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BIOMEDICAL TECHNOLOGY TRANSFER

Applications of NASA Science and Technology

Submitted by
STANFORD UNIVERSITY SCHOOL OF MEDICINE
CARDIOLOGY DIVISION

Prepared for
National Aeronautics and Space Administration
Technology Utilization Division
Washington, D.C. 20546

STANFORD UNIVERSITY BIOMEDICAL APPLICATION TEAM

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SEMI-ANNUAL REPORT

NASA Technology Utilization

Cooperative Agreement No. NCC-2-52

PREFACE

This report covers the activities of the Stanford University Biomedical Application Team for the period of 1 January through 30 June, 1980.

The work reported herein was performed at Stanford University under the direction of Donald C. Harrison, M.D. Gary L. Steinman replaced Gene V. Schmidt, M.D. as full-time Assistant Director during the period covered by this report. The Assistant Director and Luke F. Brennan provided full-time project management and biomedical engineering support. Additional engineering support was provided by part-time consultants Robert J. Debs and Robert R. Zimmerman. Marilyn P. Anderson was full-time team secretary, and Harry A. Miller and his staff provided part-time administrative support. The Team was assisted from time to time by various members of the Stanford University staff.

The Stanford University Biomedical Application Team was supported by the National Aeronautics and Space Administration (NASA) under cooperative agreement #NCC 2-52 and was monitored for NASA by Harold Sandler, M.D., Chief of the Biomedical Research Division, Ames Research Center.

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1. INTRODUCTION

During the first six months of 1980 the Stanford University Biomedical Application Team has made substantial progress in applying NASA technology and expertise to the solution of significant biomedical engineering problems.

Sixteen ongoing transfer projects are summarized in section 2 of this report. Each project addresses an important medical problem, incorporates unique NASA technology, and requires a multidisciplinary effort. Each has significant commercial or institutional transfer potential. Fifteen of the sixteen projects have been supported directly by NASA funding or have been approved for NASA funding. All the projects have received non-NASA support either through formal co-funding or cost sharing arrangements or through less formal contributions of time, facilities, or materials.

Six potential transfer projects are described in section 3. These potential projects are in the early stages of problem identification, technology identification, market analysis, or RTOP preparation.

Two previously-studied potential transfer projects have been dropped from consideration. A project to design and construct a Respiratory Therapy Negative Pressure Chamber for treatment of pediatric leukemia patients with severely compromised pulmonary function has not been pursued due to lack of widespread interest in the treatment method. A project to design and construct a Multifunction Interface for Rehabilitative Aids has not been pursued due to the lack of suitable fabrication standards for the construction of rehabilitative aids. The interface problem will be reexamined at such time that suitable standards are adopted by the rehabilitative aid industry.

Two previously-studied potential transfer projects, Improved Battery for Neonatal Transport System and Adult Critical Care Transport System, have been combined to form a single potential transfer project: Critical Care Transport System.

In addition to its project related work, the Stanford University Biomedical Application Team responds to requests for assistance, engages in program development activities, and calls or participates in professional conferences and meetings. Activities which fall into these categories are too numerous to report here. A listing of major meetings, conferences, and travel activities is given in section 4 to indicate the diversity of Team pursuits.

The twenty-two ongoing and potential projects of Sections 2 and 3 are classified in respect to funding and activity status in the Appendix.

2. ONGOING TRANSFER PROJECTS

Intracranial Pressure Monitoring
Versatile Portable Speech Prosthesis
Cardiovascular Magnetic Measurements
Improved EMG Biotelemetry for Pediatrics
Ultrasonic Kidney Stone Disintegration
Pediatric Roentgen Densitiometry
X-ray Spatial Frequency Multiplexing
Mechanical Impedance Determination of Bone Strength
Visual-to-Tactile Mobility Aid for the Blind
Purkinje Image Eyetracker and Stabilized Photocoagulator
Neurological Applications of NASA-SRI Eyetracker
ICU Synthesized Speech Alarm
NANOPHOR: Microelectrophoresis Instrument
WRISTCOM: Tactile Communication System for the Deaf-Blind
Medical Applications of NASA Liquid-Circulating Garments
Hip prostheis with Biotelemetry

2.1 INTRACRANIAL PRESSURE MONITORING SYSTEM

BATeam Personnel: Gene V. Schmidt, M.D.; Gary L. Steinman

Problem: Neurosurgery patients suffering from head trauma, brain tumor, cerebral infection, or hydrocephalus frequently have increased intracranial pressure (ICP). Optimal management of these patients requires continuous and accurate monitoring of ICP. Presently available ICP monitoring systems have one or more of the following problems which detract from their usefulness: *(i)* Highly invasive procedures are required for their installation or use. *(ii)* Data transmission between transducer and recording device and/or power transmission to the transducer require transcutaneous transmission lines which also provide a potential pathway for infectious organisms. *(iii)* Only intermittent pressure readings can be made. *(iv)* The accuracy of measurements deteriorates over periods of days to weeks due to transducer instability.

Solution: Epidural pressure monitoring offers the least invasive and safest approach known for measuring ICP. An epidural ICP monitoring system which incorporates a capacitive pressure transducer for stability and a telemetry system for continuous transmission of both pressure data and power could provide the safety and reliability required for optimal management of selected neurosurgery patients.

NASA Technology: An ICP monitoring system designed by a NASA engineer incorporates both a capacitive pressure transducer developed by NASA for wind tunnel tests of experimental aircraft and NASA expertise in miniature biotelemetry developed for the Space Program.

Principals: Thomas B. Fryer, Electronic Instruments Development Branch, NASA-Ames Research Center
Gerald D. Silverberg, M.D.; Assoc. Professor of Neurosurgery; Stanford University; Stanford, CA
Allen K. Ream, M.D.; Assoc. Professor of Anesthesia; Stanford University; Stanford, CA
Steven D. Corbin, Ph.D.; Consultant to the Cardiology Div.; Stanford University, Stanford, CA

Cost to NASA: $26K in FY77; $58K in FY78.

Cost Sharing: Konigsberg Instruments, Inc. provided $25K cost sharing in connection with the fabrication of several prototype ICP units. The cost of preclinical and clinical evaluations of these units, for which there is no separate accounting, was borne by Stanford University Medical School's Anesthesia and Neurosurgery Departments. Pacesetter Systems, Inc., Sylmar, California, has provided $447K cost sharing to-date in connection with the design and fabrication of an improved ICP monitor under a current contract with Stanford University. Pacesetter expects to bear additional costs in the future.

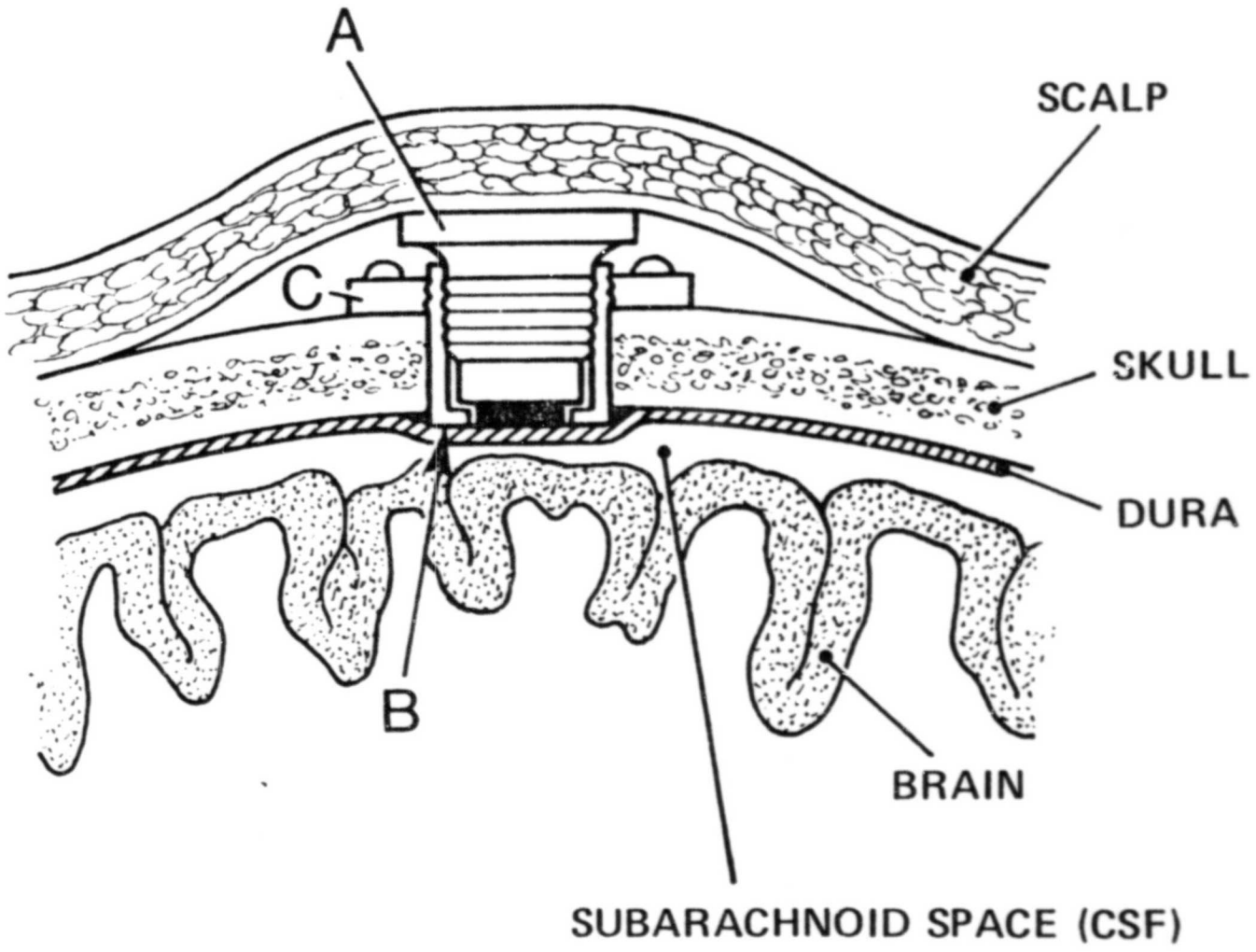
Transfer Strategy: Pacesetter Systems, Inc. has obtained a non-exclusive license from NASA and is under contract to the Stanford BATeam to develop a commercial system for routine clinical use. Plans have been made to evaluate the Pacesetter system which, if suitable for routine clinical use, will be marketed. Cordis Corporation, Miami, Florida, has also been granted a non-exclusive license by NASA and has received full documentation of the ICP monitoring system from the Stanford BATeam. Becton-Dickinson, Rutherford, New Jersey, has been in contact with the BATeam concerning their interest in commercializing the ICP monitoring system.

Status: Dr. Silverberg has submitted a paper for publication in Contemporary Neurosurgery which outlines the role of ICP monitoring in neurosurgery and which describes the relative merits of the epidural measurement approach. Pacesetter Systems, Inc. has reported substantial progress in improving the stability and reliability of the prototype ICP monitoring system.

Action: Pacesetter prototype is scheduled for delivery in November 1980. Bench and animal testing is to be completed by April 1981. Dr. Silverberg will begin clinical evaluation in mid-1981. The system will be distributed to selected institutions for further clinical evaluation when Silverberg's clinical studies are complete.

INTRACRANIAL PRESSURE MONITORING

- RELIABLE CONTINUOUS ICP MONITORING WITH MINIMAL RISK
- NASA CAPACITIVE PRESSURE TRANSDUCER & INDUCTIVELY POWERED IMPLANTABLE TELEMETRY TECHNOLOGIES
- OPTIMAL MANAGEMENT OF NEUROSURGICAL PATIENTS



2.2 VERSATILE PORTABLE SPEECH PROSTHESIS (VPSP)

BATeam Personnel: Luke F. Brennan; Gene V. Schmidt, M.D.; and Gary L. Steinman

Problem: Approximately 1.5 million non-vocal people who suffer from cerebral palsy, multiple sclerosis, Parkinson's disease, muscular dystrophy, residual aphasia from stroke, or cancer of the larynx live in the United States. Many of these people are unable to use their hands for writing, typing, or sign language and, therefore, have no effective means of communication. They need an effective communication aid for educational, vocational, and social purposes.

Solution: VPSP is a wheelchair-mounted communication aid for use by non-ambulatory, non-vocal persons which employs a user-operated, microcomputer-driven speech synthesizer. Speech is developed by a text-to-phoneme algorithm (synthesis by rule) rather than by reference to prestored phonemes (synthesis by concatenation) with the result that an unlimited vocabulary is available. Input systems have been designed which meet the needs of persons with varying degrees of motor control and messages can be constructed by reference to prestored or user-created vocabulary menus or by direct input of user-created text.

