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BIOMEDICAL APPLICATIONS TEAM

APPLICATIONS OF AEROSPACE TECHNOLOGY IN BIOLOGY AND MEDICINE

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Langley Research Center
Hampton, Virginia 23665

BIOMEDICAL APPLICATIONS TEAM
Applications of Aerospace Technology in Biology and Medicine

Final Report
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by

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Technical Monitor: Mr. John Samos

Technology Utilization and Applications Programs Office
Langley Research Center
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
Hampton, Virginia 23665

PREFACE

This report documents the activities of the Research Triangle Institute's Biomedical Applications Team program for the period 1 January 1982 through 28 February 1983. The work was performed in the Research Triangle Institute's Center for Technology Applications under the direction of Dr. D. J. Rouse. Dr. J. N. Brown, Jr., Director of the Center, participated in the methodology development and management of the team. Assistance in establishing collaborative projects with the National Institutes of Health and other Federal agencies was provided by Mr. William Z. Penland, Jr., and Mr. Bernard Maggin, RTI consultants in Washington, D.C. Other participants in the program were Dr. H. C. Beall, Mr. P. N. Kizakevich, and Ms. B. Bass. The team was assisted during the summer by Mr. Scott Fosko. To ensure close coordination of transfer projects in California, RTI supported SRI International's participation in the projects as an RTI team representative.

The work reported herein was supported by the National Aeronautics and Space Administration--Contract No. NAS1-16177. Mr. John Samos, Head, Technology Utilization and Applications Programs Office, Langley Research Center, was the technical monitor.

The authors gratefully acknowledge the contributions of many individuals to the success of the RTI Biomedical Applications Team program. The time and effort contributed by Technology Utilization officers, managers, engineers, and scientists throughout the National Aeronautics and Space Administration and by medical researchers and clinicians were absolutely essential to program success. Industry managers and technical staff have always been cooperative and open in their participation. Continuing discussions with these industry representatives have enhanced the team's understanding of medical device manufacturing and marketing practices and constraints. Finally, Mr. John Samos has contributed significantly to the success of the program and, as a technical monitor, has always been supportive.

ABSTRACT

The objective of the Research Triangle Institute (RTI) Biomedical Applications Team is to achieve widespread utilization of National Aeronautics and Space Administration (NASA) technology in medicine. This objective is best obtained by stimulating the introduction of new or improved commercially available medical products incorporating aerospace technology.

A bipolar donor-recipient model of medical technology transfer is presented to provide a basis for the team's methodology. That methodology is designed to: (1) identify medical problems and NASA technology that, in combination, constitute opportunities for successful medical products; (2) obtain the early participation of industry in the transfer process; and (3) obtain acceptance by the medical community of new medical products based on NASA technology.

During the reporting period, the team completed two commercial transfers: the Ocular Screening Device, a system for quick detection of vision problems in preschool children, and Porta-Fib III, a hospital monitoring unit. The team also completed two institutional transfers: implant materials testing, the application of NASA fracture control technology to improve reliability of metallic prostheses, and incinerator monitoring, a quadrupole mass spectrometer to monitor combustion products of municipal incinerators.

Two Phase 0 studies were completed by the team during the reporting period: Mobility Aids for the Blind and Ultrasound Diagnosis of Burn Depth.

The team identified six new projects. Five projects were inactivated due to inadequate commercial potential to justify continued development. During the operating period, progress was made in the development and commercialization of each of the fifteen currently active projects.

For the convenience of the reader, the names and addresses of the sources of certain commercial products are included in this report. This listing does not constitute an endorsement by either the National Aeronautics and Space Administration or the Research Triangle Institute.

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1.0 INTRODUCTION

The preamble to the Space Act of 1958, which created the National Aeronautics and Space Administration (NASA), states: "It is the policy of the United States that activities in space should be devoted to peaceful purposes for the benefit of all mankind."[1] This Act of Congress further charges NASA with providing "for the widest practical and appropriate dissemination of information concerning its activity and the results thereof." The NASA Technology Utilization Program was initiated in 1962 to assist in satisfying this Congressional obligation.

Since 1962, NASA has been a leader and an innovator in the establishment, operation, and evaluation of technology transfer programs. Through its Tech Briefs, special publications, technology surveys, and Industrial Applications Center programs, NASA has successfully transferred the results of aerospace research to the non-space-related sectors of society.[2]

The NASA Appropriations Act for fiscal year 1979 amended the 1958 Space Act to emphasize the application of aerospace technology to bioengineering research.[3] The following subsection was added to Section 102 of the Space Act:

> The Congress declares that the general welfare of the United States requires that the unique competence of the National Aeronautics and Space Administration in science and engineering systems be directed to assisting in bioengineering research, development and demonstration programs designed to alleviate and minimize the effects of disability.

In 1966, NASA introduced a new approach to technology transfer that involved the activities of multidisciplinary "applications teams." The objective of these applications teams--called Biomedical Applications Teams--was to effect the transfer of NASA technology to applications in medical research and clinical medicine. The general approach of the Biomedical Applications Teams was: (1) to identify problems through direct interactions with clinicians and medical researchers, (2) to identify potentially applicable NASA technology by a variety of mechanisms, and (3) to take necessary and appropriate action to effect actual utilization of NASA technology in solving technology-related medical problems.

The Research Triangle Institute (RTI) has participated in this program since 1966, when it established one of the first three NASA Biomedical Applications Teams. Since then, the Institute has made a major commitment to the successful transfer of aerospace technology to applications in medicine and to a better understanding and advancement of the technology transfer process.

1.1 Biomedical Applications Team Objectives

The primary objective of the Biomedical Applications Team program is to assist NASA in achieving widespread utilization of aerospace technology in the medical field. Widespread utilization implies that application of NASA technology to medicine benefits a significant sector of the medical field and of those seeking medical services. Implicit in this program objective is the rapid realization of this widespread utilization.

The successful transfer of NASA technology to applications in the medical field via the Biomedical Applications Team program has been demonstrated[2 4] both in clinical medicine and in medical research. These applications have resulted in advances in medical research, improved clinical diagnoses and treatments, and the introduction of new or improved medical products.

Although advances in medical research ultimately have widespread positive impact on the delivery of health care in the United States, medical research is a slow, complex, and expensive process. However, much can be accomplished in a relatively short time by solving technology-related problems in clinical medicine. Applications of technology in clinical medicine usually involve the introduction of a new or improved commercially available medical product. Thus, the approach of the NASA Biomedical Applications Teams in obtaining widespread utilization of NASA technology is to concentrate on solving problems that involve the introduction of a new or improved medical product.

This emphasis on achieving widespread utilization by commercializing NASA technology is reflected in the activities and methodology of the Biomedical Applications Team program. The team methodology has been built around the following four activities: (1) identifying medical problems and needs and potentially applicable NASA technologies that together constitute a new or improved medical product; (2) screening opportunities to find those that represent potentially successful commercial products; (3) developing commercialization strategies that take into account any necessary adaptation of NASA technology, evaluations and clinical trials, FDA regulations, manufacturer's marketing systems, and required funding; and (4) implementing and monitoring commercialization strategies. These tasks are discussed in more detail in Section 2.0, Technical Approach.

1.2 Biomedical Applications Team Staffing

The RTI Biomedical Applications Team is a multidisciplinary team of engineers and scientists whose educational backgrounds include physiology, biophysics, engineering, biochemistry, and biomedical engineering and whose experience includes basic and applied research, product development, and marketing. The team is necessarily multidisciplinary in nature because the transfer of technology to the medical field is an interdisciplinary process. That is, team members must communicate precisely and effectively with physicians, NASA scientists and engineers, industry representatives, and representatives of a variety of government agencies. Furthermore, the team must be able to deal with and contribute to the technical, clinical, financial, legal, marketing, and regulatory aspects of introducing

new medical products. The individuals who participated in the RTI Biomedical Applications Team program during the reporting period are:

Name	Professional Background	Responsibility
Dr. J. N. Brown, Jr.	Electrical Engineer	Director, Center for Technology Applications
Dr. D. J. Rouse	Biochemist, Physiologist	Director, RTI Biomedical Applications Team
Dr. H. C. Beall	Biophysicist, Physiologist	Solution Specialist
Mr. William Z. Penland, Jr.	Engineer	Washington Consultant
Mr. Scott Fosko	Microbiology	Summer Intern
Mr. P. N. Kizakevich	Biomedical Engineer	Internal Technical Consultant
Mr. Bernard Maggin	Program Manager	Washington Consultant
Dr. Anthony Marmarou	Electrical Engineer	Neurosurgery Consultant
Ms. B. C. Bass	Resource Specialist	Solution Assistant

1.3 Participating Institutions

Biomedical Applications Teams may be viewed as one component in a technology transfer network that involves NASA Headquarters, NASA field centers, medical institutions, manufacturing and marketing firms, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and other government agencies. Organizations and their roles in the technical process are listed below.

Organization	Role
National Institutes of Health Veterans Administration	Establishment of medical objectives and priorities and evaluation of devices
National Aeronautics and Space Administration	Development of advanced technology and innovations

Organization	Role
Medical institutions	Specification of needs and use of medical innovations
Industry	Manufacture and distribution of products
Biomedical Applications Teams	Coordination, planning, and reporting
Food and Drug Administration	Approval of products and establishment of medical objectives and priorities

At present, medical researchers and clinicians from 26 medical institutions participate in the RTI Biomedical Applications Team program. Medical researchers and clinicians participate in the program by: (1) identifying medical problems and needs appropriate for investigation by the Biomedical Applications Team; (2) serving as a knowledge base on medical problems and needs, markets, and potential applications of NASA technology; and (3) receiving NASA technology to be applied in their medical research programs or to be evaluated within their clinical practices. Figure 1 presents the geographical locations of participating medical institutions and NASA field centers. Table 1 lists these medical institutions, and Table 2 lists the RTI Biomedical Applications Team active projects at the NASA field centers for the past year.

The active participation of medical device manufacturers is essential to the widespread utilization of NASA technology because they incorporate that technology into commercial medical products. Manufacturers who have participated in the RTI Biomedical Applications Team program during this reporting period are listed in Table 3.

Government agencies involved in health care research, regulation, and delivery work with the RTI team to identify significant projects and to facilitate their successful completion. Agencies participating in RTI's team projects during this reporting period are listed in Table 4.

1.4 Conference Attendance and Advisory Boards

To inform the medical community of NASA's technology transfer program in medicine, RTI team members participate in biomedical conferences and serve on national advisory boards. In March 1982, Dr. Doris Rouse made a presentation on the NASA technology transfer program at the Wheelchair III conference sponsored by the Veterans Administration. The RTI team also participated in the annual conference of the Rehabilitation Engineering Society of North America (RESNA) in August. Dr. Doris Rouse was asked to chair the RESNA wheelchair committee. In November, the RTI team attended an International Workshop on Hydrocephalus. In the past year the RTI team was asked to serve on the

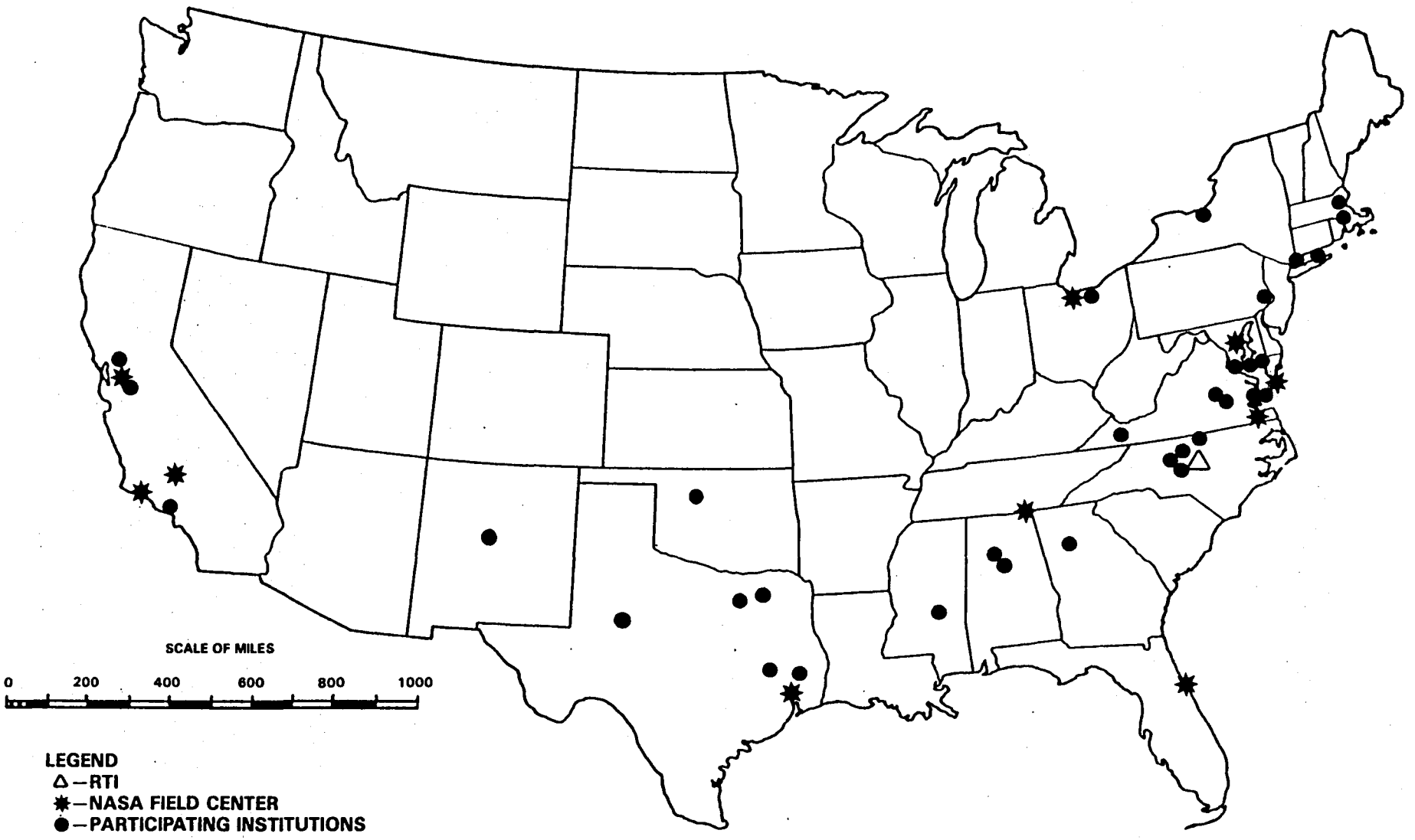

Figure 1. Biomedical Technology Transfer Network.

TABLE 1. PARTICIPATING MEDICAL INSTITUTIONS

Alabama School for the Deaf	Talladega, AL
Albert Einstein College of Medicine	Bronx, NY
Case Western Reserve University	Cleveland, OH
Cornell Medical Center	New York, NY
Duke University Medical Center (including VA Hospital)	Durham, NC
Johns Hopkins University Medical School	Baltimore, MD
M.D. Anderson Hospital	Houston, TX
Medical College of Virginia	Richmond, VA
Montefiore Hospital	New York, NY
Rochester General Hospital	Rochester, NY
Rush-Presbyterian Medical Center	Chicago, IL
St. Mary's Hospital	Richmond, VA
Shriners Burn Institute	Boston, MA
Smith-Kettlewell Eye Research Foundation	San Francisco, CA
Texas Institute for Rehabilitation and Research	Houston, TX
U.S. Army Institute of Surgical Research	San Antonio, TX
University of Alabama Department of Rehabilitation	Birmingham, AL
University of Arizona Medical School	Tucson, AZ
University of California-Irvine	Irvine, CA
University of Mississippi Medical Center	Jackson, MS
University of North Carolina School of Medicine	Chapel Hill, NC
University of Virginia Rehabilitation Engineering Center	Charlottesville, VA
University of Virginia School of Medicine	Charlottesville, VA
Veterans Administration Hospital	Norfolk, VA
Veterans Administration Rehabilitation Engineering Center	Palo Alto, CA
Wadley Institute	Dallas, TX

TABLE 2. PROJECTS WITH NASA FIELD CENTERS DURING REPORTING YEAR

AMES RESEARCH CENTER
- Digital Data Recorder for Physiological Monitoring
- Liquid-Cooled Garment Projects
  - Cooling Vests for Quadriplegics
  - Cooling for Multiple Sclerosis Therapy
- Mobility Aids for the Blind

GODDARD SPACE FLIGHT CENTER
- Computerized Hydrocephalus Implantable Pump
- Programmable Implantable Medication System

JET PROPULSION LABORATORY
- Corneal Topography
- Hydrocephalus Shunt--Ventilation

JOHNSON SPACE CENTER
- Female Incontinence Device
- Flow Sensor for an Infusion Pump
- Physician's Black Bag

KENNEDY SPACE CENTER
- High Performance Wheelchair
- Wildlife Tracking

LANGLEY RESEARCH CENTER
- Aircraft Wheelchair
- Composite Material Applications
- Fiber Optics for Knee Surgery
- High Performance Wheelchair
- Implant Materials Testing
- Incinerator Monitoring

LANGLEY RESEARCH CENTER (continued)
- Low-Cost UV Optical Dosimeter
- Microwave Thermography
- Noninvasive Lung Diagnosis
- Portable X-Ray Fluorescense Spectrometer
- Ultrasound Diagnosis of Burn Depth
- Weight Alleviation Device

LEWIS RESEARCH CENTER
- Detection of a Dislodged Temperature Probe
- Hydrocephalus Shunt--Ventilation
- Texturing for Percutaneous Connectors
- Texturing Surfaces for Cardiovascular Prostheses

MARSHALL SPACE FLIGHT CENTER
- Corneal Topography
- Detection of a Dislodged Temperature Probe
- Ocular Screening Device
- Prosthetic Urinary Sphincter

NATIONAL SPACE TECHNOLOGY LABORATORIES
- Wastewater Treatment by Vascular Aquatic Plants

TABLE 3. MANUFACTURERS PARTICIPATING IN BATEAM PROJECTS

Abbott Laboratories	Houston, TX
Air Transport Association	Washington, DC
American Hospital Supply	Glendale, CA
Analog Technology Corporation	Sunnyvale, CA
Applied Medical Technology, Inc.	Lakewood, OH
B&K Instruments	Cleveland, OH
Boeing Aircraft	Seattle, WA
Becton-Dickinson	Rutherford, NJ
CAMI Health Care, Inc.	League City, TX
Cordis Corporation	Miami, FL
Design Research Associates, Inc.	Tulsa, OK
Eagle Engineering Corporation	Houston, TX
Electro-Optics Consultants, Inc.	Huntsville, AL
Everest & Jennings	Los Angeles, CA
Hercules, Inc.	Washington, DC
Heyer Schulte Corporation	Goletka, CA
Invacare Corporation	Elyria, OH
Inductron	Grafton, VA
Johnson & Johnson	New Brunswick, NJ
Major Laboratory	Oklahoma City, OK
Medical Engineering Corporation	Racine, WI
Microwave Associates, Inc.	Burlington, MA
Miller Medical Electronics	San Diego, CA
NARCO Bio-Systems, Inc.	Houston, TX
Pacesetter Systems, Inc.	Sylmar, CA
Palm Beach Medical Corporation	E. Long Meadow, MA
Parker-Hannifin Corporation	Irvine, CA
Patscenter International, Inc.	Princeton, NJ
Preston Company	New York, NY
Pudenz-Schulte Medical Research Corporation	Irvine, CA
Scientific Industries	Bohemia, NY
Sonometric Systems, Inc.	New York, NY
Thermo Electron Corporation	Waltham, MA
United Airlines	San Francisco, CA

TABLE 4. AGENCIES PARTICIPATING IN BATEAM PROJECTS

Agency for International Development
American Foundation for the Blind
Association for Retarded Citizens
Department of Defense
Department of Transportation
Environmental Protection Agency
Food and Drug Administration
Gerontological Society of America
National Cancer Institute
National Children's Eye Care Foundation
National Eye Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases
National Institute of Child Health and Human Development
National Institute of Handicapped Research
National Institute of Neurological and Communicative Disorders and Stroke
Paralyzed Veterans of America
Rehabilitation International-USA
U.S. Coast Guard
Veterans Administration

Advisory Design Committee for the Association for Retarded Citizens (ARC). The Western Gerontology Society has asked Dr. Doris Rouse to serve on their Technology for the Aging Advisory Board this year. Other significant travel is described in Appendix A.

1.5 Report Summary

The Biomedical Applications Team's technical approach to technology transfer in medicine is described in Section 2.0. The commercialization of NASA technology is emphasized throughout the team's methodology; that is, the team's activities are divided into four major phases leading logically from the identification of opportunities for commercialization to the implementation and monitoring of commercialization strategy. Within each of these four phases, program flexibility allows for technology transfer activities related to medical research and institutional technology transfer.

Section 3.0 summarizes the two commercial transfers completed by the RTI team during the reporting period: the Ocular Screening Device, a system that can be used to screen preschool children for visual defects, and the Porta-Fib III, a hospital monitoring unit incorporating NASA technology in vital signs monitoring. Two institutional transfers, Implant Materials Testing and Incinerator Monitoring are presented in Section 4.0. In Section 5.0, the results of Phase 0 studies on Mobility Aids for the Blind and Ultrasound Diagnosis of Burn Depth are summarized.

The team's problem solving and transfer activities in active transfer projects are summarized in Section 6.0. Projects inactivated during the reporting period are discussed in Section 7.0.

Section 8.0 is a statement of conclusions and recommendations. This section emphasizes what has been learned concerning medical technology transfer and how these lessons can be applied to increase the effectiveness of the NASA Biomedical Applications Team program.

Significant travel is summarized in Appendix A. A summary of the team's project activities for the reporting period is presented in Appendix B. Problem statements describing medical requirements for improved technology, as identified by the team during the reporting period, are presented in Appendix C.

1.6 Definition of Terms

Biomedical Applications Team--A multidisciplinary group of engineers and scientists engaged in assisting NASA in achieving widespread utilization of aerospace technology in the medical field.

Commercial opportunity--The combination of a significant medical need or problem and appropriate, relevant NASA technology that constitutes the basis for a potentially successful new or improved commercial medical product.

Commercial technology transfer--The successful development and marketing of a new or improved medical product that incorporates NASA technology.

Computer information search--A computerized search of NASA's aerospace information bank at one of six Industrial Applications Centers (IACs). This information bank consists of more than 1 million documents that have been indexed and abstracted in the Scientific and Technical Aerospace Reports (STAR) and the International Aerospace Abstracts (IAA).

Donor--Organization or individual who originally developed technology that is transferred. Within the context of the Biomedical Applications Team, NASA is the donor.

Institutional technology transfer--The application of NASA technology to solve a significant medical problem that does not result in a new or improved medical product.

Medical problem (or need)--A specific and definable technology-related medical problem or need that cannot be satisfied by commercially available equipment or by the information available to the problem originator through routine information channels.

Participating institution--A medically oriented educational institution, hospital, medical center, or government agency that works with the Biomedical Applications Team in identifying medical problems and needs and in evaluating NASA technology that represents solutions to those problems and needs.

Problem originator--A clinician or medical researcher actively involved in reaching a specific medical objective and faced with a specific technology-related problem or need.

Problem statement--A concise, written description of a medical problem or need that contains sufficient details to allow a computer search to be performed and that contains sufficient information to enable NASA engineers and scientists to consider possible solutions.

Recipients--The clinical medical sector or medical researcher who uses or applies the technology transferred.

RTOP (Research and Technology Objectives and Plans)--A proposal submitted by a NASA field center to NASA Headquarters for funding of research and development projects.

Technology--All of the skills, techniques, and understanding that constitute a specific technology. Technology includes, but is not limited to, hardware.

Technology transfer--The movement of a specific technology from one situational context--the one for which it was developed--to another. As a result, changes are seen in either the technology or the situation to which it is moved or both.

Transfer agent (or linker)--The individual or organization that plans, stimulates, and facilitates technology. Within this context, the transfer agent or linker is the Biomedical Applications Team.

1.7 References

1. Public Law No. 85-568, National Aeronautics and Space Act of 1958.

2. Haggerty, J. J. Spinoff 1982--An Annual Report. National Aeronautics and Space Administration, April 1982.

3. Public Law No. 95-401, National Aeronautics and Space Authorization Act, 1979.

4. Rouse, D. J. Applications of Aerospace Technology in Biology and Medicine. Research Triangle Institute, Research Triangle Park, North Carolina, December 1981.

5. Rouse, D. J., J. N. Brown, Jr., and R. D. Whitten. Methodology for NASA Technology Transfer in Medicine. Medical Instrumentation, Vol. 15, No. 4, pp. 234-236, July-August 1981.

