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Application of Aerospace Technology in Biology and Medicine

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Space Administration

Langley Research Center
Hampton, Virginia 23665

NASA

BIOMEDICAL APPLICATIONS TEAM
Applications of Aerospace Technology in Biology and Medicine

Final Report
January 1, 1981–December 31, 1981

for

National Aeronautics and Space Administration
Langley Research Center
Technology Utilization and Applications Programs Office
Hampton, Virginia 23665

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Final Report
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by

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PREFACE

This report covers the activities of the Research Triangle Institute's Biomedical Applications Team program for the period 1 January 1981 through 31 December 1981. 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 the development of marketing strategy was provided by Dr. W. H. Clingman of William H. Clingman and Company, Inc., a marketing and management consulting firm. Other participants in the program were Dr. H. C. Beall, Mr. R. E. Eakes, Mr. P. N. Kizakevich, Dr. M. McCartney, and Ms. B. Bass.

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 managers, engineers, and scientists throughout the National Aeronautics and Space Administration, and that of 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. The continued contribution to the team's efforts by Dr. F. Thomas Wooten, an RTI Vice President, is appreciated. Finally, Mr. John Samos has contributed significantly to the success of the program, and, as a technical monitor, he 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 Stowaway, a lightweight wheelchair that provides mobility for the disabled and elderly in the cabin of commercial aircraft, and Micromed®, a portable medication infusion pump for the reliable, continuous infusion of medications such as heparin or insulin. The team also completed a study of the marketing and manufacturing factors critical to the commercialization of the lightweight walker incorporating composite materials.

The team identified five new projects. Eleven projects were inactivated as a result of completed transfers or inadequate commercial potential to justify continued development. During the reporting period, progress was made in the development and commercialization of each of the 18 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, 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 tranfer 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]

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 (BATeams)--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 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, by applying NASA technology to medicine, a significant sector of the medical field and of those seeking medical services realize some benefit. Implicit in this program objective is that widespread utilization be realized in a relatively rapid manner.

The successful transfer of NASA technology to applications in the medical field via the Biomedical Applications Team program has been demonstrated,[2 3] 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.

While 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. On the other hand, 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 direct their efforts primarily to 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

Name	Professional Background	Responsibility
Dr. D. J. Rouse	Biochemist, Physiologist	Director, RTI BATeam
Dr. H. C. Beall	Biophysicist, Physiologist	Solution Specialist
Dr. W. H. Clingman	Chemical Engineer	Marketing Consultant
Mr. R. E. Eakes	Biomedical Engineer	Solution Specialist
Mr. P. N. Kizakevich	Biomedical Engineer	Internal Technical Consultant
Dr. M. McCartney	Biomedical Engineer	Internal Technical Consultant
Ms. B. 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 individuals at 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	Establishment of medical objectives and priorities and evaluation of devices
National Aeronautics and Space Administration	Development of advanced technology and innovations
Medical institutions	Specification of needs and use of medical innovations

Organization	Role
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 28 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 Publications, Presentations, and Conference Attendance

To inform the medical community of NASA's technology transfer program in medicine, RTI team members publish journal articles and participate in biomedical conferences. These activities stimulate the discussion of technical needs in medicine with clinicians and new product opportunities with medical device manufacturers. A recent article published in Medical Instrumentation by D. J. Rouse, J. N. Brown, Jr., and R. P. Whitten entitled "Methodology for NASA Technology Transfer in Medicine" described the biomedical technology transfer program. Publications and conference presentations for the reporting period are presented in Appendix A. Other significant travel is described in Appendix B.

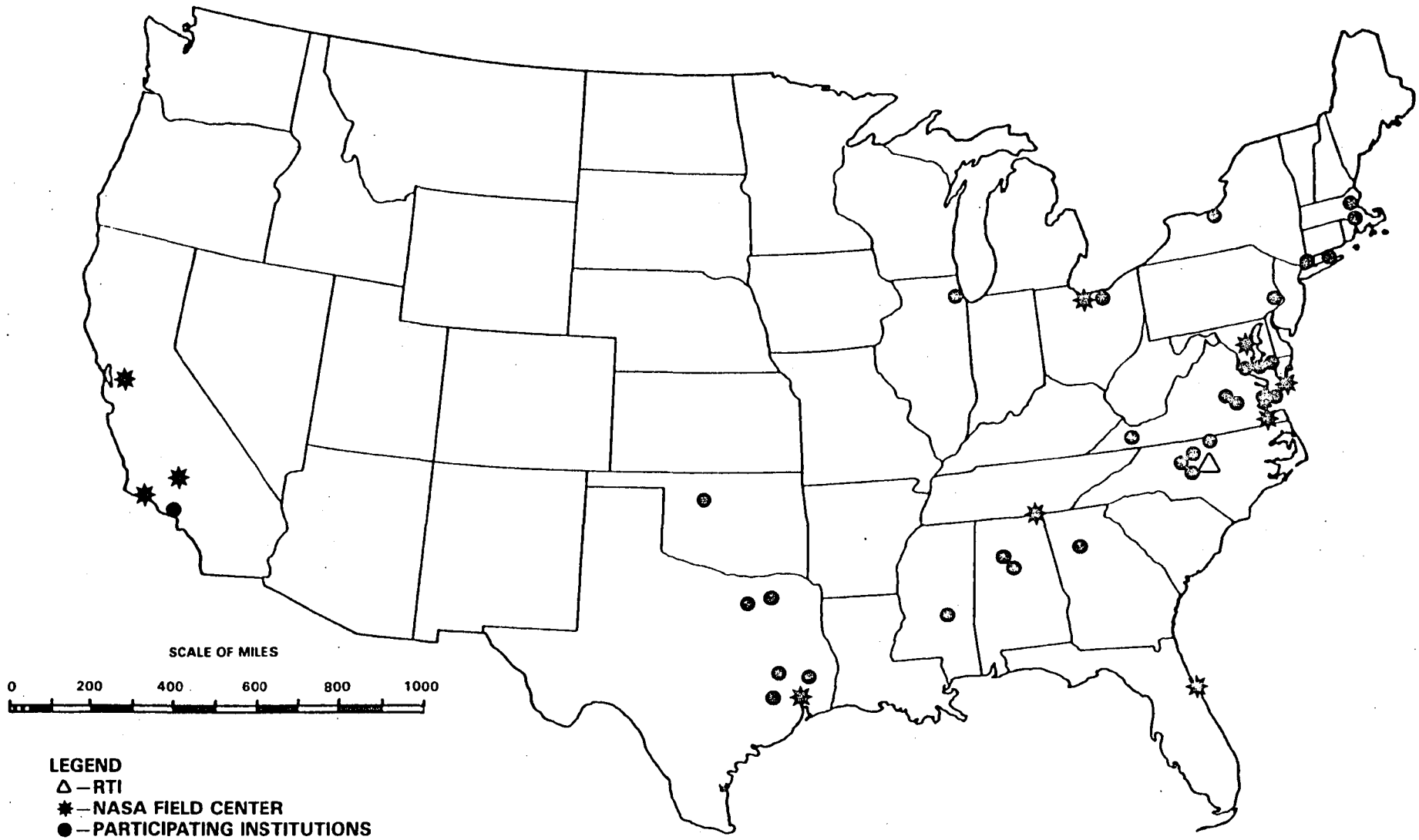

Figure 1. Biomedical Technology Transfer Network.

TABLE 1. PARTICIPATING MEDICAL INSTITUTIONS

Alabama School for the Deaf	Talladega, AL
Albert Einstein College of Medicine	Bronx, NY
Baylor College of Medicine	Houston, TX
Ben Taub Hospital	Houston, TX
Case Western Reserve University	Cleveland, OH
Cornell Medical Center	New York, NY
Duke University Medical Center (including VA Hospital)	Durham, NC
Eastern Virginia Medical School	Hampton, VA
Johns Hopkins University Medical School	Baltimore, MD
Johnston R. Bowman Health Center	Chicago, IL
M.D. Anderson Hospital	Houston, TX
Maryland Institute Emergency Medical Services	Baltimore, MD
Medical College of Virginia	Richmond, VA
Montefiore Hospital	New York, NY
Red Cross Blood Research Laboratory	Bethesda, MD
Rochester General Hospital	Rochester, NY
Rush-Presbyterian Medical Center	Chicago, IL
St. Mary's Hospital	Richmond, VA
Texas Institute for Rehabilitation and Research	Houston, TX
University of Alabama Department of Rehabilitation	Birmingham, AL
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 Hospital	Houston, TX
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

GODDARD SPACE FLIGHT CENTER
- Analyzer of Tissue Viability
- Biological Tissue Freezing System
- Programmable Implantable Medication System

JET PROPULSION LABORATORY
- Hydrocephalus Shunt--Ventilation

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

KENNEDY SPACE CENTER
- High Performance Wheelchair

LANGLEY RESEARCH CENTER
- Aircraft Wheelchair
- Analyzer of Tissue Viability
- Composite Material Applications
- Fiber Optics for Knee Surgery
- High Performance Wheelchair
- Implant Materials Testing

LANGLEY RESEARCH CENTER (continued)
- Low-Cost UV Optical Dosimeter
- Microwave Thermography
- Neuromuscular Diagnostic Unit
- Noninvasive Lung Diagnosis
- 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
- Analysis of the Retinal Reflex
- Detection of a Dislodged Temperature Probe
- Ophthalmic Screening Device
- Prosthetic Urinary Sphincter
- Retractor Tool for Brain Surgery

TABLE 3. MANUFACTURERS PARTICIPATING IN BATEAM PROJECTS

Abbott Laboratories	Houston, TX
Advex Corporation	Hampton, VA
Air Transport Association	Washington, DC
American Hospital Supply	Glendale, CA
American Polarizers, Inc.	Philadelphia, PA
Applied Medical Technology, Inc.	Lakewood, OH
B&K Instruments	Cleveland, OH
Bardon Enterprises, Inc.	Hampton, VA
Bell & Howell	Pasadena, CA
CAMI Health Care, Inc.	League City, TX
Chesebrough-Ponds, Inc.	Trumbull, CT
Cryomed	Mt. Clemmons, MI
Eagle Engineering Corporation	Houston, TX
Electro-Optics Consultants, Inc.	Huntsville, AL
Everest & Jennings	Los Angeles, CA
Hercules, Inc.	Washington, DC
Invacare Corporation	Elyria, OH
Inductron	Grafton, VA
JWM Company	Philadelphia, PA
Lumex Corporation	Bay Shore, NY
Major Laboratory	Oklahoma City, OK
Medic	Sun Valley, CA
Medical Engineering Corporation	Racine, WI
Melton Company	Oklahoma City, OK
Microwave Associates, Inc.	Burlington, MA
Miller Medical Electronics	San Diego, CA
NARCO	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
Thermo Electron Corporation	Waltham, MA
Union Carbide	Tunedo, NY
United Airlines	San Francisco, CA
United States Manufacturing Company	Pasadena, CA

TABLE 4. AGENCIES PARTICIPATING IN BATEAM PROJECTS

Administration on Aging
Agency for International Development
American Foundation for the Blind
American Red Cross
Department of Transportation
Environmental Protection Agency
Food and Drug Administration
Gerontological Society of America
National Bureau of Standards
National Cancer 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 for Occupational Safety and Health
National Institute for Dental Research
National Institute of Neurological and Communicative Disorders and Stroke
Paralyzed Veterans of America
Rehabilitation International-USA
Texas Rehabilitation Commission
U.S. Coast Guard
Veterans Administration

1.5 Report Summary

The Biomedical Applications Team's technical approach to technology transfer in medicine is described in Section 2.0. Emphasis on the commercialization of NASA technology is evident 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.

The commercialization activities presented in Section 3 summarize the two commercial transfers completed by the RTI team during the reporting period: the Stowaway, a lightweight wheelchair that provides mobility for the disabled in the cabin of commercial aircraft, and Micromed®, a portable medical infusion pump for the reliable, continuous infusion of medication such as heparin or insulin. A report on the cerebrospinal fluid control system Phase 0 study is presented in Section 4.1. The team's research on standards development committees as resources for the identification of technical needs in medicine is presented in 4.2. Section 4.3 summarizes an RTI team study on the manufacturing and marketing factors critical to the commercialization of a lightweight walker made of composite materials.

The team's problem solving and transfer activities in active transfer projects are summarized in Section 5.0. Projects inactivated during the reporting period are discussed in Section 6.0.

Section 7.0 is a statement of conclusions and recommendations. This section emphasizes what has been learned concerning medical technology transfer and how these lessons may be applied to increase the effectiveness of the NASA Biomedical Applications Team program.

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

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--Instances in which a specific technology moves 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 1981--An Annual Report. National Aeronautics and Space Administration, April 1981.

3. Rouse, D. J. Applications of Aerospace Technology in Biology and Medicine. Research Triangle Institute, Research Triangle Park, North Carolina, December 1980.

4. 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 has concluded that the donor, recipient, and manufacturer are frequently at cross purposes.[2] The recipient is primarily concerned 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 interface 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

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

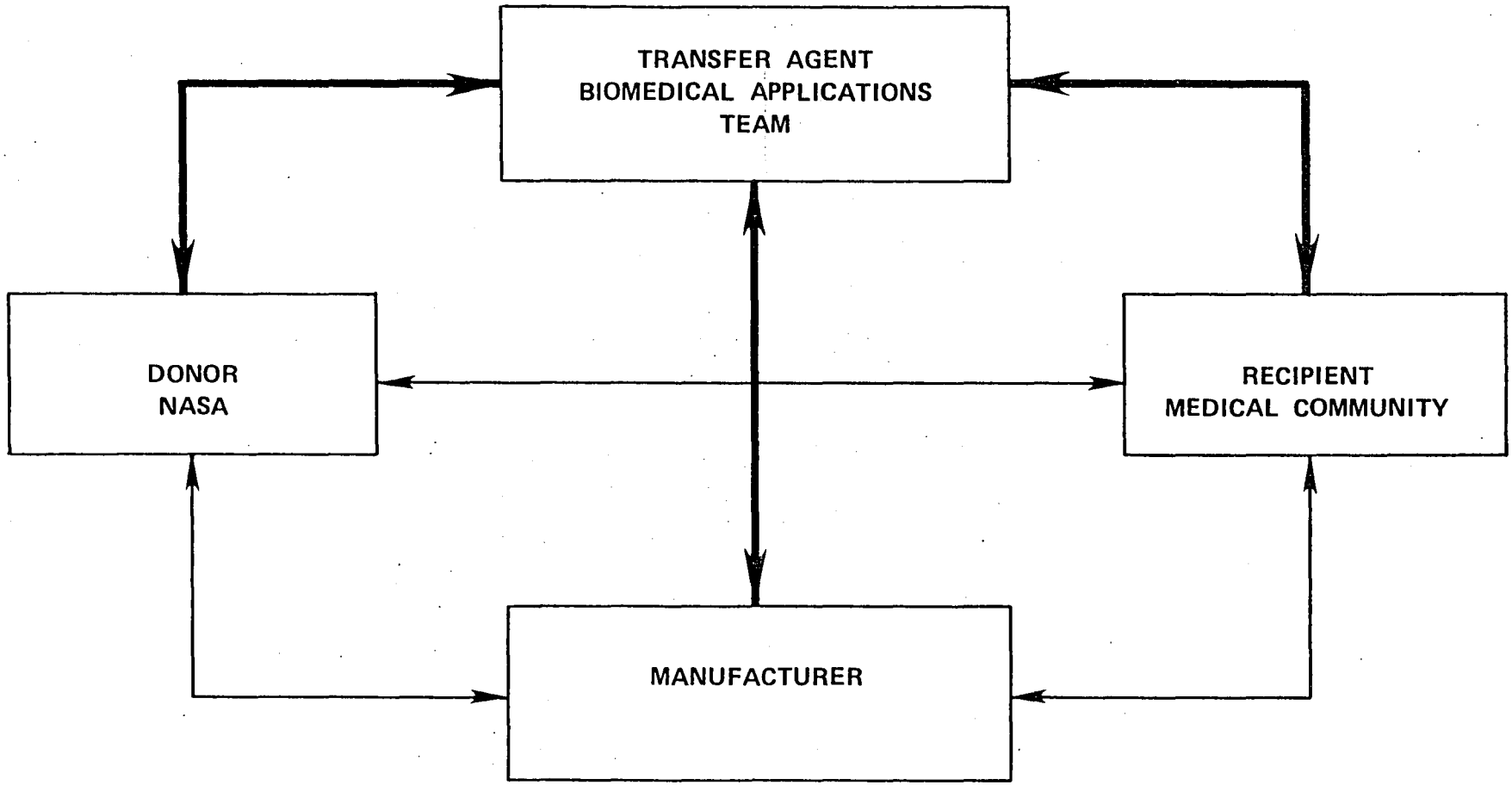

Figure 2. Conceptual Framework for Medical Technology Transfer.

quote from a Congressional Review of Intergovernmental Dissemination of Federal Research and Development Results.[3]

> 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 clinical 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 technology.[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 originally developed--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.

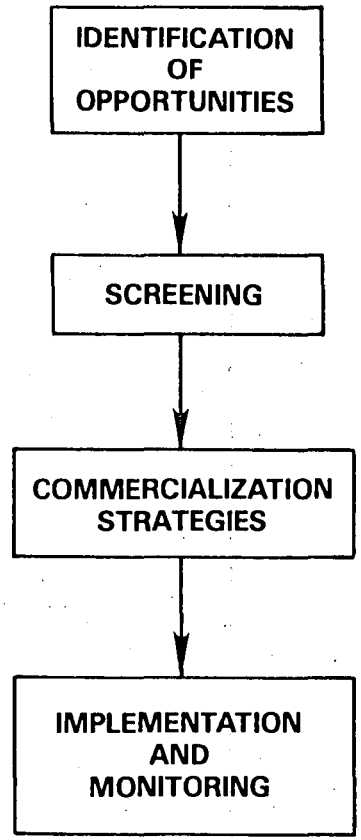

Figure 3. Phases of RTI Biomedical Applications Team activity.

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 that can potentially 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 study of medical technology transfer by the National Academy of Engineering and funded by NASA has concluded that the recipient must take the lead in defining medical problems.[6] This 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 are generally large medical centers or teaching hospitals geographically close to the place where the technology was developed. 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 located in Research Triangle Park, North Carolina. Computerized information searchers 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. Each problem statement is sent to NASA engineers and scientists working in areas that are related to the

technological aspects of the medical problem. Responses to problem statements from these engineers and scientists can lead to the identification of solutions.

Finally, the Biomedical Applications Team contacts NASA scientists and engineers 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 locating 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. In order 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 obtaining 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 intimate and 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 Figures 4 and 5 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 upon 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. The product usually must be exhibited at medical meetings. This sequence normally leads to physician acceptance.

Medical marketing and distribution frequently 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 identify and involve an organization capable of marketing and distributing those products.

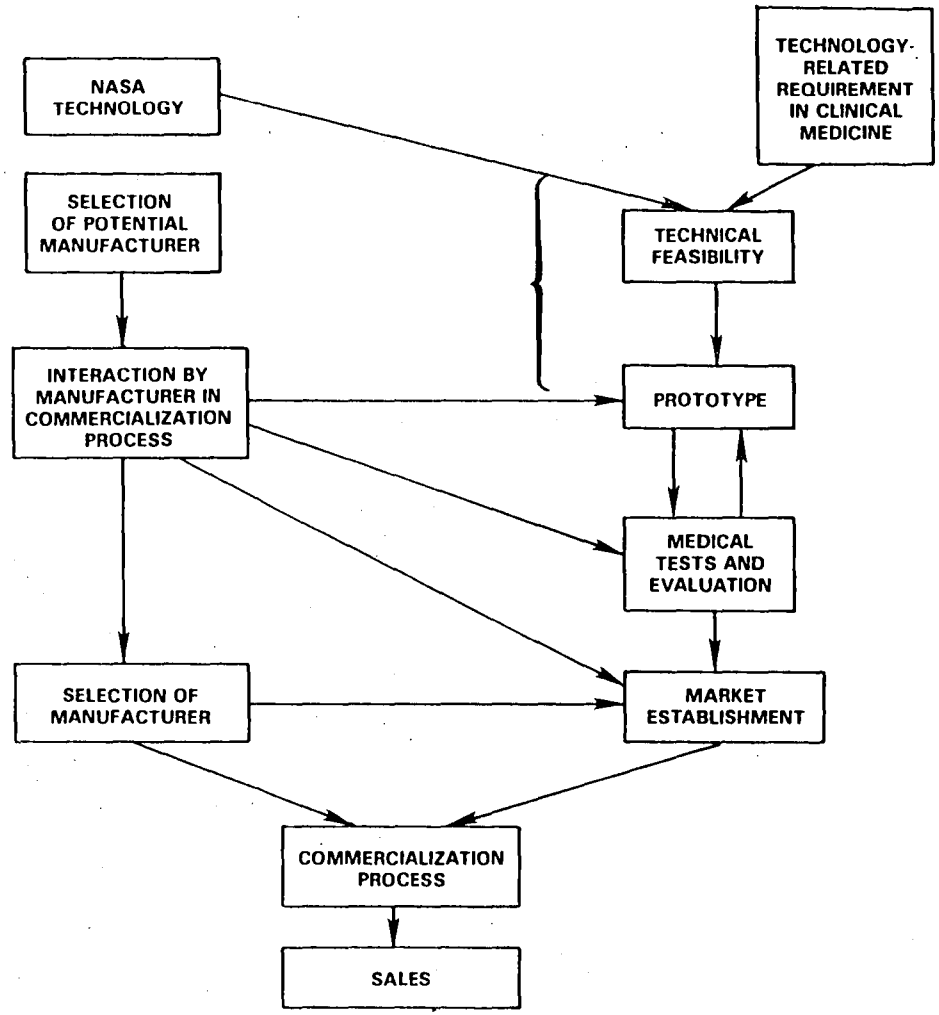

Figure 4. Medical Technology Transfer Model.