(See Section 3.1 for description of project to design and fabricate a Person-Portable Versatile Speech Prosthesis for use by ambulatory non-vocal persons.)

NASA Technology: VPSP makes extensive use of speech synthesis systems technology developed within the Man-Vehicle Systems Research Division of the NASA-Ames Research Center. The NASA speech technology, developed by Carol Simpson, Ph.D., consists of a powerful message editing software package and a system of phonetic contectual and intonation rules. This system is being used to produce efficient hierarchical language acquisition performance and maximal intelligibility.

Principals: Carol A. Simpson, Ph.D.; Psycho-Linguistic Research Associates; Menlo Park, CA
Charles Lingel, Electrical Engineering Consultant, Los Gatos, CA
Maurice A. LeBlanc, MSME; Director, Rehabilitation Engineering Center, Children's Hospital at Stanford (CH@S), Palo Alto, CA.

Cost to NASA: $20K in FY79; $40K in FY80

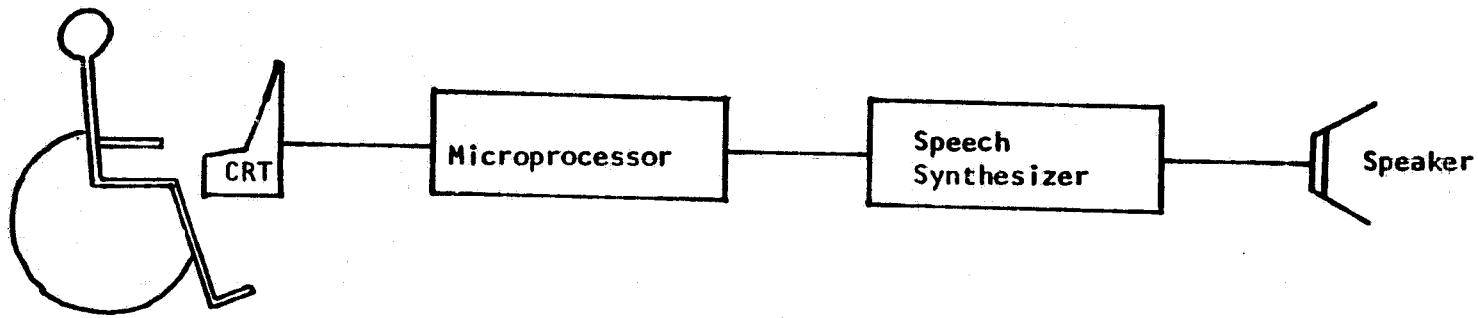
Cost Sharing: Several manufacturers, institutions, and consultants have supported the project by contributing a total of $45.7K in materials, services, and funds. This amount includes $4K in NIHR funding through CH@S, $13K for two M-L speech synthesizers from VOTRAX, $2.2K in materials from H-C Electronics, $15K in software from UCLA, and $11.5K in professional services. In addition, CH@S has borne costs in connection with demonstrating and evaluating the VPSP, which costs have not been accounted for separately.

Transfer Strategy: The VPSP group, including the Stanford University BATeam and the project principals, held a commercial demonstration of VPSP on May 28, 1980. A Request for Proposal (RFP) was issued at the demonstration to solicit new product development proposals from potential manufacturers. The group will select a manufacturer to commercialize VPSP based on the responses to the RFP and manufacturer commitment to the project.

Status: User testing has demonstrated the usability and intelligibility of the VPSP demonstration prototype. Throughout the reporting period, VPSP has received significant unsolicited "PR": *(i)* an article in the San Jose Mercury News, *(ii)* a one-half hour interview on Coast to Coast, a nationally syndicated TV show, and *(iii)* a BBC television news interview at the West Coast Computer Fair. Also, The VPSP team has produced a commercial quality video tape which has been widely distributed. The team is currently waiting for responses to the RFP which was distributed to interested manufacturers at the May 28th VPSP commercial demonstration.

Action: The VPSP team will select a manufacturer to proceed with commercial production after responses to its RFP, due July 1, 1980, have been received. A design and production schedule, including acceptance testing by the VPSP team, will be negotiated with the selected manufacturer and implemented. The BATeam will arrange a multi-facility VPSP evaluation program to validate the usefulness of the communication aid.

VERSATILE PORTABLE SPEECH PROSTHESIS



- WHEELCHAIR-MOUNTED COMMUNICATION AID FOR NON-VOCAL PEOPLE.
- NASA SYNTHESIZED SPEECH TECHNOLOGY AND EXPERTISE.
- UNLIMITED VOCABULARY MADE POSSIBLE BY TEXT-TO-PHONEME RULES
- SYSTEM DESIGNED FOR USE BY PERSONS WITH VARYING DEGREES OF MOTOR CONTROL.

2.3 CARDIOVASCULAR MAGENTIC MEASUREMENTS

BATeam Personnel: Donald C. Harrison, M.D.; Gene V. Schmidt, M.D.; Robert J. Debs, Ph.D.; Gary L. Steinman

Problem: Better non-invasive diagnostic methods are needed in cardiology for mass screening for heart disease, for cardiographic study of the bundle of His signal and of cardiac depolarization in the presence of bundle branch block, and for measurement of cardiac output.

Solution: Magnetic measurement techniques hold promise for yielding useful clinical diagnostic information in these areas.

NASA Technology: Two NASA-developed technologies are integrated into the instrumentation which has been designed and fabricated for this project: superconducting quantum interference detectors (SQUIDs) for measuring weak magnetic fields in the presence of magnetic noise and a large non-superconducting coil system for generating highly uniform strong magnetic fields. NASA expertise in magnetic field measurements and signal processing are also utilized in this project.

Principals: Donald C. Harrison, M.D.; Chief of Cardiology; Stanford University; Stanford, CA
William M. Fairbank, Professor of Physics, Stanford University, Stanford, CA
Jerry C. Griffin, M.D.; Acting Asst. Professor of Medicine; Stanford University, Stanford, CA
Mark C. Leifer, Doctoral Candidate in Physics, Stanford University, Stanford, CA
Ernest J. Iufer, Ph.D.; Director, Magnetics Test Facility; NASA-Ames Research Center, Moffett Field, CA
Ronald Sylvester, M.D.; Professor of Medicine; University of Southern California, Los Angeles, CA

Cost to NASA: $50K in FY79; $100K in FY80.

Cost Sharing: The NIH Division of Heart and Vascular Diseases is cofunding this project in the following amounts: $58K in FY79, $64K in FY80, and $79K in FY81. Also Stanford University is providing $25K worth of electronic instrumentation and laboratory space for clinical trials in support of the project.

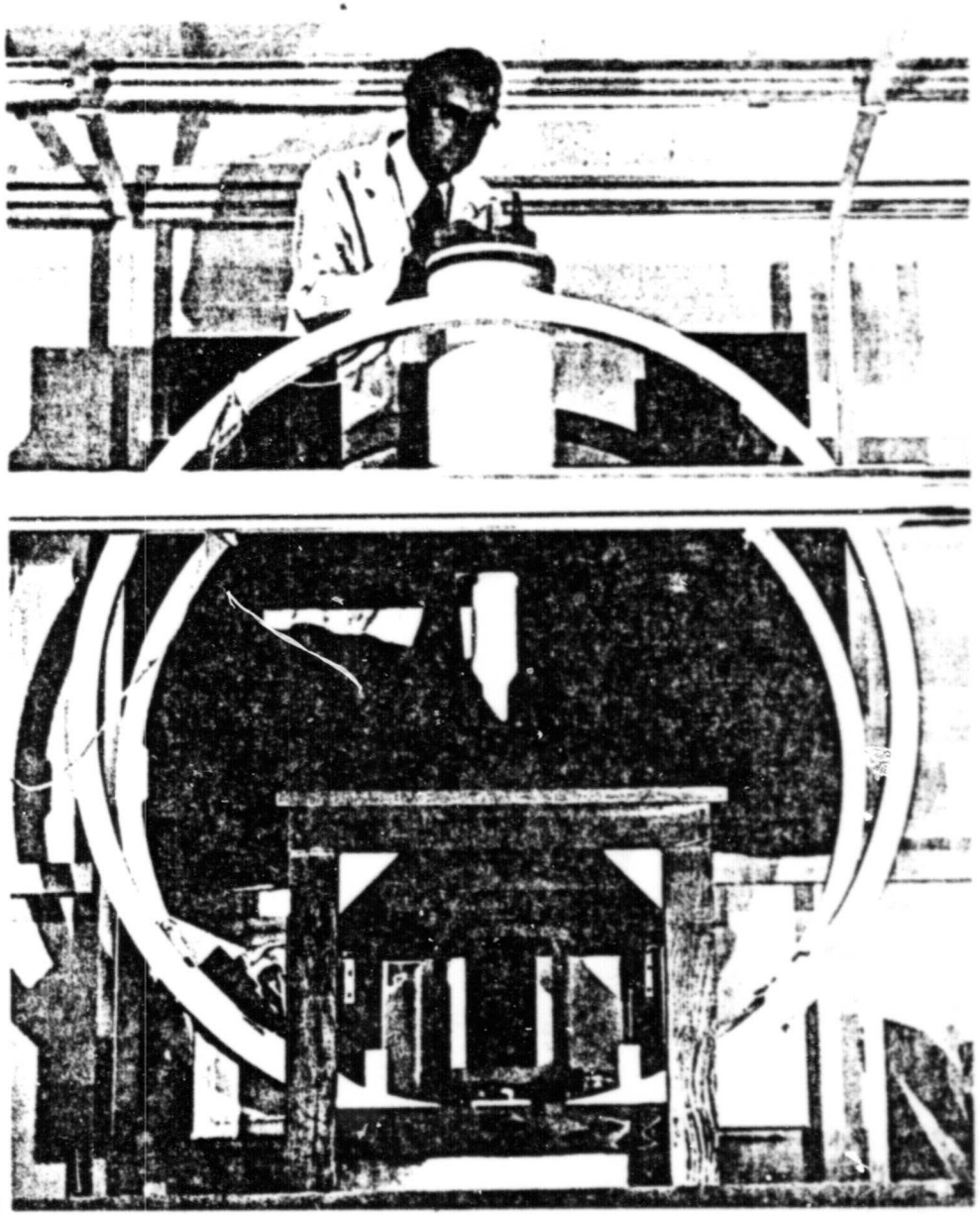
Transfer Strategy: This project involves an institutional transfer of unique NASA technology and expertise to enable Stanford University to carry on this important medical research.

Status: The SQUID, Apollo Coils, earth-field cancellation coils, and associated instrumentation have been received and assembled at Stanford. Signal averaging and filtering techniques have been implemented. Protocols have been developed for a series of animal and human studies. Leifer attended the 3rd Workshop on Biomagnetism, Berlin, Germany where on May 9, 1980, he delivered the paper: An Integrated System for Measurement of the MCG and Cardiac Output by Leifer, Griffin, Iufer, Fairbank, and Harrison. The paper was extremely well-received and sparked substantial interest among researchers who attended the workshop. A decision has been made to build a magnetocardiography room into the forthcoming Stanford University Medical Center Heart Center.

Action: Bundle of His studies on open-chested dogs are to begin in the Stanford magnetically-shielded "well" in early September. A modem will be purchased to establish a data-link with Vanderbilt University to facilitate use of special data analysis routines on Vanderbilt's high speed computer system. Selected Stanford patients will undergo magnetocardiographic studies to establish signal morphologies for specific disease states. Two Stanford cardiology fellows (MDs pursuing advanced study after having completed internship and residency) will be recruited to perform patient studies.

CARDIOVASCULAR MAGNETIC MEASUREMENTS

- NON-INVASIVE MAGNETOCARDIOGRAPHIC METHODS FOR DIAGNOSING HEART DISEASE AND MEASURING CARDIAC OUTPUT
- NASA SQUID TECHNOLOGY AND APOLLO MAGNETIC COILS
- NASA MAGNETIC MEASUREMENT AND SIGNAL PROCESSING EXPERTISE



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2.4 IMPROVED EMG BIOTELEMETRY FOR PEDIATRICS

BATeam Personnel: Luke F. Brennan

Problem: Children with cerebral palsy often develop severe gait abnormalities which make walking extremely difficult. The most appropriate therapy or orthotic device can be selected if the orthopedist's assessment of a patient's gait pattern is based on data which demonstrates the actual time sequence of muscle contraction in ambulation. An improved instrumentation system is needed to collect the required data.