2.0 TECHNICAL APPROACH

The objectives, operations, and methodology of the RTI Biomedical Applications Team are presented in this section. The conceptual framework for medical technology transfer described in Section 2.1 provides the background and rationale for the Biomedical Applications Team methodology as developed by the Research Triangle Institute and presented in Section 2.2.

2.1 Conceptual Framework for Medical Technology Transfer

A conceptual framework for medical technology transfer is diagrammed in Figure 2.[1] The framework is basically a bipolar donor-recipient model. The role of the donor, in this case NASA, is to reveal, disseminate, and promote technology. The role of the recipient, the medical community, is to seek out, evaluate, and utilize technology.

As explained in the introduction, the primary thrust of the Biomedical Applications Team program is to transfer technology by the introduction of new and improved medical products. Thus, a manufacturer of those products is included in Figure 2. Medical technology transfer normally involves the identification of a medical problem or need within the medical community. In response, the National Aeronautics and Space Administration recognizes the relevance of specific aerospace technology and makes that technology available. The manufacturer designs, develops, evaluates, and markets a new or improved medical product that incorporates aerospace technology and represents a solution to the medical problem or need.

The purpose of the transfer agent* in this framework is to plan, stimulate, and facilitate such technology transfer. This is the role of the Biomedical Applications Team.

Research into the process of medical technology transfer at the Syracuse University Research Center indicates that the donor, recipient, and manufacturer are frequently at cross purposes.[2] The recipient is concerned primarily with solving a problem. The manufacturer, by necessity, is concerned with introducing a commercially successful product. The donor obtains satisfaction as reward for involvement in the transfer process. It is the task of the transfer agent to bring the donor, recipient, and manufacturer together in such a way that each views successful technology transfer as the primary objective. A technology transfer methodology based upon an active transfer agent serving as a personal liaison has evolved from the realization that the passive dissemination of information on technology in itself seldom results in effective technology transfer. This point is illustrated by a quote from a Congressional Review of Intergovernmental Dissemination of Federal Research and Development Results.[3]

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*The term "linker" is frequently used in this context.

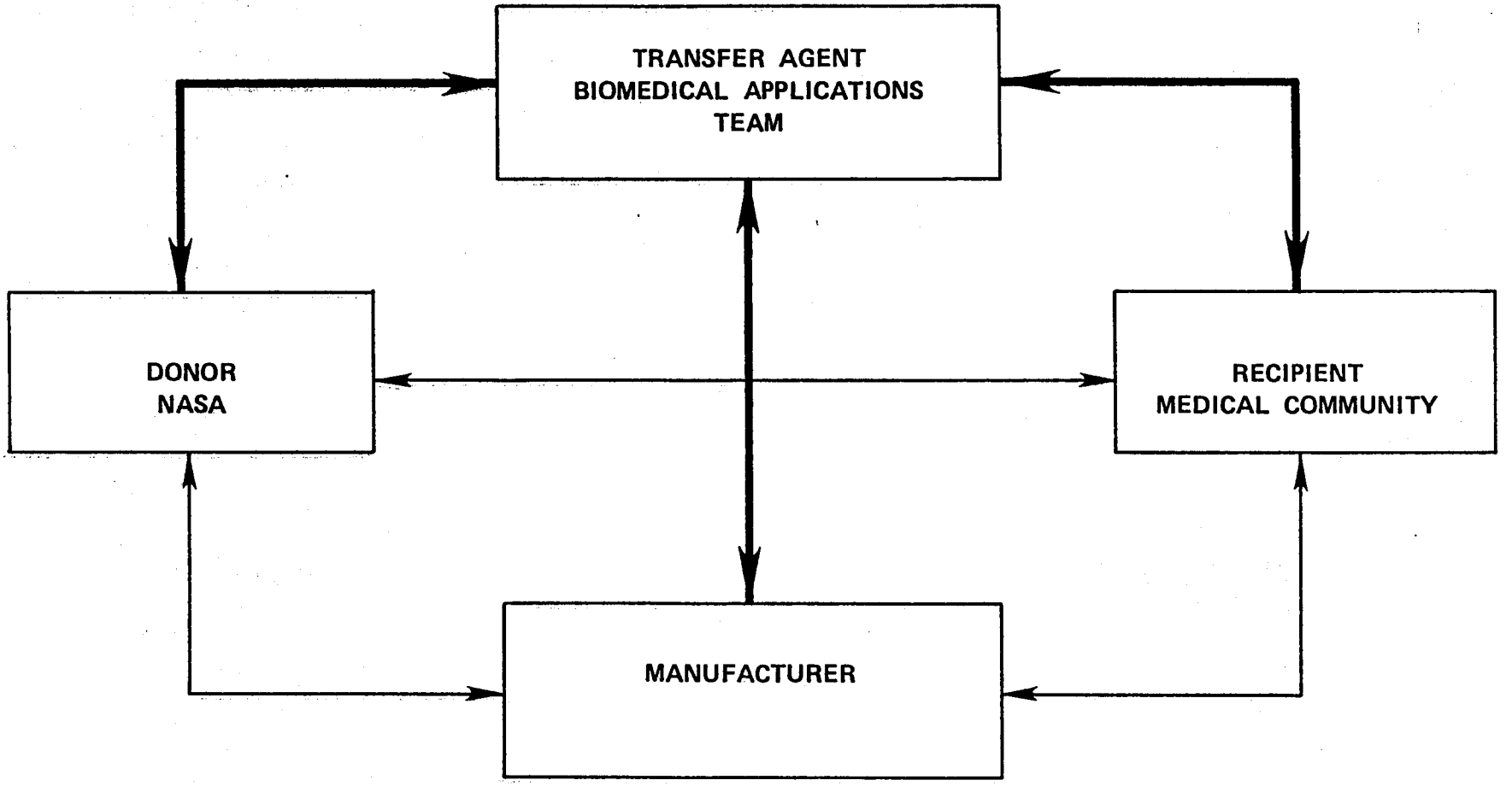

Figure 2. Conceptual Framework for Medical Technology Transfer.

> The mere availability of information does not cause its transfer or use. Printed materials alone, even expertly prepared, cannot stimulate interpersonal relations, define a problem, answer related questions, involve consulting authorities, provide follow through on problems or relate to other agencies.

The specific role of the Biomedical Applications Team depends upon the motivation, competence, and organization of the donor, recipient, and manufacturer. NASA is highly motivated to transfer aerospace technology to applications in non-space-related fields. Further, its organization is structured to facilitate the development of sophisticated and advanced technology. NASA's understanding of the medical industry and clinical medicine, on the other hand, is limited. The technological competence of the recipient is varied. Many medical researchers in large medical centers and teaching hospitals are technologically competent; the physicians in private practice, in general, lack the facilities and support staff required for technological innovation. The manufacturer of medical products may have a long and successful history of developing and marketing medical products or may be a small aggressive company with innovative ideas but lacking experience or resources for sophisticated device development and evaluation.

The relative importance and role of each participant depends on the technology gap between that participant and the technology being transferred. It is the role of the Biomedical Applications Team to recognize the strengths and weaknesses of each participant and to supply the motivation, competence, and institutional linkages to ensure success. The methodology of the Biomedical Applications Team as presented in Section 2.2 addresses these factors.

Technology will be interpreted throughout this report as including all of the skills, techniques, and understanding, as well as the materials, devices, and hardware that make up a specific science.[4] Technology transfer as used here will refer specifically to horizontal technology transfer; that is, the transfer of technology from one situational context--the one for which the technology was developed originally--to another situational context.[5] This transfer will normally result in some modification of the technology or in the situational context to which it is transferred.

2.2 Biomedical Applications Team Methodology

As noted in the introduction, and as indicated in Figure 3, the activities of the Biomedical Applications Team program are separated into four phases. Within each of these phases, the specific actions and responsibilities of the team are, to a certain extent, fixed. However, team methodology incorporates flexibility, which allows the team to respond appropriately to the specific characteristics of particular technology transfer cases. Brief descriptions of the methodologies used by the Biomedical Applications Team are presented in the following four sections.

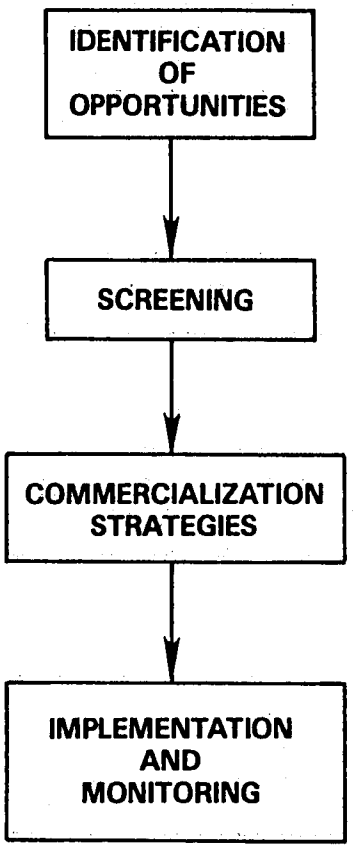

Figure 3. Phases of RTI Biomedical Applications Team activity.

2.2.1 Identification of Opportunities

The identification of technology transfer opportunities involves the identification of: (1) a medical problem or need, and (2) relevant aerospace technology with the potential to solve the medical problem or satisfy the medical need.

Medical problems are identified through the direct interaction of a team member with a researcher or physician within a medical institution. A NASA-funded study of medical technology transfer by the National Academy of Engineering concluded that the recipient must take the lead in defining medical problems.[6] This conclusion is consistent with the experience of the RTI team. As a result, the Biomedical Applications Team emphasizes obtaining complete and extensive descriptions of medical problems and needs from the problem originator or recipient. The significance of the medical problem is verified by the RTI team through literature reviews and interviews with manufacturers, health agencies, and other clinicians.

Certain medical institutions and medical professionals are more innovative than others.[7] Research has shown that the first hospitals to adopt innovation usually are large medical centers or teaching hospitals near the site of technology development. Further, those hospitals with highly trained medical staff tend to be more innovative. Finally, once a hospital has adopted an innovation, the widespread use of that innovation is enhanced if the innovating hospital interacts frequently with other medical institutions. The Biomedical Applications Team, in its problem identification activities, has considered these factors.

Because of the innovative physician's emphasis on quality, medical technology introduced in the past 10 to 20 years has tended to increase the sophistication of medical diagnosis and treatment, but has not contributed to a reduction in the cost of health care. The efforts of the Biomedical Applications Team have been directed toward the utilization of aerospace technology to reduce or contain health care costs.

Technology relevant to medical problems and needs can be identified by a variety of techniques. Once a medical problem or need is specified, a computerized information search of the aerospace literature is performed by one of the six NASA Industrial Applications Centers (IACs). The RTI team has used the services of the North Carolina Science and Technology Research Center in Research Triangle Park, North Carolina. Computerized information searches can identify information on potentially relevant technologies.

An additional approach to identifying aerospace technology is the circulation of problem statements to NASA field centers. Individual medical problems are concisely described in problem statements. At each center, a technology utilization officer, who is responsible for the management of technology transfer activities at that facility, distributes the problem description to the appropriate scientists and

engineers for review. Responses to problem statements from these engineers and scientists can lead to the identification of solutions based on NASA technology.

Finally, the Biomedical Applications Team contacts NASA personnel known to have a strong interest in transferring technology to medicine and known to be working in relevant technical areas. This is the most direct, efficient, and rapid approach to finding technology. The next phase of the program is the investigation of factors that determine which opportunities are most likely to be successful.

2.2.2 Screening

Effective screening enables the RTI Biomedical Applications Team to focus on those opportunities with the most promise for successful medical solutions and commercial products. To continue work on a particular opportunity, the team must determine that most of the following requirements are satisfied:

- The solution improves medical treatment or diagnosis or reduces the cost of health care.
- The solution is recognized by a Federal health agency and the medical community as a contribution to improved health care.
- The solution incorporates NASA technology or expertise.
- The market for the new or improved medical product justifies the required capital investment and production cost to the manufacturer.
- A manufacturer can be offered sufficient market protection, either by exclusive license or by lead time, to justify the required investment in product development.
- The solution represents a discrete, well-defined transfer of technology involving limited research and development effort.
- Candidate manufacturers with the required marketing and production capabilities have expressed an interest in commercialization.

These factors are evaluated by review of the biomedical literature, market surveys, interviews with industry representatives, and discussions with appropriate medical staff. Much of the data collected in this process is used in the development of commercialization strategies as described in the next section.

2.2.3 Commercialization Strategies

The development of strategy for successful technology transfer must consider product development and marketing, clinical trials, FDA approval, acceptance by the medical profession, and identification of funding sources for the various tasks involved. Because of the emphasis on commercialization of NASA technology, strategies must involve obtaining industry participation.

The National Academy of Engineering study of medical technology transfer referenced in the preceding section reached some important conclusions concerning strategy for technology transfer.[6] Successful technology transfer requires significant involvement of the donor and recipient throughout the transfer process. Further, the involvement of industry throughout the transfer process is essential. The manner in which new technology is introduced to the medical field is a critical factor in successful technology transfer; the new or improved product must be accepted by and applied by the medical community.

The medical technology transfer model in Figure 4 was developed by the RTI team to summarize the requirements for each phase of this complex commercialization process. An important lesson that can be taken from this model and the team's experience is that careful planning throughout the project is necessary for successful product development and transfer to industry.

The experience of the RTI Biomedical Applications Team has confirmed and expanded these conclusions. Industry must be involved throughout the transfer process and must be included as early as possible. Further, the involvement of industry generally requires some means for giving a specific manufacturer a proprietary position. This may involve either an exclusive license to a patent or lead time to allow sudden entry of the new product into the medical market. Industry tends to view new product opportunities from the outside as competition with its own internally generated product ideas, which means that opportunities for technology transfer generated through the NASA Technology Utilization Program have to compete for industry capital and management attention. These barriers can best be overcome by the Biomedical Applications Team through an analysis of patent positions, development costs, and market studies, followed by careful selection of potential manufacturers.

The acceptance of a new product by the medical community involves a fairly specific sequence of events. The product must be subjected to clinical trials and the results published by a recognized medical expert. Additionally, the product usually must be exhibited at medical meetings.

Medical marketing and distribution are not necessarily an integral function of all medical product manufacturing firms. Thus, in addition to obtaining the participation of a medical product manufacturer, the team may also need to identify and involve an organization capable of marketing and distributing those products.

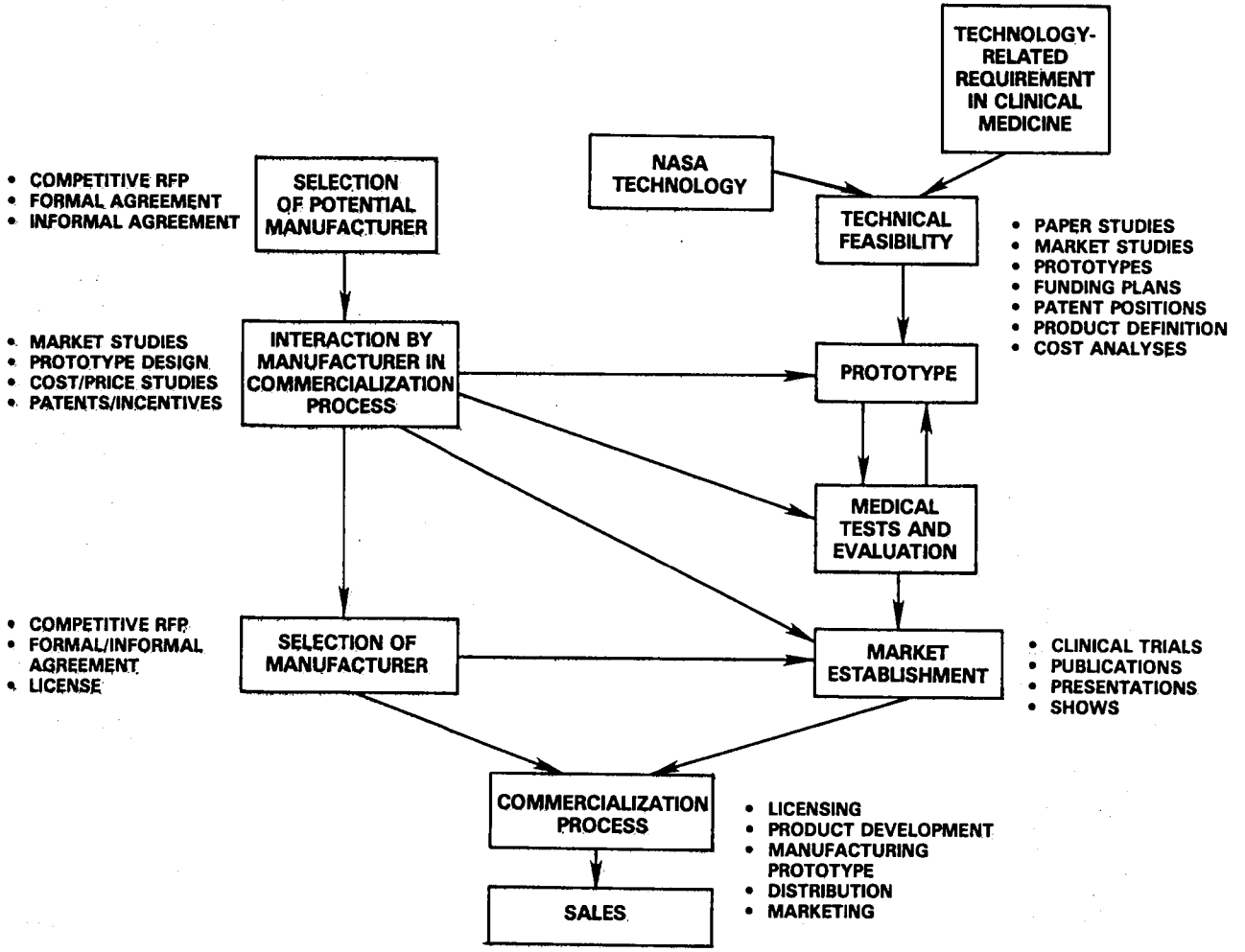

Figure 4. Medical Technology Transfer Model.

Each specific opportunity for medical technology transfer offers a new set of barriers and strategic options. Thus, the formation of strategy is not a specific activity; it is a problem-solving effort. The most important common feature of strategy formation is thoroughness; all contingencies must be anticipated.

2.2.4 Implementation and Monitoring

Experience in implementing strategy has shown that the chance for successful technology transfer is increased by active involvement of the Biomedical Applications Team throughout the transfer process. By monitoring and coordinating the activities of the participants, minor problems can be prevented from becoming major obstacles. The RTI team prepares Gantt charts and Project Evaluation and Review Technique/Critical Path Method (PERT/CPM) scheduling networks to provide systematic analysis for complex projects. These charts, which are too large to be included in this report, are sent to the participating NASA field centers and to NASA Headquarters.

Documentation is an integral part of the team methodology; it is required throughout the technology transfer process. Implementation of strategy is no exception. Periodic status reports are issued informally to keep all participants informed. Upon completion of the transfer process, the team prepares a technology transfer report documenting all important aspects of the transfer process.

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3.0 COMMERCIAL TRANSFERS

3.1 The Ocular Screening Device

The ocular screening project at Marshall Space Flight Center (MSFC) has resulted in the development of a commercially available optics system that can be used to assay the visual acuity of large numbers of persons quickly by means of color photography of the retinal (red) reflex of the eye. Electro-Optics Consultants (EOC), Inc., of Huntsville, Alabama, is responsible for manufacturing and marketing the system, called GRRIS-Model IV (generated retinal reflex imagery system). This device is especially useful for screening the vision of preschool children for defects. The performance of GRRIS has been evaluated in two screening projects and by a scientist at the Smith-Kettlewell Eye Research Foundation of San Francisco, California. Controlled tests were designed, performed, and evaluated by the scientist to determine the system's sensitivity and accuracy in revealing visual defects in preschool children and in infants.

The project has involved the cooperative efforts of the following organizations and persons: NASA Marshall Space Flight Center; S. Hutson Hay, M.D.; Joe Kerr, Ph.D., President of EOC, Inc.; the Alabama School for the Deaf at Talladega, the Lions Club of Huntsville; the National Children's Eye Care Foundation; and the Research Triangle Institute's NASA Biomedical Applications Team.

3.1.1 Background

Visual defects in preschool children can develop into permanent disabilities. For example, if amblyopia ("lazy eye") is allowed to persist for several years before a child reaches school age, the visual pathways to the brain fail to develop properly. What might have been only a minor visual defect can result in permanent loss of vision in one eye if the condition is not detected promptly. Other conditions such as cross-eye, myopia, and hyperopia can occur in early childhood and remain undetected, to the detriment of the child's mental and physical development. Ideally, each child should receive an eye exam at age three and another by age six. However, suitable eye exams are not usually obtained due to children's lack of communication skills and short attention span and parents' unawareness of the necessity for testing.

3.1.2 Development and Commercialization of GRRIS

Dr. Hay, an ophthalmic surgeon in Huntsville, Alabama, developed the concept of using the retinal reflex to screen the visual acuity of large numbers of preschool children. The reflex is the red light that is reflected from the back of the human eye. The reflex can be photographed by placing a camera and a flash unit very close together and inducing the subject to look directly at the camera lens from a distance of 5 to 12 feet. A collaborative project was established between NASA MSFC engineers, Dr. Hay, and Electro-Optics Consultants, Inc. The objective of this project was to design and fabricate a photographic system for recording and analyzing the retinal reflex and an analyzer for automatically evaluating the photos after development.

Several evaluations of the GRRIS system have been conducted. At the Alabama School for the Deaf, in Talladega, Alabama, 450 students were screened by the GRRIS system. Those students whose GRRIS photos were suspect were examined by volunteer staff of the University of Alabama Medical School at Birmingham. The eye exams corroborated the GRRIS evaluation of possible visual defects.

In a second evaluation project initiated to obtain data representative of the general population, the Lions Club of Huntsville volunteered to do the GRRIS photography at regional kindergartens. The parents of each child with a suspect GRRIS photo were advised by postcard to seek a professional eye exam for the child. Financial support for the Huntsville screening project came from the National Children's Eye Care Foundation, Washington, DC. The Lions Club is considering the expansion of this screening project to other cities within Alabama. Thus, the concept of retinal reflex screening may become statewide, or even nationwide.

A scientific evaluation of the GRRIS system took place during a 5-month period in 1982 at the Smith-Kettlewell Eye Research Foundation in San Francisco. Their evaluation verified an 88 percent positive correlation of GRRIS images in the identification of all visual defects. The system's performance was excellent in tagging major visual defects within the range of ±0.25 to 10 diopters but was less precise in the identification of visual defects within the +0.25 to -0.25 diopter range; i.e., very close to normal vision. The GRRIS system correctly flagged visual defects in several 4-month old infants, thus demonstrating its potential in testing the vision of this nonverbal sector of the population. These successful evaluations have been useful to EOC in their marketing of the system.

3.1.3 Description of the GRRIS

The GRRIS is a portable photographic system that can be transported by auto and set up quickly at schools and other public sites. The system consists of two components horizontally spaced approximately 12 feet apart. One component is a screen through which the subject's eyes are visible to the remote camera and flash unit. The screen serves to position the subject's eyes exactly at the object focus plane of the camera lens. The second component of the system is the camera and flash assembly. The flash assembly is placed adjacent to the camera lens so that the full extent of the eye's retroreflection (reflex) will be viewed by the 400-mm camera lens. A bright, blinking, light-emitting diode is placed at the rim of the camera lens to draw the subject's eyes directly toward the camera lens.

The subjects approach the GRRIS after waiting for several minutes within the dimly lit room. Thus, the subject's pupils are naturally dilated, allowing maximum flash illumination to enter the eye and maximum reflex to exit toward the camera. The actual photography of the GRRIS takes only seconds. Five to six children can be photographed within a minute's time depending on the ability of the children to follow verbal instructions. Any adult can operate the GRRIS system with only brief instruction.

The GRRIS photographs are developed by conventional color slide processing. In a typical kindergarten population, 75 percent of the slides will show normal eyes. These children are eliminated at the initial evaluation. The remaining 25 percent are reviewed more carefully and perhaps 3 to 10 percent of these are judged to be normal. The remaining slides exhibit nontypical retinal reflexes, caused by any of several visual defects.

3.1.4 Summary of the GRRIS Project

Objective

To design, fabricate, and evaluate a portable photographic system for documenting the retinal reflex from human eyes as a means of screening the visual acuity of preschool children.