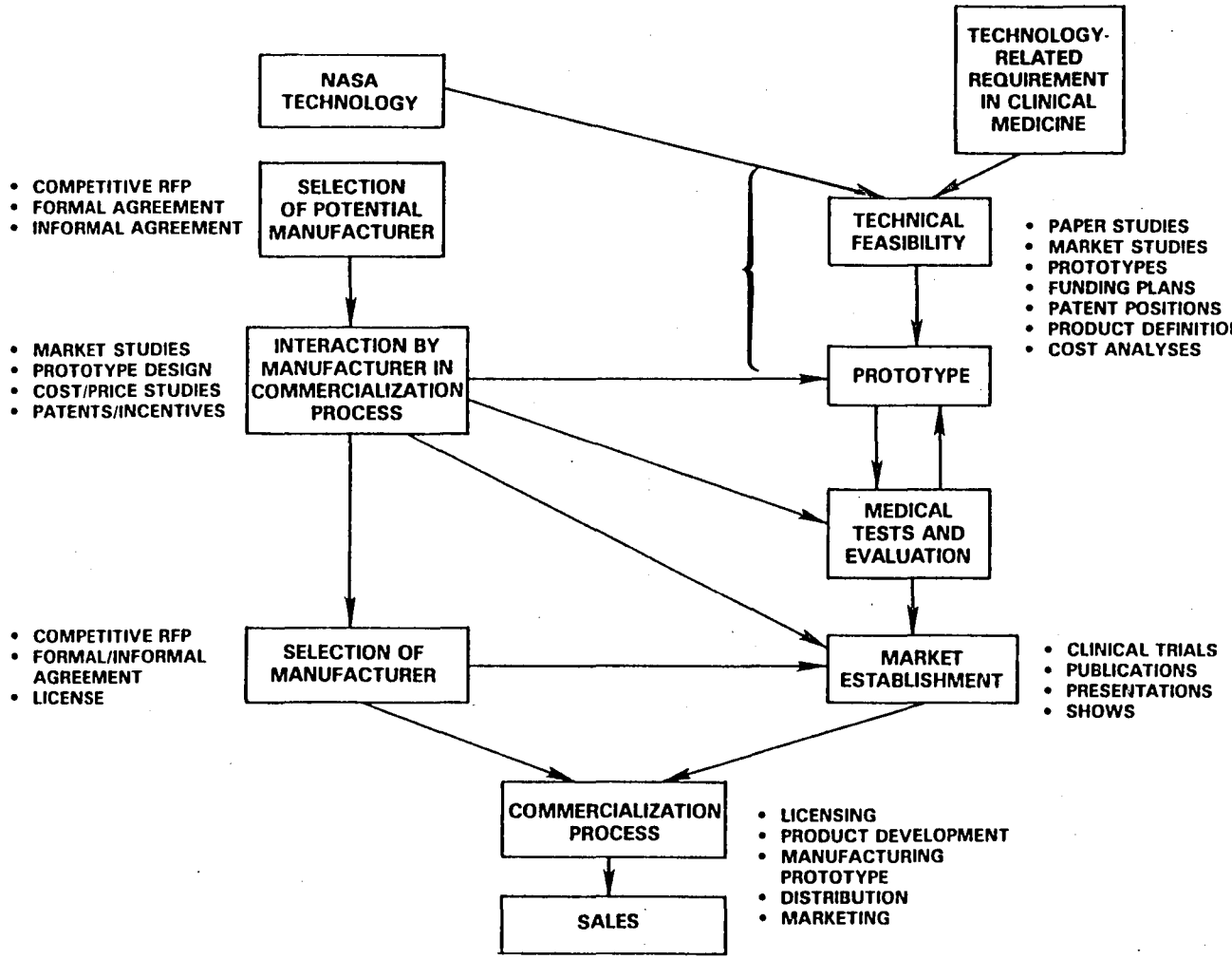

Figure 5. Medical Technology Transfer Model.

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 in itself 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 the implementation of 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 Project Evaluation and Review Technique/Critical Path Method (PERT/CPM) scheduling networks to provide systematic analysis for complex projects. Although these charts are too large to be included in this report, they are sent to the participating NASA field centers and to NASA Headquarters.

Reports and documentation are an integral part of the team methodology; they are involved 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 COMMERCIALIZATION ACTIVITIES

3.1 Aircraft Wheelchair: The Stowaway

The aircraft wheelchair project at Langley Research Center has resulted in the development of a commercially available wheelchair that allows movement down airplane aisles and access to onboard lavatories. Advex Corporation of Hampton, Virginia, is manufacturing and marketing the chair, called the Stowaway, for use in aircraft and other environments. United Airlines has negotiated the purchase of Stowaways from Advex for use on its Boeing 767s, which are scheduled for service in the Fall of 1982. Other airlines have expressed an interest in using the Stowaway on their 767s and other planes.

This project has involved the cooperative efforts of the following organizations: University of Virginia Rehabilitation Engineering Center, NASA Langley Research Center, domestic and international commercial airlines, aircraft manufacturers, Rehabilitation International-USA, and the Research Triangle Institute Biomedical Applications Team. Funding for the University of Virginia's participation in the program was provided by the National Institute of Handicapped Research.

3.1.1 Background

Airplanes are a major environmental barrier for the mobility impaired. Of the approximately 700,000 people in the United States who rely upon wheelchairs for mobility, many experience serious professional and social limitations as a result of their inability to use air travel. Requests from the disabled population and the President's Committee on Employment of the Handicapped have brought the problem of plane accessibility to the attention of the airlines. For example, in a 1978 purchase agreement for a new generation of aircraft, the Boeing 767, United Airlines requested features to make the cabins more accessible for the disabled and the elderly.

In response to these requests, the Aerospace Industries Association created a special committee, the TARC 218-2 committee, to examine the problem of aircraft accessibility. The TARC committee, which included representatives from all of the commercial aircraft manufacturers, agreed to participate in Rehabilitation International's program, Access to the Skies. The objective of this program is to make the cabins of commercial aircraft more accessible for the elderly and the disabled. Access to the Skies is supported by a grant from United Technologies Corporation. Both the TARC committee and the Access to the Skies program have identified the need for an onboard wheelchair as a key element in the entire cabin accessibility system.

3.1.2 Development and Commercialization of the Stowaway

The University of Virginia Rehabilitation Engineering Center was one of four groups to undertake the development of an onboard wheelchair. In September 1980, Dr. Colin McLaurin, Director of the University of Virginia Rehabilitation Engineering Center, met with the RTI team and Langley Research Center materials and structure analysis engineers to discuss cooperative projects. Dr. McLaurin

requested the assistance of NASA in developing an onboard aircraft wheelchair. The chair was designed by Dr. McLaurin and Ted Bruning, a graduate student at the University of Virginia.

In response to Dr. McLaurin's request, engineers at Langley optimized the design by utilizing aerospace technology in materials and structure analysis engineering. In the early summer of 1981, Ted Bruning spent several weeks working with engineers at Langley Research Center. Mr. Robert Baucom, a NASA materials engineer, was NASA's project director for the aircraft chair. The product of this joint effort was a prototype onboard aircraft chair made of graphite composites. The chair, called the Stowaway, is shown in Figures 1-3.

Evaluation of the Stowaway and other onboard chair prototypes has been coordinated and supported by the Access to the Skies program. In the evaluation program, the Stowaway has been tested by Boeing, United Airlines, Pan American World Airways, Trans World Airways, Air Canada, Aer Lingus, British Airways, Scandinavian Airlines, and South African Airlines. Other carriers are scheduling participation in the evaluation program. The results of all of these evaluations will be critical to the airlines' selection of an onboard chair. The results received thus far from United Airlines, Aer Lingus, and British Airways indicate that the Stowaway performed very well and was the preferred chair among the designs evaluated. The other airlines are expected to complete their evaluations by February 1982.

Advex Corporation in Hampton, Virginia, built the four prototypes of the Stowaway needed for the Access to the Skies evaluation program. Advex plans to continue manufacturing and marketing the chair for use in aircraft and other environments where a lightweight, compact wheelchair is needed. Commercialization of the Stowaway was coordinated by the RTI team and Mr. John Samos, Technology Utilization Officer at Langley Research Center. The RTI team will continue discussions with airlines' cabin engineering staff responsible for the selection of an onboard chair.

3.1.3 Description of the Stowaway

The Stowaway is a compact, lightweight folding wheelchair designed for conveying airline passengers from their seats to the washroom. As seen in Figure 3, the Stowaway moves easily down the narrow aisles of the plane. The wheelchair has 8-inch diameter wheels in the front and 4-inch diameter casters in the rear. This wheel pattern allows easier pushing over low sills and other obstacles without forward tipping, and it also allows easier maneuvering in the washroom area. The seat of the wheelchair is solid for easy transfer; the back is made of vinyl fabric. The footrest folds backwards for transfer. Safety belts with Velcro fasteners provide restraint for the knees and torso. Parking brakes which lock the front wheels can be operated by an occupant or an attendant.

The Stowaway is folded by squeezing a release located behind the seat. This allows the wheelchair to collapse forward into the folded position. The Stowaway is erected by grasping the crossbar at the top of the seat back and pulling to the upright position. A sharp snap at the end of the pull engages the lock.

THE STOWAWAY

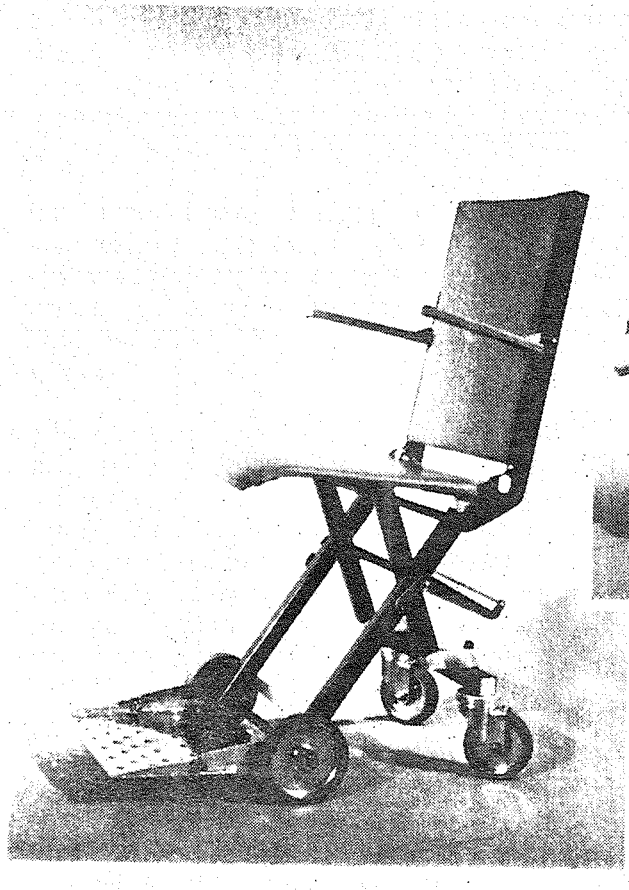


Figure 1

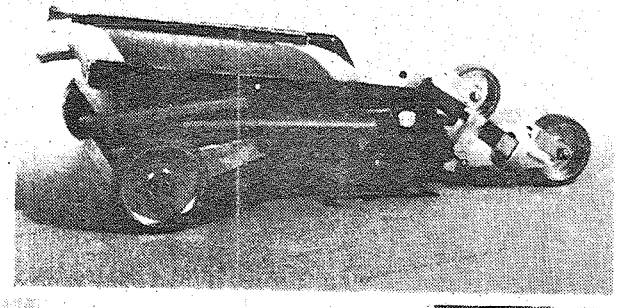


Figure 2

Figure 3

The Stowaway weighs less than 15 lbs (7 kg). Its chief features are simplicity, lightweight, and compactness. As seen in Figures 1 and 2, the Stowaway folds to an 8-inch height for easy storage on a plane. The Stowaway is especially suitable for use in washrooms with side doors such as those in the new Boeing 767s. In these washrooms, a pivot transfer permits the passenger access to the toilet from the wheelchair.

3.1.4 Aircraft Wheelchair Summary

Objective

To design, fabricate, and evaluate a lightweight wheelchair for use in commercial aircraft. The chair should be compatible with aisle width, seat height, and lavatory access.

Project Summary

September 1980	Meeting held at Langley Research Center (LaRC) with University of Virginia (UVa) wheelchair researchers, Langley materials and structure analysis engineers, and RTI team.
October-November 1980	Robert Baucom (LaRC) and Doris Rouse (RTI) visited University of Virginia Rehabilitation Engineering Center to discuss a collaborative aircraft wheelchair project between UVa and NASA.
May 1981	Ted Bruning (UVa) began summer internship at Langley to complete design and fabrication of aircraft wheelchair. Chair given the name "Stowaway."
June 1981	Composite aircraft wheelchair prototype completed. Prototype demonstrated by UVa and RTI team to Fairchild Burns, Inc., Invacare Corporation, Custom Industries, and Advex Corporation.
July 1981	Advex Corporation (Hampton, VA) awarded contract from Access to the Skies to build four UVa/NASA aircraft chairs for evaluation by airlines.
August 1981	Composite prototype evaluation begun by Pan Am, United, Boeing, and international airlines.
December 1981	Stowaway selected by United Airlines for use on their Boeing 767s. Negotiations begun between Advex Corporation and United on purchase of the chairs. Advex plans to manufacture and market the Stowaway for aircraft and other applications requiring a lightweight, compact chair.

3.2 Parker Hannifin Biomedical Products Division

Participation in NASA technology utilization projects initiated by the RTI Biomedical Applications Team has demonstrated for Parker Hannifin Corporation the considerable potential for the development of new medical devices by the utilization of hydraulic systems developed for spacecraft. In April 1981, Parker Hannifin, a major aerospace manufacturer, announced the creation of a Biomedical Products Division.

The Biomedical Applications Team acts as a catalyst and interface between aerospace technology and technical needs in medicine. The product of the team's activities is, in most cases, a new or improved medical device made possible by the utilization of technology developed by NASA. In the case study reported here, the RTI team identified NASA hydraulic control systems as a technology with especially promising potential for applications in medicine. Miniaturized, high reliability hydraulic control systems developed for use in spacecraft are sufficiently sophisticated for use in prosthetic devices to mimic the body's impaired fluid control systems. RTI team projects involving NASA hydraulics technology have thus far resulted in:

- Prosthetic Urinary Sphincter: a device for restoring bladder control is now in animal testing.
- Micromed®: a portable medication infusion pump has been approved by FDA for marketing.
- Programmable Implantable Medication System: an implantable pump is currently in animal testing for insulin delivery under funding from the National Institutes of Health.
- Parker Hannifin Biomedical Products Division: a commitment to the development and marketing of medical devices has been made by a major aerospace hydraulics manufacturer.

3.2.1 Prosthetic Urinary Sphincter

The Prosthetic Urinary Sphincter was Parker Hannifin's first involvement in the development of medical devices. In May 1976, the RTI team prepared a problem statement describing the need for a prosthetic hydraulic control system to allow the voluntary control of bladder function. (Loss of bladder control is frequently seen in spinal cord injuries, multiple sclerosis, diabetes, and postprostatectomy.) The RTI team identified the appropriate hydraulics technology at NASA's Marshall Space Flight Center (MSFC). At the suggestion of MSFC engineers, the RTI team discussed the problem with Parker Hannifin and other aerospace hydraulics manufacturers. These discussions led to a cost-sharing contract between NASA and Parker Hannifin in 1978 to modify a hydraulic control system used in the Viking lander for use in a prosthetic urinary sphincter.

The device, now in animal trials, is currently being developed in a collaborative effort between Parker Hannifin, Medical Engineering Corporation, and Rochester General Hospital. Collaboration between these three organizations in the development and testing of the prosthetic urinary sphincter has led to the development of two additional implantable devices that utilize the same hydraulic control system: a sphincter to allow the patient to open and close an ileostomy or colostomy, and a hydraulic penile prosthesis. Animal and clinical trials for these devices are expected to begin in 1982.

3.2.2 Micromed®

The application of Parker Hannifin's hydraulics technology to the problem of continuous infusion of medication has resulted in the development of an electronically controlled, automatic medication infusion pump capable of delivering volumes as small as 1 millionth of a liter. This device, the Micromed®, was approved by the FDA in November 1981 for human use. Marketing of the device, developed in a collaborative effort between Parker and Pacesetter Systems, will begin in January 1982.

This project began with the preparation of a problem statement by the RTI team in 1977 describing the need for a portable infusion pump to allow the constant delivery of medication and the attainment of a steady therapeutic level of medication in the body. (A pump of this type would be most beneficial in the management of diseases such as diabetes, thalassemia, and hormone disorders where frequent injections are required.) Before preparing the problem statement, the RTI team interviewed researchers funded by the National Institutes of Health to develop a pump of this type. These researchers indicated that NASA's technology in miniaturized hydraulic control systems had the potential for solving some of the problems they had encountered in the development of a reliable, portable system. To facilitate Parker's development of a portable medication infusion device, the RTI team arranged a meeting between the Parker project engineer, an NIH-funded researcher at the Carnegie-Mellon Institute of Research, and an RTI team member to review the status of current research in this area and to define optimal device specifications.

3.2.3 Programmable Implantable Medication System

The Programmable Implantable Medication System (PIMS) is being developed at Johns Hopkins University Applied Physics Laboratory under the direction of Robert Fischell. Goddard Space Flight Center has provided the overall project management. The PIMS is an implanted device that can be programmed by a physician after implantation to deliver a 24-hour cyclic profile of medication. In addition, the physician can tailor as many as six different delivery profiles for patient self-medication. The PIMS keeps a record of the medication volume delivered by the pump. The physician can communicate with the implanted device via telephone transceivers to check function and delivery profile. This device can be useful in the treatment of diabetes, intractable pain, hypertension, and hormone disorders.

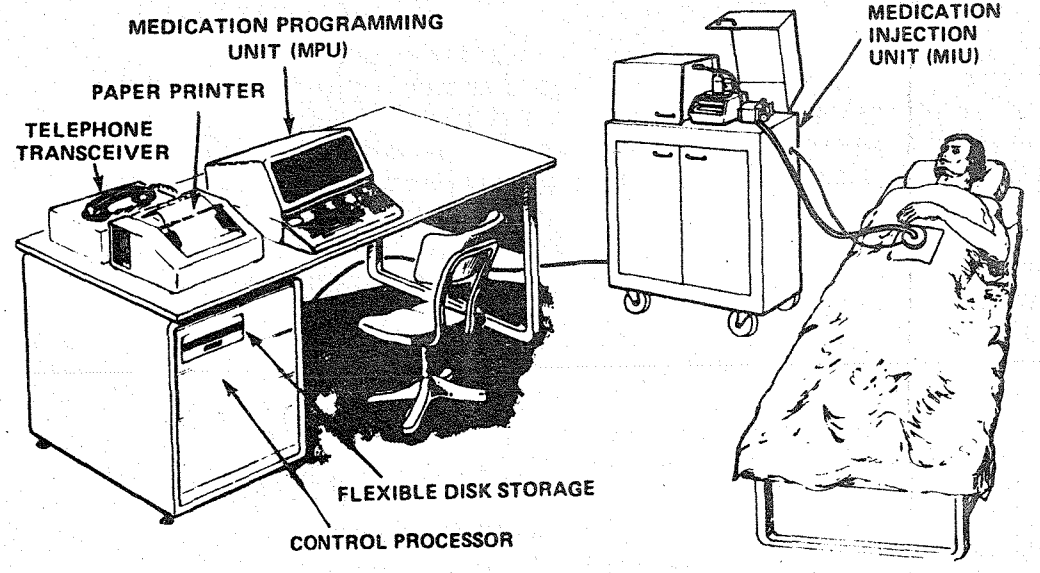
The PIMS incorporates NASA technology in three areas: (1) microminiaturized hybrid circuitry; (2) command and telemetry systems similar to those used in small, astronomy satellites and other spacecraft; and (3) miniature, high reliability hydraulic control systems. During the early development of PIMS, the RTI team worked closely with Applied Physics Laboratory and NASA's Marshall Space Flight Center to identify the appropriate technology and manufacturer for the hydraulic control system. The RTI team met with representatives from Applied Physics Laboratory and Parker Hannifin Corporation in May 1979 to discuss Parker's participation in the project. Parker Hannifin has subsequently developed the hydraulic portion of the PIMS and plans to manufacture this component for the commercial units. Pacesetter Systems, Inc., will manufacture the electronic components and market the PIMS. Animal trials for the PIMS delivery of insulin for diabetes are in progress under funding from the National Institutes of Health. Human implants are scheduled for 1982.

3.2.4 Parker Hannifin Biomedical Products Division

Participation in these projects (Figures 1-3) sponsored by NASA's Technology Utilization Program demonstrated to Parker Hannifin the commercial potential for medical devices incorporating sophisticated hydraulic control systems originally developed for the space program. A recent article in Parker Hannifin's corporate publication, Parker World (Issue 6, Summer 1981), described the creation of the Biomedical Products Division and the devices currently under development. This article is presented below:

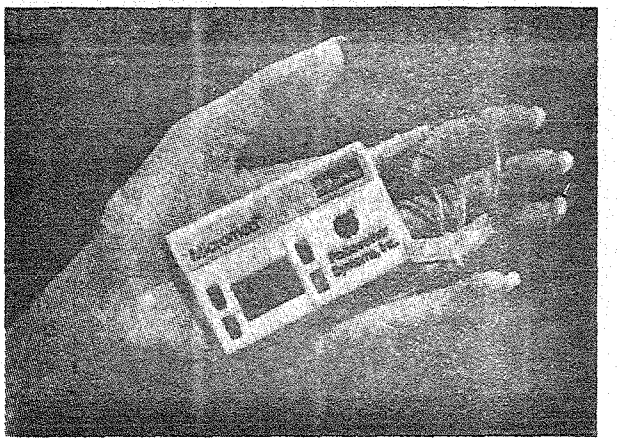
> Parker Targets New Biomedical Frontier
>
> Using technologies developed in our Aerospace Group, Parker's newly created Biomedical Products Division is currently testing devices which may revolutionize the treatment of a number of diseases.
>
> At an April press conference in Cleveland, Pat Parker announced our Company's official entry into the biomedical field, taking technology "from outer space to inner space"--the human body.
>
> Bill Webster, Aerospace Group vice president and general manager of the new Division, pointed out that the transfer of technology to this newest frontier requires Parker engineers to draw on the knowledge gained from developing miniature fluid systems for manned and unmanned space vehicles. For example, in Viking's search for life on Mars, it was Parker's latching solenoid valve, the smallest ever to fly in space, which controlled the injection of precise amounts of nutrient into the Martian soil samples.