Solution: A reliable EMG telemetry system which eliminates the need for cumbersome cables is needed. Such a system would include transmitter units to pick up and transmit EMG signals simultaneously from the several muscle groups involved in ambulation and a base station unit to receive and process the EMG signals. Maintenance of adequate received signal strength and channel separation in the presence of "noise" and transmitter motion has been a problem in previous attempts to develop such a system.

NASA Technology: In 1976 NASA-Ames Research Center developed discrete, crystal-controlled telemetry units for application in EMG gait analysis. These units, which have a flat frequency response from 20 to 2000 Hz and which have an operating range of about 15 meters, were incorporated into a six channel EMG telemetry system. An FY80 RTOP was funded to support necessary technical improvements in the existing transmitters.

Principals: Salvador A. Rositano, Ph.D.; Chief, Electro-Systems Engineering Branch; NASA-Ames Research Center
Richard M. Westbrook, Research Engineer, NASA-Ames Research Center
John Medeiros, Ph.D; Assistant Professor of Physical Therapy, Stanford University Medical School

Cost to NASA: $20K in FY76; $25K in FY80; $25K approved for FY81.

Cost Sharing: L&M Electronics, Daly City, California, has provided #30K in cost sharing. Children's Hospital at Stanford (CH@S) and Rancho Los Amigos Hospital (Downey, CA) have provided NIHR-funded

facilities and manpower in support clinical system evaluation. There is no separate accounting of the costs to these institutions.

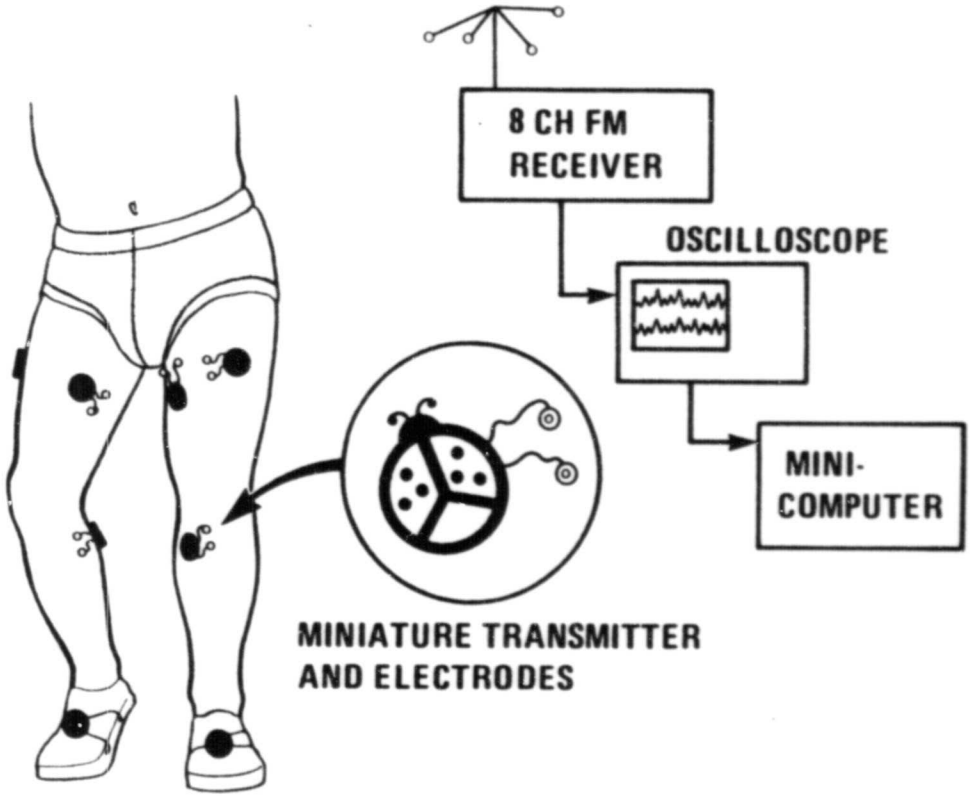
Transfer Strategy: L&M Electronics is working very closely with NASA-Ames in the development of the improved telemetry system. They will market the improved device.

Status: An improved antenna system is in place at the CH@S Gait Laboratory. A smaller, lighter transmitter, which uses a Li_2-Li_2O battery instead of a Ag_2O battery, has been designed and is in production. The receiver has been redesigned to include a common power supply for all six channels and thereby to reduce receiver cost and size.

Action: The BATeam will submit a proposal to NASA-Ames Research Center to release FY81 funds which have been approved for the next phase of this project: hybridization of transmitter circuitry. The objective of hybridization is to produce a highly reliable transmitter which is less than one-half the size of existing units and which consumes little power.

GAIT ANALYSIS BIOTELEMETRY

- GAIT ANALYSIS TO HELP CHILDREN WITH CEREBRAL PALSY WALK
- NASA DEVELOPED MINIATURE EMG SIGNAL TRANSMITTERS
- MULTIPLE CHANNEL TELEMETRY SYSTEM TO ELIMINATE CUMBERSOME CABLES



2.5 ULTRASONIC KIDNEY STONE DISINTEGRATION

BATeam Personnel: Gene Schmidt, M.D.; Gary L. Steinman

Problem: Approximately 40,000 patients per year undergo surgery for removal of kidney stones which have become firmly lodged in the ureter. Many major surgical procedures could be avoided and in excess of $100 million per year in medical costs alone could be saved if an effective nonsurgical technique were generally available.

Solution: A ureteral catheter containing a wire waveguide which is vibrated at 20 KHz (ultrasound frequency range) within seconds causes most kidney stones to crumble into small fragments. These fragments can be passed spontaneously. Inadequate maintenance of contact between waveguide and stone and premature waveguide failure due to fatigue have been major barriers to the successful implementation of this treatment strategy.

NASA Technology: NASA materials and mechanical engineering experts have recommended the use of fiberoptics to verify contact between waveguide and stone and the modification of the coupling between waveguide and ultrasonic power source to reduce time to waveguide failure. Improvements in the coupling mechanism are being made by NASA mechanical engineering experts at NASA-Goddard Space Flight Center (GSFC).

Principals: Roger B. Goodfriend, M.D., F.A.S.C.; Clinical Instructor of Urology; Stanford University.

Cost to NASA: $40K in FY80 (FY79 funds).

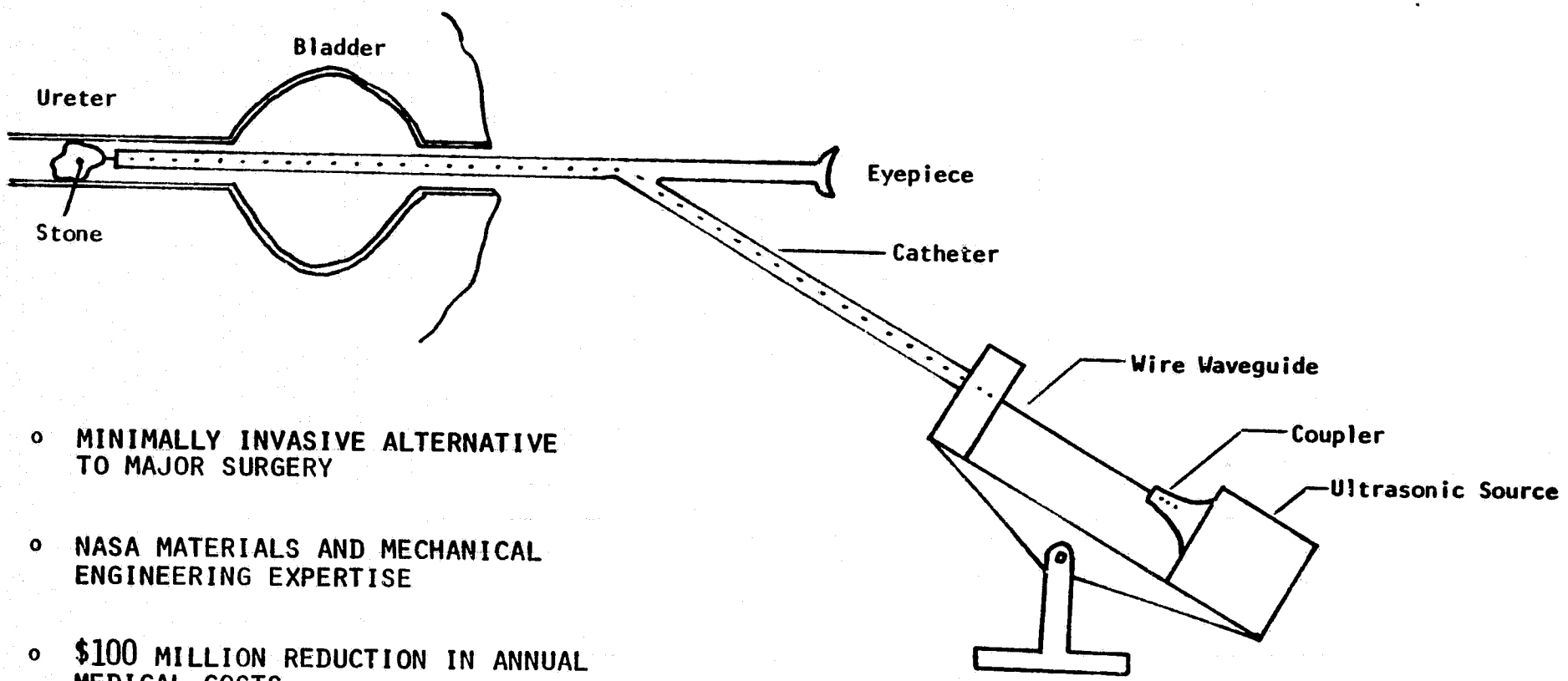
Cost Sharing: Blackstone has invested $250K (FY72-79) in the development of the Ultrasonic Kidney Stone Disintegrator (UKSD). Santa Clara Valley Medical Center provided $5K (FY73) in materials and technical support. There is no separate accounting for the costs borne by Dr. Goodfriend over the years in providing significant time, materials, and laboratory facilities to further UKSD development. The BATeam will negotiate cost sharing in excess of 50% with the manufacturer who is selected to fabricate a prototype device.

Transfer Strategy: The BATeam will select a medical device manufacturer for prototype development and commercialization.

Status: Earl Angulo, NASA mechanism Branch Chief at GSFC, has made modifications to the waveguide-source coupling device which have increased time-to-failure of the waveguide by a factor of ten. A prototype ureteral catheter which incorporates the fiberoptics that are necessary to verify waveguide-stone contact is on order.

Action: The modified unit is being shipped to Goodfriend for bench failure testing. The prototype fiberoptic ureteral catheter, once received, will be incorporated into the modified unit for further evaluation. Given satisfactory evaluation results, the BATeam will collaborate with NASA patent attorneys in the documantation of NASA technology and application for appropriate patents. Also, the BATeam will issue a commercial opportunity announcement/RFP and select a manufacturer for prototype fabrication and commercialization. Prototype manufacture and remaining RTOP milestones are scheduled for implementation in 1981.

ULTRASONIC KIDNEY STONE DISINTEGRATION



- MINIMALLY INVASIVE ALTERNATIVE TO MAJOR SURGERY
- NASA MATERIALS AND MECHANICAL ENGINEERING EXPERTISE
- $100 MILLION REDUCTION IN ANNUAL MEDICAL COSTS

2.6 PEDIATRIC ROENTGEN DENSITOMETRY

BATeam Personnel: Luke F. Brennan

Problem: Congenital heart disease is suspected (because of cyanosis) in about five percent of all infants, but only one-tenth as many infants have such disease. Cardiac catheterization, an invasive and risky procedure, must be done to confirm or rule our various forms of intracardiac shunting. A safe, non-invasive screening procedure is needed which can detect all types of shunts and which, therefore, can reduce the number of cardiac catheterizations done on infants with normal cardiac circulation.

Solution: Roentgen densitometry is an x-ray screening procedure which involves the intravenous injection of a small amount of non-radioactive, iodinated (radiopaque) dye. The dye coursing through the cardio-pulmonary system modulates the intensity of x-radiation passing through the heart and impinging on a cluster of six x-ray detectors. Analysis of the signals produced by the detectors allows classification of subjects into four clinically distinguishable categories: left-to-right shunt, right-to-left shunt, bidirectional shunt, and normal cardiac circulation.