Project Summary

May 1979	RTI team member Dr. Richard Scearce attended a presentation at MSFC during which the concept of vision screening of preschool children was brought to the attention of the MSFC Technology Utilization Office staff.
May 1979	Clark Beall of the RTI team traveled to MSFC to consult with the Technology Utilization Office staff in preparation for the NASA RTOP to fund the development of the GRRIS.
May 1980	Initial arrangement was made with the Alabama School for the Deaf to use the prototype GRRIS device to screen the vision of 450 students.
November 1980	Clark Beall visited MSFC and reported to NASA Headquarters the physiological and technical basis of the GRRIS.
February 1982	Initial arrangements were made with Smith-Kettlewell Eye Research Foundation to test the GRRIS device from May to September 1982.
December 1982	Clark Beall attended the presentation of the test results by Anthony Norcia of Smith-Kettlewell at MSFC.
December 1982	EOC, Inc., is marketing production models of the GRRIS based on the two field tests and the Smith-Kettlewell evaluation.

3.2 Portable Medical Status and Treatment System and the Porta-Fib III

The Portable Medical Status and Treatment System (PMSTS) and the Porta-Fib III are spinoffs of a NASA project known as the Physician's Black Bag, a portable monitoring and treatment system developed by Telecare, Inc., a company later acquired by Narco Scientific. The PMSTS was designed as an emergency care system for use in remote areas where treatment at a hospital may be delayed.

The Porta-Fib III, developed by Narco Scientific Bio-Systems Division, Houston, Texas, is a companion system to the PMSTS designed for use in the hospital. Both the PMSTS and the Porta-Fib III utilize NASA technology in astronaut monitoring, electronic circuitry, and microminiaturization. The RTI team's role in the project included interviews with physicians to determine the features required in the device and to estimate the market. To identify potential applications and markets for the PMSTS, the RTI team discussed the system with the U.S. State Department Office of International Health and the Peace Corps to explore use of the system in developing countries. Discussions with the Department of Transportation and the U.S. Coast Guard resulted in sponsorship of field tests by both of these organizations.

3.2.1 Portable Medical Status and Treatment System

The PMSTS is a portable, battery-powered unit that includes a vital signs monitor, a defibrillator, and a UHF transceiver for transmission of information to hospital staff. The microprocessor-based monitor includes a data recorder and scope, an electrocardiogram monitor, and respiration, temperature, and blood pressure monitors and alarms. A schematic of the vital signs monitor controls and indicators is shown in Figure 5. The scope simultaneously displays the electrocardiogram, heart rate, respiration rate, temperature, and blood pressure.

The defibrillator portion of the PMSTS is used to deliver an electric charge through the chest to the heart to restore a rhythmic heart beat. Defibrillation is needed when an erratic heartbeat is ineffective in pumping blood to the body. The PMSTS allows the selection of six different charge levels for the defibrillation paddles.

The PMSTS transceiver is a 10-channel radio with two-way voice communication. This radio system allows transmission of the patient's vital signs to a hospital and the relay of instructions to the attendant with the patient.

Two PMSTS units were evaluated by the Department of Transportation. One unit was used in the First Responder Program in Indiana County, Pennsylvania. In this program, emergency medical technician volunteers provide immediate medical care in rural areas. The second PMSTS was evaluated by the Coast Guard helicopter rescue crew in Clearwater, Florida. In this application, the PMSTS was used to provide emergency medical care and monitoring en route to a medical facility. In the helicopter evaluation, the ambient noise interfered with the blood pressure measurement and alarm detection.

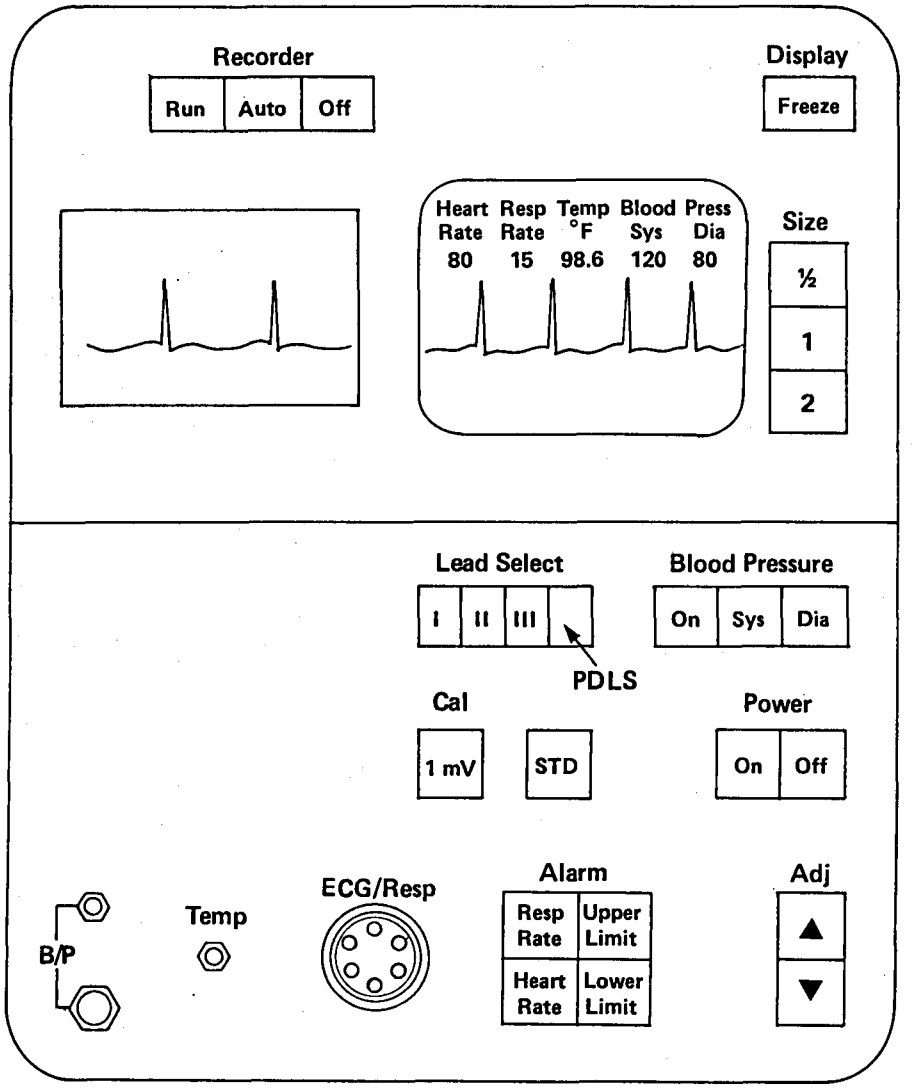

Figure 5. Vital Signs Monitor Controls.

3.2.2 Porta-Fib III

An analysis of the market resulted in a decision by Narco Scientific to commercialize the vital signs monitor technology in the PMSTS as part of a hospital monitoring unit. The two-way radio portion of the PMSTS was not required in the hospital environment. The vital signs monitor was combined with existing systems for defibrillation and display in the Porta-Fib III.

Narco Scientific Bio-Systems Division has built the first twenty Porta-Fib III units. Expanded production and marketing are expected by June of this year.

3.2.3 Summary of the PMSTS and the Porta-Fib III

Project Summary

August 1975	New Technology Transmittal on Physician's "Black Bag" submitted by Telecare, Inc., on NASA Contract NAS9-14334.
January 1979	NARCO Scientific, Inc., purchased Telecare, Inc. Narco will continue the PMSTS work with NASA.
March 1980	The RTI team completed a study on the commercialization potential for the PMSTS.
September 1980	The RTI team participated in a Final Design Review for the PMSTS at Narco Biosystems in Houston, Texas.
March 1981	Two PMSTS units delivered to Department of Transportation for evaluation in rural emergency medicine and a Coast Guard Rescue helicopter.
June 1981	Narco Bio-Systems incorporated the PMSTS vital signs monitor into a hospital monitoring unit to be called the Porta-Fib III.
February 1983	Twenty Porta-Fib III units incorporating the NASA PMSTS technology have been built by Narco Biosystems. Expanded production and marketing activities planned for 1983.

4.0 INSTITUTIONAL TRANSFERS

4.1 Implant Materials Testing

Many design and fabrication aspects of metallic surgical implants result in local regions of high stress where defects exist or develop during use. Current screening methods for these devices do not evaluate the effect of these factors. The need to improve the reliability and performance of metallic prosthetic devices is well documented.[1] [2] [3]

Aerospace material evaluation procedures have shown that screening tests using smooth samples without simulation of stress concentrations or sharp flaws can give misleading results. Fluid environments may not initiate flaws, but will drastically increase the growth rate of any preexisting flaws. Fracture control methods (material qualification, design, and inspection) developed by NASA for screening critical spacecraft hardware could be applied to metallic implants. NASA's procedures for evaluating the impact of a liquid environment on mechanical reliability would be especially applicable.

In July 1980, the RTI team met with Edward Mueller, Don Marlowe, and Daniel Chwirut from the Bureau of Medical Devices, Food and Drug Administration (FDA), to discuss the application of Johnson Space Center fracture control methods to metallic implants. It was agreed in that meeting that NASA and FDA should support a program to transfer this NASA technology to prosthetic device fabrication and testing. Eagle Engineering, Inc., an aerospace fracture control company, was selected as the contractor for this task.

Eagle Engineering completed a $19,000 feasibility study for NASA Langley Research Center in June 1981. Following a favorable review of the results, the FDA transferred funds to Langley Research Center for a 2-year continuation of the study to improve implant design and testing. As a result, Eagle Engineering has completed a handbook for medical device manufacturers on fracture control aspects of the six most common metal alloys used in implanted prostheses.

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4.2 Incinerator Monitoring

The incineration of municipal refuse is a developing technology that both disposes of wastes and provides energy. Smokestack monitoring is necessary to ensure complete combustion and to prevent the production of noxious fumes and gases. Therefore, a continuous, on-line monitoring system is needed for the immediate detection and correction of defective combustion.

Mass spectrometry is an important instrument in the detection of combustion products. The mass spectrometer is capable of differentiating between organic compounds with very similar structures and molecular weights. The General Instrumentation Branch at Langley Research Center has an active program in quadrupole mass spectrometry research and development.

In March 1982, the RTI team first discussed NASA's mass spectrometry technology with Merrill Jackson at the U.S. Environmental Protection Agency (EPA) laboratories at Research Triangle Park, NC.

The EPA is interested in a mass spectrometer because it is sensitive enough to monitor all emission products of interest and is portable enough to be mounted in a van. An instrument of this type is especially needed to monitor a new hazardous waste incinerator under construction near Boston, Massachusetts.

As a result of EPA's interest during the initial discussions, the RTI team coordinated a meeting at the EPA research facility at Research Triangle Park on April 29, 1982, of EPA personnel and NASA scientists from Langley Research Center. The objective of the meeting was to discuss the applicability of the NASA quadrupole mass spectrometer for monitoring smokestack emissions. In a followup meeting at Langley in May 1982, Dr. George Wood, Jr., demonstrated the operation of the NASA instrument. On the basis of these meetings, EPA has committed funds to obtain a NASA-Langley quadrupole mass spectrometer by a contract to Analog Technology Corporation. The EPA researchers will be trained in the use of the instrument by Dr. Wood and other Langley researchers.

5.0 PHASE 0 STUDIES

5.1 Mobility Aids for the Blind

5.1.1 Introduction

An important priority in research relating to blindness and low vision is the development of improved methods for safe mobility. Recognizing this need, the Veterans Administration (VA) requested that NASA Ames Research Center collaborate with the VA Rehabilitation Research and Development Center in Palo Alto, California, to develop an improved mobility aide for the blind. NASA Headquarters requested that the RTI team assist NASA-Ames and the VA in a Phase 0 study to establish the requirements and examine the feasibility of a new mobility aid for the blind. To ensure close coordination between the organizations, RTI supported SRI's participation in the project as an RTI team consultant. The Phase 0 study results are summarized in this section.

5.1.2 Problem Definition

Approximately 11.5 million persons in the United States suffer some degree of visual impairment. Twelve percent are unable to see well enough to read newsprint; four percent are classified as legally blind.[1]

Approximately 47,000 people become legally blind each year in the United States. There are 397,000 severely impaired and legally blind persons in the United States under the age of 65. The distribution of new cases of legal blindness by age and sex is shown in Figure 6. According to the American Foundation for the Blind, approximately 20,000 visually handicapped persons are trained by mobility and orientation specialists each year.

Audition is an important sense for safe mobility of the visually impaired. Hearing, like sight, can provide information about the environment beyond the individual's reach. In addition to obvious environment identification through hearing, the visually impaired can use reflected sound to avoid obstacles. For instance, a visually impaired person can determine when he has reached the end of a hallway by the relative absence of reflected sound. This dependence of the visually impaired on subtle sound discrimination for safe mobility must be considered in the design of a new mobility aid.

5.1.3 Mobility Aids in Use

The four most common mobility aids used by visually impaired persons are sighted human guides, canes, guide dogs, and electronic travel aids.

A sighted human guides the blind person by walking by his side and providing verbal instructions and/or a leading arm. Human aids assist in all mobility tasks and provide companionship. Human guides, however, are not always available and are expensive if the service is purchased.

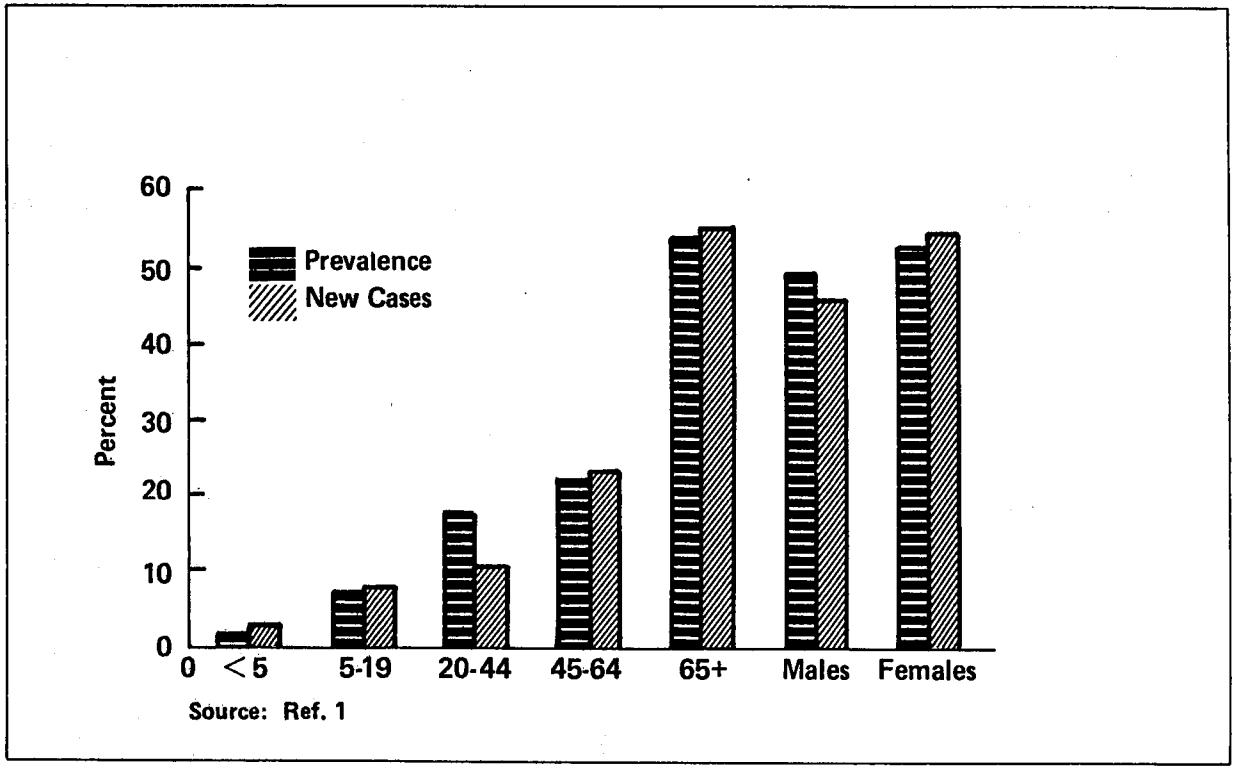

Figure 6. Distribution of Prevalence and New Cases of Blindness by Age and Sex: U.S., 1978.

A guide dog is trained to understand commands, avoid obstructions, and recognize potentially dangerous situations. The dog wears a harness that is held by the visually impaired person. Dogs usually provide reliable guiding and companionship for the user. Major disadvantages of guide dogs are the expense of extensive training and a relatively short lifetime of approximately 10 years.

Canes are the most common mobility aid used by the visually impaired. The types of canes available include the long cane, a folding or collapsible cane, and an orthopedic cane. These canes are fabricated from wood, aluminum alloy, fiberglass, plastic, and stainless steel. The cane extends the tactile sense of the user to provide information about the environment. The cane can inform the user about ground surface textures, downsteps or slopes, and obstacles. The cane thus protects the lower body from collision.

The cane is reliable, requires little maintenance, and is unaffected by adverse weather conditions. The major disadvantages of the cane are that it does not provide adequate protection against collision to the upper body and the range of information available to the user is limited by the length of the cane. In addition, extensive training is required for effective use of a cane for mobility.[2]

An electronic travel aid (ETA) is a device that emits signals to sense the environment, processes the information received, and furnishes the user with information about the environment. An ETA should warn the user of obstacles in the travel path from the ground to the head and should warn the user of any surface discontinuities that could represent a safety hazard. Advantages of the ETA over the cane are the extended detection range and ability to scan the environment allowing a better understanding of the environment and more accurate location of objects. Disadvantages of some ETAs are frequent repairs, replacement or recharging of power source, interference with natural sensory channels conveying information about the environment, and appearance that is cosmetically unacceptable to the user.

5.1.4 Electronic Travel Aids Available

Most electronic travel aids transmit an ultrasound or optical energy wave, which is reflected from objects in the traveler's path. The ETA then decodes the signal and displays the information to the traveler. The display is usually tactile or auditory. Optical transmission is used where range determination is not a specification for the device. Ultrasound systems offer excellent distance resolution, scanning beams from 5° to 90° in width, and the availability of cosmetically acceptable transducer sizes.[3]

The Russell Pathsounder was one of the first ultrasound ETAs. As shown in Figure 7, it is suspended from the neck, providing a 30° scanning beam. The Pathsounder is an obstacle detector with a 6-foot range and some range estimation capability. The output to the traveler may be tactile or auditory. With the auditory option, if an object is within 3 to 6 feet, the Pathsounder emits a low-pitched buzz;

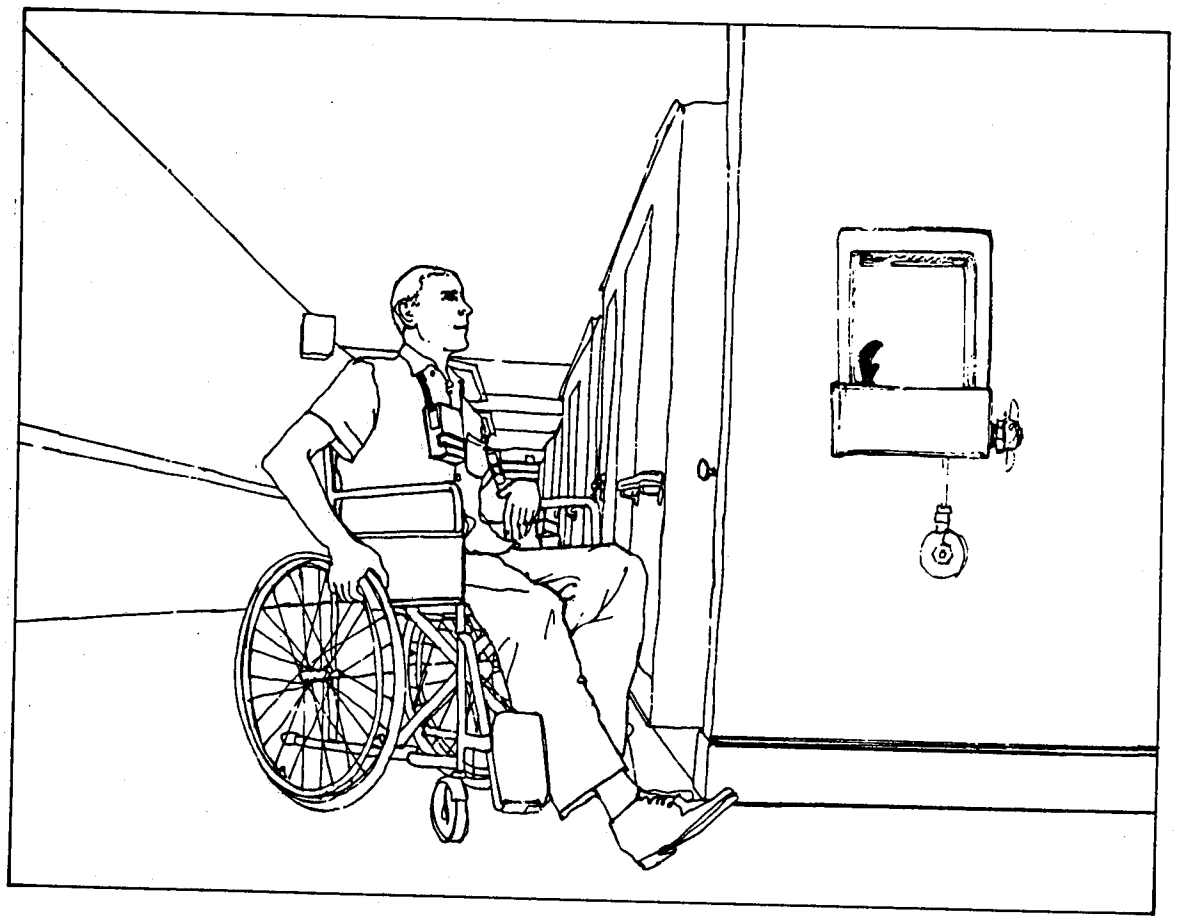

Figure 7. The Russell Pathsounder.

a higher pitched tone warns that an object is within 3 feet. A significant advantage of the Pathsounder is the simplicity of the two-tone output, which makes it easy to learn. This device is often used to help the young visually impaired become familiar with ETAs in preparation for more complex devices in the future. The disadvantage of the Pathsounder is the limited information provided to the user on the environment.

The Mowat Sensor is a hand-held ultrasound device with a vibration output to the user. The proximity of the user to an object is indicated by the vibration frequency. The user may select the short range to detect objects within 1 meter or the longer range to detect objects as far away as 4 meters. The Mowat Sensor is designed for use with a cane or guide dog to extend the range of detection with a noncontact system. It is lightweight and relatively inexpensive. The major disadvantage is that when it is used with a cane or guide dog, both hands are occupied.

The laser cane is a long cane with three infrared light emitters aimed to detect obstacles at three levels: head, waist, and ground. The output for the laser cane may be tactile or auditory.[3] The user may select a 6- or 12-foot range for detection. The laser cane can help the user find an obstacle-free path and detect drop-offs. By moving the cane from side to side, the user can determine the width of an object or detect an open doorway. A major disadvantage of the laser cane is that the cane's beams fail to register the presence of a plate glass window.

The binaural sonic aid, sold commercially as the Sonicguide™ uses a wide angle (60°-90°) ultrasonic transmitter and two receiver channels mounted in a pair of eyeglasses.[3] The receiver channels are presented to the left and right ears. The electronics and the batteries are in a small box that hangs at the user's side. An object on the user's right side will result in a louder sound to the right ear. With this stereophonic presentation and appropriate training, the user can detect an object's direction. The distance of the object is indicated by pitch. The range of the Sonicguide™ is 0 to 15 feet and 30° to each side of center.[4]

Although the Sonicguide™ provides more information about the environment than other ETAs, it is not a primary mobility aid and must be used with a cane or guide dog. The Sonicguide™ cannot be used as a primary mobility aid because it cannot detect drop-offs such as steps or curbs. The major disadvantage of the Sonicguide™ is the extensive training required to interpret the information presented to the user.[4]

Other electronic travel aids currently under development are:

- Computerized Travel Aid: American Foundation for the Blind. The CTA is an ultrasound system that includes a microprocessor for calculation of distance information before presentation to the user.

- Infrared Ranging Systems: Smith-Kettlewell Institute. This system is a hand-held device for intermittent use with a guide dog or cane. The technology in this inexpensive system was developed by Honeywell, Inc., for use in auto-focusing cameras.

- Monaural Version of the Binaural Sonic Guide: University of Canterbury, New Zealand. This system uses a narrow-beam, single-channel FM sonar system.[3] This system decreases the training necessary for the binaural system.

5.1.5 NASA Concepts for Electronic Travel Aids

Following a review of the advantages and disadvantages of current mobility aids, the following researchers suggested concepts for new devices for consideration in the Phase 0 study.

- Tak Matsumoto
  Electronic Engineer, NASA Ames Research Center

- Cesar Mina
  Electronic Technician, NASA Ames Research Center

- Vikki Velkoff
  Engineering Associate, NASA Ames Research Center

- Sally Wood
  Biomedical Research Engineer, VA Rehabilitation Research and Development Center, Palo Alto, California.