MEDICAL DEVICES DEVELOPED FROM NASA HYDRAULIC CONTROL SYSTEMS



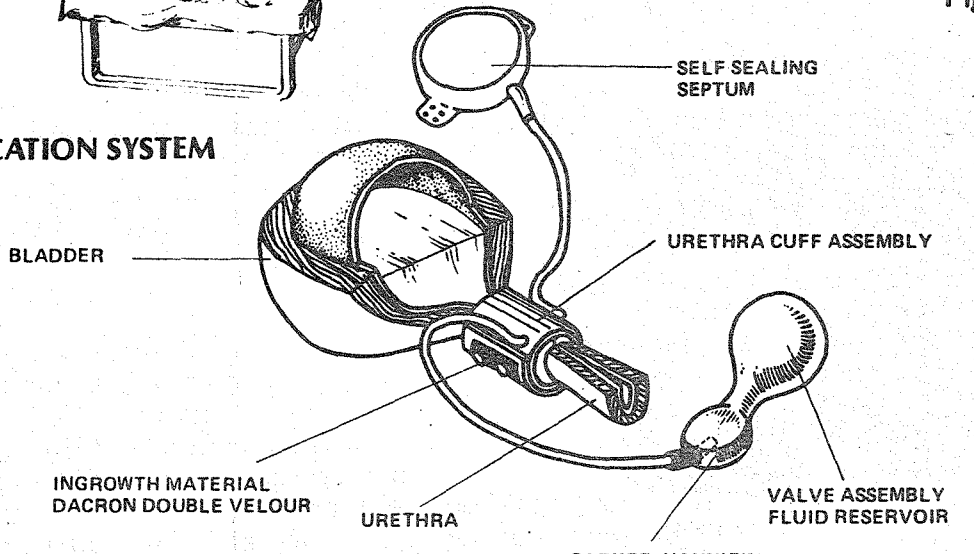
PROGRAMMABLE IMPLANTABLE MEDICATION SYSTEM

Figure 1



MICROMED

Figure 2



PROSTHETIC URINARY SPHINCTER

Figure 3

Parker's first biomedical project was started over three years ago. It is the development of an inwardly inflatable cuff with a pressure regulation system smaller than a nickel, which will be implanted in the body to control urinary incontinence. This system, developed in conjunction with NASA and the Rochester General Hospital of Rochester, New York, is currently being tested in animals and is expected to be tested in humans next year.

The project has now been expanded to include the use of the inflatable cuff to aid people with colostomies and ileostomies. These systems will be undergoing animal testing this fall.

The next biomedical project, started over two years ago, is an electronically controlled, automatic medication infusion pump, designed to deliver injection amounts as small as one millionth of a liter. One pump, the Micromed™, smaller than a business card and about 5/8 inch thick, can easily be concealed under clothing. The other, being developed in conjunction with the Applied Physics Laboratory of Johns Hopkins University, is designed to be implanted in a manner similar to a heart pacemaker.

Both of these pumps will be used in the improved treatment of diabetes, hormone disorders, cancer, mental illness, intractable pain, drug addiction and alcoholism.

There are 1,500,000 insulin dependent diabetics, 300,000 new terminal cancer patients every year and 750,000 mental patients under drug therapy. These people could all benefit from the Parker system which releases minute amounts of medication, as required, rather than occasional massive doses with possible attendant side effects.

The most recent biomedical program is an advanced method of blood plasma therapy developed by Dr. Nosé and his associates at the Cleveland Clinic. The system, which removes undesirable constituents in the blood, has shown great promise in the treatment of rheumatoid arthritis, lupus, myasthenia gravis and other autoimmune diseases.

Pat Parker, while observing the experimental treatment system at the Clinic, suggested to Dr. Nosé that Parker's aerospace technology could be employed to improve the system and make it suitable for broad application in many hospitals.

The Biomedical Products Division built the first unit, called Cryomax™, last fall and now has six additional units undergoing testing. Official Food and Drug Administration (FDA) clinical trials are underway at the Cleveland Clinic and Rush Presbyterian Hospital in Chicago, and will soon commence at Cedars Sinai in Los Angeles. Successful completion of these tests this fall should result in FDA approval for broader application early next year.

With these major projects underway, Parker is committed to providing a significant contribution to the biomedical field. Pat Parker has noted that "it is a natural transfer of aerospace fluid system technology. The human body is a complex of interacting fluid systems. Each fluid system requires precise control of flow, pressure, temperature and contamination. Only in the last 20 years has control technology approached the sophistication of the human body."

Bill Webster commented that "components for space craft and devices designed for implantation in the human body have similar technological requirements. Both require that the devices be small, lightweight, highly reliable and precise and be capable of existing in a hostile environment."

4.0 SPECIAL PROJECTS

4.1 Cerebrospinal Fluid Control System: Phase 0 Study

NASA is considering the development and clinical testing of a cerebrospinal fluid (CSF) control system under joint sponsorship with the National Institutes of Health (NIH) and industry. The proposed system would improve the management of hydrocephalus, an abnormal accumulation of cerebrospinal fluid in the central nervous system. A major goal of the new system would be to reduce the number of necessary reoperations and, thus, reduce health care costs and patient risks. The project will consist of three major phases: (1) a Phase 0 study, (2) a prototype development phase, and (3) clinical trials. NASA's involvement will be limited to the first two phases.

In August 1981, NASA asked the RTI team to conduct the Phase 0 study for the CSF control system under the direction of the Langley Research Center Technology Utilization Office. The objective of this study is to develop the information required by NASA for a decision on whether to proceed with the CSF control system development program. The decision to proceed will be based upon: demonstration of a significant need for a CSF shunt system, identification of potentially applicable NASA technology, consensus on design goals by clinicians and researchers, and cost-sharing commitments by NIH and industry. To obtain this information, the RTI team has planned the Phase 0 study as three tasks.

- Task 1: Define the Medical Problem and the State of the Art in CSF Shunts

  This task will be accomplished by a thorough literature review as well as by interviews with neurologists, neurosurgeons, and members of the medical device industry, NIH, and the Food and Drug Administration (FDA). The Task 1 study report will contain product sheets on commercially available systems and concise descriptions of ongoing research and development. Failure modes and limitations of available systems will be identified and presented. The optimum operating characteristics and configuration of a new CSF shunt will be developed and specified. The etiology of conditions leading to the need for CSF shunt systems will be summarized with disease incidence data.

- Task 2: Determine Engineering Feasibility of Design Concepts

  Functional design concepts will be based upon data obtained in Task 1. Concepts for the pressure transducer, the command/telemetry system, and the hydraulic design will be developed with the participation of subcontractors with design expertise in these areas. All items of NASA technology that will be incorporated in the CSF shunt system and supporting documentation will be identified and presented in the Task 2 study report.

- Task 3: Prepare Project Plan for Development of Improved Shunt

  A project plan will be developed that includes the following elements. Items of hardware that must be developed will be specified. A modified PERT chart with approximate cost will be prepared; critical or pacing elements and the critical path will be identified. FDA requirements for data and guidelines that apply to clinical trials will be specified and incorporated in the overall plan and PERT chart. Appropriate manufacturers for the shunt system will be developed and presented. Overall program costs will be estimated and a complete strategy for funding both the CSF system development project and clinical trials will be generated. NASA, NIH, and industry will be included in this strategy, with roles being dependent on organizational missions, policies, and objectives.

Task 1 has been completed with the exception of interviews with CSF shunt manufacturers, which are expected to take place in early January 1982. A brief summary of the Task 1 results is presented below. The complete Task 1 study report will be available in February 1982. At that time, NASA Headquarters, Langley Research Center, and the RTI team will decide whether the results support proceeding with Task 2, Determine Engineering Feasibility of Design Concepts.

4.1.1 Literature Review

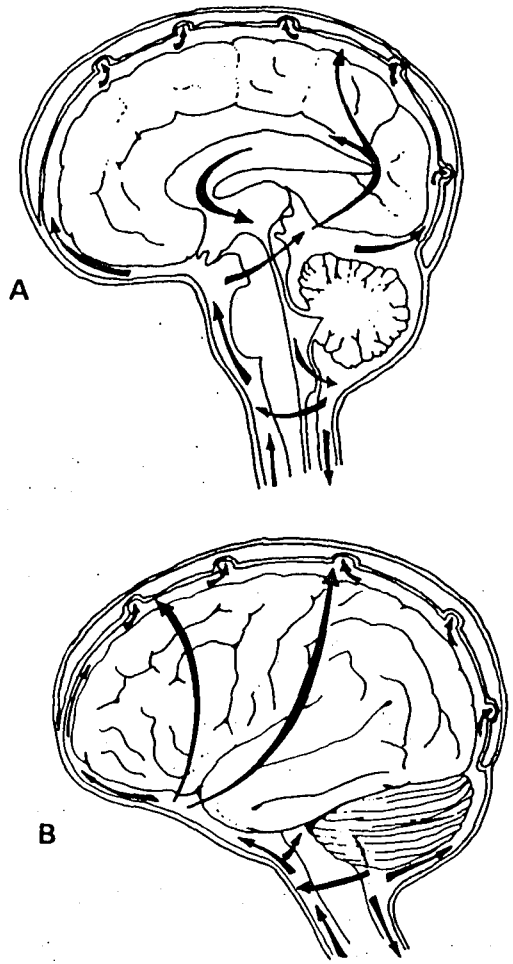
The first activity of the RTI team in the Phase 0 study was a thorough review of the relevant literature. Topics included in this study were: CSF physiology, hydrocephalus etiologies and management, shunt design, valve design, intracranial pressure monitoring, shunt failure modes, and methods for assessment of cerebrospinal fluid dynamics in patients.

CSF Physiology and Pathology

Hydrocephalus is an abnormal accumulation of cerebrospinal fluid 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. The CSF volume is 50 mL in infants and 150 mL in adults. The CSF, therefore, is renewed completely every 8 hours.

The principal production site is the choroid plexus of the ventricular system, especially in the lateral ventricles. The CSF flows from the lateral ventricles to the third ventricle and caudally to the fourth ventricle, from which it passes to the subarachnoid space surrounding the brain and spinal cord. The CSF is reabsorbed into the venous blood at the arachnoid villi. These pathways for cerebrospinal fluid flow and reabsorption are illustrated in Figure 1. These pathways are particularly vulnerable to obstruction at certain narrow sites as a result of developmental or acquired disorders.

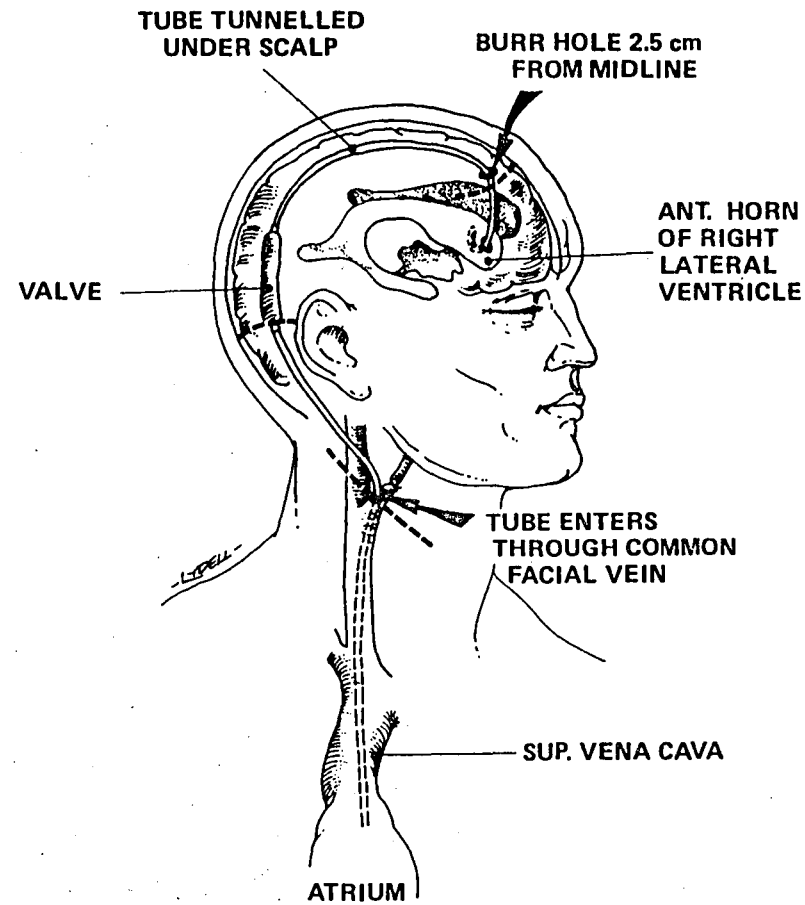
CEREBROSPINAL FLUID CONTROL SYSTEM



MAJOR PATHWAYS OF CEREBROSPINAL FLUID FLOW, SAGITTAL VIEW (A) AND LATERAL VIEW (B)

THOMAS H. MILHORAT, M.D., *HYDROCEPHALUS AND THE CEREBROSPINAL FLUID*, BALTIMORE: THE WILLIAMS AND WILKINS CO., 1972, p. 25.

Figure 1



Placement of the Ventriculovenous Shunt for Hydrocephalus.

Figure 2

Hydrocephalus resulting from a blockage of the pathways, preventing flow of CSF to the reabsorption sites, is called obstructive or noncommunicating hydrocephalus. If the CSF circulates freely but the absorption sites are impaired, then the condition is classified as communicating hydrocephalus. Both communicating and noncommunicating hydrocephalus can be congenital or acquired. For example, communicating hydrocephalus can result from a head injury with subsequent subarachnoid hemorrhage. The hemorrhage impairs the reabsorptive ability of the arachnoid villi. Noncommunicating hydrocephalus can result from the growth of a cyst or tumor or from any inflammatory swelling, causing an obstruction in the CSF pathway to the reabsorption sites. In rare cases, hydrocephalus can result from the overproduction of CSF by the choroid plexus. Infantile hydrocephalus (all cases diagnosed in the first 3 months of life) outnumbers the cases of acquired hydrocephalus by approximately 3 to 1. The most common clinical feature of infantile hydrocephalus is enlarging head size accompanied by vomiting and irritability. The dilated ventricles and increased intracranial pressure can lead to retardation of motor development, generalized spasticity, and impaired cognitive abilities.

Incidence of Hydrocephalus

As indicated in the preliminary market study, "The Potential Market for an Ion-Textured Hydrocephalus Shunt," which was conducted for NASA by ECON, Inc., the reported incidence of hydrocephalus varies widely. A major factor in this variance is that hydrocephalus is often secondary to other diseases (spina bifida, intracranial hemorrhage) and, thus, is often unreported in statistical records of hospital diagnoses. The Fact Sheet: Hydrocephalus, published by the National Institute of Neurological and Communicative Disorders and Stroke, estimates the prevalance of hydrocephalus in the following paragraph:

> Hydrocephalus at birth occurs in more than 1 of every 1,000 live births; approximately 4,200 infants annually are born with hydrocephalus in the United States. Another estimated 6,000 children develop hydrocephalus during the first 2 years of life from complications of other conditions. Adults can also develop hydrocephalus from injury or disease.

The Spina Bifida Association of America reports that over 11,000 children are born with spina bifida (cleft spine) in the United States each year. The Association estimates that 70 to 80 percent of these children develop hydrocephalus. Interviews with manufacturers should provide an estimate for the number of adults requiring a CSF shunt for the management of hydrocephalus resulting from head injury, tumor, meningitis, or intracranial bleeding.

Current CSF Shunting Techniques

The three most successful treatments for hydrocephalus are: (1) remove the lesion blocking the CSF pathway, (2) insert intracranial shunts to bypass a blockage of the pathway; or (3) divert the CSF to other body cavities by the use of extracranial shunts.

Where possible, the direct removal of the lesion is the preferred treatment. This procedure has the potential for relieving the hydrocephalus and restoring normal CSF flow to the reabsorption sites. Unfortunately, it is seldom possible to remove the obstruction because the tumor, hemorrhage, or infection is too diffuse or is in a location inaccessible for safe removal.

Intracranial shunts may be used to bypass the obstruction by providing a pathway from the ventricular system to the subarachnoid space. The success of this procedure depends upon the normal functioning of the reabsorption sites, the arachnoid villi.

Extracranial shunting of the CSF is used in communicating hydrocephalus and in cases of noncommunicating hydrocephalus where the obstruction cannot be removed or bypassed by an intracranial shunt. Most hydrocephalus patients are treated with an extracranial shunt. The two sites most often used for drainage of the CSF from the ventricle are the right atrium of the heart (ventriculoatrial) or the peritoneal cavity (ventriculoperitoneal). Placement of a ventriculoatrial shunt is illustrated in Figure 2.

Most commercial extracranial shunting devices consist of three components: the ventricular catheter, a reservoir for flushing this catheter, and the distal catheter for drainage. In shunts draining into the atrium, a one-way flow valve is necessary to prevent backflow of blood into the catheter. In some cases, a double reservoir is used to allow intraventricular injection of chemotherapy agents and antibiotics. A wide range of set pressures, flow rates, and antisiphoning features are available for selection by the surgeon.

Shunt Complications

An estimated 50 percent of hydrocephalus patients will require at least one reoperation to repair or replace a malfunctioning shunt. The distal catheter, in most cases, must be replaced several times to compensate for growth of the child.

Obstruction of either the ventricular or distal catheter is the major cause of shunt failure. The resulting inadequate drainage produces elevated ventricular pressures. In the ventricular catheter, the blockage is caused by glial cells and astrocytes and/or ingrowth of the choroid plexus. In ventriculoatrial shunts, distal obstruction is usually caused by the formation of an adherent thrombus on the atrial catheter. Ventriculoperitoneal shunts usually become obstructed distally as a result of patient growth or formation of a peritoneal cyst. Ventriculoperitoneal shunt complications are summarized in Figure 3.

The complication of overdrainage of CSF from the ventricle may result in ventricular collapse or hemorrhage.

SUMMARY OF VENTRICULAR PERITONEAL SHUNT COMPLICATIONS

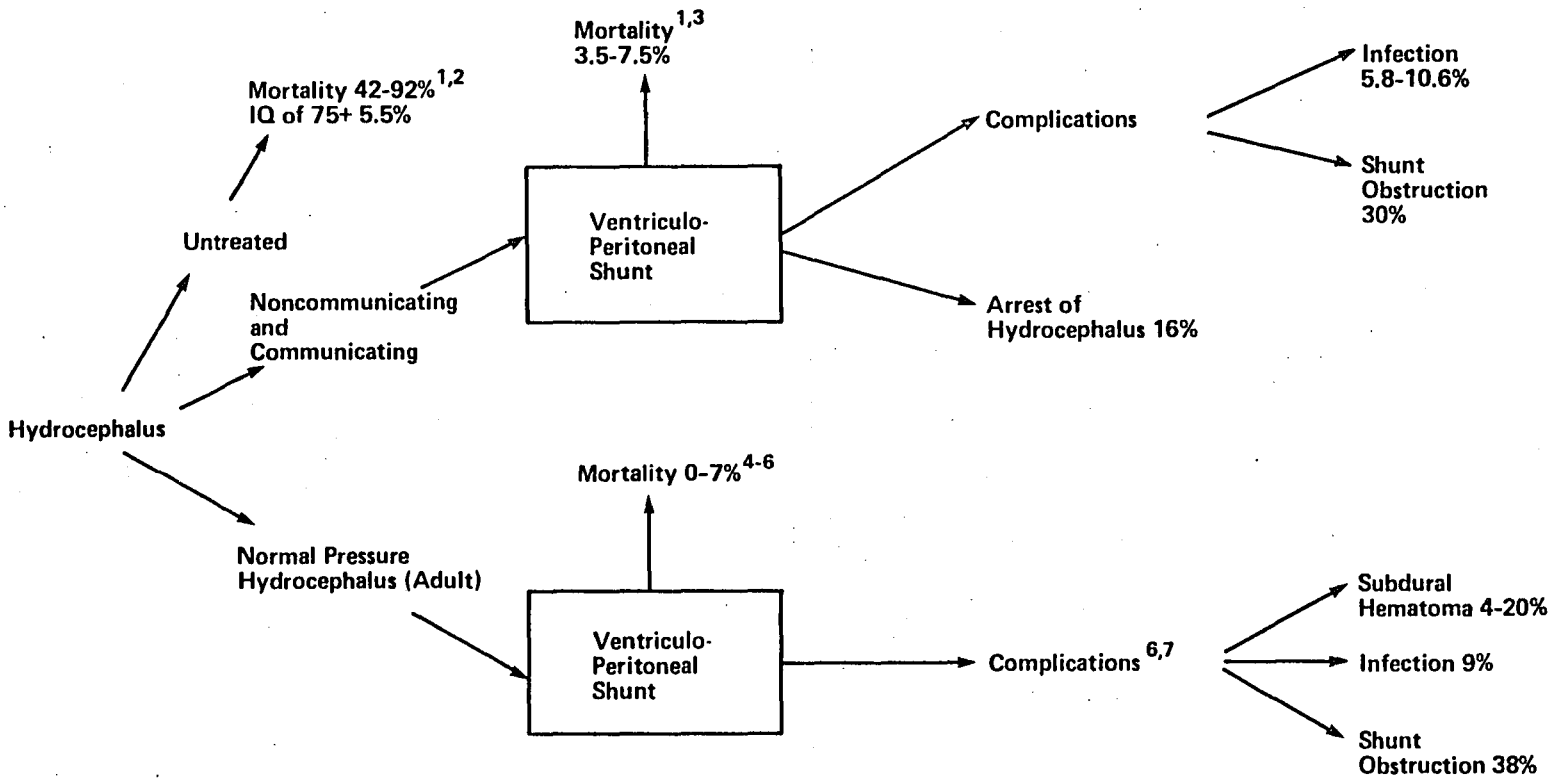


Figure 3

SOURCES

1. Foltz, E. L., and Shurtleff, D. B.: Five year comparative study of hydrocephalus in children with and without operation (113 cases). J. Neurosurg., *20*:1064–1079, 1963.
2. Nulsen, F. E., and Becker, D. P.: Shunt control of hydrocephalus. *In* Clinical Neurosurgery, vol. 14. Baltimore, The Williams & Wilkins Co., 1967, pp. 256–273.
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5. Salmon, J. H.: Adult hydrocephalus: Evaluation of shunt therapy in 80 patients. J. Neurosurg., *37*:423–428, 1978.
6. Illingworth, R. D., et al.: The ventriculocaval shunt in the treatment of adult hydrocephalus. Results and complications in 101 patients. J. Neurosurg., *35*:681–685, 1971.
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A recent study, "An Investigation of Cerebrospinal Fluid Shunt Valves," conducted for the Food and Drug Administration investigated shunt valve construction, testing, and labelling. Most CSF shunt manufacturers categorize their valves by closing pressure and offer the surgeon three to four ranges to be selected according to the patient's requirements. Several investigators, however, have found significant variance in flow characteristics of valves labeled at the same pressure range. Performance of a valve at too low a closing pressure can result in overdrainage of the ventricle. Standardized valve testing methods for quality control and uniform labeling are suggested in the FDA report. An American Society for Testing and Materials standards committee is currently addressing these same issues.