NASA Technology: NASA-developed x-ray detector arrays using Bismuth Germanate crystals optically coupled to blue-enhanced silicon photo cells are being used to detect the x-ray beams produced by conventional portable x-ray equipment.

Principals: Louis R. M. DelGuercio, M.D.; Chairman, Surgery Dept.; New York Medical College, Valhalla, NY
Gerald C. Hugh, Ph.D.; USC Medical Imaging Science Group; Marina Del Rey, CA
Richard Gans, Electrical Engineer, RSY Associates, Evergreen, CO

Cost to NASA: $20K in FY79 and $20K approved for FY80.

Cost Sharing: New York Medical College at Valhalla has funded and will continue to fund clinical trials and equipment evaluation at that institution. Stanford University and Harvard University will fund clinical trials at Stanford and Harvard, respectively. There are no separate accountings of the costs to these institutions.

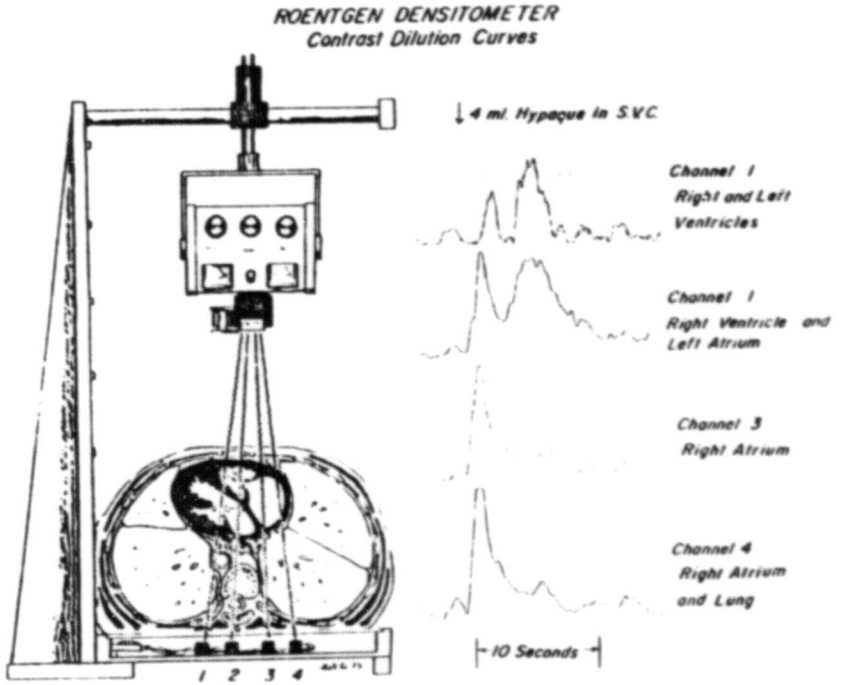
Transfer Strategy: The EAG-405 roentgen densitometer was designed and constructed by RSY Associates, Evergreen, CO. Upon completion of equipment evaluation and clinical trials, the BATeam will solicit new product development proposals from companies which produce x-ray equipment.

Status: The BATeam received three EAG-405 roentgen densitometers early this year. They have been calibrated and checked out. One densitometer was shipped to DelGuercio in April for evaluation at New York Medical College. DelGuercio is proceeding with the evaluation and with the completion of a protocol for clinical trials. The programming of a Precision Computer System 8001 for data acquisition and analysis is underway at Stanford University.

Action: The BATeam will submit a proposal to NASA-Ames Research Center to release approved project funding. Brennan will visit DelGuercio's laboratory at Valhalla, NY to facilitate transfer of experimental procedure and technique to Stanford. The completed clinical protocol will be circulated to NASA Hq., Stanford University (Brody and French), and Harvard University (Gersony at Peter Bent Brigham) for approval by November 1, 1980. Upon approval, animal trials and, subsequently, clinical trials will begin. The trials are scheduled for completion in early to mid-1981.

PEDIATRIC ROENTGEN DENSITOMETRY

- NONINVASIVE, X-RAY PROCEDURE TO DETECT DIFFERENT FORMS OF CONGENITAL HEART DISEASE
- SYSTEM INCORPORATES NASA-DEVELOPED X-RAY DETECTORS
- DILUTION CURVE MODALITY, PEAK, AND EXPONENTIAL DECAY CONSTANT REVEAL STATUS OF CARDIAC CIRCULATION



2.7 X-RAY SPATIAL FREQUENCY MULTIPLEXING

BATeam Personnel: Gene V. Schmidt, M.D.; Robert J. Debs, Ph.D.; Gary L. Steinman

Problem: X-rays are attenuated as they pass through the body. Attenuation is greater for high density tissues such as bone than for lower density soft tissues. Hence, skeletal parts can be distinguished readily on x-ray films. Unfortunately, soft tissues which underlie bone, including tumors and diseased blood vessels, are difficult if not impossible to visualize, even when toxic radiopaque dyes have been infused into such tissues to increase their apparent tissue density. A method is needed by which bone and soft tissue can be visualized separately on x-ray film.

Solution: X-ray spatial frequency multiplexing exploits the fact that the attenuation coefficients for bone and soft tissue behave differently as functions of x-ray energy below 100 KeV. Measurement of x-ray attenuation at two discrete energy levels allows the computation of soft tissue and hard tissue contributions to beam attenuation at each energy level, thereby enabling the isolation of soft tissue and hard tissue images. One technique employs a grated optical filter in which alternate bands allow passage of x-ray spectrums with energy peaks just above and just below the K-edge energy level of iodinated radiopaque dyes, respectively. This technique is extremely sensitive to low doses of iodinated dyes and enables the construction of clear images of infused soft tissues. A second technique employs alternate pulses of monoenergetic x-rays at two different energy levels which pass through the body as it is being translated. Detectors pick up the attenuated pulses and a CAT scanner computer carries out the computations required to construct the desired images.

NASA Technology: Macovski has adapted a technology for use in x-ray imaging which he originally developed for NASA. This NASA technology involved the use of optical gratings to encode Landsat color images into gray level images for transmission to earth and subsequent color restoration.

Principals: Albert Macovski, Ph.D.; Professor of Electrical Engineering and Radiology; Stanford University.
William R. Brody, M.D.; Assoc, Professor of Radiology and Electrical Engineering; Stanford University.

Cost to NASA: $20K in FY76; $25K in FY77; $30K in FY78; $30K in FY79.

Cost Sharing: NIH has provided $48K in FY76, $112K in FY77, and $112K in FY79. NSF has provided $80K in FY77 and $80K in FY78. In addition, NSF is providing a three-year grant for $200K in the general area of "X-ray Imaging Systems Using Energy Spectrum Analysis." General Electric has donated an $875K computerized axial tomographic (CAT) scanner along with field engineering support. Total cost sharing exceeds $1.5 million at this time.

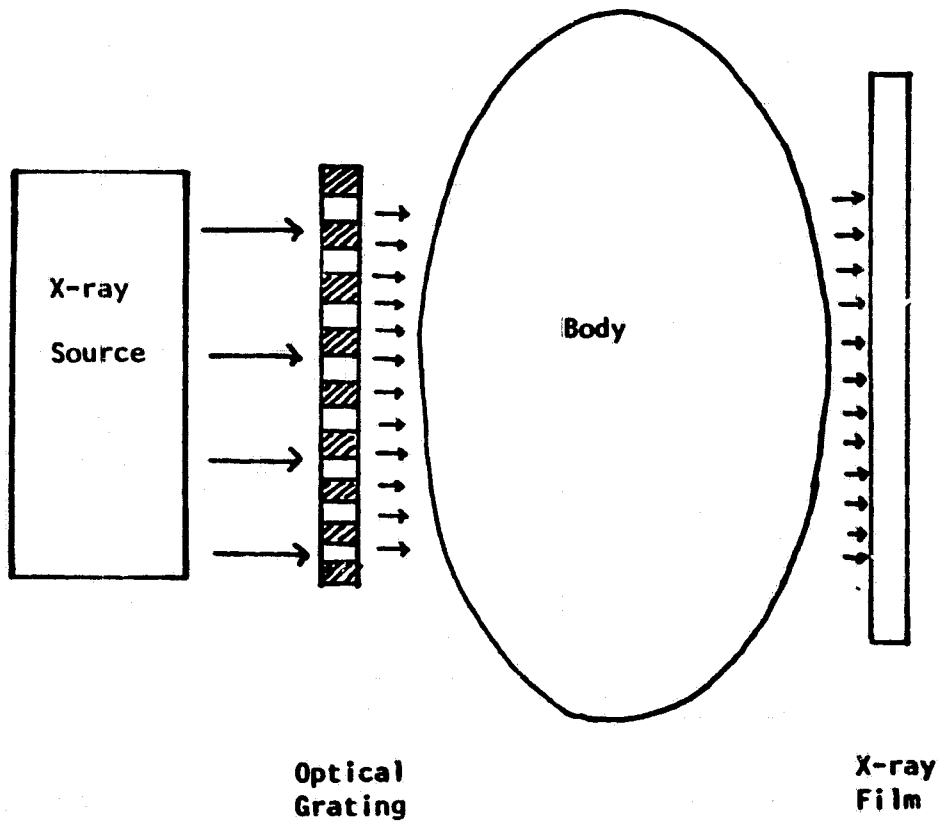
Transfer Stragegy: The spatial frequency multiplexing concepts will be evaluated by Stanford University Medical School clinicians and General Electric engineers using a modified CAT scanner. If the evaluations prove successful, General Electric will market a commercially-available x-ray scanner which will incorporate the features of this project. The possibility of retrofitting convential x-ray equipment to utilize the grated optical filter technique will be studied by the BATeam.

Status: Very considerable progress has been made in respect to the development of both spatial frequency multiplexing techniques. Specifically, images taken of composite bone and soft tissue equivalent materials have been decoded to produce separate images of the bone equivalent and soft tissue equivalent materials; very slight differences in tissue density have been made distinguishable for the first time on radiographs; separate images of bone and soft tissue have been produced from encoded x-rays taken of human subjects; clear images of human thoracic arteries have been obtained; a times 10 improvement in spatial resolution in film images has been demonstrated to be feasible; and a high voltage modulator for the CAT-scanner has been installed which greatly simplifies the x-ray examination procedure.

Action: Clinical trials will begin during the next six months to determine system capabilities in respect to detecting coronary artery stenosis and chest lesions, to identify previously undetectable radiological signs of specific diseases in man, and to compare examination results produced with a variety of typical, clinical radiation sources. Further refinements will be made in the production of high resolution films using the grated optical filter multiplexing technique, and possibilities in respect to commercializing this technique will be explored.

X-RAY SPATIAL FREQUENCY MULTIPLEXING

- SEPARATE X-RAY IMAGES OF SOFT TISSUE AND BONE
- NASA COLOR IMAGE TRANSMISSION TECHNOLOGY USED IN LANDSAT
- REDUCED DOSES OF TOXIC RADIOPAQUE DYES DYES



2.8 DETERMINATION OF BONE STRENGTH BY MECHANICAL IMPEDANCE

BATeam Personnel: Gene V. Schmidt, M.D.; Gary L. Steinman

Problem: Severe bone deterioration is experienced by one out of four women and one out of eight men annually in the United States, resulting in approximately six million spontaneous fractures. Routine x-ray examination is relatively insensitive to such deterioration and presents a radiation exposure hazard as well. an inexpensive, non-invasive technique is needed for periodically evaluating the status of selected individuals in respect to bone deterioration. Furthermore, a satisfactory method for monitoring fracture healing in all patients is needed.

Solution: An inexpensive, non-invasive method for measuring bone strength is to use the driving point mechanical impedance approach. The lateral bending stiffness of bone, which correlates with bone strength, can be calculated by measuring the ratio of the lateral force applied at a point to the lateral displacement of that point resulting from the applied force. Stanford University mechanisist Dr. Charles Steele, in cooperation with NASA research scientist Dr. Donald Young, has developed an instrument which can make these measurements non-invasively and painlessly.

NASA Technology: Scientists at the NASA-Ames Research Center have conducted extensive research into the effects of zero gravity on various bone properties. Skylab astronauts, during their 84-day voyage, experienced loss of bone calcium and increased excretion of calcium in the urine. These effects are similar to those seen in the elderly and in patients confined to bed for long periods of time. NASA scientists and university engineers have collaborated on the development of the mechanical impedance instrument for measuring bone strength. This work has involved both theoretical analyses and invasive tests on laboratory animals at Ames.