Several of these concepts are described in the following subsections.

The Video Vision Mobility Aid is designed to help a blind person travel down the middle of a sidewalk. The middle is the safest because most obstructions either on or overhanging the sidewalk are usually at the sides. This would also assist the blind traveler in walking a straight path.

The concept for this mobility aid is a video camera that would point at the sidewalk ahead. The video data would then be processed to detect and enhance edges. All data that did not conform approximately to the preconceived image of the sidewalk edges would be eliminated. This type of "intelligent" system is widely used in industry and has been well documented. The output of this device would most likely be tactile, and would include directions to move and/or turn to the right or left. The area of information transfer to the user is not trivial and would require a concerted effort by NASA and the VA.

This aid is perceived as high technology with long-range goals and is not considered an instant solution to a multifaceted problem. A working prototype is perceived within 2 years for evaluation.

The Obstacle Detector will probably use an ultrasonic transducer to detect obstacles from waist high to slightly above the head. The sensitive distance ahead of the user would probably extend farther than 6 feet. This device is perceived as being disguised as a pair of spectacles, which would allow scanning by turning of the head. The output would be tactile and indicate the presence and range of the obstacle. The most difficult problem foreseen is the design of a suitable ultrasonic transducer. Currently popular transducers such as the Polaroid unit emit field patterns unsuitable for this application and are too large. The availability of a newly developed piezoelectric plastic filter appears promising as the basis for transducer research.

The Person Detector determines the location of people primarily in social situations but it would also allow a blind person to detect the presence of someone in a room. A thermopile, which is sensitive to infrared radiation, is proposed as the sensor. A thermopile with a field of view of 90° has been tested and appears to be sensitive enough to detect a human at 3 feet. A miniature lens has been proposed for use to decrease the field of view to 30° and increase the aperture, thereby increasing the range beyond 3 feet. The sensor would work best located on the head of the user to allow scanning by turning the head. The output is proposed to be tactile. The type and amount of information to be transmitted to the user has yet to be determined.

The impetus for developing a Compass for the Blind originated as a request from the Western Blind Rehabilitation Center for a device that would help a blind person walk in a straight path where there is no environmental reference. A rough estimate of device sensitivity indicated that a device would have to be accurate to ±0.2° in order to control a person within ±2° of a straight line. Mounting a device of this accuracy on a person would probably be impractical; however, a device that is accurate to ±5° might be feasible. Such a device is pictured as a single-axis magnetometer to indicate direction. An additional device would be required to indicate how level the magnetometer is in order to obtain the directional accuracy. Single processing would be necessary to correct for tilt and to calculate the direction to which the person is pointing. It is possible that a much higher directional accuracy than ±5° can be obtained. A microprocessor would be necessary for the signal processing.

5.1.6 Completion of the Phase 0 Study

The Phase 0 study on mobility aids for the blind will be completed by May 1983. The RTI team will continue to assist NASA Ames and the VA facility in Palo Alto in that effort under funding from NASA Langley Contract NASI-17214. The tasks remaining in the study are:

- Selection of the concept most appropriate for development by NASA and the VA.
- Identification of NASA technology used in the proposed travel aid.
- Preparation of a project plan for refinement of the concept, hardware development, evaluation, and commercialization.
- Definition of the activities for the participating organizations, method for selecting the manufacturers, and cofunding committments for the project.

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5.2 Ultrasound Diagnosis of Burn Depth

5.2.1 Introduction

Early and accurate determination of the depth of a nonsuperficial burn is critical for the optimal management of burn patients. Dr. John H. Cantrell, Jr., a physicist at Langley Research Center, developed a concept for determination of skin burn depth using ultrasound. This concept is based on the observation that the acoustical impedances of burned dermis, viable dermis, and subcutaneous fat differ sufficiently to detect the interface between burned tissue and the underlying unburned tissue.

This rapid technique for burn depth determination could facilitate early excision of full-thickness burns and thus reduce mortality and lead to a more rapid and complete rehabilitation of the patient. John Samos, Technology Utilization Officer, NASA Langley Research Center, requested the RTI team's assistance in a Phase 0 study on the proposed ultrasound burn diagnosis system. The results of this study are summarized in this section.

5.2.2 Problem Definition

Approximately 2 million Americans suffer serious burns each year, and 200 to 300 thousand of these people require hospitalization. Among those hospitalized, 70 thousand receive intensive care and 10 to 12 thousand die. The cost of intensive care exceeds $300 million per year.[1] Clearly, these statistics indicate the potential impact of improvements in the prevention and treatment of burn injuries.

5.2.3 Burn Wound Classification

Burns of the skin are classified according to depth as first, second, or third degree as indicated in Figure 8. Because burn depth is critical to wound care and mortality, determination of the degree of injury is important for planning therapy and anticipating patient requirements.

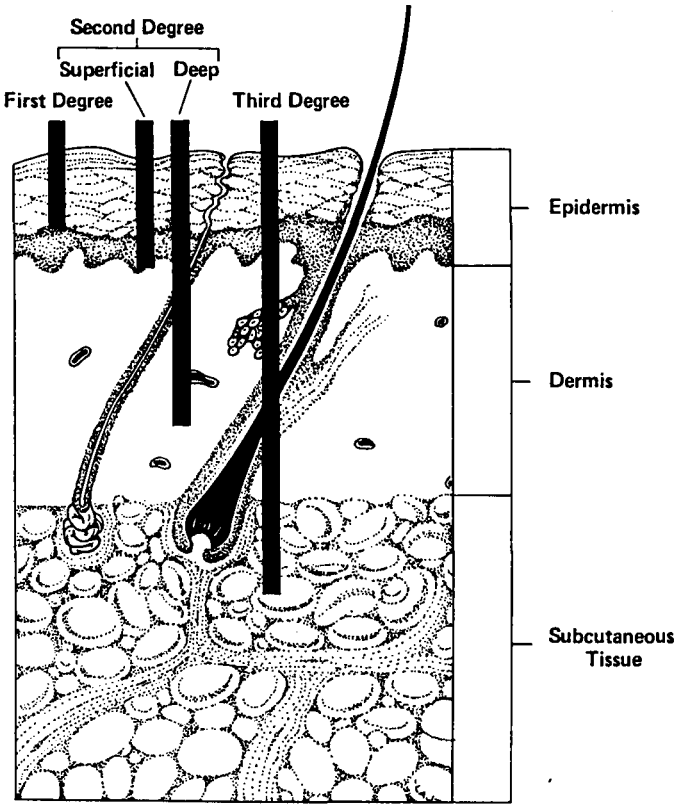
First-degree burns involve only the epidermis or superficial layer of skin. Healing will occur within 5 to 10 days with no scar formation.

Second-degree burns involve all of the epidermis and extend into the dermis. In superficial second-degree burns, healing occurs within 2 weeks. Deep second-degree burns usually require 4 weeks or more.

Third-degree burns result in destruction of the entire epidermis and dermis. Subcutaneous fat, muscle, and even bone may be affected. Extensive third-degree wounds will not heal in a timely fashion and must be grafted to achieve wound closure. Accurate and early differentiation between deep second-degree and third-degree burns is important to the surgeon for determining the extent to which grafting will be required. The new nomenclature suggested for classification of burn wounds is presented in Table 5.

TABLE 5. OLD AND NEW BURN CLASSIFICATION[29]

Nomenclature (new)	Definition	Nomenclature (old)
Superficial	Epidermis only	First degree
Partial thickness	Epidermis and dermis at varying depths	Second degree
Full thickness	Epidermis, dermis, and appendages	Third degree



Source: *Treatment of Burns.* Yang Chih-chun, Hsu Wei-shia, and Shih Tsi-siang, eds. Springer Verlag, New York, 1982.

Figure 8. Classification of Depth of Burn.

5.2.4 Burn Wound Treatment

Modern treatment of burn victims is based on early recognition, removal, and grafting of full-thickness injuries. Not only is the risk of infection minimized by this aggressive procedure,[2] but healing is hastened and dermis that otherwise would be lost to progressive necrosis may be saved. The techniques used for early removal of dead tissue include excision down to the fascia,[3] sequential or "tangential" excision to viable tissue in deep partial-thickness burns and certain full-thickness burns,[4 5] and chemical debridement.[6] For burns that present an obvious picture of full-thickness loss, the surgeon can begin excision or chemical debridement in the regions of greatest injury and appropriately extend the area of removal by noting characteristic bleeding patterns of viable fat and dermis. Unfortunately, depth of injury is difficult to diagnose except in extreme cases of tissue destruction. Clinical judgments based on surface appearance and sensation to pinprick or hair removal are unreliable and imprecise. Thus, areas of full-thickness injury can masquerade as areas of partial-thickness injury, and vice versa. The resulting erroneous diagnosis either eliminates the advantages of early removal or causes the sacrifice of tissue that would otherwise heal itself with better function and cosmesis.[7]

5.2.5 Current Methods for Burn Depth Determination

Although judgments based on surface appearance and sensation to noxious stimuli provide quick information on the general nature of the burn wound, many investigators have emphasized that these judgments do not necessarily reflect the true depth of injury.[8 15] The problem in evaluating surface appearance or discoloration is the lack of a direct relationship between the severity of surface burning and the depth of burn injury. For example, burning at the surface depends primarily on temperature, but the depth of injury depends both on temperature and duration of exposure. Burns of grossly different depths can have similar appearances when viewed from the surface. A host of factors other than temperature can affect surface appearance. These factors include the burning agent, the method of local treatment (e.g., a wound left open to the air forms crusts and eschars different from those resulting from the application of wet or greasy dressings), the presence or absence of infection, and the surface pressure applied during the burning process. Thus, surface appearance is a product of many variables that are related indirectly, if at all, to burn depth.

Sensory responses to noxious stimuli, while thought to be somewhat more reliable than surface appearance,[13 15] can also be difficult or impossible to interpret. The main problems here are that the magnitudes of these stimuli are not well controlled in the clinic; individuals vary greatly in their ability to give objective responses when under stress, the density of skin innervation is not constant over the body surface, and analgesia is often found in deep partial-thickness burns.

The limitations of standard clinical tests have led to the development of other methods for diagnosing the depth of burn injuries. Perhaps the most widely studied of these methods is evaluation of vascular perfusion and capillary permeability using intravenous tracers. Tracers that have been used

include Evans blue,[16 17] Patent blue V,[18 19] bromphenol blue,[16] fluorescein,[20] tetracycline,[21] and radio-active phosphorous.[8] Major differences among these tracers are (1) specific affinity for blood and tissue proteins, which affects the relative amount of staining due to burn-induced changes in capillary permeability, and (2) degree and type of staining reaction produced, which affects the visibility of the tracer below the skin's surface. Not surprisingly then, demarcation of the burn wound depends in a complex way on the depth of injury, the thickness of the skin, the tracer used, and the time of measurement.

Another method for diagnosing burn injuries is measurement of skin temperatures using thermography or thermal probes. This method is based on the expectation that decreased metabolism and vascular perfusion in burned tissue will lower its temperature relative to the surround; indeed, several investigators have demonstrated positive correlations between low temperatures and full-thickness loss.[22-24] However, thermography currently is not used in many clinics for the purpose of diagnosing burn injuries. The main objection to its use is that the temperature patterns measured not only reflect metabolism and vascular perfusion, but are functions of skin emissivity, thermal conductivity of the underlying tissues, dermal edema, and surface evaporation.[22 25 26] Because none of these latter variables are directly related to the depth of burn injury, interpretation of thermograms is subject to many sources of error.

The remaining methods of burn injury diagnosis included in this review are multispectral photographic analysis and histological examination of biopsied tissue. A common feature of these methods is that their aim is to characterize tissue in the burn wound rather than to measure the flow of blood through the region. In view of the problems associated with interpreting measures of vascular perfusion, this approach is logical. The key element in multispectral photographic analysis is comparison of three filtered images of the burn wound.[27] Diagnostic signatures of the biochemical character of the tissues are formed by calculating over the entire viewing area the ratios of energies in the red, green, and near-infrared portions of the spectrum. The potential artifacts of thermography are avoided to the extent that surface temperatures are manifest at wavelengths greater than those of the near-infrared band; yet the depth of penetration afforded by the latter is adequate for detection of events in the deep dermal layers. In principle then, multispectral photographic analysis integrates information present in the surface appearance of the wound along with information present in the spectral reflectance of deeper tissue. In practice, however, one might expect that performance would be degraded when the surface appearance is deceptive. Also, multispectral photographic analysis requires a complex array of cameras, optical filters, balanced sources of illumination, a scanning microdensitometer, and computer analysis of the images. Widespread clinical use of this method is thus unlikely unless improvements in diagnostic accuracy over that of surface appearance alone can be demonstrated, and unless these improvements are sufficient to justify the complexity and expense of the procedure.

5.2.6 Proposed Ultrasonic Method for Burn Depth Determination

The proposed ultrasonic method for burn depth determination uses a broadband ultrasonic pulse emitted by a clamped high frequency (typically 10-20 MHz) transducer. Such frequencies provide a resolution of approximately 0.1 mm in soft tissue. The emitted pulse propagates through a coupling path before entering the skin tissue to be characterized. The coupling path also serves as a delay line to separate ultrasonic data from high-frequency electromagnetic feedthrough. As the ultrasonic pulse propagates through the tissue, echo reflections in the time-domain record are clearly obtained from three important anatomical landmarks for partial-thickness burns. The landmarks are (1) the interface between the coupling path and the epidermal surface, (2) the interface between the necrotic and underlying viable tissue, and (3) the interface between the dermis and the subcutaneous fat. In model porcine experiments,[28] the time-domain records together with independent *in vitro* measurements of the velocity of sound in porcine skin tissue permitted a quantitative ultrasonic assessment of burn depth to within 5 percent of that obtained from histology sections taken from the same burn site. The simultaneous display of the three echo reflections provides a real-time indication of relative burn depth for partial-thickness burns.

5.2.7 Clinical Evaluation

One objective of this Phase 0 study was the selection of a clinical collaborator and the development of cofunding for the clinical studies. In this effort, the RTI team interviewed the following individuals.

Emilie A. Black, M.D.
Assistant Director for Clinical Research
National Institute of General Medical Sciences
National Institutes of Health
Bethesda, Maryland

John F. Burke, M.D.
Professor of Surgery, Harvard Medical School
Chief of Staff
Shriners Burn Institute
Boston, Massachusetts

Colonel Thomas Camp
U.S. Army Medical R&D Command
Ft. Detrick
Frederick, Maryland

Andrew M. Munster, M.D.
Director
Baltimore Regional Burn Center
Baltimore, Maryland

Basil A. Pruitt, Jr., M.D. FACS
Colonel, MC
Commander and Director
U.S. Army Institute of Surgical Research
Fort Sam Houston
San Antonio, Texas

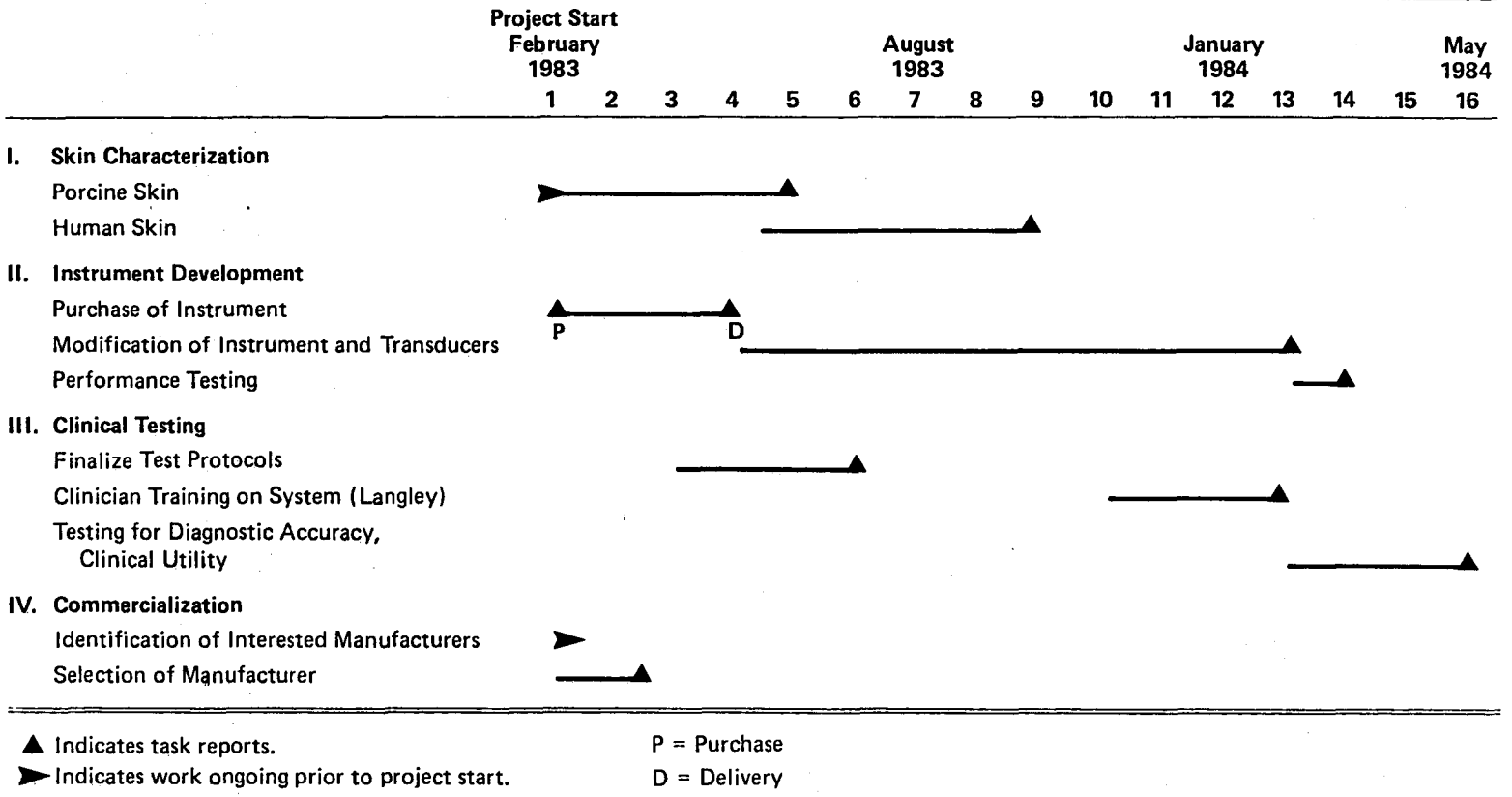


Figure 9. Project Plan for Ultrasound Diagnosis of Burn Depth.

As a result of these discussions, Dr. Black has asked NASA to present a paper on the ultrasound system at a conference on "New Frontiers in the Understanding of Burn Injuries," in Bethesda, Maryland, September 26-28, 1983. This conference is sponsored by the National Institutes of Health in collaboration with the World Health Organization and the International Society for Burn Injuries.

All of the clinicians interviewed by the RTI team were enthusiastic about the ultrasound system and offered to collaborate with NASA Langley in the project. Dr. Basil Pruitt at the U.S. Army Institute of Surgical Research (USAISR) was selected as the primary collaborator on the project. Thermally injured patients from both the continental United States and throughout the world are evacuated to USAISR. Approximately 225 seriously burned patients are admitted to this facility annually. Major objectives of USAISR are (1) the investigation of new diagnostic and therapeutic methods for optimum care of the burn patient, and (2) dissemination of the scientific advances to military and civilian medical treatment centers. Approximately 30 research projects are conducted each year at the USAISR. Dr. Pruitt has agreed to collaborate with NASA Langley and to conduct the clinical trials at USAISR at no cost to NASA.

5.2.8 Manufacturer Participation

The RTI team sent an information package on the ultrasound burn depth system to 15 manufacturers of medical ultrasound equipment. So far, two companies, Sonometric Systems, Inc., and Technicare have expressed an interest in participating in the project and marketing the device. The RTI team and Langley researchers visited Sonometric Systems in New York in October 1982 to discuss the project. Discussions with manufacturers will continue, with final selection planned for April 1983.

5.2.9 Project Plan

The RTI team worked with the NASA Langley researchers and the other participating organizations to develop the project plan shown in Figure 9.

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6.0 STATUS OF ACTIVE TRANSFER PROJECTS

CORNEAL TOPOGRAPHY

BATeam Personnel: Dr. H. Clark Beall

Problem

The cornea of the eye is the tough, transparent layer through which light rays must first pass upon entering the eye. Trauma and diseases can distort the spherical surface of the cornea to such an extent that corneal transplant surgery is required to correct the accumulated refractive error. A new surgical procedure, radial keratotomy, is an alternative to corneal transplant surgery. Both procedures require that the surgeon be able to gauge the topography of the corneal surface precisely before, during, and after the surgery.

Solution

Several optical devices are now available that reflect light from the front surface of the cornea. A photographic record can be made of the reflected light pattern; the photo can later be analyzed on an optical bench to quantify, in diopter units, the refractive power of a dozen points on the cornea. An instrument is desired that can gauge in real time the actual contour, or topography, of the corneal surface.

NASA Technology

Two separate items of technology have been proposed by two new research and technology operating plans (RTOPs) in response to the RTI problem statement.

Principals

Dr. J. Rowsey, surgeon, McGee Eye Institute, Oklahoma City, Oklahoma.
Mr. Don Griner, Marshall Space Flight Center (MSFC), Huntsville, Alabama.
Mr. R. Frazer, Jet Propulsion Laboratory (JPL), Pasadena, California.
Dr. Ralph Helmsen, National Eye Institute, Bethesda, Maryland.

Cost to NASA

JPL has received funding from NASA Headquarters for a Phase 0 study, and MSFC has committed discretionary funds to support an exploratory study. The device will be evaluated by Dr. Rowsey under his current funding from the National Eye Institute.

Commercialization Strategy

There appears to be a ready market for a new generation of gauging devices that could be used during surgery. Contacts have already been made with several manufacturers who could produce such devices.

Status

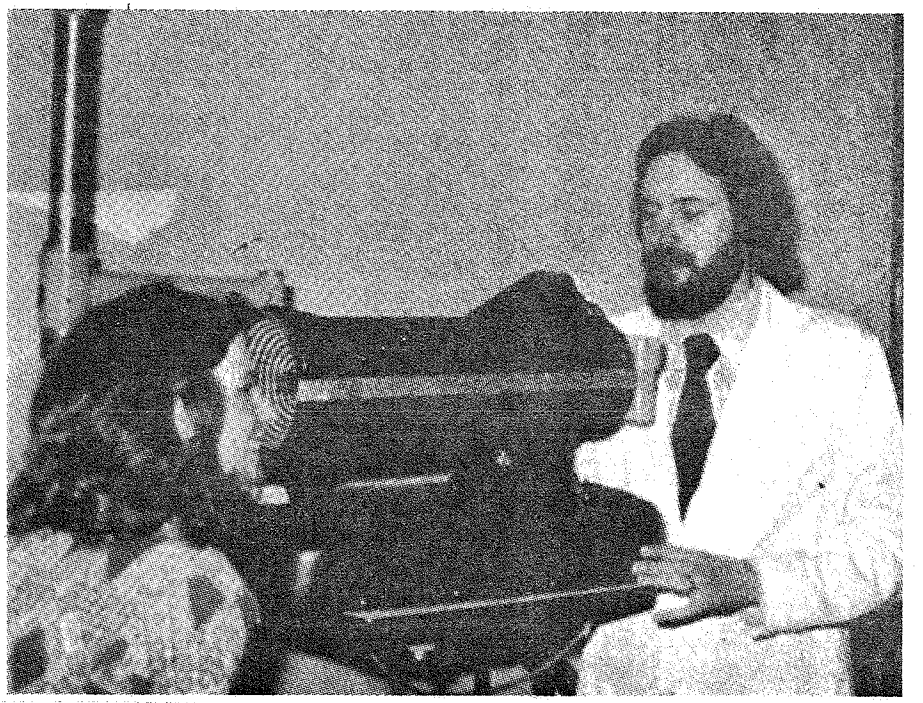
The prototype device from Marshall will be assembled and tested by an optics contractor. The Marshall engineer has prepared the work statement, design specifications, and performance parameters. The JPL optical and breadboard are complete.

Action

After the construction and testing of the prototype, Marshall will conduct a demonstration of the device. In discussions with the RTI team, Dr. Helmsen has agreed to attend the demonstration. JPL will conduct a review of the optics system for NASA headquarters in March before proceeding with the computer interface design.