Significant morbidity and mortality of hydrocephalus patients, especially those with ventriculoatrial shunts, is caused by infection. Strict aseptic surgical techniques have been suggested as the most effective means of preventing this complication. Antibiotic impregnated silicone is currently being investigated for use in hydrocephalus shunts.

4.1.2 Interviews

The interviews with neurosurgeons, NIH researchers, and FDA representatives on the CSF control system were conducted by the RTI team and two consultants active in hydrocephalus research, Dr. Anthony Marmarou of the Albert Einstein College of Medicine Department of Neurologic Surgery and Dr. Richard Johnson of the University of North Carolina Department of Biomedical Engineering.

The resulting hypothetical CSF control system is illustrated in Figure 4 and described below. The physiological objective of the proposed device is to maintain the cerebrospinal fluid compartments at normal volume and pressure. The design features of the proposed system are as follows.

1. Sensor for measurement of ventricular volume.
2. Sensor for measurement of intraventricular pressure.
3. Sensor for measurement of flow through the catheter.
4. Microprocessor control of flow rate profile for 24-hour cycle based on input volume, pressure, and flow data.
5. Capability of manual override and external control of flow rate.
6. Capability of program modification by physician using transceiver communication to readjust flow rate, profile, threshold volume, and pressure.

CEREBROSPINAL FLUID CONTROL SYSTEM

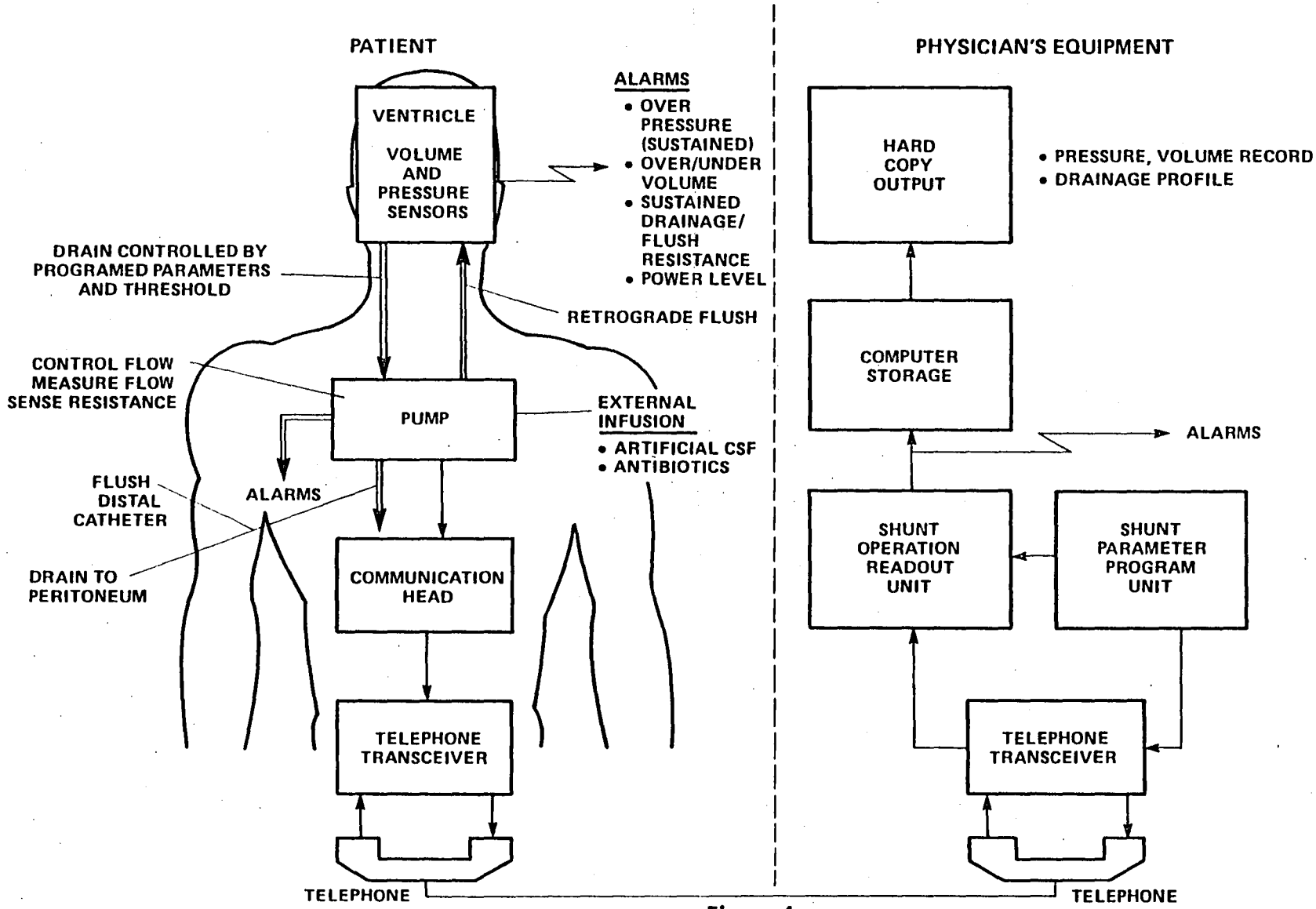


Figure 4

7. Capability of remote transmission of operating characteristics to central facility using transceiver communication.

8. Alarm for abnormal pressure, volume, or increased catheter resistance.

9. Bidirectional flow capability with pump reservoir for programmable retrograde flushing of ventricular catheter and outflow part.

10. Compensation for transient pressure increases resulting from coughing, sneezing, and change in hydrostatic level.

11. Self-contained power pack with provision of external recharge.

12. Fail-open configuration with remote alarm.

The following individuals have been interviewed by the RTI team and Drs. Marmarou and Johnson.

Robert Munzner, Ph.D.
Food and Drug Administration
Bureau of Medical Devices
Bethesda, MD

Fred Epstein, M.D.
Department of Neurological Surgery
New York University Medical Center
New York, NY

Luis Schutt, M.D.
Department of Neurosurgery
Children's Hospital of Philadelphia
Philadelphia, PA

Harold Portnoy, M.D.
Oakland Neurological Clinic
Oakland, CA

Thomas Milhorat, M.D.
Children's Hospital National Medical Center
Washington, D.C.

T. Hambrecht, M.D.
National Institute of Neurological and Communicative Disorders and Stroke
Bethesda, MD

Gerald Hochwald, M.D.
Department of Neurosurgery
New York University Medical Center
New York, NY

K. Shapiro, M.D.
Albert Einstein College of Medicine
Department of Neurological Surgery
New York, NY

A. B. Butler, M.D.
University of Virginia School of Medicine
Department of Neurosurgery
Charlottesville, VA

John Jane, M.D.
University of Virginia School of Medicine
Department of Neurosurgery
Charlottesville, VA

R. Woosley, M.D.
University of North Carolina School of Medicine
Department of Neurosurgery
Chapel Hill, NC

Drew Sullivan, M.D.
University of Kentucky School of Medicine
Department of Neurosurgery
Lexington, KY

The following questions were included in each interview:

1. Do you think this system has clinical application? In what class of patients?

2. Do you agree with the physiological objective of normal volume at normal pressure? Do you think it could be a pressure-only system?

3. Are the following desirable features: retrograde flushing, manual override, programming for a 24-hour cycle?

4. Would this system best be used as an assist device for currently available shunts or as a new shunt system in itself?

5. What is the most reasonable implant site?

6. What is the maximum size tolerated?

7. What is the minimum requirement for battery longevity?

8. Is a rechargeable system acceptable?

9. What catheter features should be incorporated to compensate for growth?

10. What other features in the system would be useful?

A summary of each interview will be included in the final report for the Phase 0 study. In general, the neurosurgeons were quite enthusiastic about a system of this type. Several offers were made for assistance in developing and evaluating the device. A representative from the NIH felt that microprocessor-controlled CSF shunts would probably be the way of the future, but that current transducer technology (pressure, volume) would be the weak link in the implementation of the proposed system.

4.1.3 Action

The RTI team and its consultants will complete the interviews with manufacturers and other NIH researchers in January 1982. The complete report on Task 1 of the Phase 0 study will be submitted to NASA Langley Research Center and NASA Headquarters in February 1982. A decision on whether to proceed with Task 2 will be made by NASA at that time.

4.2 AAMI Standards Development for Medical Devices

The Association for the Advancement of Medical Instrumentation (AAMI) coordinates the development of standards for medical devices. The standards are drafted by committees comprised of individuals representing many different interests in the health care field, including manufacturers, physicians, surgeons, nurses, engineers, medical technologists, and representatives from government regulatory agencies. During the past year, the RTI team has explored the possibility of working with these standards committees as a more efficient method for the identification of technical requirements considered significant by clinicians, researchers, manufacturers, and regulatory agencies.

4.2.1 Standards Development Process

There are four phases of approval in the process of developing an AAMI standard: (1) the draft standard, (2) the proposed standard, (3) the final standard, and (4) the American National Standard.

The draft standard is the first step in the standards development process. It represents the efforts of a small working group and is designed to identify the important operating characteristics and possible hazards of a particular family of medical devices. Safety and performance guidelines are established and included in the draft standard. The draft standard serves as an initial framework for the construction of a true standard. Its purpose is to promote response from concerned users and manufacturers to improve the draft standard before advancing it to further stages in the development process. The draft standard may go through substantial revisions during this phase and, therefore, should not be used for any purpose other than as a basis for review and discussion.

The proposed standard is the second phase in the development process. A draft standard is considered a proposed standard after approval by a formal written vote from the originating AAMI technical committee. (The committee is composed of 20 to 50 people representing various professions in health care, government, and device manufacture.) It is distributed once again for review and comment to refine it even further. The proposed standard is still subject to extensive revision, and like the draft standard, should not be used for any purpose other than as a basis for review and discussion.

The final standard is a proposed standard that has been reviewed and approved by both the originating AAMI technical committee and the AAMI Standards Board. By the time a standard reaches this phase it has been carefully reviewed by many individuals in patient care and industry. Any objections have been resolved to the satisfaction of the originating committee and the Standards Board. Resolution does not always mean the addition or deletion of requirements to the standard, but simply that the objections were reviewed further and responded to accordingly. The final standard is considered to be in the form necessary for submission to the American National Standards Institute (ANSI). Any major change(s) to the content of the standard at this stage dictates its return to the originating committee and its status reverts to a draft or proposed standard, depending on the extent of the change(s).

The final standard is sent to ANSI after it has been approved by the originating AAMI technical committee and the AAMI Standards Board. At ANSI, the standard receives final review. Upon satisfactory completion of all the compulsory requirements and procedures, the final standard is designated as an American National Standard. It can now be used by industry, government, and the health care community as a basic safety and performance guideline for a specific medical device.

4.2.2 RTI Biomedical Applications Team Activity

The RTI team developed a new problem statement this year as a result of working with one of the standards committees. The team was asked to identify a method to detect the dislodgement of the temperature control probe from an infant's skin while the infant is in an infrared radiant warmer. A dislodged probe can cause incorrect temperature feedback to the warmer's control system, which can lead to serious burns to the infant. The Biomedical Applications Team's involvement stemmed from comments made during the review of the Draft Standard for Infant Radiant Warmers. The draft called for a dislodgement detection capability. The manufacturers responded that the technology to meet the request was not available. The RTI team distributed a problem statement to the NASA field centers. A solution suggested by a Lewis Research Center engineer has been distributed to the members of the standards committee for review. If NASA technology can be utilized, the draft standard will retain the dislodgement detection requirement and will perhaps result in the use of the NASA-developed technology on all infant radiant warmers.

4.2.3 Transfer Opportunities

In working with AAMI on this problem, the RTI Biomedical Applications Team uncovered new avenues for technology transfer. The draft standard may recommend a safety or performance feature that will greatly improve a device's safe, efficient operation. The manufacturers may contend, however, that current methods would make their costs prohibitive. In such cases, NASA technology may provide the answer with either a new technology or a more efficient, low-cost alternative.

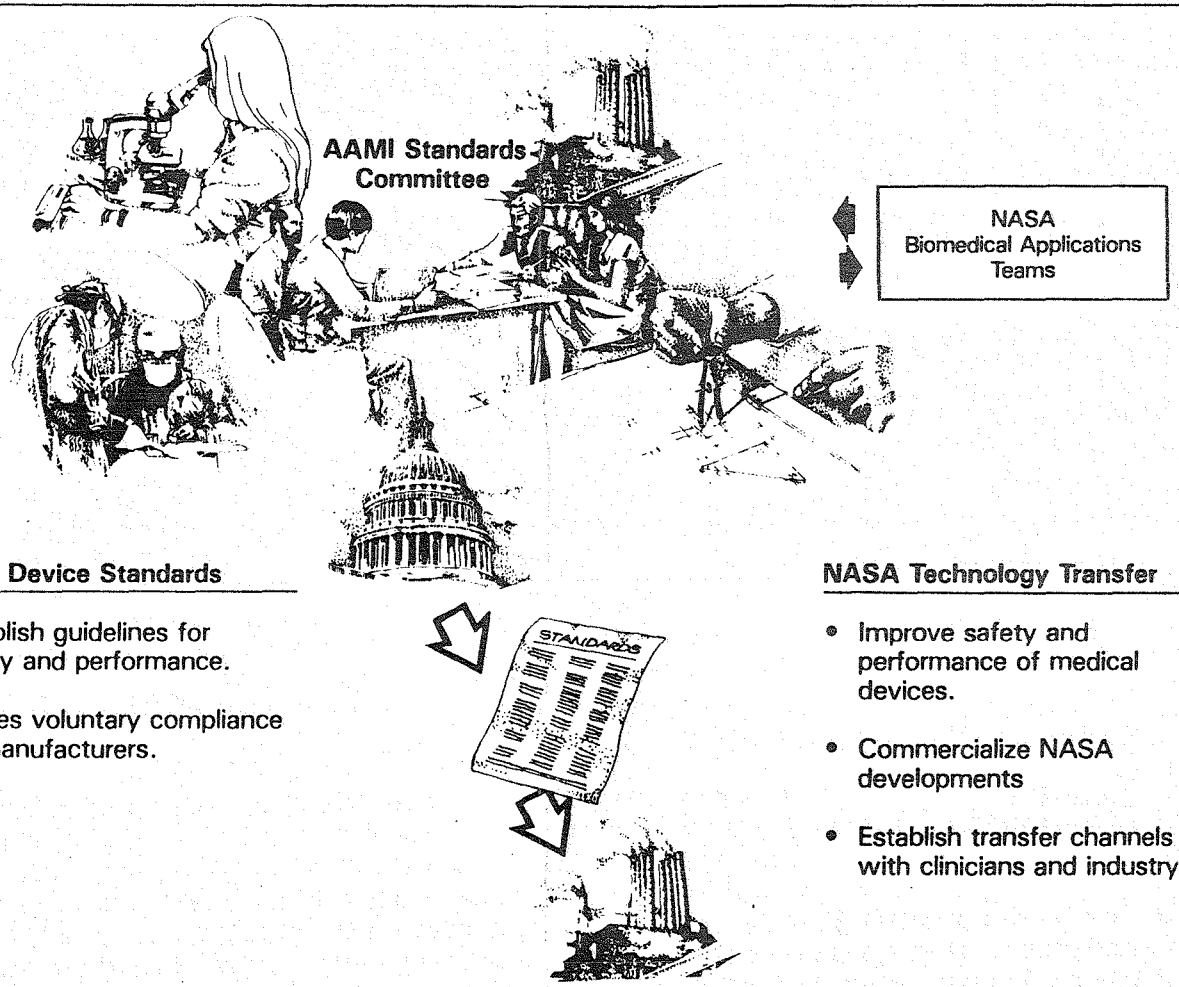
Potentially the most rewarding aspect of working with AAMI standards lies in the establishment of contacts during the investigation of specific problems. The first action usually taken by a Biomedical Applications Team member, after learning of a problem from an AAMI representative, is to interview key members of the AAMI standards committee for the device in question. These people usually have diverse backgrounds, representing industry, medicine, research, etc., and, therefore, can present the problem from several viewpoints. In addition, other opportunities for Biomedical Applications Team activity may develop during discussions with committee members. Some of the individuals are medical device manufacturers, in which case the door has been opened on commercialization sources for team projects. Discussions with a manufacturer can reveal industrywide problems and/or problems with products on which there is no AAMI activity.

The interviews provide an excellent opportunity to disseminate information on the function and capabilities of a NASA Biomedical Applications Team. The active conversation allows instantaneous response to the detailed questions surrounding a team's operation and its role in technology transfer. The result should be a boost to team productivity, since the "consumer" will be aware of the services available and seek them out in the future.

4.2.4 Conclusions

The process of developing a medical device standard brings together medical researchers, doctors, designers, marketers, regulatory agencies, and others. Problems of both manufacture and use are discussed openly, and capabilities and ideas shared. This type of situation can only have a positive effect on the performance and safety of medical devices. The involvement of the Biomedical Applications Team with the standards development process should provide an efficient method for the transfer of aerospace technology to meet significant medical needs. Figure 1 summarizes the standards development process and the interaction of the NASA Technology Transfer Program.

AAMI Standards Development



Medical Device Standards

- Establish guidelines for safety and performance.
- Implies voluntary compliance by manufacturers.

NASA Technology Transfer

- Improve safety and performance of medical devices.
- Commercialize NASA developments
- Establish transfer channels with clinicians and industry.

Figure 1

4.3 Composite Materials Walker: Market Study

Many disabled individuals with limited ambulatory capability can obtain the upright support and stability necessary for ambulation by the use of an aid known as a walker. This device is a four-legged, three-dimensional frame within which the patient stands. Ambulation is assisted by the use of arm strength in much the same manner as arm crutches. Most walkers are fabricated from aluminum with steel tubing at the stress points. They normally weigh between 2.7 and 3.6 kg (6-8 lbs) and are designed to fold for storage behind a car seat or in a truck.

As the RTI team concluded in a previous study on the market for composite orthotics and prosthetics, the aluminum and steel walkers currently available are entirely adequate for a large segment of the patients using walkers.[1] In the present study, the RTI team's objective was to define the patient population that could benefit from a more lightweight walker and to define the manufacturing and marketing factors critical to its commercial feasibility. The focus of the study was a prototype walker of composite graphite fiber/epoxy resin designed and built by Dr. Ernie Harrison of Mississippi Methodist Rehabilitation Center. Dr. Harrison did this work as part of a Langley Research Center contract entitled "Applications of Advanced Composite Materials to Orthotic Devices."

4.3.1 Description of Graphite/Epoxy Walker

The walker built by Dr. Harrison is shown in the figure on page 55. All components of the walker are graphite/epoxy. The top horizontal tube between the two side panels is made in two sections to permit folding. Each section of the horizontal tube is attached to the upper horizontal tube of each side panel by a modified right-angle connector that is free to rotate on the horizontal tube of the side panel. A large-diameter sliding graphite/epoxy tube slides into place to lock the two-piece horizontal bar into a rigid unit for the operational configuration. Dr. Harrison's walker prototype folds to a thickness that is several inches less than commercially available walkers, resulting in easier storage behind a car seat or in the home. The graphite/epoxy walker weighs 1.93 kg (4.25 lbs), which is 1.25 to 1.47 kg (2.75-3.25 lbs) less than available aluminum and steel walkers. Dr. Harrison's walker, therefore, offers advantages in weight reduction, portability, and storage.

4.3.2 Patient Population for Lightweight Walker

According to Dr. Harrison, the occasional user of a walker who has reasonable upper arm strength and upper body control has little difficulty with currently available walkers. The two classes of patients in which the weight of the walker is a problem are the very active patient and the severely disabled patient. The active patient uses a walker to assist in maintaining a normal lifestyle, which includes several daily transfers in and out of an automobile. The use of a lightweight walker would reduce the patient's required daily energy expenditure. The smaller folded thickness and reduced weight would make the storage of the walker in the backseat of an automobile a much easier task. The second category of patient, the severely disabled, would be able to ambulate more frequently with

a lightweight walker. Many of these patients are arthritic with multiple joint involvement, and have severe pain upon movement and little strength. A reduction in walker weight could make a significant difference in the frequency and ease of ambulation for these patients.

To explore further the potential uses of Dr. Harrison's walker, the RTI team demonstrated the prototype to Mr. Breur at Preston Corporation, a major distributor of walkers and other rehabilitation aids. Mr. Breur was enthusiastic about Dr. Harrison's walker. He felt that the significantly lighter weight would be especially important for elderly patients. He also pointed out that the composite walker is more durable than the aluminum devices, which are easily dented or bent. This aspect would be important for walkers used by very active patients and for those used in institutional environments. For marketing purposes, Mr. Breur suggested changing colors and rounding corners to improve the aesthetic appearance of the walker.

4.3.3 Manufacturing and Marketing Considerations

To evaluate the manufacturing and marketing factors critical to the commercialization of the lightweight walker, the RTI team interviewed the walker manufacturers and graphite composite materials suppliers indicated in Table 1. In all of the interviews, the increased cost of the graphite/epoxy composite materials over aluminum was the most critical factor for commercialization. Lumex Corporation, a major walker manufacturer, estimated a market of 100,000 lightweight walkers per year. Commercial plastics were investigated by Lumex as a low-cost alternative to graphite composite materials, but were found to lack the necessary strength for this use. Lumex indicated that the cost of manufacturing the current aluminum walkers is approximately $12 per walker. If the composite walker is to be commercially feasible, then the manufacturing costs should not be greater than $12.

