded and entered into the computer as received. It is anticipated analysis of initial and demographic data will begin in December 1986. Data analysis to test research hypotheses will begin when data collection is complete (October 1987).
Title: Relationship of Health Status Beliefs of Active Duty U.S. Army Personnel and the Non-Emergent Use of the Emergency Department.

Study Objective: To determine the relationship between the health status beliefs and general health self-concept of active military members and the non-emergent use of the Emergency Department.

Technical Approach: A demographic questionnaire that was developed by the investigator was completed by each subject. The information obtained included: age, sex, race, rank, time in service, residence as on or off post. Additional background information necessary for the study was collected concerning where health care was normally obtained, when the last time health care was needed, where that care was obtained, and what was the previous problem. This information completed the background variables which make up the elements of client singularity as proposed by the study conceptual framework.

Number of subjects enrolled: 100

Progress: This study was unable to show a relationship between the health status beliefs and health self concept and a patient's decision to seek non-emergent health care in the emergency department. This lack of findings in itself reconfirms numerous other studies which have attempted, but have been unable to successfully identify factors which influence the decision to seek health care. The frequent and disproportionate use of health care facilities by some active duty military members verifies a common held belief among military health care providers that such a problem does exist.
Date: 22 Sep 86  Prot No.: 78-14  Status: Terminated
Title: Intraocular Lens Study.

Start Date:  
Est Comp Date:  
Principal Investigator(s)  
Peter D. Fries, M.D., CPT, MC  
Facility:  
USA MEDDAC, Ft McClellan, AL  
Dept/Svc:  
Surgery/Ophthalmology  
Associate Investigators:  
Key Words:  
Accumulative MEDCASE  
Est Accumulative Periodic  
Cost:  
OMA Cost:  
Review Results  
Study Objective: Insertion in selected patients of intraocular lenses.

Technical Approach:
Number of subjects enrolled: 0

Progress: Investigator PCS'd, no replacement is anticipated. Study is terminated at Ft McClellan.
**Detail Summary Sheet**

**Date:** 9 Oct 86  
**Prot No.:** 78-14  
**Status:** Ongoing

**Title:** Intraocular Lens Study.

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<th>Oct 80</th>
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<tr>
<td><strong>Principal Investigator(s):</strong></td>
<td>William G. Carey, M.D., MAJ, MC</td>
<td>Facility: USA MEDDAC, Ft Rucker, AL</td>
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**Key Words:**
- Intraocular Lens
- Aphakia
- Implant
- Surgery
- Ophthalmology

**Accumulative MEDCASE Cost:**

**Est Accumulative OMA Cost:**

**Periodic Review Results**

**Study Objective:** The objective of the ongoing FDA study is to determine the safety of the intraocular lens implant in the human eye.

**Technical Approach:** In all primary implants during this period, the extracapsular cataract approach was used. A style 20 posterior chamber lens manufactured by Surgidev Corporation was placed in the posterior chamber. In all secondary implants, the style 10 anterior chamber lens, by Surgidev Corporation, was used.

**Subjects enrolled to date:** 335  
**Subjects enrolled for reporting period:** 69

**Progress:** No serious complications.
Date: 16 Oct 86 Prot No.: 78-14 Status: Ongoing
Title: Intraocular Lens Study.

Start Date: Nov 84
Est Comp Date:

Principal Investigator(s):
Charles S. Tressler, MD, CPT, MC

Facility:
USA MEDDAC, Ft Stewart, GA

Dept/Svc:
Surgery/Ophthalmology

Associate Investigators:

Key Words:
Accumulative MEDCASE Est Accumulative Periodic
Cost: OMA Cost: Review Results

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens.

Number of subjects enrolled to date: 22
Number of subjects enrolled for reporting period: 8

Progress: No serious complications.
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