CORNEAL TOPOGRAPHY

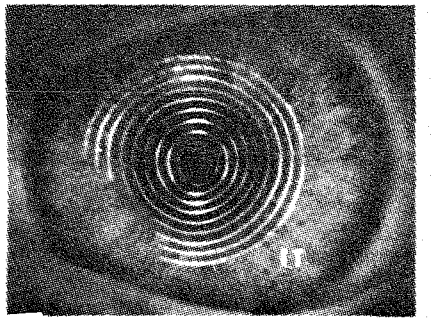
- DISTORTED PLACIDO REFLECTIONS FROM CORNEASCOPE DIFFICULT TO ANALYZE
- NEW SYSTEM NEEDED FOR REAL-TIME GAUGING OF CORNEAL TOPOGRAPHY
- APPROPRIATE NASA TECHNOLOGY:
  - OPTICAL GAUGING
  - DIGITAL IMAGE PROCESSING
  - TV DISPLAY
- McGEE EYE INSTITUTE, OKLAHOMA CITY
  LOS ALAMOS SCIENTIFIC LABORATORY
- NATIONAL EYE INSTITUTE



Corneascope

CORNEAL TOPOGRAPHY

- INSTRUMENT EASILY GAUGES CORNEAL CURVATURE FOR CONTACT LENS
- NEW INSTRUMENT NEEDED FOR REAL-TIME GAUGING OF CORNEAL TOPOGRAPHY
- APPROPRIATE NASA TECHNOLOGY:
  - OPTICAL GAUGING
  - DIGITAL IMAGE PROCESSING
  - TV DISPLAY
- McGEE EYE INSTITUTE, OKLAHOMA CITY
  LOS ALAMOS SCIENTIFIC LABORATORY
- NATIONAL EYE INSTITUTE



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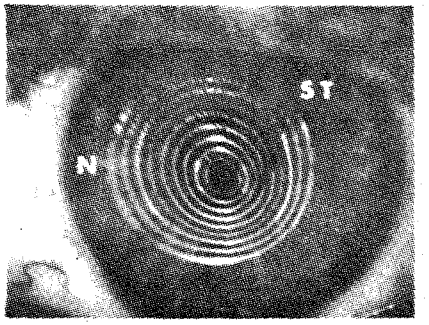

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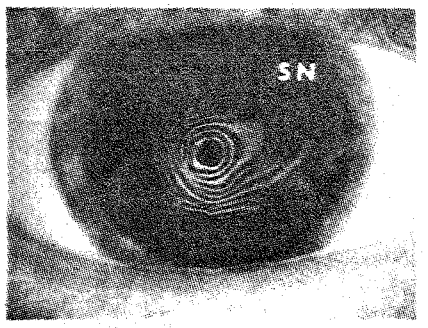

C

Corneascope photographs of three stages of keratoconus:
A. early B. progressive C. severe.

DIGITAL DATA RECORDER FOR PHYSIOLOGICAL MONITORING

BATeam Personnel: Dr. H. Clark Beall

Problem

There are approximately 20 million insomnia sufferers in the United States. By conservative estimates, 40 percent of people over 60 years of age have "sleep apnea," an inadequate blood oxygen level due to a temporary irregularity of respiration. The apnea episodes cause recurrent awakenings during sleep at night. The resultant lack of restful sleep causes confusion, drowsiness, irritability, and lack of attention during daylight hours. This is especially a problem in the elderly. Researchers who wish to study the psychology and physiology of sleep have traditionally brought patients to the laboratory where sophisticated instrumentation can record the physiological changes that occur during the various sleep stages. They have found, however, that the laboratory environment affects the sleep patterns of most patients. What is required is a means of recording physiological data in the home environment to reduce costs and improve data quality.

Principals

Dr. Elliot D. Weitzman, Montefiore Hospital and Medical Center, Bronx, New York.
Dr. Fred Hegge, Walter Reed Army Medical R&D Command, Washington, DC.

Solution

Most sleep researchers record data on multipen strip chart recorders. These recorders are quite expensive and not at all portable. Improved sleep monitoring requires a new system of battery-operated, solid-state, small digital data recorders that can be distributed to patients for use at home and returned to the laboratory for readout of the data.

NASA Technology

NASA TM-81267[1] describes a digital, solid-state recorder that features a self-contained battery, CMOS circuitry, a 2048-word digital memory, an 8-bit analog-to-digital converter, and an operating capability of several weeks. Although the device is used in the NASA Space Shuttle as a temperature recorder, the temperature transducer could be replaced with other transducers appropriate for measuring parameters such as respiration rate, movement, muscle activity, eye movement, and body temperature.

Cost to NASA

No cost to NASA is anticipated for the biomedical application of this device.

Commercialization Strategy

Descriptive literature has been mailed to several prospective manufacturers.

Status

The software and hardware that were required for the conversion of an Apple™ microcomputer into a readout station for the digital data recorder units have been completed and are operational at Ames Research Center and at the Manned Space Flight Center in Houston. The RTI team has sent a description of the recorder and its possible medical applications to several manufacturers.

Action

The new software and hardware must still be documented. One recipient of the RTI package, the Industrial Technology Research and Development Foundation of Durant, Oklahoma, has contacts with many small businesses in the southwest United States. One of these companies has contacted RTI for further information on which to base their marketing decision.

Reference

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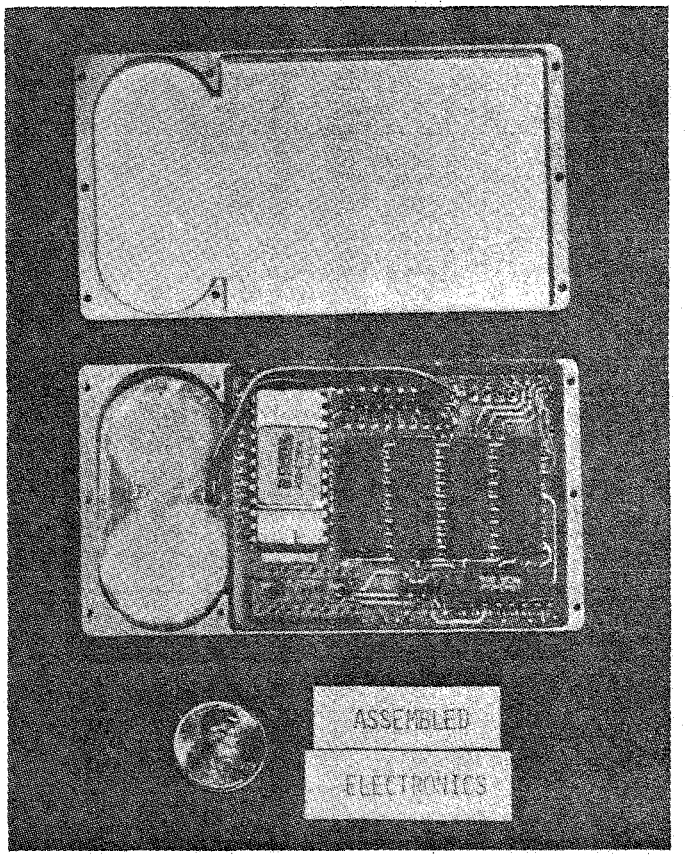
DIGITAL DATA RECORDER FOR PHYSIOLOGICAL MONITORING

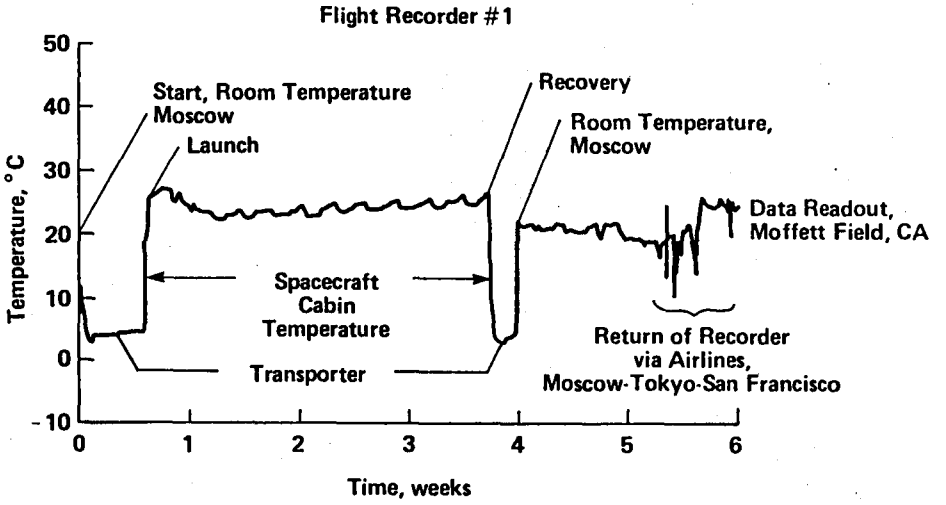
- RECORDING OF PHYSIOLOGICAL PARAMETERS DURING SLEEP
- TEMPERATURE DATA RECORDER DEVELOPED BY NASA AMES RESEARCH CENTER FOR SHUTTLE FLIGHTS
- LIGHT-WEIGHT, SMALL RECORDER WITH NO ATTENDANCE REQUIREMENT
- WALTER REED INSTITUTE OF MEDICAL RESEARCH
  ALBERT EINSTEIN COLLEGE OF MEDICINE



Recorder with cover removed

DIGITAL DATA RECORDER FOR PHYSIOLOGICAL MONITORING

- RECORDING OF PHYSIOLOGICAL PARAMETERS DURING SLEEP
- TEMPERATURE DATA RECORDER DEVELOPED BY NASA AMES RESEARCH CENTER FOR SHUTTLE FLIGHTS
- LIGHT-WEIGHT, SMALL RECORDER WITH NO ATTENDANCE REQUIREMENT
- WALTER REED INSTITUTE OF MEDICAL RESEARCH
  ALBERT EINSTEIN COLLEGE OF MEDICINE



Data from US-USSR Cosmos satellite flights

HIGH PERFORMANCE WHEELCHAIR

BATeam Personnel: Dr. Doris Rouse

Problem

Approximately 700,000 people in the United States currently rely on wheelchairs for mobility. The limitations of available chairs include heaviness, frequent breakdowns, and limited lifetime, resulting in high life-cycle costs. Recognizing these problems, the Veterans Administration (VA) and the National Institute of Handicapped Research have funded several wheelchair research projects. Most of these projects are component oriented. Few projects involve a full-scale development effort, from analysis of requirements through prototype fabrication and evaluation.

Solution

The use of improved materials as well as computer analysis and simulation could result in an advanced, lightweight wheelchair.

NASA Technology

Structure analysis computer programs used in the design of aerospace vehicles would be useful in the design of an advanced wheelchair. Graphite composite materials developed for aerospace could be incorporated in an advanced chair to reduce weight.

Principals

Mr. Robert Baucom, Materials Applications Branch, NASA Langley Research Center, Hampton, Virginia.
Dr. Colin McLaurin, University of Virginia--Rehabilitation Engineering Center, Charlottesville, Virginia.

Cost to NASA

In 1981, NASA allocated $60,000 to this project. An additional $40,000 will be expended by the University of Virginia Rehabilitation Engineering Center for the design and evaluation of the chair in the first year. Funding for the University of Virginia's participation is provided by the National Institute of Handicapped Research.

Commercialization Strategy

Invacare is very interested in marketing the chair, if the price is reasonable. The RTI team has also discussed participation in this project with several other wheelchair manufacturers. When a prototype is completed, manufacturers will be invited to Charlottesville for a demonstration and discussion of commercialization.

Status

Fabrication of the initial prototype is going smoothly. The entire upper structure of the chair will be made of the Kevlar/foam sandwich material.

Action

The initial prototype will be completed in April. The total chair weight is expected to be less than 25 pounds. The RTI team will work with the University of Virginia in planning a demonstration for manufacturers by June.

HYDROCEPHALUS SHUNT--VENTILATION

BATeam Personnel: Dr. Doris Rouse

Problem

Hydrocephalus is a condition in which the cerebral ventricles enlarge abnormally when the pressure of the cerebrospinal fluid rises. To relieve this pressure, surgeons implant a shunt to drain the excess fluid into other cavities of the body. The shunt frequently fails because the inlet is blocked by an ingrowth of choroid plexus or an accumulation of cellular or fibrin debris.

Solution

A multi-ended inlet catheter, with hundreds of tiny inlets formed by ion-etching techniques, could minimize this problem. The small holes would inhibit tissue ingrowth, and the multiplicity of holes would reduce the possibility of blockage.

NASA Technology

Technology developed in NASA's Ion Propulsion Engine Program is being used to perforate small-diameter catheters.

Principals

Mr. Bruce A. Banks, Ion Beam Applications Section, NASA Lewis Research Center, Cleveland, Ohio.
Mr. Eugene Pawlik, Jet Propulsion Laboratory (JPL), Pasadena, California.
Dr. Eldon Foltz, University of California, Irvine, California.
Pudenz-Schulte Medical Research Corporation, Irvine, California.

Cost to NASA

An RTOP totaling $123,000 was submitted in 1978. First-year funding of $41,000 was approved. Another $5,000 was allocated to get the opinions of other medical experts before beginning the second year of the project. A $40,000 feasibility study on 2- to 20-micron pores was conducted by JPL in 1981. NASA has allocated $80,000 to continue this JPL effort in 1982.

Commercialization Strategy

Pudenz-Schulte Medical Research Corporation, a manufacturer of ventricular catheters, was contracted by NASA-Lewis to develop an animal model for evaluation of the Lewis prototypes and to conduct bench tests for flow studies. Other commercial interests and FDA will be informed of the results on the shunt system as they are available.

Status

JPL technical staff has successfully formed 15-micron holes in a Teflon shunt. Ed Beckenbach from JPL and Don Vargo from NASA Headquarters met with Dr. Terry Hambrecht at National Institute of Neurological Communicative Disease and Stroke to review progress in the project. Dr. Hambrecht was enthusiastic about the results and suggested several collaborators for clinical tests.

Action

JPL will identify a new clinical collaborator and funding source for evaluation of the shunt. The RTI team will assist in identifying neurosurgeons and manufacturers if needed.

HYPERTHERMIA THERMOGRAPHY

BATeam Personnel: Dr. H. Clark Beall

Problem

The treatment of cancer by localized hyperthermia is a procedure receiving progressively more attention by oncologists. The generation of hyperthermia at localized sites within the human body can be accomplished by ultrasound irradiation, microwave irradiation, or radiofrequency irradiation. The significant technical hindrance to the therapy is the requirement for knowledge of the precise temperature at the hyperthermia site within the body. Reports in the hyperthermia literature indicate that both the exact temperature and the duration of application must be monitored and controlled during hyperthermia sessions.

Solution

NASA Headquarters assigned Langley Research Center the responsibility of devising a procedure for the remote measurement of the temperature within the human body. Initial tests at Langley had shown that passive microwave sensing of temperature was not precise enough, or localized enough, to be useful during hyperthermia.

NASA Technology

A meeting at the Langley Technology Utilization Office of NASA scientists and an RTI Biomedical Applications Team representative resulted in the derivation of several theoretical techniques for measurement of temperature by remote means. The most feasible and most novel method involves the use of ultrasound for the detection of phase transitions within strategically located deposits of organic crystalline material within or near the hyperthermia site.

Principals

Joe Heyman, Ph.D., NASA Langley Research Center, Hampton, Virginia
Dr. Thomas Cetas, University of Arizona, Tucson, Arizona.

Cost to NASA

The approved 1983 RTOP proposed $90,000 total R&D funds for this project. $50,000 has been made available to date.

Commercialization Strategy

The eventual result of the effort for hyperthermia thermography is the development of an optimized ultrasound scanning system and a set of specially formulated fat compounds with sharply defined melting points. This custom apparatus should be of commercial value to manufacturers of ultrasound and hyperthermia equipment.

Status

In discussions with the RTI team, Dr. Thomas Strike, the director of hyperthermia at the National Cancer Institute (NCI), recommended several clinical hyperthermia researchers who could profit from a new precision method of temperature measurement. Dr. Heyman has set up a collaboration with Dr. Cetas of the University of Arizona. Dr. Cetas is funded by NCI to evaluate hyperthermia techniques.

Action

Mr. Bill Swindel, the ultrasound researcher working with Dr. Cetas, will visit Dr. Heyman in April to discuss the protocol for animal and clinical trials to be conducted at the University of Arizona. Dr. Heyman has been invited to make a presentation on his hyperthermia thermography program in Bethesda in May 1983 at the NCI hyperthermia working group meeting.

MICROWAVE THERMOGRAPHY

BATeam Personnel: Dr. H. Clark Beall

Problem

Conventional thermography uses infrared frequencies (>10 GHz) to detect breast cancer. However, this technique can only detect thermal profiles at the skin's surface. Subsurface thermal anomalies, such as those produced by certain cancerous growths, are indirectly measured as sources of heat that affect the thermal profile at the surface. The inability to measure the subsurface thermal profile directly is a significant drawback of infrared thermography because: (1) surface and subsurface elements in the measured thermal profile cannot be differentiated, and (2) thermal dispersion seriously degrades the spatial resolution needed to detect heat sources buried beneath the surface.

Solution

Microwave thermography can be thought of as a low-frequency analog of infrared thermography. A shift to lower frequencies permits detection of thermal profiles up to several centimeters below the body's surface. Microwave instrumentation is needed for the high spatial resolution detection of subsurface temperature anomalies that are typical of cancerous growth.

NASA Technology

Engineers at Langley Research Center have considerable experience and expertise in microwave research resulting from studies on microwave energy propagation in condensed media.

Principals

Mr. Ken Carr, Microwaves Associates, Inc., Burlington, Massachusetts.
Dr. John D. Buckley, NASA Langley Research Center, Hampton, Virginia.
Dr. Robert Howell, Medical College of Virginia, Richmond, Virginia.

Cost to NASA

The funds committed to this project total $32,500 over 2 years.

Commercialization Strategy

A manufacturer of microwave instrumentation is currently participating in the project and plans to market the system.

Status

The refurbished instrument was found to have improperly installed batteries upon its arrival at the Medical College of Virginia (MCV) in May 1982. The unit suffered damage and was returned to the factory for repairs.

Action

The MCV evaluation project will be set back 6 months by the equipment problems. The equipment will be returned to MCV, in operational order, by April 1983.

NONINVASIVE LUNG DIAGNOSIS

BATeam Personnel: Dr. Doris Rouse

Problem

Disabling pulmonary illnesses may develop as a result of occupational and environmental factors, pulmonary vascular pathology, cystic fibrosis, asthma, or cigarette smoking. Early detection and accurate diagnosis of these illnesses give the treatment a greater chance of success.

Solution

A technique to record and analyze human respiratory sounds would make possible the detection of variations in the caliber of the airways and thus the early detection of pulmonary dysfunction.

NASA Technology

NASA research in aeroacoustics has provided a basis for a theory of the origin of human respiratory sound derived from the motion of vortices in the human lung. This theory has been supported by preliminary tests on lung models by the Medical College of Virginia and Langley Research Center.

Principals

Dr. Jay C. Hardin, Theoretical Acoustics Branch, NASA Langley Research Center, Hampton, Virginia.
Dr. John L. Patterson, Jr., Medical College of Virginia, Richmond, Virginia.
Mr. John E. Wootten, B&K Instruments, Inc., Cleveland, Ohio.

Cost to NASA

Approximately $61,000 in FY80 and FY81 funds were approved for this project. An FY83 RTOP for $40,000 was submitted. The Medical College of Virginia has allocated $15,000 from the Hundley Fund to support this work. In addition, an NIH Research Career Award supports Dr. Patterson's time on the project at a cost of approximately $30,000/year over a 5-year period. Recently, Dr. Patterson was awarded a Jeffress Research Grant for $79,000 for this project. B&K Instruments, Inc., has already contributed Mr. Wootten's consulting time during several trips to the Medical College of Virginia. In a February 4, 1983, letter to John Samos, TUO, Langley Research Center, B&K Instrument, Inc., described their plans to support this project with engineering consultation and equipment.

Commercialization Stretegy

B&K Instruments, Inc., has written to John Samos, TUO, Langley Research Center, indicating their interest in this diagnostic system as a commercial product. They predict a market for the system in employee industrial checkup centers as well as in hospitals. B&K and the Medical College of Virginia will continue to collaborate on this project.

Status

Clinical testing of the model awaits completion of the semi-anechoic chamber at the Medical College of Virginia. An RTOP for continued NASA support of this project was submitted by Langley Research Center. The RTI team obtained very positive reviews of the project from two pulmonary researchers and clinicians.

Results of this work have been published in the following:

Hardin, Jay C., and John L. Patterson, Jr. Taking Soundings of the Lungs. Airways, 4(1), 1979.

Hardin, Jay C. Noise Calculation on the Basis of Vortex Flow Models. NASA Tech Brief LAR-12271, Spring 1978.

Hardin, Jay C., and John L. Patterson, Jr. Theory of Sound Generation in the Human Lung. Presented at the Mid-Atlantic Conference on Bio-Fluid Mechanics, Blacksburg, Virginia, August 10-12, 1978.

Hardin, Jay C., and John L. Patterson, Jr. Monitoring the State of the Human Airways by Analysis of Respiratory Sound. ACTA Astronautica, 6(9), September 1979.

Hardin, Jay C., and John L. Patterson, Jr. The Pressure Flow Realation in Bronchial Airways on Expiration. Presented at the Mid-Atlantic Conference on Bio-Fluid Mechanics, Blacksburg, Virginia, May 5-7, 1980.

Hardin, Jay C., and John L. Patterson, Jr. Genesis of Breath Sounds: Theory and Application. Presented at the Fifth International Conference on Lung Sounds, London, England, September 15-16, 1980.

Hardin, Jay C., and John L. Patterson, Jr. Genesis of Breath Sounds: Theory and Application. Presented at the Federation of American Societies for Experimental Biology, 65th Annual Meeting, Atlanta, Georgia, April 12-17, 1981.

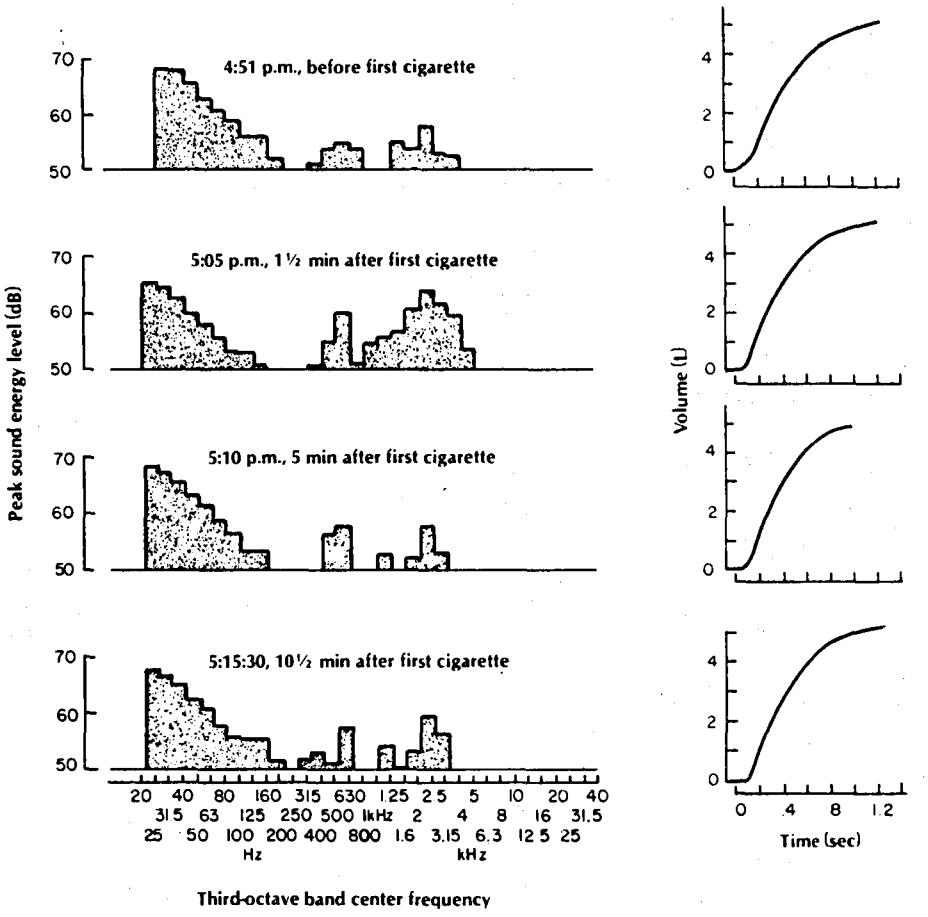
Action

In the next quarter, the RTI team will work with Dr. Patterson to document the project plan in more detail.

NONINVASIVE LUNG DIAGNOSIS

- DETECTS PULMONARY DYSFUNCTION BY ANALYZING FREQUENCY AND AMPLITUDE OF LUNG SOUNDS
- RESPONSE TO PHARMACOLOGICAL AND ENVIRONMENTAL STIMULI
- NASA LANGLEY ACOUSTICS TECHNOLOGY
- MEDICAL COLLEGE OF VIRGINIA, RICHMOND

  B & K INSTRUMENTS, INC., CLEVELAND, OH



Spectral phonopulmonograph of a 27-year-old white male showing forced exhalation before smoking and 1½, 5, and 10½ minutes after smoking one cigarette.