Cost is such a critical factor because most walkers are purchased under third-party reimbursement systems such as Medicare. These reimbursement systems use established standard allowances for walkers and will not authorize a higher reimbursement rate for a more lightweight walker. This cost constraint was emphasized by Lumex, Preston, and Invacare, another major walker manufacturer. The issue of cost constraints and third-party reimbursement was a major factor in the RTI team's earlier study on the use of prosthetics and orthotics.

The two options for resolving the problem of the higher cost for the composite materials are (1) to change Medicare policy to allow a higher reimbursement rate for the lightweight walker or (2) to utilize more inexpensive composite materials in the walker. The RTI team's discussions with Social Security personnel indicated that the first option was a remote possibility. The RTI team, therefore, investigated the use of less expensive materials by interviewing composite material suppliers.

J. R. Haracz of Union Carbide estimated that the lowest price for their PAN (polyacrylonitrile) fiber would be $15 per pound, if ordered in very large quantities. In terms of the manufacturing cost of

$12 for the 4-pound chair, however, the materials cannot exceed $3 per pound. Mr. Haracz suggested using a blend of graphite, Du Pont's Kevlar ($7/lb), and glass fibers ($0.80/lb) in the walker to reduce costs. The glass would provide body, the Kevlar would provide impact resistance, and the graphite, strength. Dr. James Leslie at the Advanced Composite Pipe and Tube Company suggested using composite materials only in the walker's tubes and using aluminum for the other components. He also suggested using Kevlar rather than 100 percent graphite for economic and safety reasons. A broken graphite tube often results in sharp protrusions while a Kevlar tube will break like a green stick. Du Pont, however, has suggested blending Kevlar with another fiber to obtain the compression characteristics required for the walker. A Kevlar/graphite blend ratio of 70:30 was suggested. The cost for materials and fabrication of the walker's tubes using this blend would be $9.80. The cost of the aluminum corners and the horizontal tube would be approximately $4 per walker. With appropriate design considerations, the assembly cost could be minimal--an estimated $l per walker. The total manufacturing cost of this walker, therefore, would be $14.80.

4.3.4 Status and Action

The materials and manufacturing options developed in this study have been presented to the walker manufacturers. Lumex is conducting a study to estimate the market for a walker at this price. The team will continue discussions with the walker manufacturers. In addition, the team will continue dialogue with the materials suppliers so that lower cost carbon fibers currently being developed will be considered as materials for lightweight walkers.

4.4 References

1. Biomedical Applications Team. Applications of Aerospace Technology in Biology and Medicine, Final Report, January 1, 1979-April 15, 1980. Prepared by Research Triangle Institute, Research Triangle Park, N.C., for the National Aeronautics and Space Administration, Hampton, Virginia.

TABLE 1. COMPOSITE WALKER INTERVIEWS

Mal Mixon, President
Donald E. Karl,
Vice President of Operations
Invacare Corporation
Elyria, Ohio 44035

Guardian Products
N. Hollywood, CA 91605

Mr. Charles Murcott, President
Mr. Coviello, Marketing Manager
Lumex, Inc.
Bayshore, New York 11706

Mr. Breur
Preston Corporation
New York, NY 10003

Dr. James Leslie
Advanced Composite Pipe and Tube
Santa Anna, CA

Mr. J. R. Haracz
Union Carbide
Chicago, IL

Mr. H. P. Bodenstab
Du Pont Company
Wilmington, DE

Bill Martin
Hercules Corporation
Washington, DC

Social Security Administration
Washington, DC

Mr. Ted Green
U.S. Manufacturing
Pasadena, CA

5.0 STATUS OF ACTIVE TRANSFER PROJECTS

COMPOSITE MATERIAL APPLICATIONS

BATeam Personnel: Dr. Doris Rouse

Problem

Many orthotic devices can be improved by reducing their weight. However, weight reduction must not be accompanied by a reduction in the strength of the material.

Solution

NASA has demonstrated the feasibility of utilizing carbon fiber composites in the fabrication of a wide variety of objects, from satellite dish antennas to automobile fenders. In many instances, the same technology can be applied to dramatically reduce weight and yet retain strength in orthotic devices or mobility aids.

NASA Technology

Although the price of the composite material has fallen, the fabrication of composite devices remains a prime obstacle. Flat or gently curved pieces are reliable and fairly easy to produce. However, most orthotic applications involve tubular members, pivot joints, and T and L joints of tubular members, and require slight bending of these components to achieve a custom fit. The technology for forming these configurations with composite material does not yet rival that of such metals as steel or aluminum. NASA has funded an RTOP to study the development of biomedical applications and the development of the material processes to achieve reliable fabrication of orthotic devices.

Principals

Mr. Robert M. Baucom, Material Applications Branch, NASA Langley Research Center, Hampton, Virginia.
Ms. Sheila T. Long, Technology Utilization Office, NASA Langley Research Center, Hampton, Virginia.
Dr. Ernest Harrison, Director of Biomedical Engineering, Mississippi Methodist Rehabilitation Center, Jackson, Mississippi.

Cost to NASA

This is a 3-year project funded under an RTOP for $45,700.

Commercialization Strategy

Under funding from Langley Research Center, Dr. Harrison developed a walker by using a technique for joining T and L joints from composite tubing. The RTI team recently completed a study of the

marketing and manufacturing factors critical to the commercialization of the composite walker. The results of this study can be useful in the identification of medical and rehabilitative devices in which the higher cost of composite materials would not be a critical factor.

Status

Dr. Harrison is developing new fiberglass/graphite/epoxy structures and structural mechanics analyses techniques for evaluation of their potential use in prosthetic devices and other aids such as wheelchairs.

Action

The RTI team will continue to assist Dr. Harrison in the identification of potential manufacturers and in the evaluation of marketing factors critical to the commercialization of prosthetic devices fabricated from composite materials.

COMPOSITE MATERIAL APPLICATIONS

- REDUCE WEIGHT OF BRACES, PROSTHETIC DEVICES, WHEELCHAIRS, WALKERS, ETC.
- SEEK MEDICAL APPLICATIONS OF NASA-DEVELOPED COMPOSITE MATERIALS AND RELATED MANUFACTURING TECHNIQUES
- WEIGHT SAVINGS OF AT LEAST 50%
- MISSISSIPPI METHODIST REHABILITATION CENTER, JACKSON

DETECTION OF A DISLODGED TEMPERATURE PROBE

BATeam Personnel: Dr. H. Clark Beall

Problem

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 single patient temperature probe that attaches to the infant's skin. If the probe becomes dislodged or is improperly applied, the warmer may deliver excess radiation to the infant who may in turn experience overheating, respiratory distress, dehydration, and other serious complications.

Solution

Currently available radiant warmers contain alarm circuits that are activated if the infant's temperature does not meet preset temperature limits. A system is needed to sound the alarm if the probe is dislodged or improperly positioned.

NASA Technology

A solution from Lewis Research Center recommended the utilization of both the selfheating properties and the passive temperature sensing capabilities of thermistors for the detection of a dislodged temperature probe.

Principals

Dr. Richard Ariagno, Neonatology, Stanford Medical Center, California.
Mr. Tim Davis, Product Safety Engineer, Ohio Medical Products, Madison, Wisconsin.

Cost to NASA

No cost is anticipated.

Commercialization Strategy

Some of the companies interviewed indicated a desire to incorporate a dislodgement alarm if it were a low-cost addition. The FDA is developing a standard for infant radiant warmers.[1] The Association for the Advancement of Medical Instrumentation (AAMI) Standards Committee is considering the addition of such a dislodgement sensor to its list of requirements for infant radiant warmers.[2]

Status

A detailed explanation of the proposed NASA technology solution to the problem has been mailed to the AAMI Standards Committee members and to several manufacturers of infant warmers. One letter of reply advises the RTI team that this type of technology is being considered for incorporation in a proprietary device.

Action

Upon request, followup assistance in the implementation of the technology will be given to recipients of the proposed solution.

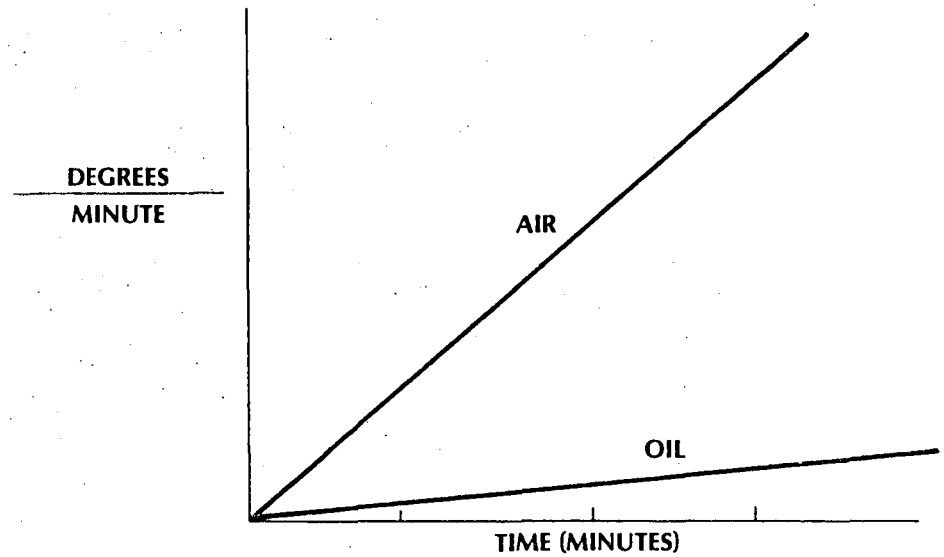
References

1. U.S. Food and Drug Adminstration. Development of a Standard for Infant Warmers and Incubators, PB-263250. National Technical Information Service, Springfield, Virginia, 1977.

2. Association for the Advancement of Medical Instrumentation. Standard for Infant Incubators. AAMI II-08/80, Arlington, Virginia.

DETECTION OF A DISLODGED TEMPERATURE PROBE

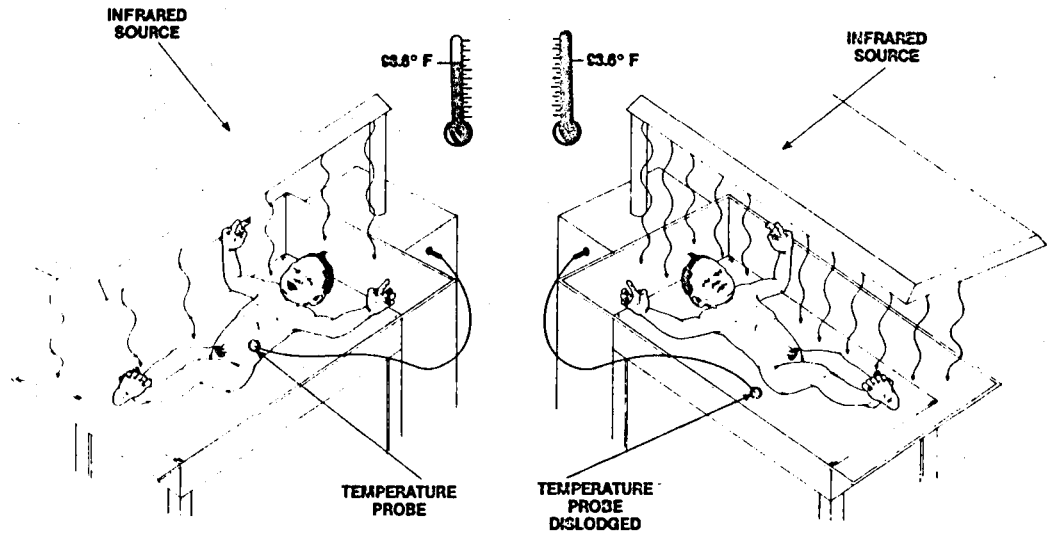
- LOW COST DETECTION OF NONCONTACT OF TEMPERATURE PROBE FROM INFANT'S SKIN IN INFANT WARMERS
- THERMISTOR DETECTION BY SELFHEATING AND PASSIVE TEMPERATURE SENSING, NASA LEWIS RESEARCH CENTER
- AAMI STANDARDS COMMITTEE



Thermistor characteristics for self-heating

DETECTION OF A DISLODGED TEMPERATURE PROBE

- ALARM SYSTEM TO PREVENT OVERHEATING DUE TO DISLODGED TEMPERATURE PROBE
- ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION



Detection of a Dislodged Temperature Probe

FIBER OPTICS SYSTEM FOR KNEE SURGERY

BATeam Personnel: Dr. H. Clark Beall

Problem

A variety of surgical procedures within the knee joint can be performed, without opening the bursa, by watching the surgical implements on closed-circuit TV. In such procedures, an arthroscope probes the inside of the knee joint and a TV camera presents the image. However, the arthroscope is prone to break because it must be rigidly connected to the camera. Also, the TV camera must be draped with sterile covers because it is so close to the surgical zone.

Solution

These problems have been described to optics engineers at NASA Langley Research Center, who recommend that the arthroscope be interfaced to the TV camera by a coherent fiber optics cable. Such a cable would allow the TV camera to be placed outside the sterile zone.

NASA Technology

Coherent fiber optics technology is most commonly utilized within NASA in the design of nondestructive test, measurement, or inspection instruments.

Principals

Dr. R. B. Caspari, orthopedic surgeon, St. Mary's Hospital, Richmond, Virginia.
Mr. David Rhodes, NASA Langley Research Center, Hampton, Virginia.
Mr. John Franke, NASA Langley Research Center, Hampton, Virginia.
Dr. F. H. Bassett, Orthopedic Surgeon, Duke University, Durham, North Carolina.

Cost to NASA

Local funds are being utilized at NASA Langley Research Center for work on interfacing the fiber optics viewing cable with the TV camera and the arthroscope.

Commercialization Strategy

After minor problems with the fiber optics system have been corrected, the RTI team will direct its efforts toward promoting the commercialization of the device.

Status

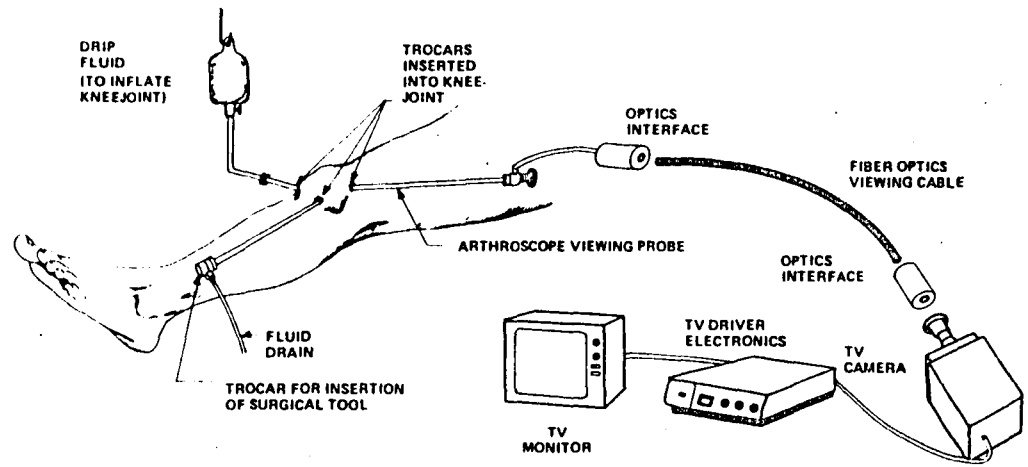
The first prototype of the fiber optics viewing system was criticized on aesthetic grounds for exhibiting too much "fishnet" masking of the image. Arrangements have been made for a second evaluation of the prototype by Dr. Bassett of Duke University.

Action

The prototype will be delivered to Duke University in January 1982. The evaluation should require less than 2 months.

FIBER OPTICS SYSTEM FOR KNEE SURGERY

- ENABLES WIDER USE OF CLOSED JOINT SURGERY
- NASA OPTICS EXPERTISE. LANGLEY RESEARCH CENTER
- ST. MARY'S HOSPITAL, RICHMOND, VA



FIBER OPTICS SYSTEM FOR KNEE SURGERY

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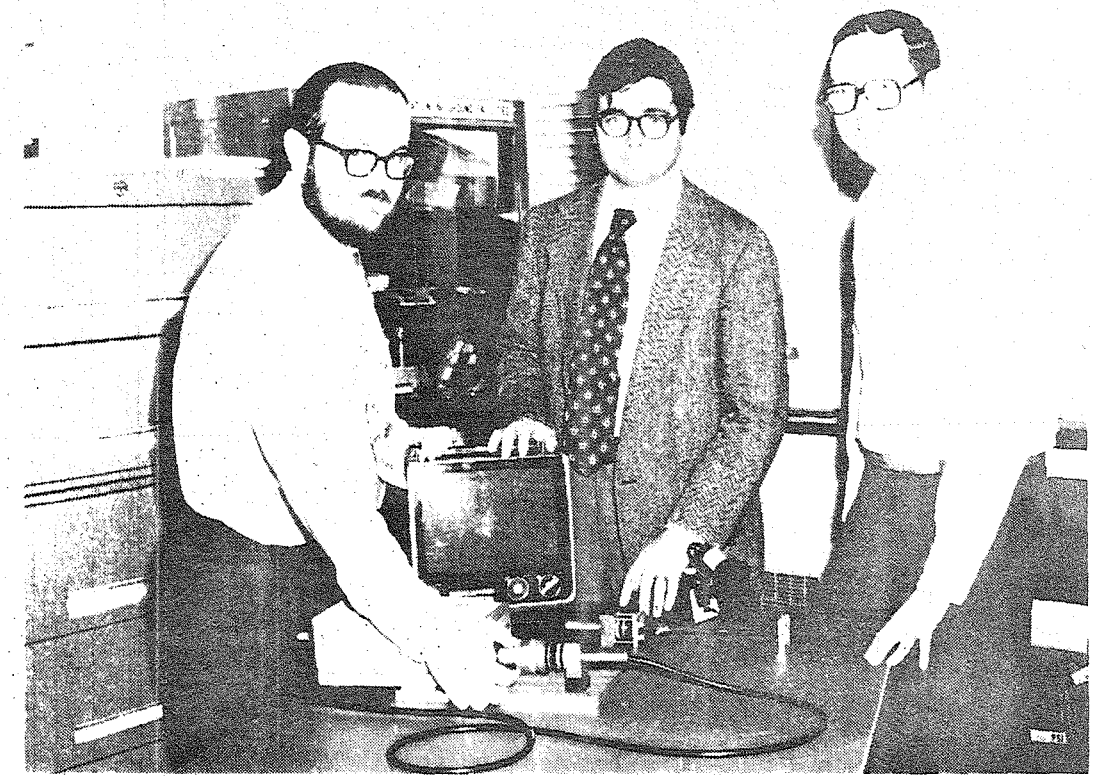


Principal Investigators with Arthroscope System

FLOW SENSOR FOR AN INFUSION PUMP

BATeam Personnel: Dr. H. Clark Beall

Problem

An infusion pump system is required that has a flow control superior to any similar device on the market. The system would be particularly useful in clinical applications where long-term infusion at well-controlled, low flow rates are necessary.

Solution

A key component would be a flow sensor that could provide a feedback signal to the pumping mechanism.

NASA Technology

Mr. Eugene Winkler of the Johnson Space Center has designed a new flow sensor that is suitable for measuring the rate of injection of intravenous biomedical fluids. The device is described in NASA Tech Briefs, Fall 1980, page 335. A disclosure of new technology has been filed on the device.

Principals

Mr. Eugene Winkler, Wastewater Quality Monitor Systems, Johnson Space Center, Houston, Texas.
Mr. Jack Wheeler, Technology Utilization Office, Johnson Space Center, Houston, Texas.
Dr. William Clingman, marketing consultant.

Cost to NASA

No cost is anticipated.

Commercialization Strategy

The RTI team has contacted several medical device manufacturers regarding commercialization of the flow sensor. As a result, inquiries about licensing the sensor have been received from three companies currently marketing infusion pumps.

Status

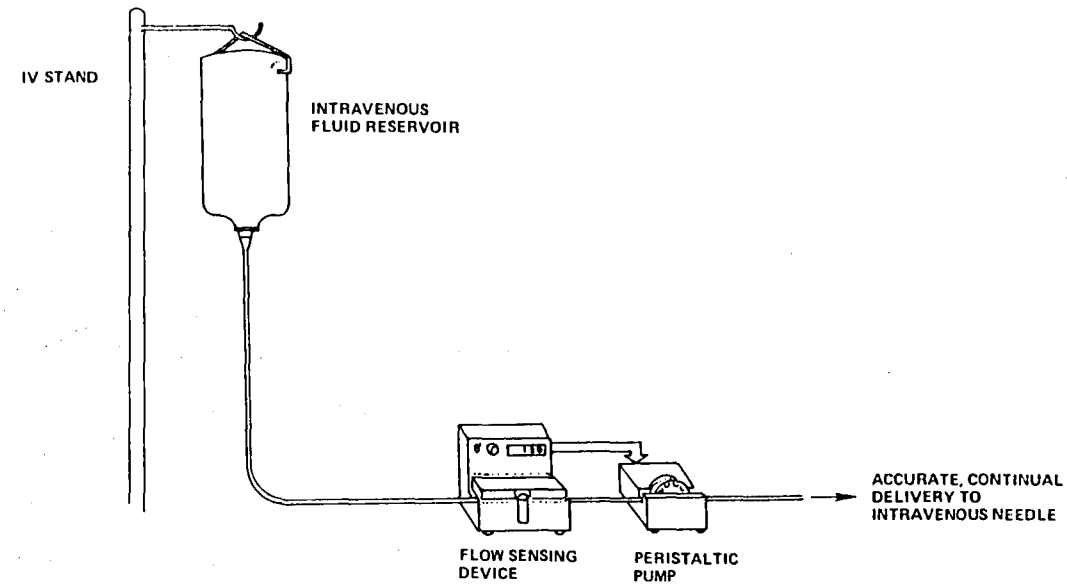
At least three serious inquiries from manufacturers have been received concerning the licensing of this technology. Negotiations have stalled on the question of exclusive licensing.

Action

The RTI team will continue to support efforts toward the commercial development of this device and resolution of the licensing question.