Principals: Charles R. Steele, Ph.D.; Prof. of Applied Mechanics; Stanford University; Stanford, CA.
Donald A. Nagel, M.D.; Head of Orthopedic Surgery; Stanford University; Stanford, CA.
David J. Schurman, M.D.; Assoc. Professor of Orthopedic Surgery; Stanford University; Stanford, CA.
Donald R. Young, Ph.D.; Research Scientist; NASA-Ames Research Center; Moffett Field, CA.

Cost to NASA: FY80 RTOP approved for $40K.

Cost Sharing: Preliminary clinical evaluations have been conducted at no cost ot NASA through the cooperation of the Stanford University Medical School Departments of Orthopedics and Medicine and through the Renal Dialysis Unit at the Palo Alto Veteran's Administration Hospital.

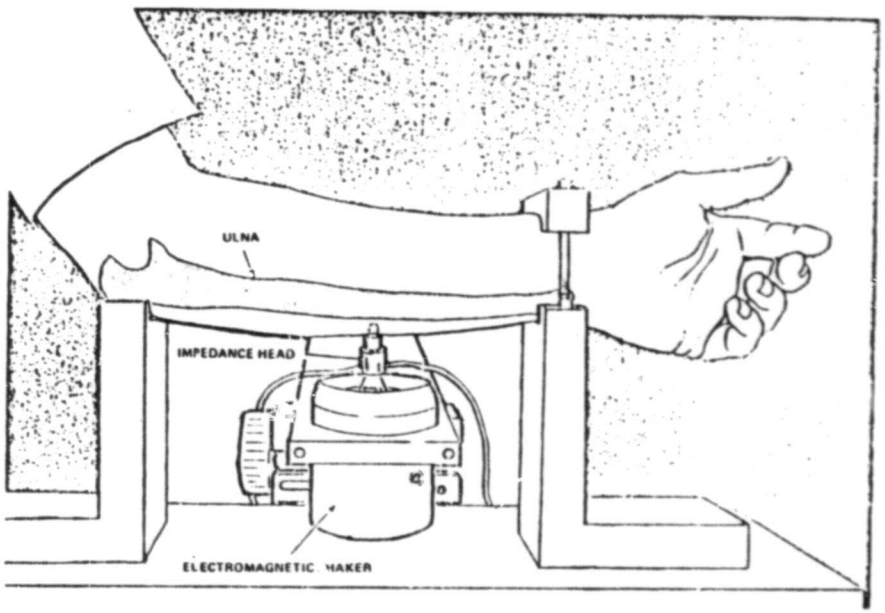
Transfer Strategy: A market survey will be undertaken and commercial contact will be made following demonstration of the device's commercial utility. It is anticipated that measurement of the mechanical impedance of bone will become routine in clinical practice.

Status: A proposal to NASA-Ames Research Center (ARC) to release funds approved for this project under the FY80 RTOP is in preparation.

Action: The BATeam will submit the proposal to ARC, and the RTOP milestone schedule will be implemented on receipt of funding.

DETERMINATION OF BONE STRENGTH BY MECHANICAL IMPEDANCE

- NON-INVASIVE TECHNIQUE TO MONITOR BONE STATUS
- NASA INSTRUMENTATION TO MONITOR DEMINERALIZATION OF ASTRONAUTS' BONES DURING LONG SPACE VOYAGES



2.9 VISUAL-TO-TACTILE MOBILITY AID FOR THE BLIND

BATeam Personnel: Robert J. Debs, Ph.D.; Gene V. Schmidt, M.D.; Gary L. Steinman

Problem: In order to walk at a normal pace, a blind pedestrian must know about obstacles beyond the reach of his long cane. A guide dog can transmit only "start" and "stop" messages to his blind owner, based on the dog's own visual impressions concerning the environment. A mobility aid is needed which the blind pedestrian can use to obtain information about the location and identity of obstacles on or near his path.

Solution: A portable outdoor guidance system is being developed at Smith-Kettlewell Institute for the Visual Sciences (SKIVS). This system would allow a blind pedestrian to make his own navigational decisions based on real-time information provided by the system in respect to the location and identity of potential obstacles in the pedestrian's environment. A miniature television camera produces an image of the user's environment which is processed by a microcomputer using artificial intelligence programming techniques to determine the location and identity of potential obstacles. The information thus produced is transmitted to the user by means of encoded tactile and synthesized speech messages.

NASA Technology: Technologies produced by NASA-funded research in artificial intelligence and computer vision are being transferred to SKIVS to facilitate the development of this mobility aid.

Principals: Carter C. Collins, Ph.D.; Assoc. Director; Smith-Kettlewell Institute of Visual Sciences, San Francisco, CA
Michael F. Deering, Doctoral Candidate, Smith-Kettlewell Institute of Visual Sciences, San Francisco, CA
J. Martin Tenenbaum, Ph.D.; Program Director-Vision; SRI International, Menlo Park, CA

Cost to NASA: FY80 RTOP for $50K approved.

Cost Sharing: The National Science Foundation has co-funded this project in the amounts of $92K for FY80 and $92K for FY81.

Transfer Strategy: The most immediate transfer objective has been to provide SKIVS with the technology they need to further their current R&D project. Although commercialization is approximately 5-10 years away, one manufacturer has already made inquires regarding the possibility of manufacturing this outdoor mobility aid when it is developed.

Status: Collins has incorporated a Motorola 68000 microprocessor into a primitive prototype scene interpretation system which can operate at a rate of one image per second. 16K bytes of additional memory are being added to increase the system's interpretation rate. Collins and Tenenbaum have begun planning a collaborative effort to improve the system's scene interpretation capabilities.

An RTOP for $50K has been approved. Release of this funding from Ames Research Center has been held up by difficulties in reaching a satisfactory mechanism to fund all parties to this project.

Action: A prototype message transmission system will be fabricated which consists of a linear array of tactile stimulators for transmitting location information to the user's abdomen and a speech synthesizer to transmit obstacle identity information to the user. The BATeam will resolve the present funding difficulty and then will implement the RTOP milestone schedule.

VISUAL-TO-TACTILE MOBILITY AID FOR THE BLIND

- INDEPENDENT OUTDOOR NAVIGATION BY BLIND PEDESTRIANS
- NASA ARTIFICIAL INTELLIGENCE AND COMPUTER VISION TECHNOLOGY
- LOCATION AND IDENTITY OF POTENTIAL OBSTACLES TRANSMITTED BY SYNTHESIZED SPEECH AND ENCODED TACTILE MESSAGES

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OF POOR QUALITY

2.10 PURKINJE IMAGE EYETRACKER AND STABILIZED PHOTOCOAGULATOR

BATeam Personnel: Robert R. Zimmerman

Problem: Retinal hemorrhages, retinal lesions, and diabetic retinopathies can be treated by means of surgical laser photocoagulation. However, the accuracy and safety with which such treatment can be performed is compromised by the unwanted motion of a patient's eye during the photocoagulation procedure. A method is needed to enable the laser photocoagulator to track any eye motion which might occur and, thus, reliably to direct the therapeutic laser beam to the desired target.

Solution: The Purkinje Image Eyetracker follows the reflections of a point of light which is formed by the front surface of the cornea and the rear surface of the lens. When coupled with the appropriate optical and electromechanical systems, the eyetracker can be used to produce a stationary, stabilized image of the retina or to direct a laser beam at a specific target on a moving retina.

NASA Technology: The Purkinje Image Eyetracker was developed for NASA-Ames Research Center to study the visual tracking, scanning, and focusing patterns of aircraft pilots. NASA also funded a transfer project in which a less complicated clinical version of the eyetracker was developed.

Principals: Hewitt D. Crane, Ph.D; Mgr., Visual Sciences Program; SRI International, Menlo Park, CA
John R. Hotson, M.D.; Asst. Professor of Neurology, Stanford University, CA
George Timberlake, Eye Research Institute, Boston, MA

Cost to NASA: $75K in FY79, $25K in FY80.

Cost Sharing: The Eye Research Institute of the Retina Foundation of Boston (RFB) will provide the photocoagulator and support laboratory and clinical trials. There is no separate accounting of the cost to RFB.

Transfer Strategy: The stabilized photocoagulator will be demonstrated to all present manufacturers of surgical photocoagulators.

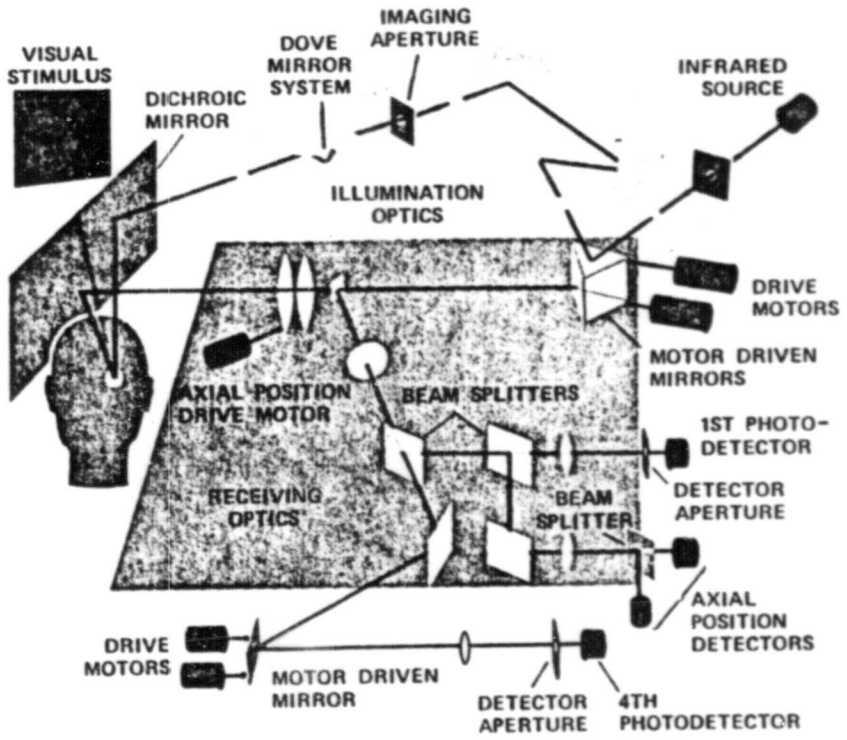
Status: The contract between NASA-Ames Research Center and SRI International has been signed after some delay caused by the retirement of a contract officer at Ames. SRI and the Retina Foundation of Boston held their first working meeting under the contract to review the system design. SRI is on schedule with the assembly of an eyetracker, and RFB is on schedule with the fabrication of a laser.

Action: An August meeting has been scheduled between SRI and RFB representatives to review specific design decisions, the division of project responsibilities, and the project schedule. Work on the eyetracker and laser will proceed as scheduled.

PURKINJE IMAGE EYETRACKER AND STABILIZED PHOTOCOAGULATOR

- EYETRACKER COMPENSATES FOR EYE MOTION DURING PHOTO-COAGULATION PROCEDURE

- EYETRACKER DEVELOPED FOR NASA TO STUDY VISUAL TRACKING, SCANNING, AND FOCUSING ABILITIES OF PILOTS



Schematic Drawing of Eyetracker Illustrating Operation

2.11 NEUROLOGICAL APPLICATIONS OF NASA-SRI EYETRACKER

BATeam Personnel: Gene V. Schmidt, M.D.; Gary L. Steinman

Problem: Fixation eye movements are small amplitude rapid flicks and slow drifts which occur continuously and unconsciously when a subject is looking at a small, fixed target. Since these eye movements, which cannot be detected by routine physical examination, require precise control by specific brain centers, certain neurological diseases such as multiple sclerosis, Parkinson's disease, and cerebellar degeneration might be detected and quantified by analyzing such minute eye movements. Instrumentation is needed by which these eye movements might be measured and recorded precisely.

Solution: The NASA-SRI Purkinje Image Eyetracker is able to measure both vertical and horizontal eye movements with angular resolution to within one minute of arc. It eliminates interference due to transitional head movements and is totally non-invasive. Recordings can be made periodically, permitting a neurologist to follow disease progression and response to drug therapy.

NASA Technology: As indicated in Section 2.10 of this report, the Purkinje Image Eyetracker was developed for NASA-Ames Research Center to study the visual tracking, scanning, and focusing patterns of aircraft pilots. A clinical version of this instrument was developed with NASA support.

Principals: Hewitt D. Crane, Ph.D.; Manager, Visual Sciences Program, SRI International, Menlo Park, CA
Michael R. Clark, Ph.D.; Research Engineer, SRI International, Menlo Park, CA
John R. Hotson, M.D.; Asst. Professor of Neurology, Stanford University, Stanford, CA

Cost to NASA: To date, no cost other than $2K from FY78 and FY79 BATeam funds has been borne by NASA since suitable instruments had been developed for other projects.