PORTABLE COOLING SYSTEM FOR QUADRIPLEGICS

BATeam Personnel: Dr. Doris Rouse

Problem

Quadriplegics are vulnerable to heat stress because they cannot perspire below the level of injury, a condition that results from the interruption of autonomic neural pathways that mediate thermoregulatory perspiration and vasomotion. Quadriplegics exposed to even moderately high temperatures risk hyperventilation, increased heart rate, and heat stroke.

Solution

A portable cooling garment would eliminate these risks, thus opening new employment and daily living opportunities for individuals previously confined to temperature-controlled environments.

NASA Technology

Technology from the development of thermal control garments to protect astronauts has been used to make a water-cooled vest for quadriplegics.

Principals

Ms. Pat Kirk, Environmental Control Research Branch, NASA Ames Research Center, Moffett Field, California.

Dr. Inder Perkash, Spinal Cord Injury Unit, Veterans Administration Medical Center, Palo Alto, California.

Cost to NASA

Fabrication of prototype vest systems for evaluation by VA Palo Alto cost NASA $15,000. The in-kind cost to the VA Palo Alto for the evaluation at VA Palo Alto will be approximately $15,000.

Commercialization Strategy

Palm Beach Medical Corporation, who has expressed an interest in marketing the quadriplegic cooling vest, is following the evaluation. Other manufacturers will be contacted as well.

Status

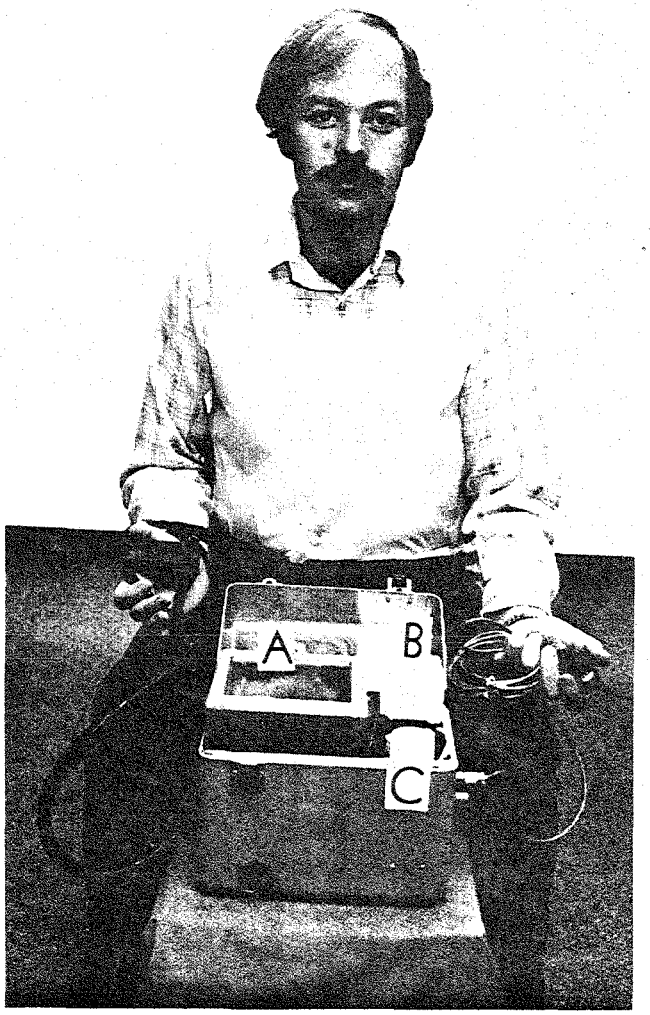
Personnel at Ames Research Center designed a small water-cooling and pumping unit for use with the vest. An informal evaluation of the system by a quadriplegic indicated that the system was quite effective. The VA Medical Center in Palo Alto has prepared a protocol for evaluation of the vest in the NASA Ames environmental chambers and in outpatient use.

Action

The evaluation by the Veterans Administration will begin in April 1983.

PORTABLE COOLING SYSTEM FOR QUADRIPLEGICS

- QUADRIPLEGICS UNABLE TO PERSPIRE BELOW LEVEL OF INJURY. VULNERABLE TO HEAT STRESS
- NASA THERMAL CONTROL TECHNOLOGY
- COOLING VEST AND PUMPING/CHILLING UNIT
- SPINAL CORD INJURY UNIT, VA MEDICAL CENTER, PALO ALTO, CA
  VA REHABILITATION RESEARCH AND DEVELOPMENT, WASHINGTON, DC



Portable cooling system. A = reservoir, B = battery, C = pump.

PORTABLE COOLING SYSTEM FOR QUADRIPLEGICS

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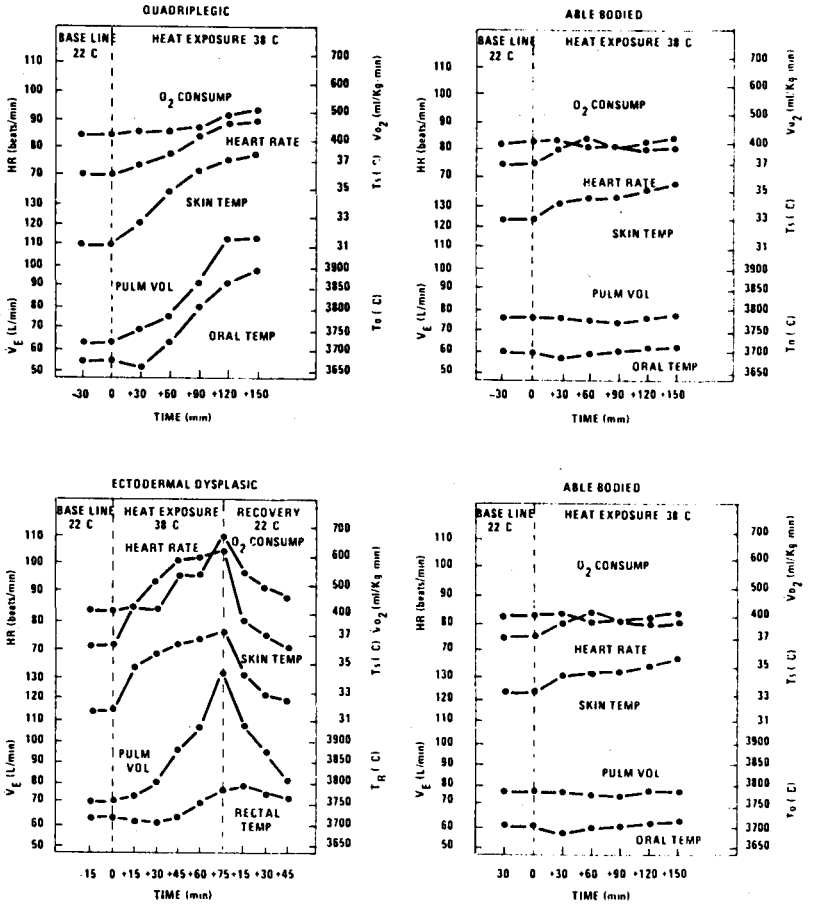

From G. L. Totel, "Physiological Responses to Heat of Resting Man with Impaired Sweating Capacity," *J. Appl. Physiol. 37,* 1974, p. 346.

PROGRAMMABLE IMPLANTABLE MEDICATION SYSTEM

BATeam Personnel: Dr. Doris Rouse

Problem

A number of chronic diseases require long-term infusion or frequent injections of medication. An implanted pump has been used for the continuous, intravenous infusion of heparin in patients for more than 24 months. One million diabetics in the United States depend on daily insulin injections to help control blood sugar levels; one in ten of these is a child.[1] A programmable implantable pump capable of several delivery rates would be extremely useful in the infusion of insulin to treat diabetes. A more reliable control of blood sugar levels throughout a diabetic's life is thought to diminish the incidence of the complications associated with diabetes--kidney disease, diabetic retinopathy, atherosclerosis, and heart attacks.[2] [3] [4]

The conventional treatment for controlling blood sugar levels in the diabetic requires two to four insulin injections daily. In addition, the patient must accept significant lifestyle and diet restrictions. Despite these efforts, however, true normalization of blood glucose is rare, because of changes in daily activity levels, changes in diet, and shortcomings in the insulin delivery system.

Plasma glucose concentration in healthy subjects remains between 70 and 120 mg/dL over a 24-hour period.[4] In contrast, a patient with juvenile-onset diabetes, who is taking multiple, daily insulin injections, will still have a hyperglycemic plasma glucose concentration of more than 200 mg/dL. The diabetic may also experience periodic hypoglycemia (plasma glucose less than 50 mg/dL).[5] Tamborlane et al. recently reported that good plasma glucose control could be obtained in juvenile diabetes patients by the use of a portable insulin infusion system that delivers a basal rate of insulin with a preprandial pulse.[6] An implantable infusion system that could achieve the plasma glucose control demonstrated in this external system would have obvious advantages.

Solution

An implantable infusion pump that could accurately deliver medication at programmed rates would have great potential in the treatment of several diseases including diabetes, leukemia, thalassemia, and hormone disorders. Safety features and reliable delivery rates would be required to insure safe medication levels.

NASA Technology

The programmable implantable medication system (PIMS) will incorporate NASA technology in three areas: (1) microminiaturized hybrid circuitry will be used for the pump system as well as the programming unit, (2) the programming unit will use command and telemetry systems with functions similar to those used on small astronomy satellites and other spacecraft, and (3) aerospace technology in

miniature, highly reliable hydraulic control systems will be used in the medication delivery portion of the system.

Principals

Mr. Don Friedman, Technology Utilization Officer, Goddard Space Flight Center.
Mr. Robert Fischell, Applied Physics Laboratory, Johns Hopkins University, Laurel, Maryland.
Mr. Al Mann, Pacesetter Systems, Inc., Sylmar, California.
Mr. Steve Wirtz, Parker-Hannifin/Biomedical Products Division, Irvine, California.
Dr. Christopher Saudek, Johns Hopkins University, Baltimore, Maryland.

Cost to NASA

An FY80 RTOP from Goddard Space Flight Center was approved for $150,000, with $950,000 in projected costs for the next 3 years. A Marshall Space Flight Center FY80 RTOP was approved for $75,000, with projected costs of $135,000 over the following 2 years. In March 1980, management of the hydraulic control RTOP was transferred to Goddard Space Flight Center. The cost sharing for the project is listed below:

National Institute of Child Health and Human Development (NICHHD)	$ 400,000
Wilson-Greatbach Limited	500,000
National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDKD)	2,500,000
Pacesetter Systems, Inc.	2,000,000
Parker-Hannifin, Inc.	3,000,000
Applied Physics Lab (APL)	50,000
Baker Foundation	2,500
Total cost sharing	$8,452,500

Commercialization Strategy

Pacesetter Systems and Parker-Hannifin plan to manufacture and market the PIMS.

Status

The second phase of the animal trials, long-term implants, has begun at Johns Hopkins. Two PIMS units are currently operating in diabetic dogs in Dr. Saudek's laboratory. The push-cart Medication Injection Unit originally designed for PIMS has been replaced by a hand-held syringe system. The NICHHD committed $400,000 to the evaluation of PIMS for reproductive endocrinology. Extensive testing of the peptide hormones by NICHHD has shown sufficient stability for use in PIMS. The RTI team discussed the use of PIMS for hepatic artery infusion of chemotherapy with Dr. Paul Sugarbush, a colorectal surgeon at the National Cancer Institute. NCI is currently conducting a trial for hepatic infusion using the Infusaid pump and is interested in using the same protocol with the PIMS. The RTI team participated in the PIMS working group meeting at APL November 10, 1982.

Action

Dr. Saudek will continue the long-term animal studies. With continued good results, human implants are expected in 1983. The RTI team will work with Don Friedman and APL to identify program directors at the National Cancer Institute who may be interested in supporting an evaluation of PIMS for intraspinal infusion of morphine for pain relief in terminal cancer patients.

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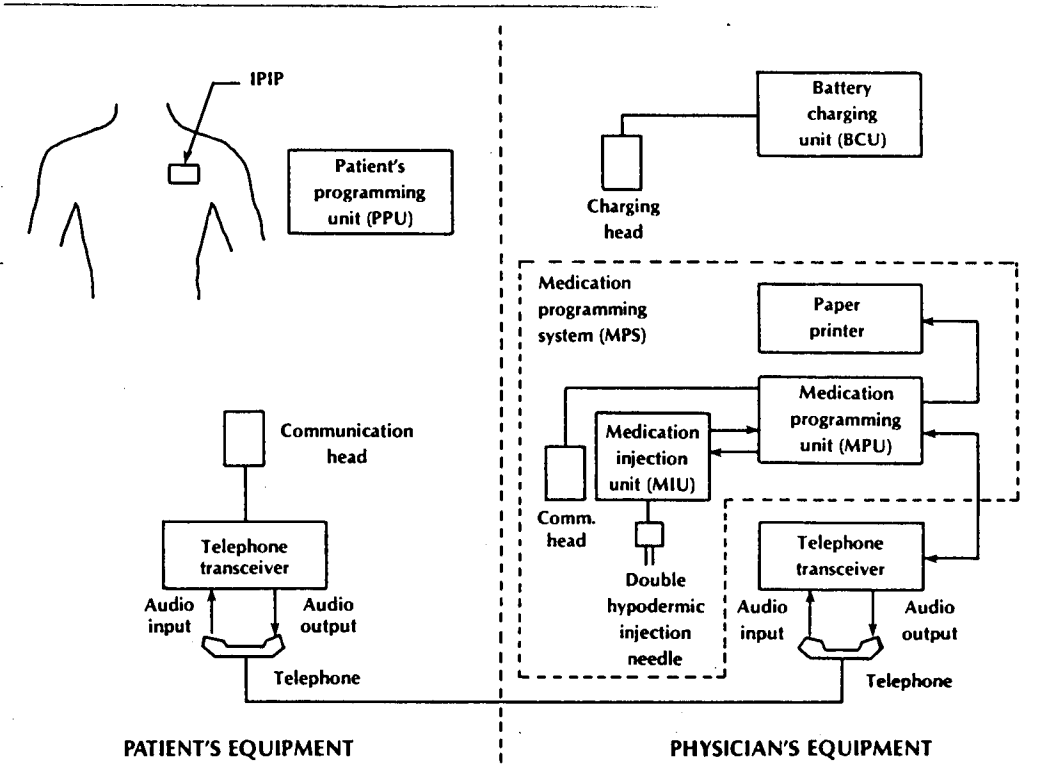
3. Siperstein, M.D. New England Journal of Medicine, 296:1060, 1977.
4. Service, F. J., et al. Diabetes, 19:644, 1970.
5. Molnar, G. D., Taylor, F. W., and A. L. Langworthy. Mayo Clinical Proceedings, 47:709-719, 1972.
6. Tamborlane, W. V., et al. New England Journal of Medicine, 300(11):573-578, March 15, 1979.

PROGRAMMABLE IMPLANTABLE MEDICATION SYSTEM

- ACCURATE DELIVERY OF MEDICATION AT PROGRAMMED RATES
- USE IN TREATMENT OF CHRONIC DISEASES SUCH AS DIABETES
- NASA COMMAND AND TELEMETRY SYSTEMS
- NASA VALVE TECHNOLOGY
- APPLIED PHYSICS LABORATORY, LAUREL, MD
  PACESETTER SYSTEMS, INC., SYLMAR, CA
  PARKER-HANNIFIN, IRVINE, CA
  JOHNS HOPKINS UNIVERSITY, BALTIMORE, MD



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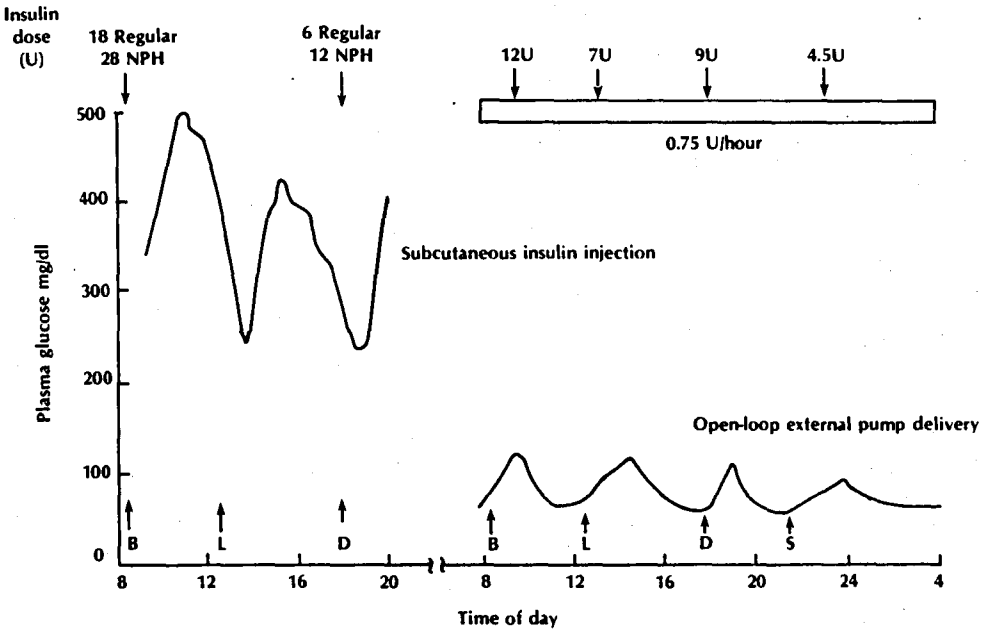


B = Breakfast
L = Lunch
D = Dinner
S = Snack
NPH = Neutral Protein Hagedorn = Isophane Insulin

From Clarke et al., *The Journal of Pediatrics*, October 1977 and Tamborlane et al., *NEJM*, March 15, 1979.

PROSTHETIC URINARY SPHINCTER

BATeam Personnel: Dr. Doris Rouse

Problem

A malfunctioning urethral sphincter is often responsible for the inability to control emptying of the bladder. This condition may result from congenital, traumatic, postsurgical, or neurogenic disorders. Continence can sometimes be restored by an implanted device that occludes the urethra and allows voluntary voiding by manual release of the occluding pressure. Two factors currently prevent widespread acceptance of such devices by the medical community: (1) the surgical complexity of the implantation procedure and (2) a high rate of device malfunction, often the result of valve failure.

Solution

A simpler, more reliable system is needed for occluding the urethra.

NASA Technology

The low-pressure, "zero" leakage, high-reliability valves used in the Viking project have been adapted for use in a prosthetic urinary sphincter.

Principals

Mr. John B. Tenney, Department of Surgery, Rochester General Hospital, Rochester, New York.
Mr. Steven Wirtz, Parker-Hannifin Corporation, Irvine, California.
Mr. Dave Sanders, President, Medical Engineering Corporation, Racine, Wisconsin.

Cost to NASA

NASA's total cost was $203,000. Parker-Hannifin Corporation has invested $250,000. Medical Engineering Corporation (MEC) has invested $250,000. In-kind contributions by Rochester General Hospital (RGH) have totaled $25,000.

Commercialization Strategy

MEC will market and distribute the system worldwide. Parker-Hannifin will supply the hydraulic control portion of the system. MEC and Parker-Hannifin are currently developing two other medical devices that utilize the NASA valve developed by Parker-Hannifin, a penile prosthesis and a continent colostomy device.

Status

RTI arranged a meeting between Parker-Hannifin, MEC, and Dr. Paul Sugarbush, a colorectal surgeon at the National Cancer Institute, to discuss NCI evaluation of the colostomy cuff.

Action

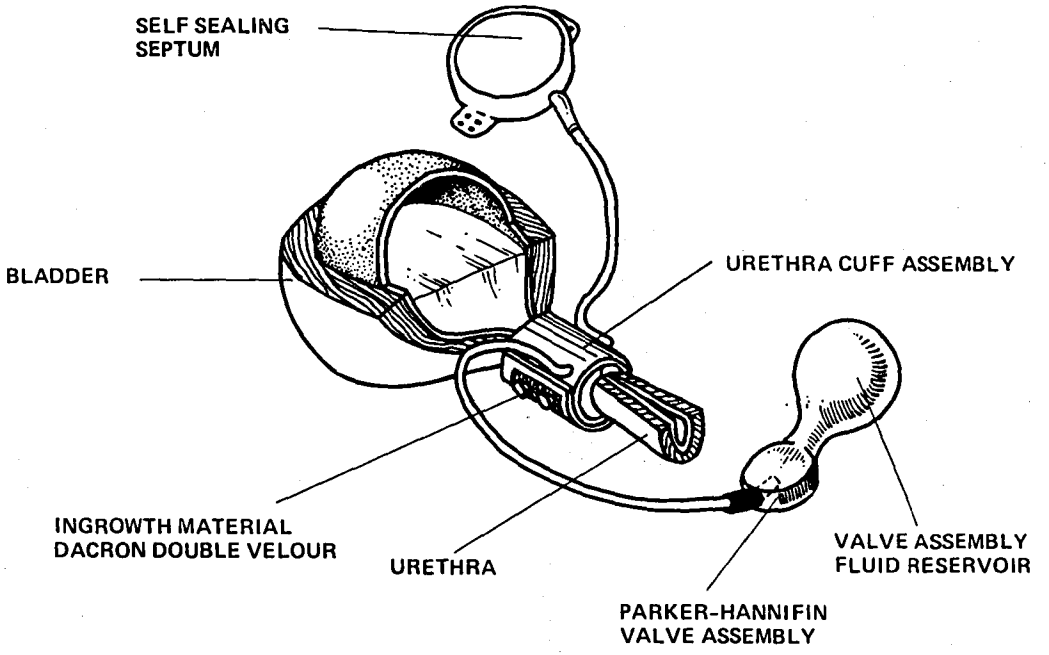
MEC plans to begin human implants of the urinary sphincter by September 1983. The RTI team is discussing possible funding for this evaluation with Paralyzed Veterans of America.

PROSTHETIC URINARY SPHINCTER

- 2%-5% OF POPULATION SUFFERS URINARY INCONTINENCE
- NASA TECHNOLOGY IN MINIATURIZED, HIGHLY RELIABLE VALVE SYSTEMS
- ROCHESTER GENERAL HOSPITAL DEPARTMENT OF SURGERY

  PARKER-HANNIFIN, IRVINE, CA

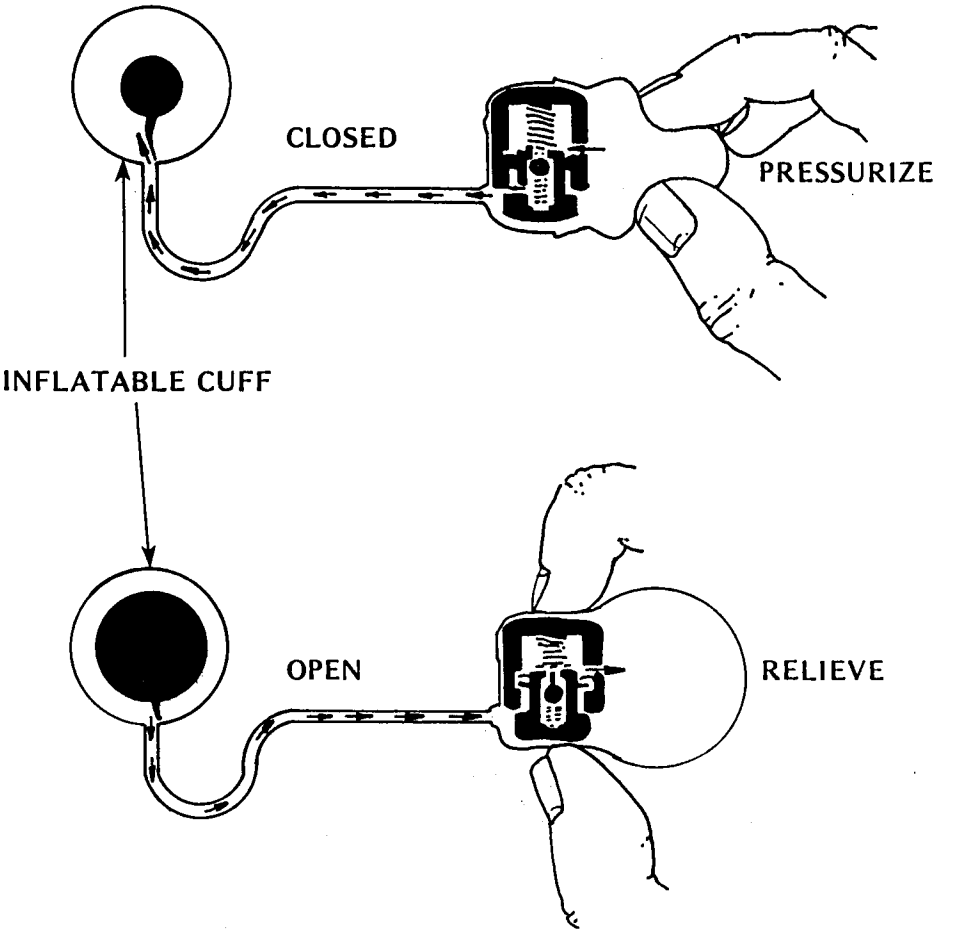
  MEDICAL ENGINEERING CORPORATION, RACINE, WI



NASA press/relieve valve concept of prosthetic urinary sphincter

PROSTHETIC URINARY SPHINCTER

- 2%-5% OF POPULATION SUFFERS URINARY INCONTINENCE
- NASA TECHNOLOGY IN MINIATURIZED, HIGHLY RELIABLE VALVE SYSTEMS
- ROCHESTER GENERAL HOSPITAL DEPARTMENT OF SURGERY
- PARKER-HANNIFIN, IRVINE, CA
- MEDICAL ENGINEERING CORPORATION, RACINE, WI



NASA press/relieve valve concept of prosthetic urinary sphincter

TEXTURING FOR PERCUTANEOUS CONNECTORS

BATeam Personnel: Dr. Doris Rouse

Problem

Percutaneous connectors are conduits through the skin that facilitate the transmission of fluids or connecting devices between the external environment and the body's internal milieu. Current percutaneous connectors are unacceptable for long-term implants because of externalization and infection.