FLOW SENSOR FOR AN INFUSION PUMP

- FLOW CONTROL SYSTEM FOR LONG-TERM INFUSION AT LOW RATES
- FLOW SENSOR FROM NASA WATER QUALITY MONITORING SYSTEM
- DETECTS FLOWS UP TO 0.5 ml/min WITH SENSITIVITY OF 0.01 ml/min
- ORION, INC., CAMBRIDGE, MA



FLOW SENSOR FOR AN INFUSION PUMP

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, has been 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 formed 15 micron holes in a Teflon shunt. Refinements in the ventilating technique are being investigated.

Action

Development of ventilation techniques will continue. Flow testing will begin in 1982. Dr. Foltz and JPL plan to submit a joint proposal to the National Institutes of Health in June 1982 for the continued development and evaluation of the ion thruster ventilated shunts.

IMPLANT MATERIALS TESTING

BATeam Personnel: Dr. James N. Brown, Jr.

Problem

Many design and fabrication aspects of metallic surgical implants result in local regions of high stress where defects can exist or develop during use. The need to improve the reliability of these prosthethic devices has been well documented.[1] [2] [3]

Solution

More effective screening procedures for metallic prosthetic devices could improve the mechanical reliability of these implants.

NASA Technology

Fracture control methods (material qualification, design, and inspection), which were developed by NASA for screening critical spacecraft hardware, can be applied to metallic implants. NASA's procedures for evaluating the impact of a liquid environment on mechanical reliability would be especially applicable.

Principals

Mr. Robert E. Johnson, Vice President, Eagle Engineering, Inc., Houston, Texas.
Mr. Don Chwirut, Bureau of Medical Devices, Food and Drug Administration, Washington, DC.
Mr. Edward Mueller, Bureau of Medical Devices, Food and Drug Administration, Washington, DC.

Cost to NASA

NASA funded a feasibility study to evaluate the application of aerospace fracture control methods to surgical implants. This study, conducted by Eagle Engineering, Inc., cost $19,000. FDA has transferred $50,000 to Langley Research Center to support the continuation of Eagle Engineering's work to improve implant design and testing.

Commercialization Strategy

The Eagle Engineering study and additional work will result in the establishment of FDA guidelines for product certification and device test protocols to be used by implant manufacturers.

Status

In discussions with the RTI team, the FDA strongly recommended that NASA investigate the application of aerospace materials evaluation techniques to surgical implants. FDA is interested in incorporating NASA technology in the Bureau of Medical Devices' fracture control program. Eagle Engineering completed a feasibility study under NASA funding in June 1981. Following a favorable review of the

results, FDA transferred funds to Langley Research Center for continuation of the study to improve implant design and testing.

Action

The FDA/NASA study on implant materials will continue. FDA is providing the materials and implant samples from Eagle's study. Sheila Long at Langley Research Center will monitor the Eagle Engineering contract. Eagle will be using Langley's electron microscope for surface studies. The fracture control methods developed in this study may be incorporated in commercial manufacturing and quality control procedures for implanted devices.

References

1. Weinstein, A., H. Amstutz, G. Pavon, and V. Franceschini. Orthopedic Implants--A Clinical and Metallurgical Analysis. Journal of Biomedical Materials Research, 4:297-325, 1973.

2. Hench, L. L. Biomaterials. Science, 208:826-831, May 23, 1980.

3. Hench, L. L. Future Developments and Applications of Biomaterials: An Overview. Biomaterials, Medical Devices, and Artificial Organs, 7(2):339-350, 1979.

LOW-COST UV OPTICAL DOSIMETER

BATeam Personnel: Dr. H. Clark Beall

Problem

If the radiation of the sun is permitted to strike exposed areas of skin on a daily basis over long periods of time, radiation of the UVB region can contribute to skin cancer. A low-cost personal dosimeter system is needed to quantify the total exposure of persons to UVB during their daily activities.

Solution

Engineers at the NASA Langley Research Center have devised a small UVB dosimeter that can be worn unobtrusively on clothing or on eyeglasses.

NASA Technology

The device utilizes three items of technology: a miniature photosensor for detecting light, a miniature electrochemical cell for recording the radiation dosage, and an optical filter for detecting only the UVB region's radiation.

Principals

Dr. Peyton Weary, University of Virginia School of Medicine, Charlottesville, Virginia.
Dr. Ian MacConochie, NASA Langley Research Center, Hampton, Virginia.
Mr. R. Adams, NASA Langley Research Center, Hampton, Virginia.

Cost to NASA

Discretionary funds at Langley Research Center have been used for the assembly of prototype dosimeters.

Commercialization Strategy

Inductron Corporation, Grafton, Virginia, indicated an interest in marketing the UV dosimeter for consumer and agricultural use. The RTI team will continue discussions with Inductron Corporation to facilitate commercialization.

Status

Although several prototypes performed satisfactorily, a wide variance was found in the performance of a set of 10 dosimeters that were assembled from commercial components. The problem seemed to be the slight variation in the optical filters. A decision has been made to measure total UV, which is a much larger signal. The detectors do not vary as much in response to total UV as they do to UVB.

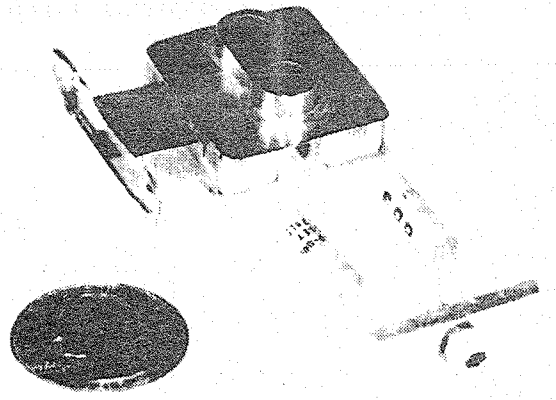
University of Cincinnati researchers have obtained a license from the Langley Research Center Patent Office for the modification and use of the dosimeter in research applications. University of Florida personnel have built several copies of the dosimeter.

Action

Mr. King of the NASA Langley Research Center Patent Office has pointed out that quite a few inquiries about licensing the dosimeter have been received. He routinely issues letters of permission for various governmental agencies to build, modify, and use the dosimeter. The RTI team and the Langley Technology Utilization Office will continue discussions with Inductron on the commercialization of the dosimeter.

LOW-COST UV OPTICAL DOSIMETER

- COMPACT SENSOR AND RECORDING DEVICE FORM A PERSONAL DOSIMETER FOR SOLAR UV
- PERSONAL DOSIMETERS CAN BE USED FOR EPIDEMIOLOGICAL STUDIES ON UV EFFECTS
- NASA TECHNOLOGY: SILICON PHOTOVOLTAIC CIRCUITRY AND ELECTROCHEMICAL COULOMETER CURRENT INTEGRATION
- UNIVERSITY OF VIRGINIA SCHOOL OF MEDICINE, CHARLOTTESVILLE, VA
- NASA LANGLEY RESEARCH CENTER



MICROWAVE THERMOGRAPHY

BATeam Personnel: Dr. H. Clark Beall, Dr. Michael McCartney

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.
Veterans Administration Hospital, Hampton, 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.

Status

The NASA-owned microwave radiometer has been recently renovated at the factory. The performance of this radiometer will be compared to the performance of the radiometer owned by the VA hospital at Hampton, Virginia.

Action

When the VA hospital team submits its protocol for testing the radiometer to the NASA Langley Research Center, the NASA radiometer will be loaned to the hospital for testing.

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, President, B&K Instruments, Inc., Cleveland, Ohio.

Cost to NASA

NASA FY80 funds designated for this project totalled $61,000. 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. B&K Instruments, Inc., has already contributed Mr. Wootten's consulting time during several trips to the Medical College of Virginia.

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

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.

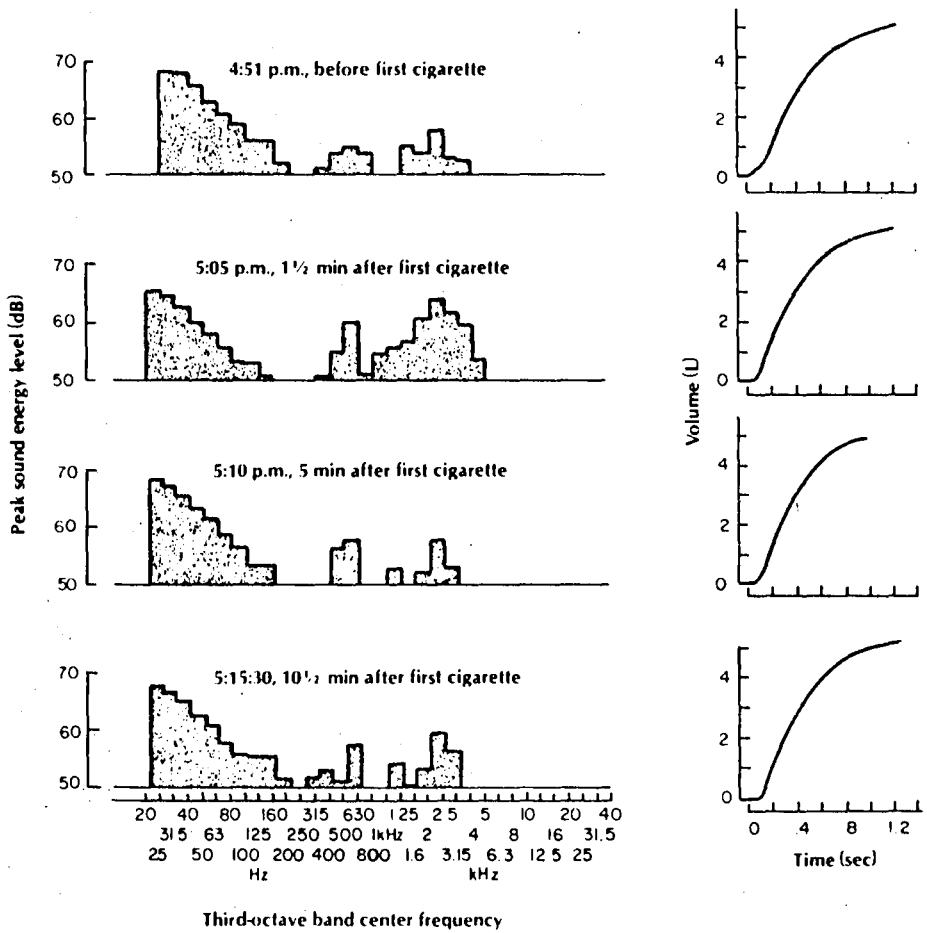
Action

The soundroom as well as the acoustic and flow measurement instrumentation have been installed at the Medical College of Virginia. Animal and human testing will continue in the next quarter at the Medical College of Virginia. Flow visualization studies will continue at Langley.

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.

OPHTHALMIC SCREENING DEVICE

BATeam Personnel: Dr. H. Clark Beall

Problem

Amblyopia is a childhood eye disease that affects approximately 4 percent of the population in the United States. It is defined as poor vision, despite correction with glasses for any refractive problem. If amblyopia is detected early and then corrected, no permanent vision damage results. Therefore, experts recommend at least two vision tests for children before age seven. Such vision tests could also identify other eye dysfunctions.

Solution

Most children have 20/20 vision; a screening test is needed to identify the 10 percent who have vision problems. The screening test should be simple and quick due to the limited attention span of preschool children. With this in mind, an ophthalmologist has devised a photographic test procedure that records the color image reflected from human eyes in response to a flash of light. This red "retinal reflex" is occasionally observed in color flash photography when the subject gazes directly at the camera the instant the flash occurs.

NASA Technology

An ophthalmologist has identified an optical correlator from Marshall Space Flight Center as a device that could be used to quickly analyze the color photographs produced by such a screening test. The correlator must be modified somewhat to perform satisfactorily in the new application. An RTOP was submitted for FY80 to accomplish this task.

Principals

Mr. Joseph H. Kerr, President, Electro-Optics Consultants, Inc., Huntsville, Alabama.
Dr. S. Hutson Hay, ophthalmologist, Huntsville, Alabama.
Dr. Bob Jayroe, NASA Marshall Flight Center, Alabama.

Cost to NASA

Marshall Space Flight Center has granted a no-cost 6-month contract extension on a $20,000 contract with Electro-Optics Consultants, Inc. (EOC), for the production and evaluation of a prototype screening device. EOC and Dr. Hay have invested $100,000 in the prototype development and evaluation.

Commercialization Strategy

An ophthalmologist representing the Dallas school system visited EOC and Marshall Space Flight Center in November 1981 for a demonstration of the ophthalmic screening device. The Dallas school system has subsequently sent a purchase order to EOC for a device to be used in the Dallas schools for routine screening.

Status

One hundred and seventy-five students of the Alabama School for the Deaf received manual eye examinations and photographic screening examinations with the NASA camera system by staff members of the Alabama School of Medicine at Birmingham. The photographic screening identified 23 students with defective retinal reflex. Subsequent manual examinations of these students by Dr. Hay revealed 22 with various visual defects. The final report for the first part of the contract to EOC has been delivered to Marshall Space Flight Center.

Action

Dr. Hay will follow up on inquiries received after his description of the screening system at the Southern Ophthalmological Association meeting at Mobile, Alabama, in November 1981. Marketing efforts will intensify in 1982.

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

Dr. Bill Williams and Ms. Pat Kirk, Environmental Control Research Branch, NASA Ames Research Center, Moffett Field, California.

Dr. Tom Krouskop, Director, Rehabilitation Engineering Center, Texas Institute for Rehabilitation and Research (TIRR), Houston, Texas.

Cost to NASA

Fabrication of prototype vest systems for evaluation by TIRR cost NASA $15,000. The cost to the National Institute of Handicapped Research (NIHR) for the evaluation at TIRR will be $20,000.

Commercialization Strategy

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

Status

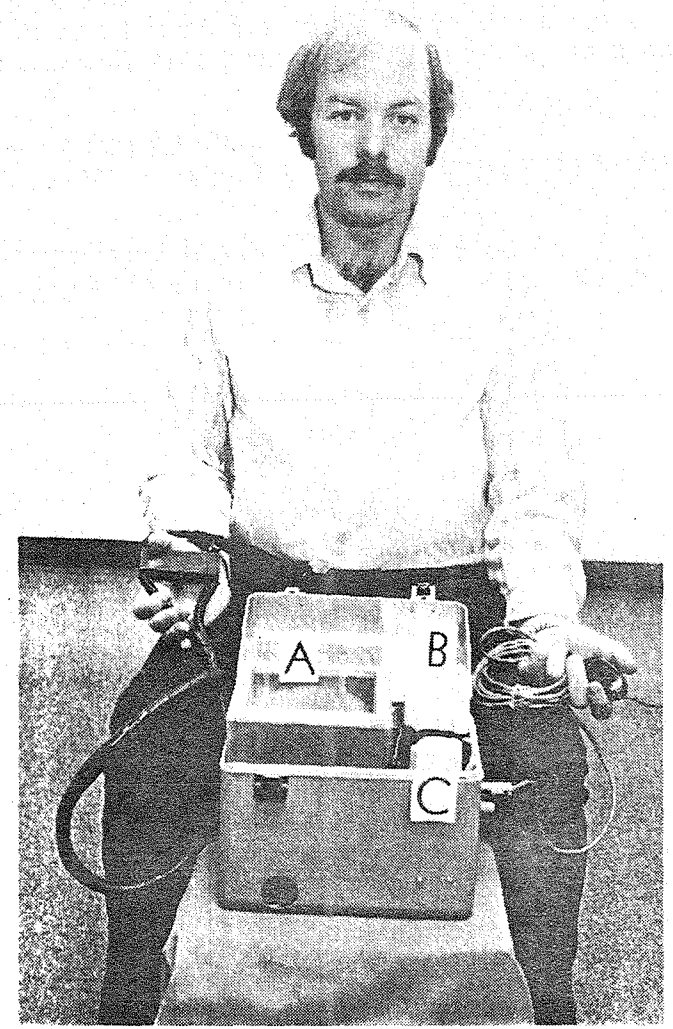
Personnel at Ames Research Center designed a small water-cooling and pumping unit as well as a vest. An informal evaluation of the system by a quadriplegic indicated that the system was quite effective. TIRR will evaluate the vest in environmental chambers and in normal outpatient use. The systems have been delivered to TIRR and volunteers have been recruited for participation in the study.

Action

Funding delays at TIRR and liability questions have prevented the start of the vest evaluation. The RTI team is working with TIRR and Ames Research Center to resolve these issues in the next quarter.

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
- TEXAS INSTITUTE OF REHABILITATION AND RESEARCH, HOUSTON



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

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
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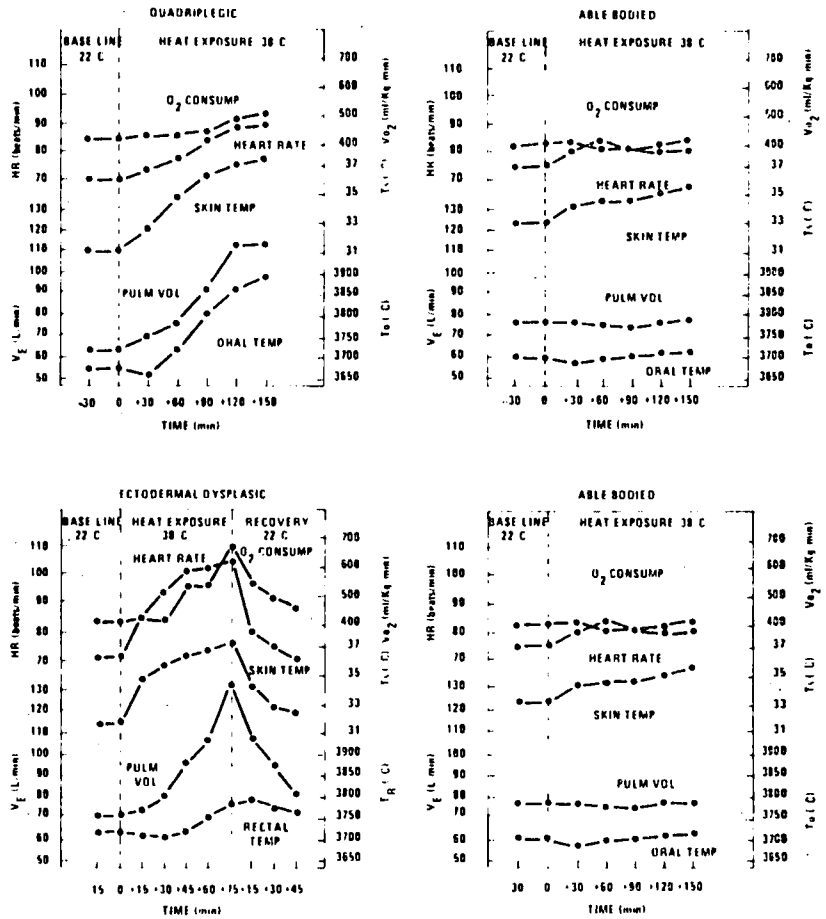

From G. L. Totel, "Physiological Responses to Heat of Resting Man with Impaired Sweating Capacity," *J. Appl. Physiol. 37*, 1974, p. 346.

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 10 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, and thalassemia. 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. (3) Aerospace technology in miniature, highly reliable hydraulic control systems will be used in the medication delivery portion of the system.

Principals

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

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 projected cost sharing for the project is listed below:

National Institute of Child Health and Human Development	$ 400,000
GTE	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.	1,500,000
Applied Physics Lab	50,000
Baker Foundation	2,500
Total cost sharing	$6,952,500

Commercialization Strategy

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

Status

NIADDKD funding for animal and clinical trials of PIMS for insulin delivery began in January 1981. The National Institute of Child Health and Human Development has allocated $400,000 for evaluation of PIMS in the management of hormonal deficiencies.

In October 1981, Dr. Christopher Saudek implanted a PIMS for insulin delivery in a dog that had been made diabetic by pancreatectomy. The pump's telemetry, programming, interrogation, patient programming unit and timing systems had worked well for 3 weeks. Obstruction of the catheter by fibrous tissue and an electrical problem necessitated removal of the pump 25 days after implantation. On examination of the unit after explant, the electrical problem was found to be a minor problem related to prototype fabrication methods.

Action

Studies on biocompatability of alternate catheter materials are being conducted by Dr. Saudek in an attempt to solve the problem of fibrotic reaction to the catheter and the resulting obstruction of flow. A second dog implant is scheduled for mid-February 1982. If the remaining animal implants are successful, the first human implant is scheduled for late 1982. The RTI team will participate in the PIMS working group meeting at APL on February 25-26, 1982.

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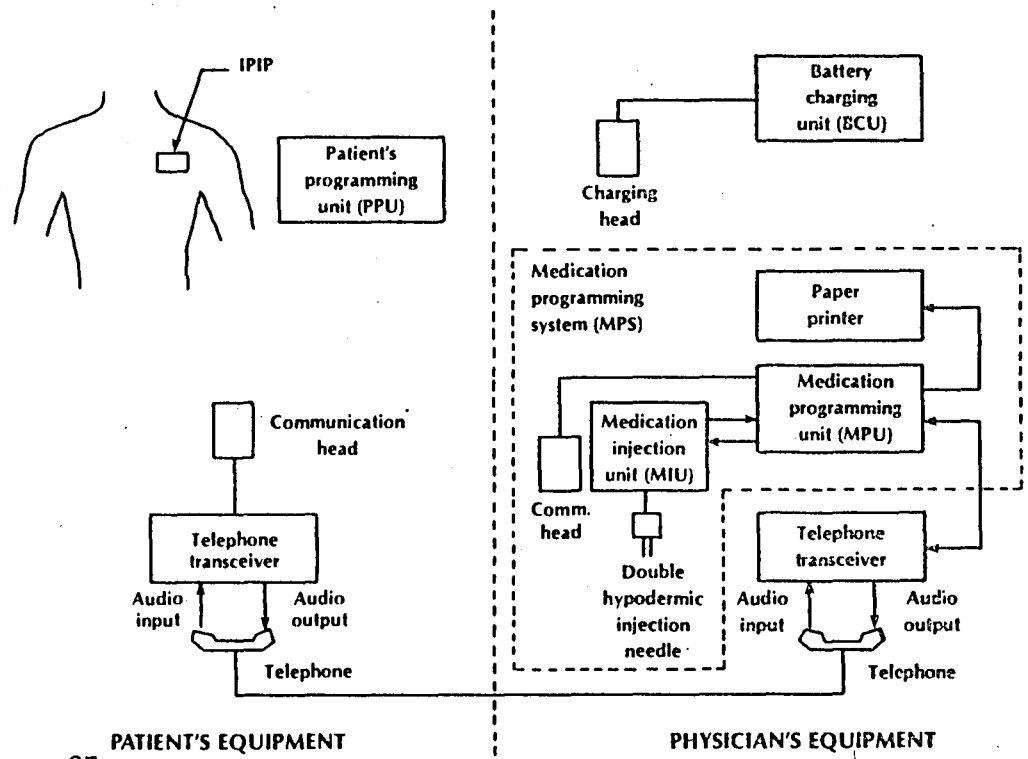
2. Cahill, G. F., Jr., D. D. Etzweiler, and N. Freinkel. New England Journal of Medicine, 294:1004, 1976.
3. Siperstein, M.D. New England Journal of Medicine, 296:1060, 1977.
4. Service, F. J., et al. Diabetes, 19:644, 1970.
5. Molnar, G. D., Taylor, F. W., and A. L. Langworthy. Mayo Clinical Proceedings 47:709-719, 1972.
6. Tamborlane, W. V., et al. New England Journal of Medicine, 300(11):573-578, March 15, 1979.