Cost Sharing: $3K in FY78-79 by the Institute for Medical Research, Santa Clara Valley Medical Center, San Jose, CA.

Transfer Stragegy: This project involves the institutional transfer of a NASA-SRI eyetracker to enable Stanford University to carry out important neurological research.

Status: Hotson's National Eye Institute (NEI) proposal to use the clinical eyetracker in clinical neurological research was reviewed by NEI and received a "high score" from the Visual Science Study Section. Because NEI funds for new research projects are unavailable at this time, the Director of Sensory-Motor Disorders at NEI recommended that the final review of the proposal be postponed until later in 1980 when funds might become available.

Action: The project is inactive at this time. The BATeam will follow the NEI funding situation with Hotson.

2.12 ICU SYNTHESIZED SPEECH ALARM

BATeam Personnel: Gary L. Steinman

Problem: Existing ICU alarm systems use lights and buzzers to alert nursing staff to critical changes in patient status. An improved system is needed which can be more easily heard and understood in the busy, noisy ICU environment.

Solution: A synthesized speech alarm system offers advantages over existing systems in respect both to specificity and intelligibility of alarm.

NASA Technology: Synthesized speech technology developed within the Man-Vehicle Systems Research Division at NASA-Ames Research Center will be incorporated into a synthesized speech alarm system which is being designed and constructed for use at the Veteran's Administration Hospital in Martinez, CA.

Principals: H. Nang Wong, M.D.; Chief of the Surgical ICU; Veteran's Administration Hospital, Martinez, CA
James E. Demetriades; Chief, Biomedical Engineering; Veteran's Administration Hospital, Martinez, CA
Carol A. Simpson, Ph.D.; Psycho-Linguistic Research Associates, Menlo Park, CA

Cost to NASA: $15K in FY79.

Cost Sharing: Physiological monitoring equipment and computer hardware worth more than $300K will be provided by the VA and time-shared on this project. In addition, the VA is providing the medical and technical support for the set-up and evaluation of the Speech Alarm System.

Transfer Strategy: This is to be an institutional transfer. However, if use of this system results in an improvement in patient care, the BATeam will organize a demonstration for medical manufacturers.

Status: Commencement of this project was delayed due to a misunderstanding between the Martinez VA fiscal office and Ames Research Center regarding the proper forms needed to effect an "interagency transfer" of funds. Additional delays have been experienced due to the budgeting process at the VA.

Action: The RTOP milestone schedule will be implemented once the funds transferred to the VA become available for use.

2.13 NANOPHOR: MICROELECTROPHORESIS INSTRUMENT

BATeam Personnel: Gene V. Schmidt, M.D.; Gary L. Steinman

Problem: Electrophoresis is a laboratory technique for physically separating and identifying the serum proteins in a medical specimen by exploiting the different rates at which serum proteins migrate when they are subjected to an electric field. Although electrophoresis instrumentation is commercially available, improvements are needed which increase the speed and accuracy of serum protein and enzyme identification and which enable an analysis to be done on nanogram (or microliter) specimen quantities.

Solution: The NANOPHOR is a versatile clinical laboratory instrument for performing electrophoresis on nanogram quantities of patient serum. Rapid and economical separation and identification of specific proteins can be achieved.

NASA Technology: NANOPHOR incorporates electrophoretic techniques developed by NASA for use in analyzing the serum proteins of Apollo Astronauts.

Principals: Benjamin W. Grunbaum, Ph.D., M.Crim.; Environmental Physiology Laboratory; University of California, Berkeley, CA

Cost to NASA: $25K over FY76-80.

Cost Sharing: Stanford University Medical Center clinical chemistry laboratories and the Santa Clara County criminal laboratories will conduct evaluations of the instrument at no cost. Sartorius, Inc., a large European-based firm with a U.S. subsidiary in Hayward, CA, has contributed $200K in support of the NANOPHOR development project.

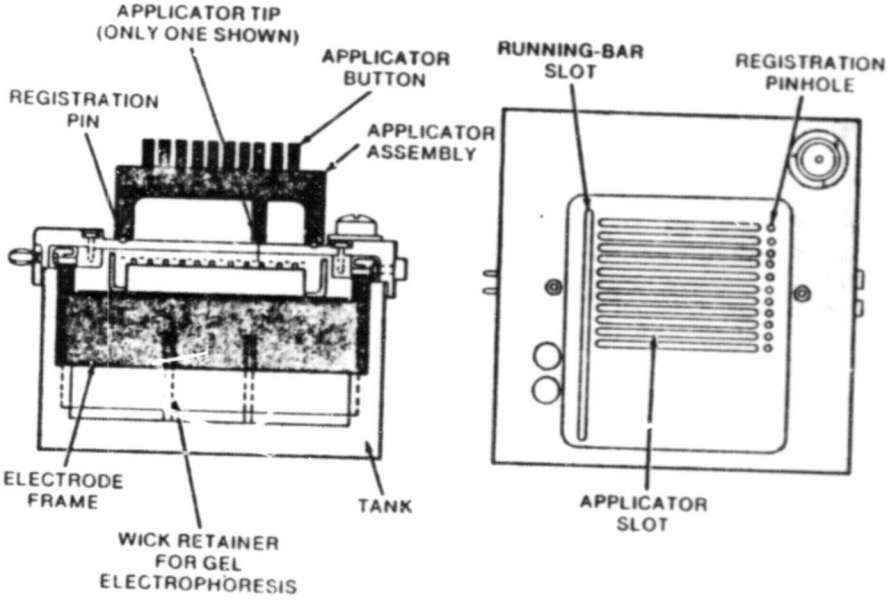
Transfer Strategy: An exclusive license to produce and market NANOPHOR has been issued by NASA to Sartorius, Inc.

Status: The BATeam is awaiting delivery from NASA-Ames Research Center of two NANOPHOR set-ups for laboratory evaluation.

Action: Laboratory evaluations will commence on delivery of the units.

NANOPHOR: MICROELECTROPHORESIS INSTRUMENT

- FAST, ACCURATE ANALYSIS OF NANOGRAM-QUANTITY SPECIMENS
- NASA TECHNOLOGY FOR ANALYSIS OF APOLLO ASTRONAUTS' SERUM PROTEINS



2.14 WRISTCOM - A TACTILE COMMUNICATIONS SYSTEM FOR THE DEAF-BLIND

BATeam Personnel: Robert R. Zimmerman

Problem: Instutionalized deaf-blind persons have little means by which to receive messages and alarms as they pursue their daily activities. A communication system is needed which does not depend on the user's ability to receive auditory or visual messages and which allows the user to move about freely.

Solution: The WRISTCOM System consists of a base station which transmits messages and alarms to wrist-worn communicators by which the deaf-blind user receives and can acknowledge such communications. The user receives tactilely encoded messages and responds with short Morse code acknowledgments. The user can summons help at any time by means of his wrist-worn unit and the base station "polls" users periodically to determine if all is well.

NASA Technology: The system draws on NASA's experience in high-reliability data encoding and RF transmission in a noisy environment, tactile feedback, and low-power microprocessor-based systems.

Principals: Fred Kruger, Ph.D.; Director of Research, National Center for the Deaf-Blind; Sands Point, NY
James A. Baer, Senior Research Engineer, SRI International, Menlo Park, CA
John A. Brabyn, Assistant Director, Rehabilitation Engineering, Smith-Kettlewell Institute of Visual Sciences, San Francisco, CA

Cost to NASA: Approximately $250K over five years.

Cost Sharing: Smith-Kettlewell Institute for the Visual Sciences will conduct a clinical evaluation of the WRISTCOM System. Several other institutions have contributed to this project over the years, but there has not been a separate accounting of the costs of these contributions.

Transfer Strategy: While the market for communications devices for the deaf-blind is quite small, it might be extended to include elderly users in nursing homes.

Status: SRI has experienced considerable delays in procuring components for the WRISTCOM system because suppliers have given priority to urgent requisitions from other government agencies. In the meantime, the NASA-Ames Research Center (ARC) contract with SRI International to design and fabricate a prototype system expired on April 31, 1980; and ARC has not responded to a request from SRI to extend the contract. Discussions continue with Brabyn at Smith-Kettlewell in San Francisco concerning evaluation protocols, but SRI cannot devote great amounts of time to this project until their contract is formally extended.

Action: SRI must receive formal notice of contract extension from the NASA-ARC contracting officer. The BATeam will attempt to identify the problem at NASA-Ames Research Center and resolve it.

2.15 MEDICAL APPLICATIONS OF NASA LIQUID-CIRCULATING GARMENTS

BATeam Personnel: Gene V. Schmidt, M.D.; Luke F. Brennan; Robert J. Debs, Ph.D.

Problem: Precise control of body temperature is necessary in many medical procedures. Available thermal blankets fail to achieve the required degree of precision, partly because they do not provide adequate body surface contact for heat exchange. Wet packs are cumbersome and can create additional problems such as skin irritation or electrical hazards. A better means of achieving precise control of body temperature is needed.

Solution: Liquid-circulating garments provide snug body contact over large areas of body surface and provide for rapid circulation of tempered water to promote heat exchange. They are less cumbersome than thermal control equipment which is currently available, and they are dry.

NASA Technology: Liquid-circulating garment technology with temperature select servo-thermal control, originally developed at Ames Research Center to protect astronauts during extravehicular excursions, has been modified for effective use in the clinical environment.

Principals: Gerald D. Silverberg, M.D.; Assoc. Professor of Neurosurgery; Stanford University; Stanford, CA.
Allen K. Ream, M.D.; Assoc. Professor of Anesthesia; Stanford University; Stanford, CA.
Colin Bamford, M.D.; University of Arizona Medical School, Tucson, AZ.
Ernest Geller, M.D.; University of Arizona Medical School, Tucson, AZ.
Jerome Block, Harbor General/UCLA Hospital, Torrance, CA.

Cost to NASA: $20K in FY79.

Cost Sharing: A large number of individual physicians and institutions have performed clinical evaluations of LCGs in a variety of medical applications at no cost to NASA.

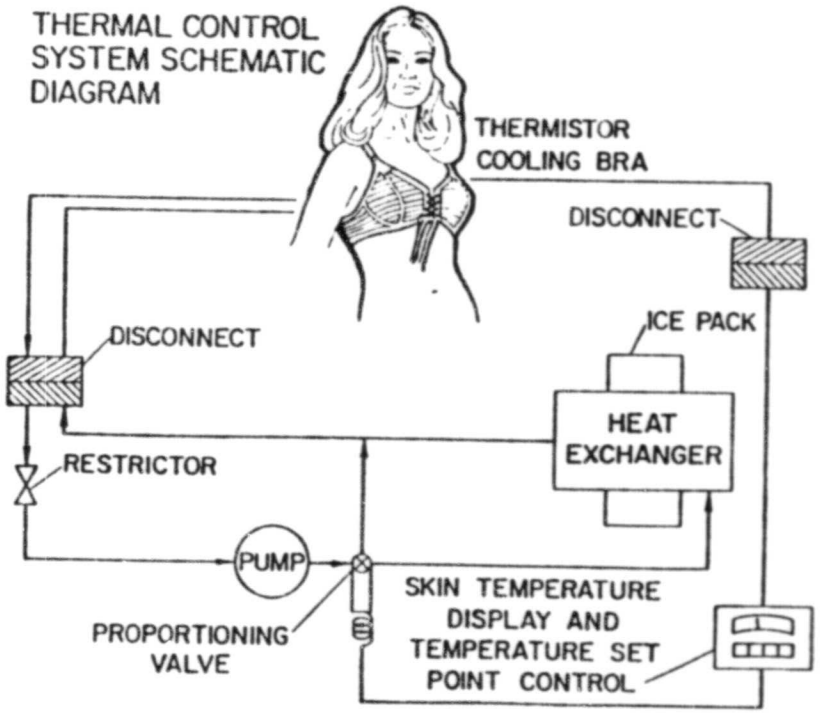
Transfer Strategy: Two manufacturers have produced prototype garments for clinical evaluation.

Status: A new cooling vest prototype has been fabricated for use by patients with spinal cord injuries who cannot control their body temperature. A pediatric LCG has been ordered for use in treating pediatric drowning victims. Clinical trials in neurosurgical applications are inactive due to the sabbatical leaves of two principals.

Action: The pediatric LCG will be lab tested on receipt and forwarded to Hackel for clinical trials.