Solution

If percutaneous connectors could be developed with a reduced tendency to externalize and with an improved body fluid seal to inhibit bacterial invasion, morbidity could be greatly reduced and new device applications could be explored.

NASA Technology

NASA electron propulsion technology may be used to ion-beam texture percutaneous connectors to prevent externalization and reduce infection.

Principals

Mr. Sandy Felder, NASA Lewis Research Center, Cleveland, Ohio.
Dr. George Picha, President, Applied Medical Technology, Inc., Lakewood, Ohio.

Cost to NASA

An FY80 RTOP was submitted for $155,000 over a 3-year period. Cost sharing by the potential manufacturer will be $252,000 over 4 years.

Commercialization Strategy

A NASA patent disclosure has been filed. Applied Medical Technology, Inc., plans to market textured connectors if the study proves successful. American Hospital Supply (AHS) Corporation is interested in collaborating with Applied Medical Technology to commercialize several devices using NASA's ion-texturing.

Status

The RTI team discussed this project with Drs. Watson and Berson in the Devices and Technology Branch, National Heart, Lung and Blood Institute (NHLBI). They found that the technical objectives of the NASA project were satisfactory and that the preliminary results were promising enough to warrant continued project support. NHLBI is supporting two contractors to develop percutaneous connectors. The RTI team has forwarded recent reports by the contractors to Dr. Picha. The RTI team attended an NHLBI contractors meeting in Bethesda. Work thus far has demonstrated that a

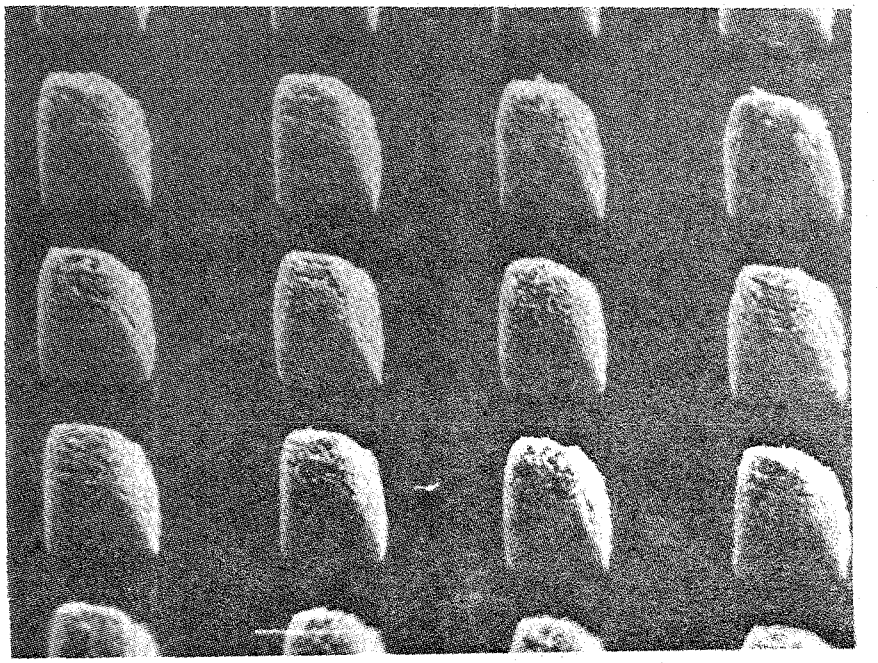
regular array of micropillars can inhibit epithelial downgrowth and subsequent rejection of the percutaneous connector. AHS would like to participate in and cofund the remaining 2 years of development for the percutaneous connectors. Pending patent protection negotiations, AHS would conduct and finance the clinical trials. Implementation of this plan for collaboration is under consideration by NASA Lewis, NASA Headquarters, and AHS.

Action

Discussions will continue with AHS on cofunding and requirements for patent protection.

PERCUTANEOUS CONNECTORS

- PREVENT INFECTION AND REJECTION OF THROUGH-THE-SKIN CONDUITS
- TEXTURE SURFACE OF CONDUIT MATERIAL FOR TISSUE ATTACHMENT
- NASA-LEWIS ION-BEAM TECHNOLOGY
- APPLIED MEDICAL TECHNOLOGY, INC. CLEVELAND, OH



Scanning electron micrograph of ion-beam textured surface

TEXTURING SURFACES FOR CARDIOVASCULAR PROSTHESES

BATeam Personnel: Dr. Doris Rouse

Problem

The ideal vascular prosthesis should promote the formation of a stable, nonthrombogenic blood interface. A material with this property would be useful for heart replacements, as heart-assist devices, and in vascular applications.

Solution

Studies have shown that a surface with a microstructure will produce a thin, uniform, and well-nourished neo-intima, or layer of blood components and cells. A thin neo-intima is desirable because it is less thrombogenic. The thickness of the neo-intima that develops on a heart-assist device bladder is directly related to the height of the pillars texturing the surface. Present mold-manufacturing technology limits this pillar height to a minimum of 250 μm. A technique to produce shorter pillars on the material may produce a thinner, less thrombogenic neo-intima.

NASA Technology

NASA electron propulsion technology can be used to make materials with smaller pillar heights.

Principals

Mr. Bruce Banks, NASA Lewis Research Center, Cleveland, Ohio.
Thermo Electron Corporation (TECO), Waltham, Massachusetts.
National Heart, Lung and Blood Institute (NHLBI), Bethesda, Maryland.

Cost to NASA

An FY80 RTOP for $133,000 over 3 years was funded. Cost sharing by NHLBI and TECO will be $119,000.

Commercialization Strategy

Successful ion-beam texturing would improve the vascular prostheses currently on the market as well as heart-assist devices, when they are available. Manufacturers of vascular prostheses will be presented with the results of this work on heart-assist pump bladders.

Status

NHLBI has cofunded a joint effort between TECO and NASA Lewis Research Center to fabricate six ion-textured bladders for left ventricular assist devices. This work complements an NHLBI-funded project at the University of Utah entitled "Development and Evaluation of Textured Surfaces." Under a contract from NASA Lewis Research Center, Diecast Dies, Inc., textured the mandrils and formed

bladders. The bladders were delivered to the University of Utah and TECO researchers for implantation and evaluation in calves.

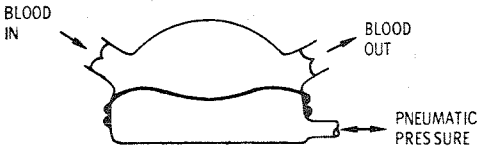
Action

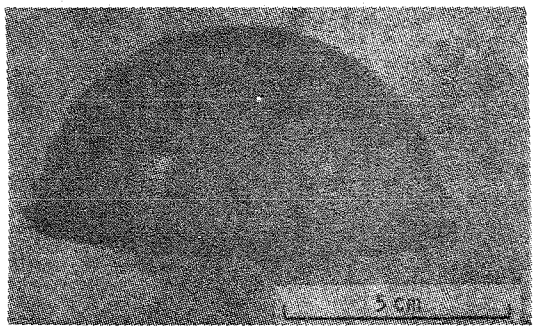
The implanted bladders will be retrieved this year for examination of the neo-intima formed on the textured surface. The RTI team will continue discussions with NHLBI on project results and plans.

TEXTURING SURFACES FOR CARDIOVASCULAR PROSTHESES

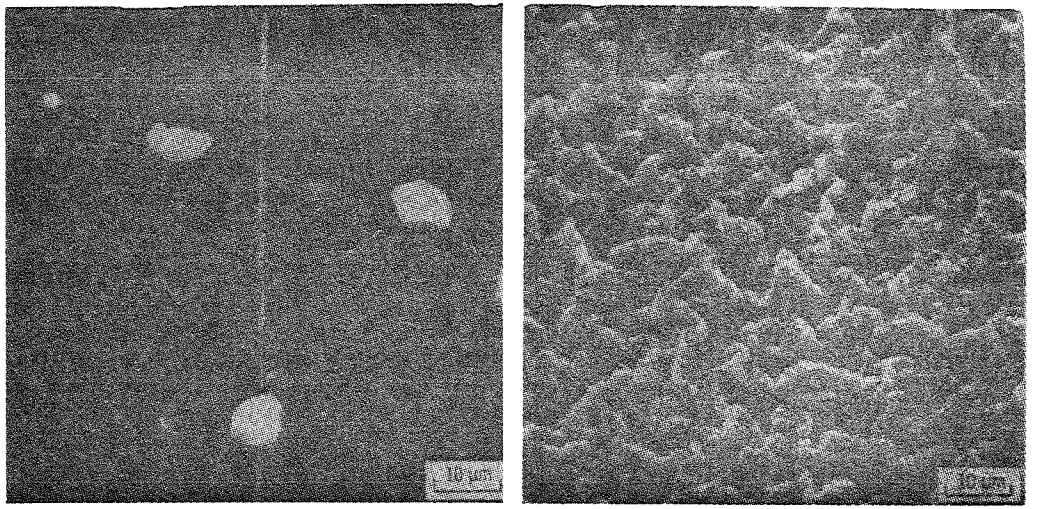
- PROMOTES STABLE, NONTHROMBOEMBOLIC BLOOD INTERFACE IN CARDIOVASCULAR PROSTHESES
- PRODUCE MICROTEXTURES AS SMALL AS 10μm
- NASA-LEWIS ION-BEAM TECHNOLOGY
- THERMO ELECTRON CORPORATION
  WALTHAM, MA

  NATIONAL HEART, LUNG AND BLOOD INSTITUTE





Artificial heart assist pump



Scanning electron micrographs of carbon-impregnated polyolefin before and after sputter etching.

ULTRASOUND DIAGNOSIS OF BURN DEPTH

BATeam Personnel: Dr. Doris Rouse

Problem

Approximately 2 million Americans suffer serious burns each year, and 200 to 300 thousand of these people require hospital treatment.[1] Among those hospitalized, 70,000 receive intensive care and 10 to 12 thousand patients die from their injuries. The cost of intensive care exceeds $300 million per year.[2] The traditional treatment of burn victims is to allow natural debridement, sloughing of necrotic tissue, to occur and then to close the resulting open wounds with skin grafts. Unfortunately, the weeks required for spontaneous sloughing often result in infection and sepsis; indeed, the major cause of death in burn victims is bacterial infection.[3] Modern treatment, therefore, is based on early recognition and removal of necrotic tissue to reduce infection and hasten healing. This surgical or chemical debridement depends upon accurate burn depth information for optimal results. Current methods for burn depth determination are inaccurate, cumbersome, or both.

Solution

Ultrasound may be used to map precisely and conveniently the depths of the interface between viable and necrotic tissue in burn injuries. Preliminary studies in pigs demonstrate a good correlation between depths of burn measured by pulse-echo ultrasound and by histological techniques.

NASA Technology

Advanced ultrasonic technology developed at Langley Research Center for the characterization of materials is directly applicable to this project.

Principals

Dr. John H. Cantrell, Jr., Langley Research Center, Hampton, Virginia.
Dr. Tom Yost, Langley Research Center, Hampton, Virginia.
Col. Basil Pruitt, Jr., M.D., U.S. Army Institute of Surgical Research (USAISR), Ft. Sam Houston, Texas.

Cost to NASA

Estimated cost for development of the prototype is $146,000. Estimated cost to the Army for evaluation of the device is $210,000 in the first year.

Commercialization Status

The RTI team has contacted 15 manufacturers of medical ultrasound devices. Thus far, Technicare and Sonometrics Systems, Inc., are interested in collaborating in the project and marketing the device. The RTI team and the Langley scientists visited Sonometrics in October to discuss the system.

Status

An FY83 RTOP for $126,000 has been submitted by Langley Research Center for support of the project. In response to inquiries by the RTI team, four major burn centers, Shriners Burn Center-Harvard, Medical College of Virginia, the Baltimore Regional Burn Center, and the USAISR at Ft. Sam Houston, have indicated a strong interest in conducting the clinical evaluation of the system. The USAISR has agreed to evaluate the device at no cost to NASA.

Action

The RTI team and Langley scientists will visit USAISR to discuss the system and the clinical protocols for evaluation. Selection of the manufacturer will be completed by May 1983. Dr. Cantrell has been invited to present a paper on the device at a conference on burns in September 1983. This conference will be sponsored by the National Institutes of Health, World Health Organization, and the International Society for Burn Injuries.

References

1. Jay, K. M., Bartlett, R. N., Danet, R. and Allyn, P. A. Burn epidemiology: A basis for burn prevention. J. Trauma, 17:943-947, 1977.
2. Montgomery, B. J. Consensus for treatment of the "sickest patients you'll ever see." JAMA, 241:344-346, 1979.
3. Epsteen, C. M. Burns: The immediacy of care. Int. Surg., 63:59-60, 1978.

WASTEWATER TREATMENT BY VASCULAR AQUATIC PLANTS

BATeam Personnel: Dr. H. Clark Beall

Problem

The purification of wastewater is a problem faced by municipal treatment plants throughout the United States. The effluent from such plants must meet standards set by EPA before it can be released from the treatment plant. Sanitation engineers are searching continually for new technologies that can be applied to water treatment to reduce costs, time, and energy required to process wastewater.

Solution

Use of aquatic plants, one of several new procedures for wastewater treatment, shows promise in terms of speed, operating cost, and effectiveness.

NASA Technology

Research at the National Space Technology Laboratories has focused on the treatment of wastewater by vascular aquatic plants. The first effort dealt with a system based on the water hyacinth, Eichhornia crassipes. This system worked well in warm climates in wastewater treatment and biomass energy production.

Principals

Bill Wolverton, Ph.D., National Space Technology Laboratories, Mississippi.

Cost to NASA

The current RTOP request for this work is $40,000 with an additional $80,000 being funded by EPA.

Commercialization Strategy

The City of San Diego is now using the water hyacinth system as one means to bring effluent water to potable standards. An engineering firm from Baton Rouge, Louisiana, Owens and White, Inc., has based its designs for two new municipal treatment plants on the NASA-published data of microorganism/vascular plant wastewater treatment. The designs are being reviewed by EPA and await local funding under the Innovative Technology program of the State of Louisiana.

Status

There are thousands of small food-processing plants in the United States that could benefit from treatment of wastewater by vascular plant systems. Dr. Wolverton has agreed to assist in the design of a wastewater treatment plant for a crab meat processing plant in Crestfield, Maryland.

Action

The RTI team will work with faculty members of North Carolina State University Food Science Department, Raleigh, North Carolina, to evaluate applications in the food processing industry, especially poultry processing plants.

Reference

Wolverton, B. C. New Hybrid Wastewater Treatment System Using Anaerobic Microorganisms and Reed (Phragmites communis). NASA Technical Memorandum, TM-X-72739, June 1981.

7.0 INACTIVATED PROJECTS

COMPOSITE MATERIAL APPLICATIONS

BATeam Personnel: Dr. Doris Rouse

This project has been integrated into the high performance wheelchair project. In that project, composite materials are being used to decrease the weight of a standard wheelchair from 50 to 25 pounds.

DETECTION OF A DISLODGED TEMPERATURE PROBE

BATeam Personnel: Dr. H. Clark Beall

Infant radiant warmers are widely used in hospital delivery rooms and nurseries to maintain the correct body temperature of newborn babies. These devices, which radiate energy in the far infrared spectrum, are servocontrolled via a patient temperature probe that attaches to the infant's skin. If the probe becomes dislodged, the warmer may deliver excess radiation to the infant. In discussions with the RTI team, the Association for the Advancement of Medical Instrumentation indicated that a sensor was needed to alert the staff if the temperature probe were dislodged. Lewis Research Center submitted a sensor design in response to an RTI team problem statement. The RTI team distributed the concept to radiant warmer manufacturers. One letter of reply advised RTI that the same technology was currently under development as a proprietary device.

FIBER OPTICS SYSTEM FOR KNEE SURGERY

BATeam Personnel: Dr. H. Clark Beall

A second test of the utility of the fiber optics system as an orthoscope-TV camera interface took place in 1982 at Duke University Medical Center. Light passed by the fiberoptics system was insufficient to produce an acceptable color TV image. Both tests of the fiber optics system indicated its limitations as an adequate surgical imaging device. In addition, there are now on the market several very small, low-light, color TV cameras specifically designed for medical applications. These color TV cameras will fill the need for which the fiber optics device was originally developed. The fiber optics device has been returned to Langley Research Center, accompanied by a memorandum describing the clinical evaluations.

LOW-COST UV OPTICAL DOSIMETER

BATeam Personnel: Dr. H. Clark Beall

Engineers at Langley Research Center demonstrated how the technologies of the photovoltaic solar cell and the electrochemical current-recording cell could contribute to the extremely simple design of a solar dosimeter to detect and integrate the incident solar irradiation over long periods of time. Several models of the solar dosimeter were fabricated. The entire instrument was so small that it could be worn unobtrusively or attached to eyeglass frames.

An effort was made to construct dosimeters that recorded exclusively the UVB radiation from the sun. The UVB radiation is the portion of solar radiation that causes sunburn, initiates suntanning, and perhaps causes skin cancer in humans. Although prototypes of the UVB dosimeters seemed to operate satisfactorily in laboratory tests, efforts to produce a batch of more than a dozen identical units produced instead a set of devices having a diversity of spectral responses. Special optical filters are required to isolate the UVB band from the total solar radiation adequately. In addition, special blue-sensitive detectors are required to convert the UVB radiation to electric current. The cost of these special items exceeded the cost of the basic dosimeter by twenty-fold, thus compromising the low-cost feature of the original dosimeter design.

PORTABLE X-RAY FLUORESCENCE SPECTROMETER

BATeam Personnel: Dr. H. Clark Beall

The concept of using the X-ray fluorescence technique outside the laboratory has been proved by a Langley Research Center researcher, Warren Kelliher, Ph.D. He has designed and contracted the fabrication of a hand-held, portable X-ray fluorometer. The device has been evaluated in several applications projects. The first project was jointly funded by NASA and the U.S. Bureau of Mines to test the X-ray fluorometer in the onsite elemental analysis of ores and prospect samples. The second project demonstrated the use of the device as a quantitative detector of heavy metals in water samples for the EPA laboratory in Las Vegas. The device has also been used to type the exact metal alloy of aircraft parts without dismounting or damaging the parts. The device can similarly be used to quickly verify individual alloys of metal stock in aircraft and shipbuilding facilities and at machine shops.

The X-ray fluorometer has been improved in the last several years by the addition of new detector crystals and detector head configuration. A patent disclosure of the device has been prepared describing the device's configuration during the Bureau of Mines project.

The RTI team interviewed clinicians to identify potential medical applications for the X-ray fluorometer. Staff members of the Department of Radiology of the Duke University Medical School considered their requirements for a portable X-ray fluorometer and found that their needs were adequately served by mobile X-ray fluorometer units that utilize AC power sources.

8.0 CONCLUSIONS

During the reporting period, the RTI Biomedical Applications Team conducted problem-solving and commercialization activities for 15 active projects, 2 commercial transfers, and 2 institutional transfers. Each of these projects has the potential for introducing new or improved commercial medical devices incorporating NASA technology. The projects selected by the team reflect an emphasis on transferring NASA technology via the introduction of commercially available devices. The objective of this commercial emphasis is to achieve widespread availability of the devices developed in the technology transfer process. To accomplish this commercialization objective, the RTI team has continued to develop improved methods for project selection and development. Implementation of techniques developed by the RTI team for reducing the time and costs for transfer of the technology has resulted in a more effective utilization of the funds available to the team, NASA field centers, and participating agencies. Techniques implemented during the reporting period to enhance the team's efficiency are described below.

1. Washington Office

   Close collaboration between the RTI team and Federal health agencies in the identification and screening of opportunities and the selection of clinical investigators has been effective in establishing successful technology transfer projects that address significant requirements in medicine. Most of the agencies that participate in the NASA program are located in the Washington, DC, area: The National Institutes of Health, National Institute of Handicapped Research, Veterans Administration, and Paralyzed Veterans of America. In the past year, Mr. Bernard Maggin and Mr. William Penland, Jr., have served as consultants for the RTI team in the Washington, DC, area. They have assisted the team in developing and implementing strategies for collaboration with Federal agencies in NASA applications projects. The objectives of the RTI team in establishing this Washington office were: (1) to establish more effective communication with the agencies, and (2) to decrease the team's travel costs associated with agency collaboration. In this first year of operation, the Washington office has proven to be quite an effective and efficient method for expanding the team's access to other agencies.

2. Phase 0 Studies

   At the request of NASA Langley Research Center and NASA Headquarters, the team has conducted two Phase 0 studies in the past year. The objectives of these studies were to evaluate the technical feasibility of the project, evaluate the market and the economic feasibility of the concept, establish mission agency collaboration and cofunding, identify a clinical investigator, and establish manufacturer interest in the project. These Phase 0 studies have provided a basis for the development of a more effective project plan.

Data gathered in the study and discussions with collaborating organizations identified in the study clarify the objectives of the project. As a result, the development project following the Phase 0 study will be more directed and thus more cost effective.

APPENDIX A

TRAVEL

APPENDIX A. TRAVEL

January 25, 1982	Dr. J. N. Brown, Jr., met with Ray Whitten at NASA Headquarters to discuss RTI team projects.
February 4, 1982	Dr. Doris Rouse participated in the planning session for the High Performance Wheelchair project at Langley Research Center.
February 5, 1982	Dr. Doris Rouse visited the University of Virginia to continue discussions on the high performance wheelchair and the NASA Lewis-UVa wheelchair battery project.
February 23, 1982	Dr. Doris Rouse met with Dr. John L. Patterson to discuss the status of the Non-invasive Lung Diagnostic Device at the Medical College of Virginia.
February 24, 1982	Dr. Doris Rouse met with Mr. John Samos, Mr. Les Rose, and Mr. Ray Whitten at Langley Research Center to discuss several projects.
February 25-26, 1982	Dr. Doris Rouse participated in the Programmable Implantable Medication System working group meeting at Applied Physics Laboratory, Laurel, Maryland.
March 25-27, 1982	Dr. Doris Rouse participated in the Wheelchair III Conference at La Jolla, California. The Veterans Administration Rehabilitation Engineering Research and Development Service sponsored this conference and funded Dr. Rouse's travel.
May 24, 1982	Dr. Clark Beall attended a presentation for EPA representatives at Langley Research Center on the capabilities of the NASA quadrupole mass spectrometer system.
April 6, 1982	Dr. Doris Rouse met in Washington with Dr. Giannini, Director, Rehabilitative Engineering Research and Development for the Veterans Administration to discuss NASA/VA collaboration on rehabilitation projects.
April 9, 1982	Dr. James Brown met with Technology Utilization Office representatives at Kennedy Space Center to discuss plans for FY83 RTOPs.
April 22, 1982	Dr. Doris Rouse met with Dr. Jim Beebe and Don Vargo at the Science and Technology Information Facility, Baltimore, to discuss technology summaries for NIH.
April 23, 1982	Dr. Doris Rouse met with Don Friedman, Goddard Technology Utilization Officer, to discuss the CSF control system Phase Zero study.