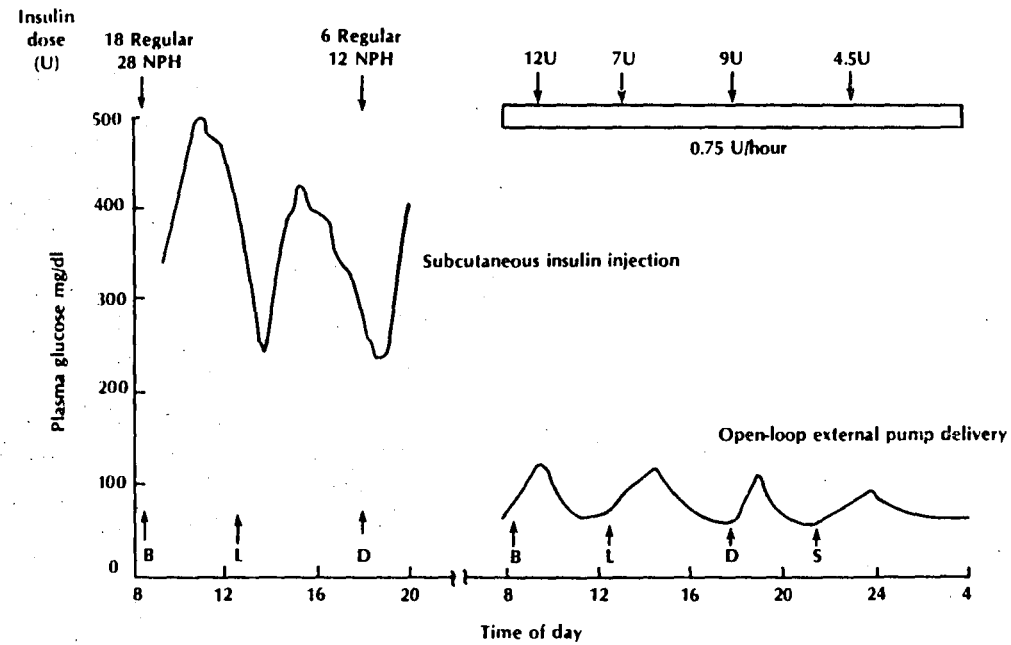
PROGRAMMABLE IMPLANTABLE MEDICATION SYSTEM

- 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
  CORNELL MEDICAL CENTER, NEW YORK, NY



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
  CORNELL MEDICAL CENTER, NEW YORK, NY



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.

Status

Problems encountered in the manufacture of the polysulfone valves have been resolved. Valves for animal testing were delivered to MEC in November. Although the valves performed to specification, the flexibility characteristics of the reservoir material resulted in inadequate maintenance of pres-

sure in the system. Design and material changes to overcome this problem were discussed at a November 30, 1981, meeting in Racine, Wisconsin.

Action

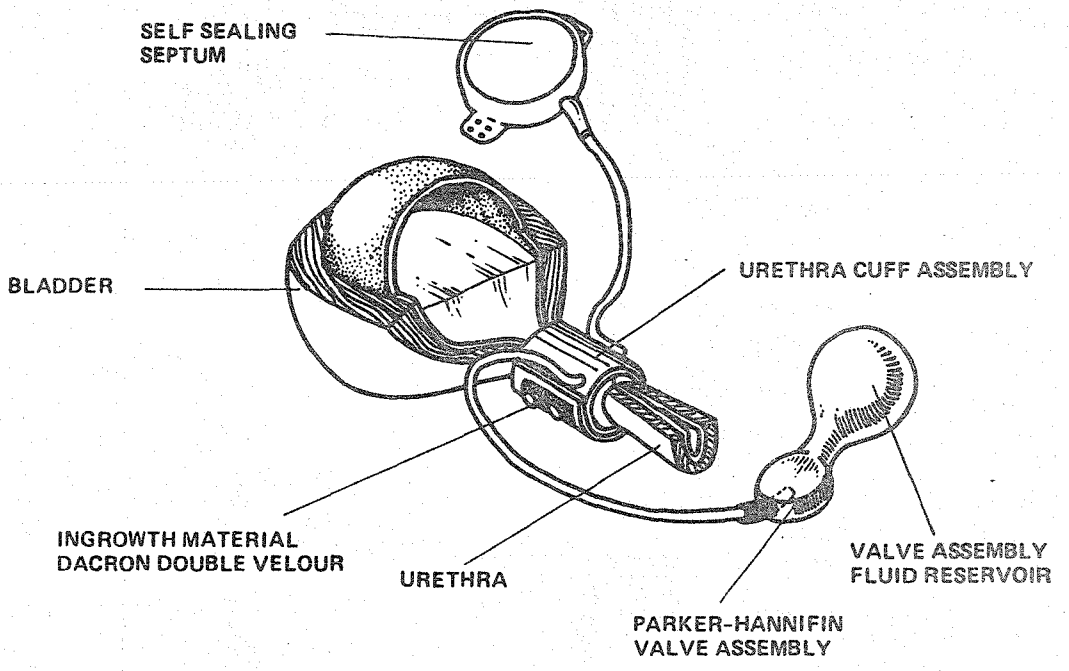
To solve the pressure maintenance problem, the reservoir material will be changed by MEC. Formal animal trials are now expected to begin in March 1982 and human implants to begin in December 1982. MEC will be responsible for coordinating the clinical trials and obtaining FDA approval.

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

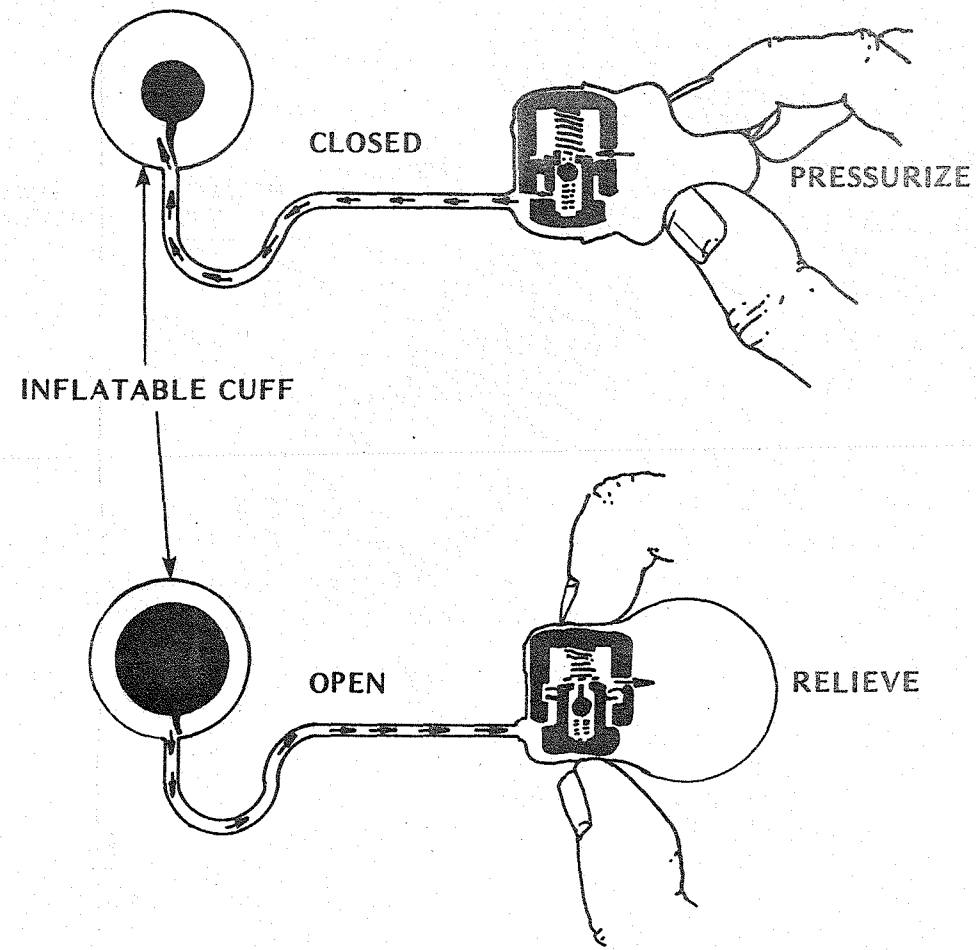
  MEDICAL ENGINEERING CORPORATION, RACINE, WI



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. Bruce Banks, 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.

Status

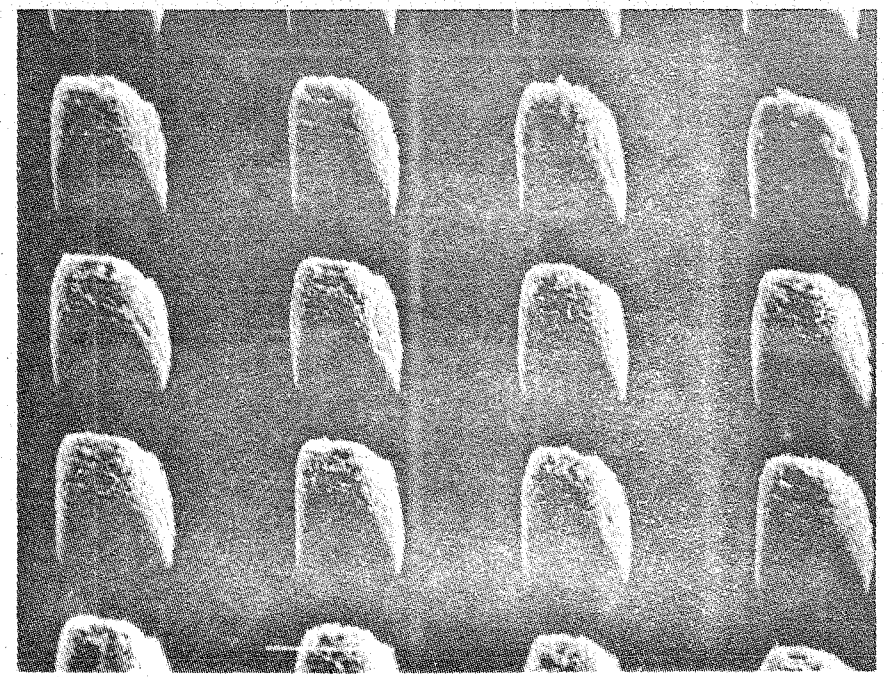
In September, Applied Medical Technology, Inc., submitted the first annual report on the NASA Lewis Research Center contract to evaluate surface morphologies for percutaneous connectors. This study demonstrated that a regular array of micropillars can inhibit epithelial downgrowth and subsequent rejection of the percutaneous connector. Consistent and reproducible success of this morphology is, however, limited by other variables such as surgical technique, tissue mechanics, and postoperative care.

Action

The contract with Applied Medical Technology will continue through 1982.

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.

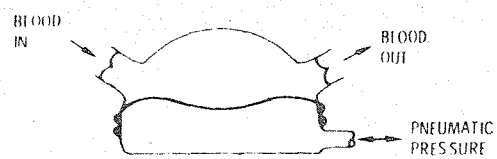
Action

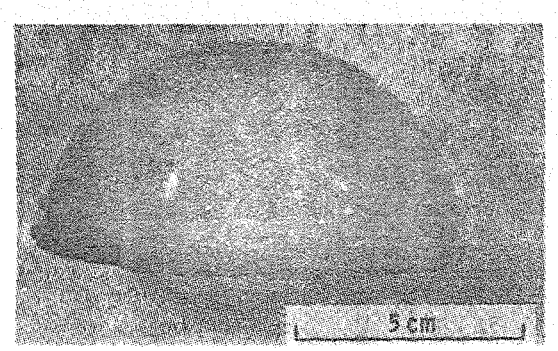
Within 6 months, the implanted bladders will be retrieved for examination of the neo-intima formed on the textured surface.

TEXTURING SURFACES FOR CARDIOVASCULAR PROSTHESES

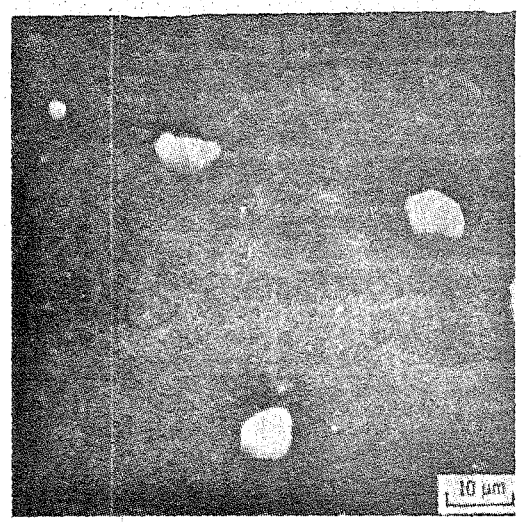
- PROMOTES STABLE, NONTHROMBOEMBOLIC BLOOD INTERFACE IN CARDIOVASCULAR PROSTHESES
- PRODUCE MICROTEXTURES AS SMALL AS 10μm
- NASA-LEWIS ION-BEAM TECHNOLOGY
- THERMO ELECTRON CORPORATION
  WALTHAM, MA

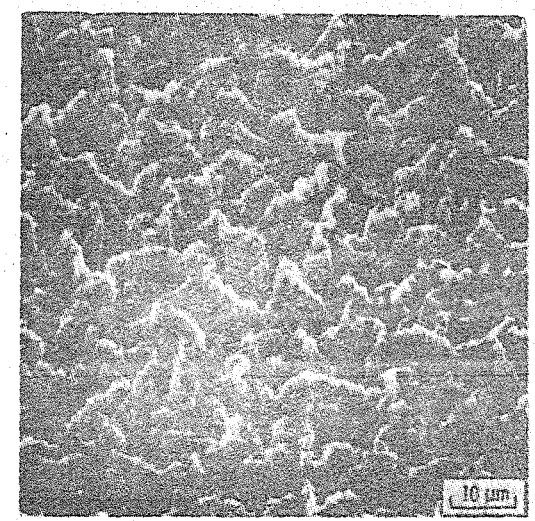
  NATIONAL HEART, LUNG AND BLOOD INSTITUTE





Artificial heart assist pump





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

6.0 INACTIVATED PROJECTS

ANALYSIS OF THE RETINAL REFLEX

BATeam Personnel: Dr. H. Clark Beall

The team's problem statement received only two suggestions of appropriate technology items. Neither was comprehensive enough to accomplish the thorough analysis of the retinal reflex that was described in the problem statement. The proposed analysis required a large research component in addition to the identification of appropriate technology. The development of a successful system, therefore, would probably not be in the scope of a technology utilization application project.

ANALYZER OF TISSUE VIABILITY

BATeam Personnel: Dr. H. Clark Beall

The RTI team has confirmed the need for a novel, noninvasive probe of tissue viability and has identified a physiological process that could serve as a unique assay of tissue viability. However, the development and testing of the envisioned device appears to require no items of technology unique to NASA technology or NASA engineering expertise.

BIOLOGICAL TISSUE FREEZING SYSTEM

BATeam Personnel: Dr. H. Clark Beall

During 1980, several modifications to the freezing system improved the performance of the device in obtaining strictly linear freezing rates. However, the device cannot automatically eliminate or prevent the heat-of-fusion perturbation of the freezing process; therefore, the device offers no outstanding competitive advantage over existing commercial freezing units.

ESOPHAGEAL PRESSURE TRANSDUCER

BATeam Personnel: Dr. H. Clark Beall

Although semiconductor pressure transducers have been identified that are capable of measuring absolute pressure in the range +100 mm Hg to -100 mm Hg, none is small enough to be incorporated within an easily swallowed capsule. Because such a capsule would be connected to wires leading outside the esophagus, elaborate electrical isolation circuits would be required within the capsule and at the wires' external terminals to ensure electrical safety. Both of these considerations would require enlargement of the capsule beyond practical limits.

HEARING AID INTELLIGIBILITY

BATeam Personnel: Dr. H. Clark Beall

Improving the intelligibility of hearing aids requires tailored speech processing and noise filtering circuitry that have operational characteristics that are unique to virtually each hearing aid wearer. These technologies are now based more on microcomputer software than hardware items. For these reasons, one can foresee a research program more than a technology utilization program for the eventual development of an appropriate wearable device.

NEUROMUSCULAR DIAGNOSTIC UNIT

BATeam Personnel: Dr. James N. Brown, Jr.

Financial conditions and engineering staff turnover have prevented Miller Medical Electronics, Inc., from completing the prototype neuromuscular diagnostic tester for evaluation by the National Institute of Neurological and Communicative Disorders and Stoke of the National Institutes of Health (NIH). The RTI team has discussed the project with JWM, Inc., a medical electronics manufacturer. The team has provided JWM with information on the design of the tester, Dr. Somjen's test results, and the interest by NIH in evaluating the tester as a diagnostic and therapy monitoring system. JWM expressed an interest in developing the system, but could not commit resources to the project at this time. The RTI team will keep in touch with JWM during 1982.

PRESSURE TRANSDUCER CALIBRATOR

BATeam Personnel: Dr. James N. Brown, Jr.

Bell and Howell has decided not to fund an evaluation of the calibrator at Baylor College of Medicine. The RTI team, therefore, is inactivating the project as a result of insufficient commercial interest.

RETRACTOR TOOL FOR BRAIN SURGERY

BATeam Personnel: Dr. H. Clark Beall

A concensus opinion could not be reached among the neurosurgeons the team interviewed concerning the need for an improved retractor tool and the details of construction and operation. The engineer who proposed the initial design of the retractor tool retired from NASA service and cannot be available for future prototype construction and modification.

SELECTIVE CALL TELEMETRY

BATeam Personnel: Dr. H. Clark Beall

NASA engineers pointed out that special integrated circuits and radio frequency circuits were commercially available for the design of many types of telemetry command devices. This information was forwarded to the problem originator, together with the names and phone numbers of NASA engineers who could advise him concerning his specific needs.

TEXTURING DENTAL IMPLANTS

BATeam Personnel: Dr. Doris Rouse

Lack of funding has resulted in reduced activity on this project at Case Western Reserve Dental School in the past year. The project is scheduled to be phased out in 1982.

WEIGHT ALLEVIATION DEVICE

BATeam Personnel: Dr. H. Clark Beall

Rush Presbyterian-St. Lukes Hospital was interested in evaluating the device for elderly stroke victims, but concluded that design and liability complications outweighed the potential benefits of the device. To resolve the liability question, the manufacturer, Melton Corporation, will assume responsibility for evaluation of the device. The RTI team has given Melton the names of rehabilitation centers that have expressed an interest in this device.

7.0 CONCLUSIONS

During the reporting period, the RTI Biomedical Applications Team conducted problem-solving and commercialization acitivities for 18 active projects and two commercial 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 most effectively, the RTI team has continued to refine its methodology for technology transfer in medicine.

In the past year, the development of a more efficient methodology for the team's activities has been an important goal of the RTI team. 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 and NASA field centers as well as to participating agencies and manufacturers. Techniques implemented during the reporting period to enhance the team's efficiency are described below:

1. Identify Multiple Applications for Technology

   In an effort to improve the technology transfer methodology, the team examined critical factors for NASA technology transfer cases, successful and unsuccessful, from the past several years. This study revealed that certain technologies had provided the solution to several technical needs in medicine. In many cases, however, the multiple applications of a technology had not been coordinated, resulting in inefficiencies in development and difficulty in commercialization. In those cases where several applications for a technology were identified and their development coordinated, the transfer process was more efficient and commercialization more successful. The RTI team's methodology, therefore, has been modified to include an emphasis on the analysis of second applications for technologies identified as solutions for team projects.

   Second applications may result in reduced development costs for each project and a more attractive business opportunity for potential manufacturers. An example of a successful second applications analysis is seen in the hydraulic control technology. A valve developed for the Viking lander experiments met the requirements for high reliability and miniaturization necessary for an improved prosthetic urinary sphincter. A second applications analysis revealed that this same valve could be used to develop a sphincter for colostomies and a control mechanism for a hydraulic penile prosthesis. All three applications of this valve technology are now under development by a medical device manufacturer. Currently, the

team is evaluating the feasibility of a cerebrospinal fluid control system that utilizes aerospace technology incorporated in the programmable implantable medication system.

2. Coordination With Manufacturer/Consumer Committees

In recent years, several agencies have formed committees to develop performance and safety standards for medical devices. These committees include representatives from industry, research, and clinical practice. In the past year, the RTI team worked with two of these committees to evaluate their potential as sources of new projects with a high probability of successful commercialization. The results from both committees were very successful. RTI team discussions with the AAMI Committee for Infant Radiant Warmers resulted in a suggestion by NASA engineers for a new temperature probe dislodgement detector. This detector is currently being evaluated by manufacturers for incorporation in their radiant heaters. As described in Section 3.1, the Aerospace Industries Association established a committee to examine the problem of commercial aircraft accessibility for the elderly and disabled. The RTI team's work with this committee resulted in the development and commercialization of an onboard wheelchair, a key element in the entire cabin accessibility system.

The team will continue this effective coordination with standards committees by participation in the Wheelchair Standards Committee recently formed by the Rehabilitation Engineering Society of North America.