MEDICAL APPLICATIONS OF NASA LIQUID-CIRCULATING GARMENTS

- PRECISE CONTROL OF BODY TEMPERATURE
- NASA DEVELOPED GARMENTS TO PROTECT ASTRONAUTS DURING "SPACE WALKS"
- GARMENT ELIMINATES ELECTRICAL HAZARD AND SKIN IRRITATION PROBLEMS



2.16 HIP PROSTHESIS WITH BIOTELEMETRY

BATeam Personnel: Luke F. Brennan

Problem: The significant failure rate in total hip prostheses indicate that present prosthesis designs are inadequate for young, active persons who require total hip replacement. Data on the dynamic forces to which hip prostheses are subjected, which cannot be obtained with currently available instrumentation, is needed to facilitate the design of a more durable implant.

Solution: Such dynamic force data can be collected *in vivo* by means of a special hip joint prosthesis which incorporates strain guages and an inductively powered, miniaturized telemetry system. Ultimately, patients would benefit from a shortened period of convalescence, from a return to more normal activities, and from a reduced risk of prosthesis failure and repeat surgery.

NASA Technology: NASA expertise in miniaturized R-F powered biotelemetry systems, microminiature electronic fabrication and packaging, sterilization, and reliability testing are indispensable to this project.

Principals: James F. Boreham, Electrical Engineer, Jet Propulsion Laborartory, Pasadena, CA
Richard Postal, Electrical Engineer, Jet Propulsion Laboratory, Pasadena, CA
Raymond Luntz, Electrical Engineer, Jet Propulsion Laboratory, Pasadena, CA
Keith Markolf, Ph.D.; Mechanical Engineering; UCLA; Los Angeles, CA
Harlan Amstutz, M.D.; Chief of Orthopedics; UCLA; Los Angeles, CA

Cost to NASA: $75K in FY79; $105K in FY80.

Cost Sharing: A proposal has been submitted to NIH for approximately $250K annually starting in FY81.

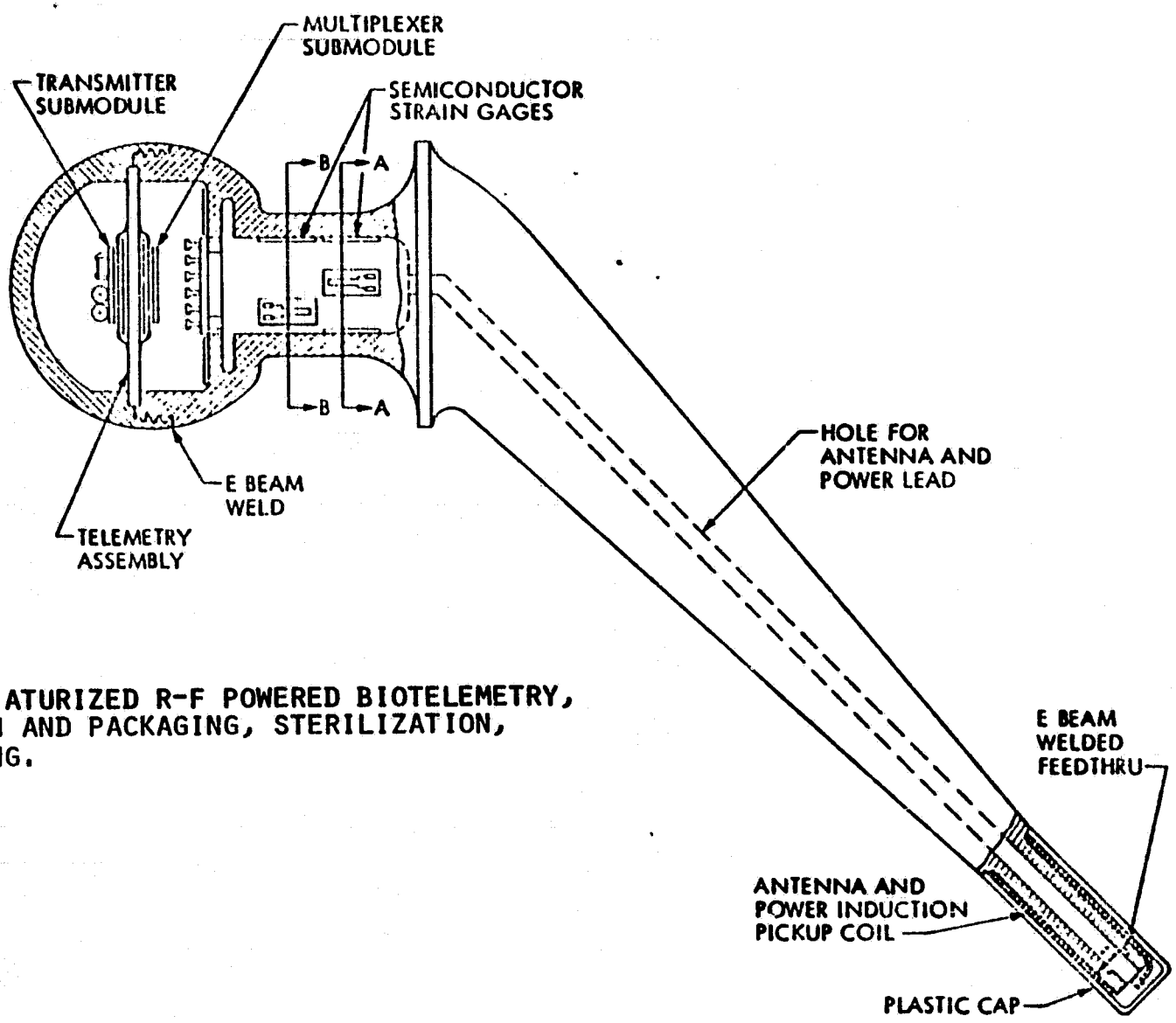
Transfer Strategy: The end-product of this project will be an improved design for a total hip joint replacement. Although actual human implant of the instrumented prosthesis is not anticipated prior to 1981, the Zimmer Manufacturing Company, Warsaw, IN, which markets a complete line of orthopedic, prosthetic, and orthotic components, has expressed interest in the data resulting from the project and will consider possible commercial collaboration after the preliminary results of the human implants are available for review.

Status: The telemetry system has been subjected to extensive mechanical testing with the result that both mechanical and electrical integrity were maintained. The power induction system meets or exceeds design goals; and JPL has successfully transmitted power to and received telemetered data from a mock-up telemetry system implanted in a human cadaver leg. Fabrication of the console is 90% complete. Efforts have been made to accomodate a delay in the fabrication of metal parts by a UCLA machinist who has been ill.

Action: Contingent on receipt of NIH funding during the first quarter of 1981, the prototype system will be complete by March, 1981. NASA funding terminates in September, 1980.

HIP PROSTHESIS WITH BIOTELEMETRY

- A SYSTEM TO OBTAIN DATA NEEDED FOR DESIGN OF BETTER PROSTHESIS



- NASA EXPERTISE IN MINIATURIZED R-F POWERED BIOTELEMETRY, ELECTRONIC FABRICATION AND PACKAGING, STERILIZATION, AND RELIABILITY TESTING.

3. POTENTIAL TRANSFER PROJECTS

Person-Portable Versatile Speech Prosthesis
Critical Care Transport System
Clinical Information System for Cardiology
Programmable Biofeedback Orthosis for Scoliosis
Pediatric Long-Bone Reconstruction
Spinal Immobilization Apparatus.

3.1 PERSON-PORTABLE VERSATILE SPEECH PROSTHESIS (MINI-VPSP)

BATeam Personnel: Gary L. Steinman, Luke F. Brennan

Problem: Approximately 1.5 million non-vocal people suffering from cerebral palsy, multiple sclerosis, Parkinson's disease, muscular dystrophy, stroke with residual aphasia, or cancer of the larynx live in the United States. Many of these people are unable to use their hands for writing, typing, or sign language; and, therefore, have no effective means of communication. The wheelchair-mounted VPSP, which has been described in section 2.2 of this report, has been designed to serve the needs of the non-ambulatory segment of the subject population. The approximately 300,000 persons in this non-vocal population who can walk, however, need a truly person-portable speech prosthesis with VPSP capability.

Solution: A feasibility study has been proposed to identify technologies which can be applied to reducing VPSP weight and size and to determine whether sufficient weight and size reduction can be achieved without loss of VPSP capabilities.

NASA Technology: VPSP, which itself was developed with NASA support, makes extensive use of speech synthesis systems technology developed at the Man-Vehicle Systems Research Division of NASA-Ames research Center. The BATeam will conduct a search for additional NASA technologise to achieve the required reduction in VPSP size and weight.

Principals: Douglas H. Williams, Ph.D.; Psycho-Linguistic Research Associates; Menlo Park, CA
Carol A. Simpson, Ph.D.; Psycho-Linguistic Research Associates; Menlo Park, CA

Cost to NASA: An FY81 RTOP for $17K is in preparation which proposes funding of the feasibility study. If mini-VPSP is found to be feasible, the BATeam will seek further NASA funding to support a mini-VPSP development project.

Cost Sharing: As part of the feasibility study, the BATeam will seek mission agency co-funding for a mini-VPSP development project and will solicit support from manufacturers of communication aids. Several manufacturers and institutions provided manpower, materials, or facilities in support of the VPSP development project.

Transfer Strategy: As part of the feasibility study, the BATeam will seek information from a variety of sources which will facilitate assessment of the commercial potential of mini-VPSP. The Technology Utilization Office of NASA Hq. will be asked to order a market study, and a dialogue will be established with potential manufacturers and mission agencies.

Status: An FY81 RTOP is in preparation.

Action: The RTOP milestone schedule is to be implemented on approval and receipt of RTOP funding.

3.2 CRITICAL CARE TRANSPORT SYSTEM

BATeam Personnel: Robert R. Zimmerman, Gary L. Steinman

Problem: An integrated life support and monitoring system for adult and pediatric critical care transport is not available at the present time. Such a system is necessary to support a regional patient transport system for transferring critically ill or injured patients to specialized critical care facilities.

Solution: The BATeam is in the process of isolating the specific problems involved in designing and fabricating a transport system for critically ill and injured patients.

NASA Technology: It is anticipated that NASA technology and expertise will be required in the following areas: hybrid circuitry for patient monitoring modules, data recording and display systems, and biomedical data analysis.

Principals: Alvin Hackel, M.D.; Assoc. Professor of Pediatrics and Anesthesia; Stanford University. Other principals to be determined.

Cost to NASA: Not determined.

Cost Sharing: Possible major cofunding from NIH, DOD, and other agencies is being explored.

Transfer Strategy: Contacts are being made with several manufacturers to solicit their early participation in this potential project.

Status: This potential project is still in the early problem definition, solution concept formulation stage.

Action: Contingent on satisfactory progress in respect to problem definition, solution concept, and mission agency interest, the BATeam will prepare an FY81 RTOP for submission to NASA.

3.3 CLINICAL INFORMATION SYSTEM FOR CARDIOLOGY

BATeam Personnel: Gary L. Steinman

Problem: The proliferation of discrete clinical computer systems to carry out various in-hospital testing, reporting, and data-handling functions has created as well as solved a number of problems. Each computer system independently produces items of information, usually in a format unique to the system, which must be incorporated into a patient's medical record and which must be assimilated by the patient's physician. Too many pieces of paper and too many formats make the medical record difficult to use; too many computers and too many complications in their use make direct access to computers by physicians and nurses difficult; and too many items of information make medical decision-making difficult.

Solution: A three-part solution concept is under study. First, discrete computer systems in a given facility are interfaced so that the computers can communicate directly with one another and so that the collection of discrete systems can be treated, in effect, as a single computer system. Second, easy-to-use, interactive access systems are designed and installed so that physicians and nurses can and will choose to use the computers directly rather than indirectly through medical records. Third, computer-aided medical decision-making software is developed and incorporated into the resulting system to ease the data assimilation and processing burden of physicians.

NASA Technology: Although the search for applicable NASA technologies is by no means finished at this time, it is anticipated that NASA technology and expertise will be indispensable in two main parts of the above solution: *(i)* In connection with the interfacing of discrete computer systems, NASA experience in hardware computer interfacing systems and in software emulation of computer hardware will be indispensable. *(ii)* In connection with the development of interactive computer access systems, NASA experience in computer graphics, presentation of data, touch control of computer terminals, voice recognition, and speech synthesis will be indispensable.

Principals: Gary L. Steinman, Assistant Director, BATeam, Stanford University, Stanford, CA.
William J. Sanders; Director of Cardiology Computer Group; Stanford University; Stanford, CA.
Gary Sanders, Cardiology Computer Group, Stanford University, Stanford, CA.