April 23, 1982	Dr. Doris Rouse met with Lynn Phillips, Director of Research, Paralyzed Veterans of America, in Bethesda to discuss wheelchair innovations.
May 5, 1982	Dr. Doris Rouse met with the marketing and engineering staff at Cordis Corp., Miami, to discuss the CSF control system project.
May 11, 1982	Dr. James Brown and Dr. Doris Rouse met at NASA Headquarters with Ray Whitten, Don Vargo, and Don Friedman to discuss status of Biomedical Applications Team projects.
May 12, 1982	Dr. Doris Rouse participated in a meeting in Washington, sponsored by the Veterans Administration, to identify new technology and designs for power wheelchairs.
May 24, 1982	Blake Wilson and Dr. Doris Rouse met with John Samos, Les Rose and Dr. John Cantrell, Jr., at Langley Research Center to discuss the Ultrasound Diagnosis of Burn Depth.
May 26, 1982	Dr. Doris Rouse met with Dr. George Picha, Sandy Felder, and Roger Drake, Director of the American Hospital Supply Technology Center, to discuss commercialization of ion-textured devices developed by NASA.
June 3, 1982	Dr. James Brown and Dr. Doris Rouse met at NASA Headquarters with Charles Yost to discuss a proposed shuttle experiment on blood preservation.
June 9, 1982	Dr. James Brown and Dr. Doris Rouse coordinated a meeting at the Pentagon with Col. Phillip Winter, M.D., and Parker-Hannifin representatives to discuss the NASA TU program and military medical applications of the MICROMED.
June 23-24, 1982	Dr. Doris Rouse participated in the 9th PIMS Working Group Meeting at Applied Physics Laboratory, Laurel, MD.
June 28-30, 1982	Dr. Doris Rouse participated in the Advisory Design Committee Meeting for the Association for Retarded Citizens in Arlington, Texas.
July 29-30, 1982	Dr. Doris Rouse met with John Samos, Les Rose, and Don Vargo at Langley Research Center to discuss Langley Technology Utilization projects.
August 12, 1982	Bill Penland, Bernie Maggin, and Dr. Doris Rouse met with Don Vargo at NASA Headquarters to prepare for the RTOP review.

August 17, 1982	Dr. Doris Rouse participated in a Washington meeting sponsored by the Veterans Administration Rehabilitation Research and Development to prepare specifications for a power wheelchair Request for Proposal.
August 20-26, 1982	Dr. Doris Rouse participated in the conference of the Rehabilitation Engineering Society of North America in Houston, Texas.
August 24, 1982	Dr. Doris Rouse met with Jack Wheeler, Technology Utilization Officer, Johnson Space Center, to discuss JSC transfer projects.
August 26-27, 1982	Dr. Clark Beall visited McGee Eye Institute in Oklahoma City, Oklahoma, with JPL and MSFC personnel to discuss the corneal topography project.
August 31, 1982	Dr. James Brown met with Ron Phillips at NASA Headquarters to discuss RTI's technology transfer program.
September 1-2, 1982	Dr. Doris Rouse and RTI team consultants Bill Penland and Bernie Maggin participated in the RTOP review at the NASA Scientific and Technical Information Facility, Baltimore/Washington International Airport, Maryland.
September 15, 1982	Dr. James Brown and Dr. Doris Rouse met with Ray Whitten in Washington, D.C., to discuss several team projects.
October 7, 1982	Bill Penland and Dr. Doris Rouse met with Dr. Emilie Black at NIH to discuss ultrasound analysis of burn depth.
October 8, 1982	Bill Penland and Dr. Doris Rouse met with Bob Fischell at Applied Physics Laboratory in Laurel, Maryland, to discuss team assistance to APL in NASA Technology Utilization projects.
October 13, 1982	Dr. Doris Rouse, Bill Penland, and Dr. John Cantrell met with Dr. John Burke at the Shriners Burn Institute, Massachusetts General Hospital, Boston, to discuss ultrasound analysis of burn depth.
October 14, 1982	Dr. Doris Rouse and Dr. John Cantrell met with Sonometric Systems, Inc., in New York to discuss commercialization of the ultrasound system for burn depth analysis.

October 19, 1982	Dr. James Brown met with Don Smith at the University of Michigan to discuss NASA technology transfer and robotics.
October 20, 1982	Dr. James Brown met with Ray Whitten to discuss team projects.
November 9-10, 1982	Dr. James Brown met with Reed Barnett at Kennedy Space Center to discuss wildlife tracking.
November 12-14, 1982	Dr. Doris Rouse and Don Friedman met with Tom Loarie, President of Heyer Schulte Corporation, to discuss the microprocessor-based hydrocephalus shunt. These discussions were held during a workshop on hydrocephalus management in Napa, California.
November 15, 1982	Dr. Doris Rouse met with SRI and the Veterans Administration Rehabilitation Engineering Center in Palo Alto to discuss mobility aids for the blind.
November 16, 1982	Dr. Doris Rouse met with Stan Miller at NASA Ames to discuss TU projects.
November 17, 1982	Dr. H. Clark Beall met with Don Vargo and Ray Whitten in Washington to discuss team projects.
November 23, 1982	Dr. James Brown met with Ray Whitten to discuss team projects and plans.
December 6-7, 1982	Dr. Doris Rouse participated in an Advisory Design Committee meeting for the Association for Retarded Citizens in Arlington, Texas.
December 8-9, 1982	Dr. H. Clark Beall met with Don Vargo, Dr. Giannini, Sandy Felder, Don Friedman, and Case Western University researchers to discuss functional electrical stimulation.
December 14, 1982	Dr. H. Clark Beall attended a presentation by Smith-Kettlewell researchers at Marshall Space Flight Center on the results of their evaluation of the ophthalmic screening device.
January 25, 1983	Tony Sigmon met at Lewis Research Center with Harrison Allen and representatives for the Department of Energy and the Air Force to discuss a collaborative project on the magnetic heat pump.
January 31, 1983	Tony Sigmon met at Kennedy Space Center with Reed Barnett and Ray Gilbert to discuss a Phase 0 study on heat pipe applications.

APPENDIX B

PROJECT ACTIVITY SUMMARY

TABLE B-1. SUMMARY OF BIOMEDICAL APPLICATIONS TEAM ACTIVITIES
January 1, 1981 - December 31, 1981

Activity	Number
New Projects	6
Commercial Transfers	2
Institutional Transfers	2
Phase 0 Studies	2
Inactivated Projects	5
Current Active Projects	15
Field Centers Visited	7
Field Centers Participating in Team Projects	9
Manufacturers Participating	38
Medical Institutions Participating	28
Health Agencies Participating	21
IAC Information Searches	6
Medical Literature Searches	12

TABLE B-2. COMMERCIAL TRANSFERS

Porta-Fib III	Ocular Screening Device

TABLE B-3. INSTITUTIONAL TRANSFERS

Implant Materials Testing	Incinerator Monitoring

TABLE B-4. PHASE 0 STUDIES

Mobility Aids for the Blind	Ultrasound Diagnosis of Burn Depth

TABLE B-5. NEW PROBLEMS

Computerized Hydrocephalus Implantable Pump	Portable X-Ray Fluorescence Spectrometer
Hyperthermia Thermography	Ultrasound Diagnosis of Burn Depth
Incinerator Monitoring	Wastewater Treatment by Vascular Aquatic Plants

TABLE B-6. INACTIVATED PROJECTS

Composite Material Applications	Low Cost UV Optical Dosimeter
Detection of a Dislodged Temperature Probe	Portable X-Ray Fluorescence Spectrometer
Fiber Optics System for Knee Surgery	

TABLE B-7. ACTIVE PROJECTS AS OF FEBRUARY 28, 1983

Computerized Hydrocephalus Implantable Pump	Portable Cooling System for Quadriplegics
Corneal Topography	Programmable Implantable Medication System
Digital Data Recorder	Prosthetic Urinary Sphincter
High Performance Wheelchair	Texturing for Percutaneous Connectors
Hydrocephalus Shunt--Ventilation	Texturing Surfaces for Cardiovascular Prostheses
Hyperthermia Thermography	Ultrasound Diagnosis of Burn Depth
Microwave Thermography	Wastewater Treatment by Vascular Aquatic Plants
Noninvasive Lung Diagnosis	

APPENDIX C

NEW PROJECTS

APPENDIX C. NEW PROJECTS

COMPUTERIZED HYDROCEPHALUS IMPLANTABLE PUMP (December 1982)

BATeam Personnel: Dr. Doris Rouse

Problem

Hydrocephalus is an abnormal accumulation of cerebrospinal fluid (CSF) within the ventricles of the central nervous system. These ventricles are fluid-filled chambers that support and protect the brain and spinal cord. Cerebrospinal fluid is normally produced at a rate of approximately 0.35 mL per minute or about 504 mL per day. Normal CSF volume is 50 mL in infants and 150 mL in adults. The CSF, therefore, is renewed completely every 8 hours. Pathways for circulation or absorption of CSF can be blocked by congenital defects, trauma, infections, or tumors. The resulting fluid accumulation results in dilated ventricles and increased intracranial pressure with clinical sequela of impaired cognitive abilities, spasticity, or death.

Surgical insertion of a tube to shunt the CSF from the ventricles to another body cavity is often the only treatment. Unfortunately, currently available shunts often drain too much or too little CSF causing ventricular collapse or increased intracranial pressure.

Principals

Mr. Don Friedman, Technology Utilization Officer, Goddard Space Flight Center.

Solution

A microprocessor-controlled shunt capable of measuring intracranial pressure and flow through the shunt would allow the neurosurgeon to adjust the shunt parameters to achieve optimal CSF diversion and normal ventricle size. This system would also allow the neurosurgeon to wean the patient gradually from dependence on the shunt for CSF diversion in some cases.

NASA Technology

NASA technology in miniaturized, high-reliability fluid systems and microelectronics could be used in developing a microprocessor-controlled shunt.

Cost to NASA

An engineering feasibility study is planned for 1983 at an estimated cost of $100,000.

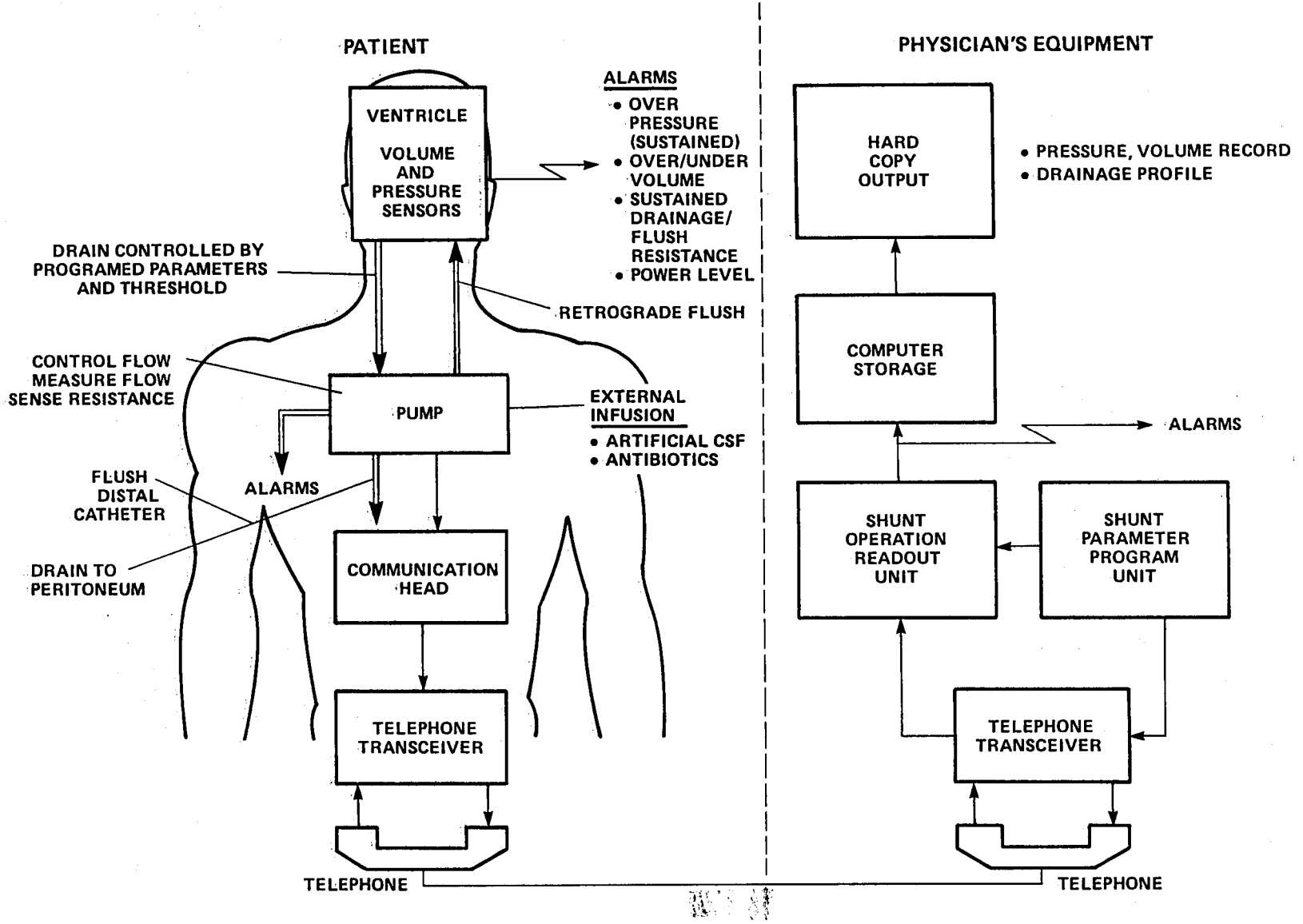
Commercialization Strategy

The RTI team has discussed the project with two major manufacturers of CSF shunt systems. Both companies indicated an interest in a collaborative project with NASA. A request for proposals to develop the system design will be issued by Goddard Space Flight Center.

Status

The RTI team completed a Phase 0 Study this year.

CEREBROSPINAL FLUID CONTROL SYSTEM



HYPERTHERMIA THERMOGRAPHY (January 1982)

BATeam Personnel: Dr. H. Clark Beall

Problem

The treatment of cancer by localized hyperthermia is a procedure receiving progressively more attention by oncologists. The generation of hyperthermia at localized sites within the human body can be accomplished by ultrasound irradiation, microwave irradiation, or radiofrequency irradiation. The significant technical hindrance to the therapy is the requirement for knowledge of the precise temperature at the hyperthermia site within the body. Reports in the hyperthermia literature indicate that both the exact temperature and the duration of application must be monitored and controlled during hyperthermia sessions.

Solution

NASA Headquarters assigned Langley Research Center the responsibility of devising a procedure for the remote measurement of the temperature within the human body. Initial tests at Langley had shown that passive microwave sensing of temperature was not precise enough, or localized enough, to be useful during hyperthermia.

NASA Technology

A meeting at the Langley Technology Utilization Office of NASA scientists and an RTI Biomedical Applications Team representative resulted in the derivation of several theoretical techniques for measurement of temperature by remote means. The most feasible and most novel method involves the use of ultrasound for the detection of phase transitions within strategically located fat deposits within, or near, the hyperthermia site.

Principals

Joe Heyman, Ph.D., NASA Langley Research Center, Hampton, Virginia
H. Clark Beall, Ph.D., RTI Biomedical Applications Team, Research Triangle Park, North Carolina.

Cost to NASA

The feasibility of the temperature measurement scheme could be tested immediately in the laboratory at Langley with a model system at an anticipated cost of $20,000.

Commercialization Strategy

The eventual result of the effort for hyperthermia thermography is the development of an optimized ultrasound scanning system and a set of specially formulated fat compounds with sharply defined melting points. This custom apparatus should be of commercial value to manufacturers of ultrasound equipment and hyperthermia equipment.

Status

The physical and physiological bases of the new technique have been presented in the form of an advocacy package to NASA Headquarters.

Action

The RTI Biomedical Applications Team will assist the Langley ultrasound personnel in the selection of appropriate lipid compounds for use in the proposed remote temperature measurement technique.

INCINERATOR MONITORING (January 1982)

BATeam Personnel: Dr. H. Clark Beall

Problem

The incineration of municipal refuse is a developing technology that not only disposes of wastes but also is a source of energy. Incineration is virtually the only disposal means for toxic, nonbiodegradable compounds such as PCB or agent orange. Smokestack monitoring is necessary to ensure complete combustion and to prevent dispersal into the air of noxious fumes and gases. A continuous, on-line monitoring program is desirable so that defective combustion can be sensed immediately and corrected.

Solution

Mass spectroscopic analysis of flue gases appears to detect any of a wide variety of common combustion products. The spectrometer can be tuned to detect fragments of organic molecules that differ in the presence of a single hydrogen atom or a single electronic charge.

NASA Technology

The General Instrumentation Branch at Langley Research Center has an ongoing program of development of, and applications for, quadrupole mass spectrometer systems.

Principals

George Wood, Jr., NASA Langley Research Center, Hampton, Virginia.
Merril Jackson, U.S. Environmental Protection Agency (EPA), Research Triangle Park, North Carolina.

Cost to NASA

The spectrometer program at Langley is supported by mission funding. Modifications to the basic system for special applications require additional funding.

Commercialization Strategy

This spectrometer project would lead to the development of a specialized controller, consisting of hardware and computer software, for application specifically to the monitoring of incinerators. Such technology would be commercially valuable for the extensive monitoring of incinerators nationwide.

Status

EPA is interested in the mass spectrometer as a device that is tunable and sensitive enough to monitor all emission products of interest and is also portable enough to be mounted in a van for monitoring the environment of incinerators. In particular, EPA wishes to apply the mass spectrometer to the monitoring of a new hazardous waste incinerator that is being constructed near Boston, Massachusetts.

Action

The RTI team has planned a meeting at the EPA facility in Research Triangle Park of personnel from EPA, NASA, and EPA contractors to discuss the proposed application and funding of the mass spectrometer program.

PORTABLE X-RAY FLUORESCENCE SPECTROMETER (January 1982)

BATeam Personnel: Dr. H. Clark Beall

Problem

The analysis of all elements present in a sample is a complex and expensive procedure. Moreover, geological and environmental sampling programs can proceed more quickly if an immediate analysis for elements can be accomplished away from laboratory facilities.

Solution

Mass spectrometers, ion probe scanning electron microscopes, and X-ray fluorescence spectrometers are examples of established laboratory-based instruments that are capable of comprehensive elemental analysis. Historically, none of these instruments is considered to be portable enough to be carried into the field by one man. It now appears, however, that the X-ray fluorescence spectrometer can be configured with modern solid-state digital electronic circuitry and a display device to the extent that the complete system can be contained in one portable device the size of a small suitcase.

NASA Technology

A NASA contractor working with Langley Research Center has developed a portable X-ray fluorescence spectrometer that is capable of analyzing X-ray-induced fluorescence in the range 5 keV to 100 keV. The instrument appears to have applications as an analytical tool in the area of geological and environmental sampling.

Principals

Warren Kelliher, NASA Langley Research Center, Hampton, Virginia.

Cost to NASA

The prototype instrument has already been developed for NASA mission applications. Thus, the device can be considered mature technology and can be used in other applications without further modification.

Commercialization Status

Discussions continue between NASA and the NASA contractor concerning items of technology that were built into the X-ray fluorescence spectrometer. No commercialization efforts are appropriate until the patent status is resolved.

Status

Extensive applications testing of the device will not be required. The primary effort will be in the development of appropriate sample preparation techniques for medical applications.

Action

As soon as the patent status of the device is established, efforts can be directed to commercialization.

ULTRASOUND DIAGNOSIS OF BURN DEPTH (April 1982)

BATeam Personnel: Blake S. Wilson

Problem

Approximately 2 million Americans suffer serious burns each year, and 200 to 300 thousand of these people require hospital treatment.[1] Among those hospitalized, 70,000 receive intensive care and 10 to 12 thousand patients die from their injuries. The cost of intensive care exceeds $300 million per year.[2] The traditional treatment of burn victims is to allow natural debridement, sloughing of necrotic tissue, to occur and then to close the resulting open wounds with skin grafts. Unfortunately, the weeks required for spontaneous sloughing often result in infection and sepsis; indeed, the major cause of death in burn victims is bacterial infection.[3] Modern treatment, therefore, is based on early recognition and removal of necrotic tissue to reduce infection and hasten healing. This surgical or chemical debridement depends upon accurate burn depth information for optimal results. Current methods for burn depth determination are inaccurate, cumbersome, or both.

Solution

Ultrasound may be used to map precisely and conveniently the depths of the interface between viable and necrotic tissue in burn injuries. Preliminary studies in pigs demonstrate a good correlation between depths of burn measured by pulse-echo ultrasound and by histological techniques.

NASA Technology

Advanced ultrasonic technology developed at Langley Research Center for the characterization of materials is directly applicable to this project.

Principals

Dr. John H. Cantrell, Jr., Langley Research Center, Hampton, Virginia.

Cost to NASA

Estimated cost for development of the prototype is $180K.

Commercialization Status

The RTI team has contacted three medical ultrasound system manufacturers. Responses are expected in the next quarter.

Status

An FY83 RTOP has been submitted by Langley Research Center for support of the project. Two major burn centers, Medical College of Virginia and the Baltimore Regional Burn Center, have indicated a strong interest in conducting the clinical evaluation of the system.

Action

The RTI team and Dr. Cantrell will interview burn center personnel to identify the most appropriate clinical collaborators and funding sources. Discussions with manufacturers and NIH will continue.

References

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WASTEWATER TREATMENT BY VASCULAR AQUATIC PLANTS (April 1982)

BATeam Personnel: Dr. H. Clark Beall

Problem

The purification of wastewater is a problem faced by municipal treatment plants throughout the United States. The effluent from such plants must meet standards set by EPA before it can be released from the treatment plant. Sanitation engineers are searching continually for new technologies that can be applied to water treatment to reduce costs, time, and energy required to process wastewater.

Solution

Use of aquatic plants, one of several new procedures for wastewater treatment, shows promise in terms of speed, operating cost, and effectiveness.

NASA Technology

Research at the National Space Technology Laboratories has focused on the treatment of wastewater by vascular aquatic plants. The first effort dealt with a system based on the water hyacinth, Eichhornia crassipes. This system worked well in warm climates in wastewater treatment and biomass energy production.

Principals

Bill Wolverton, Ph.D., National Space Technology Laboratories, Mississippi.

Cost to NASA

The current RTOP request for this work is $40K with an additional $80K being funded by EPA.

Commercialization Strategy

The City of San Diego is now using the water hyacinth system as one means to bring effluent water to potable standards. An engineering firm from Baton Rouge, Louisiana, Owens and White, Inc., has based its designs for two new municipal treatment plants on the NASA-published data of microorganism/vascular plant wastewater treatment. The designs are being reviewed by EPA and await local funding under the Innovative Technology program of the State of Louisiana.

Status

During the last 2 years, NSTL effort has centered upon evaluation of a hybrid system in which septic digestion is followed by a rock bed filter containing the common reed Phragmites communis. The reed's rhizome system fluorishes in cold climates unlike the water hyacinth, which dies in cold weather.

Action

The technical acceptance of the hybrid reed system by the engineering firm of Owens and White, Inc., is expected to be followed by the funding of the technology and the construction of functioning urban systems.

Reference

Wolverton, B. C. New Hybrid Wastewater Treatment System Using Anaerobic Microorganisms and Reed (Phragmites communis). NASA Technical Memorandum, TM-X-72739, June 1981.

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15. Supplementary Notes

Langley Technical Monitor: John Samos
Final Report - January 1, 1982-February 28, 1983

16. Abstract

The objective of the Research Triangle Institute (RTI) Biomedical Applications Team is to achieve widespread utilization of National Aeronautics and Space Administration (NASA) technology in medicine. This objective is best obtained by stimulating the introduction of new or improved commercially available medical products incorporating aerospace technology. A bipolar donor-recipient model of medical technology transfer is presented to provide a basis for the team's methodology. That methodology is designed to: (1) identify medical problems and NASA technology that, in combination, constitute opportunities for successful medical products; (2) obtain the early participation of industry in the transfer process; and (3) obtain acceptance by the medical community of new medical products based on NASA technology. During the reporting period, the team completed two commercial transfers: the Ocular Screening Device, a system for quick detection of vision problems in preschool children, and Porta-Fib III, a hospital monitoring unit. The team also completed two institutional transfers: implant materials testing, the application of NASA fracture control technology to improve reliability of metallic prostheses, and incinerator monitoring, a quadrupole mass spectrometer to monitor combustion products of municipal incinerators. Two Phase 0 studies were completed by the team during the reporting period: Mobility Aids for the Blind and Ultrasound Diagnosis of Burn Depth. The team identified six new projects. Five projects were inactivated due to inadequate commercial potential to justify continued development. During the operating period, progress was made in the development and commercialization of each of the 15 currently active projects. For the convenience of the reader, the names and addresses of the sources of certain commercial products are included in this report. This listing does not constitute an endorsement by either NASA or RTI.

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