3. Publication in Medical Device Industry Journals

Access to the medical device industry is an important component in the team's successful conversion of medical problems into commercial solutions based on aerospace technology. Many medical device manufacturers, however, remain unaware of NASA's biomedical technology transfer program. To inform industry of the NASA program and its potential in the development of commercially successful medical devices, the RTI team has made presentations and published articles in journals of interest to the medical device industry.

The response by manufacturers to these presentations and publications has been enthusiastic. This efficient and effective technique for accessing the medical device industry will continue as an important component of the RTI team's methodology.

Results during the past year, therefore, indicate that the team's use of these three techniques will enhance the efficiency of the technology transfer process. The team's continuing experience in project development and commercilization will result in further refinement of the team's operating methodology in the next year.

Perhaps the most important lesson that can be derived from the team's experience in working with medical manufacturers is that technology transfer in medicine is extremely complex. The barriers to technology transfer are numerous and include the characteristics of medical-device manufacturers, Federal regulatory agencies, medical marketing distribution practices, acceptance of a new product by the medical community, and all the well-known barriers to technology transfer, in general, and not peculiar to the medical field. The team's better understanding of medical manufacturing, marketing, and distribution has enhanced its ability to form successful commercialization strategies. However, there is still much to be learned concerning this aspect of medical technology transfer and the team will continue to expand its interactions with the medical industry in order to gain this understanding. Of most importance are ways to effectively handle patents and licensing agreements. More generally, all aspects of government/industry interfaces must be understood and facilitated.

To ensure concentration on medical needs perceived as problems by a significant portion of the medical community, the team continues to work with clinicians, researchers, and engineers in 28 medical institutions, as well as health agencies such as the National Institutes of Health, the Veterans Administration, and the Food and Drug Administration. The expertise and experience of the staffs of these institutions and agencies have assisted the team in defining and validating specific medical needs. The support and cooperation of the 38 participating medical device manufacturers have resulted in a continuity in the transfer projects from problem identification through commercial development. Problem-solving activities during the reporting period have involved eight NASA field centers. This extensive interaction between RTI and NASA scientists and engineers has been essential to the identification of technologies applicable to a variety of medical needs. The RTI team visited five NASA field centers during the reporting period. The frequent communication with and visits to the field center technology utilization offices have allowed the team to serve as a responsive resource for these offices on biomedical projects.

APPENDIX A

PUBLICATIONS AND PRESENTATIONS

APPENDIX A

PUBLICATIONS AND PRESENTATIONS

Rouse, D. J., Discussion Leader of Workshop Session. Target Group and Human Factor Considerations in Product Design. Symposium on Product Design in the 80's. Sponsored by the National Endowment for the Humanities, Wilmington, Delaware, March 27, 1981.

Rouse, D. J. Methodology for NASA Technology Transfer in Medicine. Presented at the 16th Annual Meeting for the Association for the Advancement of Medical Instrumentation, Washington, D.C., May 10, 1981.

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

Rouse, D. J. The NASA Technology Transfer Process. Invited presentation at the National Research Conference on Technology and Aging, Racine, Wisconsin, July 29, 1981.

Rouse, D. J. Appointed Chairperson of Wheelchair Committee for the Rehabilitation Engineering Society for North America, August 1981.

Brown, J. N. Biomedical Applications - From NASA to Business. Presented at Profit Through Innovations Conference, Raleigh, North Carolina, September 10, 1981.

APPENDIX B

TRAVEL

APPENDIX B

TRAVEL

January 21, 1981	Dr. James Brown and Dr. Doris Rouse met with John Samos, Sheila Long, and Bob Baucom at Langley Research Center to discuss project plans.
February 11, 1981	Dr. Clark Beall traveled to the University of Maryland's Emergency Medical Services Trauma Center to discuss the need for instrumentation to measure tissue viability in trauma patients.
February 23, 1981	Dr. Doris Rouse met with the Stanford University and SRI Applications Teams to discuss collaborative projects.
February 24, 1981	Dr. Doris Rouse met with Stan Miller, Pat Kirk, Bill Williams, and Daryll Rasmussen at Ames Research Center to discuss liquid cooling garment projects.
February 25-26, 1981	Dr. Doris Rouse participated in a Prosthetic Urinary Sphincter project review at Parker-Hannifin Corporation, Irvine, California.
March 5, 1981	Dr. Clark Beall visited Langley Research Center to discuss RTI team projects and to discuss the applicability of photoacoustic spectroscopy for patient monitoring.
March 17, 1981	Dr. Clark Beall visited Johns Hopkins Medical Center to document the functioning of the tissue-freezing unit.
March 23, 1981	Dr. Clark Beall participated in a panel discussion at Langley Research Center concerning appropriate technology for monitoring temperature gradients within human tissue and tumors.
March 25-26, 1981	Dr. Doris Rouse participated in a Programmable Implantable Medication System review at the Applied Physics Laboratory in Laurel, Maryland.
March 27, 1981	Dr. Doris Rouse led a workshop on "Target Group and Human Factor Considerations in Product Planning" in a Symposium on Product Design in the 1980s in Wilmington, Delaware.

April 9-10, 1981	Dr. Clark Beall visited Dr. Kaizer's laboratory at Johns Hopkins University to conduct blood-freezing unit experiments.
April 24, 1981	Mr. Randy Eakes met with Ray Gilbert, Don Vargo, and Nelson Milder at NASA Headquarters to discuss RTI team projects.
May 8, 1981	Dr. James N. Brown, Jr., met with John Samos at Langley Research Center to review the team's activities for the first quarter.
May 10, 1981	Dr. Doris Rouse presented a paper entitled "Methodology for NASA Technology Transfer in Medicine" at the 16th Annual Meeting of the Association for the Advancement of Medical Instrumentation in Washington, D.C.
May 15, 1981	Dr. Doris Rouse and Dr. W. H. Clingman met with Don Vargo, Ed Sullivan, and Bill Martin, Hercules' technical representative, at NASA Headquarters to discuss the use of composite materials in devices for the handicapped.
June 2-3, 1981	Dr. Clark Beall conducted tissue-freezing experiments and modified the freezing unit in Dr. Kaizer's laboratory at Johns Hopkins University.
June 4, 1981	Dr. Doris Rouse met with Mal Mixon, President of Invacare, and Dr. Colin McLaurin at the University of Virginia in Charlottesville to discuss the use of composite materials in wheelchairs.
June 11, 1981	Dr. Doris Rouse met with the Fairchild Burns' New Product Development Group in Winston Salem, NC, to discuss commercialization of the aircraft wheelchair.
July 27-29, 1981	Dr. Doris Rouse led a panel at the Veterans Administration sponsored meeting on Wheelchair Research and Manufacturing in Charlottesville, Virginia.
July 30-August 1, 1981	Dr. Doris Rouse presented a paper on NASA Technology Transfer at the National Research Conference on Technology and Aging in Racine, Wisconsin.
August 20, 1981	Dr. Doris Rouse participated in a planning session for development of a high performance wheelchair at Langley Research Center.

September 1-2, 1981	Dr. Doris Rouse participated in the annual conference of the Rehabilitation Engineering Society of North American (RESNA) in Washington, D.C. She was appointed chairman of the RESNA wheelchair committee.
September 3, 1981	Dr. Doris Rouse visited NASA Headquarters to discuss project status.
September 9-10, 1981	Dr. Doris Rouse participated in the Programmable Implantable Medication System review at Applied Physics Laboratory in Laurel, Maryland.
September 10, 1981	Dr. James N. Brown, Jr., made a presentation entitled "Biomedical Applications--From NASA to Business," at the Profit Through Innovations Conference in Raleigh, North Carolina.
September 15, 1981	Dr. Clark Beall participated in a workshop on Instrumented Prostheses for In Vivo Measurement of Joint Mechanics sponsored by NIH in Bethesda, Maryland.
September 18, 1981	Dr. Clark Beall and Dr. Doris Rouse participated in the RTI team review at Langley Research Center.
October 2, 1981	Mr. Charles Eastwood, NASA Headquarters, and Dr. H. Clark Beall met with Dr. Allen S. Berson at the Devices and Technology Branch of the National Heart, Lung, and Blood Institute in Bethesda, Maryland, to discuss potential applications of NASA technology in the artificial heart development program.
October 6-7, 1981	Dr. J. N. Brown, Jr., attended the AIAA/NASA-sponsored seminar on Advanced Materials Processing and Related Technologies at Langley Research Center. The seminar, hosting representatives of the nonaerospace Fortune 500, focused on technology transfer.
October 8, 1981	Dr. H. Clark Beall met with Dr. F. W. Hegge, Walter Reed Institute of Medical Research, to discuss the solid-state digital recorder for physiological recording.
December 10-11, 1981	Dr. H. Clark Beall participated in a symposium on corneal topography at Los Alamos Scientific Laboratories. The objective of the symposium was to review the state-of-the-art and define the requirements for improved methods for characterizing the corneal topography.

APPENDIX C

PROJECT ACTIVITY SUMMARY

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

Activity	Number
New Projects	5
Inactivated Projects	11
Current Active Projects	18
Field Centers Visited	5
Field Centers Participating in Team Projects	8
Manufacturers Participating	38
Medical Institutions Participating	28
Health Agencies Participating	23
IAC Information Searches	5
Medical Literature Searches	13

TABLE C-2. COMMERCIAL TRANSFERS

Portable Medication Infusion Pump	Micromed®

TABLE C-3. NEW PROBLEMS

Analyzer of Tissue Viability	Esophageal Pressure Transducer
Corneal Topography	High Performance Wheelchair
Digital Data Recorder for Physiological Monitoring	

TABLE C-4. INACTIVATED PROJECTS

Analysis of the Retinal Reflex	Pressure Transducer Calibrator
Analyzer of Tissue Viability	Retractor Tool for Brain Surgery
Biological Tissue Freezing System	Selective Call Telemetry
Hearing Aid Intelligibility	Texturing Dental Implants
Esophageal Pressure Transducer	Weight Alleviation Device
Neuromuscular Diagnostic Unit	

TABLE C-5. ACTIVE PROJECTS AS OF DECEMBER 31, 1981

Composite Material Applications	Low-Cost UV Optical Dosimeter
Corneal Topography	Microwave Thermography
Detection of a Dislodged Temperature Probe	Noninvasive Lung Diagnosis
Digital Data Recorder	Ophthalmic Screening Device
Fiber Optics System for Knee Surgery	Portable Cooling System for Quadriplegics
Flow Sensor for an Infusion Pump	Programmable Implantable Medication System
High Performance Wheelchair	Prosthetic Urinary Sphincter
Hydrocephalus Shunt--Ventilation	Texturing for Percutaneous Connectors
Implant Materials Testing	Texturing Surfaces for Cardiovascular Prostheses

APPENDIX D

PROBLEM STATEMENTS

APPENDIX D

PROBLEM STATEMENTS

ANALYZER OF TISSUE VIABILITY

BATeam Personnel: Dr. H. Clark Beall

Problem

There are many situations of clinical care in which a physician wishes to determine the present state of viability of a tissue or an organ. An instrument is needed that can quantify the state of recovery of human tissue following trauma, burns, or surgery.

Solution

A device is required that objectively measures a pertinent factor of basic metabolism. The oxidation state of the cytochromes of the mitochondria is an example of a parameter that can be measured instrumentally and that is a sensitive indicator of basic metabolism.

NASA Technology

Photoacoustic spectroscopy is a newly developing technology that can be utilized to sample the oxidation/reduction ratio of cytochromes in living tissue.

Principles

Dr. Barry Burns, University of Maryland Trauma Center, Baltimore, Maryland.
Dr. John Cantrell, NASA Langley Research Center, Hampton, Virginia.

Cost to NASA

No cost is anticipated within the next 3 months.

Commercialization Strategy

No strategy has yet been formulated.

Status

Evidence from theory, numerical calculations, and the scientific literature show that the proposed new instrumentation is feasible.

Action

A demonstration of the operation of the optical transducer is being scheduled at Langley Research Center.

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 precisely gauge the topography of the corneal surface 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

Laser illumination of objects offers several unique characteristics that could be applied to the gauging of corneal topography.

Principals

Dr. J. Rowsey, surgeon, McGee Eye Institute, Oklahoma City, Oklahoma.
Mr. J. D. Doss, Los Alamos National Laboratory, New Mexico.
Mr. Bert Kortegaard, Los Alamos National Laboratory, New Mexico.

Cost to NASA

Discretionary funds are available at Los Alamos National Laboratory for prototype and development work on a new device for noncontact contouring of the cornea of the eye. The University of Oklahoma has been funded by the National Eye Institute to evaluate corneal topography measurement techniques. No additional funds will be required from NASA.

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

Dr. Rowsey called a workshop on this subject at Los Alamos National Laboratory on December 11, 1981. Manufacturers and academicians described the operation of devices that have been designed to gauge corneal contour. Although slow, most of the devices can measure corneal contour if the contour is regular, i.e. for fitting contact lens. However, for corneal surfaces that have been irregularly distorted by trauma or disease, the presently used reflective devices are of no use.

Action

The RTI team will identify NASA technology that can be utilized in the design of a new generation of devices for gauging corneal topography. The team will work with personnel at Los Alamos National Laboratory and the University of Oklahoma in the implementation of the technology into a working prototype.

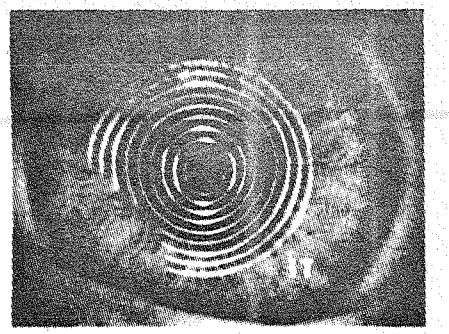
CORNEAL TOPOGRAPHY

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

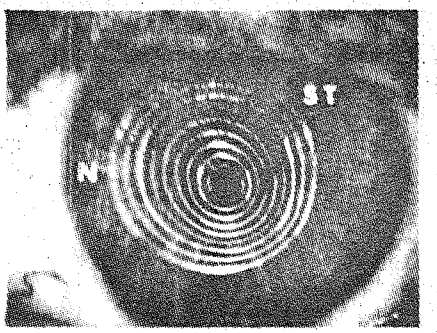
Corneascope

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



A



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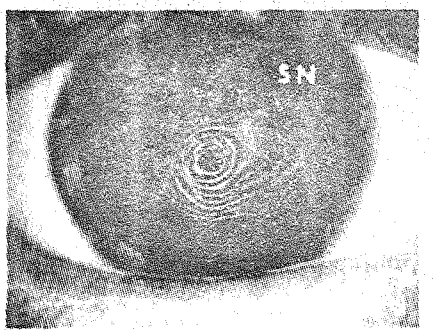


C

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 apena," an inadequate blood oxygen level due to a temporary irregularity of respiration. The apena 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 in order to reduce costs and improve the quality of data.

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 stripchart 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. The recorders can be returned to the laboratory for readout of the data.

NASA Technology

NASA TM-81267[1] describes a digital, solid-state recorder that features a selfcontained 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 that are appropriate for measuring parameters such as respiration rate, activity, muscle activity, eye movement, or 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 RTI team has discussed this system with Dr. Weitzman (for sleep research) and with Dr. Hegge (for physiological monitoring in the field). Both researchers plan to utilize the recorder in their research.

Action

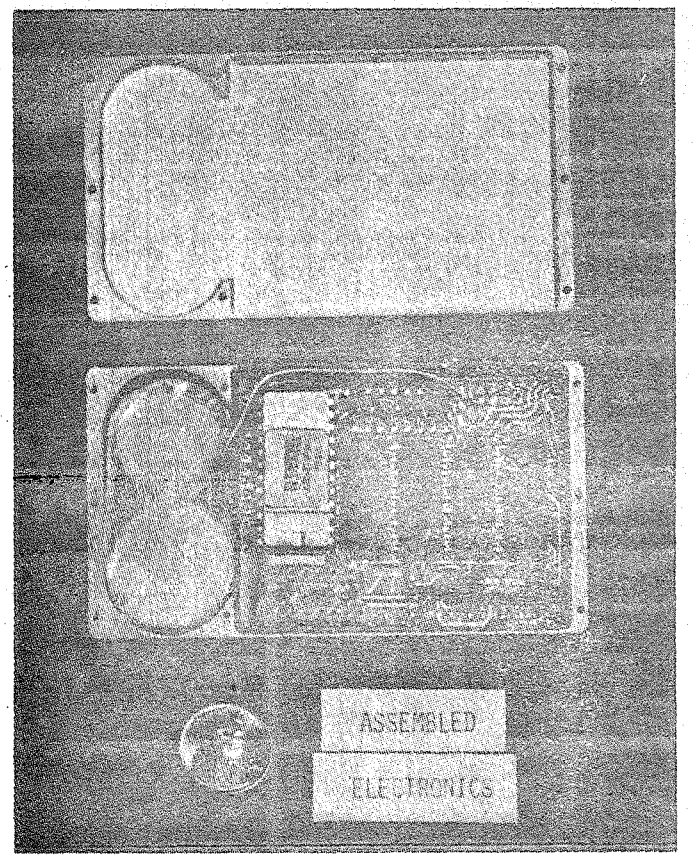
The base station readout facility for the digital recorder has been recently redesigned to operate with an Apple® microcomputer. The engineers at the NASA Ames Research Center will provide the new hardware diagrams and software listing for the base station as soon as the system has been debugged. The RTI team will continue discussions with manufacturers and researchers.

Reference

1. Westbrook, R. M., L. D. Bennett, R. A. Steinhauer, and G. J. Deboo. A Solid-State Digital Temperature Recorder for Space Use. NASA TM-81267, NASA Ames Research Center, 1981.

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
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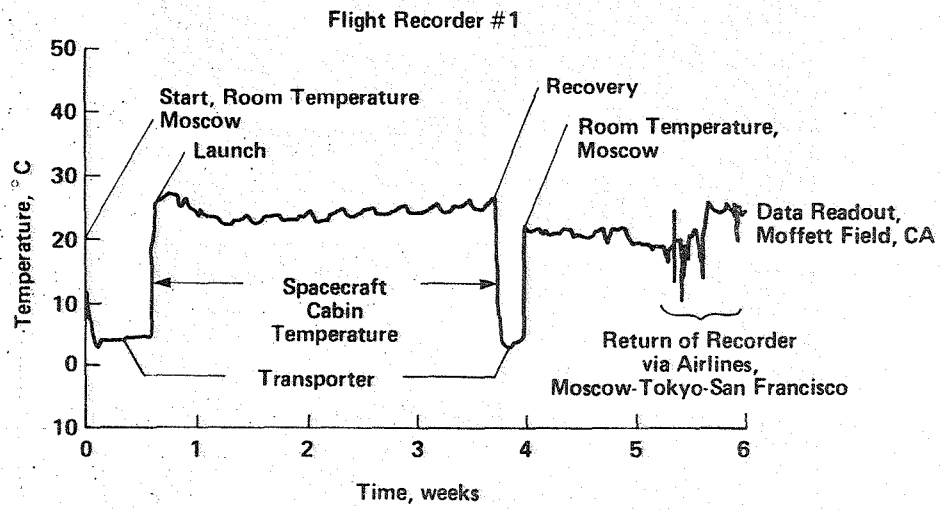

Data from US-USSR Cosmos satellite flights

ESOPHAGEAL PRESSURE TRANSDUCER

BATeam Personnel: Mr. R. E. Eakes

Problem

The insertion of a nasogastric balloon catheter to measure esophageal pressure is extremely uncomfortable for the majority of patients undergoing pulmonary function testing and simply cannot be accomplished in others due to activation of the "gag" reflex. In addition, the balloon often ruptures during insertion and the patient is subjected to the same ordeal once again.

Solution

An alternate method of obtaining esophageal pressure measurements during pulmonary function testing is needed.

NASA Technology

A problem statement was distributed to all NASA field centers in January 1981.

Principals

Dr. Nelson Leatherman, Pulmonary Function Laboratory, Duke University Medical Center, Durham, North Carolina.

Dr. John L. Patterson, Jr., Professor of Medicine, Division of Cardiopulmonary Laboratories and Research, Medical College of Virginia, Richmond, Virginia.

Cost to NASA

No cost is anticipated.

Commercialization Strategy

A significant improvement in esophageal pressure measurement for pulmonary function testing would have possible applications in esophageal motility and esophageal sphincter studies as well. There are several manufacturers of equipment for the latter two categories who are possible sources of commercialization.

Status

A problem statement was circulated to all NASA field centers in January 1981.

Action

Problem statement responses will be reviewed with the principals as they are received.

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 heavy weight, frequent breakdowns, and limited lifetime, resulting in high life-cycle costs. Recognizing these problems, the Veterans Administration and the National Institute on Handicapped Research have funded several wheelchair research projects. Most of these projects are component oriented. Few projects involve a full-scale deveopment 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

Dr. Doris Rouse met with Mal Mixon, President of Invacare Corporation, and Dr. McLaurin to discuss commercialization of the chair. Invacare is very interested in marketing the chair, if the price is reasonable. Invacare invited participants in this project to visit their plant in Ohio to discuss possible prototype fabrication. The RTI team has also discussed participation in this project with other wheelchair manufacturers.

Status

An initial planning meeting was held at Langley Research Center on August 20, 1981. The design criteria and performance goals have been documented by the University of Virginia. Dr. Aileen Rogers of Drexel University submitted a proposal to Langley to perform the computer analysis in the project. Dr. Rogers plans to do this work at Langley Research Center.

Action

A review and planning meeting for the project is scheduled for January 1982. The RTI team will participate in this meeting. Preliminary designs are scheduled to be completed by August 1982. Otto Fedor at Kennedy Space Center has contacted the RTI team about the development of an advanced wheelchair. RTI will keep him informed of the Langley project and will facilitate his group's participation.

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15. Supplementary Notes

Langley technical monitor: John Samos
Final Report

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 Stowaway, a lightweight wheelchair that provides mobility for the disabled and elderly in the cabin of commercial aircraft, and Micromed®, a portable medication infusion pump for the reliable, continuous infusion of medications such as heparin or insulin. The team also completed a study of the marketing and manufacturing factors critical to the commercialization of the lightweight walker incorporating composite materials. The team identified five new projects. Eleven projects were inactivated as a result of completed transfers or inadequate commercial potential to justify continued development. During the reporting period, progress was made in the development and commercialization of each of the 18 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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