Cost to NASA: There has to-date been no cost to NASA. Future costs are to be determined.

Cost Sharing: To be determined.

Transfer Strategy: A feasibility study is planned in connection with this project. This study includes an examination of the commercial potential of a system which interfaces existing clinical computer systems and provides easy user access to stored data and data processing capabilities.

Status: An FY81 RTOP to obtain NASA support for a feasibility study is in preparation.

Action: The FY81 RTOP is to be submitted. The feasibility study is to commence on receipt of funding.

3.4 PROGRAMMABLE BIODEEDBACK ORTHOSIS FOR SCOLIOSIS

BATeam Personnel: Luke F. Brennan, Gary L. Steinman

Problem: Current practice in treating juvenile and adolescent forms of idiopathic scoliosis (lateral curvature of the spine) advocates immediate use of the Milwaukee Brance (MB) orthosis. While the MB is somewhat effective, it is extremely unattractive, provides only passive support, and requires an average of three year's use.

Solution: Eugene E. Bleck, M.. of Children's Hospital at Stanford (CH@S), Palo Alto CA, has developed a potentially better bracing system which employs tactile biofeedback to provide corrective voluntary musculoskeletal action by the user. Early research results suggest that the biofeedback orthosis improves the rate of spinal stabilization in scoliosis. The orthosis is also cosmetically acceptable.

NASA Technology: NASA expertise in process control, small volume circuit packaging, miniature transducers, microprocessor interfacing, and high energy density battery technologies will be applied to the design and fabrication of reliable tactile biofeedback subsystems for the orthosis.

Principals: Eugene E. Bleck, M.D.; Chief of Orthopedic and Rehabilitation Services; CH@S
Larry D. Mortenson, Head of Orthotics, CH@S
Harold Sandler, M.D.; Chief, Biomedical Research Div.; NASA-Ames Research Center; Moffett Field, CA

Cost to NASA: FY81 RTOP for $40K in preparation.

Cost Sharing: $19K plus overhead in NIHR funding (FY79-80) to CH@S has supported early research phases of this work. Continued NIHR funding has been proposed in the amount of $12K plus overhead to support clinical trials; and additional funding may be sought from other federal agencies. CH@S has borne the cost of certain orthotic services which were not covered by NIHR funding.

Transfer Strategy: The present transfer objective is to facilitate development of the tactile biofeedback technique by providing CH@S with reliable electromechanical biofeedback subsystems. When the efficacy of this technique has been verified, the BATeam will initiate commercial contacts with brace manufacturing companies.

Status: Eighteen scoliosis patients have been or are being fitted with primitive biofeedback orthoses. They are being followed by CH@S. An FY81 RTOP is in preparation.

Action: Milestone schedule will be implemented on receipt of NASA funding.

3.5 PEDIATRIC LONG-BONE RECONSTRUCTION

BATeam Personnel: Luke F. Brennan, Gary L. Steinman

Problem: Pediatric lower-limb long-bone reconstruction (LBR) is an orthopedic procedure which is performed in cases of congenital lower-limb deficiency, radical tumor resection, or severe fracture to correct a child's leg length. Current post-operative techniques, which require six to eight month's use of a body cast and bed rest, prevent a child from promptly resuming needed, near-normal walking activity during convalescence.

Solution: If a special orthopedic plate (Wagner Plate) were used to provide internal bone fixation at the reparative site, an external ischial weight-bearing brace (IWBB) could be used to control loading of the effected limb. This technique promises to promote rapid healing and early ambulation as well as to reduce medical costs substantially. However, instrumentation is needed to measure strain at the reparative site as a function of partial limb loading so that suitable IWBBs might be designed.

NASA Technology: The investigators will employ an implantable strain gauge telemetry system, which was developed at NASA-Ames Research Center, to measure three components of strain at the reparative site. Initial data obtained by means of this system will facilitate the design of suitable IWBBs. When employed on individual patients, the system will enable clinicians to control partial limb loading in order to optimize the healing rate.

Principals: Donald R. Young, Ph.D.; Research Engineer; NASA-Ames Research Center; Moffett Field, CA.
Harold M. Dick, M.D.; Chief of Pediatric Orthopedics, College of Physicians & Surgeons; Columbia Presbyterian Medical Center; New York, NY.
Robert J. Pawluk, Ph.D.; Director of the Orthopedic Biomechanics Laboratory; College of Physicians & Surgeons; Columbia University; New York, NY.

Cost to NASA: An FY81 RTOP for $40K has been submitted.

Cost Sharing: Columbia University in New York and the Swiss AO Institute in Davos, Switzerland, will provide technical support and will fund all animal and clinical trials.

Transfer Strategy: When the therapeutic efficacy of this technique has been validated by animal and clinical trials, limb-loading strain data will be made available to brace manufacturers so that they might improve the designs of their IWBB's. The Columbia Orthopedics Laboratory has available to it a mechanism by which it can provide "packaged" pilot instrumentation to other investigators for the purpose of expanding this technology.

Status: An FY81 RTOP has been submitted to NASA.

Action: Implementation of milestone schedule to commence on approval and receipt of funding.

3.6 SPINAL IMMOBILIZATION APPARATUS

BATeam Personnel: Gene V. Schmidt, M.D.; Gary L. Steinman

Problem: A means for immoblizing the spinal column of an accident victim is needed to facilitate safe removal from the accident scene, and subsequent transport to and within the hospital.

NASA Technology: Hubert Vykukal, a NASA-Ames space suit designer, has developed a spine immobillization apparatus consisting of a flexible plastic bladder containing glass microspheres and having Velcro straps for attachment to the victim's torso and head. When a vacuum is applied to the bladder, the microspheres become tightly packed into a configuration providing uniform support and rigid immobilization.

Principals: Hubert C. Vykukal, Research Scientist, Advanced Life Support Office, NASA-Ames Research Center.
Glen G. Reynolds, M.D.; Asst. Professor of Surgery, Stanford University, Stanford, CA.
Erwin Springel, Project Administrator, California Regional Spinal Cord Injury Care System, San Jose, CA.
Richard D. Hamilton, M.D.; Professor of Surgery, Stanford University, Stanford, CA.

Cost to NASA: NASA costs have yet to be determined.

Cost Sharing: Clinical evaluations will be done at the Santa Clara Valley Medical Center, San Jose, CA, at no cost.

Transfer Strategy: The BATeam will assist the Ames TU office in identifying manufacturers once preliminary tests of feasibility have been successfully completed.

Status: Vykukal has obtained several patents on essential features of his design. However, the BATeam has found a Canadian immobilization device which also uses the evacuated bladder prinicpal to achieve device rigidity. Information has been exchanged between representatives of the Canadian inventor and

NASA patent attorneys to determine whether the devices are sufficiently different to warrant continuing both development projects.

Action: Vykukal will fabricate a prototype so that the deformation characteristics of his device can be determined. The decision to further develop and transfer this device awaits the outcome of the discussions between NASA and the Canadian inventor's representatives.

4. CONFERENCES, MEETINGS, AND TRAVEL

January 24, 1980	Brennan attended meeting at NASA-ARC to discuss potential project in pediatric long-bone reconstruction.
February 27 - March 6, 1980	Brennan attended weekly IEEE microprocessor seminar at Stanford University.
March 27, 1980	Brennan hosted NASA site visit by Lou Mogavero et al to Stanford University BATeam.
April 14-16, 1980	Schmidt and Brennan attended AAMI meetings in San Francisco.
April 28, 1980	Steinman made introductory visit to Ray Whitten and Don Vargo at NASA Hq., Washington, DC.
April, 28, 1980	Steinman made introductory visits to Don Friedman and Earl Angulo at NASA-GSFC, Greenbelt, MD.
April 30, 1980	Schmidt, Ream, and Silverberg attended ICPM design review meeting at Pacesetter Systems, Inc., Sylmar, CA.
May 8, 1980	Brennan attended meeting with Becton-Dickinson representatives at NASA-ARC concerning their interest in BATeam's ICPM project.
May 10, 1980	Brennan attended meeting at Children's Hospital at Stanford concerning EMG project.
May 15, 1980	Brennan attended luncheon at Children's Hospital at Stanford for Dr. Margaret J. Giannini, Director of NIHR.
May 28, 1980	Schmidt, Brennan, Steinman and other members of VPSP research team presented demonstration of VPSP to potential manufacturers at Stanford University Medical Center.
May 29, 1980	Steinman, Debs, and Zimmerman attended meeting at SRI International, Menlo Park, CA to discuss visual-to-Tactile Mobility Aid project with Tenenbaum.
May 29, 1980	Steinman, Debs, and Zimmerman attended WRISTCOM design review at SRI International, Menlo Park, CA

June 2-4, 1980	Steinman attended and made two presentations at TU conference at NASA-GSFC, Greenbelt, MD.
June 12, 1980	Steinman made introductory visit to Esta Bakas, Cleve Foss, Hal Sandler, Ester Bugna, and Don Young at NASA-ARC, Moffett Field, CA.
June 15-21, 1980	Steinman attended International Conference on Rehabilitation Engineering in Toronto, Ontario, Canada.

APPENDIX

FUNDING STATUS OF PROJECTS

PROJECT OR POTENTIAL PROJECT	NASA FUNDING PREFUNDING	NASA FUNDING FUNDING	COFUNDING OR COST SHARING
Intracranial Pressure Monitoring		$ 84K	$ 672K + undetermined amounts
Versatile Portable Speech Prosthesis		60K	45.7K + undetermined amounts
Cardiovascular Magnetic Measurements		150K	226K
Improved EMG Biotelemetry for Pediatrics	$25K approved	45K	30K + undetermined amounts
Ultrasonic Kidney Stone Disintegration		40K	255K + undetermined amounts
Pediatric Roentgen Densitometry	20K approved	20K	Amounts not determined
X-ray Spatial Frequency Multiplexing		105K	1505K
Mechanical Impedance Determination of Bone Strength	40K approved		Amounts not determined
Visual-to-Tactile Mobility Aid for the Blind	50K approved		184K
Purkinje Image Eyetracker and Stabilized Photocoagulator		100K	Amounts not determined
Neurological Applications of NASA-SRI Eyetracker			3K
ICU Synthesized Speech Alarm System		15K	300K
Nanophor		25K	200K + undetermined amounts
Wristcom		250K	Amounts not determined
Medical Applications of NASA Liquid-Circulating Garments		20K	Amounts not determined
Hip Prosthesis With Biotelemetry		180K	250K proposed for FY81
PROJECT TOTAL	$135K approved	$1094K	$3422.7K + undetermined amounts + 250K proposed for FY81
Mini-VPSP	$17K proposed		
Critical Care Transport System	To be determined		
Clinical Information System for Cardiology	To be determined		Undetermined amounts
Programmable Biofeedback Orthosis for Scoliosis	14K proposed		$31K + undetermined amounts
Pediatric Long-Bone Reconstruction	40K proposed		Undetermined amounts
Spinal Immobilization Apparatus	To be determined		
POTENTIAL PROJECT TOTAL	$71K + amounts to be determined	0	$31K + undetermined amounts

CLASSIFICATION OF PROJECTS BY ACTIVITY STATUS

Project or Potential Project	Activity Status				
	Problem ID	Technology ID	Adaptive Engr.	Demo & Evaluation	Transfer
Intracranial Pressure Monitoring			X		
Versatile Portable Speech Prosthesis					X
Cardiovascular Magnetic Measurements			X		
Improved EMB Biotelemetry for Pediatrics			X		
Ultrasonic Kidney Stone Disintegration			X		
Pediatric Roentgen Densitometry				X	
X-ray Spatial Frequency Multiplexing			X		
Mechanical Impedance Determination of Bone Strength			X		
Visual-to-Tactile Mobility Aid for the Blind			X		
Purkinje Image Eyetracker & Stabilized Photocoagulator			X		
Neurological Applications of NASA-SRI Eyetracker		Not Applicable			
ICU Synthesized Speech Alarm System			X		
NANOPHOR: Microelectrophoresis Instrument				X	
WRISTCOM: Tactile Communications System for the Deaf-Blind			X		
Medical Applications of NASA Liquid-Circulating Garments				X	
Hip Prosthesis for Biotelemetry			X		
Person-Portable Versatile Speech Prosthesis	X				
Critical Care Transport System	X				
Clinical Information System for Cardiology	X				
Programmable Biofeedback Orthosis for Scoliosis	X				
Pediatric Long-Bone Reconstruction			X		
Spinal Immobilization Apparatus			X		